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GlobalData
MediPoint

HERNIA REPAIR – GLOBAL ANALYSIS AND MARKET FORECASTS

Executive Summary

Overall Hernia Repair, Key Metrics in Major Markets		
	2012	2019
Prevalence of Hernias*	19 million	20 million
Procedure Volumes+		
US	1.172m	1.248m
5EU	769,000	780,000
South America	609,000	646,000
APAC	5.430m	5.817m
Market Sales ($m)		
US	$422m	$444m
5EU	$239m	$232m
South America	$172m	$204m
APAC	$1.011bn	$1.239bn
Market Drivers	**Importance**	**Satisfaction**
Consistent Hernia Prevalence	↑↑↑	↑↑
Transition from Open to Laparoscopic Hernia Repair	↑↑↑	↑↑
Fall of Watchful Waiting	↑↑↑	↑↑
Residents Being Trained in Laparoscopic Hernia Repair	↑↑↑	↑
Market Barriers		
Group Purchasing Organizations		
Reimbursement		
Cost		
Self-Gripping Technology		
Mosquito Net Mesh		

Source: GlobalData, Primary Research Interviews with Leading Herniologists and General Surgeons (2013).

Note: 5EU = France, Germany, Italy, Spain, and UK.

*Assuming that the hernia market is solely composed of inguinal, incisional, and umbilical hernias.

+Procedure volumes are approximated. See accompanying forecast model for specific numbers.

Sales for Hernia Mesh Repair by Region

GlobalData estimates the overall hernia repair market in 2012 to be $1.844 billion across the 10 regions covered in this report, which are the United States (US), France, Germany, Italy, Spain, the United Kingdom (UK), Japan, Brazil, China, and India. By the end of the forecast period in 2019, sales will have grown to over $2.120 billion with a Compound Annual Growth Rate (CAGR) of 2.01%.

While the developed economies of Japan and the United States occupy a large proportion of the global hernia repair market, it is the developing nation of India that occupies nearly a third of the global market, at 30% in 2012. The sheer population of the country and their improving market access to healthcare is fueling annual procedural volumes upwards of three million. Additionally, the country has an overwhelming adoption of composite meshes for incisional hernia repair that is driving growth in market value through their higher average selling prices.

Besides India, the United States is one of the largest economies represented in the global market in 2012, with a 24% share. While the procedure volumes are a third of India's procedure volumes, the country derives its significant market valuation through its adoption of more expensive meshes such as biological, composite and 3D meshes.

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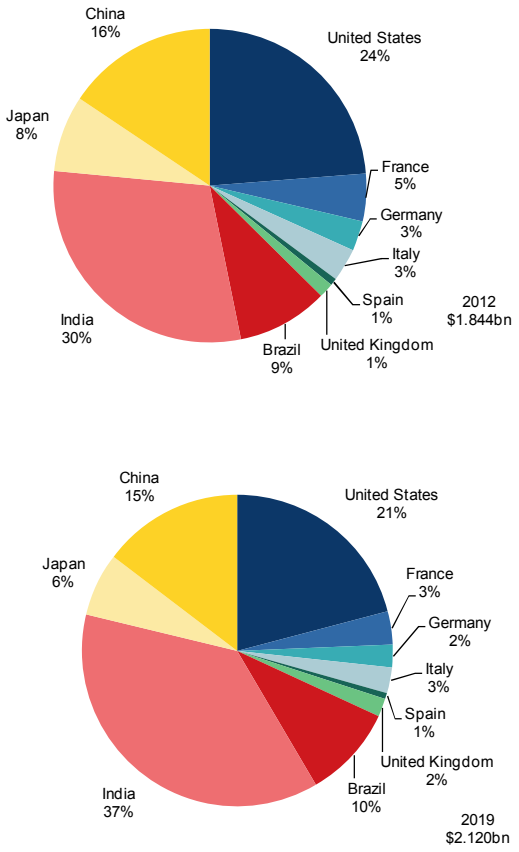
Over the course of the forecast, India's position as a market-leading economy will be further cemented. India's share of the global hernia repair market is expected to significantly increase, so that it occupies 37% by 2019. The primary drivers for this growth are the large growth in the population and the adoption of the laparoscopic technique.

Overall Hernia Mesh Repair Revenue by Major Market, 2012 and 2019



Source: GlobalData, Primary Research Interviews with Leading Herniologists and General Surgeons (2013).

Growth of the Laparoscopic Technique

Hernia repair has evolved over the years to address the challenges in treating patients and to continue the mission of reducing the recurrence rates and the incidences of postoperative pain. More recently, there has been a shift in surgical technique from an open approach to a laparoscopic approach that has resulted in improvements in a variety of patient outcomes. Clinical trials have validated laparoscopy's positive impact on chronic pain, average recovery period, and recurrence rate. The major markets covered in this report are experiencing varying adoption levels of this technique. Some countries, such as the United States and India, will experience significant adoption over the forecast period, while other countries, such as Italy and Spain, are going to have stagnant growth over the forecast period.

