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Indian Orthopedic Devices Market A \$2.4 Bn Opportunity

Succeeding in the Evolving Landscape



White Paper
October 2016

Acknowledgement

The orthopedic device landscape in India is complex and rapidly evolving. We would like to acknowledge the contributions of various stakeholders whose time and inputs were fundamental to our research and analysis. We would like to specifically acknowledge inputs from leading clinicians who consented to be interviewed, the forum co-ordinator at Association of Indian Medical Device Industry (AIMED), business leaders at various domestic and multinational companies and lastly, members of the investment fraternity. These perspectives have been invaluable in shaping this publication.

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Executive Summary



Executive Summary

Significant growth expected to continue and market anticipated to reach USD 2.4 Bn by 2030

We estimate that current size of the Indian orthopedic devices market is around USD 375 M (Rs. 2,400 crores) and it will grow at around 20% every year for the next decade to reach USD 2.5Bn (Rs. 16,000 crores) by 2030. As a largely out-of-pocket healthcare market with less than 300 million Indians covered by insurance, the medical devices market benefits from higher disposable income in an economy growing at around 7-7.5%. Additionally, growing incidence of diabetes, obesity, osteoarthritis and osteoporosis are further expanding the clinical need.

On the other hand, global orthopedics industry is estimated to grow at a comparatively modest rate of 5% annually. This has thus increased global interest in the Indian orthopedics industry.

Evolving market composition will alter the orthopedic devices landscape

Today, multinational companies dominate the market with up to 70% market share. The market is split evenly between the joints segment (knee and hip) and the trauma-spine segments. The joints market in fact, has a higher percentage of multinationals, at around 80%. Comparatively, the low-value trauma segment has seen minimal participation from MNCs, with Indian companies traditionally occupying up to 90% of the market share.

However, this landscape is gradually evolving today. We see an increased desire on the part of Indian companies to move up the value chain and participate in the knee and hip segments. Several Indian companies are seeking technology collaborations and are obtaining global approvals such as the CE marking and USFDA approvals to signify product and technology sophistication. Similarly, multinational companies too are introducing Chinese products into the trauma segment to compete with domestic players on price.

Fostering innovation in India

On the policy and regulatory front too, there have been several changes, including the introduction of a draft proposal of the Medical Device Rules, 2016, which is expected to bring the domestic regulatory standard on par with global standards. The formulation of the Indian Certification of Medical Devices (ICMED), which is a new quality assurance certification scheme for Indian products, will also help to bring credibility to the quality of Indian implants.

From a policy perspective, there have been several initiatives introduced such as an increase in funding platforms such as the BIPP and SBIRI programs by the Department of Biotechnology and the formation of partnerships with Indian academic and research institutions to foster innovation in medical technology.

However, there is a need for more support at the policy level. Indian orthopedic manufacturers bemoan the lack of support infrastructure such as common testing laboratories and HA coating facilities which can help them to improve validation of their products and bring down costs.

Given the dominance of imported implants in the market today, the government is also considering price controls as an option to bring down costs for patients. But there are mixed opinions on whether this will help patients in the long run, as this might disincentivize both domestic as well as multinational companies from pursuing innovation.

Increase in M&A and PE deals

Inbound M&A and PE investment in the Indian ortho space has been minimal because of a lack of technology and market leadership among domestic companies. However, in the future we perceive an increase in investment and acquisitions in this sector. Supportive policies will make it easier for multinationals to buy, rather than build, with potential targets being midsize companies with good quality processes and strong market presence. We also anticipate more private equity investment transactions that will support mid-tier Indian companies to build scale, access technology, invest in product validation and finally capture a more significant share of Indian and export markets.

Outbound interest will also increase, with Indian manufacturers looking to acquire innovative technology from foreign companies with strong R&D capabilities.

The Indian Orthopedics market is at a turning point

The Indian ortho market is at a pivotal point today. There is potential for accelerated and vast growth in the market, but it remains to be seen whether multinationals continue to capture significant share or if more domestic companies can transform themselves sufficiently to compete effectively. Changes in the market composition, policy and regulatory environments will alter the landscape in the near future. The domestic industry also needs to improve their R&D capability and collaborate with academic institutions to introduce innovative products that can expand the market and drive price rationalization. India will continue to be a very attractive market for device manufacturers; and with a supportive environment, India can also emerge as an export hub for medical devices in the Rest of the World markets.

Indian Orthopedic Device Industry: Overview



1.1 Overview of the Indian Orthopedic Industry

1.1 Global Orthopedics Market

The global orthopedic devices market is expected to reach \$41.2 billion by 2019¹. The market is expected to grow at compounded annual growth rate of 4.9% during the period. A growing geriatric population and increasing demand for noninvasive treatments are boosting the market. The knee segment leads the market in terms of revenue. The hip segment is growing at a CAGR of 5.9%, due to an increased number of hip fractures.

North America dominates the market for orthopedic devices because of the prevalence of obesity and osteoarthritis and higher value per device. The Asia Pacific market will see significant growth due to increasing population density and expanding healthcare markets.



Figure 1 Size of the global Orthopedics market

Major players in the orthopedic devices market include Zimmer-Biomet, DePuy Synthes, Stryker, Smith & Nephew and Medtronic.

1.2 Indian Orthopedics Market – Market size and Competitive Landscape

The Indian Orthopedics market is characterized by a large number of companies, comprising both domestic and international players. More than 70% of the sector is supplied by imports which offer products with premium quality and prices. Most domestic manufacturers have largely participated in the lower value end of the market and compete on prices. Physicians however, prefer to use international products because of their superior technology and quality. For e.g., about 80% of the joint replacement implants used by Indian surgeons are imported. Some of the key characteristics of the Indian market are described below.

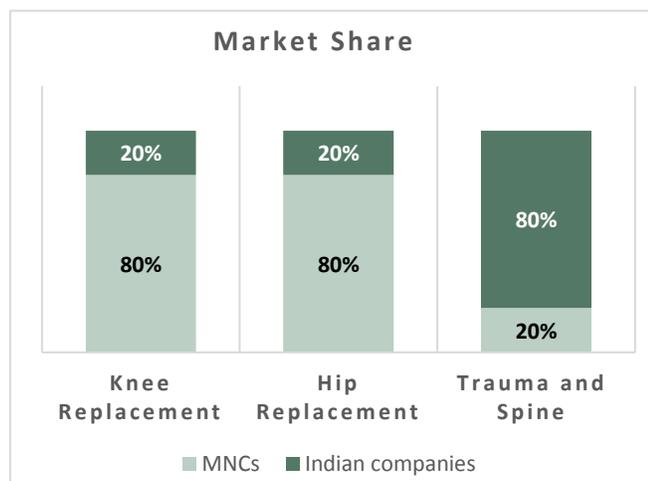


Figure 2 Market Share - Domestic Vs Imports

¹ Orthopedic Devices Market - Global Industry Analysis, Size, Share, Growth, Trends and Forecast, TransparencyMarketResearch, 2013 - 2019

1.2.1 Market Composition, Structure and Sizing

We estimate that the current market size of the Indian orthopedic implants market is around USD 375 Mn (Rs. 2,400 crores)². We expect the overall market to grow at an annual rate of around 20% between 2017 and 2020, propelled by growth in the joints segment. Growth will subsequently moderate to around 13% between 2020 and 2025 and will flatten to around 10% by 2030.

The orthopedic implants market can be broadly divided on the basis of the area of treatment, into 4 major segments: Trauma, Spine, Knee and Hip. The market is shared approximately in an equal ratio between the Trauma & Spine segments on one hand and joints (Knee & Hip) on the other.

While Indian manufacturers are largely confined to the trauma and spine market with an estimated 80% market share, multinational companies dominate the higher value knee and hip segments, capturing more than 80% of the market.

