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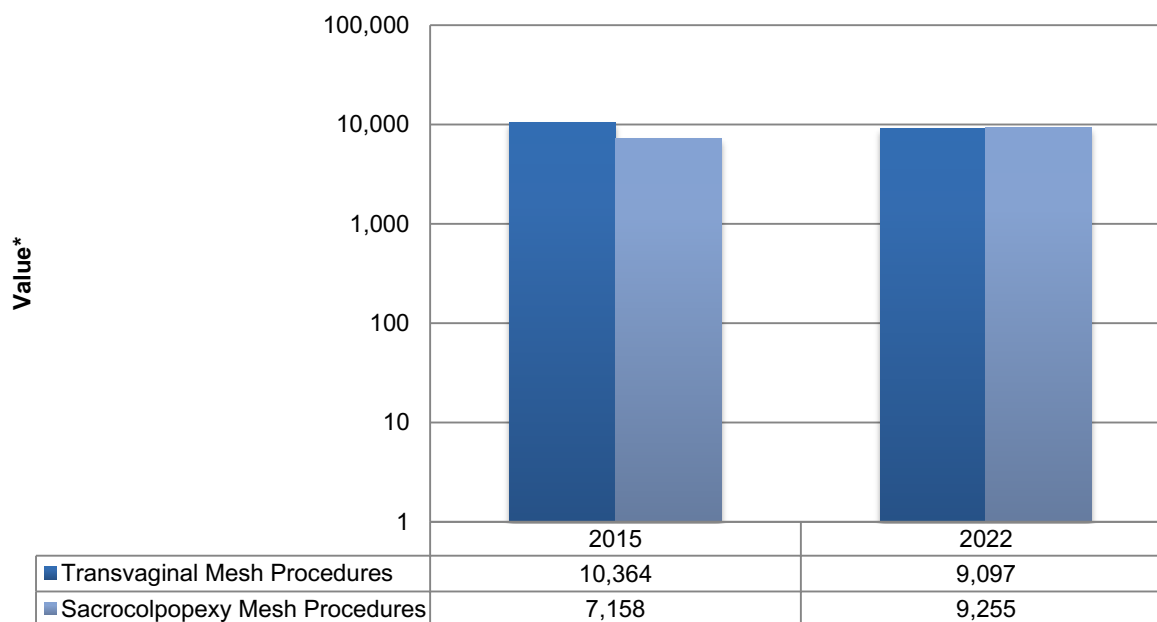
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EXECUTIVE SUMMARY

EUROPEAN MARKET FOR GYNECOLOGICAL DEVICES OVERVIEW

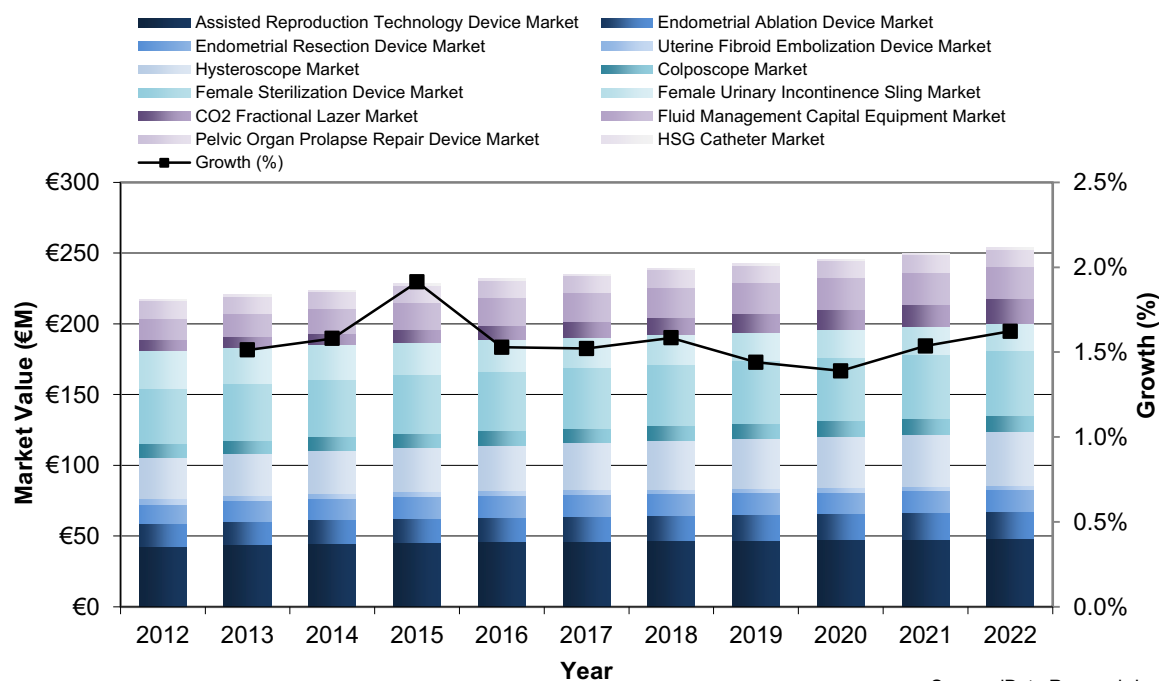
- The full report suite on the European market for gynecology includes assisted reproduction devices, endometrial ablation, endometrial resection, uterine fibroid embolization, hysteroscopes, colposcopes, transcervical female sterilization, female urinary incontinence slings, laser technology, fluid management equipment, pelvic organ prolapse repair devices and hysterosalpingography catheters.
- The different cultural attitudes throughout Europe drive the market shares of the different sub-markets within the field of gynecology. In France, uterine fibroid embolization procedures remain popular due to a conservative market that pioneered embolization therapy for uterine fibroids. In Italy, the country is leading the adoption of laser technology, while the market value of assisted reproduction is quelled due to local laws. The United Kingdom is advancing assisted reproduction technology, yet is slow to invest in fluid management equipment. The differences in cultural norms, procedure training and choice of alternative treatments demonstrates the opportunities that exist to maximize and grow markets.
- The predominant trend throughout Europe is the eagerness to invest in less-invasive, office based procedures. The untapped market value of clinics and offices investing in capital equipment is fueling growth in a struggling economy. This results in higher unit sales and an associated growth in market value. Understanding the way ASP's are influencing practitioners and what equipment they're buying allows companies to strategically market products for optimized sales.
- Despite downward economic pressure, assisted reproduction and laser technology are hot markets. The projected growth of embryo time lapse incubators is causing assisted reproduction to have a stable growth rate. With patient safety at the forefront, the erosion of other markets in favor of laser treatments for dyspareunia and stress urinary incontinence is occurring at exponential rates.

- Overall, the European gynecology market was valued at €228.2 million in 2015. This is expected to increase over the forecast period to reach €253.6 million by 2022.

Chart 1-1: Gynecological Device Market by Segment, Europe, 2012 – 2022

*Axis is on logarithmic scale.

Source: iData Research Inc.
Note: Values reflect rounding.

Chart 1-2: Gynecological Device Market Overview, Europe, 2012 & 2022

Source: iData Research Inc.

COMPETITIVE ANALYSIS

- Karl Storz held the lead in three of the twelve sub-markets within Gynecology in 2015, holding an 11.05% total market share. Karl Storz offers a diverse product portfolio as market leader in Endometrial Resection Devices, Hysteroscopes and Fluid Management Equipment. The partnership between Karl Storz and MTP (Medical Technical Promotion gmbh) has contributed to the company's strong growth and consistent sales in a recovering economy. Karl Storz increased their market share from 9.85% in 2014, moving from the fourth highest market share to the second highest market share in 2016.
- Cooper Surgical also led three of the twelve sub-markets in 2015, with a 6.9% overall market share. Cooper Surgical includes the acquisitions of Reprogenetics, Origio and Research Instruments. Despite a strong market lead throughout the Assisted Reproduction Market, Cooper Surgical's market share declined from 2014. The company's growth is projected to remain stable through to 2022.
- Vitrolife has surged in the gynecology market, increasing their market share to 20.01% in the assisted reproduction sub-segment. This increase is largely attributable to the addition of time lapse embryo incubators gaining prominence in the assisted reproduction market. The company is widely recognized in the field of assisted reproduction and is expected to continue increasing their market value through their reproduction media and time lapse system sales.

**Figure 1-1: Gynecological Device Competitor Market Share Ranking by Segment, Europe, 2015
(1 of 3)**

Position	Assisted Reproduction Device Market	Endometrial Ablation Device Market	Endometrial Resection Device Market	Uterine Fibroid Embolization Device Market
1 st	Cooper Surgical	Johnson & Johnson	Karl Storz	Merit Medical Systems
2 nd	Cook Medical	Hologic	Olympus	Boston Scientific
3 rd	Vitrolife	Boston Scientific	Johnson & Johnson	Terumo
Source: iData Research Inc.				

**Figure 1-2: Gynecological Device Competitor Market Share Ranking by Segment, Europe, 2015
(2 of 3)**

Position	Hysteroscope Market	Colposcope Market	Transcervical Female Sterilization Device Market	Female Urinary Incontinence Sling Market
1 st	Karl Storz	Cooper Surgical	Bayer Medical	Johnson & Johnson
2 nd	Richard Wolf	Carl Zeiss	–	Astora Women's Health
3 rd	Olympus	Olympus	–	Boston Scientific
Source: iData Research Inc.				

**Figure 1-3: Gynecological Device Competitor Market Share Ranking by Segment, Europe, 2015
(3 of 3)**

Position	Laser Technology Market	Fluid Management Equipment Market	Pelvic Organ Prolapse Repair Device Market	Hysterosalping ography Catheter Market
1 st	Deka Medical Systems	Karl Storz	Astora Women's Health	Cooper Surgical
2 nd	Alma Surgical	Richard Wolf	Boston Scientific	Cook Medical
3 rd	Fotona	Olympus	CR Bard	–
Source: iData Research Inc.				

Figure 1-4: Companies Researched in this Report, Europe, 2015

Companies	
<ul style="list-style-type: none"> • Alma Surgical • Astora Women's Health • Asclepion • Bayer • Bison • Boston Scientific • BTG • Carl Zeiss • CCD • Coloplast • Cook Medical • Cooper Surgical • CR Bard • Deka Medical Lasers • Esco • Fotona • Gynetics • Genea BioMedix • Hologic 	<ul style="list-style-type: none"> • Irvine • Johnson & Johnson • JCD • Kaps • Karl Storz (+MTP) • Kebomed • Lumenis • Medtronic • Merck KgbA • Merit Medical Systems • Olympus • Richard Wolf • Sciton • Serag Weissner • Smiths Medical • Terumo • The LifeGlobal® Group • Vitrolife • Wallace Needles
Source: iData Research Inc.	

MARKET TRENDS

Figure 1-5: Factors Impacting the Gynecological Device Market by Segment, Europe (1 of 3)


Factor	Assisted Reproduction Device Market	Endometria l Ablation Market	Endometrial Resection Device Market	Uterine Fibroid Embolization Device Market	Hysteroscope Market	Colposcope Market
New Technology		-		-	-	
Efficacy Concerns			-		-	-
Resistance to Change			-		-	-
Increase in Office Procedures	-		-			-
Reimbursement			-	-	-	
Lack of Trained Physicians	-					-
Alternative Treatment Options	-				-	-
Patient Population				-	-	-
Concerns for Patient Safety				-	-	-
Weak Economy & International Competition		-	-	-		
Note: The opacity of an arrow indicates the magnitude of each factor's positive or negative impact on each market.						
Source: iData Research Inc.						

Figure 1-6: Factors Impacting the Gynecological Device Market by Segment, Europe (2 of 3)






























Factor	Transcervical Female Sterilization Market	Female Urinary Incontinence Sling Market	Laser Technology Market	Fluid Management Equipment Market
New Technology	–	–		
Efficacy Concerns (short & long term results)		–		–
Resistance to Change		–		
Increase in Office Procedures		–		–
Reimbursement		–		–
Lack of Trained Physicians	–	–		–
Alternative Treatment Options				–
Patient Population				–
Concerns for Patient Safety				
Weak Economy & International Competition	–	–	–	
Note: The opacity of an arrow indicates the magnitude of each factor's positive or negative impact on each market.				
Source: iData Research Inc.				

Figure 1-7: Factors Impacting the Gynecological Device Market by Segment, Europe (3 of 3)

Factor	Pelvic Organ Prolapse Repair Device Market	Hysterosalpingography Catheter Market
New Technology	–	–
Efficacy Concerns (short & long term results)		–
Resistance to Change	–	–
Increase in Office Procedures	–	–
Reimbursement	–	–
Lack of Trained Physicians	–	–
Alternative Treatment Options		–
Patient Population		
Concerns for Patient Safety		–
Weak Economy & International Competition	–	
Note: The opacity of an arrow indicates the magnitude of each factor's positive or negative impact on each market.		
Source: iData Research Inc.		

MARKET DEVELOPMENTS

Figure 1-8: Recent Events in Gynecological Device Market, Europe, 2012 – 2016

Date	Product Type	Event
June 1 st , 2016	Assisted Reproduction	Cooper Surgical acquires Reprogenetics UK
May 18 th , 2016	Endometrial Resection/ Uterine Fibroid Embolization	Medtronic acquires Smith & Nephew's Gynecology business
April 2016	Assisted Reproduction	Sweden votes to allow state-funded fertility treatment for single parents effective April 2016 (Vote passed January 2016)
March 31 st , 2016	Urinary Incontinence	Astora Women's Health closes down
January 4 th , 2016	Urinary Incontinence	FDA raises transvaginal meshes to high-risk classification
November 10 th , 2015	Uterine Fibroid Embolization	Boston Scientific acquires CeloNova Biosciences Interventional Radiology Business
August 4 th , 2015	Urinary Incontinence	Boston Scientific acquires American Medical Systems male urology portfolio
January 26 th , 2015	Urinary Incontinence	Medtronic acquires Covidien
April 2013	Transcervical Female Sterilization	Bayer acquires Conceptus
June 2012	Assisted Reproduction	Cooper Surgical acquires Origio
Source: iData Research Inc.		

PROCEDURE NUMBERS

Figure 1-9: Gynecological Procedures Covered, Europe, 2015

Procedure Performed	
Assisted Reproduction	Procedure Table
Uterine Fibroid Embolization Device Market	Procedure Table (Microspheres/ PVA Particle procedures)
Transcervical Female Sterilization Market	Procedures
Female Urinary Incontinence Slings Market	Procedures
Pelvic Organ Prolapse Repair Device Market	Procedures
Source: iData Research Inc.	

MARKETS INCLUDED

Figure 1-10: Gynecological Device Markets Covered, Europe, 2015 (1 of 2)

Market Segment		
Assisted Reproduction Device Market	Device Type	
	Oocyte Retrieval Needle Market	
	Micropipette Market	Device Type
		Flexible Pipette
		Microinjection and Holding Pipette
	Embryo Transfer Catheter Market	
	Reproduction Media Market	Media Type
		One Step Media
		Sequential Media
		Sperm Preparation Media
Freeze/Thaw Media		
Embryo Time Lapse Incubator Market		
Endometrial Ablation Device Market	Device Type	
	Thermal Balloon Ablation Devices	
	Radiofrequency Ablation Devices	
Endometrial Resection Device Market	Device Type	
	Resectoscope Market	Monopolar Loop Electrode
		Bipolar Loop Electrode
		Electrosurgical Rollerball
Uterine Fibroid Embolization Device Market	Device Type	
	Microspheres	
	PVA Particles	
Hysteroscope Market	Device Type	
	Rigid Hysteroscopes	
	Flexible Hysteroscopes	
Colposcope Market		
Transcervical Female Sterilization Market		
Source: iData Research Inc.		

Figure 1-11: Gynecological Device Markets Covered, Europe, 2015 (2 of 2)

Market Segment	
Female Urinary Incontinence Sling Market	Device Type
	Synthetic Slings
	Non-Synthetic Slings
Laser Technology	
Fluid Management Equipment Market	Device Type
	Fluid Management Capital Equipment
	Fluid Management Tubing
Pelvic Organ Prolapse Repair Device Market	Device Type
	Trans- Vaginal Mesh
	Sacrocolpopexy Mesh
HSG Catheter Market	
Source: iData Research Inc.	

KEY REPORT UPDATES

Figure 1-12: Key Report Updates (1 of 3)

Market Segment	2014 Report	2016 Report
Assisted Reproduction Device Market	<ul style="list-style-type: none"> - Reproduction Media (Segmentation changed from: Culture Media Sperm Preparation Media Cryopreservation Media Manipulation Media) 	<ul style="list-style-type: none"> - Oocyte Retrieval Needles (new -including units/procedure) - Micropipettes (new - including units/procedure) - Flexible Pipettes (including units/procedure) - Microinjection & Holding Pipettes (including units per procedure) - Embryo Transfer Catheters (new – including units/procedure) - Reproduction Media (Segmentation changed to: One Step Media Sequential Media Sperm Preparation Media Freeze/Thaw Media) New – Reproductive Media Type % by country - Embryo Time Lapse Incubator Systems (including % of clinics using time lapse by country) - Leading Competitive Analysis
Source: iData Research Inc.		

Figure 1-13: Key Report Updates (2 of 3)

Market Segment	2014 Report	2016 Report
Endometrial Ablation Device Market	- Not included	<ul style="list-style-type: none"> - Thermal Balloon Ablation Devices - Radiofrequency Ablation Devices - Leading Competitors – By Segment - Leading Competitors – Total by Country (Both 2015 & 2016)
Endometrial Resection Device Market	- Leading Competitors – By Segment (no longer included in 2016 report)	<ul style="list-style-type: none"> - Electrosurgical Rollerball Market - Leading Competitors – Total by Country
Uterine Fibroid Embolization Device Market	- Not included	<ul style="list-style-type: none"> - Procedure Table - Microspheres & PVA Particles: # units per procedure - Microspheres - PVA Particles - Leading Competitors – Total by Country
Source: iData Research Inc.		

Figure 1-14: Key Report Updates (3 of 3)

Market Segment	2014 Report	2016 Report
Hysteroscope Market	- Not included	- Rigid Hysteroscope - Flexible Hysteroscope - Leading Competitors – Total by Country
Colposcope Market	- Not included	- Leading Competitors – Total by Country
Transcervical Female Sterilization Market	- Not included	- Leading Competitors – Total by Country
Female Urinary Incontinence Device Market	- Not included	- Leading Competitors – Total by Country (Both 2015 & 2016)
Laser Technology & Dyspareunia Treatments	- Not included	- New Chapter Added: - Units Sold - Leading Competitors – Total by Country - Leading Competitors – Vaginal Atrophy Procedures - Leading Competitors – Female Urinary Incontinence Procedures - Multidisciplinary Treatment Options for Dyspareunia
Fluid Management Equipment Market	- Not included	- Fluid Management Equipment Country Comparison in % for both 2015 and 2022 (between Fluid Management Equipment & Gravity Bags) - Fluid Management Price Comparison 2015 (between Fluid Management Equipment & Gravity Bags) - Leading Competitors – Total by Country
Pelvic Organ Prolapse Repair Device Market	- Not included	- Leading Competitors – Total by Country (Both 2015 & 2016)
Hysterosalpingography Catheter Market	- Same as 2016	- Same as 2014
Source: iData Research Inc.		

VERSION HISTORY

Figure 1-15: Version History

Date	Event
October 2016	Publication of first edition.
Source: iData Research Inc.	

1

RESEARCH METHODOLOGY

1.1 RESEARCH SCOPE

This report aims to analyze and evaluate the current state of the market, including existing and potential markets, product average selling prices, and unit volumes. The report also highlights the opportunities and potential hazards involved, and presents strategies for successfully navigating the market landscape. Furthermore, it seeks to identify the trends and technologies that will affect the future of each market segment and prepares an unbiased critical assessment of such market drivers and limiters.

1.2 IDATA'S 9-STEP METHODOLOGY

The reports published by iData meet the highest standards of quality because each one is the product of our rigorous and systematic 9-Step Market Research Methodology. This methodology has been shown to consistently produce accurate, reliable and relevant assessments of both present and future markets. The key advantages of this research system are:

- Solid foundation of data collected from the “bottom up”
- Original primary research that consists of the most up-to-date market data
- Strong foundation of quantitative, not just qualitative, research
- Focused on the needs and strategic challenges of the industry participants

1.2.1 Step 1: Project Initiation & Team Selection

A research project is initiated if it is determined that there is a compelling need within the industry for it. During this preliminary investigation, all staff members involved in the industry meet and discuss the topic in detail. The interdisciplinary research team analyzes the market to identify and anticipate key opportunities and challenges facing the industry. The results of this process are combined with feedback

from iData's sales force, consultants and research managers. With the resulting information, a decision on whether or not to proceed with the project is made.

Once approved, the research objectives and project scope are defined in detail. Specific market research measurements, segmentation, and instrumentation, are selected. A preliminary list of key issues and trends is created, and competitors are identified. This step culminates in the selection of the research team members. The success of any research project depends ultimately on the skills of the team members and on their ability to operate synergistically, therefore team selection is a critical step. Research teams are typically comprised of the lead analyst, the support analyst, research managers, market consultants, account managers, partners, industry advisors, and key customers.

Lead Analyst

The primary function of the lead analyst is to design and implement the research project. This includes performing or supervising the collection and analysis of the project data. The lead analyst is also responsible for ensuring that the quality, thoroughness, and accuracy of the research, meet the high standards required by the iData Research methodology.

Support Analyst

The support analyst conducts and assists with data collection and analysis, in cooperation with the lead analyst.

Research Managers

Research managers direct the research projects within their respective industry segments. They function to ensure consistency among research reports, and to manage and support the analysis team. Research managers also select the industry segment research teams, and ensure their skills and background are appropriate for their duties. All iData research managers are experienced in the market research field, and therefore play a key role in guiding each project to a successful conclusion.

Market Consultants

In cases where iData's customers have specific marketing or business needs, market consultants work in conjunction with the customers to develop tailored solutions. Market consultants can also work with customers to establish larger-scale research or survey projects, including: mergers and acquisitions; new product positioning and pricing investigations; and strategic planning for market share increases.

Account Managers

Account managers are responsible for ensuring that customer input and feedback is reflected in the results of research projects, including responses to prior research reports and customer requests for future research directions. Additionally, their role is to facilitate communication and feedback between customers and analysts.

Industry Advisors and Key Customers

Where required for specific projects, iData will employ industry advisors and consultants to better handle implications and subtleties of specific subjects.

It regularly occurs that iData's customers will participate in the research process. They are most often involved in the segmentation planning, scope of analysis, and general research design.

1.2.2 Step 2: Prepare Data Systems and Perform Secondary Research

The first task of the research team is to prepare for the data collection process: Filing systems and relational databases are developed as needed. The required low-level data is then identified, and the fields are assembled into figures and charts. Once the organizational framework is complete, secondary research (i.e., data collected from all sources besides interviews) commences.

- An initial survey of the industry segments is conducted using:
- Internal databases and libraries
- Online sources such as web-casts and newsletters
- University library affiliations
- SEC Filings
- FDA Filings
- National Health Statistics
- Company Annual Reports
- Product Brochures
- Corporate Profiles

Next, the analyst team develops an in-depth Table of Contents to serve as the organizational framework of the market research investigation. A customer and competitor database is prepared, and market estimates, which may be assembled from secondary sources are compiled.

1.2.3 Step 3: Preparation for Interviews & Questionnaire Design

The core of all iData research reports is primary market research. Interviews with industry insiders represent the single most reliable way to obtain accurate, current data about market conditions, trends, threats and opportunities. Effective interviewing is therefore critical to the success of every research project, and all iData research analysts undergo extensive training in interview designs, strategies and techniques.

Before conducting interviews with end-users or industry insiders, studies are carefully designed and tested to ensure they meet the following criteria:

- Readily understandable and avoid unnecessary jargon
- Yield all of the required information
- Gather quantitative data in the same units
- Encourage the cooperation of respondents
- Elicit specific and relevant information
- Explore the respondent's subject expertise
- Guard against industry biases and unintentional over or under estimations

1.2.4 Step 4: Performing Primary Research

At this stage, interviews are performed using contacts and information acquired in the secondary research phase. Valuable strategic information is obtained from market participants, and is then used to modify market models and cross-verify secondary research and competitor insights.

Sources Consulted

During primary research, a variety of industry and end-user sources are consulted in a complementary fashion, in order to foster greater accuracy:

- Industry Sources
- Product Managers
- Marketing Managers and Directors
- Business Development Managers
- Vice Presidents
- Chief Financial and Executive Officers
- End Users
- Key Opinion Leaders
- Physicians and Specialists
- Hospitals and Group Purchasing Organizations

Bottom-up Approach

iData relies primarily on a bottom-up approach to market estimation. In this method, each final market measurement is a sum of the data provided by each market participant. The annual shipments or revenues of market competitors are also obtained by interviews, and competitor market sizes and associated forecasts are added to obtain the total market estimate.

In contrast, the top-down approach surveys industry participants to obtain total estimates of the market size and growth rate. The resulting values are then averaged to obtain the final estimates. Although iData also obtains top-down data for verification purposes, it is considered to be significantly less reliable than bottom-up data for the simple reason that, in general, company spokespeople have a much better understanding of their own market segment than they do of the total market. Some industry participants may in fact have a poor picture of the total market state, and the inclusion of their data can significantly bias the results. Furthermore, the bottom-up approach has the capacity to generate truly “new”

information, instead of merely returning the average of what industry participants have already estimated.

Cross-Verification

Critical analysis of data received during interviews is an important phase of primary research. A report is only as accurate as the information on which it is based, and sometimes respondents may knowingly or unknowingly pass on inaccurate data. iData research analysts are trained to detect when misleading or incorrect information is being introduced into an interview. Furthermore, wherever possible iData cross-verifies all data from each respondent by interviewing others in the same industry. Answers are also confirmed by speaking to other competitors, end users and customers. Results are also corroborated with estimates obtained from secondary research, and from top-down models developed concurrently during the interview process. Misleading information is, in this way, almost always revealed, and any such data is discarded.

Measuring Growth Rate

At iData Research, market estimates are characterized for three years prior to, and seven years following the baseline year, for a 10-year total market characterization period. Growth rates are estimated using the compound annual growth rate (CAGR) calculation, which accounts for both the annual changes in revenue, and changes in the revenue growth rate. The CAGR is therefore the average yearly growth rate that would be required to yield the forecasted value, starting from the baseline figure. In iData reports, future revenue estimates are always reported in base-year U.S. dollars, for consistency.

Market Segments

During interviews with industry participants, iData analysts ensure that the way markets and products are segmented is understood and agreed upon by all parties involved. If revenue or unit estimates overlap among segments, significant biases or inaccuracies could be introduced. iData interviews are therefore carefully designed to prevent such errors.

1.2.5 Step 5: Research Analysis: Establishing Baseline Estimates

Following the completion of the primary research phase, the collected information must be synthesized into an accurate view of the market status. The most important question is the current state of the market; this must be resolved before any company can cogently formulate business plans and strategic tactics. Base year conditions can typically be determined using the following data:

- Market share
- Previous market growth rate
- Market size
- Market segmentation
- Average Selling Prices
- Competitive activities
- Market maturity
- Intensity of competition
- Customer base measurements

1.2.6 Step 6: Market Forecast and Analysis

To compete effectively, companies also require quantitative estimates of the future growth and qualitative nature of the market. iData reports feature not only our specific market forecasts, but also include significant value-added commentary on:

- Market trends
- Technological trends and innovations
- Regulatory trends
- Reimbursement trends
- Market maturity indicators
- Market share movements
- Market drivers and limiters
- New entrants into the market
- Consumer demographics

iData Forecast Methodology

iData Research uses a proprietary method to combine statistical data and opinions of industry experts to forecast future market values. Data alone is often an inadequate forecasting method, since the underlying information sometimes cannot be found. Moreover, market history does not necessarily reflect market future — new trends, technologies and treatments may arise that can render historically based inferences meaningless. In contrast, expert opinions have been found to incorporate the changes in market drivers and limiters in a more reliable way. The experts consulted include, among others, key customers, government regulators, marketing managers, sales managers, Research and Development managers, business development managers, market research consultants, management consultants, trade press journalists and company executives. Although these expert opinions are strongly weighted, care is taken to also seek dissenting opinions to avoid the hazard of group-think and band wagon effects. The insights and estimates of industry experts are then synthesized into a comprehensive forecast, constructed in light of the available historic data and other demographic or econometric variables. If the data and forecasts conflict, the standard Delphi technique is used to review the market forecasts with the industry experts previously interviewed.

Although every effort is made to provide accurate, quantitative forecasts, there are many uncontrollable and chaotic variables in the marketplace and it is virtually impossible to guarantee specific predicted

values. As such our forecasts are to be considered a “best effort” at market prediction. Fortunately, completely unexpected events are generally rare and often tend to affect the timing of the market trends rather than changing the trends themselves. The key test of forecast credibility is whether or not the analyst team has integrated all the critical elements of the market into the forecast. If the important present and future market drivers and limiters have been properly considered, the forecast will have strong credibility. In practice, it is the direction and approximate rate of change of the market that must be determined accurately, and this is where the integrated expert opinion forecasting method excels. Ultimately, growth rate forecasts tend to fall into the following conceptual categories:

- **Rapid growth:** more than 20 percent growth per year
- **Strong growth:** 10 to 20 percent growth per year
- **Moderate growth:** 5 to 10 percent growth per year
- **Low growth:** 0 to 5 percent growth per year
- **Low decline:** 0 to 5 percent decline per year
- **Medium decline:** 5 to 10 percent decline per year
- **Strong decline:** 10 to 20 percent decline per year
- **Rapid decline:** more than 20 percent decline

Strategic decisions within companies are typically made based on the category of growth expected, and should not be dependent upon accuracy to within a few percentage points. Although market research efforts increase the probability that the decisions will be profitable, it cannot eliminate all risk from any company’s business decisions.

1.2.7 Step 7: Identify Strategic Opportunities

In the process of developing the bottom-up model of the market and the integrated expert-opinion forecasts, iData analysts identify in broad terms why some companies are gaining or losing share within a given market segment. Changes in market share are the most telling indication of the effectiveness of corporate strategies; it is important to identify those who are succeeding in the market and those who are failing, and the cause of the market flux. From this understanding of the forces driving the market, the analyst team prepares its strategic recommendations. The guidelines developed are not tailored to a specific company, but describe the course of action required to succeed within the market segment. Ultimately, it is this market wisdom, beyond even the market data and forecasts, that is the most valuable component of iData market research reports and which provides our customers with the greatest competitive edge.

However, iData always advises clients that our forecasts should only be one tool among many for decision making at their companies. It should be one more source of input for their work in investigating the market and developing a strategy with a competitive edge. iData has found that our clients use the insights and forecasts from our reports in the following ways:

- Gauging timing and size of research and development activities
- Helping production departments plan to gear up or gear down to meet demand
- Assessing how quickly to increase or decrease sales force activities
- Aiding in allocating management attention
- Creating strategies for new product development
- Supporting investment decisions
- Aiding in the business planning process
- Serving as a credible, independent check on company internal forecasts
- Supporting acquisition strategies
- Assisting in allocating marketing investments
- Supporting company financial and cash flow planning

1.2.8 Step 8: Final Review and Market Release

An integral part of the iData research methodology is a built-in philosophy of quality control and continuing improvement is integral to the iData philosophy.

Quality Control

Each analyst team bears final responsibility for the quality and accuracy of their reports. This is achieved through a process of cross-verification and comparison among alternative estimators. Estimates are thus verified and refined to help guarantee superior, accurate results for iData clients.

Final Review

At the conclusion of the market research work, the responsible research manager and analyst team review and distill the results. Care is taken to ensure that all issues have been covered, all measurements have been included, and the conclusions and analysis are logical and sound. The report must be found to be as accurate, comprehensive, and as detailed as possible, given the schedule for the research. Any approved changes or additional information are also added to the report at this stage. Lastly, the final report preparation team checks several important elements of the report for consistency, accuracy, and completeness, before a report is published.

1.2.9 Step 9: Customer Feedback and Market Monitoring

iData's philosophy of continuous improvement requires that reports be monitored after publication for customer feedback and market accuracy.

Customer Feedback

Every iData customer is encouraged to provide feedback and to pose further questions, as prompted by our research reports. Free clarification and elucidation of any issues is gladly provided to our customers. iData research teams immediately correct any reported inconsistencies, mistakes or other errors to ensure that reports are accurate and up-to-date.

Continuous Market Monitoring

iData research publications are considered dynamic market databases. By constantly monitoring the markets on which research has been performed, an enduring market research relationship is fostered. Reports are updated and corrected as new or better information is discovered. This means that our clients will always have a reliable source for up-to-date research, and our analysts are always available to help clients with their unique research needs.

2

EUROPEAN GYNECOLOGICAL DEVICE MARKET OVERVIEW

2.1 INTRODUCTION

The main conditions dealt with by women's health professionals in Europe are osteoporosis, cancer, incontinence, infertility and menstrual complications. Increasingly, sub-specialties are arising, particularly in gynecology, as urologists and oncologists move into the territory originally considered a gynecology specialty, and as gynecologists move into urology and other surgical specialties.

This report includes market analysis and forecasting for the sub-segments: assisted reproduction, endometrial ablation, endometrial resection, uterine fibroid embolization, hysteroscopes, colposcopes, transcervical sterilization, female urinary incontinence slings, laser technology and dyspareunia (qualitative only), fluid management equipment, pelvic organ prolapse repair and hysterosalpingography catheters.

2.2 CURRENCY EXCHANGE RATE

Unless otherwise noted, the market values and estimates published in this report are quoted in U.S. dollars and euros. The exchange rate between the U.S. dollar and euros is listed below. These numbers are based on the average exchange rate between the currencies in 2015 from the beginning of January to the end of December.

Figure 2-1: Currency Exchange Rate, 2015

Currency	Average Exchange Rate (Local Currency per US\$)
Euro (€)	€ 0.9049
Notes: 1) All market values, ASPs and forecasts in this report are calculated using euros. 2) The numbers above are based on the average exchange rate from January to December, 2015.	
Source: iData Research Inc.	

2.3 MARKET OVERVIEW

In 2015, the European gynecology market was valued at €228.2 million, a 1.9% increase over 2014. The assisted reproduction market is causally linked to the procedure numbers, which are expected to increase at a rate of 0.8% over the forecast period. Despite the fact that the procedure numbers, and therefore sales numbers are projected to increase, the market value in four of the five sub-segments are declining due to price erosion. The assisted reproduction market is growing by unit sales, fueled by decreasing fertility, a higher age for pregnancy, government funding and new technology that is generating buzz.

Global endometrial ablation and endometrial resection are indirectly linked, offering competing treatment options for the same patients. Both segments are growing modestly at 1.5% and 0.2% respectively. The largest change in this market is the exit of Johnson & Johnson from the endometrial ablation market in March 2016, leaving over a 30% market share to be redistributed among the remaining competitors.

The uterine fibroid embolization device market is currently stable, with a 0.1% growth in total sales in 2015. The market consists of microspheres and PVA particles. Overall, procedure numbers have decreased from 2012 to 2016, as more women seek alternative treatments. In Southern Europe, many women are also delaying treatment due to the struggling economy.

Hysteroscopes and colposcopes both experienced positive growth from 2012 to 2016. Overall, both of these markets are well established and stable with similar growth projected through to 2022.

The transcervical female sterilization market is comprised of the Bayer product Essure. Essure is a set of inserts that create bilateral occlusion of the fallopian tubes. Essure is a permanent birth control option that is an alternative to surgical methods of tubal ligation and does not require general anesthesia. Essure is currently only offered in France, Italy, Spain, Portugal, the United Kingdom and the Benelux and Scandinavian regions.

The female urinary incontinence market has suffered from the negative side effects of mesh widely reported both in the United States and Europe. Overall, procedures using both synthetic and biological slings have decreased, with a transition towards autologous tissue and allogenic grafts or alternative treatment options. The market, however, saw an artificial stability in 2015 with only a 2.4% decrease in unit sales. On March 31st 2016, Astora Women's Health (previously American Medical Systems) was shut

down, causing an artificial increase in sales as clients stockpiled products. The market is expected to consistently decline in unit sales with CAGR of -1.8% over the forecast period.

Laser treatment options are an emerging market in European gynecology. Growing at an average rate of 10% over the reporting period, lasers are the fastest growing market in gynecology. Laser technology includes CO₂ lasers, neodymium: yttrium-aluminum-garnet (Nd:YAG), erbium-YAG (Er:YAG) and hybrid fractional lasers (HFL). The most common procedures are to treat vaginal atrophy and stress urinary incontinence.

The fluid management equipment market is divided into capital equipment and the tubing sub-segments. Fluid management equipment has become the new standard of care for hospitals, as monitoring standard intrauterine pressure increases patient safety during complex procedures. Despite the increased safety, some countries have been slow to invest in fluid management equipment. The capital equipment market is growing at a modest 1.6% over the reporting period while procedures using tubing are increasing at 0.5% over the reporting period.

The pelvic organ prolapse market has been heavily impacted by the negative side-effects associated with mesh. In 2008 and 2011, the FDA issued public health notifications warning about the safety risks, primarily concerning transvaginal mesh. While the backlash was smaller in Europe than the United States, the market is projecting a stable growth of 0.7% in unit sales over the forecast period. The growth is attributable to aging demographics and the increase in potential patients. However, the growth in women requiring treatment is larger than the growth in the pelvic organ prolapse repair device market.

The hysterosalpingography (HSG) catheter market value is expected to decline by a CAGR of 0.4% during the forecast period. The HSG catheter market is stable with positive growth in unit sales. Overall, the number of units sold is expected to remain stable as procedures requiring HSG catheters are expected to remain consistent. The reduction in market value is attributed to a declining ASP which offsets the sales growth.

Overall, the European gynecology market will decrease at a CAGR of -2.3% over the forecast period. Assisted reproduction had the highest market value in 2015 at €45.5 million and the HSG catheter market had the lowest market value of only €0.8 million in 2015. It is worth noting that the assisted reproduction market encompasses the most sub-segments to contribute to the market value. Overall, the gynecology market has positively growing market values, with only two out of twelve markets projecting negative growth.

Figure 2-2: Total Gynecological Device Market, Europe, 2012 – 2022 (€M)

Year	Total Market	Growth (%)
2012	€ 217.16	
2013	€ 220.45	1.5%
2014	€ 223.93	1.6%
2015	€ 228.21	1.9%
2016	€ 231.70	1.5%
2017	€ 235.23	1.5%
2018	€ 238.95	1.6%
2019	€ 242.39	1.4%
2020	€ 245.76	1.4%
2021	€ 249.54	1.5%
2022	€ 253.59	1.6%
CAGR ('15–'22)		-2.3%
Source: iData Research Inc.		

Figure 2-3: Total Gynecological Device Market, Europe, 2012 – 2022 (US\$M)

Year	Total Market	Growth (%)
2012	\$240.09	
2013	\$243.72	1.5%
2014	\$247.58	1.6%
2015	\$252.31	1.9%
2016	\$256.17	1.5%
2017	\$260.07	1.5%
2018	\$264.19	1.6%
2019	\$267.99	1.4%
2020	\$271.71	1.4%
2021	\$275.89	1.5%
2022	\$280.36	1.6%
CAGR ('15–'22)		-2.3%
Source: iData Research Inc.		

Figure 2-4: Gynecological Device Market by Segment, Europe, 2012 – 2022 (€M) (1 of 2)

Year	Assisted Reproduction Technology Device Market	Endometrial Ablation Device Market	Endometrial Resection Device Market	Uterine Fibroid Embolization Device Market	Hysteroscope Market	Colposcope Market	Female Sterilization Device Market	Female Urinary Incontinence Sling Market
2012	€42.81	€16.18	€13.71	€3.81	€28.86	€9.72	€39.38	€27.00
2013	€44.16	€16.38	€14.35	€3.54	€29.64	€9.74	€39.98	€25.61
2014	€44.85	€16.65	€14.97	€3.33	€30.48	€9.80	€40.62	€24.42
2015	€45.46	€16.91	€15.57	€3.22	€31.40	€9.91	€41.32	€23.38
2016	€46.06	€17.13	€15.54	€3.19	€32.38	€10.05	€42.04	€22.48
2017	€46.45	€17.38	€15.50	€3.24	€33.35	€10.20	€42.73	€21.70
2018	€46.95	€17.65	€15.45	€3.27	€34.30	€10.39	€43.44	€21.02
2019	€47.23	€17.92	€15.39	€3.27	€35.24	€10.59	€44.10	€20.42
2020	€47.47	€18.21	€15.33	€3.26	€36.18	€10.79	€44.74	€19.86
2021	€47.77	€18.47	€15.57	€3.26	€37.12	€10.97	€45.47	€19.39
2022	€48.22	€18.73	€15.83	€3.26	€38.04	€11.15	€46.32	€18.97
CAGR (‘15–’22)	0.8%	1.5%	0.2%	0.1%	2.8%	1.7%	1.6%	-2.9%

Source: iData Research Inc.

Figure 2-5: Gynecological Device Market by Segment, Europe, 2012 – 2022 (€M) (2 of 2)

Year	CO2 Fractional Laser Market	Fluid Management Capital Equipment Market	Pelvic Organ Prolapse Repair Device Market	HSG Catheter Market	Total Market	Growth (%)
2012	€7.50	€15.08	€12.26	€0.85	€ 217.16	
2013	€7.86	€16.06	€12.28	€0.85	€ 220.45	1.5%
2014	€8.28	€17.37	€12.31	€0.85	€ 223.93	1.6%
2015	€8.79	€19.05	€12.36	€0.85	€ 228.21	1.9%
2016	€9.70	€19.97	€12.32	€0.85	€ 231.70	1.5%
2017	€10.79	€20.69	€12.36	€0.85	€ 235.23	1.5%
2018	€11.99	€21.27	€12.38	€0.84	€ 238.95	1.6%
2019	€13.25	€21.75	€12.41	€0.84	€ 242.39	1.4%
2020	€14.52	€22.13	€12.42	€0.83	€ 245.76	1.4%
2021	€15.83	€22.42	€12.44	€0.83	€ 249.54	1.5%
2022	€17.15	€22.64	€12.46	€0.82	€ 253.59	1.6%
CAGR ('15-'22)	10.0%	2.5%	0.1%	-0.4%		-2.3%

Source: iData Research Inc.

Figure 2-6: Gynecological Device Market by Segment, Europe, 2012 – 2022 (US\$M) (1 of 2)

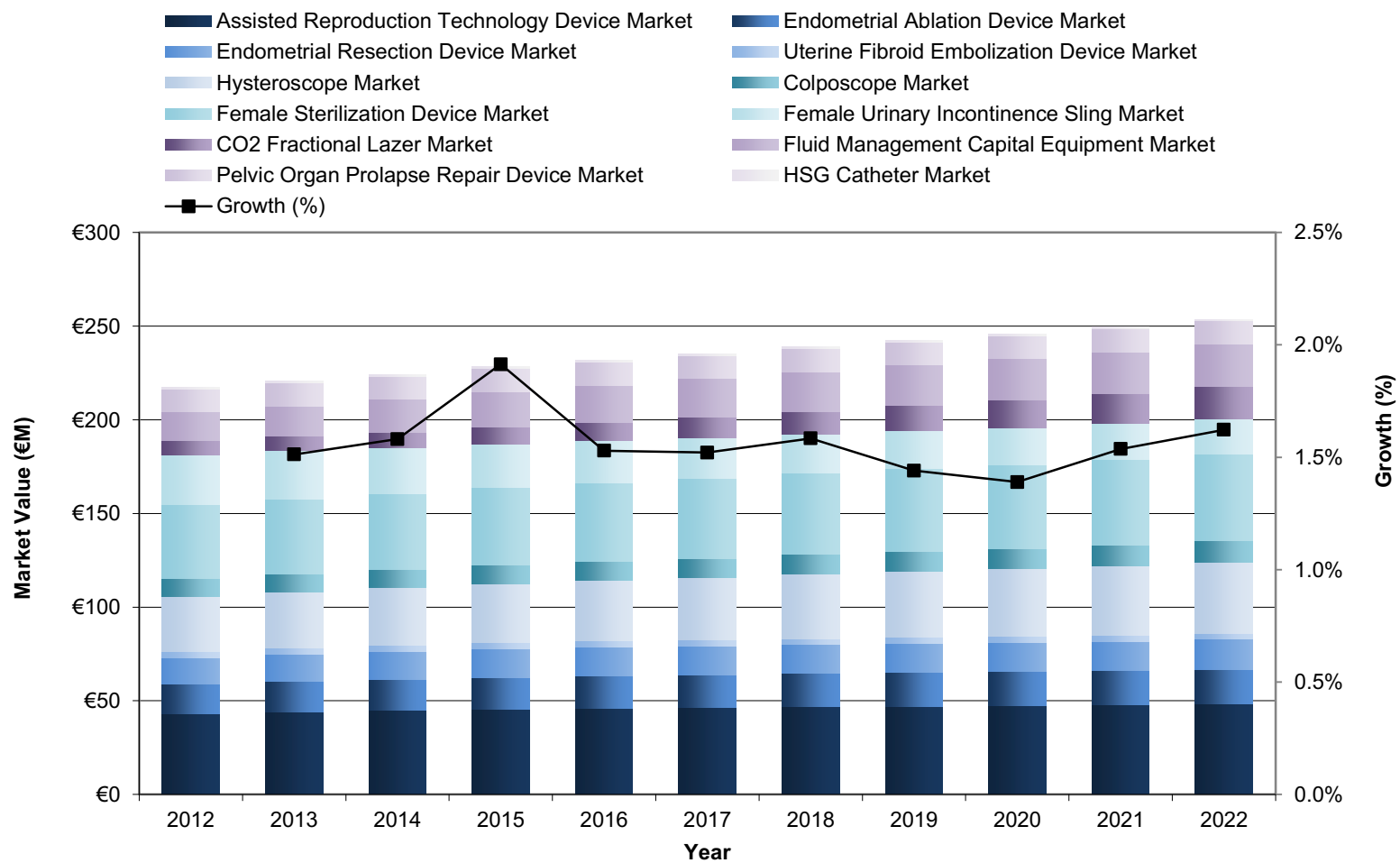
Year	Assisted Reproduction Technology Device Market	Endometrial Ablation Device Market	Endometrial Resection Device Market	Uterine Fibroid Embolization Device Market	Hysteroscope Market	Colposcope Market	Female Sterilization Device Market	Female Urinary Incontinence Sling Market
2012	\$47.33	\$17.88	\$15.16	\$4.21	\$31.91	\$10.74	\$43.54	\$29.85
2013	\$48.83	\$18.11	\$15.86	\$3.91	\$32.77	\$10.77	\$44.20	\$28.31
2014	\$49.59	\$18.41	\$16.55	\$3.69	\$33.70	\$10.84	\$44.91	\$27.00
2015	\$50.26	\$18.70	\$17.21	\$3.57	\$34.71	\$10.96	\$45.68	\$25.85
2016	\$50.92	\$18.94	\$17.18	\$3.53	\$35.80	\$11.11	\$46.48	\$24.85
2017	\$51.36	\$19.22	\$17.14	\$3.58	\$36.87	\$11.28	\$47.24	\$23.99
2018	\$51.91	\$19.52	\$17.08	\$3.61	\$37.93	\$11.48	\$48.02	\$23.24
2019	\$52.22	\$19.82	\$17.01	\$3.61	\$38.96	\$11.70	\$48.76	\$22.58
2020	\$52.49	\$20.13	\$16.95	\$3.61	\$40.01	\$11.93	\$49.47	\$21.96
2021	\$52.81	\$20.42	\$17.21	\$3.60	\$41.04	\$12.13	\$50.28	\$21.43
2022	\$53.31	\$20.71	\$17.50	\$3.60	\$42.06	\$12.32	\$51.22	\$20.97
CAGR (‘15–’22)	0.8%	1.5%	0.2%	0.1%	2.8%	1.7%	1.6%	-2.9%

Source: iData Research Inc.

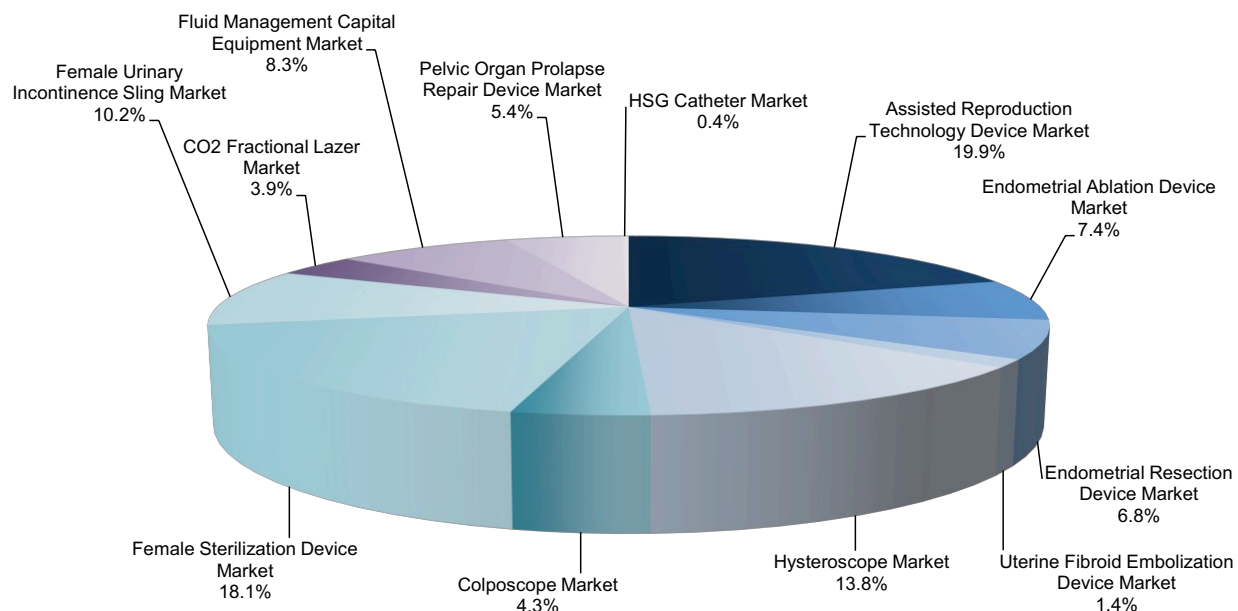
Figure 2-7: Gynecological Device Market by Segment, Europe, 2012 – 2022 (US\$M) (2 of 2)

Year	CO2 Fractional Laser Market	Fluid Management Capital Equipment Market	Pelvic Organ Prolapse Repair Device Market	HSG Catheter Market	Total Market	Growth (%)
2012	\$8.30	\$16.67	\$13.56	\$0.94	\$240.09	
2013	\$8.69	\$17.76	\$13.58	\$0.94	\$243.72	1.5%
2014	\$9.15	\$19.20	\$13.61	\$0.94	\$247.58	1.6%
2015	\$9.71	\$21.06	\$13.66	\$0.94	\$252.31	1.9%
2016	\$10.72	\$22.08	\$13.62	\$0.94	\$256.17	1.5%
2017	\$11.93	\$22.87	\$13.66	\$0.94	\$260.07	1.5%
2018	\$13.26	\$23.51	\$13.69	\$0.93	\$264.19	1.6%
2019	\$14.65	\$24.04	\$13.72	\$0.93	\$267.99	1.4%
2020	\$16.06	\$24.47	\$13.74	\$0.92	\$271.71	1.4%
2021	\$17.50	\$24.79	\$13.76	\$0.92	\$275.89	1.5%
2022	\$18.96	\$25.03	\$13.78	\$0.91	\$280.36	1.6%
CAGR (‘15–’22)	10.0%	2.5%	0.1%	-0.4%		-2.3%

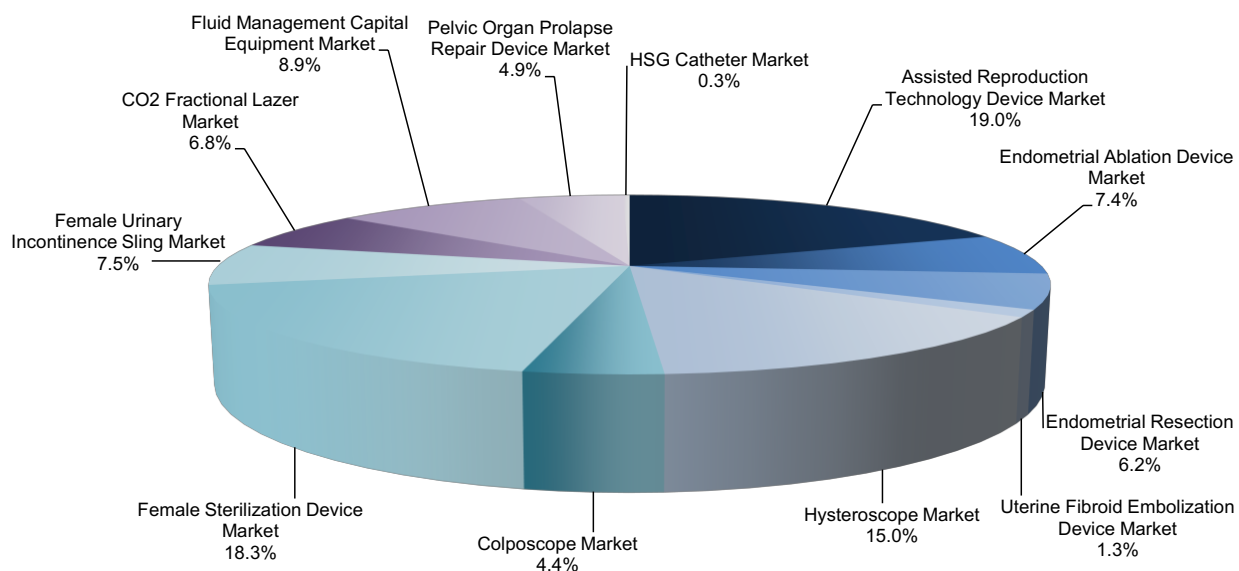
Source: iData Research Inc.

Chart 2-1: Gynecological Device Market by Segment, Europe, 2012 – 2022

Source: iData Research Inc.

Chart 2-2: Gynecological Device Market Breakdown, Europe, 2015

Source: iData Research Inc.

Chart 2-3: Gynecological Device Market Breakdown, Europe, 2022

Source: iData Research Inc.

2.4 TREND ANALYSIS

The assisted reproduction device market is directly related to procedure numbers. The trends in procedures for IVF/ICSI are driven by country legislation and reimbursement. Italy has the most conservative laws, prohibiting assisted reproduction for single women or homosexual couples. Strict legislation has led to reproductive tourism becoming a hot industry in Europe, with countries such as Spain and Portugal receiving thousands of patients from other countries annually. Additionally, emerging technologies in the field are fueling market growth. Embryo time lapse incubators and vitrification equipment are both fast growing segments of the market bolstering the overall market value.

Endometrial ablation and endometrial resection trends are interlinked. Overall, endometrial resection procedures are decreasing. Endometrial resection is necessary when fibroids are present. Otherwise, endometrial ablation is gaining favor again as the preferred treatment option. Within the endometrial resection market, the dominant trend is a dramatic shift from monopolar loops to bipolar loops between 2012 and 2015. Overall, the resectoscope market is a replacement market; however, sales have been stable as gynecologists invest in resectoscopes made for bipolar loops.

The endometrial ablation market is experiencing a gain in procedures, as procedure numbers shift from endometrial resection to ablation. Thermal balloon ablation and radiofrequency ablation are the principle types of ablation procedures, with nominal numbers of hydrothermal or cryoablation procedures being performed. There is also laser frequency ablation. However, this procedure is not covered in this report. Prior to Johnson & Johnson leaving the market, procedures had an average split of 60% radiofrequency procedures to 40% thermal balloon ablation procedures. The preference towards radiofrequency ablation may be exacerbated in the remainder of the forecast period as there are fewer competitors offering thermal balloon ablation products.

The uterine fibroid embolization market is stable, with a CAGR of 0.1% over the reporting period. The dominant trend affecting this market is the difference between public and private sales tenders. The private market is less expensive than public tenders. As more competitors are working with clients privately, the ASP is falling with a CAGR of -0.6% over the forecast period.

The hysteroscope market is comprised of rigid and flexible hysteroscopes. The rigid hysteroscope segment of the market has cannibalized the flexible hysteroscope market, comprising 92% of the market in 2015. Rigid hysteroscopes offer a wider range of procedures for hospitals and clinics that cannot

afford to invest in redundant equipment. The market shift towards rigid hysteroscopes is expected to continue over the forecast period.

Colposcopes are a very stable and mature market with high saturation. The biggest trend in colposcopes is the division between low-end cost effective colposcopes and new high-end options with documentation systems. The sales in this market are largely driven by the resources available to doctors, hospitals and clinics purchasing the equipment.

The transcervical sterilization market consists of a single product. The largest trend in female sterilization is the level of cultural acceptance towards female sterilization and the concerns about adverse side effects.

The female urinary incontinence sling market consists of synthetic and biological slings. The market trend is a transition from biological slings to synthetic slings, despite the controversy surrounding mesh. Synthetic slings are less expensive than biological slings, resulting in a falling ASP.

The largest trend in lasers is the transition from predominantly dermatologists performing non-invasive, in-office laser procedures to gynecologists starting to invest in the technology. While different countries have very different adoption rates, the market is expected to grow substantially through 2022.

The largest trend in fluid management equipment is the division between fluid management equipment compared to traditional gravity bags. The United Kingdom has the lowest adoption rate at only 25%. This is a stark contrast to Austria, which has the highest adoption rate in at 70%. Overall, countries are slowly transitioning to take advantage of the added safety that fluid management equipment offers patients.

The pelvic organ prolapse repair device market is shifting from transvaginal mesh to Sacrocolpopexy mesh which is perceived to be safer. Transvaginal mesh is decreasing by a CAGR of -1.8% while Sacrocolpopexy mesh is increasing at a rate of 3.7%, creating a net growth over the projected period.

The HSG catheter market is again influenced by the difference between public tenders vs. private sales, similar to the uterine fibroid embolization device market. HSG catheters are also competing against Asian competitors with a lower ASP. Overall, the downward pressure on ASP has created a CAGR of -1% growth in ASP over the reporting period.

Figure 2-8: Growth Rates by Segment, Gynecological Device Market, Europe, 2012 – 2022 (1 of 2)

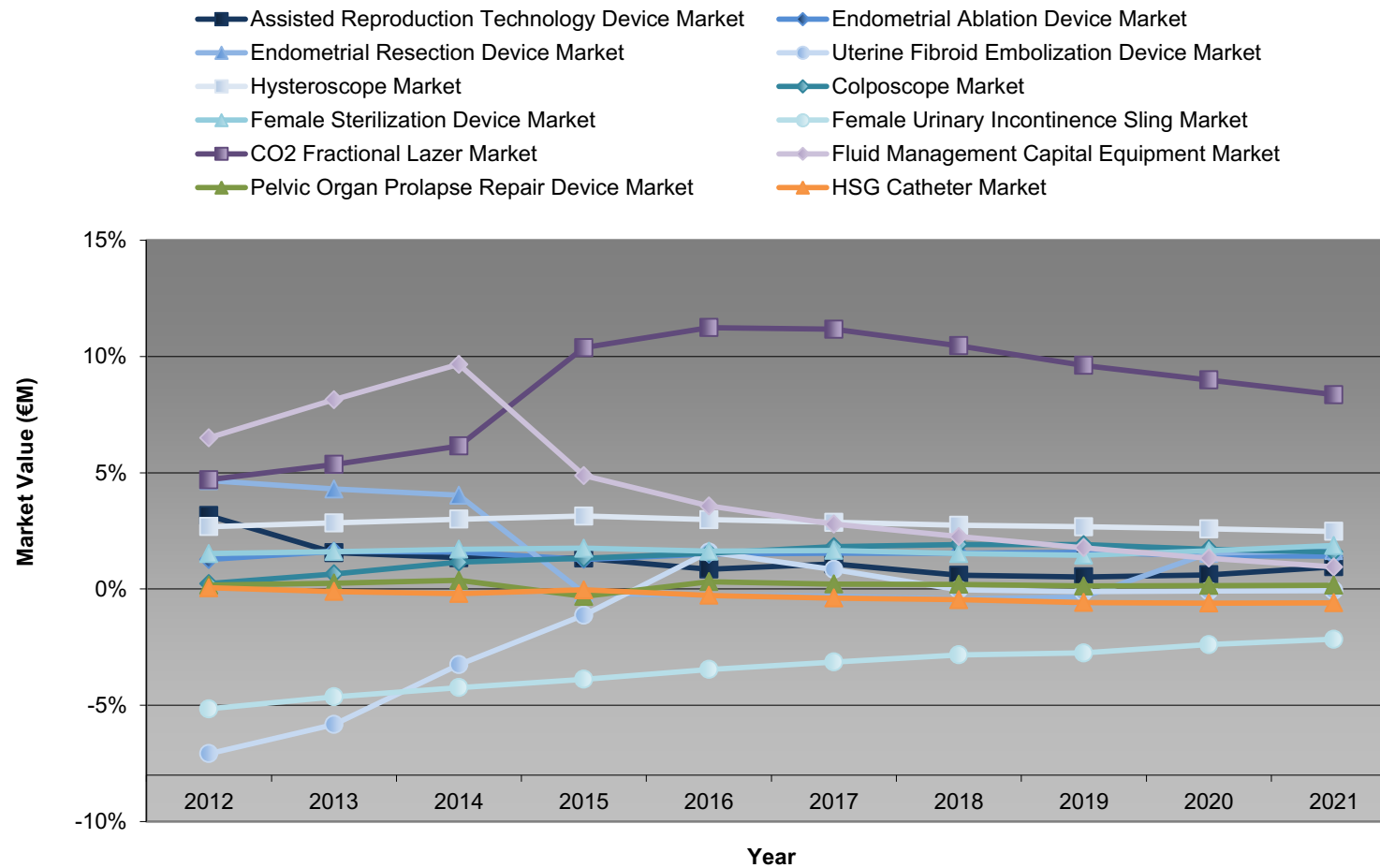
Year	Assisted Reproduction Technology Device Market	Endometrial Ablation Device Market	Endometrial Resection Device Market	Uterine Fibroid Embolization Device Market	Hysteroscope Market	Colposcope Market	Female Sterilization Device Market	Female Urinary Incontinence Sling Market
2012								
2013	3.2%	1.3%	4.7%	-7.1%	2.7%	0.2%	1.5%	-5.2%
2014	1.6%	1.6%	4.3%	-5.8%	2.8%	0.7%	1.6%	-4.6%
2015	1.3%	1.6%	4.0%	-3.3%	3.0%	1.2%	1.7%	-4.2%
2016	1.3%	1.3%	-0.2%	-1.1%	3.1%	1.3%	1.8%	-3.9%
2017	0.9%	1.5%	-0.3%	1.6%	3.0%	1.5%	1.6%	-3.5%
2018	1.1%	1.5%	-0.3%	0.8%	2.9%	1.8%	1.7%	-3.1%
2019	0.6%	1.5%	-0.4%	0.0%	2.7%	1.9%	1.5%	-2.8%
2020	0.5%	1.6%	-0.3%	-0.1%	2.7%	1.9%	1.5%	-2.8%
2021	0.6%	1.4%	1.5%	-0.1%	2.6%	1.7%	1.6%	-2.4%
2022	1.0%	1.4%	1.7%	-0.1%	2.5%	1.6%	1.9%	-2.2%
CAGR (‘15–’22)	0.8%	1.5%	0.2%	0.1%	2.8%	1.7%	1.6%	-2.9%

Source: iData Research Inc.

Figure 2-9: Growth Rates by Segment, Gynecological Device Market, Europe, 2012 – 2022 (2 of 2)

Year	CO2 Fractional Laser Market	Fluid Management Capital Equipment Market	Pelvic Organ Prolapse Repair Device Market	HSG Catheter Market	Total Market
2012					
2013	4.7%	6.5%	0.2%	0.1%	1.51%
2014	5.4%	8.1%	0.3%	-0.1%	1.58%
2015	6.1%	9.7%	0.4%	-0.2%	1.91%
2016	10.4%	4.9%	-0.3%	0.0%	1.53%
2017	11.2%	3.6%	0.3%	-0.3%	1.52%
2018	11.2%	2.8%	0.2%	-0.4%	1.58%
2019	10.5%	2.3%	0.2%	-0.5%	1.44%
2020	9.6%	1.8%	0.1%	-0.6%	1.39%
2021	9.0%	1.3%	0.1%	-0.6%	1.54%
2022	8.4%	0.9%	0.2%	-0.6%	1.62%
CAGR (‘15–’22)	10.0%	2.5%	0.1%	-0.4%	-2.3%

Source: iData Research Inc.

Chart 2-4: Growth Rates by Segment, Gynecological Device Market, Europe, 2012 – 2022

Source: iData Research Inc.

2.5 DRIVERS AND LIMITERS

2.5.1 Market Drivers

In-Office Procedures

Gynecologists and patients are favoring less invasive, in-office procedures where possible. This trend is motivated by the potential for increased revenue for the physician and increased procedure numbers, as hospital availability is not required. Many patients also prefer in-office procedures because they tend to have faster recovery times and do not require the use of general anesthesia.

Aging Population

The female population in Europe is aging. This trend is fueling the gynecology market as the majority of procedures are needed by older women. As the potential number of patients increase, the number of procedures will increase as well. In ten years, this trend is projected to reverse. As women who are 30 to 34 in 2016 reach the age of 40 to 44 in 2026, the population will be starting to decrease substantially, resulting in fewer potential patients. In 15 years, in 2031, the fall in population will increase exponentially resulting in a retraction in the European gynecology market.

New Technology

Despite the struggling economies in Europe, healthcare is more recession proof than most industries as governments are reluctant to cut healthcare budgets. As technological advancements continue, there will always be a market for new products that improve patient safety, procedure outcomes and offer improved surgical techniques. In 2016, the investments in assisted reproduction, scopes with superior optics, laser treatments and safer fluid management equipment all illustrate this trend.

2.5.2 Market Limiters

Safety and Efficacy Concerns

Due to a number of adverse side effects, both doctors and patients are becoming more diligent about patient safety and efficacy regarding procedures. The female urinary incontinence sling market, the pelvic organ prolapse repair device market and the transcervical female sterilization market have all lost market value due to safety concerns. Additionally, safety and efficacy concerns can hinder market penetration with greater research and clinical evidence needed prior to doctors investing in new equipment; as is the case with laser treatments.

Legislation and Cultural Norms

Every country in Europe has unique laws and cultural attitudes towards medical procedures. This can pose a substantial limitation towards increasing potential patients, as both doctors and patients may prefer alternative treatment options. Both of these factors are limiters on the industry, however, it both benefits and hurts countries simultaneously. For example, Italy is the market leader for lasers and is very accepting of a new technology. However, the country's laws regarding assisted reproduction drastically reduces the size of the potential market. Each country has procedures with both higher and lower growth rates than the European average.

Weak Economy

While the European economy has partially recovered from the 2008 recession, the economy is still weak in many areas. With the combination of high competition and more international competitors with inexpensive products entering the market, the ASP is already starting to decrease. As this trend continues, despite increased sales the market values of different segments will decrease.

Figure 2-10: Drivers and Limiters, Gynecological Device Market, Europe, 2015

Market Drivers
In-Office Procedures Aging Population New Technology
Market Limiters
Safety and Efficacy Concerns Legislation and Cultural Norms Weak Economy
Source: iData Research Inc.

2.6 COMPETITIVE MARKET SHARE ANALYSIS

Bayer

Bayer held the largest overall market share in 2015 with 18.11% due to the company's exclusive hold on the transcervical female sterilization market throughout Europe. In April 2013, Bayer purchased Conceptus in order to add *Essure*®, a permanent contraceptive, to its line of products. The *Essure*® product was approved by the FDA in 2002 and is clinically proven to be 99.8% effective in preventing pregnancy, based on a four year follow-up. *Essure*® is available in nine countries worldwide.

The *Essure*® device is inserted into the fallopian tubes; the patient's body then grows a barrier around the device that blocks ova from passing through. The procedure is performed in less than ten minutes without the need for anesthesia. The patient returns in three months to confirm that tissue growth is sufficient to prevent pregnancy. *Essure*® has been available since 2002 and is as efficient as surgical methods for birth control.

Karl Storz

Karl Storz holds an 11.05% market share in the European gynecology market, offering products in endometrial ablation, endometrial resection, hysteroscopes, and fluid management equipment.

In endometrial ablation, Karl Storz is a smaller competitor with only 4.83% market share. Offering the Intrauterine BIGATTI Shaver (IBS®) with the HYSTEROMAT E.A.S.I.® system. This system is for rapid tissue ablation with a small diameter and can be used in an office setting. The system is for mechanical resection and offers an alternative approach to operative hysteroscopy.

Karl Storz is the market leader in endometrial resection, in partnership with MTP (Medical Technical Promotion gmbh). MTP produces single-use medical products and accessories approved and tested exclusively for Karl Storz. This partnership between MTP and Karl Storz has allowed the companies to effectively target the entire endometrial resection market and maintain both sales and market share despite the volatile transition from monopolar loop electrodes to bipolar loop electrodes.

Karl Storz is the market leader in the European hysteroscope market, with a 42.86% market share. Their product portfolio includes a wide range of both miniaturization hysteroscopes intended for offices as well as a product line for standard gynecological procedures.

Finally, holding a 40.12% market share in the fluid management market, Karl Storz also offers the The *HYSTEROMAT E.A.S.I.*®.

Karl Storz is known for their high-quality instruments and enjoys excellent brand recognition within the medical community. The company, founded in Tuttlingen, Germany in 1945, produces medical instruments for a wide range of medical fields. Their long history in the field of medical devices has contributed to their experience and market presence.

Johnson & Johnson

In 2015, Ethicon, a Johnson & Johnson company, was the third leading competitor in the gynecological device market. Its market share can be attributed to its diversity, with significant presence in five segments, as well as having the largest market share in global endometrial ablation and female urinary incontinence slings in 2015.

In the global endometrial ablation segment, Ethicon produces the *GYNECARE™ THERMACHOICE® III* uterine balloon therapy system. This was one of the first endometrial ablation methods available; many physicians, even if they have been trained on other methods, are familiar with how to perform this procedure. This has allowed Ethicon to achieve a high penetration rate in the office market.

Ethicon offers the *Artisyn™* for pelvic organ prolapse. The repercussions of adverse effects due to pelvic floor mesh have prompted Johnson & Johnson to discontinue its line of transvaginal mesh products. However, it is still a part of the pelvic floor repair market with a mesh product for sacrocolpopexy. This device is a Y-shaped mesh indicated for sacrocolpopexy and made of both absorbable and non-absorbable fibers. The material enables distention of the vaginal flaps while the sacral flaps of the device minimize elongation.

Ethicon has removed its transvaginal mesh from the market due to litigation and FDA requirements. Its urinary incontinence sling products include the *Gynecare® TVT™* sling, which is synthetic. The *Gynecare® TVT™* sling was among one of the first products that could be implanted via a minimally invasive procedure. One of the company's competitive strategies is to market its products to gynecologists directly by increasing the awareness of the benefits of the product. As a result, gynecologists are more likely to refer patients to urologists that use this particular sling. Despite significant declines in the transvaginal mesh market for Johnson & Johnson in terms of sales, litigations and the removal of products, the company is expected to recover some footing in the pelvic organ prolapse device market through its sacrocolpopexy devices. However, one concern is that much of the profits from its women's health divisions may be swallowed by litigation costs due to the transvaginal mesh legal proceedings.

Johnson & Johnson consists of at least 230 subsidiary companies, of which Ethicon is one. Ethicon joined the Johnson & Johnson family of companies in 1949 in order to help diversify Johnson & Johnson's portfolio. Although Ethicon is known for its dominance in wound closure devices, it maintains a highly diverse product line of medical devices. Its endometrial resection system is one of many products made by one of the four companies under the Ethicon corporate umbrella.

Cooper Surgical

Cooper Surgical held a 6.90% market share due to a diverse line of products involved in multiple markets including assisted reproductive technologies, colposcopes and HSG catheters.

Cooper Surgical's acquisition of ORIGIO in June 2012 cemented the company's lead in the assisted reproduction technology segment. It led the reproduction media segment with a 31.1% market share due to multiple products including the *Sequential Series™* (for fertilization, culture and transfer), the *Sage 1-Step™* (for continuous embryo culture and transfer), the *OocyteFreeze™* and *OocyteThaw™* (for freezing and thawing embryos) and many more medias within the ART market. Cooper Surgical was also in third place in the oocyte retrieval needle market with a 19.3% share. Cooper offered both single and double lumen oocyte retrieval needles. In the embryo transfer catheter market, Cooper Surgical held second place with the *R.G. Edwards® Embryo Transfer Products* and the *STRIPPER®* at 32.4%. Cooper Surgical's products are highly regarded and trusted in the assisted reproduction segment.

Prior to the acquisition, ORIGIO was known for its diverse product lines of micropipettes and media. The pipettes include the ICSI, which is available in many different sizes and angles so that physicians can customize what is required for the procedure. Cooper Surgical has also expanded its presence within the embryo transfer catheter segment with this acquisition.

Its German-made *Leisegang®* line of colposcopes has enjoyed excellent brand recognition and popularity throughout the world. Its *Optik®* colposcope uses light-emitting diodes to provide over double the brightness of halogen bulbs and increased clarity. It also contains a digital SLR camera for documentation. Cooper Surgical offers a standard model as well as a model with digital imaging. It also has the *CerviPATH™*, which integrates with the *Leisegang Optik®*.

Additionally, Cooper Surgical offers a wide variety of HSG and H/S catheters specialized for either hysterosalpingography, sonohysterography or both. Its devices include the *EZ-HSG™*, which is a balloonless and latex-free catheter, the *H/S Elliptosphere™*, which is offered as a catheter set and tray, and a standard H/S catheter that is available with or without an integrated stylet. Its various H/S and

HSG catheters are available with adjustments for various patient types. Diversifying its HSG catheters may allow the company more extensive penetration into the end-user market. Its lead in this market can be attributed, in part, to its exceptional brand recognition within the health care community, large supply network and established distribution channels.

Cooper Surgical, a branch of Cooper Companies, is a company that is dedicated to women's health products. It has a wide range of products available for women's health and has, over the years, acquired a wide portfolio of companies in order to deliver an expansive range of healthcare products to women. These products are available at the three major point-of-care areas for women, which consist of offices, hospitals and fertility clinics.

On June 1st 2016, Cooper Surgical also acquired Reprogenetics UK. Reprogenetics UK is one of the preeminent genetics laboratories specializing in preimplantation screening (PGS) and preimplantation diagnosis (PGD). It is also worth noting that as part of the acquisition, Reprogenetics UK will maintain its association with Reprogenetics, its U.S. counterpart. Cooper Surgical now includes an extensive lineup of ART genetic testing companies that includes Reprogenetics, Genesis Genetics (including its U.K. division) and the newly acquired Recombine.

Richard Wolf

Richard Wolf holds a 6.27% overall market share, offering products in endometrial resection, hysteroscopes and fluid management equipment. Engineering resectoscopes compatible with both monopolar and bipolar loop electrodes has enabled their market share to remain stable amidst larger competitors. Richard Wolf also offers the "Princess" hysteroscope, the smallest resectoscope on the market. Richard Wolf is the second leading competitor in the European hysteroscope market, offering compact hysteroscopes and held a 26.99% share in the fluid management market.

Astora Women's Health

Endo Health Solutions acquired American Medical Systems in 2011. Following the acquisition, Endo rebranded American Medical System's Women's Health division to Astora Women's Health. As part of the initial acquisition of AMS, Endo Health Solutions also acquired over 22,000 lawsuits regarding AMS's vaginal mesh products for the treatment of pelvic organ prolapse and urinary incontinence. On March 31st 2016, Endo Health Solutions officially closed Astora Women's Health, leaving a large gap in the market.

In 2015, American Medical Systems held the second highest market share in the female urinary incontinence market at 25.90%. AMS offered an extensive line of TVT and TOT synthetic slings. The company also offered a series of single-incision slings, biological slings and the first hybrid device.

Vitrolife

Vitrolife offers assisted reproduction products in the sub-segments oocyte retrieval needles, micropipettes, reproduction media and embryo time lapse incubators. Established in 1994, Vitrolife has successfully completed several acquisitions to expand their market share and product range. Vitrolife is the leader in embryo time lapse incubators, with the first product being used in 2009. In July 2016, Vitrolife announced the introduction of the EmbryoScope+ system, the company's second generation of embryo time lapse incubators.

Boston Scientific

Boston Scientific held a 4.07% market share of the gynecological device market in 2015. This corresponds to its products across four markets. In the global endometrial ablation market, it offers the *Hydro ThermAblator™* (HTA) system, which is the only endometrial ablation method performed as a hysteroscopic procedure, allowing the physician direct visualization during the treatment. This method, which uses heated saline to destroy the lining, has had excellent success rates in clinical studies, particularly over the long term.

Boston Scientific also held a large share of the vaginal mesh market. Boston Scientific offers the *Uphold™* vaginal support system, an intra-vaginal system that requires only a small incision and mesh. This uses the *Capio® Suture Capturing Device* and the *Polyform™ Synthetic Mesh* that is made from uncoated monofilament macroporous polypropylene. This device has a blue centering line to improve visual orientation and easy mesh leg assembly.

Within the urinary sling market, Boston Scientific offers a wide range of products, including the *Advantage Fit™ System*, which features innovative mid-urethral slings, the *Advantage® Transvaginal*, *Lynx® Suprapubic* and *Obtryx® Transobturator* mid-urethral sling systems. The *Advantage® Mesh* is designed to reduce the risk of deformation and vaginal wall irritation.

The sale of American Medical Systems' urology portfolio in March 2015 to Boston Scientific did not include American Medical Systems' pelvic organ prolapse or female stress urinary incontinence products. Thus, this \$1.65 billion acquisition had no effect on this market.

Boston Scientific is also involved with the uterine fibroid embolization market where it was the second leading competitor with a 27.29% share. It offers both *Contour SE* microspheres and *Contour PVA* embolization particles.

Deka Medical Lasers

Deka Medical Lasers is the leader in the laser technology segment with a 41.68% market share. As the first to market in Europe, Deka offers the *MonaLisa Touch*® utilizing the Smartxide² V²LR CO₂ laser configuration. The *MonaLisa Touch* is effective treating vaginal atrophy and dryness, vaginal laxity and stress urinary incontinence. As a non-surgical, non-pharmaceutical treatment, the *MonaLisa Touch*® also has the most scientific analysis and clinical findings supporting the technology.

Merit Medical Systems

Merit Medical Systems gained 0.48% of the overall gynecological device market; however, they represent the market leader in the uterine fibroid embolization device market with a 33.76% share. Merit is involved in both the microsphere and PVA particle segments of embolotherapy, which work by reducing blood flow to targeted areas of the body. It was the first company to receive FDA approval to market its *Embosphere*® *Microspheres* as a product for UFE and thus gave it a strong hold on the microsphere market that it has maintained. The company's offerings in particle embolics include *Bearing™ nsPVA particles*, *Embosphere*® *Microspheres* and *WuadraSphere*® *Microspheres*. Merit produces and packages all of its microspheres and also offers *EmboCath*®, which is a catheter that aids in delivering its embolic products.

Merit Medical Systems is a medical device company that is primarily focused on the production and distribution of disposable medical products. The market segments in which it specializes are cardiology, endoscopy and radiology. While this company is international, with manufacturing companies worldwide, it is headquartered in the United States.

Figure 2-11: Leading Competitors, Gynecological Device Market, Europe, 2015 (1 of 4)

Company	Assisted Reproduction Technology Device Market	Endometrial Ablation Device Market	Endometrial Resection Device Market	Uterine Fibroid Embolization Device Market	Hysteroscope Market	Colposcope Market	Female Sterilization Device Market	Female Urinary Incontinence Sling Market
Bayer	—	—	—	—	—	—	100.00%	—
Karl Storz	—	4.83%	21.24%	—	42.86%	—	—	—
Johnson & Johnson	—	30.88%	18.43%	—	4.61%	—	—	26.21%
Cooper Surgical	27.38%	—	—	—	—	30.15%	—	—
Olympus	—	—	21.02%	—	15.94%	15.15%	—	—
Richard Wolf	—	—	15.60%	—	21.44%	—	—	—
Cook Medical	26.47%	—	—	—	—	—	—	—
Astora Women's Health	—	—	—	—	—	—	—	25.90%
Boston Scientific	—	13.37%	—	27.29%	—	—	—	17.37%
Vitrolife	20.01%	—	—	—	—	—	—	—
Hologic	—	29.66%	—	—	—	—	—	—
Coloplast	—	—	—	—	—	—	—	11.73%
Deka	—	—	—	—	—	—	—	—
CR Bard	0.08%	—	—	—	—	—	—	6.89%
Medtronic	—	6.60%	12.61%	—	—	—	—	—
Carl Zeiss	—	—	—	—	—	28.29%	—	—
Smiths Medical	4.28%	—	—	—	—	—	—	—
AlmaSurgical	—	—	—	—	—	—	—	—
Fotona	—	—	—	—	—	—	—	—
Kaps Optik GmbH	—	—	—	—	—	12.81%	—	—
CCD	2.77%	—	—	—	—	—	—	—

Source: iData Research Inc.

Figure 2-12: Leading Competitors, Gynecological Device Market, Europe, 2015 (2 of 4)

Company	CO2 Fractional Lazer Market	Fluid Management Capital Equipment Market	Pelvic Organ Prolapse Repair Device Market	HSG Catheter Market	Total Market Share
Bayer	—	—	—	—	18.11%
Karl Storz	—	40.12%	—	—	11.05%
Johnson & Johnson	—	—	6.00%	—	7.19%
Cooper Surgical	—	—	—	37.34%	6.90%
Olympus	—	24.11%	—	—	6.30%
Richard Wolf	—	26.99%	—	—	6.27%
Cook Medical	—	—	—	35.23%	5.40%
Astora Women's Health	—	—	31.62%	—	4.37%
Boston Scientific	—	—	16.88%	—	4.07%
Vitrolife	—	—	—	—	3.98%
Hologic	—	—	—	—	2.20%
Coloplast	—	—	12.80%	—	1.90%
Deka	41.68%	—	—	—	1.60%
CR Bard	—	—	15.02%	—	1.54%
Medtronic	—	—	—	—	1.35%
Carl Zeiss	—	—	—	—	1.23%
Smiths Medical	—	—	—	—	0.85%
AlmaSurgical	18.92%	—	—	—	0.73%
Fotona	18.31%	—	—	—	0.71%
Kaps Optik GmbH	—	—	—	—	0.56%
CCD	—	—	—	—	0.55%

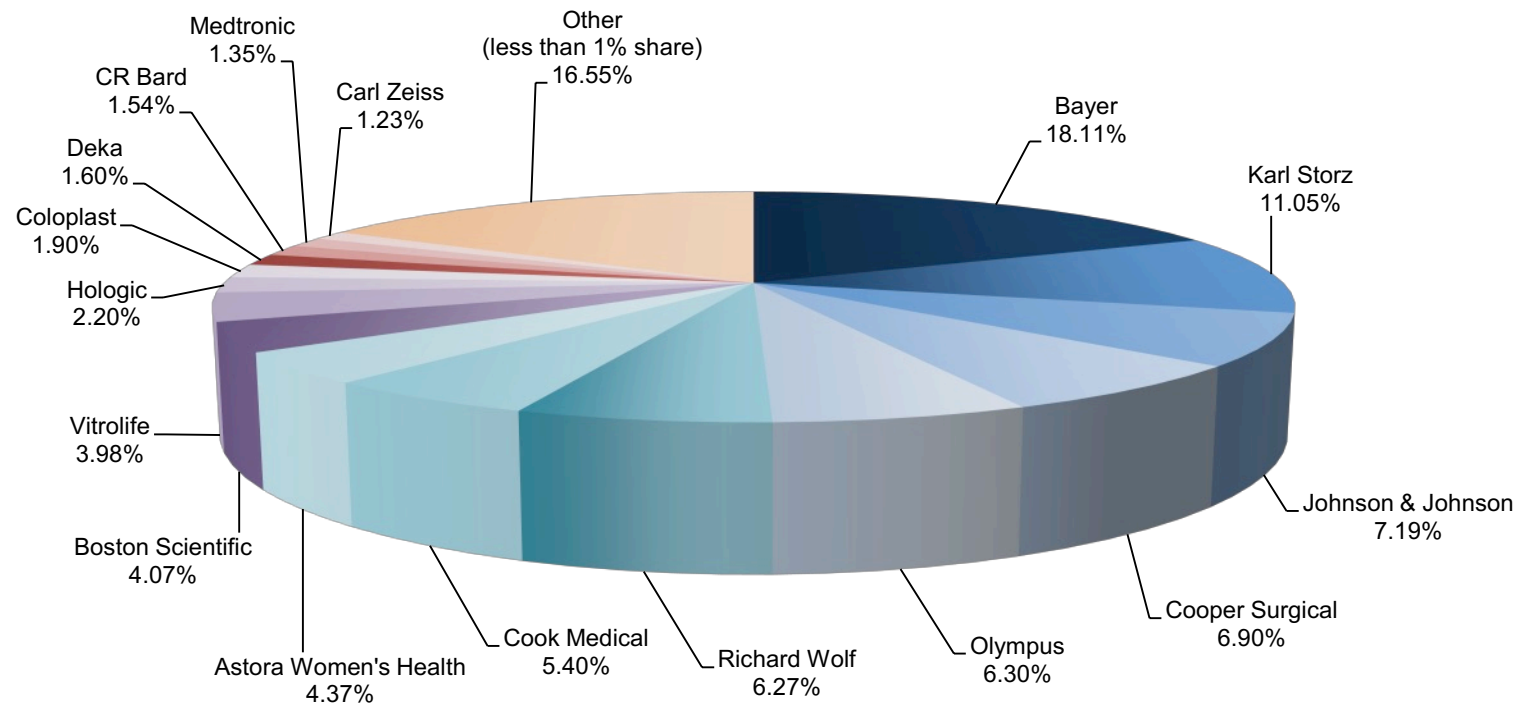
Source: iData Research Inc.

Figure 2-13: Leading Competitors, Gynecological Device Market, Europe, 2015 (3 of 4)

Company	Assisted Reproduction Technology Device Market	Endometrial Ablation Device Market	Endometrial Resection Device Market	Uterine Fibroid Embolization Device Market	Hysteroscope Market	Colposcope Market	Female Sterilization Device Market	Female Urinary Incontinence Sling Market
Merit Medical Systems	—	—	—	33.76%	—	—	—	—
JCD	2.17%	—	—	—	—	—	—	—
Kebomed	—	—	4.75%	—	—	—	—	—
Gynetics	1.46%	—	—	—	—	—	—	—
Merck KGaA - Genea Biomedx	1.32%	—	—	—	—	—	—	—
Serag Weisner	—	—	—	—	—	—	—	—
Sciton	—	—	—	—	—	—	—	—
Terumo	—	—	—	16.11%	—	—	—	—
Lumenis	—	—	—	—	—	—	—	—
Esco	1.05%	—	—	—	—	—	—	—
Irvine Scientific	0.09%	—	—	—	—	—	—	—
BTG	—	—	—	1.21%	—	—	—	—
The LifeGlobal Group	0.06%	—	—	—	—	—	—	—
Other	12.87%	14.66%	6.34%	21.63%	15.16%	13.59%	0.00%	11.90%
Total	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
Market Value (€M)	€45.5	€16.9	€15.6	€3.2	€31.4	€9.9	€41.3	€23.4
Others include: FertiPro, Gynemed, Hunter Scientific (distributor), InVitroCare, Kitazato, Labotect, Reproline, Rocket Medical, Smiths Medical, Sunlight Medical, TPC, Idoman, Thermablate, Inova Diagnostics, Cordis, Stryker, Leica, Agency for Medical Innovations (A.M.I.), B. Braun, Caldera Medical, Helioscopie, Neomedic International, Aesculap, Cousin Biotech, CL Medical Abiss, Neomedic, GCD, Argon, Mermaid Medical etc								
Source: iData Research Inc.								

Figure 2-14: Leading Competitors, Gynecological Device Market, Europe, 2015 (4 of 4)

Company	CO2 Fractional Lazer Market	Fluid Management Capital Equipment Market	Pelvic Organ Prolapse Repair Device Market	HSG Catheter Market	Total Market Share
Merit Medical Systems	—	—	—	—	0.48%
JCD	—	—	—	—	0.43%
Kebomed	—	—	—	—	0.32%
Gynetics	—	—	—	—	0.29%
Merck KGaA - Genea Biomedx	—	—	—	—	0.26%
Serag Weisner	—	—	4.57%	—	0.25%
Sciton	6.13%	—	—	—	0.24%
Terumo	—	—	—	—	0.23%
Lumenis	6.06%	—	—	—	0.23%
Esco	—	—	—	—	0.21%
Irvine Scientific	—	—	—	—	0.02%
BTG	—	—	—	—	0.02%
The LifeGlobal Group	—	—	—	—	0.01%
Other	8.90%	8.78%	13.11%	27.43%	10.17%
Total	100.0%	100.0%	100.0%	100.0%	100.0%
Market Value (€M)	€8.8	€19.0	€12.4	€0.8	€228.2
Others include: FertiPro, Gynemed, Hunter Scientific (distributor), InVitroCare, Kitazato, Labotect, Reproline, Rocket Medical, Smiths Medical, Sunlight Medical, TPC, Idoman, Thermablate, Inova Diagnostics, Cordis, Stryker, Leica, Agency for Medical Innovations (A.M.I.), B. Braun, Caldera Medical, Helioscopie, Neomedic International, Aesculap, Cousin Biotech, CL Medical Abiss, Neomedic, GCD, Argon, Mermaid Medical etc.					
Source: iData Research Inc.					

Chart 2-5: Leading Competitors, Gynecological Device Market, Europe, 2015

Source: iData Research Inc.

2.7 MERGERS AND ACQUISITIONS

Cooper Surgical acquired Reprogenetics UK

On June 1st 2016, Cooper Surgical also acquired Reprogenetics UK. Reprogenetics UK is one of the preeminent genetics laboratories specializing in preimplantation screening (PGS) and preimplantation diagnosis (PGD). It is also worth noting that as part of the acquisition, Reprogenetics UK will maintain its association with Reprogenetics, its USA counterpart. Cooper Surgical now includes an extensive lineup of ART genetic testing companies that includes Reprogenetics, Genesis Genetics (including its UK division) and the newly acquired Recombine.

Medtronic acquired Smith & Nephew's Gynecology Business

On May 18th, 2016, Medtronic announced it has signed an agreement to acquire Smith & Nephew's gynecology business for app. USD \$350 million. The acquisition is expected to close in the summer of 2016. Smith and Nephew's gynecology portfolio includes the TRUCLEAR System, a pathology-optimizing, hysteroscopic tissue removal system. Medtronic believes the acquisition will be a valuable addition helping the company to expand their less-invasive treatment options to help abnormal uterine bleeding.

Cooper Surgical acquired Research Instruments Limited

On December 17, 2015, Cooper Surgical acquired Research Instruments Limited for app. \$51 million USD. Research Instruments Limited specializes in in-vitro fertilization (IVF) medical devices and systems. Headquartered in the UK, the company offers specialized manufacturing and a strong distribution network as an addition to Cooper Surgical's women's health care unit.

Boston Scientific acquired CeloNova Biosciences Interventional Radiology Business

On November 10, 2015, Boston Scientific announced its definitive agreement to acquire the interventional radiology portfolio of CeloNova, including their drug-eluting microspheres and spherical embolic products used to treat uterine fibroids and other conditions. The initial acquisition price was \$70 million with additional payments expected based on regulations and sales benchmarks.

Boston Scientific acquired American Medical Systems' Urology Portfolio

In March 2015, American Medical Systems' urology portfolio was purchased by Boston Scientific for \$1.65 billion. The acquisition only included AMS' Men's Health and Prostate Health businesses. \$1.6 billion of the purchase was upfront cash and the additional \$50 million is dependent on 2016 sales. The products included in the acquisition treat benign prostatic hyperplasia (BPH), male stress urinary

incontinence and erectile dysfunction. These products should complement Boston Scientific's existing urology and gynecology portfolios well.

The acquisition did not include American Medical Systems' pelvic organ prolapse or female stress urinary incontinences products. Thus, this \$1.65 billion acquisition had no effect on this market.

Bayer acquired Conceptus

In April 2013, Bayer acquired Conceptus for approximately \$1.1 billion in cash. The purchase was focused on adding the *Essure*®, a permanent contraceptive device, to its portfolio. This device provided Bayer with dominance of the female sterilization device market and nicely complemented its other offerings in women's health.

Upon purchase, Conceptus shareholders received \$31 a share in cash, a price that was 20% above its most recent closing value before the purchase.

C.R. Bard acquired Rochester Medical Corporation

On September 4, 2013, C.R. Bard announced the acquisition of Rochester Medical, Inc. The acquisition closed at approximately \$262 million USD or a share price of \$20 USD. Rochester Medical is a leading developer and supplier of silicone urinary incontinence and urine drainage products. The transaction was structured as a merger and leaves both companies in an advantageous position to compete in the global homecare market.

Cooper Surgical acquires ORIGIO

In June 2012, all outstanding shares and warrants for ORIGIO were acquired by Cooper Surgical for \$189 million. Of the \$189 million, \$151 million purchased equity and \$38 million paid off remaining debt. This acquisition greatly expanded Cooper Surgical's presence in the assisted reproductive technology market.

Founded in 1987, ORIGIO was a global leader in the ART market with its array of culture media, needles and catheters. It is based in Malov, Denmark, and has approximately 320 employees. It now operates as a Cooper Surgical company, thus maintaining the brand recognition of the ORIGIO name.

3

COUNTRY PROFILES

3.1 INTRODUCTION

3.1.1.1 Population

In 2015, the population of the European market covered in this report was 395,674,067. This encompasses 15 countries and regions. While the female population is app. 51.8% of the total population for a potential patient base of 205,150,794, the value of the women's health market corresponds to the population size. Additional factors such as reimbursement rates and country laws also affect procedure rates and unit sales for specific markets in certain countries.

Figure 3-1: Population by Country, Europe, 2015

Country	Population (Millions)
Germany	80,688,545
France	64,395,345
U.K.	64,523,579
Italy	57,797,685
Spain	46,121,699
Benelux*	28,791,231
Scandinavia**	26,162,931
Switzerland	8,298,663
Austria	8,544,586
Portugal	10,349,803
Average Per Country	
*Benelux comprises Belgium, the Netherlands and Luxembourg	
**Scandinavia comprises Sweden, Norway, Denmark and Finland	
Source: iData Research Inc.	

Figure 3-2: Population, Benelux, 2015

Country	Population (Millions)
Belgium	11,299,192
Netherlands	16,924,929
Luxembourg	567,110
Source: iData Research Inc.	

Figure 3-3: Scandinavia, Europe, 2015

Country	Population (Millions)
Sweden	9,779,426
Norway	5,210,967
Denmark	5,669,081
Finland	5,503,457
Source: iData Research Inc.	

3.1.1.2 Median Age

The Median age in Europe is 38.4 years for men and 41.3 years for women. As European population pyramids continue to reflect an aging majority demographic, the female gynecology market is expected to expand as procedures correlate with higher ages.

3.1.1.3 GDP Per Capita

GDP per capita is the economic output of a country in a given year divided by the population of that country. The index measures the nominal purchasing power of an average inhabitant in a particular year. Countries with high GDP per capita tend to have higher spending on women's health devices and higher penetration rates for newer devices. Increased GDP also translates to higher funding and reimbursement rates which often encourages physicians to purchase more expensive capital equipment.

Figure 3-4: GDP per Capita, Europe, 2015

Country	GDP per Capita (US\$ Thousands)
Germany	46.2
France	40.5
U.K.	39.8
Italy	35.1
Spain	33.8
Benelux*	47.1
Scandinavia**	48.9
Switzerland	58.1
Austria	46.6
Portugal	27.1
European Average	
Source: iData Research Inc.	

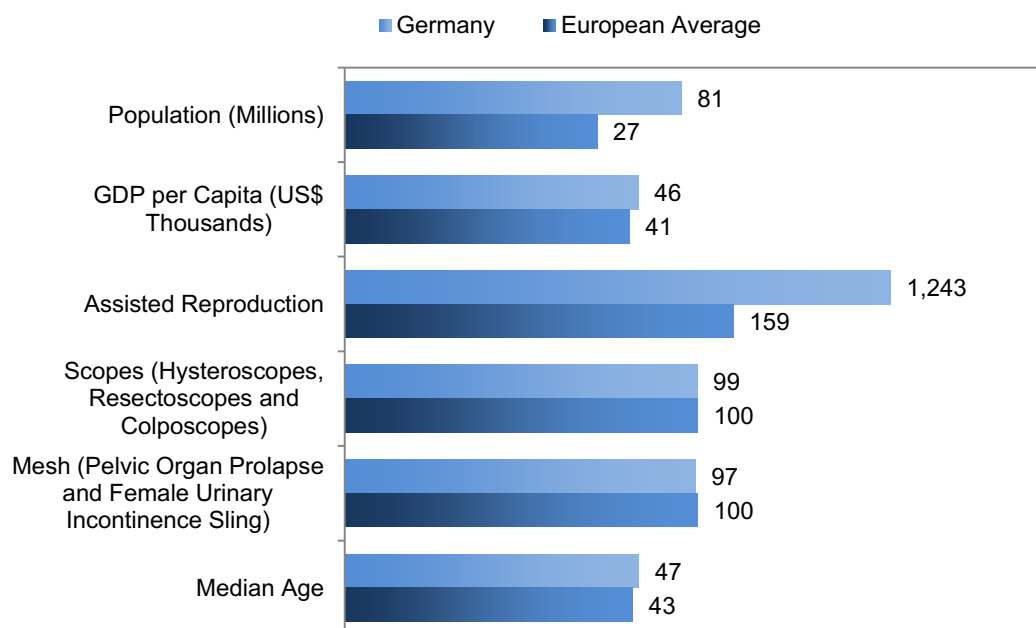
3.1.1.4 Price Index

The price index for country comparison examines the ASP of gynecology capital equipment scopes; specifically Resectoscopes, Hysteroscopes and Colposcopes. The price index is calculated by combining the ASP in a specific country and dividing the result by the European average. For example, a price index of 110 means that women's health devices are 10% more expensive in that country. A selection of scopes was chosen as a benchmark example because these markets accurately depict the dominant European trends across markets. The market value of these categories combined also corresponds well with population size and health of the economy.

3.2 GERMANY

In 2015, the price index for Germany was 99, meaning that the price of gynecological devices was 1% below the European average. Overall, Germany has consistently average to slightly above average ASP's for devices. As the German economy is considered to be stable, the quality of devices tends to be higher in Germany, lending itself to higher prices. However, Germany is centrally located and many manufacturers are located or based in Germany and sell direct to clients. This negates price increases from VAT exchange rates, costly shipping and avoids the price markup present with distributors. The GDP in Germany is on par with the European Average. In comparison with some other countries where reimbursement is declining rapidly, Germany has a much more stable market, both in terms of ASP as well as unit sales. Because Germany is the most populous country in Europe, it tends to be the largest market for most segments.

Chart 3-1: Country Profile, Germany, 2015



Note:

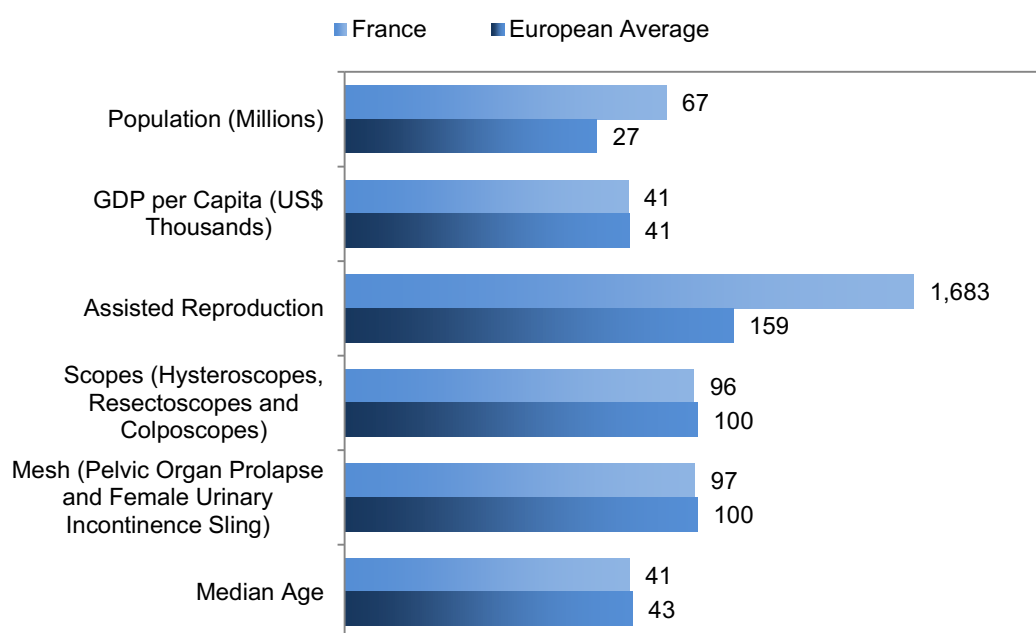
- 1) Numbers for Europe are based on the average for the listed countries.
- 2) Price Index = 100 for the European average.
- 3) GDP per capita based on 2015 US\$ values.
- 4) Chart is in logarithmic scale.

Source: iData Research Inc.

3.3 FRANCE

The price index for France was 96 in 2015, meaning that the price of gynecological devices was 4% below the European average. France has a conservative market that is slower to adopt new technology relative to other European countries. This is the result of patients and practitioners trusting traditional methods with proven safe outcomes and constraints on resources. France is the second most populous country in Europe, which is often reflected in the market size of each segment.

Chart 3-2: Country Profile, France, 2015



Note:

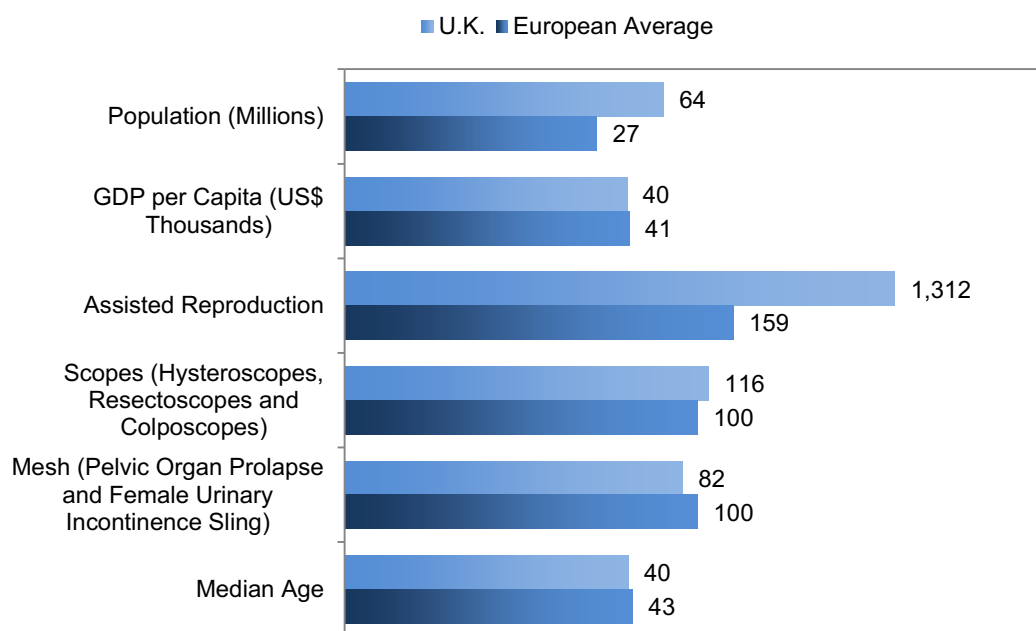
- 1) Numbers for Europe are based on the average for the listed countries.
- 2) Price Index = 100 for the European average.
- 3) GDP per capita based on 2015 US\$ values.
- 4) Chart is in logarithmic scale.

Source: iData Research Inc.

3.4 UNITED KINGDOM

In 2015, the price index for the U.K. was 116, meaning that the price of gynecological devices was 16% above the European average. The exchange rate between the British Pound and Euro is, in part, the cause for this trend, as the GBP closed 2015 at 0.74 cents to €1 driving up the prices in the United Kingdom. The United Kingdom also had a GDP per capita of \$39.8 USD, lower than the European average of \$41 USD. The National Health Service (NHS) has also been a strong influencer in the market, examining the safety risks of mesh products with greater scrutiny and examining the cost-effectiveness of medical device purchases. The U.K. presents a unique bimodal trend, being very conservative and slow to adopt certain new technologies (fluid management equipment) while also on the forefront of innovation (embryo time lapse incubators for assisted reproduction). Overall, a trend consistent across Europe including the U.K. is the movement towards office-based and outpatient procedures fueling capital equipment purchases.

Chart 3-3: Country Profile, United Kingdom, 2015



Note:

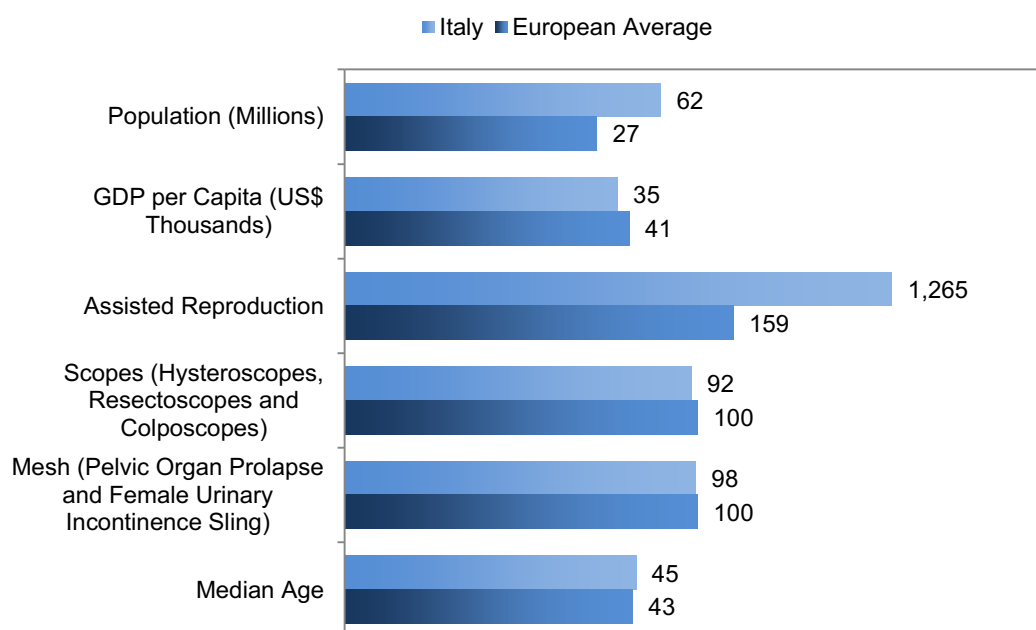
- 1) Numbers for Europe are based on the average for the listed countries.
- 2) Price Index = 100 for the European average.
- 3) GDP per capita based on 2015 US\$ values.
- 4) Chart is in logarithmic scale.

Source: iData Research Inc.

3.5 ITALY

In 2015, the price index for Italy was 92, meaning that the price of gynecological devices was 8% lower than the European average. Italy's healthcare system is highly regionalized, and there are differences in reimbursement and policy from one area to the next. Again, we see that a lowered ASP correlates with a lower-than-average GDP. Italy's resource-strapped healthcare system creates an environment of decreasing ASP as manufacturers price competitively in order to gain available accounts. The pricing environment is being further exacerbated by the popularity and introduction of Asian manufacturers offering a lower price point than western manufacturers. The lower ASP in Italy is also reflective of different types of products being purchased, often less sophisticated systems at a lower ASP are preferred more so than the same product being offered at a lower price point compared to other countries.

Chart 3-4: Country Profile, Italy, 2015



Note:

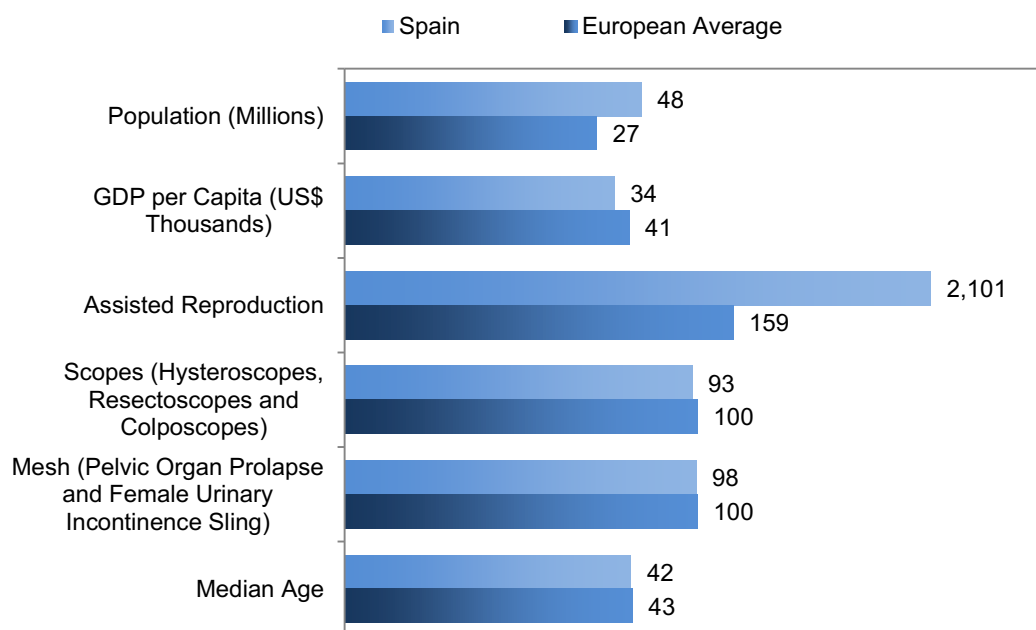
- 1) Numbers for Europe are based on the average for the listed countries.
- 2) Price Index = 100 for the European average.
- 3) GDP per capita based on 2015 US\$ values.
- 4) Chart is in logarithmic scale.

Source: iData Research Inc.

3.6 SPAIN

In 2015, the price index for Spain was 93, meaning that the price of gynecological devices was 7% below the European average. The downturn in Spain's economy has limited market growth in the gynecology sector. Overall, Spain is seeking cost-saving alternatives and waiting longer to replace capital equipment. However, Spain has a strong trend of preferring high end microscopic equipment. This is potentially caused by both the national and multinational competitors located in Spain. This has led to particular "hot markets" including assisted reproduction tourism, microscopes and gynecology scopes equipped with documentation systems. Overall, Spain's existing trends of preferring inexpensive equipment with lower technology due to budget constraints is expected to continue throughout the reporting period; with a few markets continuing to be an exception.

Chart 3-5: Country Profile, Spain, 2015



Note:

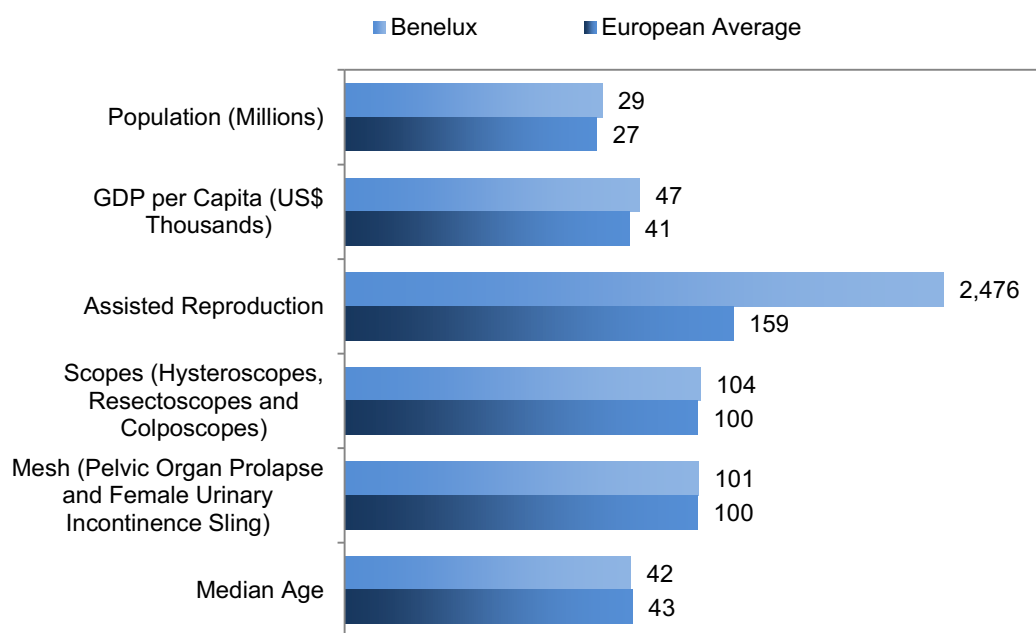
- 1) Numbers for Europe are based on the average for the listed countries.
- 2) Price Index = 100 for the European average.
- 3) GDP per capita based on 2015 US\$ values.
- 4) Chart is in logarithmic scale.

Source: iData Research Inc.

3.7 BENELUX

Benelux includes Belgium, the Netherlands and Luxembourg. In 2015, the price index for Benelux was 104, meaning that the price of gynecological devices was higher than the European average. In the Netherlands, the national health care system is very progressive, and is quick to adopt new technologies and procedures. Belgium reimburses procedures performed in hospitals, but the government only partially reimburses for those done in clinics. Devices used by the surgeons are paid for by the hospital or charged to the patient. Therefore, the Belgian market is heavily influenced by hospitals. As a result of this, we see that most scope sales in Benelux are in hospitals. Unlike the U.S. or German-speaking countries in Europe, the market for lower-end devices is still overwhelmingly dominant. The drive for optimizing cost-effective health care encourages hospitals to purchase less-expensive or moderately priced capital equipment. However, a high standard of care and stable economy places ASP's close to the European average rather than going too much below it as seen with price-sensitive countries such as Portugal or Italy.

Chart 3-6: Country Profile, Benelux, 2015



Note:

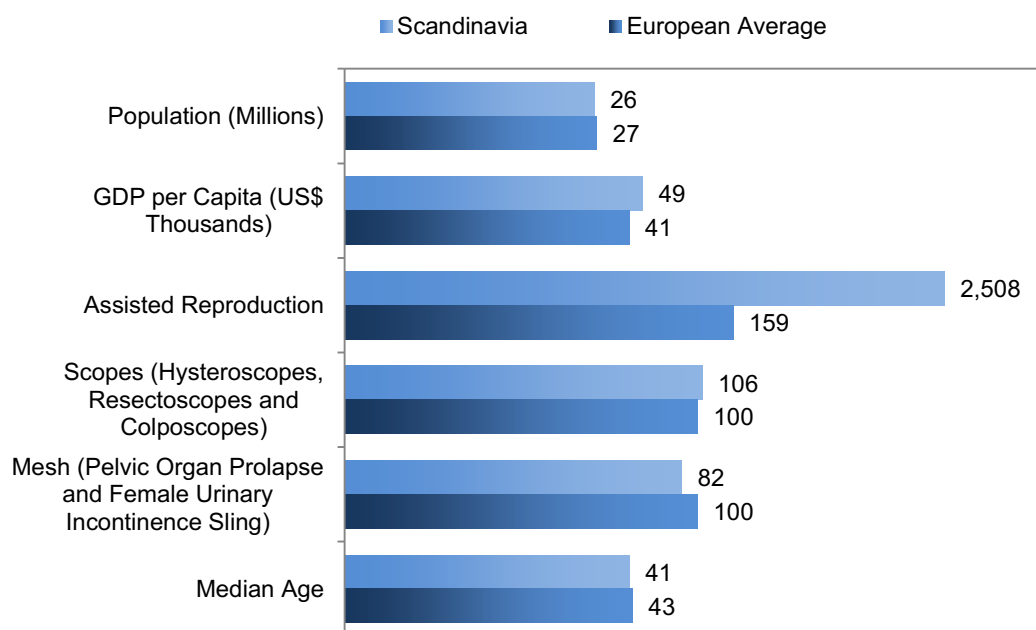
- 1) Numbers for Europe are based on the average for the listed countries.
- 2) Price Index = 100 for the European average.
- 3) GDP per capita based on 2015 US\$ values.
- 4) Chart is in logarithmic scale.

Source: iData Research Inc.

3.8 SCANDINAVIA

Scandinavia includes Sweden, Denmark, Finland and Norway. In 2015, the price index for Scandinavia was 106, meaning that the price of gynecological devices was 6% above the European average. Notably, the average number of scopes sold per million in Scandinavia is higher than the European average. This correlates to the exceptionally high GDP seen for this region. Hospitals are able to afford both higher-end devices as well as a higher number of devices. The Nordic countries do have an underlying trend of consistent investment in capital equipment. At the same time, it is common for there to be a two to three year delay in the uptake of new procedures and new capital equipment. While the market is stable, the presence of companies is often lower with smaller sales team; leading to more gradual changes in practices and procedures.

