Executive Summary

Total Primary Hip Replacements, Key Metrics in Major Markets

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<tr>
<td>2012 Global Market Sales for Total Primary Hip Replacement ($m)</td>
<td>$6,176m</td>
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<tr>
<td>US</td>
<td>$3,416m</td>
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<tr>
<td>5EU</td>
<td>$1,038m</td>
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<tr>
<td>Asia-Pacific</td>
<td>$1,304m</td>
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<td>South America</td>
<td>$412.4m</td>
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Key Events (2012–2019)

- (2013) Stryker lawsuits continue to mount in high numbers in New Jersey with its hip stems
- (2013) Johnson & Johnson to discontinue its metal-on-metal product lines, completely phasing out that part of its business
- (2013) Continued growth of pipeline products from Asian players entering US market and low-cost US manufacturers
- (2013) Wright Medical to sell Orthorecon unit to Microport of China thereby shedding their hip and knee portfolio

Competitive Assessment

Number of Devices in Marketing Phase 100+

2019 Global Market Sales for Primary Hip Replacement ($m)

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<th>2019 Global Market Sales for Primary Hip Replacement ($m)</th>
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<tr>
<td>US</td>
<td>$4,055m</td>
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<tr>
<td>5EU</td>
<td>$1,048m</td>
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<tr>
<td>Asia-Pacific</td>
<td>$1,535m</td>
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<tr>
<td>Brazil</td>
<td>$465m</td>
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Source: GlobalData, primary research interviews with leading hip orthopedic surgeons in 10 markets (US, France, Germany, Italy, Spain, UK, Japan, Brazil, China, and India).
Note: 5EU = France, Germany, Italy, Spain, and the UK; Asia-Pacific = Japan, India, and China.

Sales for Total Hip Replacements

The total hip replacement (THR) sales market in 2012 is estimated to be $6,176m across the 10 major markets covered in this report, which are the United States, France, Germany, Italy, Spain, the United Kingdom, Japan, Brazil, China, and India. The revision market is estimated to be $613m across the 10 major markets. Combined, the market is $6,789m.

By the end of the forecast, the THR sales will grow to over $7,102m with a Compound Annual Growth Rate (CAGR) of 2.02%. The revision sales will grow to over $671m with a CAGR of 1.79%.

The key drivers for the market in the forecast are:

- The growing prevalence of symptomatic osteoarthritis and post-traumatic arthritis due to the growing aging segment of the population across the globe
- The major underserved population for joint replacement of the hip in late-stage arthritis in the emerging markets driving procedural numbers up for the hip replacement market
- The desire for health policy makers to pressure implant prices to drop to keep up with surgical volume needs
- The need to address the THR revision market as replacement volumes continue to rise
Executive Summary

As of 2012, the US consisted of the largest piece of the hip replacement market, with a global market share of 55%. The other major markets with significant volume include Japan and China at 9% and 10% for THR. GlobalData estimates that the market share will remain relatively stable for the forecast period across the 10 major markets. There is expected to be an increase in procedural volumes with a CAGR of 2.48% over the forecast period in the US for THR and revision. China follows with a yearly growth rate of 2.42% and Japan at 2.36%. The remaining markets grow at 1.08% to 2.09%. Adoption rates will be slow for new products entering the market unless the device price is markedly low. This is due to the lack of differentiation in design in the new products. The innovation will be in cutting manufacturing and distribution costs to maximize profit. Markets that are price-sensitive, such as China, India and Brazil, will continue to choose cemented prostheses due to the lower cost opposed to cementless ones. Clinical study availability and proper documentation will be key to gaining the acceptance of new low-cost implants. But ample opportunities exist in countries like India, where procedure volumes continue to rise.

Unmet Needs Remain a Challenge

THR technology has developed greatly over the last 40 years and the market has become highly mature, with surgeons happy with the product designs available for use. Additionally, many large manufacturers offer a wide array of sizes and combinations with femoral heads and acetabular cups. Though design has come to an optimal level with implants lasting up to 20 years, there is still much room for technological advancement with material wear. Physicians see the development in material science and improved wear to be next focus in the upcoming years of research. Finer materials and better coatings for biological fixation and bearings are areas of need.
Executive Summary

Orthopedic surgeons had once enjoyed the growth of resurfacing products to be an alternative to traditional hip replacement. The future focus to bring back minimally invasive and less bone-resecting options will be a growth area. Once confidence is restored in resurfacing and products using different materials, as opposed to metal-on-metal, are used, there will be a return in this market.

Orthopedic surgeons have also called for devices with better long-term follow-up. With the glut of products available on the market, many have not been documented with long-term clinical trials. A centralized method of following implants will better track future patient outcomes for clinical efficacy.

Finally, better surgical training is needed for tier II surgeons, as orthopedic surgery is one where “practice makes perfect” will help reduce the need for revision surgery.

