

The Medical Device Industry in India

Therapeutic Areas



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Foreword



Foreword

In 2015, as a part of SKP's series that focuses on the healthcare sector in India, we published a report, *The Medical Device Industry in India*, providing an overview of the changing dynamics and environment of the industry, the impact on various players and the opportunities likely to arise in the coming years. In continuation, we present to you our latest report, *The Medical Device Industry in India: Therapeutic Areas*.

The Indian medical device sector, valued at USD 4.9 billion in 2015, is relatively small in the Indian healthcare industry, but has seen unprecedented growth in the last few years. Growing at a CAGR of 17% over the last five years, the sector is expected to continue witnessing double-digit growth with a CAGR of 15% in the coming decade. Currently, there is no standard market classification used globally due to the overlap between the various methods and the various applications of medical devices. As a result, most companies and industry experts use their own classification for the market.

In our series, we have attempted to classify medical devices according to their usage areas. This report provides insights on four major therapeutic areas – cardiovascular, diabetes care, orthopaedics and neurology. For each of these areas, besides an overview of the market, we discuss the classification, players, challenges, outlook, and finally, a cluster synopsis of the major Indian medical device manufacturers, distributors and exporters.

The increasing prevalence of lifestyle-related ailments is leading to growing demand for more advanced medical device support. Presently, although 13.7% of global deaths due to cardiovascular diseases occur in India, the Indian cardiovascular device market is only about 1.8% of the global market. Affordability of devices and the high cost of surgery are the major challenges faced by this segment. India has the second highest diabetes patients in the world. In addition, given the large number of people who remain undiagnosed, we can see that the Indian diabetes care device market is underpenetrated. The rising number of arthritis patients and increasing awareness of joint replacements are some of the key drivers of the fast-growing Indian orthopaedics and prosthetics market. The neurological device market is expected to be driven by patients with disorders such as multiple sclerosis, brain cancer, Parkinson's disease, etc.

Given the requirements and potential of this sector, the Indian government is taking steps to strengthen the regulatory and policy framework. Furthermore, campaigns such as 'Make in India', the increasing focus on innovation in research and development (R&D), and growing investments from the government and private companies are expected to increase opportunities for both domestic as well as international players.



Saloni Jhaveri
Partner
Business Advisory
SKP

SECTION 01

Market Overview



Market Overview

The Indian medical device market was valued at USD 4.9 billion in 2015. Macroeconomic factors and upcoming developments in the regulatory and policy framework are expected to accelerate growth of the sector at an estimated 10-year CAGR of 15%. The industry is highly fragmented and dominated by imports with almost 70-75% of demand being met through imports.¹

The value chain includes manufacturers, distributors, dealers and health establishments (hospitals, chemists, etc.). Margins for health establishments are the highest, followed by manufacturers, distributors and dealers. For distributors, margins are high, e.g., for implants (cardiac, orthopaedic and neurological) as compared to diagnostic devices. The distributors in India sell to health establishments which result in lower margins, compared to their international counterparts who create a market for the products and brands.

Manufacturer's Margin	Moderate
Distributor's Margin	Low
Dealer's Margin	Low
Health Establishment's Margin	High

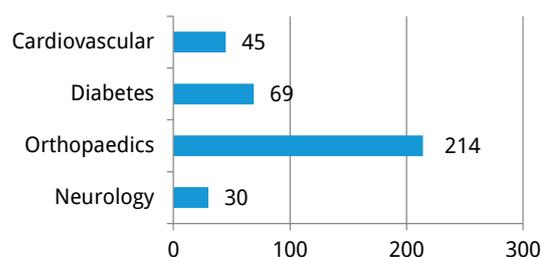
Source: SKP Analysis

Recent changes with respect to regulatory policies and domestic innovation, especially with the government's focus on the Make in India campaign, is likely to promote local manufacturing of components and devices, and improve penetration of healthcare services in rural areas, among others.

In terms of market classification, there is no standard system followed globally as there is an overlap between the various methods and the various applications of medical devices, hence companies and industry experts tend to use their own classification. Based on our analysis, we have broadly classified the sector on the basis of therapeutic areas.