Chart 3-7: Country Profile, Scandinavia, 2015



Note:

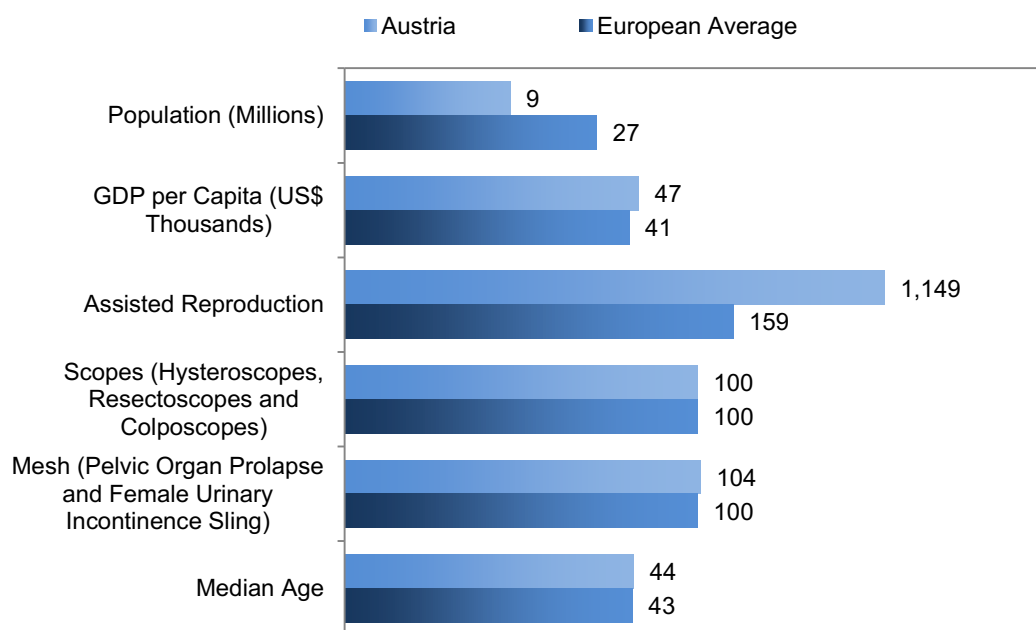
- 1) Numbers for Europe are based on the average for the listed countries.
- 2) Price Index = 100 for the European average.
- 3) GDP per capita based on 2015 US\$ values.
- 4) Chart is in logarithmic scale.

Source: iData Research Inc.

3.9 AUSTRIA

In 2015, the price index for Austria was 100, meaning that the price of gynecological devices was equal to the European average. In 2015, unit sales increased; however, market growth may be curtailed in future years. Austria experienced a 25% loss of procedures in 2015 following an amendment to the Working Time Act for hospitals and doctors. The largest point of contention was the Act previously allowed doctors to work up to 72 hours per week, which the European Commission deemed a violation of the Working Time Directive 2003/88/EC. The amendment which came into effect in 2015 limits a Doctors work week to 48 hours, lowering the overall number of procedures able to be performed. The effect on procedure numbers has had a greater impact on certain markets; two examples are uterine fibroid embolization and pelvic organ prolapse procedures.

Overall, Austria is still a stable market with consistent investment in gynecology. Scopes, especially colposcopes have experienced a resurgence among young physicians which is fueling unit sales. Colposcopy offers a superior ability to visualize cellular changes *in situ*. As Austria is increasing funding to cancer screening and diagnostic initiatives, improvements in sales for oncology related medical devices are seen. This increased demand for colposcopes as well as a higher-than-average GDP correlates to higher-than-average ASPs.

Chart 3-8: Country Profile, Austria, 2015**Note:**

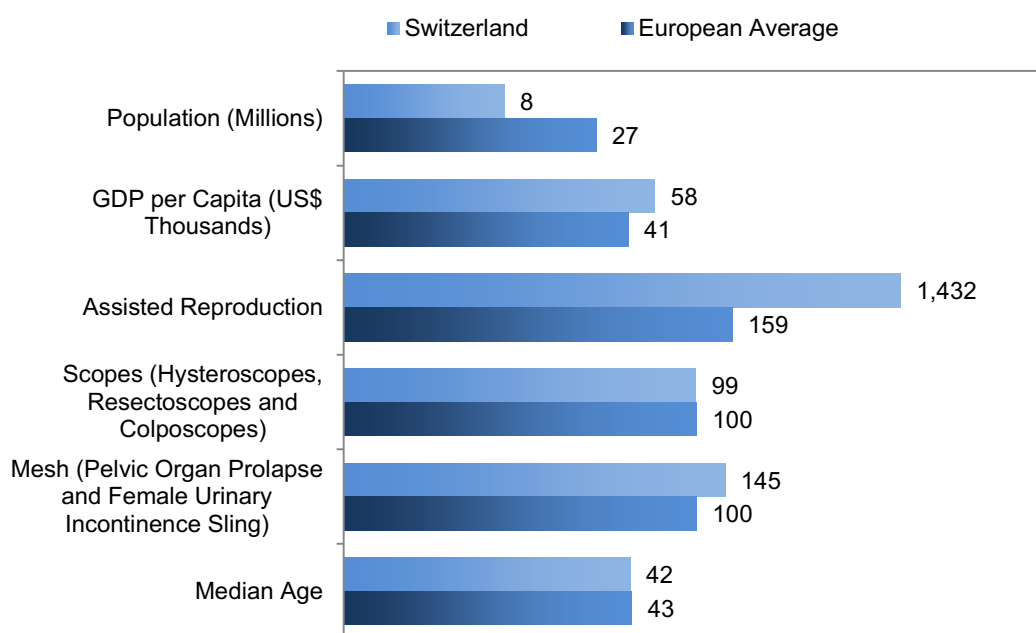
- 1) Numbers for Europe are based on the average for the listed countries.
- 2) Price Index = 100 for the European average.
- 3) GDP per capita based on 2015 US\$ values.
- 4) Chart is in logarithmic scale.

Source: iData Research Inc.

3.10 SWITZERLAND

In 2015, the price index for Switzerland was 99, meaning that the price of gynecological devices was 1% below the European average. In general, Switzerland offers an average market price point in Europe with smaller market shocks and diverse trends compared to other European countries. Switzerland benefits from a strong GDP per capita that is well above the European average. This allows Swiss hospitals and clinics to purchase new technology at higher prices. Lower-than-average unit sales per million in Switzerland can be attributed to the small population and country size.

Chart 3-9: Country Profile, Switzerland, 2015



Note:

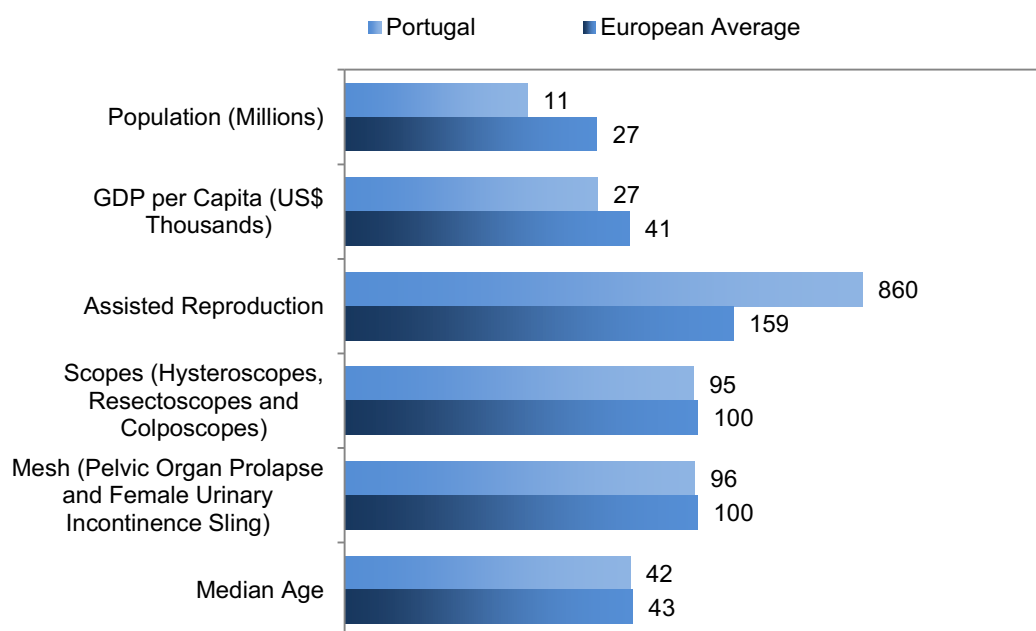
- 1) Numbers for Europe are based on the average for the listed countries.
- 2) Price Index = 100 for the European average.
- 3) GDP per capita based on 2015 US\$ values.
- 4) Chart is in logarithmic scale.

Source: iData Research Inc.

3.11 PORTUGAL

In 2015, the price index for Portugal was 95, meaning that the price of gynecological devices was 5% below the European average. Portuguese hospitals are very price-sensitive and often purchase less expensive devices. The struggling Portuguese economy, as seen in its extremely low GDP, has affected its health care system significantly. Similar to Italy and Spain, Portugal has also seen an influx of Asian competitors offering less sophisticated products at a lower price point. This increase in competition has added pressure to western manufacturers in an already price sensitive market. Overall, physicians and hospitals are delaying unnecessary expenditures and is projected to remain a price driven market.

Chart 3-10: Country Profile, Portugal, 2015



Note:

- 1) Numbers for Europe are based on the average for the listed countries.
- 2) Price Index = 100 for the European average.
- 3) GDP per capita based on 2015 US\$ values.
- 4) Chart is in logarithmic scale.

Source: iData Research Inc.

4

EUROPEAN GYNECOLOGICAL DEVICE MARKET PROCEDURE NUMBERS

4.1 PROCEDURE ANALYSIS AND FORECAST

4.1.1 Introduction

The procedures included in this segment all link to the unit sales for capital equipment. The Assisted Reproduction device market demonstrates the relationship between the average number and types of supplies used per cycle of IVF or ICSI. The procedural data also helps to clarify the unit sales in the different sub-segments of the gynecology market. In the case of Uterine Fibroid Embolization, the number of patients receiving treatments also demonstrates the number of procedures being performed using Microspheres compared to PVA particles. The changes in Essure® procedures provides a context for the adverse health effects currently being publicized and the impact it is having on potential patients. Finally, for both Female Urinary Incontinence Sling procedures and Pelvic Organ Prolapse procedures, there is a 1:1 ratio between unit sales and the number of procedures performed. However, the procedure numbers illustrate doctor and patient preferences as there is a shift in the types of slings and meshes used for procedures.

4.1.2 Assisted Reproduction Procedures

The aging maternal demographic of Europe is aiding the growth of the Assisted Reproduction Device market. As women continue to have children later in life, the number of women requiring assisted reproduction is increasing. The procedures included in this report combine the different stages of IVF and ICSI to provide an accurate summation of the capital equipment market. The number of procedures does not equal the number of patients as women can undergo multiple cycles. The Assisted Reproduction procedures listed below include IVF and ICSI cycles as well as FER, PGD, ED, IVM and FOR treatments. Cycles in IVF and ICSI refer to initiated cycles, FER refers to thawing, PGD contains both fresh and frozen cycles and refers to initiated cycles in the fresh cycles and thawing in the frozen cycles, ED refers to transfers and contains fresh and frozen cycles, IVM refers to aspirations and FOR refers to thawings.

Figure 4-1: Assisted Reproduction Procedures by Country, Europe, 2011 – 2022

Year	Germany	France	U.K.	Italy	Spain	Benelux	Scandi- navia	Austria	Switzer- land	Portugal	Europe	Growth (%)
2011	67354	85253	60377	63777	70030	54401	51068	6676	9456	7107	475,499	
2012	71,251	85,487	60,621	64,197	70,961	56,003	51,057	8,388	9,546	7,315	484,826	2.0%
2013	69,441	85,718	64,600	64,447	78,942	59,700	51,057	8,947	9,729	7,527	500,108	3.2%
2014	74,657	85,949	63,534	64,834	80,126	61,491	50,036	9,215	9,700	7,678	507,220	1.4%
2015	77,315	86,181	64,678	65,223	80,927	62,106	50,286	8,294	9,690	7,754	512,454	1.0%
2016	80,067	86,414	65,842	65,027	81,737	62,416	50,537	8,294	9,739	7,832	517,905	1.1%
2017	82,918	86,647	66,171	64,962	82,554	62,729	50,537	8,335	9,700	7,863	522,416	0.9%
2018	85,869	86,881	66,006	65,287	82,967	63,042	50,740	8,377	9,748	7,895	526,812	0.8%
2019	86,299	87,116	65,676	65,679	83,548	63,357	50,943	8,419	9,729	7,926	528,690	0.4%
2020	86,385	87,351	65,347	65,810	84,383	63,674	51,146	8,461	9,748	7,958	530,264	0.3%
2021	86,471	87,587	66,523	66,205	84,805	63,993	51,351	8,503	9,787	7,990	533,215	0.6%
2022	86,558	87,823	67,854	66,602	85,229	64,312	51,556	8,546	9,816	8,022	536,319	0.6%
CAGR (‘15–’22)	1.6%	0.3%	0.7%	0.3%	0.7%	0.5%	0.4%	0.4%	0.2%	0.5%	0.7%	

Source: iData Research Inc.

4.1.3 Uterine Fibroid Embolization Procedures

Uterine Fibroid Embolization procedures can be performed using either Microspheres or PVA particles. Microspheres require an average of 2.5 units per procedure whereas PVA Particles require an average of 1.4 units per procedure. The overall number of Uterine Fibroid Embolization procedures is stable, with the trend projected to continue through to 2022. Germany and Austria have consistent procedure numbers attributable to reimbursement being available to patients with insurance. Alternatively, private insurance in Switzerland is less likely to cover the procedure causing more women to seek alternative treatment options.

Figure 4-2: Uterine Fibroid Embolization Procedures by Country, Europe, 2012 – 2022

Year	Germany	France	U.K.	Italy	Spain	Benelux	Scandi- navia	Austria	Switzer- land	Portugal	Europe	Growth (%)
2012	902	3,874	697	666	823	542	335	181	134	191	8,344	
2013	829	3,602	715	661	750	526	354	172	136	172	7,917	-5.1%
2014	780	3,386	729	655	702	510	369	165	139	158	7,593	-4.1%
2015	750	3,200	740	650	670	490	378	140	142	150	7,310	-3.7%
2016	743	3,168	747	646	653	485	378	139	144	147	7,250	-0.8%
2017	745	3,178	755	643	643	483	376	140	145	146	7,252	0.0%
2018	747	3,187	760	641	642	484	374	140	145	146	7,266	0.2%
2019	749	3,197	759	639	644	485	373	141	144	147	7,278	0.2%
2020	751	3,206	756	638	647	487	372	141	143	148	7,290	0.2%
2021	754	3,216	754	638	651	489	371	142	141	149	7,303	0.2%
2022	756	3,225	751	638	654	491	371	142	139	150	7,318	0.2%
CAGR (‘15–’22)	0.1%	0.1%	0.2%	-0.3%	-0.3%	0.0%	-0.3%	0.2%	-0.3%	0.0%		0.0%

Source: iData Research Inc.

4.1.4 Transcervical Female Sterilization Procedures

The Essure® device manufactured by Bayer has experienced substantial scrutiny in 2016 for the health and safety risks associated with the product. The adverse health effects are discussed at greater length in the Female Sterilization Device segment. Despite the health risks, Essure remains the predominant option for a minimally invasive female sterilization procedure. While the device may be possible to obtain in Germany, Austria and Switzerland, it is not sold by Bayer in these countries. The ratio of procedures to sales is 1:1, as one Essure® device is required per procedure.

Figure 4-3: Transcervical Female Sterilization Procedures by Country, Europe, 2012 – 2022

Year	Germany	France	U.K.	Italy	Spain	Benelux	Scandi- navia	Austria	Switzer- land	Portugal	Europe	Growth (%)
2012	–	17,594	1,475	8,964	11,208	824	1,244	–	–	1,629	42,937	
2013	–	17,787	1,487	9,045	11,309	831	1,250	–	–	1,644	43,352	1.0%
2014	–	18,001	1,494	9,127	11,410	839	1,257	–	–	1,658	43,786	1.0%
2015	–	18,217	1,500	9,218	11,536	843	1,265	–	–	1,675	44,253	1.1%
2016	–	18,435	1,503	9,319	11,674	840	1,271	–	–	1,690	44,734	1.1%
2017	–	18,675	1,501	9,412	11,791	836	1,276	–	–	1,704	45,196	1.0%
2018	–	18,918	1,500	9,507	11,909	830	1,280	–	–	1,717	45,661	1.0%
2019	–	19,107	1,502	9,611	12,016	831	1,284	–	–	1,726	46,077	0.9%
2020	–	19,260	1,507	9,698	12,160	833	1,288	–	–	1,736	46,481	0.9%
2021	–	19,452	1,513	9,795	12,294	835	1,292	–	–	1,748	46,929	1.0%
2022	–	19,666	1,519	9,902	12,429	838	1,296	–	–	1,764	47,414	1.0%
CAGR (‘15–’22)	–	1.1%	0.2%	1.0%	1.1%	-0.1%	0.3%	–	–	0.7%		1.0%

Source: iData Research Inc.

4.1.5 Female Urinary Incontinence Sling Procedures

The Female Urinary Incontinence Sling market shares a direct relationship between sales and the number of procedures performed. Each procedure requires one unit, creating a 1:1 ratio between sales and the number of procedures performed. The total procedure numbers include both synthetic sling and non-synthetic sling procedures to treat Female Urinary Incontinence.

Figure 4-4: Female Urinary Incontinence Sling Procedures by Country, Europe, 2012 – 2022

Year	Germany	France	U.K.	Italy	Spain	Benelux	Scandi- navia	Austria	Switzer- land	Portugal	Europe	Growth (%)
2012	17,241	10,817	10,315	8,670	1,768	7,823	7,971	1,804	1,867	1,668	69,945	
2013	16,237	10,499	9,746	8,611	1,746	7,826	7,977	1,765	1,866	1,645	67,919	-2.9%
2014	15,279	10,237	9,297	8,538	1,720	7,830	7,989	1,720	1,864	1,622	66,096	-2.7%
2015	14,385	10,030	8,958	8,461	1,694	7,832	8,000	1,668	1,861	1,597	64,486	-2.4%
2016	13,536	9,850	8,671	8,379	1,667	7,829	8,007	1,614	1,858	1,572	62,981	-2.3%
2017	12,738	9,720	8,475	8,291	1,639	7,818	8,010	1,562	1,853	1,546	61,652	-2.1%
2018	11,973	9,638	8,362	8,198	1,610	7,800	8,010	1,519	1,848	1,520	60,480	-1.9%
2019	11,339	9,579	8,245	8,100	1,581	7,773	8,006	1,486	1,842	1,494	59,446	-1.7%
2020	10,812	9,522	8,144	7,997	1,552	7,732	7,997	1,458	1,835	1,467	58,517	-1.6%
2021	10,374	9,470	8,065	7,897	1,524	7,693	7,992	1,434	1,829	1,441	57,717	-1.4%
2022	9,990	9,423	7,991	7,796	1,495	7,654	7,986	1,414	1,822	1,414	56,985	-1.3%
CAGR (‘15–’22)	-5.1%	-0.9%	-1.6%	-1.2%	-1.8%	-0.3%	0.0%	-2.3%	-0.3%	-1.7%		-1.8%

Source: iData Research Inc.

4.1.5.1 Synthetic Sling Procedures

Figure 4-5: Synthetic Sling Procedures by Country, Europe, 2012 – 2022

Year	Germany	France	U.K.	Italy	Spain	Benelux	Scandi- navia	Austria	Switzer- land	Portugal	Europe	Growth (%)
2012	15,862	10,060	9,644	7,803	1,538	6,885	6,695	1,570	1,643	1,434	63,135	
2013	15,100	9,838	9,063	7,836	1,536	6,926	6,860	1,554	1,652	1,448	61,814	-2.1%
2014	14,362	9,674	8,600	7,813	1,531	6,969	6,951	1,530	1,659	1,443	60,532	-2.1%
2015	13,666	9,529	8,241	7,784	1,525	7,049	7,040	1,501	1,675	1,437	59,447	-1.8%
2016	12,873	9,387	7,891	7,734	1,517	7,085	7,206	1,469	1,690	1,430	58,281	-2.0%
2017	12,126	9,273	7,670	7,669	1,500	7,115	7,289	1,437	1,705	1,422	57,206	-1.8%
2018	11,423	9,205	7,484	7,657	1,481	7,137	7,369	1,405	1,719	1,406	56,286	-1.6%
2019	10,885	9,157	7,289	7,582	1,463	7,151	7,445	1,382	1,732	1,389	55,476	-1.4%
2020	10,412	9,112	7,192	7,518	1,444	7,152	7,518	1,363	1,734	1,379	54,823	-1.2%
2021	10,000	9,072	7,017	7,502	1,425	7,154	7,592	1,348	1,737	1,360	54,207	-1.1%
2022	9,640	9,027	6,912	7,414	1,406	7,156	7,587	1,329	1,749	1,344	53,564	-1.2%
CAGR (‘15–’22)	-4.9%	-0.8%	-2.5%	-0.7%	-1.2%	0.2%	1.1%	-1.7%	0.6%	-1.0%		-1.5%

Source: iData Research Inc.

4.1.5.2 Non-Synthetic Sling Procedures

Figure 4-6: Non-Synthetic Sling Procedures by Country, Europe, 2012 – 2022

Year	Germany	France	U.K.	Italy	Spain	Benelux	Scandi- navia	Austria	Switzer- land	Portugal	Europe	Growth (%)
2012	1,379	757	670	867	230	939	1,275	235	224	233	6,810	
2013	1,137	661	682	775	209	900	1,117	212	215	197	6,105	-10.3%
2014	917	563	697	726	189	861	1,039	189	205	178	5,565	-8.9%
2015	719	502	717	677	169	783	960	167	186	160	5,039	-9.4%
2016	663	463	780	645	150	744	801	145	167	141	4,700	-6.7%
2017	611	447	805	622	139	704	721	125	148	124	4,446	-5.4%
2018	551	434	878	541	129	663	641	114	129	114	4,194	-5.7%
2019	454	421	956	518	119	622	560	104	111	105	3,970	-5.3%
2020	400	409	953	480	109	580	480	95	101	88	3,694	-6.9%
2021	373	398	1,048	395	99	538	400	86	91	81	3,510	-5.0%
2022	350	396	1,079	382	90	497	399	85	73	71	3,421	-2.5%
CAGR (‘15–’22)	-9.8%	-3.3%	6.0%	-7.8%	-8.7%	-6.3%	-11.8%	-9.2%	-12.5%	-11.0%		-5.4%

Source: iData Research Inc.

4.1.6 Pelvic Organ Prolapse Procedures

The Pelvic Organ Prolapse repair device market has remained stable, with a 1.1% growth rate in 2015. The total procedures for Pelvic Organ Prolapse encompass Transvaginal mesh and Sacrocolpopexy Mesh procedures. Each procedure has a 1:1 ratio to sales as 1 unit of mesh is used per procedure. While the total number of procedures being performed appears stable, there is a drastic shift towards Sacrocolpopexy procedures and away from transvaginal mesh procedures.

Figure 4-7: Pelvic Organ Prolapse Procedures by Country, Europe, 2012 – 2022

Year	Germany	France	U.K.	Italy	Spain	Benelux	Scandi- navia	Austria	Switzer- land	Portugal	Europe	Growth (%)
2012	4,746	2,667	2,260	1,599	710	1,187	1,758	543	1,266	290	17,026	
2013	4,779	2,659	2,235	1,596	701	1,211	1,876	546	1,282	287	17,172	0.9%
2014	4,817	2,651	2,206	1,593	692	1,235	2,004	548	1,304	285	17,335	0.9%
2015	4,863	2,646	2,175	1,590	682	1,259	2,144	551	1,330	282	17,522	1.1%
2016	4,916	2,635	2,131	1,586	672	1,282	2,294	441	1,359	278	17,595	0.4%
2017	4,956	2,625	2,084	1,581	662	1,306	2,432	445	1,391	274	17,757	0.9%
2018	4,986	2,612	2,034	1,576	653	1,330	2,559	451	1,425	271	17,896	0.8%
2019	5,010	2,596	1,983	1,570	644	1,354	2,680	456	1,462	267	18,023	0.7%
2020	5,031	2,581	1,932	1,565	634	1,379	2,787	463	1,499	264	18,133	0.6%
2021	5,046	2,573	1,874	1,561	628	1,404	2,893	470	1,539	260	18,246	0.6%
2022	5,056	2,565	1,816	1,556	623	1,429	2,994	477	1,580	256	18,351	0.6%
CAGR (‘15–’22)	0.6%	-0.4%	-2.5%	-0.3%	-1.3%	1.8%	4.9%	-2.1%	2.5%	-1.4%		0.7%

Source: iData Research Inc.

4.1.6.1 Trans-Vaginal Mesh Procedures

Figure 4-8: Trans-Vaginal Mesh Procedures by Country, Europe, 2012 – 2022

Year	Germany	France	U.K.	Italy	Spain	Benelux	Scandi- navia	Austria	Switzer- land	Portugal	Europe	Growth (%)
2012	2,895	1,867	1,227	1,119	518	843	1,284	315	810	217	11,095	
2013	2,867	1,808	1,114	1,102	498	848	1,351	311	808	212	10,919	-1.6%
2014	2,649	1,750	1,009	1,083	484	852	1,423	307	808	208	10,574	-3.2%
2015	2,529	1,720	910	1,073	471	856	1,501	303	798	203	10,364	-2.0%
2016	2,458	1,687	819	1,015	450	859	1,571	234	788	194	10,076	-2.8%
2017	2,379	1,627	734	996	447	862	1,654	232	793	189	9,913	-1.6%
2018	2,293	1,593	656	977	438	864	1,715	230	798	184	9,748	-1.7%
2019	2,255	1,558	584	958	418	867	1,769	228	804	179	9,619	-1.3%
2020	2,213	1,522	518	939	406	869	1,811	227	794	174	9,475	-1.5%
2021	2,069	1,492	458	921	396	870	1,851	225	785	169	9,236	-2.5%
2022	2,022	1,462	406	902	387	872	1,886	224	774	161	9,097	-1.5%
CAGR (‘15–’22)	-3.1%	-2.3%	-10.9%	-2.4%	-2.8%	0.3%	3.3%	-4.2%	-0.4%	-3.3%		-1.8%

Source: iData Research Inc.

4.1.6.2 Sacrocolpopexy Procedures

Figure 4-9: Sacrocolpopexy Procedures by Country, Europe, 2012 – 2022

Year	Germany	France	U.K.	Italy	Spain	Benelux	Scandi- navia	Austria	Switzer- land	Portugal	Europe	Growth (%)
2012	1,851	800	1,034	480	192	344	475	228	456	72	5,932	
2013	1,912	851	1,121	495	203	363	525	235	474	75	6,254	5.4%
2014	2,168	901	1,197	510	208	383	581	241	495	77	6,761	8.1%
2015	2,334	926	1,264	517	211	403	643	248	532	79	7,158	5.9%
2016	2,458	949	1,312	571	222	423	723	207	571	83	7,519	5.0%
2017	2,577	997	1,350	585	215	444	778	214	598	85	7,844	4.3%
2018	2,692	1,019	1,378	599	215	465	845	221	627	87	8,148	3.9%
2019	2,756	1,038	1,399	612	225	488	911	228	658	88	8,404	3.1%
2020	2,817	1,058	1,414	626	228	510	975	236	704	90	8,659	3.0%
2021	2,977	1,081	1,416	640	233	533	1,041	244	754	91	9,009	4.0%
2022	3,033	1,103	1,410	654	237	557	1,108	253	806	95	9,255	2.7%
CAGR (‘15–’22)	3.8%	2.5%	1.6%	3.4%	1.6%	4.7%	8.1%	0.3%	6.1%	2.6%		3.7%

Source: iData Research Inc.

5

ASSISTED REPRODUCTION DEVICE MARKET

5.1 INTRODUCTION

Assisted reproduction technologies (ART) help women or couples conceive children. Most couples who use ART are affected by infertility, although ART can also be used to help lesbian couples or single women. A couple is considered to be infertile if they have not conceived after one year of intercourse without birth control.

While there are a number of techniques used to aid fertilization, the products discussed in this chapter are those used for in-vitro fertilization (IVF) and intracytoplasmic sperm injection (ICSI). An IVF procedure removes the woman's eggs and then fertilizes them with sperm in a lab setting. IVF has been very successful in helping couples become pregnant within their first or second cycle. ICSI takes a sperm cell and injects it directly into an egg. ICSI can facilitate fertilization in conjunction with IVF.

IVF begins with the woman taking fertility drugs in order to produce more eggs. A number of eggs are then removed from the woman using a retrieval needle and are brought to a lab where they are mixed in a Petri dish with the man's sperm. Handling of the sperm, eggs or embryos in the lab are done with micropipettes. After fertilization, the embryo develops in the lab for a few days and is then inserted back into the lining of the woman's uterus using a transfer catheter. Frequently, multiple embryos are inserted in hopes of increasing the chance of pregnancy. Remaining embryos are usually frozen in order to preserve them in the case that the woman does not become pregnant. A treatment cycle that uses these stored embryos is called frozen embryo replacement (FER). In some countries in Europe, unfertilized oocytes can be donated to other couples who may have infertility problems associated with the woman.

5.1.1.1 Media

Reproductive media products contain various components including nutrients, vitamins and growth factors. In this report, we have provided the percentage breakdown between single step culture media and sequential media. Single step culture media utilizes the theory that the media contains the appropriate concentration of components and the embryo determines when and which compounds are needed for suitable development. Sequential media consists of transferring the embryos to different media types for different stages of development. There are numerous different types of sequential media, ranging from media that combine sub-types to create fewer steps or utilizing a different media for every stage.

In this report we have included culture media, manipulation media, sperm preparation media and cryopreservation media. Sperm preparation media are used during the purification of semen. Seminal plasma, dead sperm and other cells are removed, and only sperm with the greatest motility are selected. Oocytes and fertilized embryos from the woman are handled and manipulated in manipulation media. Culture media are then used when the embryo develops into the cleavage and blastocyst stages. Cryopreservation media are designed to support the survival of sperm, oocytes or embryos during the freezing and thawing process.

5.1.1.2 Vitrification

Vitrification is a new cryopreservation technique that rapidly freezes cells rather than gradually freezing them, as is done in traditional methods. In this method, ice crystals, which can damage frozen cells and embryos, are not formed. Vitrification has shown improved results in gamete and embryo survival and increased rates of live birth when using thawed cells.

5.1.1.3 Embryo Time Lapse Incubator System

Time lapse technology has been utilized in Assisted Reproduction since the 1990's. The introduction of time lapse embryo incubators is rapidly becoming the required standard in the industry. This trend is further fueled by the fact that Britain was the first country to have a successful IVF pregnancy and Europe is often a market leader for IVF technology.

Time-lapse embryo incubators provide the benefit of time-lapse embryo culture that improves embryo selection, implantation and pregnancy rates and reduces pregnancy loss. The key benefit differentiating embryo incubators equipped with time-lapse is the ability to maintain homeostasis. When the incubator

is opened and closed, it has to recover the temperature, CO₂ and O₂ concentrations. When time-lapse is incorporated specialists can watch and monitor embryo growth without needing to disturb the embryos providing a superior environment. Additional benefits are potentially superior embryo selection for implantation, better quality management in labs and the ability to improve the quality control assay used to test media for embryotoxicity.

An additional unintended benefit of time lapse embryo incubators is that it limits the number of patients per incubator. As there is no industry standard, a time-lapse system typically accommodates four to six patients whereas big box incubators have large patient numbers with a high number of door openings, thus, negatively influencing the quality of the culture environment.

5.2 MARKET OVERVIEW

In 2015, the European assisted reproduction market was valued at over €45.46 million, a 1.3% increase over 2014. The assisted reproduction market consists of the oocyte retrieval needle, micropipette, embryo transfer catheter, reproductive media and embryo time-lapse incubator sub-segments. Vitrification is another sub-segment growing prominently in the market; however, it is not included in this report. In 2015, oocyte retrieval needles accounted for 29.52% of the total market, micropipettes accounted for 25.09%, embryo transfer catheters accounted for 30.77% and reproductive media accounted for 1.93%. The remaining 12.67% of the market is comprised by the market uptake of embryo time-lapse incubators.

The market value of Assisted Reproduction devices is tied to the number of cycles performed. In this report, the cycle procedure numbers include both IVF and ICSI cycles. In Assisted Reproductive Technology, there is no international, or in many cases, national standard protocols in place. This means that labs vary by technique, equipment, types and units of supplies used etc. Part of the difference between country market values is due to procedure number variations, and part of the difference is due to the variations in common lab processes between countries.

There were 512,454 cycles of IVF/ICSI performed in Europe in 2015, a 1.0% growth over 2014. The average cost to the patient for a cycle of IVF/ICSI can vary significantly, ranging from free to €10,000 per cycle, depending on the country as well as the type of treatment. Each country in Europe sets their own reimbursement rate for the devices, drugs and procedures used in assisted reproduction. Many other factors are also limited by governments. The number of cycles attempted before pregnancy varies by country, and the age of the potential parents is also a factor. Also, some countries only reimburse certain types of procedures or reimburse some procedures at better rates. Excluding the cost of capital equipment and doctor's fees, there is still a large profit margin to be had by ART clinics.

The cost to patients per cycle depends greatly on the existence of any reimbursement programs in the country where the procedure is being done. Belgium, France and Sweden provided coverage under their national health plans, but the number of cycles reimbursed ranged from one to six. Other countries only had partial reimbursement for a limited number of cycles. Expectedly, Belgium, which offers complete coverage for ART, had high proportions of babies conceived by ART. Although the cost of ART treatments is quite high, the number of assisted reproduction cycles continues to increase throughout almost all Western European countries even though the European economy is still experiencing a downturn.

Eligibility for assisted reproduction treatments also varies across Europe. Italy is heavily influenced by the Roman Catholic Church, with a much tighter relationship between Catholicism and the government than other European countries. In May 2016, the Italian government finally gave approval to a law recognizing civil unions of same-sex couples, although it is limited as it does not grant full equality to same-sex couples. This has dampened the assisted reproduction market in Italy as it is illegal for both single women and homosexual couple to use assisted reproduction treatments, with fines up to €300,000. It is estimated over 10,000 Italians travel abroad every year to receive Assisted Reproductive treatments. If the laws are overturned in the future, the Italian market has the potential to increase substantially.

Assisted Reproduction tourism, however, is benefitting other countries. Portugal and Spain, for example receive an influx of patients seeking Assisted Reproduction treatment leading to a higher number of cycles being performed relative to the country population. It was also announced in January 2016 that single women in Sweden will soon be eligible for free IVF cycles, which is projected to lead to an increase in procedure numbers.

In Europe, the assisted reproduction market is expected to grow at a CAGR of 0.8%, reaching a value of €48.22 million by 2022. The market is expected to continue its moderate growth as European countries attempt to offset their low birth rates by promoting IVF as part of their family-planning policies. The high reimbursement of this treatment also makes it accessible to infertile women and couples who are looking to start a family.

Figure 5-1: Assisted Reproduction Device Market by Segment, Europe, 2012 – 2022 (€M)

Year	Oocyte Retrieval Needle Market	Micropipette Market	Embryo Transfer Catheter Market	Reproduction Media Market	Embryo Time Lapse Incubator Market	Total Market	Growth (%)
2012	€13.04	€11.33	€13.49	€0.86	€4.09	€42.81	
2013	€13.36	€11.48	€13.88	€0.88	€4.57	€44.16	3.2%
2014	€13.40	€11.48	€13.96	€0.88	€5.13	€44.85	1.6%
2015	€13.42	€11.41	€13.99	€0.88	€5.76	€45.46	1.3%
2016	€13.44	€11.35	€14.01	€0.88	€6.39	€46.06	1.3%
2017	€13.43	€11.27	€14.00	€0.88	€6.88	€46.45	0.9%
2018	€13.41	€11.18	€14.00	€0.87	€7.49	€46.95	1.1%
2019	€13.32	€11.04	€13.95	€0.87	€8.05	€47.23	0.6%
2020	€13.23	€10.89	€13.90	€0.86	€8.59	€47.47	0.5%
2021	€13.19	€10.77	€13.88	€0.86	€9.06	€47.77	0.6%
2022	€13.16	€10.65	€13.87	€0.85	€9.69	€48.22	1.0%
CAGR ('15-'22)	-0.3%	-1.0%	-0.1%	-0.4%	7.7%		0.8%

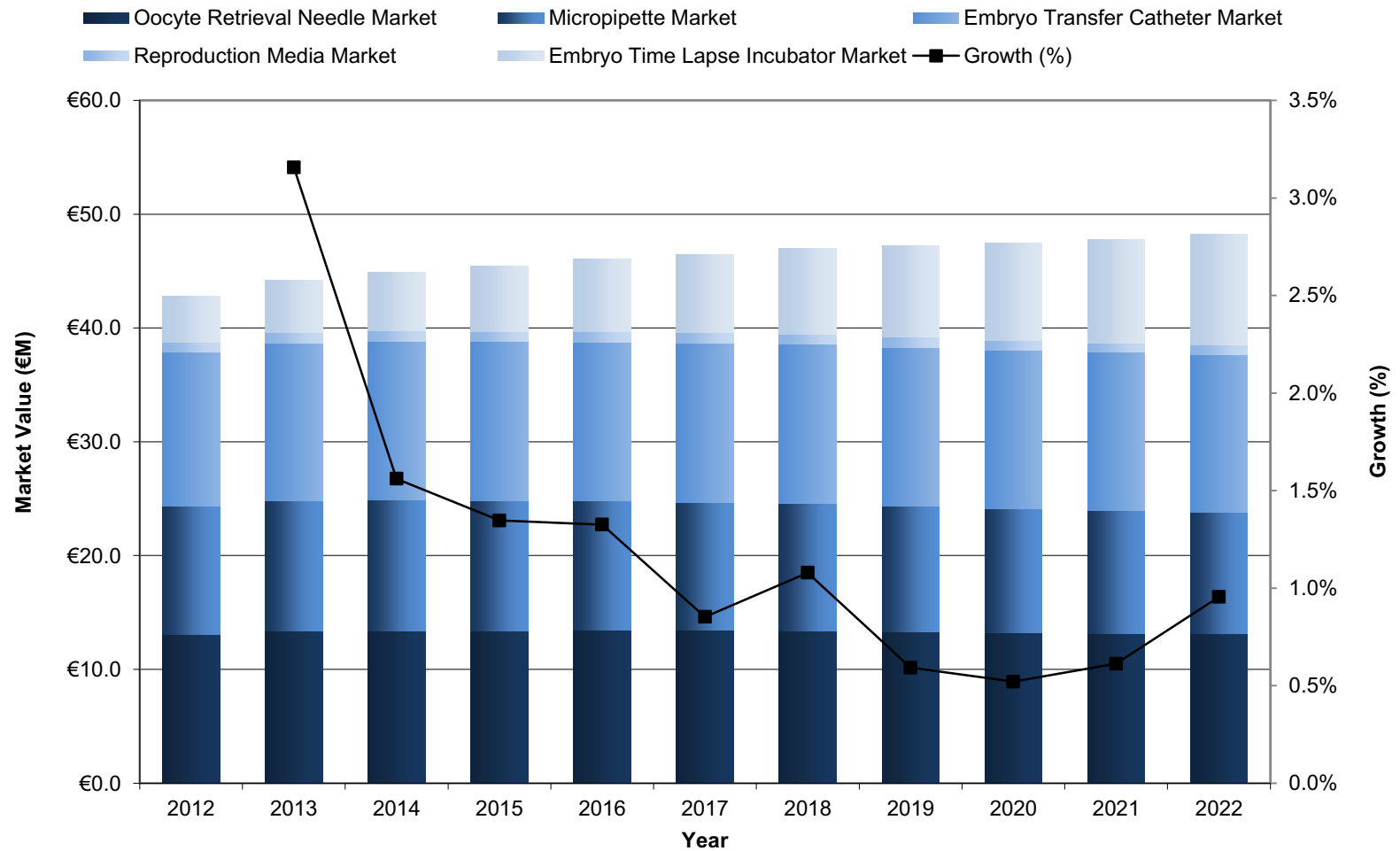
Source: iData Research Inc.

Figure 5-2: Assisted Reproduction Device Market by Segment, Europe, 2012 – 2022 (US\$M)

Year	Oocyte Retrieval Needle Market	Micropipette Market	Embryo Transfer Catheter Market	Reproduction Media Market	Embryo Time Lapse Incubator Market	Total Market	Growth (%)
2012	\$14.42	\$12.53	\$14.92	\$0.95	\$4.52	\$47.33	
2013	\$14.77	\$12.69	\$15.34	\$0.97	\$5.05	\$48.83	3.2%
2014	\$14.82	\$12.69	\$15.44	\$0.97	\$5.67	\$49.59	1.6%
2015	\$14.83	\$12.61	\$15.47	\$0.97	\$6.37	\$50.26	1.3%
2016	\$14.86	\$12.55	\$15.49	\$0.97	\$7.06	\$50.92	1.3%
2017	\$14.84	\$12.46	\$15.48	\$0.97	\$7.61	\$51.36	0.9%
2018	\$14.82	\$12.37	\$15.47	\$0.97	\$8.28	\$51.91	1.1%
2019	\$14.73	\$12.21	\$15.42	\$0.96	\$8.90	\$52.22	0.6%
2020	\$14.63	\$12.04	\$15.37	\$0.95	\$9.50	\$52.49	0.5%
2021	\$14.58	\$11.91	\$15.35	\$0.95	\$10.02	\$52.81	0.6%
2022	\$14.55	\$11.78	\$15.34	\$0.94	\$10.71	\$53.31	1.0%
CAGR ('15–'22)	-0.3%	-1.0%	-0.1%	-0.4%	7.7%		0.8%

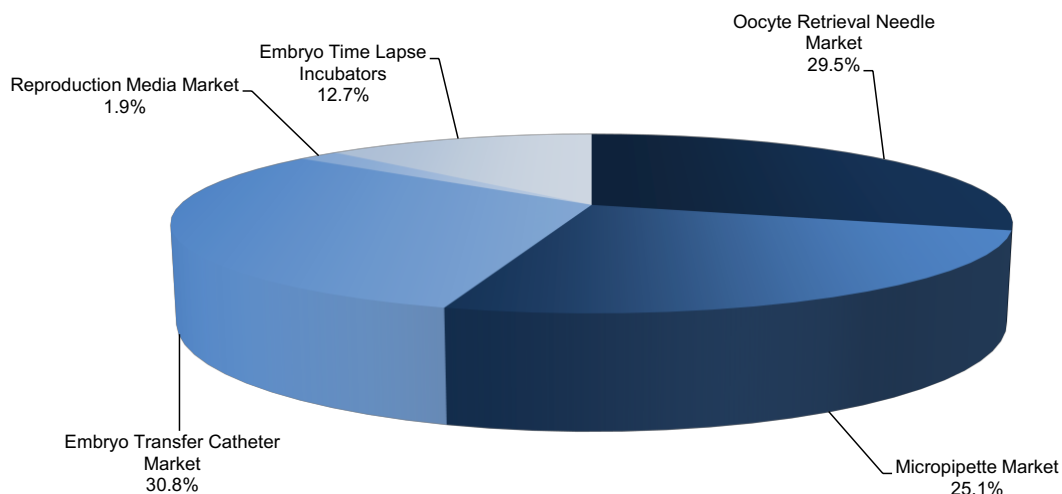
Source: iData Research Inc.

Chart 5-1: Assisted Reproduction Device Market by Segment, Europe, 2015



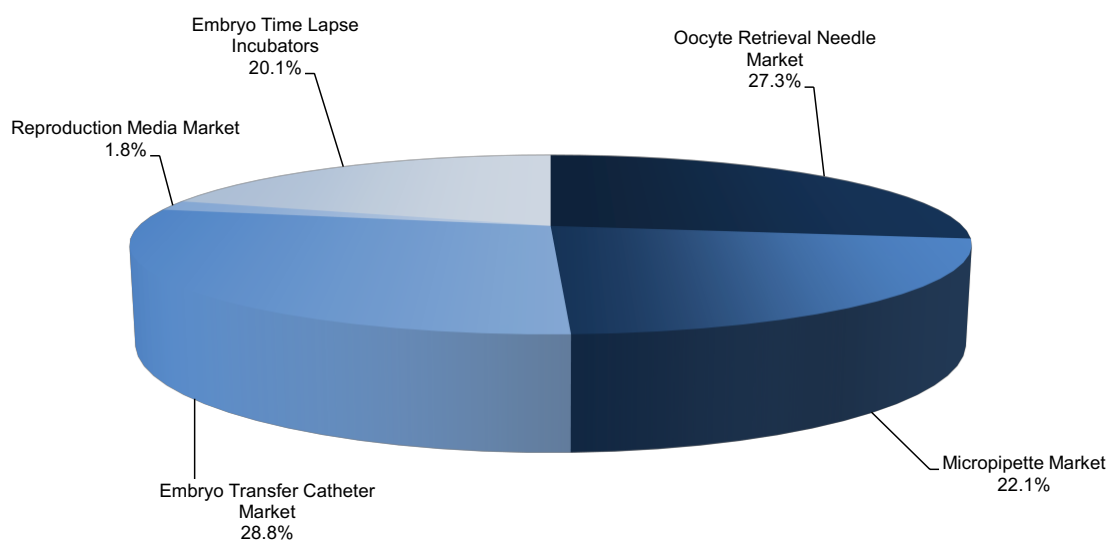
Source: iData Research Inc.

Chart 5-2: Assisted Reproduction Device Market Breakdown, Europe, 2015



Source: iData Research Inc.

Chart 5-3: Assisted Reproduction Device Market Breakdown, Europe, 2022



Source: iData Research Inc.

5.3 MARKET ANALYSIS AND FORECAST

5.3.1 Total Assisted Reproduction Device Market

Procedures in the assisted reproduction market are projected to experience strong but stable growth throughout the forecast period. Unlike other industries within gynecology, the assisted reproduction market is minimally affected by economic downturns. This is potentially because unlike costly procedures that are able to be delayed, the age of females significantly impacts fertility and the success rate of becoming pregnant.

The largest changes in the market are in terms of emerging technology and superior processes to perform assisted reproduction treatments. As more research is published, the industry is adapting to optimize success rates. Patient reimbursement and differing legislation by country also produces a substantial impact on procedure numbers across Europe.

While procedure numbers are increasing, the overall market value is stable. Despite increasing procedures, four out of the five sub-segments in the market have a declining market value. This is due to ASPs declining at a faster rate than the market is growing. The only exception within the market is embryo time lapse incubators. The net gain provided by the embryo time lapse incubator market results in a total market CAGR of 0.8%.

5.3.2 Oocyte Retrieval Needle Market

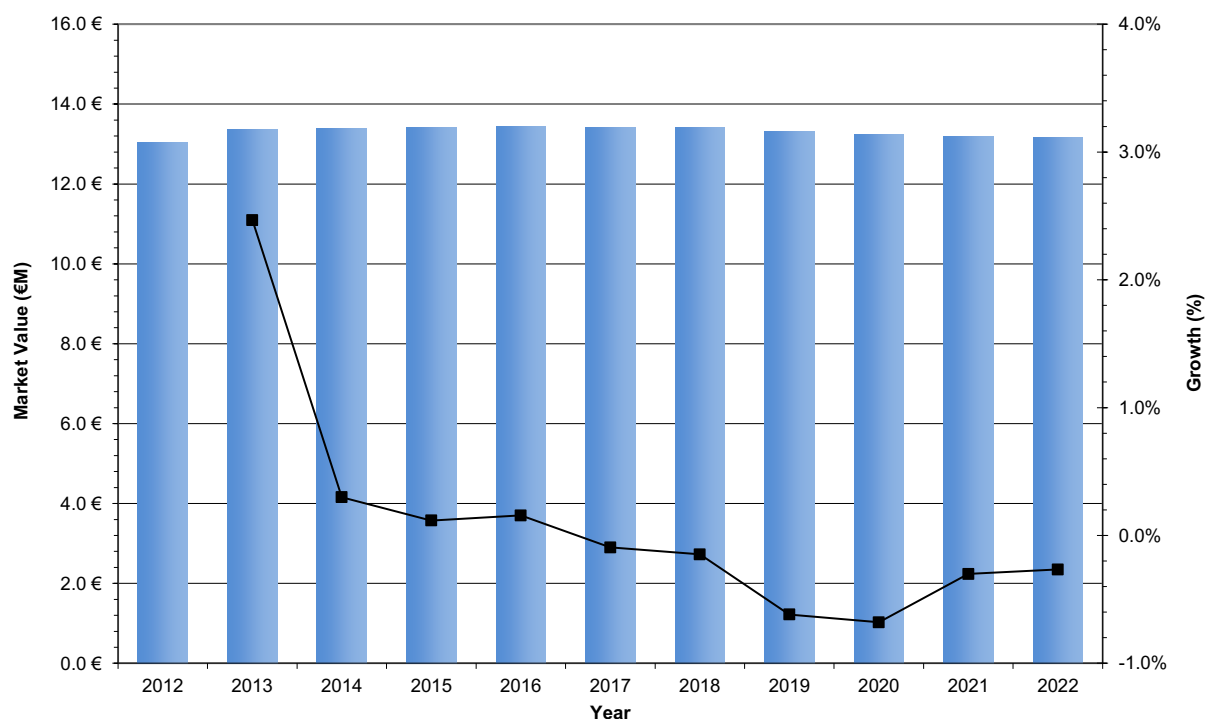
The oocyte retrieval needle market is directly linked to procedure numbers for assisted reproduction technology (ART). The difference between markets, however, is accentuated by the number of units used per cycle. On average, 1.3 oocyte retrieval needles will be used per cycle. The Benelux region had the lowest ratio with only 1.15 oocyte retrieval needles being used per cycle. Alternatively, the market in France uses a high percent of JCD oocyte retrieval needle products. JCD offers a less expensive product; however, the needles are also more likely to break requiring two needles per cycle. Overall, the unit sales are increasing at a CAGR of 0.7%, with a causal link to the increase in ART cycles across Europe.

The ASP of the oocyte retrieval needle market is causing the overall market value to decline. Prices across Europe are falling, although by a very slim degree. The only exception to this trend is the use of improved aspiration pumps with gauges. The high pressures caused by aspirating oocytes with hand held syringes have been shown to cause detrimental fractures of the zona pellucida (the thick transparent membrane surrounding a mammalian ovum before implantation). As labs continue to transition between manual technologies to pumps, the ASP will be held stable to potentially increase. This is because the pumps are a superior and more expensive technology. This trend is currently the most prominent in France and attributes to the stability to slight increase in price.

Figure 5-3: Oocyte Retrieval Needle Market, Europe, 2012 – 2022 (€ and US\$)

Year	Units Sold	Growth (%)	ASP (€)	ASP (US\$)	Growth (%)	Market Value (€M)	Market Value (US\$M)	Growth (%)
2012	609,381		€21.40	\$23.66		€13.0	\$14.4	
2013	628,173	3.1%	€21.27	\$23.52	-0.6%	€13.4	\$14.8	2.5%
2014	637,013	1.4%	€21.04	\$23.26	-1.1%	€13.4	\$14.8	0.3%
2015	643,732	1.1%	€20.84	\$23.04	-0.9%	€13.4	\$14.8	0.1%
2016	650,738	1.1%	€20.65	\$22.83	-0.9%	€13.4	\$14.9	0.2%
2017	656,518	0.9%	€20.45	\$22.61	-1.0%	€13.4	\$14.8	-0.1%
2018	662,120	0.9%	€20.25	\$22.38	-1.0%	€13.4	\$14.8	-0.1%
2019	664,441	0.4%	€20.05	\$22.17	-1.0%	€13.3	\$14.7	-0.6%
2020	666,375	0.3%	€19.86	\$21.95	-1.0%	€13.2	\$14.6	-0.7%
2021	670,092	0.6%	€19.69	\$21.77	-0.9%	€13.2	\$14.6	-0.3%
2022	674,008	0.6%	€19.52	\$21.58	-0.8%	€13.2	\$14.5	-0.3%
CAGR ('15-'22)		0.7%			-0.9%			-0.3%

Source: iData Research Inc.

Chart 5-4: Oocyte Retrieval Needle Market, Europe, 2012 – 2022


Source: iData Research Inc.

Figure 5-4: Units Sold by Country, Oocyte Retrieval Needle Market, Europe, 2012 – 2022

Year	Germany	France	U.K.	Italy	Spain	Benelux	Scandi- navia	Austria	Switzer- land	Portugal	Europe	Growth (%)
2012	92,626	111,133	78,807	77,036	88,701	64,403	66,374	10,066	11,455	8,778	609,381	
2013	90,273	111,433	83,980	77,336	98,678	68,655	66,374	10,736	11,675	9,033	628,173	3.1%
2014	97,054	111,734	82,594	77,800	100,158	70,715	65,047	11,058	11,640	9,213	637,013	1.4%
2015	100,509	112,036	84,081	78,267	101,159	71,422	65,372	9,953	11,628	9,305	643,732	1.1%
2016	104,087	112,338	85,594	78,032	102,171	71,779	65,699	9,953	11,686	9,398	650,738	1.1%
2017	107,793	112,642	86,022	77,954	103,193	72,138	65,699	10,002	11,640	9,436	656,518	0.9%
2018	111,630	112,946	85,807	78,344	103,709	72,498	65,962	10,052	11,698	9,474	662,120	0.9%
2019	112,188	113,251	85,378	78,814	104,434	72,861	66,225	10,103	11,674	9,512	664,441	0.4%
2020	112,301	113,556	84,951	78,972	105,479	73,225	66,490	10,153	11,698	9,550	666,375	0.3%
2021	112,413	113,863	86,480	79,446	106,006	73,591	66,756	10,204	11,744	9,588	670,092	0.6%
2022	112,525	114,170	88,210	79,922	106,536	73,959	67,023	10,255	11,780	9,626	674,008	0.6%
CAGR (‘15–’22)	1.6%	0.3%	0.7%	0.3%	0.7%	0.5%	0.4%	0.4%	0.2%	0.5%		0.7%

Source: iData Research Inc.

Figure 5-5: Units per Procedure by Country, Oocyte Retrieval Needle Market, Europe, 2012 – 2022

Year	Germany	France	U.K.	Italy	Spain	Benelux	Scandi- navia	Austria	Switzer- land	Portugal	Europe	Growth (%)
2015	1.3	1.3	1.3	1.2	1.25	1.15	1.3	1.2	1.2	1.2		
Source: iData Research Inc.												

Figure 5-6: Average Selling Price by Country, Oocyte Retrieval Needle Market, Europe, 2012 – 2022 (€)

Year	Germany	France	U.K.	Italy	Spain	Benelux	Scandi- navia	Austria	Switzer- land	Portugal	Europe	Growth (%)
2012	€19.55	€14.09	€25.06	€23.52	€23.52	€20.67	€25.77	€23.23	€26.73	€23.66	€21.40	
2013	€19.38	€14.40	€25.04	€23.00	€23.00	€20.45	€25.51	€22.81	€26.14	€23.10	€21.27	-0.6%
2014	€19.19	€14.71	€25.02	€22.49	€22.49	€20.22	€25.25	€22.40	€25.56	€22.54	€21.04	-1.1%
2015	€19.00	€15.00	€25.00	€22.00	€22.00	€20.00	€25.00	€22.00	€25.00	€22.00	€20.84	-0.9%
2016	€18.80	€15.29	€24.98	€21.52	€21.52	€19.78	€24.75	€21.60	€24.45	€21.47	€20.65	-0.9%
2017	€18.59	€15.56	€24.96	€21.04	€21.04	€19.56	€24.50	€21.22	€23.91	€20.96	€20.45	-1.0%
2018	€18.38	€15.83	€24.94	€20.58	€20.58	€19.35	€24.26	€20.83	€23.39	€20.45	€20.25	-1.0%
2019	€18.15	€16.09	€24.92	€20.13	€20.13	€19.13	€24.01	€20.46	€22.87	€19.96	€20.05	-1.0%
2020	€17.92	€16.33	€24.90	€19.68	€19.68	€18.92	€23.77	€20.09	€22.37	€19.48	€19.86	-1.0%
2021	€17.68	€16.57	€24.88	€19.23	€19.27	€18.72	€23.54	€19.75	€22.35	€18.99	€19.69	-0.9%
2022	€17.43	€16.81	€24.86	€18.76	€18.89	€18.51	€23.30	€19.43	€22.33	€18.54	€19.52	-0.8%
CAGR (‘15–’22)	-1.2%	1.6%	-0.1%	-2.2%	-2.2%	-1.1%	-1.0%	-1.8%	-1.6%	-2.4%		-0.9%
Source: iData Research Inc.												

Figure 5-7: Average Selling Price by Country, Oocyte Retrieval Needle Market, Europe, 2012 – 2022 (US\$)

Year	Germany	France	U.K.	Italy	Spain	Benelux	Scandi- navia	Austria	Switzer- land	Portugal	Europe	Growth (%)
2012	\$21.62	\$15.58	\$27.71	\$26.00	\$26.00	\$22.86	\$28.49	\$25.69	\$29.55	\$26.16	\$23.66	
2013	\$21.42	\$15.92	\$27.68	\$25.43	\$25.43	\$22.61	\$28.20	\$25.22	\$28.90	\$25.53	\$23.52	-0.6%
2014	\$21.22	\$16.26	\$27.66	\$24.87	\$24.87	\$22.36	\$27.92	\$24.77	\$28.26	\$24.92	\$23.26	-1.1%
2015	\$21.01	\$16.58	\$27.64	\$24.32	\$24.32	\$22.11	\$27.64	\$24.32	\$27.64	\$24.32	\$23.04	-0.9%
2016	\$20.79	\$16.90	\$27.62	\$23.79	\$23.79	\$21.87	\$27.36	\$23.89	\$27.03	\$23.74	\$22.83	-0.9%
2017	\$20.56	\$17.20	\$27.60	\$23.26	\$23.26	\$21.63	\$27.09	\$23.46	\$26.44	\$23.17	\$22.61	-1.0%
2018	\$20.32	\$17.50	\$27.57	\$22.75	\$22.75	\$21.39	\$26.82	\$23.03	\$25.86	\$22.61	\$22.38	-1.0%
2019	\$20.07	\$17.78	\$27.55	\$22.25	\$22.25	\$21.16	\$26.55	\$22.62	\$25.29	\$22.07	\$22.17	-1.0%
2020	\$19.82	\$18.06	\$27.53	\$21.76	\$21.76	\$20.92	\$26.29	\$22.21	\$24.73	\$21.54	\$21.95	-1.0%
2021	\$19.55	\$18.32	\$27.51	\$21.26	\$21.31	\$20.69	\$26.02	\$21.83	\$24.71	\$21.00	\$21.77	-0.9%
2022	\$19.27	\$18.58	\$27.48	\$20.74	\$20.88	\$20.46	\$25.76	\$21.48	\$24.69	\$20.49	\$21.58	-0.8%
CAGR (‘15–’22)	-1.2%	1.6%	-0.1%	-2.2%	-2.2%	-1.1%	-1.0%	-1.8%	-1.6%	-2.4%		-0.9%

Source: iData Research Inc.

Figure 5-8: Market Value by Country, Oocyte Retrieval Needle Market, Europe, 2012 – 2022 (€M)

Year	Germany	France	U.K.	Italy	Spain	Benelux	Scandi- navia	Austria	Switzer- land	Portugal	Europe	Growth (%)
2012	€1.81	€1.57	€1.97	€1.81	€2.09	€1.33	€1.71	€0.23	€0.31	€0.21	€13.04	
2013	€1.75	€1.60	€2.10	€1.78	€2.27	€1.40	€1.69	€0.24	€0.31	€0.21	€13.36	2.5%
2014	€1.86	€1.64	€2.07	€1.75	€2.25	€1.43	€1.64	€0.25	€0.30	€0.21	€13.40	0.3%
2015	€1.91	€1.68	€2.10	€1.72	€2.23	€1.43	€1.63	€0.22	€0.29	€0.20	€13.42	0.1%
2016	€1.96	€1.72	€2.14	€1.68	€2.20	€1.42	€1.63	€0.22	€0.29	€0.20	€13.44	0.2%
2017	€2.00	€1.75	€2.15	€1.64	€2.17	€1.41	€1.61	€0.21	€0.28	€0.20	€13.43	-0.1%
2018	€2.05	€1.79	€2.14	€1.61	€2.13	€1.40	€1.60	€0.21	€0.27	€0.19	€13.41	-0.1%
2019	€2.04	€1.82	€2.13	€1.59	€2.10	€1.39	€1.59	€0.21	€0.27	€0.19	€13.32	-0.6%
2020	€2.01	€1.85	€2.12	€1.55	€2.08	€1.39	€1.58	€0.20	€0.26	€0.19	€13.23	-0.7%
2021	€1.99	€1.89	€2.15	€1.53	€2.04	€1.38	€1.57	€0.20	€0.26	€0.18	€13.19	-0.3%
2022	€1.96	€1.92	€2.19	€1.50	€2.01	€1.37	€1.56	€0.20	€0.26	€0.18	€13.16	-0.3%
CAGR (‘15–’22)	0.4%	1.9%	0.6%	-2.0%	-1.4%	-0.6%	-0.6%	-1.3%	-1.4%	-1.9%		-0.3%

Source: iData Research Inc.

Figure 5-9: Market Value by Country, Oocyte Retrieval Needle Market, Europe, 2012 – 2022 (US\$M)

Year	Germany	France	U.K.	Italy	Spain	Benelux	Scandi- navia	Austria	Switzer- land	Portugal	Europe	Growth (%)
2012	\$2.00	\$1.73	\$2.18	\$2.00	\$2.31	\$1.47	\$1.89	\$0.26	\$0.34	\$0.23	\$14.42	
2013	\$1.93	\$1.77	\$2.32	\$1.97	\$2.51	\$1.55	\$1.87	\$0.27	\$0.34	\$0.23	\$14.77	\$0.025
2014	\$2.06	\$1.82	\$2.28	\$1.93	\$2.49	\$1.58	\$1.82	\$0.27	\$0.33	\$0.23	\$14.82	\$0.003
2015	\$2.11	\$1.86	\$2.32	\$1.90	\$2.46	\$1.58	\$1.81	\$0.24	\$0.32	\$0.23	\$14.83	\$0.001
2016	\$2.16	\$1.90	\$2.36	\$1.86	\$2.43	\$1.57	\$1.80	\$0.24	\$0.32	\$0.22	\$14.86	\$0.002
2017	\$2.22	\$1.94	\$2.37	\$1.81	\$2.40	\$1.56	\$1.78	\$0.23	\$0.31	\$0.22	\$14.84	-\$0.001
2018	\$2.27	\$1.98	\$2.37	\$1.78	\$2.36	\$1.55	\$1.77	\$0.23	\$0.30	\$0.21	\$14.82	-\$0.001
2019	\$2.25	\$2.01	\$2.35	\$1.75	\$2.32	\$1.54	\$1.76	\$0.23	\$0.30	\$0.21	\$14.73	-\$0.006
2020	\$2.23	\$2.05	\$2.34	\$1.72	\$2.30	\$1.53	\$1.75	\$0.23	\$0.29	\$0.21	\$14.63	-\$0.007
2021	\$2.20	\$2.09	\$2.38	\$1.69	\$2.26	\$1.52	\$1.74	\$0.22	\$0.29	\$0.20	\$14.58	-\$0.003
2022	\$2.17	\$2.12	\$2.42	\$1.66	\$2.22	\$1.51	\$1.73	\$0.22	\$0.29	\$0.20	\$14.55	-\$0.003
CAGR (‘15–’22)	0.4%	1.9%	0.6%	-2.0%	-1.4%	-0.6%	-0.6%	-1.3%	-1.4%	-1.9%		-0.3%

Source: iData Research Inc.

5.3.3 Micropipette Market

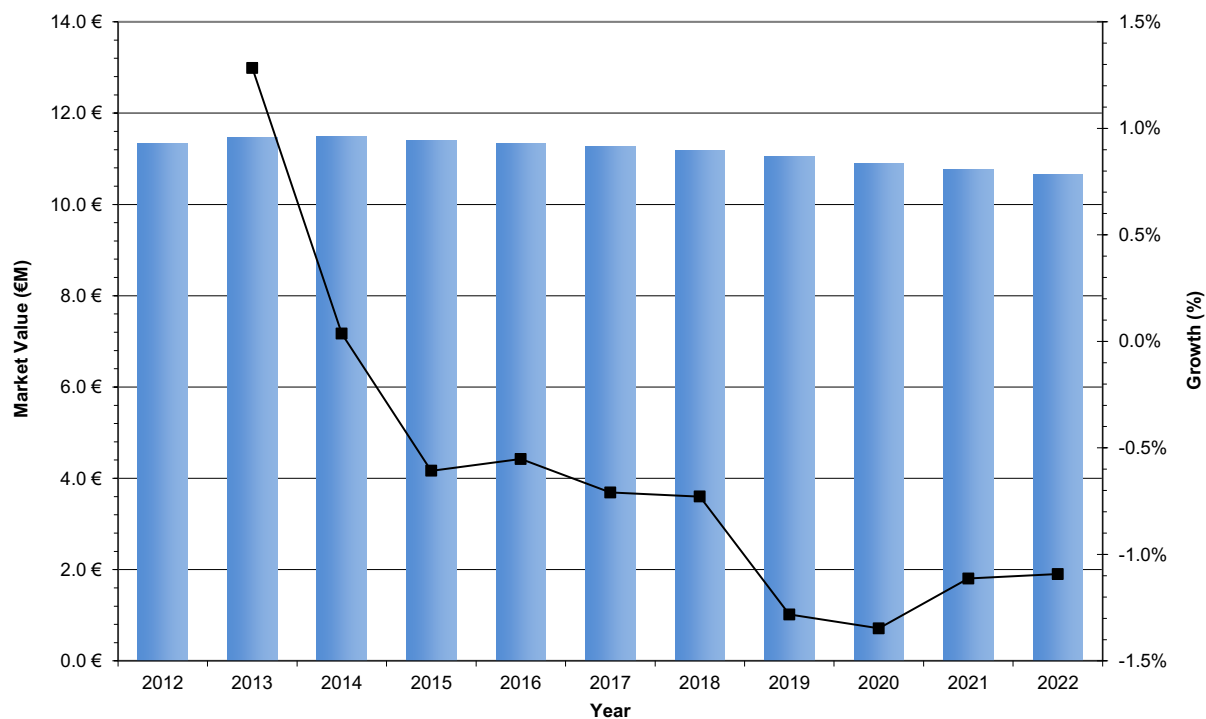
The micropipette market is divided into two sub-segments: the flexible pipette market and the microinjection and holding pipettes market. Flexible pipettes are used for diluting and manipulating the oocyte and sperm media whereas microinjection pipettes are used to inject a single sperm into a single oocyte. Holding pipettes are used to hold the oocyte or embryo when performing ICSI or other micromanipulation procedures. A higher ratio of flexible pipettes are used than microinjection and holding pipettes. An average of 1.5 units of flexible pipettes are used per cycle compared to only 1.2 units of micro and holding pipettes. Combined, an average of 2.6 micropipettes are used per procedure cycle. Again, the micropipette market sales are correlated with ART procedures.

Flexible pipettes are drastically less expensive than Microinjection and holding pipettes. A flexible pipette ranges from starting at €2 in the Scandinavian region to €8. Holding pipettes are slightly more expensive than microinjection pipettes. Microinjection pipettes range from €15 -€19. Holding pipettes are an average of €19. Overall prices of Micropipettes are decreasing slowly, and at a faster rate the Oocyte retrieval needles.

Figure 5-10: Micropipette Market, Europe, 2012 – 2022 (€ and US\$)

Year	Units Sold	Growth (%)	ASP (€)	ASP (US\$)	Growth (%)	Market Value (€M)	Market Value (US\$M)	Growth (%)
2012	1,194,547		€9.48	\$10.49		€11.3	\$12.5	
2013	1,232,661	3.2%	€9.31	\$10.29	-1.8%	€11.5	\$12.7	1.3%
2014	1,251,064	1.5%	€9.18	\$10.14	-1.4%	€11.5	\$12.7	0.0%
2015	1,263,791	1.0%	€9.03	\$9.98	-1.6%	€11.4	\$12.6	-0.6%
2016	1,277,088	1.1%	€8.88	\$9.82	-1.6%	€11.3	\$12.5	-0.6%
2017	1,288,183	0.9%	€8.75	\$9.67	-1.6%	€11.3	\$12.5	-0.7%
2018	1,298,805	0.8%	€8.61	\$9.52	-1.5%	€11.2	\$12.4	-0.7%
2019	1,303,344	0.3%	€8.47	\$9.37	-1.6%	€11.0	\$12.2	-1.3%
2020	1,307,232	0.3%	€8.33	\$9.21	-1.6%	€10.9	\$12.0	-1.3%
2021	1,314,363	0.5%	€8.19	\$9.06	-1.6%	€10.8	\$11.9	-1.1%
2022	1,321,859	0.6%	€8.06	\$8.91	-1.7%	€10.7	\$11.8	-1.1%
CAGR ('15-'22)		0.6%			-1.6%			-1.0%

Source: iData Research Inc.

Chart 5-5: Micropipette Market, Europe, 2012 – 2022

Source: iData Research Inc.

Figure 5-11: Units Sold by Country, Micropipette Market, Europe, 2012 – 2022

Year	Germany	France	U.K.	Italy	Spain	Benelux	Scandi- navia	Austria	Switzer- land	Portugal	Europe	Growth (%)
2012	171,002	256,461	145,490	128,394	163,210	168,009	102,114	20,131	22,910	16,825	1,194,547	
2013	166,658	257,153	155,040	128,894	181,567	179,100	102,114	21,473	23,350	17,312	1,232,661	3.2%
2014	179,177	257,848	152,482	129,667	184,290	184,473	100,072	22,117	23,280	17,659	1,251,064	1.5%
2015	185,555	258,544	155,226	130,445	186,133	186,318	100,572	19,905	23,256	17,835	1,263,791	1.0%
2016	192,161	259,242	158,020	130,054	187,994	187,249	101,075	19,905	23,373	18,014	1,277,088	1.1%
2017	199,002	259,942	158,810	129,924	189,874	188,186	101,075	20,005	23,279	18,086	1,288,183	0.9%
2018	206,087	260,644	158,413	130,574	190,824	189,126	101,479	20,105	23,395	18,158	1,298,805	0.8%
2019	207,117	261,348	157,621	131,357	192,159	190,072	101,885	20,205	23,349	18,231	1,303,344	0.3%
2020	207,324	262,053	156,833	131,620	194,081	191,022	102,293	20,306	23,395	18,304	1,307,232	0.3%
2021	207,532	262,761	159,656	132,409	195,051	191,978	102,702	20,408	23,489	18,377	1,314,363	0.5%
2022	207,739	263,470	162,849	133,204	196,027	192,937	103,113	20,510	23,559	18,450	1,321,859	0.6%
CAGR (‘15–’22)	1.6%	0.3%	0.7%	0.3%	0.7%	0.5%	0.4%	0.4%	0.2%	0.5%		0.6%

Source: iData Research Inc.

Figure 5-12: Units per Procedure by Country, Micropipette Market, Europe, 2012 – 2022

Year	Germany	France	U.K.	Italy	Spain	Benelux	Scandi- navia	Austria	Switzer- land	Portugal	Europe	Growth (%)
2015	2.4	3	2.4	2	2.3	3	4	2.4	2.4	2.3		
Source: iData Research Inc.												

Figure 5-13: Average Selling Price by Country, Micropipette Market, Europe, 2012 – 2022 (€)

Year	Germany	France	U.K.	Italy	Spain	Benelux	Scandi- navia	Austria	Switzer- land	Portugal	Europe	Growth (%)
2012	€11.00	€9.52	€9.04	€10.05	€8.47	€9.69	€7.55	€11.00	€12.20	€7.14	€9.48	
2013	€10.86	€9.34	€8.86	€9.86	€8.31	€9.57	€7.45	€10.86	€12.05	€6.99	€9.31	-1.8%
2014	€10.72	€9.17	€8.68	€9.68	€8.15	€9.45	€7.35	€10.72	€11.90	€6.84	€9.18	-1.4%
2015	€10.58	€9.00	€8.50	€9.50	€8.00	€9.33	€7.25	€10.58	€11.75	€6.70	€9.03	-1.6%
2016	€10.45	€8.83	€8.33	€9.32	€7.85	€9.22	€7.15	€10.45	€11.60	€6.55	€8.88	-1.6%
2017	€10.32	€8.67	€8.15	€9.15	€7.70	€9.10	€7.06	€10.32	€11.46	€6.41	€8.75	-1.6%
2018	€10.19	€8.50	€7.99	€8.98	€7.56	€8.99	€6.96	€10.19	€11.32	€6.28	€8.61	-1.5%
2019	€10.06	€8.34	€7.82	€8.81	€7.41	€8.87	€6.87	€10.06	€11.18	€6.14	€8.47	-1.6%
2020	€9.93	€8.19	€7.66	€8.64	€7.27	€8.76	€6.78	€9.93	€11.04	€6.01	€8.33	-1.6%
2021	€9.80	€8.03	€7.50	€8.48	€7.14	€8.65	€6.69	€9.80	€10.90	€5.88	€8.19	-1.6%
2022	€9.68	€7.88	€7.35	€8.32	€7.00	€8.54	€6.60	€9.68	€10.77	€5.76	€8.06	-1.7%
CAGR (‘15–’22)	-1.3%	-1.9%	-2.1%	-1.9%	-1.9%	-1.3%	-1.3%	-1.3%	-1.2%	-2.1%		-1.6%

Source: iData Research Inc.

Figure 5-14: Average Selling Price by Country, Micropipette Market, Europe, 2012 – 2022 (US\$)

Year	Germany	France	U.K.	Italy	Spain	Benelux	Scandi- navia	Austria	Switzer- land	Portugal	Europe	Growth (%)
2012	\$12.16	\$10.53	\$10.00	\$11.11	\$9.36	\$10.72	\$8.34	\$12.16	\$13.49	\$7.89	\$10.49	
2013	\$12.00	\$10.33	\$9.79	\$10.90	\$9.19	\$10.58	\$8.23	\$12.00	\$13.32	\$7.73	\$10.29	-1.8%
2014	\$11.85	\$10.14	\$9.59	\$10.70	\$9.01	\$10.45	\$8.12	\$11.85	\$13.15	\$7.56	\$10.14	-1.4%
2015	\$11.70	\$9.95	\$9.40	\$10.50	\$8.84	\$10.32	\$8.02	\$11.70	\$12.99	\$7.40	\$9.98	-1.6%
2016	\$11.55	\$9.76	\$9.20	\$10.31	\$8.68	\$10.19	\$7.91	\$11.55	\$12.83	\$7.24	\$9.82	-1.6%
2017	\$11.41	\$9.58	\$9.01	\$10.11	\$8.51	\$10.06	\$7.80	\$11.41	\$12.67	\$7.09	\$9.67	-1.6%
2018	\$11.26	\$9.40	\$8.83	\$9.92	\$8.35	\$9.93	\$7.70	\$11.26	\$12.51	\$6.94	\$9.52	-1.5%
2019	\$11.12	\$9.23	\$8.65	\$9.74	\$8.20	\$9.81	\$7.60	\$11.12	\$12.36	\$6.79	\$9.37	-1.6%
2020	\$10.98	\$9.05	\$8.47	\$9.56	\$8.04	\$9.69	\$7.50	\$10.98	\$12.20	\$6.65	\$9.21	-1.6%
2021	\$10.84	\$8.88	\$8.29	\$9.38	\$7.89	\$9.57	\$7.40	\$10.84	\$12.05	\$6.50	\$9.06	-1.6%
2022	\$10.70	\$8.72	\$8.12	\$9.20	\$7.74	\$9.45	\$7.30	\$10.70	\$11.90	\$6.36	\$8.91	-1.7%
CAGR (‘15–’22)	-1.3%	-1.9%	-2.1%	-1.9%	-1.9%	-1.3%	-1.3%	-1.3%	-1.2%	-2.1%		-1.6%

Source: iData Research Inc.

Figure 5-15: Micropipette Market by Country, Europe, 2012 – 2022 (€M)

Year	Germany	France	U.K.	Italy	Spain	Benelux	Scandi- navia	Austria	Switzer- land	Portugal	Europe	Growth (%)
2012	€1.88	€2.44	€1.32	€1.29	€1.38	€1.63	€0.77	€0.22	€0.28	€0.12	€11.33	
2013	€1.81	€2.40	€1.37	€1.27	€1.51	€1.71	€0.76	€0.23	€0.28	€0.12	€11.48	1.3%
2014	€1.92	€2.36	€1.32	€1.26	€1.50	€1.74	€0.74	€0.24	€0.28	€0.12	€11.48	0.0%
2015	€1.96	€2.33	€1.32	€1.24	€1.49	€1.74	€0.73	€0.21	€0.27	€0.12	€11.41	-0.6%
2016	€2.01	€2.29	€1.32	€1.21	€1.48	€1.73	€0.72	€0.21	€0.27	€0.12	€11.35	-0.6%
2017	€2.05	€2.25	€1.29	€1.19	€1.46	€1.71	€0.71	€0.21	€0.27	€0.12	€11.27	-0.7%
2018	€2.10	€2.22	€1.27	€1.17	€1.44	€1.70	€0.71	€0.20	€0.26	€0.11	€11.18	-0.7%
2019	€2.08	€2.18	€1.23	€1.16	€1.42	€1.69	€0.70	€0.20	€0.26	€0.11	€11.04	-1.3%
2020	€2.06	€2.15	€1.20	€1.14	€1.41	€1.67	€0.69	€0.20	€0.26	€0.11	€10.89	-1.3%
2021	€2.03	€2.11	€1.20	€1.12	€1.39	€1.66	€0.69	€0.20	€0.26	€0.11	€10.77	-1.1%
2022	€2.01	€2.08	€1.20	€1.11	€1.37	€1.65	€0.68	€0.20	€0.25	€0.11	€10.65	-1.1%
CAGR (‘15–’22)	0.3%	-1.6%	-1.4%	-1.6%	-1.2%	-0.8%	-1.0%	-0.8%	-1.1%	-1.7%		-1.0%

Source: iData Research Inc.

Figure 5-16: Micropipette Market by Country, Europe, 2012 – 2022 (US\$M)

Year	Germany	France	U.K.	Italy	Spain	Benelux	Scandi- navia	Austria	Switzer- land	Portugal	Europe	Growth (%)
2012	\$2.08	\$2.70	\$1.45	\$1.43	\$1.53	\$1.80	\$0.85	\$0.24	\$0.31	\$0.13	\$12.53	
2013	\$2.00	\$2.66	\$1.52	\$1.41	\$1.67	\$1.90	\$0.84	\$0.26	\$0.31	\$0.13	\$12.69	1.3%
2014	\$2.12	\$2.61	\$1.46	\$1.39	\$1.66	\$1.93	\$0.81	\$0.26	\$0.31	\$0.13	\$12.69	0.0%
2015	\$2.17	\$2.57	\$1.46	\$1.37	\$1.65	\$1.92	\$0.81	\$0.23	\$0.30	\$0.13	\$12.61	-0.6%
2016	\$2.22	\$2.53	\$1.45	\$1.34	\$1.63	\$1.91	\$0.80	\$0.23	\$0.30	\$0.13	\$12.55	-0.6%
2017	\$2.27	\$2.49	\$1.43	\$1.31	\$1.62	\$1.89	\$0.79	\$0.23	\$0.29	\$0.13	\$12.46	-0.7%
2018	\$2.32	\$2.45	\$1.40	\$1.30	\$1.59	\$1.88	\$0.78	\$0.23	\$0.29	\$0.13	\$12.37	-0.7%
2019	\$2.30	\$2.41	\$1.36	\$1.28	\$1.57	\$1.86	\$0.77	\$0.22	\$0.29	\$0.12	\$12.21	-1.3%
2020	\$2.28	\$2.37	\$1.33	\$1.26	\$1.56	\$1.85	\$0.77	\$0.22	\$0.29	\$0.12	\$12.04	-1.3%
2021	\$2.25	\$2.33	\$1.32	\$1.24	\$1.54	\$1.84	\$0.76	\$0.22	\$0.28	\$0.12	\$11.91	-1.1%
2022	\$2.22	\$2.30	\$1.32	\$1.23	\$1.52	\$1.82	\$0.75	\$0.22	\$0.28	\$0.12	\$11.78	-1.1%
CAGR (‘15–’22)	0.3%	-1.6%	-1.4%	-1.6%	-1.2%	-0.8%	-1.0%	-0.8%	-1.1%	-1.7%		-1.0%
Source: iData Research Inc.												

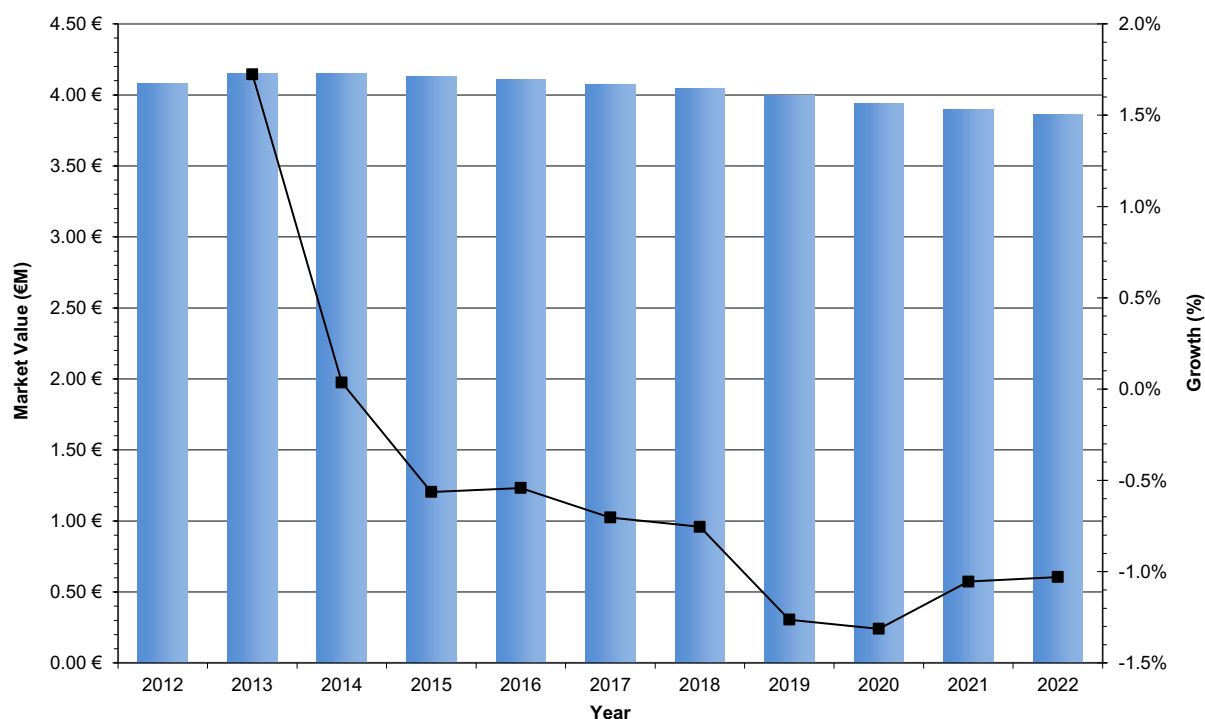
5.3.3.1 Flexible Pipette Market

Figure 5-17: Flexible Pipette Market, Europe, 2012 – 2022 (€ and US\$)

Year	Units Sold	Growth (%)	ASP (€)	ASP (US\$)	Growth (%)	Market Value (€M)	Market Value (US\$M)	Growth (%)
2012	701,556		€5.81	\$6.43		€4.1	\$4.5	
2013	721,930	2.9%	€5.75	\$6.35	-1.1%	€4.1	\$4.6	1.7%
2014	732,513	1.5%	€5.67	\$6.26	-1.4%	€4.2	\$4.6	0.0%
2015	739,818	1.0%	€5.58	\$6.17	-1.5%	€4.1	\$4.6	-0.6%
2016	747,473	1.0%	€5.49	\$6.07	-1.6%	€4.1	\$4.5	-0.5%
2017	753,803	0.8%	€5.41	\$5.98	-1.5%	€4.1	\$4.5	-0.7%
2018	759,957	0.8%	€5.32	\$5.89	-1.6%	€4.0	\$4.5	-0.8%
2019	762,495	0.3%	€5.24	\$5.79	-1.6%	€4.0	\$4.4	-1.3%
2020	764,610	0.3%	€5.16	\$5.70	-1.6%	€3.9	\$4.4	-1.3%
2021	768,714	0.5%	€5.07	\$5.61	-1.6%	€3.9	\$4.3	-1.1%
2022	773,032	0.6%	€4.99	\$5.52	-1.6%	€3.9	\$4.3	-1.0%
CAGR ('15-'22)		0.6%			-1.6%			-1.0%

Source: iData Research Inc.

Chart 5-6: Flexible Pipette Market, Europe, 2012 – 2022



Source: iData Research Inc.

Figure 5-18: Units Sold by Country, Flexible Pipette Market, Europe, 2012 – 2022

Year	Germany	France	U.K.	Italy	Spain	Benelux	Scandi- navia	Austria	Switzer- land	Portugal	Europe	Growth (%)
2012	99,751	170,974	84,869	64,197	70,961	112,006	66,374	11,743	13,364	7,315	701,556	
2013	97,217	171,436	90,440	64,447	78,942	119,400	66,374	12,526	13,621	7,527	721,930	2.9%
2014	104,520	171,899	88,948	64,834	80,126	122,982	65,047	12,902	13,580	7,678	732,513	1.5%
2015	108,241	172,363	90,549	65,223	80,927	124,212	65,372	11,611	13,566	7,754	739,818	1.0%
2016	112,094	172,828	92,179	65,027	81,737	124,833	65,699	11,611	13,634	7,832	747,473	1.0%
2017	116,085	173,295	92,639	64,962	82,554	125,457	65,699	11,669	13,579	7,863	753,803	0.8%
2018	120,217	173,763	92,408	65,287	82,967	126,084	65,962	11,728	13,647	7,895	759,957	0.8%
2019	120,818	174,232	91,946	65,679	83,548	126,715	66,225	11,786	13,620	7,926	762,495	0.3%
2020	120,939	174,702	91,486	65,810	84,383	127,348	66,490	11,845	13,647	7,958	764,610	0.3%
2021	121,060	175,174	93,133	66,205	84,805	127,985	66,756	11,905	13,702	7,990	768,714	0.5%
2022	121,181	175,647	94,995	66,602	85,229	128,625	67,023	11,964	13,743	8,022	773,032	0.6%
CAGR (‘15–’22)	1.6%	0.3%	0.7%	0.3%	0.7%	0.5%	0.4%	0.4%	0.2%	0.5%		0.6%

Source: iData Research Inc.

Figure 5-19: Units per Procedure by Country, Flexible Pipette Market, Europe, 2012 – 2022

Year	Germany	France	U.K.	Italy	Spain	Benelux	Scandi- navia	Austria	Switzer- land	Portugal	Europe	Growth (%)
2015	1.4	2	1.4	1	1	2	2	1.4	1.4	1		
Source: iData Research Inc.												

Figure 5-20: Average Selling Price by Country, Flexible Pipette Market, Europe, 2012 – 2022 (€)

Year	Germany	France	U.K.	Italy	Spain	Benelux	Scandi- navia	Austria	Switzer- land	Portugal	Europe	Growth (%)
2012	€6.18	€5.31	€6.37	€7.43	€8.49	€5.15	€2.06	€6.18	€8.24	€5.31	€5.81	
2013	€6.12	€5.20	€6.24	€7.28	€8.32	€5.10	€2.04	€6.12	€8.16	€5.20	€5.75	-1.1%
2014	€6.06	€5.10	€6.12	€7.14	€8.16	€5.05	€2.02	€6.06	€8.08	€5.10	€5.67	-1.4%
2015	€6.00	€5.00	€6.00	€7.00	€8.00	€5.00	€2.00	€6.00	€8.00	€5.00	€5.58	-1.5%
2016	€5.94	€4.90	€5.88	€6.86	€7.84	€4.95	€1.98	€5.94	€7.92	€4.90	€5.49	-1.6%
2017	€5.88	€4.80	€5.76	€6.72	€7.68	€4.90	€1.96	€5.88	€7.84	€4.80	€5.41	-1.5%
2018	€5.82	€4.71	€5.65	€6.59	€7.53	€4.85	€1.94	€5.82	€7.76	€4.71	€5.32	-1.6%
2019	€5.76	€4.61	€5.53	€6.46	€7.38	€4.80	€1.92	€5.76	€7.68	€4.61	€5.24	-1.6%
2020	€5.71	€4.52	€5.42	€6.33	€7.23	€4.75	€1.90	€5.71	€7.61	€4.52	€5.16	-1.6%
2021	€5.65	€4.43	€5.32	€6.20	€7.09	€4.71	€1.88	€5.65	€7.53	€4.43	€5.07	-1.6%
2022	€5.59	€4.34	€5.21	€6.08	€6.95	€4.66	€1.86	€5.59	€7.46	€4.34	€4.99	-1.6%
CAGR (‘15–’22)	-1.0%	-2.0%	-2.0%	-2.0%	-2.0%	-1.0%	-1.0%	-1.0%	-1.0%	-2.0%		-1.6%

Source: iData Research Inc.

Figure 5-21: Average Selling Price by Country, Flexible Pipette Market, Europe, 2012 – 2022 (US\$)

Year	Germany	France	U.K.	Italy	Spain	Benelux	Scandi- navia	Austria	Switzer- land	Portugal	Europe	Growth (%)
2012	\$6.83	\$5.87	\$7.04	\$8.21	\$9.39	\$5.70	\$2.28	\$6.83	\$9.11	\$5.87	\$6.43	
2013	\$6.77	\$5.75	\$6.90	\$8.05	\$9.20	\$5.64	\$2.26	\$6.77	\$9.02	\$5.75	\$6.35	-1.1%
2014	\$6.70	\$5.64	\$6.77	\$7.89	\$9.02	\$5.58	\$2.23	\$6.70	\$8.93	\$5.64	\$6.26	-1.4%
2015	\$6.63	\$5.53	\$6.63	\$7.74	\$8.84	\$5.53	\$2.21	\$6.63	\$8.84	\$5.53	\$6.17	-1.5%
2016	\$6.57	\$5.42	\$6.50	\$7.58	\$8.67	\$5.47	\$2.19	\$6.57	\$8.76	\$5.42	\$6.07	-1.6%
2017	\$6.50	\$5.31	\$6.37	\$7.43	\$8.49	\$5.42	\$2.17	\$6.50	\$8.67	\$5.31	\$5.98	-1.5%
2018	\$6.44	\$5.20	\$6.24	\$7.28	\$8.32	\$5.36	\$2.15	\$6.44	\$8.58	\$5.20	\$5.89	-1.6%
2019	\$6.37	\$5.10	\$6.12	\$7.14	\$8.16	\$5.31	\$2.12	\$6.37	\$8.50	\$5.10	\$5.79	-1.6%
2020	\$6.31	\$5.00	\$6.00	\$7.00	\$7.99	\$5.26	\$2.10	\$6.31	\$8.41	\$5.00	\$5.70	-1.6%
2021	\$6.25	\$4.90	\$5.88	\$6.86	\$7.84	\$5.20	\$2.08	\$6.25	\$8.33	\$4.90	\$5.61	-1.6%
2022	\$6.18	\$4.80	\$5.76	\$6.72	\$7.68	\$5.15	\$2.06	\$6.18	\$8.24	\$4.80	\$5.52	-1.6%
CAGR (‘15–’22)	-1.0%	-2.0%	-2.0%	-2.0%	-2.0%	-1.0%	-1.0%	-1.0%	-1.0%	-2.0%		-1.6%

Source: iData Research Inc.

Figure 5-22: Flexible Pipette Market by Country, Europe, 2012 – 2022 (€M)

Year	Germany	France	U.K.	Italy	Spain	Benelux	Scandi- navia	Austria	Switzer- land	Portugal	Europe	Growth (%)
2012	€0.62	€0.91	€0.54	€0.48	€0.60	€0.58	€0.14	€0.07	€0.11	€0.04	€4.08	
2013	€0.60	€0.89	€0.56	€0.47	€0.66	€0.61	€0.14	€0.08	€0.11	€0.04	€4.15	1.7%
2014	€0.63	€0.88	€0.54	€0.46	€0.65	€0.62	€0.13	€0.08	€0.11	€0.04	€4.15	0.0%
2015	€0.65	€0.86	€0.54	€0.46	€0.65	€0.62	€0.13	€0.07	€0.11	€0.04	€4.13	-0.6%
2016	€0.67	€0.85	€0.54	€0.45	€0.64	€0.62	€0.13	€0.07	€0.11	€0.04	€4.10	-0.5%
2017	€0.68	€0.83	€0.53	€0.44	€0.63	€0.61	€0.13	€0.07	€0.11	€0.04	€4.08	-0.7%
2018	€0.70	€0.82	€0.52	€0.43	€0.62	€0.61	€0.13	€0.07	€0.11	€0.04	€4.05	-0.8%
2019	€0.70	€0.80	€0.51	€0.42	€0.62	€0.61	€0.13	€0.07	€0.10	€0.04	€3.99	-1.3%
2020	€0.69	€0.79	€0.50	€0.42	€0.61	€0.61	€0.13	€0.07	€0.10	€0.04	€3.94	-1.3%
2021	€0.68	€0.78	€0.50	€0.41	€0.60	€0.60	€0.13	€0.07	€0.10	€0.04	€3.90	-1.1%
2022	€0.68	€0.76	€0.49	€0.40	€0.59	€0.60	€0.12	€0.07	€0.10	€0.03	€3.86	-1.0%
CAGR (‘15–’22)	0.6%	-1.7%	-1.3%	-1.7%	-1.3%	-0.5%	-0.6%	-0.6%	-0.8%	-1.5%		-1.0%
Source: iData Research Inc.												

Figure 5-23: Flexible Pipette Market by Country, Europe, 2012 – 2022 (US\$M)

Year	Germany	France	U.K.	Italy	Spain	Benelux	Scandi- navia	Austria	Switzer- land	Portugal	Europe	Growth (%)
2012	\$0.68	\$1.00	\$0.60	\$0.53	\$0.67	\$0.64	\$0.15	\$0.08	\$0.12	\$0.04	\$4.51	
2013	\$0.66	\$0.99	\$0.62	\$0.52	\$0.73	\$0.67	\$0.15	\$0.08	\$0.12	\$0.04	\$4.59	1.7%
2014	\$0.70	\$0.97	\$0.60	\$0.51	\$0.72	\$0.69	\$0.15	\$0.09	\$0.12	\$0.04	\$4.59	0.0%
2015	\$0.72	\$0.95	\$0.60	\$0.50	\$0.72	\$0.69	\$0.14	\$0.08	\$0.12	\$0.04	\$4.56	-0.6%
2016	\$0.74	\$0.94	\$0.60	\$0.49	\$0.71	\$0.68	\$0.14	\$0.08	\$0.12	\$0.04	\$4.54	-0.5%
2017	\$0.75	\$0.92	\$0.59	\$0.48	\$0.70	\$0.68	\$0.14	\$0.08	\$0.12	\$0.04	\$4.51	-0.7%
2018	\$0.77	\$0.90	\$0.58	\$0.48	\$0.69	\$0.68	\$0.14	\$0.08	\$0.12	\$0.04	\$4.47	-0.8%
2019	\$0.77	\$0.89	\$0.56	\$0.47	\$0.68	\$0.67	\$0.14	\$0.08	\$0.12	\$0.04	\$4.42	-1.3%
2020	\$0.76	\$0.87	\$0.55	\$0.46	\$0.67	\$0.67	\$0.14	\$0.07	\$0.11	\$0.04	\$4.36	-1.3%
2021	\$0.76	\$0.86	\$0.55	\$0.45	\$0.66	\$0.67	\$0.14	\$0.07	\$0.11	\$0.04	\$4.31	-1.1%
2022	\$0.75	\$0.84	\$0.55	\$0.45	\$0.65	\$0.66	\$0.14	\$0.07	\$0.11	\$0.04	\$4.27	-1.0%
CAGR (‘15–’22)	0.6%	-1.7%	-1.3%	-1.7%	-1.3%	-0.5%	-0.6%	-0.6%	-0.8%	-1.5%		-1.0%

Source: iData Research Inc.

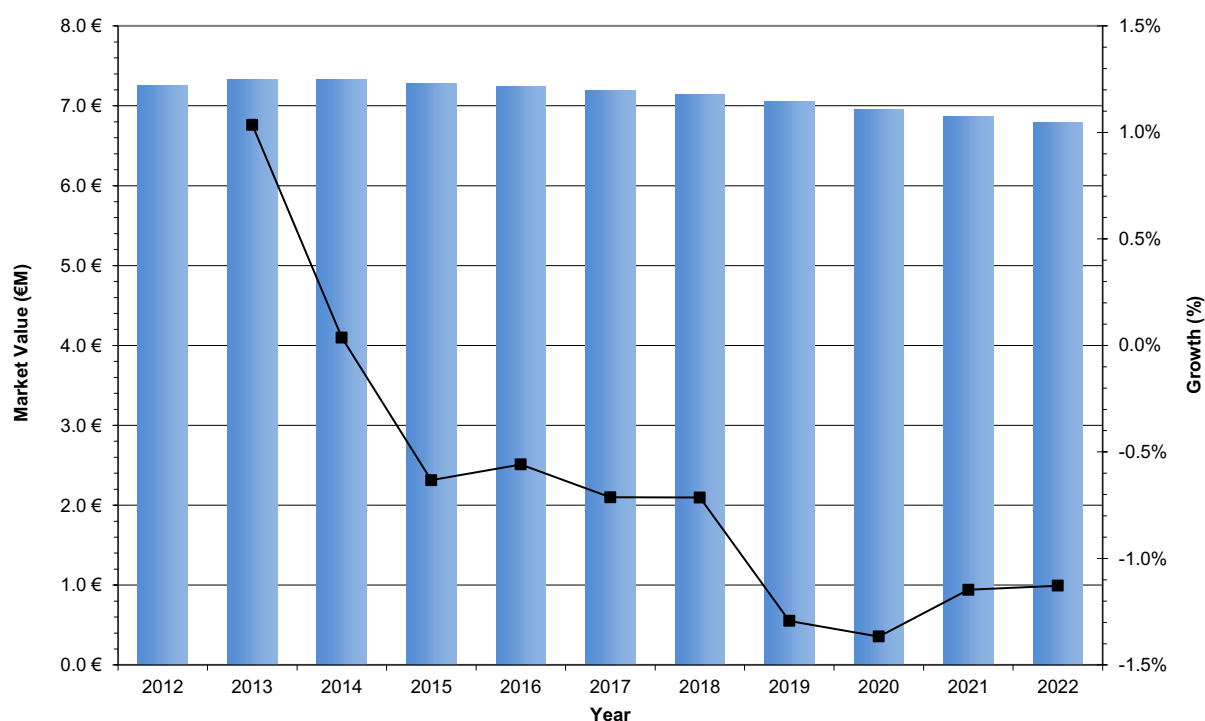
5.3.3.2 Microinjection and Holding Pipettes Market

Figure 5-24: Microinjection and Holding Pipette Market, Europe, 2012 – 2022 (€ and US\$)

Year	Units Sold	Growth (%)	ASP (€)	ASP (US\$)	Growth (%)	Market Value (€M)	Market Value (US\$M)	Growth (%)
2012	492,992		€14.71	\$16.26		€7.3	\$8.0	
2013	510,732	3.6%	€14.34	\$15.86	-2.5%	€7.3	\$8.1	1.0%
2014	518,550	1.5%	€14.13	\$15.63	-1.5%	€7.3	\$8.1	0.0%
2015	523,973	1.0%	€13.90	\$15.37	-1.7%	€7.3	\$8.1	-0.6%
2016	529,614	1.1%	€13.67	\$15.12	-1.6%	€7.2	\$8.0	-0.6%
2017	534,380	0.9%	€13.46	\$14.88	-1.6%	€7.2	\$7.9	-0.7%
2018	538,848	0.8%	€13.25	\$14.65	-1.5%	€7.1	\$7.9	-0.7%
2019	540,850	0.4%	€13.03	\$14.40	-1.7%	€7.0	\$7.8	-1.3%
2020	542,622	0.3%	€12.81	\$14.16	-1.7%	€7.0	\$7.7	-1.4%
2021	545,648	0.6%	€12.59	\$13.92	-1.7%	€6.9	\$7.6	-1.1%
2022	548,827	0.6%	€12.38	\$13.68	-1.7%	€6.8	\$7.5	-1.1%
CAGR ('15-'22)		0.7%			-1.6%			-1.0%

Source: iData Research Inc.

Chart 5-7: Microinjection and Holding Pipette Market, Europe, 2012 – 2022



Source: iData Research Inc.

Figure 5-25: Units Sold by Country, Microinjection and Holding Pipette Market, Europe, 2012 – 2022

Year	Germany	France	U.K.	Italy	Spain	Benelux	Scandi- navia	Austria	Switzer- land	Portugal	Europe	Growth (%)
2012	71,251	85,487	60,621	64,197	92,249	56,003	35,740	8,388	9,546	9,510	492,992	
2013	69,441	85,718	64,600	64,447	102,625	59,700	35,740	8,947	9,729	9,785	510,732	3.6%
2014	74,657	85,949	63,534	64,834	104,164	61,491	35,025	9,215	9,700	9,981	518,550	1.5%
2015	77,315	86,181	64,678	65,223	105,206	62,106	35,200	8,294	9,690	10,081	523,973	1.0%
2016	80,067	86,414	65,842	65,027	106,258	62,416	35,376	8,294	9,739	10,182	529,614	1.1%
2017	82,918	86,647	66,171	64,962	107,320	62,729	35,376	8,335	9,700	10,222	534,380	0.9%
2018	85,869	86,881	66,006	65,287	107,857	63,042	35,518	8,377	9,748	10,263	538,848	0.8%
2019	86,299	87,116	65,676	65,679	108,612	63,357	35,660	8,419	9,729	10,304	540,850	0.4%
2020	86,385	87,351	65,347	65,810	109,698	63,674	35,802	8,461	9,748	10,345	542,622	0.3%
2021	86,471	87,587	66,523	66,205	110,246	63,993	35,946	8,503	9,787	10,387	545,648	0.6%
2022	86,558	87,823	67,854	66,602	110,798	64,312	36,089	8,546	9,816	10,428	548,827	0.6%
CAGR (‘15–’22)	1.6%	0.3%	0.7%	0.3%	0.7%	0.5%	0.4%	0.4%	0.2%	0.5%		0.7%

Source: iData Research Inc.

Figure 5-26: Units per Procedure by Country, Microinjection and Holding Pipette Market, Europe, 2012 – 2022

Year	Germany	France	U.K.	Italy	Spain	Benelux	Scandi- navia	Austria	Switzer- land	Portugal	Europe	Growth (%)
2015	1	1	1	1	1.3	1	2	1	1	1.3		
Source: iData Research Inc.												

Figure 5-27: Average Selling Price by Country, Microinjection and Holding Pipette Market, Europe, 2012 – 2022 (€)

Year	Germany	France	U.K.	Italy	Spain	Benelux	Scandi- navia	Austria	Switzer- land	Portugal	Europe	Growth (%)
2012	€17.73	€17.95	€12.79	€12.67	€8.45	€18.78	€17.73	€17.73	€17.73	€8.55	€14.71	
2013	€17.49	€17.63	€12.52	€12.44	€8.30	€18.51	€17.49	€17.49	€17.49	€8.36	€14.34	-2.5%
2014	€17.24	€17.31	€12.26	€12.22	€8.15	€18.26	€17.24	€17.24	€17.24	€8.18	€14.13	-1.5%
2015	€17.00	€17.00	€12.00	€12.00	€8.00	€18.00	€17.00	€17.00	€17.00	€8.00	€13.90	-1.7%
2016	€16.76	€16.69	€11.75	€11.78	€7.86	€17.75	€16.76	€16.76	€16.76	€7.82	€13.67	-1.6%
2017	€16.53	€16.39	€11.50	€11.57	€7.71	€17.50	€16.53	€16.53	€16.53	€7.65	€13.46	-1.6%
2018	€16.30	€16.10	€11.26	€11.36	€7.58	€17.25	€16.30	€16.30	€16.30	€7.48	€13.25	-1.5%
2019	€16.07	€15.81	€11.02	€11.16	€7.44	€17.01	€16.07	€16.07	€16.07	€7.32	€13.03	-1.7%
2020	€15.84	€15.52	€10.79	€10.96	€7.31	€16.77	€15.84	€15.84	€15.84	€7.16	€12.81	-1.7%
2021	€15.62	€15.24	€10.57	€10.76	€7.17	€16.54	€15.62	€15.62	€15.62	€7.00	€12.59	-1.7%
2022	€15.40	€14.97	€10.34	€10.57	€7.04	€16.31	€15.40	€15.40	€15.40	€6.85	€12.38	-1.7%
CAGR (‘15–’22)	-1.4%	-1.8%	-2.1%	-1.8%	-1.8%	-1.4%	-1.4%	-1.4%	-1.4%	-2.2%		-1.6%

Source: iData Research Inc.

Figure 5-28: Average Selling Price by Country, Microinjection and Holding Pipette Market, Europe, 2012 – 2022 (US\$)

Year	Germany	France	U.K.	Italy	Spain	Benelux	Scandi- navia	Austria	Switzer- land	Portugal	Europe	Growth (%)
2012	\$19.61	\$19.85	\$14.14	\$14.01	\$9.34	\$20.76	\$19.61	\$19.61	\$19.61	\$9.46	\$16.26	
2013	\$19.33	\$19.49	\$13.84	\$13.76	\$9.17	\$20.47	\$19.33	\$19.33	\$19.33	\$9.25	\$15.86	-2.5%
2014	\$19.06	\$19.14	\$13.55	\$13.51	\$9.01	\$20.18	\$19.06	\$19.06	\$19.06	\$9.04	\$15.63	-1.5%
2015	\$18.80	\$18.80	\$13.27	\$13.27	\$8.84	\$19.90	\$18.80	\$18.80	\$18.80	\$8.84	\$15.37	-1.7%
2016	\$18.53	\$18.46	\$12.99	\$13.03	\$8.69	\$19.62	\$18.53	\$18.53	\$18.53	\$8.65	\$15.12	-1.6%
2017	\$18.27	\$18.12	\$12.72	\$12.79	\$8.53	\$19.35	\$18.27	\$18.27	\$18.27	\$8.46	\$14.88	-1.6%
2018	\$18.02	\$17.80	\$12.45	\$12.56	\$8.38	\$19.08	\$18.02	\$18.02	\$18.02	\$8.27	\$14.65	-1.5%
2019	\$17.76	\$17.48	\$12.19	\$12.34	\$8.22	\$18.81	\$17.76	\$17.76	\$17.76	\$8.09	\$14.40	-1.7%
2020	\$17.52	\$17.16	\$11.93	\$12.12	\$8.08	\$18.55	\$17.52	\$17.52	\$17.52	\$7.91	\$14.16	-1.7%
2021	\$17.27	\$16.85	\$11.68	\$11.90	\$7.93	\$18.29	\$17.27	\$17.27	\$17.27	\$7.74	\$13.92	-1.7%
2022	\$17.03	\$16.55	\$11.44	\$11.68	\$7.79	\$18.03	\$17.03	\$17.03	\$17.03	\$7.57	\$13.68	-1.7%
CAGR (‘15–’22)	-1.4%	-1.8%	-2.1%	-1.8%	-1.8%	-1.4%	-1.4%	-1.4%	-1.4%	-2.2%		-1.6%

Source: iData Research Inc.

Figure 5-29: Microinjection and Holding Pipette Market by Country, Europe, 2012 – 2022 (€M)

Year	Germany	France	U.K.	Italy	Spain	Benelux	Scandi- navia	Austria	Switzer- land	Portugal	Europe	Growth (%)
2012	€1.26	€1.53	€0.78	€0.81	€0.78	€1.05	€0.63	€0.15	€0.17	€0.08	€7.25	
2013	€1.21	€1.51	€0.81	€0.80	€0.85	€1.11	€0.62	€0.16	€0.17	€0.08	€7.33	1.0%
2014	€1.29	€1.49	€0.78	€0.79	€0.85	€1.12	€0.60	€0.16	€0.17	€0.08	€7.33	0.0%
2015	€1.31	€1.47	€0.78	€0.78	€0.84	€1.12	€0.60	€0.14	€0.16	€0.08	€7.28	-0.6%
2016	€1.34	€1.44	€0.77	€0.77	€0.83	€1.11	€0.59	€0.14	€0.16	€0.08	€7.24	-0.6%
2017	€1.37	€1.42	€0.76	€0.75	€0.83	€1.10	€0.58	€0.14	€0.16	€0.08	€7.19	-0.7%
2018	€1.40	€1.40	€0.74	€0.74	€0.82	€1.09	€0.58	€0.14	€0.16	€0.08	€7.14	-0.7%
2019	€1.39	€1.38	€0.72	€0.73	€0.81	€1.08	€0.57	€0.14	€0.16	€0.08	€7.05	-1.3%
2020	€1.37	€1.36	€0.71	€0.72	€0.80	€1.07	€0.57	€0.13	€0.15	€0.07	€6.95	-1.4%
2021	€1.35	€1.34	€0.70	€0.71	€0.79	€1.06	€0.56	€0.13	€0.15	€0.07	€6.87	-1.1%
2022	€1.33	€1.31	€0.70	€0.70	€0.78	€1.05	€0.56	€0.13	€0.15	€0.07	€6.79	-1.1%
CAGR (‘15–’22)	0.2%	-1.5%	-1.4%	-1.5%	-1.1%	-0.9%	-1.0%	-1.0%	-1.2%	-1.7%		-1.0%

Source: iData Research Inc.

Figure 5-30: Microinjection and Holding Pipette Market by Country, Europe, 2012 – 2022 (US\$M)

Year	Germany	France	U.K.	Italy	Spain	Benelux	Scandi- navia	Austria	Switzer- land	Portugal	Europe	Growth (%)
2012	\$1.40	\$1.70	\$0.86	\$0.90	\$0.86	\$1.16	\$0.70	\$0.16	\$0.19	\$0.09	\$8.02	
2013	\$1.34	\$1.67	\$0.89	\$0.89	\$0.94	\$1.22	\$0.69	\$0.17	\$0.19	\$0.09	\$8.10	1.0%
2014	\$1.42	\$1.65	\$0.86	\$0.88	\$0.94	\$1.24	\$0.67	\$0.18	\$0.18	\$0.09	\$8.10	0.0%
2015	\$1.45	\$1.62	\$0.86	\$0.87	\$0.93	\$1.24	\$0.66	\$0.16	\$0.18	\$0.09	\$8.05	-0.6%
2016	\$1.48	\$1.59	\$0.86	\$0.85	\$0.92	\$1.22	\$0.66	\$0.15	\$0.18	\$0.09	\$8.01	-0.6%
2017	\$1.52	\$1.57	\$0.84	\$0.83	\$0.92	\$1.21	\$0.65	\$0.15	\$0.18	\$0.09	\$7.95	-0.7%
2018	\$1.55	\$1.55	\$0.82	\$0.82	\$0.90	\$1.20	\$0.64	\$0.15	\$0.18	\$0.08	\$7.89	-0.7%
2019	\$1.53	\$1.52	\$0.80	\$0.81	\$0.89	\$1.19	\$0.63	\$0.15	\$0.17	\$0.08	\$7.79	-1.3%
2020	\$1.51	\$1.50	\$0.78	\$0.80	\$0.89	\$1.18	\$0.63	\$0.15	\$0.17	\$0.08	\$7.68	-1.4%
2021	\$1.49	\$1.48	\$0.78	\$0.79	\$0.87	\$1.17	\$0.62	\$0.15	\$0.17	\$0.08	\$7.60	-1.1%
2022	\$1.47	\$1.45	\$0.78	\$0.78	\$0.86	\$1.16	\$0.61	\$0.15	\$0.17	\$0.08	\$7.51	-1.1%
CAGR (‘15–’22)	0.2%	-1.5%	-1.4%	-1.5%	-1.1%	-0.9%	-1.0%	-1.0%	-1.2%	-1.7%		-1.0%

Source: iData Research Inc.

5.3.4 Embryo Transfer Catheter Market

Unit sales will increase at the same rate as the overall market, since unit sales are dependent on the number of reproduction cycles. Approximately 1.2 embryo transfer catheters are required per cycle. More than one catheter is required if placement is not achieved.

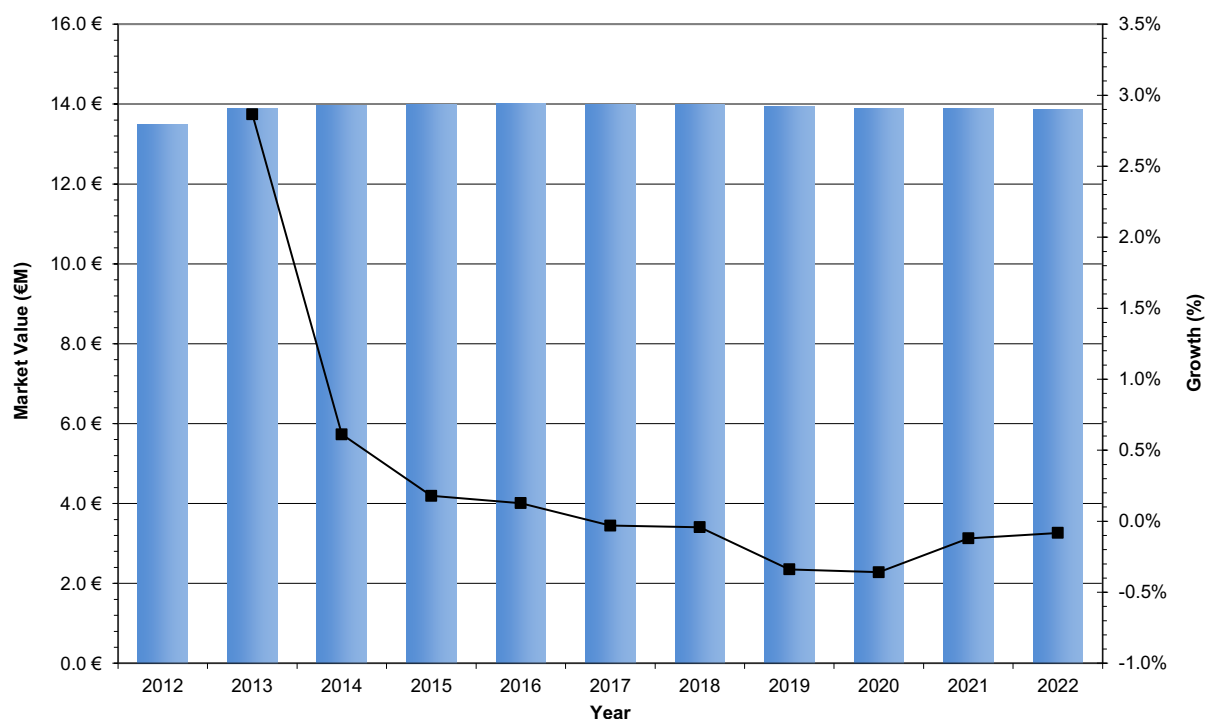
The average ASP of an embryo transfer catheter in 2015 was €22. The range in prices is impacted by whether the country has transitioned to quick transfer catheters from more traditional catheters. In France, the price is increasing because the country is actively upgrading from inexpensive options to the more expensive quick transfer catheters. A less expensive catheter starts at €4, whereas a quick transfer catheter is between €20 and €45. In the Benelux region, the price is higher because labs almost exclusively use quick transfer catheters. Finally, the Scandinavian market is bi-modal. The average price is €24 as the majority of labs purchase quick transfer catheters. The notable exception is one large competitor that is selling inexpensive catheters at €12 holding down the ASP as an anchor. As more labs continue to use exclusively quick transfer catheters the price in the Scandinavian region will increase to mirror the Benelux region. Overall, the market CAGR is decreasing. This is because despite the transition to more expensive technology, the number of competitors in the market is constantly creating a downward pressure to lower product prices.

Figure 5-31: Embryo Transfer Catheter Market, Europe, 2012 – 2022 (€M and US\$)

Year	Units Sold	Growth (%)	ASP (€)	ASP (US\$)	Growth (%)	Market Value (€M)	Market Value (US\$M)	Growth (%)
2012	599,692		€22.50	\$24.87		€13.5	\$14.9	
2013	619,408	3.3%	€22.41	\$24.77	-0.4%	€13.9	\$15.3	2.9%
2014	627,930	1.4%	€22.24	\$24.59	-0.8%	€14.0	\$15.4	0.6%
2015	633,963	1.0%	€22.07	\$24.40	-0.8%	€14.0	\$15.5	0.2%
2016	639,887	0.9%	€21.89	\$24.20	-0.8%	€14.0	\$15.5	0.1%
2017	644,897	0.8%	€21.71	\$24.01	-0.8%	€14.0	\$15.5	0.0%
2018	649,801	0.8%	€21.54	\$23.81	-0.8%	€14.0	\$15.5	0.0%
2019	652,261	0.4%	€21.39	\$23.64	-0.7%	€13.9	\$15.4	-0.3%
2020	654,415	0.3%	€21.24	\$23.48	-0.7%	€13.9	\$15.4	-0.4%
2021	657,902	0.5%	€21.10	\$23.33	-0.7%	€13.9	\$15.3	-0.1%
2022	661,545	0.6%	€20.97	\$23.18	-0.6%	€13.9	\$15.3	-0.1%
CAGR ('15-'22)		0.6%			-0.7%			-0.1%

Source: iData Research Inc.

Chart 5-8: Embryo Transfer Catheter Market, Europe, 2012 – 2022



Source: iData Research Inc.

Figure 5-32: Units Sold by Country, Embryo Transfer Catheter Market, Europe, 2012 – 2022

Year	Germany	France	U.K.	Italy	Spain	Benelux	Scandi- navia	Austria	Switzer- land	Portugal	Europe	Growth (%)
2012	71,251	128,231	60,621	83,456	92,249	84,005	54,631	8,388	9,546	7,315	599,692	
2013	69,441	128,577	64,600	83,781	102,625	89,550	54,631	8,947	9,729	7,527	619,408	3.3%
2014	74,657	128,924	63,534	84,284	104,164	92,237	53,538	9,215	9,700	7,678	627,930	1.4%
2015	77,315	129,272	64,678	84,789	105,206	93,159	53,806	8,294	9,690	7,754	633,963	1.0%
2016	80,067	129,621	65,842	84,535	106,258	93,625	54,075	8,294	9,739	7,832	639,887	0.9%
2017	82,918	129,971	66,171	84,451	107,320	94,093	54,075	8,335	9,700	7,863	644,897	0.8%
2018	85,869	130,322	66,006	84,873	107,857	94,563	54,291	8,377	9,748	7,895	649,801	0.8%
2019	86,299	130,674	65,676	85,382	108,612	95,036	54,509	8,419	9,729	7,926	652,261	0.4%
2020	86,385	131,027	65,347	85,553	109,698	95,511	54,727	8,461	9,748	7,958	654,415	0.3%
2021	86,471	131,380	66,523	86,066	110,246	95,989	54,945	8,503	9,787	7,990	657,902	0.5%
2022	86,558	131,735	67,854	86,583	110,798	96,469	55,165	8,546	9,816	8,022	661,545	0.6%
CAGR (‘15–’22)	1.6%	0.3%	0.7%	0.3%	0.7%	0.5%	0.4%	0.4%	0.2%	0.5%		0.6%

Source: iData Research Inc.