Key Players in the THR Market

The three large players in the THR market in the US are DePuy Synthes, Stryker and Zimmer Holdings; combined, they comprise almost 70% of the market. Another 25% is shared primarily by Smith & Nephew, Biomet, and to a lesser degree Wright Medical and Exactech. Another 5% of the market consists of smaller players, which is part of the pie that is expected to rise over time with low-cost manufacturers. In countries like China, around 60% of the products are produced by multinational manufacturers, with 40% being lower-cost local manufacturers. Based on feedback from interviews by GlobalData of key opinion leaders in the EU, the market there is dominated still by the same top manufacturers listed above. Additionally, there is a large group of European mid-cap manufacturers that look to capitalize in the local markets. This would lead to the top players potentially losing some market share in the US and EU. The opportunity is great in the emerging markets, as there is a large untapped population with the surgical need. GlobalData believes that penetration of the developing nations can drive their growth and increase market share. Most importantly, long-term data of new products and proper follow-up of patients will ensure patient and surgeon confidence.

THR Market Future Outlook

The THR market is a slow-growing market with a CAGR of 1.97% globally. It is a mature orthopedic market that is expected to continue to grow but only moderately. The market is based on and will be driven by the rising prevalence of osteoarthritis and the rising aging population, as well as the increasing indications where THR is used. Younger patients are also getting more THR and this trend will continue in the future. Countries to watch are India and China, but these markets depend heavily on physician training beyond the major cities and the distribution networks. As procedural volumes continue to rise while revenues shrink, a market to watch is revision of primary THR.
Executive Summary

What Do Physicians Think?

Physicians are concerned about the cost of implantation products.

“They probably might limit [spending] in the near future with the global crisis and everything. They might limit the use of premium implants. In here we call them generic implants which have the lowest price. Probably there will be a trend towards using generic implants. Unless you want the premium implants you will have to pay yourself for it. Or through private insurance.”

Key Opinion Leader, May 2013

“For me, if I have to name number one, it is save money. Give me good cheap implants. And innovate such that the utilization of those implants by the hospitals and by the providers is done at a cheaper cost. Innovate in the utilization. Innovate in the number of trays you are giving me to do the operation. Whatever you want, but lower the cost. Improve your processes so it is less costly. Improve your packaging so you can pack less. Whatever you want to do.”

Key Opinion Leader, April 2013

Many small players are entering the market and attempting to steal market share from the leaders with low-cost implants.

“Medicare only has so many dollars. The smaller players are filling that niche that the government and FDA needs. They are always looking at the fact that if I get enough market share, someone will buy me. We will make a lot of money. And that has been proven quite a bit.”

Industry Key Opinion Leader, May 2013

Physicians expect to see continued growth despite the difficulties with recent recalls, due to the immense success with traditional primary hip implants.

“Well, with the changes in the economy, there are changes in the use of hip replacements. You can see that in 2000, five years ago with the [metal-on-metal implant recall] crisis. There was a big drop in the use of hip replacements. But again these patients keep getting worse. So at some point they have no option [but to come for a hip replacement].”

Key Opinion Leader, April 2013

“Yeah, I don’t know whether it is the lifestyle changes or if it is diet or what it is, but more and more, younger patients seem to be getting arthritis now. And also with the modern hip replacements, the quality of life achieved after replacements is much better than in the past.”

Key Opinion Leader, March 2013
**Executive Summary**

With so many new products out in the market by new companies, physicians expect more long-term studies to substantiate these upgraded versions for efficacy compared with the traditionally accepted ones.

*Number one is that patients live longer. Number two is that we perfected this procedure. We are using it in more patients than the year before. We are using it in more patients in the following sense. Patients that were very old and very sick years ago were deemed to be not good surgical candidates for hip replacements, [but] now we can do them. And take the pain away in those patients. On the other hand the very young and very active who [were] asked not to have a hip replacement twenty years ago, now they have a hip replacement at a young age. So it is a little bit of the baby boomer effect and little bit of the expansion of the indications for surgery.*

*Key Opinion Leader, April 2013*

Materials innovation is a driver for the hip replacement market, as physicians and patients demand higher performance from implants. While implant design has developed well, there is still room for materials research.

“There is still room for a lot of improvement. Till this day we don’t have a bearing that doesn’t have a down side. And there is scope for improvement in materials and design, in fixation methods of the implants to the bone.”

*Key Opinion Leader, March 2013*

Physicians believe that the revision market is one to carefully watch, as procedural numbers rise and younger patients continue to receive THR.

“Well, in general terms, the higher your volume, the lower your real revision rate. Because essentially the more times you do a surgery the better you become at it. And also there is patient selection factor. If you select your patients carefully, your revision rate is lower.”

*Key Opinion Leader, April 2013*

Physician training and education is a continued need, with tier II doctors performing a bulk of the total procedural volume.