In India, as the majority of the population suffers from orthopaedic, cardiovascular, neurological ailments and diabetes, these therapeutic areas are the most prominent in the Indian medical device industry.

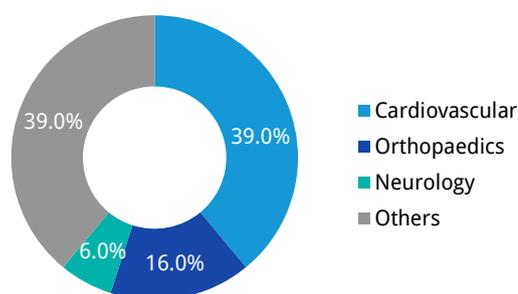
**Number of People Suffering: 2015
(in millions)**



Source: SKP Analysis

Considering the number of medical device registrations from 2006 to 2014, cardiovascular device registrations were the highest, followed by orthopaedic devices.

Number of Device Registrations: 2006 - 2014



Source: SKP Analysis, Morulaa

¹ The Medical Device Industry in India, SKP, January 2016, http://www.skpgroup.com/data/resource/skp_the_medical_device_industry_in_india_.pdf

SECTION 02

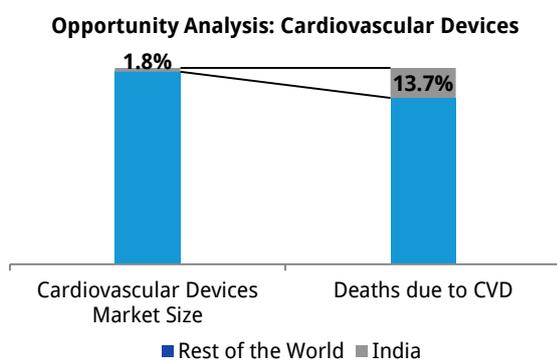
Cardiovascular Devices



Cardiovascular Devices

Market Overview

The Indian cardiovascular device market is a meagre 1.8% of the global market.² However, of the 17.5 million deaths due to cardiovascular diseases (CVD) in the world,³ approximately 2.4 million deaths occur in India.⁴ Considering these facts, the cardiovascular device market, valued at approximately USD 1 billion in 2015 and growing at about 15% per year, is likely to witness major growth.



Source: SKP Analysis

Drivers

The growing rate of heart diseases, increasing awareness among people, a preference for less invasive surgical methods, and technological advancements are the main drivers of growth. On the demand side, hospitals are the major driver, especially private hospitals that demand the latest technologies in cardiovascular monitoring and treatment systems.

Classification

Broadly, the cardiovascular device market can be classified into four segments: circulatory support devices, interventional devices, cardiac rhythm management devices and vascular surgery devices.

Under interventional devices, coronary stents account for the largest share while under cardiac rhythm management devices, pacemakers (external and internal) and defibrillators hold the largest share.

Cardiovascular Devices

Classification	Examples
Circulatory Support Devices	Artificial hearts
	Ventricular assist devices (VAD)
	Cardiopulmonary resuscitation (CPR) devices
Interventional Devices	Stents, catheters
	Diagnostic devices (intravascular ultrasound, optical coherence tomography (OCT))
	Valve replacements
Cardiac Rhythm Management Devices	Pacemakers (external and internal)
	Defibrillators
	Stimulators
Vascular Surgery Devices	Clamps
	Grafts
	Filters

Source: SKP Analysis

SKP Primary Research Insights

Most cardiac-surgeons in India see the need for technological intervention in interventional devices

² Cardiovascular Medical Devices: World Market, Industry, Trends and Revenue Forecasts 2015-2025, Visiongain, November 2015, <https://www.visiongain.com/Report/1537/Cardiovascular-Medical-Devices-World-Market-Industry-Trends-and-Revenue-Forecasts-2015-2025>

³ Cardiovascular diseases, Fact sheet No. 317, World Health Organization, January 2015, <http://www.who.int/mediacentre/factsheets/fs317/en/>

⁴ World Heart Day 2014: Is India Staring at a Heart Disease Epidemic?, NDTV Food, 29 September 2014, <http://food.ndtv.com/health/world-heart-day-2014-is-india-staring-at-a-heart-disease-epidemic-696152>

Players

Companies from USA and Europe are the major players in this segment and include Medtronic, Boston Scientific, Sunshine Heart Company, Sandvik AB and Philips. Indian companies operating in this segment include Sahajanand Medical Technologies (SMT), Opto Circuits and Relisys.