Figure 5-33: Units per Procedure by Country, Embryo Transfer Catheter Market, Europe, 2012 – 2022

Year	Germany	France	U.K.	Italy	Spain	Benelux	Scandi- navia	Austria	Switzer- land	Portugal	Europe	Growth (%)
2015	1	1.5	1	1.3	1.3	1.5	1.07	1	1	1		
Source: iData Research Inc.												

Figure 5-34: Average Sales Price by Country, Embryo Transfer Catheter Market, Europe, 2012 – 2022 (€)

Year	Germany	France	U.K.	Italy	Spain	Benelux	Scandi- navia	Austria	Switzer- land	Portugal	Europe	Growth (%)
2012	€18.83	€18.85	€24.10	€18.54	€19.01	€36.85	€24.54	€20.86	€24.00	€18.04	€22.45	
2013	€18.55	€19.22	€23.86	€18.35	€18.67	€36.22	€24.42	€20.57	€23.59	€17.72	€22.36	-0.4%
2014	€18.27	€19.61	€23.62	€18.17	€18.33	€35.61	€24.30	€20.28	€23.19	€17.40	€22.20	-0.7%
2015	€18.00	€20.00	€23.38	€17.99	€18.00	€35.00	€24.18	€20.00	€22.80	€17.09	€22.02	-0.8%
2016	€17.73	€20.40	€23.15	€17.81	€17.68	€34.41	€24.06	€19.72	€22.41	€16.78	€21.85	-0.8%
2017	€17.46	€20.81	€22.92	€17.63	€17.36	€33.82	€23.94	€19.44	€22.03	€16.48	€21.67	-0.8%
2018	€17.20	€21.22	€22.69	€17.45	€17.05	€33.25	€23.82	€19.17	€21.65	€16.18	€21.50	-0.8%
2019	€16.94	€21.65	€22.46	€17.28	€16.74	€32.68	€23.70	€18.90	€21.29	€15.89	€21.34	-0.7%
2020	€16.69	€22.08	€22.24	€17.10	€16.44	€32.12	€23.58	€18.64	€20.92	€15.60	€21.20	-0.7%
2021	€16.44	€22.52	€22.01	€16.93	€16.14	€31.58	€23.46	€18.38	€20.57	€15.32	€21.06	-0.6%
2022	€16.19	€22.97	€21.79	€16.76	€15.85	€31.04	€23.34	€18.12	€20.22	€15.05	€20.93	-0.6%
CAGR (‘15–’22)	-1.5%	2.0%	-1.0%	-1.0%	-1.8%	-1.7%	-0.5%	-1.4%	-1.7%	-1.8%	-0.7%	-0.7%

Source: iData Research Inc.

Figure 5-35: Average Sales Price by Country, Embryo Transfer Catheter Market, Europe, 2012 – 2022 (US\$)

Year	Germany	France	U.K.	Italy	Spain	Benelux	Scandi- navia	Austria	Switzer- land	Portugal	Europe	Growth (%)
2012	\$20.82	\$20.84	\$26.64	\$20.49	\$21.02	\$40.74	\$27.14	\$23.07	\$26.53	\$19.95	\$24.82	
2013	\$20.51	\$21.25	\$26.38	\$20.29	\$20.64	\$40.05	\$27.00	\$22.74	\$26.08	\$19.59	\$24.72	-0.4%
2014	\$20.20	\$21.68	\$26.11	\$20.09	\$20.27	\$39.37	\$26.87	\$22.43	\$25.64	\$19.24	\$24.54	-0.7%
2015	\$19.90	\$22.11	\$25.85	\$19.89	\$19.90	\$38.70	\$26.73	\$22.11	\$25.20	\$18.89	\$24.35	-0.8%
2016	\$19.60	\$22.55	\$25.59	\$19.69	\$19.54	\$38.04	\$26.60	\$21.80	\$24.78	\$18.55	\$24.15	-0.8%
2017	\$19.31	\$23.01	\$25.34	\$19.49	\$19.19	\$37.39	\$26.46	\$21.50	\$24.35	\$18.22	\$23.96	-0.8%
2018	\$19.02	\$23.47	\$25.08	\$19.30	\$18.85	\$36.76	\$26.33	\$21.20	\$23.94	\$17.89	\$23.77	-0.8%
2019	\$18.73	\$23.93	\$24.83	\$19.10	\$18.51	\$36.13	\$26.20	\$20.90	\$23.53	\$17.57	\$23.60	-0.7%
2020	\$18.45	\$24.41	\$24.58	\$18.91	\$18.17	\$35.52	\$26.07	\$20.61	\$23.13	\$17.25	\$23.44	-0.7%
2021	\$18.18	\$24.90	\$24.34	\$18.72	\$17.85	\$34.91	\$25.94	\$20.32	\$22.74	\$16.94	\$23.28	-0.6%
2022	\$17.90	\$25.40	\$24.10	\$18.53	\$17.52	\$34.32	\$25.81	\$20.03	\$22.35	\$16.64	\$23.14	-0.6%
CAGR (‘15–’22)	-1.5%	2.0%	-1.0%	-1.0%	-1.8%	-1.7%	-0.5%	-1.4%	-1.7%	-1.8%		-0.7%

Source: iData Research Inc.

Figure 5-36: Embryo Transfer Catheter Market, Europe, 2012 – 2022 (€M)

Year	Germany	France	U.K.	Italy	Spain	Benelux	Scandi- navia	Austria	Switzer- land	Portugal	Europe	Growth (%)
2012	€1.34	€2.42	€1.46	€1.55	€1.75	€3.10	€1.34	€0.18	€0.23	€0.13	€13.49	
2013	€1.29	€2.47	€1.54	€1.54	€1.92	€3.24	€1.33	€0.18	€0.23	€0.13	€13.88	2.9%
2014	€1.36	€2.53	€1.50	€1.53	€1.91	€3.28	€1.30	€0.19	€0.22	€0.13	€13.96	0.6%
2015	€1.39	€2.59	€1.51	€1.53	€1.89	€3.26	€1.30	€0.17	€0.22	€0.13	€13.99	0.2%
2016	€1.42	€2.64	€1.52	€1.51	€1.88	€3.22	€1.30	€0.16	€0.22	€0.13	€14.01	0.1%
2017	€1.45	€2.70	€1.52	€1.49	€1.86	€3.18	€1.29	€0.16	€0.21	€0.13	€14.00	0.0%
2018	€1.48	€2.77	€1.50	€1.48	€1.84	€3.14	€1.29	€0.16	€0.21	€0.13	€14.00	0.0%
2019	€1.46	€2.83	€1.48	€1.48	€1.82	€3.11	€1.29	€0.16	€0.21	€0.13	€13.95	-0.3%
2020	€1.44	€2.89	€1.45	€1.46	€1.80	€3.07	€1.29	€0.16	€0.20	€0.12	€13.90	-0.4%
2021	€1.42	€2.96	€1.46	€1.46	€1.78	€3.03	€1.29	€0.16	€0.20	€0.12	€13.88	-0.1%
2022	€1.40	€3.03	€1.48	€1.45	€1.76	€2.99	€1.29	€0.15	€0.20	€0.12	€13.87	-0.1%
CAGR (‘15–’22)	0.1%	2.3%	-0.3%	-0.7%	-1.1%	-1.2%	-0.1%	-1.0%	-1.5%	-1.3%		-0.1%

Source: iData Research Inc.

Figure 5-37: Embryo Transfer Catheter Market, Europe, 2012 – 2022 (US\$M)

Year	Germany	France	U.K.	Italy	Spain	Benelux	Scandi- navia	Austria	Switzer- land	Portugal	Europe	Growth (%)
2012	\$1.48	\$2.67	\$1.62	\$1.71	\$1.94	\$3.42	\$1.48	\$0.19	\$0.25	\$0.15	\$14.92	
2013	\$1.42	\$2.73	\$1.70	\$1.70	\$2.12	\$3.59	\$1.48	\$0.20	\$0.25	\$0.15	\$15.34	2.9%
2014	\$1.51	\$2.79	\$1.66	\$1.69	\$2.11	\$3.63	\$1.44	\$0.21	\$0.25	\$0.15	\$15.44	0.6%
2015	\$1.54	\$2.86	\$1.67	\$1.69	\$2.09	\$3.60	\$1.44	\$0.18	\$0.24	\$0.15	\$15.47	0.2%
2016	\$1.57	\$2.92	\$1.69	\$1.66	\$2.08	\$3.56	\$1.44	\$0.18	\$0.24	\$0.15	\$15.49	0.1%
2017	\$1.60	\$2.99	\$1.68	\$1.65	\$2.06	\$3.52	\$1.43	\$0.18	\$0.24	\$0.14	\$15.48	0.0%
2018	\$1.63	\$3.06	\$1.66	\$1.64	\$2.03	\$3.48	\$1.43	\$0.18	\$0.23	\$0.14	\$15.47	0.0%
2019	\$1.62	\$3.13	\$1.63	\$1.63	\$2.01	\$3.43	\$1.43	\$0.18	\$0.23	\$0.14	\$15.42	-0.3%
2020	\$1.59	\$3.20	\$1.61	\$1.62	\$1.99	\$3.39	\$1.43	\$0.17	\$0.23	\$0.14	\$15.37	-0.4%
2021	\$1.57	\$3.27	\$1.62	\$1.61	\$1.97	\$3.35	\$1.43	\$0.17	\$0.22	\$0.14	\$15.35	-0.1%
2022	\$1.55	\$3.35	\$1.63	\$1.60	\$1.94	\$3.31	\$1.42	\$0.17	\$0.22	\$0.13	\$15.34	-0.1%
CAGR (‘15–’22)	0.1%	2.3%	-0.3%	-0.7%	-1.1%	-1.2%	-0.1%	-1.0%	-1.5%	-1.3%		-0.1%

Source: iData Research Inc.

5.3.5 Reproduction Media Market

The reproduction media market units are broken into one step media, sequential media, sperm preparation media and cryopreservation media. The definition for reproductive media has been updated and is defined as one 100ml bottle of media. Based on primary research conducted with embryologists, doctors and clinics, this report defines the average amount of reproductive media used per petridish as 500 microliters or 0.5ml. Tables have also been included for the total number of doses used for each of the four media types broken out by country. A dose is the 0.5ml required per petri dish, which can also be explained as the total number of petri dishes used per country.

Clinics have started to use microdrops of reproductive media, which greatly reduce the total volume of media used. Conversion to this new technique has been gradual and produces similar results. As the use of microdrops increases, the average volume of media used per procedure will decrease. This is expected to decrease sales as the same volume of media can be used for a higher number of procedure cycles. Overall, the number of procedures will remain the same; however, the conversion to microdrops has the potential to decrease sales in the future.

One step media, sperm preparation media and cryopreservation media all have a 1:1 ratio between the amounts of media used per cycle. In this report, we are defining sequential media as a three stage process using three media types per cycle. Comparing one step media with sequential media, there have been a number of clinical studies published stating the equal effectiveness of both types. Both one step media and sequential media are expected to maintain similar sales in the near future until more clinical evidence exists recommending one over the other.

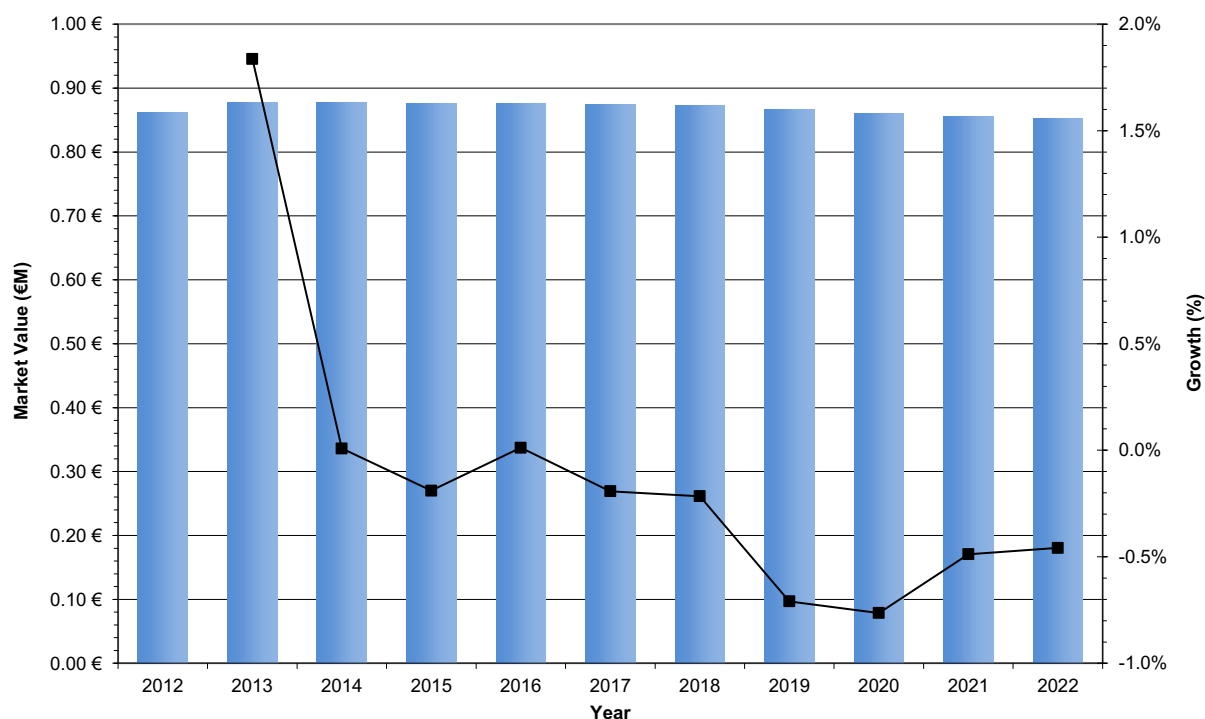
The ASP of reproduction media varies significantly depending on the quality and type. Overall, the United Kingdom and Switzerland have the highest prices in the market whereas Italy and Spain have the lowest prices. In terms of volumes of media sold, culture media has the highest unit sales followed by manipulation media. Manipulation media is required for best practices of IVF, however, the sales volumes are lower because not all labs use manipulation media. Culture media is also the most expensive media type and manipulation media is the least expensive. Sperm preparation media and cryopreservation media both have an ASP in the range between culture and manipulation media. Vitrification media has not been included in this report.

Figure 5-38: Reproduction Media Market, Europe, 2012 – 2022 (€M and US\$)

Year	Units Sold	Growth (%)	ASP (€)	ASP (US\$)	Growth (%)	Market Value (€M)	Market Value (US\$M)	Growth (%)
2012	7,472		€115	\$128		€0.86	\$0.95	
2013	7,717	3.3%	€114	\$126	-1.4%	€0.88	\$0.97	1.8%
2014	7,831	1.5%	€112	\$124	-1.4%	€0.88	\$0.97	0.0%
2015	7,914	1.1%	€111	\$122	-1.2%	€0.88	\$0.97	-0.2%
2016	8,000	1.1%	€110	\$121	-1.1%	€0.88	\$0.97	0.0%
2017	8,071	0.9%	€108	\$120	-1.1%	€0.88	\$0.97	-0.2%
2018	8,141	0.9%	€107	\$119	-1.1%	€0.87	\$0.97	-0.2%
2019	8,171	0.4%	€106	\$117	-1.1%	€0.87	\$0.96	-0.7%
2020	8,196	0.3%	€105	\$116	-1.1%	€0.86	\$0.95	-0.8%
2021	8,242	0.6%	€104	\$115	-1.0%	€0.86	\$0.95	-0.5%
2022	8,289	0.6%	€103	\$114	-1.0%	€0.85	\$0.94	-0.5%
CAGR ('15-'22)		0.7%			-1.1%			-0.4%

Source: iData Research Inc.

Chart 5-9: Reproduction Media Market, Europe, 2012 – 2022



Source: iData Research Inc.

Figure 5-39: Units Sold by Country, Reproduction Media Market, Europe, 2012 – 2022

Year	Germany	France	U.K.	Italy	Spain	Benelux	Scandi- navia	Austria	Switzer- land	Portugal	Europe	Growth (%)
2012	1,558	1,572	1,246	1,346	1,645	1,243	1,159	169	213	154	7,472	
2013	1,519	1,577	1,328	1,352	1,830	1,325	1,159	180	217	158	7,717	3.3%
2014	1,633	1,581	1,306	1,360	1,858	1,365	1,136	186	216	161	7,831	1.5%
2015	1,691	1,585	1,329	1,368	1,876	1,378	1,142	167	216	163	7,914	1.1%
2016	1,751	1,589	1,353	1,364	1,895	1,385	1,147	167	217	165	8,000	1.1%
2017	1,813	1,594	1,360	1,362	1,914	1,392	1,147	168	216	165	8,071	0.9%
2018	1,878	1,598	1,357	1,369	1,924	1,399	1,152	169	217	166	8,141	0.9%
2019	1,887	1,602	1,350	1,378	1,937	1,406	1,157	170	217	167	8,171	0.4%
2020	1,889	1,607	1,343	1,380	1,956	1,413	1,161	170	217	167	8,196	0.3%
2021	1,891	1,611	1,367	1,389	1,966	1,420	1,166	171	218	168	8,242	0.6%
2022	1,893	1,615	1,395	1,397	1,976	1,427	1,170	172	219	169	8,289	0.6%
CAGR (‘15–’22)	1.6%	0.3%	0.7%	0.3%	0.7%	0.5%	0.4%	0.4%	0.2%	0.5%		-8.3%

Source: iData Research Inc.

Figure 5-40: Average Sales Price by Country, Reproduction Media Market, Europe, 2012 – 2022 (€)

Year	Germany	France	U.K.	Italy	Spain	Benelux	Scandi- navia	Austria	Switzer- land	Portugal	Europe	Growth (%)
2012	€81	€85	€90	€77	€77	€90	€88	€88	€91	€79	€115	
2013	€80	€84	€89	€75	€75	€88	€87	€87	€90	€78	€114	-1.4%
2014	€80	€84	€89	€74	€74	€87	€85	€85	€89	€76	€112	-1.4%
2015	€79	€83	€88	€73	€72	€85	€84	€84	€88	€75	€111	-1.2%
2016	€79	€82	€87	€72	€72	€84	€83	€83	€86	€74	€110	-1.1%
2017	€78	€82	€87	€72	€71	€82	€81	€81	€85	€72	€108	-1.1%
2018	€78	€81	€86	€71	€70	€81	€80	€80	€84	€71	€107	-1.1%
2019	€77	€81	€86	€70	€69	€80	€78	€79	€83	€70	€106	-1.1%
2020	€76	€80	€85	€69	€69	€78	€77	€77	€82	€69	€105	-1.1%
2021	€76	€80	€84	€69	€68	€77	€76	€76	€80	€68	€104	-1.0%
2022	€75	€79	€84	€68	€67	€76	€74	€75	€79	€67	€103	-1.0%
CAGR (‘15–’22)	-0.7%	-0.7%	-0.7%	-1.0%	-1.0%	-1.7%	-1.7%	-1.6%	-1.4%	-1.5%		-1.1%

Source: iData Research Inc.

Figure 5-41: Average Sales Price by Country, Reproduction Media Market, Europe, 2012 – 2022 (US\$)

Year	Germany	France	U.K.	Italy	Spain	Benelux	Scandi- navia	Austria	Switzer- land	Portugal	Europe	Growth (%)
2012	\$89	\$94	\$99	\$85	\$85	\$99	\$98	\$97	\$101	\$88	\$128	
2013	\$89	\$93	\$99	\$83	\$83	\$98	\$96	\$96	\$100	\$86	\$126	-1.4%
2014	\$88	\$92	\$98	\$82	\$82	\$96	\$94	\$94	\$98	\$85	\$124	-1.4%
2015	\$88	\$92	\$97	\$81	\$80	\$94	\$93	\$93	\$97	\$83	\$122	-1.2%
2016	\$87	\$91	\$97	\$80	\$79	\$93	\$91	\$91	\$95	\$81	\$121	-1.1%
2017	\$86	\$90	\$96	\$79	\$78	\$91	\$90	\$90	\$94	\$80	\$120	-1.1%
2018	\$86	\$90	\$95	\$78	\$78	\$90	\$88	\$88	\$93	\$79	\$119	-1.1%
2019	\$85	\$89	\$95	\$78	\$77	\$88	\$87	\$87	\$92	\$78	\$117	-1.1%
2020	\$85	\$89	\$94	\$77	\$76	\$87	\$85	\$86	\$90	\$76	\$116	-1.1%
2021	\$84	\$88	\$93	\$76	\$75	\$85	\$84	\$84	\$89	\$75	\$115	-1.0%
2022	\$83	\$87	\$93	\$75	\$75	\$84	\$82	\$83	\$88	\$74	\$114	-1.0%
CAGR (‘15–’22)	-0.7%	-0.7%	-0.7%	-1.0%	-1.0%	-1.7%	-1.7%	-1.6%	-1.4%	-1.5%		-1.1%

Source: iData Research Inc.

Figure 5-42: Reproduction Media Market, Europe, 2012 – 2022 (€M)

Year	Germany	France	U.K.	Italy	Spain	Benelux	Scandi- navia	Austria	Switzer- land	Portugal	Europe	Growth (%)
2012	€0.13	€0.13	€0.11	€0.10	€0.13	€0.11	€0.10	€0.01	€0.02	€0.01	€0.86	
2013	€0.12	€0.13	€0.12	€0.10	€0.14	€0.12	€0.10	€0.02	€0.02	€0.01	€0.88	1.8%
2014	€0.13	€0.13	€0.12	€0.10	€0.14	€0.12	€0.10	€0.02	€0.02	€0.01	€0.88	0.0%
2015	€0.13	€0.13	€0.12	€0.10	€0.14	€0.12	€0.10	€0.01	€0.02	€0.01	€0.88	-0.2%
2016	€0.14	€0.13	€0.12	€0.10	€0.14	€0.12	€0.09	€0.01	€0.02	€0.01	€0.88	0.0%
2017	€0.14	€0.13	€0.12	€0.10	€0.14	€0.11	€0.09	€0.01	€0.02	€0.01	€0.88	-0.2%
2018	€0.15	€0.13	€0.12	€0.10	€0.13	€0.11	€0.09	€0.01	€0.02	€0.01	€0.87	-0.2%
2019	€0.15	€0.13	€0.12	€0.10	€0.13	€0.11	€0.09	€0.01	€0.02	€0.01	€0.87	-0.7%
2020	€0.14	€0.13	€0.11	€0.10	€0.13	€0.11	€0.09	€0.01	€0.02	€0.01	€0.86	-0.8%
2021	€0.14	€0.13	€0.12	€0.10	€0.13	€0.11	€0.09	€0.01	€0.02	€0.01	€0.86	-0.5%
2022	€0.14	€0.13	€0.12	€0.10	€0.13	€0.11	€0.09	€0.01	€0.02	€0.01	€0.85	-0.5%
CAGR (‘15–’22)	0.9%	-0.4%	0.0%	-0.7%	-0.3%	-1.2%	-1.3%	-1.2%	-1.2%	-1.1%		-0.4%

Source: iData Research Inc.

Figure 5-43: Reproduction Media Market, Europe, 2012 – 2022 (US\$M)

Year	Germany	France	U.K.	Italy	Spain	Benelux	Scandi- navia	Austria	Switzer- land	Portugal	Europe	Growth (%)
2012	\$0.14	\$0.15	\$0.12	\$0.11	\$0.14	\$0.12	\$0.11	\$0.02	\$0.02	\$0.01	\$0.95	
2013	\$0.13	\$0.15	\$0.13	\$0.11	\$0.15	\$0.13	\$0.11	\$0.02	\$0.02	\$0.01	\$0.97	1.8%
2014	\$0.14	\$0.15	\$0.13	\$0.11	\$0.15	\$0.13	\$0.11	\$0.02	\$0.02	\$0.01	\$0.97	0.0%
2015	\$0.15	\$0.15	\$0.13	\$0.11	\$0.15	\$0.13	\$0.11	\$0.02	\$0.02	\$0.01	\$0.97	-0.2%
2016	\$0.15	\$0.14	\$0.13	\$0.11	\$0.15	\$0.13	\$0.10	\$0.02	\$0.02	\$0.01	\$0.97	0.0%
2017	\$0.16	\$0.14	\$0.13	\$0.11	\$0.15	\$0.13	\$0.10	\$0.02	\$0.02	\$0.01	\$0.97	-0.2%
2018	\$0.16	\$0.14	\$0.13	\$0.11	\$0.15	\$0.13	\$0.10	\$0.01	\$0.02	\$0.01	\$0.97	-0.2%
2019	\$0.16	\$0.14	\$0.13	\$0.11	\$0.15	\$0.12	\$0.10	\$0.01	\$0.02	\$0.01	\$0.96	-0.7%
2020	\$0.16	\$0.14	\$0.13	\$0.11	\$0.15	\$0.12	\$0.10	\$0.01	\$0.02	\$0.01	\$0.95	-0.8%
2021	\$0.16	\$0.14	\$0.13	\$0.11	\$0.15	\$0.12	\$0.10	\$0.01	\$0.02	\$0.01	\$0.95	-0.5%
2022	\$0.16	\$0.14	\$0.13	\$0.11	\$0.15	\$0.12	\$0.10	\$0.01	\$0.02	\$0.01	\$0.94	-0.5%
CAGR (‘15–’22)	0.9%	-0.4%	0.0%	-0.7%	-0.3%	-1.2%	-1.3%	-1.2%	-1.2%	-1.1%		-0.4%

Source: iData Research Inc.

5.3.5.1 One Step Media Market

Figure 5-44: Total Doses by Country, One Step Media Market, Europe, 2012 – 2022

Year	Germany	France	U.K.	Italy	Spain	Benelux	Scandi- navia	Austria	Switzer- land	Portugal	Europe	Growth (%)
2012	39,188	68,390	36,373	33,382	28,384	30,802	25,529	5,033	5,728	4,023	276,831	3.0%
2013	38,193	68,574	38,760	33,512	31,577	32,835	25,529	5,368	5,837	4,140	284,325	2.7%
2014	41,061	68,759	38,120	33,714	32,050	33,820	25,018	5,529	5,820	4,223	288,115	1.3%
2015	42,523	68,945	38,807	33,916	32,371	34,158	25,143	4,976	5,814	4,265	290,918	1.0%
2016	44,037	69,131	39,505	33,814	32,695	34,329	25,269	4,976	5,843	4,308	293,907	1.0%
2017	45,605	69,318	39,703	33,780	33,022	34,501	25,269	5,001	5,820	4,325	296,342	0.8%
2018	47,228	69,505	39,603	33,949	33,187	34,673	25,370	5,026	5,849	4,342	298,733	0.8%
2019	47,464	69,693	39,405	34,153	33,419	34,847	25,471	5,051	5,837	4,359	299,700	0.3%
2020	47,512	69,881	39,208	34,221	33,753	35,021	25,573	5,077	5,849	4,377	300,472	0.3%
2021	47,559	70,070	39,914	34,426	33,922	35,196	25,675	5,102	5,872	4,394	302,131	0.6%
2022	47,607	70,259	40,712	34,633	34,092	35,372	25,778	5,127	5,890	4,412	303,882	0.6%
CAGR (‘15–’22)	1.6%	0.3%	0.7%	0.3%	0.7%	0.5%	0.4%	0.4%	0.2%	0.5%		0.6%

Source: iData Research Inc.

5.3.5.2 Sequential Media Market

Figure 5-45: Total Doses by Country, Sequential Media Market, Europe, 2012 – 2022

Year	Germany	France	U.K.	Italy	Spain	Benelux	Scandi- navia	Austria	Switzer- land	Portugal	Europe	Growth (%)
2012	96,189	51,292	72,745	92,444	127,730	75,604	76,586	10,066	11,455	9,875	623,985	4.0%
2013	93,745	51,431	77,520	92,804	142,096	80,595	76,586	10,736	11,675	10,162	647,349	3.7%
2014	100,787	51,570	76,241	93,361	144,227	83,013	75,054	11,058	11,640	10,365	657,315	1.5%
2015	104,375	51,709	77,613	93,921	145,669	83,843	75,429	9,953	11,628	10,469	664,608	1.1%
2016	108,091	51,848	79,010	93,639	147,126	84,262	75,806	9,953	11,686	10,573	671,995	1.1%
2017	111,939	51,988	79,405	93,545	148,597	84,684	75,806	10,002	11,640	10,615	678,222	0.9%
2018	115,924	52,129	79,207	94,013	149,340	85,107	76,109	10,052	11,698	10,658	684,237	0.9%
2019	116,503	52,270	78,811	94,577	150,386	85,532	76,414	10,103	11,674	10,701	686,970	0.4%
2020	116,620	52,411	78,417	94,766	151,889	85,960	76,720	10,153	11,698	10,743	689,377	0.4%
2021	116,737	52,552	79,828	95,335	152,649	86,390	77,026	10,204	11,744	10,786	693,252	0.6%
2022	116,853	52,694	81,425	95,907	153,412	86,822	77,335	10,255	11,780	10,830	697,312	0.6%
CAGR (‘15–’22)	1.6%	0.3%	0.7%	0.3%	0.7%	0.5%	0.4%	0.4%	0.2%	0.5%		0.7%

Source: iData Research Inc.

5.3.5.3 Sperm Preparation Media Market

Figure 5-46: Total Doses by Country, Sperm Preparation Media Market, Europe, 2012 – 2022

Year	Germany	France	U.K.	Italy	Spain	Benelux	Scandi- navia	Austria	Switzer- land	Portugal	Europe	Growth (%)
2012	71,251	85,487	60,621	64,197	70,961	56,003	51,057	8,388	9,546	7,315	484,826	3.5%
2013	69,441	85,718	64,600	64,447	78,942	59,700	51,057	8,947	9,729	7,527	500,108	3.2%
2014	74,657	85,949	63,534	64,834	80,126	61,491	50,036	9,215	9,700	7,678	507,220	1.4%
2015	77,315	86,181	64,678	65,223	80,927	62,106	50,286	8,294	9,690	7,754	512,454	1.0%
2016	80,067	86,414	65,842	65,027	81,737	62,416	50,537	8,294	9,739	7,832	517,905	1.1%
2017	82,918	86,647	66,171	64,962	82,554	62,729	50,537	8,335	9,700	7,863	522,416	0.9%
2018	85,869	86,881	66,006	65,287	82,967	63,042	50,740	8,377	9,748	7,895	526,812	0.8%
2019	86,299	87,116	65,676	65,679	83,548	63,357	50,943	8,419	9,729	7,926	528,690	0.4%
2020	86,385	87,351	65,347	65,810	84,383	63,674	51,146	8,461	9,748	7,958	530,264	0.3%
2021	86,471	87,587	66,523	66,205	84,805	63,993	51,351	8,503	9,787	7,990	533,215	0.6%
2022	86,558	87,823	67,854	66,602	85,229	64,312	51,556	8,546	9,816	8,022	536,319	0.6%
CAGR (‘15–’22)	1.6%	0.3%	0.7%	0.3%	0.7%	0.5%	0.4%	0.4%	0.2%	0.5%		0.7%

Source: iData Research Inc.

5.3.5.4 Freeze/Thaw Media Market

Figure 5-47: Total Doses by Country, Freeze/Thaw Media Market, Europe, 2012 – 2022

Year	Germany	France	U.K.	Italy	Spain	Benelux	Scandi- navia	Austria	Switzer- land	Portugal	Europe	Growth (%)
2012	19,330	22,834	10,912	5,213	11,489	17,809	14,898	1,018	4,118	1,088	108,709	3.0%
2013	18,839	22,895	11,628	5,233	12,781	18,985	14,898	1,086	4,197	1,119	111,662	2.7%
2014	20,254	22,957	11,436	5,264	12,972	19,554	14,600	1,119	4,184	1,142	113,484	1.6%
2015	20,976	23,019	11,642	5,296	13,102	19,750	14,673	1,007	4,180	1,153	114,798	1.2%
2016	21,722	23,081	11,852	5,280	13,233	19,848	14,747	1,007	4,201	1,165	116,136	1.2%
2017	22,496	23,144	11,911	5,275	13,365	19,948	14,747	1,012	4,184	1,169	117,250	1.0%
2018	23,296	23,206	11,881	5,301	13,432	20,047	14,806	1,017	4,205	1,174	118,366	1.0%
2019	23,413	23,269	11,822	5,333	13,526	20,148	14,865	1,022	4,197	1,179	118,773	0.3%
2020	23,436	23,331	11,762	5,344	13,662	20,248	14,925	1,027	4,205	1,183	119,124	0.3%
2021	23,460	23,394	11,974	5,376	13,730	20,350	14,984	1,032	4,222	1,188	119,711	0.5%
2022	23,483	23,458	12,214	5,408	13,799	20,451	15,044	1,037	4,235	1,193	120,322	0.5%
CAGR (‘15–’22)	1.6%	0.3%	0.7%	0.3%	0.7%	0.5%	0.4%	0.4%	0.2%	0.5%		0.7%

Source: iData Research Inc.

Figure 5-48: Reproductive Media Type, Sales in Percent (%), Europe, 2015

Reproductive Media Type	Germany	France	U.K.	Italy	Spain	Benelux	Scandi-navia	Austria	Switzer-land	Portugal
Sequential Media	45%	20%	40%	48%	60%	45%	50%	40%	40%	45%
One-Step Media	55%	80%	60%	52%	40%	55%	50%	60%	60%	55%
Sperm Prep Media	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%
Freeze/Thaw Media	27%	27%	18%	8%	16%	32%	29%	12%	43%	15%
Source: iData Research Inc.										

5.3.6 Emerging Market: Embryo Time-Lapse Incubators

Embryo time lapse incubators are an emerging market that is rapidly becoming the new standard for assisted reproduction. Currently, the United Kingdom is the market leader by a considerable margin with 55% of labs utilizing embryo time lapse incubators. The market is projected to experience substantial growth in sales over the forecast period, with a CAGR of 7.7%. In more established markets, labs are beginning to invest in multiple systems which is helping to fuel growth. This market is far from saturated and is predicted to experience a strong market value increase.

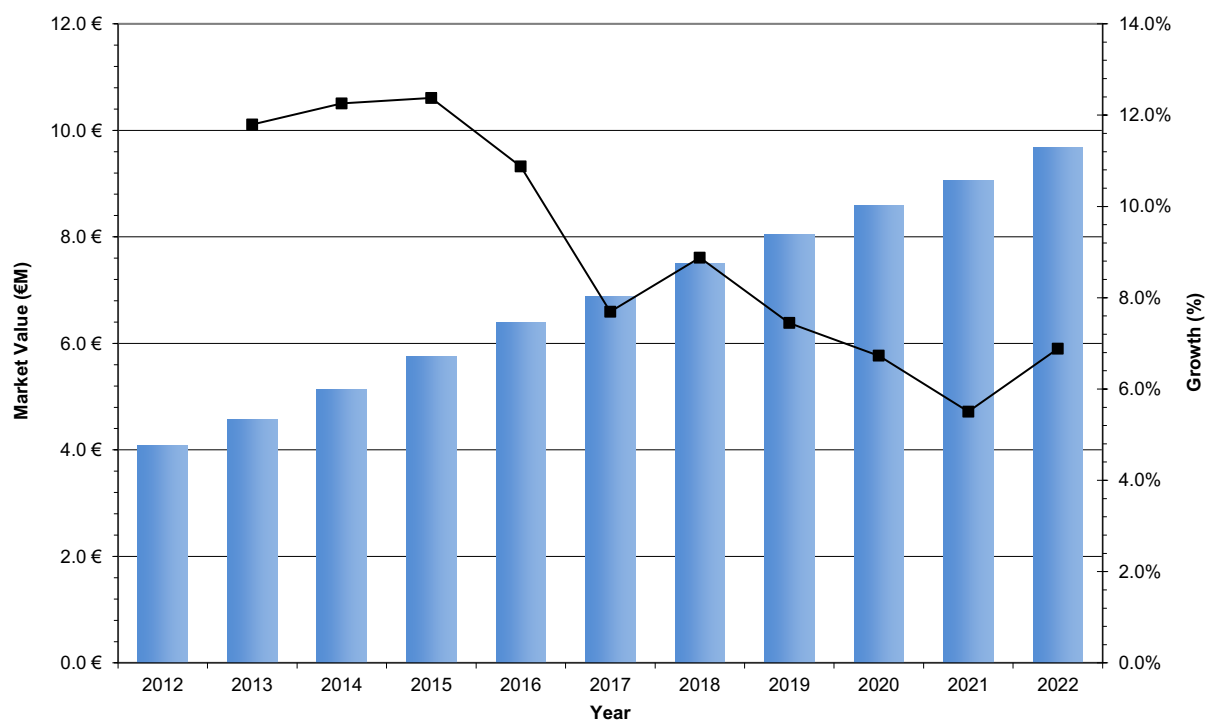
The ASP is predicted to remain relatively stable with nominal decreases. While there is strong competition in the market between competitors, the technology is still new and expensive. All competitors are continuing to release new systems which are maintaining a high price point.

Figure 5-49: Embryo Time-Lapse Incubators Market, Europe, 2012 – 2022 (€M and US\$)

Year	Units Sold	Growth (%)	ASP (€)	ASP (US\$)	Growth (%)	Market Value (€M)	Market Value (US\$M)	Growth (%)
2012	59		€69,260	\$76,573		€4.1	\$4.5	
2013	66	11.9%	€69,216	\$76,526	-0.1%	€4.6	\$5.1	11.8%
2014	74	12.1%	€69,300	\$76,618	0.1%	€5.1	\$5.7	12.3%
2015	83	12.2%	€69,432	\$76,764	0.2%	€5.8	\$6.4	12.4%
2016	92	10.8%	€69,452	\$76,786	0.0%	€6.4	\$7.1	10.9%
2017	99	7.6%	€69,506	\$76,845	0.1%	€6.9	\$7.6	7.7%
2018	108	9.1%	€69,369	\$76,695	-0.2%	€7.5	\$8.3	8.9%
2019	116	7.4%	€69,393	\$76,721	0.0%	€8.0	\$8.9	7.4%
2020	124	6.9%	€69,284	\$76,600	-0.2%	€8.6	\$9.5	6.7%
2021	131	5.6%	€69,191	\$76,498	-0.1%	€9.1	\$10.0	5.5%
2022	140	6.9%	€69,200	\$76,508	0.0%	€9.7	\$10.7	6.9%
CAGR ('15-'22)		7.8%			0.0%			7.7%

Source: iData Research Inc.

Chart 5-10: Embryo Time-Lapse Incubators Market, Europe, 2012 – 2022



Source: iData Research Inc.

Figure 5-50: Units Sold by Country, Embryo Time-Lapse Incubators Market, Europe, 2012 – 2022

Year	Germany	France	U.K.	Italy	Spain	Benelux	Scandi- navia	Austria	Switzer- land	Portugal	Europe	Growth (%)
2012	6	8	24	3	5	2	2	3	3	3	59	
2013	7	8	26	3	6	3	2	3	4	4	66	11.9%
2014	8	9	28	4	7	3	2	4	4	5	74	12.1%
2015	10	10	30	5	8	3	3	5	4	5	83	12.2%
2016	12	10	32	6	9	4	3	5	5	6	92	10.8%
2017	13	11	33	6	10	5	3	6	6	6	99	7.6%
2018	14	12	34	7	11	7	4	6	6	7	108	9.1%
2019	15	13	35	7	12	8	4	7	7	8	116	7.4%
2020	16	14	36	8	13	9	5	7	7	9	124	6.9%
2021	16	15	37	9	14	9	6	8	7	10	131	5.6%
2022	17	15	38	11	14	10	7	9	9	10	140	6.9%
CAGR (‘15–’22)	7.9%	6.0%	3.4%	11.9%	8.3%	18.8%	12.9%	8.8%	12.3%	10.4%		7.8%

Source: iData Research Inc.

Figure 5-51: Percentage of clinics using embryo time-lapse incubators by Country, Embryo Time-Lapse Incubators Market, Europe, 2012 – 2022

Year	Germany	France	U.K.	Italy	Spain	Benelux	Scandi- navia	Austria	Switzer- land	Portugal	Europe	Growth (%)
2015	20%	13%	55%	5%	12%	2%	3%	10%	10%	8%		
Source: iData Research Inc.												

Figure 5-52: Average Sales Price by Country, Embryo Time-Lapse Incubators Market, Europe, 2012 – 2022 (€)

Year	Germany	France	U.K.	Italy	Spain	Benelux	Scandi- navia	Austria	Switzer- land	Portugal	Europe	Growth (%)
2012	€80,563	€70,210	€64,185	€70,422	€68,204	€67,559	€68,823	€80,385	€74,446	€70,422	€69,260	
2013	€80,402	€70,140	€64,121	€70,210	€68,102	€67,336	€68,479	€80,224	€74,297	€70,281	€69,216	-0.1%
2014	€80,241	€70,070	€64,057	€70,070	€68,034	€67,134	€68,205	€80,104	€74,148	€70,140	€69,300	0.1%
2015	€80,000	€70,000	€63,929	€70,000	€68,000	€67,000	€68,000	€80,000	€74,000	€70,000	€69,432	0.2%
2016	€79,760	€69,930	€63,801	€69,965	€67,973	€66,933	€67,864	€79,960	€73,852	€69,930	€69,452	0.0%
2017	€79,497	€69,860	€63,674	€69,944	€67,949	€66,866	€67,796	€79,928	€73,704	€69,874	€69,506	0.1%
2018	€79,298	€69,790	€63,514	€69,927	€67,929	€66,839	€67,762	€79,896	€73,483	€69,832	€69,369	-0.2%
2019	€79,100	€69,720	€63,356	€69,913	€67,912	€66,819	€67,742	€79,816	€73,189	€69,804	€69,393	0.0%
2020	€78,942	€69,651	€63,197	€69,899	€67,898	€66,803	€67,725	€79,696	€72,896	€69,783	€69,284	-0.2%
2021	€78,784	€69,581	€63,008	€69,892	€67,888	€66,789	€67,711	€79,537	€72,532	€69,769	€69,191	-0.1%
2022	€78,626	€69,511	€62,819	€69,885	€67,881	€66,779	€67,701	€79,298	€72,169	€69,762	€69,200	0.0%
CAGR (‘15–’22)	-0.2%	-0.1%	-0.3%	0.0%	0.0%	0.0%	-0.1%	-0.1%	-0.4%	0.0%		0.0%

Source: iData Research Inc.

Figure 5-53: Average Sales Price by Country, Embryo Time-Lapse Incubators Market, Europe, 2012 – 2022 (US\$)

Year	Germany	France	U.K.	Italy	Spain	Benelux	Scandi- navia	Austria	Switzer- land	Portugal	Europe	Growth (%)
2012	\$89,070	\$77,625	\$70,963	\$77,858	\$75,407	\$74,693	\$76,090	\$88,874	\$82,307	\$77,858	\$76,573	
2013	\$88,892	\$77,547	\$70,892	\$77,625	\$75,294	\$74,447	\$75,710	\$88,696	\$82,143	\$77,702	\$76,526	-0.1%
2014	\$88,714	\$77,469	\$70,822	\$77,469	\$75,218	\$74,224	\$75,407	\$88,563	\$81,978	\$77,547	\$76,618	0.1%
2015	\$88,448	\$77,392	\$70,680	\$77,392	\$75,181	\$74,075	\$75,181	\$88,448	\$81,814	\$77,392	\$76,764	0.2%
2016	\$88,183	\$77,315	\$70,539	\$77,353	\$75,151	\$74,001	\$75,030	\$88,404	\$81,651	\$77,315	\$76,786	0.0%
2017	\$87,892	\$77,237	\$70,397	\$77,330	\$75,124	\$73,927	\$74,955	\$88,368	\$81,487	\$77,253	\$76,845	0.1%
2018	\$87,672	\$77,160	\$70,221	\$77,311	\$75,102	\$73,898	\$74,918	\$88,333	\$81,243	\$77,206	\$76,695	-0.2%
2019	\$87,453	\$77,083	\$70,046	\$77,295	\$75,083	\$73,875	\$74,895	\$88,245	\$80,918	\$77,176	\$76,721	0.0%
2020	\$87,278	\$77,006	\$69,871	\$77,280	\$75,068	\$73,857	\$74,877	\$88,112	\$80,594	\$77,152	\$76,600	-0.2%
2021	\$87,103	\$76,929	\$69,661	\$77,272	\$75,057	\$73,842	\$74,862	\$87,936	\$80,191	\$77,137	\$76,498	-0.1%
2022	\$86,929	\$76,852	\$69,452	\$77,264	\$75,049	\$73,831	\$74,851	\$87,672	\$79,790	\$77,129	\$76,508	0.0%
CAGR (‘15–’22)	-0.2%	-0.1%	-0.3%	0.0%	0.0%	0.0%	-0.1%	-0.1%	-0.4%	0.0%		0.0%

Source: iData Research Inc.

Figure 5-54: Embryo Time-Lapse Incubators Market, Europe, 2012 – 2022 (€M)

Year	Germany	France	U.K.	Italy	Spain	Benelux	Scandi- navia	Austria	Switzer- land	Portugal	Europe	Growth (%)
2012	€0.48	€0.56	€1.54	€0.21	€0.34	€0.14	€0.14	€0.24	€0.22	€0.21	€4.09	
2013	€0.56	€0.56	€1.67	€0.21	€0.41	€0.20	€0.14	€0.24	€0.30	€0.28	€4.57	11.8%
2014	€0.64	€0.63	€1.79	€0.28	€0.48	€0.20	€0.14	€0.32	€0.30	€0.35	€5.13	12.3%
2015	€0.80	€0.70	€1.92	€0.35	€0.54	€0.20	€0.20	€0.40	€0.30	€0.35	€5.76	12.4%
2016	€0.96	€0.70	€2.04	€0.42	€0.61	€0.27	€0.20	€0.40	€0.37	€0.42	€6.39	10.9%
2017	€1.03	€0.77	€2.10	€0.42	€0.68	€0.33	€0.20	€0.48	€0.44	€0.42	€6.88	7.7%
2018	€1.11	€0.84	€2.16	€0.49	€0.75	€0.47	€0.27	€0.48	€0.44	€0.49	€7.49	8.9%
2019	€1.19	€0.91	€2.22	€0.49	€0.81	€0.53	€0.27	€0.56	€0.51	€0.56	€8.05	7.4%
2020	€1.26	€0.98	€2.28	€0.56	€0.88	€0.60	€0.34	€0.56	€0.51	€0.63	€8.59	6.7%
2021	€1.26	€1.04	€2.33	€0.63	€0.95	€0.60	€0.41	€0.64	€0.51	€0.70	€9.06	5.5%
2022	€1.34	€1.04	€2.39	€0.77	€0.95	€0.67	€0.47	€0.71	€0.65	€0.70	€9.69	6.9%
CAGR (‘15–’22)	7.6%	5.9%	3.2%	11.9%	8.3%	18.7%	12.8%	8.6%	11.9%	10.4%		7.7%
Source: iData Research Inc.												

Figure 5-55: Embryo Time-Lapse Incubators Market, Europe, 2012 – 2022 (US\$M)

Year	Germany	France	U.K.	Italy	Spain	Benelux	Scandi- navia	Austria	Switzer- land	Portugal	Europe	Growth (%)
2012	\$0.53	\$0.62	\$1.70	\$0.23	\$0.38	\$0.15	\$0.15	\$0.27	\$0.25	\$0.23	\$4.52	
2013	\$0.62	\$0.62	\$1.84	\$0.23	\$0.45	\$0.22	\$0.15	\$0.27	\$0.33	\$0.31	\$5.05	11.8%
2014	\$0.71	\$0.70	\$1.98	\$0.31	\$0.53	\$0.22	\$0.15	\$0.35	\$0.33	\$0.39	\$5.67	12.3%
2015	\$0.88	\$0.77	\$2.12	\$0.39	\$0.60	\$0.22	\$0.23	\$0.44	\$0.33	\$0.39	\$6.37	12.4%
2016	\$1.06	\$0.77	\$2.26	\$0.46	\$0.68	\$0.30	\$0.23	\$0.44	\$0.41	\$0.46	\$7.06	10.9%
2017	\$1.14	\$0.85	\$2.32	\$0.46	\$0.75	\$0.37	\$0.22	\$0.53	\$0.49	\$0.46	\$7.61	7.7%
2018	\$1.23	\$0.93	\$2.39	\$0.54	\$0.83	\$0.52	\$0.30	\$0.53	\$0.49	\$0.54	\$8.28	8.9%
2019	\$1.31	\$1.00	\$2.45	\$0.54	\$0.90	\$0.59	\$0.30	\$0.62	\$0.57	\$0.62	\$8.90	7.4%
2020	\$1.40	\$1.08	\$2.52	\$0.62	\$0.98	\$0.66	\$0.37	\$0.62	\$0.56	\$0.69	\$9.50	6.7%
2021	\$1.39	\$1.15	\$2.58	\$0.70	\$1.05	\$0.66	\$0.45	\$0.70	\$0.56	\$0.77	\$10.02	5.5%
2022	\$1.48	\$1.15	\$2.64	\$0.85	\$1.05	\$0.74	\$0.52	\$0.79	\$0.72	\$0.77	\$10.71	6.9%
CAGR (‘15–’22)	7.6%	5.9%	3.2%	11.9%	8.3%	18.7%	12.8%	8.6%	11.9%	10.4%		7.7%
Source: iData Research Inc.												

5.4 DRIVERS AND LIMITERS

5.4.1 Market Drivers

New Techniques

The advancement of technology, specifically embryo time lapse incubators and Vitrification, will increase the overall value of the market. Time lapse imaging provides the opportunity to improve the outcomes of IVF. By examining the embryos in greater detail over the entire development stage allows embryos to be selected with the highest opportunity for success. The technology has already been shown to improve pregnancy rates from IVF treatments.

In cryopreservation, there is also a gradual shift from slow freezing to vitrification, which is said to achieve better results. It is also a more expensive method, which will increase the value of the market.

Changing Maternal Demographics

The age of first maternal birth is increasing across Europe, most notably in France and the Netherlands. The higher age of motherhood has two implications for the growth of the assisted reproduction device market. As parental age increases, there is a reduced chance of pregnancy. Therefore, it is expected that more women will seek reproductive assistance in the coming years. Additionally, as older couples tend to have more economic stability, they will be able to afford more assisted reproduction cycle attempts than younger, less economically secure couples.

Single Women and the LGBTQ Community

The reimbursement policies of certain countries do not allow assisted reproduction for single women or homosexual couples wishing to have a child through IVF. Whereas Belgium, Spain, Sweden and Denmark, for example, already have legislation in place to allow these groups access to IVF, Italian legislation prohibits IVF treatment for single women and homosexuals, which drives these individuals to other countries with fewer restrictions. The market will be driven by the anticipated expansion of reimbursement policies.

Better Reimbursement

Cost-benefit analysis of assisted reproduction in recent years shows that the monetary benefit to a country's gross national product through increased birth rates greatly outweighs the initial financial burden of the treatment cycles. Governments are looking at assisted reproduction for the long-term benefits and will adopt more generous reimbursement programs to boost the country's birth rate.

Improved Practices

In conjunction with governmental legislation, clinics in many countries have changed their practices to only transfer one or two embryos per cycle. Previously, a high rate of multiple babies in a birth caused low birth weight. This increased costs to the health care system for post-partum care and long-term care for individuals born with disabilities. Physicians agree that limiting the number of embryos reduces the likelihood of multiple births and does not compromise the rate of successful pregnancies. The reduced overall financial cost to the government and increased safety for mother and child will drive the market as IVF becomes regarded as a safe and effective procedure.

5.4.2 Market Limiters

Alternatives to Assisted Reproduction

For those who either cannot or choose not to pay the high costs for assisted reproduction, there are other alternatives available to them. Patients may choose to adopt a child, enter a foster care program or choose not to have a child at all.

High Cost

Assisted reproduction is not affordable to everyone. Patients have to pay between €3,500 and €10,000 per cycle. Pregnancy is not guaranteed within the first or second cycle, as age or health factors can extend the duration of treatment. Although many people cannot conceive without assisted reproductive technologies, some do not have the discretionary income for it if they cannot receive government reimbursement.

Reproductive Tourism

There are no two countries in Europe with the same legislation and reimbursement policies for assisted reproduction. Differences in laws regarding cryopreservation, egg and sperm donation, and surrogacy, as well as differences in the cost of treatment, have caused many infertile individuals and couples to take their business to countries with more lenient regulations and less expensive procedures. If laws are not standardized and relaxed and low reimbursement continues, many will travel outside their home countries to other places that will allow them to treat their infertility. This will limit the markets in countries that have restrictive reimbursement but will boost the market of countries with more reimbursement.

Switch to Microdrops

When using media, 2 mL to 3 mL is the amount used by the majority of clinics. In order to reduce costs, clinics have started to use 0.5 mL or less, which produces similar results. In this report, a unit of media is defined as the volume used per cycle. As the use of microdrops increases, the average volume of media used per procedure will decrease. The units represent smaller volumes, but the number of units used per procedure remains the same. As the average volume used decreases, the ASP per unit will decline. A drop of ASP in the reproductive media market will negatively affect the overall ART market.

Patient Concern over Assisted Reproduction

As children successfully conceived through assisted reproduction grow up, more information is being gained about the long term positives and negatives attached with ART. There is increasing evidence that ART conceived children are at a higher risk of poor perinatal outcome, birth defects and epigenetic disorders. As increasing information and clinical data becomes available over long-term patient follow-up, potential mothers may opt for alternative options over ART.

Figure 5-56: Drivers and Limiters, Assisted Reproduction Device Market, Europe, 2015

Market Drivers
<ul style="list-style-type: none"> New Techniques Changing Maternal Demographics Single Women and the LGBTQ Community Better Reimbursement Improved Practices
Market Limiters
<ul style="list-style-type: none"> Alternatives to Assisted Reproduction High Cost Reproductive Tourism Switch to Microdrops Patient Concern over Assisted Reproduction
Source: iData Research Inc.

5.5 COMPETITIVE MARKET SHARE ANALYSIS

Cooper Surgical

In 2015, Cooper Surgical led the assisted reproduction device market with a 27.4% share. Their *SAGE*® product line dominated the reproduction media market with a 31.1% share, and their acquisition of ORIGIO allowed them to lead in the European micropipette market with a 44.3% share. They also controlled a healthy amount of the embryo transfer catheter market with catheter products such as the *R.G. Edwards*® *Embryo Transfer Products* at 32.4%. Cooper Surgical's products are highly regarded and trusted in assisted reproduction.

Cooper Surgical acquired ORIGIO in 2012. In 2010, ORIGIO held fifth place in the assisted reproduction market. The expansion of Cooper Surgical's product portfolio has significantly increased their market share. Prior to the acquisition, ORIGIO was known for their diverse product lines of micropipettes and media. The pipets include the ICSI, which is available in many different sizes and angles so that physicians can customize what is required for the procedure. Cooper Surgical has also expanded their presence within the embryo transfer catheter segment with this acquisition. ORIGIO was originally the Danish company MediCult. Expertise, established sales and distribution channels in Europe has allowed Cooper Surgical to excel in the region after the acquisition.

On June 1st 2016, Cooper Surgical also acquired Reprogenetics UK. Reprogenetics UK is one of the preeminent genetics laboratories specializing in preimplantation screening (PGS) and preimplantation diagnosis (PGD). It is also worth noting that as part of the acquisition, Reprogenetics UK will maintain its association with Reprogenetics, its U.S. counterpart. Cooper Surgical now includes an extensive lineup of ART genetic testing companies that includes Reprogenetics, Genesis Genetics (including its U.K. division) and the newly acquired Recombine.

Cook Medical

Cook Medical was the second leading competitor in 2015, with 26.5% of the market. They led the oocyte retrieval needle market with a 27.3% share. This company has over 15 different retrieval needles available in various product lines, including their *Disposable EchoTip*® *Lancet Needle*, standard *EchoTip*® needles and the *Ova-Stiff*™ *Ovum Aspiration* needles. They were the leader in the embryo transfer catheter market with a 43.1% share with their *EchoTip*®, *Guardia*™ and *Soft-Pass*™ catheters, as well as others. They also held second place in the micropipette market with a 18.5% share, with their line of more than ten *Cook*® micropipettes.

One of Cook Medical's strengths is their variety of different devices in each market segment. This allows the company to cater to many different clients. However, in Europe, the presence of many country- or regional-level local companies increases competition. These smaller companies often compete on price. Or, due to their smaller size, these companies are able to customize their orders more flexibly than larger companies, like Cook Medical, are able to do.

Vitrolife

Vitrolife held a 20.0% share in the assisted reproduction device market. They competed strongly in the oocyte retrieval needle market, micropipette market, reproduction media market and are the market leaders in embryo time lapse incubators. Established in 1994, this company began in the culture media market. They have since expanded their portfolio with several acquisitions. Vitrolife acquired Swemed in 2006, allowing them to better compete in the retrieval needle markets.

Vitrolife is currently the market leader in embryo time-lapse incubator systems. As the first to market in many European countries, it has been used in more than 300,000 patient treatments since 2009. Currently, new competitors have entered the market with newer systems and updated technology. Overall, Vitrolife is expected to maintain its competitive edge as they announced the EmbryoScope+ system in July 2016. The new time lapse system is currently being validated and used clinically in five Scandinavian clinics. The company has publicized the system has already been used in more than 250 treatments. As the new system is approved to expand product offerings, they are expected to continue to hold a stable market share.

Vitrolife also offers the Rapid i-Vitrification System. One of the systems new features are colour coded straws. Although not covered in this report, Vitrification is a new standard with a high ASP in assisted reproduction technology. As Vitrolife remains on the cutting edge of new products available, they are expected to maintain a strong market value over the forecast period.

Merck KgaA / GeneaBioMedx

Merck KgaA signed a deal in May 2015 announcing a global collaboration agreement with Genea Biomedx, providing Merck with the global marketing and commercialization right for Genea Biomedx manufactured products. In June 2015, the Gavi and Geri embryo time lapse incubator systems achieved CE Mark certifications. Currently, Merck and Genea Biomedx hold a small market share due to the recent approval of the disk that is required for the incubator. It is projected their market share in the embryo time lapse incubator sub-segment will increase between 5% and 10% in the next three years.

Esco

Esco offers the Miri® embryo time lapse incubator and was the second competitor to market in Europe. While the Miri® system was unveiled in Europe in 2013, in June 2016 Esco also announced they have secured FDA clearance for commercial distribution of Miri® TL. This is expected to increase their market share both in the United States and Europe as they gain greater market recognition. A key difference separating Miri from the competition is the stability of the dish within the incubator, as the camera moves around the dishes. Esco's distribution channels vary across Europe, selling directly to clients or through distributors depending on the country. Esco's market share varies across Europe. As the company gains greater market penetration, their market share is expected to become more consistent across Europe and increase slightly.

Other Notable Competitors: Laboratoires-JCD, Smiths Medical and Irvine

Laboratoires-JCD in France offers hardware, culture media, reagent and single use consumables. JCD is known for lower price points and is popular in France as well as the Benelux region.

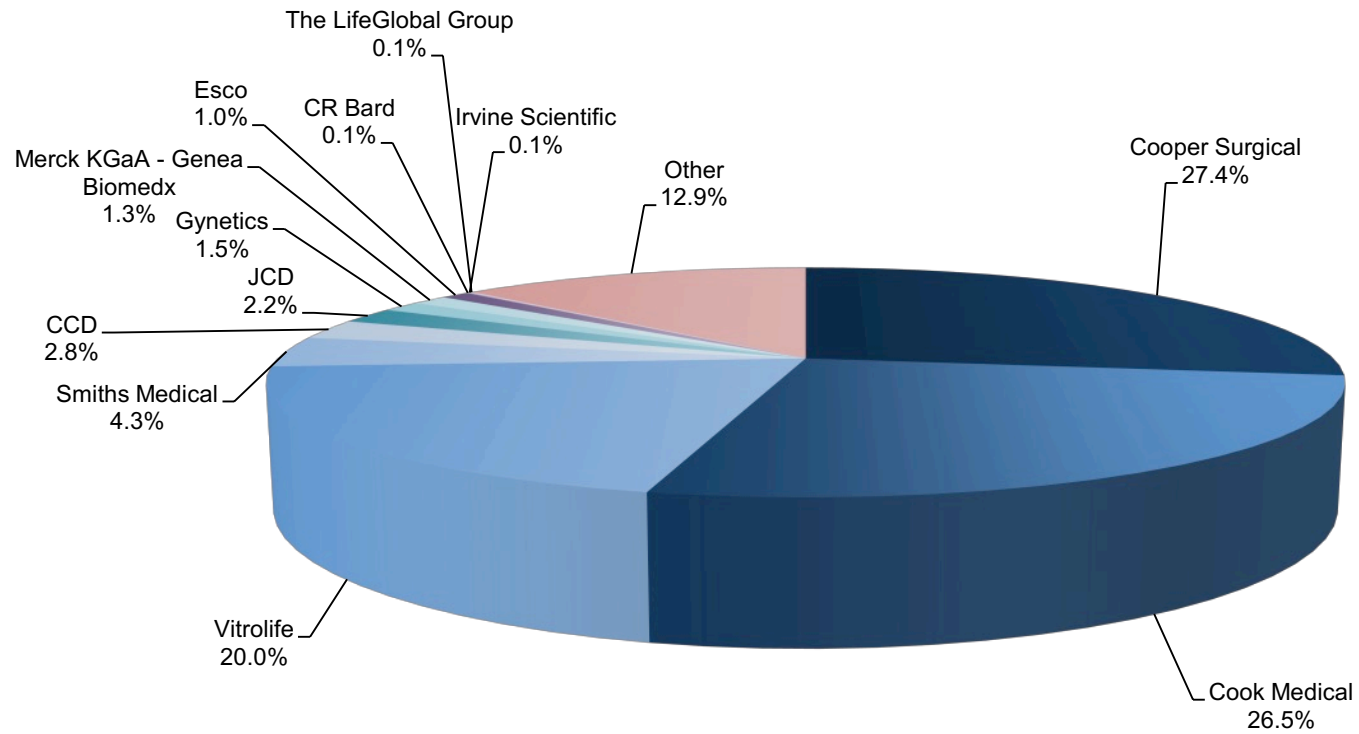
Smiths Medical offers Wallace® micropipettes, needles and catheters for IVF. Notably, Wallace® products are popular across Europe; however, they comprise 50.1% of the Scandinavian oocyte retrieval needle market.

Irvine Scientific offers reproductive media products known for their quality, consistency and reliability. Irvine Scientific has offered products for Assisted Reproduction since 1986 and has a stable market share, especially in France, the U.K., Switzerland and the Benelux region.

Figure 5-57: Leading Competitors by Country, Total Assisted Reproduction Device Market, Europe, 2015

Company	Germany	France	U.K.	Italy	Spain	Benelux	Scandi- navia	Austria	Switzer- land	Portugal	Total Market Share
Cooper Surgical	33.1%	27.8%	21.8%	33.6%	32.7%	33.4%	3.2%	24.6%	27.5%	20.9%	27.4%
Cook Medical	28.5%	22.9%	24.7%	25.0%	24.3%	32.7%	32.5%	20.1%	23.9%	15.0%	26.5%
Vitrolife	24.1%	15.3%	26.1%	24.2%	25.7%	5.9%	7.1%	41.0%	31.7%	47.5%	20.0%
Smiths Medical	—	—	11.5%	—	—	—	28.8%	—	—	—	4.3%
CCD	—	17.0%	—	—	—	—	—	—	—	—	2.8%
JCD	—	3.5%	—	—	—	10.8%	—	—	—	—	2.2%
Gynetics	—	1.2%	—	—	—	4.0%	7.5%	—	—	—	1.5%
Merck KGaA - Genea Biomedx	1.2%	1.2%	2.4%	0.7%	1.1%	0.2%	0.5%	4.6%	2.9%	6.2%	1.3%
Esco	0.9%	0.8%	3.4%	0.4%	0.4%	0.2%	0.3%	2.4%	1.8%	1.8%	1.0%
CR Bard	—	0.3%	—	—	—	0.3%	—	—	—	—	0.1%
Irvine Scientific	—	0.2%	0.2%	—	—	0.2%	—	—	0.2%	—	0.1%
The LifeGlobal Group	—	0.2%	0.1%	—	—	0.2%	—	—	—	—	0.1%
Other	12.3%	9.7%	9.9%	16.2%	15.8%	12.1%	20.0%	7.4%	12.0%	8.7%	12.9%
Total	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
Others include: FertiPro, Gynemed, Hunter Scientific (distributor), InVitroCare, Labotect, Reproline, Rocket Medical, Smiths Medical, Sunlight Medical, TPC, etc.											
Source: iData Research Inc.											

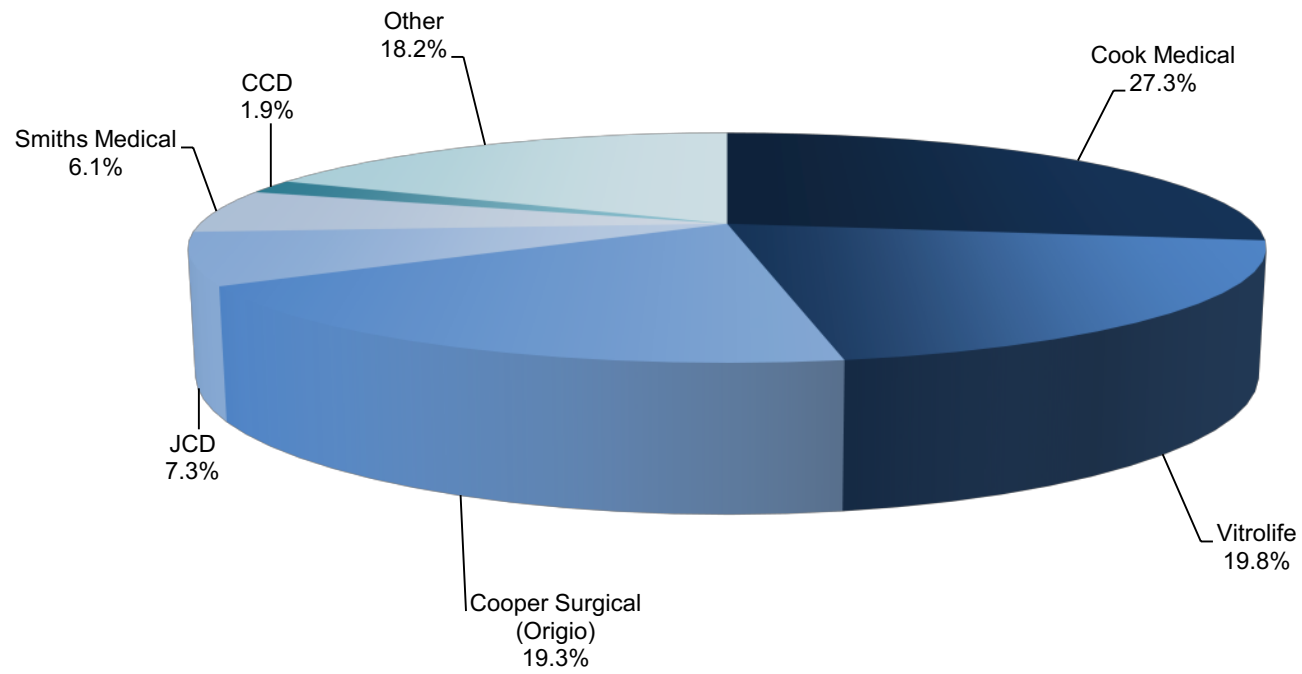
Chart 5-11: Leading Competitors, Total Assisted Reproduction Device Market, Europe, 2015



Source: iData Research Inc.

Figure 5-58: Leading Competitors by Country, Oocyte Retrieval Needle Market, Europe, 2015

Company	Germany	France	U.K.	Italy	Spain	Benelux	Scandi- navia	Austria	Switzer- land	Portugal	Total Market Share
Cook Medical	41.1%	35.2%	32.4%	18.9%	18.4%	15.1%	25.4%	40.6%	40.2%	19.2%	27.3%
Vitrolife	20.6%	5.7%	15.6%	35.4%	37.0%	15.3%	–	22.7%	22.0%	38.3%	19.8%
Cooper Surgical (Origio)	24.3%	19.9%	28.7%	23.1%	22.9%	6.0%	–	33.2%	24.5%	26.4%	19.3%
JCD	–	15.4%	–	–	–	50.8%	–	–	–	–	7.3%
Smiths Medical	–	–	–	–	–	–	50.1%	–	–	–	6.1%
CCD	–	15.2%	–	–	–	–	–	–	–	–	1.9%
Other	14.0%	8.6%	23.3%	22.6%	21.7%	12.8%	24.5%	3.5%	13.3%	16.1%	18.2%
Total	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
Market Value (€M)	€1.9	€1.7	€2.1	€1.7	€2.2	€1.4	€1.6	€0.2	€0.3	€0.2	€13.4
Others include: Kitazato, etc.											
Source: iData Research Inc.											

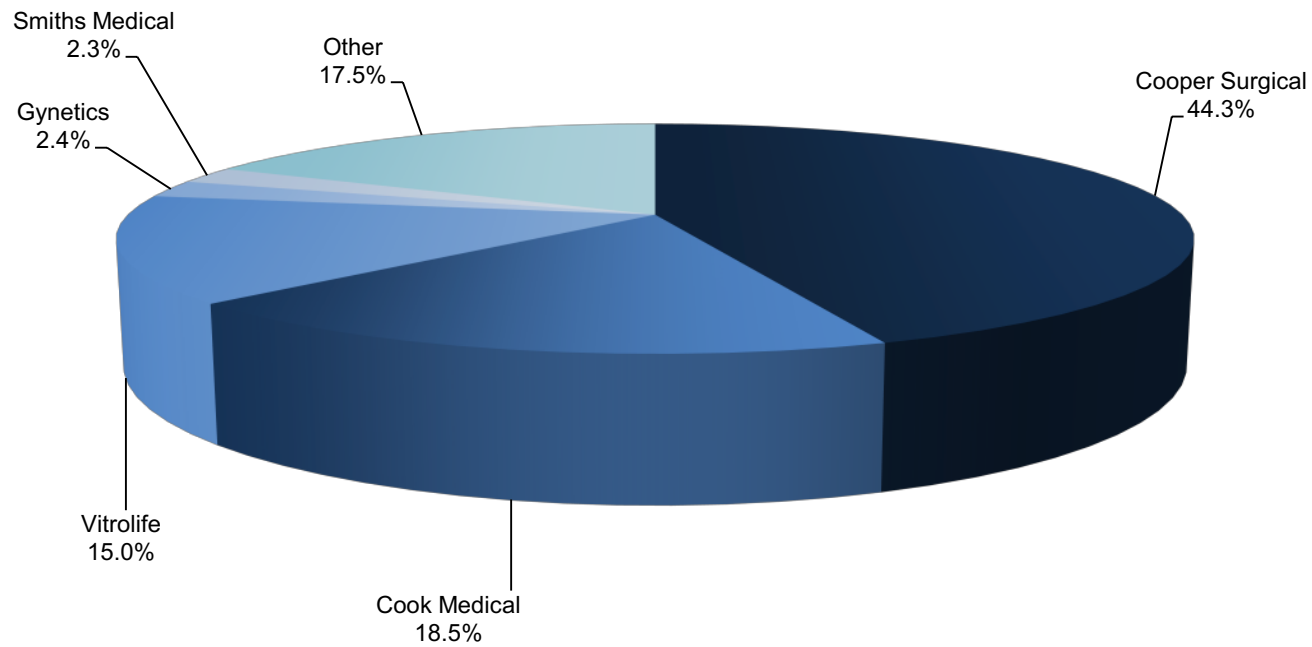
Chart 5-12: Leading Competitors, Oocyte Retrieval Needle Market, Europe, 2015

Source: iData Research Inc.

Figure 5-59: Leading Competitors by Country, Micropipette Market, Europe, 2015

Company	Germany	France	U.K.	Italy	Spain	Benelux	Scandi- navia	Austria	Switzer- land	Portugal	Total Market Share
Cooper Surgical	49.8%	49.4%	49.8%	49.6%	49.8%	30.0%	12.6%	49.0%	50.3%	50.2%	44.3%
Cook Medical	15.9%	15.9%	25.0%	15.2%	15.9%	18.5%	35.4%	16.1%	15.4%	15.9%	18.5%
Vitrolife	21.3%	21.3%	–	21.1%	21.3%	–	12.0%	21.6%	20.9%	21.6%	15.0%
Gynetics	–	–	–	–	–	15.7%	–	–	–	–	2.4%
Smiths Medical	–	–	20.2%	–	–	–	–	–	–	–	2.3%
Other	13.0%	13.4%	5.0%	14.1%	13.0%	35.8%	40.0%	13.3%	13.4%	12.3%	17.5%
Total	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
Market Value (€M)	€2.0	€2.3	€1.3	€1.2	€1.5	€1.7	€0.7	€0.2	€0.3	€0.1	€11.4
Others include: Gynemed, Labotect, Smiths Medical (Wallace®), Sunlight Medical, TPC etc.											
Source: iData Research Inc.											

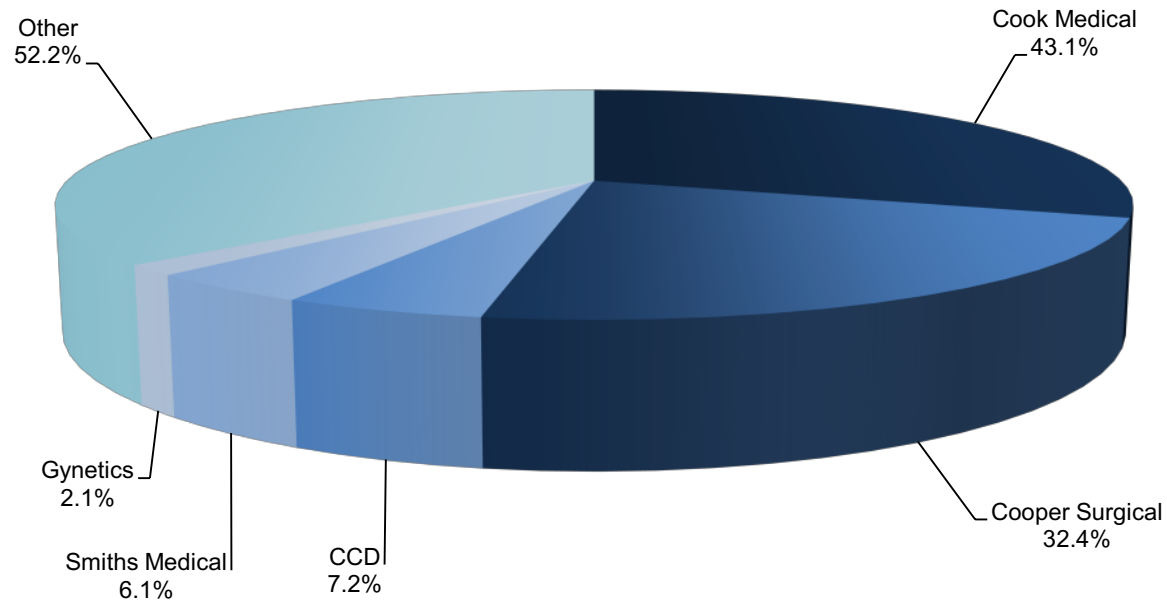
Chart 5-13: Leading Competitors, Micropipette Market, Europe, 2015



Source: iData Research Inc.

Figure 5-60: Leading Competitors by Country, Embryo Transfer Catheter Market, Europe, 2015

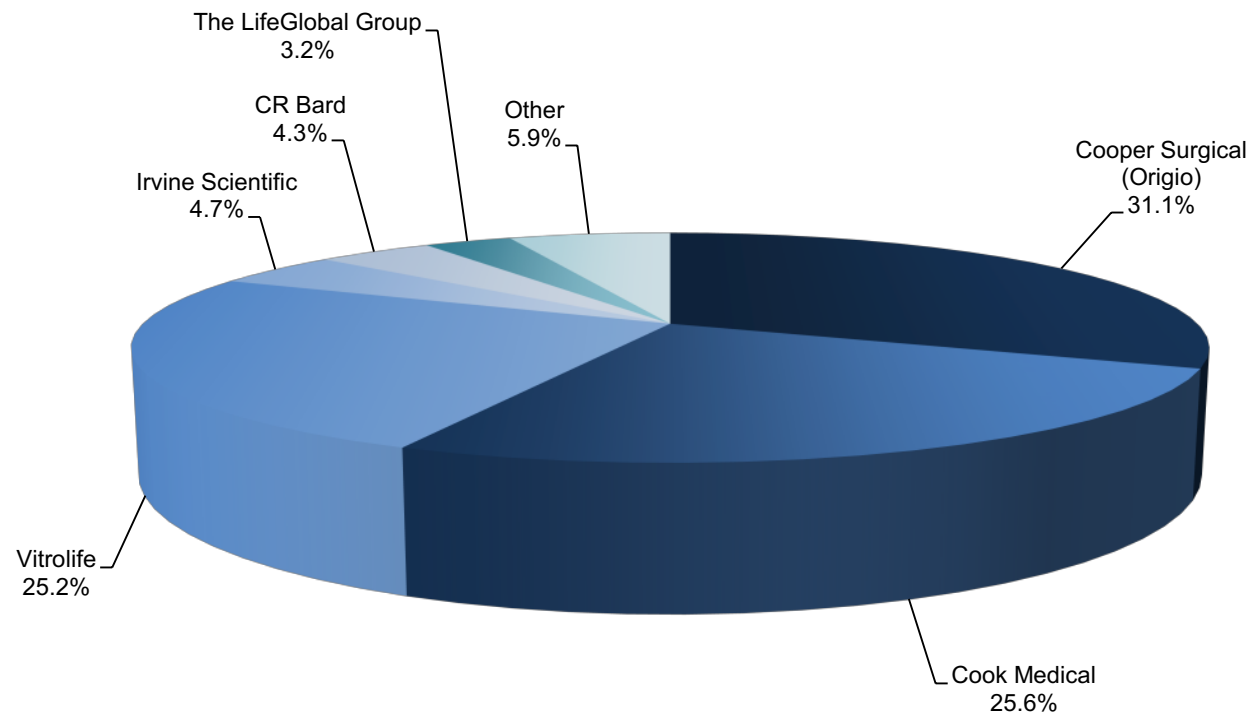
Company	Germany	France	U.K.	Italy	Spain	Benelux	Scandi- navia	Austria	Switzer- land	Portugal	Total Market Share
Cook Medical	45.7%	27.5%	44.7%	45.4%	44.6%	50.4%	45.2%	46.0%	44.8%	46.1%	43.1%
Cooper Surgical	40.3%	21.0%	14.6%	40.1%	40.4%	49.6%	–	40.6%	39.6%	40.2%	32.4%
CCD	–	38.8%	–	–	–	–	–	–	–	–	7.2%
Smiths Medical	–	–	35.5%	–	–	–	24.7%	–	–	–	6.1%
Gynetics	–	–	–	–	–	–	23.0%	–	–	–	2.1%
Other	59.7%	40.2%	49.9%	59.9%	59.6%	50.4%	52.3%	59.4%	60.4%	59.8%	52.2%
Total	145.7%	127.5%	144.7%	145.4%	144.6%	150.4%	145.2%	146.0%	144.8%	146.1%	100.0%
Market Value (€M)	€1.4	€2.6	€1.5	€1.5	€1.9	€3.3	€1.3	€0.2	€0.2	€0.1	€14.0
Others include: Gynemed, Labotect, Rocket Medical, Smiths Medical (Wallace®), etc.											
Source: iData Research Inc.											

Chart 5-14: Leading Competitors, Embryo Transfer Catheter Market, Europe, 2015

Source: iData Research Inc.

Figure 5-61: Leading Competitors by Country, Reproductive Media Market, Europe, 2015

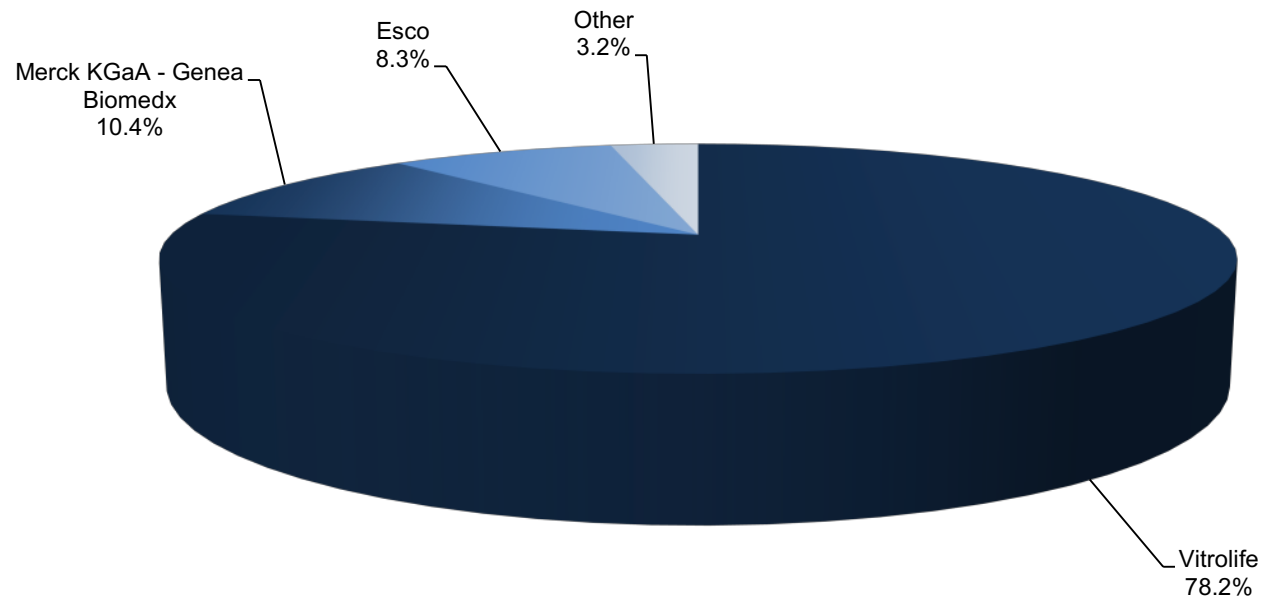
Company	Germany	France	U.K.	Italy	Spain	Benelux	Scandi- navia	Austria	Switzer- land	Portugal	Total Market Share
Cooper Surgical (Origio)	35.5%	26.6%	31.3%	33.4%	29.8%	26.2%	36.3%	35.6%	31.0%	29.4%	31.1%
Cook Medical	26.2%	21.9%	27.2%	29.5%	26.0%	20.2%	29.2%	26.7%	27.2%	26.2%	25.6%
Vitrolife	28.3%	15.7%	22.2%	30.5%	35.3%	16.1%	27.4%	28.5%	22.7%	35.0%	25.2%
Irvine Scientific	–	10.4%	10.6%	–	–	10.8%	–	–	11.4%	–	4.7%
CR Bard	–	15.1%	–	–	–	14.9%	–	–	–	–	4.3%
The LifeGlobal Group	–	8.5%	5.0%	–	–	9.4%	–	–	–	–	3.2%
Other	10.0%	1.8%	3.6%	6.6%	8.9%	2.4%	7.1%	9.2%	7.7%	9.4%	5.9%
Total	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
Market Value (€M)	€0.1	€0.1	€0.1	€0.1	€0.1	€0.1	€0.1	€0.0	€0.0	€0.0	€0.9
Others include: FertiPro, Gynemed, InVitroCare, etc.											
Source: iData Research Inc.											

Chart 5-15: Leading Competitors, Reproductive Media Market, Europe, 2015

Source: iData Research Inc.

Figure 5-62: Leading Competitors by Country, Reproductive Media Market, Europe, 2015

Company	Germany	France	U.K.	Italy	Spain	Benelux	Scandi- navia	Austria	Switzer- land	Portugal	Total Market Share
Vitrolife	80.4%	75.3%	76.5%	83.1%	78.6%	80.0%	82.9%	78.7%	75.3%	80.1%	78.2%
Merck KGaA - Genea	9.2%	12.9%	8.6%	9.8%	13.2%	7.1%	10.1%	11.5%	10.8%	14.5%	10.4%
Biomedx											
Esco	6.8%	8.4%	12.3%	5.2%	4.4%	7.3%	5.5%	6.0%	6.7%	4.2%	8.3%
Other	3.6%	3.4%	2.6%	1.9%	3.8%	5.6%	1.5%	3.8%	7.2%	1.2%	3.2%
Total	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
Market Value (€M)	€0.8	€0.7	€1.9	€0.4	€0.5	€0.2	€0.2	€0.4	€0.3	€0.4	€5.8
Source: iData Research Inc.											

Chart 5-16: Leading Competitors, Embryo Time Lapse Incubator Market, Europe, 2015

Source: iData Research Inc.

6

ENDOMETRIAL ABLATION DEVICE MARKET

6.1 INTRODUCTION

Global endometrial ablation (GEA) is a minimally invasive surgical procedure that can remove some or all of the lining of the uterus. It is performed on women who experience abnormal or extremely heavy bleeding, also known as menorrhagia. GEA requires less training for practitioners than the earlier forms of ablation, enabling more doctors to perform the procedure and making it more accessible to patients. The first GEA products were available on the market in 1997. The other types became available mostly between 2001 and 2002. There are a number of methods by which GEA can be performed: uterine balloon, heated fluid, high-frequency radio wave, cryoablation, microwave or roller-ball.

6.1.1 Uterine Balloon Therapy

This method uses a probe with a balloon attached to the end that is inserted into the endometrial cavity and expanded with a sterile fluid until it fits the size and shape of the uterus. The fluid is then heated to 87 degrees Celsius and circulated around the balloon for eight minutes to destroy the endometrial lining. The lining then sheds off over seven to ten days, similar to menstruation. This procedure is a same-day surgical procedure and is done under local anesthetic.

6.1.2 Hydrothermal Ablation

Hydrothermal ablation uses heat to destroy the lining of the uterus but differs slightly from uterine balloon therapy. During this hysteroscopic procedure, hot water is circulated through the uterus with computer-controlled pressure, burning the lining in approximately ten minutes. The pressure is kept low

and closely monitored, shutting off at any sign of pressure change or leakage. This method is indicated for women with an abnormally shaped uterus, as the water flows freely throughout the entire cavity.

6.1.3 Radiofrequency Ablation

In this method, bipolar radiofrequency energy is used to destroy the lining of the uterus. This is the fastest ablation procedure available, taking only 90 seconds to destroy the endometrial lining. During this procedure, a thin sheath containing an electrode is inserted into the cervix. The sheath is retracted slightly and the electrode expands to fill the uterine cavity and is then activated. After the treatment is complete, the electrode automatically shuts off and is retracted into the sheath. It can be done with local or general anesthesia. No pre-treatment is necessary.

6.1.4 Cryoablation

Cryoablation uses sub-zero temperatures to disintegrate the lining of the uterus. During the procedure, a narrow probe is inserted into the cervix and begins to freeze tissue around its tip. Cryoablation has been around for a long time and is commonly used in many other applications such as dermatology and gynecology. This method is the least painful of all methods described in this chapter. It is done in the doctor's office under local anesthesia.

6.1.5 Microwave Ablation

During microwave ablation, a small probe is inserted into the cervix, and a high-frequency microwave current is used to burn the lining of the uterus. The probe is moved around the uterus until the treatment is complete, taking approximately 10 minutes. It is considered a same-day procedure and requires a pre-test to check the thickness of the woman's lining.

6.1.6 Roller-Ball Ablation

Rollerball endometrial ablation uses a heated ball to burn the endometrium under direct visualization with a hysteroscope. The roller-ball or cylinder-tipped electrode emits energy, vaporizes the endometrium and is subsequently used to coagulate the lining of the uterus. The technique is relatively easy to learn, but the procedure can be very time consuming, taking up to 45 minutes. It is a same-day surgical procedure and is done under general anesthesia.

6.2 MARKET OVERVIEW

In 2015, the global endometrial ablation (GEA) market was valued at €16.9 million, representing a 1.6% growth over 2014. Over the forecast period, the GEA market is expected to increase at a CAGR of 1.5% to €18.7 million.

The endometrial ablation market has experienced consistent growth from 2012-2016. The modest growth can be attributed to downward pressure on ASP due to past competition in the market. Endometrial ablation procedures are expected to continue to increase, as the European market is still actively growing and has yet to reach saturation. Medical professionals are further fueling the growth of endometrial ablation procedures. In the past the surgery performed to treat menorrhagia (heavy menstrual bleeding) has favored endometrial resection over endometrial ablation. Recently, this trend has started to reverse and endometrial ablation is gaining traction in procedure numbers, eroding the number of endometrial resection procedures being performed annually.

The procedure for endometrial ablation is most commonly performed using the thermal balloon ablation or radiofrequency ablation technique. The procedure numbers can be further broken down into the technique used to perform the endometrial ablation procedure. Competitors in the market normally specialize and offer systems for a single type of endometrial ablation only. This is relevant because there is a correlation between the technique used and the market shares of different competitors.

In 2016, Johnson & Johnson removed the GYNECARE THERMACHOICE® line of products and withdrew from the market. This will create significant volatility and opportunity as an average of 30.9% of market share is being redistributed between new and pre-existing competitors. The GYNECARE THERMACHOICE® line of products was a Uterine Balloon Therapy System. As doctors and hospitals move to alternative competitors the technique used to perform endometrial ablation is expected to change, reflecting the new market shares and the technique of the new competitors systems.

Due to the disproportionate number of procedures being performed in Europe using the thermal balloon ablation and radiofrequency ablation techniques, this market is segmented based on these two sub-markets.

Figure 6-1: Endometrial Ablation Device Market by Segment, Europe, 2012 – 2022 (€M)

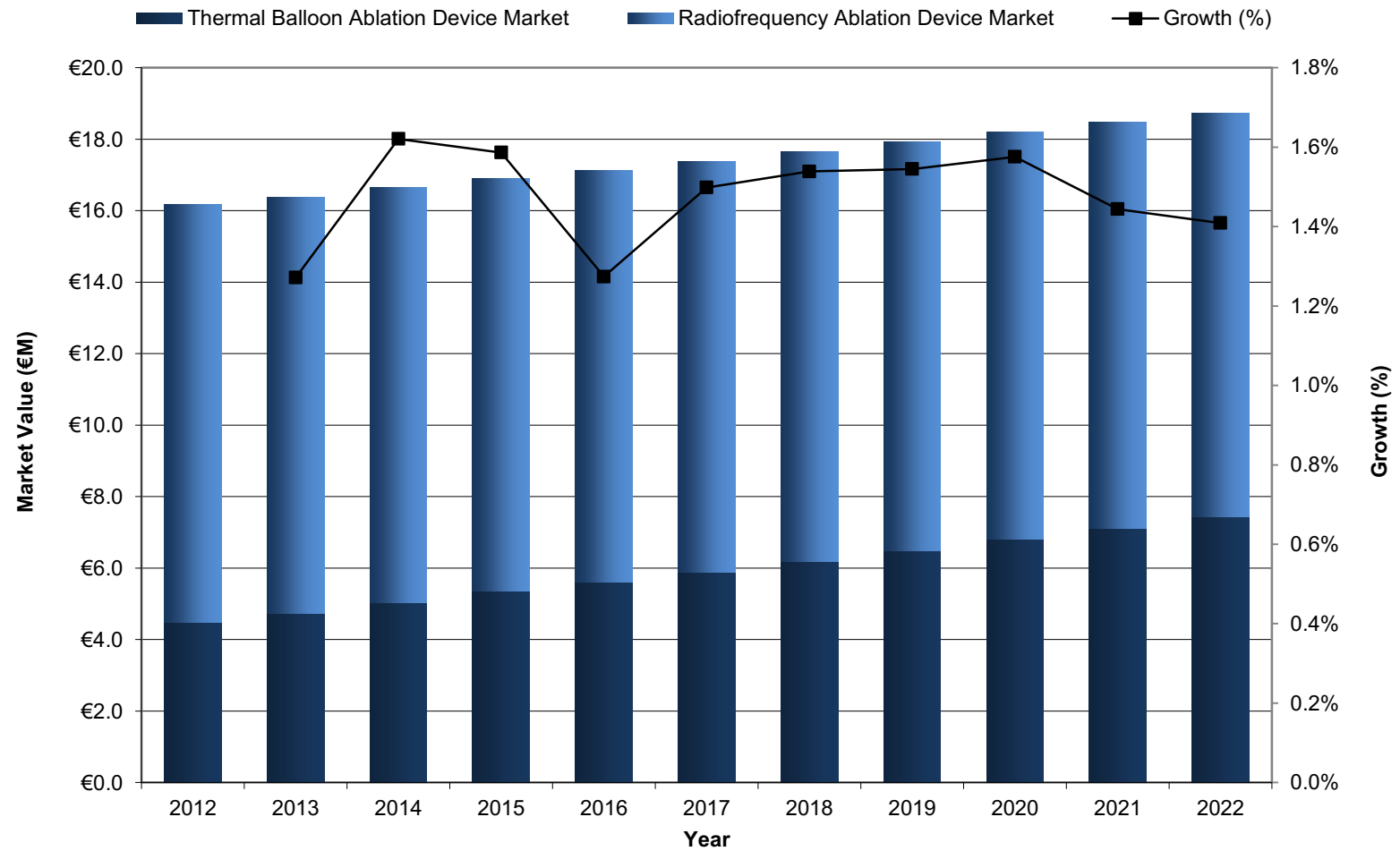
Year	Thermal Balloon Ablation Market	Radiofrequency Ablation Market	Total Market	Growth (%)
2012	€4.5	€11.7	€16.2	
2013	€4.7	€11.6	€16.4	1.3%
2014	€5.0	€11.6	€16.6	1.6%
2015	€5.3	€11.6	€16.9	1.6%
2016	€5.6	€11.5	€17.1	1.3%
2017	€5.9	€11.5	€17.4	1.5%
2018	€6.2	€11.5	€17.7	1.5%
2019	€6.5	€11.4	€17.9	1.5%
2020	€6.8	€11.4	€18.2	1.6%
2021	€7.1	€11.4	€18.5	1.4%
2022	€7.4	€11.3	€18.7	1.4%
CAGR (‘15–’22)	4.8%	-0.3%		1.5%

Source: iData Research Inc.

Figure 6-2: Endometrial Ablation Device Market by Segment, Europe, 2012 – 2022 (US\$M)

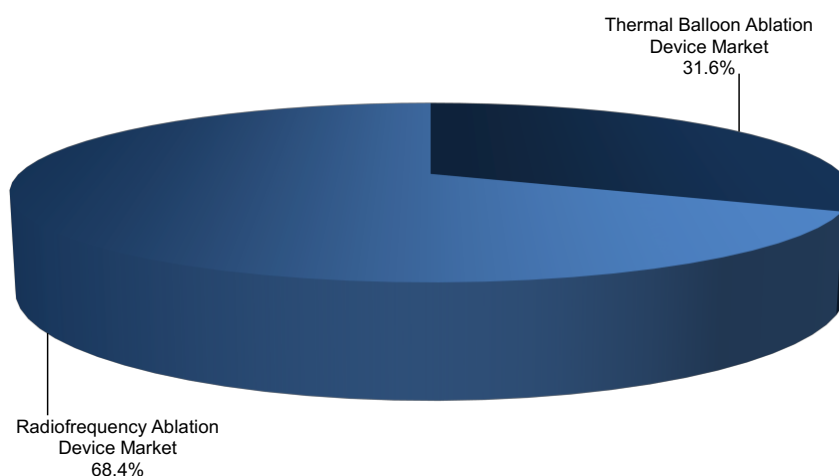
Year	Thermal Balloon Ablation Market	Radiofrequency Ablation Market	Total Market	Growth (%)
2012	\$5.0	\$12.9	\$17.9	
2013	\$5.2	\$12.9	\$18.1	1.3%
2014	\$5.6	\$12.8	\$18.4	1.6%
2015	\$5.9	\$12.8	\$18.7	1.6%
2016	\$6.2	\$12.7	\$18.9	1.3%
2017	\$6.5	\$12.7	\$19.2	1.5%
2018	\$6.8	\$12.7	\$19.5	1.5%
2019	\$7.2	\$12.6	\$19.8	1.5%
2020	\$7.5	\$12.6	\$20.1	1.6%
2021	\$7.9	\$12.6	\$20.4	1.4%
2022	\$8.2	\$12.5	\$20.7	1.4%
CAGR (‘15–’22)	4.8%	-0.3%		1.5%

Source: iData Research Inc.

Chart 6-1: Endometrial Ablation Device Market by Segment, Europe, 2015

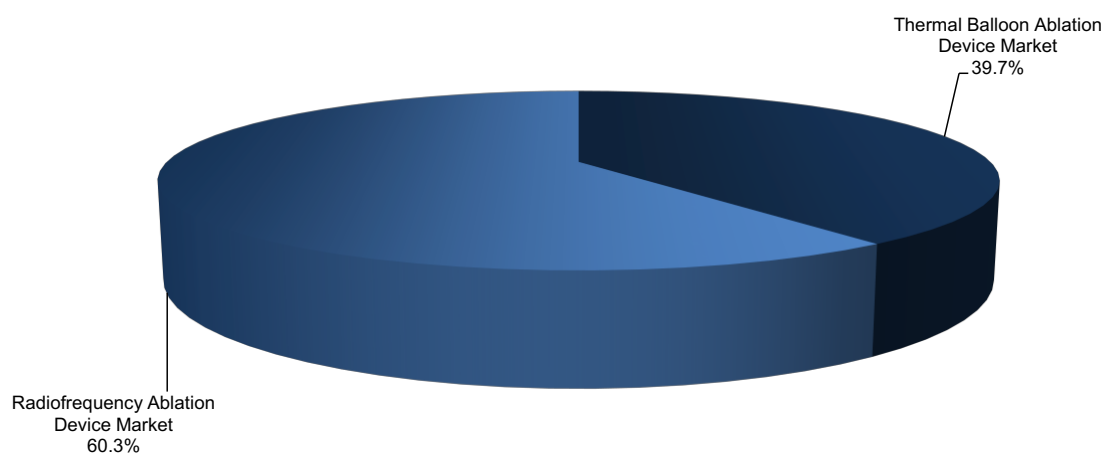
Source: iData Research Inc.

Chart 6-2: Endometrial Ablation Device Market Breakdown, Europe, 2022



Source: iData Research Inc.

Chart 6-3: Endometrial Ablation Device Market Breakdown, Europe, 2022



Source: iData Research Inc.

6.3 MARKET ANALYSIS AND FORECAST

6.3.1 Total Endometrial Ablation Device Market

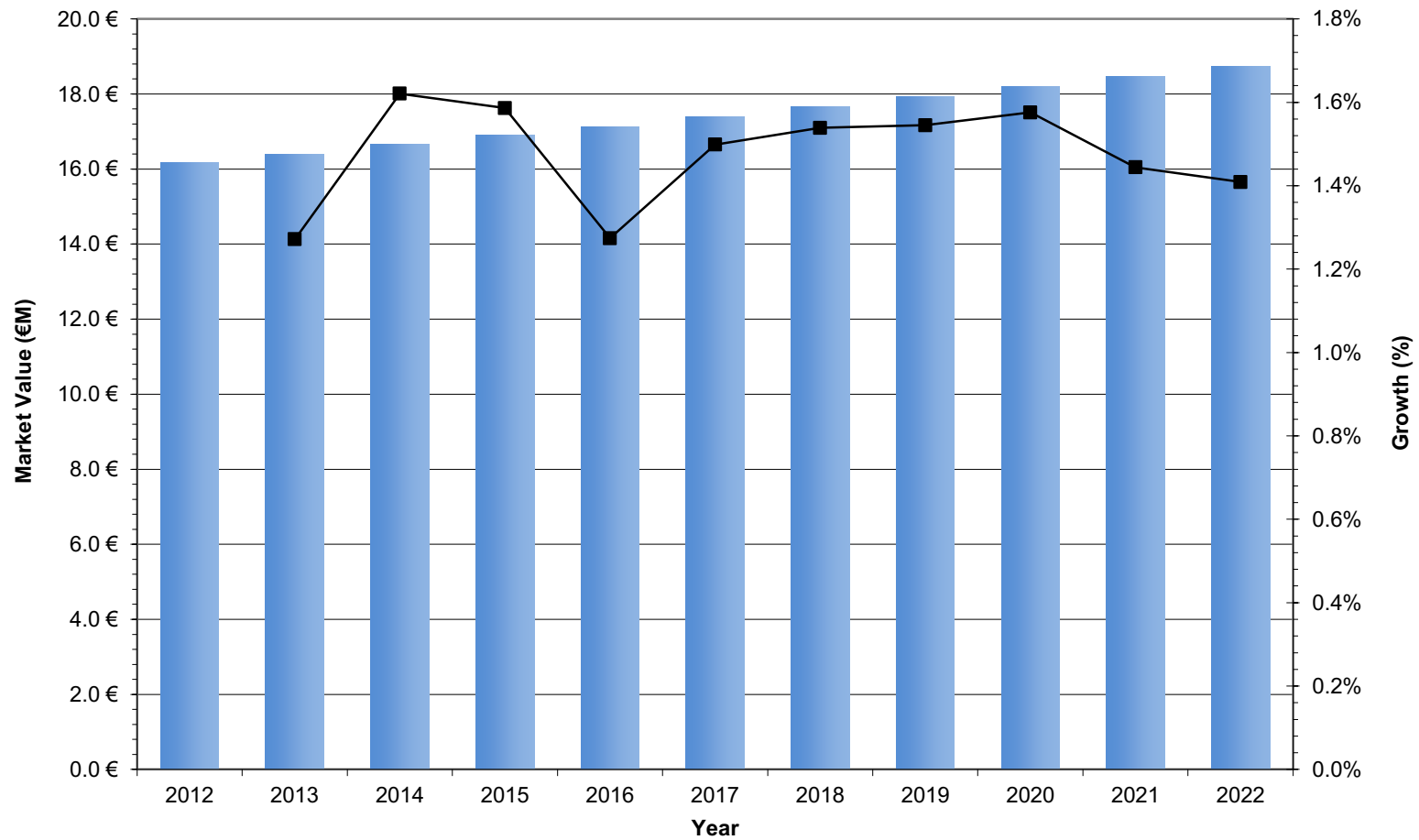
The endometrial ablation market is predominantly comprised of uterine balloon therapy ablation procedures and radiofrequency ablation procedures. Thermal balloon ablation procedures make up 40% of the total market with radiofrequency ablation procedures comprising the 60% majority market share. The overall market trend is a shift from endometrial ablation procedures being performed using radiofrequency ablation to thermal balloon ablation.

The shift in the market is projected to occur gradually from 2016-2022. The withdrawal of Johnson & Johnson from the market is expected to hinder the transition to thermal balloon ablation procedures. As Johnson & Johnson was the leading manufacturer of thermal balloon ablation devices, it is expected that sales of radiofrequency ablation devices will remain strong while the remaining competitors fill the gap left in the market. While the removal of the Gynecare Thermachoice product is expected to impact sales within the thermal balloon ablation sub-segment, the overall market trend is expected to remain the same.

Figure 6-3: Global Endometrial Ablation Market, Europe, 2012 – 2022 (€ and US\$)

Year	Units Sold	Growth (%)	ASP (€)	ASP (US\$)	Growth (%)	Market Value (€M)	Market Value (US\$M)	Growth (%)
2012	49,011		€330	\$365		€16.2	\$17.9	
2013	50,133	2.3%	€327	\$361	-1.0%	€16.4	\$18.1	1.3%
2014	51,468	2.7%	€323	\$358	-1.0%	€16.6	\$18.4	1.6%
2015	52,765	2.5%	€321	\$354	-0.9%	€16.9	\$18.7	1.6%
2016	53,876	2.1%	€318	\$351	-0.8%	€17.1	\$18.9	1.3%
2017	55,103	2.3%	€315	\$349	-0.8%	€17.4	\$19.2	1.5%
2018	56,337	2.2%	€313	\$346	-0.7%	€17.7	\$19.5	1.5%
2019	57,598	2.2%	€311	\$344	-0.7%	€17.9	\$19.8	1.5%
2020	58,866	2.2%	€309	\$342	-0.6%	€18.2	\$20.1	1.6%
2021	60,103	2.1%	€307	\$340	-0.6%	€18.5	\$20.4	1.4%
2022	61,327	2.0%	€305	\$338	-0.6%	€18.7	\$20.7	1.4%
CAGR ('15-'22)		2.2%			-0.7%			1.5%

Source: iData Research Inc.

Chart 6-4: Global Endometrial Ablation Market, Europe, 2012 – 2022

Source: iData Research Inc.

Figure 6-4: Units Sold by Country, Global Endometrial Ablation Market, Europe, 2012 – 2022

Year	Germany	France	U.K.	Italy	Spain	Benelux	Scandi- navia	Austria	Switzer- land	Portugal	Europe	Growth (%)
2012	8,185	8,548	10,074	4,653	3,567	4,635	2,426	2,875	3,068	980	49,011	2.3
2013	8,390	8,702	10,376	4,820	3,671	4,793	2,402	2,918	3,053	1,009	50,133	2.3%
2014	8,658	8,928	10,740	4,971	3,755	4,960	2,390	2,974	3,053	1,039	51,468	2.7%
2015	8,892	9,160	11,094	5,108	3,823	5,134	2,390	3,030	3,068	1,066	52,765	2.5%
2016	9,105	9,334	11,405	5,174	3,880	5,267	2,438	3,091	3,090	1,092	53,876	2.1%
2017	9,333	9,567	11,735	5,236	3,927	5,415	2,499	3,152	3,120	1,118	55,103	2.3%
2018	9,576	9,787	12,087	5,294	3,966	5,561	2,549	3,219	3,155	1,143	56,337	2.2%
2019	9,825	10,003	12,462	5,331	4,025	5,706	2,595	3,286	3,196	1,170	57,598	2.2%
2020	10,090	10,213	12,836	5,363	4,078	5,848	2,646	3,358	3,237	1,196	58,866	2.2%
2021	10,342	10,417	13,208	5,390	4,118	5,989	2,705	3,432	3,279	1,222	60,103	2.1%
2022	10,580	10,625	13,578	5,412	4,156	6,127	2,767	3,508	3,329	1,246	61,327	2.0%
CAGR (‘15–’22)	2.5%	2.1%	2.9%	0.8%	1.2%	2.6%	2.1%	2.1%	1.2%	2.3%		2.2%

Source: iData Research Inc.

Figure 6-5: Average Selling Price by Country, Global Endometrial Ablation Market, Europe, 2012 – 2022 (€)

Year	Germany	France	U.K.	Italy	Spain	Benelux	Scandi- navia	Austria	Switzer- land	Portugal	Europe	Growth (%)
2012	€301	€297	€374	€317	€308	€305	€379	€309	€428	€306	€330	
2013	€298	€293	€371	€312	€306	€302	€377	€301	€428	€303	€327	-1.0%
2014	€295	€289	€369	€308	€303	€300	€375	€293	€427	€301	€323	-1.0%
2015	€293	€286	€367	€304	€301	€297	€374	€286	€429	€299	€321	-0.9%
2016	€290	€283	€365	€299	€298	€293	€372	€285	€430	€296	€318	-0.8%
2017	€288	€279	€363	€295	€296	€291	€370	€284	€429	€294	€315	-0.8%
2018	€286	€276	€361	€291	€294	€288	€368	€283	€429	€291	€313	-0.7%
2019	€284	€274	€359	€288	€291	€286	€366	€283	€429	€289	€311	-0.7%
2020	€282	€271	€357	€284	€289	€283	€364	€283	€430	€287	€309	-0.6%
2021	€281	€268	€356	€280	€286	€281	€363	€282	€429	€284	€307	-0.6%
2022	€279	€265	€354	€277	€284	€279	€361	€282	€429	€282	€305	-0.6%
CAGR (‘15–’22)	-0.7%	-1.1%	-0.5%	-1.3%	-0.8%	-0.9%	-0.5%	-0.2%	0.0%	-0.8%		-0.7%

Source: iData Research Inc.

Figure 6-6: Average Selling Price by Country, Global Endometrial Ablation Market, Europe, 2012 – 2022 (US\$)

Year	Germany	France	U.K.	Italy	Spain	Benelux	Scandi- navia	Austria	Switzer- land	Portugal	Europe	Growth (%)
2012	\$333	\$328	\$413	\$351	\$341	\$337	\$419	\$341	\$473	\$338	\$365	
2013	\$330	\$324	\$411	\$345	\$338	\$334	\$417	\$333	\$474	\$335	\$361	-1.0%
2014	\$327	\$320	\$408	\$340	\$335	\$331	\$415	\$324	\$473	\$333	\$358	-1.0%
2015	\$323	\$316	\$406	\$336	\$333	\$329	\$413	\$316	\$474	\$330	\$354	-0.9%
2016	\$321	\$312	\$403	\$331	\$330	\$324	\$411	\$315	\$475	\$327	\$351	-0.8%
2017	\$318	\$309	\$401	\$327	\$327	\$321	\$409	\$314	\$474	\$325	\$349	-0.8%
2018	\$316	\$306	\$399	\$322	\$325	\$319	\$407	\$313	\$474	\$322	\$346	-0.7%
2019	\$314	\$302	\$397	\$318	\$322	\$316	\$405	\$313	\$474	\$320	\$344	-0.7%
2020	\$312	\$299	\$395	\$314	\$319	\$313	\$403	\$312	\$476	\$317	\$342	-0.6%
2021	\$310	\$296	\$393	\$310	\$317	\$311	\$401	\$312	\$474	\$314	\$340	-0.6%
2022	\$309	\$293	\$391	\$306	\$314	\$308	\$399	\$312	\$475	\$312	\$338	-0.6%
CAGR (‘15–’22)	-0.7%	-1.1%	-0.5%	-1.3%	-0.8%	-0.9%	-0.5%	-0.2%	0.0%	-0.8%		-0.7%
Source: iData Research Inc.												

Figure 6-7: Market Value by Country, Global Endometrial Ablation Market, Europe, 2012 – 2022 (€M)

Year	Germany	France	U.K.	Italy	Spain	Benelux	Scandi- navia	Austria	Switzer- land	Portugal	Europe	Growth (%)
2012	€2.46	€2.54	€3.77	€1.48	€1.10	€1.41	€0.92	€0.89	€1.31	€0.30	€16.18	
2013	€2.50	€2.55	€3.85	€1.51	€1.12	€1.45	€0.91	€0.88	€1.31	€0.31	€16.38	1.3%
2014	€2.56	€2.58	€3.96	€1.53	€1.14	€1.49	€0.90	€0.87	€1.30	€0.31	€16.65	1.6%
2015	€2.60	€2.62	€4.07	€1.55	€1.15	€1.53	€0.89	€0.87	€1.31	€0.32	€16.91	1.6%
2016	€2.64	€2.64	€4.16	€1.55	€1.16	€1.54	€0.91	€0.88	€1.33	€0.32	€17.13	1.3%
2017	€2.69	€2.67	€4.26	€1.55	€1.16	€1.57	€0.92	€0.90	€1.34	€0.33	€17.38	1.5%
2018	€2.74	€2.71	€4.36	€1.54	€1.16	€1.60	€0.94	€0.91	€1.35	€0.33	€17.65	1.5%
2019	€2.79	€2.74	€4.47	€1.53	€1.17	€1.63	€0.95	€0.93	€1.37	€0.34	€17.92	1.5%
2020	€2.85	€2.77	€4.59	€1.52	€1.18	€1.66	€0.96	€0.95	€1.39	€0.34	€18.21	1.6%
2021	€2.90	€2.79	€4.70	€1.51	€1.18	€1.68	€0.98	€0.97	€1.41	€0.35	€18.47	1.4%
2022	€2.95	€2.82	€4.81	€1.50	€1.18	€1.71	€1.00	€0.99	€1.43	€0.35	€18.73	1.4%
CAGR (‘15–’22)	1.8%	1.0%	2.4%	-0.5%	0.4%	1.6%	1.6%	1.9%	1.2%	1.4%		1.5%
Source: iData Research Inc.												

Figure 6-8: Market Value by Country, Global Endometrial Ablation Market, Europe, 2012 – 2022 (US\$M)

Year	Germany	France	U.K.	Italy	Spain	Benelux	Scandi- navia	Austria	Switzer- land	Portugal	Europe	Growth (%)
2012	\$2.72	\$2.81	\$4.17	\$1.63	\$1.21	\$1.56	\$1.02	\$0.98	\$1.45	\$0.33	\$17.88	
2013	\$2.77	\$2.82	\$4.26	\$1.66	\$1.24	\$1.60	\$1.00	\$0.97	\$1.45	\$0.34	\$18.11	1.3%
2014	\$2.83	\$2.86	\$4.38	\$1.69	\$1.26	\$1.64	\$0.99	\$0.96	\$1.44	\$0.35	\$18.41	1.6%
2015	\$2.88	\$2.90	\$4.50	\$1.71	\$1.27	\$1.69	\$0.99	\$0.96	\$1.45	\$0.35	\$18.70	1.6%
2016	\$2.92	\$2.92	\$4.60	\$1.71	\$1.28	\$1.71	\$1.00	\$0.97	\$1.47	\$0.36	\$18.94	1.3%
2017	\$2.97	\$2.95	\$4.71	\$1.71	\$1.28	\$1.74	\$1.02	\$0.99	\$1.48	\$0.36	\$19.22	1.5%
2018	\$3.03	\$2.99	\$4.82	\$1.71	\$1.29	\$1.77	\$1.04	\$1.01	\$1.50	\$0.37	\$19.52	1.5%
2019	\$3.08	\$3.03	\$4.94	\$1.70	\$1.30	\$1.80	\$1.05	\$1.03	\$1.52	\$0.37	\$19.82	1.5%
2020	\$3.15	\$3.06	\$5.07	\$1.68	\$1.30	\$1.83	\$1.07	\$1.05	\$1.54	\$0.38	\$20.13	1.6%
2021	\$3.21	\$3.09	\$5.19	\$1.67	\$1.30	\$1.86	\$1.08	\$1.07	\$1.56	\$0.38	\$20.42	1.4%
2022	\$3.26	\$3.11	\$5.31	\$1.66	\$1.31	\$1.89	\$1.10	\$1.09	\$1.58	\$0.39	\$20.71	1.4%
CAGR (‘15–’22)	1.8%	1.0%	2.4%	-0.5%	0.4%	1.6%	1.6%	1.9%	1.2%	1.4%		1.5%

Source: iData Research Inc.

6.3.2 Thermal Balloon Ablation Device Market

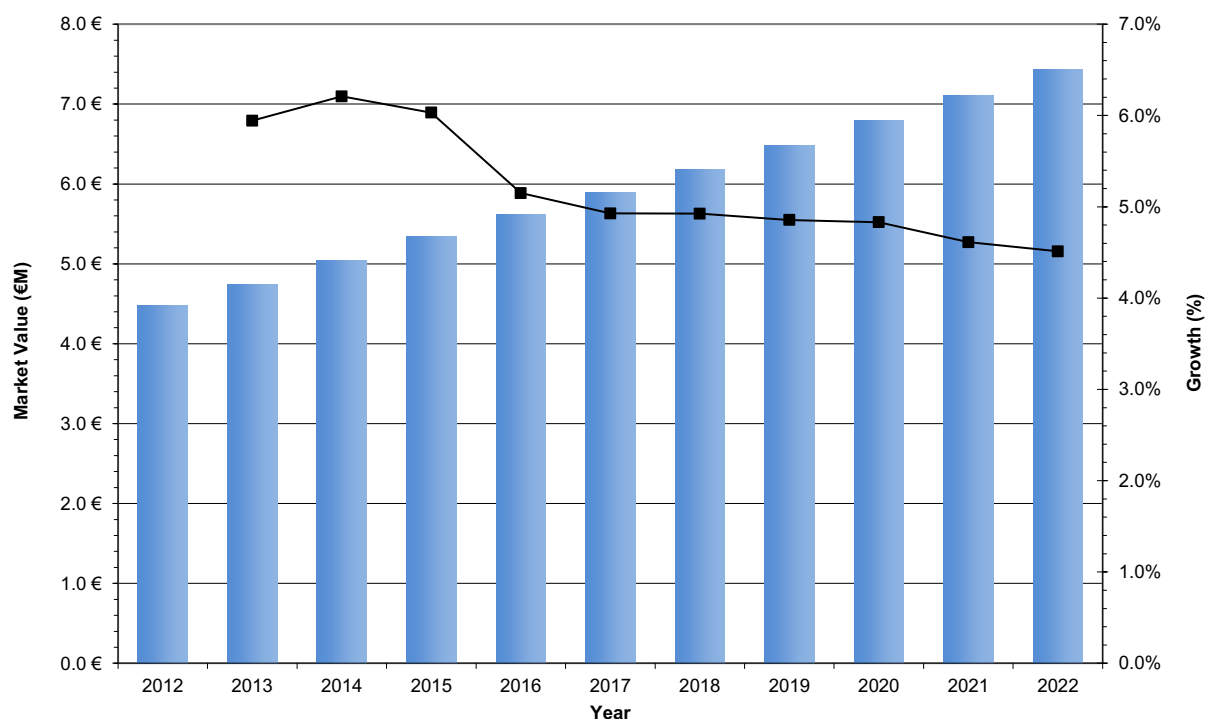
In 2015, the thermal balloon ablation device technique accounted for 40% of total European procedures. This percentage changes quite significantly when broken down by country and region within Europe. The Thermal Balloon technique is still the most popular in Germany and Austria, with the total percentage of procedures using thermal balloon ablation at 50% and 70% respectively. Spain and Portugal, alternatively, have the lowest percent of thermal balloon ablation, comprising only 28% of total endometrial ablation procedures.

Growth in sales is driven by the approval of national reimbursement programs and a market trend toward office procedures. Europe has been slow to adopt GEA procedures, which are second-generation uterus lining removal methods. First-generation ablation methods, such as roller-ball therapy and endometrial resection, are still popular with many physicians, especially in Spain and Portugal. Initially, radiofrequency ablation was the preferred form of GEA. This trend is shifting towards the thermal balloon technique, as it is being viewed as the more general technique with radiofrequency being reserved for specific types of patient cases. By 2022, the mean is projected to be 47.7% in contrast to only 38.9% in 2015.

