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GlobalData
MediPoint

PROSTHETIC HEART VALVES — GLOBAL ANALYSIS AND MARKET FORECASTS

Executive Summary

Key Metrics in Major Markets

Prosthetic Heart Valves, Key Metrics in Major Markets	
(2013) Global Sales Volume	**386,464**
(2013) Global Market Value ($m)	**$2,082.4m**
(2013) US Market Value ($m)	$762.8m
(2013) 5EU Market Value ($m)	$882.4m
(2013) Asia-Pacific Market Value ($m)	$404.5m
(2013) Brazil Market Value ($m)	$32.6m
Key Events	
(2013) Edwards Lifesciences receives regulatory approval to market Sapien XT in Japan	
(2014) Strong pipeline of transcatheter aortic valve replacement devices that are fully repositionable and retrievable	
Forecast	
(2020) Global Sales Volume	**592,257**
(2020) Global Market Value ($m)	**$4,455.1m**
(2020) US Market Value ($m)	$1,527m
(2020) 5EU Market Value	$2,319m
(2020) Asia-Pacific Market Value ($m)	$560.6m
(2020) Brazil Market Value ($m)	$48.4m

Source: GlobalData, primary research interviews with leading cardiac surgeons and interventional cardiologists in 10 markets (US, France, Germany, Italy, Spain, UK, Japan, China, India, and Brazil)

5EU = France, Germany, Italy, Spain, and the UK; Asia-Pacific = Japan, China, and India

The global prosthetic heart valve market in 2013 is estimated to be valued at $2,082m across the 10 major markets covered in this reported, which includes the United States, France, Germany, Italy, Spain, the United Kingdom, Japan, India, China, and Brazil.

By the end of the forecast period in 2020, the global prosthetic heart valve market will grow to approximately $4,455m at a Compound Annual Growth Rate (CAGR) of 11.4%.

The key drivers for the market in the forecast are:

- The growing prevalence of valvular heart disease and an aging population around the globe
- Technological advancements in the field of interventional cardiology that include transcatheter aortic valve replacement (TAVR) and the desire to eliminate the need for open surgical procedures for valve replacements
- The development of TAVR devices that are fully repositionable and retrievable, providing better clinical outcomes and reducing complications associated with valve replacement procedures

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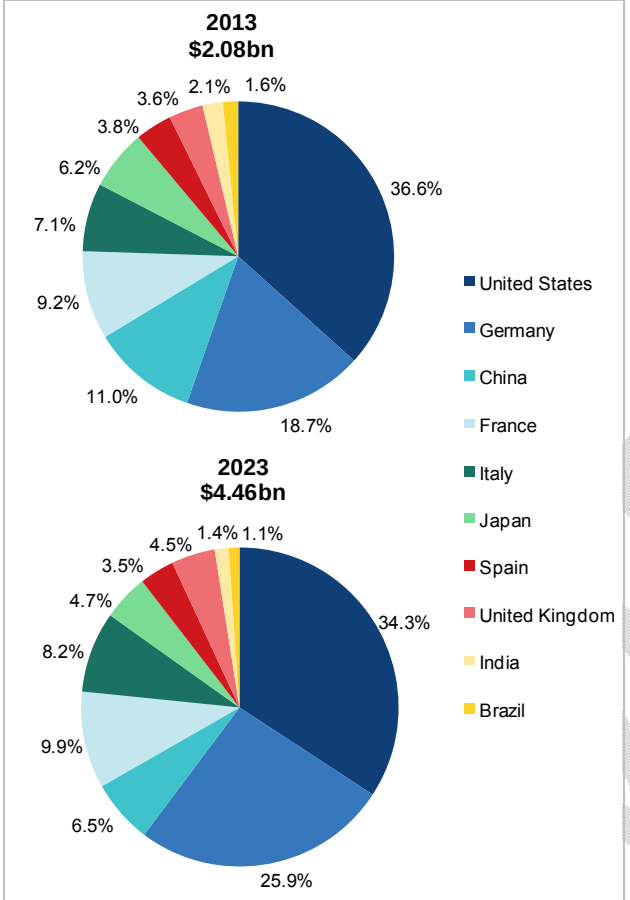
Global Market Share Comparison By Major Market, 2013 & 2020