Indian companies have been focused on the production of stents, catheters and defibrillators while foreign companies have a larger product portfolio in India.

Some of the latest innovations in the segment include non-invasive vascular screening monitor for the prevention of cardiovascular diseases by Omron Healthcare India and Medtronic's EV-ICD system (under development), which is a new approach to Implantable Cardioverter Defibrillator (ICD) therapy by placing leads outside the heart and veins and under the rib cage. Also, a team of international scientists have developed a stapler-like device that will help doctors perform heart surgery while it beats. Hence, in the future, innovation will be driving this segment in order to simplify the treatment of CVDs globally as well as in India.

Major Product Portfolio Analysis

Cardiovascular Devices	Domestic Players			Foreign Players in India*		
	Opto Circuits	SMT	Relisys	India Medtronic	Boston Scientific	Philips Healthcare
Circulatory Support Devices						
Interventional Devices						
Cardiac Rhythm Management Devices						
Vascular Surgery Devices						

*Foreign Players present in India either through distributors or their own set-up

Challenges and Outlook

In India, high surgical costs and lack of accessibility make the timely treatment of cardiac diseases difficult for most people. Other challenges include the lack of clarity on segment-specific regulatory policies, shortage of skilled surgeons, complex surgical procedures, and higher imports due to the increasing sophistication in cardiovascular devices.

In the future, poor lifestyle choices (lack of exercise, consuming more fast food, smoking, etc.) and environmental stressors are likely to increase cardiac diseases among Indians. Estimates suggest there could be more than 30 million heart patients in India.⁵ On the bright side, safe and comfortable

SKP Primary Research Insights

Most cardiac surgeons believe that lack of affordability of cardiovascular devices and the high cost of surgeries are the major challenges in cardiovascular therapy.

Cardiac surgeons' top requirements from medical device manufacturers are:

- Improve devices to increase their accuracy and reduce surgery time
- Innovate and have a range of new products

⁵ India needs a comprehensive approach to combating heart disease - Vice President inaugurates 11th World Heart Day event, Press Information Bureau, 27 September 2015, <http://pib.nic.in/newsite/PrintRelease.aspx?relid=128227>

SECTION 03

Diabetes Care Devices



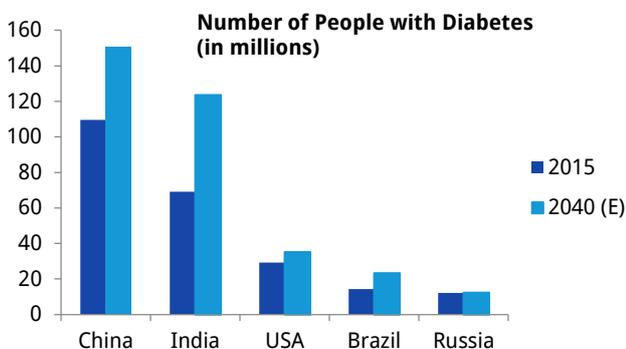
Diabetes Care Devices

Market Overview

Among the BRIC nations, India is the third largest market for diabetes care devices after China and Brazil. The Indian market is valued at more than USD 200 million and is expected to grow at a CAGR of nearly 6.5% until 2019. India is expected to witness the highest growth rate as compared to other BRIC nations.⁶