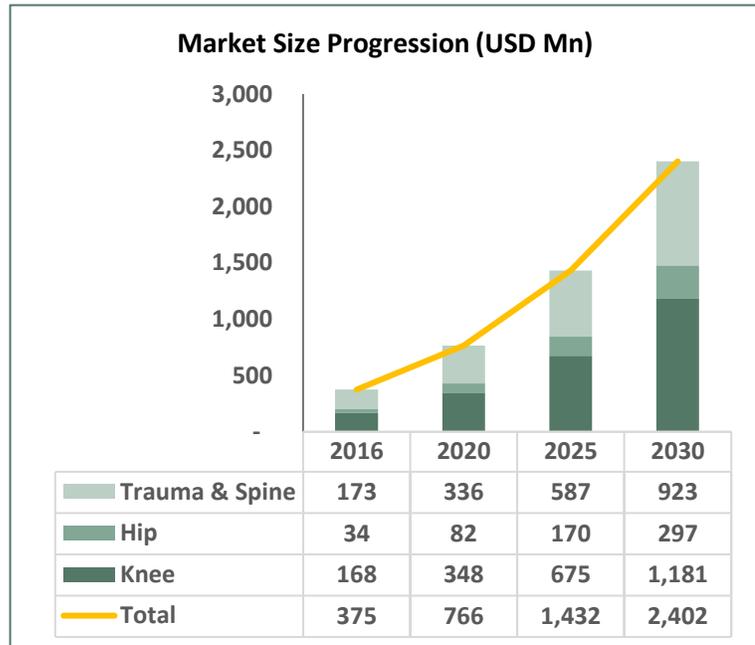


Figure 3 Market Size Progression of Indian orthopedic market

Growth in the Joints Segment

The joints market is split between knee and hip procedures. While globally the hip market is larger than the knee market, the situation is reverse in India. Today, 5 times as many knee procedures take place as hip procedures. This is due to hereditary and lifestyle factors where the Indian knee sees far more wear and tear than the hip (for e.g., squatting tends to lead to higher stress in the knee).

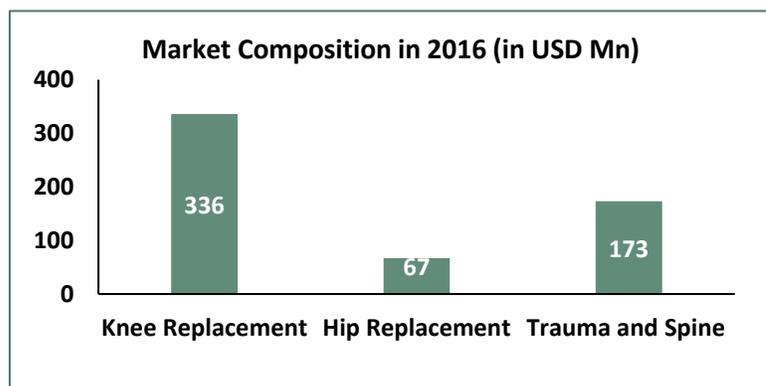


Figure 4 Market Composition by segment

² Based on Sathguru internal estimate

There is also a tendency to delay or avoid the expenditure on the hip replacement in a market with low penetration of insurance coverage.

It is estimated that both of these segments will experience significant growth, with the knee segment growing at a rate of 20% over the next 5 years, and growth moderating to 15% by 2030. The hip segment will experience a slightly higher growth rate, owing to the smaller number of procedures being performed currently. We anticipate that this will also decline to around 15% in the next decade.

Knee: Many of the knee implants available today are either designed for western populations' knees which are larger, or consist of a smaller range of available sizes. More customization is required to suit the smaller Indian knee, but, this in turn pushes the manufacturing cost upwards. Hence, not too many manufacturers are willing to provide customized knees. The knee segment is

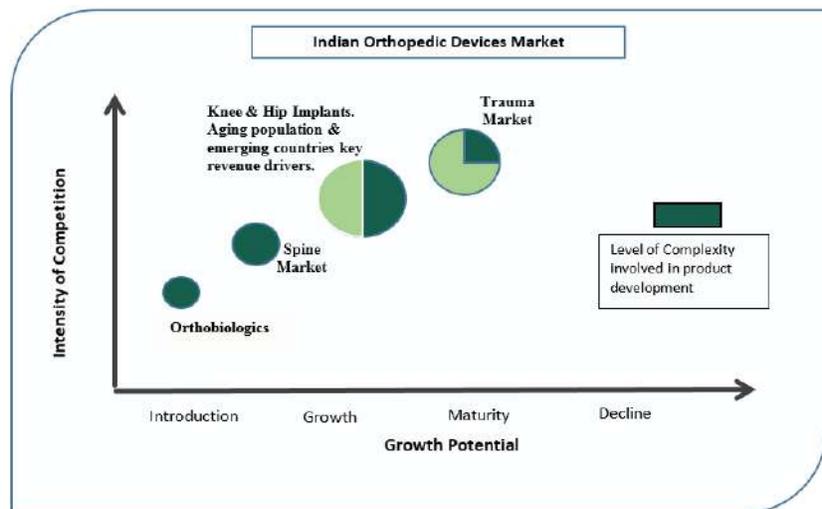


Figure 5 Competition, Growth Potential and Technology complexity

dominated by multinationals, with dominant players being Zimmer Biomet, Depuy Synthes, Stryker and Smith & Nephew. Domestic companies which are active in this space include Meril, Inor, Biorad Medisys (which markets the Indus knee, India's first totally indigenous Posterior Stabilized knee prosthesis), TTK and Sharma Orthopedics.

Hip: The hip implants market in India is much smaller in comparison to the knee segment. Patients in India prefer to live with pain in the hip rather than spend for the cost of the procedure. Older patients especially will sacrifice mobility for cost. Some of the major MNC companies in this sector include Zimmer Biomet, Depuy Synthes and Stryker, while Inor, Sharma Ortho, Meril and SH Pitkar are among the few domestic players to participate in this market, but they often lack total hip solutions.

Growth in the Trauma-Spine segment

Trauma: The trauma market is dominated by domestic manufacturers capturing more than 80% of the market. This is because a trauma implant does not have to remain in the patient's body for a very long period, so factors such as endurance and biocompatibility become less important than the price. The trauma market is in fact a highly commoditized sector with low margins.

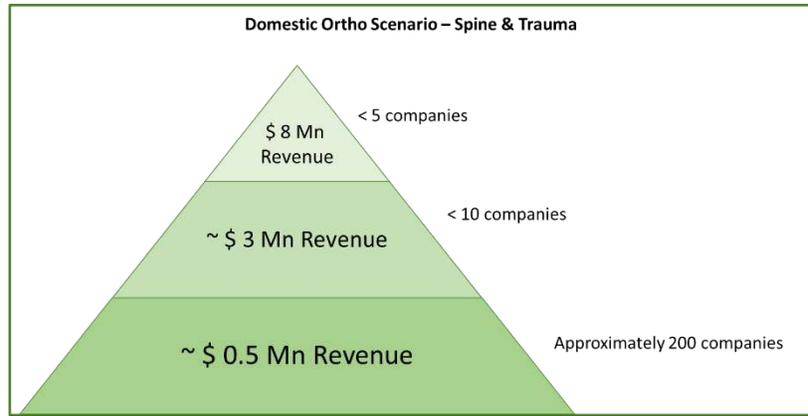


Figure 6 Domestic Ortho scenario - Spine and Trauma

The trauma market is deeply fragmented, with just a handful of companies having revenues greater than \$ 8 Mn. The mid-tier of the trauma market comprises of less than a dozen companies with revenues of around \$ 3-5 Mn. But the largest number of companies occupy the lowest-tier of the market with revenues of less than \$ 0.5 Mn. Some estimates put this number at around 200 companies, and they comprise both small organized players as well as the unorganized sector. Some of the notable companies in the trauma segment include Sharma Orthopedics, Matrix Meditec and Inor Orthopedics.

Spine: Unlike trauma, the spine market does not have too many domestic players. It is currently a fairly small market in India, and offers a steep growth opportunity. The spine segment is however is limited by its elective nature and high out-of-pocket costs. Continued growth is expected in the spine market over the long term because there is an increasing demand for motion preservation technologies. Fusion devices still make up the largest market share for spinal devices, but the non-fusion market is expected to grow through 2019. Medtronic, Zimmer Biomet and Depuy Synthes dominate the market while domestic companies such as Matrix, Inor, SH Pitkar and Biorad Medisys also have a smaller market share.

Market share	International > 70%
Key International companies	Zimmer Biomet, Medtronic, DePuy Synthes, Smith & Nephew, Stryker
Key domestic companies	Meril, Sharma Ortho, Biorad, TTK, S. H. Pitkar, Matrix Meditec, Inor
Tiers of competition	Tier 1: Zimmer Biomet, Medtronic, DePuy Synthes, Smith & Nephew, Stryker Tier 2 : Others (Local and international)
Distribution structure	Private: Done mainly through distributors and dealers, less of bulk procurement from manufacturer. Sales depend on relationship between doctor and distributor/sales execs. Public: Through tenders usually awarded by price (L1)
Key End user groups	Government teaching hospitals, private specialty hospitals mainly in Tier-I, Tier-II cities

Figure 7 Key Industry Players – Indian Orthopedic Devcies

1.2.2 Increasing local presence and strategic focus of leading MNCs in India

Over the past decade, some of the leading global players have set up local innovation hubs and manufacturing units in the medical devices space. India is recognized as an important market with growth rates being 2-3 times higher than in the United States and Western Europe. After China, India represents the fastest growing healthcare market due to demographic and policy related factors. Some notable examples are:

- **Orchid Orthopedics**, a US-based company has opened a new 28,400 square feet manufacturing site in Pune, India and plans to service the Asian market as well as global customers looking for additional manufacturing options.
- **Stryker** is strategically focused on accelerating growth in emerging markets such as India and China and has setup an R&D center in Gurgaon to roll out new products more suitable for emerging markets. It recently announced the development of a no-frills power tool used for cutting, drilling and shaping bones during joint replacement and trauma procedures. The product, branded System G, designed at their Gurgaon-based research center is expected to be commercialized soon and will be positioned in the mid-tier segment of the market. The company will seek to increase contribution of emerging markets to its global sales from 8% at present to 12-14% over the next five years.³

³ US Firm Stryker banks on India R&D to gain edge in emerging markets, orthospinenews, 9 Apr, 2016.

