The medical device industry in India

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Contents

Foreword

For a developed society, it is imperative that healthcare services are available to every citizen throughout the country. Over the past five years, the Indian medical device industry has grown at a healthy rate of 15%. The sector witnessed strong policy, regulatory and technological changes over the past year and is expected to grow at a significant rate in the future as well.

The government and industry have both been moving towards achieving the goal of providing affordable healthcare services to patients in India. These challenges have been addressed through policy, regulatory, financial reforms and product and technological innovation. Through the set-up of medical device parks and other initiatives, the government has been providing support to the industry to manufacture quality products in an affordable manner. However, for a country as large as India, the implementation of these industrial incentives will come with its fair share of challenges.

There has also been a significant increase in investment in research and development (R&D) conducted by the domestic players and the introduction of products customised for India. This growth has further driven the use of technology to reimagine healthcare delivery in the remotest parts of the country.

With the support of government reforms, technological innovation and customisation, the medical device industry is now moving towards greater inclusiveness while increasing patient-reach and reducing consumer spend.

Industry update

The Indian medical device industry is growing at Compounded Annual Growth Rate (CAGR) of around 15% against the expected global industry growth of 4-6% and is expected to reach INR 602 billion by 2020. According to a report issued by the HealthCare Federation of India (NATHEALTH), the Indian medical device industry would grow faster than the global medical devices industry by 2020.

The industry believes that the future growth potential is huge for India; by growing at around 28%, the industry can reach up to INR 3.5 trillion by 2025.

To develop the market, the Indian government is structuring its initiatives through various policy measures such as Make in India, medical device parks, etc. on which the government is relying on developing India as a manufacturing hub for medical devices. The objective behind this initiative is to reduce the dependence on imports in this sector.

Recently, the Ministry of Health and Family Welfare (MoHFW) announced that they would introduce (i) separate rules under the existing Act for regulating medical devices; and (ii) introduce separate legislations for regulating medical devices and drugs and cosmetics. It has also asked the states and central health agencies to open their doors to Indian products while procuring medical devices like coronary stents.

Moreover, they have asked health agencies to consider the Central Drug Standards Control Organisation (CDSCO) permitted medical devices rather than insisting on the US Food and Drug Administration (USFDA) approval.

India has not only taken steps in policy and regulatory reforms but also in ensuring the quality of the products manufactured in India. However, with the Indian Certification for Medical Devices (ICMED) certification, Materiovigilance Programme of India (MvPI) and other initiatives, the medical device industry will build much-needed confidence and creditability in domestic manufactured products.

The medical devices industry has also attracted a few young entrepreneurs who want to bring change and disrupt the market through cutting-edge technology and innovation. Their aim is to provide high-quality life-saving medical technology to everyone at an affordable price. Medical technology accounts for 20-25%[1] of the total healthcare delivery cost, especially in the medical devices and the diagnostics space.

Since the late 2000's, India has started to become an active hub for exciting technology start-ups in various fields and sectors. These start-ups are establishing themselves and competing with established global giants despite the regulations being inadequate.

1. http://economictimes.indiatimes.com/small-biz/startups/indias-medical-devices-startups-grabbing-the-worlds-attention-with-advanced-and-affordable-technologies/articleshow/51640537.cms?utm_source=contentofinterest&utm_medium=text&utm_campaign=cppst

Sectoral initiative

Drugs and Cosmetics (Amendment) Bill

- Under the Make in India initiative, the government of India declared medical devices as one of the focus 25 sectors and cemented its commitment by allowing 100% FDI in the sector for both greenfield and brownfield projects.
- A draft amendment, the Drugs and Cosmetics (Amendment) Bill, 2015 had been introduced so that medical devices can be separated from the ambit of drugs.
- To encourage Make in India, it is imperative for the law to facilitate ease of doing business and ensure the quality and efficacy of the products manufactured.
- Bearing in mind the requirements of the sector and the changes in the healthcare delivery mechanism in India, the government withdrew the Bill in a Cabinet meeting in June 2016[2]. The reason behind the withdrawal of the Bill was that amending the existing Act would not do justice fully to their objectives.
- The MoHFW will frame separate rules for medical devices under the existing Act and bring out separate legislations for regulating medical devices, drugs and cosmetics.
- The ministry released the draft Medical Device Rules, 2016 on 12 July 2016[3] and invited feedback from all stakeholders.
- The draft Rules comment upon device registration in India, device definitions and classification, Notified Body roles, etc. The draft rules seem to be in sync with the rules issued by the Global Harmonization Task Force (GHTF) bringing India on par with the global standards. For e.g. all devices including in vitro diagnostic's (IVD) will be categorised into four groups:-
  - low risk - Class A;
  - low-moderate risk - Class B;
  - moderate-high risk - Class C;
  - high risk - Class D
- The rules would apply to all medical devices and IVD devices currently covered under the country's Drugs and Cosmetics Act, 1940, as well as any devices specified from time to time by the central government.