Figure 6-9: Thermal Balloon Ablation Device Market, Europe, 2012 – 2022 (€ and US\$)

Year	Units Sold	Growth (%)	ASP (€)	ASP (US\$)	Growth (%)	Market Value (€M)	Market Value (US\$M)	Growth (%)
2012	17,505		€256	\$283		€4.5	\$5.0	
2013	18,675	6.7%	€254	\$281	-0.7%	€4.7	\$5.2	5.9%
2014	19,972	6.9%	€252	\$279	-0.7%	€5.0	\$5.6	6.2%
2015	21,291	6.6%	€251	\$277	-0.5%	€5.3	\$5.9	6.0%
2016	22,494	5.7%	€250	\$276	-0.5%	€5.6	\$6.2	5.2%
2017	23,704	5.4%	€249	\$275	-0.4%	€5.9	\$6.5	4.9%
2018	24,950	5.3%	€248	\$274	-0.3%	€6.2	\$6.8	4.9%
2019	26,237	5.2%	€247	\$273	-0.3%	€6.5	\$7.2	4.9%
2020	27,561	5.0%	€247	\$273	-0.2%	€6.8	\$7.5	4.8%
2021	28,899	4.9%	€246	\$272	-0.2%	€7.1	\$7.9	4.6%
2022	30,259	4.7%	€246	\$272	-0.2%	€7.4	\$8.2	4.5%
CAGR ('15-'22)		5.1%			-0.3%			4.8%

Source: iData Research Inc.

Chart 6-5: Thermal Balloon Ablation Device Market, Europe, 2012 – 2022

Source: iData Research Inc.

Figure 6-10: Units Sold by Country, Thermal Balloon Ablation Device Market, Europe, 2012-2022

Year	Germany	France	U.K.	Italy	Spain	Benelux	Scandi- navia	Austria	Switzer- land	Portugal	Europe	Growth (%)
2012	3,847	3,009	3,727	1,117	849	1,548	611	1,581	982	233	17,505	6.6
2013	4,027	3,202	3,943	1,253	925	1,668	644	1,751	1,007	254	18,675	6.7%
2014	4,243	3,428	4,188	1,392	999	1,796	679	1,933	1,038	276	19,972	6.9%
2015	4,446	3,664	4,438	1,532	1,070	1,930	717	2,121	1,074	298	21,291	6.6%
2016	4,644	3,883	4,676	1,656	1,141	2,128	770	2,163	1,112	321	22,494	5.7%
2017	4,853	4,133	4,929	1,780	1,209	2,263	830	2,207	1,155	344	23,704	5.4%
2018	5,075	4,385	5,198	1,906	1,277	2,402	887	2,253	1,199	368	24,950	5.3%
2019	5,305	4,641	5,483	2,026	1,353	2,545	944	2,300	1,246	393	26,237	5.2%
2020	5,549	4,902	5,776	2,145	1,427	2,690	1,006	2,351	1,295	418	27,561	5.0%
2021	5,792	5,167	6,076	2,264	1,499	2,839	1,071	2,403	1,345	445	28,899	4.9%
2022	6,031	5,440	6,382	2,381	1,571	2,990	1,140	2,456	1,398	471	30,259	4.7%
CAGR (‘15-’22)	4.5%	5.8%	5.3%	6.5%	5.6%	6.4%	6.8%	2.1%	3.8%	6.7%		5.1%

Source: iData Research Inc.

Figure 6-11: Average Sales Price by Country, Thermal Balloon Ablation Device Market, Europe, 2012-2022 (€)

Year	Germany	France	U.K.	Italy	Spain	Benelux	Scandi- navia	Austria	Switzer- land	Portugal	Europe	Growth (%)
2012	€228.41	€192.11	€313.44	€197.49	€200.90	€210.95	€313.13	€253.79	€503.52	€206.23	€255.81	
2013	€227.27	€191.34	€312.18	€196.50	€200.60	€210.63	€312.75	€252.52	€502.51	€205.82	€254.04	-0.7%
2014	€226.13	€190.57	€310.93	€195.72	€200.30	€210.32	€312.37	€251.26	€500.00	€205.41	€252.29	-0.7%
2015	€225.00	€190.00	€310.00	€195.00	€200.00	€210.00	€312.00	€250.00	€500.00	€205.00	€250.93	-0.5%
2016	€224.10	€189.43	€309.07	€194.29	€199.70	€209.69	€311.63	€249.00	€500.00	€204.59	€249.74	-0.5%
2017	€223.43	€188.86	€308.14	€193.77	€199.40	€209.37	€311.25	€248.25	€497.50	€204.18	€248.67	-0.4%
2018	€222.98	€188.67	€307.22	€193.25	€199.10	€209.06	€310.88	€247.76	€496.51	€203.77	€247.89	-0.3%
2019	€222.53	€188.48	€306.30	€192.73	€198.80	€208.74	€310.51	€247.26	€495.51	€203.36	€247.17	-0.3%
2020	€222.31	€188.30	€305.68	€192.35	€198.50	€208.43	€310.13	€247.01	€495.51	€202.96	€246.67	-0.2%
2021	€222.09	€188.11	€305.07	€191.96	€198.21	€208.12	€309.76	€246.77	€493.03	€202.55	€246.10	-0.2%
2022	€221.87	€187.92	€304.46	€191.58	€197.91	€207.80	€309.39	€246.52	€492.05	€202.15	€245.64	-0.2%
CAGR (‘15-’22)	-0.2%	-0.2%	-0.3%	-0.3%	-0.1%	-0.1%	-0.1%	-0.2%	-0.2%	-0.2%		-0.3%

Source: iData Research Inc.

Figure 6-12: Average Sales Price by Country, Thermal Balloon Ablation Device Market, Europe, 2012-2022 (US\$)

Year	Germany	France	U.K.	Italy	Spain	Benelux	Scandi- navia	Austria	Switzer- land	Portugal	Europe	Growth (%)
2012	\$252.53	\$212.39	\$346.53	\$218.35	\$222.12	\$233.22	\$346.19	\$280.59	\$556.69	\$228.01	\$282.82	
2013	\$251.27	\$211.54	\$345.15	\$217.25	\$221.78	\$232.87	\$345.78	\$279.18	\$555.58	\$227.56	\$280.86	-0.7%
2014	\$250.01	\$210.70	\$343.77	\$216.39	\$221.45	\$232.52	\$345.36	\$277.79	\$552.80	\$227.10	\$278.93	-0.7%
2015	\$248.76	\$210.06	\$342.74	\$215.59	\$221.12	\$232.18	\$344.95	\$276.40	\$552.80	\$226.65	\$277.42	-0.5%
2016	\$247.76	\$209.43	\$341.71	\$214.80	\$220.79	\$231.83	\$344.53	\$275.29	\$552.80	\$226.19	\$276.11	-0.5%
2017	\$247.02	\$208.81	\$340.68	\$214.23	\$220.46	\$231.48	\$344.12	\$274.47	\$550.04	\$225.74	\$274.93	-0.4%
2018	\$246.53	\$208.60	\$339.66	\$213.66	\$220.13	\$231.13	\$343.71	\$273.92	\$548.94	\$225.29	\$274.06	-0.3%
2019	\$246.03	\$208.39	\$338.64	\$213.09	\$219.80	\$230.79	\$343.29	\$273.37	\$547.84	\$224.84	\$273.27	-0.3%
2020	\$245.79	\$208.18	\$337.96	\$212.66	\$219.47	\$230.44	\$342.88	\$273.10	\$547.84	\$224.39	\$272.72	-0.2%
2021	\$245.54	\$207.97	\$337.29	\$212.24	\$219.14	\$230.09	\$342.47	\$272.83	\$545.10	\$223.94	\$272.08	-0.2%
2022	\$245.30	\$207.76	\$336.61	\$211.81	\$218.81	\$229.75	\$342.06	\$272.55	\$544.01	\$223.49	\$271.58	-0.2%
CAGR (‘15-’22)	-0.2%	-0.2%	-0.3%	-0.3%	-0.1%	-0.1%	-0.1%	-0.2%	-0.2%	-0.2%		-0.3%
Source: iData Research Inc.												

Figure 6-13: Thermal Balloon Ablation Device Market by Country, Europe, 2012-2022 (€M)

Year	Germany	France	U.K.	Italy	Spain	Benelux	Scandi- navia	Austria	Switzer- land	Portugal	Europe	Growth (%)
2012	€0.88	€0.58	€1.17	€0.22	€0.17	€0.33	€0.19	€0.40	€0.49	€0.05	€4.48	
2013	€0.92	€0.61	€1.23	€0.25	€0.19	€0.35	€0.20	€0.44	€0.51	€0.05	€4.74	5.9%
2014	€0.96	€0.65	€1.30	€0.27	€0.20	€0.38	€0.21	€0.49	€0.52	€0.06	€5.04	6.2%
2015	€1.00	€0.70	€1.38	€0.30	€0.21	€0.41	€0.22	€0.53	€0.54	€0.06	€5.34	6.0%
2016	€1.04	€0.74	€1.45	€0.32	€0.23	€0.45	€0.24	€0.54	€0.56	€0.07	€5.62	5.2%
2017	€1.08	€0.78	€1.52	€0.34	€0.24	€0.47	€0.26	€0.55	€0.57	€0.07	€5.89	4.9%
2018	€1.13	€0.83	€1.60	€0.37	€0.25	€0.50	€0.28	€0.56	€0.60	€0.08	€6.18	4.9%
2019	€1.18	€0.87	€1.68	€0.39	€0.27	€0.53	€0.29	€0.57	€0.62	€0.08	€6.49	4.9%
2020	€1.23	€0.92	€1.77	€0.41	€0.28	€0.56	€0.31	€0.58	€0.64	€0.08	€6.80	4.8%
2021	€1.29	€0.97	€1.85	€0.43	€0.30	€0.59	€0.33	€0.59	€0.66	€0.09	€7.11	4.6%
2022	€1.34	€1.02	€1.94	€0.46	€0.31	€0.62	€0.35	€0.61	€0.69	€0.10	€7.43	4.5%
CAGR (‘15-’22)	4.2%	5.6%	5.1%	6.2%	5.5%	6.3%	6.7%	1.9%	3.6%	6.5%		4.8%

Source: iData Research Inc.

Figure 6-14: Thermal Balloon Ablation Device Market by Country, Europe, 2012-2022 (US\$M)

Year	Germany	France	U.K.	Italy	Spain	Benelux	Scandi- navia	Austria	Switzer- land	Portugal	Europe	Growth (%)
2012	\$0.97	\$0.64	\$1.29	\$0.24	\$0.19	\$0.36	\$0.21	\$0.44	\$0.55	\$0.05	\$4.95	
2013	\$1.01	\$0.68	\$1.36	\$0.27	\$0.21	\$0.39	\$0.22	\$0.49	\$0.56	\$0.06	\$5.24	5.9%
2014	\$1.06	\$0.72	\$1.44	\$0.30	\$0.22	\$0.42	\$0.23	\$0.54	\$0.57	\$0.06	\$5.57	6.2%
2015	\$1.11	\$0.77	\$1.52	\$0.33	\$0.24	\$0.45	\$0.25	\$0.59	\$0.59	\$0.07	\$5.91	6.0%
2016	\$1.15	\$0.81	\$1.60	\$0.36	\$0.25	\$0.49	\$0.27	\$0.60	\$0.61	\$0.07	\$6.21	5.2%
2017	\$1.20	\$0.86	\$1.68	\$0.38	\$0.27	\$0.52	\$0.29	\$0.61	\$0.64	\$0.08	\$6.52	4.9%
2018	\$1.25	\$0.91	\$1.77	\$0.41	\$0.28	\$0.56	\$0.30	\$0.62	\$0.66	\$0.08	\$6.84	4.9%
2019	\$1.31	\$0.97	\$1.86	\$0.43	\$0.30	\$0.59	\$0.32	\$0.63	\$0.68	\$0.09	\$7.17	4.9%
2020	\$1.36	\$1.02	\$1.95	\$0.46	\$0.31	\$0.62	\$0.34	\$0.64	\$0.71	\$0.09	\$7.52	4.8%
2021	\$1.42	\$1.07	\$2.05	\$0.48	\$0.33	\$0.65	\$0.37	\$0.66	\$0.73	\$0.10	\$7.86	4.6%
2022	\$1.48	\$1.13	\$2.15	\$0.50	\$0.34	\$0.69	\$0.39	\$0.67	\$0.76	\$0.11	\$8.22	4.5%
CAGR (‘15-’22)	4.2%	5.6%	5.1%	6.2%	5.5%	6.3%	6.7%	1.9%	3.6%	6.5%		4.8%

Source: iData Research Inc.

6.3.3 Radiofrequency Ablation Device Market

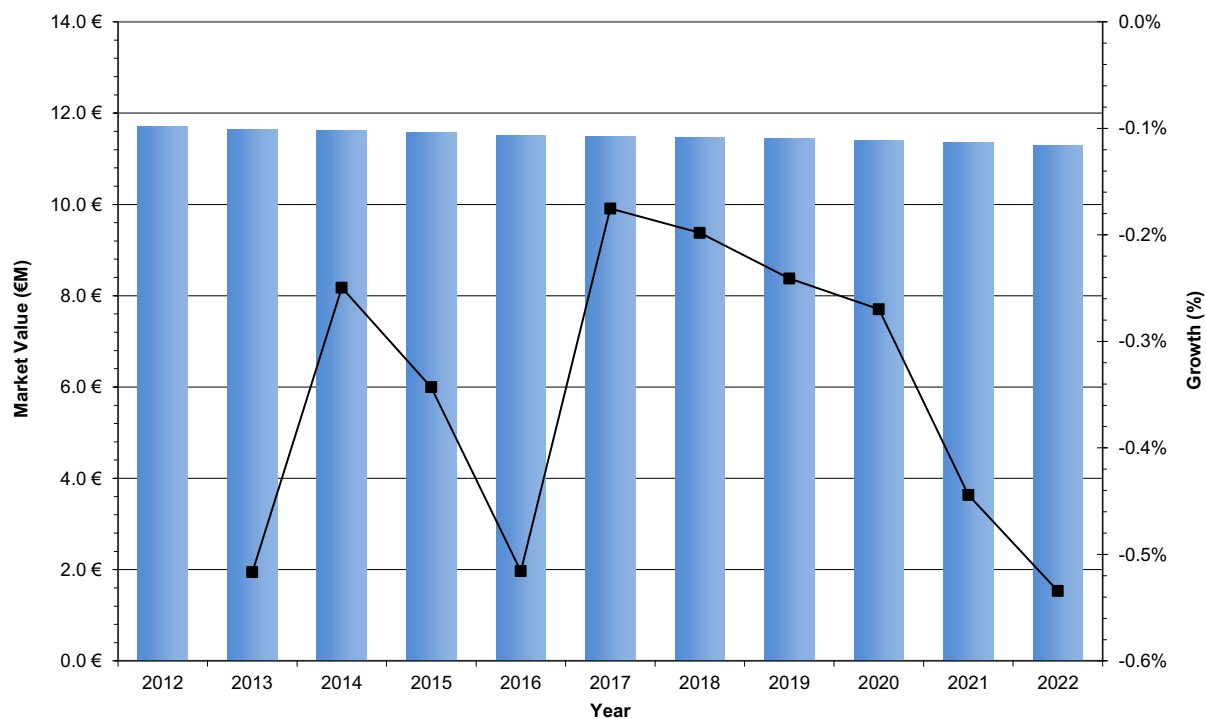
In 2015, the radiofrequency ablation device technique accounted for 60% of total European procedures. As Global Endometrial Ablation became main stream, radiofrequency ablation was the initial technique performed. Spain and Portugal have the highest percentage of procedures being performed using the radiofrequency technique at 72%, followed closely by Italy and the Scandinavia region.

Radiofrequency ablation is the preferred method by many physicians partially due to the speed of the procedure: it can be performed under local anesthesia and takes only a few minutes. Longer procedures take up more of the physician's time and increase patient stress and discomfort. However, radiofrequency ablation devices are the more expensive option, with an ASP of €368 opposed to only €251 for thermal balloon ablation devices.

Radiofrequency ablation procedures are projected to remain steady with modest increases as overall procedure numbers increase. The percentage of procedures being performed using radiofrequency ablation had a mean of 61% in 2015 and is expected to fall to 52% by 2022.

Figure 6-15: Radiofrequency Ablation Device Market, Europe, 2012 – 2022 (€ and US\$)

Year	Units Sold	Growth (%)	ASP (€)	ASP (US\$)	Growth (%)	Market Value (€M)	Market Value (US\$M)	Growth (%)
2012	31,506		€371	\$411		€11.7	\$12.9	
2013	31,458	-0.2%	€370	\$409	-0.4%	€11.6	\$12.9	-0.5%
2014	31,496	0.1%	€369	\$408	-0.4%	€11.6	\$12.8	-0.2%
2015	31,474	-0.1%	€368	\$406	-0.3%	€11.6	\$12.8	-0.3%
2016	31,381	-0.3%	€367	\$405	-0.2%	€11.5	\$12.7	-0.5%
2017	31,400	0.1%	€366	\$405	-0.2%	€11.5	\$12.7	-0.2%
2018	31,388	0.0%	€365	\$404	-0.2%	€11.5	\$12.7	-0.2%
2019	31,361	-0.1%	€365	\$403	-0.2%	€11.4	\$12.6	-0.2%
2020	31,305	-0.2%	€364	\$403	-0.1%	€11.4	\$12.6	-0.3%
2021	31,204	-0.3%	€364	\$402	-0.1%	€11.4	\$12.6	-0.4%
2022	31,068	-0.4%	€364	\$402	-0.1%	€11.3	\$12.5	-0.5%
CAGR ('15-'22)		-0.2%			-0.2%			-0.3%
Source: iData Research Inc.								

Chart 6-6: Radiofrequency Ablation Device Market, Europe, 2012 – 2022

Source: iData Research Inc.

Figure 6-16: Units Sold by Country, Radiofrequency Ablation Device Market, Europe, 2012-2022

Year	Germany	France	U.K.	Italy	Spain	Benelux	Scandi- navia	Austria	Switzer- land	Portugal	Europe	Growth (%)
2012	4,338	5,539	6,347	3,536	2,718	3,087	1,815	1,294	2,086	747	31,506	
2013	4,363	5,499	6,433	3,567	2,746	3,125	1,758	1,167	2,045	755	31,458	-0.2%
2014	4,416	5,500	6,551	3,579	2,756	3,165	1,711	1,041	2,015	763	31,496	0.1%
2015	4,446	5,496	6,656	3,576	2,752	3,204	1,673	909	1,994	768	31,474	-0.1%
2016	4,462	5,451	6,729	3,519	2,739	3,139	1,667	927	1,977	771	31,381	-0.3%
2017	4,480	5,434	6,807	3,456	2,717	3,152	1,669	946	1,966	774	31,400	0.1%
2018	4,501	5,403	6,890	3,388	2,689	3,159	1,662	966	1,956	775	31,388	0.0%
2019	4,519	5,361	6,979	3,305	2,673	3,161	1,650	986	1,949	777	31,361	-0.1%
2020	4,540	5,311	7,060	3,218	2,651	3,158	1,641	1,008	1,942	777	31,305	-0.2%
2021	4,551	5,250	7,132	3,126	2,619	3,150	1,634	1,030	1,935	777	31,204	-0.3%
2022	4,549	5,185	7,196	3,030	2,585	3,137	1,627	1,052	1,931	775	31,068	-0.4%
CAGR (‘15-’22)	0.3%	-0.8%	1.1%	-2.3%	-0.9%	-0.3%	-0.4%	2.1%	-0.5%	0.1%		-0.2%

Source: iData Research Inc.

Figure 6-17: Average Sales Price by Country, Radiofrequency Ablation Device Market, Europe, 2012-2022 (€)

Year	Germany	France	U.K.	Italy	Spain	Benelux	Scandi- navia	Austria	Switzer- land	Portugal	Europe	Growth (%)
2012	€365	€354	€409	€355	€342	€352	€401	€376	€393	€337	€371	
2013	€364	€352	€408	€353	€341	€351	€401	€374	€392	€336	€370	-0.4%
2014	€362	€351	€406	€351	€341	€351	€400	€372	€390	€336	€369	-0.4%
2015	€360	€350	€405	€350	€340	€350	€400	€370	€390	€335	€368	-0.3%
2016	€359	€349	€404	€349	€339	€349	€400	€369	€390	€334	€367	-0.2%
2017	€357	€348	€403	€348	€339	€349	€399	€367	€388	€334	€366	-0.2%
2018	€357	€348	€401	€347	€338	€348	€399	€367	€387	€333	€365	-0.2%
2019	€356	€347	€400	€346	€338	€348	€398	€366	€386	€332	€365	-0.2%
2020	€356	€347	€399	€345	€337	€347	€398	€366	€386	€332	€364	-0.1%
2021	€355	€347	€399	€344	€337	€347	€397	€365	€385	€331	€364	-0.1%
2022	€355	€346	€398	€344	€336	€346	€397	€365	€384	€330	€364	-0.1%
CAGR (‘15-’22)	-0.2%	-0.2%	-0.3%	-0.3%	-0.1%	-0.1%	-0.1%	-0.2%	-0.2%	-0.2%		-0.2%

Source: iData Research Inc.

Figure 6-18: Average Sales Price by Country, Radiofrequency Ablation Device Market, Europe, 2012-2022 (US\$)

Year	Germany	France	U.K.	Italy	Spain	Benelux	Scandi- navia	Austria	Switzer- land	Portugal	Europe	Growth (%)
2012	\$404	\$391	\$453	\$392	\$378	\$389	\$444	\$415	\$434	\$373	\$411	
2013	\$402	\$390	\$451	\$390	\$377	\$388	\$443	\$413	\$433	\$372	\$409	-0.4%
2014	\$400	\$388	\$449	\$388	\$376	\$388	\$443	\$411	\$431	\$371	\$408	-0.4%
2015	\$398	\$387	\$448	\$387	\$376	\$387	\$442	\$409	\$431	\$370	\$406	-0.3%
2016	\$396	\$386	\$446	\$385	\$375	\$386	\$442	\$407	\$431	\$370	\$405	-0.2%
2017	\$395	\$385	\$445	\$384	\$375	\$386	\$441	\$406	\$429	\$369	\$405	-0.2%
2018	\$394	\$384	\$444	\$383	\$374	\$385	\$441	\$405	\$428	\$368	\$404	-0.2%
2019	\$394	\$384	\$442	\$382	\$374	\$385	\$440	\$405	\$427	\$367	\$403	-0.2%
2020	\$393	\$383	\$442	\$382	\$373	\$384	\$440	\$404	\$427	\$367	\$403	-0.1%
2021	\$393	\$383	\$441	\$381	\$373	\$383	\$439	\$404	\$425	\$366	\$402	-0.1%
2022	\$392	\$383	\$440	\$380	\$372	\$383	\$439	\$403	\$424	\$365	\$402	-0.1%
CAGR (‘15-’22)	-0.2%	-0.2%	-0.3%	-0.3%	-0.1%	-0.1%	-0.1%	-0.2%	-0.2%	-0.2%		-0.2%
Source: iData Research Inc.												

Figure 6-19: Female Urinary Incontinence Sling Market by Country, Europe, 2012-2022 (€M)

Year	Germany	France	U.K.	Italy	Spain	Benelux	Scandi- navia	Austria	Switzer- land	Portugal	Europe	Growth (%)
2012	€1.59	€1.96	€2.60	€1.25	€0.93	€1.09	€0.73	€0.49	€0.82	€0.25	€11.70	
2013	€1.59	€1.94	€2.62	€1.26	€0.94	€1.10	€0.70	€0.44	€0.80	€0.25	€11.64	-0.5%
2014	€1.60	€1.93	€2.66	€1.26	€0.94	€1.11	€0.69	€0.39	€0.79	€0.26	€11.61	-0.2%
2015	€1.60	€1.92	€2.70	€1.25	€0.94	€1.12	€0.67	€0.34	€0.78	€0.26	€11.57	-0.3%
2016	€1.60	€1.90	€2.72	€1.23	€0.93	€1.10	€0.67	€0.34	€0.77	€0.26	€11.51	-0.5%
2017	€1.60	€1.89	€2.74	€1.20	€0.92	€1.10	€0.67	€0.35	€0.76	€0.26	€11.49	-0.2%
2018	€1.61	€1.88	€2.77	€1.17	€0.91	€1.10	€0.66	€0.35	€0.76	€0.26	€11.47	-0.2%
2019	€1.61	€1.86	€2.79	€1.14	€0.90	€1.10	€0.66	€0.36	€0.75	€0.26	€11.44	-0.2%
2020	€1.62	€1.84	€2.82	€1.11	€0.89	€1.10	€0.65	€0.37	€0.75	€0.26	€11.41	-0.3%
2021	€1.62	€1.82	€2.84	€1.08	€0.88	€1.09	€0.65	€0.38	€0.74	€0.26	€11.36	-0.4%
2022	€1.61	€1.79	€2.86	€1.04	€0.87	€1.09	€0.65	€0.38	€0.74	€0.26	€11.30	-0.5%
CAGR (‘15-’22)	0.1%	-1.0%	0.9%	-2.6%	-1.0%	-0.5%	-0.5%	1.9%	-0.7%	-0.1%		-0.3%

Source: iData Research Inc.

Figure 6-20: Female Urinary Incontinence Sling Market by Country, Europe, 2012-2022 (US\$M)

Year	Germany	France	U.K.	Italy	Spain	Benelux	Scandi- navia	Austria	Switzer- land	Portugal	Europe	Growth (%)
2012	\$1.75	\$2.17	\$2.87	\$1.39	\$1.03	\$1.20	\$0.81	\$0.54	\$0.91	\$0.28	\$12.93	
2013	\$1.75	\$2.14	\$2.90	\$1.39	\$1.04	\$1.21	\$0.78	\$0.48	\$0.89	\$0.28	\$12.87	-0.5%
2014	\$1.77	\$2.13	\$2.94	\$1.39	\$1.04	\$1.23	\$0.76	\$0.43	\$0.87	\$0.28	\$12.83	-0.2%
2015	\$1.77	\$2.13	\$2.98	\$1.38	\$1.03	\$1.24	\$0.74	\$0.37	\$0.86	\$0.28	\$12.79	-0.3%
2016	\$1.77	\$2.10	\$3.00	\$1.36	\$1.03	\$1.21	\$0.74	\$0.38	\$0.85	\$0.28	\$12.72	-0.5%
2017	\$1.77	\$2.09	\$3.03	\$1.33	\$1.02	\$1.22	\$0.74	\$0.38	\$0.84	\$0.29	\$12.70	-0.2%
2018	\$1.78	\$2.08	\$3.06	\$1.30	\$1.01	\$1.22	\$0.73	\$0.39	\$0.84	\$0.29	\$12.68	-0.2%
2019	\$1.78	\$2.06	\$3.09	\$1.26	\$1.00	\$1.22	\$0.73	\$0.40	\$0.83	\$0.29	\$12.65	-0.2%
2020	\$1.79	\$2.04	\$3.12	\$1.23	\$0.99	\$1.21	\$0.72	\$0.41	\$0.83	\$0.28	\$12.61	-0.3%
2021	\$1.79	\$2.01	\$3.14	\$1.19	\$0.98	\$1.21	\$0.72	\$0.42	\$0.82	\$0.28	\$12.56	-0.4%
2022	\$1.79	\$1.98	\$3.16	\$1.15	\$0.96	\$1.20	\$0.71	\$0.42	\$0.82	\$0.28	\$12.49	-0.5%
CAGR (‘15-’22)	0.1%	-1.0%	0.9%	-2.6%	-1.0%	-0.5%	-0.5%	1.9%	-0.7%	-0.1%		-0.3%

Source: iData Research Inc.

6.4 DRIVERS AND LIMITERS

6.4.1 Market Drivers

Ease of Use

Global endometrial ablation methods do not require the same level of training needed for more traditional methods. This has allowed a greater number of physicians to learn how to perform these procedures, making endometrial ablation more accessible to women who request it.

Increase in Office Procedures

Office-based procedures are growing for a number of reasons. Many patients do not want to go to the hospital and go under general anesthesia. Office-based procedures are faster, more comfortable and have rapid recovery times. Physicians also do not have to compete for space in hospital operating rooms. GEA procedures can be done in the office as opposed to a hospital setting. In addition, many procedures are reimbursed at a higher rate in the office than in a hospital setting. This is encouraging physicians to retrain themselves for GEA procedures and purchase devices for their office.

Reimbursement Rates

Once a country approves it as part of their reimbursement system, office-based GEA usually becomes better reimbursed than alternative procedures. This is another main factor behind the movement towards these methods.

Patient Population

Approximately 25% of women will be candidates for endometrial ablation procedures in their lifetime. While many of these women will receive either an alternative procedure or no treatment, there are a significant number of available patients that will continue to drive the endometrial ablation device market.

Physician Awareness

As more physicians receive training in and become aware of more modern methods, the market for ablation devices will increase. Endometrial ablation is a minimally invasive procedure, and patients recover much more quickly than with other methods that treat excessive uterine bleeding. These factors will encourage physicians to become trained in new methods to increase patient comfort.

6.4.2 Market Limiters

Complications and Lack of Effectiveness

At first, total endometrial ablation seemed extremely safe in the short term. However, as time passed, certain long-term complications became evident. The problem is that after this procedure, intrauterine scarring and contracture can occur. The percentage of amenorrhea (no further periods) is only 45% with endometrial ablation relative to 85% with endometrial resection. There is also a 25% chance that a second procedure will be required with endometrial ablation compared to only 5% with endometrial resection. 25% of women undergo a hysterectomy within three to four years of ablation to relieve the symptoms caused by the procedure. The number of women who are dissatisfied with the results is likely to be higher but many of them simply elect to accept their results and not undergo further surgery.

Reimbursement

While ablation procedures are well reimbursed as an office procedure, there has been a trend of hospitals performing a larger number of endometrial ablation procedures. This both increases cost and discomfort for the patient, as they must pay extra hospital fees and travel to the hospitals. In addition, some insurance providers will not cover an ablation procedure performed in a hospital, which could cause the patient to either delay or neglect having the procedure performed.

Popularity of Intrauterine Devices

Intrauterine devices are a popular method of birth control in Europe. They are safe, reversible, require little maintenance and have a high rate of effectiveness. Hormonal IUDs have also been prescribed by many physicians for relieving symptoms of menorrhagia. For these reasons, patients and physicians may regard IUDs as a more suitable alternative to GEA. IUDs are especially popular in Scandinavia, France and Austria.

Resistance to Change

Physicians are familiar with hysterectomies and first-generation ablation devices (such as resection) and are trained to perform them. Many do not consider the new methods in second-generation ablation devices necessary or do not want to be retrained to perform a novel procedure. Reluctance to switch over to the newer GEA techniques limits growth in this market.

Pharmaceutical Treatments

There are several available pharmaceutical treatments for heavy menstrual bleeding (HMB). Although these treatments tend to have lower efficacy rates than surgical treatments, pharmaceutical treatments are more appropriate for the younger population of women who still desire to have children. Both hormonal and non-hormonal pharmaceutical treatments are options for HMB. This method of treatment poses a threat to the GEA market, especially in younger demographics of women.

Figure 6-21: Drivers and Limiters, Global Endometrial Ablation Market, Europe, 2015

Market Drivers
Ease of Use
Increase in Office Procedures
Reimbursement Rates
Patient Population
Physician Awareness
Market Limiters
Complications and Lack of Effectiveness
Reimbursement
Popularity of Reimbursement Devices
Resistance to Change
Pharmaceutical Treatments
Source: iData Research Inc.

6.5 COMPETITIVE MARKET SHARE ANALYSIS

Johnson & Johnson

Ethicon, a Johnson & Johnson company, was the leading competitor in 2015 with a 30.9% market share, owing to its well-known *GYNECARE™* product the *THERMACHOICE® III* uterine balloon therapy system. This was one of the first endometrial ablation methods available; many physicians, even if they have been trained on other methods, are familiar with how to perform this procedure. This has allowed Ethicon to achieve a high penetration rate in the office market.

In March 2016, Ethicon elected to discontinue the *GYNECARE THERMACHOICE® III* Uterine Balloon Therapy System. This includes the worldwide commercialization (sales, distribution and promotion) of the controller and umbilical cable components effective immediately. The decision is not related to their safety or efficacy and is a voluntary action by Ethicon. To date, Ethicon is no longer a competitor in the endometrial ablation market.

Hologic

In 2015, Hologic was the second leading competitor, with a 29.7% share from their radiofrequency ablation device: *NovaSure™*. At 90 seconds, this is the fastest ablation method available to patients. In addition, patients expressed a high degree of satisfaction, and the method was found to be safe, with long-term efficacy in many studies.

Despite pressures on elective procedures, Hologic has seen consistent growth in international sales over the past few years.

Boston Scientific

In 2015, Boston Scientific had a 13.4% share of the European GEA market. In early in 2010, Boston Scientific received CE mark approval for their *Genesys Hydro ThermAblator® (HTA) System*. It is the only endometrial ablation method performed as a hysteroscopic procedure, allowing the physician direct visualization during the treatment. This method, which uses heated saline to destroy the lining, has had excellent success rates in clinical studies, particularly over the long term.

Medtronic

Medtronic offers a wide range of endometrial ablation products including the *Cool-tip™* radiofrequency ablation systems, the *Evident™* microwave ablation system, and the new *Emprint™* ablation system with *Thermosphere™* technology. Although Medtronic has a smaller market share, the company has been

manufacturing energy based medical systems for more than 40 years and is a growing competitor across Europe.

Karl Storz

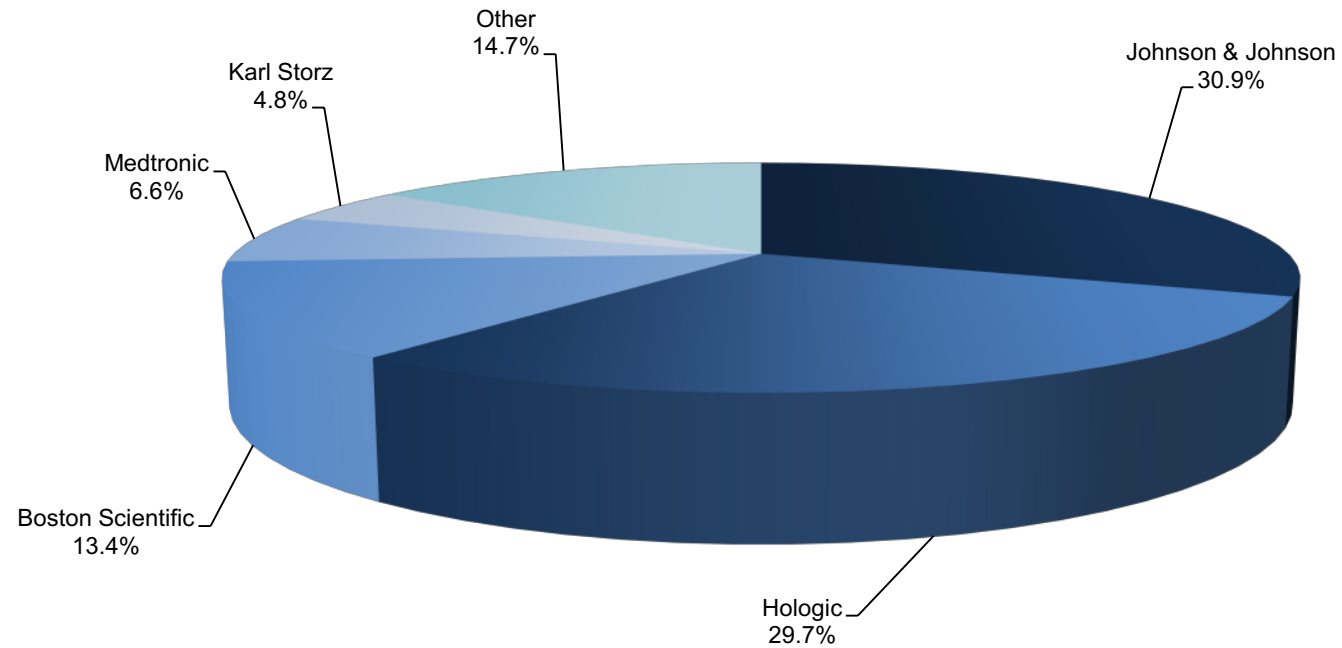
Karl Storz offers the Intrauterine BIGATTI Shaver (IBS®) with the HYSTEROMAT E.A.S.I.® system. This system is for rapid tissue ablation with a small diameter and can be used in an office setting. The system is for mechanical resection and offers an alternative approach to operative hysteroscopy. Karl Storz is a smaller market player, however, the system is still popular in Germany, Austria, Italy and the United Kingdom.

Other Notable Competitors: Olympus

Olympus offers Trans Cervical Resection in saline (TCRis). TCRis (Trans Cervical Resection in saline) is a safe and fast way to treat abnormal bleeding by endometrial ablation, or bipolar resection of intracavitary myomas, uterine septa or uterine polyps. It is worth noting the device can be used to perform both endometrial Ablation and endometrial resection procedures and is a competitor in both markets.

Figure 6-22: Leading Competitors by Country, Global Endometrial Ablation Market, Europe, 2015

Company	Germany	France	U.K.	Italy	Spain	Benelux	Scandi- navia	Austria	Switzer- land	Portugal	Total Market Share
Johnson & Johnson	28.6%	30.3%	30.8%	38.7%	50.4%	30.2%	40.8%	–	25.0%	30.5%	30.9%
Hologic	35.3%	29.9%	40.9%	10.3%	15.7%	30.1%	30.5%	18.4%	25.6%	25.4%	29.7%
Boston Scientific	10.2%	15.5%	9.9%	11.5%	11.3%	18.4%	20.2%	25.7%	12.1%	10.9%	13.4%
Medtronic	8.4%	10.6%	6.7%	–	–	–	–	24.3%	10.4%	–	6.6%
Karl Storz	10.1%	–	4.2%	15.9%	–	–	–	15.8%	–	–	4.8%
Other	7.4%	13.7%	7.5%	23.6%	22.6%	21.3%	8.5%	15.8%	26.9%	33.2%	14.7%
Total	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
Market Value (€M)	€2.6	€2.6	€4.1	€1.6	€1.1	€1.5	€0.9	€0.9	€1.3	€0.3	€16.9
Others include: Idoman, Olympus, Thermablate, etc.											
Source: iData Research Inc.											

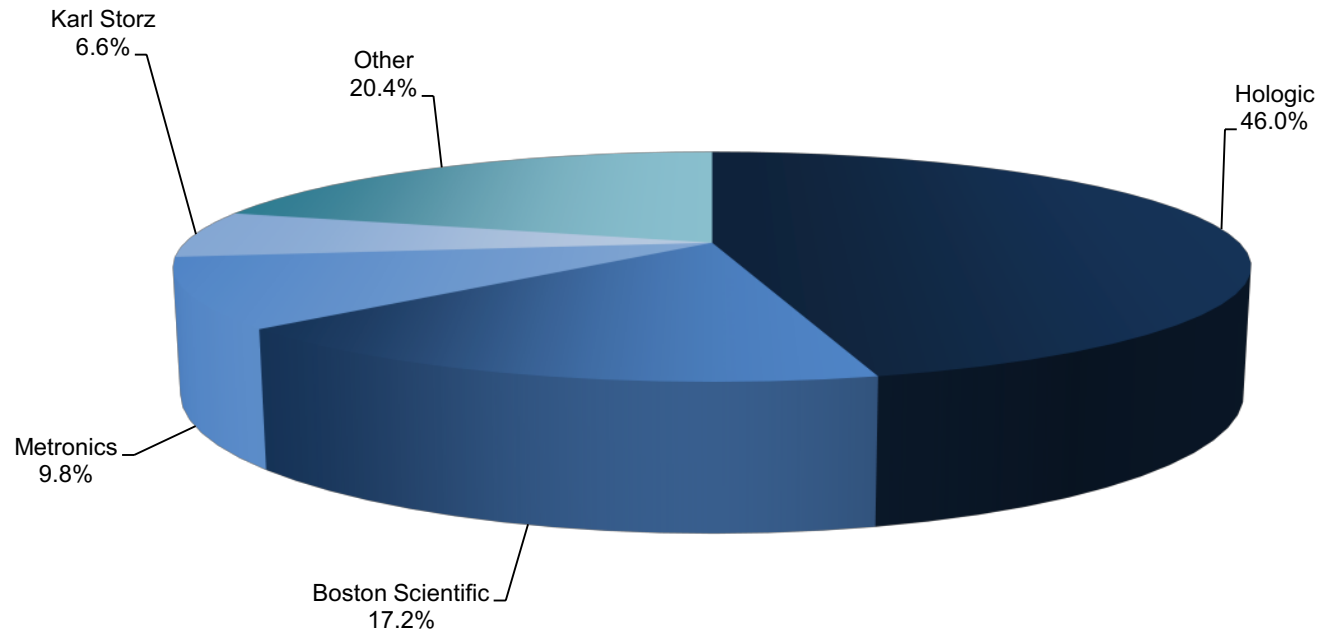
Chart 6-7: Leading Competitors, Global Endometrial Ablation Market, Europe, 2015

Source: iData Research Inc.

Figure 6-23: Projected Leading Competitors by Country, Global Endometrial Ablation Market, Europe, 2016

Company	Germany	France	U.K.	Italy	Spain	Benelux	Scandi- navia	Austria	Switzer- land	Portugal	Total Market Share
Hologic	51.3%	50.2%	46.5%	41.6%	38.8%	59.2%	61.0%	15.7%	32.1%	41.4%	46.0%
Boston Scientific	12.7%	19.7%	13.3%	16.9%	16.5%	21.4%	24.4%	27.3%	18.6%	16.3%	17.2%
Metronics	11.9%	15.4%	12.7%	–	–	–	–	24.9%	15.7%	–	9.8%
Karl Storz	12.6%	–	8.4%	20.1%	–	–	–	14.8%	–	–	6.6%
Other	11.5%	14.7%	19.1%	21.4%	44.7%	19.4%	14.6%	17.3%	33.6%	42.3%	20.4%
Total	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
Market Value (€M)	€2.6	€2.6	€4.2	€1.5	€1.2	€1.5	€0.9	€0.9	€1.3	€0.3	€17.1
Others include: Idoman, Olympus, Thermablate, etc.											
Source: iData Research Inc.											

Chart 6-8: Projected Leading Competitors, Global Endometrial Ablation Market, Europe, 2016



Source: iData Research Inc.

7

ENDOMETRIAL RESECTION DEVICE MARKET

7.1 INTRODUCTION

While global endometrial ablation is a popular treatment for menorrhagia, another common treatment is endometrial resection. This is performed as a hysteroscopic procedure and uses a resectoscope and an electrosurgical loop electrode to remove the endometrial lining. This procedure is done as an alternative to a hysterectomy for treatment of menorrhagia or heavy bleeding. Heavy bleeding is sometimes referred to as 80mL or more per menstrual cycle, which can interfere with a woman's daily life. Endometrial resection is appropriate for women who have pure menorrhagia but no other additional abnormalities, such as endometriosis, endometrial hyperplasia or very large or rapidly growing fibroids. Many patients of endometrial resection, in addition to having a reduction of menorrhagia symptoms, also experience a reduction in other symptoms related to premenstrual syndrome (PMS).

Before the procedure, the cervix is dilated, and the cavity is inspected for any abnormalities. The procedure can range anywhere from 20 minutes to one hour, depending on the size of the cavity and if there are any endometrial polyps or fibroids present that also need to be removed. While the risk of complications is less with endometrial resection than with a hysterectomy, the failure rate is higher; up to 20% of cases still have bleeding heavy enough to require further treatment. This technique requires a significant amount of skill and experience to perform safely. The procedure has risks as significant as major surgery, including infertility.

In resection, standard electricity is modified to create high-frequency electrosurgical energy that has the ability to cut or coagulate tissue. This electrosurgical current is passed through the resectoscope into an attached electrode and either causes a vaporization (cutting) or coagulation of the endometrial lining.

The uterine cavity is distended with fluid to allow for visualization and adequate room for the resection tools.

7.1.1 Resectoscopes

A resectoscope is a type of endoscope with a wide-angle scope that also contains an electrosurgical element for fibroid tissue removal. In addition to gynecological applications, a resectoscope can be used to examine and remove tissues from the prostate or bladder.

7.1.2 Monopolar Electrodes

Traditionally, resections were performed using monopolar electrodes. In a monopolar electrode, current travels through the patient. Therefore, in this procedure, the uterine cavity must be filled with a non-electrolytic solution. A current that travels through the patient can cause complications such as unwanted muscle contraction or skin burns. If too much of the non-electrolytic solution is absorbed by the patient, this could cause hyponatremia: an imbalance in the electrolytes of the patient's blood.

7.1.3 Bipolar Electrodes

Bipolar electrodes are safer than monopolar electrodes, as the current enters and leaves the patient through the same device via the active and return electrodes; the current does not travel through the patient. It is also a safer technology because the uterine cavity is distended using an isotonic solution (such as glycine or saline), which does not cause imbalances in the patient's blood when absorbed. This technique is the current standard of care, even though it is a more expensive procedure.

7.1.4 Electrosurgical Rollerball

Rollerball endometrial ablation uses a heated ball to burn the endometrium under direct visualization with a hysteroscope. The roller-ball or cylinder-tipped electrode emits energy, vaporizes the endometrium and is subsequently used to coagulate the lining of the uterus. The technique is relatively easy to learn, but the procedure can be very time consuming, taking up to 45 minutes. It is a same-day surgical procedure and is done under general anesthesia.

7.2 MARKET OVERVIEW

The prevailing market trend for endometrial resection has been a sharp transition from monopolar loop electrodes to bipolar loop electrodes, moving from an average of 64% total sales being monopolar in 2012 to only 26% in 2015. The shift is being driven by patient safety and an overall decrease in the number of procedures being performed. As patients are opting for alternative treatment options, the remaining procedures being performed of endometrial resection are utilizing the superior method of bipolar loop electrodes. Overall the total number of monopolar and bipolar loop electrode units sold are experiencing a modest decline of -0.36% from 2014 to 2015 following a similar trend throughout the reporting period.

Electrosurgical rollerballs are often used in conjunction with endometrial loop electrodes. Italy and Spain have the highest unit numbers sold per year, using one electrosurgical rollerball unit per every three to four patients treated. In contrast, France and the Scandinavia region have the lowest sales, only using one electrosurgical rollerball for one to two out of every ten patients treated.

The resectoscope market unit sales are deceptively positive with a neutral growth despite the decline in the number of procedures being performed. This is because the resectoscope market is a replacement market, with current sales replacing monopolar resectoscopes and upgrading to purchase bipolar resectoscopes. The future trend is a stable to modest decline in sales as fewer endometrial resection procedures are performed.

Figure 7-1: Endometrial Resection Device Market by Segment, Europe, 2012 – 2022 (€M)

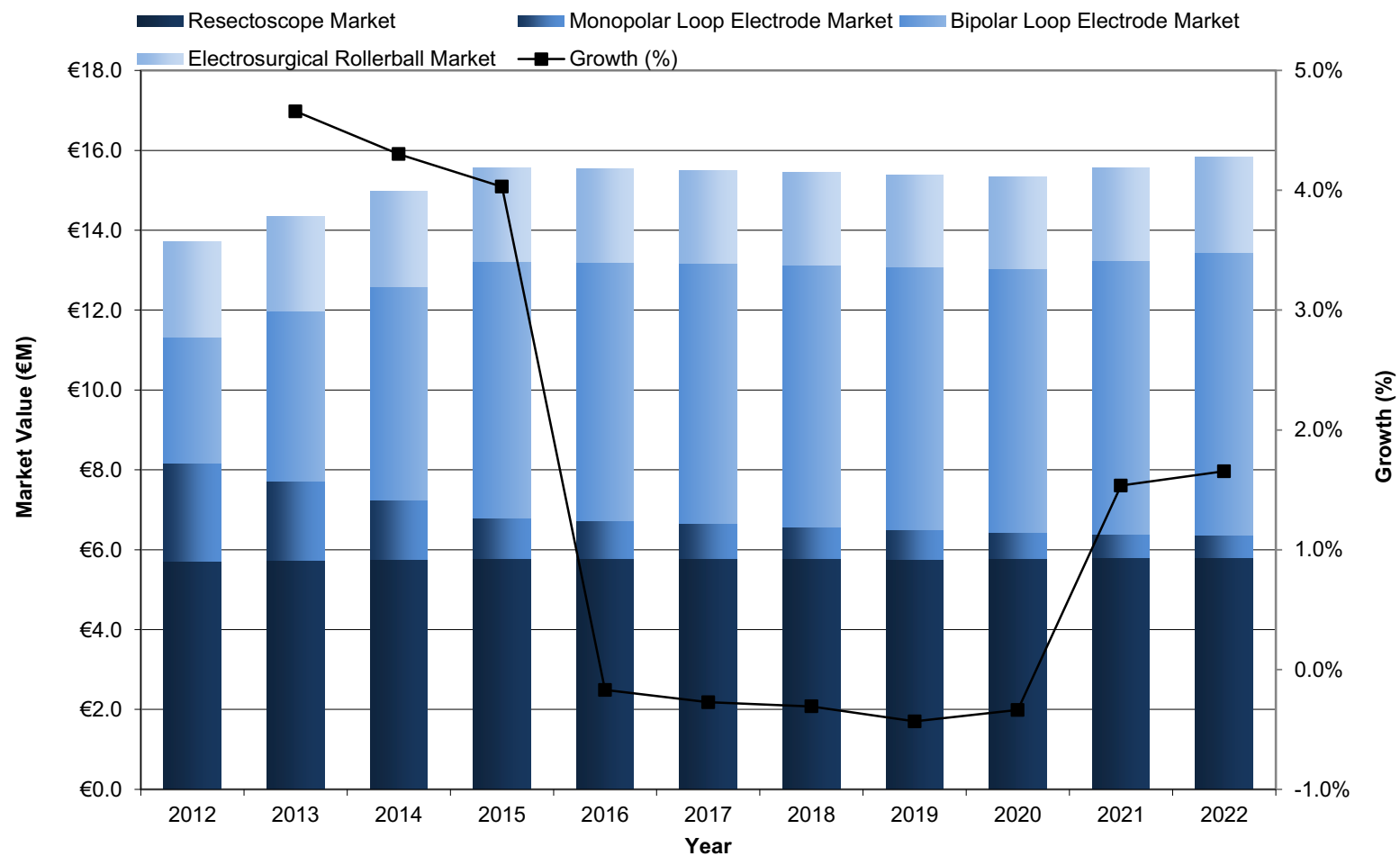
Year	Resectoscope Market	Monopolar Loop Electrode Device Market	Bipolar Loop Electrode Device Market	Electrosurgical Rollerball Device Market	Total Market	Growth (%)
2012	€5.71	€2.47	€3.14	€2.39	€13.71	
2013	€5.73	€1.98	€4.26	€2.38	€14.35	4.7%
2014	€5.75	€1.50	€5.35	€2.37	€14.97	4.3%
2015	€5.78	€1.02	€6.41	€2.36	€15.57	4.0%
2016	€5.78	€0.94	€6.47	€2.34	€15.54	-0.2%
2017	€5.78	€0.87	€6.52	€2.33	€15.50	-0.3%
2018	€5.78	€0.79	€6.56	€2.32	€15.45	-0.3%
2019	€5.77	€0.72	€6.59	€2.30	€15.39	-0.4%
2020	€5.79	€0.64	€6.61	€2.29	€15.33	-0.3%
2021	€5.80	€0.59	€6.84	€2.33	€15.57	1.5%
2022	€5.80	€0.55	€7.09	€2.38	€15.83	1.7%
CAGR ('15-'22)	0.1%	-8.4%	1.4%	0.2%		0.2%

Source: iData Research Inc.

Figure 7-2: Endometrial Resection Device Market by Segment, Europe, 2012 – 2022 (US\$M)

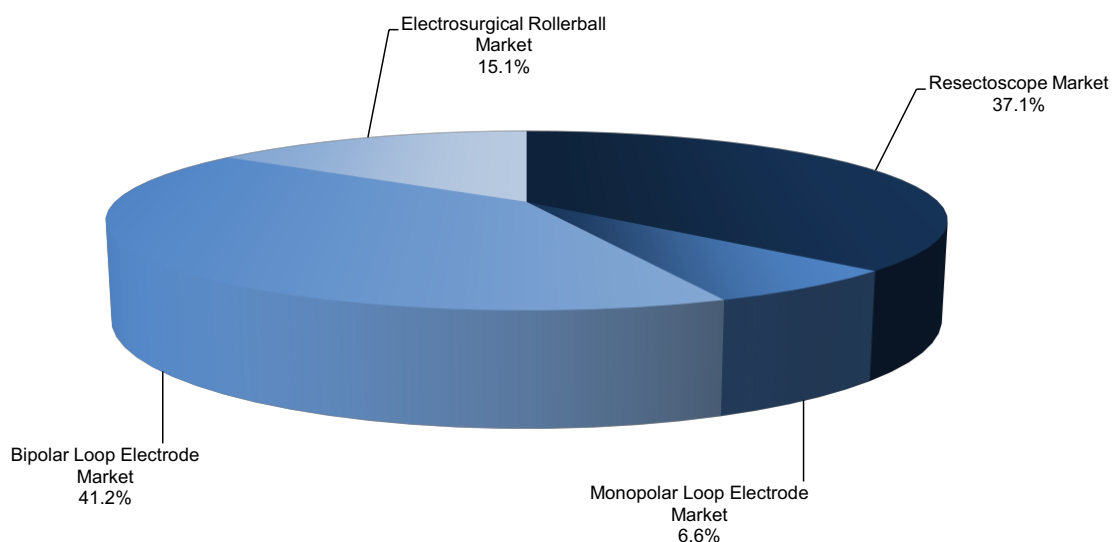
Year	Resectoscope Market	Monopolar Loop Electrode Device Market	Bipolar Loop Electrode Device Market	Electrosurgical Rollerball Device Market	Total Market	Growth (%)
2012	\$6.31	\$2.73	\$3.48	\$2.64	\$15.16	
2013	\$6.33	\$2.19	\$4.71	\$2.63	\$15.86	4.7%
2014	\$6.36	\$1.66	\$5.91	\$2.62	\$16.55	4.3%
2015	\$6.39	\$1.13	\$7.09	\$2.61	\$17.21	4.0%
2016	\$6.39	\$1.04	\$7.16	\$2.59	\$17.18	-0.2%
2017	\$6.39	\$0.96	\$7.21	\$2.58	\$17.14	-0.3%
2018	\$6.39	\$0.88	\$7.26	\$2.56	\$17.08	-0.3%
2019	\$6.38	\$0.79	\$7.29	\$2.55	\$17.01	-0.4%
2020	\$6.40	\$0.71	\$7.31	\$2.53	\$16.95	-0.3%
2021	\$6.41	\$0.66	\$7.57	\$2.58	\$17.21	1.5%
2022	\$6.42	\$0.61	\$7.84	\$2.64	\$17.50	1.7%
CAGR (‘15–’22)	0.1%	-8.4%	1.4%	0.2%		0.2%

Source: iData Research Inc.

Chart 7-1: Endometrial Resection Device Market by Segment, Europe, 2015

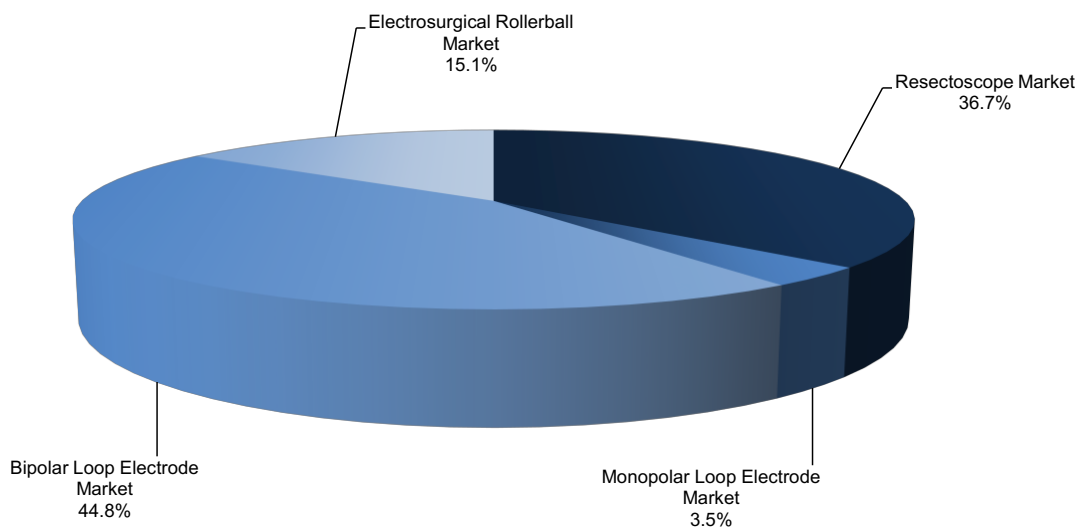
Source: iData Research Inc.

Chart 7-2: Endometrial Resection Device Market Breakdown, Europe, 2015



Source: iData Research Inc.

Chart 7-3: Endometrial Resection Device Market Breakdown, Europe, 2022



Source: iData Research Inc.

7.3 MARKET ANALYSIS AND FORECAST

7.3.1 Resectoscope Market

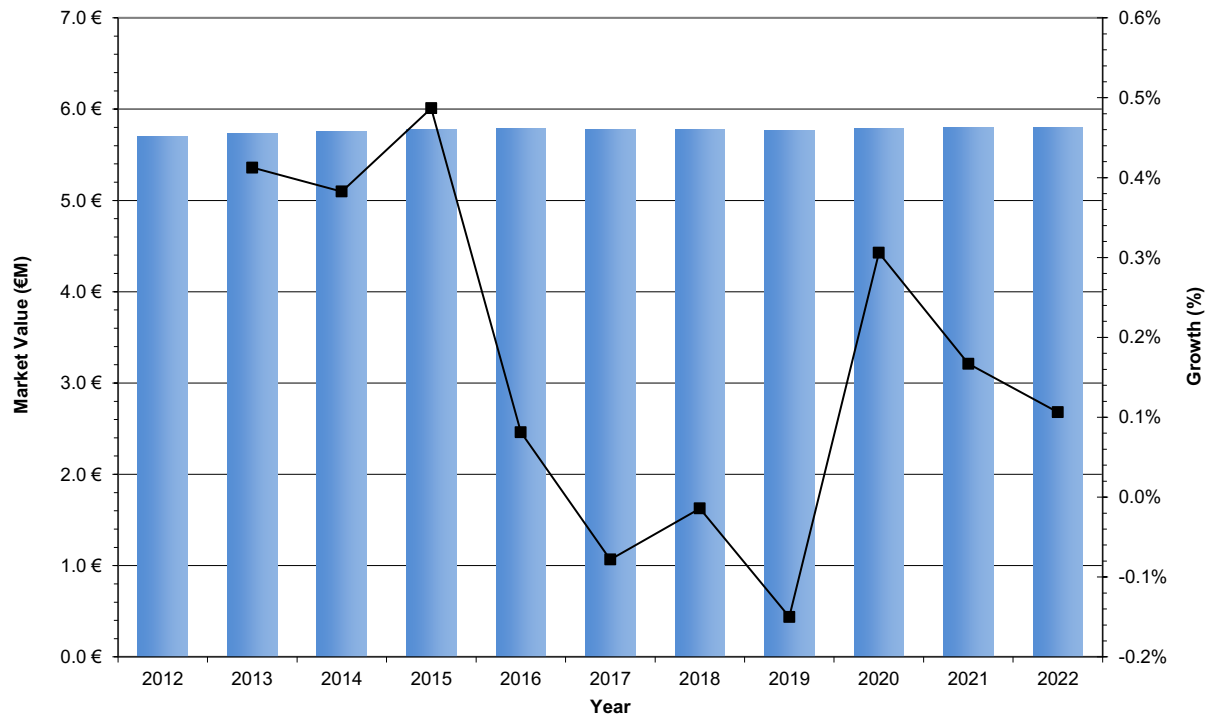
The European resectoscope market as a whole is stable, with a consistent market value of €5.78M. The growth of the market varies by country with inconsistent patterns both in sales and ASP. The consistent market trend is that all segments in the endometrial resection device market are being limited by endometrial ablation devices, as they treat the same or similar conditions.

Few gynecologists have been trained to use resectoscopes. The skill and training required to perform this procedure limits the amount of potential purchasers and thus limits the sales. In Europe, the training varies significantly by country. For example, Italy has exemplary training with an above average number of doctors able to perform endometrial resection while Germany tends to prefer endometrial ablation procedures with a much smaller emphasis on resectoscope training and resection procedures.

Figure 7-3: Resectoscope Market, Europe, 2012 – 2022 (€ and US\$)

Year	Units Sold	Growth (%)	ASP (€)	ASP (US\$)	Growth (%)	Market Value (€M)	Market Value (US\$M)	Growth (%)
2012	1,406		€4,058	\$4,486		€5.71	\$6.31	
2013	1,411	0.4%	€4,060	\$4,489	0.1%	€5.73	\$6.33	0.4%
2014	1,415	0.3%	€4,064	\$4,493	0.1%	€5.75	\$6.36	0.4%
2015	1,421	0.4%	€4,068	\$4,497	0.1%	€5.78	\$6.39	0.5%
2016	1,420	0.0%	€4,073	\$4,503	0.1%	€5.78	\$6.39	0.1%
2017	1,418	-0.1%	€4,075	\$4,506	0.1%	€5.78	\$6.39	-0.1%
2018	1,417	-0.1%	€4,078	\$4,508	0.1%	€5.78	\$6.39	0.0%
2019	1,415	-0.1%	€4,077	\$4,508	0.0%	€5.77	\$6.38	-0.1%
2020	1,420	0.4%	€4,075	\$4,506	0.0%	€5.79	\$6.40	0.3%
2021	1,423	0.2%	€4,073	\$4,504	0.0%	€5.80	\$6.41	0.2%
2022	1,425	0.1%	€4,072	\$4,502	0.0%	€5.80	\$6.42	0.1%
CAGR ('15-'22)		0.0%			0.0%			0.1%

Source: iData Research Inc.

Chart 7-4: Resectoscope Market, Europe, 2012 – 2022

Source: iData Research Inc.

Figure 7-4: Units Sold by Country, Resectoscope Market, Europe, 2012 – 2022

Year	Germany	France	U.K.	Italy	Spain	Benelux	Scandi- navia	Austria	Switzer- land	Portugal	Europe	Growth (%)
2012	285	216	224	213	168	119	93	30	30	26		
2013	285	217	225	214	168	118	93	30	30	26	1,406	
2014	284	218	226	215	169	119	92	30	31	27	1,411	0.4%
2015	283	218	227	217	170	120	91	29	32	28	1,415	0.3%
2016	283	219	228	218	170	121	91	29	33	28	1,421	0.4%
2017	281	220	229	218	171	121	90	28	33	29	1,420	0.0%
2018	280	220	230	219	171	120	89	27	33	29	1,418	-0.1%
2019	280	221	231	220	170	119	88	26	33	29	1,417	-0.1%
2020	278	222	232	220	170	118	87	26	34	28	1,415	-0.1%
2021	279	222	233	221	171	118	86	27	34	29	1,420	0.4%
2022	279	221	234	222	172	117	87	26	35	30	1,423	0.2%
	278	222	235	222	173	117	87	26	35	30	1,425	0.1%
CAGR (‘15–’22)												
Source: iData Research Inc.												

Figure 7-5: Average Selling Price by Country, Resectoscope Market, Europe, 2012 – 2022 (€)

Year	Germany	France	U.K.	Italy	Spain	Benelux	Scandi- navia	Austria	Switzer- land	Portugal	Europe	Growth (%)
2012	€3,543	€4,154	€4,303	€4,242	€3,939	€4,334	€4,318	€4,031	€4,128	€3,789	€4,058	
2013	€3,550	€4,150	€4,305	€4,241	€3,947	€4,332	€4,316	€4,032	€4,129	€3,796	€4,060	0.1%
2014	€3,561	€4,148	€4,308	€4,240	€3,959	€4,329	€4,314	€4,034	€4,131	€3,808	€4,064	0.1%
2015	€3,571	€4,143	€4,308	€4,239	€3,970	€4,327	€4,312	€4,038	€4,135	€3,819	€4,068	0.1%
2016	€3,585	€4,141	€4,310	€4,238	€3,986	€4,325	€4,310	€4,042	€4,139	€3,834	€4,073	0.1%
2017	€3,593	€4,139	€4,312	€4,237	€3,994	€4,323	€4,308	€4,046	€4,144	€3,842	€4,075	0.1%
2018	€3,603	€4,137	€4,313	€4,236	€3,998	€4,321	€4,306	€4,050	€4,148	€3,846	€4,078	0.1%
2019	€3,603	€4,135	€4,314	€4,235	€3,993	€4,319	€4,303	€4,054	€4,152	€3,841	€4,077	0.0%
2020	€3,602	€4,133	€4,314	€4,234	€3,991	€4,316	€4,301	€4,053	€4,151	€3,839	€4,075	0.0%
2021	€3,600	€4,131	€4,312	€4,233	€3,989	€4,314	€4,299	€4,051	€4,149	€3,838	€4,073	0.0%
2022	€3,598	€4,129	€4,310	€4,232	€3,987	€4,312	€4,297	€4,049	€4,147	€3,836	€4,072	0.0%
CAGR (‘15–’22)	0.1%	0.0%	0.0%	0.0%	0.1%	0.0%	0.0%	0.0%	0.0%	0.1%		0.0%

Source: iData Research Inc.

Figure 7-6: Average Selling Price by Country, Resectoscope Market, Europe, 2012 – 2022 (US\$)

Year	Germany	France	U.K.	Italy	Spain	Benelux	Scandi- navia	Austria	Switzer- land	Portugal	Europe	Growth (%)
2012	\$3,917	\$4,592	\$4,758	\$4,690	\$4,355	\$4,791	\$4,775	\$4,457	\$4,564	\$4,189	\$4,486	
2013	\$3,925	\$4,588	\$4,760	\$4,689	\$4,363	\$4,789	\$4,772	\$4,458	\$4,565	\$4,197	\$4,489	0.1%
2014	\$3,936	\$4,586	\$4,762	\$4,688	\$4,377	\$4,787	\$4,770	\$4,460	\$4,567	\$4,210	\$4,493	0.1%
2015	\$3,948	\$4,581	\$4,762	\$4,687	\$4,390	\$4,784	\$4,767	\$4,464	\$4,572	\$4,223	\$4,497	0.1%
2016	\$3,964	\$4,579	\$4,765	\$4,685	\$4,407	\$4,782	\$4,765	\$4,469	\$4,577	\$4,239	\$4,503	0.1%
2017	\$3,972	\$4,576	\$4,767	\$4,684	\$4,416	\$4,779	\$4,763	\$4,473	\$4,581	\$4,248	\$4,506	0.1%
2018	\$3,984	\$4,574	\$4,768	\$4,683	\$4,420	\$4,777	\$4,760	\$4,478	\$4,586	\$4,252	\$4,508	0.1%
2019	\$3,984	\$4,572	\$4,770	\$4,682	\$4,415	\$4,775	\$4,758	\$4,482	\$4,590	\$4,247	\$4,508	0.0%
2020	\$3,982	\$4,570	\$4,770	\$4,681	\$4,413	\$4,772	\$4,755	\$4,481	\$4,589	\$4,245	\$4,506	0.0%
2021	\$3,980	\$4,567	\$4,767	\$4,680	\$4,411	\$4,770	\$4,753	\$4,479	\$4,587	\$4,243	\$4,504	0.0%
2022	\$3,978	\$4,565	\$4,765	\$4,678	\$4,409	\$4,768	\$4,751	\$4,477	\$4,585	\$4,241	\$4,502	0.0%
CAGR (‘15–’22)	0.1%	0.0%	0.0%	0.0%	0.1%	0.0%	0.0%	0.0%	0.0%	0.1%		0.0%

Source: iData Research Inc.

Figure 7-7: Market Value by Country, Resectoscope Market, Europe, 2012 – 2022 (€M)

Year	Germany	France	U.K.	Italy	Spain	Benelux	Scandi- navia	Austria	Switzer- land	Portugal	Europe	Growth (%)
2012	€1.01	€0.90	€0.97	€0.91	€0.66	€0.51	€0.40	€0.12	€0.12	€0.10	€5.71	
2013	€1.01	€0.90	€0.97	€0.91	€0.67	€0.52	€0.40	€0.12	€0.13	€0.10	€5.73	0.4%
2014	€1.01	€0.90	€0.98	€0.92	€0.67	€0.52	€0.39	€0.12	€0.13	€0.11	€5.75	0.4%
2015	€1.01	€0.91	€0.98	€0.92	€0.67	€0.52	€0.39	€0.12	€0.14	€0.11	€5.78	0.5%
2016	€1.01	€0.91	€0.99	€0.92	€0.68	€0.52	€0.39	€0.11	€0.14	€0.11	€5.78	0.1%
2017	€1.01	€0.91	€0.99	€0.93	€0.68	€0.52	€0.38	€0.11	€0.14	€0.11	€5.78	-0.1%
2018	€1.01	€0.91	€1.00	€0.93	€0.68	€0.51	€0.38	€0.11	€0.14	€0.11	€5.78	0.0%
2019	€1.00	€0.92	€1.00	€0.93	€0.68	€0.51	€0.37	€0.11	€0.14	€0.11	€5.77	-0.1%
2020	€1.00	€0.92	€1.01	€0.94	€0.68	€0.51	€0.37	€0.11	€0.14	€0.11	€5.79	0.3%
2021	€1.00	€0.91	€1.01	€0.94	€0.69	€0.50	€0.37	€0.11	€0.15	€0.12	€5.80	0.2%
2022	€1.00	€0.92	€1.01	€0.94	€0.69	€0.50	€0.37	€0.11	€0.15	€0.12	€5.80	0.1%
CAGR (‘15–’22)	-0.1%	0.1%	0.4%	0.2%	0.3%	-0.5%	-0.8%	-1.7%	0.9%	1.1%		0.1%

Source: iData Research Inc.

Figure 7-8: Market Value by Country, Resectoscope Market, Europe, 2012 – 2022 (US\$M)

Year	Germany	France	U.K.	Italy	Spain	Benelux	Scandi- navia	Austria	Switzer- land	Portugal	Europe	Growth (%)
2012	\$1.12	\$1.00	\$1.07	\$1.00	\$0.73	\$0.57	\$0.44	\$0.13	\$0.14	\$0.11	\$6.31	
2013	\$1.11	\$1.00	\$1.08	\$1.01	\$0.74	\$0.57	\$0.44	\$0.13	\$0.14	\$0.11	\$6.33	0.4%
2014	\$1.11	\$1.00	\$1.08	\$1.02	\$0.74	\$0.57	\$0.43	\$0.13	\$0.15	\$0.12	\$6.36	0.4%
2015	\$1.12	\$1.00	\$1.09	\$1.02	\$0.75	\$0.58	\$0.44	\$0.13	\$0.15	\$0.12	\$6.39	0.5%
2016	\$1.11	\$1.01	\$1.09	\$1.02	\$0.75	\$0.58	\$0.43	\$0.13	\$0.15	\$0.12	\$6.39	0.1%
2017	\$1.11	\$1.01	\$1.10	\$1.03	\$0.76	\$0.57	\$0.42	\$0.12	\$0.15	\$0.12	\$6.39	-0.1%
2018	\$1.12	\$1.01	\$1.10	\$1.03	\$0.75	\$0.57	\$0.42	\$0.12	\$0.15	\$0.12	\$6.39	0.0%
2019	\$1.11	\$1.01	\$1.11	\$1.03	\$0.75	\$0.56	\$0.41	\$0.12	\$0.16	\$0.12	\$6.38	-0.1%
2020	\$1.11	\$1.01	\$1.11	\$1.03	\$0.75	\$0.56	\$0.41	\$0.12	\$0.16	\$0.12	\$6.40	0.3%
2021	\$1.11	\$1.01	\$1.12	\$1.04	\$0.76	\$0.56	\$0.41	\$0.12	\$0.16	\$0.13	\$6.41	0.2%
2022	\$1.11	\$1.01	\$1.12	\$1.04	\$0.76	\$0.56	\$0.41	\$0.12	\$0.16	\$0.13	\$6.42	0.1%
CAGR (‘15–’22)	-0.1%	0.1%	0.4%	0.2%	0.3%	-0.5%	-0.8%	-1.7%	0.9%	1.1%		0.1%

Source: iData Research Inc.

7.3.2 Monopolar Loop Electrode Device Market

The decline of this market is due to cannibalization by bipolar electrodes, which many physicians prefer. Adoption of bipolar devices as a replacement for monopolar devices is expected to continue throughout the forecast period. Despite being a less expensive procedure, use of monopolar electrodes is less safe than bipolar electrodes, prompting practitioner movement away from the use of monopolar electrode devices.

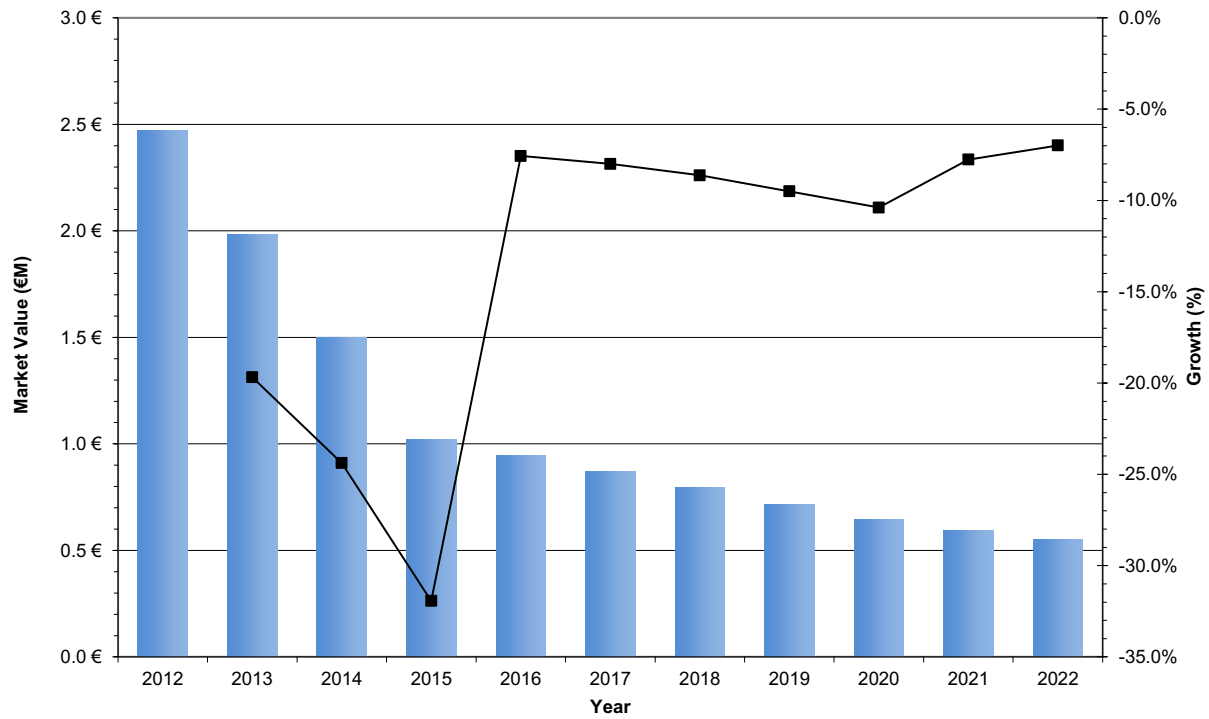
Unit sales are declining both due to the increase of bipolar electrodes as well as the decrease in the use of endometrial resection devices overall. The strong decline in unit sales is also generating a slight downward pressure on ASP, leading to a monopolar loop electrode market that is declining rapidly.

Figure 7-9: Monopolar Loop Electrode Market, Europe, 2012 – 2022 (€ and US\$)

Year	Units Sold	Growth (%)	ASP (€)	ASP (US\$)	Growth (%)	Market Value (€M)	Market Value (US\$M)	Growth (%)
2012	57,907		€43	\$47		€2.5	\$2.7	
2013	46,524	-19.7%	€43	\$47	0.0%	€2.0	\$2.2	-19.7%
2014	35,141	-24.5%	€43 r	\$47	0.1%	€1.5	\$1.7	-24.4%
2015	23,756	-32.4%	€43	\$48	0.7%	€1.0	\$1.1	-31.9%
2016	22,070	-7.1%	€43	\$47	-0.5%	€0.9	\$1.0	-7.6%
2017	20,383	-7.6%	€43	\$47	-0.4%	€0.9	\$1.0	-8.0%
2018	18,697	-8.3%	€42	\$47	-0.4%	€0.8	\$0.9	-8.6%
2019	17,011	-9.0%	€42	\$47	-0.5%	€0.7	\$0.8	-9.5%
2020	15,324	-9.9%	€42	\$46	-0.5%	€0.6	\$0.7	-10.4%
2021	14,226	-7.2%	€42	\$46	-0.6%	€0.6	\$0.7	-7.8%
2022	13,332	-6.3%	€41	\$46	-0.7%	€0.6	\$0.6	-7.0%
CAGR ('15-'22)		-7.9%			-0.5%			-8.4%

Source: iData Research Inc.

Chart 7-5: Monopolar Loop Electrode Market, Europe, 2012 – 2022



Source: iData Research Inc.

Figure 7-10: Units Sold by Country, Monopolar Loop Electrode Market, Europe, 2012 – 2022

Year	Germany	France	U.K.	Italy	Spain	Benelux	Scandi- navia	Austria	Switzer- land	Portugal	Europe	Growth (%)
2012	10,740	9,209	5,923	6,393	5,873	7,473	6,235	1,857	2,187	2,017	57,907	
2013	8,255	7,641	5,729	4,790	4,921	5,814	4,540	1,464	1,744	1,626	46,524	-19.7%
2014	5,770	6,073	5,535	3,187	3,969	4,155	2,845	1,071	1,301	1,235	35,141	-24.5%
2015	3,284	4,505	5,340	1,585	3,016	2,495	1,151	678	859	843	23,756	-32.4%
2016	3,140	4,045	5,067	1,485	2,648	2,354	1,097	624	823	786	22,070	-7.1%
2017	2,996	3,585	4,794	1,385	2,280	2,213	1,043	571	787	729	20,383	-7.6%
2018	2,852	3,125	4,521	1,285	1,912	2,072	990	517	752	672	18,697	-8.3%
2019	2,708	2,665	4,248	1,185	1,544	1,931	936	464	716	615	17,011	-9.0%
2020	2,564	2,205	3,974	1,086	1,176	1,789	882	410	680	557	15,324	-9.9%
2021	2,436	1,985	3,696	1,032	1,000	1,700	847	373	646	512	14,226	-7.2%
2022	2,314	1,786	3,419	1,001	920	1,615	821	354	621	481	13,332	-6.3%
CAGR (‘15–’22)	-4.9%	-12.4%	-6.2%	-6.4%	-15.6%	-6.0%	-4.7%	-8.9%	-4.5%	-7.7%		-7.9%

Source: iData Research Inc.

Figure 7-11: Average Selling Price by Country, Monopolar Loop Electrode Market, Europe, 2012 – 2022 (€)

Year	Germany	France	U.K.	Italy	Spain	Benelux	Scandi- navia	Austria	Switzer- land	Portugal	Europe	Growth (%)
2012	€38.89	€42.00	€53.04	€46.93	€38.29	€42.04	€43.69	€39.46	€41.11	€38.34	€42.67	
2013	€38.77	€41.79	€52.77	€46.46	€38.19	€41.83	€43.47	€39.33	€41.11	€38.23	€42.65	0.0%
2014	€38.65	€41.59	€52.24	€46.23	€38.10	€41.41	€43.04	€39.20	€41.11	€38.11	€42.70	0.1%
2015	€38.50	€41.38	€51.72	€46.00	€38.00	€41.00	€42.39	€39.00	€40.91	€38.00	€42.99	0.7%
2016	€38.33	€41.17	€51.20	€45.77	€37.91	€40.69	€41.97	€38.81	€40.70	€37.89	€42.77	-0.5%
2017	€38.14	€41.05	€50.69	€45.77	€37.81	€40.49	€41.76	€38.61	€40.30	€37.77	€42.61	-0.4%
2018	€38.33	€40.92	€49.93	€45.77	€37.72	€40.29	€41.55	€38.34	€39.89	€37.66	€42.44	-0.4%
2019	€38.06	€40.80	€49.18	€45.54	€37.62	€40.17	€41.34	€38.07	€39.69	€37.55	€42.22	-0.5%
2020	€37.79	€40.70	€48.44	€45.09	€37.53	€40.09	€41.22	€37.81	€39.50	€37.43	€42.00	-0.5%
2021	€38.07	€40.60	€47.47	€44.63	€37.43	€40.01	€41.10	€37.54	€39.38	€37.32	€41.73	-0.6%
2022	€38.36	€40.52	€46.53	€43.97	€37.34	€39.93	€40.97	€37.28	€39.26	€37.21	€41.42	-0.7%
CAGR (‘15–’22)	-0.1%	-0.3%	-1.5%	-0.6%	-0.2%	-0.4%	-0.5%	-0.6%	-0.6%	-0.3%		-0.5%

Source: iData Research Inc.

Figure 7-12: Average Selling Price by Country, Monopolar Loop Electrode Market, Europe, 2012 – 2022 (US\$)

Year	Germany	France	U.K.	Italy	Spain	Benelux	Scandi- navia	Austria	Switzer- land	Portugal	Europe	Growth (%)
2012	\$42.99	\$46.44	\$58.64	\$51.89	\$42.33	\$46.48	\$48.31	\$43.62	\$45.46	\$42.39	\$47.17	
2013	\$42.87	\$46.21	\$58.34	\$51.37	\$42.22	\$46.25	\$48.06	\$43.48	\$45.46	\$42.27	\$47.15	0.0%
2014	\$42.74	\$45.98	\$57.76	\$51.11	\$42.12	\$45.79	\$47.58	\$43.34	\$45.46	\$42.14	\$47.20	0.1%
2015	\$42.57	\$45.75	\$57.18	\$50.86	\$42.01	\$45.33	\$46.87	\$43.12	\$45.23	\$42.01	\$47.53	0.7%
2016	\$42.37	\$45.52	\$56.61	\$50.60	\$41.91	\$44.99	\$46.40	\$42.90	\$45.00	\$41.89	\$47.29	-0.5%
2017	\$42.16	\$45.38	\$56.04	\$50.60	\$41.80	\$44.76	\$46.17	\$42.69	\$44.55	\$41.76	\$47.11	-0.4%
2018	\$42.37	\$45.25	\$55.20	\$50.60	\$41.70	\$44.54	\$45.94	\$42.39	\$44.11	\$41.64	\$46.92	-0.4%
2019	\$42.08	\$45.11	\$54.38	\$50.35	\$41.59	\$44.41	\$45.71	\$42.09	\$43.89	\$41.51	\$46.68	-0.5%
2020	\$41.78	\$45.00	\$53.56	\$49.85	\$41.49	\$44.32	\$45.57	\$41.80	\$43.67	\$41.39	\$46.43	-0.5%
2021	\$42.10	\$44.89	\$52.49	\$49.35	\$41.39	\$44.23	\$45.43	\$41.51	\$43.54	\$41.26	\$46.13	-0.6%
2022	\$42.41	\$44.80	\$51.44	\$48.61	\$41.28	\$44.14	\$45.30	\$41.21	\$43.41	\$41.14	\$45.79	-0.7%
CAGR (‘15–’22)	-0.1%	-0.3%	-1.5%	-0.6%	-0.2%	-0.4%	-0.5%	-0.6%	-0.6%	-0.3%		-0.5%

Source: iData Research Inc.

Figure 7-13: Market Value by Country, Monopolar Loop Electrode Market, Europe, 2012 – 2022 (€M)

Year	Germany	France	U.K.	Italy	Spain	Benelux	Scandi- navia	Austria	Switzer- land	Portugal	Europe	Growth (%)
2012	€0.42	€0.39	€0.31	€0.30	€0.22	€0.31	€0.27	€0.07	€0.09	€0.08	€2.47	
2013	€0.32	€0.32	€0.30	€0.22	€0.19	€0.24	€0.20	€0.06	€0.07	€0.06	€1.98	-19.7%
2014	€0.22	€0.25	€0.29	€0.15	€0.15	€0.17	€0.12	€0.04	€0.05	€0.05	€1.50	-24.4%
2015	€0.13	€0.19	€0.28	€0.07	€0.11	€0.10	€0.05	€0.03	€0.04	€0.03	€1.02	-31.9%
2016	€0.12	€0.17	€0.26	€0.07	€0.10	€0.10	€0.05	€0.02	€0.03	€0.03	€0.94	-7.6%
2017	€0.11	€0.15	€0.24	€0.06	€0.09	€0.09	€0.04	€0.02	€0.03	€0.03	€0.87	-8.0%
2018	€0.11	€0.13	€0.23	€0.06	€0.07	€0.08	€0.04	€0.02	€0.03	€0.03	€0.79	-8.6%
2019	€0.10	€0.11	€0.21	€0.05	€0.06	€0.08	€0.04	€0.02	€0.03	€0.02	€0.72	-9.5%
2020	€0.10	€0.09	€0.19	€0.05	€0.04	€0.07	€0.04	€0.02	€0.03	€0.02	€0.64	-10.4%
2021	€0.09	€0.08	€0.18	€0.05	€0.04	€0.07	€0.03	€0.01	€0.03	€0.02	€0.59	-7.8%
2022	€0.09	€0.07	€0.16	€0.04	€0.03	€0.06	€0.03	€0.01	€0.02	€0.02	€0.55	-7.0%
CAGR (‘15–’22)	-4.9%	-12.6%	-7.6%	-7.0%	-15.8%	-6.4%	-5.2%	-9.4%	-5.1%	-8.0%		-8.4%

Source: iData Research Inc.

Figure 7-14: Market Value by Country, Monopolar Loop Electrode Market, Europe, 2012 – 2022 (US\$M)

Year	Germany	France	U.K.	Italy	Spain	Benelux	Scandi- navia	Austria	Switzer- land	Portugal	Europe	Growth (%)
2012	\$0.46	\$0.43	\$0.35	\$0.33	\$0.25	\$0.35	\$0.30	\$0.08	\$0.10	\$0.09	\$2.73	
2013	\$0.35	\$0.35	\$0.33	\$0.25	\$0.21	\$0.27	\$0.22	\$0.06	\$0.08	\$0.07	\$2.19	-19.7%
2014	\$0.25	\$0.28	\$0.32	\$0.16	\$0.17	\$0.19	\$0.14	\$0.05	\$0.06	\$0.05	\$1.66	-24.4%
2015	\$0.14	\$0.21	\$0.31	\$0.08	\$0.13	\$0.11	\$0.05	\$0.03	\$0.04	\$0.04	\$1.13	-31.9%
2016	\$0.13	\$0.18	\$0.29	\$0.08	\$0.11	\$0.11	\$0.05	\$0.03	\$0.04	\$0.03	\$1.04	-7.6%
2017	\$0.13	\$0.16	\$0.27	\$0.07	\$0.10	\$0.10	\$0.05	\$0.02	\$0.04	\$0.03	\$0.96	-8.0%
2018	\$0.12	\$0.14	\$0.25	\$0.07	\$0.08	\$0.09	\$0.05	\$0.02	\$0.03	\$0.03	\$0.88	-8.6%
2019	\$0.11	\$0.12	\$0.23	\$0.06	\$0.06	\$0.09	\$0.04	\$0.02	\$0.03	\$0.03	\$0.79	-9.5%
2020	\$0.11	\$0.10	\$0.21	\$0.05	\$0.05	\$0.08	\$0.04	\$0.02	\$0.03	\$0.02	\$0.71	-10.4%
2021	\$0.10	\$0.09	\$0.19	\$0.05	\$0.04	\$0.08	\$0.04	\$0.02	\$0.03	\$0.02	\$0.66	-7.8%
2022	\$0.10	\$0.08	\$0.18	\$0.05	\$0.04	\$0.07	\$0.04	\$0.01	\$0.03	\$0.02	\$0.61	-7.0%
CAGR (‘15–’22)	-4.9%	-12.6%	-7.6%	-7.0%	-15.8%	-6.4%	-5.2%	-9.4%	-5.1%	-8.0%		-8.4%
Source: iData Research Inc.												

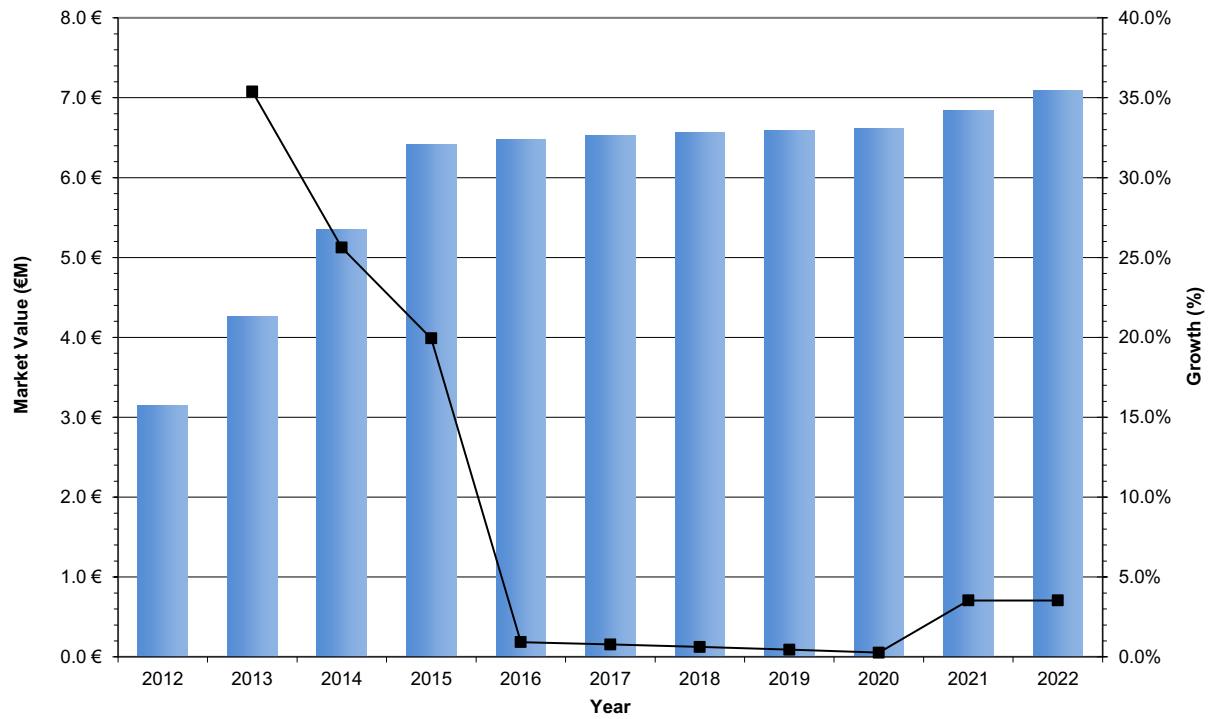
7.3.3 Bipolar Loop Electrode Device Market

Bipolar loop electrodes are the strongest growing segment in the endometrial resection device market, with continuing growth projected throughout the reporting period. Unit sales growth is due to both procedural growth as well as the cannibalization of the monopolar loop electrode device market. Despite the slight decline in ASP, the unit growth offsets the difference resulting in a modestly increasing market segment.

Figure 7-15: Bipolar Loop Electrode Market, Europe, 2012 – 2022 (€ and US\$)

Year	Units Sold	Growth (%)	ASP (€)	ASP (US\$)	Growth (%)	Market Value (€M)	Market Value (US\$M)	Growth (%)
2012	32,316		€97	\$108		€3.1	\$3.5	
2013	43,383	34.2%	€98	\$108	0.8%	€4.3	\$4.7	35.4%
2014	54,450	25.5%	€98	\$109	0.1%	€5.3	\$5.9	25.6%
2015	65,517	20.3%	€98	\$108	-0.3%	€6.4	\$7.1	19.9%
2016	66,929	2.2%	€97	\$107	-1.2%	€6.5	\$7.2	0.9%
2017	68,342	2.1%	€95	\$106	-1.3%	€6.5	\$7.2	0.8%
2018	69,754	2.1%	€94	\$104	-1.4%	€6.6	\$7.3	0.6%
2019	71,166	2.0%	€93	\$102	-1.5%	€6.6	\$7.3	0.5%
2020	72,578	2.0%	€91	\$101	-1.7%	€6.6	\$7.3	0.3%
2021	75,333	3.8%	€91	\$100	-0.3%	€6.8	\$7.6	3.5%
2022	78,185	3.8%	€91	\$100	-0.2%	€7.1	\$7.8	3.5%
CAGR ('15-'22)		2.6%			-1.1%			1.4%

Source: iData Research Inc.

Chart 7-6: Bipolar Loop Electrode Device Market, Europe, 2012 – 2022

Source: iData Research Inc.

Figure 7-16: Units Sold by Country, Bipolar Loop Electrode Market, Europe, 2012 – 2022

Year	Germany	France	U.K.	Italy	Spain	Benelux	Scandi- navia	Austria	Switzer- land	Portugal	Europe	Growth (%)
2012	6,041	6,139	2,419	5,230	4,430	2,626	2,801	587	1,178	865	32,316	
2013	8,406	7,597	2,530	7,023	5,299	4,245	4,434	972	1,645	1,232	43,383	34.2%
2014	10,771	9,055	2,641	8,816	6,168	5,864	6,067	1,357	2,112	1,599	54,450	25.5%
2015	13,136	10,513	2,751	10,608	7,036	7,484	7,700	1,743	2,578	1,968	65,517	20.3%
2016	13,201	10,910	2,996	10,684	7,354	7,617	7,748	1,794	2,607	2,019	66,929	2.2%
2017	13,266	11,307	3,240	10,759	7,672	7,751	7,795	1,846	2,635	2,071	68,342	2.1%
2018	13,331	11,704	3,485	10,835	7,990	7,884	7,843	1,897	2,664	2,123	69,754	2.1%
2019	13,397	12,101	3,729	10,910	8,308	8,017	7,890	1,948	2,693	2,174	71,166	2.0%
2020	13,462	12,498	3,974	10,986	8,625	8,150	7,937	1,999	2,722	2,226	72,578	2.0%
2021	14,135	12,897	4,252	11,755	8,935	8,289	7,985	2,053	2,752	2,280	75,333	3.8%
2022	14,842	13,297	4,533	12,577	9,248	8,429	8,033	2,109	2,782	2,335	78,185	3.8%
CAGR (‘15–’22)	1.8%	3.4%	7.4%	2.5%	4.0%	1.7%	0.6%	2.8%	1.1%	2.5%		2.6%

Source: iData Research Inc.

Figure 7-17: Average Selling Price by Country, Bipolar Loop Electrode Market, Europe, 2012 – 2022 (€)

Year	Germany	France	U.K.	Italy	Spain	Benelux	Scandi- navia	Austria	Switzer- land	Portugal	Europe	Growth (%)
2012	€87.04	€85.05	€91.93	€97.65	€82.81	€133.89	€140.01	€91.98	€102.73	€89.39	€97.29	
2013	€86.40	€84.08	€91.33	€96.84	€81.99	€133.00	€139.00	€91.35	€101.89	€88.10	€98.11	0.8%
2014	€85.71	€83.07	€90.69	€95.97	€81.09	€132.07	€137.89	€90.71	€100.97	€86.69	€98.20	0.1%
2015	€85.00	€82.00	€90.00	€95.00	€80.00	€131.13	€136.76	€90.00	€100.00	€85.00	€97.89	-0.3%
2016	€84.28	€80.87	€89.26	€93.93	€78.69	€130.18	€135.63	€89.21	€98.97	€82.98	€96.71	-1.2%
2017	€83.55	€79.67	€88.47	€92.75	€77.13	€129.21	€134.48	€88.34	€97.89	€80.58	€95.45	-1.3%
2018	€82.80	€78.41	€87.62	€91.44	€75.26	€128.24	€133.33	€87.37	€96.74	€77.74	€94.10	-1.4%
2019	€82.04	€77.08	€86.71	€90.00	€73.03	€127.26	€132.16	€86.30	€95.53	€74.40	€92.65	-1.5%
2020	€81.26	€75.68	€85.74	€88.42	€70.41	€126.26	€130.98	€85.12	€94.25	€70.50	€91.09	-1.7%
2021	€81.26	€75.68	€85.74	€88.42	€70.41	€126.26	€130.98	€85.12	€94.25	€70.50	€90.86	-0.3%
2022	€81.26	€75.68	€85.74	€88.42	€70.41	€126.26	€130.98	€85.12	€94.25	€70.50	€90.64	-0.2%
CAGR (‘15–’22)	-0.6%	-1.1%	-0.7%	-1.0%	-1.8%	-0.5%	-0.6%	-0.8%	-0.8%	-2.6%		-1.1%
Source: iData Research Inc.												

Figure 7-18: Average Selling Price by Country, Bipolar Loop Electrode Market, Europe, 2012 – 2022 (US\$)

Year	Germany	France	U.K.	Italy	Spain	Benelux	Scandi- navia	Austria	Switzer- land	Portugal	Europe	Growth (%)
2012	\$96.23	\$94.03	\$101.64	\$107.96	\$91.56	\$148.03	\$154.80	\$101.69	\$113.58	\$98.83	\$108	
2013	\$95.52	\$92.96	\$100.97	\$107.06	\$90.65	\$147.04	\$153.68	\$101.00	\$112.65	\$97.40	\$108	0.8%
2014	\$94.76	\$91.84	\$100.26	\$106.10	\$89.65	\$146.02	\$152.45	\$100.29	\$111.63	\$95.84	\$109	0.1%
2015	\$93.98	\$90.66	\$99.50	\$105.03	\$88.45	\$144.97	\$151.21	\$99.50	\$110.56	\$93.98	\$108	-0.3%
2016	\$93.18	\$89.41	\$98.69	\$103.85	\$87.00	\$143.92	\$149.95	\$98.63	\$109.42	\$91.74	\$107	-1.2%
2017	\$92.37	\$88.09	\$97.81	\$102.54	\$85.27	\$142.86	\$148.69	\$97.67	\$108.22	\$89.09	\$106	-1.3%
2018	\$91.54	\$86.69	\$96.88	\$101.10	\$83.21	\$141.78	\$147.41	\$96.60	\$106.95	\$85.95	\$104	-1.4%
2019	\$90.70	\$85.22	\$95.87	\$99.51	\$80.75	\$140.69	\$146.11	\$95.41	\$105.61	\$82.25	\$102	-1.5%
2020	\$89.84	\$83.67	\$94.80	\$97.75	\$77.84	\$139.60	\$144.81	\$94.11	\$104.20	\$77.95	\$101	-1.7%
2021	\$89.84	\$83.67	\$94.80	\$97.75	\$77.84	\$139.60	\$144.81	\$94.11	\$104.20	\$77.95	\$100	-0.3%
2022	\$89.84	\$83.67	\$94.80	\$97.75	\$77.84	\$139.60	\$144.81	\$94.11	\$104.20	\$77.95	\$100	-0.2%
CAGR (‘15–’22)	-0.6%	-1.1%	-0.7%	-1.0%	-1.8%	-0.5%	-0.6%	-0.8%	-0.8%	-2.6%		-1.1%

Source: iData Research Inc.

Figure 7-19: Market Value by Country, Bipolar Loop Electrode Market, Europe, 2012 – 2022 (€M)

Year	Germany	France	U.K.	Italy	Spain	Benelux	Scandi- navia	Austria	Switzer- land	Portugal	Europe	Growth (%)
2012	€0.53	€0.52	€0.22	€0.51	€0.37	€0.35	€0.39	€0.05	€0.12	€0.08	€3.14	
2013	€0.73	€0.64	€0.23	€0.68	€0.43	€0.56	€0.62	€0.09	€0.17	€0.11	€4.26	35.4%
2014	€0.92	€0.75	€0.24	€0.85	€0.50	€0.77	€0.84	€0.12	€0.21	€0.14	€5.35	25.6%
2015	€1.12	€0.86	€0.25	€1.01	€0.56	€0.98	€1.05	€0.16	€0.26	€0.17	€6.41	19.9%
2016	€1.11	€0.88	€0.27	€1.00	€0.58	€0.99	€1.05	€0.16	€0.26	€0.17	€6.47	0.9%
2017	€1.11	€0.90	€0.29	€1.00	€0.59	€1.00	€1.05	€0.16	€0.26	€0.17	€6.52	0.8%
2018	€1.10	€0.92	€0.31	€0.99	€0.60	€1.01	€1.05	€0.17	€0.26	€0.16	€6.56	0.6%
2019	€1.10	€0.93	€0.32	€0.98	€0.61	€1.02	€1.04	€0.17	€0.26	€0.16	€6.59	0.5%
2020	€1.09	€0.95	€0.34	€0.97	€0.61	€1.03	€1.04	€0.17	€0.26	€0.16	€6.61	0.3%
2021	€1.15	€0.98	€0.36	€1.04	€0.63	€1.05	€1.05	€0.17	€0.26	€0.16	€6.84	3.5%
2022	€1.21	€1.01	€0.39	€1.11	€0.65	€1.06	€1.05	€0.18	€0.26	€0.16	€7.09	3.5%
CAGR (‘15–’22)	1.1%	2.2%	6.7%	1.4%	2.1%	1.2%	0.0%	1.9%	0.2%	-0.2%		1.4%

Source: iData Research Inc.

Figure 7-20: Market Value by Country, Bipolar Loop Electrode Market, Europe, 2012 – 2022 (US\$M)

Year	Germany	France	U.K.	Italy	Spain	Benelux	Scandi- navia	Austria	Switzer- land	Portugal	Europe	Growth (%)
2012	\$0.58	\$0.58	\$0.25	\$0.56	\$0.41	\$0.39	\$0.43	\$0.06	\$0.13	\$0.09	\$3.48	
2013	\$0.80	\$0.71	\$0.26	\$0.75	\$0.48	\$0.62	\$0.68	\$0.10	\$0.19	\$0.12	\$4.71	35.4%
2014	\$1.02	\$0.83	\$0.26	\$0.94	\$0.55	\$0.86	\$0.92	\$0.14	\$0.24	\$0.15	\$5.91	25.6%
2015	\$1.23	\$0.95	\$0.27	\$1.11	\$0.62	\$1.09	\$1.16	\$0.17	\$0.28	\$0.18	\$7.09	19.9%
2016	\$1.23	\$0.98	\$0.30	\$1.11	\$0.64	\$1.10	\$1.16	\$0.18	\$0.29	\$0.19	\$7.16	0.9%
2017	\$1.23	\$1.00	\$0.32	\$1.10	\$0.65	\$1.11	\$1.16	\$0.18	\$0.29	\$0.18	\$7.21	0.8%
2018	\$1.22	\$1.01	\$0.34	\$1.10	\$0.66	\$1.12	\$1.16	\$0.18	\$0.28	\$0.18	\$7.26	0.6%
2019	\$1.22	\$1.03	\$0.36	\$1.09	\$0.67	\$1.13	\$1.15	\$0.19	\$0.28	\$0.18	\$7.29	0.5%
2020	\$1.21	\$1.05	\$0.38	\$1.07	\$0.67	\$1.14	\$1.15	\$0.19	\$0.28	\$0.17	\$7.31	0.3%
2021	\$1.27	\$1.08	\$0.40	\$1.15	\$0.70	\$1.16	\$1.16	\$0.19	\$0.29	\$0.18	\$7.57	3.5%
2022	\$1.33	\$1.11	\$0.43	\$1.23	\$0.72	\$1.18	\$1.16	\$0.20	\$0.29	\$0.18	\$7.84	3.5%
CAGR (‘15–’22)	1.1%	2.2%	6.7%	1.4%	2.1%	1.2%	0.0%	1.9%	0.2%	-0.2%		1.4%

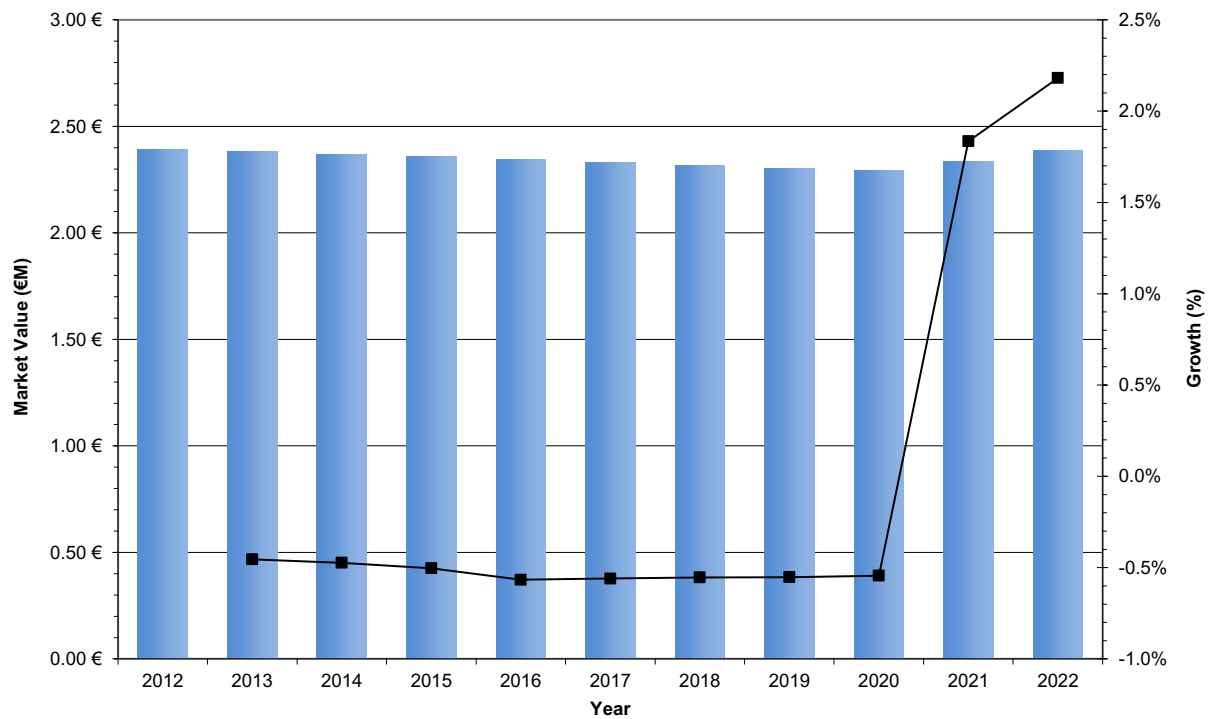
Source: iData Research Inc.

7.3.4 Electrosurgical Rollerball Device Market

The electrosurgical rollerball device market is positively correlated to the overall procedure numbers of endometrial resection performed. Despite being a first generation ablation technique, endometrial resection with a rollerball is still common practice in Europe. On average, an electrosurgical rollerball is used per every 3 patients in Europe. As endometrial resection numbers continue to fall and stabilize, electrosurgical rollerball units will match the same trend. The prices of both monopolar and bipolar electrosurgical rollerballs also mirror the 2015 prices of the corresponding loop electrode. The price of electrosurgical rollerballs, however, is projected to decrease at an accelerated rate relative to loops.

Figure 7-21: Electrosurgical Rollerball Device Market, Europe, 2012 – 2022 (€ and US\$)

Year	Units Sold	Growth (%)	ASP (€)	ASP (US\$)	Growth (%)	Market Value (€M)	Market Value (US\$M)	Growth (%)
2012	24,934		€95.87	\$106.00		€2.39	\$2.64	
2013	24,873	-0.2%	€95.67	\$105.78	-0.2%	€2.38	\$2.63	-0.5%
2014	24,812	-0.2%	€95.45	\$105.53	-0.2%	€2.37	\$2.62	-0.5%
2015	24,750	-0.2%	€95.21	\$105.26	-0.3%	€2.36	\$2.61	-0.5%
2016	24,670	-0.3%	€94.98	\$105.01	-0.2%	€2.34	\$2.59	-0.6%
2017	24,591	-0.3%	€94.75	\$104.76	-0.2%	€2.33	\$2.58	-0.6%
2018	24,511	-0.3%	€94.53	\$104.52	-0.2%	€2.32	\$2.56	-0.6%
2019	24,431	-0.3%	€94.32	\$104.28	-0.2%	€2.30	\$2.55	-0.6%
2020	24,351	-0.3%	€94.11	\$104.05	-0.2%	€2.29	\$2.53	-0.5%
2021	24,888	2.2%	€93.78	\$103.68	-0.4%	€2.33	\$2.58	1.8%
2022	25,523	2.6%	€93.44	\$103.30	-0.4%	€2.38	\$2.64	2.2%
CAGR ('15-'22)		0.4%			-0.3%			0.2%
Source: iData Research Inc.								

Chart 7-7: Electrosurgical Rollerball Device Market, Europe, 2012 – 2022

Source: iData Research Inc.

Figure 7-22: Units Sold by Country, Electrosurgical Rollerball Market, Europe, 2012 – 2022

Year	Germany	France	U.K.	Italy	Spain	Benelux	Scandi- navia	Austria	Switzer- land	Portugal	Europe	Growth (%)
2012	5,034	3,070	2,753	4,417	3,606	2,020	1,084	831	1,110	1,009	24,934	
2013	4,998	3,048	2,726	4,489	3,577	2,012	1,077	828	1,118	1,000	24,873	-0.2%
2014	4,962	3,026	2,698	4,561	3,548	2,004	1,069	825	1,126	992	24,812	-0.2%
2015	4,926	3,004	2,670	4,633	3,518	1,996	1,062	823	1,134	984	24,750	-0.2%
2016	4,902	2,991	2,661	4,624	3,501	1,994	1,061	822	1,132	982	24,670	-0.3%
2017	4,879	2,978	2,651	4,615	3,483	1,993	1,061	822	1,130	980	24,591	-0.3%
2018	4,855	2,966	2,642	4,605	3,466	1,991	1,060	821	1,127	978	24,511	-0.3%
2019	4,831	2,953	2,633	4,596	3,448	1,990	1,059	820	1,125	976	24,431	-0.3%
2020	4,808	2,941	2,623	4,587	3,430	1,988	1,058	819	1,123	974	24,351	-0.3%
2021	4,971	2,976	2,623	4,859	3,477	1,998	1,060	825	1,121	977	24,888	2.2%
2022	5,147	3,017	2,624	5,160	3,559	2,009	1,062	837	1,123	986	25,523	2.6%
CAGR (‘15–’22)	0.6%	0.1%	-0.2%	1.5%	0.2%	0.1%	0.0%	0.2%	-0.1%	0.0%		0.4%

Source: iData Research Inc.

Figure 7-23: Average Selling Price by Country, Electrosurgical Rollerball Market, Europe, 2012 – 2022 (€)

Year	Germany	France	U.K.	Italy	Spain	Benelux	Scandi- navia	Austria	Switzer- land	Portugal	Europe	Growth (%)
2012	€85.86	€82.82	€100.45	€95.48	€80.30	€134.93	€153.04	€90.81	€100.66	€89.78	€95.87	
2013	€85.51	€82.54	€100.45	€95.48	€79.98	€135.27	€151.51	€90.54	€100.66	€89.34	€95.67	-0.2%
2014	€85.26	€82.27	€100.25	€95.48	€79.74	€135.27	€150.75	€90.27	€100.33	€88.44	€95.45	-0.2%
2015	€85.00	€82.00	€100.00	€95.00	€80.00	€135.00	€150.00	€90.00	€100.00	€88.00	€95.21	-0.3%
2016	€84.75	€81.73	€99.75	€94.53	€80.26	€134.73	€149.25	€89.78	€99.70	€87.56	€94.98	-0.2%
2017	€84.49	€81.46	€99.45	€94.05	€80.53	€134.46	€148.80	€89.55	€99.40	€87.12	€94.75	-0.2%
2018	€84.28	€81.19	€99.15	€93.68	€80.73	€134.06	€148.36	€89.37	€99.00	€86.77	€94.53	-0.2%
2019	€84.07	€80.92	€98.76	€93.40	€80.93	€133.65	€147.91	€89.19	€98.51	€86.43	€94.32	-0.2%
2020	€83.90	€80.66	€98.36	€93.11	€81.09	€133.25	€147.54	€89.01	€98.02	€86.17	€94.11	-0.2%
2021	€83.73	€80.39	€97.87	€92.84	€81.26	€132.81	€147.17	€88.84	€97.62	€85.91	€93.78	-0.4%
2022	€83.57	€80.12	€97.38	€92.56	€81.42	€132.38	€146.88	€88.66	€97.43	€85.74	€93.44	-0.4%
CAGR (‘15–’22)	-0.2%	-0.3%	-0.4%	-0.4%	0.3%	-0.3%	-0.3%	-0.2%	-0.4%	-0.4%		-0.3%
Source: iData Research Inc.												

Figure 7-24: Average Selling Price by Country, Electrosurgical Rollerball Market, Europe, 2012 – 2022 (US\$)

Year	Germany	France	U.K.	Italy	Spain	Benelux	Scandi- navia	Austria	Switzer- land	Portugal	Europe	Growth (%)
2012	\$94.92	\$91.56	\$111.06	\$105.56	\$88.78	\$149.18	\$169.20	\$100.40	\$111.29	\$99.27	\$106.00	
2013	\$94.54	\$91.26	\$111.06	\$105.56	\$88.42	\$149.56	\$167.51	\$100.10	\$111.29	\$98.77	\$105.78	-0.2%
2014	\$94.26	\$90.96	\$110.84	\$105.56	\$88.16	\$149.56	\$166.67	\$99.80	\$110.93	\$97.78	\$105.53	-0.2%
2015	\$93.98	\$90.66	\$110.56	\$105.03	\$88.45	\$149.26	\$165.84	\$99.50	\$110.56	\$97.29	\$105.26	-0.3%
2016	\$93.69	\$90.36	\$110.28	\$104.51	\$88.74	\$148.96	\$165.01	\$99.26	\$110.23	\$96.81	\$105.01	-0.2%
2017	\$93.41	\$90.06	\$109.95	\$103.98	\$89.03	\$148.66	\$164.52	\$99.01	\$109.90	\$96.32	\$104.76	-0.2%
2018	\$93.18	\$89.76	\$109.62	\$103.57	\$89.26	\$148.21	\$164.02	\$98.81	\$109.46	\$95.94	\$104.52	-0.2%
2019	\$92.95	\$89.47	\$109.18	\$103.26	\$89.48	\$147.77	\$163.53	\$98.61	\$108.91	\$95.55	\$104.28	-0.2%
2020	\$92.76	\$89.17	\$108.75	\$102.95	\$89.66	\$147.33	\$163.12	\$98.41	\$108.37	\$95.27	\$104.05	-0.2%
2021	\$92.58	\$88.88	\$108.20	\$102.64	\$89.84	\$146.84	\$162.71	\$98.22	\$107.93	\$94.98	\$103.68	-0.4%
2022	\$92.39	\$88.59	\$107.66	\$102.33	\$90.02	\$146.35	\$162.39	\$98.02	\$107.72	\$94.79	\$103.30	-0.4%
CAGR (‘15–’22)	-0.2%	-0.3%	-0.4%	-0.4%	0.3%	-0.3%	-0.3%	-0.2%	-0.4%	-0.4%		-0.3%

Source: iData Research Inc.

Figure 7-25: Market Value by Country, Electrosurgical Rollerball Market, Europe, 2012 – 2022 (€M)

Year	Germany	France	U.K.	Italy	Spain	Benelux	Scandi- navia	Austria	Switzer- land	Portugal	Europe	Growth (%)
2012	€0.43	€0.25	€0.28	€0.42	€0.29	€0.27	€0.17	€0.08	€0.11	€0.09	€2.39	
2013	€0.43	€0.25	€0.27	€0.43	€0.29	€0.27	€0.16	€0.07	€0.11	€0.09	€2.38	-0.5%
2014	€0.42	€0.25	€0.27	€0.44	€0.28	€0.27	€0.16	€0.07	€0.11	€0.09	€2.37	-0.5%
2015	€0.42	€0.25	€0.27	€0.44	€0.28	€0.27	€0.16	€0.07	€0.11	€0.09	€2.36	-0.5%
2016	€0.42	€0.24	€0.27	€0.44	€0.28	€0.27	€0.16	€0.07	€0.11	€0.09	€2.34	-0.6%
2017	€0.41	€0.24	€0.26	€0.43	€0.28	€0.27	€0.16	€0.07	€0.11	€0.09	€2.33	-0.6%
2018	€0.41	€0.24	€0.26	€0.43	€0.28	€0.27	€0.16	€0.07	€0.11	€0.08	€2.32	-0.6%
2019	€0.41	€0.24	€0.26	€0.43	€0.28	€0.27	€0.16	€0.07	€0.11	€0.08	€2.30	-0.6%
2020	€0.40	€0.24	€0.26	€0.43	€0.28	€0.26	€0.16	€0.07	€0.11	€0.08	€2.29	-0.5%
2021	€0.42	€0.24	€0.26	€0.45	€0.28	€0.27	€0.16	€0.07	€0.11	€0.08	€2.33	1.8%
2022	€0.43	€0.24	€0.26	€0.48	€0.29	€0.27	€0.16	€0.07	€0.11	€0.08	€2.38	2.2%
CAGR (‘15–’22)	0.4%	-0.3%	-0.6%	1.2%	0.4%	-0.2%	-0.3%	0.0%	-0.5%	-0.3%		0.2%

Source: iData Research Inc.