- **Zimmer Biomet** has signed a 3-year deal with the Indo UK Institutes of Health (IUIH) to build Biomet Institute of India, a 30,000-square-foot training facility to train more than 1,000 orthopedic surgeons a year on new procedures and Zimmer Biomet technology. Zimmer is planning to invest more than \$5 million into this initiative. Apart from this, IUIH and the U.K.'s National Health Service (NHS) intend to build 11 more training campuses in India with each campus including a 1,000-bed hospital, medical and nursing schools and a third party-run training and education center focused on a particular specialty.
- **The DePuy Institute for Advanced Education and Research**, established in Chennai, is expected to train 1,000 surgeons a year in the latest techniques and technologies, significantly improving access to top-class medical care throughout India. This 30,000 square-foot facility is the largest DePuy facility of its kind outside the US.

1.2.3 Emergence of Indian players with intent to move up the value chain

While the domestic market has been dominated by multinationals, several Indian companies are now aspiring to move up the value chain. These players have evolved from manufacturing low-tech products such as screws and plates, to building full-fledged knee or hip implant systems. Several companies are leveraging technology collaborations to develop products comparable to that of global companies. These forward looking and growth oriented companies are actively pursuing regulatory approvals such as CE marking and USFDA approvals to establish reliability and technical sophistication of their products. They herald in the next phase of the Indian orthopedic devices

Maxx Medical and Meril Lifesciences

Maxx Medical is a global orthopedics company developing products primarily in the knee segment. Maxx is supported by Bilakhia Holdings, the promoter of several successful companies including Micro Inks, Bilag, and Meril Lifesciences. Meril itself operates in the Cardiovascular, Orthopedic, Diagnostics, Endo-surgery and ENT segments and is a leading player in India.

The Freedom Knee

The Freedom Total Knee® System was developed by Maxx and launched in India in 2009. It has received 510(K) clearance by the USFDA and has recently completed over 25,000 successful implantations worldwide. The Freedom Knee is a high-flexion knee replacement system specifically engineered to address the unmet market need for smaller sized and differently proportioned implants that better support Indian lifestyle and physiology.

Patients in India, especially women with arthritis, are smaller than their Western counterparts and require full bending of the knee. The Freedom Knee comes in a multitude of small sizes with high flexion to address this requirement. It is the only system sold globally yet designed with features that specifically address Asian patients' needs.

Collaboration with Meril

Meril and Maxx successfully collaborated to bring the Freedom Knee to India. Meril has also introduced another knee implant called the Destiknee, which again has been developed considering Asian patients' anatomy. The Destiknee is a CE-certified product. Together, they have ensured that clinicians in India have access to a certified, regulated and advanced product backed by strong clinical data but at competitive prices. Meril has emerged as the trend setter in the Indian orthopedic devices segment with the focus on building formidable presence based on a strong portfolio.

market, where domestic companies are seeking to compete with superior products, gain share from multinationals and also emerge as strong players in the Rest of the World export market. Examples include Biorad Medisys' knee and hip replacement systems as well as Maxx Medical's Freedom Knee⁴ replacement systems. They are also setting examples and leading the trend with several mid-segment players now considering it plausible to break-into the knee implant and hip implant markets. With support from a favorable policy environment and active funding landscape, these changes will drive sustainable structural shifts in the Indian orthopedic devices market.

1.3 Growth Drivers

We expect CAGR of around 15% to 20% to continue into the next five years, with joint replacement products driving the growth. We discuss below broader growth drivers that will influence the market through the coming decade:

Increasing incidence of osteoporosis, osteoarthritis, obesity

In India approximately 15% of the population, i.e. 180 Million people are suffering from Arthritis⁵. Expanding incidence of diabetes and obesity further compound the problem. Due to these health considerations, the patient base itself is anticipated to grow through the next five to eight years.

Increase in aging population

India has one of the world's youngest populations today. However, the proportion of the population older than 60 years of age is expected to increase to 19% by 2050⁶. Rapid ageing, greater life expectancy as well as altered lifestyle are expected to become key drivers for the growth of osteoarthritis in India.

Untapped potential and expanding healthcare access

Vast majority of the Indian population does not have access to quality healthcare. Most of the hospitals performing orthopedic procedures, including larger public hospitals, are present only in the metros, Tier-I cities and a few Tier-II cities. Urban cities in India which house 28% of the population, have access to 66% of available hospital beds in India. Even here, not all patients can afford to pay for these procedures. With the introduction of state and national government insurance schemes in the recent past and insurance coverage as a whole expanding 16% year on year, more patients will be able to undergo treatment, thereby growing the market for all healthcare procedures in general.

Part of this potential needs to be met with a middle-tier of medical devices which is almost non-existent today. Currently, most implants fall into either of two categories; high-price, superior-

⁴ Invivio and Maxx Orthopedics collaborate on knee replacement technology, Invivio ,22 September, 2016

⁵ Overview of Rheumatology, arthritis-India

⁶ The United Nations Department of Economic and Social Affairs (DESA)

quality, sophisticated high-end devices, or low-price devices whose quality is not comparable to the high-end devices. We anticipate highest growth in this middle segment where reasonably priced quality products will be introduced.

Improvement in quality of Healthcare Delivery

The healthcare delivery sector has undergone a vast transformation in the past decade. Several large multispecialty hospital chains offering world-class treatment options and facilities have been established. With the emergence of a more prosperous middle class demanding better quality of healthcare, these hospitals have thrived. A more recent trend has been the establishment of single-specialty chains in areas such as oncology, nephrology and obstetrics which offer focused, specialized care. These centers have also been instrumental in driving the growth in medical tourism to India.

Promotion of Medical tourism

India offers quality and cost-effective care in world-class, accredited hospitals with highly skilled doctors and is positioned well to grow its share of the medical tourism market. An estimated 184,298 foreign tourists visited India for medical treatment in 2014. The Ministry of Tourism has recently constituted a National Medical and Wellness Tourism Board for the promotion of medical tourism. This Board is expected to act as a facilitator and support the medical/wellness segment in promoting India as a medical and wellness destination. If promoted appropriately, there is significant potential to expand revenues in India for orthopedic implant procedures in the medical tourism segment.

Increased availability of minimally invasive procedures

The popularity of minimally invasive procedures has been rising due to the reduced tissue trauma, lesser blood loss and faster recovery. This will encourage more patients to opt for procedures which they would otherwise avoid.

The advantages of minimally invasive technology driving adoption include:

- Shorter recovery time
- Shorter scar length
- Low infection risk
- Less bleeding
- Shorter hospital stays

1.4 Market Restraints

Overall procedure costs are often unaffordable

Knee replacement surgery costs USD 4500 to USD 8000 (Rs 3 Lakhs to Rs 5 Lakhs) for one knee and computer-aided procedures will cost 5-10% more. Despite insurance coverage expanding by CAGR of 16%, currently less than 300 million (30 crore) Indians are covered by health insurance under one of the sources available – Government provided coverage, corporate group coverage and private retail plans. As a large out-of-pocket market, the segment's potential is limited by affordability constraints for expensive orthopedic implant procedures. The lower number of hip replacements in India is also often attributed to the affordability problem and consequent propensity to delay or avoid the procedure.

Lack of infrastructure capacity to perform surgery limits its penetration and adoption

Since most of the healthcare facilities are present in larger cities, the rural population which forms 72% of the total population, is deprived of these procedures. While leading hospitals are expanding into Tier 2 locations to tap into this potential, bridging the glaring inequity in healthcare delivery capacity for tertiary care is challenging.

Intense competition in the orthopedics market

The trauma segment largely dominated by domestic companies is saturated and highly fragmented with very few barriers to entry. Manufacturers depend on price cuts and relationships with clinicians to preserve market share. Even in joint replacement products, there is intense competition amongst MNCs present in India, emerging Indian players with products developed to global standards and commencement of Chinese imports.