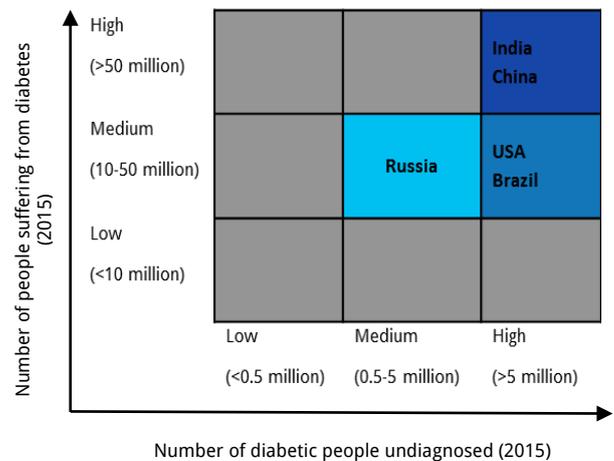
India accounts for the world's second highest number of diabetes patients (69.2 million in 2015) that are expected to rise to 123.5 million by 2040.⁷ Also, the number of people (20–79 years) in India with undiagnosed diabetes stood at over 36 million in 2015.⁸ Despite these high numbers, India is not among the top ten countries in terms of diabetes-related health expenditure.

Based on SKP's opportunity analysis, it can be concluded that the Indian diabetes care device market is still underpenetrated, providing many opportunities for market players. The growing prevalence of diabetes, increasing awareness about the disease, changing food habits and lifestyle are some of the key drivers.



Source: SKP Analysis, International Diabetes Federation

Opportunity Analysis: Diabetes Care Devices



Source: SKP Analysis

Classification

Diabetes care devices can be classified into two broad segments: blood glucose monitoring devices and diabetes management devices.

The diabetes management device market is projected to increase at a CAGR of over 9% during 2015–2020, while the market for blood glucose monitoring devices is expected to grow at a higher rate in the future.

Diabetes Care Devices

Classification	Examples
Blood Glucose Monitoring Devices	Testing strips, lancets
	Self-monitoring blood glucose meters
	Continuous glucose monitors
Diabetes Management Devices	Insulin pumps
	Insulin syringes
	Insulin jet injectors
	Insulin pens

Source: SKP Analysis

⁶ India Diabetes Devices Market - Growth, Trends & Forecast (2015-2020), Mordor Intelligence, March 2016,

<http://www.mordorintelligence.com/industry-reports/india-diabetes-devices-market#>

⁷ IDF Diabetes Atlas - 7th Edition, International Diabetes Federation, <http://www.diabetesatlas.org/across-the-globe.html>

⁸ International Diabetes Federation, 2015, <http://www.idf.org/membership/sea/india>

Players

The diabetes care market is highly fragmented with almost half being controlled by the top 5-6 players and the remaining half by several small players and a few global players that are trying to establish themselves in the growing Indian market. Many American and European companies have strong portfolios of diabetes care products in India. These include Sanofi, Gambro, Becton Dickinson, Novo Nordisk, Medtronic, Bayer, and Roche, while the Indian players in this segment include Biocon and Mehar Healthcare Corporation.

As seen in cardiovascular devices, foreign players in India are supplying a larger portfolio of products compared to domestic companies. Foreign companies have been innovating with respect to blood glucose meters, insulin pens, etc. and updating them with smart features e.g. Novo Nordisk's smart insulin pen.

Major Product Portfolio Analysis

Diabetes Care Devices	Domestic Players		Foreign Players in India			
	Biocon Ltd	Mehar Healthcare	Sanofi India	Becton Dickinson	Novo Nordisk	Roche
Blood Glucose Monitoring Devices						
Diabetes Management Devices						

*Foreign Players present in India either through distributors or their own set-up

Challenges and Outlook

Many top players such as Becton Dickinson (BD), Sanofi and Biocon are working towards increasing diabetes awareness through patient screening and counselling (e.g. BD's Beat Diabetes programme; Biocon's joining hands with Bayer for creating awareness for self-monitoring devices). However, introducing relevant, innovative solutions is proving difficult as the industry has many small companies, of which very few are focused on creating solutions.

According to the International Diabetes Federation, an average Indian patient with diabetes spent as little as USD 95⁹ on health maintenance, which poses another challenge for players in India. This has led to the entry of cheaper self-testing devices in the country that are banned in several developed countries due to their unreliable test results.