Figure 7-26: Market Value by Country, Electrosurgical Rollerball Market, Europe, 2012 – 2022 (US\$M)

Year	Germany	France	U.K.	Italy	Spain	Benelux	Scandi- navia	Austria	Switzer- land	Portugal	Europe	Growth (%)
2012	\$0.48	\$0.28	\$0.31	\$0.47	\$0.32	\$0.30	\$0.18	\$0.08	\$0.12	\$0.10	\$2.64	
2013	\$0.47	\$0.28	\$0.30	\$0.47	\$0.32	\$0.30	\$0.18	\$0.08	\$0.12	\$0.10	\$2.63	-0.5%
2014	\$0.47	\$0.28	\$0.30	\$0.48	\$0.31	\$0.30	\$0.18	\$0.08	\$0.12	\$0.10	\$2.62	-0.5%
2015	\$0.46	\$0.27	\$0.30	\$0.49	\$0.31	\$0.30	\$0.18	\$0.08	\$0.13	\$0.10	\$2.61	-0.5%
2016	\$0.46	\$0.27	\$0.29	\$0.48	\$0.31	\$0.30	\$0.18	\$0.08	\$0.12	\$0.10	\$2.59	-0.6%
2017	\$0.46	\$0.27	\$0.29	\$0.48	\$0.31	\$0.30	\$0.17	\$0.08	\$0.12	\$0.09	\$2.58	-0.6%
2018	\$0.45	\$0.27	\$0.29	\$0.48	\$0.31	\$0.30	\$0.17	\$0.08	\$0.12	\$0.09	\$2.56	-0.6%
2019	\$0.45	\$0.26	\$0.29	\$0.47	\$0.31	\$0.29	\$0.17	\$0.08	\$0.12	\$0.09	\$2.55	-0.6%
2020	\$0.45	\$0.26	\$0.29	\$0.47	\$0.31	\$0.29	\$0.17	\$0.08	\$0.12	\$0.09	\$2.53	-0.5%
2021	\$0.46	\$0.26	\$0.28	\$0.50	\$0.31	\$0.29	\$0.17	\$0.08	\$0.12	\$0.09	\$2.58	1.8%
2022	\$0.48	\$0.27	\$0.28	\$0.53	\$0.32	\$0.29	\$0.17	\$0.08	\$0.12	\$0.09	\$2.64	2.2%
CAGR (‘15–’22)	0.4%	-0.3%	-0.6%	1.2%	0.4%	-0.2%	-0.3%	0.0%	-0.5%	-0.3%		0.2%

Source: iData Research Inc.

7.4 DRIVERS AND LIMITERS

7.4.1 Market Drivers

Bipolar Loop Electrodes

Bipolar loop electrodes are substantially more expensive than monopolar loop electrodes; on average at least twice the price. Patient safety has been a driving force in the endometrial resection market with a massive shift from monopolar loop electrodes to bipolar loop electrodes as the procedural standard since 2012. Bipolar loop electrodes are safer for the patient because the electricity is routed back into the device, protecting the patient from injury. As this trend continues, the higher price of bipolar loop electrodes will increase the market value.

Aging Population

The average age of the female demographic across Europe is increasing. 20 to 80% of females will develop fibroids by the age of 50, with the most common age bracket being 40 to 50. As more individuals enter an age bracket where the risk of endometrial fibroids and heavy uterine bleeding are occurring, the number of resections should also see a corresponding increase. This higher demand for endometrial resection may translate to higher sales for these devices for both resectoscopes and loop electrodes for gynecological use.

Patient Requests and Patient Safety

Patients have become increasingly involved in their own medical care. With the emergence of patients conducting their own research and inquiring about alternative treatment options, endometrial resection may remain the preferred procedure. The success rate of endometrial resection to achieve Amenorrhea (no further periods) is 85% in contrast to only 45% with endometrial ablation. There is also only a 5% chance that additional procedure(s) will be required versus a 25% with endometrial ablation.

7.4.2 Market Limiters

Lack of Physicians

Since physicians began to practice GEA methods, training for endometrial resection has slowed. GEA methods are easier to perform, and most of the newer physicians are being trained on these procedures instead. Endometrial resection requires a higher level of skill and expertise to perform safely and takes a significant amount of time to master in comparison to newer ablation methods. With fewer physicians learning how to perform endometrial resection, market growth will be limited.

Global Endometrial Ablation

Global endometrial ablation devices are cannibalizing the endometrial resection device market, as they are easier for physicians to learn to use and offer faster procedures. While some physicians will continue to prefer resection devices, and some procedures are better suited for resection, more physicians are expected to switch to global endometrial ablation when possible, which will limit the sales of resection devices.

Figure 7-27: Drivers and Limiters, Endometrial Resection Device Market, Europe, 2015

Market Drivers
Bipolar Loop Electrodes Aging Population Patient Requests and Patient Safety
Market Limiters
Lack of Physicians Global Endometrial Ablation
Source: iData Research Inc.

7.5 COMPETITIVE MARKET SHARE ANALYSIS

Karl Storz

Karl Storz is the market leader in Endometrial Resection, with a market share of 21.2% across Europe. This market share includes products sold by MTP (Medical Technical Promotion gmbh). MTP produces single-use medical products and accessories approved and tested exclusively for Karl Storz. Monopolar loop electrodes are produced by MTP offering products such as the Unipolar Electrodes for Karl Storz Resectoscope Systems. Karl Storz alternatively, caters to the expanding bipolar loop electrode market offering products such as their Bipolar Resectoscope system compatible with cutting loops in addition to other reusable instruments. This partnership between MTP and Karl Storz has allowed the companies to effectively target the entire endometrial resection market and maintain both sales and market share despite the volatile transition from monopolar loop electrodes to bipolar loop electrodes.

Olympus

Olympus offers the OES Pro line of devices, which are classic resectoscopes, as well as the TCRis (Trans Cervical Resection in saline) procedure. Olympus' acquisition of Gyrus ACMI back in 2012 has resulted in its large share of the monopolar electrode device market, as ACMI held a significant market share in Europe prior to being acquired.

Olympus has bridged the gap between endometrial ablation and endometrial resection by offering products in both markets and their TCRis technology offers a safe and fast way to treat abnormal bleeding by endometrial ablation, or bipolar resection of intracavitary myomas, uterine septa or uterine polyps. Due to their strategic positioning and innovative technology, Olympus is expected to maintain a consistent market share throughout the reporting period.

Richard Wolf

Richard Wolf offers a range of resectoscopes that are compatible with both monopolar and bipolar loop electrodes. With a range in sizes available, Richard Wolf offers one of the smallest resectoscopes on the market, the Princess Slim 7mm resectoscope for minimal dilation effort. The company also promotes its Bipolar vaporization electrode "BiVAP" as the ideal treatment for endometrial ablation and myomas offering a unique shape.

Johnson & Johnson

Ethicon, a Johnson & Johnson Company, held a 18.4% share in the endometrial resection market in 2015 through their line of *Gynecare* products. Ethicon achieved being first to market for bipolar loop

electrodes generating excellent brand recognition in the endometrial resection market. This advantage will allow Johnson & Johnson to increase their share as more gynecologists switch from monopolar to bipolar resection. The *GYNECARE VERSAPOINT™ Bipolar Electrosurgery System* includes both electrodes and resectoscopes. This is the most popular bipolar system and is indicated for the treatment of myomas, polyps, intrauterine adhesions and uterine septa.

It is worth noting that since Ethicon left the endometrial ablation market in March 2016, this may reduce their market share in endometrial resection. Due to the overlap between these two markets, many clients may prefer to purchase the same brand of products for both procedure types, opening up the opportunity for clients to change manufacturers.

Kebomed

Kebomed is most popular in France and the Benelux region of Europe. Kebomed's product range includes the Lina Gold Loop and the Lina Bipolar Loop as two of their top products for minimally invasive gynecology surgery. The Lina Gold Loop is a monopolar loop electrode.

Medtronic

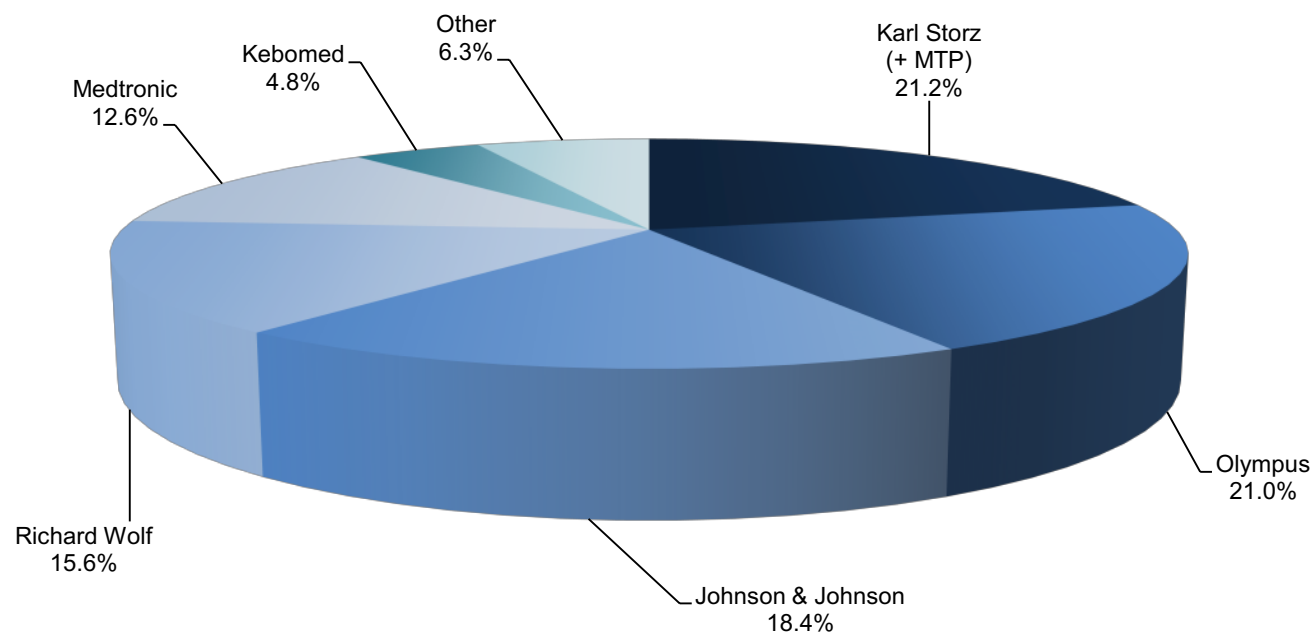
Medtronic acquired Covidien in January 2015 expanding its endometrial resection portfolio. Covidien Products extend to include electrosurgical electrodes and electrosurgical hardware. Medtronic has a loyal client base throughout Europe providing a stable foundation to maintain a consistent market share throughout the reporting period.

Other Notable Competitors

Other competitors accounted for the remaining 6.0% market share in 2015. Aesculap and Stryker comprise the majority of the other market share with sales throughout Europe.

Figure 7-28: Leading Competitors by Country, Endometrial Resection Device Market, Europe, 2015

Company	Germany	France	U.K.	Italy	Spain	Benelux	Scandi- navia	Austria	Switzer- land	Portugal	Total Market Share
Karl Storz (+ MTP)	40.4%	12.5%	39.6%	5.1%	24.7%	–	15.9%	40.3%	38.4%	25.1%	21.2%
Olympus	23.1%	25.1%	28.0%	9.6%	14.3%	20.6%	28.4%	23.1%	24.5%	15.8%	21.0%
Johnson & Johnson	8.2%	10.4%	9.0%	45.2%	9.5%	17.3%	34.0%	8.1%	8.0%	10.2%	18.4%
Richard Wolf	25.9%	15.8%	21.5%	5.7%	18.9%	–	15.7%	25.6%	23.9%	18.6%	15.6%
Medtronic	–	12.3%	–	30.3%	19.4%	29.8%	–	–	–	19.4%	12.6%
Kebomed	–	12.2%	–	–	–	25.1%	–	–	–	–	4.8%
Other	2.4%	11.7%	1.9%	4.1%	13.2%	7.2%	6.0%	2.9%	5.2%	10.9%	6.3%
Total	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
Market Value (€M)	€2.7	€2.2	€1.8	€2.4	€1.6	€1.9	€1.7	€0.4	€0.5	€0.4	€15.6
Others: Aesculap, Stryker etc.											
Source: iData Research Inc.											

Chart 7-8: Leading Competitors, Endometrial Resection Device Market, Europe, 2015

Source: iData Research Inc.

8

UTERINE FIBROID EMBOLIZATION DEVICE MARKET

8.1 INTRODUCTION

Uterine fibroid embolization (UFE), also known as uterine artery embolization (UAE) is a radiology treatment for fibroids. Fibroids, also known as myomas, are masses of muscle tissue and fiber located on the wall of the uterus that can cause heavy bleeding and pain. Fibroids depend on the uterine arteries for nourishment, and they take significant blood supply from these vessels. UFE restricts blood flow to fibroids, causing them to shrink significantly. This procedure does not involve general anesthesia and is appropriate for women who want an alternative to a myomectomy, also known as fibroidectomy. It is a much less invasive way to treat fibroids than a hysterectomy, has a much shorter recovery time and leaves almost no scarring. The effects of UFE on fertility are being researched; some results suggest that fertility after UFE is comparable to fertility after myomectomy.

During this procedure, a small incision is made in the groin, and a small catheter is inserted into the nearby artery. X-ray guidance is used to move the catheter through the artery into the uterus. A mixture of minuscule plastic particles and X-ray dye is then injected into the artery, flowing and accumulating in the fibroids and blocking the blood supply. The flow of particles is carefully monitored with the X-ray equipment by watching the flow of dye. This procedure can take anywhere from 40 minutes to three hours to complete. The fibroids shrink and disappear over a period of several months.

There are several types of embolic agents used in UFE. These particles can be non-spherical or spherical in shape. They may consist of polyvinyl alcohol (PVA) or polyacrylamide microspheres. Non-spherical particles are less expensive; however, they can block the catheters used in UFE, and there is a greater frequency of reoccurring fibroids requiring re-embolization.

8.1.1 Microspheres

Embolization via microspheres is the most popular and most studied modality for embolization and is regarded as the gold standard for uterine fibroid embolization; according to some sources, microspheres are used in as much as 73% of all uterine fibroid cases. Microspheres are made from trisacryl cross linked with gelatin and stop blood flow to the tumor by physically blocking the vessel lumen leading to the tumor. Of all the forms of embolization, microspheres are most familiar with patients and, as such, have the highest volume sold per annum of all the four different embolization segments covered.

8.1.2 Polyvinyl Alcohol Particles

Embolization via polyvinyl alcohol (PVA) particles involves the placement of tiny, irregular PVA particles near the cancerous tumor. These particles have been around for decades and, next to microspheres, are the second most studied form of particle embolization available. PVA embolization was first introduced in the mid-1970s in the form of a sponge and has since taken on various forms, most commonly as foam. This foam is injected in the form of a small “torpedo” into the desired region and provides a physical (mechanical) barrier between the tumor and the blood vessels.

8.1.3 Drug-eluting Particles

Embolization via drug-eluting beads (DEBs) involves the placement of beads that have been filled with a therapeutic agent. These beads are fed through a catheter into the desired area and slowly release their agent. This treatment is less often used for the treatment of uterine fibroids and thus has not been included in the scope of this report.

8.2 MARKET OVERVIEW

In 2015, the uterine fibroid embolization (UFE) device market continued to retract, representing a -2.9% growth in total units sold. The complete market is comprised of the microsphere and PVA particle market sub-segments respectively. Overall, the market as a whole is decreasing. However, the sub-segment of microspheres is continuing to increase. The microsphere segment comprises the majority of the uterine fibroid embolization market with a share of 90% in 2015. The microsphere segment will continue to cannibalize the PVA particle segment, resulting in an even higher proportion of the UFE market by 2022. The microsphere market is larger because microspheres are preferred by physicians and cost almost twice as much as PVA particles. Physicians may prefer the use of microspheres over PVA particles due to peer-reviewed journals that outline how microspheres result in reduced blood loss and higher efficacy in the reduction of fibroids compared to the alternative. PVA particles are more commonly found in price sensitive markets.

The UFE market has decreased in growth over the past couple of years as there has been a reduction of active marketing. Moreover, UFE must compete with a wide array of procedures available to treat heavy bleeding due to uterine fibroids. These other treatments and procedures include hysterectomy, pharmacological alternatives, global endometrial ablation, endometrial resection and other minimally invasive surgical procedures. For more price-sensitive countries, such as France, Spain, Italy and Portugal, alternative treatments present significant competition as patients and physicians look for inexpensive methods for the management or treatment of uterine fibroids. Moreover, because of the economic situation, many women are delaying surgical treatments.

Figure 8-1: Uterine Fibroid Embolization Device Market by Segment, Europe, 2012 – 2022 (€M)

Year	Microspheres Market	PVA Particles Market	Total Market	Growth (%)
2012	€3.58	€0.23	€3.81	
2013	€3.34	€0.20	€3.54	-€0.07
2014	€3.14	€0.19	€3.33	-€0.06
2015	€3.08	€0.15	€3.22	-€0.03
2016	€3.05	€0.14	€3.19	-€0.01
2017	€3.12	€0.11	€3.24	€0.02
2018	€3.16	€0.10	€3.27	€0.01
2019	€3.17	€0.10	€3.27	€0.00
2020	€3.17	€0.10	€3.26	€0.00
2021	€3.17	€0.09	€3.26	€0.00
2022	€3.17	€0.09	€3.26	€0.00
CAGR ('15-'22)	0.4%	-7.1%		0.1%

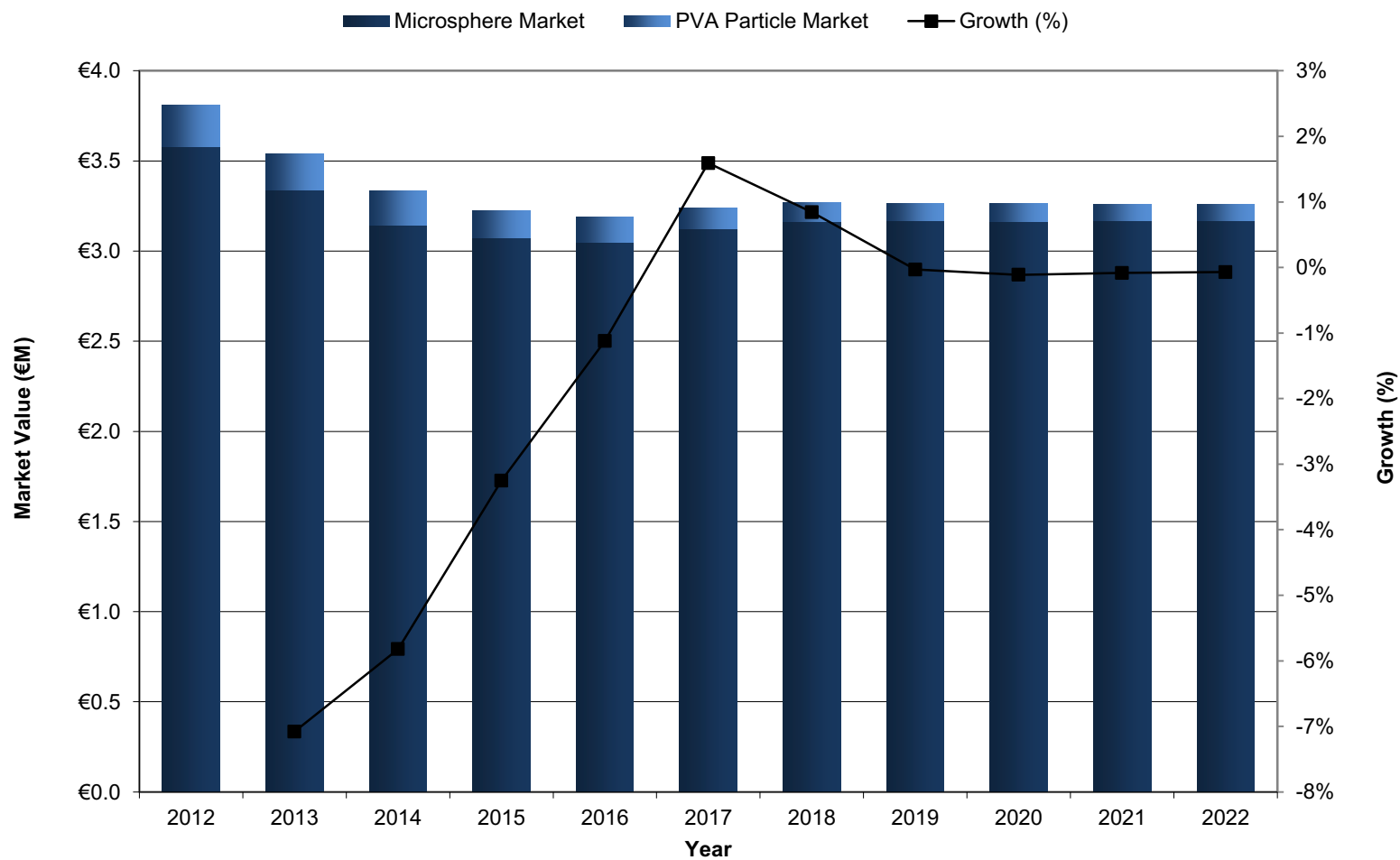
Source: iData Research Inc.

Figure 8-2: Uterine Fibroid Embolization Device Market by Segment, Europe, 2012 – 2022 (US\$M)

Year	Microspheres Market	PVA Particles Market	Total Market	Growth (%)
2012	\$3.96	\$0.25	\$4.21	
2013	\$3.69	\$0.22	\$3.91	-7.1%
2014	\$3.48	\$0.21	\$3.69	-5.8%
2015	\$3.40	\$0.17	\$3.57	-3.3%
2016	\$3.37	\$0.15	\$3.53	-1.1%
2017	\$3.45	\$0.13	\$3.58	1.6%
2018	\$3.50	\$0.12	\$3.61	0.8%
2019	\$3.50	\$0.11	\$3.61	0.0%
2020	\$3.50	\$0.11	\$3.61	-0.1%
2021	\$3.50	\$0.10	\$3.60	-0.1%
2022	\$3.50	\$0.10	\$3.60	-0.1%
CAGR ('15-'22)	0.4%	-7.1%		0.1%

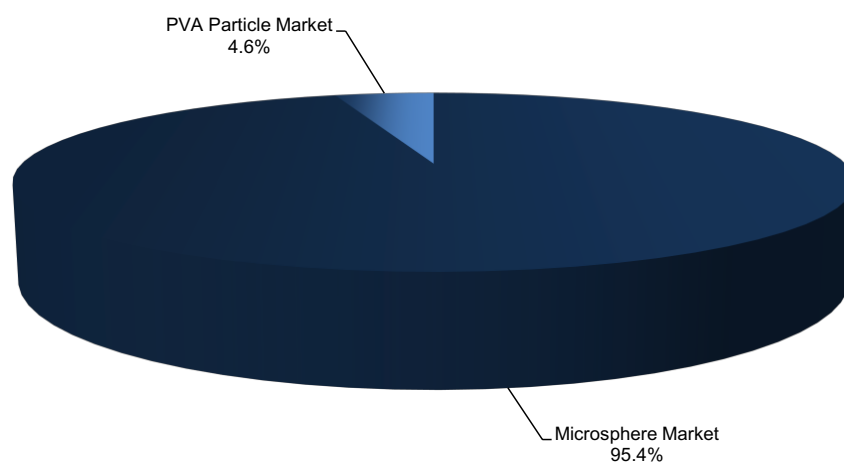
Source: iData Research Inc.

Chart 8-1: Uterine Fibroid Embolization Device Market by Segment, Europe, 2015



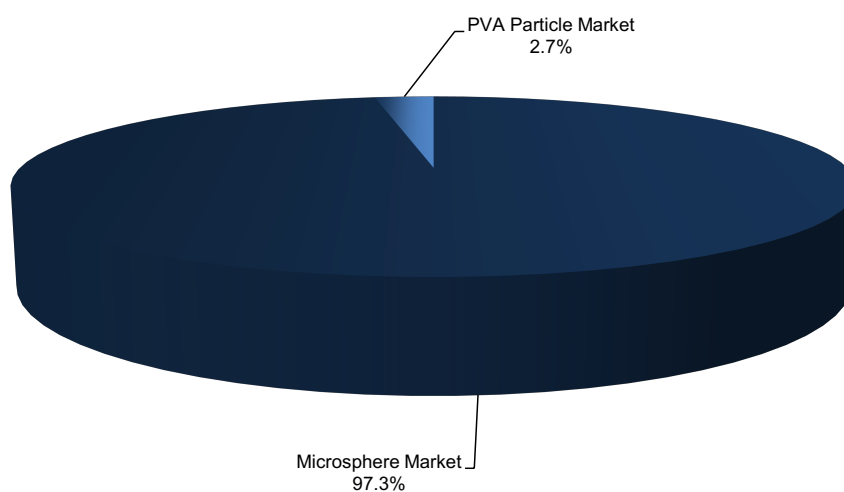
Source: iData Research Inc.

Chart 8-2: Uterine Fibroid Embolization Device Market Breakdown, Europe, 2015



Source: iData Research Inc.

Chart 8-3: Uterine Fibroid Embolization Device Market Breakdown, Europe, 2022



Source: iData Research Inc.

8.3 MARKET ANALYSIS AND FORECAST

8.3.1 Uterine Fibroid Embolization Procedures

France leads the uterine fibroid embolization market, with four times the procedure numbers as other European countries. Embolization therapy for uterine fibroids was pioneered in France and continues to be a very popular treatment method. In contrast, Austria experienced a 25% loss of procedures in 2015 following an amendment to the Working Time Act for hospitals and doctors. The largest point of contention was the Act previously allowed doctors to work up to 72 hours per week, which the European Commission deemed a violation of the Working Time Directive 2003/88/EC. The amendment which came into effect in 2015 limits a doctor's work week to 48 hours, lowering the overall number of procedures able to be performed.

The ASP of the UFE Device market fell by 0.4% in 2015. Two factors that affect the variation in price across Europe are the split between private and public sales tenders and reimbursement. Switzerland has a majority private market compared to public. Portugal is also transitioning from public to private domain sales. The private sales market is perceived to be faster and often less expensive than public tenders. Competition and price pressure are stronger in the public sector. Due to the increased perceived efficiency and decreased cost, it's not surprising more markets are starting to favor private market sales.

Reimbursement affects both the ASP of UFE devices as well as the number of procedures performed. Currently Germany, Austria and the Netherlands all have reimbursement for UFE procedures, leading to higher procedure numbers. Switzerland does not have reimbursement and it is a contributing factor for their disproportionately small market share.

The market has had steady declining growth since 2012. This has been attributed to financial instability during the recession. Additionally, there have been reduced levels of active product promotion and minimally invasive surgeries are becoming a more accessible alternative to patients and doctors. Therefore, surgical excision of fibroids and the availability of other treatments have negatively impacted the number of UFE procedures that are recommended by practitioners. Nevertheless, new entrants in this market may stimulate and help maintain the growth rate as they slowly gain more traction. Moreover, as the population ages, more women are diagnosed with fibroid conditions that will require treatment, which should assist in maintaining the growth of the UFE device market.

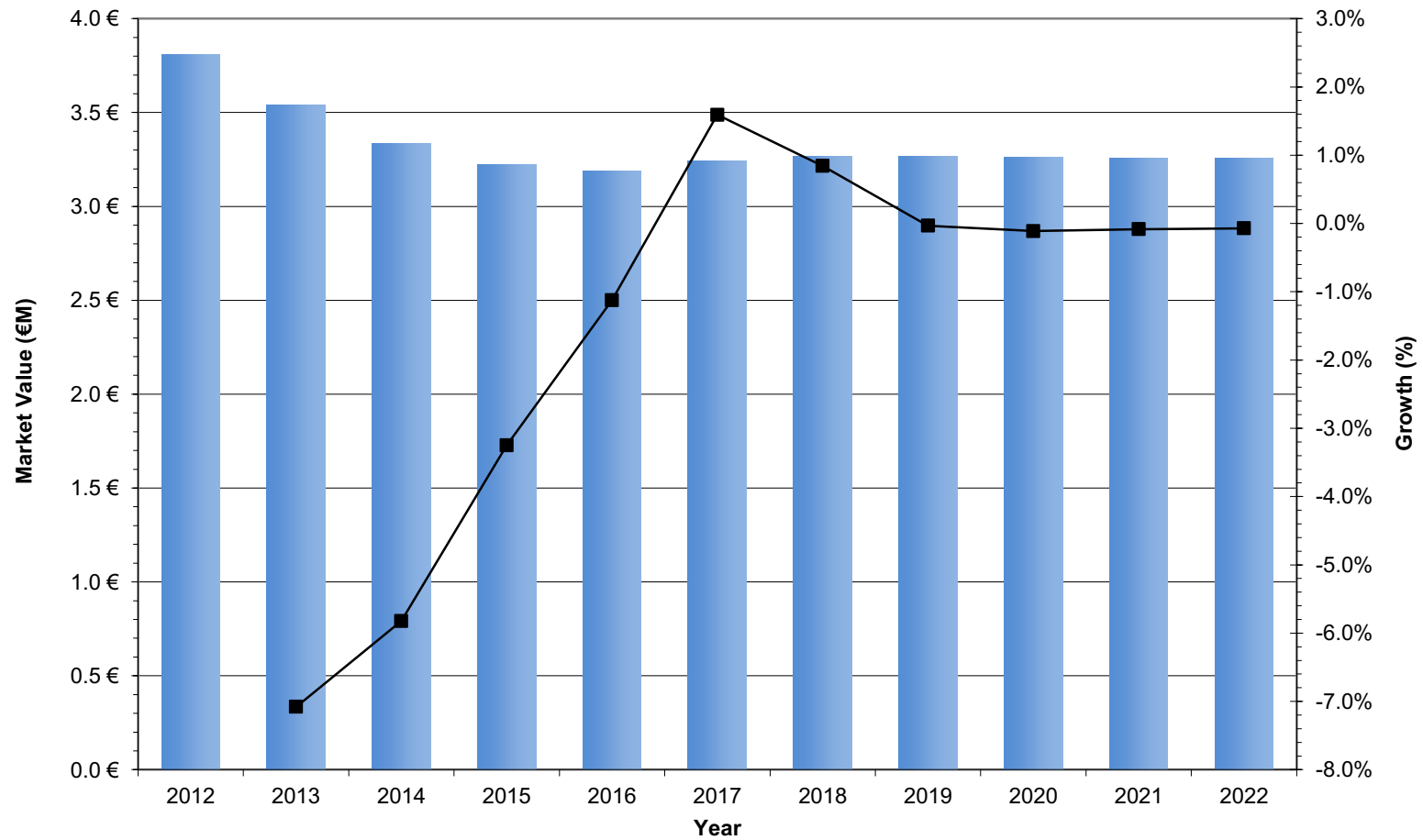
The summation of the above factors has led to the decline in procedures. The trend is expected to level off resulting in the market holding at a stable rate for the remaining of the projected period.

For the purpose of this report, a unit of embolic agent is a 1 mL or 2 mL vial. The number of vials used per procedure is outlined in the tables below. The ASP of the UFE device market represents the cost of the embolic agent used per procedure.

Figure 8-3: Uterine Fibroid Embolization Device Market, Europe, 2012 – 2022 (€ and US\$)

Year	Units Sold	Growth (%)	ASP (€)	ASP (US\$)	Growth (%)	Market Value (€M)	Market Value (US\$M)	Growth (%)
2012	22,190		€172	\$190		€3.81	\$4.21	
2013	20,968	-5.5%	€169	\$187	-1.7%	€3.54	\$3.91	-7.1%
2014	20,030	-4.5%	€166	\$184	-1.4%	€3.33	\$3.69	-5.8%
2015	19,452	-2.9%	€166	\$183	-0.4%	€3.22	\$3.57	-3.3%
2016	19,319	-0.7%	€165	\$182	-0.4%	€3.19	\$3.53	-1.1%
2017	19,564	1.3%	€166	\$183	0.3%	€3.24	\$3.58	1.6%
2018	20,348	4.0%	€161	\$177	-3.0%	€3.27	\$3.61	0.8%
2019	20,409	0.3%	€160	\$177	-0.3%	€3.27	\$3.61	0.0%
2020	20,462	0.3%	€159	\$176	-0.4%	€3.26	\$3.61	-0.1%
2021	20,509	0.2%	€159	\$176	-0.3%	€3.26	\$3.60	-0.1%
2022	20,555	0.2%	€158	\$175	-0.3%	€3.26	\$3.60	-0.1%
CAGR ('15-'22)		0.8%			-0.6%			0.1%

Source: iData Research Inc.

Chart 8-4: Uterine Fibroid Embolization Device Market, Europe, 2012 – 2022

Source: iData Research Inc.

Figure 8-4: Units Sold by Country, Uterine Fibroid Embolization Device Market, Europe, 2012 – 2022

Year	Germany	France	U.K.	Italy	Spain	Benelux	Scandi- navia	Austria	Switzer- land	Portugal	Europe	Growth (%)
2012	2,015	12,686	1,492	1,232	1,645	1,275	687	438	290	429	22,190	
2013	1,854	11,798	1,501	1,222	1,501	1,237	751	416	298	390	20,968	-5.5%
2014	1,742	11,090	1,502	1,245	1,403	1,199	784	399	306	359	20,030	-4.5%
2015	1,676	10,720	1,477	1,235	1,340	1,176	832	340	312	345	19,452	-2.9%
2016	1,659	10,613	1,492	1,227	1,307	1,164	859	338	318	342	19,319	-0.7%
2017	1,664	10,883	1,495	1,221	1,287	1,158	856	339	322	338	19,564	1.3%
2018	1,669	10,916	1,505	1,249	1,283	1,839	879	340	324	344	20,348	4.0%
2019	1,674	10,948	1,502	1,246	1,288	1,844	893	341	322	349	20,409	0.3%
2020	1,679	10,981	1,498	1,244	1,295	1,851	902	343	319	351	20,462	0.3%
2021	1,685	11,014	1,493	1,243	1,301	1,857	900	344	315	357	20,509	0.2%
2022	1,685	11,047	1,488	1,243	1,309	1,865	899	345	312	363	20,555	0.2%
CAGR (‘15–’22)	0.1%	0.4%	0.1%	0.1%	-0.3%	6.8%	1.1%	0.2%	0.0%	0.7%		0.8%

Source: iData Research Inc.

Figure 8-5: Average Selling Price by Country, Uterine Fibroid Embolization Device Market, Europe, 2012 – 2022 (€)

Year	Germany	France	U.K.	Italy	Spain	Benelux	Scandi- navia	Austria	Switzer- land	Portugal	Europe	Growth (%)
2012	€187	€173	€204	€173	€94	€200	€201	€180	€178	€94	€172	
2013	€183	€169	€206	€169	€91	€194	€212	€175	€173	€91	€169	-1.7%
2014	€181	€165	€204	€168	€89	€189	€217	€171	€169	€88	€166	-1.4%
2015	€178	€165	€197	€165	€88	€188	€225	€168	€167	€86	€166	-0.4%
2016	€176	€163	€199	€164	€88	€185	€232	€166	€165	€86	€165	-0.4%
2017	€175	€165	€196	€163	€88	€183	€232	€165	€164	€86	€166	0.3%
2018	€174	€164	€196	€166	€89	€120	€235	€164	€163	€88	€161	-3.0%
2019	€174	€164	€193	€165	€91	€119	€234	€163	€163	€89	€160	-0.3%
2020	€173	€163	€191	€165	€92	€118	€232	€163	€163	€90	€159	-0.4%
2021	€172	€163	€189	€165	€94	€117	€229	€163	€163	€92	€159	-0.3%
2022	€171	€163	€186	€165	€94	€117	€225	€163	€162	€94	€158	-0.3%
CAGR (‘15–’22)	-0.6%	-0.1%	-0.9%	-0.1%	1.1%	-6.6%	0.0%	-0.5%	-0.4%	1.2%		-0.6%

Source: iData Research Inc.

Figure 8-6: Average Selling Price by Country, Uterine Fibroid Embolization Device Market, Europe, 2012 – 2022 (US\$)

Year	Germany	France	U.K.	Italy	Spain	Benelux	Scandi- navia	Austria	Switzer- land	Portugal	Europe	Growth (%)
2012	\$207	\$191	\$226	\$191	\$104	\$221	\$222	\$199	\$196	\$104	\$190	
2013	\$203	\$186	\$227	\$186	\$101	\$215	\$234	\$194	\$191	\$100	\$187	-1.7%
2014	\$200	\$182	\$226	\$185	\$98	\$209	\$240	\$189	\$187	\$97	\$184	-1.4%
2015	\$197	\$182	\$218	\$183	\$97	\$208	\$249	\$186	\$184	\$95	\$183	-0.4%
2016	\$195	\$180	\$220	\$182	\$97	\$205	\$256	\$184	\$183	\$95	\$182	-0.4%
2017	\$194	\$182	\$217	\$181	\$97	\$202	\$256	\$182	\$181	\$95	\$183	0.3%
2018	\$193	\$182	\$216	\$183	\$99	\$133	\$260	\$181	\$181	\$97	\$177	-3.0%
2019	\$192	\$181	\$214	\$183	\$101	\$132	\$259	\$181	\$180	\$99	\$177	-0.3%
2020	\$191	\$181	\$211	\$182	\$101	\$131	\$257	\$180	\$180	\$99	\$176	-0.4%
2021	\$190	\$180	\$208	\$182	\$104	\$130	\$253	\$180	\$180	\$101	\$176	-0.3%
2022	\$189	\$180	\$206	\$182	\$104	\$129	\$249	\$180	\$180	\$104	\$175	-0.3%
CAGR (‘15–’22)	-0.6%	-0.1%	-0.9%	-0.1%	1.1%	-6.6%	0.0%	-0.5%	-0.4%	1.2%		-0.6%

Source: iData Research Inc.

Figure 8-7: Market Value by Country, Uterine Fibroid Embolization Device Market, Europe, 2012 – 2022 (€M)

Year	Germany	France	U.K.	Italy	Spain	Benelux	Scandi- navia	Austria	Switzer- land	Portugal	Europe	Growth (%)
2012	€0.38	€2.19	€0.30	€0.21	€0.15	€0.26	€0.14	€0.08	€0.05	€0.04	€3.81	
2013	€0.34	€1.99	€0.31	€0.21	€0.14	€0.24	€0.16	€0.07	€0.05	€0.04	€3.54	-7.1%
2014	€0.31	€1.83	€0.31	€0.21	€0.12	€0.23	€0.17	€0.07	€0.05	€0.03	€3.33	-5.8%
2015	€0.30	€1.77	€0.29	€0.20	€0.12	€0.22	€0.19	€0.06	€0.05	€0.03	€3.22	-3.3%
2016	€0.29	€1.73	€0.30	€0.20	€0.11	€0.22	€0.20	€0.06	€0.05	€0.03	€3.19	-1.1%
2017	€0.29	€1.79	€0.29	€0.20	€0.11	€0.21	€0.20	€0.06	€0.05	€0.03	€3.24	1.6%
2018	€0.29	€1.79	€0.29	€0.21	€0.11	€0.22	€0.21	€0.06	€0.05	€0.03	€3.27	0.8%
2019	€0.29	€1.79	€0.29	€0.21	€0.12	€0.22	€0.21	€0.06	€0.05	€0.03	€3.27	0.0%
2020	€0.29	€1.79	€0.29	€0.21	€0.12	€0.22	€0.21	€0.06	€0.05	€0.03	€3.26	-0.1%
2021	€0.29	€1.80	€0.28	€0.20	€0.12	€0.22	€0.21	€0.06	€0.05	€0.03	€3.26	-0.1%
2022	€0.29	€1.80	€0.28	€0.20	€0.12	€0.22	€0.20	€0.06	€0.05	€0.03	€3.26	-0.1%
CAGR (‘15–’22)	-0.5%	0.3%	-0.8%	0.0%	0.8%	-0.2%	1.1%	-0.2%	-0.4%	1.9%		0.1%

Source: iData Research Inc.

Figure 8-8: Market Value by Country, Uterine Fibroid Embolization Device Market, Europe, 2012 – 2022 (US\$M)

Year	Germany	France	U.K.	Italy	Spain	Benelux	Scandi- navia	Austria	Switzer- land	Portugal	Europe	Growth (%)
2012	\$0.42	\$2.43	\$0.34	\$0.24	\$0.17	\$0.28	\$0.15	\$0.09	\$0.06	\$0.04	\$4.21	
2013	\$0.38	\$2.20	\$0.34	\$0.23	\$0.15	\$0.27	\$0.18	\$0.08	\$0.06	\$0.04	\$3.91	-7.1%
2014	\$0.35	\$2.02	\$0.34	\$0.23	\$0.14	\$0.25	\$0.19	\$0.08	\$0.06	\$0.03	\$3.69	-5.8%
2015	\$0.33	\$1.95	\$0.32	\$0.23	\$0.13	\$0.24	\$0.21	\$0.06	\$0.06	\$0.03	\$3.57	-3.3%
2016	\$0.32	\$1.91	\$0.33	\$0.22	\$0.13	\$0.24	\$0.22	\$0.06	\$0.06	\$0.03	\$3.53	-1.1%
2017	\$0.32	\$1.98	\$0.32	\$0.22	\$0.12	\$0.23	\$0.22	\$0.06	\$0.06	\$0.03	\$3.58	1.6%
2018	\$0.32	\$1.98	\$0.33	\$0.23	\$0.13	\$0.24	\$0.23	\$0.06	\$0.06	\$0.03	\$3.61	0.8%
2019	\$0.32	\$1.98	\$0.32	\$0.23	\$0.13	\$0.24	\$0.23	\$0.06	\$0.06	\$0.03	\$3.61	0.0%
2020	\$0.32	\$1.98	\$0.32	\$0.23	\$0.13	\$0.24	\$0.23	\$0.06	\$0.06	\$0.03	\$3.61	-0.1%
2021	\$0.32	\$1.99	\$0.31	\$0.23	\$0.13	\$0.24	\$0.23	\$0.06	\$0.06	\$0.04	\$3.60	-0.1%
2022	\$0.32	\$1.99	\$0.31	\$0.23	\$0.14	\$0.24	\$0.22	\$0.06	\$0.06	\$0.04	\$3.60	-0.1%
CAGR (‘15–’22)	-0.5%	0.3%	-0.8%	0.0%	0.8%	-0.2%	1.1%	-0.2%	-0.4%	1.9%		0.1%

Source: iData Research Inc.

8.3.1.1 Microspheres Market

The majority of European markets are gradually shifting towards Microspheres as the standard of care in UFE treatments. This particle is a clear acrylic flexible sphere and is the most effective particle type to block the fibroid vessels without closing the entire uterine arteries. Microspheres are substantially more expensive than alternative particles, but they are less likely to block the catheter used in the procedure.

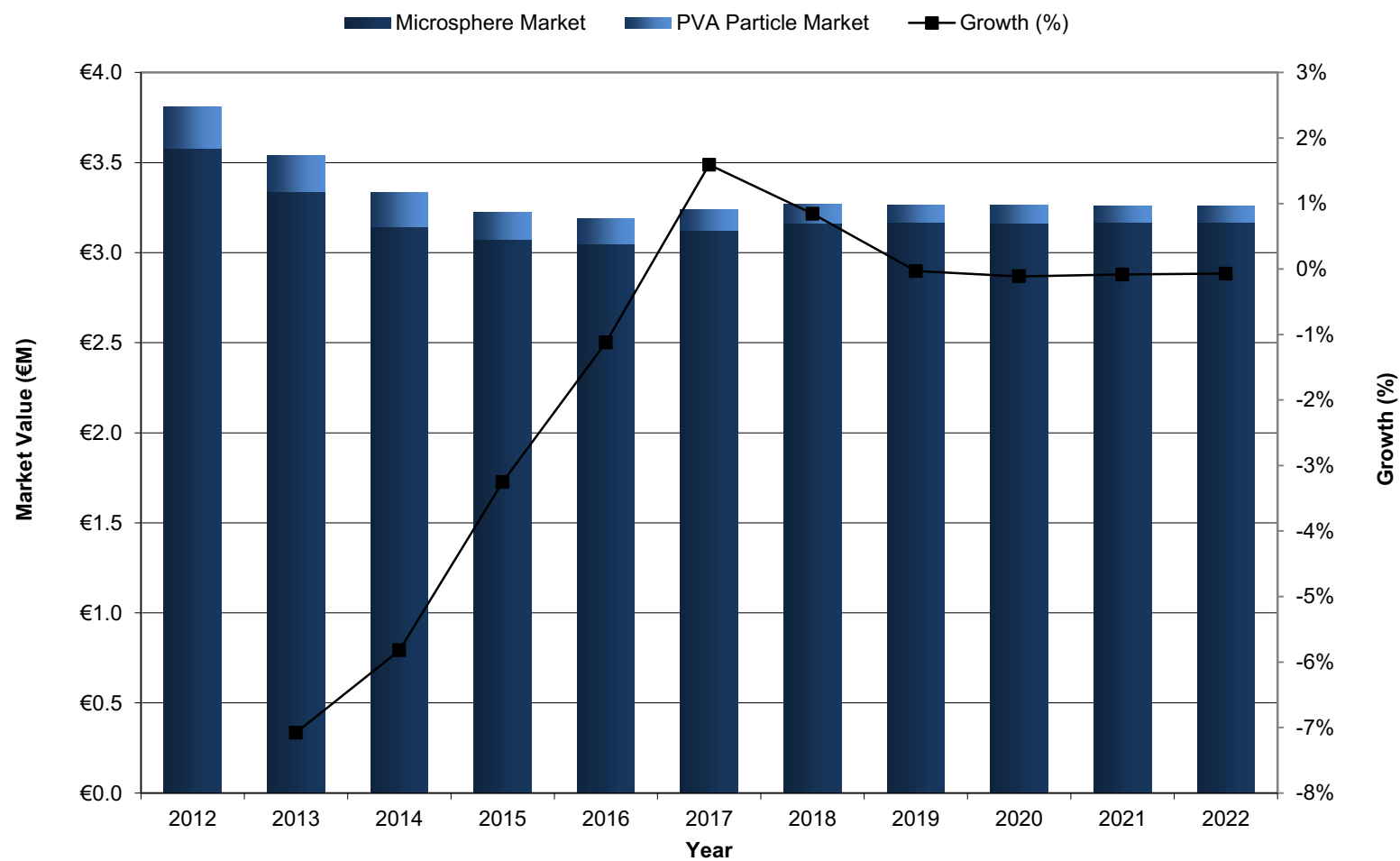
As an anomaly, the U.K. has a much lower percent of UFE procedures being performed using Microspheres and is experiencing negative growth. The microsphere market is projected to stabilize and remain consistent with only a 70% share of the total market by 2017. This is due to the fact that the U.K. is price conscious and more willing to embrace original technology, as microspheres are equally effective and have not yet been shown to offer improved patient safety.

Microspheres do require substantially higher volumes than PVA particles; on average three times the volume is required. Italy and Spain reported the lowest ratio of two vials per procedure, whereas the U.K. reported the highest ratio by a margin of five to six vials per procedure.

Figure 8-9: Microspheres Market, Europe, 2012 – 2022 (€ and US\$)

Year	Units Sold	Growth (%)	ASP (€)	ASP (US\$)	Growth (%)	Market Value (€M)	Market Value (US\$M)	Growth (%)
2012	19,579		€183	\$202		€3.58	\$3.96	
2013	18,571	-5.2%	€180	\$199	-1.8%	€3.34	\$3.69	-6.8%
2014	17,722	-4.6%	€177	\$196	-1.3%	€3.14	\$3.48	-5.8%
2015	17,598	-0.7%	€175	\$193	-1.5%	€3.08	\$3.40	-2.2%
2016	17,582	-0.1%	€173	\$192	-0.8%	€3.05	\$3.37	-0.8%
2017	18,123	3.1%	€172	\$191	-0.6%	€3.12	\$3.45	2.5%
2018	18,419	1.6%	€172	\$190	-0.4%	€3.16	\$3.50	1.2%
2019	18,566	0.8%	€171	\$189	-0.6%	€3.17	\$3.50	0.2%
2020	18,623	0.3%	€170	\$188	-0.4%	€3.17	\$3.50	-0.1%
2021	18,747	0.7%	€169	\$187	-0.6%	€3.17	\$3.50	0.1%
2022	18,804	0.3%	€168	\$186	-0.3%	€3.17	\$3.50	0.0%
CAGR ('15-'22)		1.0%			-0.5%			0.4%

Source: iData Research Inc.

Chart 8-5: Microspheres Market, Europe, 2012 – 2022

Source: iData Research Inc.

Figure 8-10: Units Sold by Country, Microspheres Market, Europe, 2012 – 2022

Year	Germany	France	U.K.	Italy	Spain	Benelux	Scandi- navia	Austria	Switzer- land	Portugal	Europe	Growth (%)
2012	1,970	11,524	1,283	1,132	987	1,153	587	429	277	238	19,579	
2013	1,812	10,717	1,233	1,123	975	1,118	663	407	286	236	18,571	-5.2%
2014	1,703	10,074	1,174	1,179	912	1,085	691	391	295	217	17,722	-4.6%
2015	1,639	10,080	1,055	1,170	938	1,103	756	333	300	225	17,598	-0.7%
2016	1,622	9,979	1,066	1,162	980	1,091	802	331	308	239	17,582	-0.1%
2017	1,627	10,565	1,042	1,157	965	1,086	799	332	313	236	18,123	3.1%
2018	1,632	10,597	1,049	1,217	1,026	1,149	842	333	316	256	18,419	1.6%
2019	1,637	10,629	1,047	1,214	1,095	1,153	867	334	315	276	18,566	0.8%
2020	1,642	10,661	1,044	1,213	1,100	1,157	883	336	312	277	18,623	0.3%
2021	1,647	10,693	1,041	1,211	1,171	1,161	881	337	308	297	18,747	0.7%
2022	1,647	10,725	1,037	1,211	1,178	1,165	880	338	305	318	18,804	0.3%
CAGR (‘15–’22)	0.1%	0.9%	-0.2%	0.5%	3.3%	0.8%	2.2%	0.2%	0.2%	5.1%		1.0%

Source: iData Research Inc.

Figure 8-11: Units per Procedure, Microspheres Market, Europe, 2012 – 2022

Year	Germany	France	U.K.	Italy	Spain	Benelux	Scandi- navia	Austria	Switzer- land	Portugal	Europe	Growth (%)
2015	2-3	3-5	2-3	2	2-3	2-3	2-4	2-3	2-3	2-3		
Source: iData Research Inc.												

Figure 8-12: Average Selling Price by Country, Microspheres Market, Europe, 2012 – 2022 (€)

Year	Germany	France	U.K.	Italy	Spain	Benelux	Scandi- navia	Austria	Switzer- land	Portugal	Europe	Growth (%)
2012	€189	€181	€220	€181	€106	€211	€220	€182	€182	€106	€183	
2013	€186	€177	€228	€176	€101	€205	€228	€177	€177	€101	€180	-1.8%
2014	€183	€173	€235	€173	€98	€200	€235	€173	€173	€98	€177	-1.3%
2015	€180	€170	€240	€170	€95	€195	€240	€170	€170	€95	€175	-1.5%
2016	€178	€168	€242	€169	€94	€192	€242	€168	€168	€94	€173	-0.8%
2017	€177	€167	€242	€168	€94	€190	€242	€166	€166	€94	€172	-0.6%
2018	€176	€167	€242	€168	€95	€188	€242	€165	€165	€95	€172	-0.4%
2019	€176	€166	€239	€168	€95	€186	€239	€165	€165	€95	€171	-0.6%
2020	€175	€166	€236	€167	€96	€185	€236	€165	€165	€96	€170	-0.4%
2021	€174	€166	€232	€167	€97	€184	€232	€165	€165	€97	€169	-0.6%
2022	€173	€166	€228	€167	€97	€183	€228	€164	€164	€97	€168	-0.3%
CAGR (‘15–’22)	-0.6%	-0.4%	-0.7%	-0.3%	0.3%	-0.9%	-0.7%	-0.5%	-0.5%	0.3%		-0.5%

Source: iData Research Inc.

Figure 8-13: Average Selling Price by Country, Microspheres Market, Europe, 2012 – 2022 (US\$)

Year	Germany	France	U.K.	Italy	Spain	Benelux	Scandi- navia	Austria	Switzer- land	Portugal	Europe	Growth (%)
2012	\$209	\$201	\$243	\$200	\$118	\$234	\$243	\$201	\$201	\$118	\$202	
2013	\$205	\$196	\$253	\$195	\$112	\$227	\$253	\$196	\$196	\$112	\$199	-1.8%
2014	\$202	\$191	\$260	\$191	\$108	\$221	\$260	\$191	\$191	\$108	\$196	-1.3%
2015	\$199	\$188	\$265	\$188	\$105	\$216	\$265	\$188	\$188	\$105	\$193	-1.5%
2016	\$197	\$186	\$268	\$187	\$103	\$212	\$268	\$186	\$186	\$103	\$192	-0.8%
2017	\$196	\$185	\$268	\$186	\$104	\$210	\$268	\$184	\$184	\$104	\$191	-0.6%
2018	\$195	\$184	\$268	\$186	\$105	\$207	\$268	\$183	\$183	\$105	\$190	-0.4%
2019	\$194	\$184	\$264	\$185	\$105	\$206	\$264	\$183	\$183	\$105	\$189	-0.6%
2020	\$193	\$183	\$261	\$185	\$106	\$204	\$261	\$182	\$182	\$106	\$188	-0.4%
2021	\$192	\$183	\$257	\$185	\$107	\$203	\$257	\$182	\$182	\$107	\$187	-0.6%
2022	\$191	\$183	\$253	\$185	\$108	\$202	\$253	\$182	\$182	\$108	\$186	-0.3%
CAGR (‘15–’22)	-0.6%	-0.4%	-0.7%	-0.3%	0.3%	-0.9%	-0.7%	-0.5%	-0.5%	0.3%		-0.5%

Source: iData Research Inc.

Figure 8-14: Market Value by Country, Microspheres Market, Europe, 2012 – 2022 (€M)

Year	Germany	France	U.K.	Italy	Spain	Benelux	Scandi- navia	Austria	Switzer- land	Portugal	Europe	Growth (%)
2012	€0.37	€2.09	€0.28	€0.20	€0.10	€0.24	€0.13	€0.08	€0.05	€0.03	€3.58	
2013	€0.34	€1.90	€0.28	€0.20	€0.10	€0.23	€0.15	€0.07	€0.05	€0.02	€3.34	-6.8%
2014	€0.31	€1.74	€0.28	€0.20	€0.09	€0.22	€0.16	€0.07	€0.05	€0.02	€3.14	-5.8%
2015	€0.29	€1.71	€0.25	€0.20	€0.09	€0.21	€0.18	€0.06	€0.05	€0.02	€3.08	-2.2%
2016	€0.29	€1.68	€0.26	€0.20	€0.09	€0.21	€0.19	€0.06	€0.05	€0.02	€3.05	-0.8%
2017	€0.29	€1.77	€0.25	€0.19	€0.09	€0.21	€0.19	€0.06	€0.05	€0.02	€3.12	2.5%
2018	€0.29	€1.77	€0.25	€0.20	€0.10	€0.22	€0.20	€0.06	€0.05	€0.02	€3.16	1.2%
2019	€0.29	€1.77	€0.25	€0.20	€0.10	€0.21	€0.21	€0.06	€0.05	€0.03	€3.17	0.2%
2020	€0.29	€1.77	€0.25	€0.20	€0.11	€0.21	€0.21	€0.06	€0.05	€0.03	€3.17	-0.1%
2021	€0.29	€1.77	€0.24	€0.20	€0.11	€0.21	€0.20	€0.06	€0.05	€0.03	€3.17	0.1%
2022	€0.29	€1.78	€0.24	€0.20	€0.11	€0.21	€0.20	€0.06	€0.05	€0.03	€3.17	0.0%
CAGR (‘15–’22)	-0.5%	0.5%	-1.0%	0.2%	3.7%	-0.1%	1.5%	-0.2%	-0.3%	5.4%		0.4%

Source: iData Research Inc.

Figure 8-15: Market Value by Country, Microspheres Market, Europe, 2012 – 2022 (US\$M)

Year	Germany	France	U.K.	Italy	Spain	Benelux	Scandi- navia	Austria	Switzer- land	Portugal	Europe	Growth (%)
2012	\$0.41	\$2.31	\$0.31	\$0.23	\$0.12	\$0.27	\$0.14	\$0.09	\$0.06	\$0.03	\$3.96	
2013	\$0.37	\$2.10	\$0.31	\$0.22	\$0.11	\$0.25	\$0.17	\$0.08	\$0.06	\$0.03	\$3.69	-6.8%
2014	\$0.34	\$1.93	\$0.31	\$0.23	\$0.10	\$0.24	\$0.18	\$0.07	\$0.06	\$0.02	\$3.48	-5.8%
2015	\$0.33	\$1.89	\$0.28	\$0.22	\$0.10	\$0.24	\$0.20	\$0.06	\$0.06	\$0.02	\$3.40	-2.2%
2016	\$0.32	\$1.86	\$0.29	\$0.22	\$0.10	\$0.23	\$0.22	\$0.06	\$0.06	\$0.02	\$3.37	-0.8%
2017	\$0.32	\$1.96	\$0.28	\$0.22	\$0.10	\$0.23	\$0.21	\$0.06	\$0.06	\$0.02	\$3.45	2.5%
2018	\$0.32	\$1.95	\$0.28	\$0.23	\$0.11	\$0.24	\$0.23	\$0.06	\$0.06	\$0.03	\$3.50	1.2%
2019	\$0.32	\$1.95	\$0.28	\$0.23	\$0.12	\$0.24	\$0.23	\$0.06	\$0.06	\$0.03	\$3.50	0.2%
2020	\$0.32	\$1.96	\$0.27	\$0.22	\$0.12	\$0.24	\$0.23	\$0.06	\$0.06	\$0.03	\$3.50	-0.1%
2021	\$0.32	\$1.96	\$0.27	\$0.22	\$0.13	\$0.24	\$0.23	\$0.06	\$0.06	\$0.03	\$3.50	0.1%
2022	\$0.32	\$1.97	\$0.26	\$0.22	\$0.13	\$0.24	\$0.22	\$0.06	\$0.06	\$0.03	\$3.50	0.0%
CAGR (‘15–’22)	-0.5%	0.5%	-1.0%	0.2%	3.7%	-0.1%	1.5%	-0.2%	-0.3%	5.4%		0.4%

Source: iData Research Inc.

8.3.1.2 PVA Particles Market

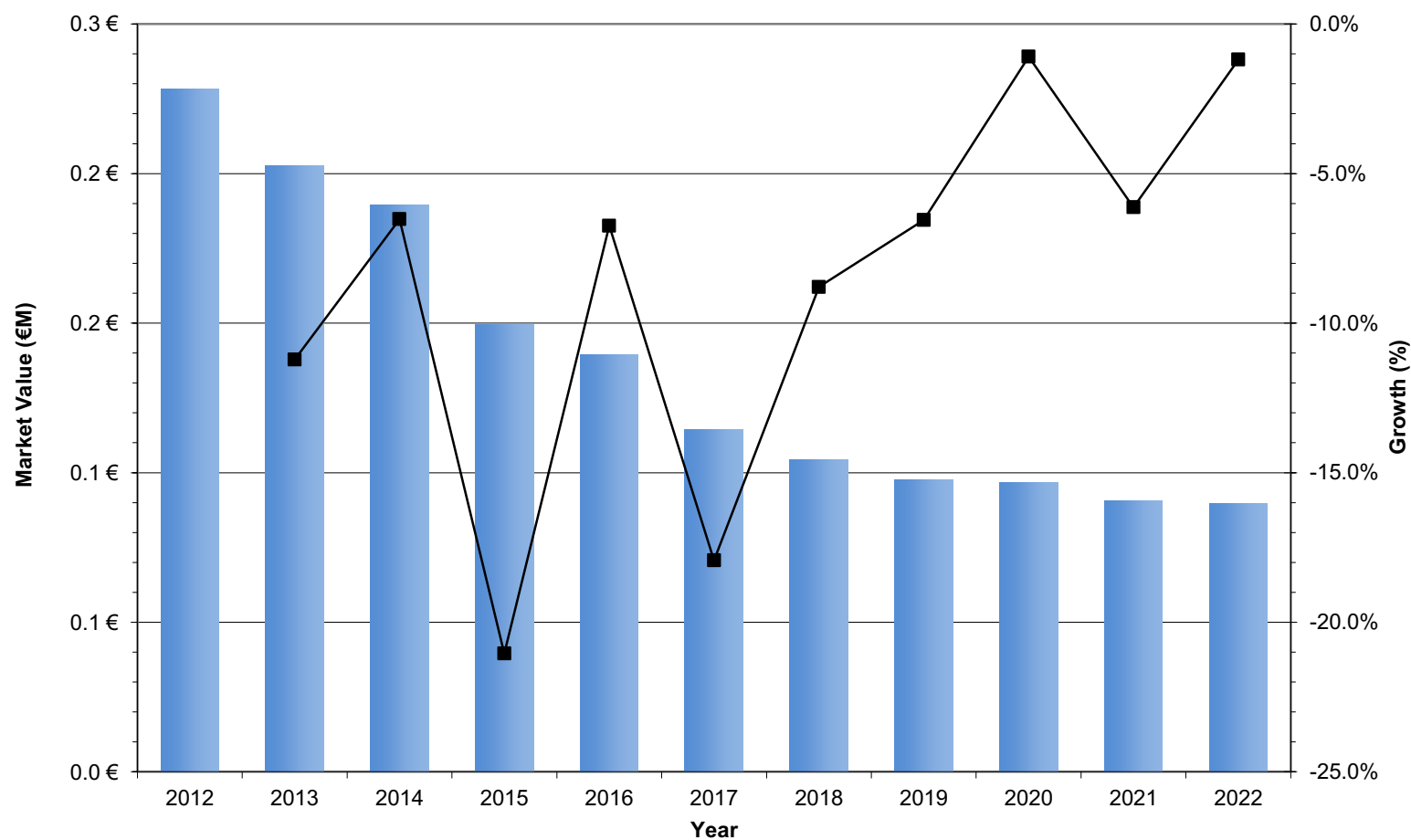
Limited growth in the volume of UFE procedures and physician preference for microspheres will cause unit sales of PVA particles to decrease over the forecast period. Falling prices have also led the market value to further contract, a trend continuing throughout the forecast period. Despite PVA particles' lack of presence, they remain a more viable product in regions where price sensitivity might outweigh treatment efficacy.

Unless either additional indications become approved or a substitute product becomes unaffordable, growth in the PVA market is expected to be virtually non-existent. However, market penetration that has been achieved is likely to linger due to the cost advantage afforded by PVA products.

Figure 8-16: PVA Particles Market, Europe, 2012 – 2022 (€ and US\$)

Year	Units Sold	Growth (%)	ASP (€)	ASP (US\$)	Growth (%)	Market Value (€M)	Market Value (US\$M)	Growth (%)
2012	2,610		€87.48	\$96.72		€0.23	\$0.25	
2013	2,397	-8.2%	€84.59	\$93.53	-3.3%	€0.20	\$0.22	-11.2%
2014	2,308	-3.7%	€82.11	\$90.78	-2.9%	€0.19	\$0.21	-6.5%
2015	1,854	-19.7%	€80.71	\$89.24	-1.7%	€0.15	\$0.17	-21.0%
2016	1,737	-6.3%	€80.32	\$88.80	-0.5%	€0.14	\$0.15	-6.7%
2017	1,440	-17.1%	€79.51	\$87.90	-1.0%	€0.11	\$0.13	-17.9%
2018	1,310	-9.0%	€79.72	\$88.14	0.3%	€0.10	\$0.12	-8.8%
2019	1,220	-6.9%	€79.98	\$88.43	0.3%	€0.10	\$0.11	-6.6%
2020	1,213	-0.6%	€79.60	\$88.01	-0.5%	€0.10	\$0.11	-1.1%
2021	1,132	-6.7%	€80.07	\$88.52	0.6%	€0.09	\$0.10	-6.1%
2022	1,120	-1.0%	€79.92	\$88.36	-0.2%	€0.09	\$0.10	-1.2%
CAGR ('15-'22)		-6.9%			-0.1%			-7.1%
Source: iData Research Inc.								

Chart 8-6: PVA Particles Market, Europe, 2012 – 2022



Source: iData Research Inc.

Figure 8-17: Units Sold by Country, PVA Particles Market, Europe, 2012 – 2022

Year	Germany	France	U.K.	Italy	Spain	Benelux	Scandi- navia	Austria	Switzer- land	Portugal	Europe	Growth (%)
2012	45	1,162	209	100	658	122	101	9	13	191	2,610	
2013	41	1,081	268	99	525	118	88	9	12	154	2,397	-8.2%
2014	39	1,016	328	66	491	115	92	8	11	142	2,308	-3.7%
2015	38	640	422	65	402	74	76	7	11	120	1,854	-19.7%
2016	37	634	426	65	327	73	57	7	10	103	1,737	-6.3%
2017	37	318	453	64	322	72	56	7	9	102	1,440	-17.1%
2018	37	319	456	32	257	70	37	7	7	88	1,310	-9.0%
2019	37	320	455	32	193	69	26	7	7	73	1,220	-6.9%
2020	38	321	454	32	194	68	19	7	7	74	1,213	-0.6%
2021	38	322	452	32	130	66	19	7	7	59	1,132	-6.7%
2022	38	323	451	32	131	69	19	7	7	45	1,120	-1.0%
CAGR (‘15–’22)	0.1%	-9.3%	1.0%	-9.7%	-14.8%	-0.9%	-18.2%	0.2%	-6.7%	-13.1%		-6.9%

Source: iData Research Inc.

Figure 8-18: Units per Procedure, PVA Particles Market, Europe, 2012 – 2022

Year	Germany	France	U.K.	Italy	Spain	Benelux	Scandi- navia	Austria	Switzer- land	Portugal	Europe	Growth (%)
2015	1	2	1-2	1	2	1-2	1	1	1	2		
Source: iData Research Inc.												

Figure 8-19: Average Selling Price by Country, PVA Particles Market, Europe, 2012 – 2022 (€)

Year	Germany	France	U.K.	Italy	Spain	Benelux	Scandi- navia	Austria	Switzer- land	Portugal	Europe	Growth (%)
2012	€97.61	€89.86	€109.04	€87.25	€75.92	€94.59	€93.83	€93.62	€83.30	€79.13	€87.48	
2013	€94.19	€86.26	€100.32	€83.76	€73.26	€91.28	€87.73	€89.88	€81.22	€75.17	€84.59	-3.3%
2014	€91.84	€83.67	€94.30	€80.83	€71.43	€88.08	€82.90	€87.18	€79.59	€72.16	€82.11	-2.9%
2015	€90.00	€82.00	€91.00	€78.00	€70.00	€85.00	€80.00	€85.00	€78.00	€70.00	€80.71	-1.7%
2016	€88.65	€81.18	€90.09	€76.44	€69.30	€82.45	€78.40	€83.73	€76.83	€68.60	€80.32	-0.5%
2017	€87.32	€80.37	€89.19	€75.29	€68.95	€79.98	€77.22	€82.47	€76.06	€67.91	€79.51	-1.0%
2018	€86.19	€79.56	€88.74	€74.47	€68.75	€78.22	€76.07	€81.56	€75.68	€67.57	€79.72	0.3%
2019	€85.24	€78.77	€88.48	€73.72	€68.54	€77.04	€75.30	€80.91	€75.45	€67.57	€79.98	0.3%
2020	€84.38	€77.98	€88.30	€73.13	€68.33	€76.50	€74.93	€80.50	€75.30	€67.57	€79.60	-0.5%
2021	€83.54	€77.20	€88.21	€72.77	€68.33	€76.12	€74.70	€80.10	€75.23	€67.64	€80.07	0.6%
2022	€82.71	€76.43	€88.21	€72.40	€68.40	€75.74	€74.48	€79.70	€75.23	€67.78	€79.92	-0.2%
CAGR (‘15–’22)	-1.2%	-1.0%	-0.4%	-1.1%	-0.3%	-1.6%	-1.0%	-0.9%	-0.5%	-0.5%		-0.1%

Source: iData Research Inc.

Figure 8-20: Average Selling Price by Country, PVA Particles Market, Europe, 2012 – 2022 (US\$)

Year	Germany	France	U.K.	Italy	Spain	Benelux	Scandi- navia	Austria	Switzer- land	Portugal	Europe	Growth (%)
2012	\$107.92	\$99.34	\$120.56	\$96.46	\$83.93	\$104.58	\$103.73	\$103.51	\$92.09	\$87.48	\$96.72	
2013	\$104.14	\$95.37	\$110.91	\$92.61	\$81.00	\$100.92	\$96.99	\$99.37	\$89.79	\$83.11	\$93.53	-3.3%
2014	\$101.53	\$92.51	\$104.26	\$89.36	\$78.97	\$97.38	\$91.66	\$96.39	\$88.00	\$79.79	\$90.78	-2.9%
2015	\$99.50	\$90.66	\$100.61	\$86.24	\$77.39	\$93.98	\$88.45	\$93.98	\$86.24	\$77.39	\$89.24	-1.7%
2016	\$98.01	\$89.75	\$99.60	\$84.51	\$76.62	\$91.16	\$86.68	\$92.57	\$84.94	\$75.84	\$88.80	-0.5%
2017	\$96.54	\$88.86	\$98.61	\$83.24	\$76.23	\$88.42	\$85.38	\$91.18	\$84.09	\$75.09	\$87.90	-1.0%
2018	\$95.29	\$87.97	\$98.11	\$82.33	\$76.01	\$86.48	\$84.10	\$90.17	\$83.67	\$74.71	\$88.14	0.3%
2019	\$94.24	\$87.09	\$97.82	\$81.51	\$75.78	\$85.18	\$83.26	\$89.45	\$83.42	\$74.71	\$88.43	0.3%
2020	\$93.30	\$86.22	\$97.62	\$80.85	\$75.55	\$84.58	\$82.84	\$89.01	\$83.26	\$74.71	\$88.01	-0.5%
2021	\$92.36	\$85.35	\$97.53	\$80.45	\$75.55	\$84.16	\$82.59	\$88.56	\$83.17	\$74.79	\$88.52	0.6%
2022	\$91.44	\$84.50	\$97.53	\$80.05	\$75.63	\$83.74	\$82.34	\$88.12	\$83.17	\$74.93	\$88.36	-0.2%
CAGR (‘15–’22)	-1.2%	-1.0%	-0.4%	-1.1%	-0.3%	-1.6%	-1.0%	-0.9%	-0.5%	-0.5%		-0.1%

Source: iData Research Inc.

Figure 8-21: Market Value by Country, PVA Particles Market, Europe, 2012 – 2022 (€M)

Year	Germany	France	U.K.	Italy	Spain	Benelux	Scandi- navia	Austria	Switzer- land	Portugal	Europe	Growth (%)
2012	€0.004	€0.104	€0.023	€0.009	€0.050	€0.012	€0.009	€0.001	€0.001	€0.015	€0.228	
2013	€0.004	€0.093	€0.027	€0.008	€0.038	€0.011	€0.008	€0.001	€0.001	€0.012	€0.203	-11.2%
2014	€0.004	€0.085	€0.031	€0.005	€0.035	€0.010	€0.008	€0.001	€0.001	€0.010	€0.190	-6.5%
2015	€0.003	€0.052	€0.038	€0.005	€0.028	€0.006	€0.006	€0.001	€0.001	€0.008	€0.150	-21.0%
2016	€0.003	€0.051	€0.038	€0.005	€0.023	€0.006	€0.004	€0.001	€0.001	€0.007	€0.140	-6.7%
2017	€0.003	€0.026	€0.040	€0.005	€0.022	€0.006	€0.004	€0.001	€0.001	€0.007	€0.115	-17.9%
2018	€0.003	€0.025	€0.040	€0.002	€0.018	€0.005	€0.003	€0.001	€0.001	€0.006	€0.104	-8.8%
2019	€0.003	€0.025	€0.040	€0.002	€0.013	€0.005	€0.002	€0.001	€0.001	€0.005	€0.098	-6.6%
2020	€0.003	€0.025	€0.040	€0.002	€0.013	€0.005	€0.001	€0.001	€0.001	€0.005	€0.097	-1.1%
2021	€0.003	€0.025	€0.040	€0.002	€0.009	€0.005	€0.001	€0.001	€0.001	€0.004	€0.091	-6.1%
2022	€0.003	€0.025	€0.040	€0.002	€0.009	€0.005	€0.001	€0.001	€0.001	€0.003	€0.090	-1.2%
CAGR (‘15–’22)	-1.1%	-10.2%	0.5%	-10.6%	-15.1%	-2.5%	-19.0%	-0.7%	-7.2%	-13.5%		-7.1%
Source: iData Research Inc.												

Figure 8-22: Market Value by Country, PVA Particles Market, Europe, 2012 – 2022 (US\$M)

Year	Germany	France	U.K.	Italy	Spain	Benelux	Scandi- navia	Austria	Switzer- land	Portugal	Europe	Growth (%)
2012	\$0.005	\$0.115	\$0.025	\$0.010	\$0.055	\$0.013	\$0.010	\$0.001	\$0.001	\$0.017	\$0.252	
2013	\$0.004	\$0.103	\$0.030	\$0.009	\$0.043	\$0.012	\$0.009	\$0.001	\$0.001	\$0.013	\$0.224	-11.2%
2014	\$0.004	\$0.094	\$0.034	\$0.006	\$0.039	\$0.011	\$0.008	\$0.001	\$0.001	\$0.011	\$0.210	-6.5%
2015	\$0.004	\$0.058	\$0.042	\$0.006	\$0.031	\$0.007	\$0.007	\$0.001	\$0.001	\$0.009	\$0.165	-21.0%
2016	\$0.004	\$0.057	\$0.042	\$0.005	\$0.025	\$0.007	\$0.005	\$0.001	\$0.001	\$0.008	\$0.154	-6.7%
2017	\$0.004	\$0.028	\$0.045	\$0.005	\$0.025	\$0.006	\$0.005	\$0.001	\$0.001	\$0.008	\$0.127	-17.9%
2018	\$0.004	\$0.028	\$0.045	\$0.003	\$0.020	\$0.006	\$0.003	\$0.001	\$0.001	\$0.007	\$0.115	-8.8%
2019	\$0.004	\$0.028	\$0.045	\$0.003	\$0.015	\$0.006	\$0.002	\$0.001	\$0.001	\$0.005	\$0.108	-6.6%
2020	\$0.004	\$0.028	\$0.044	\$0.003	\$0.015	\$0.006	\$0.002	\$0.001	\$0.001	\$0.006	\$0.107	-1.1%
2021	\$0.003	\$0.027	\$0.044	\$0.003	\$0.010	\$0.006	\$0.002	\$0.001	\$0.001	\$0.004	\$0.100	-6.1%
2022	\$0.003	\$0.027	\$0.044	\$0.003	\$0.010	\$0.006	\$0.002	\$0.001	\$0.001	\$0.003	\$0.099	-1.2%
CAGR (‘15–’22)	-1.1%	-10.2%	0.5%	-10.6%	-15.1%	-2.5%	-19.0%	-0.7%	-7.2%	-13.5%		-7.1%

Source: iData Research Inc.

8.4 DRIVERS AND LIMITERS

8.4.1 Market Drivers

Minimal Invasiveness

This minimally invasive procedure offers several advantages that make it preferable over other treatments. There is no surgical incision, the procedure involves minimal scarring and stitches and does not involve a prolonged stay in the hospital or general anesthesia. All fibroids can be treated at the same time. After the procedure, the woman is observed overnight and can return to work in several weeks. The recovery period is much shorter compared with the four to six-week recovery time after a hysterectomy.

In-Office Treatments

UFE can be done in an office setting, as opposed to surgical procedures, which must be conducted in a hospital. Office-based procedures are faster, have a lower level of discomfort and have higher recovery rates. UFE is done using intravenous conscious sedation, which involves fewer risks than general anesthesia.

Patient Satisfaction

Uterine fibroids can cause pelvic pain, heavy bleeding and infertility. In several follow-up studies, patients reported substantial relief of symptoms and increased quality of life. The quick recovery time and minimal invasiveness of UFE compared with hysterectomy increases the level of patient satisfaction.

8.4.2 Market Limiters

Lack of Long-Term Studies

This method has not been practiced for a significant amount of time, so there is no long-term data available yet on the reoccurrence rates of fibroids over many years. The effect of this treatment on pregnancy is also unknown, so it is recommended only for those women who do not intend to become pregnant.

Lack of Awareness

Since the procedure is relatively new, many physicians are still unaware of the positive clinical data associated with uterine fibroid embolization. They either do not think of recommending it or are hesitant to do so. Patient awareness is even lower, so without physicians recommending, or at least mentioning

the procedure as an option, the market will continue to be limited. Active marketing in the area has also been reduced. New procedures are believed to result via word-of-mouth through patient populations.

Physician Preference

The standard treatments for uterine fibroids are hysterectomy and myomectomy. Physicians continue to recommend these two surgical procedures because they are familiar with the techniques and their benefits. The efficacy and benefits of UFE may be unknown to most physicians. Gynecologists may be reluctant to recommend UFE, since it is interventional radiologists that perform the procedure. Gynecologists normally do not perform UFE, and they would lose potential patients if they were to recommend the procedure.

High-Level Training

Transcatheter embolization involves the targeted occlusion of certain blood vessels. The nature of this procedure—inducing an occlusion via the formation of an embolus—can be dangerous. This is because the procedure involves the use of diffusible liquids or particles, which can migrate to non-target locations. For example, even experienced physicians could run into difficulties calculating the polymerization time for glues. This can lead to glue residue on the catheter if the polymerization occurs too fast, or the glue could disperse to non-target areas if the polymerization proceeds too slowly. Because significant training is required to carry out embolization procedures, not all physicians are qualified to perform these procedures, thus limiting the market.

Competing Modalities

As is the case in many segments, the amount of competing modalities all attempting to capture the same market means that competition is immense. Companies will be forced to market their products either via performance or price. While not all modalities have synonymous indications, there still exists a large degree of overlap between embolization and other treatments.

Figure 8-23: Drivers and Limiters, Uterine Fibroid Embolization Device Market, Europe, 2015

Market Drivers
<ul style="list-style-type: none"> Minimal Invasiveness In-office Treatments Patient Satisfaction
Market Limiters
<ul style="list-style-type: none"> Lack of Long-Term Studies Lack of Awareness Physician Preference High-Level Training Competing Modalities
Source: iData Research Inc.

8.5 COMPETITIVE MARKET SHARE ANALYSIS

Merit Medical Systems

In 2010, Merit Medical Systems acquired Biosphere Medical, which was the leader in the uterine fibroid embolization market. With this acquisition, Merit Medical Systems held 33.8% of the overall European UFE device market in 2015.

Merit is involved in both the microsphere and PVA particle segments of embolotherapy, which work by reducing blood flow to targeted areas of the body. Their main product is the *Embosphere® Microspheres*. These microspheres have been the most clinically studied round embolic and claim to be the gold standard in uterine embolization. Merit's portfolio of embolics consists of *Bearing™ nsPVA*, *EmboGold®*, *Embosphere®*, *HepaSphere®* and *QuadraSphere®*.

Boston Scientific

Boston Scientific was the second leading competitor, with a 27.3% share in the UFE market. It offers both *Contour® SE* microspheres and *Contour® PVA* embolization particles. On November 10th, 2015, it was announced that Boston Scientific would purchase CeloNova Biosciences' Interventional Radiology portfolio. This portfolio included drug eluting microspheres and spherical embolic products used to treat uterine fibroids. Prior to the acquisition, CeloNova Biosciences was a leading competitor in the particle embolic space.

BTG / Terumo

BTG was the third leading competitor in the UFE market. Their BeadBlock® product portfolio consists of a range of hydrogel microspheres produced from polyvinyl alcohol (PVA). BeadBlock® microspheres are intended to be used for the embolization of hypervascular tumours including uterine fibroids.

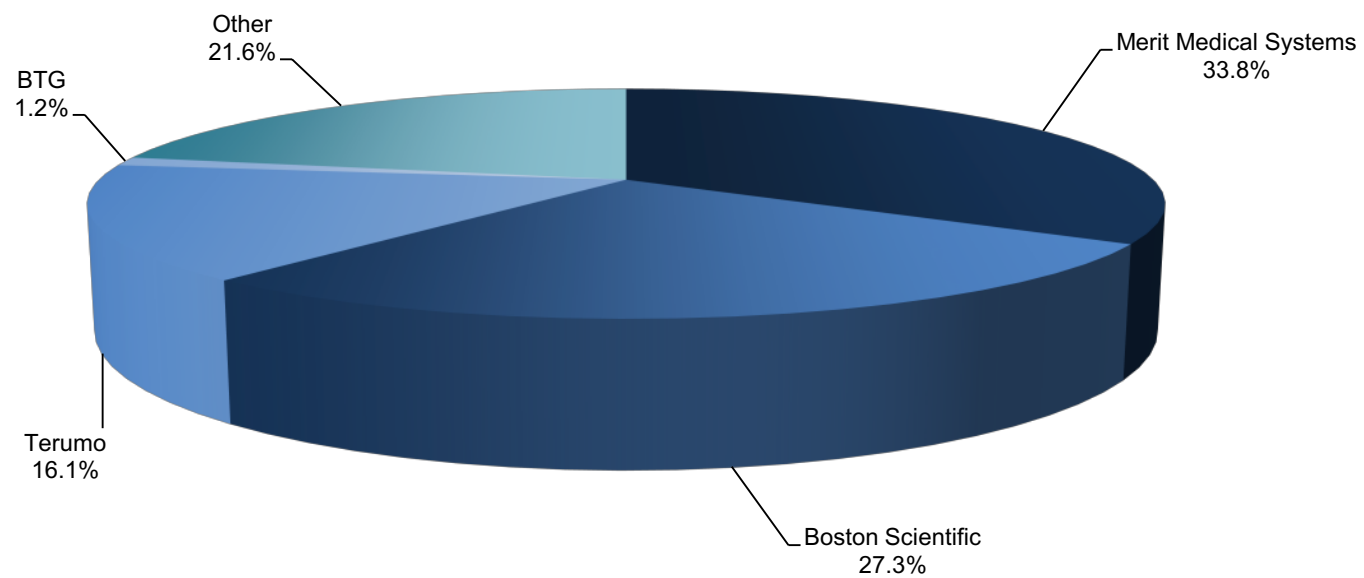
Terumo Corporation held the contract with BTG to distribute their drug-eluting bead and embolization products in Europe, a contract that expired on March 31st 2015. Terumo has previously been accredited with a high market share in the PVA market due to their contract with BTG to sell the DC Bead® and Bead Block®, directly to customers in eleven European countries. Since the contract expired, it is expected that the majority of their market share will be re-allocated back to BTG.

Other Notable Competitors

Other competitors accounted for the remaining 21.1% market share in 2015. These competitors include Cook Medical, Inova Diagnostics and Cordis among others.

Figure 8-24: Leading Competitors by Country, Uterine Fibroid Embolization Device Market, Europe, 2015

Company	Germany	France	U.K.	Italy	Spain	Benelux	Scandi- navia	Austria	Switzer- land	Portugal	Total Market Share
Merit Medical Systems	34.7%	35.1%	30.3%	35.6%	27.3%	35.5%	27.1%	22.7%	40.1%	30.6%	33.8%
Boston Scientific	29.5%	27.4%	30.0%	29.8%	19.7%	20.0%	31.3%	21.3%	30.3%	20.2%	27.3%
Terumo	–	23.7%	–	–	10.4%	24.4%	14.6%	7.5%	–	10.9%	16.1%
BTG	–	–	–	–	–	–	17.2%	11.8%	–	–	1.2%
Other	35.8%	13.8%	39.7%	34.6%	42.6%	20.1%	9.8%	36.7%	29.6%	38.3%	21.6%
Total	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
Market Value (€M)	€0.3	€1.8	€0.3	€0.2	€0.1	€0.2	€0.2	€0.1	€0.1	€0.0	€3.2
Others include: Cook Medical, Inova Diagnostics, Cordis, etc.											
Source: iData Research Inc.											

Chart 8-7: Leading Competitors, Uterine Fibroid Embolization Device Market, Europe, 2015

Source: iData Research Inc.

9

HYSTEROSCOPE MARKET

9.1 INTRODUCTION

Hysteroscopy is a procedure to view and operate in the endometrial cavity from a transcervical approach; either for diagnostic or treatment purposes. Hysteroscopy is performed using a hysteroscope. The procedure is minimally invasive and can be used for the diagnosis and treatment of intrauterine and endocervical problems; including endometrial ablation and myomectomy procedures.

Hysteroscope equipment includes three parts: the eyepiece, the barrel and the objective lens. Requirements such as a sheath will increase the size of the hysteroscope. There are multiple types and configurations of hysteroscopes available, including rigid and flexible (used most commonly in clinical settings). Additional sub-categories such as contact hysteroscopes are not covered in this report.

Diagnostic procedures are generally done in an office while operative procedures are most often done in a hospital setting. Media, such as sodium chloride solution, can be administered through the hysteroscope to distend the endometrial cavity. The larger area offers the physician operating room and improved visualization. The procedure takes an average of 40 minutes and local or general anesthesia can be used.

9.2 MARKET OVERVIEW

The market for hysteroscopes includes both the rigid and flexible hysteroscope segments. Trends for both the rigid and flexible segments of the hysteroscope market include movement towards devices with more advanced optic technology and better image quality. By an overwhelming margin, the dominant segment in the total hysteroscope market is rigid hysteroscopes. The hysteroscope market is growing slightly; however, the more relevant trend is the shift from flexible to rigid hysteroscopes. In 2015, the rigid hysteroscope market accounted for 92% of total hysteroscope sales. Rigid hysteroscope sales are growing at an average of 1.7% per annum, while flexible hysteroscopes are decreasing by -2.2% per annum.

By 2022, the rigid hysteroscope segment will comprise 94% of the total market. Rigid hysteroscopes are available in a wide range of diameters, to accommodate simple office procedures to complex operations. Both rigid and flexible hysteroscopes can have operating channels to allow for the insertion of surgical instruments. Due to the range in hysteroscope types and configurations, prices can be significantly different depending on the set-up. In this report, the ASP represents the median price of the most common hysteroscopes purchased.

Growth within the hysteroscope market is limited as the patient population will not significantly change. Although, as the population ages, the number of diagnostic and operative procedures for uterine conditions should increase slightly, resulting in a higher demand for these devices. The overall hysteroscope market is constrained by the number of doctors trained to perform hysteroscopy procedures. This is especially true in the Benelux region and the United Kingdom; it is estimated that only 10% to 15% of U.K. gynecologists are trained in hysteroscopy. Due to the mature, stable nature of the hysteroscope market, the projection for the remainder of the reporting period is expected to be stable to modest growth.

Figure 9-1: Hysteroscope Market by Segment, Europe, 2012 – 2022 (€M)

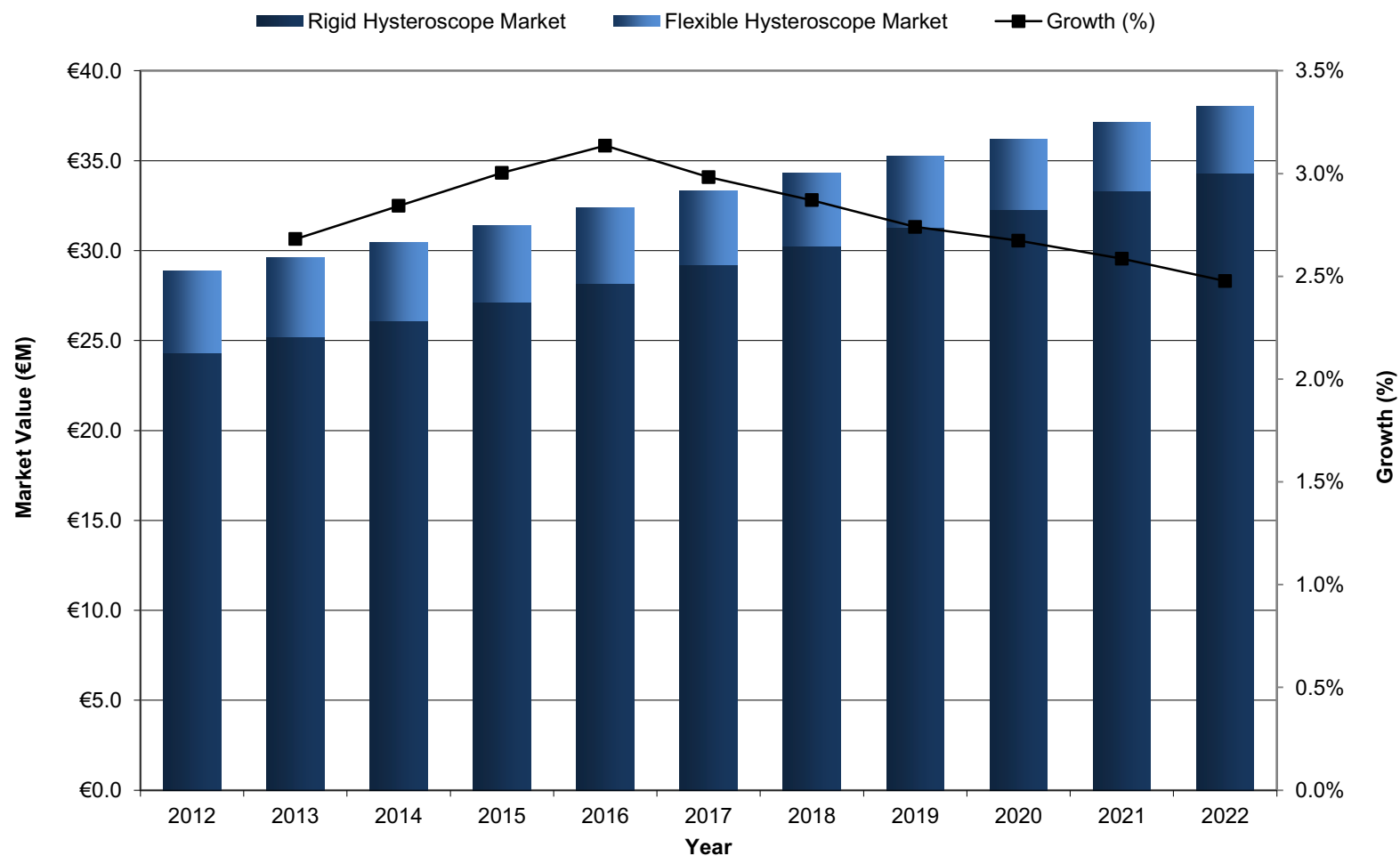
Year	Rigid Hysteroscope Market	Flexible Hysteroscope Market	Total Market	Growth (%)
2012	€24.3	€4.5	€28.9	
2013	€25.2	€4.4	€29.6	2.7%
2014	€26.1	€4.4	€30.5	2.8%
2015	€27.1	€4.3	€31.4	3.0%
2016	€28.2	€4.2	€32.4	3.1%
2017	€29.2	€4.1	€33.3	3.0%
2018	€30.3	€4.0	€34.3	2.9%
2019	€31.3	€4.0	€35.2	2.7%
2020	€32.3	€3.9	€36.2	2.7%
2021	€33.3	€3.8	€37.1	2.6%
2022	€34.3	€3.7	€38.0	2.5%
CAGR (‘15–’22)	3.4%	-2.0%		2.8%

Source: iData Research Inc.

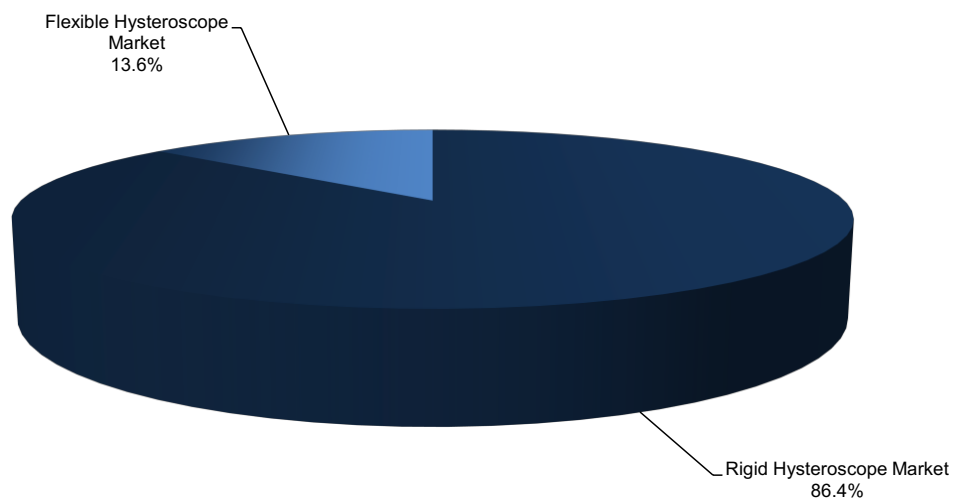
Figure 9-2: Hysteroscope Market by Segment, Europe, 2012 – 2022 (US\$M)

Year	Rigid Hysteroscope Market	Flexible Hysteroscope Market	Total Market	Growth (%)
2012	\$26.9	\$5.0	\$31.9	
2013	\$27.9	\$4.9	\$32.8	2.7%
2014	\$28.9	\$4.8	\$33.7	2.8%
2015	\$30.0	\$4.7	\$34.7	3.0%
2016	\$31.2	\$4.6	\$35.8	3.1%
2017	\$32.3	\$4.6	\$36.9	3.0%
2018	\$33.5	\$4.5	\$37.9	2.9%
2019	\$34.6	\$4.4	\$39.0	2.7%
2020	\$35.7	\$4.3	\$40.0	2.7%
2021	\$36.8	\$4.2	\$41.0	2.6%
2022	\$37.9	\$4.1	\$42.1	2.5%
CAGR (‘15–’22)	3.4%	-2.0%		2.8%

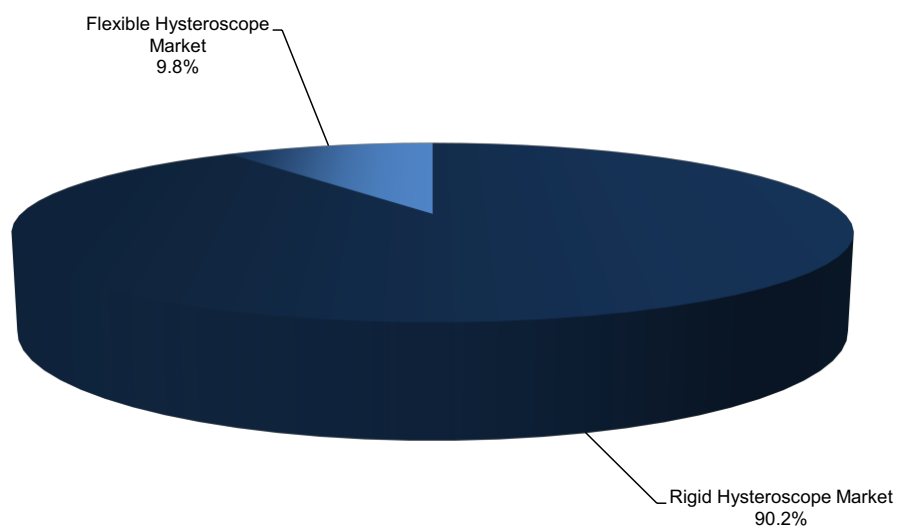
Source: iData Research Inc.

Chart 9-1: Hysteroscope Market by Segment, Europe, 2015

Source: iData Research Inc.

Chart 9-2: Hysteroscope Market Breakdown, Europe, 2015

Source: iData Research Inc.

Chart 9-3: Hysteroscope Market Breakdown, Europe, 2022

Source: iData Research Inc.

9.3 MARKET ANALYSIS AND FORECAST

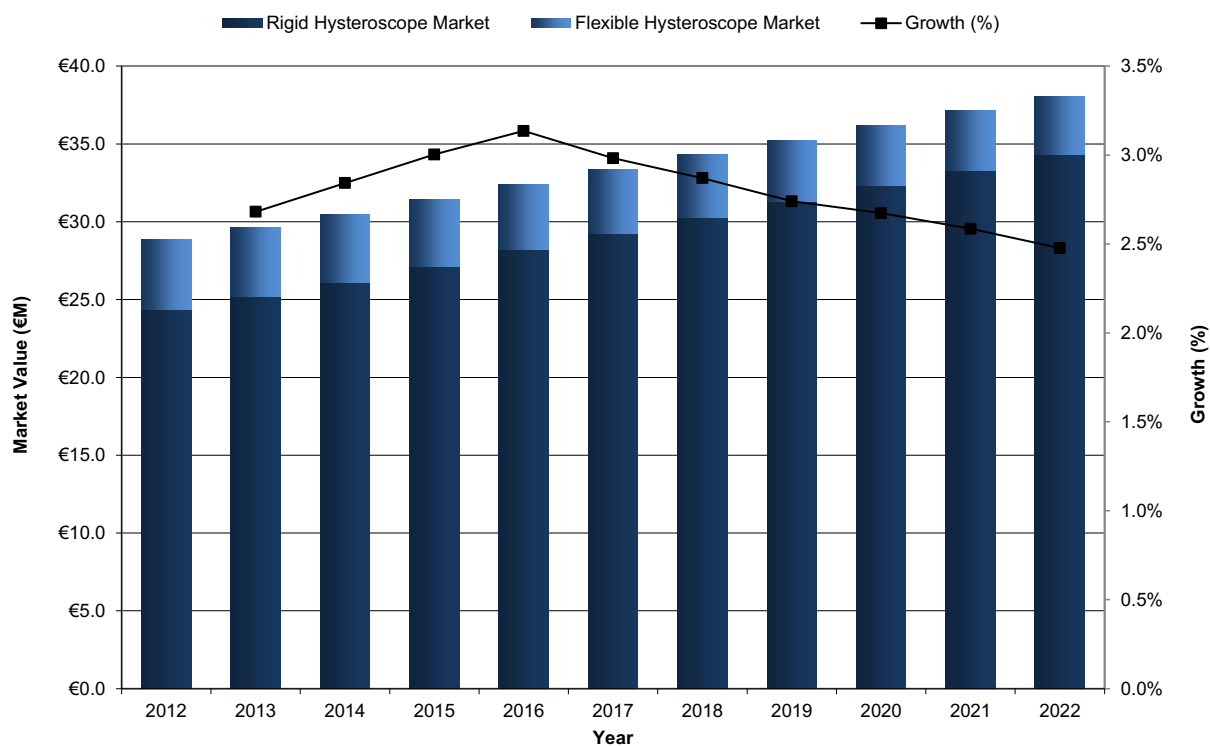
9.3.1 Hysteroscope Market

It is worth noting that the ASP of the hysteroscope market is often a misnomer. While the ASP of a rigid hysteroscope in 2015 was €4,878, this price does not take into account the trade in discount available for both rigid and flexible hysteroscopes. Many manufacturers offer a replacement discount of approximately 35% when trading in a scope from the same manufacturer. This makes replacement costs significantly lower than the initial cost of buying a hysteroscope. This should also be kept in mind when reviewing the market values provided.

Figure 9-3: Hysteroscope Market, Europe, 2012 – 2022 (€ and US\$)

Year	Units Sold	Growth (%)	ASP (€)	ASP (US\$)	Growth (%)	Market Value (€M)	Market Value (US\$M)	Growth (%)
2012	6,171		€4,677	\$5,171		€28.9	\$31.9	
2013	6,257	1.4%	€4,737	\$5,237	1.3%	€29.6	\$32.8	2.7%
2014	6,345	1.4%	€4,804	\$5,311	1.4%	€30.5	\$33.7	2.8%
2015	6,437	1.4%	€4,878	\$5,393	1.5%	€31.4	\$34.7	3.0%
2016	6,531	1.5%	€4,958	\$5,481	1.6%	€32.4	\$35.8	3.1%
2017	6,630	1.5%	€5,029	\$5,561	1.4%	€33.3	\$36.9	3.0%
2018	6,730	1.5%	€5,097	\$5,635	1.3%	€34.3	\$37.9	2.9%
2019	6,830	1.5%	€5,160	\$5,704	1.2%	€35.2	\$39.0	2.7%
2020	6,930	1.5%	€5,221	\$5,773	1.2%	€36.2	\$40.0	2.7%
2021	7,029	1.4%	€5,281	\$5,839	1.1%	€37.1	\$41.0	2.6%
2022	7,124	1.4%	€5,339	\$5,903	1.1%	€38.0	\$42.1	2.5%
CAGR ('15-'22)		1.5%			1.3%			2.8%

Source: iData Research Inc.

Chart 9-4: Hysteroscope Market, Europe, 2012 – 2022

Source: iData Research Inc.

Figure 9-4: Units Sold by Country, Hysteroscope Market, Europe, 2012-2022

Year	Germany	France	U.K.	Italy	Spain	Benelux	Scandi- navia	Austria	Switzer- land	Portugal	Europe	Growth (%)
2012	1,190	1,158	973	1,113	749	306	226	148	146	161	6,171	
2013	1,205	1,167	993	1,125	757	313	236	150	148	163	6,257	1.4%
2014	1,220	1,177	1,013	1,136	766	320	245	151	151	166	6,345	1.4%
2015	1,236	1,188	1,035	1,145	776	327	253	154	153	168	6,437	1.4%
2016	1,253	1,200	1,058	1,155	786	335	261	156	156	171	6,531	1.5%
2017	1,271	1,213	1,081	1,164	797	343	269	159	159	174	6,630	1.5%
2018	1,289	1,226	1,105	1,173	809	350	278	162	162	177	6,730	1.5%
2019	1,307	1,239	1,129	1,181	821	358	286	165	165	180	6,830	1.5%
2020	1,325	1,251	1,153	1,189	833	366	294	168	168	183	6,930	1.5%
2021	1,342	1,264	1,178	1,196	845	374	302	171	171	186	7,029	1.4%
2022	1,358	1,276	1,200	1,204	857	382	310	174	174	189	7,124	1.4%
CAGR (‘15-’22)	1.4%	1.0%	2.1%	0.7%	1.4%	2.2%	2.9%	1.8%	1.8%	1.7%		1.5%

Source: iData Research Inc.

Figure 9-5: Average Sales Price by Country, Hysteroscope Market, Europe, 2012-2022 (€)

Year	Germany	France	U.K.	Italy	Spain	Benelux	Scandi- navia	Austria	Switzer- land	Portugal	Europe	Growth (%)
2012	€4,302	€4,828	€4,602	€4,768	€4,794	€4,835	€5,068	€4,782	€4,642	€4,733	€4,677	
2013	€4,468	€4,846	€4,617	€4,814	€4,833	€4,914	€5,120	€4,810	€4,702	€4,774	€4,737	1.3%
2014	€4,648	€4,869	€4,634	€4,865	€4,877	€5,007	€5,183	€4,841	€4,766	€4,819	€4,804	1.4%
2015	€4,851	€4,893	€4,651	€4,923	€4,928	€5,100	€5,253	€4,876	€4,830	€4,868	€4,878	1.5%
2016	€5,075	€4,923	€4,672	€4,972	€4,986	€5,200	€5,335	€4,915	€4,900	€4,922	€4,958	1.6%
2017	€5,240	€4,955	€4,697	€5,021	€5,054	€5,306	€5,429	€4,959	€4,965	€4,983	€5,029	1.4%
2018	€5,376	€4,991	€4,724	€5,069	€5,119	€5,422	€5,520	€5,008	€5,029	€5,044	€5,097	1.3%
2019	€5,481	€5,032	€4,753	€5,115	€5,183	€5,544	€5,613	€5,062	€5,093	€5,107	€5,160	1.2%
2020	€5,579	€5,074	€4,785	€5,160	€5,248	€5,664	€5,705	€5,117	€5,156	€5,167	€5,221	1.2%
2021	€5,675	€5,113	€4,814	€5,202	€5,314	€5,776	€5,797	€5,169	€5,220	€5,229	€5,281	1.1%
2022	€5,770	€5,151	€4,842	€5,241	€5,380	€5,884	€5,884	€5,221	€5,281	€5,291	€5,339	1.1%
CAGR (‘15-’22)	2.5%	0.7%	0.6%	0.9%	1.3%	2.1%	1.6%	1.0%	1.3%	1.2%		1.3%

Source: iData Research Inc.

Figure 9-6: Average Sales Price by Country, Hysteroscope Market, Europe, 2012-2022 (US\$)

Year	Germany	France	U.K.	Italy	Spain	Benelux	Scandi- navia	Austria	Switzer- land	Portugal	Europe	Growth (%)
2012	\$4,756	\$5,338	\$5,088	\$5,272	\$5,300	\$5,346	\$5,604	\$5,287	\$5,132	\$5,233	\$5,171	
2013	\$4,939	\$5,358	\$5,105	\$5,322	\$5,343	\$5,433	\$5,661	\$5,318	\$5,198	\$5,278	\$5,237	1.3%
2014	\$5,139	\$5,383	\$5,123	\$5,379	\$5,392	\$5,536	\$5,730	\$5,352	\$5,269	\$5,327	\$5,311	1.4%
2015	\$5,363	\$5,409	\$5,143	\$5,443	\$5,448	\$5,639	\$5,808	\$5,391	\$5,340	\$5,382	\$5,393	1.5%
2016	\$5,611	\$5,443	\$5,166	\$5,497	\$5,513	\$5,749	\$5,898	\$5,435	\$5,418	\$5,441	\$5,481	1.6%
2017	\$5,793	\$5,478	\$5,193	\$5,552	\$5,587	\$5,867	\$6,002	\$5,483	\$5,490	\$5,509	\$5,561	1.4%
2018	\$5,944	\$5,519	\$5,223	\$5,605	\$5,660	\$5,994	\$6,103	\$5,537	\$5,560	\$5,577	\$5,635	1.3%
2019	\$6,059	\$5,564	\$5,255	\$5,656	\$5,730	\$6,129	\$6,206	\$5,596	\$5,631	\$5,647	\$5,704	1.2%
2020	\$6,168	\$5,610	\$5,290	\$5,705	\$5,802	\$6,262	\$6,308	\$5,658	\$5,700	\$5,713	\$5,773	1.2%
2021	\$6,275	\$5,653	\$5,323	\$5,752	\$5,875	\$6,386	\$6,409	\$5,714	\$5,771	\$5,781	\$5,839	1.1%
2022	\$6,379	\$5,695	\$5,353	\$5,794	\$5,948	\$6,506	\$6,506	\$5,772	\$5,838	\$5,850	\$5,903	1.1%
CAGR (‘15-’22)	2.5%	0.7%	0.6%	0.9%	1.3%	2.1%	1.6%	1.0%	1.3%	1.2%		1.3%

Source: iData Research Inc.

Figure 9-7: Hysteroscope Market by Country, Europe, 2012-2022 (€M)

Year	Germany	France	U.K.	Italy	Spain	Benelux	Scandi- navia	Austria	Switzer- land	Portugal	Europe	Growth (%)
2012	€5.12	€5.59	€4.48	€5.31	€3.59	€1.48	€1.15	€0.71	€0.68	€0.76	€28.86	
2013	€5.38	€5.65	€4.58	€5.42	€3.66	€1.54	€1.21	€0.72	€0.70	€0.78	€29.64	2.7%
2014	€5.67	€5.73	€4.70	€5.52	€3.74	€1.60	€1.27	€0.73	€0.72	€0.80	€30.48	2.8%
2015	€6.00	€5.81	€4.81	€5.64	€3.82	€1.67	€1.33	€0.75	€0.74	€0.82	€31.40	3.0%
2016	€6.36	€5.91	€4.94	€5.74	€3.92	€1.74	€1.39	€0.77	€0.77	€0.84	€32.38	3.1%
2017	€6.66	€6.01	€5.08	€5.85	€4.03	€1.82	€1.46	€0.79	€0.79	€0.87	€33.35	3.0%
2018	€6.93	€6.12	€5.22	€5.95	€4.14	€1.90	€1.53	€0.81	€0.82	€0.89	€34.30	2.9%
2019	€7.16	€6.23	€5.36	€6.04	€4.25	€1.99	€1.60	€0.83	€0.84	€0.92	€35.24	2.7%
2020	€7.39	€6.35	€5.52	€6.14	€4.37	€2.07	€1.68	€0.86	€0.87	€0.94	€36.18	2.7%
2021	€7.62	€6.46	€5.67	€6.22	€4.49	€2.16	€1.75	€0.88	€0.89	€0.97	€37.12	2.6%
2022	€7.84	€6.57	€5.81	€6.31	€4.61	€2.25	€1.83	€0.91	€0.92	€1.00	€38.04	2.5%
CAGR (‘15-’22)	3.9%	1.8%	2.7%	1.6%	2.7%	4.3%	4.6%	2.8%	3.1%	2.9%		2.8%

Source: iData Research Inc.

Figure 9-8: Hysteroscope Market by Country, Europe, 2012-2022 (US\$M)

Year	Germany	France	U.K.	Italy	Spain	Benelux	Scandi- navia	Austria	Switzer- land	Portugal	Europe	Growth (%)
2012	\$5.66	\$6.18	\$4.95	\$5.87	\$3.97	\$1.64	\$1.27	\$0.78	\$0.75	\$0.84	\$31.91	
2013	\$5.95	\$6.25	\$5.07	\$5.99	\$4.04	\$1.70	\$1.34	\$0.80	\$0.77	\$0.86	\$32.77	2.7%
2014	\$6.27	\$6.34	\$5.19	\$6.11	\$4.13	\$1.77	\$1.41	\$0.81	\$0.79	\$0.88	\$33.70	2.8%
2015	\$6.63	\$6.43	\$5.32	\$6.23	\$4.23	\$1.85	\$1.47	\$0.83	\$0.82	\$0.90	\$34.71	3.0%
2016	\$7.03	\$6.53	\$5.46	\$6.35	\$4.33	\$1.93	\$1.54	\$0.85	\$0.85	\$0.93	\$35.80	3.1%
2017	\$7.36	\$6.65	\$5.61	\$6.46	\$4.46	\$2.01	\$1.62	\$0.87	\$0.87	\$0.96	\$36.87	3.0%
2018	\$7.66	\$6.77	\$5.77	\$6.57	\$4.58	\$2.10	\$1.69	\$0.89	\$0.90	\$0.98	\$37.93	2.9%
2019	\$7.92	\$6.89	\$5.93	\$6.68	\$4.70	\$2.19	\$1.77	\$0.92	\$0.93	\$1.01	\$38.96	2.7%
2020	\$8.17	\$7.02	\$6.10	\$6.78	\$4.83	\$2.29	\$1.85	\$0.95	\$0.96	\$1.04	\$40.01	2.7%
2021	\$8.42	\$7.14	\$6.27	\$6.88	\$4.96	\$2.39	\$1.94	\$0.98	\$0.99	\$1.07	\$41.04	2.6%
2022	\$8.66	\$7.27	\$6.43	\$6.97	\$5.10	\$2.48	\$2.02	\$1.01	\$1.02	\$1.10	\$42.06	2.5%
CAGR (‘15–’22)	3.9%	1.8%	2.7%	1.6%	2.7%	4.3%	4.6%	2.8%	3.1%	2.9%		2.8%

Source: iData Research Inc.

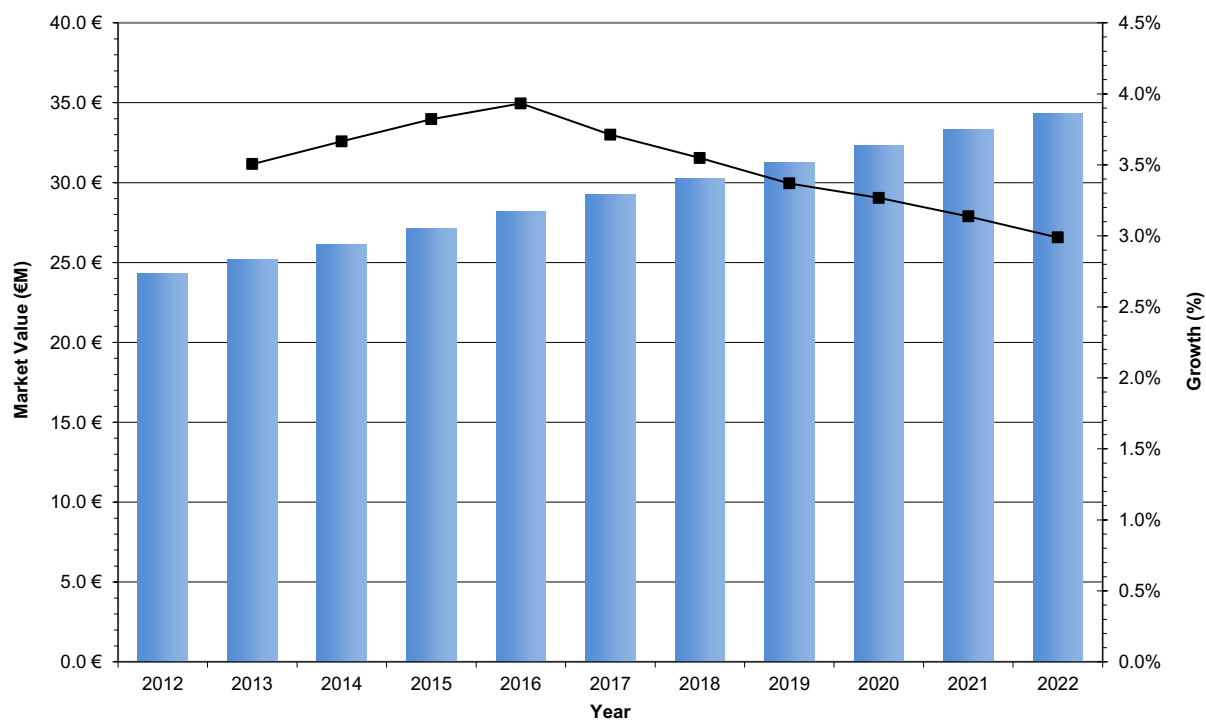
9.3.1.1 Rigid Hysteroscope Market

Rigid hysteroscopes are the most common type of hysteroscope with approximately half the ASP of a flexible hysteroscope. While movement towards more advanced technology normally results in an increasing ASP, the maturity of the market and strong competition act as a counter-measure. The result is a stable market with a modestly growing ASP. The trend of certain countries and medical professionals favoring flexible hysteroscopes also acts as an incentive to keep prices reasonable while the shift from flexible to rigid hysteroscopes is being encouraged as the new standard.

Figure 9-9: Rigid Hysteroscope Market, Europe, 2012 – 2022 (€ and US\$)

Year	Units Sold	Growth (%)	ASP (€)	ASP (US\$)	Growth (%)	Market Value (€M)	Market Value (US\$M)	Growth (%)
2012	5,642		€4,314	\$4,770		€24.34	\$26.91	
2013	5,738	1.7%	€4,390	\$4,854	1.8%	€25.19	\$27.85	3.5%
2014	5,838	1.7%	€4,473	\$4,945	1.9%	€26.11	\$28.87	3.7%
2015	5,941	1.8%	€4,564	\$5,045	2.0%	€27.11	\$29.98	3.8%
2016	6,047	1.8%	€4,660	\$5,152	2.1%	€28.18	\$31.15	3.9%
2017	6,156	1.8%	€4,747	\$5,249	1.9%	€29.23	\$32.31	3.7%
2018	6,266	1.8%	€4,829	\$5,339	1.7%	€30.26	\$33.46	3.5%
2019	6,377	1.8%	€4,905	\$5,423	1.6%	€31.28	\$34.59	3.4%
2020	6,486	1.7%	€4,980	\$5,506	1.5%	€32.30	\$35.72	3.3%
2021	6,595	1.7%	€5,052	\$5,586	1.4%	€33.32	\$36.84	3.1%
2022	6,700	1.6%	€5,122	\$5,662	1.4%	€34.31	\$37.94	3.0%
CAGR ('15-'22)		1.7%			1.7%			3.4%

Source: iData Research Inc.

Chart 9-5: Rigid Hysteroscope Market, Europe, 2012 – 2022

Source: iData Research Inc.

Figure 9-10: Units Sold by Country, Rigid Hysteroscope Market, Europe, 2012-2022

Year	Germany	France	U.K.	Italy	Spain	Benelux	Scandi- navia	Austria	Switzer- land	Portugal	Europe	Growth (%)
2012	1,074	977	937	1,078	645	289	221	138	138	143	5,642	
2013	1,091	991	957	1,090	657	296	231	140	141	146	5,738	1.7%
2014	1,107	1,006	978	1,101	669	303	240	142	143	148	5,838	1.7%
2015	1,125	1,022	1,000	1,111	683	311	248	144	146	151	5,941	1.8%
2016	1,143	1,038	1,023	1,121	697	319	256	147	149	154	6,047	1.8%
2017	1,163	1,056	1,046	1,130	711	327	265	150	152	158	6,156	1.8%
2018	1,182	1,073	1,070	1,139	725	335	273	153	155	161	6,266	1.8%
2019	1,202	1,091	1,095	1,148	741	342	281	156	158	164	6,377	1.8%
2020	1,221	1,108	1,119	1,156	755	350	289	159	161	167	6,486	1.7%
2021	1,240	1,124	1,144	1,163	771	358	298	162	164	171	6,595	1.7%
2022	1,257	1,141	1,167	1,171	785	367	306	165	167	174	6,700	1.6%
CAGR (‘15-’22)	1.6%	1.6%	2.2%	0.8%	2.0%	2.4%	3.0%	1.9%	2.0%	2.0%		1.7%

Source: iData Research Inc.

Figure 9-11: Average Sales Price by Country, Rigid Hysteroscope Market, Europe, 2012-2022 (€)

Year	Germany	France	U.K.	Italy	Spain	Benelux	Scandi- navia	Austria	Switzer- land	Portugal	Europe	Growth (%)
2012	€3,814	€4,288	€4,393	€4,611	€4,146	€4,726	€4,945	€4,489	€4,388	€4,206	€4,314	
2013	€4,009	€4,320	€4,412	€4,661	€4,225	€4,806	€5,004	€4,523	€4,454	€4,276	€4,390	1.8%
2014	€4,218	€4,359	€4,434	€4,717	€4,310	€4,902	€5,074	€4,559	€4,525	€4,349	€4,473	1.9%
2015	€4,450	€4,400	€4,459	€4,780	€4,400	€5,000	€5,150	€4,600	€4,600	€4,425	€4,564	2.0%
2016	€4,705	€4,448	€4,487	€4,833	€4,497	€5,105	€5,238	€4,646	€4,681	€4,505	€4,660	2.1%
2017	€4,894	€4,500	€4,518	€4,886	€4,602	€5,217	€5,337	€4,697	€4,755	€4,590	€4,747	1.9%
2018	€5,050	€4,556	€4,552	€4,937	€4,703	€5,339	€5,433	€4,753	€4,828	€4,675	€4,829	1.7%
2019	€5,171	€4,617	€4,587	€4,986	€4,799	€5,467	€5,531	€4,815	€4,901	€4,761	€4,905	1.6%
2020	€5,285	€4,678	€4,625	€5,034	€4,895	€5,593	€5,628	€4,879	€4,972	€4,842	€4,980	1.5%
2021	€5,396	€4,737	€4,660	€5,079	€4,990	€5,711	€5,723	€4,938	€5,043	€4,922	€5,052	1.4%
2022	€5,504	€4,793	€4,693	€5,120	€5,082	€5,825	€5,815	€4,997	€5,111	€5,004	€5,122	1.4%
CAGR (‘15-’22)	3.1%	1.2%	0.7%	1.0%	2.1%	2.2%	1.7%	1.2%	1.5%	1.8%		1.7%

Source: iData Research Inc.