Public Healthcare spending is low

Just 30% of the total healthcare expenditure is public spending, compared to 56% for China and 48.3% for USA. This means that just 1.4% of the GDP is public spending in India, as against 3.1% for China and 8.3% for USA⁷. Considering that the only recourse for the rural and poor population is public healthcare systems, India needs to make a quantum leap in its current public health expenditure to ensure universal access to healthcare.

⁸ World Health Organization Global Health Expenditure database

Regulatory Environment



2. Regulatory Environment

2.1 Medical Device Rules, 2016

As is widely known, medical devices in India do not have a separate regulatory framework and are thus largely unregulated. Before 2005, only medical devices such as disposable hypodermic syringes, condoms etc., were required to be registered in India. The Government has since then issued notifications or guidelines multiple times to regulate more devices. These have been classified as “Drugs” and are subject to the Drugs and Cosmetics Act, 1940. There are 22 such Notified Medical Devices including orthopedic implants.

Several domestic manufacturers in India believe that a strong regulatory framework is of great importance since Indian companies are otherwise forced to follow foreign standards such as CE or USFDA even to sell products within India; an expensive process especially for smaller companies. Indian government tenders tend to use CE or USFDA as a criterion to narrow down the field in the absence of a reliable Indian standard, leaving domestic manufacturers at a disadvantage.

Since there was a crying need for specific regulations for medical devices, the Government has recently released the draft notification for the Medical Device Rules, 2016 for specifically regulating medical devices. The salient points of this notification are:

- Rules have been laid out for manufacturing, import and sale of medical devices as well as for clinical trials, labeling and inspection.
- Medical devices to be classified based on risk with high risk (Class C or D) devices to be regulated by the Drug Controller General of India (DCGI) and Class A & B devices by the appropriate state authority
- The devices should conform to specific standards applicable to them (BIS / ISO etc.)
- Shelf life of devices should not exceed 60 months unless satisfactory evidence is produced by the manufacturer to justify an extension
- Medical devices already marketed in India prior to the commencement of these rules shall continue to be marketed subject to the condition that the manufacturer should provide evidence of previous sale in India and should apply for a licensee within a period of one hundred and eighty days from the date the device is notified.
- Medical devices already notified and marketed in India prior to the commencement of these rules shall continue to be marketed as before, till the expiry of eighteen months or the current validity of the license, whichever is later, from the commencement of these rules.

2.2 Indian Certification for Medical Devices (ICMED)

The Quality Council of India (QCI) along with the Association of Indian Medical Device Industry (AIMED) and the National Accreditation Board for Certification Bodies (NABCB) have recently rolled out a new quality assurance certification scheme for Indian products, called the Indian Certification of Medical Devices (ICMED). This scheme will reduce the time and cost involved in obtaining globally accepted quality certifications and will enhance patient safety as well as improve the credibility and competitiveness of Indian manufacturers. The scheme is also expected to reduce the manufacturing and use of substandard products.

One of the ways in which the ICMED could be beneficial for domestic industry is by certifying the quality of the material used in domestic implants. Indian manufacturers use the 316L grade of Stainless steel for manufacturing, as opposed to the 316LVM grade which is the global standard and is mandated by CE. This is not available in India and is costly to import, forcing domestic companies to use the 316L grade of steel which is supposed to be of equivalent quality. This however puts them at a disadvantage when supplying to customers, especially for tenders. If the ICMED scheme is universally accepted, it will definitely prove beneficial to domestic industry.

2.3 Need for Enforcement of Standards

At present, a minority of domestic manufacturers attempt to obtain the Indian regulator's certification, let alone CE or USFDA. Apart from strengthening the current regulations, it is also important to reinforce the implementation of the standards and ensure that the industry is mandatorily regulated. A stronger regulatory standard will serve to curb the unorganized sector in implants, which produces substandard products by keeping costs low in abysmal manufacturing conditions. Such companies compete purely on price, with no thought given to product quality and patient safety. The unorganized sector is also widely blamed for the mediocre reputation of Indian products which are exported to other developing countries. To enable a fairer market for domestic manufacturers, both within the country and in export markets, it is therefore essential to regulate the unorganized sector and have stronger environment of enforcement.

Evolving Policy & Regulatory Landscape



3. Evolving Policy & Regulatory Landscape

The Indian medical devices sector is in a constant state of flux today. It has immense potential for growth, provided there is a suitable policy framework in place to support this growth. Several policy measures are being contemplated which will have significant impact, especially for notified medical devices such as orthopedic implants.

3.1 Rise in Import Duties

Recently, the government raised import duties on several medical devices from 5% to 7.5% to encourage domestic manufacturing. The government also withdrew exemptions to the special additional duty (SAD) of 4% for medical devices. Apart from this, basic customs duty was reduced to 2.5% and exemption from SAD on raw materials, parts and accessories was announced for manufacture of medical devices. This is in line with the government's 'Make in India' campaign. However, an increase in import duties alone will not help the domestic industry. This will need to be combined with other initiatives too, such as development of support infrastructure for product development and validation and increase in R&D funding platforms, which are discussed in Part 4 of our White Paper.

3.2 Concern over Price Controls

The government is mulling price controls for notified medical device, similar to those for drugs. The National Health Systems Resource Centre (NHSRC), a government body under the Ministry of Health has suggested ceiling prices in its report submitted to the drug pricing regulator National Pharmaceutical Pricing Authority (NPPA).

In fact, a recent development has been the decision to include all types of coronary stents in the National List of Essential Medicines (NLEM), a precursor to instituting price caps for these devices. Stents are Notified Medical Devices, classified as Drugs and subject to the Drugs and Cosmetics Act, 1940. Industry players are apprehensive that other such Notified Medical Devices (including orthopedic implants) may slowly also be included in the NLEM and be subjected to price controls.

3.2.1 Opaque prices, lack of understanding of complete cost of product development and dis-incentivizing innovation

The market for medical devices comprises 70% of imports and is largely dominated by MNCs. The Government's move to introduce price controls is led by the intent to ensure healthcare access. There have been allegations that final price to patient of imported orthopedic implants is 3 to 4 times the landed cost. For instance, import price of knee-replacement kit is around Rs 35,000-40,000 (around USD 500 to USD 600) but the patient pays more than Rs 1 Lakh -1.5 Lakh (USD 1500 to USD 2000) for the same product. However, the industry perspective that price controls will curb innovation and do not recognize the total cost of product development including cost of generating clinical data over long periods of time will need to be appropriately considered by

the Government. Additionally, the Government should also consider other complexities in the value chain, such as opacity in pricing, high margins to distributors and hospitals and a preference for higher priced products by profit driven private hospitals. Unless all these issues are substantively addressed, broader healthcare access will remain an aspiration.

While price controls might benefit lower cost domestic manufacturers in the near term, the current low level of innovation engagement and relative dearth of sophisticated product options with Indian manufactures will still allow room for MNCs to compete with their globally recognized products. More than price control, the segment truly needs expansion of health access to the lower income sections of Indian society and empowering Indian manufacturer's with an innovation ecosystem that allows them to compete more effectively, based on products.

3.2.2 Price controls detrimental to domestic manufacturers as well

On the other hand, even for domestic manufacturers in the Trauma segment, extremely low prices could eat into their already meagre margins and will push them out of the market. Some manufacturers feel the need for a Minimum Selling Price (MSP) rather than a Maximum Retail Price (MRP), to curb the rampant proliferation of low-quality, unregulated devices from the unorganized sector, which sell at extremely low prices and eat into the market share of the organized sector.

There is also some concern about how the price controls will be implemented. The orthopedics sector is very vast with hundreds of variants available for a single item. There might therefore be some difficulty in obtaining an accurate comparison of different products in order to determine the price ceiling.

3.3 Establishment of Medical Technology Parks and Shared Infrastructure Platforms

Various state governments are in the process of establishing parks for medical technology to encourage the government's "Make in India" initiative. These technology parks are expected to encourage local manufacturing, and will focus on different subsectors of the medical devices sector. Three parks are being established by the states of AP (electrical devices), Maharashtra (consumables, orthopedic implants and surgical instruments) and Gujarat (disposables). At the proposed parks, companies will have access to readymade infrastructure as well as quality control units, logistics, regulatory and engineering services. Low cost rentals and revenue-support services for companies are also being considered. The parks will help small entrepreneurs tap into the expertise of larger companies and could help reduce manufacturing costs and logistics costs significantly.