Source: GlobalData, 2014

The US market accounts for the largest segment of the prosthetic heart valve market. While China owns a significant portion of the market in 2013, its share is expected to decrease in the forecast period due to the emergence of TAVR, which is expected to experience rapid growth and is not yet approved in China. The 5EU countries (France, Germany, Italy, Spain, and the UK) are technologically the most advanced market, with the best availability of TAVR devices. The emerging markets see the most open surgical procedures and are restricted due to the high cost of minimally invasive procedures. As training programs for surgeons and product prices reduce, the emerging markets present a strong market opportunity for additional revenue for manufacturers. The growing need for multinational companies will be to better target the fast-growing markets and continue to be a leader in development to combat the threat of rising local manufacturers.

Technological Trends

While heart valve replacement has been around for decades, minimally invasive techniques have only come into the picture recently. Modern heart valve replacements show increased durability, improved conformance to native tissue, and improved hemodynamics over older models. Advancements in diagnostic imaging have also streamlined the valve replacement process by allowing the physician to visualize the diseased valve and appropriately size the prosthetic. These imaging techniques represent an opportunity for prosthetic heart valve manufacturers to continue training programs for early detection of asymptomatic valve disease.

The technological developments in this space will continue to result in positive market growth. The primary technological drivers for TAVR devices include the development of low-profile, repositionable, and retrievable systems. Low-profile devices are of particular interest in the Asian

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market, where patient arteries are smaller in diameter. Generally, there remains room for improvement in the efficacy of TAVR devices, and as the products evolve, there will be continued growth in this market.

Key Players in the Prosthetic Heart Valve Market

Currently, the prosthetic heart valve market is dominated by two players: Edwards Lifesciences and Medtronic. Medtronic has a strong presence in all three segments of this market (mechanical, tissue, and transcatheter), while Edwards has built a trusted brand in tissue valves and TAVR. In terms of transcatheter valves, these companies have launched products that are considered the gold standard in the market, and continue to innovate within this space. Direct Flow Medical and Boston Scientific are currently developing the next-generation in TAVR systems, along with the top two players, and early data from their devices have been very positive. St. Jude Medical and Sorin Group are the two big players in the surgical valve market segments (mechanical and tissue). St. Jude Medical currently manufactures what is considered the gold standard in mechanical valves, and also has a line of tissue valve products as well.

Prosthetic Heart Valve Market Future Outlook

The growth of the prosthetic heart valve market will be driven primarily by the adoption of TAVR around the globe. While surgical valves will continue to have a presence in the market, they are not expected to see rapid growth in any of the regions. Despite the high product price of TAVR, physicians recognize the clinical benefits of a minimally invasive procedure as opposed to open surgery. As physician education improves and they have access to more robust clinical data, the outlook for the TAVR market looks strong, with much room for further product improvement in next-generation devices.

The global market is expected to grow at a CAGR of 11.4%. The fastest growing markets will be Germany, Italy, and France, at CAGRs of 16.6%, 13.5%, and 12.5%, respectively. This is because a much greater number of TAVR devices are approved in the major European markets as opposed to others. The slowest growth will be seen in Brazil, India, and China, with CAGRs of 5.7%, 5.2%, and 3.3%, respectively. This is because high device cost restricts patient access to TAVR in Brazil and India, while China has not yet approved the procedure at all.

The market outlook for prosthetic heart valves looks strong in Western markets, as there is still much room for product adoption and growth. Regionally, one can expect slightly different drivers for growth. In the Western markets, availability of TAVR devices is expected to drive growth. In the Asia-Pacific (APAC) countries, lower costing devices will allow for more widespread adoption. In Japan in particular, low-profile devices will allow manufacturers to access a larger subset of patients.

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What Do Physicians Think?

Physicians assert that the future of TAVR is bright due to positive clinical outcomes:

"I have a conflict of interest because I do the procedure, of course, but the outlook is very positive, clearly. The results are very positive. The discussion now is: where do the indications stop?"

Key Opinion Leader

"The market opportunity is going to be to let most referring physicians and general internists and cardiologists know that there's a whole world out there that they can offer their patients that will both improve their symptoms and lengthen their lives."