Figure 9-12: Average Sales Price by Country, Rigid Hysteroscope Market, Europe, 2012-2022 (US\$)

Year	Germany	France	U.K.	Italy	Spain	Benelux	Scandi- navia	Austria	Switzer- land	Portugal	Europe	Growth (%)
2012	\$4,217	\$4,741	\$4,857	\$5,097	\$4,584	\$5,225	\$5,467	\$4,963	\$4,852	\$4,651	\$4,770	
2013	\$4,432	\$4,776	\$4,878	\$5,154	\$4,671	\$5,313	\$5,532	\$5,000	\$4,924	\$4,728	\$4,854	1.8%
2014	\$4,663	\$4,819	\$4,903	\$5,215	\$4,765	\$5,420	\$5,610	\$5,040	\$5,003	\$4,808	\$4,945	1.9%
2015	\$4,920	\$4,865	\$4,930	\$5,285	\$4,865	\$5,528	\$5,694	\$5,086	\$5,086	\$4,892	\$5,045	2.0%
2016	\$5,202	\$4,918	\$4,961	\$5,343	\$4,972	\$5,644	\$5,791	\$5,137	\$5,175	\$4,980	\$5,152	2.1%
2017	\$5,410	\$4,975	\$4,996	\$5,402	\$5,088	\$5,768	\$5,901	\$5,193	\$5,258	\$5,075	\$5,249	1.9%
2018	\$5,584	\$5,037	\$5,032	\$5,458	\$5,199	\$5,903	\$6,007	\$5,255	\$5,338	\$5,169	\$5,339	1.7%
2019	\$5,718	\$5,104	\$5,072	\$5,513	\$5,306	\$6,044	\$6,115	\$5,324	\$5,418	\$5,264	\$5,423	1.6%
2020	\$5,843	\$5,172	\$5,114	\$5,565	\$5,412	\$6,184	\$6,222	\$5,395	\$5,497	\$5,353	\$5,506	1.5%
2021	\$5,966	\$5,237	\$5,152	\$5,615	\$5,517	\$6,314	\$6,328	\$5,459	\$5,576	\$5,442	\$5,586	1.4%
2022	\$6,085	\$5,300	\$5,188	\$5,660	\$5,619	\$6,440	\$6,429	\$5,525	\$5,651	\$5,532	\$5,662	1.4%
CAGR (‘15-’22)	3.1%	1.2%	0.7%	1.0%	2.1%	2.2%	1.7%	1.2%	1.5%	1.8%		1.7%

Source: iData Research Inc.

Figure 9-13: Rigid Hysteroscope Market by Country, Europe, 2012-2022 (€M)

Year	Germany	France	U.K.	Italy	Spain	Benelux	Scandi- navia	Austria	Switzer- land	Portugal	Europe	Growth (%)
2012	€4.10	€4.19	€4.12	€4.97	€2.68	€1.37	€1.09	€0.62	€0.61	€0.60	€24.34	
2013	€4.37	€4.28	€4.22	€5.08	€2.78	€1.42	€1.16	€0.63	€0.63	€0.62	€25.19	3.5%
2014	€4.67	€4.38	€4.34	€5.19	€2.89	€1.49	€1.22	€0.65	€0.65	€0.65	€26.11	3.7%
2015	€5.01	€4.50	€4.46	€5.31	€3.00	€1.56	€1.28	€0.66	€0.67	€0.67	€27.11	3.8%
2016	€5.38	€4.62	€4.59	€5.42	€3.13	€1.63	€1.34	€0.68	€0.70	€0.70	€28.18	3.9%
2017	€5.69	€4.75	€4.73	€5.52	€3.27	€1.70	€1.41	€0.70	€0.72	€0.72	€29.23	3.7%
2018	€5.97	€4.89	€4.87	€5.63	€3.41	€1.79	€1.48	€0.73	€0.75	€0.75	€30.26	3.5%
2019	€6.22	€5.03	€5.02	€5.72	€3.55	€1.87	€1.55	€0.75	€0.77	€0.78	€31.28	3.4%
2020	€6.45	€5.18	€5.18	€5.82	€3.70	€1.96	€1.63	€0.78	€0.80	€0.81	€32.30	3.3%
2021	€6.69	€5.32	€5.33	€5.91	€3.84	€2.05	€1.70	€0.80	€0.83	€0.84	€33.32	3.1%
2022	€6.92	€5.47	€5.48	€6.00	€3.99	€2.14	€1.78	€0.83	€0.85	€0.87	€34.31	3.0%
CAGR (‘15-’22)	4.7%	2.8%	3.0%	1.8%	4.1%	4.6%	4.8%	3.2%	3.5%	3.8%		3.4%

Source: iData Research Inc.

Figure 9-14: Rigid Hysteroscope Market by Country, Europe, 2012-2022 (US\$M)

Year	Germany	France	U.K.	Italy	Spain	Benelux	Scandi- navia	Austria	Switzer- land	Portugal	Europe	Growth (%)
2012	\$4.53	\$4.63	\$4.55	\$5.50	\$2.96	\$1.51	\$1.21	\$0.69	\$0.67	\$0.67	\$26.91	
2013	\$4.83	\$4.73	\$4.67	\$5.62	\$3.07	\$1.57	\$1.28	\$0.70	\$0.69	\$0.69	\$27.85	3.5%
2014	\$5.16	\$4.85	\$4.79	\$5.74	\$3.19	\$1.64	\$1.35	\$0.72	\$0.72	\$0.71	\$28.87	3.7%
2015	\$5.54	\$4.97	\$4.93	\$5.87	\$3.32	\$1.72	\$1.41	\$0.73	\$0.74	\$0.74	\$29.98	3.8%
2016	\$5.95	\$5.11	\$5.07	\$5.99	\$3.46	\$1.80	\$1.48	\$0.75	\$0.77	\$0.77	\$31.15	3.9%
2017	\$6.29	\$5.25	\$5.23	\$6.11	\$3.62	\$1.88	\$1.56	\$0.78	\$0.80	\$0.80	\$32.31	3.7%
2018	\$6.60	\$5.41	\$5.39	\$6.22	\$3.77	\$1.97	\$1.64	\$0.80	\$0.83	\$0.83	\$33.46	3.5%
2019	\$6.87	\$5.57	\$5.55	\$6.33	\$3.93	\$2.07	\$1.72	\$0.83	\$0.86	\$0.86	\$34.59	3.4%
2020	\$7.14	\$5.73	\$5.72	\$6.43	\$4.09	\$2.17	\$1.80	\$0.86	\$0.88	\$0.90	\$35.72	3.3%
2021	\$7.40	\$5.89	\$5.90	\$6.53	\$4.25	\$2.26	\$1.88	\$0.89	\$0.91	\$0.93	\$36.84	3.1%
2022	\$7.65	\$6.05	\$6.06	\$6.63	\$4.41	\$2.36	\$1.97	\$0.91	\$0.94	\$0.96	\$37.94	3.0%
CAGR (‘15-’22)	4.7%	2.8%	3.0%	1.8%	4.1%	4.6%	4.8%	3.2%	3.5%	3.8%		3.4%

Source: iData Research Inc.

9.3.1.2 Flexible Hysteroscope Market

Flexible hysteroscopes are more common for solely office procedures and are associated with less pain during outpatient hysteroscopy compared with rigid hysteroscopes. The tip of flexible hysteroscopes offers a range of 120° to 160° which is necessary for an irregularly shaped uterus and to maneuver around intrauterine lesions. Traditionally, flexible hysteroscopes offered a “ground-glass quality”, an inferior view compared to rigid hysteroscopes. The lower technology contributed to the market shift towards favoring rigid hysteroscopes. However, technology has advanced and there are new, digitally enhanced flexible hysteroscopes that offer a comparable quality to a rigid hysteroscope lens available on the market.

Flexible hysteroscopes have a significantly higher ASP than rigid hysteroscopes. This is attributed to the fragile, smaller nature of the scope relative to a rigid hysteroscope. The ASP needs to account for the flexible hysteroscope breaking more frequently and the client incurring a higher replacement cost compared to alternative types of hysteroscopes.

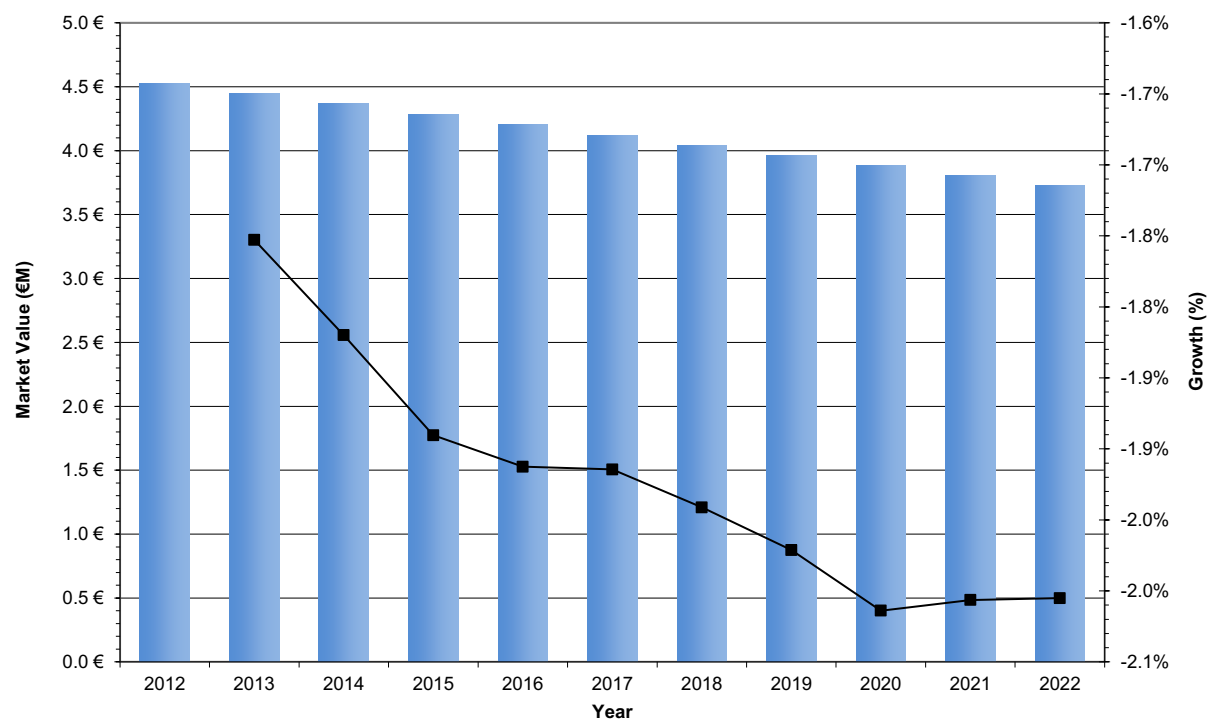
France is an anomaly in the hysteroscope market with a substantially higher percentage of flexible hysteroscopes than the rest of Europe. Flexible hysteroscopes have remained popular and overall doctors are less inclined to change technologies or prefer to invest in both flexible and rigid hysteroscopes.

Overall, flexible hysteroscopes comprise a small niche of the market. Although flexible hysteroscopes can be useful in diagnostic procedures, given the current economic climate, the purchase of redundant devices by hospitals and offices has and will continue to be minimal. The market is projected to experience a slight decrease in sales as the market continues to be eroded by medical professionals transitioning to rigid hysteroscopes.

Figure 9-15: Flexible Hysteroscope Market, Europe, 2012 – 2022 (€ and US\$)

Year	Units Sold	Growth (%)	ASP (€)	ASP (US\$)	Growth (%)	Market Value (€M)	Market Value (US\$M)	Growth (%)
2012	530		€8,543	\$9,445		€4.53	\$5.00	
2013	518	-2.2%	€8,583	\$9,489	0.5%	€4.45	\$4.92	-1.8%
2014	507	-2.2%	€8,617	\$9,527	0.4%	€4.37	\$4.83	-1.8%
2015	495	-2.2%	€8,645	\$9,557	0.3%	€4.28	\$4.74	-1.9%
2016	485	-2.2%	€8,670	\$9,585	0.3%	€4.20	\$4.64	-1.9%
2017	474	-2.2%	€8,694	\$9,612	0.3%	€4.12	\$4.56	-1.9%
2018	464	-2.2%	€8,715	\$9,635	0.2%	€4.04	\$4.47	-1.9%
2019	454	-2.2%	€8,734	\$9,656	0.2%	€3.96	\$4.38	-2.0%
2020	444	-2.2%	€8,749	\$9,673	0.2%	€3.88	\$4.29	-2.0%
2021	434	-2.2%	€8,763	\$9,689	0.2%	€3.80	\$4.20	-2.0%
2022	425	-2.1%	€8,775	\$9,702	0.1%	€3.73	\$4.12	-2.0%
CAGR ('15-'22)		-2.2%			0.2%			-2.0%

Source: iData Research Inc.

Chart 9-6: Flexible Hysteroscope Market, Europe, 2012 – 2022

Source: iData Research Inc.

Figure 9-16: Units Sold by Country, Flexible Hysteroscope Market, Europe, 2012-2022

Year	Germany	France	U.K.	Italy	Spain	Benelux	Scandi- navia	Austria	Switzer- land	Portugal	Europe	Growth (%)
2012	117	180	36	35	103	17	5	9	8	18	530	
2013	115	176	36	35	100	17	5	9	8	18	518	-2.2%
2014	113	171	36	35	96	17	5	9	8	17	507	-2.2%
2015	111	166	35	34	93	16	5	9	8	17	495	-2.2%
2016	110	162	35	34	90	16	5	9	8	16	485	-2.2%
2017	108	157	34	34	87	16	5	9	8	16	474	-2.2%
2018	107	153	34	34	83	16	5	9	7	16	464	-2.2%
2019	105	148	34	33	80	16	5	9	7	16	454	-2.2%
2020	104	144	34	33	77	16	5	9	7	15	444	-2.2%
2021	103	139	33	33	74	16	5	9	7	15	434	-2.2%
2022	101	135	33	33	72	15	4	9	7	15	425	-2.1%
CAGR (‘15-’22)	-1.3%	-2.9%	-0.9%	-0.7%	-3.7%	-0.9%	-1.8%	-0.5%	-0.8%	-1.9%		-2.2%

Source: iData Research Inc.

Figure 9-17: Average Sales Price by Country, Flexible Hysteroscope Market, Europe, 2012-2022 (€)

Year	Germany	France	U.K.	Italy	Spain	Benelux	Scandi- navia	Austria	Switzer- land	Portugal	Europe	Growth (%)
2012	€8,790	€7,756	€9,989	€9,589	€8,840	€6,708	€10,087	€9,086	€9,082	€8,890	€8,543	
2013	€8,829	€7,814	€10,069	€9,574	€8,831	€6,828	€10,167	€9,127	€9,154	€8,881	€8,583	0.5%
2014	€8,865	€7,869	€10,119	€9,565	€8,818	€6,931	€10,239	€9,163	€9,200	€8,868	€8,617	0.4%
2015	€8,900	€7,920	€10,119	€9,560	€8,800	€7,000	€10,300	€9,200	€9,200	€8,850	€8,645	0.3%
2016	€8,931	€7,968	€10,119	€9,557	€8,782	€7,063	€10,362	€9,232	€9,200	€8,832	€8,670	0.3%
2017	€8,961	€8,011	€10,118	€9,555	€8,765	€7,120	€10,419	€9,263	€9,199	€8,815	€8,694	0.3%
2018	€8,988	€8,051	€10,117	€9,554	€8,743	€7,169	€10,471	€9,290	€9,198	€8,793	€8,715	0.2%
2019	€9,010	€8,088	€10,115	€9,554	€8,721	€7,212	€10,518	€9,314	€9,196	€8,771	€8,734	0.2%
2020	€9,028	€8,120	€10,113	€9,554	€8,695	€7,248	€10,560	€9,332	€9,194	€8,744	€8,749	0.2%
2021	€9,046	€8,147	€10,111	€9,554	€8,669	€7,277	€10,597	€9,351	€9,193	€8,718	€8,763	0.2%
2022	€9,060	€8,171	€10,108	€9,554	€8,643	€7,299	€10,632	€9,365	€9,190	€8,692	€8,775	0.1%
CAGR (‘15-’22)	0.3%	0.4%	0.0%	0.0%	-0.3%	0.6%	0.5%	0.3%	0.0%	-0.3%		0.2%

Source: iData Research Inc.

Figure 9-18: Average Sales Price by Country, Flexible Hysteroscope Market, Europe, 2012-2022 (US\$)

Year	Germany	France	U.K.	Italy	Spain	Benelux	Scandi- navia	Austria	Switzer- land	Portugal	Europe	Growth (%)
2012	\$9,718	\$8,575	\$11,044	\$10,601	\$9,773	\$7,416	\$11,152	\$10,045	\$10,041	\$9,829	\$9,445	
2013	\$9,762	\$8,639	\$11,132	\$10,585	\$9,763	\$7,549	\$11,241	\$10,091	\$10,121	\$9,819	\$9,489	0.5%
2014	\$9,801	\$8,700	\$11,188	\$10,575	\$9,749	\$7,663	\$11,320	\$10,131	\$10,172	\$9,804	\$9,527	0.4%
2015	\$9,840	\$8,756	\$11,188	\$10,570	\$9,729	\$7,739	\$11,388	\$10,172	\$10,172	\$9,785	\$9,557	0.3%
2016	\$9,874	\$8,809	\$11,188	\$10,566	\$9,710	\$7,809	\$11,456	\$10,207	\$10,172	\$9,765	\$9,585	0.3%
2017	\$9,907	\$8,857	\$11,187	\$10,564	\$9,690	\$7,871	\$11,519	\$10,241	\$10,171	\$9,745	\$9,612	0.3%
2018	\$9,937	\$8,902	\$11,185	\$10,563	\$9,666	\$7,926	\$11,577	\$10,272	\$10,169	\$9,721	\$9,635	0.2%
2019	\$9,961	\$8,942	\$11,183	\$10,563	\$9,642	\$7,974	\$11,629	\$10,297	\$10,167	\$9,697	\$9,656	0.2%
2020	\$9,981	\$8,977	\$11,181	\$10,563	\$9,613	\$8,014	\$11,675	\$10,318	\$10,165	\$9,668	\$9,673	0.2%
2021	\$10,001	\$9,007	\$11,179	\$10,563	\$9,584	\$8,046	\$11,716	\$10,338	\$10,163	\$9,639	\$9,689	0.2%
2022	\$10,016	\$9,034	\$11,175	\$10,563	\$9,555	\$8,070	\$11,755	\$10,354	\$10,160	\$9,610	\$9,702	0.1%
CAGR (‘15-’22)	0.3%	0.4%	0.0%	0.0%	-0.3%	0.6%	0.5%	0.3%	0.0%	-0.3%		0.2%

Source: iData Research Inc.

Figure 9-19: Flexible Hysteroscope Market by Country, Europe, 2012-2022 (€M)

Year	Germany	France	U.K.	Italy	Spain	Benelux	Scandi- navia	Austria	Switzer- land	Portugal	Europe	Growth (%)
2012	€1.03	€1.40	€0.36	€0.34	€0.91	€0.11	€0.05	€0.09	€0.07	€0.16	€4.53	
2013	€1.01	€1.37	€0.36	€0.33	€0.88	€0.11	€0.05	€0.09	€0.07	€0.16	€4.45	-1.8%
2014	€1.00	€1.35	€0.36	€0.33	€0.85	€0.11	€0.05	€0.08	€0.07	€0.15	€4.37	-1.8%
2015	€0.99	€1.32	€0.36	€0.33	€0.82	€0.11	€0.05	€0.08	€0.07	€0.15	€4.28	-1.9%
2016	€0.98	€1.29	€0.35	€0.33	€0.79	€0.11	€0.05	€0.08	€0.07	€0.15	€4.20	-1.9%
2017	€0.97	€1.26	€0.35	€0.32	€0.76	€0.11	€0.05	€0.08	€0.07	€0.14	€4.12	-1.9%
2018	€0.96	€1.23	€0.35	€0.32	€0.73	€0.11	€0.05	€0.08	€0.07	€0.14	€4.04	-1.9%
2019	€0.95	€1.20	€0.34	€0.32	€0.70	€0.11	€0.05	€0.08	€0.07	€0.14	€3.96	-2.0%
2020	€0.94	€1.17	€0.34	€0.32	€0.67	€0.11	€0.05	€0.08	€0.07	€0.13	€3.88	-2.0%
2021	€0.93	€1.14	€0.34	€0.31	€0.64	€0.11	€0.05	€0.08	€0.07	€0.13	€3.80	-2.0%
2022	€0.92	€1.10	€0.33	€0.31	€0.62	€0.11	€0.05	€0.08	€0.07	€0.13	€3.73	-2.0%
CAGR (‘15-’22)	-1.1%	-2.5%	-0.9%	-0.7%	-3.9%	-0.3%	-1.3%	-0.2%	-0.8%	-2.1%		-2.0%

Source: iData Research Inc.

Figure 9-20: Flexible Hysteroscope Market by Country, Europe, 2012-2022 (US\$M)

Year	Germany	France	U.K.	Italy	Spain	Benelux	Scandi- navia	Austria	Switzer- land	Portugal	Europe	Growth (%)
2012	\$1.13	\$1.55	\$0.40	\$0.37	\$1.01	\$0.13	\$0.06	\$0.09	\$0.08	\$0.18	\$5.00	
2013	\$1.12	\$1.52	\$0.40	\$0.37	\$0.98	\$0.13	\$0.06	\$0.09	\$0.08	\$0.17	\$4.92	-1.8%
2014	\$1.11	\$1.49	\$0.40	\$0.37	\$0.94	\$0.13	\$0.06	\$0.09	\$0.08	\$0.17	\$4.83	-1.8%
2015	\$1.09	\$1.46	\$0.39	\$0.36	\$0.91	\$0.13	\$0.06	\$0.09	\$0.08	\$0.16	\$4.74	-1.9%
2016	\$1.08	\$1.43	\$0.39	\$0.36	\$0.87	\$0.13	\$0.06	\$0.09	\$0.08	\$0.16	\$4.64	-1.9%
2017	\$1.07	\$1.39	\$0.39	\$0.36	\$0.84	\$0.13	\$0.06	\$0.09	\$0.08	\$0.16	\$4.56	-1.9%
2018	\$1.06	\$1.36	\$0.38	\$0.35	\$0.81	\$0.13	\$0.06	\$0.09	\$0.08	\$0.15	\$4.47	-1.9%
2019	\$1.05	\$1.33	\$0.38	\$0.35	\$0.77	\$0.13	\$0.05	\$0.09	\$0.08	\$0.15	\$4.38	-2.0%
2020	\$1.04	\$1.29	\$0.38	\$0.35	\$0.74	\$0.13	\$0.05	\$0.09	\$0.07	\$0.15	\$4.29	-2.0%
2021	\$1.03	\$1.26	\$0.37	\$0.35	\$0.71	\$0.12	\$0.05	\$0.09	\$0.07	\$0.14	\$4.20	-2.0%
2022	\$1.02	\$1.22	\$0.37	\$0.35	\$0.68	\$0.12	\$0.05	\$0.09	\$0.07	\$0.14	\$4.12	-2.0%
CAGR (‘15-’22)	-1.1%	-2.5%	-0.9%	-0.7%	-3.9%	-0.3%	-1.3%	-0.2%	-0.8%	-2.1%		-2.0%

Source: iData Research Inc.

9.4 DRIVERS AND LIMITERS

9.4.1 Market Drivers

New Procedures

This market is benefiting from the transcervical sterilization market, which requires a hysteroscope to perform the procedure. Endometrial ablation can also use a hysteroscopy procedure that benefits this market in a similar way. Both of these markets are experiencing growth, which aids the growth of the hysteroscope market as well.

Increase in Office Procedures

Many newer procedures can be done in the office as opposed to in a hospital setting, increasing the number of office-based procedures performed. Moreover, the number of office-based procedures is growing for a number of reasons. One reason is that patients do not want to go to the hospital and go under general anesthesia. Office-based procedures are faster and have a lower level of discomfort. In addition, many procedures have higher reimbursement levels in the office than in a hospital setting. This is causing more physicians to purchase hysteroscopes for their office.

9.4.2 Market Limiters

Difficulty Training Surgeons

Training surgeons on the usage of hysteroscopes is very difficult, as it is quite hard to convince them that the hysteroscopy procedure has benefits. Not only is it hard to convince surgeons, but patients need to be educated about the procedure as well.

Economy

Due to the less-than-favorable economic situation in Europe, physicians in some price-sensitive markets are delaying the purchase or replacement of capital equipment devices, including hysteroscopes. This also affects sales of flexible and semi-flexible hysteroscopes, which some physicians view as a peripheral device.

Figure 9-21: Drivers and Limiters, Hysteroscope Market, Europe, 2015

Market Drivers
New Procedures Increase in Office Procedures
Market Limiters
Difficulty Training Surgeons Economy
Source: iData Research Inc.

9.5 COMPETITIVE MARKET SHARE ANALYSIS

Karl Storz

Karl Storz is the driving market leader in the European hysteroscope market with a 42.9% market share. Karl Storz offers a wide range of both miniaturization hysteroscopes intended for offices as well as a product line for standard gynecological procedures using hysteroscopic and/or laparoscopic techniques.

Richard Wolf

Richard Wolf is second in the European hysteroscope market, holding a market share of 21.4% in 2015. Richard Wolf offers a portfolio including compact hysteroscopes. Offering a PANOVUE telescope with a 30° direction of view and separate inflow and outflow of channels, their products are excellent for fertility and sterility patients.

Olympus

Olympus has the third largest market share, with 15.9% in Europe. Olympus is known for the quality of their optical and imaging solutions. Creating flexible 3D surgical endoscopy options, Olympus is leading the way in solutions that provide depth perception and spatial views of anatomy that are not possible with 2D systems. Olympus has a vast portfolio of hysteroscope options in both the flexible and rigid sub-segments.

Johnson & Johnson

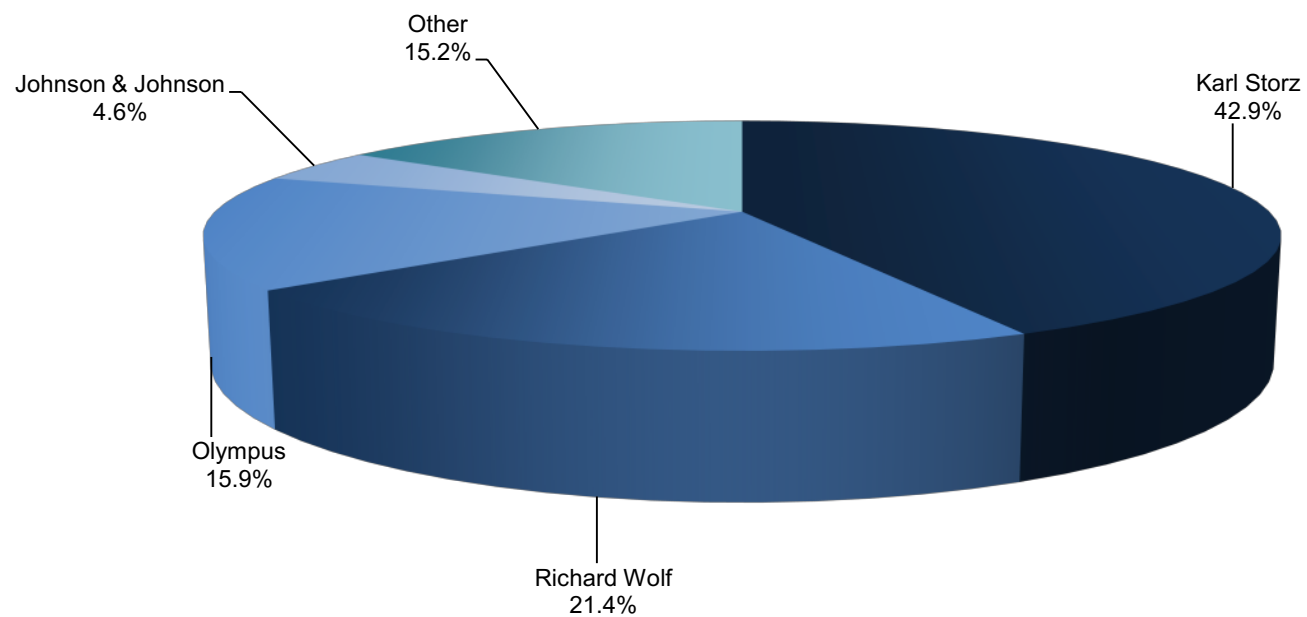
Ethicon, a Johnson & Johnson company, offers hysteroscopes for gynecology as part of their Gynecare portfolio. Gynecare is the smallest in the European market, with only a 4.6% market share in 2015. The Gynecare Versascope™ is their most popular hysteroscope, providing a high resolution 90° field of view with a 10° deflected sheath design.

Other Notable Competitors: Medtronic

In May 2016, Medtronic announced its acquisition of Smith & Nephew's gynecology business. Smith & Nephew's vital product is the TRUCLEAR System, utilizing a hysteroscope (instead of a resectoscope) the systems advantage is a simple mechanical approach to remove intrauterine tissue. The TRUCLEAR procedure is a minimally invasive surgical option that is also able to be performed as an outpatient procedure. Smith & Nephew has more than ten years of experience in Gynecology medical devices.

Figure 9-22: Leading Competitors by Country, Hysteroscope Market, Europe, 2015

Company	Germany	France	U.K.	Italy	Spain	Benelux	Scandi- navia	Austria	Switzer- land	Portugal	Total Market Share
Karl Storz	37.4%	34.3%	38.5%	65.1%	41.3%	37.4%	40.1%	34.0%	44.8%	45.2%	42.9%
Richard Wolf	26.1%	22.8%	18.4%	16.8%	24.8%	8.2%	24.3%	21.2%	27.6%	28.9%	21.4%
Olympus	15.8%	19.6%	18.2%	5.7%	15.9%	30.3%	14.8%	19.8%	13.9%	19.1%	15.9%
Johnson & Johnson	–	–	22.6%	–	–	21.5%	–	–	–	–	4.6%
Other	20.7%	23.3%	2.3%	12.4%	18.0%	2.6%	20.8%	25.0%	13.7%	6.8%	15.2%
Total	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
Market Value (€M)	€6.0	€5.8	€4.8	€5.6	€3.8	€1.7	€1.3	€0.7	€0.7	€0.8	€31.4
Others include: Medtronic, Hologic, Stryker, etc.											
Source: iData Research Inc.											

Chart 9-7: Leading Competitors, Hysteroscope Market, Europe, 2015

Source: iData Research Inc.

10

HYSTEROSCOPIC MORCELLATION

10.1 INTRODUCTION

10.2 MARKET ANALYSIS AND FORECAST

10.3 DRIVERS AND LIMITERS

10.3.1 Market Drivers

10.3.2 Market Limiters

10.4 COMPETITIVE MARKET SHARE

11

COLPOSCOPE MARKET

11.1 INTRODUCTION

A colposcope is a low-power stereoscopic, binocular field microscope with a powerful light source used for magnified visual examination of the uterine cervix, vaginal wall and vulva to help in diagnosis.

Colposcopy, a procedure using a colposcope, is performed if there is a positive screening test (ex. positive cytology, abnormal Pap smear etc.). Colposcopy procedures can accurately detect premalignant and malignant lesions. The results of this procedure may show evidence of dysplasia, cancer, HPV or atypical squamous cells of undetermined significance (ASCUS). Biopsies can be taken for further pathological examinations. For collecting evidence from victims of rape and sexual assault, specialized colposcopes equipped with a camera are used.

A colposcopy is a ten to fifteen minute procedure in which the woman lies in a gynecological chair with her feet in footrests. An acetic acid solution is placed on the cervix, causing the cervical cells to fill with water and block the passage of light. Areas showing abnormalities in the cervix appear white, and abnormal blood vessels can also be seen. Lesions can be treated by freezing with liquid nitrogen, with a laser or with a cream. A colposcopy is done in a hospital or clinic, and the patient can leave as soon as it is over.

11.2 MARKET ANALYSIS AND FORECAST

In 2015, the colposcope market was valued at €9.9 million, representing a 1.2% increase over 2014. This is a very mature and stable market, consisting primarily of replacement sales. However, there are significant variations across various countries in terms of market preferences and growth. The market is expected to grow at a CAGR of 1.7% over the forecast period, reaching €11.1 million. Growth in this market is due to the expansion or creation of health care facilities, as well as due to facilities that wish to replace a system early to take advantage of new technological advances.

Unit sales are largely dependent on the population of a country, since the market is largely saturated. The colposcope market is bi-modal, with a strong segmentation visible between lower-end, less expensive systems and high-end systems with advanced documentation, optics and light source. The lower-end systems are affordable options for health care facilities that are less willing or unable to purchase a high-end system at an increased expense; they are also aimed at younger physicians that are building their new practices. The high-end colposcope systems tend to be sold to larger health facilities that require robust technology capabilities and can be equipped for ceiling mounts.

In Scandinavia and Benelux, the market is still dominated by sales of lower-end systems; cost-effective purchases are still a high priority. In Benelux, most colposcope sales have been to hospitals, as offices are more hesitant to purchase these more expensive medical devices.

In Switzerland, Germany and especially in Austria, there seems to be a rising interest in colposcopy, particularly with younger physicians because it has been shown that colposcopy is able to examine changes in tissue better than cytology. Increased funding for cancer screenings in these countries have been driving growth in sales numbers as well as ASP. Moreover, there is a higher interest in exams for sexual assault cases, which has benefited sales of colposcopes with documentation systems.

The price of a colposcope in Europe ranges anywhere from €3,000 to €20,000. However, the ASP was €9,623 in 2015, representing a 0.2% increase from 2014.

Trends in ASP vary extensively across Europe. Due to favorable reimbursement, increased funding and increased interest in colposcopy, the ASPs for Germany, Austria and Switzerland are increasing at a CAGR in the low single digits. These countries are the most likely to purchase higher-end systems with more technical capabilities. Benelux and Scandinavia, on the other hand, have quite stable ASPs as the market in these countries is very mature and will not undergo many changes over the forecast period.

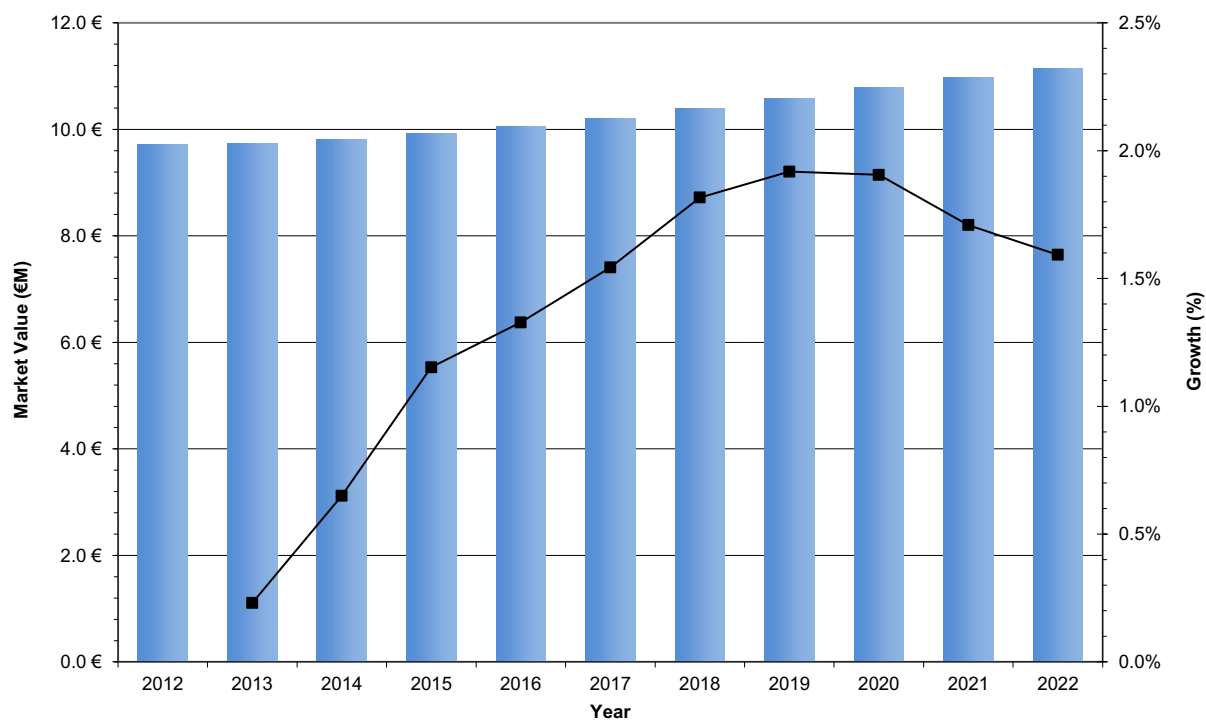
Italy, Spain and Portugal all have a lower ASP relative to the rest of Europe. Due to the less-than-favorable economy in these countries, there has been a significant trend to choose price over quality with cost effective colposcope products from Asia becoming popular.

Most countries will slowly move towards more advanced systems over the forecast period. While the ASP's are increasing across Europe, the price of individual colposcope products is decreasing slightly. The ASP growth is generated from most countries transitioning towards higher end colposcopes from less expensive lower-end systems.

Figure 11-1: Colposcope Market, Europe, 2012 – 2022 (€ and US\$)

Year	Units Sold	Growth (%)	ASP (€)	ASP (US\$)	Growth (%)	Market Value (€M)	Market Value (US\$M)	Growth (%)
2012	1,008		€9,636	\$10,653		€9.7	\$10.7	
2013	1,013	0.5%	€9,609	\$10,624	-0.3%	€9.7	\$10.8	0.2%
2014	1,021	0.7%	€9,605	\$10,619	0.0%	€9.8	\$10.8	0.7%
2015	1,030	1.0%	€9,623	\$10,639	0.2%	€9.9	\$11.0	1.2%
2016	1,041	1.0%	€9,650	\$10,669	0.3%	€10.0	\$11.1	1.3%
2017	1,053	1.2%	€9,687	\$10,710	0.4%	€10.2	\$11.3	1.5%
2018	1,067	1.3%	€9,737	\$10,765	0.5%	€10.4	\$11.5	1.8%
2019	1,081	1.3%	€9,792	\$10,826	0.6%	€10.6	\$11.7	1.9%
2020	1,094	1.2%	€9,858	\$10,899	0.7%	€10.8	\$11.9	1.9%
2021	1,107	1.1%	€9,914	\$10,961	0.6%	€11.0	\$12.1	1.7%
2022	1,119	1.1%	€9,962	\$11,014	0.5%	€11.1	\$12.3	1.6%
CAGR ('15-'22)		1.2%			0.5%			1.7%

Source: iData Research Inc.

Chart 11-1: Colposcope Market, Europe, 2012 – 2022

Source: iData Research Inc.

Figure 11-2: Units Sold by Country, Colposcope Market, Europe, 2012-2022

Year	Germany	France	U.K.	Italy	Spain	Benelux	Scandi- navia	Austria	Switzer- land	Portugal	Europe	Growth (%)
2012	132	92	185	181	149	89	87	31	30	32	1,008	
2013	133	91	186	183	147	90	87	33	31	31	1,013	0.5%
2014	135	91	188	185	145	90	88	35	33	29	1,021	0.7%
2015	138	92	191	186	144	90	88	38	34	28	1,030	1.0%
2016	140	93	194	187	144	91	89	41	35	28	1,041	1.0%
2017	142	94	196	188	144	91	89	44	37	27	1,053	1.2%
2018	145	96	199	188	144	92	90	47	39	27	1,067	1.3%
2019	147	99	202	188	145	92	90	50	40	28	1,081	1.3%
2020	150	101	205	189	145	93	91	52	42	28	1,094	1.2%
2021	152	104	206	189	146	93	91	54	44	28	1,107	1.1%
2022	154	107	208	189	146	93	92	55	46	29	1,119	1.1%
CAGR (‘15-’22)	1.7%	2.1%	1.2%	0.2%	0.2%	0.5%	0.6%	5.5%	4.5%	0.1%		1.2%

Source: iData Research Inc.

Figure 11-3: Average Sales Price by Country, Colposcope Market, Europe, 2012-2022 (€)

Year	Germany	France	U.K.	Italy	Spain	Benelux	Scandi- navia	Austria	Switzer- land	Portugal	Europe	Growth (%)
2012	€9,657	€9,574	€11,510	€8,627	€9,194	€8,912	€9,839	€9,060	€8,922	€9,387	€9,636	
2013	€9,771	€9,335	€11,614	€8,476	€9,033	€8,951	€9,878	€9,218	€9,017	€9,262	€9,609	-0.3%
2014	€9,888	€9,148	€11,742	€8,349	€8,897	€8,991	€9,919	€9,393	€9,114	€9,151	€9,605	0.0%
2015	€10,011	€8,992	€11,906	€8,249	€8,791	€9,033	€9,964	€9,575	€9,212	€9,050	€9,623	0.2%
2016	€10,136	€8,858	€12,097	€8,150	€8,685	€9,078	€10,013	€9,699	€9,312	€8,964	€9,650	0.3%
2017	€10,271	€8,769	€12,290	€8,060	€8,590	€9,128	€10,064	€9,806	€9,415	€8,889	€9,687	0.4%
2018	€10,407	€8,769	€12,474	€7,980	€8,504	€9,181	€10,117	€9,912	€9,518	€8,853	€9,737	0.5%
2019	€10,546	€8,773	€12,662	€7,908	€8,427	€9,235	€10,173	€10,018	€9,626	€8,844	€9,792	0.6%
2020	€10,687	€8,779	€12,788	€7,908	€8,419	€9,291	€10,232	€10,124	€9,737	€8,853	€9,858	0.7%
2021	€10,829	€8,786	€12,852	€7,908	€8,427	€9,347	€10,288	€10,231	€9,850	€8,871	€9,914	0.6%
2022	€10,973	€8,794	€12,865	€7,916	€8,444	€9,407	€10,329	€10,340	€9,965	€8,892	€9,962	0.5%
CAGR (‘15-’22)	1.3%	-0.3%	1.1%	-0.6%	-0.6%	0.6%	0.5%	1.1%	1.1%	-0.3%		0.5%

Source: iData Research Inc.

Figure 11-4: Average Sales Price by Country, Colposcope Market, Europe, 2012-2022 (US\$)

Year	Germany	France	U.K.	Italy	Spain	Benelux	Scandi- navia	Austria	Switzer- land	Portugal	Europe	Growth (%)
2012	\$10,676	\$10,585	\$12,726	\$9,538	\$10,165	\$9,853	\$10,878	\$10,016	\$9,864	\$10,378	\$10,653	
2013	\$10,803	\$10,320	\$12,840	\$9,371	\$9,987	\$9,896	\$10,921	\$10,192	\$9,969	\$10,240	\$10,624	-0.3%
2014	\$10,932	\$10,114	\$12,982	\$9,231	\$9,837	\$9,940	\$10,967	\$10,385	\$10,076	\$10,117	\$10,619	0.0%
2015	\$11,068	\$9,942	\$13,163	\$9,120	\$9,719	\$9,987	\$11,016	\$10,586	\$10,185	\$10,006	\$10,639	0.2%
2016	\$11,206	\$9,793	\$13,374	\$9,011	\$9,602	\$10,037	\$11,070	\$10,723	\$10,296	\$9,911	\$10,669	0.3%
2017	\$11,355	\$9,695	\$13,588	\$8,912	\$9,497	\$10,092	\$11,127	\$10,841	\$10,409	\$9,828	\$10,710	0.4%
2018	\$11,506	\$9,695	\$13,792	\$8,822	\$9,402	\$10,151	\$11,186	\$10,959	\$10,523	\$9,788	\$10,765	0.5%
2019	\$11,660	\$9,700	\$13,999	\$8,743	\$9,317	\$10,211	\$11,247	\$11,076	\$10,642	\$9,778	\$10,826	0.6%
2020	\$11,815	\$9,706	\$14,139	\$8,743	\$9,308	\$10,272	\$11,312	\$11,193	\$10,765	\$9,788	\$10,899	0.7%
2021	\$11,972	\$9,713	\$14,209	\$8,743	\$9,317	\$10,335	\$11,375	\$11,312	\$10,890	\$9,808	\$10,961	0.6%
2022	\$12,132	\$9,722	\$14,224	\$8,752	\$9,336	\$10,401	\$11,420	\$11,432	\$11,018	\$9,831	\$11,014	0.5%
CAGR (‘15-’22)	1.3%	-0.3%	1.1%	-0.6%	-0.6%	0.6%	0.5%	1.1%	1.1%	-0.3%		0.5%

Source: iData Research Inc.

Figure 11-5: Colposcope Market by Country, Europe, 2012-2022 (€M)

Year	Germany	France	U.K.	Italy	Spain	Benelux	Scandi- navia	Austria	Switzer- land	Portugal	Europe	Growth (%)
2012	€1.27	€0.88	€2.13	€1.56	€1.37	€0.80	€0.85	€0.28	€0.27	€0.30	€9.72	
2013	€1.30	€0.85	€2.16	€1.55	€1.32	€0.80	€0.86	€0.31	€0.28	€0.29	€9.74	0.2%
2014	€1.34	€0.84	€2.21	€1.54	€1.29	€0.81	€0.87	€0.33	€0.30	€0.27	€9.80	0.7%
2015	€1.38	€0.83	€2.27	€1.54	€1.27	€0.82	€0.88	€0.36	€0.31	€0.26	€9.91	1.2%
2016	€1.42	€0.82	€2.34	€1.52	€1.25	€0.82	€0.89	€0.40	€0.33	€0.25	€10.05	1.3%
2017	€1.46	€0.83	€2.41	€1.51	€1.24	€0.83	€0.90	€0.43	€0.35	€0.24	€10.20	1.5%
2018	€1.51	€0.84	€2.49	€1.50	€1.23	€0.84	€0.91	€0.46	€0.37	€0.24	€10.39	1.8%
2019	€1.55	€0.87	€2.56	€1.49	€1.22	€0.85	€0.92	€0.50	€0.39	€0.25	€10.59	1.9%
2020	€1.60	€0.89	€2.62	€1.49	€1.22	€0.86	€0.93	€0.52	€0.41	€0.25	€10.79	1.9%
2021	€1.65	€0.91	€2.65	€1.49	€1.23	€0.87	€0.94	€0.55	€0.44	€0.25	€10.97	1.7%
2022	€1.69	€0.94	€2.68	€1.49	€1.23	€0.88	€0.95	€0.57	€0.46	€0.25	€11.15	1.6%
CAGR (‘15-’22)	3.0%	1.8%	2.4%	-0.4%	-0.4%	1.0%	1.1%	6.6%	5.7%	-0.1%		1.7%

Source: iData Research Inc.

Figure 11-6: Colposcope Market by Country, Europe, 2012-2022 (US\$M)

Year	Germany	France	U.K.	Italy	Spain	Benelux	Scandi- navia	Austria	Switzer- land	Portugal	Europe	Growth (%)
2012	\$1.40	\$0.97	\$2.35	\$1.73	\$1.51	\$0.88	\$0.94	\$0.31	\$0.30	\$0.34	\$10.74	
2013	\$1.44	\$0.94	\$2.39	\$1.72	\$1.46	\$0.89	\$0.95	\$0.34	\$0.31	\$0.32	\$10.77	0.2%
2014	\$1.48	\$0.92	\$2.45	\$1.71	\$1.43	\$0.90	\$0.96	\$0.37	\$0.33	\$0.30	\$10.84	0.7%
2015	\$1.52	\$0.92	\$2.51	\$1.70	\$1.40	\$0.90	\$0.97	\$0.40	\$0.35	\$0.28	\$10.96	1.2%
2016	\$1.57	\$0.91	\$2.59	\$1.69	\$1.38	\$0.91	\$0.98	\$0.44	\$0.37	\$0.27	\$11.11	1.3%
2017	\$1.61	\$0.92	\$2.67	\$1.67	\$1.37	\$0.92	\$0.99	\$0.47	\$0.39	\$0.27	\$11.28	1.5%
2018	\$1.66	\$0.93	\$2.75	\$1.66	\$1.36	\$0.93	\$1.00	\$0.51	\$0.41	\$0.27	\$11.48	1.8%
2019	\$1.72	\$0.96	\$2.83	\$1.65	\$1.35	\$0.94	\$1.01	\$0.55	\$0.43	\$0.27	\$11.70	1.9%
2020	\$1.77	\$0.98	\$2.89	\$1.65	\$1.35	\$0.95	\$1.02	\$0.58	\$0.46	\$0.27	\$11.93	1.9%
2021	\$1.82	\$1.01	\$2.93	\$1.65	\$1.36	\$0.96	\$1.04	\$0.61	\$0.48	\$0.28	\$12.13	1.7%
2022	\$1.87	\$1.04	\$2.96	\$1.65	\$1.36	\$0.97	\$1.05	\$0.63	\$0.51	\$0.28	\$12.32	1.6%
CAGR (‘15–’22)	3.0%	1.8%	2.4%	-0.4%	-0.4%	1.0%	1.1%	6.6%	5.7%	-0.1%		1.7%

Source: iData Research Inc.

11.3 DRIVERS AND LIMITERS

11.3.1 Market Drivers

More Physicians Performing Colposcopy

More physicians of other specialties are becoming competent with gynecological examinations, thus resulting in increasing screenings, which helps drive the market. Family doctors in particular are buying colposcopes and their associated devices, which helps to drive the colposcope market.

Sexual Assault Clinics

The rise of specialty clinics to treat victims of sexual assault is aiding the growth of the colposcope market. Colposcopies provide valuable information about the sexual assault case because the physician can get a photographic recording of the patient's injuries. The clinical evidence is recorded in a single examination and can be reviewed without the need for further tests. For these reasons, social workers and physicians are recommending colposcopies whenever possible for in the case of sexual assault.

Increased Funding

There is increased funding, especially in Germany and Austria, for general diagnostics and pre-screening for cancer. This will drive growth in the market. It has been suggested that colposcopy better shows cellular changes.

Preference for Higher-End Devices

Market growth for colposcopes has increased due to a rise in ASP. This growth in ASP can be attributed to a shift in the demand for mid- to higher-end colposcopes. These scopes may often have features such as documentation capabilities for sexual assault examinations. Additional amenities or higher-end technologies can raise the selling price of a colposcope unit significantly.

11.3.2 Market Limiters

Market Maturity

The colposcope market has long reached the maturity. Colposcopy is a well-established procedure, and although there are more physicians performing the procedure, it is still largely a replacement market.

Economy

Although the economy is recovering from the recession in 2008, office sales of colposcopes have still been stagnant due to the limiting factors of slow economic growth. The majority of colposcopes sales

have been to hospitals rather than offices. In certain countries, the constraints of a weak economy have also led to the bimodal trend with a significant percent of the market share still buying based on a lower ASP over quality.

Figure 11-7: Drivers and Limiters, Colposcope Market, Europe, 2015

Market Drivers
More Physicians Performing Colposcopy Sexual Assault Clinics Increased Funding Preference for Higher-End Devices
Market Limiters
Market Maturity Economy
Source: iData Research Inc.

11.4 COMPETITIVE MARKET SHARE ANALYSIS

Cooper Surgical

In 2015, Cooper Surgical was the market leader in colposcopes, with a 30.2% share. Its German-made *Leisegang*® line of colposcopes has enjoyed excellent brand recognition and popularity throughout the world. Its *Optik*® colposcope uses light-emitting diodes to provide over double the brightness of halogen bulbs and increased clarity. It also contains a digital SLR camera for documentation. Cooper Surgical offers a standard model as well as a model with digital imaging. It also has the *CerviPATH*™, which integrates with the *Leisegang Optik*®.

Cooper Surgical, a branch of Cooper Companies, is a company that is dedicated to women's health products. They have a wide range of products available for women's health and have, over the years, acquired a wide portfolio of companies in order to deliver an expansive range of health care products to women. These products are available at the three major point-of-care areas for women, which consist of offices, hospitals and fertility clinics.

Carl Zeiss

Carl Zeiss Meditec Inc. has excellent brand recognition and offers products known for high quality optics and high performance illumination. The products in this market are the Kolposkop 150 FC and the Kolposkop E. Both are affordable options, with the Kolposkop E in a mid-price range and the Kolposkop 150FC offering a high end option. The Kolposkop 150 FC can be integrated with a video camera, enabling it to be used as a documentation system. The majority of Carl Zeiss's market share is in the hospital consumer segment.

Olympus

Olympus produces the OCS-500 colposcope, featuring optical focusing and 6x continuous zoom for picture and video documentation. The company held a 15% market share for 2015. The OCS-500 can also be used in hysteroscopy due to its universal lighting and video system.

Kaps Optik GmbH

Kaps Optik is a German based, family owned company with 40 employees exporting to more than 80 countries. The company offers a range of colposcopes, including the Kaps Videokolposkop ViCo equipped with video imaging. In addition to the gynecology portfolio, the company specializes in microscopes for clinical applications such as ENT and neurology. Due to the fact that Kaps Optik is a smaller-sized

company, they are able to customize orders; which is an option that is more difficult for large companies to offer. Kaps Optik GmbH relies heavily on high quality in its branding strategy.

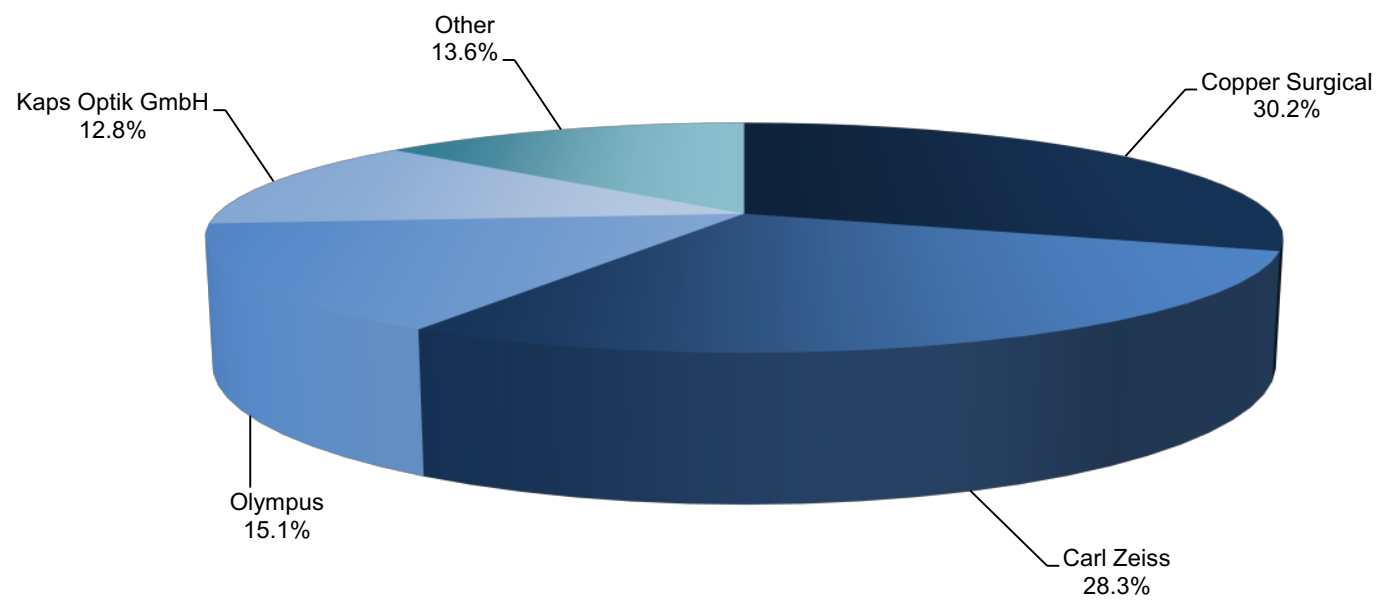
Other notable competitors: Dysis and Leica

DySIS is a newer competitor in the market offering a new technology with an advanced cervical scan. The DySIS colposcope measures aceto-whitening automatically and generates the DySIS map. In 2015, the company aggressively targeted the U.K. market. It is expected their market share will increase from a nominal percentage within the period of this report.

Leica Microsystems Ltd. offers the high-performance stereomicroscope with five steps Leica MS5. The Leica MS5 is the most flexible routine stereomicroscope in the world. The Leica MS5 and Leica MZ6 Colposcopes offer the optical performance of Leica now available for gynecological diagnosis. Leica Microsystems has better market penetration in Germany, Austria, Switzerland and the United Kingdom, matching the locations of their European product development locations. They are also one of the leading colposcope market competitors in the Benelux region, with a market share that is projecting to continue increasing throughout the period of this report.

Figure 11-8: Leading Competitors by Country, Colposcope Market, Europe, 2015

Company	Germany	France	U.K.	Italy	Spain	Benelux	Scandi- navia	Austria	Switzer- land	Portugal	Total Market Share
Copper Surgical	39.8%	47.0%	9.1%	36.2%	37.7%	10.5%	40.4%	39.8%	39.1%	40.1%	30.2%
Carl Zeiss	35.6%	32.3%	32.4%	18.0%	15.6%	14.9%	49.2%	34.6%	35.2%	17.9%	28.3%
Olympus	5.5%	—	28.7%	18.1%	17.9%	23.1%	—	4.1%	5.3%	18.6%	15.1%
Kaps Optik GmbH	15.1%	7.4%	15.2%	11.9%	12.3%	23.0%	—	15.8%	11.6%	13.5%	12.8%
Other	4.0%	13.3%	14.6%	15.8%	16.5%	28.5%	10.4%	5.7%	8.8%	9.9%	13.6%
Total	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
Market Value (€M)	€1.4	€0.8	€2.3	€1.5	€1.3	€0.8	€0.9	€0.4	€0.3	€0.3	€9.9
Others include: Leica, etc.											
Source: iData Research Inc.											

Chart 11-2: Leading Competitors, Colposcope Market, Europe, 2015

Source: iData Research Inc.

12

TRANSCERVICAL FEMALE STERILIZATION MARKET

12.1 INTRODUCTION

Female sterilization is a permanent form of birth control, requiring invasive surgery to reverse. Female sterilization prevents ova from coming down the fallopian tubes and blocks fertilization by sperm. There are different procedures to perform female sterilization, including tubal ligation, mechanical blockage with a clip or band, bipolar electrocoagulation or transcervical implants. In this report, only the transcervical implant market is covered.

12.1.1 Tubal Ligation

Tubal ligation (also known as “having your tubes tied”) is the most common form of female sterilization. Tubal ligation is a laparoscopic procedure and is minimally invasive, with a physician making one or two small incisions in the abdomen. In this procedure, the fallopian tubes are cut, burned, tied or blocked off. Some forms of tubal ligation are reversible, and the two ends of the fallopian tube can be re-attached.

12.1.2 Mechanical Sterilization

Mechanical sterilization uses either a clip (titanium or plastic) or a band. Ligation clips clamp the fallopian tube, cutting off blood supply to create fibrosis or scarring. Ligation bands, also known as Falope-ring bands, cinch a loop in the middle of the fallopian tube.

12.1.3 Bipolar Electrocoagulation

Bipolar sterilization is a laparoscopic procedure that uses electric current from bipolar forceps to scar the fallopian tubes until they close. The high-energy current burns the tubes so that they coagulate, permanently blocking the tubes.

12.1.4 Transcervical Implant

The final method, a transcervical implant, is a hysteroscopic procedure in which soft micro-inserts are implanted into the fallopian tubes. There is no cutting involved; the transcervical device is inserted using a flexible delivery catheter.

The implants are metal coils with mesh fibers that cause an inflammatory reaction. The resulting scar tissue growth into and around the implant takes approximately three months to completely occlude the fallopian tubes. During that period of time another form of birth control is necessary, whereas the other three sterilization methods are effective immediately.

Transcervical implants are less invasive compared to mechanical and bipolar coagulation methods of sterilization, and require minimal anesthesia. The procedure can be conducted in physician offices rather than operating rooms.

12.2 MARKET ANALYSIS AND FORECAST

The transcervical implant market in Europe currently consists of Bayer AG as the sole competitor offering the Essure® procedure. Essure® was first developed by the company Conceptus in 2001 and was certified for sale throughout Europe, with the first sale occurring in October 2002. In the United States, Essure® was subsequently approved by the FDA on November 4th, 2002. In April 2013, Bayer AG acquired Conceptus to offer Essure® as part of their contraceptive portfolio. The United Kingdom was the last country to approve the Essure® procedure in Europe, with NICE granting approval in 2009. Since the Essure® procedure entered the market in 2002, other notable competitors have been the Ovabloc System and the Adiana procedure. Both of these procedures have since been discontinued.

In 2015, the European transcervical sterilization market was valued at €41.3 million representing a 1.6% increase over 2014. The number of Essure® units sold in 2015 exceeded 44,000 throughout Europe. The Essure® procedure has been received by European countries with differing levels of success. In France, female sterilization has been widely accepted providing the largest market for transcervical implants outside of the United States. In 2015, the market value for France was €16.1M comprising 41% of total European sales. Alternatively, the trend towards the hysteroscopic placement of transcervical implants has been dissipating recently in the United Kingdom and the Netherlands in response to limitations relating to the safety and efficacy of the transcervical implant procedure. The laparoscopic approaches are gaining favor, mirroring the procedure trends in the United States.

Lately, it has become clear that there are several key limitations in the form of conditions that must be met in order for transcervical implants to be 100% effective. Firstly, bilateral placement is required, meaning there is a technique involved in placing the coils in the correct position on both tubes, which can be difficult. Secondly, occlusion must be confirmed for up to 6 months after the operation. The third limitation is the contraception: the patient needs to continue some method of contraception for up to 6 months until when they can assess that the tubes have truly been blocked. If the patient cannot meet even one of these conditions, transcervical implants are not a viable option. Furthermore, the coils of transcervical implants are much more invasive than the mechanical sterilization devices in the sense that they puncture other organs, resulting in a serious risk factor.

Due to these limitations, transcervical sterilization is certainly not 100% effective, and this is reflected in a recent meta-analysis that concluded that the chances of pregnancy following the sterilization procedure is ten times higher when using the hysteroscopic transcervical implant method as opposed to

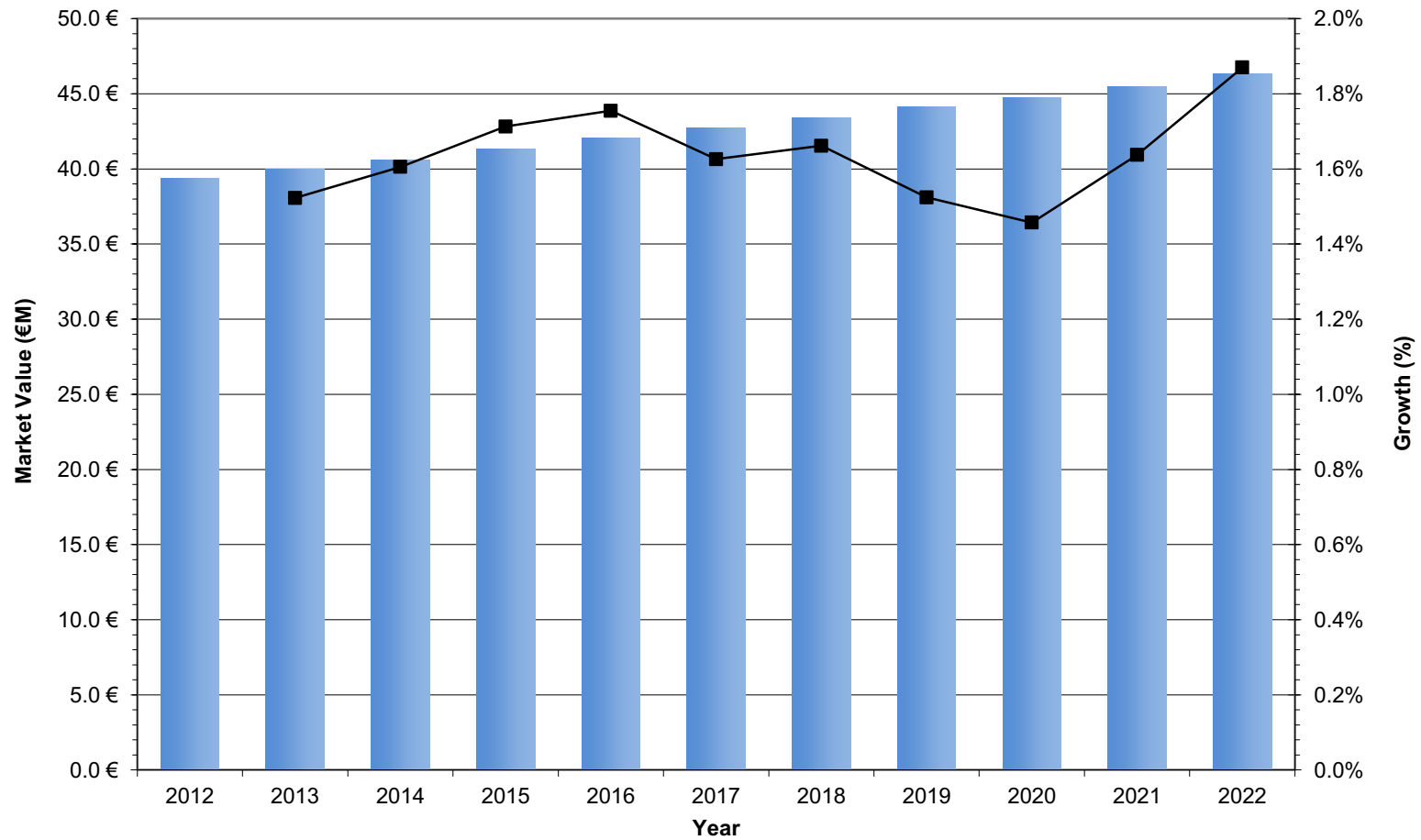
the laparoscopic sterilization methods. Even if the transcervical implant method can be performed in an office and does not require anesthesia, unlike the laparoscopic methods it takes months for sterilization to be achieved and the success of the operation depends on the myriad of factors mentioned above.

The European female sterilization market offers fewer options than in North America. Mechanical sterilization methods such as Cooper Surgical's Filshie Tubal Ligation system are not offered in Europe. Cooper Surgical's Filshie Tubal Ligation system does not have distribution rights outside of the United States and Olympus's Falope Ring Band is not actively promoted in Europe with nominal sales figures. The absence of mechanical sterilization options has resulted in the transcervical implant market growing substantially since its inception. The future trends across Europe for the preferred method of female sterilization will be inconsistent across countries. The United Kingdom, Benelux and Scandinavian regions are projecting to move back towards laparoscopic sterilization methods while France and other mainland European countries are fueling continued growth of transcervical implants sales.

Figure 12-1: Transcervical Female Sterilization Market, Europe, 2012 – 2022 (€ and US\$)

Year	Units Sold	Growth (%)	ASP (€)	ASP (US\$)	Growth (%)	Market Value (€M)	Market Value (US\$M)	Growth (%)
2012	42,937		€917	\$1,014		€39.4	\$43.5	
2013	43,352	1.0%	€922	\$1,020	0.6%	€40.0	\$44.2	1.5%
2014	43,786	1.0%	€928	\$1,026	0.6%	€40.6	\$44.9	1.6%
2015	44,253	1.1%	€934	\$1,032	0.6%	€41.3	\$45.7	1.7%
2016	44,734	1.1%	€940	\$1,039	0.7%	€42.0	\$46.5	1.8%
2017	45,196	1.0%	€945	\$1,045	0.6%	€42.7	\$47.2	1.6%
2018	45,661	1.0%	€951	\$1,052	0.6%	€43.4	\$48.0	1.7%
2019	46,077	0.9%	€957	\$1,058	0.6%	€44.1	\$48.8	1.5%
2020	46,481	0.9%	€963	\$1,064	0.6%	€44.7	\$49.5	1.5%
2021	46,929	1.0%	€969	\$1,071	0.7%	€45.5	\$50.3	1.6%
2022	47,414	1.0%	€977	\$1,080	0.8%	€46.3	\$51.2	1.9%
CAGR ('15–'22)		1.0%			0.7%			1.6%

Source: iData Research Inc.

Chart 12-1: Transcervical Female Sterilization Market, Europe, 2012 – 2022

Source: iData Research Inc.

Figure 12-2: Units Sold by Country, Transcervical Female Sterilization Market, Europe, 2012-2022

Year	Germany	France	U.K.	Italy	Spain	Benelux	Scandi- navia	Austria	Switzer- land	Portugal	Europe	Growth (%)
2012	–	17,594	1,475	8,964	11,208	824	1,244	–	–	1,629	42,937	
2013	–	17,787	1,487	9,045	11,309	831	1,250	–	–	1,644	43,352	1.0%
2014	–	18,001	1,494	9,127	11,410	839	1,257	–	–	1,658	43,786	1.0%
2015	–	18,217	1,500	9,218	11,536	843	1,265	–	–	1,675	44,253	1.1%
2016	–	18,435	1,503	9,319	11,674	840	1,271	–	–	1,690	44,734	1.1%
2017	–	18,675	1,501	9,412	11,791	836	1,276	–	–	1,704	45,196	1.0%
2018	–	18,918	1,500	9,507	11,909	830	1,280	–	–	1,717	45,661	1.0%
2019	–	19,107	1,502	9,611	12,016	831	1,284	–	–	1,726	46,077	0.9%
2020	–	19,260	1,507	9,698	12,160	833	1,288	–	–	1,736	46,481	0.9%
2021	–	19,452	1,513	9,795	12,294	835	1,292	–	–	1,748	46,929	1.0%
2022	–	19,666	1,519	9,902	12,429	838	1,296	–	–	1,764	47,414	1.0%
CAGR (‘15–’22)	–	1.1%	0.2%	1.0%	1.1%	-0.1%	0.3%	–	–	0.7%		1.0%

Source: iData Research Inc.

Figure 12-3: Average Sales Price by Country, Transcervical Female Sterilization Market, Europe, 2012-2022 (€)

Year	Germany	France	U.K.	Italy	Spain	Benelux	Scandi- navia	Austria	Switzer- land	Portugal	Europe	Growth (%)
2012	–	€870	€953	€1,061	€875	€942	€910	–	–	€883	€917	
2013	–	€875	€963	€1,068	€879	€947	€913	–	–	€886	€922	0.6%
2014	–	€879	€977	€1,077	€884	€952	€917	–	–	€890	€928	0.6%
2015	–	€884	€988	€1,086	€889	€943	€920	–	–	€893	€934	0.6%
2016	–	€891	€978	€1,097	€895	€934	€923	–	–	€899	€940	0.7%
2017	–	€896	€973	€1,106	€901	€934	€928	–	–	€903	€945	0.6%
2018	–	€901	€977	€1,115	€906	€937	€933	–	–	€908	€951	0.6%
2019	–	€906	€983	€1,125	€910	€940	€938	–	–	€913	€957	0.6%
2020	–	€910	€990	€1,134	€915	€945	€943	–	–	€917	€963	0.6%
2021	–	€916	€997	€1,144	€920	€948	€946	–	–	€921	€969	0.7%
2022	–	€923	€1,005	€1,156	€928	€952	€951			€927	€977	0.8%
CAGR (‘15–’22)	–	0.6%	0.3%	0.9%	0.6%	0.1%	0.5%	–	–	0.5%		0.7%

Source: iData Research Inc.

Figure 12-4: Average Sales Price by Country, Transcervical Female Sterilization Market, Europe, 2012-2022 (US\$)

Year	Germany	France	U.K.	Italy	Spain	Benelux	Scandi- navia	Austria	Switzer- land	Portugal	Europe	Growth (%)
2012	–	\$962	\$1,054	\$1,173	\$967	\$1,041	\$1,006	–	–	\$976	\$1,014	
2013	–	\$967	\$1,064	\$1,181	\$972	\$1,047	\$1,009	–	–	\$980	\$1,020	0.6%
2014	–	\$972	\$1,080	\$1,190	\$977	\$1,053	\$1,013	–	–	\$984	\$1,026	0.6%
2015	–	\$978	\$1,092	\$1,201	\$983	\$1,042	\$1,018	–	–	\$988	\$1,032	0.6%
2016	–	\$985	\$1,081	\$1,213	\$990	\$1,033	\$1,021	–	–	\$994	\$1,039	0.7%
2017	–	\$991	\$1,076	\$1,223	\$996	\$1,033	\$1,026	–	–	\$999	\$1,045	0.6%
2018	–	\$997	\$1,080	\$1,233	\$1,002	\$1,036	\$1,032	–	–	\$1,004	\$1,052	0.6%
2019	–	\$1,002	\$1,086	\$1,244	\$1,007	\$1,039	\$1,037	–	–	\$1,010	\$1,058	0.6%
2020	–	\$1,007	\$1,094	\$1,254	\$1,012	\$1,044	\$1,042	–	–	\$1,014	\$1,064	0.6%
2021	–	\$1,013	\$1,103	\$1,265	\$1,018	\$1,049	\$1,046	–	–	\$1,019	\$1,071	0.7%
2022	–	\$1,021	\$1,112	\$1,278	\$1,026	\$1,053	\$1,052	–	–	\$1,025	\$1,080	0.8%
CAGR (‘15–’22)	–	0.6%	0.3%	0.9%	0.6%	0.1%	0.5%	–	–	0.5%		0.7%

Source: iData Research Inc.

Figure 12-5: Transcervical Female Sterilization Market by Country, Europe, 2012-2022 (€M)

Year	Germany	France	U.K.	Italy	Spain	Benelux	Scandi- navia	Austria	Switzer- land	Portugal	Europe	Growth (%)
2012	–	€15.31	€1.41	€9.51	€9.81	€0.78	€1.13	–	–	€1.44	€39.38	
2013	–	€15.56	€1.43	€9.66	€9.94	€0.79	€1.14	–	–	€1.46	€39.98	1.523%
2014	–	€15.83	€1.46	€9.83	€10.08	€0.80	€1.15	–	–	€1.48	€40.62	1.605%
2015	–	€16.11	€1.48	€10.01	€10.25	€0.79	€1.16	–	–	€1.50	€41.32	1.713%
2016	–	€16.42	€1.47	€10.23	€10.45	€0.79	€1.17	–	–	€1.52	€42.04	1.755%
2017	–	€16.73	€1.46	€10.41	€10.62	€0.78	€1.18	–	–	€1.54	€42.73	1.626%
2018	–	€17.05	€1.47	€10.60	€10.79	€0.78	€1.19	–	–	€1.56	€43.44	1.662%
2019	–	€17.31	€1.48	€10.81	€10.94	€0.78	€1.20	–	–	€1.58	€44.10	1.524%
2020	–	€17.53	€1.49	€11.00	€11.13	€0.79	€1.21	–	–	€1.59	€44.74	1.457%
2021	–	€17.82	€1.51	€11.21	€11.32	€0.79	€1.22	–	–	€1.61	€45.47	1.637%
2022	–	€18.16	€1.53	€11.44	€11.53	€0.80	€1.23	–	–	€1.64	€46.32	1.870%
CAGR (‘15–’22)	–	1.7%	0.4%	1.9%	1.7%	0.1%	0.8%	–	–	1.3%		1.6%

Source: iData Research Inc.

Figure 12-6: Transcervical Female Sterilization Market by Country, Europe, 2012-2022 (US\$M)

Year	Germany	France	U.K.	Italy	Spain	Benelux	Scandi- navia	Austria	Switzer- land	Portugal	Europe	Growth (%)
2012	–	\$16.93	\$1.55	\$10.51	\$10.84	\$0.86	\$1.25	–	–	\$1.59	\$43.54	
2013	–	\$17.20	\$1.58	\$10.68	\$10.99	\$0.87	\$1.26	–	–	\$1.61	\$44.20	1.5%
2014	–	\$17.50	\$1.61	\$10.87	\$11.15	\$0.88	\$1.27	–	–	\$1.63	\$44.91	1.6%
2015	–	\$17.81	\$1.64	\$11.07	\$11.34	\$0.88	\$1.29	–	–	\$1.65	\$45.68	1.7%
2016	–	\$18.15	\$1.62	\$11.31	\$11.55	\$0.87	\$1.30	–	–	\$1.68	\$46.48	1.8%
2017	–	\$18.50	\$1.62	\$11.51	\$11.74	\$0.86	\$1.31	–	–	\$1.70	\$47.24	1.6%
2018	–	\$18.85	\$1.62	\$11.72	\$11.93	\$0.86	\$1.32	–	–	\$1.72	\$48.02	1.7%
2019	–	\$19.14	\$1.63	\$11.95	\$12.10	\$0.86	\$1.33	–	–	\$1.74	\$48.76	1.5%
2020	–	\$19.39	\$1.65	\$12.16	\$12.30	\$0.87	\$1.34	–	–	\$1.76	\$49.47	1.5%
2021	–	\$19.70	\$1.67	\$12.39	\$12.51	\$0.88	\$1.35	–	–	\$1.78	\$50.28	1.6%
2022	–	\$20.07	\$1.69	\$12.65	\$12.75	\$0.88	\$1.36	–	–	\$1.81	\$51.22	1.9%
CAGR (‘15–’22)	–	1.7%	0.4%	1.9%	1.7%	0.1%	0.8%	–	–	1.3%		1.6%

Source: iData Research Inc.

12.3 DRIVERS AND LIMITERS

12.3.1 Market Drivers

Transcervical Sterilization

Regardless of the recent deceleration of unit sales growth, transcervical implants will continue to drive the female sterilization device market as it continues to make sterilization more feasible for a greater number of patients. Transcervical sterilization does not involve incisions or abdominal penetration, and can be done easily in the doctor's office. Until unit sales begin to substantially decrease or the regulatory framework changes, sales of transcervical implants will drive the female sterilization market.

Reimbursement

The reimbursement landscape is a strong incentive or deterrent that determines which form of contractive women choose. Certain countries such as France have removed an age requirement to qualify for reimbursement. France has also legislated that physicians are obligated to counsel their patients about transcervical implants as a sterilization option.

Alternative to Surgery

Women who undergo many surgeries around their abdomen or reproductive organs tend to have fibrous scar tissue that make tubal or mechanical ligation using abdominal or laparoscopic approaches technically difficult. The option of transcervical sterilization is also open to women with heart conditions who are not eligible for the general anesthesia required for tubal ligation. Transcervical female sterilization offers these women an option for permanent sterilization without surgery.

Increase in Office Procedures

Transcervical female sterilization is able to be performed in an office setting, as it is a minimally invasive procedure and requires no general anesthesia. This is a significant advantage for doctors, enabling them to treat higher volumes of patients at a significantly reduced cost per patient. Office procedures also remove the barrier of securing OR time. Patient advantages include short recovery times, absence of surgery and the procedure is free of hormones.

Strategic Partnerships

Olympus formed an alliance with Conceptus (now Bayer) in order to increase Olympus's 5.5mm hysteroscopy system and video endoscopy equipment's market share through the provision of surgeon

training linked to *ESSURE*[®] transcervical contraception. This enhanced marketing and sales for Bayer is driving unit growth for transcervical female sterilization.

12.3.2 Market Limiters

Competing Birth Control Methods

Women may not wish to undergo surgery, with its associated risks and complications, when other non-invasive methods of birth control are available. Alternative choices include female condoms, diaphragms, sponges, oral contraceptives, patches, rings, implants, injections, intrauterine systems (IUS) and intrauterine devices (IUD).

Emerging Male Birth Control Methods

Male Birth Control is currently in development throughout Europe and North America. The prominent types in development are non-hormonal contraception options and synthetic testosterone and other steroid combinations. The most publicized non-hormonal contraception is the Reversible Inhibition of Sperm Under Guidance (RISUG) technique. Currently under development by the Parsemus Foundation, Vasalget is a non-hormonal male birth control method. It successfully passed its most recent trial in March 2016 and is projected to be available to the public in North America in as soon as 2018. Vasalget is a polymer hydrogel that is injected through the scrotum into the vas deferens. The gel reacts and blocks the vas deferens, killing sperm when they come in contact with it. The chemical is effective almost immediately after injection. The chemical stays in place until a man decides that he wants to have children. It can then be washed out using another injection which dissolves and flushes it out of the vas deferens. Another option, similar to Vasalget, is the intra-vas device (IVD). It involves injecting a "plug" into the vas deferens which can be removed later. The IVD filters out the sperm as it passes through the vas deferens.

Synthetic testosterone and other steroid combinations

Similar to "*the pill*" for women, a pill comprised of synthetic testosterone and other steroid combinations is a second option currently in development for men. The pill will consist of a synthetic version of testosterone together with the hormone progestogen. This approach works by stopping the testes from producing testosterone which inhibits normal sperm production. Several trials in different countries are looking at the effectiveness and long-term safety of hormonal contraceptives for men, including some phase III trials. Phase III trials are the last clinical trials carried out before a medicine is given a

marketing license. The availability of a male contraceptive alternative is expected to erode the female sterilization market in the future.

Resistance to Change

Physicians are accustomed to performing tubal ligations and bipolar electrocoagulation and are already trained in the procedures. Attitudes within the medical profession do not think that a new method for sterilization is necessary or do not want to be retrained to perform a novel procedure. The lack of doctors proficient at using hysteroscopes to perform transcervical sterilization is a substantial market limiter. Cultural attitudes also vary affecting a patient's likelihood of requesting female sterilization. The United Kingdom, Benelux and Scandinavia have traditionally favored male vasectomies as an alternative treatment to female sterilization. The cultural aversion to the concept of female sterilization is an attitude that limits the number of procedures, and is slow to change.

Permanence of Procedure

The permanence of female sterilization limits the market, as many surgeons are hesitant to or refuse to operate on young women. They are concerned that patients may change their minds if changes occur in their lives. Unfortunately, there are strict and tedious requirements that must be met to qualify for a female sterilization procedure. Female sterilization is also difficult if not impossible to reverse if the patient later wishes to have children. Reversing tubal ligation requires fallopian tube reconnection; the success rate for this is very low. This hesitance on the part of doctors decreases procedure numbers, thus limiting the market.

Lack of Availability/ Reimbursement

Transcervical Implants as an option for Female Sterilization are not sold in all the European countries covered in this report. Currently, transcervical implants are not sold directly in Germany, Austria, Switzerland, Belgium and Luxembourg. Transcervical devices are also only partially or not reimbursed in several European countries, which is one of the strongest barriers limiting market share.

Safety concerns of Transcervical Implants

Transcervical implants have received substantial criticism and concern regarding the serious health risks associated with the device. Women to receive a transcervical implant are up to ten times more likely to require a repeat operation compared to the traditional laparoscopic methods of female sterilization. Reports have ranged from the device migrating to elsewhere in their body, the device breaking, scar tissue forming outside of the fallopian tubes to other side effects such as migraines and significant decreases in patient quality of life. In March 2016, the FDA mandated that new warnings are required on

the product. Overall, the negative press and lawsuits regarding the product will act as a deterrent for many women who will opt for a laparoscopic method of female sterilization.

Figure 12-7: Drivers and Limiters, Transcervical Female Sterilization Market, Europe, 2015

Market Drivers
Transcervical Sterilization Reimbursement Alternative to Surgery Increase in Office Procedures Strategic Partnerships
Market Limiters
Competing Birth Control Methods Emerging Male Birth Control Methods Resistance to Change Permanence of Procedure Lack of Availability/ Reimbursement Safety Concerns of Transcervical Implants
Source: iData Research Inc.

12.4 COMPETITIVE MARKET SHARE ANALYSIS

Bayer AG

In April 2013, Bayer acquired Conceptus and its *Essure*® contraception device. This product allowed the company to dominate the European transcervical implant market with a 100% share. The *Essure*® procedure was approved by the FDA in 2002 and is clinically proven to be 99.8% effective in preventing pregnancy, based on a four year follow-up. *Essure*® is currently available in nine countries.

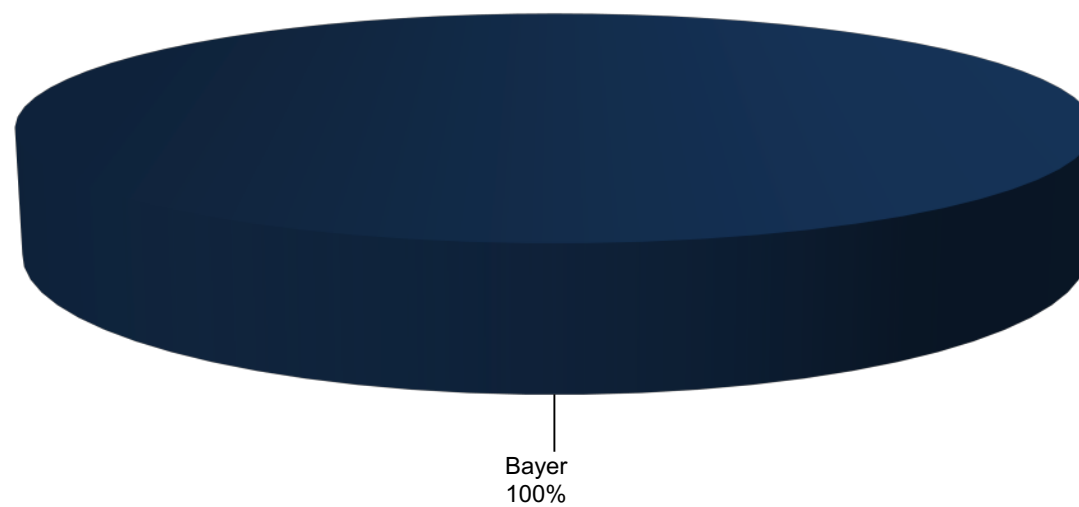
Reimbursement varies significantly by country and is the greatest determinant for the growth or decline of the Female Sterilization market in the short term. The market growth of transcervical implants as a form of female sterilization is inconsistent across Europe. Countries such as the United Kingdom, Benelux and Scandinavian regions are scrutinizing the *Essure*® procedure to re-evaluate the safety of the product. The negative publicity is projected to result in a stable market for transcervical implants, with a growing trend of procedures returning to laparoscopic techniques. In France and other mainland European countries, attitudes are more favorable with the transcervical sterilization market projecting with moderate, steady increases.

Worldwide, female sterilization is one of the most popular forms of contraception for women. It is worth noting that the development of male birth control options is expected to be on the market as soon as 2018 or 2019. The introduction of male birth control alternatives is expected to slowly erode the female sterilization market near the end of the forecast period.

Figure 12-8: Leading Competitors by Country, Transcervical Female Sterilization Market, Europe, 2015

Company	Germany	France	U.K.	Italy	Spain	Benelux	Scandi- navia	Austria	Switzer- land	Portugal	Total Market Share
Bayer	–	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	–	–	100.0%	100%
Total Market Value (€M)	–	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	–	–	100.0%	100.0%
	–	€16.1	€1.5	€10.0	€10.3	€0.8	€1.2	–	–	€1.5	€41.3
Source: iData Research Inc.											

Chart 12-2: Leading Competitors, Transcervical Female Sterilization Market, Europe, 2015



Source: iData Research Inc.

13

FEMALE URINARY INCONTINENCE SLING MARKET

13.1 INTRODUCTION

Female urinary incontinence affects approximately 10% of the population at some point in their lives. Urinary incontinence affects both women and men; however, there is a greater prevalence of incontinence amongst women. The difference is often attributed to changes that occur during pregnancy and childbirth as well as additional factors such as menopause. There are four main categories recognized for urinary incontinence, with 50% of cases diagnosed as stress urinary incontinence (SUI). Surgical treatment using a urinary incontinence sling is one of the most recommended options to help SUI patients become incontinence-free.

Urinary incontinence slings can be made of synthetic mesh, non-synthetic mesh or autologous tissue harvested from the patient to create a sling or “hammock” under the patients urethra or bladder neck (the area of thickened muscle where the bladder connects to the urethra). Vaginal slings always require a surgical procedure for installation; however, the degree of invasiveness of the procedure varies depending on the type of sling.

Procedure options include the installation of tension-free vaginal tape surgery (TVT) for mid-urethral sling procedures, transobturator tape slings (TOT) for the transobturator approach and single-incision, also known as mini-slings, for SUI.

The mid-urethral sling procedure is the most common surgery for incontinence and is a minimally-invasive, outpatient procedure. Although the mid-urethral procedure has been successful for many women, many national health authorities such as the FDA have issued warnings about the complications and side-effects which have been documented with surgical mesh procedures. In 2008 and 2011, the

FDA issued public health notifications on serious complications associated with surgical mesh placed through the vagina (transvaginal placement) to treat SUI and pelvic organ prolapse (POP). The response in the United States has been more severe than in Europe, with many women filing lawsuits and vaginal sling procedures declining. This is possibly due to the absence of public health care in the United States and the increased costs associated with repeat procedures and additional required medical treatments.

Although the European market has experienced a smaller backlash against the negative consequences due to vaginal slings, there is still a significant movement toward treatment options such as increased use of autologous tissue or non-surgical procedures such as laser procedures to treat mild to moderate SUI.

13.2 MARKET OVERVIEW

The female urinary incontinence sling market includes both synthetic slings and non-synthetic slings. Autologous tissue and allogenic grafts are also available options for slings; however, these treatments are not the focus of this report.

In 2015, the female urinary incontinence sling market shrunk by 2.4% from 2014. The retraction in the market is attributed towards ongoing scrutiny by healthcare regulatory agencies such as the FDA in the United States and adverse reactions documented by the MHRA (Medicine and Healthcare Products Regulatory Agency) in the United Kingdom. The controversy surrounding urinary incontinence slings predominantly concerns synthetic slings. Due to the negative side effects publicized about slings, however, procedures using both synthetic and biological slings have decreased. The adverse side-effects have resulted in patients and, to a lesser degree, physicians, becoming more cautious about sling procedures. While the repercussions of this controversy will still extend throughout the forecast period, as a result surgeons are giving greater attention to stronger patient consent protocols including full disclaimers of the risks involved.

The negative publicity regarding slings has had the greatest impact in countries without public healthcare. In countries such as the Scandinavian region, there has been a faster response to treat patients with adverse effects with no additional costs for the patient. This has led to fewer lawsuits and complaints regarding the procedure helping to keep the market stable.

Despite the contraction of the urinary incontinence sling market, the number of procedures is still substantial. The number of patients suffering from female urinary incontinence is increasing. The number of patients is also expected to continue increasing throughout the reporting period, as urinary incontinence affects older demographics.

Biological slings procedures have been less adversely affected by the healthcare warnings. This segment comprises a very small portion of the overall market because many believe that collagen based mesh is not as applicable in this indication compared to other areas such as breast reconstruction or hernia repair. There is also a lack of European clinical data supporting the use of biologic mesh over synthetic mesh for the treatment of stress incontinence.

On March 31st 2016, Astora Women's Health (previously American Medical Systems) was shut down. Endo International PLC, the parent company of Astora, made the announcement providing enough time

for hospitals and clinics to stockpile products of the popular brand. This has created a unique trend in the market with artificially high sales in 2015 and 2016 and an anticipated lull in sales expected in 2017. The withdrawal of Astora from the market also helped to stabilize the declining procedure numbers because the sales during this period exceed the number of procedures being performed.

Most vaginal sling implantation procedures are performed on an in-patient basis; however, recently the trend has been moving towards out-patient surgery. This trend is due to the gaining popularity of single-incision slings and other easier to install versions of traditional vaginal sling devices that reduce the degree of invasiveness of the implantation procedure, which shortens the surgical time, allowing the procedure to be conducted in an out-patient setting.

It is worth noting that slings are encountering significant competition in the market as alternative treatment options become more popular. The female urinary incontinence market, especially for cases of mild to moderate incontinence, has a wide array of treatment options available. Gynecologists are expanding their training and investing in capital equipment to provide safer and less invasive options to patients. Laser therapy treatments, for example, are expected to erode 25% of the sling market by 2022.

Figure 13-1: Female Urinary Incontinence Sling Market by Segment, Europe, 2012 – 2022 (€M)

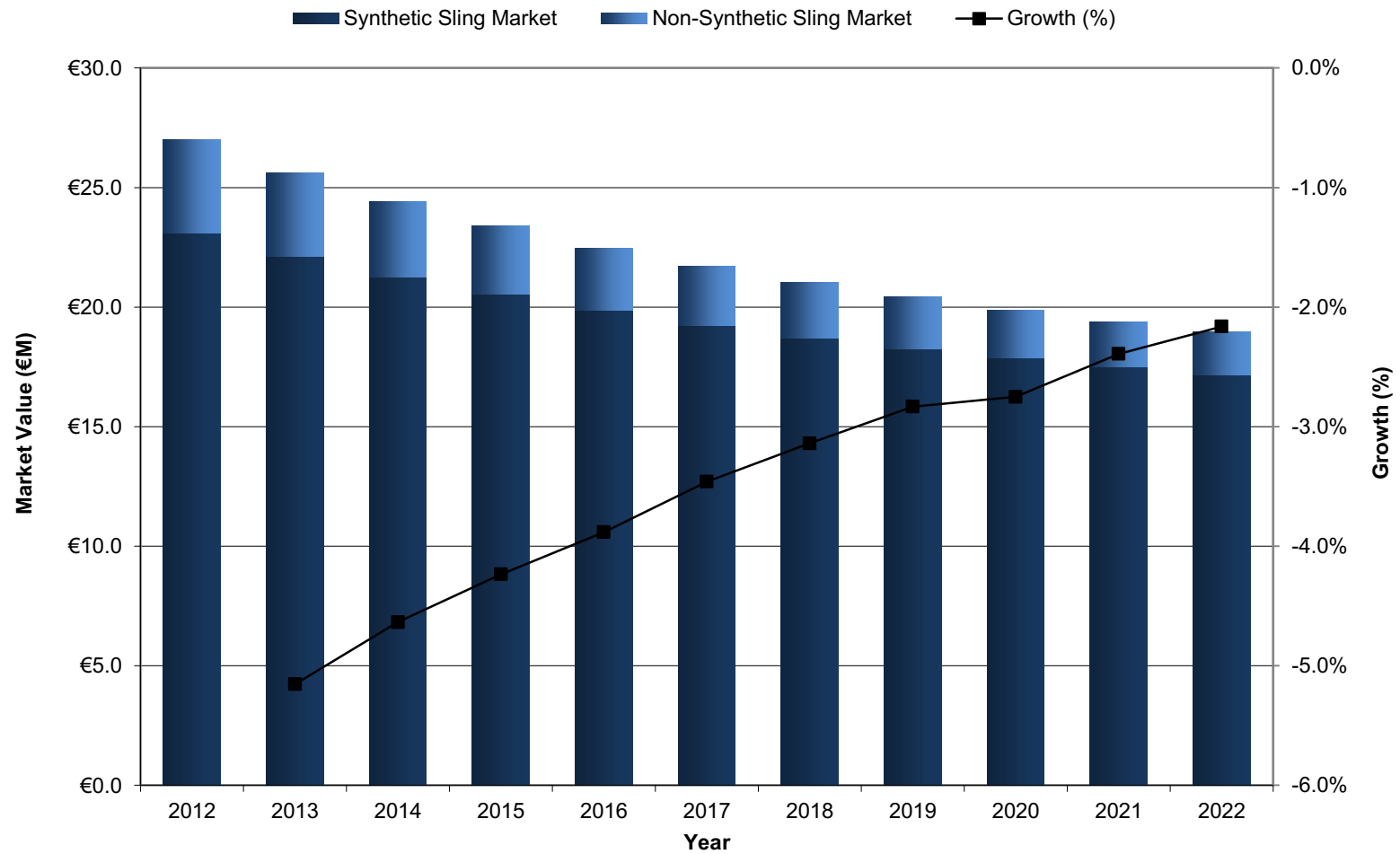
Year	Synthetic Sling Market	Non-Synthetic Sling Market	Total Market	Growth (%)
2012	€23.1	€3.9	€27.0	
2013	€22.1	€3.5	€25.6	-5.2%
2014	€21.3	€3.1	€24.4	-4.6%
2015	€20.6	€2.8	€23.4	-4.2%
2016	€19.9	€2.6	€22.5	-3.9%
2017	€19.2	€2.5	€21.7	-3.5%
2018	€18.7	€2.3	€21.0	-3.1%
2019	€18.3	€2.2	€20.4	-2.8%
2020	€17.9	€2.0	€19.9	-2.8%
2021	€17.5	€1.9	€19.4	-2.4%
2022	€17.2	€1.8	€19.0	-2.2%
CAGR ('15-'22)	-2.5%	-6.2%		-2.9%

Source: iData Research Inc.

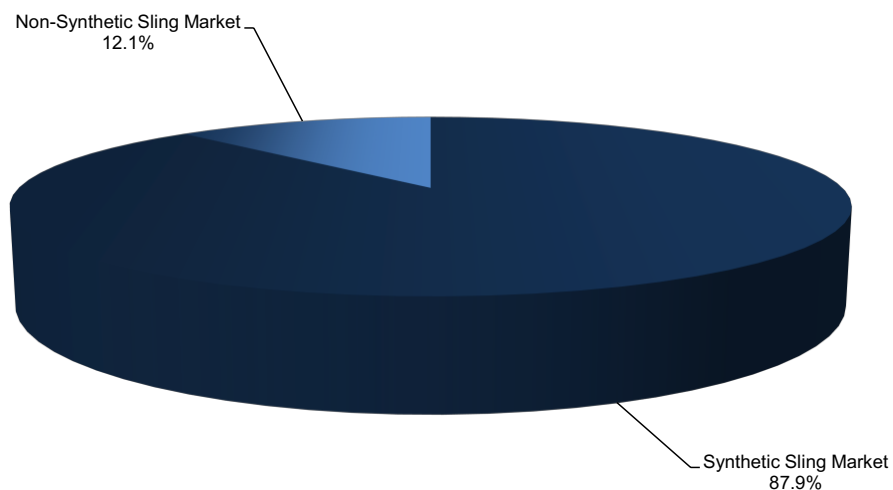
Figure 13-2: Female Urinary Incontinence Sling Market by Segment, Europe, 2012 – 2022 (US\$M)

Year	Synthetic Sling Market	Non-Synthetic Sling Market	Total Market	Growth (%)
2012	\$25.5	\$4.3	\$29.8	
2013	\$24.5	\$3.8	\$28.3	-5.2%
2014	\$23.5	\$3.5	\$27.0	-4.6%
2015	\$22.7	\$3.1	\$25.9	-4.2%
2016	\$22.0	\$2.9	\$24.8	-3.9%
2017	\$21.3	\$2.7	\$24.0	-3.5%
2018	\$20.7	\$2.5	\$23.2	-3.1%
2019	\$20.2	\$2.4	\$22.6	-2.8%
2020	\$19.8	\$2.2	\$22.0	-2.8%
2021	\$19.4	\$2.1	\$21.4	-2.4%
2022	\$19.0	\$2.0	\$21.0	-2.2%
CAGR ('15-'22)	-2.5%	-6.2%		-2.9%

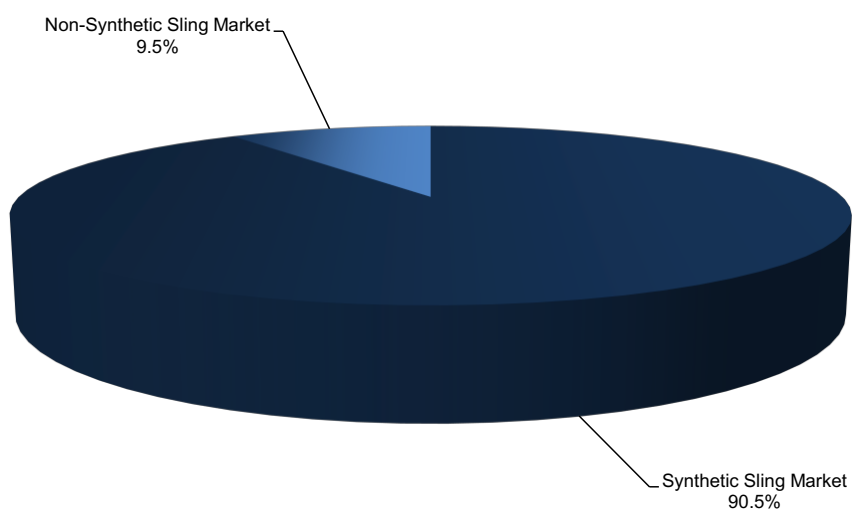
Source: iData Research Inc.

Chart 13-1: Female Urinary Incontinence Sling Market by Segment, Europe, 2015

Source: iData Research Inc.

Chart 13-2: Female Urinary Incontinence Sling Market Breakdown, Europe, 2015

Source: iData Research Inc.

Chart 13-3: Female Urinary Incontinence Sling Market Breakdown, Europe, 2022

Source: iData Research Inc.

13.3 MARKET ANALYSIS AND FORECAST

13.3.1 Total Female Urinary Incontinence Sling Market

There were 64,486 vaginal slings sold in 2015, a 4.2% decrease compared to 2014. Throughout Europe, synthetic vaginal sling sales constituted 92.2% of total vaginal sling sales volumes. The decrease was due to concerns pertaining to synthetic slings resulting from the controversy originating in the United States. Another limiting factor of this market is the competition from alternative methods of treatment. Urinary incontinence sling procedures are very invasive procedures which may deter some patients from undergoing treatment. Thus, procedures which are less invasive may be more desirable. This issue has been recently addressed by major manufacturers with the introduction of single incision slings, which reduces the invasiveness of the procedure considerably. The total number of vaginal slings sold will decrease at a CAGR of -1.8%, falling to 56,985 by 2022.

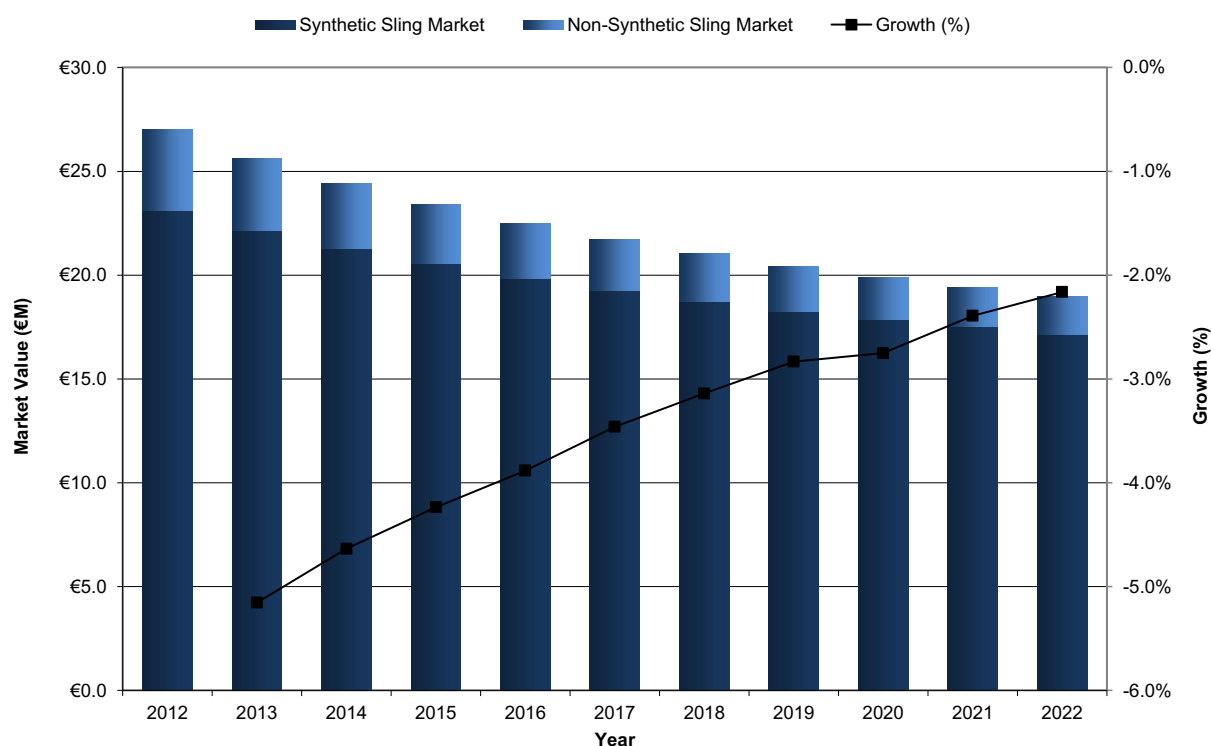
France is an anomaly in the European urinary incontinence sling market, contracting slowly by -0.9% in contrast to Germany's contraction of -5.1%. France was one of the initial European countries to adopt synthetic sling procedures. This has resulted in a larger and more stable market that is significantly more adverse to new and alternative treatments for stress urinary incontinence. These two factors combined have caused the reported negative side effects of slings to have a minimal impact on the French market.

The ASP of vaginal slings was €363 in 2015, a 1.8% decrease from the previous year. The consistent decrease in price has been due to the transition from more expensive biological slings to more affordable synthetic slings. Despite the controversies surrounding slings, the market is also well established. The maturity of the market, volatility and high competition are also strong incentives for the downward pressure in price.

Figure 13-3: Female Urinary Incontinence Sling Market, Europe, 2012 – 2022 (€ and US\$)

Year	Units Sold	Growth (%)	ASP (€)	ASP (US\$)	Growth (%)	Market Value (€M)	Market Value (US\$M)	Growth (%)
2012	69,945		€386	\$427		€27.0	\$29.8	
2013	67,919	-2.9%	€377	\$417	-2.3%	€25.6	\$28.3	-5.2%
2014	66,096	-2.7%	€369	\$408	-2.0%	€24.4	\$27.0	-4.6%
2015	64,486	-2.4%	€363	\$401	-1.8%	€23.4	\$25.9	-4.2%
2016	62,981	-2.3%	€357	\$395	-1.6%	€22.5	\$24.8	-3.9%
2017	61,652	-2.1%	€352	\$389	-1.4%	€21.7	\$24.0	-3.5%
2018	60,480	-1.9%	€348	\$384	-1.3%	€21.0	\$23.2	-3.1%
2019	59,446	-1.7%	€344	\$380	-1.1%	€20.4	\$22.6	-2.8%
2020	58,517	-1.6%	€339	\$375	-1.2%	€19.9	\$22.0	-2.8%
2021	57,717	-1.4%	€336	\$371	-1.0%	€19.4	\$21.4	-2.4%
2022	56,985	-1.3%	€333	\$368	-0.9%	€19.0	\$21.0	-2.2%
CAGR ('15-'22)		-1.8%			-1.2%			-2.9%

Source: iData Research Inc.

Chart 13-4: Female Urinary Incontinence Sling Market, Europe, 2012 – 2022

Source: iData Research Inc.

Figure 13-4: Units Sold by Country, Female Urinary Incontinence Sling Market, Europe, 2012-2022

Year	Germany	France	U.K.	Italy	Spain	Benelux	Scandi- navia	Austria	Switzer- land	Portugal	Europe	Growth (%)
2012	17,241	10,817	10,315	8,670	1,768	7,823	7,971	1,804	1,867	1,668	69,945	
2013	16,237	10,499	9,746	8,611	1,746	7,826	7,977	1,765	1,866	1,645	67,919	-2.9%
2014	15,279	10,237	9,297	8,538	1,720	7,830	7,989	1,720	1,864	1,622	66,096	-2.7%
2015	14,385	10,030	8,958	8,461	1,694	7,832	8,000	1,668	1,861	1,597	64,486	-2.4%
2016	13,536	9,850	8,671	8,379	1,667	7,829	8,007	1,614	1,858	1,572	62,981	-2.3%
2017	12,738	9,720	8,475	8,291	1,639	7,818	8,010	1,562	1,853	1,546	61,652	-2.1%
2018	11,973	9,638	8,362	8,198	1,610	7,800	8,010	1,519	1,848	1,520	60,480	-1.9%
2019	11,339	9,579	8,245	8,100	1,581	7,773	8,006	1,486	1,842	1,494	59,446	-1.7%
2020	10,812	9,522	8,144	7,997	1,552	7,732	7,997	1,458	1,835	1,467	58,517	-1.6%
2021	10,374	9,470	8,065	7,897	1,524	7,693	7,992	1,434	1,829	1,441	57,717	-1.4%
2022	9,990	9,423	7,991	7,796	1,495	7,654	7,986	1,414	1,822	1,414	56,985	-1.3%
CAGR (‘15-’22)	-5.1%	-0.9%	-1.6%	-1.2%	-1.8%	-0.3%	0.0%	-2.3%	-0.3%	-1.7%		-1.8%

Source: iData Research Inc.

Figure 13-5: Average Sales Price by Country, Female Urinary Incontinence Sling Market, Europe, 2012-2022 (€)

Year	Germany	France	U.K.	Italy	Spain	Benelux	Scandi- navia	Austria	Switzer- land	Portugal	Europe	Growth (%)
2012	€ 361	€ 377	€ 385	€ 389	€ 402	€ 373	€ 375	€ 388	€ 814	€ 382	€386	
2013	€ 347	€ 370	€ 372	€ 383	€ 396	€ 370	€ 368	€ 384	€ 770	€ 375	€377	-2.3%
2014	€ 336	€ 364	€ 362	€ 377	€ 390	€ 367	€ 363	€ 380	€ 732	€ 369	€369	-2.0%
2015	€ 326	€ 359	€ 353	€ 371	€ 384	€ 362	€ 358	€ 376	€ 699	€ 363	€363	-1.8%
2016	€ 319	€ 354	€ 346	€ 365	€ 377	€ 359	€ 350	€ 372	€ 674	€ 357	€357	-1.6%
2017	€ 314	€ 349	€ 340	€ 359	€ 371	€ 355	€ 345	€ 368	€ 653	€ 351	€352	-1.4%
2018	€ 311	€ 345	€ 336	€ 350	€ 365	€ 352	€ 340	€ 364	€ 635	€ 345	€348	-1.3%
2019	€ 307	€ 342	€ 335	€ 344	€ 359	€ 348	€ 334	€ 360	€ 620	€ 340	€344	-1.1%
2020	€ 305	€ 339	€ 331	€ 336	€ 353	€ 344	€ 329	€ 357	€ 608	€ 333	€339	-1.2%
2021	€ 305	€ 336	€ 331	€ 327	€ 347	€ 340	€ 324	€ 353	€ 598	€ 327	€336	-1.0%
2022	€ 305	€ 331	€ 330	€ 320	€ 341	€ 336	€ 321	€ 350	€ 590	€ 321	€333	-0.9%
CAGR (‘15–’22)	-1.0%	-1.1%	-1.0%	-2.1%	-1.7%	-1.1%	-1.5%	-1.0%	-2.4%	-1.8%		-1.2%

Source: iData Research Inc.

Figure 13-6: Average Sales Price by Country, Female Urinary Incontinence Sling Market, Europe, 2012-2022 (US\$)

Year	Germany	France	U.K.	Italy	Spain	Benelux	Scandi- navia	Austria	Switzer- land	Portugal	Europe	Growth (%)
2012	\$399	\$416	\$426	\$430	\$444	\$413	\$415	\$429	\$900	\$423	\$427	
2013	\$384	\$409	\$412	\$423	\$438	\$409	\$406	\$425	\$851	\$414	\$417	-2.3%
2014	\$371	\$402	\$400	\$417	\$431	\$406	\$401	\$420	\$809	\$408	\$408	-2.0%
2015	\$360	\$397	\$391	\$410	\$424	\$401	\$395	\$416	\$773	\$402	\$401	-1.8%
2016	\$353	\$391	\$383	\$403	\$417	\$397	\$387	\$411	\$745	\$395	\$395	-1.6%
2017	\$348	\$386	\$376	\$396	\$410	\$393	\$381	\$406	\$721	\$388	\$389	-1.4%
2018	\$344	\$382	\$372	\$387	\$404	\$389	\$375	\$402	\$702	\$382	\$384	-1.3%
2019	\$340	\$379	\$370	\$380	\$397	\$384	\$370	\$398	\$685	\$376	\$380	-1.1%
2020	\$338	\$375	\$366	\$372	\$390	\$380	\$364	\$394	\$672	\$368	\$375	-1.2%
2021	\$337	\$371	\$366	\$362	\$384	\$376	\$358	\$391	\$661	\$362	\$371	-1.0%
2022	\$337	#REF!	\$365	\$354	\$377	\$372	\$355	\$387	\$652	\$355	\$368	-0.9%
CAGR (‘15-’22)	-1.0%	#REF!	-1.0%	-2.1%	-1.7%	-1.1%	-1.5%	-1.0%	-2.4%	-1.8%		-1.2%

Source: iData Research Inc.

Figure 13-7: Female Urinary Incontinence Sling Market by Country, Europe, 2012-2022 (€M)

Year	Germany	France	U.K.	Italy	Spain	Benelux	Scandi- navia	Austria	Switzer- land	Portugal	Europe	Growth (%)
2012	€6.22	€3.95	€3.97	€3.37	€0.71	€2.92	€2.99	€0.70	€1.52	€0.64	€27.00	
2013	€5.64	€3.79	€3.63	€3.29	€0.69	€2.90	€2.93	€0.68	€1.44	€0.62	€25.61	-5.2%
2014	€5.13	€3.65	€3.36	€3.22	€0.67	€2.87	€2.90	€0.65	€1.36	€0.60	€24.42	-4.6%
2015	€4.69	€3.54	€3.17	€3.14	€0.65	€2.84	€2.86	€0.63	€1.30	€0.58	€23.38	-4.2%
2016	€4.32	€3.44	€3.00	€3.06	€0.63	€2.81	€2.80	€0.60	€1.25	€0.56	€22.48	-3.9%
2017	€4.00	€3.37	€2.88	€2.97	€0.61	€2.78	€2.76	€0.57	€1.21	€0.54	€21.70	-3.5%
2018	€3.72	€3.31	€2.81	€2.87	€0.59	€2.74	€2.72	€0.55	€1.17	€0.53	€21.02	-3.1%
2019	€3.49	€3.26	€2.76	€2.78	€0.57	€2.70	€2.68	€0.54	€1.14	€0.51	€20.42	-2.8%
2020	€3.30	€3.21	€2.69	€2.69	€0.55	€2.66	€2.63	€0.52	€1.12	€0.49	€19.86	-2.8%
2021	€3.16	€3.17	€2.67	€2.58	€0.53	€2.62	€2.59	€0.51	€1.09	€0.47	€19.39	-2.4%
2022	€3.05	€3.12	€2.63	€2.50	€0.51	€2.57	€2.56	€0.49	€1.07	€0.45	€18.97	-2.2%
CAGR (‘15-’22)	-6.0%	-1.8%	-2.6%	-3.2%	-3.4%	-1.4%	-1.6%	-3.3%	-2.7%	-3.4%		-2.9%

Source: iData Research Inc.

Figure 13-8: Female Urinary Incontinence Sling Market by Country, Europe, 2012-2022 (US\$M)

Year	Germany	France	U.K.	Italy	Spain	Benelux	Scandi- navia	Austria	Switzer- land	Portugal	Europe	Growth (%)
2012	\$6.88	\$4.37	\$4.39	\$3.72	\$0.79	\$3.23	\$3.31	\$0.77	\$1.68	\$0.71	\$29.85	
2013	\$6.23	\$4.19	\$4.01	\$3.64	\$0.76	\$3.20	\$3.24	\$0.75	\$1.59	\$0.68	\$28.31	-5.2%
2014	\$5.67	\$4.03	\$3.72	\$3.56	\$0.74	\$3.18	\$3.20	\$0.72	\$1.51	\$0.66	\$27.00	-4.6%
2015	\$5.18	\$3.91	\$3.50	\$3.47	\$0.72	\$3.14	\$3.16	\$0.69	\$1.50	\$0.64	\$25.85	-4.2%
2016	\$4.78	\$3.80	\$3.32	\$3.38	\$0.69	\$3.11	\$3.10	\$0.66	\$1.38	\$0.62	\$24.85	-3.9%
2017	\$4.43	\$3.72	\$3.18	\$3.29	\$0.67	\$3.07	\$3.05	\$0.63	\$1.34	\$0.60	\$23.99	-3.5%
2018	\$4.11	\$3.66	\$3.11	\$3.18	\$0.65	\$3.03	\$3.01	\$0.61	\$1.30	\$0.58	\$23.24	-3.1%
2019	\$3.85	\$3.60	\$3.05	\$3.08	\$0.63	\$2.99	\$2.96	\$0.59	\$1.26	\$0.56	\$22.58	-2.8%
2020	\$3.65	\$3.55	\$2.98	\$2.97	\$0.61	\$2.94	\$2.91	\$0.57	\$1.23	\$0.54	\$21.96	-2.8%
2021	\$3.50	\$3.50	\$2.95	\$2.86	\$0.58	\$2.89	\$2.86	\$0.56	\$1.21	\$0.52	\$21.43	-2.4%
2022	\$3.37	\$3.45	\$2.91	\$2.76	\$0.56	\$2.85	\$2.83	\$0.55	\$1.19	\$0.50	\$20.97	-2.2%
CAGR (‘15-’22)	-6.0%	-1.8%	-2.6%	-3.2%	-3.4%	-1.4%	-1.6%	-3.3%	-3.3%	-3.4%		-2.9%

Source: iData Research Inc.

13.3.2 Synthetic Sling Market

In 2015, the European market for synthetic slings was valued at €20.6 million, a 3.4% decrease from 2014. This segment has been decreasing since the FDA warnings from the United States in 2008 and 2011, although the negative growth is projected to slow by 2018. Synthetic slings remain the most popular type of vaginal sling used for treating urinary incontinence. The synthetic sling market includes TVTs, TOTs and single incision slings.