Other shared infrastructure platforms recently established include biocompatibility testing labs such as one approved in Vadodara, Gujarat. There is great need to continue such infrastructure creation efforts so that the need for domestic companies to always leverage foreign service providers for product testing and validation can diminish.

3.4 FDI in medical devices

100% FDI has been approved in the medical devices sector under the automatic route for greenfield as well as brownfield investments. Earlier, 100% FDI was allowed under the automatic route only for greenfield units while FIPB approval would be required for brownfield units. However, domestic industry is concerned that this would lead to setting up of subsidiaries by foreign companies which are used for trading rather than manufacturing.

3.5 Competition from Chinese products

Several domestic as well as multinational companies see a threat in the introduction of competitive implants from Chinese manufacturers. With the recent acquisition of certain Chinese companies by global orthopedic companies, these products are now slowly being introduced in India. Backed by the brand name of the parent company, Chinese products can compete on both price as well as quality, with products sold by Indian companies. This trend could prove to be a serious threat to Indian industry.

3.6 Emergence of Biologic Alternatives

While, there will continue to be significant growth in the overall market size, several alternatives to traditional forms of therapy are gaining share globally. One of them has been the increasing use of orthobiologics for treatment of the spine or knee. The global orthobiologics market is estimated to be worth \$ 5.5 billion by the end of 2019. Major players include Medtronic, Stryker, DePuy Synthes and Zimmer Biomet, smaller players such as Orthofix and Arthrex and a few biotech pharma companies like Genzyme and Ferring.

Orthobiologics are made from substances found naturally within the body and uses biomaterials and cell-based therapies to speed up the recovery process. They can include bone graft substitutes (Autografts, Allografts, Bone Morphogenic Proteins (BMPs), Demineralized Bone Matrix (DBM)), Viscosupplements (hyaluronic acid – HA), Bone Growth Stimulators, Platelet Rich Plasma (PRP), and bone marrow concentrate, Stem Cell and others.

Among these orthobiologics, Viscosupplements have the highest market share, followed by BMPs. However, PRPs and Stem cell treatments though new, are attracting significant interest due to their comparative advantages.

Orthobiologic procedures are considered to be less invasive and more effective as compared to traditional implantation procedures. They are especially useful in cases where implants may not be possible, such as when the patient is too old for a knee replacement and surgery could be risky, or if the patient needs to postpone the implantation procedure till they are older.

3.4.1 Orthobiologics in India

The usage of Biologics is not very prolific in India. Autologous BMAC procedures are being performed in several hospitals today, but there is still some skepticism about the effectiveness of Biologics due to differences in healing rates of patients. Other biologics such as Hyaluronic Acid (HA) injections are yet to gain much traction. Market adoption of Allografts has also been slow. A few Indian companies such as Stempeutics⁸ are doing pioneering work in stem-cell therapy, but they are yet to be commercialized.

This segment offers high growth potential but needs clinical education and awareness creation. In addition to spine, we believe that this is one of the less crowded segments where companies can aim for future market dominance by playing a pivotal role in market creation and growth.

Stempeutics

One of the pioneering names developing stem-cell therapy in India is Bangalore-based Stempeutics Research, incorporated by the Manipal Group and supported by Cipla. The company's flagship product is Stempeucel[®], an on-demand, off-the-shelf product based on pooled, allogeneic Mesenchymal Stromal Cells (MSC) derived from bone marrow of healthy, adult volunteers. The product has been granted limited marketing approval for treatment of Critical Limb Ischemia (CLI) patients due to Buerger's disease.

Another product, Stempeucel[®] OA is being developed for the treatment of osteoarthritis of the knee joint. This is a first of its kind allogeneic, MSC-based therapy. With no other allogeneic pooled MSC therapy in development, Stempeucel[®] OA has the potential to provide significant pain and inflammation reduction, improve quality of life, and stall the progress of OA and other debilitating diseases.

⁸ Stempeutics.com

Fostering Innovation in India



4 Fostering Innovation in India

Domestic manufacturers have a strong presence in the trauma segment, but they have very limited presence in the hip and knee segments. If Indian companies need to move up the value chain into these high-value product categories, they need to overcome several barriers to innovation. If the country's dependence on imports has to reduce and an equitable mix of

Matrix Meditec – Illustrating Innovation in India

Matrix Meditec is a 12-year old Ahmedabad-based company which is a mid-segment manufacturer of orthopedic implants for Trauma and Spine. The company has more than a hundred distributors across the country and exports to countries in Latin America and South East Asia as well. The promoters of Matrix were erstwhile distributors for Synthes in the state of Gujarat, before they decided to move into manufacturing. Today they have successfully evolved into a growth oriented mid-tiered company. Over the next couple of years, the company will be expanding its product portfolio into the hip and knee segments as well.

The company has recently developed a Gentamicin sustained release implant, only the second company in the world to make such a product. Matrix's product is a sustained release implant which delivers Gentamicin (an antibiotic), slowly over a period of time as opposed to a similar competitive product which is a Gentamicin-coated implant. The company is planning to launch this product soon.

domestic and multinational companies is to be nurtured, several measures need to be taken to foster and support innovation in the local industry. Some of these are outlined below.

4.1 Development of Support Infrastructure

Domestic companies complain about the lack of translational research centers and testing laboratories that multinational companies have been able to leverage in home countries for their product development and validation efforts. There is a severe dearth of laboratories for testing and validation of medical devices, with not even a single biocompatibility laboratory in India. The government has recently approved the Gujarat Food and Drugs Control Administration (FDCA) plea for setting up the country's first government biocompatibility and medical device testing lab in Vadodara⁹. Additionally, another testing lab has been announced in Noida for testing electrical and electronic medical devices. Domestic manufacturers are presently forced to

send their devices to other countries like Singapore to get their products tested, which is an expensive and time-consuming process.

⁹ Gujarat govt approves setting up India's first medical device testing lab Pharmabiz, 27 August, 2016

Setting up of the dedicated medical device testing labs in the country, will help Indian manufacturers adhere to standards.

The industry needs to be empowered with domestic research and development capability across academia and healthcare delivery institutions so that domestic industry can be competitive with global peers. Global references such as the translational center and simulating testing capability in Massachusetts General Hospital, Boston, serve as benchmarks. While couple of companies might have capital backing and global connectivity to seek such partnerships with global institutions, in the long term interest of the industry and Indian patients, there is strong need to nurture such capability in India.

Another common constraint highlighted by Indian companies is the need for a common facility to perform Hydroxyapatite coating on uncemented implants. Again, lack of common infrastructure makes them uncompetitive as they have to access international service providers for such needs.

4.2 Increase in funding platforms

In order for domestic technology companies to flourish, adequate funding is needed for early-stage medtech companies and products which are in the pre-commercialization phase. Some of

Global reference center - Comprehensive translational research facility for orthopedic implants at Massachusetts General Hospital, Boston

Technology Implementation Research Center (TIRC)

Core Focus : Translational research in biomechanics and biomaterial science for bringing disruptive technology to active clinical use.

Focused on improved understanding of human joint biomechanics to enable better implant designs.

Development of advanced biomaterials used in joint replacement and repair, and clinical follow-up studies to provide evidence-based feedback to improve surgical outcomes.

Harris Orthopedics Lab

Core focus : Biomaterial development for joint replacement and repair systems.

Experience across material and polymer science, biomaterials and biomechanics testing, bench to clinic implant development, follow-up testing of explanted devices.

Noted developments include formulations of highly cross-linked ultrahigh molecular weight polyethylene (UHMWPE), stabilized by re-melting or vitamin E, current gold standard in hip implants.

the more prominent funding programmes include the schemes instituted by the Biotechnology Industry Research Assistance Council (BIRAC) set up by the Department of Biotechnology. These include the Small Business Innovation Research Initiative (SBIRI) and the Biotechnology Industry Partnership Programme (BIPP), which promote pre proof of concept as well as late-stage development in small and medium companies in India¹⁰. Other funding opportunities include the Technology Development Board constituted by the Government of India in 1996 to provide low-cost funding for the commercialization of innovative research¹¹ and the Global Innovation & Technology Alliance (GITA), initiated by CII and the Department of Science & Technology (DST).

While several excellent technologies have emerged with the support of these platforms, there is urgent need to adapt the programs better for late stage validation that needs greater quantum of funding in a more time sensitive process. Most mid-tier Indian device companies enjoy market reach and commercial knowledge to grow at an accelerated pace but need to be equipped with clinically validated contemporary products that can make them competitive. Novel de-risking funding mechanisms need to be created to help cross this barrier and also support technology access.