Key Opinion Leader

High procedure and device cost is the primary barrier to adoption of TAVR in emerging markets:

"The costing is important in the US… and the costing will be important here also. There has to be a practical and pragmatic approach to that. It should not be too expensive."

Key Opinion Leader

There is an increasing patient preference for bioprosthetic valves over mechanical valves:

"We don't see many patients under the age of 15 needing valve surgery, but when we do, we have to emphasize to them that it probably is in their best overall long-term interest to have the mechanical valve, but sometimes that takes some persuading."

Key Opinion Leader

Physicians mention unmet needs in the transcatheter valve space:

"…we thought the issue of severe aortic stenosis is solved if the patient has a new valve. And if he is still suffering from moderate paravalvular aortic regurgitation that will not be an issue for the patient. But actually, we were not right, and many of these patients did not really come out very well out of the procedure."

Key Opinion Leader

"I think the only uncertainties are… the durability question, because we simply don't have the data. I think we need to solve the Pacemaker issue, particularly in some of the device[s]… and we need to work out how we're going to deliver… to match the demand."

Key Opinion Leader

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"…we need to learn from the TAVR story and get busy in the mitral valve as well. That's the next major area for development, in my opinion… there's an opportunity waiting to be filled by somebody who can work out the easiest and safest way to put devices into the mitral position."

Key Opinion Leader

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2 Introduction

2.1 Anatomy

Healthy heart valves ensure that blood flows in the proper direction at the appropriate time and with the appropriate pressure. The contraction and relaxation of the heart generates pressure differences that cause the valves to open and shut, allowing blood to fill the atria and ventricles at alternating times. The four valves in the heart are the aortic, mitral, pulmonic, and tricuspid valves. Note that the aortic, pulmonic and tricuspid valves consist of three leaflets each, while the mitral, or bicuspid, valve consists of two leaflets, anterior and posterior.

2.2 Epidemiology

Valvular heart disease (VHD) is characterized by damage to one of the four valves. The most commonly affected valves are the aortic valve, which controls blood flow between the aorta and the rest of the body, and the mitral valve, which controls blood flow between the atria and ventricles. Depending on the severity of damage, VHD can result in congestive heart failure (CHF) or other serious complications.

VHD can be treated via implantation of a prosthetic heart valve that mimics the function of a human heart valve, thus improving hemodynamics. These prostheses have a passive mode of functioning in that they open and close in response to pressure and flow changes within the heart. For the purposes of this report, the aortic and mitral valves are of primary concern because they are most commonly affected by this disorder.

Valve replacement, whether surgical or via transcatheter methods, has been shown to improve both patient morbidity and mortality outcomes.

Valve replacement, whether surgical or via transcatheter methods, has been shown to improve both patient morbidity and mortality outcomes. These days, surgeons utilize both open-heart as well as percutaneous valve replacement devices. However, while both the aortic and mitral valves are commonly replaced using open-heart techniques, transcatheter technology has thus far focused on the aortic valve; there are no transcatheter mitral valve replacement products on the market to date.

While the transcatheter mitral market segment is slowly growing, the majority of heart valve prosthesis global revenue is generated by three categories of devices: mechanical heart valves and tissue heart valves, which are both designed for open-heart replacement of the mitral or aortic valve, and transcatheter aortic valve replacement (TAVR). Mechanical valves are typically made

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from non-biological materials such as metals, while tissue valves originate from animals such as pigs. The implantation of both mechanical valves and bioprosthetic valves requires surgery, while TAVR is breaking new ground as a minimally invasive technique that improves patient comfort and recovery time.

2.3 Related Reports

- GlobalData (2014). Coronary Stents – Global Market Analysis and Forecasts, December 2014, GDME1119CFR
- GlobalData (2013). Drug Eluting Balloons – Global Market Analysis and Forecasts, September 2013, GDME0179MAR
- GlobalData (2013). Cardiac Assist Devices – Global Market Analysis and Forecasts, March 2013, GDME0175MAR
- GlobalData (2012). Bioabsorbable Stents – Global Market Analysis and Forecasts, December 2012, GDME0164MAR

Appendix

14.7 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.

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14.8 Disclaimer