In the future, a surge in the domestic manufacturing of diabetes care devices, especially diabetes management devices, is expected to play an important role in their adoption due to their reduced cost. Moreover, the lack of exercise and dietary habits (consuming food rich in fat and sugar) are likely to increase the number of diabetic patients, leading to higher demand for such devices.

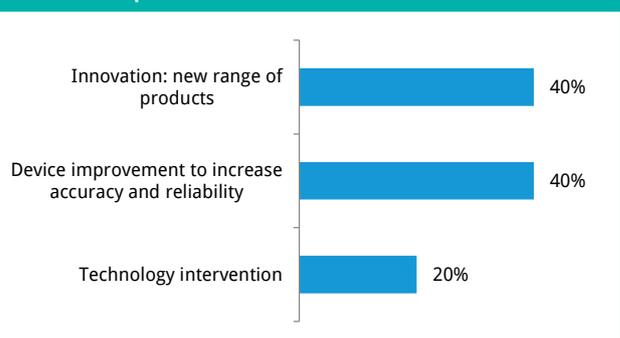
SKP Primary Research Insights

Most MDs/physicians/endocrinologists believe the most important challenges in the diabetes care area are:

- Lack of awareness about the disease/cure options
- Affordability of diabetes care devices
- Poor compliance of the patient for the advised treatment

SKP Primary Research Insights

MDs/physicians/endocrinologists' responses on being asked about the most important need of diabetes



⁹ IDF Diabetes Atlas - 7th Edition, International Diabetes Federation, <http://www.diabetesatlas.org/across-the-globe.html>

SECTION 04

Orthopaedic Devices



Orthopaedic Devices

Market Overview

According to our estimates, the Indian orthopaedic and prosthetic device market is valued at over USD 450 million, and is growing at over 30% per year. It is considered to be the most dynamic sector of the medical device market.

Although the market is highly fragmented and most implants are imported, there is still high potential for growth due to the growing ageing population (55 years and above), which accounted for about 12% of India's population according to the 2011 Census of India.

Classification

The market can be broadly classified as follows:

Orthopaedic Devices

Classification	Examples
Artificial Joints	Joint prostheses (knee, shoulder, hip, elbow, foot, ankle)
Fixation Devices	Fracture (bone plates, screws)
	Reconstructive devices (knee implants, hip implants, spinal disc replacements, etc.)
	Soft tissue
Consumables	Braces
	Belts, bandages
	Bone cement
Prosthetics	Artificial limbs
Arthroscopes	-

Source: SKP Analysis

In this segment, the market for reconstructive devices and soft tissues is expected to witness the highest growth in the future. The demand for artificial joints is also increasing with the rise in arthritis cases. The most widely practiced surgical options for arthritis globally – total knee arthroplasty (TKA) and total hip arthroplasty (THA) – are also rising in India. Almost 70,000 joint replacement surgeries were performed in India in 2011 alone.¹⁰

SKP Primary Research Insights

Orthopaedic surgeons would like to see good quality domestic devices

Players

Imports account for over 85% of the orthopaedic and prosthetic market. In 2014, USA accounted for over 50% of India's imports, followed by the European Union accounting for 26.6%, led by Ireland (16.3%), mainly due to the manufacturing activities of US multinationals in the EU. Switzerland supplied 9.1% of imports, including 20% of all imported artificial joints.¹¹

The key foreign players in this segment are Stryker, Zimmer, Medtronic, ArthroCare, ConMed and Exatec. Major Indian players in this segment are Atlas Surgical, Narang Medical, Apothecaries Sundries Manufacturing Co. (ASCO) and Invicta Meditek Ltd.

Artificial joints and fixation devices are the two major segments in the orthopaedic segment. With respect to these two, the Indian players are at par with foreign companies; however, foreign players provide a larger product portfolio.

The innovations in this area include Stryker's Mako robotic-arm assisted reconstructive surgery, Philips's BV Vectra which is a C-arm system dedicated to orthopaedic surgical procedures and Zimmer's Persona Knee System, which makes successful knee replacements by focusing on each patient's unique needs.