“Education is a major issue. Maybe more especially in the US. I’m talking about surgeons and education and practice. Because in terms of surgical technique, and also in terms of implant choice, I’m sure you are aware that half of the hip replacements done in the US are done by surgeons that do like 10 a year or something like that. Probably their level of training is not as good as others. And that is a major issue.”

*Key Opinion Leader, March 2013*
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Introduction

2 Introduction

Osteoarthritis has become a global public health concern with no cure. It is the most common form of arthritis, and is primarily due to wear and tear of the joints. With the aging global population, this is an indication that is growing rapidly, with the hip being one of the most common joints afflicted. While the primary indication for total hip replacement (THR) is osteoporosis, the other major indication is osteonecrosis. A small percentage of fracture patients go on to receive THR, almost always the older patients, above the age of 65.

Generally therapeutic and more conservative treatments are preferred, but surgical treatment has been gradually used over the last few decades with increasing consistency. Hip replacement surgery has increasingly become one of the most successful and cheapest surgical treatments over the years, due to the sheer volume being done. It has transformed from a surgery that was performed as a last resort, on only the aged, to one that is commonly done amongst younger and active patients, with successful outcomes.

As people live longer and with younger patients also receiving implants, the revision rates for primary hip replacements are also expected to rise. Essentially, after 15–20 years of a primary hip implant, one can expect a revision surgery due to wear and tear of the original implant. Primary hip replacement has become one of the most successful surgeries, with a variety of femoral and acetabular components available from a wide selection of manufacturers. In recent years there have been a slew of recalls and legal proceedings due to resurfacing implants, a procedure which has been an alternative to THR in younger, more active patients. This procedure is bone-stock preserving and had been widely used primarily in countries like the US and UK. While the benefit of this surgery was to resect and remove much less bone compared with the traditional hip replacements, the metal-on-metal articulating surface has been a problem, leading to metal toxicity in patients, severe pain and high revision rates.

This report focuses on the total primary hip replacement market along with the primary revision market. The global hip replacement market which has been estimated in this report includes the US, France, Germany, Italy, Spain, the UK, Japan, Brazil, China and India. The report provides unmet needs, future adoption and compound annual growth rates (CAGR). GlobalData’s analysis shows that the hip replacement market has become a mature market where products have become commodities. The future of the market lies in the ability of manufacturers to provide implants at a very low cost while continuing to provide the same level of clinical efficacy.
Introduction

very low cost while continuing to provide the same level of clinical efficacy. The product development need lies primarily in revising the resurfacing products’ articulating surface with new materials, rather than developing new acetabular and femoral components. Additionally, the major opportunity lies within the emerging markets, which are the countries that have a higher CAGR and will provide the key for growth and grabbing market share.

2.1 Catalyst

The mature market in the design of hip replacement products has led to a shift in the focus of developing orthopedic implants. Orthopedic surgery in the hip has become more minimally invasive unlike that of the past, with smaller incision sizes, the development of computer-navigated arthroplasty systems and even bone-preserving techniques such as resurfacing. While these systems at times offer unique advantages, all these methods may not have been fully adopted or been successful. While technologically surgeons have been happy with the products available lasting from 15–20 years in patients, today younger patients are receiving hip replacements and have higher expectations that exceed those of the past. GlobalData believes that from a product perspective, the focus of development will continue to be on implant products that preserve bone stock on younger patients, and continued materials research to reduce wear.

As materials research develops addressing the issues surrounding metal-on-metal implants, there lies the task of preparing long-term data. While long-term data has been overall good for both cemented and cementless products, the emergence of multitudes of products from small manufacturers and others without proper clinical follow-up has been a problem.

Most importantly, product and surgery costs have led to a new challenge for manufacturers: keeping profits up while producing low-cost product portfolios. EU austerity and the cutbacks in reimbursement have led to a decline in revenue over the past few years, while procedure numbers have still continued to grow, though modestly. As the population of individuals with osteoarthritis and other indications continues to grow, especially in the emerging markets, the need for the big players to cut costs in an innovative fashion will be pertinent.

This report addresses the various unmet needs, presents the current technology and the drivers for the future and market growth in the US, 5EU, China, India, Japan and Brazil. Adoption rates are examined, as well as the decision-makers, in order capture market share.
2.2 Related Reports

- MediPoint: Total Ankle Replacement Implants – Global Analysis and Market Forecasts
  GDME0167MAR / Published February 2013

- MediPoint: Total Wrist Reconstruction – Global Analysis and Market Forecasts
  GDME0171MAR / Published March 2013

- MediPoint: Total Shoulder Replacement – Global Analysis and Market Forecasts
  GDME0177MAR / Published June 2013

2.3 Upcoming Related Reports

- MediPoint: Knee Replacement – Global Market Analysis and Market Forecasts
- MediPoint: Trauma Fixation – Global Market Analysis and Forecasts
11.6 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.

11.7 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. GlobalData has offices in New York, Boston, London, India and Singapore.

11.8 Disclaimer

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