Barriers Impede Growth

Mesh manufacturers in the hernia repair market not only face the typical hurdles of reimbursement but also face competition from market substitutes. Manufacturers of higher-priced composite, 3D and biological meshes are not being adequately reimbursed. Flatsheet meshes are close to a third of their prices and offer comparable results for certain clinical outcomes. Additionally, a new category of self-fixating meshes has the potential to emerge. Surgeons are optimistic of the technology despite its ambivalent clinical outcomes. If these clinical outcomes prove to be substantial enough to drastically improve patient

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outcomes or reduce operating costs, this new class of meshes will significantly reduce the market shares of older mesh classes. Additionally, the excellent clinical trial results of mosquito net mesh are significantly impacting the entrance of traditional mesh manufacturer's product lines into poorer economies.

While the clinical investigation of the laparoscopic technique has produced significant improvements in patient outcomes, it has only produced the initial momentum for this dynamic shift, and additional forces will be needed to sustain its growth. Laparoscopy still has a lot of skeptics despite the state of its clinical trial data, its added costs, and the large learning curve required to achieve a high rate of operative success. Additional clinical investigations need to be conducted in order to validate this technique's clinical and economic benefits in the treatment of hernias. This is where the majority of this market's unmet needs lie. A successful undertaking of these types of investigations would not only appeal to surgeons and patients but also to insurance companies, who are playing an increasing role in determining a modality's success

Opportunities for Current and Future Players

Despite the challenges that the hernia repair market faces, there are still opportunities for medical device manufacturers to increase revenue and continue to improve patient outcomes. Published literature has cemented the benefits of the laparoscopic technique and surgeons have begun flocking to the technique as a result. Certain meshes utilized with the laparoscopic technique carry a much higher average selling price than the standard flatsheet meshes and thus present a significant opportunity for revenue growth.

Literature has also revealed the long learning curve associated with the technique. Surgeons are expected to respond to this by operating in a more specialized setting so they can achieve better patient outcomes. The needs of these specialized laparoscopic surgeons are going to be drastically different than the needs of the general surgeon in a large community hospital. Companies can incorporate these needs into specialized meshes that offer properties and prices that appeal to this surgeon population.

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What Do Physicians Think?

There has been a large shift in surgical technique from an open repair to a laparoscopic approach. Clinical investigations have found the approach to produce lower incidences of chronic pain and recurrence and a reduced recovery period for patients to return to normal activities.

"There is a big push from the patients and the industry to have less invasive procedures now."

-Key Opinion Leader, April 2013

More specifically, surgeons have become more partial to performing laparoscopic transabdominal pre-peritoneal (TAPP) procedures rather than totally extraperitoneal (TEP) procedures. The TAPP procedure is technically much easier to perform than TEP, since the latter procedure is associated with a much more difficult field of view.

"Most of the surgeons that do laparoscopic [procedures] do TAPP but we are the rare [clinic] that does TEP."

-Key Opinion Leader, April 2013

Some surgeons remain skeptical on the benefits of the laparoscopic approach.

"[Laparoscopy] has not [demonstrated enough added] benefit that it will change [the] number of procedures done laparoscopically."

-Key Opinion Leader, April 2013

"[I will do] a laparoscopic repair but I prefer to do an open repair. I feel it can be as good. You have to select the cases. I'm only comfortable doing laparoscopic when it's a relatively small defect."

-Key Opinion Leader, April 2013

However, there exists reluctance among the surgeon community to adopt the laparoscopic approach given the immensely higher learning curve for the procedure. This is not expected to be an issue with the next generation of surgeons who are currently being trained in the procedure and are receiving the practice early in their career.

"You do need to train the residents to do the procedures. The residents do like doing the laparoscopic procedures. The next generation of guys will want to do everything laparoscopically."

-Key Opinion Leader, April 2013

Watchful waiting is a concept that was derived from the high complication rates associated with hernia surgery, including infection, recurrence, and chronic pain. Some surgeons thought delaying surgical interventions in asymptomatic patients would shield patients from unnecessary treatment. However, recently published clinical trial data has found that watchful waiting only delays surgery and a large percentage of patients will inevitably have to undergo repair. However, there are some surgeons that utilize watchful waiting in certain patient circumstances.

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"Yes. Watchful waiting is very popular, especially for umbilical hernia and especially if the patient is not symptomatic or not obese. If the patient is obese, than watchful waiting is not really a good idea. But if it's a lean patient and he can palpitate his own hernia and he does not feel any pain then it's no problem to keep it."

-Key Opinion Leader, April 2013

Besides watchful waiting, the reimbursement landscape presents a large hurdle for the adoption of more expensive meshes. Large pore and small pore meshes have average selling prices that are approximately a third of the average selling price of composite, biological, or 3D meshes.