As the sensationalized negative media coverage has dissipated, the use of synthetic slings is still declining but to a lesser extent than in past years. Although most of the media scrutiny of these devices occurred in the United States, these events adversely affected the European market as well, although not as drastically. The scare around mesh products led Ethicon into recalling their *GYNECARE PROLIFT*® product, among others, off the market. The German market favored synthetic slings more than any other country in Europe, with 95% of all vaginal sling unit sales consisting of synthetics in 2015. Throughout Europe, sales of TVTs predominated, constituting approximately 60% of sales volumes. TOTs made up around 30% of unit sales, and single incision slings took up the remaining 10% unit sales shares. Due to a struggling economy, there were significantly less units sold within Spain, as patients suffering from SUI were more often treated with inexpensive, less invasive methods. Products that were shown to cause complications via erosion were mostly composed of non-absorbable polyester or polypropylene mesh. As better types of synthetic slings are developed using safer, more superior materials, this market will gain more traction. The number of synthetic slings sold annually will continue to decrease, although the magnitude of the yearly declines in sales volumes will shrink over time. Synthetic vaginal sling unit sales will decrease at a CAGR of -1.8%, ending up at 53,564 by 2022.

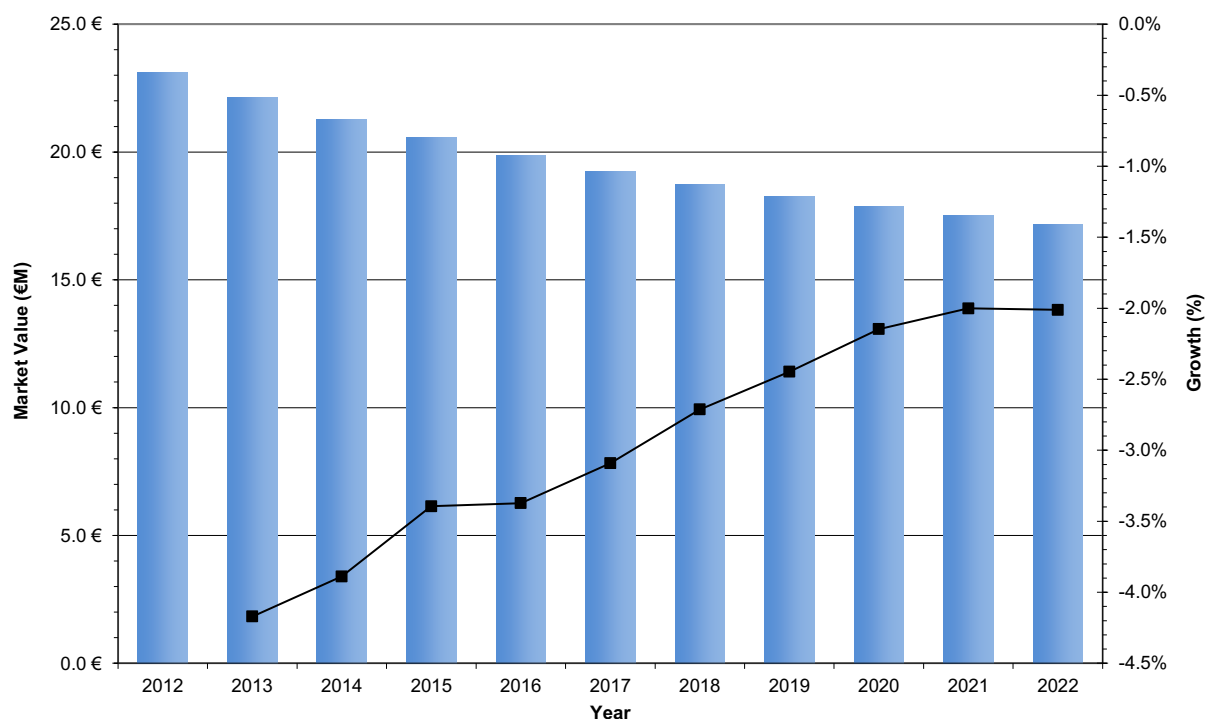
The ASP of a synthetic sling was €346 in 2015, a 1.6% decrease compared to the previous year. While TVTs and TOTs are similar in price, single incision slings are significantly more expensive, averaging at over €150 more than TVTs and TOTs. Since the notable price decrease, the ASP has continued to decline, albeit at a slower rate. This trend is expected to continue over the forecast period with the ASP decreasing at a CAGR of -1.1%, to falling to €320.

Continued decreases in unit sales and ASP will result in significant market value declines in the coming years. Total market value for synthetic slings will decrease at a CAGR of -2.5% to decrease from a market value of €20.6 million to €17.2 million by 2022.

Figure 13-9: Synthetic Sling Market, Europe, 2012 – 2022 (€ and US\$)

Year	Units Sold	Growth (%)	ASP (€)	ASP (US\$)	Growth (%)	Market Value (€M)	Market Value (US\$M)	Growth (%)
2012	63,135		€366	\$404		€23.1	\$25.5	
2013	61,814	-2.1%	€358	\$396	-2.1%	€22.1	\$24.5	-4.2%
2014	60,532	-2.1%	€351	\$389	-1.9%	€21.3	\$23.5	-3.9%
2015	59,447	-1.8%	€346	\$382	-1.6%	€20.6	\$22.7	-3.4%
2016	58,281	-2.0%	€341	\$377	-1.4%	€19.9	\$22.0	-3.4%
2017	57,206	-1.8%	€336	\$372	-1.3%	€19.2	\$21.3	-3.1%
2018	56,286	-1.6%	€333	\$368	-1.1%	€18.7	\$20.7	-2.7%
2019	55,476	-1.4%	€329	\$364	-1.0%	€18.3	\$20.2	-2.4%
2020	54,823	-1.2%	€326	\$360	-1.0%	€17.9	\$19.8	-2.1%
2021	54,207	-1.1%	€323	\$357	-0.9%	€17.5	\$19.4	-2.0%
2022	53,564	-1.2%	€320	\$354	-0.8%	€17.2	\$19.0	-2.0%
CAGR ('15-'22)		-1.5%			-1.1%			-2.5%

Source: iData Research Inc.

Chart 13-5: Synthetic Sling Market, Europe, 2012 – 2022

Source: iData Research Inc.

Figure 13-10: Units Sold by Country, Synthetic Sling Market, Europe, 2012-2022

Year	Germany	France	U.K.	Italy	Spain	Benelux	Scandi- navia	Austria	Switzer- land	Portugal	Europe	Growth (%)
2012	15,862	10,060	9,644	7,803	1,538	6,885	6,695	1,570	1,643	1,434	63,135	
2013	15,100	9,838	9,063	7,836	1,536	6,926	6,860	1,554	1,652	1,448	61,814	-2.1%
2014	14,362	9,674	8,600	7,813	1,531	6,969	6,951	1,530	1,659	1,443	60,532	-2.1%
2015	13,666	9,529	8,241	7,784	1,525	7,049	7,040	1,501	1,675	1,437	59,447	-1.8%
2016	12,873	9,387	7,891	7,734	1,517	7,085	7,206	1,469	1,690	1,430	58,281	-2.0%
2017	12,126	9,273	7,670	7,669	1,500	7,115	7,289	1,437	1,705	1,422	57,206	-1.8%
2018	11,423	9,205	7,484	7,657	1,481	7,137	7,369	1,405	1,719	1,406	56,286	-1.6%
2019	10,885	9,157	7,289	7,582	1,463	7,151	7,445	1,382	1,732	1,389	55,476	-1.4%
2020	10,412	9,112	7,192	7,518	1,444	7,152	7,518	1,363	1,734	1,379	54,823	-1.2%
2021	10,000	9,072	7,017	7,502	1,425	7,154	7,592	1,348	1,737	1,360	54,207	-1.1%
2022	9,640	9,027	6,912	7,414	1,406	7,156	7,587	1,329	1,749	1,344	53,564	-1.2%
CAGR (‘15-’22)	-4.9%	-0.8%	-2.5%	-0.7%	-1.2%	0.2%	1.1%	-1.7%	0.6%	-1.0%		-1.5%

Source: iData Research Inc.

Figure 13-11: Average Sales Price by Country, Synthetic Sling Market, Europe, 2012-2022 (€)

Year	Germany	France	U.K.	Italy	Spain	Benelux	Scandi- navia	Austria	Switzer- land	Portugal	Europe	Growth (%)
2012	€348	€347	€369	€367	€377	€344	€333	€371	€843	€351	€366	
2013	€336	€345	€354	€363	€373	€342	€331	€370	€792	€349	€358	-2.1%
2014	€326	€342	€342	€359	€369	€340	€329	€367	€749	€345	€351	-1.9%
2015	€318	€340	€332	€354	€365	€338	€327	€365	€711	€342	€346	-1.6%
2016	€312	€338	€322	€349	€360	€337	€325	€362	€683	€338	€341	-1.4%
2017	€307	€335	€314	€343	€355	€335	€322	€360	€659	€334	€336	-1.3%
2018	€304	€332	€308	€337	€350	€332	€320	€357	€639	€330	€333	-1.1%
2019	€302	€330	€303	€330	€345	€330	€317	€354	€623	€325	€329	-1.0%
2020	€300	€327	€299	€324	€340	€327	€314	€352	€611	€320	€326	-1.0%
2021	€300	€324	€296	€317	€335	€325	€312	€349	€600	€316	€323	-0.9%
2022	€301	€322	€294	€310	€330	€322	€309	€346	€591	€311	€320	-0.8%
CAGR (‘15-’22)	-0.8%	-0.8%	-1.7%	-1.9%	-1.4%	-0.7%	-0.8%	-0.8%	-2.6%	-1.4%		-1.1%
Source: iData Research Inc.												

Figure 13-12: Average Sales Price by Country, Synthetic Sling Market, Europe, 2012-2022 (US\$)

Year	Germany	France	U.K.	Italy	Spain	Benelux	Scandi- navia	Austria	Switzer- land	Portugal	Europe	Growth (%)
2012	\$385	\$384	\$408	\$406	\$417	\$380	\$369	\$411	\$932	\$389	\$404	
2013	\$372	\$381	\$392	\$402	\$413	\$378	\$366	\$409	\$876	\$385	\$396	-2.1%
2014	\$361	\$379	\$378	\$397	\$408	\$376	\$364	\$406	\$828	\$382	\$389	-1.9%
2015	\$352	\$376	\$367	\$391	\$404	\$374	\$362	\$404	\$786	\$378	\$382	-1.6%
2016	\$345	\$373	\$356	\$386	\$398	\$372	\$359	\$401	\$755	\$374	\$377	-1.4%
2017	\$339	\$370	\$347	\$379	\$393	\$370	\$356	\$398	\$728	\$369	\$372	-1.3%
2018	\$336	\$368	\$340	\$372	\$387	\$367	\$353	\$395	\$707	\$365	\$368	-1.1%
2019	\$334	\$365	\$335	\$365	\$382	\$365	\$351	\$392	\$689	\$360	\$364	-1.0%
2020	\$332	\$362	\$331	\$358	\$376	\$362	\$348	\$389	\$675	\$354	\$360	-1.0%
2021	\$332	\$359	\$328	\$350	\$370	\$359	\$345	\$386	\$664	\$349	\$357	-0.9%
2022	\$332	\$356	\$326	\$343	\$365	\$356	\$341	\$382	\$654	\$344	\$354	-0.8%
CAGR (‘15-’22)	-0.8%	-0.8%	-1.7%	-1.9%	-1.4%	-0.7%	-0.8%	-0.8%	-2.6%	-1.4%		-1.1%
Source: iData Research Inc.												

Figure 13-13: Synthetic Sling Market by Country, Europe, 2012-2022 (€M)

Year	Germany	France	U.K.	Italy	Spain	Benelux	Scandi- navia	Austria	Switzer- land	Portugal	Europe	Growth (%)
2012	€5.53	€3.50	€3.56	€2.86	€0.58	€2.37	€2.23	€0.58	€1.38	€0.50	€23.10	
2013	€5.08	€3.39	€3.21	€2.85	€0.57	€2.37	€2.27	€0.57	€1.31	€0.50	€22.13	-4.2%
2014	€4.68	€3.31	€2.94	€2.80	€0.57	€2.37	€2.29	€0.56	€1.24	€0.50	€21.27	-3.9%
2015	€4.35	€3.24	€2.73	€2.76	€0.56	€2.39	€2.30	€0.55	€1.19	€0.49	€20.55	-3.4%
2016	€4.01	€3.17	€2.54	€2.70	€0.55	€2.38	€2.34	€0.53	€1.15	€0.48	€19.86	-3.4%
2017	€3.72	€3.11	€2.41	€2.63	€0.53	€2.38	€2.35	€0.52	€1.12	€0.48	€19.24	-3.1%
2018	€3.47	€3.06	€2.30	€2.58	€0.52	€2.37	€2.36	€0.50	€1.10	€0.46	€18.72	-2.7%
2019	€3.28	€3.02	€2.21	€2.50	€0.51	€2.36	€2.36	€0.49	€1.08	€0.45	€18.26	-2.4%
2020	€3.13	€2.98	€2.15	€2.43	€0.49	€2.34	€2.36	€0.48	€1.06	€0.44	€17.87	-2.1%
2021	€3.00	€2.94	€2.08	€2.38	€0.48	€2.32	€2.37	€0.47	€1.04	€0.43	€17.51	-2.0%
2022	€2.90	€2.90	€2.04	€2.30	€0.46	€2.31	€2.34	€0.46	€1.03	€0.42	€17.16	-2.0%
CAGR (‘15-’22)	-5.6%	-1.6%	-4.1%	-2.6%	-2.6%	-0.5%	0.2%	-2.5%	-2.0%	-2.3%		-2.5%

Source: iData Research Inc.

Figure 13-14: Synthetic Sling Market by Country, Europe, 2012-2022 (US\$M)

Year	Germany	France	U.K.	Italy	Spain	Benelux	Scandi- navia	Austria	Switzer- land	Portugal	Europe	Growth (%)
2012	\$6.11	\$3.86	\$3.94	\$3.17	\$0.64	\$2.62	\$2.47	\$0.64	\$1.53	\$0.56	\$25.53	
2013	\$5.61	\$3.75	\$3.55	\$3.15	\$0.63	\$2.62	\$2.51	\$0.63	\$1.45	\$0.56	\$24.47	-4.2%
2014	\$5.18	\$3.66	\$3.25	\$3.10	\$0.63	\$2.62	\$2.53	\$0.62	\$1.37	\$0.55	\$23.52	-3.9%
2015	\$4.80	\$3.58	\$3.02	\$3.05	\$0.62	\$2.64	\$2.55	\$0.61	\$1.32	\$0.54	\$22.72	-3.4%
2016	\$4.44	\$3.50	\$2.81	\$2.98	\$0.60	\$2.64	\$2.59	\$0.59	\$1.28	\$0.53	\$21.95	-3.4%
2017	\$4.12	\$3.43	\$2.66	\$2.91	\$0.59	\$2.63	\$2.60	\$0.57	\$1.24	\$0.53	\$21.28	-3.1%
2018	\$3.84	\$3.38	\$2.54	\$2.85	\$0.57	\$2.62	\$2.60	\$0.55	\$1.21	\$0.51	\$20.70	-2.7%
2019	\$3.63	\$3.34	\$2.44	\$2.77	\$0.56	\$2.61	\$2.61	\$0.54	\$1.19	\$0.50	\$20.19	-2.4%
2020	\$3.46	\$3.30	\$2.38	\$2.69	\$0.54	\$2.59	\$2.61	\$0.53	\$1.17	\$0.49	\$19.76	-2.1%
2021	\$3.32	\$3.25	\$2.30	\$2.63	\$0.53	\$2.57	\$2.62	\$0.52	\$1.15	\$0.47	\$19.36	-2.0%
2022	\$3.21	\$3.21	\$2.25	\$2.54	\$0.51	\$2.55	\$2.59	\$0.51	\$1.14	\$0.46	\$18.97	-2.0%
CAGR (‘15-’22)	-5.6%	-1.6%	-4.1%	-2.6%	-2.6%	-0.5%	0.2%	-2.5%	-2.0%	-2.3%		-2.5%

Source: iData Research Inc.

13.3.3 Non-Synthetic Sling Market

In 2015, the European market for biologic slings was valued at €2.8M, a 9.9% decrease from 2014. The market for biologic slings is composed mostly of xenograft products, many of which are primarily indicated for pelvic floor reconstruction (PFR), but come in sizes that can be used for sling implantation to treat urinary incontinence. The biologic sling market in Europe consists mainly of xenografts due to the stern regulations surrounding the distribution of human derived tissue for soft tissue defects. Biologic slings come in the form of TVTs and TOTs, but not single-incision slings, as those products are exclusively synthetic and function differently than TVTs and TOTs.

Unlike in the United States, where the controversy surrounding synthetic slings has benefited sales of biologic slings, Europe has not experienced a comparable surge in biologic sling sales. This is partly due to how biologic slings have yet to be subjected to the relatively high adoption rates that these products have experienced in the United States.

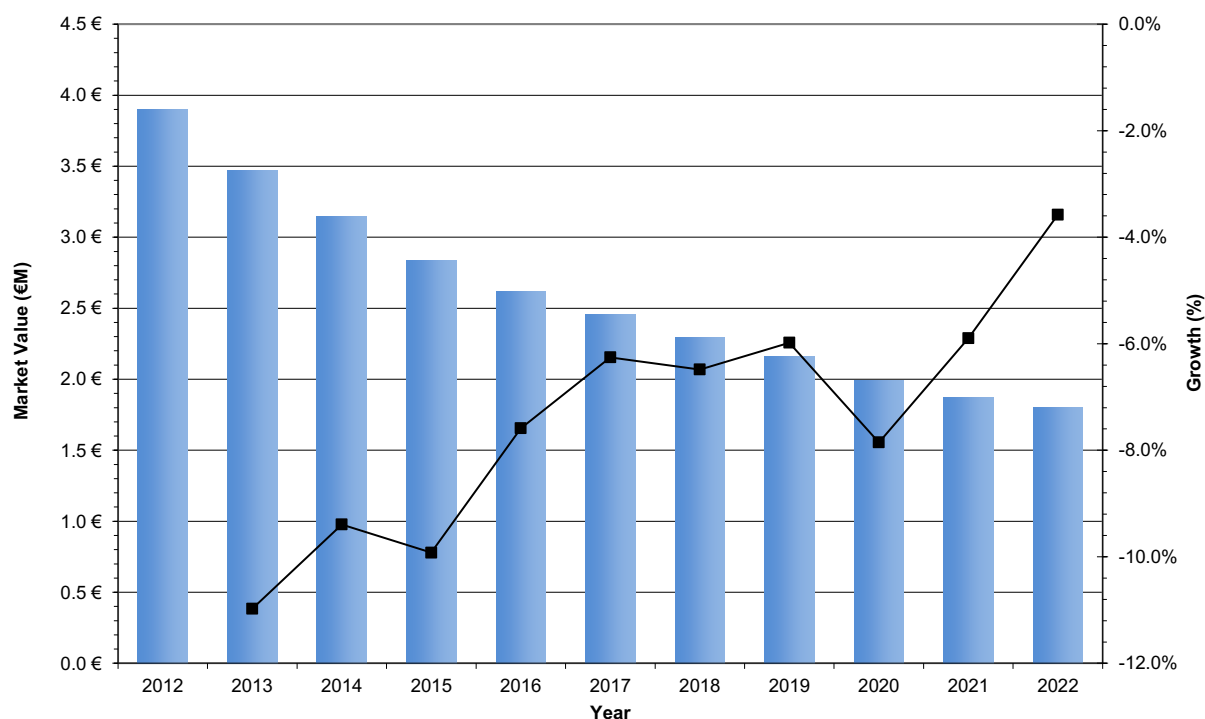
The ASP of a biologic sling was valued at €562 in 2015, a 0.5% decrease from the previous year. Reimbursement for biologic slings was especially low in Germany, which explains why the country has a reduced ASP relative to most countries. Ongoing Europe-wide reductions in reimbursement will continue to drive down the price of biologic slings into the near future. The ASP for a biologic sling will decline at a CAGR of -0.9%, dropping to €528 by 2022.

Overall, decreasing reimbursement will result in moderate declines in ASP in the coming years, compounded by decreasing unit sales growth. Over the forecast period, the market value for biologic slings will decline at a CAGR of -6.2%, falling to €1.8 million.

Figure 13-15: Non-Synthetic Sling Market, Europe, 2012 – 2022 (€ and US\$)

Year	Units Sold	Growth (%)	ASP (€)	ASP (US\$)	Growth (%)	Market Value (€M)	Market Value (US\$M)	Growth (%)
2012	6,810		€573	\$633		€3.9	\$4.3	
2013	6,105	-10.3%	€569	\$629	-0.7%	€3.5	\$3.8	-11.0%
2014	5,565	-8.9%	€565	\$625	-0.6%	€3.1	\$3.5	-9.4%
2015	5,039	-9.4%	€562	\$622	-0.5%	€2.8	\$3.1	-9.9%
2016	4,700	-6.7%	€557	\$616	-0.9%	€2.6	\$2.9	-7.6%
2017	4,446	-5.4%	€552	\$611	-0.9%	€2.5	\$2.7	-6.3%
2018	4,194	-5.7%	€548	\$605	-0.9%	€2.3	\$2.5	-6.5%
2019	3,970	-5.3%	€544	\$601	-0.7%	€2.2	\$2.4	-6.0%
2020	3,694	-6.9%	€538	\$595	-1.0%	€2.0	\$2.2	-7.9%
2021	3,510	-5.0%	€533	\$590	-0.9%	€1.9	\$2.1	-5.9%
2022	3,421	-2.5%	€528	\$583	-1.1%	€1.8	\$2.0	-3.6%
CAGR ('15-'22)		-5.4%			-0.9%			-6.2%

Source: iData Research Inc.

Chart 13-6: Non-Synthetic Sling Market, Europe, 2012 – 2022

Source: iData Research Inc.

Figure 13-16: Units Sold by Country, Non-Synthetic Sling Market, Europe, 2012-2022

Year	Germany	France	U.K.	Italy	Spain	Benelux	Scandi- navia	Austria	Switzer- land	Portugal	Europe	Growth (%)
2012	1,379	757	670	867	230	939	1,275	235	224	233	6,810	
2013	1,137	661	682	775	209	900	1,117	212	215	197	6,105	-10.3%
2014	917	563	697	726	189	861	1,039	189	205	178	5,565	-8.9%
2015	719	502	717	677	169	783	960	167	186	160	5,039	-9.4%
2016	663	463	780	645	150	744	801	145	167	141	4,700	-6.7%
2017	611	447	805	622	139	704	721	125	148	124	4,446	-5.4%
2018	551	434	878	541	129	663	641	114	129	114	4,194	-5.7%
2019	454	421	956	518	119	622	560	104	111	105	3,970	-5.3%
2020	400	409	953	480	109	580	480	95	101	88	3,694	-6.9%
2021	373	398	1,048	395	99	538	400	86	91	81	3,510	-5.0%
2022	350	396	1,079	382	90	497	399	85	73	71	3,421	-2.5%
CAGR (‘15-’22)	-9.8%	-3.3%	6.0%	-7.8%	-8.7%	-6.3%	-11.8%	-9.2%	-12.5%	-11.0%		-5.4%

Source: iData Research Inc.

Figure 13-17: Average Sales Price by Country, Non-Synthetic Sling Market, Europe, 2012-2022 (€)

Year	Germany	France	U.K.	Italy	Spain	Benelux	Scandi- navia	Austria	Switzer- land	Portugal	Europe	Growth (%)
2012	€503	€605	€617	€583	€570	€592	€594	€499	€605	€573	€573	
2013	€494	€600	€612	€577	€564	€587	€590	€491	€600	€567	€569	-0.7%
2014	€486	€595	€606	€570	€559	€582	€586	€483	€595	€562	€565	-0.6%
2015	€478	€590	€601	€564	€553	€577	€582	€475	€590	€556	€562	-0.5%
2016	€470	€585	€595	€557	€547	€572	€577	€466	€585	€550	€557	-0.9%
2017	€462	€581	€589	€551	€541	€566	€573	€458	€579	€544	€552	-0.9%
2018	€454	€575	€583	€544	€535	€560	€568	€448	€574	€538	€548	-0.9%
2019	€445	€570	€576	€537	€530	€554	€563	€440	€568	€532	€544	-0.7%
2020	€437	€565	€569	€530	€524	€548	€558	€432	€563	€527	€538	-1.0%
2021	€428	€560	€562	€524	€517	€541	€553	€424	€557	€520	€533	-0.9%
2022	€419	€555	€555	€517	€511	€535	€548	€417	€551	€514	€528	-1.1%
CAGR (‘15-’22)	-1.9%	-0.9%	-1.1%	-1.2%	-1.1%	-1.1%	-0.9%	-1.9%	-1.0%	-1.1%		-0.9%
Source: iData Research Inc.												

Figure 13-18: Average Sales Price by Country, Non-Synthetic Sling Market, Europe, 2012-2022 (US\$)

Year	Germany	France	U.K.	Italy	Spain	Benelux	Scandi- navia	Austria	Switzer- land	Portugal	Europe	Growth (%)
2012	\$556	\$669	\$682	\$645	\$630	\$654	\$657	\$551	\$669	\$634	\$633	
2013	\$546	\$663	\$677	\$638	\$624	\$649	\$653	\$543	\$663	\$627	\$629	-0.7%
2014	\$537	\$658	\$671	\$630	\$618	\$644	\$648	\$534	\$658	\$621	\$625	-0.6%
2015	\$528	\$652	\$664	\$624	\$611	\$638	\$643	\$525	\$652	\$615	\$622	-0.5%
2016	\$519	\$647	\$658	\$616	\$605	\$632	\$638	\$516	\$646	\$609	\$616	-0.9%
2017	\$511	\$642	\$651	\$609	\$599	\$626	\$633	\$506	\$641	\$602	\$611	-0.9%
2018	\$501	\$636	\$644	\$601	\$592	\$619	\$628	\$496	\$635	\$595	\$605	-0.9%
2019	\$492	\$630	\$637	\$594	\$586	\$612	\$623	\$486	\$629	\$589	\$601	-0.7%
2020	\$483	\$625	\$629	\$586	\$579	\$605	\$617	\$477	\$622	\$582	\$595	-1.0%
2021	\$473	\$619	\$622	\$579	\$572	\$598	\$612	\$469	\$616	\$575	\$590	-0.9%
2022	\$463	\$613	\$614	\$571	\$565	\$591	\$606	\$461	\$609	\$568	\$583	-1.1%
CAGR (‘15-’22)	-1.9%	-0.9%	-1.1%	-1.2%	-1.1%	-1.1%	-0.9%	-1.9%	-1.0%	-1.1%		-0.9%

Source: iData Research Inc.

Figure 13-19: Non-Synthetic Sling Market by Country, Europe, 2012-2022 (€M)

Year	Germany	France	U.K.	Italy	Spain	Benelux	Scandi- navia	Austria	Switzer- land	Portugal	Europe	Growth (%)
2012	€0.69	€0.46	€0.41	€0.51	€0.13	€0.56	€0.76	€0.12	€0.14	€0.13	€3.90	
2013	€0.56	€0.40	€0.42	€0.45	€0.12	€0.53	€0.66	€0.10	€0.13	€0.11	€3.47	-11.0%
2014	€0.45	€0.33	€0.42	€0.41	€0.11	€0.50	€0.61	€0.09	€0.12	€0.10	€3.15	-9.4%
2015	€0.34	€0.30	€0.43	€0.38	€0.09	€0.45	€0.56	€0.08	€0.11	€0.09	€2.83	-9.9%
2016	€0.31	€0.27	€0.46	€0.36	€0.08	€0.43	€0.46	€0.07	€0.10	€0.08	€2.62	-7.6%
2017	€0.28	€0.26	€0.47	€0.34	€0.08	€0.40	€0.41	€0.06	€0.09	€0.07	€2.46	-6.3%
2018	€0.25	€0.25	€0.51	€0.29	€0.07	€0.37	€0.36	€0.05	€0.07	€0.06	€2.30	-6.5%
2019	€0.20	€0.24	€0.55	€0.28	€0.06	€0.34	€0.32	€0.05	€0.06	€0.06	€2.16	-6.0%
2020	€0.17	€0.23	€0.54	€0.25	€0.06	€0.32	€0.27	€0.04	€0.06	€0.05	€1.99	-7.9%
2021	€0.16	€0.22	€0.59	€0.21	€0.05	€0.29	€0.22	€0.04	€0.05	€0.04	€1.87	-5.9%
2022	€0.15	€0.22	€0.60	€0.20	€0.05	€0.27	€0.22	€0.04	€0.04	€0.04	€1.81	-3.6%
CAGR (‘15-’22)	-11.5%	-4.2%	4.8%	-9.0%	-9.7%	-7.3%	-12.5%	-10.9%	-13.4%	-12.0%		-6.2%

Source: iData Research Inc.

Figure 13-20: Non-Synthetic Sling Market by Country, Europe, 2012-2022 (US\$M)

Year	Germany	France	U.K.	Italy	Spain	Benelux	Scandi- navia	Austria	Switzer- land	Portugal	Europe	Growth (%)
2012	\$0.77	\$0.51	\$0.46	\$0.56	\$0.14	\$0.61	\$0.84	\$0.13	\$0.15	\$0.15	\$4.31	
2013	\$0.62	\$0.44	\$0.46	\$0.49	\$0.13	\$0.58	\$0.73	\$0.12	\$0.14	\$0.12	\$3.84	-11.0%
2014	\$0.49	\$0.37	\$0.47	\$0.46	\$0.12	\$0.55	\$0.67	\$0.10	\$0.13	\$0.11	\$3.48	-9.4%
2015	\$0.38	\$0.33	\$0.48	\$0.42	\$0.10	\$0.50	\$0.62	\$0.09	\$0.12	\$0.10	\$3.13	-9.9%
2016	\$0.34	\$0.30	\$0.51	\$0.40	\$0.09	\$0.47	\$0.51	\$0.07	\$0.11	\$0.09	\$2.90	-7.6%
2017	\$0.31	\$0.29	\$0.52	\$0.38	\$0.08	\$0.44	\$0.46	\$0.06	\$0.09	\$0.07	\$2.71	-6.3%
2018	\$0.28	\$0.28	\$0.57	\$0.33	\$0.08	\$0.41	\$0.40	\$0.06	\$0.08	\$0.07	\$2.54	-6.5%
2019	\$0.22	\$0.27	\$0.61	\$0.31	\$0.07	\$0.38	\$0.35	\$0.05	\$0.07	\$0.06	\$2.39	-6.0%
2020	\$0.19	\$0.26	\$0.60	\$0.28	\$0.06	\$0.35	\$0.30	\$0.05	\$0.06	\$0.05	\$2.20	-7.9%
2021	\$0.18	\$0.25	\$0.65	\$0.23	\$0.06	\$0.32	\$0.24	\$0.04	\$0.06	\$0.05	\$2.07	-5.9%
2022	\$0.16	\$0.24	\$0.66	\$0.22	\$0.05	\$0.29	\$0.24	\$0.04	\$0.04	\$0.04	\$2.00	-3.6%
CAGR (‘15-’22)	-11.5%	-4.2%	4.8%	-9.0%	-9.7%	-7.3%	-12.5%	-10.9%	-13.4%	-12.0%		-6.2%

Source: iData Research Inc.

13.4 DRIVERS AND LIMITERS

13.4.1 Market Drivers

Aging Population

The incidence of urinary incontinence generally increases with age. In that regard, the aging population combined with longer life expectancies will help drive the market for urinary incontinence treatments in the future. In the elderly, urinary incontinence may result from a confluence of factors including comorbid conditions, medications, neuro-urinary pathology, etc. Studies have found urinary incontinence in an estimated one third of women between 60 and 90 years of age.

Less Incontinence Stigma

Physicians are struggling to reduce the negative stigma associated with incontinence. By increasing patient comfort with discussing the disease, more people with the condition are likely to come forward and undergo treatment. However, while perceptions of incontinence might be an internal motivator to seek treatment, other external factors might limit a patient's ability to receive treatment.

13.4.2 Market Limiters

Influence of Controversy in the United States

The FDA warnings regarding the use of surgical mesh to repair pelvic organ prolapse (POP) and stress urinary incontinence (SUI) that were an issue in 2008 and 2011 have negatively impacted the market for slings in Europe. Complications included erosion of the vaginal epithelium, infection, pain or even recurrence of prolapse or incontinence. In some cases, there was vaginal scarring and mesh erosion leading to a significant decline in quality of life. The incidence for the total number of patients was low. Despite the fact that these cases took place in the United States, European markets have been negatively affected by the bad publicity.

Invasive Implantation Procedures

Vaginal slings involve a surgical procedure that results in difficulty for female patients to vaginally deliver children in the future. In addition, active patients who cannot afford six to eight weeks of recovery time after an incontinence sling procedure will opt for other alternatives such as bulking agents, radiofrequency or laser treatments. This problem has been partially remedied by the increasing popularity of single-incision slings, which vastly reduces the invasiveness, and thereby recovery time, of the implantation procedure.

Autologous Pubovaginal Slings

If a patient does not desire a mesh implantation procedure to treat urinary incontinence, an autologous sling can be harvested from the patient's own tissue during the procedure. Fascia is normally taken from the abdomen and used as a sling that is inserted under the urethra to prevent leakage.

Figure 13-21: Drivers and Limiters, Female Urinary Incontinence Sling Market, Europe, 2015

Market Drivers
Aging Population Less Incontinence Stigma
Market Limiters
Influence of Controversy in the United States Invasive Implantation Procedures Autologous Pubovaginal Slings
Source: iData Research Inc.

13.5 COMPETITIVE MARKET SHARE ANALYSIS

Johnson & Johnson

The leading competitor in the vaginal sling market was Ethicon, part of the Johnson & Johnson group of companies, with a 26.2% share in 2015.

Ethicon's *Gynecare TVT™* sling was among the first that could be implanted via a minimally invasive procedure. Marketing has been targeted at gynecologists, leading them to refer patients to urologists that use this particular sling. In addition, some gynecologists are starting to perform sling procedures as well. As a result, gynecologists are more likely to refer patients to urologists that use this particular sling. In August 2010, Ethicon added the *Gynecare TVT EXACT™* retropubic sling to the *Gynecare TVT™* family of products, which offers tension-free support for incontinence. The company also offers the *Gynecare TVT ABBREVO®* system.

Ethicon was hit hard by the recent lawsuits over in the U.S. and ended up pulling out four of its synthetic vaginal sling products from the U.S. and European markets. The discontinued products included one indicated solely for SUI treatment, the *Gynecare TVT® Secure System*, and three indicated for both SUI and POP, including *Gynecare Prolift®*, *Gynecare Prolift® + M*, *Gynecare Prosima®*. These recalls initially reduced the company's presence in this market significantly, although due to the historic success of their products on the market, they have since recovered.

Astora Women's Health

Astora Women's Health held the second highest market share in the female urinary incontinence market in 2015 with a 25.9% market share. The company offered an extensive line of TVT and TOT synthetic slings including *RetroArc™ Retropubic Sling System*, *Monarc® Sling/Subfascial Hammock* and *SPARC®*. Astora also offered a series of single-incision slings under the *MiniArc™* brand. Along with the original *MiniArc™*, the company released upgraded versions including the *MiniArc Precise™*, and the most recent edition released in 2013, the *MiniArc Pro™*, featuring repeatable, standardized tension control. These recent product modifications to the *MiniArc™* series of slings allowed the company to endure the FDA repercussions stemming from the U.S. and remain the market leader in Europe.

Astora Women's Health also offered the *BioArc®*, which belongs to the unique emerging segment of hybrid devices. This was the first hybrid device product marketed for this indication and is a fusion of both synthetic and biologic materials. The company also competed in the biologic sling market with the

InteXen® LP™, a xenograft derived from porcine dermis that is primarily indicated for pelvic floor reconstruction but comes in sizes fit for vaginal sling implantation.

Endo Health Solutions acquired American Medical Systems in 2011. Following the acquisition, Endo rebranded American Medical System's Women's Health division to Astora Women's Health. As part of the initial acquisition of AMS, Endo Health Solutions also acquired over 22,000 lawsuits regarding AMS's vaginal mesh products for the treatment of pelvic organ prolapse and urinary incontinence. Announced in March 2016, Endo International began the process of shutting down Astora Women's Health. Astora closed on March 31st 2016 to "reduce the potential for product liability related to future mesh implants". The withdrawal of Astora from the female urinary incontinence sling market created a major opportunity, with 25.5% of the market available. This report includes leading competitive analyses for both 2015 and 2016, pre and post Astora in the market, to demonstrate how the company's market share has been reallocated in the market.

Boston Scientific

Boston Scientific offers urinary incontinence slings for pre-pubic, transobturator and retropubic placement. Products include the *Obtryx® Transobturator Mid-Urethral Sling System Obtryx™ Sling System* and *Lynx®* suprapubic mid-urethral and *Advantage Fit™ Transvaginal Mid-Urethral Sling* systems. All systems use *Advantage®* mesh, which is designed to reduce the risks of deformation and vaginal wall irritation. The company also offers one single-incision product, the *Solyx™ Single-Incision Sling*.

Boston Scientific also has a biologic xenograft product, *Xenform®*, which is derived from bovine dermal matrix. This product is primarily used for pelvic floor reconstruction to treat pelvic organ prolapse, but has also been successful in penetrating the biologic vaginal sling market.

While some of Boston Scientific's synthetic vaginal sling products have been involved with some of the recent lawsuits in the United States, they nonetheless managed to gain market share at the expense of other companies that were more heavily affected.

On March 2nd, 2015 Boston Scientific Corporation announced the acquisition of the American Medical Systems urology portfolio from Endo International plc. The portfolio included the Men's Health and Prostate Health businesses. The AMS women's health business for treating pelvic organ prolapse and female stress urinary incontinence was not included in the acquisition. Despite this fact, Boston Scientific is expected to increase their market share in the female urinary incontinence market substantially between 2015 and 2016. Part of this increase is attributable to relationships with customers who will

continue to order products from the AMS male portfolio and thus also order products from Boston Scientific's female portfolio.

Coloplast

Coloplast offers a large variety of vaginal slings, including the *Aris*®, *Supris*®, and *Altis*®, which was launched in November of 2012. The company also offers the *Altis Single-Incision Sling*, which is designed to reduce the length and invasiveness of the implantation procedure. Coloplast has two popular allograft biologic slings, *Suspend*® and *Axis*™, that are both popular in the United States but are not as readily available in Europe due to the strict regulations surrounding human-derived soft tissue regenerative products.

CR Bard

The company offers the *Align*® family of synthetic slings. The *Align*® is available in retropubic-suprapubic and trans-obturator urethral support systems.

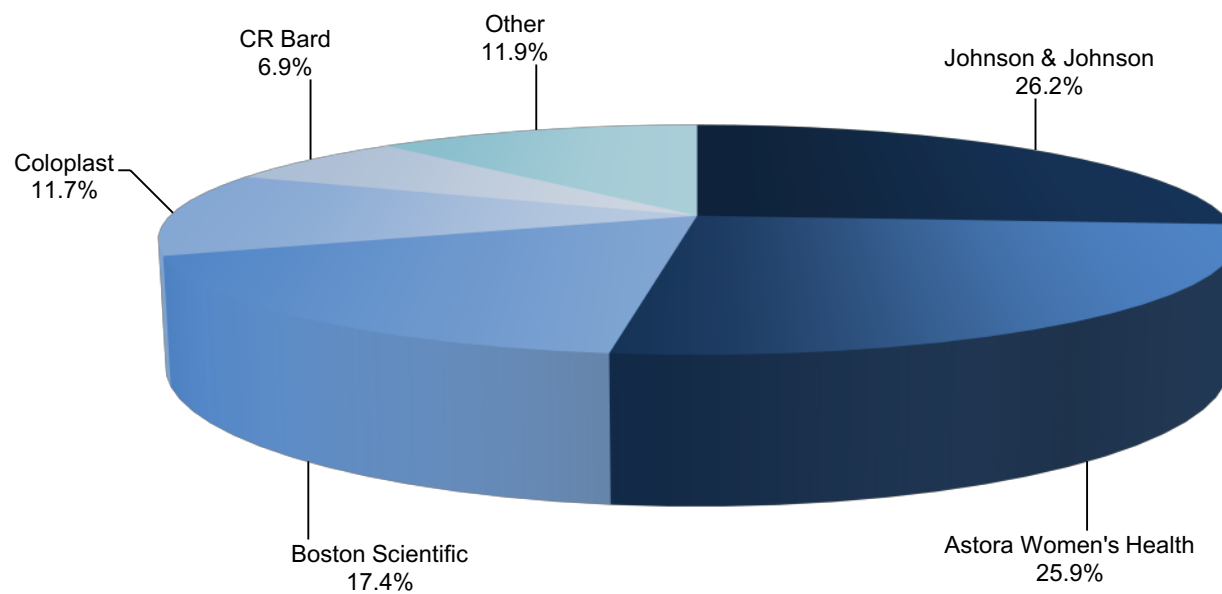
Bard Medical also offered two biological xenograft slings indicated for POP and SUI, *PelviLace*® and *Pelvicol*®, as well as the synthetic single-incision sling, *ADJUST*®, but these products were subjected to highly publicized lawsuits and have since been taken down from their website. The company also offered a hybrid biosynthetic mesh product, *Avaulta*® Plus, which was officially pulled from the market in July 2012.

Other Notable Competitors: Serag Weissner

Serag-Wiessner has a notable presence in Germany with its *SERASIS*® and *SERASIS*® PA products. *SERASIS*® is a standard polypropylene based synthetic mesh, whereas *SERASIS*® PA had a partially resorbable biologic component composed of hexafilament fibers.

Figure 13-22: Leading Competitors by Country, Female Urinary Incontinence Sling Market, Europe, 2015

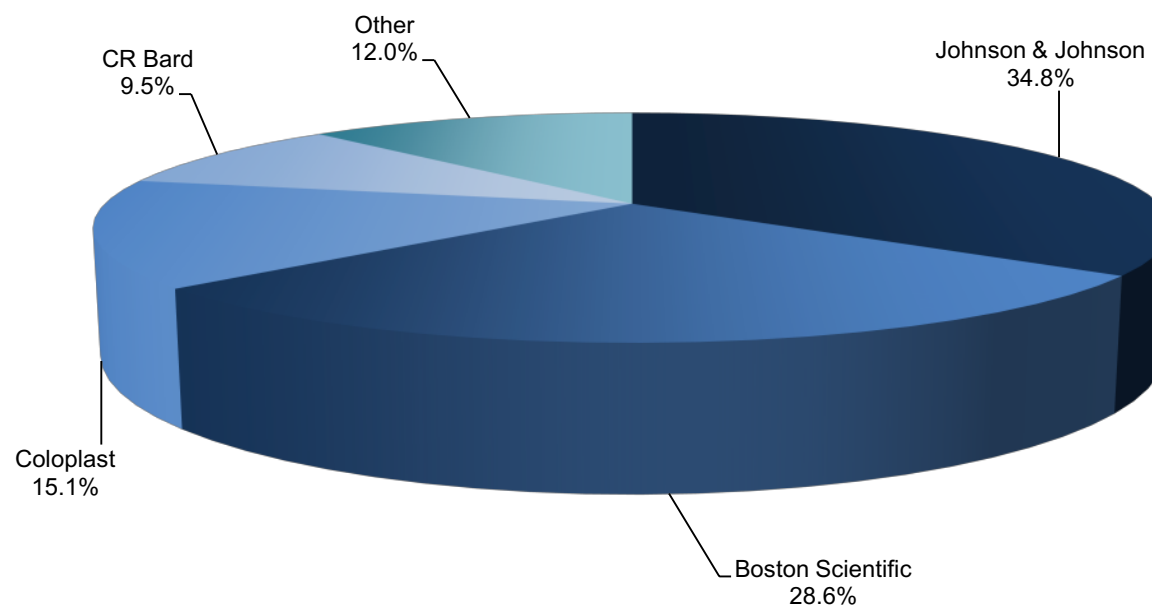
Company	Germany	France	U.K.	Italy	Spain	Benelux	Scandi- navia	Austria	Switzer- land	Portugal	Total Market Share
Johnson & Johnson	24.2%	24.9%	28.6%	19.5%	8.2%	32.0%	34.7%	24.8%	32.9%	10.2%	26.2%
Astora Women's Health	23.8%	23.2%	24.2%	31.9%	59.7%	22.4%	20.6%	25.3%	23.1%	48.5%	25.9%
Boston Scientific	14.4%	18.9%	20.4%	24.9%	7.1%	15.2%	15.2%	13.2%	15.7%	15.8%	17.4%
Coloplast	13.0%	13.2%	12.6%	13.7%	14.2%	9.0%	6.3%	13.1%	11.8%	12.9%	11.7%
CR Bard	7.4%	6.8%	7.1%	7.5%	8.0%	5.1%	6.2%	8.6%	5.9%	10.3%	6.9%
Other	17.2%	13.0%	7.1%	2.5%	2.8%	16.3%	17.0%	15.0%	10.6%	2.3%	11.9%
Total	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
Market Value (€M)	€4.7	€3.5	€3.2	€3.1	€0.7	€2.8	€2.9	€0.6	€1.3	€0.6	€23.4
Others include: Agency for Medical Innovations (A.M.I.), B. Braun, Caldera Medical Cousin Biotech, CL Medical, Helioscopie, Neomedic International, etc.											
Source: iData Research Inc.											

Chart 13-7: Leading Competitors, Female Urinary Incontinence Sling Market, Europe, 2015

Source: iData Research Inc.

Figure 13-23: Projected Leading Competitors by Country, Female Urinary Incontinence Sling Market, Europe, 2016

Company	Germany	France	U.K.	Italy	Spain	Benelux	Scandi- navia	Austria	Switzer- land	Portugal	Total Market Share
Johnson & Johnson	33.0%	32.5%	36.2%	30.9%	25.7%	40.5%	38.9%	35.2%	40.7%	25.2%	34.8%
Boston Scientific	21.4%	32.0%	34.2%	35.5%	27.4%	21.3%	31.6%	20.6%	30.5%	25.0%	28.6%
Coloplast	17.9%	15.8%	13.8%	17.4%	20.1%	12.8%	9.0%	15.9%	14.1%	18.6%	15.1%
CR Bard	11.1%	9.1%	8.4%	8.8%	13.6%	7.2%	9.5%	10.1%	9.4%	16.2%	9.5%
Other	16.6%	10.6%	7.4%	7.4%	13.2%	18.2%	11.0%	18.2%	5.3%	15.0%	12.0%
Total	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
Market Value (€M)	€4.3	€3.4	€3.0	€3.1	€0.6	€2.8	€2.8	€0.6	€1.3	€0.6	€22.5
Others include: Agency for Medical Innovations (A.M.I.), B. Braun, Caldera Medical Cousin Biotech, CL Medical, Helioscopie, Neomedic International, etc.											
Source: iData Research Inc.											

Chart 13-8: Projected Leading Competitors, Female Urinary Incontinence Sling Market, Europe, 2016

Source: iData Research Inc.

14

LASER TECHNOLOGY AND DYSPAREUNIA TREATMENT MARKET

14.1 INTRODUCTION

14.1.1 Laser Technology

The application of laser technology in gynecology first emerged in 1973, when CO₂ lasers were successfully used to treat cervical erosions. While the use of lasers for gynecology treatments is well established, the use of laser treatments has historically been more popular in the field of dermatology. Starting in 2012, there has been a resurgence of gynecologists investing in laser systems and the treatments are rapidly becoming more popular both with medical professionals and patients. The projected growth for lasers in gynecology is 10% annually.

Several types of lasers are available reflecting the advancements in the field of laser technology. The CO₂ laser is the most versatile and common type of laser on the market. Due to its limited depth of penetration (0.1 mm to 0.5 mm) and lateral thermal damage (0.5 mm), CO₂ lasers have been proven to be a safe and effective treatment option. Additional laser types include: neodymium: yttrium-aluminum-garnet (Nd:YAG), Erbium-YAG (Er:YAG), and Hybrid Fractional Laser (HFL).

All of the laser types mentioned in this report have proven to be highly effective in the treatment of various gynecological conditions, including: vaginal atrophy, endometriosis, mild to moderate stress urinary incontinence and uterine fibroids. While lasers can be used for both extra and intra-abdominal applications in laparoscopic and endoscopy procedures, they are gaining popularity for non-invasive applications. Laser treatments offer minimally invasive outpatient solutions that can be performed in hospital or clinics. The procedures are fast, safe, offer minimal adverse effects and produce highly effective results.

Laser treatments initially gained popularity in the 1980's, however, due to budget constraints alternative, less expensive technology diminished enthusiasm and use of laser energy. As the benefits of laser energy gain increased recognition and patient demand continues to increase, more gynecologists are expected to seek training to become certified in the different types of lasers and invest in laser systems.

14.1.2 Laser Procedures: the treatment of Dyspareunia

Dyspareunia is defined as persistent or recurrent genital pain that occurs just before, during or after intercourse (or penetration). Although pain during intercourse will occur to the vast majority of women at some point in their lives, Dyspareunia can be debilitating, emotionally stressful and is often reported to decrease quality of life; the combination of which often further cements the problem. Conditions that fall under dyspareunia include (but are not limited to): vaginal atrophy, endometriosis and vulvodynia (provoked vulvodynia and generalized vulvodynia).

Vaginal atrophy is the thinning, drying and inflammation of the vaginal walls due to a women's body having less estrogen, occurring most often after menopause. Approximately 40% of women with vaginal atrophy report suffering from dyspareunia.

Endometriosis occurs when tissue that normally lines the inside of a women's uterus, the endometrium, grows outside the uterus (endometrial implant). Endometriosis most commonly involves the ovaries, bowel and/or the tissue lining the pelvis. When endometriosis involves the ovaries, cysts called endometriomas may also form. Up to 50% of women with endometriosis also report suffering from dyspareunia as a result of the condition.

Vulvodynia is when a women experiences chronic vulvar pain without an identifiable cause. The two main subtypes of vulvodynia (which may co-exist) are provoked vestibulodynia (PVD, also known as vulvar vestibulitis, localized vulvar dysesthesia) and generalized vulvodynia. PVD is diagnosed when pain is localized to the vestibule (the area surrounding the vaginal opening) and occurs during or after touch or pressure is applied to the area. PVD is the most common type of superficial dyspareunia affecting 16% of women at some point in their life. Generalized vulvodynia is diagnosed when symptoms are localized or may occur in several areas of the vulva. Both subtypes of vulvodynia result in dyspareunia.

Overall, conditions causing dyspareunia are difficult to diagnosis and not well recognized even in the field of gynecology. The average woman with PVD, for example, takes seven years to receive an accurate

diagnosis not including treatment. Treatment options for conditions causing dyspareunia are extensive and normally utilize a multidisciplinary approach for the highest success rates to resolve. Laser treatments are competing with alternative treatment methods in patients suffering from vaginal atrophy and endometriosis.

An introductory list includes:

Figure 14-1: Multidisciplinary Treatment Options for Dyspareunia

Non-Surgical Treatments	Surgical Treatments	Psychological Treatments
<ul style="list-style-type: none"> • Low Oxalate Diet • Topical Medications • Oral Medications • Nerve Blocks • Alternative Medicine (Acupuncture) • Biofeedback/Physical Therapy • Injections • Hormone Therapy (including the Mirena IUD) • Laser Treatments 	<ul style="list-style-type: none"> • Endometrial Ablation • Laser Thermal Ablation • Heat Thermal Ablation • Endometrial Resection • Hysterectomy • Vestibuladectomy 	<ul style="list-style-type: none"> • Clinical Studies for Dyspareunia • Cognitive Behavioral Therapy/Mindfulness • Further Education (ex. Understanding the Sexual Response Cycle)
Source: iData Research Inc.		

14.2 MARKET OVERVIEW

The prevalence of non-invasive, outpatient procedures is fueling the growth of laser energy in Gynecology. As controversy and concern over safety risks of alternative procedures gains more publicity, the safety and efficacy of lasers is compounding the positive growth of the market. Focusing on outpatient procedures, the different types of laser energy produce the best results, specific to certain procedures. There is preliminary clinical evidence supporting the use of lasers (both CO₂ lasers and a combination of Nd: YAG and Er: YAG lasers) for the treatment of vaginal atrophy. There is not yet enough clinical evidence proving the effectiveness of laser treatments for stress urinary incontinence. However, patient reports following the procedure give a strong positive result that laser treatments do improve mild to moderate cases of stress urinary incontinence. As more clinical studies are completed, both in Europe and Internationally, the body of research analyzing the effects of lasers and patient outcomes is expected to increase significantly over the reporting period.

CO₂ laser energy is highly absorbed in water and cuts tissue by vaporizing the water content of cells at the tissue surface. The CO₂ laser produces a wavelength of 10,800 nm. As 10,800 nm is in the non-visible part of the electromagnetic spectrum, a helium-neon laser is also used that produces a red light to identify the location of the CO₂ beam. In addition to vaporization, CO₂ lasers can also be used for excision or incision by increasing the power density. CO₂ lasers were the initial laser type used in Gynecology. Although the number of clinical studies on CO₂ lasers is limited, the results have been consistently positive that they are an effective and safe treatment for vaginal atrophy.

Nd: YAG lasers and Er: YAG lasers are often used in combination. Nd: YAG lasers have a wavelength of 1064 nm and are guided using a helium-neon spot, similar to a CO₂ laser. The Nd: YAG laser is absorbed with a deep tissue penetration of 3mm to 4 mm. Nd: YAG lasers are also resistant to fluid absorption. In contrast, Er: YAG lasers offer the highest absorption in water, with a peak wavelength of 2940nm. The Er: YAG laser is best suited for superficial treatment of the vaginal walls as the optical absorption depth in the mucosal tissue is very small. The use of Nd: YAG lasers and Er: YAG lasers in gynecology are also well established, with more than 15 years of experience. Similar to CO₂ lasers, combination Nd: YAG and Er: YAG lasers are offered to treat both vaginal atrophy and stress urinary incontinence.

The hybrid fractional laser is a new system on the market, delivering both ablative and non-ablative wavelengths to the same or different microscopic treatment zones. The system offers both 1470 nm wavelength for coagulation to the vaginal mucosa and 2940 nm wavelength for ablation.

The laser treatment market is growing through two incentives. In the past, dermatologists have been taking advantage of patients seeking laser treatments for vaginal atrophy and more recently stress urinary incontinence. The market is expected to grow as more gynecologists move into this field to expand their treatment offerings. The market is also eroding the stress urinary incontinence market and is projected to gain at least 10% of the urinary incontinence market by 2018. By 2022, the market is forecasted to erode potentially as high as 20% of the female urinary incontinence sling market. This is a cautious consensus in the industry as it relies heavily on the assumption that more clinical studies will support positive results for laser treatments of stress urinary incontinence. Overall, there are multiple factors fueling the growth of the laser market in Europe.

14.3 MARKET ANALYSIS

Southern Europe has been the market leader for laser treatments in Gynecology. A number of the top competitors in the market are based in southern Europe driving the trend, most notably Deka Medical Lasers in Italy. The market thus far has been limited by the smaller funds gynecologists often have compared with other specialties. Compiling lack of non-essential spending with newer applications for lasers, more conservative countries and doctors have previously had a lackluster attitude towards adopting laser treatments. Overall, Italy and Spain have been leading the laser market. The United Kingdom is quickly following with the fastest growth rate in the laser market. Germany is slowly moving towards gynecologists performing laser treatments. France is expected to maintain smaller growth with laser treatments starting to grow near the end of the reporting period.

While this report is focused on five European countries, the use of laser treatments in the Scandinavian and Benelux regions is currently minimal. By contrast, Portugal is near the top of the trend for utilization, with percentages slightly lower than Spain. The laser market in all European countries is also nowhere near saturated. In Italy, less than 1% of stress urinary incontinence patients are currently using a laser treatment option.

The ASP in laser treatments varies across countries. This is attributed to sales through distributors compared to direct sales. For the majority of competitors, sales in the U.K. are made through distributors driving up the price. In contrast, sales in Germany are occurring directly from the manufacturer contributing to the lower sales price. Of the companies covered in this report, the prices ranged from an average of €60,000 to €80,000 for a laser system. Part of the difference in price is also attributable to the differences in VAT exchange rates as well as which competitors have higher sales in different countries. The prices are predicted to stay stable due to the release of new systems and the increasing patient numbers seeking treatment.

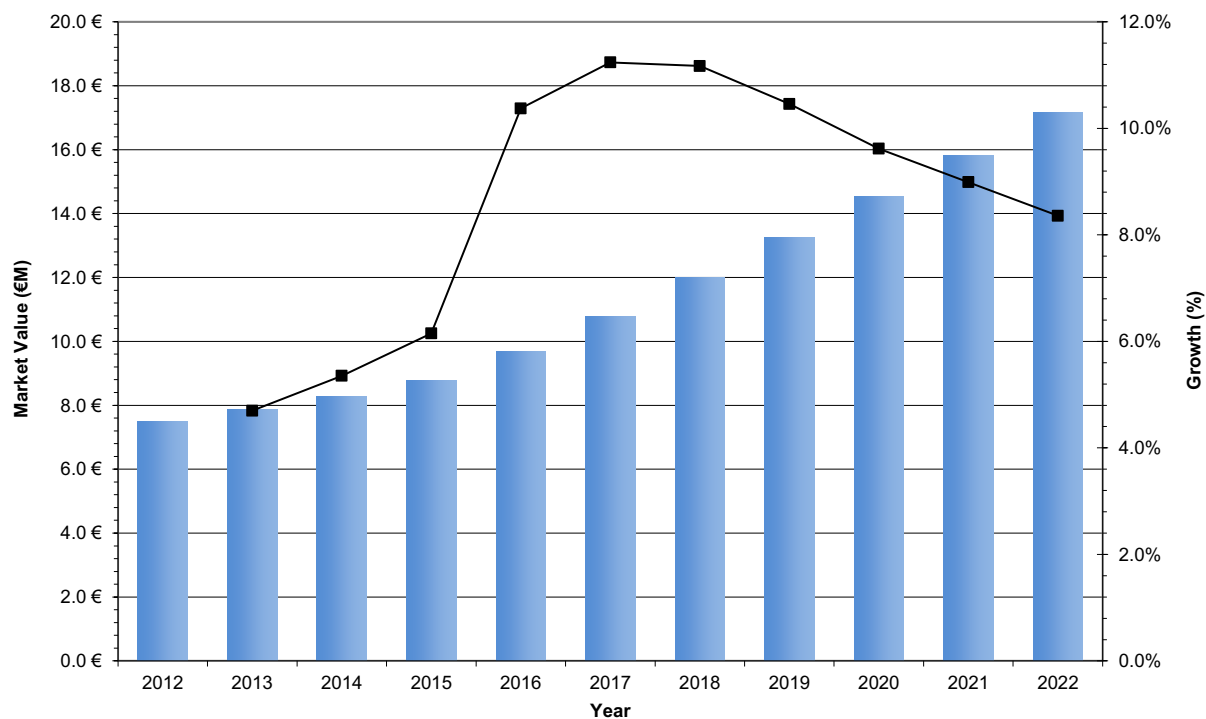
It is important to note that the market value does not reflect the number of systems being distributed by competitors annually. As competitors and medical professionals are actively trying to increase utilization and clinical studies regarding laser treatments, a number of systems are being provided for certain purposes free of charge. To illustrate this, there are two tables included in this report; one table provides the number of units sold including the units provided at no cost, and one table reflecting regular unit sales and is used to calculate the accurate market share.

Non-invasive laser treatments are still primarily used for the treatment of vaginal atrophy. The competitive analysis provides a breakdown between competitor market shares for vaginal atrophy compared to female stress urinary incontinence as well as the total competitor analysis of the market overall.

**Figure 14-2: Laser Technology Market, Europe, 2012 – 2022
(€ and US\$)**

Year	Units Sold	Growth (%)	ASP (€)	ASP (US\$)	Growth (%)	Market Value (€M)	Market Value (US\$M)	Growth (%)
2012	100		€74,732	\$82,624		€7.5	\$8.3	
2013	107	6.9%	€73,182	\$80,910	-2.1%	€7.9	\$8.7	4.7%
2014	115	7.6%	€71,678	\$79,248	-2.1%	€8.3	\$9.2	5.4%
2015	125	8.2%	€70,330	\$77,757	-1.9%	€8.8	\$9.7	6.1%
2016	136	8.9%	€71,311	\$78,842	1.4%	€9.7	\$10.7	10.4%
2017	150	10.0%	€72,085	\$79,697	1.1%	€10.8	\$11.9	11.2%
2018	165	10.2%	€72,716	\$80,395	0.9%	€12.0	\$13.3	11.2%
2019	182	10.3%	€72,807	\$80,495	0.1%	€13.2	\$14.6	10.5%
2020	200	10.0%	€72,523	\$80,181	-0.4%	€14.5	\$16.1	9.6%
2021	219	9.6%	€72,151	\$79,770	-0.5%	€15.8	\$17.5	9.0%
2022	240	9.2%	€71,570	\$79,128	-0.8%	€17.2	\$19.0	8.4%
CAGR ('15-'22)		9.8%			0.2%			10.0%

Source: iData Research Inc.

Chart 14-1: Laser Technology Market, Europe, 2012 – 2022

Source: iData Research Inc.

Figure 14-3: Units Sold by Country, Laser Technology Market, Europe, 2012-2022

Year	Germany	France	U.K.	Italy	Spain	Europe	Growth (%)
2012	23	17	18	24	18	100	
2013	24	18	19	26	20	107	6.9%
2014	26	18	21	29	22	115	7.6%
2015	28	19	23	32	24	125	8.2%
2016	30	20	25	35	26	136	8.9%
2017	33	21	28	39	29	150	10.0%
2018	36	23	31	43	32	165	10.2%
2019	40	24	35	47	35	182	10.3%
2020	45	27	38	52	38	200	10.0%
2021	50	29	42	56	42	219	9.6%
2022	55	33	45	61	46	240	9.2%
CAGR ('15-'22)	10.3%	7.8%	10.4%	9.7%	10.0%	9.8%	1.7%

Source: iData Research Inc.

Figure 14-4: Total New Units in Market (including free units, clinical trials etc.), Laser Technology Market, Europe, 2012-2022

Year	Germany	France	U.K.	Italy	Spain	Europe
2015	39	24	32	46	36	177

Source: iData Research Inc.

Figure 14-5: Average Sales Price by Country, Laser Technology Market, Europe, 2012-2022 (€)

Year	Germany	France	U.K.	Italy	Spain	Europe	Growth (%)
2012	€ 65,579	€ 78,048	€ 78,750	€ 75,705	€ 77,868	€74,732	
2013	€ 63,478	€ 77,044	€ 77,737	€ 73,998	€ 76,113	€73,182	-2.1%
2014	€ 61,445	€ 76,053	€ 76,737	€ 72,330	€ 74,397	€71,678	-2.1%
2015	€60,060	€75,075	€75,750	€70,700	€72,720	€70,330	-1.9%
2016	€60,843	€75,677	€77,497	€71,621	€73,668	€71,311	1.4%
2017	€61,635	€76,283	€78,507	€72,195	€74,627	€72,085	1.1%
2018	€62,438	€76,895	€79,530	€72,412	€75,226	€72,716	0.9%
2019	€62,939	€77,125	€79,768	€71,903	€75,451	€72,807	0.1%
2020	€63,128	€76,970	€79,607	€71,397	€74,921	€72,523	-0.4%
2021	€63,001	€76,429	€79,447	€70,895	€74,394	€72,151	-0.5%
2022	€62,558	€75,892	€79,287	€70,397	€73,125	€71,570	-0.8%
CAGR ('15-'22)	0.6%	0.2%	0.7%	-0.1%	0.1%		0.2%

Source: iData Research Inc.

Figure 14-6: Average Sales Price by Country, Laser Technology Market, Europe, 2012-2022 (US\$)

Year	Germany	France	U.K.	Italy	Spain	Europe	Growth (%)
2012	\$72,504	\$86,290	\$87,066	\$83,699	\$86,090	\$82,624	
2013	\$70,181	\$85,180	\$85,946	\$81,812	\$84,150	\$80,910	-2.1%
2014	\$67,934	\$84,084	\$84,840	\$79,968	\$82,253	\$79,248	-2.1%
2015	\$66,402	\$83,003	\$83,749	\$78,166	\$80,399	\$77,757	-1.9%
2016	\$67,268	\$83,668	\$85,680	\$79,184	\$81,447	\$78,842	1.4%
2017	\$68,144	\$84,339	\$86,797	\$79,819	\$82,508	\$79,697	1.1%
2018	\$69,032	\$85,015	\$87,928	\$80,059	\$83,169	\$80,395	0.9%
2019	\$69,585	\$85,270	\$88,192	\$79,496	\$83,419	\$80,495	0.1%
2020	\$69,794	\$85,098	\$88,014	\$78,937	\$82,832	\$80,181	-0.4%
2021	\$69,653	\$84,500	\$87,837	\$78,382	\$82,250	\$79,770	-0.5%
2022	\$69,164	\$83,906	\$87,660	\$77,831	\$80,847	\$79,128	-0.8%
CAGR ('15-'22)	0.6%	0.2%	0.7%	-0.1%	0.1%		0.2%

Source: iData Research Inc.

Figure 14-7: Laser Technology Market by Country, Europe, 2012-2022 (€M)

Year	Germany	France	U.K.	Italy	Spain	Europe	Growth (%)
2012	€1.5	€1.4	€1.4	€1.8	€1.4	€7.5	
2013	€1.5	€1.4	€1.5	€1.9	€1.5	€7.9	4.7%
2014	€1.6	€1.4	€1.6	€2.1	€1.6	€8.3	5.4%
2015	€1.7	€1.4	€1.7	€2.2	€1.7	€8.8	6.1%
2016	€1.8	€1.5	€1.9	€2.5	€1.9	€9.7	10.4%
2017	€2.0	€1.6	€2.2	€2.8	€2.2	€10.8	11.2%
2018	€2.3	€1.7	€2.5	€3.1	€2.4	€12.0	11.2%
2019	€2.5	€1.9	€2.8	€3.4	€2.6	€13.2	10.5%
2020	€2.8	€2.1	€3.0	€3.7	€2.9	€14.5	9.6%
2021	€3.1	€2.2	€3.3	€4.0	€3.1	€15.8	9.0%
2022	€3.4	€2.5	€3.6	€4.3	€3.4	€17.2	8.4%
CAGR ('15-'22)	10.9%	8.0%	11.1%	9.6%	10.1%		10.0%

Source: iData Research Inc.

Figure 14-8: Laser Technology Market by Country, Europe, 2012-2022 (US\$M)

Year	Germany	France	U.K.	Italy	Spain	Europe	Growth (%)
2012	\$1.7	\$1.5	\$1.5	\$2.0	\$1.6	\$8.3	
2013	\$1.7	\$1.5	\$1.6	\$2.2	\$1.7	\$8.7	4.7%
2014	\$1.7	\$1.6	\$1.8	\$2.3	\$1.8	\$9.2	5.4%
2015	\$1.8	\$1.6	\$1.9	\$2.5	\$1.9	\$9.7	6.1%
2016	\$2.0	\$1.7	\$2.1	\$2.8	\$2.1	\$10.7	10.4%
2017	\$2.2	\$1.8	\$2.4	\$3.1	\$2.4	\$11.9	11.2%
2018	\$2.5	\$1.9	\$2.7	\$3.5	\$2.6	\$13.3	11.2%
2019	\$2.8	\$2.1	\$3.1	\$3.8	\$2.9	\$14.6	10.5%
2020	\$3.1	\$2.3	\$3.4	\$4.1	\$3.2	\$16.1	9.6%
2021	\$3.5	\$2.5	\$3.7	\$4.4	\$3.5	\$17.5	9.0%
2022	\$3.8	\$2.7	\$4.0	\$4.7	\$3.7	\$19.0	8.4%
CAGR ('15-'22)	10.9%	8.0%	11.1%	9.6%	10.1%		10.0%

Source: iData Research Inc.

14.4 DRIVERS & LIMITERS

14.4.1 Market Drivers

Non-invasive Surgery

Laser therapy treatments can be performed in a doctor's office or in an outpatient setting. The treatment does not require anesthesia or down time ensuring women can return to normal activities quickly. Laser procedures normally require two to three treatments over an 18 week period and will require annual maintenance treatment once completed. Despite the recurrent treatments, many patients are requesting laser treatments in favor of more invasive procedures; perceived to have potentially greater safety risks and longer recovery periods. As more women become aware of laser treatment option, patient demand is expected to increase. Additionally, there is also an advantage for doctors as there can be a higher profit margin for in office procedures and higher patient volumes.

Ease of Use

While laser systems do require gynecologists to become certified, the technology is simple to learn and straightforward to use. The convenience and simplicity of the procedure will minimize resistance by doctors to adopt a new technology and receive training.

Aging Population

Vaginal atrophy and stress urinary incontinence affect the highest percentage of women in older demographics. As the European population continues to be skewed to a higher percentage of the population in older demographics, more women will be seeking treatment solutions increasing the number of potential patients.

Concern over competing treatments

In 2008 and 2011, the FDA issued public health warnings regarding mesh used in female urinary incontinence sling procedures. Despite an increase in the number of women suffering from stress urinary incontinence, there has been a sharp move towards alternative treatment options. The controversy surrounding mesh is helping to fuel the transition towards slings for less severe cases of mild to moderate female urinary incontinence slings.

14.4.2 Market Limiters

Conservative Specialty and Lower Discretionary Income

Gynecology commonly receives lower funding relative to other specialties. With lower discretionary income, gynecologists can be more reluctant to invest, or unable to invest in new technology and equipment. As laser treatments become more common for gynecologists, the sales will gradually increase.

Lack of Clinical Evidence

Currently, there are a limited number of clinical trials and studies completed to support the efficacy of laser treatments. Of the studies that have been completed, the majority are also only twelve weeks in duration. Another limitation of only having short term studies available is the uncertainty regarding long term results and long term complications. As more research is published, the skepticism and concerns regarding lasers as a new procedure will decrease. It is also worth noting that the majority of the studies to date and patient reports have all had positive results.

Additional training/ certification required

With any new procedure, additional training is required. All the competitor products included in this report stipulate that training in the procedure and with the technology is required prior to treating patients. While the barriers to training are very low and training is accessible, the factors of time and cost act as a deterrent for gynecologists who do not feel they need to offer an additional treatment option.

Reimbursement

Laser treatments are not currently reimbursed by governments in Europe. Laser treatments cost on average €1188.90 or £1000 per treatment and an average of three treatments are needed over a three to five month period. The high patient cost is a deterrent for patients. As reimbursement improves, the number of patients utilizing laser treatments is expected to improve.

Figure 14-9: Drivers and Limiters, Laser Technology and Dyspareunia Treatment Market, Europe, 2015

Market Drivers
Non-invasive Surgery Ease of Use Aging Population Concern over Competing Treatments
Market Limiters
Conservative Specialty and Lower Discretionary Income Lack of Clinical Evidence Additional Training/ Certification Required Reimbursement
Source: iData Research Inc.

14.5 COMPETITIVE ANALYSIS

Deka Medical Lasers

Deka Medical Lasers is the industry leader offering the Monalisa Touch®, a laser therapy for vaginal atrophy symptoms in menopausal and postpartum women. The Monalisa Touch uses the Smartxide² V²LR CO₂ laser configuration, combining D-Pulse and a fractional emission mode (DOT therapy). The Monalise Touch is effective treating vaginal atrophy and dryness, vaginal laxity and stress urinary incontinence. Deka offered the first non-invasive laser treatment on the market and has the largest number of clinical studies supporting the technology.

Alma Lasers

Alma Lasers offers FemiLift, a non-invasive CO₂ laser treatment for vaginal tightening and stress urinary incontinence. Utilizes fractional CO₂ laser technology, the system enables vaginal collagen remodeling, without causing aggressive ablation. The system also offers the FemiLift Slim probe for narrower anatomical structures. Alma Surgical has an excellent distributor network and a strong sales team which has helped build and maintain their strong market share.

Fotona

Fotona offers their IncontiLase technology, a patent-pending, non-invasive Er:YAG laser therapy. Fotona offers two laser systems, the Fotona Smooth SP and the Fotona Smooth XS. Separating Fotona from the competition, the Fotona Smooth SP multi-application laser system utilized Er:YAG, Nd: YAG and QCW* Nd: YAG lasers. Utilizing Fotona's proprietary Variable Square Pulse technology, the lasers prevent unnecessary energy being deposited into the tissue. The Fotona laser is effective treating mild to moderate urinary incontinence as well as vaginal tightening.

Lumenis

Lumenis offers FemTouch, a CO₂ fractional laser system to treat vaginal atrophy, vaginal laxity and stress urinary incontinence. Femtouch entered the European market in 2016, with releases as recent as entering the German market in July 2016. Femtouch has gained traction in the UK and is expected to continue a steady growth of its European market share in the future.

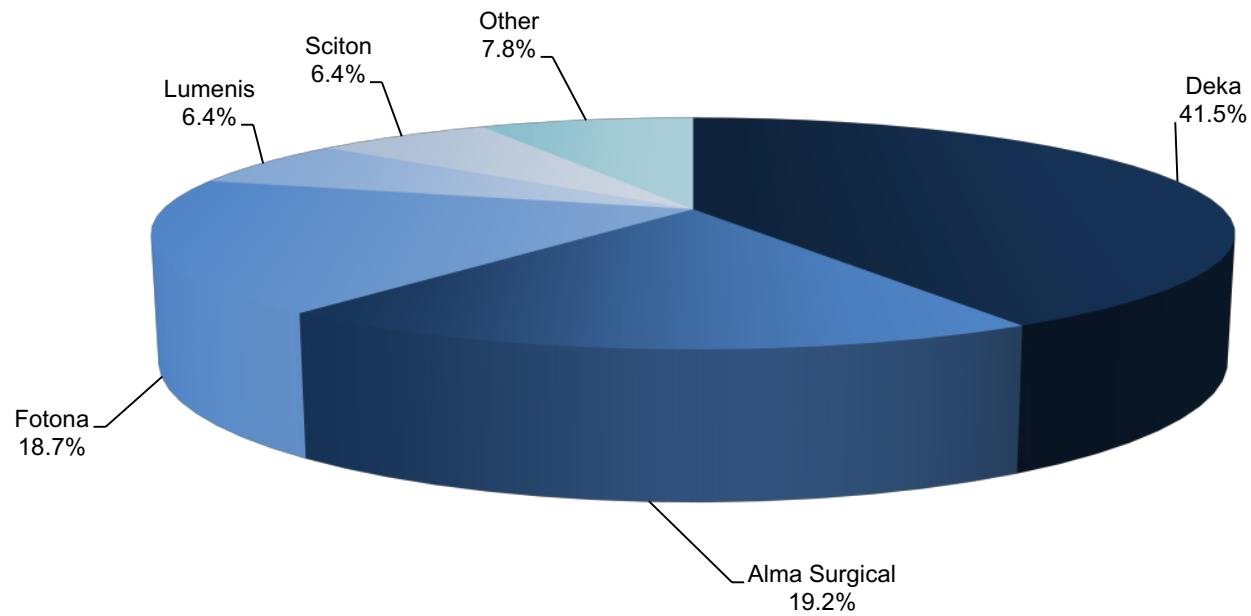
Sciton

Offering the Diva Laser Vaginal Therapy Treatment, Sciton utilizes a Hybrid Fractional Laser technology. The HFL technology provides independent levels of ablation, coagulation and different density levels.

Sciton holds a small but consistent European market share and are projected to remain stable throughout the reporting period.

Figure 14-10: Leading Competitors by Country, Laser Technology Market, Europe, 2015

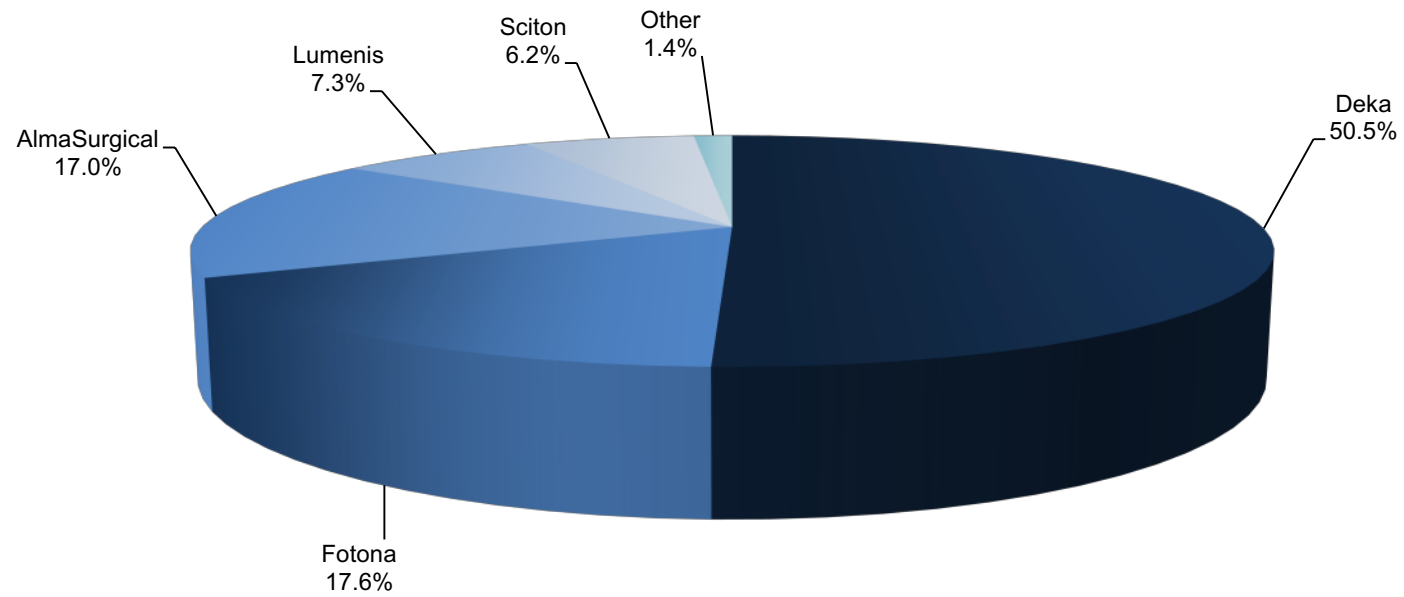
Company	Germany	France	U.K.	Italy	Spain	Total Market Share
Deka	42.2%	41.0%	37.6%	45.2%	40.3%	41.5%
AlmaSurgical	20.3%	20.4%	23.8%	15.7%	16.9%	19.2%
Fotona	14.9%	16.8%	15.5%	25.1%	18.6%	18.7%
Lumenis	3.6%	5.7%	11.4%	6.1%	5.2%	6.4%
Sciton	7.4%	6.2%	6.6%	5.0%	7.4%	6.4%
Other	11.6%	9.9%	5.1%	2.9%	11.6%	7.8%
Total	100.0%	100.0%	100.0%	100.0%	100.0%	100%
Market Value (€M)	€1.7	€1.4	€1.7	€2.2	€1.7	€8.8
Others: Intermedic etc.						
Source: iData Research Inc.						

Chart 14-2: Leading Competitors, Laser Technology Market, Europe, 2015

Source: iData Research Inc.

Figure 14-11: Leading Competitors by Procedure Type, Vaginal Atrophy Treatment Market, Europe, 2015

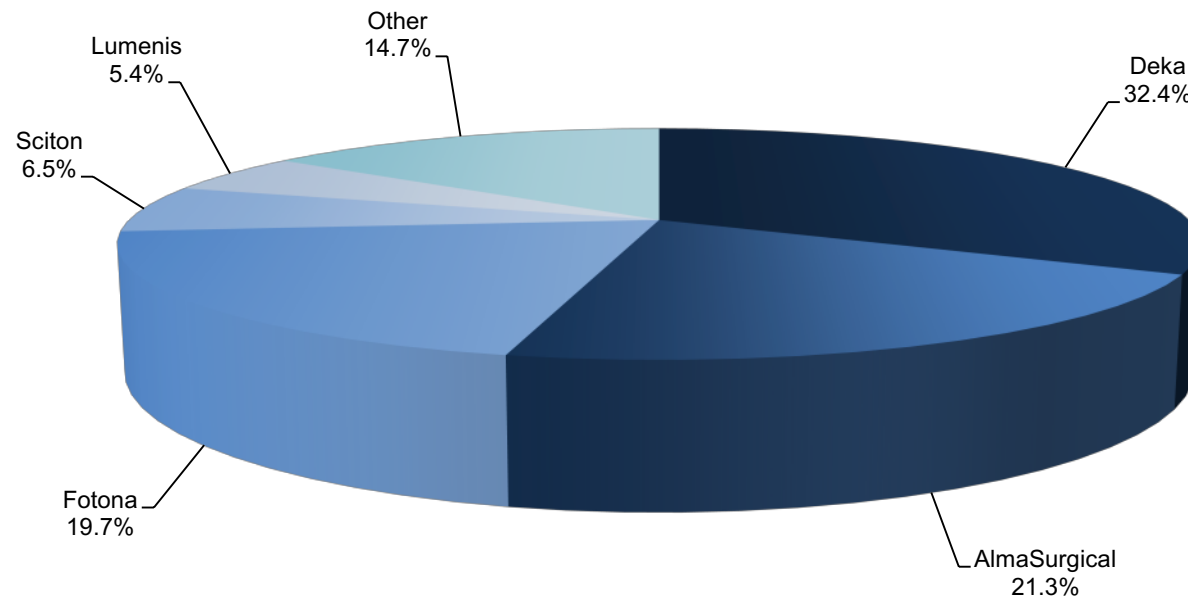
Company	Total Market Share
Deka	50.5%
Fotona	17.6%
AlmaSurgical	17.0%
Lumenis	7.3%
Sciton	6.2%
Other	1.4%
Total	100.0%
Source: iData Research Inc.	

Chart 14-3: Leading Competitors by Procedure Type, Vaginal Atrophy Treatment Market, Europe, 2015

Source: iData Research Inc.

Figure 14-12: Leading Competitors by Procedure Type, Stress Urinary Incontinence Treatment Market, Europe, 2015

Company	Total Market Share
Deka	32.4%
AlmaSurgical	21.3%
Fotona	19.7%
Sciton	6.5%
Lumenis	5.4%
Other	14.7%
Total	100.0%
Source: iData Research Inc.	

Chart 14-4: Leading Competitors by Procedure Type, Stress Urinary Incontinence Treatment Market, Europe, 2015

Source: iData Research Inc.

15

FLUID MANAGEMENT EQUIPMENT MARKET

15.1 INTRODUCTION

Fluid management involves the monitoring and measurement of intrauterine pressure and fluid deficit of a patient undergoing a hysteroscopic procedure. In a hysteroscopic procedure, fluid passes through tubes into the uterine vessels, around the cervix, and out via outflow tubes, which results in a pressure gradient. Fluid management equipment gives the physician control of the situation by manipulating the valve to obtain satisfactory distention and visualization. Fluid management systems can greatly lessen the chance of distention due to fluid overload during operative hysteroscopy, as long as the physician pays attention to the information available to them. Both the risks associated with fluid overload and amount of fluid that is able to be in deficit is dependent on the type of distention media used.

Fluid management systems are computer-driven and safe. They keep uterine distention balanced, give clear vision and reduce the risk of bleeding entry into the blood vessels. They balance purity, pressure control and measurements of fluid deficit, providing all the information the physician needs to monitor the safety of the patient. Excessive fluid absorption or deficit can be extremely dangerous to the patient, so it is recommended that fluid management systems be used in more complex hysteroscopic procedures where that can occur. These devices assist doctors and nurses in determining uterine distention, fluid deficit and absorption.

These systems are used alongside many surgical procedures. These procedures mainly include hysteroscopic procedures, both diagnostic and operative, but may also include tubal ligations, hysterectomies, myomectomies as well as laparoscopic procedures that involve the removal of polyps, fibroids and cysts.

15.2 MARKET OVERVIEW

The fluid management equipment market is segmented into capital equipment and tubing. As more physicians realize the importance of fluid management pumps for patient safety, this market is projected to continue growing. Pressure-sensitive pumps reduce the flow rate when the preset level is reached, opposed to gravity bags or simple pump devices that continue to press fluid into the uterine cavity regardless of resistance. While the benefit of using pressure-sensitive pumps is less vital for diagnostic hysteroscopy and simple procedures, maintenance of a standard intrauterine pressure is essential for prolonged operative interventions. Fluid management equipment is the focus of this report; however, the breakdown between fluid management equipment and the more inexpensive alternative of gravity bags is also included. The breakdown demonstrates the differences across Europe as well as the market potential for growth towards capital equipment.

The fastest growing markets are the Scandinavian and Benelux regions. The momentum from hospitals converting from gravity bags to pumps is affecting unit sales in the near future. Towards the end of the reporting period, it is expected the growth will continue as clinics start to transition to pumps as well. The most mature markets are Italy and Austria. Italy has the strongest market for doctors trained in hysteroscopy; this has led to an investment in fluid management equipment earlier than other countries in Europe.

The United Kingdom is by far the slowest to transition from gravity bags to pumps. The consensus in the U.K. is that gravity bags with a pressure cuff work well enough and many hospitals and clinics feel their resources are better allocated towards other priorities. Ireland and Scotland have a negligible market for fluid management equipment, with the majority of sales occurring in Great Britain. The priority of patient safety regarding fluid management is still not well emphasized in the United Kingdom. As fluid management increasingly becomes the standard of care, both in Europe and internationally, the trend from gravity bags to pumps in the U.K. will gradually occur.

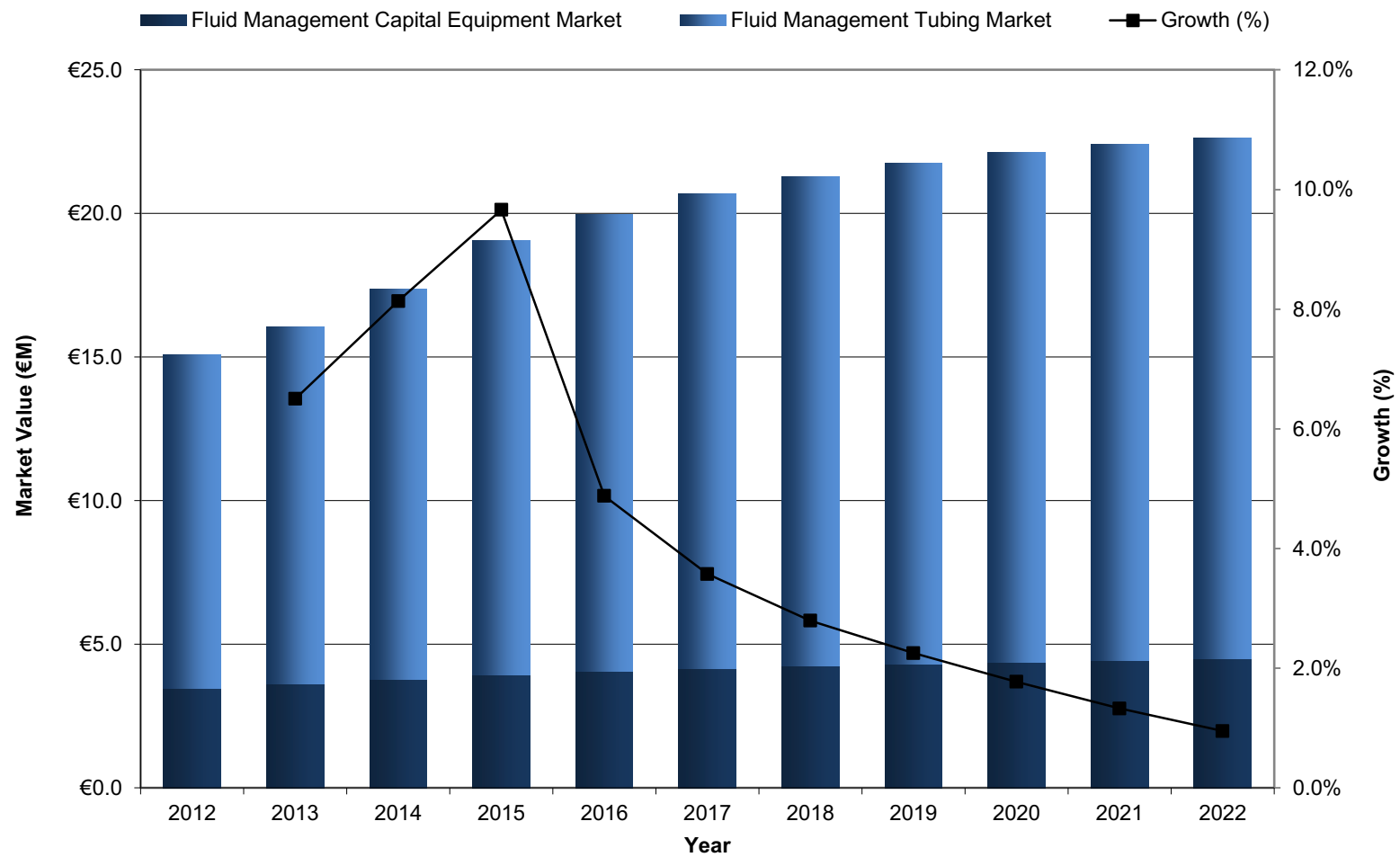
The European market value is increasing over the reporting period. However, it is worth noting that the growth rate is positive but shrinking. The market overall is projecting stable ASP's across Europe. Germany, Italy and Switzerland are all projected to decline by 2022.

Figure 15-1: Fluid Management Equipment Market by Segment, Europe, 2012 – 2022 (€M)

Year	Fluid Management Capital Equipment Market	Fluid Management Tubing Market	Total Market	Growth (%)
2012	€3.5	€11.6	€15.1	
2013	€3.6	€12.5	€16.1	6.5%
2014	€3.8	€13.6	€17.4	8.1%
2015	€3.9	€15.1	€19.0	9.7%
2016	€4.1	€15.9	€20.0	4.9%
2017	€4.2	€16.5	€20.7	3.6%
2018	€4.2	€17.0	€21.3	2.8%
2019	€4.3	€17.4	€21.7	2.3%
2020	€4.4	€17.7	€22.1	1.8%
2021	€4.4	€18.0	€22.4	1.3%
2022	€4.5	€18.2	€22.6	0.9%
CAGR (‘15–’22)	1.9%	2.6%		2.5%
Source: iData Research Inc.				

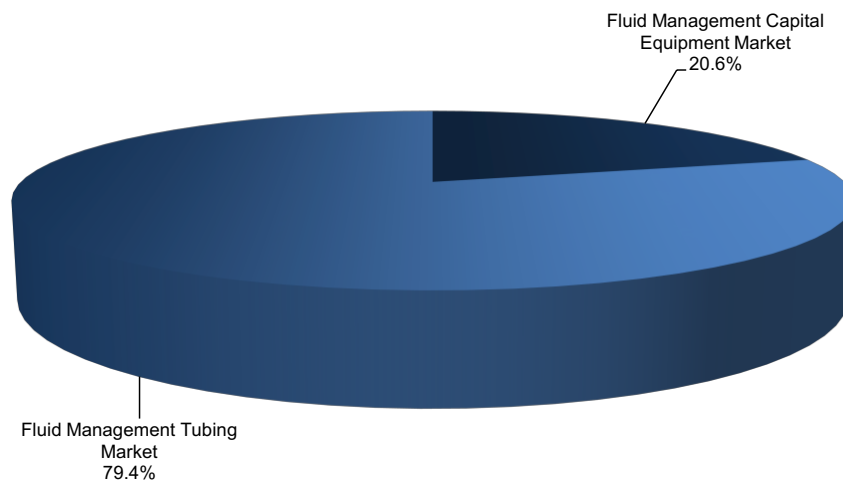
Figure 15-2: Fluid Management Equipment Market by Segment, Europe, 2012 – 2022 (US\$M)

Year	Fluid Management Capital Equipment Market	Fluid Management Tubing Market	Total Market	Growth (%)
2012	\$3.8	\$12.9	\$16.7	
2013	\$4.0	\$13.8	\$17.8	6.5%
2014	\$4.2	\$15.0	\$19.2	8.1%
2015	\$4.3	\$16.7	\$21.1	9.7%
2016	\$4.5	\$17.6	\$22.1	4.9%
2017	\$4.6	\$18.3	\$22.9	3.6%
2018	\$4.7	\$18.8	\$23.5	2.8%
2019	\$4.8	\$19.3	\$24.0	2.3%
2020	\$4.8	\$19.6	\$24.5	1.8%
2021	\$4.9	\$19.9	\$24.8	1.3%
2022	\$5.0	\$20.1	\$25.0	0.9%
CAGR (‘15–’22)	1.9%	2.6%		2.5%
Source: iData Research Inc.				

Chart 15-1: Fluid Management Equipment Market by Segment, Europe, 2015

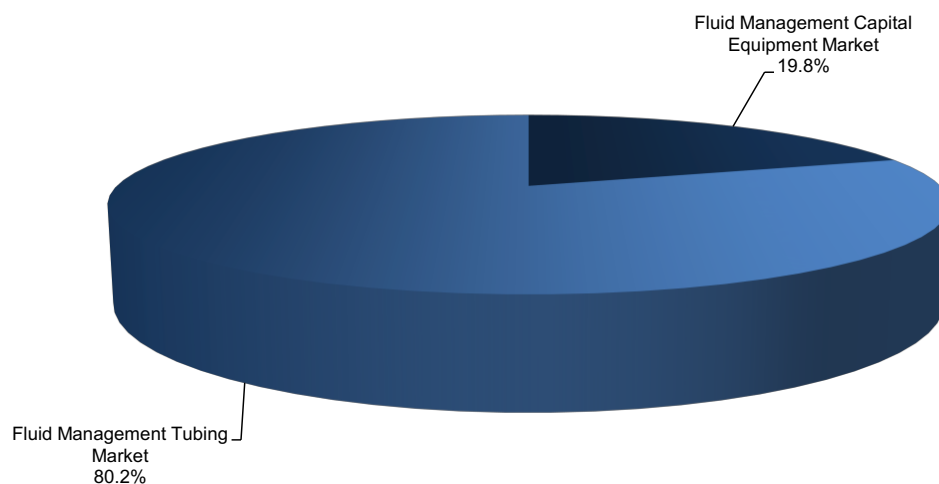
Source: iData Research Inc.

Chart 15-2: Fluid Management Equipment Market Breakdown, Europe, 2015



Source: iData Research Inc.

Chart 15-3: Fluid Management Equipment Market Breakdown, Europe, 2022



Source: iData Research Inc.

15.3 MARKET ANALYSIS AND FORECAST

15.3.1 Fluid Management Capital Equipment Market

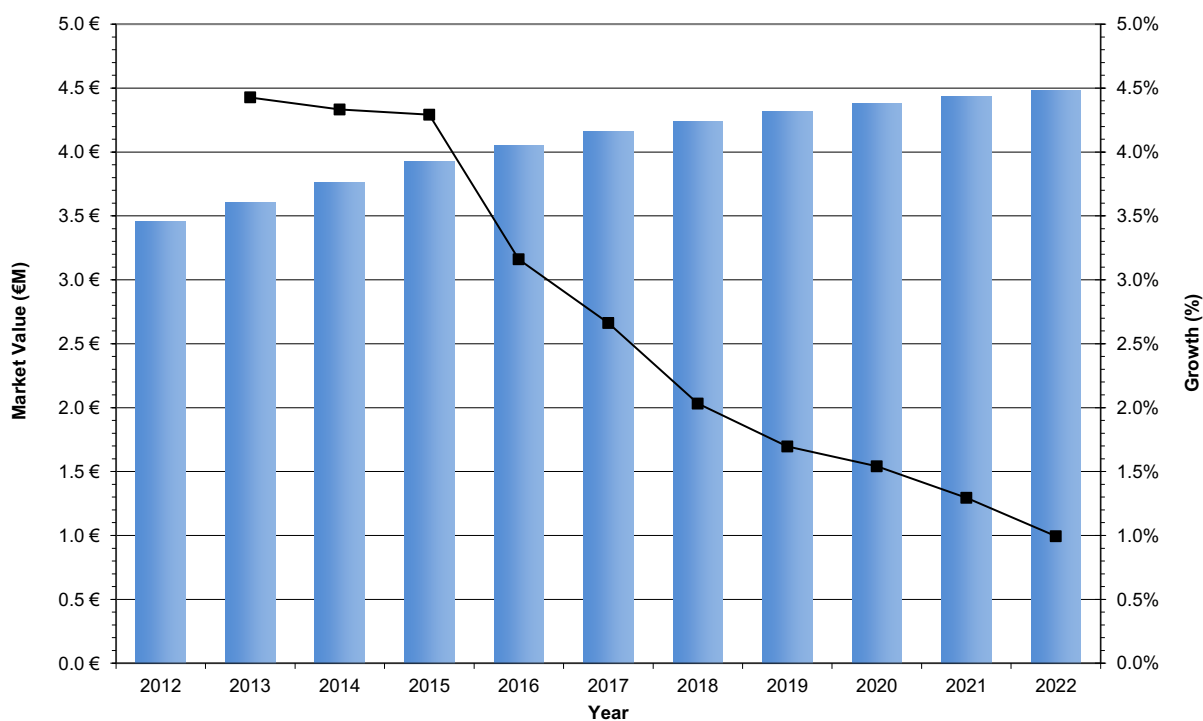
Hospitals are leading the trend towards fluid management capital equipment throughout Europe. Hospitals are upgrading from gravity bags to pumps as well as there is a small replacement market as hospitals upgrade to pumps with superior technology. Overall, clinics will continue to comprise a small, stable share of the market. Many clinics and physicians are still cost-conscious as the economy is continuing to recover from the 2008 recession. This has led to hesitation about investing in new products that are non-essential. The growth in fluid management capital equipment will continue to increase, however, the growth in unit sales is expected to mirror the health of the economy overall.

The ASP of capital equipment is expected to remain stable with a slight increase year over year. The growth in price is dropping; however, the average growth will still remain positive across Europe. The price is increasing to reflect the technology advancements are increased value of the pumps. The stability in the market is being generated by the modest demand and consistent competition.

Figure 15-3: Fluid Management Capital Equipment Market, Europe, 2012 – 2022 (€ and US\$)

Year	Units Sold	Growth (%)	ASP (€)	ASP (US\$)	Growth (%)	Market Value (€M)	Market Value (US\$M)	Growth (%)
2012	401		€8,620	\$9,530		€3.5	\$3.8	
2013	407	1.6%	€8,860	\$9,796	2.8%	€3.6	\$4.0	4.4%
2014	414	1.7%	€9,094	\$10,054	2.6%	€3.8	\$4.2	4.3%
2015	421	1.8%	€9,318	\$10,302	2.5%	€3.9	\$4.3	4.3%
2016	429	1.9%	€9,435	\$10,431	1.3%	€4.1	\$4.5	3.2%
2017	438	1.9%	€9,503	\$10,507	0.7%	€4.2	\$4.6	2.7%
2018	445	1.8%	€9,526	\$10,532	0.2%	€4.2	\$4.7	2.0%
2019	453	1.7%	€9,526	\$10,532	0.0%	€4.3	\$4.8	1.7%
2020	460	1.6%	€9,520	\$10,526	-0.1%	€4.4	\$4.8	1.5%
2021	467	1.4%	€9,507	\$10,511	-0.1%	€4.4	\$4.9	1.3%
2022	472	1.2%	€9,488	\$10,490	-0.2%	€4.5	\$5.0	1.0%
CAGR ('15-'22)		1.6%			0.3%			1.9%

Source: iData Research Inc.

Chart 15-4: Fluid Management Capital Equipment Market, Europe, 2012 – 2022

Source: iData Research Inc.

Figure 15-4: Units Sold by Country, Fluid Management Capital Equipment Market, Europe, 2012-2022

Year	Germany	France	U.K.	Italy	Spain	Benelux	Scandi- navia	Austria	Switzer- land	Portugal	Europe	Growth (%)
2012	67	59	29	57	52	21	34	33	27	20	401	
2013	68	60	29	59	52	22	36	34	28	21	407	1.6%
2014	68	60	30	60	52	23	38	34	28	21	414	1.7%
2015	69	60	30	61	52	24	41	35	28	21	421	1.8%
2016	70	60	30	62	53	25	44	36	28	21	429	1.9%
2017	71	61	31	63	53	27	47	36	29	22	438	1.9%
2018	72	61	31	63	53	28	50	36	29	22	445	1.8%
2019	73	61	31	63	54	29	53	36	30	22	453	1.7%
2020	75	62	32	63	54	30	55	36	30	23	460	1.6%
2021	76	62	32	63	55	31	56	36	31	23	467	1.4%
2022	78	62	32	63	56	32	58	36	32	23	472	1.2%
CAGR (‘15-’22)	1.7%	0.6%	1.1%	0.5%	0.9%	4.3%	5.0%	0.5%	1.7%	1.6%		1.6%

Source: iData Research Inc.

Figure 15-5: Fluid Management Equipment, Type of Equipment in Percent (%), Europe, 2015

Fluid Management Equipment	Germany	France	U.K.	Italy	Spain	Benelux	Scandi-navia	Austria	Switzer-land	Portugal
Gravity Bags	60%	57%	75%	47%	70%	66%	62%	30%	65%	65%
Pumps	40%	43%	25%	53%	30%	34%	38%	70%	35%	35%
Source: iData Research Inc.										

Figure 15-6: Fluid Management Equipment, Type of Equipment in Percent (%), Europe, 2022

Fluid Management Equipment	Germany	France	U.K.	Italy	Spain	Benelux	Scandi-navia	Austria	Switzer-land	Portugal
Gravity Bags	52%	46%	62%	36%	60%	50%	48%	25%	52%	57%
Pumps	48%	54%	38%	64%	40%	50%	52%	75%	48%	43%
Source: iData Research Inc.										

Figure 15-7: Fluid Management Equipment, Price Comparison in Euro (€), Europe, 2015

Fluid Management Equipment	Germany	France	U.K.	Italy	Spain	Benelux	Scandi-navia	Austria	Switzer-land	Portugal
Gravity Bags	€21	€14	€7	€15	€12	€150	€95	€22	€14	€13
Pumps	€5,300	€6,000	€5,500	€6,500	€5,000	€4,800	€6,500	€6,100	€5,999	€5,948
Source: iData Research Inc.										

Figure 15-8: Average Sales Price by Country, Fluid Management Capital Equipment Market, Europe, 2012-2022 (€)

Year	Germany	France	U.K.	Italy	Spain	Benelux	Scandi- navia	Austria	Switzer- land	Portugal	Europe	Growth (%)
2012	€8,466	€7,840	€12,590	€10,485	€7,387	€7,295	€8,654	€7,932	€7,845	€7,053	€8,620	
2013	€8,805	€7,997	€13,219	€10,695	€7,412	€7,427	€8,914	€8,265	€8,080	€7,158	€8,860	2.8%
2014	€9,245	€8,263	€13,616	€10,856	€7,442	€7,545	€9,003	€8,563	€8,363	€7,302	€9,094	2.6%
2015	€9,800	€8,552	€13,888	€11,000	€7,475	€7,644	€9,048	€8,802	€8,530	€7,448	€9,318	2.5%
2016	€10,192	€8,706	€14,013	€11,033	€7,512	€7,682	€9,078	€8,861	€8,573	€7,522	€9,435	1.3%
2017	€10,396	€8,793	€14,125	€11,055	€7,554	€7,713	€9,108	€8,890	€8,607	€7,597	€9,503	0.7%
2018	€10,396	€8,855	€14,196	€11,066	€7,599	€7,736	€9,131	€8,890	€8,633	€7,658	€9,526	0.2%
2019	€10,292	€8,899	€14,243	€11,066	€7,647	€7,751	€9,149	€8,890	€8,650	€7,716	€9,526	0.0%
2020	€10,189	€8,929	€14,286	€11,055	€7,698	€7,759	€9,163	€8,881	€8,659	€7,770	€9,520	-0.1%
2021	€10,057	€8,947	€14,321	€11,044	€7,748	€7,759	€9,172	€8,881	€8,659	€7,816	€9,507	-0.1%
2022	€9,926	€8,955	€14,350	€11,027	€7,795	€7,751	€9,172	€8,881	€8,650	€7,855	€9,488	-0.2%
CAGR (‘15-’22)	0.2%	0.7%	0.5%	0.0%	0.6%	0.2%	0.2%	0.1%	0.2%	0.8%		0.3%

Source: iData Research Inc.

Figure 15-9: Average Sales Price by Country, Fluid Management Capital Equipment Market, Europe, 2012-2022 (US\$)

Year	Germany	France	U.K.	Italy	Spain	Benelux	Scandi- navia	Austria	Switzer- land	Portugal	Europe	Growth (%)
2012	\$9,360	\$8,668	\$13,919	\$11,593	\$8,168	\$8,066	\$9,568	\$8,770	\$8,673	\$7,797	\$9,530	
2013	\$9,735	\$8,841	\$14,615	\$11,825	\$8,195	\$8,211	\$9,855	\$9,138	\$8,934	\$7,914	\$9,796	2.8%
2014	\$10,222	\$9,136	\$15,054	\$12,002	\$8,227	\$8,342	\$9,954	\$9,467	\$9,246	\$8,073	\$10,054	2.6%
2015	\$10,835	\$9,456	\$15,355	\$12,162	\$8,264	\$8,451	\$10,004	\$9,732	\$9,431	\$8,234	\$10,302	2.5%
2016	\$11,268	\$9,626	\$15,493	\$12,198	\$8,306	\$8,493	\$10,037	\$9,796	\$9,478	\$8,316	\$10,431	1.3%
2017	\$11,494	\$9,722	\$15,617	\$12,222	\$8,351	\$8,527	\$10,070	\$9,829	\$9,516	\$8,400	\$10,507	0.7%
2018	\$11,494	\$9,790	\$15,695	\$12,235	\$8,401	\$8,553	\$10,095	\$9,829	\$9,545	\$8,467	\$10,532	0.2%
2019	\$11,379	\$9,839	\$15,747	\$12,235	\$8,455	\$8,570	\$10,115	\$9,829	\$9,564	\$8,530	\$10,532	0.0%
2020	\$11,265	\$9,872	\$15,794	\$12,222	\$8,511	\$8,578	\$10,130	\$9,819	\$9,573	\$8,590	\$10,526	-0.1%
2021	\$11,118	\$9,891	\$15,834	\$12,210	\$8,566	\$8,578	\$10,140	\$9,819	\$9,573	\$8,642	\$10,511	-0.1%
2022	\$10,974	\$9,901	\$15,865	\$12,192	\$8,618	\$8,570	\$10,140	\$9,819	\$9,564	\$8,685	\$10,490	-0.2%
CAGR (‘15-’22)	0.2%	0.7%	0.5%	0.0%	0.6%	0.2%	0.2%	0.1%	0.2%	0.8%		0.3%

Source: iData Research Inc.

Figure 15-10: Fluid Management Capital Equipment Market by Country, Europe, 2012-2022 (€M)

Year	Germany	France	U.K.	Italy	Spain	Benelux	Scandi- navia	Austria	Switzer- land	Portugal	Europe	Growth (%)
2012	€0.57	€0.47	€0.37	€0.60	€0.38	€0.16	€0.29	€0.26	€0.21	€0.14	€3.46	
2013	€0.60	€0.48	€0.39	€0.63	€0.38	€0.16	€0.32	€0.28	€0.22	€0.15	€3.61	4.4%
2014	€0.63	€0.49	€0.40	€0.65	€0.39	€0.17	€0.34	€0.29	€0.23	€0.15	€3.76	4.3%
2015	€0.68	€0.51	€0.42	€0.67	€0.39	€0.18	€0.37	€0.31	€0.24	€0.16	€3.93	4.3%
2016	€0.71	€0.52	€0.42	€0.68	€0.40	€0.19	€0.40	€0.31	€0.24	€0.16	€4.05	3.2%
2017	€0.74	€0.53	€0.43	€0.69	€0.40	€0.20	€0.43	€0.32	€0.25	€0.16	€4.16	2.7%
2018	€0.75	€0.54	€0.44	€0.70	€0.41	€0.22	€0.46	€0.32	€0.25	€0.17	€4.24	2.0%
2019	€0.75	€0.54	€0.44	€0.70	€0.41	€0.23	€0.48	€0.32	€0.26	€0.17	€4.31	1.7%
2020	€0.76	€0.55	€0.45	€0.70	€0.42	€0.24	€0.50	€0.32	€0.26	€0.18	€4.38	1.5%
2021	€0.77	€0.55	€0.46	€0.70	€0.43	€0.24	€0.52	€0.32	€0.27	€0.18	€4.44	1.3%
2022	€0.77	€0.56	€0.46	€0.70	€0.43	€0.25	€0.53	€0.32	€0.27	€0.18	€4.48	1.0%
CAGR (‘15-’22)	1.9%	1.2%	1.5%	0.5%	1.5%	4.5%	5.2%	0.6%	1.9%	2.4%		1.9%

Source: iData Research Inc.

Figure 15-11: Fluid Management Capital Equipment Market by Country, Europe, 2012-2022 (US\$M)

Year	Germany	France	U.K.	Italy	Spain	Benelux	Scandi- navia	Austria	Switzer- land	Portugal	Europe	Growth (%)
2012	\$0.63	\$0.51	\$0.41	\$0.66	\$0.42	\$0.17	\$0.32	\$0.29	\$0.24	\$0.16	\$3.82	
2013	\$0.66	\$0.53	\$0.43	\$0.69	\$0.43	\$0.18	\$0.35	\$0.31	\$0.25	\$0.16	\$3.99	4.4%
2014	\$0.70	\$0.55	\$0.45	\$0.72	\$0.43	\$0.19	\$0.38	\$0.33	\$0.26	\$0.17	\$4.16	4.3%
2015	\$0.75	\$0.57	\$0.46	\$0.74	\$0.43	\$0.20	\$0.41	\$0.34	\$0.26	\$0.17	\$4.34	4.3%
2016	\$0.79	\$0.58	\$0.47	\$0.76	\$0.44	\$0.21	\$0.44	\$0.35	\$0.27	\$0.18	\$4.48	3.2%
2017	\$0.81	\$0.59	\$0.48	\$0.76	\$0.44	\$0.23	\$0.48	\$0.35	\$0.27	\$0.18	\$4.60	2.7%
2018	\$0.83	\$0.60	\$0.48	\$0.77	\$0.45	\$0.24	\$0.51	\$0.36	\$0.28	\$0.19	\$4.69	2.0%
2019	\$0.83	\$0.60	\$0.49	\$0.77	\$0.46	\$0.25	\$0.53	\$0.36	\$0.28	\$0.19	\$4.77	1.7%
2020	\$0.84	\$0.61	\$0.50	\$0.78	\$0.46	\$0.26	\$0.55	\$0.36	\$0.29	\$0.19	\$4.84	1.5%
2021	\$0.85	\$0.61	\$0.51	\$0.78	\$0.47	\$0.27	\$0.57	\$0.36	\$0.30	\$0.20	\$4.91	1.3%
2022	\$0.85	\$0.62	\$0.51	\$0.77	\$0.48	\$0.28	\$0.58	\$0.36	\$0.30	\$0.20	\$4.95	1.0%
CAGR (‘15-’22)	1.9%	1.2%	1.5%	0.5%	1.5%	4.5%	5.2%	0.6%	1.9%	2.4%		1.9%

Source: iData Research Inc.

15.3.2 Fluid Management Tubing Market

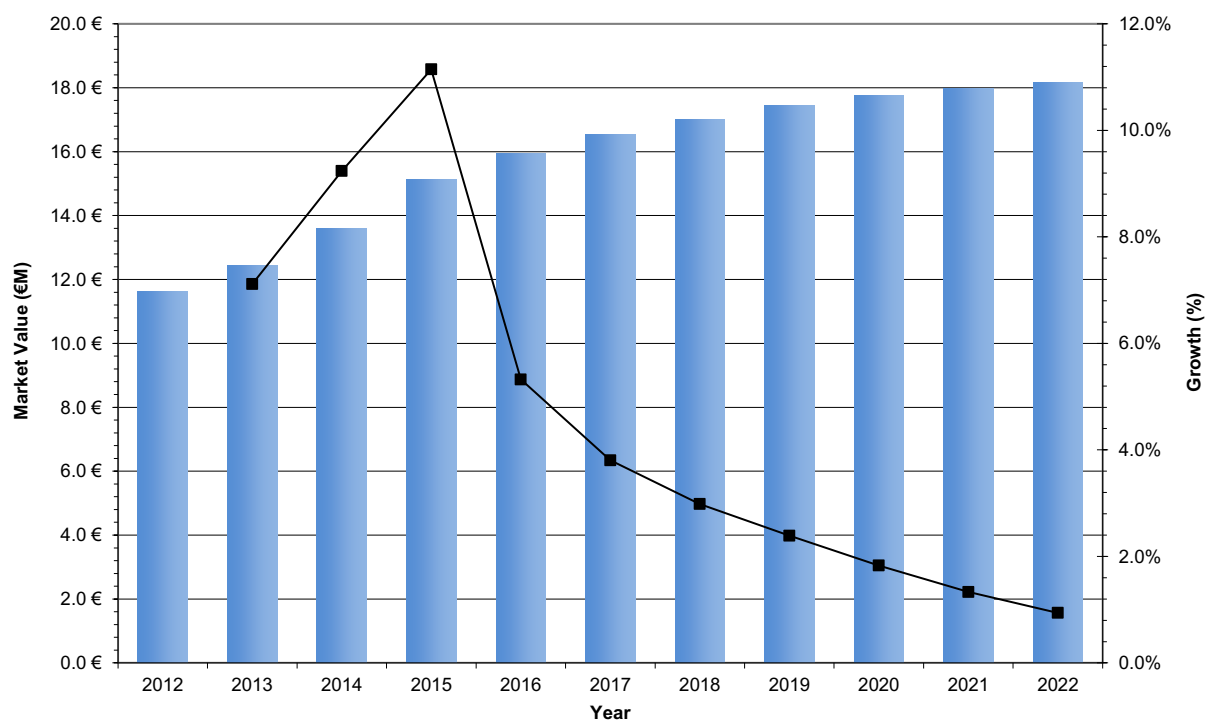
Fluid management tubing comprises the largest part of the market value increase for fluid management equipment. This market is largely affected by unit sales, as the ASP is expected to remain stable, to slightly increase over the forecast period. As a disposable product, the unit sales for this market are largely reliant on procedure numbers. The tubing sets in fluid management equipment comprise the disposable segment of the market, with at least a 1:1 ratio between procedures and tubing. Often the ratio of procedures to tubing is higher as units include both in-flow and out-flow tubes.

The trend among physicians to perform less invasive procedures will drive this market; procedures utilizing hysteroscopy are anticipated to increase which will require increased units of tubing and the use of fluid management systems. Additionally, as the population ages, the use of fluid management systems will increase as procedures common in age demographics over the age of 50 will continue to increase.

Figure 15-12: Fluid Management Tubing Market, Europe, 2012 – 2022 (€ and US\$)

Year	Units Sold	Growth (%)	ASP (€)	ASP (US\$)	Growth (%)	Market Value (€M)	Market Value (US\$M)	Growth (%)
2012	318,794		€36	\$40		€11.6	\$12.9	
2013	320,197	0.4%	€39	\$43	6.6%	€12.5	\$13.8	7.1%
2014	321,600	0.4%	€42	\$47	8.8%	€13.6	\$15.0	9.2%
2015	323,008	0.4%	€47	\$52	10.7%	€15.1	\$16.7	11.1%
2016	324,430	0.4%	€49	\$54	4.9%	€15.9	\$17.6	5.3%
2017	325,860	0.4%	€51	\$56	3.3%	€16.5	\$18.3	3.8%
2018	327,307	0.4%	€52	\$58	2.5%	€17.0	\$18.8	3.0%
2019	328,774	0.4%	€53	\$59	1.9%	€17.4	\$19.3	2.4%
2020	330,277	0.5%	€54	\$59	1.4%	€17.7	\$19.6	1.8%
2021	331,820	0.5%	€54	\$60	0.9%	€18.0	\$19.9	1.3%
2022	333,389	0.5%	€54	\$60	0.5%	€18.2	\$20.1	0.9%
CAGR ('15-'22)		0.5%			2.2%			2.6%

Source: iData Research Inc.

Chart 15-5: Fluid Management Tubing Market, Europe, 2012 – 2022

Source: iData Research Inc.

Figure 15-13: Units Sold by Country, Fluid Management Tubing Market, Europe, 2012-2022

Year	Germany	France	U.K.	Italy	Spain	Benelux	Scandi- navia	Austria	Switzer- land	Portugal	Europe	Growth (%)
2012	68,398	55,242	45,363	52,072	32,898	22,164	19,028	8,015	7,534	8,080	318,794	
2013	68,658	55,364	45,567	52,384	32,997	22,270	19,157	8,059	7,615	8,126	320,197	0.4%
2014	68,925	55,475	45,781	52,672	33,102	22,380	19,291	8,101	7,699	8,173	321,600	0.4%
2015	69,201	55,580	46,010	52,936	33,212	22,491	19,428	8,142	7,786	8,222	323,008	0.4%
2016	69,478	55,680	46,263	53,174	33,328	22,608	19,570	8,181	7,875	8,272	324,430	0.4%
2017	69,763	55,769	46,541	53,387	33,448	22,729	19,715	8,218	7,967	8,324	325,860	0.4%
2018	70,052	55,853	46,843	53,584	33,568	22,852	19,863	8,254	8,061	8,376	327,307	0.4%
2019	70,347	55,925	47,171	53,772	33,692	22,977	20,012	8,289	8,158	8,431	328,774	0.4%
2020	70,649	55,992	47,525	53,955	33,821	23,106	20,164	8,323	8,257	8,486	330,277	0.5%
2021	70,960	56,054	47,905	54,135	33,949	23,240	20,319	8,356	8,358	8,543	331,820	0.5%
2022	71,279	56,116	48,288	54,317	34,081	23,377	20,477	8,389	8,463	8,601	333,389	0.5%
CAGR (‘15-’22)	0.4%	0.1%	0.7%	0.4%	0.4%	0.6%	0.8%	0.4%	1.2%	0.6%		0.5%

Source: iData Research Inc.