¹⁰ Indian Society of Hip and Knee Surgeons Joint Registry: A Preliminary Report, September 2013, <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3796925/>

¹¹ India Medical Devices Report, Q1 2016, BMI Research

Major Product Portfolio Analysis

Orthopaedic Devices	Domestic Players			Foreign Players in India*		
	Narang Medical	ASCO	Atlas Surgical	Stryker	Zimmer Biomet	ConMed
Artificial Joints						
Fixation Devices						
Consumables						
Arthroscopes						

*Foreign Players present in India either through distributors or their own set-up

Challenges

Awareness about joint replacements is very low in India – surveys indicate that only 10% of the urban population is aware of the detection and prevention of joint-related problems.¹² According to a FICCI report, only 2% of the relevant patients in India undertake knee implants.¹³ Also, many Indians avoid such fixation surgeries due to the risks involved and the prolonged recovery period. Issues related to the wearing out of surfaces with time and the generation of harmful particulate debris are other factors that discourage people from getting implants.

SKP Primary Research Insights

According to orthopaedic surgeons, the major challenges in this segment are:

- High recovery period and post-surgery complications
- Affordability of devices and high cost of surgeries

Outlook

Better and smoother implants and less invasive surgeries for joint replacements, fracture fixation, etc. will become more prominent in the future. Currently, research on orthopaedics is not considerable in India as it is an expensive proposition and needs major infrastructural support. India can utilise its reserve of intellect to develop this field in the future.

SKP Primary Research Insights

The top needs of orthopaedic surgeons from device/equipment manufacturers include:

- Device improvement to increase accuracy and reduce surgery time
- Innovation to expand the range of products

¹² Overview of Orthopedic Joint Replacement Market in India, Frost & Sullivan, <http://www.frost.com/prod/servlet/report-brochure.pag?id=P54D-01-00-00-00>

¹³ Medical devices industry: Realising the “Make in India” opportunity, FICCI, December 2015

SECTION 05

Neurological Devices



Neurological Devices

Market Overview

The global neurological device market was valued at USD 5 billion in 2012 and is expected to reach USD 13.6 billion in 2019, growing at a CAGR of 15.4%.¹⁴

Classification

The broad classification of the market is as follows:

Neurological Medical Devices

Classification	Examples
Neuro-stimulation Devices	Stimulation of spinal cord, vagus nerve, deep brain, gastric nerve, etc.
Interventional Devices	Neurovascular catheters
	Aneurysm coiling
	Cerebral balloon angioplasty
Cerebral Spinal Fluid (CSF) Management Devices	CSF shunts
	CSF drainage
Neurosurgery Devices	Neuro-endoscopes
	Stereotactic systems
	Ultrasound aspirators

Neuro-stimulation devices form the largest segment of the market.

The neurological devices market is expected to be driven by patients with neurological disorders such as multiple sclerosis, brain cancer, Parkinson's disease, Alzheimer's disease, epilepsy, etc.

Players

Most of the devices are imported from USA and Europe. Some key foreign players in India include Philips, J&J, Siemens, B. Braun, Stryker, Medtronic and W.L. Gore. There are no notable Indian players in this segment.

Challenges and Outlook

Neurological treatment involves complex, high-risk surgeries and an extended recovery time. Today, stealth technology is used to perform complicated neurosurgeries for the back and spine resulting in greater accuracy and reduced surgery time. Also, implants are becoming more specialised. The brain can now be regulated by modulating devices implanted in the neural network.

SKP Primary Research Insights

Most neurosurgeons seek the need of technological intervention in interventional devices and neuro-surgery devices.