"I always try to convince people that it is not the administration that is doing the surgery, it's the surgeons. What is best for the patients is the best for all of us. That is not the typical approach of our society or healthcare."

-Key Opinion Leader, April 2013

"I think the reimbursement is going to be the [clearest] decision in the future. In the UK, they are trying to decrease the prices by doing a Lichtenstein with local anesthesia. So composite meshes are just too expensive."

-Key Opinion Leader, April 2013

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2 Introduction

Hernia is a term used to describe the protrusion of an internal organ or tissue through a weak portion of a muscle or connective tissue. The majority of hernias occur in the abdomen, where they are caused by a combination of increased abdominal pressure and a weakness in a particular portion of the abdomen (which is often present at birth). Certain conditions such as obesity and persistent coughing can cause an increase in intra-abdominal pressure and contribute to hernia development.

There are several types and subtypes of hernias, classified based on their location, pathophysiology, and the presence of the condition or contributing factors at birth. There are three hernia types that essentially comprise the entire hernia market, inguinal (71%), umbilical (14%), and incisional (4.7%) (Dabbas et al., 2011). While another form of hernia, epigastric, was found to have a slightly higher prevalence than incisional (6.6%), it is not the focal point of medical and industry research as incisional hernia repairs are. Inguinal hernias occur when intra-abdominal contents protrude through a weak spot in the abdominal wall near the groin. Incisional hernias develop after an incision from an abdominal surgery does not properly heal. Umbilical hernias are protrusions of intra-abdominal contents through the abdominal wall near the naval region. The most common symptom with these types of hernias is persistent pain, which is present in varying degrees.

Since the various types of hernias differ in patients by severity, the amount of resultant pain can range from nonexistent to debilitating. Currently, a debate exists amongst surgeons over whether to surgically manage a hernia upon its diagnosis or to wait until the hernia begins producing debilitating symptoms. Thus the percentage of patients with a particular type of hernia that are surgically managed varies between geographies.

Introduction

When discussing those patients that decide to undergo surgical interventions for their hernia, the topic will typically turn towards the method of operation. We are in the midst of a tidal shift from the standard method of open repair to the technically difficult method of laparoscopic repair. The laparoscopic approach has been shown to decrease hospital stays but is characterized by a longer learning curve and the potential for serious complications (Salameh et al., 2002). Additionally, the procedure has been shown to decrease recurrence rates and reduce postoperative pain (Liem et al., 1997). With this transition to a minimally invasive technique comes the utilization of a new type of mesh.

This report focuses on the adoption patterns in hernia mesh and surgical techniques in 10 major global markets (the United States, France, Germany, Italy, Spain, the United Kingdom, Japan, Brazil, China and India) presently and through 2019.

2.1 Catalyst

The advancement of hernia repair has been hallmarked by three significant shifts in surgical treatment. The first was the transition from the “tension” techniques, which involved the use of sutures to tie adjacent tissue layers together, to a “tension-free” technique that incorporated flat sheets of mesh to bridge the defect. The second transition was the overwhelming adoption of large pore meshes in replacement of small pore meshes. Both shifts were prompted by improvements in patient outcomes. The third transition is currently underway as surgeons adopt the laparoscopic technique over the standard open technique.

Instead of a large abdominal incision, a laparoscopic repair involves several small incisions in the abdominal cavity. Clinical trials have found favorable outcomes for both patients and surgeons, including lower recurrence rates, lower post-operative pain rates and a decreased recovery time. This transition is significant to medical device manufacturers because it affects the types of meshes that surgeons will be using in the future. This means that certain mesh products from a company’s portfolio will become less utilized in favor of other products that are more applicable to the needs of minimally invasive surgery. As more players enter the market and operations become international, it is increasingly imperative that companies understand how to properly adapt to growing trends in order to succeed. This report examines the implications of this transition and discusses how medical device companies can capitalize on it to gain market share.

Appendix

11.7 About MediPoint

MediPoint is the flagship product for GlobalData's Medical team. Each MediPoint report is built from the ground up by our team of healthcare analysts in the US and UK. Each report includes input from experienced physicians and leading Key Opinion Leaders (KOL). Running throughout each report in the series, "What Physicians Think" quotes provide a unique insight into how healthcare professionals are reacting to events within the industry, and what their responses could mean for industry strategists.

11.8 About GlobalData

GlobalData is a leading global provider of business intelligence in the Healthcare industry. GlobalData provides its clients with up-to-date information and analysis on the latest developments in drug research, disease analysis, and clinical research and development. Our integrated business intelligence solutions include a range of interactive online databases, analytical tools, reports and forecasts. Our analysis is supported by a 24/7 client support and analyst team. GlobalData has offices in New York, Boston, London, India and Singapore.

11.9 Disclaimer