4.3 Industry-Academia Technology partnerships

Research converging clinical, engineering and biochemical expertise has been structurally difficult in India given the institutional silos in the Indian education system. Forerunners such as the Sree Chitra Tirunal Institute in Trivandrum have contributed impactful innovation in devices. However, the larger ecosystem needs to be transformed to create a ripe landscape where academia provides the research and innovation advantage to industry. Several initiatives triggered in this direction during the last decade include:

- The Healthcare Technology Innovation Centre (HTIC) located

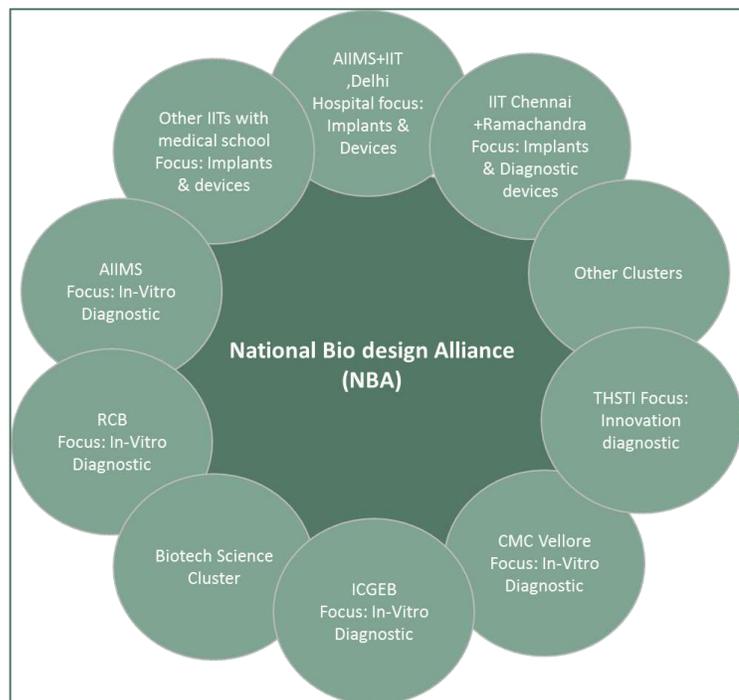


Figure 8 National Biodesign Alliance

¹⁰ Biotechnology Industry Research Assistance Council, India

¹¹ Technology Development Board, India

at IIT Madras (IITM), a joint initiative of IITM and Department of Biotechnology (DBT).

- The National Biodesign Alliance (NBA), a multi-institutional partnership program in Biodesign initiated by the Department of Biotechnology (DBT) and includes partners such as IIT Delhi, IIT Madras, All India Institute of Medical Sciences (AIIMS), and CMC Vellore among others.
- Sree Chitra Tirunal Institute for Medical Sciences and Technology (SCTIMST), Trivandrum - Biomedical Technology Wing (BMT Wing), committed to medical device development, research and teaching.
- The Stanford-India Biodesign (SIB) programme initiated by the Department of Biotechnology (DBT) with partners in All India Institute of Medical Sciences (AIIMS) and IIT Delhi.
- The Centre for Biodesign and in-vitro Diagnostics at Translational Health Science & Technology (THSTI), Faridabad.

While the recent efforts imply a more engaged and applied research system, India needs multi-fold increase in focus on contemporary research in academia that can support industry with competitive products and technologies. Nurturing this potential during the current decade will be important to propel Indian industry towards its potential.

4.4 Focus on Clinical Validation

Hospitals and orthopedic doctors in India cite lack of establishment of quality of Indian implants as the main reason for their reluctance to use them in clinical procedures, especially in non-trauma cases such as hip, spine and knee replacement procedures, where the product has to remain implanted for a longer period of time. On the other hand, however, domestic manufacturers claim comparability in quality of their products due to commonality in materials and designs. This gap in understanding can be bridged through adequate clinical validation. Currently, only couple of Indian companies have clinically validated products. Indian companies can compete more effectively if they lay greater emphasis on clinical validation to generate comparable data, and produce studies and papers to support their claims on quality and longevity. It is important to orient industry to criticality of holistic validation including in-vivo studies, simulated studies and rigorous clinical validation. Funding support from the Government and creation of centers of excellence for implant validation could support this critical transition.

4.5 Partnering with Global Companies

By building partnerships with global companies and collaborating on technology programs, domestic companies can seek access to innovation and adapt such technology to suit domestic requirements in terms of price and product customizations. Collaborative models such as Joint Ventures or Technology licensing partnerships could help industry compete with globally validated designs and products and provide more reliable options to clinicians. We perceive significant opportunity for such synergistic partnerships between Indian companies and international mid-sized partners. While Indian companies such as Meril, Biorad, TTK and Sharma Orthopedics have pursued such collaborations, there is a need to greatly intensify level of activity on such collaborations.

4.6 Revision of Import Duties Structure

The current duty structure is skewed towards imports with duties on imported medical devices being significantly lower than the duties on imports of raw materials for manufacturing the same devices. For instance, even with the recent hike in duties for orthopedic implants, importers

Sharma Orthopedics

Sharma Orthopedics is one of the larger domestic orthopedic companies in India, with presence in the Trauma, Knee and Hip segments. Based out of Vadodara, India, it is one amongst the fewer Indian firm to have obtained CE approval for its products and it exports products to over 80 countries around the world. The company has 400 distributors across India and around 100 distributors globally.

With vision for market leadership by 2030, Sharma Ortho is scaling up by continuing the emphasis on quality, seeking technology collaborations and identifying high growth market opportunities.

Technology and Product Innovation

In the knee segment Sharma Ortho intends to launch a total knee replacement system by end of this year. They have innovated in **Revision Knee procedures** by providing products at a fraction of the cost of imported implants. Revision knee surgeries are longer and more complex and require extensive planning and specialized implants and tools to achieve good results. They form around 2-3% of total knee surgeries performed.

Sharma Ortho has also differentiated itself by providing superior instrumentation, a practice not common with other Indian companies given the need for high investments.

Partnering with Global Companies

Sharma Ortho partners has partnered with a company in Europe to gain access to innovative technologies. Sharma Ortho has been leveraging this technology advantage along with its inherent access to clinicians to prioritize technology and product need and low cost but high quality manufacturing base in India.

pay a mere 7.5% duty, while the import of materials like titanium can be as high as 28%. Domestic manufacturers thus focus on improving their quality and keeping price margins down rather than on innovating technology. In certain countries such as Egypt and Brazil, the respective governments have banned the import of medical products to support local manufacturers with only a handful of companies allowed to supply the products. In China, there is a strong bias towards locally manufactured products.

While price controls and other extreme measures might only be detrimental to the industry, it is important that equitable competition is nurtured and the duty structure is further rationalized to give domestic players a level playing field and foster domestic innovation and manufacturing.

4.7 Increase enforcement of Indian Regulatory Standards

Domestic manufacturers are at a severe disadvantage when competing with multinationals when it comes to obtaining regulatory approvals. The cost of obtaining CE or USFDA certification is cost-prohibitive, especially when companies are selling primarily within India. However, almost every government tender floated today uses the CE or USFDA mark as a criterion to shortlist bidders. This is an understandable step in the absence of strong regulatory requirements and enforcement mechanisms in India. As a first step, the government must strengthen the Indian standard, and make it mandatory for Indian companies to meet this, and then slowly ease out the practice of using foreign regulatory approvals as a qualifying criterion.

Deal Outlook



5 Deal Outlook

Osteoarthritis affects over 15 million adults every year. By 2025, the number of osteoarthritis cases in India are expected to grow to 60 million, spurred by factors like ageing, sedentary lifestyles and increasing incidence of obesity and diabetes. Surgical intervention is considered the best treatment option for patients today. There is also a vast untapped market with several sections of the population lacking access to healthcare. India's healthcare expenditure is a mere 4.7% of its GDP compared to 17% for the US and is expected to grow 2-3 times faster than the global average. We have discussed below finer aspects of the investments and M&A landscape we perceive in the segment.

5.1 Mergers and Acquisitions (M&A) in Orthopedic Devices

The close to 20% growth offered by the Indian orthopedic devices market in India continues to attract interest from multinational device companies as well Indian corporate groups seeking a share of the market. We believe that multinationals as well as new Indian entrants into the market will judiciously engage in pursuing selective inorganic growth opportunities. Recent changes to allow 100% FDI in not only greenfield projects but also brownfield projects supports this potential.

However till date, M&A deals in the orthopedic space have been few and far between, such as Smith & Nephew's acquisition of Sushrut-Adler in 2013. Historically, given the primary focus on trauma, most Indian companies have offered neither substantial market share nor innovative portfolios.

Looking east – the China example

We have discussed below the M&A landscape in the Chinese orthopedic device companies. Given the focus of global medical device companies to strengthen presence across China and India, we believe this could be reflective of possibilities in India if the focus on enhancing product portfolio continues in top tier of the market and gradual consolidation occurs across middle tier.