The major challenges according to most surgeons are:

- The complicated nature and low success rate of surgeries
- Lack of awareness about the disease/cure options available

The most important requirements of neurosurgeons from device/equipment manufacturers are:

- Technological intervention
- Innovation to expand the range of products

¹⁴ Neurology Devices Market - Global Industry Analysis, Size, Share, Growth, Trends and Forecast, 2013 – 2019, Transparency Market Research, January 2015, <http://www.transparencymarketresearch.com/pressrelease/neurology-devices-market.htm>

SECTION 06

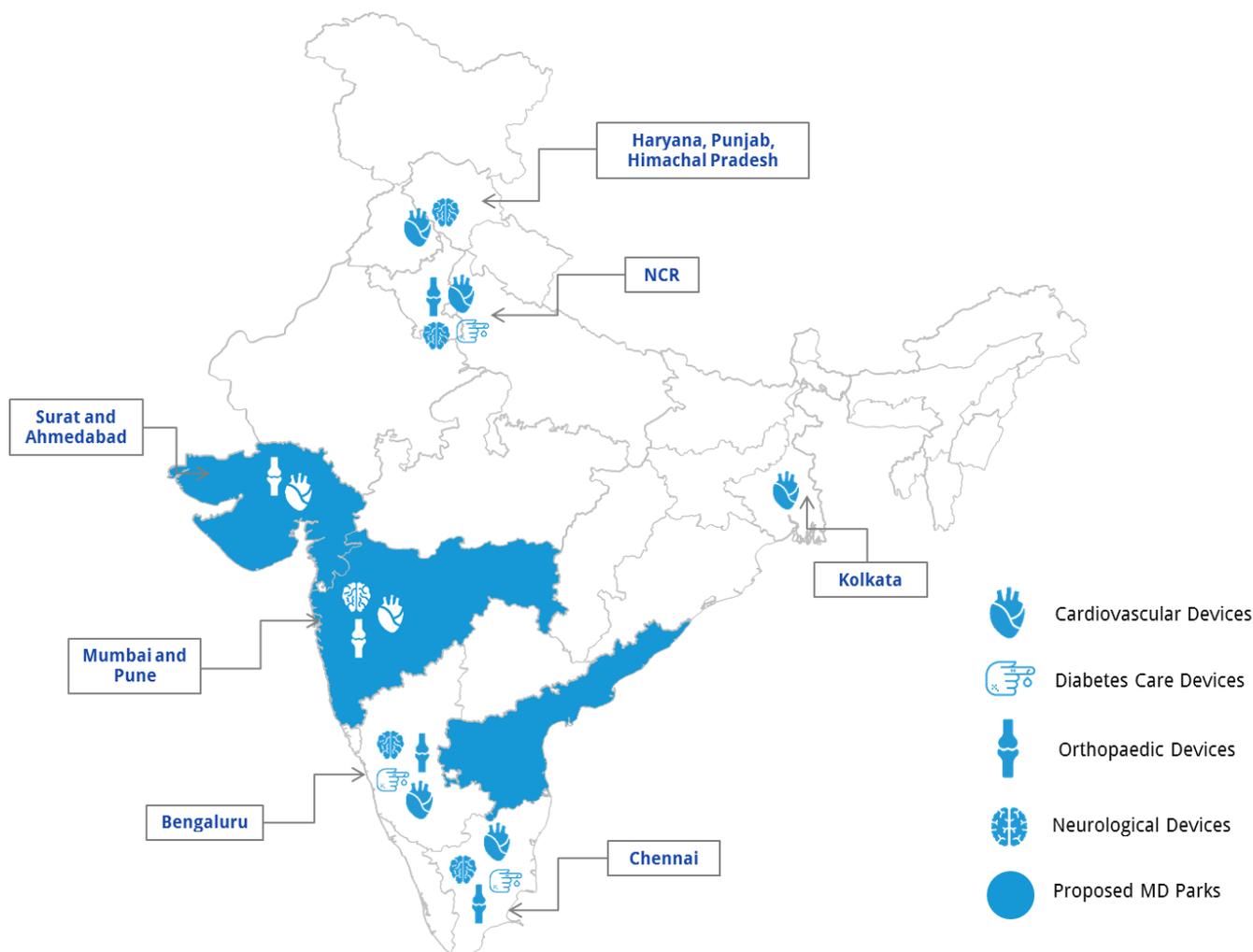
Cluster Synopsis



Cluster Synopsis

The following map highlights the major medical device clusters in India and their state-wise strengths in terms of the different therapeutic areas. Chennai, Bengaluru, Mumbai and Pune, being electronic hubs in India, are well equipped for manufacturing electro-medical devices and equipment. Gujarat state is known for its orthopaedic implant manufacturers. Gujarat, Maharashtra and Andhra Pradesh are among the few states that have taken the lead in setting up medical device parks.