Figure 15-14: Average Sales Price by Country, Fluid Management Tubing Market, Europe, 2012-2022 (€)

Year	Germany	France	U.K.	Italy	Spain	Benelux	Scandi- navia	Austria	Switzer- land	Portugal	Europe	Growth (%)
2012	€35.53	€30.72	€40.03	€36.17	€35.56	€49.86	€25.44	€48.53	€42.59	€40.89	€35.53	
2013	€38.02	€33.48	€43.03	€39.07	€36.63	€54.35	€25.82	€48.53	€44.29	€41.84	€38.02	6.6%
2014	€41.44	€37.17	€47.33	€43.36	€38.10	€60.87	€26.34	€48.29	€46.95	€42.88	€41.44	8.8%
2015	€46.00	€42.00	€53.01	€49.00	€40.00	€70.00	€27.00	€48.00	€50.00	€44.00	€46.00	10.7%
2016	€48.30	€44.10	€55.66	€51.94	€42.00	€73.50	€27.68	€47.69	€52.00	€45.19	€48.30	4.9%
2017	€50.47	€45.42	€57.33	€54.02	€43.26	€75.34	€28.51	€47.35	€53.56	€46.50	€50.47	3.3%
2018	€52.49	€46.33	€58.76	€55.10	€44.56	€76.24	€29.45	€47.16	€54.63	€47.89	€52.49	2.5%
2019	€54.33	€47.03	€59.47	€55.65	€45.89	€76.85	€30.49	€47.01	€55.45	€49.47	€54.33	1.9%
2020	€55.96	€47.50	€59.77	€55.65	€46.81	€77.24	€31.61	€46.87	€56.19	€51.21	€55.96	1.4%
2021	€57.08	€47.50	€59.95	€55.65	€47.28	€77.47	€32.85	€46.77	€56.47	€53.10	€57.08	0.9%
2022	€57.36	€47.50	€59.95	€55.65	€47.75	€77.47	€34.23	€46.73	€56.47	€55.17	€57.36	0.5%
CAGR (‘15–’22)	3.2%	1.8%	1.8%	1.8%	2.6%	1.5%	3.4%	-0.4%	1.8%	3.3%		2.2%
Source: iData Research Inc.												

Figure 15-15: Average Sales Price by Country, Fluid Management Tubing Market, Europe, 2012-2022 (US\$)

Year	Germany	France	U.K.	Italy	Spain	Benelux	Scandi- navia	Austria	Switzer- land	Portugal	Europe	Growth (%)
2012	\$39.28	\$33.96	\$44.25	\$39.99	\$39.32	\$55.13	\$28.13	\$53.66	\$47.08	\$45.20	\$40.32	
2013	\$42.03	\$37.02	\$47.57	\$43.19	\$40.50	\$60.09	\$28.55	\$53.66	\$48.97	\$46.26	\$43.00	6.6%
2014	\$45.82	\$41.09	\$52.33	\$47.94	\$42.12	\$67.30	\$29.12	\$53.39	\$51.91	\$47.41	\$46.77	8.8%
2015	\$50.86	\$46.44	\$58.61	\$54.17	\$44.22	\$77.39	\$29.85	\$53.07	\$55.28	\$48.65	\$51.75	10.7%
2016	\$53.40	\$48.76	\$61.54	\$57.42	\$46.44	\$81.26	\$30.60	\$52.72	\$57.49	\$49.96	\$54.27	4.9%
2017	\$55.80	\$50.22	\$63.38	\$59.72	\$47.83	\$83.29	\$31.52	\$52.35	\$59.22	\$51.41	\$56.09	3.3%
2018	\$58.04	\$51.22	\$64.97	\$60.92	\$49.26	\$84.29	\$32.56	\$52.15	\$60.40	\$52.95	\$57.50	2.5%
2019	\$60.07	\$51.99	\$65.75	\$61.53	\$50.74	\$84.97	\$33.70	\$51.97	\$61.31	\$54.70	\$58.62	1.9%
2020	\$61.87	\$52.51	\$66.08	\$61.53	\$51.76	\$85.39	\$34.95	\$51.82	\$62.12	\$56.61	\$59.42	1.4%
2021	\$63.11	\$52.51	\$66.28	\$61.53	\$52.27	\$85.65	\$36.31	\$51.71	\$62.43	\$58.71	\$59.93	0.9%
2022	\$63.42	\$52.51	\$66.28	\$61.53	\$52.80	\$85.65	\$37.84	\$51.66	\$62.43	\$61.00	\$60.21	0.5%
CAGR (‘15-’22)	3.2%	1.8%	1.8%	1.8%	2.6%	1.5%	3.4%	-0.4%	1.8%	3.3%		2.2%
Source: iData Research Inc.												

Figure 15-16: Fluid Management Tubing Market by Country, Europe, 2012-2022 (€M)

Year	Germany	France	U.K.	Italy	Spain	Benelux	Scandi- navia	Austria	Switzer- land	Portugal	Europe	Growth (%)
2012	€2.43	€1.70	€1.82	€1.88	€1.17	€1.11	€0.48	€0.39	€0.32	€0.33	€11.63	
2013	€2.61	€1.85	€1.96	€2.05	€1.21	€1.21	€0.49	€0.39	€0.34	€0.34	€12.45	7.1%
2014	€2.86	€2.06	€2.17	€2.28	€1.26	€1.36	€0.51	€0.39	€0.36	€0.35	€13.60	9.2%
2015	€3.18	€2.33	€2.44	€2.59	€1.33	€1.57	€0.52	€0.39	€0.39	€0.36	€15.12	11.1%
2016	€3.36	€2.46	€2.58	€2.76	€1.40	€1.66	€0.54	€0.39	€0.41	€0.37	€15.92	5.3%
2017	€3.52	€2.53	€2.67	€2.88	€1.45	€1.71	€0.56	€0.39	€0.43	€0.39	€16.53	3.8%
2018	€3.68	€2.59	€2.75	€2.95	€1.50	€1.74	€0.59	€0.39	€0.44	€0.40	€17.02	3.0%
2019	€3.82	€2.63	€2.81	€2.99	€1.55	€1.77	€0.61	€0.39	€0.45	€0.42	€17.43	2.4%
2020	€3.95	€2.66	€2.84	€3.00	€1.58	€1.78	€0.64	€0.39	€0.46	€0.43	€17.75	1.8%
2021	€4.05	€2.66	€2.87	€3.01	€1.61	€1.80	€0.67	€0.39	€0.47	€0.45	€17.99	1.3%
2022	€4.09	€2.67	€2.89	€3.02	€1.63	€1.81	€0.70	€0.39	€0.48	€0.47	€18.16	0.9%
CAGR (‘15-’22)	3.6%	1.9%	2.5%	2.2%	2.9%	2.0%	4.2%	0.0%	3.0%	4.0%		2.6%

Source: iData Research Inc.

Figure 15-17: Fluid Management Tubing Market by Country, Europe, 2012-2022 (US\$M)

Year	Germany	France	U.K.	Italy	Spain	Benelux	Scandi- navia	Austria	Switzer- land	Portugal	Europe	Growth (%)
2012	\$2.69	\$1.88	\$2.01	\$2.08	\$1.29	\$1.22	\$0.54	\$0.43	\$0.35	\$0.37	\$12.85	
2013	\$2.89	\$2.05	\$2.17	\$2.26	\$1.34	\$1.34	\$0.55	\$0.43	\$0.37	\$0.38	\$13.77	7.1%
2014	\$3.16	\$2.28	\$2.40	\$2.53	\$1.39	\$1.51	\$0.56	\$0.43	\$0.40	\$0.39	\$15.04	9.2%
2015	\$3.52	\$2.58	\$2.70	\$2.87	\$1.47	\$1.74	\$0.58	\$0.43	\$0.43	\$0.40	\$16.72	11.1%
2016	\$3.71	\$2.71	\$2.85	\$3.05	\$1.55	\$1.84	\$0.60	\$0.43	\$0.45	\$0.41	\$17.61	5.3%
2017	\$3.89	\$2.80	\$2.95	\$3.19	\$1.60	\$1.89	\$0.62	\$0.43	\$0.47	\$0.43	\$18.28	3.8%
2018	\$4.07	\$2.86	\$3.04	\$3.26	\$1.65	\$1.93	\$0.65	\$0.43	\$0.49	\$0.44	\$18.82	3.0%
2019	\$4.23	\$2.91	\$3.10	\$3.31	\$1.71	\$1.95	\$0.67	\$0.43	\$0.50	\$0.46	\$19.27	2.4%
2020	\$4.37	\$2.94	\$3.14	\$3.32	\$1.75	\$1.97	\$0.70	\$0.43	\$0.51	\$0.48	\$19.62	1.8%
2021	\$4.48	\$2.94	\$3.17	\$3.33	\$1.77	\$1.99	\$0.74	\$0.43	\$0.52	\$0.50	\$19.89	1.3%
2022	\$4.52	\$2.95	\$3.20	\$3.34	\$1.80	\$2.00	\$0.77	\$0.43	\$0.53	\$0.52	\$20.07	0.9%
CAGR (‘15-’22)	3.6%	1.9%	2.5%	2.2%	2.9%	2.0%	4.2%	0.0%	3.0%	4.0%		2.6%

Source: iData Research Inc.

15.4 DRIVERS AND LIMITERS

15.4.1 Market Drivers

Patient Safety

During a hysteroscope procedure, the uterine cavity can be filled with fluid. While the type of fluid used varies based on the patient's needs and the physician's preference, it is very important for the fluid pressure and absorption to be closely monitored by the physician for all types of fluid. Excess pressure can damage the uterine cavity. If the patient absorbs too much fluid, they can suffer respiratory issues, agitation, vomiting or even lapse into a coma. Since patient safety is a primary concern for physicians, hysteroscope procedures are rarely performed without fluid monitoring equipment to prevent these issues.

Minimally Invasive Procedures

Most physicians prefer to perform the least invasive procedures possible both for patient comfort and safety. As the use of hysteroscopes and other less invasive methods increase, more procedures will require the use of fluid management equipment, which will drive the market.

15.4.2 Market Limiters

Physician Resistance to Change

Some physicians do not think that the use of fluid management is necessary in many hysteroscopy procedures. If they are used to doing procedures without fluid management and they have never experienced any problems, it is difficult to convince them that it is essential to patient safety. Additionally, some physicians remain comfortable with surgical or other methods and will not need fluid management systems.

Cost of Capital Equipment

Fluid management equipment systems are extremely expensive in comparison to utilizing a gravity bag and pressure cuff or simple pump device. Transitioning to a more sophisticated technology requires budgeting in advance and increased public pressure creating an incentive to invest in the technology.

Figure 15-18: Drivers and Limiters, Fluid Management Equipment Market, Europe, 2015

Market Drivers
Patient Safety Minimally Invasive Procedures
Market Limiters
Physician Resistance to Change Cost of Capital Equipment
Source: iData Research Inc.

15.5 COMPETITIVE MARKET SHARE ANALYSIS

Karl Storz

In 2015, Karl Storz held a 40.1% share in the fluid management market. The *HYSTEROMAT E.A.S.I.*® is an intelligent fluid management system that uses a pressure-controlled double roller pump to maintain a constant preset intrauterine pressure and simultaneous continuous flow. This ensures that the uterine cavity is both properly dilated and that the physician has a clear view during the procedure.

Richard Wolf

In 2015, Richard Wolf held a 27.0% market share in the fluid management market. Richard Wolf has produced systems such as the Fluid Manager system. It automatically updates every 30 seconds and has additional alarms at each 100ml over the deficit limit and if the deficit changes more than 300ml in 30 seconds.

Olympus (KeyMed)

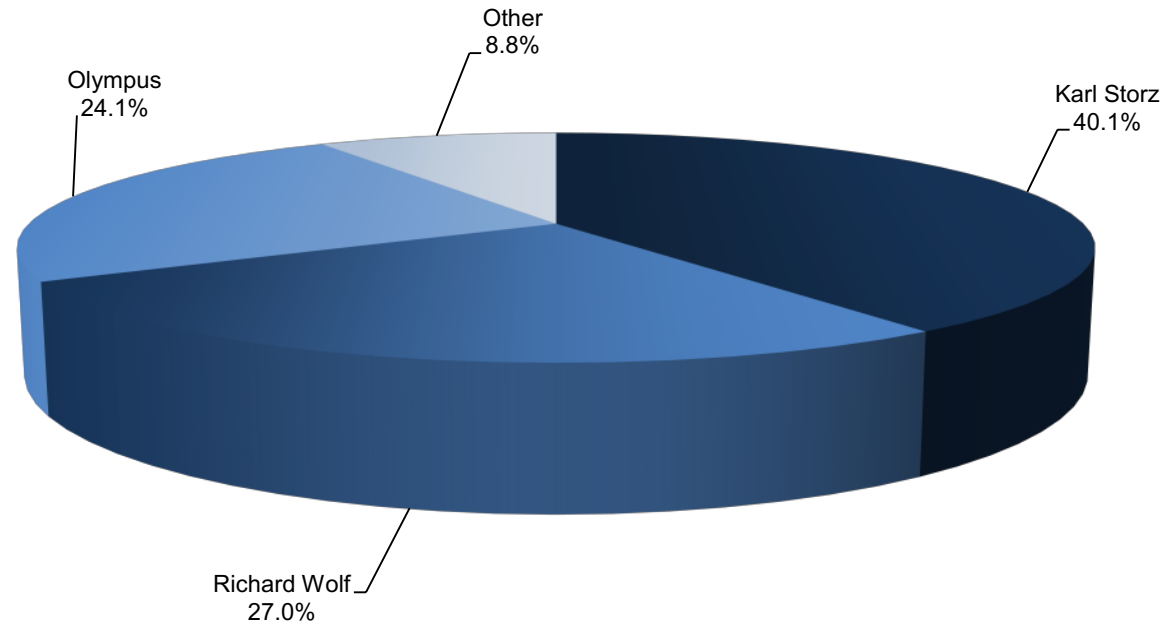
In 2015, Olympus held a 24.1% share in the fluid management market producing the HysteroFlow/HysteroBalance II System. The system provides accurate and easy measurement of the fluid balance and intrauterine pressure in a closed system during hysteroscopy and resection.

Other Notable Competitors

Other notable competitors, including Aesculap, Hologic and Stryker accounted for the remaining 9.6% market share. Stryker's *FluidSafe* fluid management system has pre-set pressure and flow rates, adjustable audible and visual deficit warnings, flow rates up to 500 mL/min and pressure as high as 200 mm Hg. Hologic has recently entered the market with their *Aquilex™ System*. This system is often sold with their *MyoSure*® *Tissue Removal System*. Although sales of this system have not been as robust in Europe as they have been in the U.S., the *MyoSure*® system is slowly gaining traction in Europe. The creation of a line of office-based devices has helped position Hologic in both the U.S. and European markets.

Figure 15-19: Leading Competitors by Country, Fluid Management Equipment Market, Europe, 2015

Company	Germany	France	U.K.	Italy	Spain	Benelux	Scandi- navia	Austria	Switzer- land	Portugal	Total Market Share
Karl Storz	40.6%	43.1%	40.6%	38.2%	37.5%	40.0%	39.6%	38.3%	41.7%	40.2%	40.1%
Richard Wolf	24.9%	26.7%	31.2%	29.1%	22.0%	25.7%	24.4%	35.2%	26.5%	22.7%	27.0%
Olympus	21.0%	21.4%	23.7%	25.8%	25.2%	31.3%	30.2%	20.8%	19.0%	25.8%	24.1%
Other	13.5%	8.8%	4.5%	6.9%	15.3%	3.0%	5.8%	5.7%	12.8%	11.3%	8.8%
Total	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
Market Value (€M)	€3.9	€2.8	€2.9	€3.3	€1.7	€1.8	€0.9	€0.7	€0.6	€0.5	€19.0
Others include: Aesculap, Hologic, Stryker, etc.											
Source: iData Research Inc.											

Chart 15-6: Leading Competitors, Fluid Management Equipment Market, Europe, 2015

Source: iData Research Inc.

16

PELVIC ORGAN PROLAPSE REPAIR DEVICE MARKET

16.1 INTRODUCTION

In the pelvis, the pelvic floor holds the vagina, bladder and uterus in place. The pelvic floor is made of ligaments that stretch across the inside of the pelvis. In a normal situation, the uterus, bladder and the upper part of the urethra lie above the pelvic floor. The vagina, rectum and the lower part of the urethra all pass through the pelvic floor to the outside. The vagina passes through the center of the pelvic floor, with the urethra to the front of it and the rectum behind.

Situations like childbirth, chronic cough, obesity or hormonal changes can cause the organs held in place by the pelvic floor to drop; this condition is also known as prolapse. Different types of prolapse exist: cystocele, a prolapse of the bladder into the front wall of the vagina; hysterocele, a prolapse of the uterus into the back, front or top of the vagina; rectocele, a prolapse of the rectum into the back wall of the vagina; urethrocele, a prolapse of the urethra into the lower front wall of the vagina; and enterocele, a prolapse that contains loops of bowel.

Symptoms experienced usually range from a pressure sensation to pain. Some patients do not experience anything. If there is mild prolapse, pelvic floor electrical stimulation or a pessarium can be used. When the situation is worse, surgery is necessary to reverse the prolapse. During the surgery, the prolapsed organs are moved to their original position and the ligaments are tightened. To provide additional vaginal support, a mesh can be implanted. Alternatively, a native tissue repair can also be used to provide the additional support required. In severe cases of prolapse, some of the organs need to be removed.

When a mesh is utilized, there are two main types: transvaginal mesh and sacrocolpopexy mesh. A transvaginal or intra-vaginal mesh is inserted to support the organs in the pelvis during a pelvic floor repair procedure. A pelvic floor repair procedure treats pelvic organ prolapse of the vagina or the uterus using a vaginal approach. An alternative to pelvic floor repair is sacrocolpopexy, which is another surgical method to repair pelvic organ prolapse. With sacrocolpopexy, incisions are made in through the abdomen and mesh is used to lift apical portion of the vaginal vault in order to suspend the vagina. This method may be performed laparoscopically, robotically assisted or openly through the abdomen. While pelvic floor repair is reported to have shorter recovery times than the abdominal method of surgical treatment, pelvic floor repair has had more reported adverse effects. Both of these procedures may be performed concomitantly with a hysterectomy or surgery for stress urinary incontinence.

16.2 MARKET OVERVIEW

The total market value for pelvic organ prolapse repair devices in 2015 was valued at €12.36M, a 0.4% increase from 2014. The market consists of the transvaginal mesh sub-segment and the sacrocolpopexy mesh sub-segment.

Pelvic organ prolapse afflicts up to 50% of women who have had children or have undergone menopause. The lifetime risk of requiring surgery for this condition is approximately 11%. The primary driver of growth for this device market is an increase in procedure numbers, driven by an aging female demographic. However, in 2012 there was a sharp decline in procedures triggered by reports of negative and serious side effects including numerous litigations surrounding the vaginal mesh market. The majority of the concern was about transvaginal mesh. Overall, the combination of these factors has led to a stable market overall with a small growth of 0.7% in unit sales expected over the forecast period.

The market has begun and is expected to continue a substantial shift from transvaginal mesh to sacrocolpopexy mesh. While transvaginal mesh sales currently comprise the majority of the market, their dominance will decrease as physicians move towards sacrocolpopexy mesh at increasing rates. Although the U.S. market was struck heavily by the FDA warnings issued in 2011, the European market was never as substantially impacted. The United Kingdom has been by far the most impacted, possibly because of the high degree of cross-over in negative press between the two countries regarding pelvic organ prolapse procedures using mesh. Modifications to the mesh, extra clinical trials to prove safety and pre-emptive marketing is helping to clarify the safety and health risks associated with mesh to curb the decline in procedures.

Even though the transvaginal mesh market is declining, a smaller but solid demand for this product will remain over the forecast period. In 2015, the transvaginal mesh sub-segment accounted for 59% of the total market or €7.5 million. As procedures using transvaginal mesh continue to decline, the market share is projected to continue falling accounting for only 49% or €6.3 million by 2022. Correspondingly, the sacrocolpopexy mesh market will increase quickly as women opt to have sacrocolpopexy procedures over the transvaginal method of treating this condition. It is expected that the sacrocolpopexy mesh segment will have 49% of the pelvic organ prolapse device market by 2022 with a value of €6.1 million.

ASPs for both types of mesh have been relatively stable, with a slight decline on average over the past few years. In Europe, there are many smaller companies that compete in the incontinence sling market. Competitive pricing, which pushes down ASP, is one of the tactics that allows these smaller companies to

thrive amongst larger medical device corporations. Changes in the market due to companies choosing to leave the market, notably Johnson & Johnson's transvaginal mesh products, has allowed many smaller competitors to better position themselves in their respective markets.

**Figure 16-1: Pelvic Organ Prolapse Repair Device Market by Segment, Europe
2012 – 2022 (€M)**

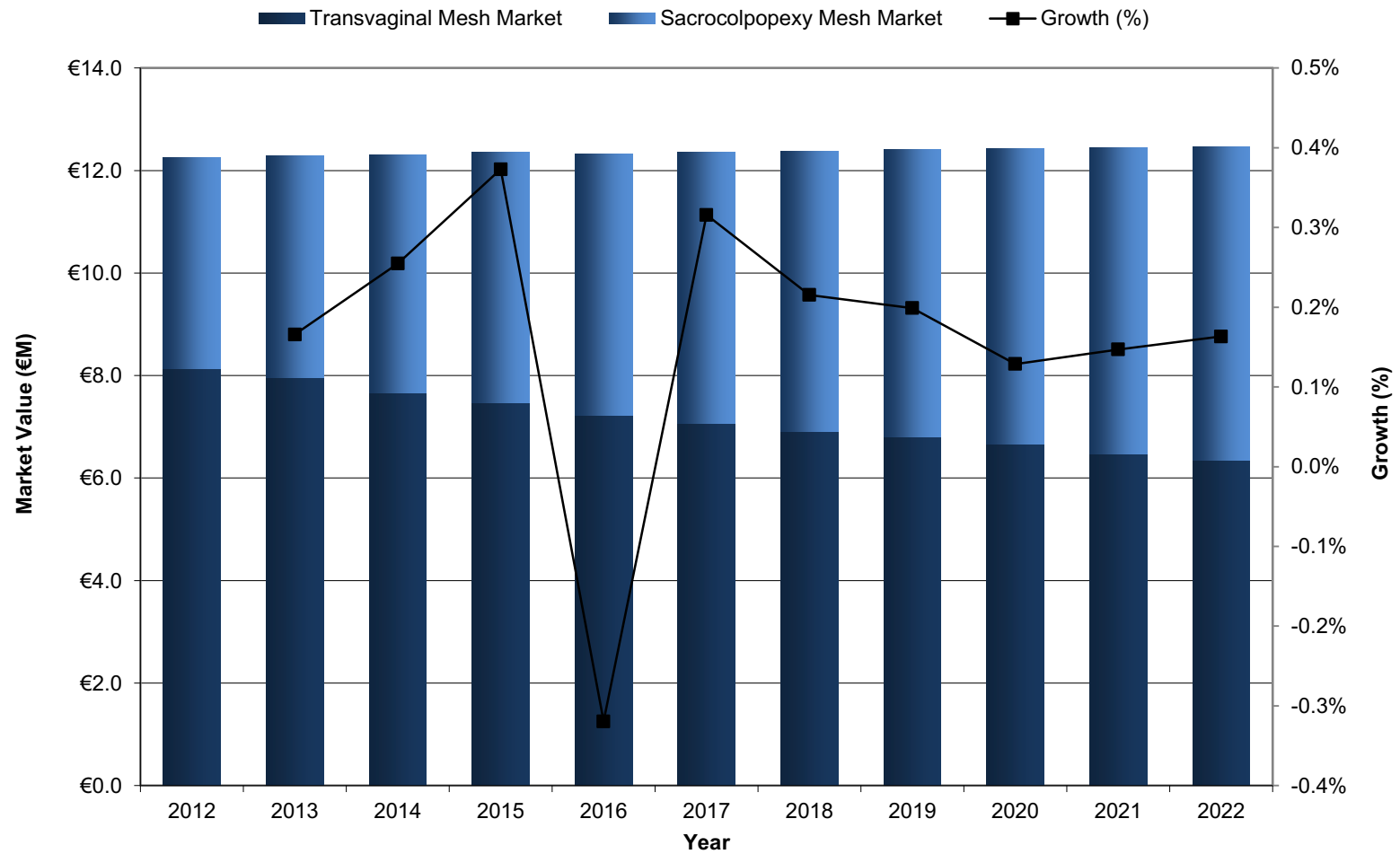
Year	Transvaginal Mesh Market	Sacrocolpopexy Mesh Market	Total Market	Growth (%)
2012	€8.13	€4.13	€12.26	
2013	€7.96	€4.32	€12.28	0.2%
2014	€7.66	€4.65	€12.31	0.3%
2015	€7.47	€4.89	€12.36	0.4%
2016	€7.22	€5.10	€12.32	-0.3%
2017	€7.07	€5.29	€12.36	0.3%
2018	€6.92	€5.47	€12.38	0.2%
2019	€6.80	€5.61	€12.41	0.2%
2020	€6.67	€5.76	€12.42	0.1%
2021	€6.47	€5.97	€12.44	0.1%
2022	€6.35	€6.12	€12.46	0.2%
CAGR (‘15–’22)	-2.3%	3.2%		0.1%

Source: iData Research Inc.

**Figure 16-2: Pelvic Organ Prolapse Repair Device Market by Segment, Europe
2012 – 2022 (US\$M)**

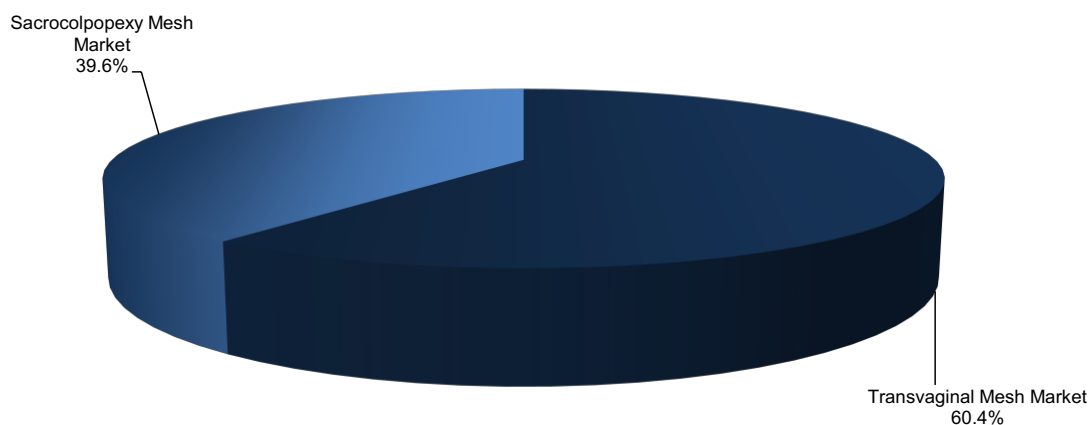
Year	Transvaginal Mesh Market	Sacrocolpopexy Mesh Market	Total Market	Growth (%)
2012	\$8.99	\$4.57	\$13.56	
2013	\$8.80	\$4.78	\$13.58	0.2%
2014	\$8.47	\$5.14	\$13.61	0.3%
2015	\$8.25	\$5.41	\$13.66	0.4%
2016	\$7.98	\$5.64	\$13.62	-0.3%
2017	\$7.81	\$5.85	\$13.66	0.3%
2018	\$7.65	\$6.04	\$13.69	0.2%
2019	\$7.52	\$6.20	\$13.72	0.2%
2020	\$7.37	\$6.36	\$13.74	0.1%
2021	\$7.15	\$6.60	\$13.76	0.1%
2022	\$7.02	\$6.76	\$13.78	0.2%
CAGR (‘15–’22)	-2.3%	3.2%		0.1%
Source: iData Research Inc.				

Chart 16-1: Pelvic Organ Prolapse Repair Device Market by Segment, Europe, 2012 – 2022



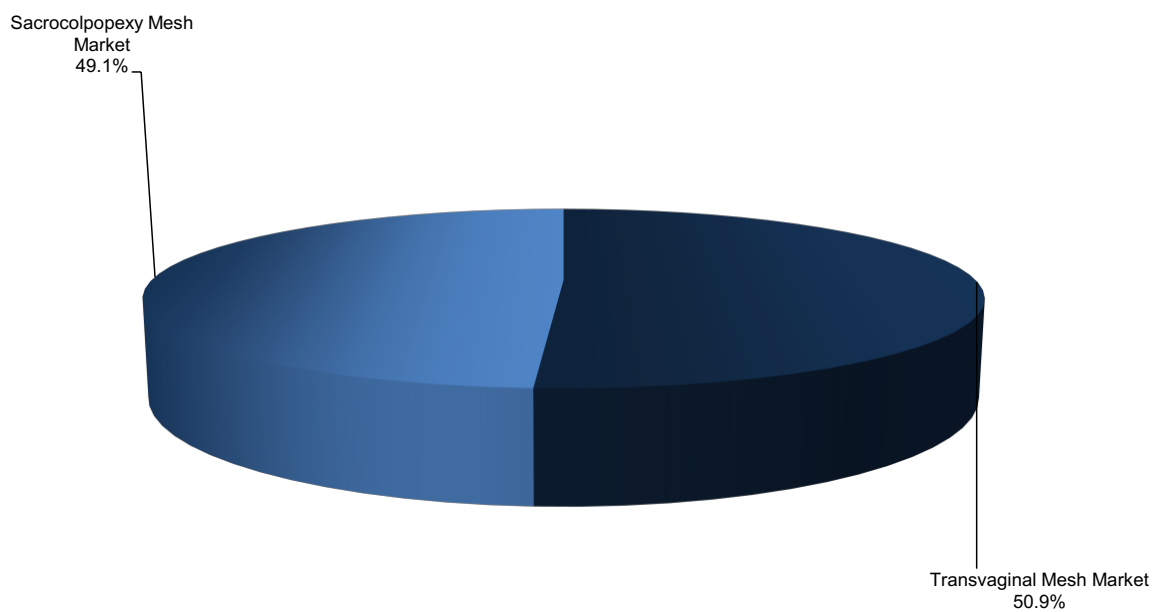
Source: iData Research Inc.

Chart 16-2: Pelvic Organ Prolapse Repair Device Market Breakdown, Europe, 2015



Source: iData Research Inc.

Chart 16-3: Pelvic Organ Prolapse Repair Device Market Breakdown, Europe, 2022



Source: iData Research Inc.

16.3 MARKET ANALYSIS AND FORECAST

16.3.1 Total Pelvic Organ Prolapse Repair Device Market

The pelvic organ prolapse device market is stable, projecting a slight growth of 0.7% over the forecast period. The stability is caused by consistent procedure numbers simply because a high number of patients suffer from Pelvic organ prolapse. While a native tissue repair can be performed in place of a mesh, the positive results are only temporary leading to a high rate of repeat procedures. Therefore, despite the controversy regarding mesh it is still the recommended course of treatment.

Although the mesh market has consistent sales, there is a major shift from transvaginal mesh to the safer option of sacrocolpopexy mesh. The negative growth trend for transvaginal mesh is being offset by the positive growth trend in sacrocolpopexy mesh over the forecast period.

Similar to female urinary incontinence slings, the negative side-effects from Pelvic organ prolapse created a stronger problem for patients in the United States than in Europe. This is potentially attributable to the absence of public healthcare in the United States. The cost to reverse negative side effects is extreme and can take longer than in Europe. Doctors throughout Europe have also been taking additional time to ensure they are performing the safest and least invasive treatment options for patients with pelvic organ prolapse. The renewed attention to conduct clinical trials, time to ensure patients are correct candidates and that patients are well informed of the safety risks is allowing trust and patient confidence in mesh procedures to recover.

The United Kingdom has a substantially more drastic trend compared to the rest of Europe. The United Kingdom has experienced a stronger backlash closer to the United States regarding mesh. This is possibly due to the cross-over in press between the two countries leading to higher patient awareness about the adverse side effects. This has led to a rapid shift in procedures from transvaginal mesh to sacrocolpopexy mesh. The number of procedures performed will decline at a CAGR of -2.5% by 2022.

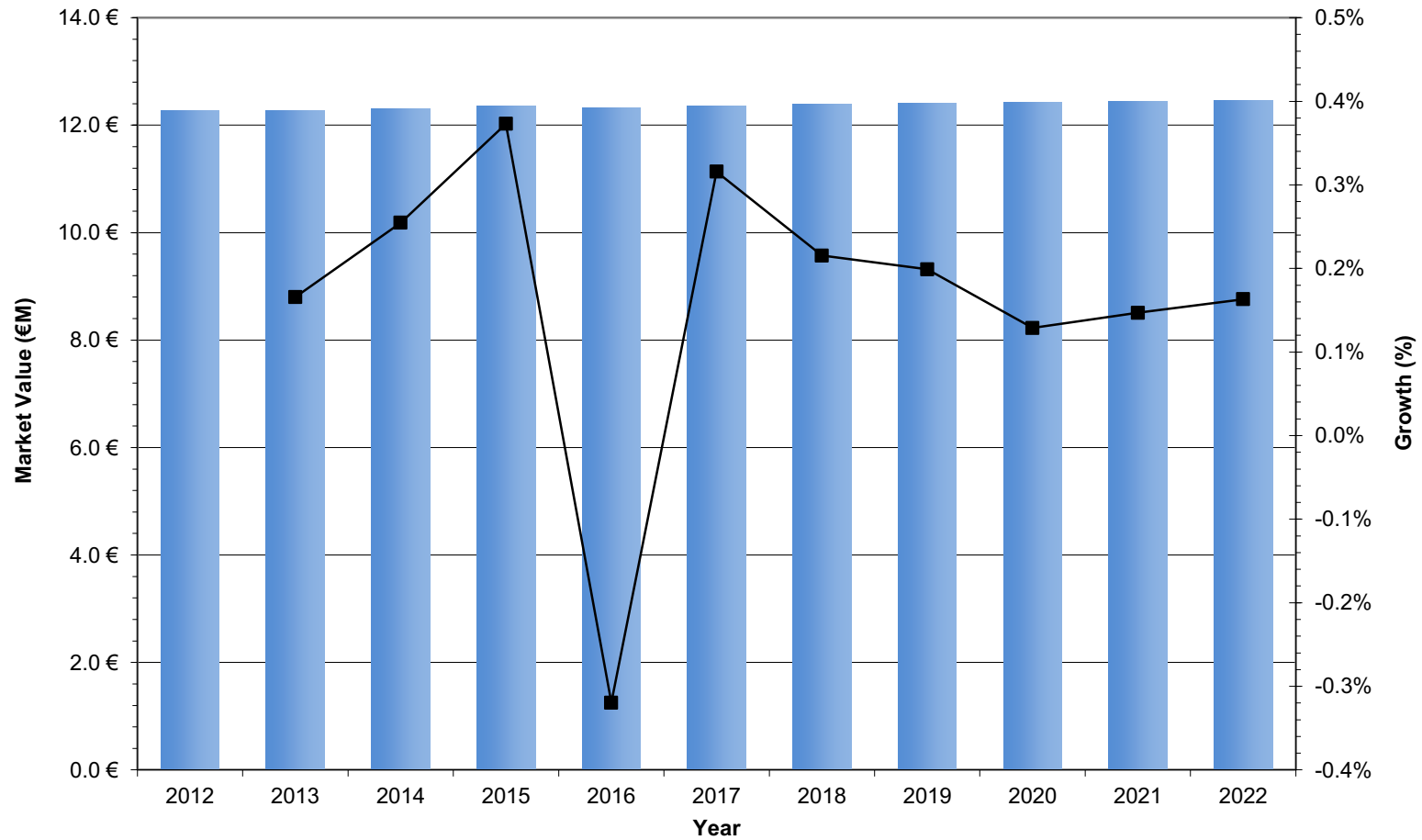
The ASP of these devices is expected to undergo a decline as demand shifts from transvaginal mesh to sacrocolpopexy mesh, which has a lower average selling price. Overall the total procedure numbers are increasing. The combined outcome is the market value is projected to remain stable to increase slightly over the reporting period.

**Figure 16-3: Total Pelvic Organ Prolapse Repair Device Market, Europe, 2012 – 2022
(€ and US\$)**

Year	Units Sold	Growth (%)	ASP (€)	ASP (US\$)	Growth (%)	Market Value (€M)	Market Value (US\$M)	Growth (%)
2012	17,026		€720.09	\$796.13		€12.26	\$13.56	
2013	17,172	0.9%	€715.16	\$790.68	-0.7%	€12.28	\$13.58	0.2%
2014	17,335	0.9%	€710.26	\$785.27	-0.7%	€12.31	\$13.61	0.3%
2015	17,522	1.1%	€705.30	\$779.78	-0.7%	€12.36	\$13.66	0.4%
2016	17,595	0.4%	€700.13	\$774.06	-0.7%	€12.32	\$13.62	-0.3%
2017	17,757	0.9%	€695.94	\$769.43	-0.6%	€12.36	\$13.66	0.3%
2018	17,896	0.8%	€692.00	\$765.08	-0.6%	€12.38	\$13.69	0.2%
2019	18,023	0.7%	€688.51	\$761.21	-0.5%	€12.41	\$13.72	0.2%
2020	18,133	0.6%	€685.18	\$757.54	-0.5%	€12.42	\$13.74	0.1%
2021	18,246	0.6%	€681.97	\$753.99	-0.5%	€12.44	\$13.76	0.1%
2022	18,351	0.6%	€679.14	\$750.86	-0.4%	€12.46	\$13.78	0.2%
CAGR ('15-'22)		0.7%			-0.5%			0.1%

Source: iData Research Inc.

Chart 16-4: Total Pelvic Organ Prolapse Repair Device Market, Europe, 2012 – 2022



Source: iData Research Inc.

Figure 16-4: Units Sold by Country, Total Pelvic Organ Prolapse Repair Device Market, Europe, 2012-2022

Year	Germany	France	U.K.	Italy	Spain	Benelux	Scandi- navia	Austria	Switzer- land	Portugal	Europe	Growth (%)
2012	4,746	2,667	2,260	1,599	710	1,187	1,758	543	1,266	290	17,026	
2013	4,779	2,659	2,235	1,596	701	1,211	1,876	546	1,282	287	17,172	0.9%
2014	4,817	2,651	2,206	1,593	692	1,235	2,004	548	1,304	285	17,335	0.9%
2015	4,863	2,646	2,175	1,590	682	1,259	2,144	551	1,330	282	17,522	1.1%
2016	4,916	2,635	2,131	1,586	672	1,282	2,294	441	1,359	278	17,595	0.4%
2017	4,956	2,625	2,084	1,581	662	1,306	2,432	445	1,391	274	17,757	0.9%
2018	4,986	2,612	2,034	1,576	653	1,330	2,559	451	1,425	271	17,896	0.8%
2019	5,010	2,596	1,983	1,570	644	1,354	2,680	456	1,462	267	18,023	0.7%
2020	5,031	2,581	1,932	1,565	634	1,379	2,787	463	1,499	264	18,133	0.6%
2021	5,046	2,573	1,874	1,561	628	1,404	2,893	470	1,539	260	18,246	0.6%
2022	5,056	2,565	1,816	1,556	623	1,429	2,994	477	1,580	256	18,351	0.6%
CAGR (‘15-’22)	0.6%	-0.4%	-2.5%	-0.3%	-1.3%	1.8%	4.9%	-2.1%	2.5%	-1.4%		0.7%

Source: iData Research Inc.

Figure 16-5: Average Sales Price by Country, Total Pelvic Organ Prolapse Repair Device Market, Europe, 2012-2022 (€)

Year	Germany	France	U.K.	Italy	Spain	Benelux	Scandi- navia	Austria	Switzer- land	Portugal	Europe	Growth (%)
2012	€ 746	€ 713	€ 672	€ 704	€ 698	€ 759	€ 525	€ 775	€ 870	€ 697	€ 697	
2013	€ 743	€ 708	€ 663	€ 701	€ 695	€ 755	€ 527	€ 770	€ 859	€ 694	€ 692	-0.7%
2014	€ 739	€ 703	€ 655	€ 698	€ 693	€ 750	€ 530	€ 765	€ 847	€ 691	€ 688	-0.6%
2015	€ 735	€ 699	€ 649	€ 695	€ 690	€ 745	€ 533	€ 760	€ 833	€ 688	€ 684	-0.6%
2016	€ 731	€ 694	€ 643	€ 690	€ 686	€ 740	€ 536	€ 753	€ 818	€ 686	€ 680	-0.5%
2017	€ 727	€ 690	€ 639	€ 686	€ 683	€ 735	€ 539	€ 747	€ 806	€ 684	€ 679	-0.3%
2018	€ 724	€ 687	€ 635	€ 682	€ 680	€ 730	€ 543	€ 742	€ 794	€ 682	€ 677	-0.2%
2019	€ 721	€ 683	€ 631	€ 677	€ 676	€ 724	€ 546	€ 737	€ 784	€ 679	€ 677	-0.1%
2020	€ 719	€ 680	€ 628	€ 673	€ 672	€ 719	€ 550	€ 731	€ 772	€ 677	€ 677	0.0%
2021	€ 717	€ 677	€ 626	€ 669	€ 668	€ 713	€ 554	€ 725	€ 763	€ 675	€ 677	0.1%
2022	€ 715	€ 675	€ 624	€ 665	€ 664	€ 707	€ 558	€ 719	€ 754	€ 673	€ 661	-2.4%
CAGR ('15-'22)	-0.4%	-0.5%	-0.6%	-0.6%	-0.5%	-0.7%	0.7%	-0.8%	-1.4%	-0.3%		-0.5%

Source: iData Research Inc.

Figure 16-6: Average Sales Price by Country, Total Pelvic Organ Prolapse Repair Device Market, Europe, 2012-2022 (US\$)

Year	Germany	France	U.K.	Italy	Spain	Benelux	Scandi- navia	Austria	Switzer- land	Portugal	Europe	Growth (%)
2012	\$824	\$788	\$743	\$778	\$771	\$839	\$580	\$857	\$962	\$771	\$770	
2013	\$821	\$783	\$733	\$775	\$769	\$834	\$583	\$851	\$949	\$768	\$765	-0.7%
2014	\$817	\$777	\$724	\$772	\$766	\$829	\$586	\$846	\$936	\$764	\$760	-0.6%
2015	\$813	\$772	\$717	\$768	\$762	\$824	\$589	\$840	\$920	\$761	\$756	-0.6%
2016	\$808	\$768	\$711	\$763	\$759	\$818	\$593	\$832	\$905	\$758	\$752	-0.5%
2017	\$804	\$763	\$706	\$759	\$755	\$813	\$596	\$826	\$891	\$756	\$750	-0.3%
2018	\$800	\$759	\$702	\$754	\$752	\$807	\$600	\$820	\$878	\$754	\$749	-0.2%
2019	\$797	\$755	\$698	\$749	\$747	\$801	\$604	\$815	\$867	\$751	\$748	-0.1%
2020	\$795	\$752	\$695	\$744	\$743	\$795	\$608	\$808	\$854	\$748	\$748	0.0%
2021	\$792	\$749	\$692	\$739	\$738	\$788	\$612	\$801	\$843	\$746	\$749	0.1%
2022	\$790	\$746	\$689	\$735	\$734	\$782	\$617	\$794	\$834	\$744	\$731	-2.4%
CAGR (‘15-’22)	-0.4%	-0.5%	-0.6%	-0.6%	-0.5%	-0.7%	0.7%	-0.8%	-1.4%	-0.3%		-0.5%

Source: iData Research Inc.

Figure 16-7: Total Pelvic Organ Prolapse Repair Device Market by Country, Europe, 2012-2022 (€M)

Year	Germany	France	U.K.	Italy	Spain	Benelux	Scandi- navia	Austria	Switzer- land	Portugal	Europe	Growth (%)
2012	€3.54	€1.90	€1.52	€1.13	€0.50	€0.90	€1.06	€0.42	€1.10	€0.20	€12.26	
2013	€3.55	€1.88	€1.48	€1.12	€0.49	€0.91	€1.13	€0.42	€1.10	€0.20	€12.28	0.2%
2014	€3.56	€1.86	€1.45	€1.11	€0.48	€0.93	€1.21	€0.42	€1.10	€0.20	€12.31	0.3%
2015	€3.57	€1.85	€1.41	€1.10	€0.47	€0.94	€1.29	€0.42	€1.11	€0.19	€12.36	0.4%
2016	€3.59	€1.83	€1.37	€1.09	€0.46	€0.95	€1.38	€0.33	€1.11	€0.19	€12.32	-0.3%
2017	€3.60	€1.81	€1.33	€1.08	€0.45	€0.96	€1.47	€0.33	€1.12	€0.19	€12.36	0.3%
2018	€3.61	€1.79	€1.29	€1.07	€0.44	€0.97	€1.55	€0.33	€1.13	€0.18	€12.38	0.2%
2019	€3.61	€1.77	€1.25	€1.06	€0.43	€0.98	€1.63	€0.34	€1.15	€0.18	€12.41	0.2%
2020	€3.62	€1.76	€1.21	€1.05	€0.43	€0.99	€1.69	€0.34	€1.16	€0.18	€12.42	0.1%
2021	€3.62	€1.74	€1.17	€1.04	€0.42	€1.00	€1.76	€0.34	€1.17	€0.18	€12.44	0.1%
2022	€3.61	€1.73	€1.13	€1.03	€0.41	€1.01	€1.82	€0.34	€1.19	€0.17	€12.46	0.2%
CAGR (‘15-’22)	0.2%	-0.9%	-3.1%	-0.9%	-1.8%	1.1%	5.0%	-2.8%	1.1%	-1.7%		0.1%

Source: iData Research Inc.

Figure 16-8: Total Pelvic Organ Prolapse Repair Device Market by Country, Europe, 2012-2022 (US\$M)

Year	Germany	France	U.K.	Italy	Spain	Benelux	Scandi- navia	Austria	Switzer- land	Portugal	Europe	Growth (%)
2012	\$3.9	\$2.1	\$1.7	\$1.2	\$0.5	\$1.0	\$1.2	\$0.5	\$1.2	\$0.2	\$13.6	
2013	\$3.9	\$2.1	\$1.6	\$1.2	\$0.5	\$1.0	\$1.2	\$0.5	\$1.2	\$0.2	\$13.6	0.2%
2014	\$3.9	\$2.1	\$1.6	\$1.2	\$0.5	\$1.0	\$1.3	\$0.5	\$1.2	\$0.2	\$13.6	0.3%
2015	\$4.0	\$2.0	\$1.6	\$1.2	\$0.5	\$1.0	\$1.4	\$0.5	\$1.2	\$0.2	\$13.7	0.4%
2016	\$4.0	\$2.0	\$1.5	\$1.2	\$0.5	\$1.0	\$1.5	\$0.4	\$1.2	\$0.2	\$13.6	-0.3%
2017	\$4.0	\$2.0	\$1.5	\$1.2	\$0.5	\$1.1	\$1.6	\$0.4	\$1.2	\$0.2	\$13.7	0.3%
2018	\$4.0	\$2.0	\$1.4	\$1.2	\$0.5	\$1.1	\$1.7	\$0.4	\$1.3	\$0.2	\$13.7	0.2%
2019	\$4.0	\$2.0	\$1.4	\$1.2	\$0.5	\$1.1	\$1.8	\$0.4	\$1.3	\$0.2	\$13.7	0.2%
2020	\$4.0	\$1.9	\$1.3	\$1.2	\$0.5	\$1.1	\$1.9	\$0.4	\$1.3	\$0.2	\$13.7	0.1%
2021	\$4.0	\$1.9	\$1.3	\$1.2	\$0.5	\$1.1	\$1.9	\$0.4	\$1.3	\$0.2	\$13.8	0.1%
2022	\$4.0	\$1.9	\$1.3	\$1.1	\$0.5	\$1.1	\$2.0	\$0.4	\$1.3	\$0.2	\$13.8	0.2%
CAGR (‘15-’22)	0.2%	-0.9%	-3.1%	-0.9%	-1.8%	1.1%	5.0%	-2.8%	1.1%	-1.7%		0.1%

Source: iData Research Inc.

16.3.2 Transvaginal Mesh Market

The unit sales of transvaginal mesh have dropped due to the adverse side effects and increased concern for patient safety. Additionally due to litigation and further scrutiny of transvaginal mesh, many companies have withdrawn their devices, most notably Astora Women's Health in 2016.

The overall market, despite the problems associated with transvaginal mesh, will continue to comprise the majority of the market up to 2021. By 2022, the majority of the market will switch to sacrocolpopexy procedures. The decline is significantly more gradual compared to the United States due to less patient complaints. In the Scandinavian region for example, the number of procedures performed with transvaginal mesh is continuing to increase. This trend is attributed to the low level of complications, doctor preference and overall increase in pelvic organ prolapse procedures.

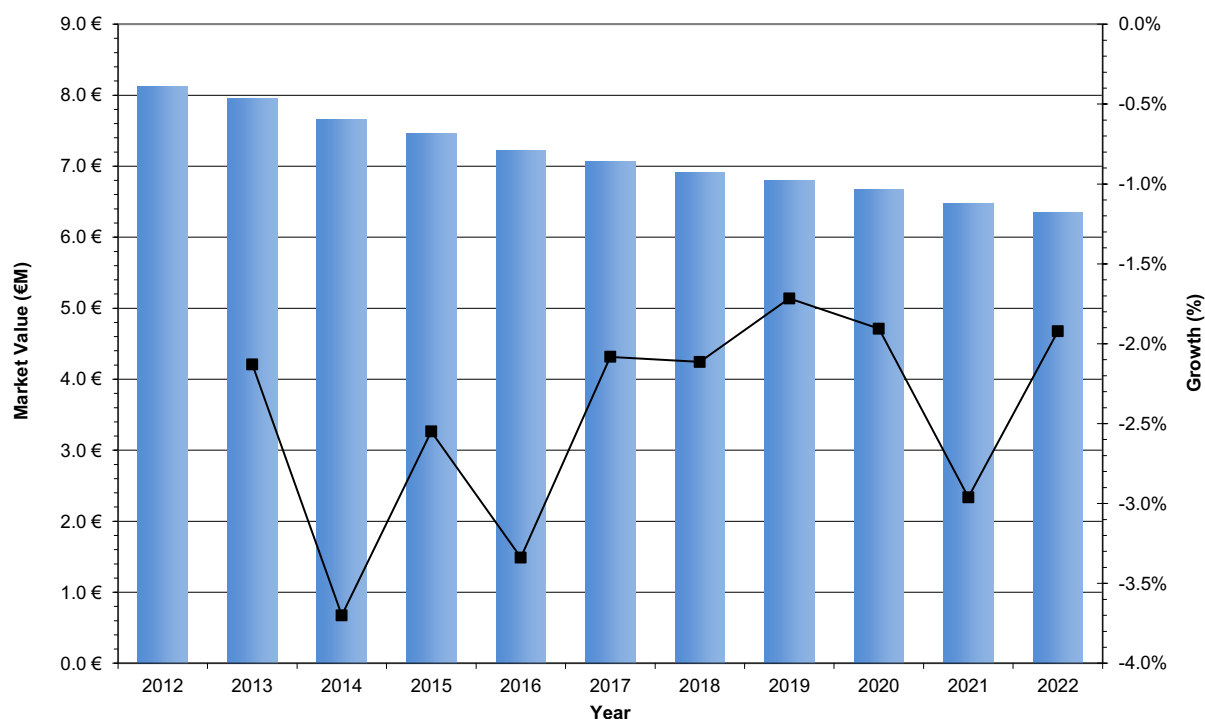
As a whole, the pelvic organ prolapse market is less saturated than the United States. This is helping to mitigate the trend away from transvaginal mesh. While fewer patients are being recommended the procedure, overall patient numbers for pelvic organ prolapse are increasing resulting in a similar to slightly lower number of procedures being performed.

The market value of transvaginal mesh is falling faster than the unit sales, with a CAGR of -2.3%. The ASP per procedure is being eroded exacerbating the downward trend and compounding the contraction of the market.

Figure 16-9: Transvaginal Mesh Market, Europe, 2012 – 2022 (€ and US\$)

Year	Units Sold	Growth (%)	ASP (€)	ASP (US\$)	Growth (%)	Market Value (€M)	Market Value (US\$M)	Growth (%)
2012	11,095		€733	\$810		€8.1	\$9.0	
2013	10,919	-1.6%	€729	\$806	-0.5%	€8.0	\$8.8	-2.1%
2014	10,574	-3.2%	€725	\$801	-0.6%	€7.7	\$8.5	-3.7%
2015	10,364	-2.0%	€720	\$796	-0.6%	€7.5	\$8.3	-2.5%
2016	10,076	-2.8%	€716	\$792	-0.6%	€7.2	\$8.0	-3.3%
2017	9,913	-1.6%	€713	\$788	-0.5%	€7.1	\$7.8	-2.1%
2018	9,748	-1.7%	€710	\$785	-0.5%	€6.9	\$7.6	-2.1%
2019	9,619	-1.3%	€707	\$781	-0.4%	€6.8	\$7.5	-1.7%
2020	9,475	-1.5%	€704	\$778	-0.4%	€6.7	\$7.4	-1.9%
2021	9,236	-2.5%	€701	\$775	-0.5%	€6.5	\$7.2	-3.0%
2022	9,097	-1.5%	€698	\$771	-0.4%	€6.3	\$7.0	-1.9%
CAGR ('15-'22)		-1.8%			-0.5%			-2.3%

Source: iData Research Inc.

Chart 16-5: Transvaginal Mesh Market, Europe, 2012 – 2022


Source: iData Research Inc.

Figure 16-10: Units Sold by Country, Transvaginal Mesh Market, Europe, 2012-2022

Year	Germany	France	U.K.	Italy	Spain	Benelux	Scandi- navia	Austria	Switzer- land	Portugal	Europe	Growth (%)
2012	2,895	1,867	1,227	1,119	518	843	1,284	315	810	217	11,095	
2013	2,867	1,808	1,114	1,102	498	848	1,351	311	808	212	10,919	-1.6%
2014	2,649	1,750	1,009	1,083	484	852	1,423	307	808	208	10,574	-3.2%
2015	2,529	1,720	910	1,073	471	856	1,501	303	798	203	10,364	-2.0%
2016	2,458	1,687	819	1,015	450	859	1,571	234	788	194	10,076	-2.8%
2017	2,379	1,627	734	996	447	862	1,654	232	793	189	9,913	-1.6%
2018	2,293	1,593	656	977	438	864	1,715	230	798	184	9,748	-1.7%
2019	2,255	1,558	584	958	418	867	1,769	228	804	179	9,619	-1.3%
2020	2,213	1,522	518	939	406	869	1,811	227	794	174	9,475	-1.5%
2021	2,069	1,492	458	921	396	870	1,851	225	785	169	9,236	-2.5%
2022	2,022	1,462	406	902	387	872	1,886	224	774	161	9,097	-1.5%
CAGR (‘15-’22)	-3.1%	-2.3%	-10.9%	-2.4%	-2.8%	0.3%	3.3%	-4.2%	-0.4%	-3.3%		-1.8%

Source: iData Research Inc.

Figure 16-11: Average Sales Price by Country, Transvaginal Mesh Market, Europe, 2012-2022 (€)

Year	Germany	France	U.K.	Italy	Spain	Benelux	Scandi- navia	Austria	Switzer- land	Portugal	Europe	Growth (%)
2012	€753	€715	€707	€708	€702	€768	€609	€825	€925	€701	€733	
2013	€750	€711	€696	€706	€699	€764	€610	€820	€920	€698	€729	-0.5%
2014	€747	€707	€688	€704	€697	€760	€611	€815	€913	€695	€725	-0.6%
2015	€744	€704	€682	€702	€695	€756	€612	€809	€905	€691	€720	-0.6%
2016	€741	€701	€678	€699	€692	€752	€613	€801	€896	€689	€716	-0.6%
2017	€737	€699	€676	€696	€690	€747	€615	€794	€886	€686	€713	-0.5%
2018	€734	€696	€674	€693	€687	€743	€616	€787	€876	€684	€710	-0.5%
2019	€732	€694	€671	€690	€684	€738	€617	€779	€866	€682	€707	-0.4%
2020	€729	€692	€669	€687	€681	€733	€619	€769	€858	€681	€704	-0.4%
2021	€727	€690	€667	€683	€678	€729	€620	€759	€850	€680	€701	-0.5%
2022	€725	€688	€665	€680	€675	€724	€620	€748	€842	€679	€698	-0.4%
CAGR (‘15-’22)	-0.4%	-0.3%	-0.3%	-0.4%	-0.4%	-0.6%	0.2%	-1.1%	-1.0%	-0.3%		-0.5%
Source: iData Research Inc.												

Figure 16-12: Average Sales Price by Country, Transvaginal Mesh Market, Europe, 2012-2022 (US\$)

Year	Germany	France	U.K.	Italy	Spain	Benelux	Scandi- navia	Austria	Switzer- land	Portugal	Europe	Growth (%)
2012	\$833	\$791	\$781	\$782	\$776	\$849	\$673	\$912	\$1,023	\$775	\$810	
2013	\$830	\$786	\$770	\$781	\$773	\$845	\$674	\$907	\$1,017	\$772	\$806	-0.5%
2014	\$826	\$782	\$760	\$778	\$771	\$840	\$675	\$901	\$1,010	\$768	\$801	-0.6%
2015	\$823	\$778	\$754	\$776	\$768	\$836	\$677	\$894	\$1,000	\$764	\$796	-0.6%
2016	\$819	\$775	\$749	\$773	\$766	\$831	\$678	\$886	\$991	\$761	\$792	-0.6%
2017	\$815	\$773	\$747	\$770	\$762	\$826	\$680	\$878	\$980	\$759	\$788	-0.5%
2018	\$812	\$770	\$745	\$766	\$759	\$821	\$681	\$870	\$968	\$756	\$785	-0.5%
2019	\$809	\$768	\$742	\$763	\$756	\$816	\$683	\$861	\$958	\$755	\$781	-0.4%
2020	\$806	\$765	\$740	\$759	\$753	\$811	\$684	\$851	\$948	\$753	\$778	-0.4%
2021	\$804	\$763	\$738	\$755	\$750	\$806	\$685	\$839	\$939	\$752	\$775	-0.5%
2022	\$802	\$761	\$736	\$752	\$746	\$800	\$686	\$827	\$930	\$751	\$771	-0.4%
CAGR (‘15-’22)	-0.4%	-0.3%	-0.3%	-0.4%	-0.4%	-0.6%	0.2%	-1.1%	-1.0%	-0.3%		-0.5%
Source: iData Research Inc.												

Figure 16-13: Transvaginal Mesh Market by Country, Europe, 2012-2022 (€M)

Year	Germany	France	U.K.	Italy	Spain	Benelux	Scandi- navia	Austria	Switzer- land	Portugal	Europe	Growth (%)
2012	€2.18	€1.34	€0.87	€0.79	€0.36	€0.65	€0.78	€0.26	€0.75	€0.15	€8.13	
2013	€2.15	€1.29	€0.78	€0.78	€0.35	€0.65	€0.82	€0.25	€0.74	€0.15	€7.96	-2.1%
2014	€1.98	€1.24	€0.69	€0.76	€0.34	€0.65	€0.87	€0.25	€0.74	€0.14	€7.66	-3.7%
2015	€1.88	€1.21	€0.62	€0.75	€0.33	€0.65	€0.92	€0.25	€0.72	€0.14	€7.47	-2.5%
2016	€1.82	€1.18	€0.55	€0.71	€0.31	€0.65	€0.96	€0.19	€0.71	€0.13	€7.22	-3.3%
2017	€1.75	€1.14	€0.50	€0.69	€0.31	€0.64	€1.02	€0.18	€0.70	€0.13	€7.07	-2.1%
2018	€1.68	€1.11	€0.44	€0.68	€0.30	€0.64	€1.06	€0.18	€0.70	€0.13	€6.92	-2.1%
2019	€1.65	€1.08	€0.39	€0.66	€0.29	€0.64	€1.09	€0.18	€0.70	€0.12	€6.80	-1.7%
2020	€1.61	€1.05	€0.35	€0.64	€0.28	€0.64	€1.12	€0.17	€0.68	€0.12	€6.67	-1.9%
2021	€1.50	€1.03	€0.31	€0.63	€0.27	€0.63	€1.15	€0.17	€0.67	€0.11	€6.47	-3.0%
2022	€1.47	€1.01	€0.27	€0.61	€0.26	€0.63	€1.17	€0.17	€0.65	€0.11	€6.35	-1.9%
CAGR (‘15-’22)	-3.5%	-2.6%	-11.2%	-2.9%	-3.2%	-0.4%	3.5%	-5.3%	-1.5%	-3.5%		-2.3%

Source: iData Research Inc.

Figure 16-14: Transvaginal Mesh Market by Country, Europe, 2012-2022 (US\$M)

Year	Germany	France	U.K.	Italy	Spain	Benelux	Scandi- navia	Austria	Switzer- land	Portugal	Europe	Growth (%)
2012	\$2.41	\$1.48	\$0.96	\$0.88	\$0.40	\$0.72	\$0.86	\$0.29	\$0.83	\$0.17	\$8.99	
2013	\$2.38	\$1.42	\$0.86	\$0.86	\$0.38	\$0.72	\$0.91	\$0.28	\$0.82	\$0.16	\$8.80	-2.1%
2014	\$2.19	\$1.37	\$0.77	\$0.84	\$0.37	\$0.72	\$0.96	\$0.28	\$0.82	\$0.16	\$8.47	-3.7%
2015	\$2.08	\$1.34	\$0.69	\$0.83	\$0.36	\$0.72	\$1.02	\$0.27	\$0.80	\$0.16	\$8.25	-2.5%
2016	\$2.01	\$1.31	\$0.61	\$0.78	\$0.34	\$0.71	\$1.07	\$0.21	\$0.78	\$0.15	\$7.98	-3.3%
2017	\$1.94	\$1.26	\$0.55	\$0.77	\$0.34	\$0.71	\$1.12	\$0.20	\$0.78	\$0.14	\$7.81	-2.1%
2018	\$1.86	\$1.23	\$0.49	\$0.75	\$0.33	\$0.71	\$1.17	\$0.20	\$0.77	\$0.14	\$7.65	-2.1%
2019	\$1.82	\$1.20	\$0.43	\$0.73	\$0.32	\$0.71	\$1.21	\$0.20	\$0.77	\$0.14	\$7.52	-1.7%
2020	\$1.78	\$1.17	\$0.38	\$0.71	\$0.31	\$0.70	\$1.24	\$0.19	\$0.75	\$0.13	\$7.37	-1.9%
2021	\$1.66	\$1.14	\$0.34	\$0.70	\$0.30	\$0.70	\$1.27	\$0.19	\$0.74	\$0.13	\$7.15	-3.0%
2022	\$1.62	\$1.11	\$0.30	\$0.68	\$0.29	\$0.70	\$1.29	\$0.19	\$0.72	\$0.12	\$7.02	-1.9%
CAGR (‘15-’22)	-3.5%	-2.6%	-11.2%	-2.9%	-3.2%	-0.4%	3.5%	-5.3%	-1.5%	-3.5%		-2.3%
Source: iData Research Inc.												

16.3.3 Sacrocolpopexy Mesh Market

This treatment is the currently the gold standard for the surgical treatment of apical pelvic prolapse. With a decline in transvaginal procedures to treat pelvic organ prolapse, it is expected that the sacrocolpopexy market will increase in sales. . Additionally, minimally invasive techniques are a major direction in which women's health care is driven. As sacrocolpopexy can be done laparoscopically, it is expected that this trend will help support growth in sacrocolpopexy procedure rates. Sacrocolpopexy is also cutting edge in the sense that they procedure can be performed using robotically assisted technology, bolstering procedure numbers.

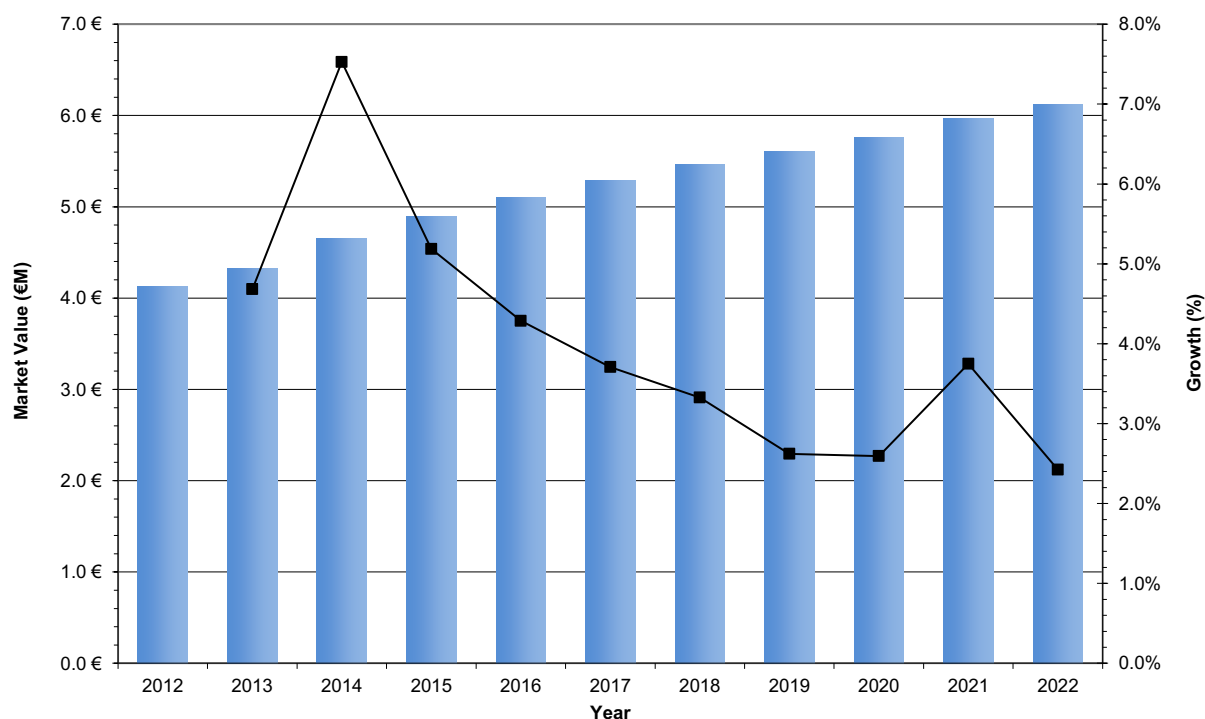
In addition to physicians and their patients moving towards abdominal surgical methods of treating this condition, such as sacrocolpopexy, due to the adverse events surrounding transvaginal mesh devices, the prevalence of pelvic organ prolapse is expected to increase over the forecast period. Pelvic organ prolapse can occur in women over a wide range of ages, although prevalence is highest amongst older demographics. As the population ages, it is expected that the prevalence, and therefore the number of surgical procedures for the treatment of this condition, will increase.

As reimbursements for pelvic prolapse procedures have risen within the past few years, in conjunction with increased demand for these procedures, the ASP of these units will increase. The rapid growth of this market is due to increased prevalence of organ prolapse, the decimation of the transvaginal pelvic repair market as well as stable ASP.

Figure 16-15: Sacrocolpopexy Mesh Market, Europe, 2012 – 2022 (€ and US\$)

Year	Units Sold	Growth (%)	ASP (€)	ASP (US\$)	Growth (%)	Market Value (€M)	Market Value (US\$M)	Growth (%)
2012	5,932		€697	\$770		€4.1	\$4.6	
2013	6,254	5.4%	€692	\$765	-0.7%	€4.3	\$4.8	4.7%
2014	6,761	8.1%	€688	\$760	-0.5%	€4.7	\$5.1	7.5%
2015	7,158	5.9%	€683	\$756	-0.6%	€4.9	\$5.4	5.2%
2016	7,519	5.0%	€678	\$750	-0.7%	€5.1	\$5.6	4.3%
2017	7,844	4.3%	€675	\$746	-0.6%	€5.3	\$5.8	3.7%
2018	8,148	3.9%	€671	\$742	-0.5%	€5.5	\$6.0	3.3%
2019	8,404	3.1%	€668	\$738	-0.5%	€5.6	\$6.2	2.6%
2020	8,659	3.0%	€665	\$735	-0.4%	€5.8	\$6.4	2.6%
2021	9,009	4.0%	€663	\$733	-0.3%	€6.0	\$6.6	3.7%
2022	9,255	2.7%	€661	\$731	-0.3%	€6.1	\$6.8	2.4%
CAGR ('15-'22)		3.7%			-0.5%			3.2%

Source: iData Research Inc.

Chart 16-6: Sacrocolpopexy Mesh Market, Europe, 2012 – 2022


Source: iData Research Inc.

Figure 16-16: Units Sold by Country, Sacrocolpopexy Mesh Market, Europe, 2012-2022

Year	Germany	France	U.K.	Italy	Spain	Benelux	Scandi- navia	Austria	Switzer- land	Portugal	Europe	Growth (%)
2012	1,851	800	1,034	480	192	344	475	228	456	72	5,932	
2013	1,912	851	1,121	495	203	363	525	235	474	75	6,254	5.4%
2014	2,168	901	1,197	510	208	383	581	241	495	77	6,761	8.1%
2015	2,334	926	1,264	517	211	403	643	248	532	79	7,158	5.9%
2016	2,458	949	1,312	571	222	423	723	207	571	83	7,519	5.0%
2017	2,577	997	1,350	585	215	444	778	214	598	85	7,844	4.3%
2018	2,692	1,019	1,378	599	215	465	845	221	627	87	8,148	3.9%
2019	2,756	1,038	1,399	612	225	488	911	228	658	88	8,404	3.1%
2020	2,817	1,058	1,414	626	228	510	975	236	704	90	8,659	3.0%
2021	2,977	1,081	1,416	640	233	533	1,041	244	754	91	9,009	4.0%
2022	3,033	1,103	1,410	654	237	557	1,108	253	806	95	9,255	2.7%
CAGR (‘15-’22)	3.8%	2.5%	1.6%	3.4%	1.6%	4.7%	8.1%	0.3%	6.1%	2.6%		3.7%

Source: iData Research Inc.

Figure 16-17: Average Sales Price by Country, Sacrocolpopexy Mesh Market, Europe, 2012-2022 (€)

Year	Germany	France	U.K.	Italy	Spain	Benelux	Scandi- navia	Austria	Switzer- land	Portugal	Europe	Growth (%)
2012	€733	€707	€631	€695	€687	€736	€578	€705	€772	€686	€697	
2013	€731	€702	€630	€690	€685	€732	€578	€704	€755	€684	€692	-0.7%
2014	€728	€695	€628	€685	€681	€727	€580	€702	€739	€682	€688	-0.5%
2015	€725	€688	€625	€680	€677	€722	€581	€700	€724	€681	€683	-0.6%
2016	€722	€682	€621	€675	€673	€717	€582	€698	€711	€680	€678	-0.7%
2017	€718	€677	€618	€669	€669	€711	€584	€697	€700	€679	€675	-0.6%
2018	€715	€671	€616	€663	€665	€706	€585	€696	€690	€678	€671	-0.5%
2019	€713	€667	€615	€657	€660	€700	€586	€695	€683	€672	€668	-0.5%
2020	€711	€663	€613	€653	€655	€694	€587	€694	€676	€668	€665	-0.4%
2021	€709	€659	€612	€648	€650	€687	€588	€693	€672	€665	€663	-0.3%
2022	€708	€657	€612	€644	€645	€681	€589	€692	€670	€662	€661	-0.3%
CAGR (‘15-’22)	-0.3%	-0.7%	-0.3%	-0.8%	-0.7%	-0.8%	0.2%	-0.2%	-1.1%	-0.4%		-0.5%
Source: iData Research Inc.												

Figure 16-18: Average Sales Price by Country, Sacrocolpopexy Mesh Market, Europe, 2012-2022 (US\$)

Year	Germany	France	U.K.	Italy	Spain	Benelux	Scandi- navia	Austria	Switzer- land	Portugal	Europe	Growth (%)
2012	\$811	\$782	\$698	\$769	\$760	\$814	\$639	\$780	\$854	\$758	\$770	
2013	\$808	\$776	\$696	\$763	\$757	\$809	\$640	\$778	\$834	\$756	\$765	-0.7%
2014	\$805	\$769	\$694	\$758	\$753	\$804	\$641	\$776	\$817	\$754	\$760	-0.5%
2015	\$802	\$761	\$691	\$752	\$749	\$798	\$642	\$774	\$800	\$753	\$756	-0.6%
2016	\$798	\$754	\$687	\$746	\$745	\$793	\$644	\$772	\$786	\$751	\$750	-0.7%
2017	\$794	\$748	\$684	\$739	\$740	\$787	\$645	\$771	\$773	\$750	\$746	-0.6%
2018	\$791	\$742	\$682	\$733	\$736	\$780	\$647	\$769	\$763	\$750	\$742	-0.5%
2019	\$788	\$737	\$680	\$727	\$730	\$774	\$648	\$768	\$755	\$744	\$738	-0.5%
2020	\$786	\$733	\$678	\$721	\$724	\$767	\$649	\$767	\$747	\$739	\$735	-0.4%
2021	\$784	\$729	\$677	\$716	\$719	\$760	\$650	\$766	\$743	\$735	\$733	-0.3%
2022	\$783	\$726	\$676	\$712	\$713	\$753	\$651	\$766	\$741	\$732	\$731	-0.3%
CAGR (‘15-’22)	-0.3%	-0.7%	-0.3%	-0.8%	-0.7%	-0.8%	0.2%	-0.2%	-1.1%	-0.4%		-0.5%
Source: iData Research Inc.												

Figure 16-19: Sacrocolpopexy Mesh Market by Country, Europe, 2012-2022 (€M)

Year	Germany	France	U.K.	Italy	Spain	Benelux	Scandi- navia	Austria	Switzer- land	Portugal	Europe	Growth (%)
2012	€1.36	€0.57	€0.65	€0.33	€0.13	€0.25	€0.27	€0.16	€0.35	€0.05	€4.13	
2013	€1.40	€0.60	€0.71	€0.34	€0.14	€0.27	€0.30	€0.17	€0.36	€0.05	€4.32	4.7%
2014	€1.58	€0.63	€0.75	€0.35	€0.14	€0.28	€0.34	€0.17	€0.37	€0.05	€4.65	7.5%
2015	€1.69	€0.64	€0.79	€0.35	€0.14	€0.29	€0.37	€0.17	€0.39	€0.05	€4.89	5.2%
2016	€1.77	€0.65	€0.81	€0.39	€0.15	€0.30	€0.42	€0.14	€0.41	€0.06	€5.10	4.3%
2017	€1.85	€0.68	€0.83	€0.39	€0.14	€0.32	€0.45	€0.15	€0.42	€0.06	€5.29	3.7%
2018	€1.93	€0.68	€0.85	€0.40	€0.14	€0.33	€0.49	€0.15	€0.43	€0.06	€5.47	3.3%
2019	€1.96	€0.69	€0.86	€0.40	€0.15	€0.34	€0.53	€0.16	€0.45	€0.06	€5.61	2.6%
2020	€2.00	€0.70	€0.87	€0.41	€0.15	€0.35	€0.57	€0.16	€0.48	€0.06	€5.76	2.6%
2021	€2.11	€0.71	€0.87	€0.41	€0.15	€0.37	€0.61	€0.17	€0.51	€0.06	€5.97	3.7%
2022	€2.15	€0.72	€0.86	€0.42	€0.15	€0.38	€0.65	€0.17	€0.54	€0.06	€6.12	2.4%
CAGR (‘15-’22)	3.5%	1.8%	1.3%	2.6%	0.9%	3.9%	8.3%	0.1%	4.9%	2.2%		3.2%
Source: iData Research Inc.												

Figure 16-20: Sacrocolpopexy Mesh Market by Country, Europe, 2012-2022 (US\$M)

Year	Germany	France	U.K.	Italy	Spain	Benelux	Scandi- navia	Austria	Switzer- land	Portugal	Europe	Growth (%)
2012	\$1.50	\$0.63	\$0.72	\$0.37	\$0.15	\$0.28	\$0.30	\$0.18	\$0.39	\$0.05	\$4.57	
2013	\$1.55	\$0.66	\$0.78	\$0.38	\$0.15	\$0.29	\$0.34	\$0.18	\$0.40	\$0.06	\$4.78	4.7%
2014	\$1.75	\$0.69	\$0.83	\$0.39	\$0.16	\$0.31	\$0.37	\$0.19	\$0.40	\$0.06	\$5.14	7.5%
2015	\$1.87	\$0.70	\$0.87	\$0.39	\$0.16	\$0.32	\$0.41	\$0.19	\$0.43	\$0.06	\$5.41	5.2%
2016	\$1.96	\$0.72	\$0.90	\$0.43	\$0.17	\$0.34	\$0.47	\$0.16	\$0.45	\$0.06	\$5.64	4.3%
2017	\$2.05	\$0.75	\$0.92	\$0.43	\$0.16	\$0.35	\$0.50	\$0.16	\$0.46	\$0.06	\$5.85	3.7%
2018	\$2.13	\$0.76	\$0.94	\$0.44	\$0.16	\$0.36	\$0.55	\$0.17	\$0.48	\$0.06	\$6.04	3.3%
2019	\$2.17	\$0.77	\$0.95	\$0.44	\$0.16	\$0.38	\$0.59	\$0.18	\$0.50	\$0.07	\$6.20	2.6%
2020	\$2.21	\$0.78	\$0.96	\$0.45	\$0.17	\$0.39	\$0.63	\$0.18	\$0.53	\$0.07	\$6.36	2.6%
2021	\$2.33	\$0.79	\$0.96	\$0.46	\$0.17	\$0.41	\$0.68	\$0.19	\$0.56	\$0.07	\$6.60	3.7%
2022	\$2.37	\$0.80	\$0.95	\$0.47	\$0.17	\$0.42	\$0.72	\$0.19	\$0.60	\$0.07	\$6.76	2.4%
CAGR (‘15-’22)	3.5%	1.8%	1.3%	2.6%	0.9%	3.9%	8.3%	0.1%	4.9%	2.2%		3.2%
Source: iData Research Inc.												

16.4 DRIVERS AND LIMITERS

16.4.1 Market Drivers

Procedure Numbers

The majority of individuals afflicted with pelvic organ prolapse are within the older female population. As the population ages, it is expected that the number of procedures and treatment required for pelvic organ prolapse will increase significantly. Although many women experience asymptomatic prolapse, in more severe cases there are very few options besides surgery.

Transition to Trans-Abdominal Approach

While sacrocolpopexy is not yet the largest pelvic organ prolapse device segment in Europe, it is projected to reach a majority market share by 2022. This is because of a higher interest in minimally invasive as well as robotically-assisted procedures, which can be done with Sacrocolpopexy mesh. Moreover, concerns over the transvaginal method of implanting organ prolapse mesh are expected to drive physician usage of sacrocolpopexy mesh.

16.4.2 Market Limiters

Complications with Repair Devices

In July 2011, the FDA safety communication reported that serious complications associated with the transvaginal placement of surgical mesh for pelvic organ prolapse were not rare. It also stated that it was not clear at that time whether repair with mesh was more effective than traditional non-mesh repair in patients with pelvic organ prolapse and may expose patients to greater risk. This is expected to negatively impact the market for transvaginal mesh pelvic floor repair.

Alternative Treatment Methods

There are several different surgical and non-surgical methods available to treat pelvic organ prolapse. As doctors implement stricter requirements for eligibility and patients are adverse to the negative side effects of mesh, alternative methods are expected to continue increasing as the preferred treatment option.

**Figure 16-21: Drivers and Limiters, Pelvic Prolapse Repair Device Market
Europe, 2015**

Market Drivers
<p>Procedure Numbers</p> <p>Transition to Trans-Abdominal Approach</p>
Market Limiters
<p>Complications with Repair Devices</p> <p>Alternative Treatment Methods</p>
Source: iData Research Inc.

16.5 COMPETITIVE MARKET SHARE ANALYSIS

Astora Women's Health

In 2015, ASTORA, formerly known as American Medical Systems, held a 31.6% market share in the European pelvic organ prolapse repair device market. In the transvaginal mesh segment this company offers the *Elevate™ Apical and Posterior Prolapse Repair System* as well as the *Elevate™ Anterior and Apical Prolapse Repair System*. Both of these systems use grafts to treat either posterior and apical compartment prolapse or anterior and apical compartment prolapse. In the sacrocolpopexy market, ASTORA offers the *Y-Mesh™ Sacrocolpopexy Y-Graft*. The *Y-Mesh™* is designed to repair vaginal vault prolapse and can be implemented using an open abdominal, laparoscopic or robotic approach.

Endo Health Solutions acquired American Medical Systems in 2011. Following the acquisition, Endo rebranded American Medical System's Women's Health division to Astora Women's Health. As part of the initial acquisition of AMS, Endo Health Solutions also acquired over 22,000 lawsuits regarding AMS's vaginal mesh products for the treatment of pelvic organ prolapse and urinary incontinence. Announced in March 2016, Endo International began the process of shutting down Astora Women's Health. Astora closed on March 31st 2016 to "reduce the potential for product liability related to future mesh implants". The withdrawal of Astora from the pelvic organ prolapse repair device market created a major opportunity, with 31.8% of the market available. This report includes leading competitive analyses for both 2015 and 2016, pre- and post-Astora in the market, to demonstrate how the company's market share has been reallocated in the market.

Boston Scientific

Boston Scientific held the second leading position in the pelvic organ prolapse repair device market with a share of 16.9% in 2015. They are projected to dramatically increase their market share in 2016 due to Astora's withdrawal from the market, reaching a market share of 28% in 2016. The product portfolio includes: the *Upsylon™ Y-Mesh* as a bridging material for sacrocolpopexy treatment of a vaginal vault prolapse, the *Colpassist™ Vaginal Positioning Device* to place the mesh during the procedure and the *Capio™ SLIM Suture Capturing Device* is then used to suture the mesh into place. Finally, the product portfolio also includes the *Xenform™ Soft Tissue Repair Matrix*.

CR Bard

In 2015, C. R. Bard held a 15.0% share of the market. C.R. Bard produces the *Alyte® Y-Mesh Graft and FIXT™ Suturing Device*. The mesh has a Y-shape large-pore polypropylene mesh that provides long-term

reinforcement for support structures. This device is also aimed for sacrocolpopexy. Its *Avaulta™ Synthetic Support System* has a soft knit in the central section for compliant organ support, with a stronger knit on the sides to increase the overall strength of the mesh.

Coloplast

Coloplast held a 12.8% share in the market in 2015. Coloplast offers both synthetic and biologic products. For pelvic organ prolapse repair, Coloplast offers both synthetic and biologic products. Their synthetic option is a polypropylene mesh product called *Exair®*, which uses *Novasilk®* synthetic mesh. This company also offers a line of products under the name of *Restorelle* that consists of a full array of products for pelvic organ prolapse repair.

Johnson & Johnson

Ethicon, a Johnson & Johnson company, held the fifth leading position in the 2015 pelvic organ prolapse repair device market with a 6.0% share. Ethicon offers the *Artisyn™*. It is a Y-shaped mesh indicated for sacrocolpopexy and is made of both absorbable and non-absorbable fibers. The material enables the distention of the vaginal flaps while the sacral flaps minimize elongation. In 2012, Ethicon removed its transvaginal mesh from the market due to litigation and more stringent FDA requirements, which reduced the market lead that Ethicon formerly held.

Serag Weisner

Serag Weisner offers the the Seratom® portfolio of textile implants for the pelvic floor. Holding 15.8% of the market in Germany, the company has a total European market share of 4.6%. Serag Weisner is a competitor throughout Europe with the strongest sales in German speaking countries.

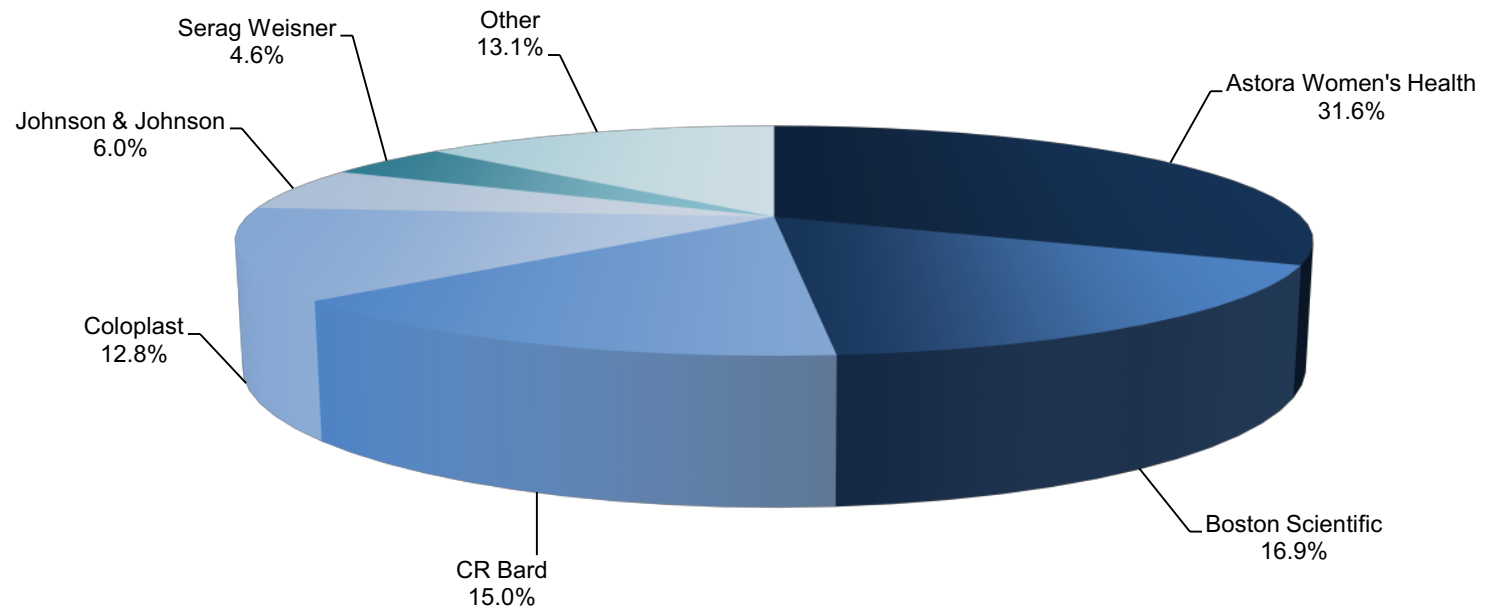
Other Notable Competitors

Other notable competitors, which comprised 13.1% of the market in 2015, include Cousin Biotech, CL Medical Abiss and Neomedic.

Figure 16-22: Leading Competitors by Country, Pelvic Organ Prolapse Repair Device Market, Europe, 2015

Company	Germany	France	U.K.	Italy	Spain	Benelux	Scandi- navia	Austria	Switzer- land	Portugal	Total Market Share
Astora Women's Health	25.2%	40.6%	25.4%	36.7%	40.4%	35.2%	30.4%	30.3%	33.6%	41.8%	31.6%
Boston Scientific	10.1%	18.3%	28.8%	21.4%	16.8%	20.5%	16.7%	16.0%	14.2%	17.0%	16.9%
CR Bard	20.9%	7.4%	15.2%	8.5%	6.4%	9.7%	20.1%	17.4%	17.8%	6.6%	15.0%
Coloplast	10.7%	15.2%	9.1%	17.3%	15.1%	15.6%	15.9%	14.5%	7.7%	15.4%	12.8%
Johnson & Johnson	–	10.5%	7.0%	8.4%	13.0%	7.3%	4.3%	–	13.0%	13.9%	6.0%
Serag Weisner	15.8%	–	–	–	–	–	–	–	–	–	4.6%
Other	17.3%	8.0%	14.5%	7.7%	8.3%	11.7%	12.6%	21.8%	13.7%	5.3%	13.1%
Total	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
Market Value (€M)	€3.6	€1.8	€1.4	€1.1	€0.5	€0.9	€1.3	€0.4	€1.1	€0.2	€12.4
Others include: Cousin Biotech, CL Medical Abiss, Neomedic etc.											
Source: iData Research Inc.											

Chart 16-7: Leading Competitors, Pelvic Organ Prolapse Repair Device Market, Europe, 2015

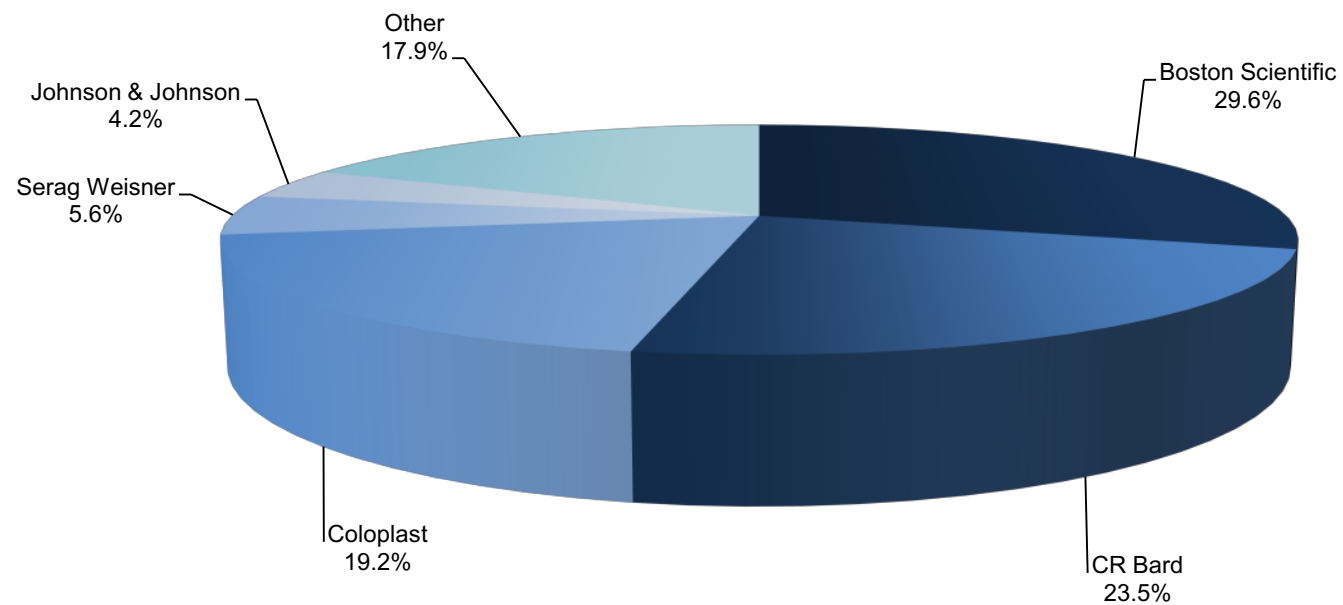


Source: iData Research Inc.

Figure 16-23: Projected Leading Competitors by Country, Pelvic Organ Prolapse Repair Device Market, Europe, 2016

Company	Germany	France	U.K.	Italy	Spain	Benelux	Scandi- navia	Austria	Switzer- land	Portugal	Total Market Share
Boston Scientific	20.3%	32.0%	38.4%	36.6%	28.5%	36.7%	30.7%	31.4%	30.3%	28.4%	29.6%
CR Bard	30.1%	10.0%	22.6%	13.4%	32.4%	15.2%	28.5%	25.6%	30.8%	32.6%	23.5%
Coloplast	15.8%	22.1%	14.7%	26.2%	22.8%	21.9%	22.9%	20.2%	15.5%	22.1%	19.2%
Serag Weisner	19.2%	—	—	—	—	—	—	—	—	—	5.6%
Johnson & Johnson	—	6.5%	4.3%	8.1%	7.6%	5.7%	4.0%	—	8.4%	7.8%	4.2%
Other	14.6%	29.4%	20.0%	15.7%	8.7%	20.5%	13.9%	22.8%	15.0%	9.1%	17.9%
Total	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
Market Value (€M)	€3.6	€1.8	€1.4	€1.1	€0.5	€0.9	€1.4	€0.3	€1.1	€0.2	€12.3
Others include: Cousin Biotech, CL Medical Abiss, Neomedic etc.											
Source: iData Research Inc.											

Chart 16-8: Projected Leading Competitors, Pelvic Organ Prolapse Repair Device Market, Europe, 2016



Source: iData Research Inc.

17

HYSTEROSALPINGOGRAPHY CATHETER MARKET

17.1 INTRODUCTION

Hysterosalpingography (HSG) catheters, also known as HS catheters, are used for hysterosalpingography and sonohysterography procedures. These devices are used by practitioners to inject either a contrast media or sterile saline into the uterine cavity and fallopian tubes through the cervical opening. These procedures are used to evaluate infertility, pregnancy loss, uterine bleeding or menstrual disorders, and to assess tubal patency and uterine pathology.

Hysterosalpingography (HSG) requires the infusion of radiographic contrast dye via the HSG catheter. This radiologic procedure uses X-rays to determine if there are blockages in the fallopian tubes and where they may be located as the dye travels through the reproductive tract. Sonohysterography, on the other hand, uses sterile saline to help render images of the uterus and any abnormalities with the aid of a transabdominal ultrasound.

Alternatives to hysterosalpingography and sonohysterography include hysteroscopy and transvaginal ultrasounds, which do not necessitate the use of HSG catheters. As these procedures are often used to examine fertility, other procedures that compete with the fertility testing aspect of HSG catheter use are home ovulation test kits, blood tests to check hormone levels and cervical functioning tests.

HSG catheters contain a soft plastic sheath, with the catheter and stopper on one end and a stopcock on the other for the infusion of contrast media or sterile fluid. It is necessary for HSG catheters to have stoppers that obstruct the external cervical opening in order to facilitate the retention of fluid within the uterus. These blocking elements may be latex or latex-free balloons, or be a foam based stopper. The

sheath of the catheter is traditionally flexible, but may be available in rigid as well as malleable forms for difficult cases or easier insertion.

17.2 MARKET ANALYSIS AND FORECAST

HSG catheters, also sometimes called HS, SIS or SGH catheters, are used for hysterosalpingography and sonohysterography. Technically, HSG catheters are used for hysterosalpingography procedures while HS, SIS and SGH catheters are simpler and are utilized during a sonohysterography procedure. However, these catheters are used interchangeably and can be used for both procedures. For the purpose of this report, as these catheters are used interchangeably, they will both be considered under the HSG catheter market. Despite the slight decline in market value, the unit growth is positive, thus the reduction in market value is due to ASP depreciation.

Unit sales are expected to increase during the forecast period due to increases in procedure rates. As HSG catheters are often used to test female fertility, the projected increases in unit sales correspond to the increases in fertility treatments. Fertility treatments are becoming more common as the average age of pregnancy has increased substantially. As women continue to delay pregnancy, the need for fertility treatments is projected to increase.

Additional gynecological treatments that utilize HSG catheters are in cases of women with damaged fallopian tubes. Finally, as the population demographic continues to skew towards an aging population, HSG catheters are also required for the treatment of uterine conditions. The use of HSG catheters to treat different conditions that are projected to have increasing procedure numbers is a strong indication the market sales will continue to be similar to increasing throughout the reporting period.

Catheters are often sold in packages of five for an ASP of approximately €105. The list price, however, can receive discounts up to 30% off, with a closer ASP for a box of five being €70 to €80. The market is also significantly different between the private sales market and public tenders by manufacturers. The ASP of an HSG catheter by public tender is €20 per unit, compared to €25 in the private market. This also affects market share distribution, as smaller manufacturers are more likely to have private sales opposed to winning public contracts.

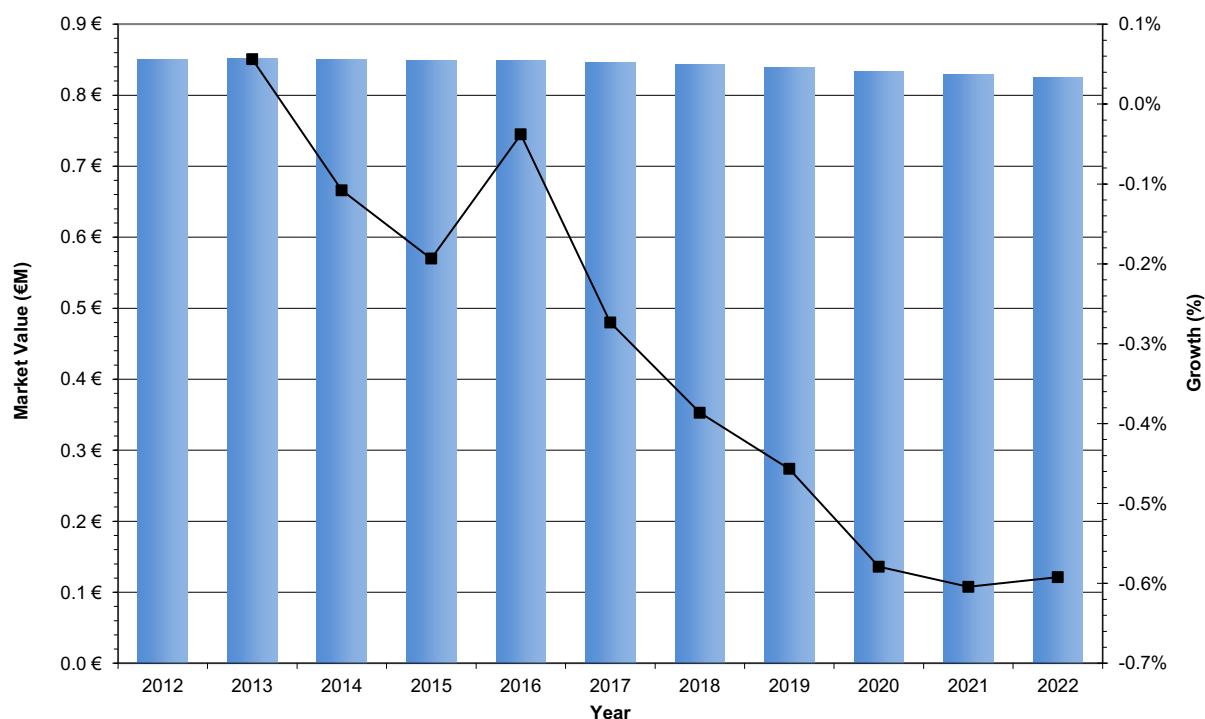
The decrease in the ASP of HSG catheters is attributable to the entrance of Asian-made catheters into the market. Asian HSG catheters, or inexpensive options, are popular in price sensitive economies such as Spain and Portugal. The resulting effect is the market becoming bi-model with two different price points for differing standards of quality. The introduction of less expensive competitor products is also causing a downward pressure and price erosion in the market.

Imaging technology is one aspect of the health care industry that influences HSG/SIS sales. As patients and their doctors move away from the use of X-rays due to radiation concerns, the number of SIS procedures is expected to increase in comparison to HSG procedures. Moreover, not only is the availability of ultrasound units greater than X-ray units, great strides have been seen in the past few years in ultrasound technology, which should further increase the popularity of SIS procedures performed as the forecast period progresses.

Figure 17-1: Hysterosalpingography Catheter Market, Europe, 2012 – 2022 (€ and US\$)

Year	Units Sold	Growth (%)	ASP (€)	ASP (US\$)	Growth (%)	Market Value (€M)	Market Value (US\$M)	Growth (%)
2012	38,000		€22.39	\$24.76		€0.85	\$0.94	
2013	38,425	1.1%	€22.16	\$24.49	-1.1%	€0.85	\$0.94	0.1%
2014	38,796	1.0%	€21.92	\$24.23	-1.1%	€0.85	\$0.94	-0.1%
2015	39,146	0.9%	€21.68	\$23.97	-1.1%	€0.85	\$0.94	-0.2%
2016	39,472	0.8%	€21.49	\$23.76	-0.9%	€0.85	\$0.94	0.0%
2017	39,773	0.8%	€21.27	\$23.52	-1.0%	€0.85	\$0.94	-0.3%
2018	40,054	0.7%	€21.04	\$23.26	-1.1%	€0.84	\$0.93	-0.4%
2019	40,320	0.7%	€20.81	\$23.01	-1.1%	€0.84	\$0.93	-0.5%
2020	40,544	0.6%	€20.57	\$22.75	-1.1%	€0.83	\$0.92	-0.6%
2021	40,748	0.5%	€20.35	\$22.50	-1.1%	€0.83	\$0.92	-0.6%
2022	40,922	0.4%	€20.14	\$22.27	-1.0%	€0.82	\$0.91	-0.6%
CAGR ('15-'22)		0.6%			-1.0%			-0.4%

Source: iData Research Inc.

Chart 17-1: Hysterosalpingography Catheter Market, Europe, 2012 – 2022

Source: iData Research Inc.

Figure 17-2: Units Sold by Country, Hysterosalpingography Catheter Market, Europe, 2012-2022

Year	Germany	France	U.K.	Italy	Spain	Benelux	Scandi- navia	Austria	Switzer- land	Portugal	Europe	Growth (%)
2012	7,436	7,477	6,323	5,660	4,224	2,408	2,046	753	738	934	38,000	
2013	7,532	7,477	6,538	5,728	4,279	2,381	2,025	765	753	946	38,425	1.1%
2014	7,615	7,459	6,735	5,791	4,339	2,353	2,002	777	767	958	38,796	1.0%
2015	7,691	7,434	6,923	5,849	4,404	2,322	1,982	788	782	970	39,146	0.9%
2016	7,753	7,397	7,103	5,908	4,472	2,291	1,973	799	796	981	39,472	0.8%
2017	7,799	7,352	7,281	5,961	4,543	2,260	1,966	809	809	992	39,773	0.8%
2018	7,834	7,301	7,455	6,015	4,613	2,229	1,962	819	823	1,002	40,054	0.7%
2019	7,860	7,246	7,627	6,069	4,682	2,198	1,960	829	835	1,012	40,320	0.7%
2020	7,868	7,190	7,787	6,117	4,748	2,167	1,960	838	844	1,022	40,544	0.6%
2021	7,868	7,133	7,943	6,166	4,810	2,136	1,960	847	853	1,032	40,748	0.5%
2022	7,860	7,075	8,086	6,209	4,867	2,106	1,962	854	861	1,041	40,922	0.4%
CAGR (‘15-’22)	0.3%	-0.7%	2.2%	0.9%	1.4%	-1.4%	-0.1%	1.2%	1.4%	1.0%		0.6%

Source: iData Research Inc.

Figure 17-3: Average Sales Price by Country, Hysterosalpingography Catheter Market, Europe, 2012-2022 (€)

Year	Germany	France	U.K.	Italy	Spain	Benelux	Scandi- navia	Austria	Switzer- land	Portugal	Europe	Growth (%)
2012	€21.60	€25.83	€22.60	€20.74	€19.63	€22.35	€23.81	€21.53	€22.50	€19.88	€22.39	
2013	€21.40	€25.57	€22.41	€20.51	€19.44	€22.24	€23.33	€21.27	€22.21	€19.60	€22.16	-1.1%
2014	€21.20	€25.29	€22.21	€20.26	€19.22	€22.12	€23.16	€21.00	€21.97	€19.21	€21.92	-1.1%
2015	€21.00	€25.00	€22.00	€20.00	€19.00	€22.00	€23.00	€20.73	€21.73	€19.00	€21.68	-1.1%
2016	€20.79	€24.70	€21.79	€19.74	€18.77	€21.87	€23.92	€20.45	€21.51	€18.81	€21.49	-0.9%
2017	€20.57	€24.40	€21.58	€19.52	€18.53	€21.74	€24.16	€20.16	€21.29	€18.62	€21.27	-1.0%
2018	€20.35	€24.08	€21.36	€19.31	€18.28	€21.60	€24.28	€19.86	€21.08	€18.44	€21.04	-1.1%
2019	€20.12	€23.76	€21.13	€19.12	€18.03	€21.46	€24.38	€19.56	€20.87	€18.25	€20.81	-1.1%
2020	€19.88	€23.43	€20.92	€18.92	€17.76	€21.31	€24.45	€19.25	€20.68	€18.09	€20.57	-1.1%
2021	€19.65	€23.10	€20.71	€18.72	€17.58	€21.16	€24.50	€18.95	€20.50	€17.92	€20.35	-1.1%
2022	€19.41	€22.78	€20.51	€18.49	€17.58	€21.01	€24.50	€18.65	€20.33	€17.78	€20.14	-1.0%
CAGR (‘15–’22)	-1.1%	-1.3%	-1.0%	-1.1%	-1.1%	-0.7%	0.9%	-1.5%	-0.9%	-0.9%		-1.0%
Source: iData Research Inc.												

Figure 17-4: Average Sales Price by Country, Hysterosalpingography Catheter Market, Europe, 2012-2022 (US\$)

Year	Germany	France	U.K.	Italy	Spain	Benelux	Scandi- navia	Austria	Switzer- land	Portugal	Europe	Growth (%)
2012	\$23.88	\$28.55	\$24.99	\$22.93	\$21.70	\$24.71	\$26.32	\$23.81	\$24.88	\$21.98	\$24.76	
2013	\$23.67	\$28.27	\$24.77	\$22.68	\$21.49	\$24.59	\$25.80	\$23.51	\$24.56	\$21.67	\$24.49	-1.1%
2014	\$23.44	\$27.96	\$24.55	\$22.40	\$21.25	\$24.46	\$25.61	\$23.22	\$24.29	\$21.24	\$24.23	-1.1%
2015	\$23.22	\$27.64	\$24.32	\$22.11	\$21.01	\$24.32	\$25.43	\$22.92	\$24.02	\$21.01	\$23.97	-1.1%
2016	\$22.98	\$27.31	\$24.09	\$21.82	\$20.75	\$24.18	\$26.45	\$22.61	\$23.78	\$20.80	\$23.76	-0.9%
2017	\$22.75	\$26.97	\$23.85	\$21.58	\$20.49	\$24.04	\$26.71	\$22.29	\$23.54	\$20.59	\$23.52	-1.0%
2018	\$22.50	\$26.63	\$23.61	\$21.35	\$20.21	\$23.88	\$26.84	\$21.96	\$23.31	\$20.38	\$23.26	-1.1%
2019	\$22.24	\$26.27	\$23.37	\$21.13	\$19.93	\$23.72	\$26.95	\$21.63	\$23.07	\$20.18	\$23.01	-1.1%
2020	\$21.98	\$25.90	\$23.13	\$20.92	\$19.64	\$23.56	\$27.03	\$21.29	\$22.87	\$20.00	\$22.75	-1.1%
2021	\$21.72	\$25.54	\$22.90	\$20.69	\$19.44	\$23.39	\$27.09	\$20.95	\$22.66	\$19.82	\$22.50	-1.1%
2022	\$21.46	\$25.18	\$22.67	\$20.44	\$19.44	\$23.23	\$27.09	\$20.62	\$22.48	\$19.66	\$22.27	-1.0%
CAGR (‘15-’22)	-1.1%	-1.3%	-1.0%	-1.1%	-1.1%	-0.7%	0.9%	-1.5%	-0.9%	-0.9%		-1.0%

Source: iData Research Inc.

Figure 17-5: Hysterosalpingography Catheter Market by Country, Europe, 2012-2022 (€M)

Year	Germany	France	U.K.	Italy	Spain	Benelux	Scandi- navia	Austria	Switzer- land	Portugal	Europe	Growth (%)
2012	€0.161	€0.193	€0.143	€0.117	€0.083	€0.054	€0.049	€0.016	€0.017	€0.019	€0.851	
2013	€0.161	€0.191	€0.147	€0.117	€0.083	€0.053	€0.047	€0.016	€0.017	€0.019	€0.851	0.06%
2014	€0.161	€0.189	€0.150	€0.117	€0.083	€0.052	€0.046	€0.016	€0.017	€0.018	€0.850	-0.11%
2015	€0.162	€0.186	€0.152	€0.117	€0.084	€0.051	€0.046	€0.016	€0.017	€0.018	€0.849	-0.19%
2016	€0.161	€0.183	€0.155	€0.117	€0.084	€0.050	€0.047	€0.016	€0.017	€0.018	€0.848	-0.04%
2017	€0.160	€0.179	€0.157	€0.116	€0.084	€0.049	€0.047	€0.016	€0.017	€0.018	€0.846	-0.27%
2018	€0.159	€0.176	€0.159	€0.116	€0.084	€0.048	€0.048	€0.016	€0.017	€0.018	€0.843	-0.39%
2019	€0.158	€0.172	€0.161	€0.116	€0.084	€0.047	€0.048	€0.016	€0.017	€0.018	€0.839	-0.46%
2020	€0.156	€0.168	€0.163	€0.116	€0.084	€0.046	€0.048	€0.016	€0.017	€0.018	€0.834	-0.58%
2021	€0.155	€0.165	€0.165	€0.115	€0.085	€0.045	€0.048	€0.016	€0.017	€0.019	€0.829	-0.60%
2022	€0.153	€0.161	€0.166	€0.115	€0.086	€0.044	€0.048	€0.016	€0.017	€0.019	€0.824	-0.59%
CAGR (‘15-’22)	-0.8%	-2.0%	1.2%	-0.3%	0.3%	-2.0%	0.8%	-0.4%	0.4%	0.1%		-0.4%

Source: iData Research Inc.

Figure 17-6: Hysterosalpingography Catheter Market by Country, Europe, 2012-2022 (US\$M)

Year	Germany	France	U.K.	Italy	Spain	Benelux	Scandi- navia	Austria	Switzer- land	Portugal	Europe	Growth (%)
2012	\$0.178	\$0.214	\$0.158	\$0.130	\$0.092	\$0.059	\$0.054	\$0.018	\$0.018	\$0.021	\$0.941	
2013	\$0.178	\$0.211	\$0.162	\$0.130	\$0.092	\$0.059	\$0.052	\$0.018	\$0.018	\$0.021	\$0.941	0.1%
2014	\$0.179	\$0.209	\$0.165	\$0.130	\$0.092	\$0.058	\$0.051	\$0.018	\$0.019	\$0.020	\$0.940	-0.1%
2015	\$0.179	\$0.205	\$0.168	\$0.129	\$0.093	\$0.056	\$0.050	\$0.018	\$0.019	\$0.020	\$0.938	-0.2%
2016	\$0.178	\$0.202	\$0.171	\$0.129	\$0.093	\$0.055	\$0.052	\$0.018	\$0.019	\$0.020	\$0.938	0.0%
2017	\$0.177	\$0.198	\$0.174	\$0.129	\$0.093	\$0.054	\$0.053	\$0.018	\$0.019	\$0.020	\$0.935	-0.3%
2018	\$0.176	\$0.194	\$0.176	\$0.128	\$0.093	\$0.053	\$0.053	\$0.018	\$0.019	\$0.020	\$0.932	-0.4%
2019	\$0.175	\$0.190	\$0.178	\$0.128	\$0.093	\$0.052	\$0.053	\$0.018	\$0.019	\$0.020	\$0.928	-0.5%
2020	\$0.173	\$0.186	\$0.180	\$0.128	\$0.093	\$0.051	\$0.053	\$0.018	\$0.019	\$0.020	\$0.922	-0.6%
2021	\$0.171	\$0.182	\$0.182	\$0.128	\$0.093	\$0.050	\$0.053	\$0.018	\$0.019	\$0.020	\$0.917	-0.6%
2022	\$0.169	\$0.178	\$0.183	\$0.127	\$0.095	\$0.049	\$0.053	\$0.018	\$0.019	\$0.020	\$0.911	-0.6%
CAGR (‘15-’22)	-0.8%	-2.0%	1.2%	-0.3%	0.3%	-2.0%	0.8%	-0.4%	0.4%	0.1%		-0.4%

Source: iData Research Inc.

17.3 DRIVERS AND LIMITERS

17.3.1 Market Drivers

Aging Population

As the population ages, an increased prevalence of age related conditions, such as abnormal uterine bleeding, should occur and will require a corresponding increase in the number of hysterosalpingography and sonohysterography procedures done. Moreover, as the average age of pregnancy increases, higher rates of fertility testing will be required. This trend is further supported by elevated rates of STIs, which are potentially damaging to the fallopian tubes and are currently a major public health concern across Europe. The implication of increased procedure numbers is increased unit sales for HSG catheters.

17.3.2 Market Limiters

Foreign Entrants

In recent years, there have been more foreign companies offering HSG catheters at lower prices. This creates a climate of price pressurization, which has led to a steady decline in ASP that will continue throughout the forecast period.

**Figure 17-7: Drivers and Limiters, Hysterosalpingography Catheter Market
Europe, 2015**

Market Drivers
Aging Population
Market Limiters
Foreign Entrants
Source: iData Research Inc.

17.4 COMPETITIVE MARKET SHARE ANALYSIS

Cooper Surgical

In 2015, Cooper Surgical led the HSG catheter market with a 37.3% share. Cooper Surgical offers a wide variety of HSG and HS catheters specialized for either hysterosalpingography, sonohysterography or both. Its devices include the *EZ-HSG™*, which is a balloonless and latex-free catheter, the *H/S Elliptosphere™*, which is offered as a catheter set and tray, and a standard H/S catheter that is available with or without an integrated stylet. Its various HS and HSG catheters are available with adjustments for various patient types. Diversifying its HSG catheters may allow it more extensive penetration into the end-user market. The company's lead in this market can be attributed, in part, to its exceptional brand recognition within the health care community, large supply network and established distribution channels.

Cooper Surgical, a branch of Cooper Companies, is a company that is dedicated to women's health products. It has a wide range of products available for women's health and has, over the years, acquired a wide portfolio of companies in order to deliver an expansive range of healthcare products to women. These products are available at the three major point-of-care areas for women, which consist of offices, hospitals and fertility clinics.

Cook Medical

Cook Medical held the second largest share in 2015 with 35.2% of the market with its extensive variety of gynecological imaging catheters in a multitude of product families. The Cook-branded *Cook® Silicone Balloon Catheter* is ideal for saline infusion for sonohysterography. Some of the other families of products that Cook medical distributes are the *uVue™ HSG/SHG Catheter* and the *Goldstein Sonohysterography Catheter*.

Cook Medical manufacturing companies, a collection of companies in the corporate family of Cook Group, is involved with the worldwide sales of various medical products. Some of the medical specialties of which Cook Medical manufactures devices for include endovascular therapy, critical care medicine, general surgery, urology, endoscopy and obstetrics and gynecology. The large network of companies and established brand allows Cook Medical products to be able to be distributed and sold widely. Moreover, as the company is globally situated, it is better equipped to handle any depressions in the economy. However, as the company is large, individual attention to struggling or smaller market products is difficult.

Other Notable Competitors

Due to the disposable nature of these devices, there are a plethora of companies that produce and distribute HSG catheters. These companies, who accounted for 28% of the market, include Angiotech/Argon Medical, Bioteque, CRI/Thomas Medical, GTA Medical Products, MedGyn, Mermaid Medical, Monarch Medical, Rocket Medical, Shanghai Sonen International Logistics Co. Ltd. and Qingdao Sinoland International Trade Co. Ltd.

Monarch products include catheters for both HSG and SIS procedures in both 5 Fr and 7 Fr sizes with a balloon stopper. Its HSG catheters are used for both hysterosalpingography and sonohysterography procedures, while its SIS/SHG catheter with cervical cone is specified for sonohysterography alone.

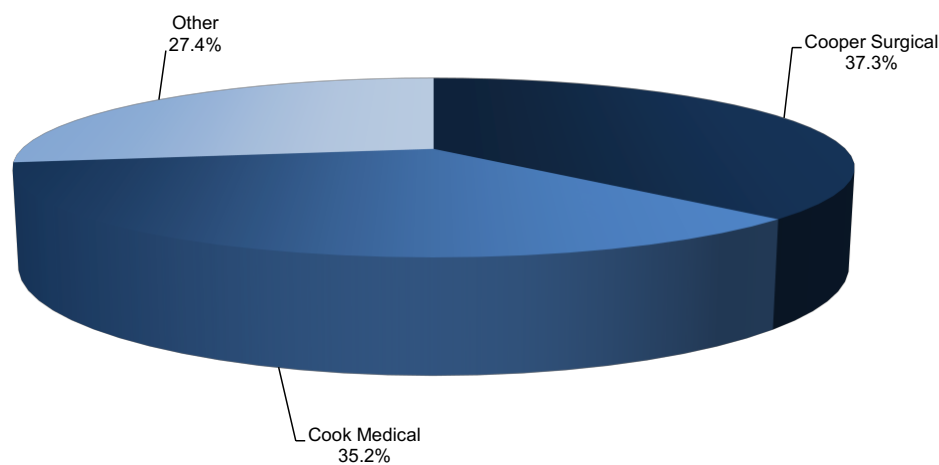
Thomas Medical, a division of Catheter Research Inc. (CRI), offers a wide variety of HS/HSG catheters. It offers its catheters in two sizes, 5 Fr and 7 Fr, and provides a stylet. Its family of products includes the *Sono-Inject Sonohysterography Catheter*, the *Shapeable HS catheter* and *EZinject Sonohysterography Catheter*, among many others.

CRI/Thomas Medical has also launched the HSG catheter, the *Miller Advance Catheter™*, which is a premium quality brand catheter with new technology. Designed in partnership with Dr. Charles Miller, this catheter is indicated for use in HSG and SIS procedures. The catheter has a thinner diameter and a memory sheath, both of which maximize comfort for the patient and the procedure time for the practitioner. The shapeable shaft of this catheter also enables a more comfortable procedure for patients with atypically curved cervix canals.

CRI/Thomas Medical's new catheter is branded as a premium quality HSG catheter featuring technological innovations, which the market has not seen for several years. This is allowing the company to pursue an aggressive price point. Active marketing due to the launch and higher asking price of the product should drive growth and help slow the ASP depreciation. By diversifying the quality of its HSG catheter devices and entering into a design partnership, CRI/Thomas Medical is creating a niche for itself within the large HSG market.

Figure 17-8: Leading Competitors, Hysterosalpingography Catheter Market, Europe, 2015

Company	Market Share
Cooper Surgical	37.3%
Cook Medical	35.2%
Other	27.4%
Total	100.0%
Market Value (€M)	€0.8
Others include: GCD, Argon, Mermaid Medical, etc.	
Source: iData Research Inc.	

Chart 17-2: Leading Competitors, Hysterosalpingography Catheter Market, Europe, 2015

Source: iData Research Inc.

18

ABBREVIATIONS

ART	Assisted Reproduction Technologies
ASP	Average Selling Price
CAGR	Compound Annual Growth Rate
FDA	Food and Drug Administration
FER	Frozen Embryo Replacement
EU	European Union
GDP	Gross Domestic Product
GEA	Global Endometrial Ablation
HSG	Hysterosalpingography
ICSI	Intracytoplasmic Sperm Injection
IVF	In-Vitro Fertilization
IUD	Intra-Uterine Device
IUS	Intra-Uterine System
POP	Pelvic Organ Prolapse
PVA	Polyvinyl Alcohol
SUI	Stress Urinary Incontinence
TO Slings	Transobturator Slings
TVT	Tension-Free Vaginal Tape
UAE	Uterine Artery Embolization
UFE	Uterine Fibroid Embolization
UTI	Urinary Tract Infection