China initiated large-scale healthcare reforms in 2010 to expand access to healthcare, improve the quality and reduce the cost of care. To encourage domestic industry, the Chinese government has issued a number of preferential policies for local companies. It has been promoting Chinese

Acquisition of Sushrut Surgicals

Sushrut-Adler was acquired by global orthopedic firm, Smith & Nephew in 2013. The Indian firm is a Pune-based midsize orthopedic company with significant market presence in the Trauma segment. Sushrut was started in 1973 and was one of India's oldest and most trusted companies in the orthopedics space. It was the first Indian orthopedic device manufacturer to secure CE approval in 2003.

With this acquisition, Smith & Nephew gained a foothold in the Indian trauma market along with a strong and experienced sales force and marketing channels.

branded medical devices in hospitals and medical institutions, both to encourage domestic industry and to control its soaring healthcare costs. It has also set up funds to improve R&D capabilities of domestic manufacturers, overhauled its regulatory process in 2014 (including setting up a fast-track regulatory process for innovative devices such as high-risk implants) and updated its Device GMP in 2015 to improve domestic quality and encourage innovation.

There has been an active landscape of multinationals acquiring or entering into joint ventures with Chinese companies, as well as establishing production facilities in China. Some of the notable deals in orthopedics are summarized below.

China - Inbound				
Target	Acquirer/Investor	Deal Type	Deal Value (\$M)	Year
Wuhan Dragonbio Surgical Implant Co	Mindray Medical	Acquisition	73 (49%), 35 (51%)	2015, 2012
Suzhou Xinrong Best Medical Instrument Co	Blackstone Group	Equity investment	~ 100 (not confirmed)	2014
Trauson Holdings, HK	Stryker	Acquisition	764	2013
Kanghui Holdings	Medtronic	Acquisition	816	2012
Beijing Montagne Medical Device Co	Zimmer	Acquisition	52	2010
Bonovo Orthopedics	OrbiMed Asia Partners, Legend Capital etc	Equity Investment	10	2010
China - Outbound				
OrthoRecon business of Wright Medical, USA	MicroPort Scientific, Shanghai	Acquisition	290	2013

Figure 9 Deal Snapshot in the Chinese Orthopedic Industry

India – Way Forward

We expect more active pursuit of M&A opportunities in the future due to the following reasons:

1. Emergence of substantial Indian companies in the hip and knee implant segment

In the last eight to ten years, couple of Indian companies have entered the market with total knee replacement products, have globally partnered to access technologies and have obtained certifications such as CE and USFDA approvals for their products. They are aggressively gaining market share as well as valuations.

2. Private Equity funding supporting scale-up of mid-tier Indian companies and priming potential acquisition targets

Handful of healthcare focused private equity funds have emerged in India and they have the appetite to fuel growth in the mid-tier companies. They can support scale up of companies present in knee and hip implants and help expand market share for credible companies in trauma. They can also support the investments and risk required to be shouldered for dominant companies in trauma to expand portfolios into high-value joint replacements segment.

These mid-tier companies offer high potential for growth given their regional dominance in hospital relationships, respect for regulations and desire to remain organized. If support for next level scale-up, several strong acquisition targets can emerge in this segment.

3. Acquisition of relationships beyond Tier 1

While most multinationals focus on strong clinical engagement and have nurtured relationships with several Key Opinion Leaders, the mid-tier Indian companies offer hospital and clinician relationship strengths in regional pockets and tier 2 markets.

4. Gradual consolidation within trauma segment creating players with larger market presence

We foresee gradual consolidation in the highly fragmented trauma market. In addition to private equity funding, consolidation within the segment will lead to more companies emerging with stronger market share and more convincing acquisition rationale.

5. Interest from Indian corporate groups not present in medical devices/orthopedic

The Indian medical devices segment is attracting interest from not only multinationals but also Indian corporate houses with presence in related areas (pharma, industrial ceramics and precision machining etc.). These potential new entrants are exploring both possibilities – domestic acquisitions to get a foothold in the market as well as international acquisitions to gain the product and technology advantage.

5.2 Private Equity Investment in Orthopedic Device Companies

There is high appetite amongst Private Equity funds to invest in the Indian medical devices segment overall and such appetite extends to the orthopedic devices segment. This is spurred by both emergence of companies poised for growth in the current landscape and funds with a fit on investment size. A recent example would be India Life Sciences Fund II's investment in Biorad Medisys¹² in January 2016.

Several mid-tier companies in trauma now aspire to more aggressively gain greater market share as well as make the high risk transition to include knee implants and/or hip implants in their portfolio. In addition to infrastructure investments, technology access from global sources and market seeding investments are critical for such transition. Growth oriented Indian companies that already have a knee implant product in their portfolio are seeking private equity support to cross the capital-intensive path to CE marked devices backed by clinical data. Lastly, armed with CE marking and global technology, there is great potential for private equity capital to fuel growth in international markets, with a particular focus on rest of the world.

Given this landscape, we perceive more momentum in investments that range between USD 4 Mn (Rs. 20 crores) to USD 15 Mn (Rs. 100 crores). Given the expanding presence of private equity funds with mid-segment interest in Indian healthcare, we present a very optimistic outlook on private equity investments in this segment. Such investment will either prime the market for subsequent M&A activity or position investee companies as successful IPO candidates.

PE Investment in Biorad Medisys

Biorad Medisys is a 17-year old Pune-based company operating in the hip and knee segments in India. The company manufactures the Indus Knee, India's first totally indigenous Posterior Stabilized knee prosthesis which was developed by Dr K H Sancheti in 2006. Apart from this the company also offers total hip replacement (THR) systems. It is the first Indian company to introduce ceramic heads with its uncemented THR system in India.

The company has strong clinical validation for its products, with multiple studies and papers being generated to prove its efficacy. It has also launched India's first registry initiative to map the clinical performance of medical devices used in arthroplasty.

Biorad Medisys recently secured investment of Rs 50 crore from PE firm, Invascent, in January this year, which it plans to use for expansion and acquisitions.

¹² Invascent Capital's investment in Biorad Medisys, Vccircle.com, March 2016

Conclusion



Conclusion

The Indian orthopedic industry has tremendous potential for growth. Demographic and lifestyle factors have made this one of the highest growth markets globally, attracting several multinational companies to sell and in some cases, establish local knowledge and research centers in India. Growth is expected to be more rapid in the knee segment vs the hip or spine segment.

The market landscape is also evolving in several ways. Firstly, while multinationals have long dominated the market, there has also been the emergence of a handful of domestic manufacturers which are producing products backed by global collaborations for technology and often even global regulatory approvals. In terms of market segments as well, while domestic companies have led in trauma, they are now also innovating and moving up the value chain to start competing in the higher-value hip and knee segments. Some companies are also expanding market territory and are aggressively seeking opportunity in export markets. India needs to address current challenges of the domestic industry, foster an innovation ecosystem and nurture more competitive Indian companies to create a balanced market structure.

In terms of investments in the orthopedics space, we anticipate more robust activity on M&A and PE deals. Outbound deals to acquire innovative technology should increase, while inbound M&A could be a fuel for growth.

A robust regulatory framework and accommodating political environment is essential if the twin goals of affordable healthcare and innovation are to be achieved. The industry also needs to improve their R&D capability, and collaborate with academic institutions to introduce innovative products that can expand the market and drive price rationalization.

The evolving market structure calls for Indian companies and multinationals to adapt their strategies to participate in the expected growth as the Indian market surges towards the potential of USD 2.5 Bn.