Cluster Analysis: Indian Medical Device Manufacturers, Distributors and Exporters



Conclusion

Enhancement of technology and software such as computer navigation and robotic surgery will play an important role in improving the quality of surgery in the future. Along with improvements in technology, increasing spending power, population growth, and the rising number of health-insurance-policy takers would also contribute to the growth of the sector across therapeutic areas. The growth of the hospital sector will continue to drive the growth of the medical devices industry. Also, R&D expenditure in India needs to increase to be able to substitute imports.

Upcoming regulatory policies, national campaigns such as 'Make in India', and increasing focus on innovation in R&D and growing private and public investment will also be driving factors for this industry.

Our Team



Guljit Singh | Executive Vice-Chairperson

A former Director of Hollister Inc, USA, Guljit has over 40 years of experience, with a focus on strategic growth, in all aspects of running a global business – business and quality regulations, setting up legal entities, acquisitions, restructuring, marketing, legal, financing, manufacturing, human resources, information technology, product development, land acquisition, government relations, etc. He played a major role in setting up three large entities in USA, Europe and Asia. His last major undertaking was a greenfield project to set up a world-class medical device plant in North India in record time and on budget.



Deepti Ahuja | Partner

With over 13 years of experience, Deepti heads SKP's business advisory and consulting practice. She has experience in handling advisory assignments across several industries including banking, textiles, pharmaceuticals, manufacturing, services and non-profit entities. Deepti has handled several valuation assignments for various purposes including mergers, regulatory, joint ventures, acquisitions, goodwill and brand. She has led various due diligence assignments on behalf of leading multinational companies, private equity firms and venture capitalists and she has assisted several multinationals in establishing a presence in India.



Saloni Jhaveri | Partner

With over 16 years of experience in private equity and corporate finance, Saloni has executed several cross-border and domestic transactions involving mergers, acquisitions, joint ventures, private equity funding as well as entry-strategy assignments across sectors such as healthcare, retail, consumer and real estate. She has led deal teams to successfully close transactions involving the preparation and review of financial models and business plans, development of transaction strategy and deal structures. She has been involved in presentations to investors/clients, negotiation and drafting of letters of intent including key commercial terms, managing due diligence reviews, coordination with multiple advisers and counterparties.

Business Advisory

Whether you are an Indian business looking to expand your existing operations in the country or a foreign company planning to set up in India, we provide a one-stop solution and handhold you through the intricacies of the process.

Business Establishment	Regulatory Consulting	Business Consulting
<ul style="list-style-type: none"> Pre-Investment Regulatory Advisory Entity Formation Business Registrations Government Incentives 	<ul style="list-style-type: none"> FDI Regulations Company Law Direct and Indirect Taxation Exchange Control Regulations Capital Structuring Foreign Trade Policy Labour and Employment Regulations Factory Regulations Industry-specific Regulations 	<ul style="list-style-type: none"> Market Research and Strategy Greenfield Set-ups Process Consulting Business Plan Reviews
Transaction Advisory	Competition Policy and Analysis	Project Management
<ul style="list-style-type: none"> Acquisition and Joint Venture Advisory Due Diligence Valuation Transaction Structuring Restructuring 	<ul style="list-style-type: none"> Mergers and Acquisitions Prohibition of Anti-competitive Agreements Monopolistic Behaviour and Other Business Practices 	<ul style="list-style-type: none"> One-stop shop for: Greenfield Set-ups Restructuring Transitions Mergers and Acquisitions

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From consulting on entry strategies to implementing business set-up and M&A transactional support, the SKP team assists clients with assurance, domestic and international tax, transfer pricing, corporate services, and finance and accounting outsourcing matters, all under one roof. Our team is dedicated to ensuring clients receive continuity of support, right across the business lifecycle.

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