Abbreviations

AIMED	Association of Indian Medical Device Industry
AP	Andhra Pradesh
BIPP	Biotechnology Industry Partnership Programme
BIRAC	Biotechnology Industry Research Assistance Council
BIS	Bureau of Indian Standards
BMAC	Bone Marrow Aspiration Concentrate
BMP	Bone morphogenetic protein
Bn	Billion
CAGR	Compounded Annual Growth Rate
CE	Conformité Européene
CLI	Critical limb ischemia
CRAMS	Contract Research And Manufacturing Services
DBM	Demineralized bone matrix
DBT	Department of Biotechnology
DST	Department of Science & Technology
ENT	Ear, Nose , Throat
FDCA	Gujarat Food and Drug Control Administration
FDI	Foreign Direct Investment

IIPM	Industry Innovation Programme on Medical Electronics
GITA	Global Innovation & Technology Alliance
INR	Indian National Rupee
ISO	International Organization for Standardization
Mn	Million
MRP	Maximum Retail Price
MSC	Mesenchymal stem cells
MSP	Minimum Selling Price
NABCB	National Accreditation Board for Certification Bodies
NHSRC	National Health Systems Resource Centre
NLEM	National List of Essential Medicines
NPPA	National Pharmaceutical Pricing Authority
OA	Osteoarthritis
PRP	Platelet-Rich Plasma
QCI	Quality Council of India
SAD	Special Additional Duty
US FDA	Food and Drug Administration
USD	U.S. Dollar

Appendix

Recent Global M&A and partnership activity in the Orthopedics industry

1. DePuy Synthes part of Johnson & Johnson, acquired BioMedical Enterprises in May, 2016.
2. Stryker acquired Stanmore Implants, UK for \$52M in May, 2016.
3. Stryker completed its acquisition of the CareFusion vertebral compression fracture portfolio of products from Becton, Dickinson and Company in April, 2016.
4. Stryker acquired Physio-Control Inc. from Bain Capital for \$1.28 billion in April, 2016.
5. Stryker Spine acquired SafeWire's Y-Wire guidewire and Tiger Jamshidi Needle Family portfolio in April, 2016.
6. Novastep, a manufacturer of orthopedic products for foot and ankle, entered into an agreement with Vivex Biomedical to gain access to Vivex' catalog of allograft materials.
7. Xtant Medical, an Ohio-based developer and manufacturer of implants and surgical instruments for surgery of the spine, entered into a distribution agreement with Vivex Biomedical.
8. NuVasive Inc, a medical device company focused on spine surgery, entered into a definitive agreement to acquire Mega Surgical, its exclusive distributor in Brazil, in March, 2016.
9. Zimmer Biomet entered into a definitive agreement to acquire Cayenne Medical, a leader in the soft tissue repair and reconstruction segment of sports medicine in April, 2016.
10. Zimmer Biomet completed the acquisition of Colorado-based Ortho Transmission LLC, a developer of skeletal implant technology in March, 2016.
11. Zimmer Biomet acquired French company, Medtech SA in July, 2016 at a valuation of \$132 million. Medtech develops robotic products for use in surgical procedures, primarily the brain.
12. Zimmer Biomet acquired LDR Holdings, USA for \$1.08 billion in June, 2016. LDR develops medical devices used in spinal surgical procedures.

Upcoming trends

<p>Orthobiologics¹³</p> <ul style="list-style-type: none"> • The global orthobiologics market is anticipated to grow at a CAGR of 7.03% between 2016 and 2020 • Genzyme was the largest player in the Indian biologics market in 2015 with its Synvisc and SynviscOne HA products. 	
<p>Bone graft substitutes</p> <ul style="list-style-type: none"> • These include DBMS, BMPs and synthetic bone graft extenders. DBMS and synthetic substitutes such as ceramic are used in combination with the patient's own bone while BMPs can be used independently. • Medtronic leads the bone graft substitute market with nearly 20 percent of the market share in 2014. Medtronic is also a leader in spinal fusions, which is an effective sales channel for bone graft substitute products. • Within the Indian bone grafts substitutes market specifically, DePuy Synthes was the leader in terms of sales with its synthetic-based ChronosOn product portfolio. 	<p>Bone morphogenetic protein (BMPs)</p> <ul style="list-style-type: none"> • BMPs are a group of growth factors used in spinal fusions and nonunions. • This market shows sluggish growth in some areas, according to a Research and Markets report. • The rhBMP-2 segment had the largest share of the global market in terms of revenue in 2013. It has been widely accepted by physicians due to effectiveness in treating spinal fusions. However it causes more overgrown bone than any other BMPs and is widely used off-label.
<p>Viscosupplementation</p> <ul style="list-style-type: none"> • It is a method of injecting hyaluronic acid in stiff joints, growth expected 	<p>Platelet Rich Plasma (PRP)</p>

¹³ Beckersspine.com

<p>from the rise in aged population suffering from osteoarthritis.</p> <ul style="list-style-type: none"> • The viscosupplementation market is expected to grow to a value of \$ 2.65 billion by 2021. Japan is the second largest market after the US, with significant growth expected in APAC in the near-term. • Major players include Ferring, Anika Therapeutics, Bioventus and Chugai. 	<ul style="list-style-type: none"> • This is a method of injecting blood plasma that has been enriched with a higher concentration of platelets. • The increase in the number of sports and musculoskeletal injuries and ageing will drive this markets. • Key players include Arthrex, Stryker, DePuy, Zimmer Biomet, Terumo, Glofinn Oy, Medira, and Regen Lab S.A, AdiStem Ltd., Biomet, Inc., DePuy Synthes, Inc., EmCyte Corporation, Harvest Technologies Corp., and Stryker Corporation. • The PRP market is expected to grow to \$ 350 million by 2020.
<p>Stem Cells</p> <ul style="list-style-type: none"> • Stem cells, especially Mesenchymal stromal cells (MSC) which are found in post-natal organs are being used for the treatment of osteoarthritis. • Faster recovery, lower costs and no risk of transmission will drive future growth. • This market is still in its infancy but is projected to grow the fastest globally. 	<p>Bone Marrow Aspirate Concentrate (BMAC)</p> <ul style="list-style-type: none"> • BMAC is a minimally invasive autologous blood therapy procedure that uses the patient’s own stem cells in concentrated form to stimulate the healing process¹⁴. • BMAC harnesses the body's natural ability to heal itself by using regenerative cells found in a patient's own bone marrow. • The BMAC concentrate is capable of regenerating tissues to a greater degree than the PRP. • It is usually reserved for cases in which there is significant tissue damage. • It is the latest and most-promising of all the biologics.

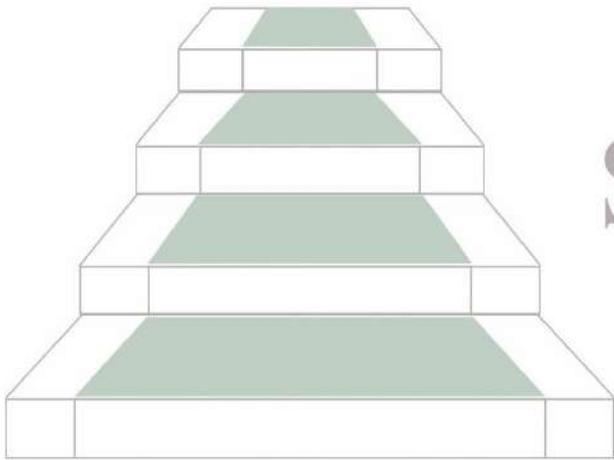
¹⁴ Thebloodcompany.com

Robotic surgery

Stryker	Stryker was first to invest into robotics with the acquisition of MAKO Surgical in late 2013 for \$1.6 billion
Smith & Nephew	Smith & Nephew acquired Blue Belt Technologies' Navio robotic system in Jan 2016.
Medtronic PLC	Mazor Robotics, a leading developer of innovative bone mounted surgical robotic guidance systems, entered into two strategic agreements with Medtronic in May 2016. Medtronic plans to launch the robot before 2019, and will have the first systems roll out in India
Zimmer Biomet	Zimmer Biomet plans to acquire majority stake in MedTech, a France-based company focused on the ROSA Robotic System for brain and spine surgery which already has regulatory approval in Europe and achieved FDA clearance in January 2016. There are 82 ROSA robots installed worldwide
Verb Surgical	Verb Surgical, a startup supported by Johnson & Johnson, may likely be a competitor for Medtronic's robot. Alphabet's Google is also in the development phase of a surgical robot.

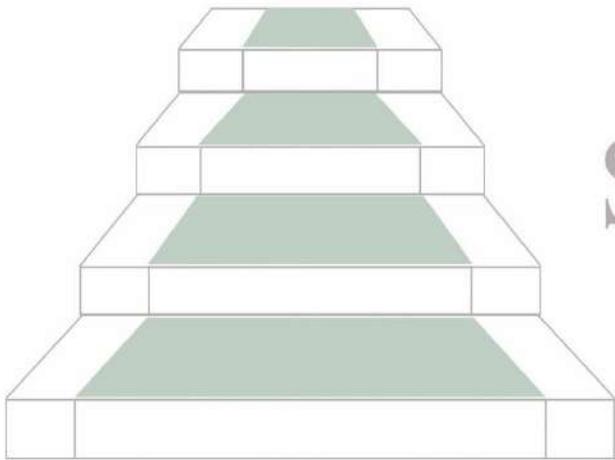
Surgical navigation systems market

The global surgical navigation systems market reached \$385.5 million in 2012 and is expected to grow to \$631.9 million in 2018. The orthopedics systems market within the surgical navigation systems market reached \$120.5 million in 2012 and is expected to grow to \$201.9 million in 2018.



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