The government withdrew the Drugs and Cosmetics (Ammendment) Bill, 2013 and announced that the MoHFW will proceed at two levels (i) to frame separate rules for medical devices under the existing Act; and (ii) to introduce separate legislations for regulating medical devices, drugs and cosmetics.

- After extensive discussions with all stakeholders, the draft Rules for regulating medical devices will be notified shortly. The government intends to table these Acts in the winter session of the parliament and, according to the MoHFW, no new medical devices would be notified till this new Act is passed[4].

2. http://pib.nic.in/newsite/erelease.aspx?relid=146413
3. http://www.cdsco.nic.in/writereaddata/Draft_Medical%20Devices%20Rules%202016.pdf
4. http://www.business-standard.com/content/b2b-pharma/govt-plans-to-table-medical-device-act-in-parliament-during-winter-session-116071900572_1.html

The new National Medical Devices (NMD) policy

- The draft NMD policy was introduced by the Department of Pharmaceuticals (DoP) which falls under the Ministry of Chemical and Fertilizers. The draft policy was released in June 2015 and suggestions and comments from all the stakeholders and the general public were invited.
- The objective of the policy was to strengthen the medical device industry by reducing import and setting up a robust domestic manufacturing base for all types of medical devices. The policy prescribed that an independent and autonomous body National Medical Device Authority (NMDA) be created under the DoP.
- The draft policy discusses a separate entry of medical devices in the list of essential commodities, creating a separate pricing division under the National Pharmaceutical Pricing Authority (NPPA) and a separate price control for identified medical devices under the current Medical Devices Price Control Order (MDPCO).
- The DoP, within six months from June 2015, was to come up with a detailed proposal for the creation of the NMDA along with its mission, vision, objectives and budgetary allocation for approval of the competent authority. The DoP was also expected to bring separate proposals for the amendment of the Essential Commodities Act, the amendment in the scope of National Pharmaceutical Pricing Authority and the new NMD Pricing Policy.
- The progress on all of the aforementioned policy initiatives has been slow. The DoP is yet to release any of the documents for the policy mentioned above and the regulatory framework.
- However, considering the recent development of the introduction of two separate Acts for medical devices, it is unclear how the NMD will be positioned or whether it will be withdrawn or incorporated under any of the Acts.

Proposed Pricing Policy

- The NMD, as stated above, will have an impact on the prices of all medical devices. It will introduce a separate price control order specific to medical devices. In the first week of March 2016, the DoP formally proposed (to the Health Ministry) to bring certain Medical Devices under the Drug Price Control Order[5].
- After a study conducted by Advanced Medical Technology Association (AvaMed), the central government is considering bringing certain medical devices like stents under the price control regime as the reduction in prices by the manufacturers was not being passed on to the end consumer[6].
- The DoP issued a proposed draft notification to cap the trading margins on medical devices at 35% in March. To take this step, the government set up a committee headed by the Joint Secretary of the DoP which included members from leading industry bodies, NGOs, NPPA and the Competition Commission of India. However, this move was not welcomed by the industry who requested the government to withdraw the notification.

The industry is of the view that the non-widening of the trade margin of 35% will cripple innovation, whereas India as a country needs it. Also, it hampers the introduction of high-quality, affordable products in the Indian market. The industry believes that hospitals have no obligation to pass on it's savings to the patient and the government's goal of reducing the cost of healthcare may remain unfulfilled.

- The government incorporated two categories of stents in the National List of Essential Medicines (NLEM), a step expected to reduce the prices of the device. The health ministry addeding drug-eluting stents (DES) and bare-metal stents (BMS) to the NLEM 2015 list in a notification. Most of the stents used in India are sold by MNC's and the order is expected to bring relief to patients burdened by increasing prices of stents.[7]
- The industry is of the view that a holistic approach has to be taken in this regard so that the costs can be controlled appropriately. The Chairman of the Confederation of Indian Industries (CII) Medical Technology Division, on behalf of the industry, mentioned that unpredictability in pricing norms and talk of bringing medical devices under the Essential Commodities Act will hamper foreign direct investment (FDI), Make-in-India and investments in R&D.

5. http://economictimes.indiatimes.com/industry/healthcare/biotech/healthcare/medical-devices-should-come-under-drug-price-control-order-department-of-pharmaceuticals/articleshow/51210680.cms
6. http://www.business-standard.com/article/pti-stories/hospitals-not-passing-drop-in-stent-prices-to-patients-ims-116061500986_1.html
7. http://economictimes.indiatimes.com/industry/healthcare/biotech/healthcare/price-of-stent-set-to-reduce-as-government-includes-two-categories-in-nlem/articleshow/53310592.cms

ICMED certification

- Industry experts have recommended the Centre to make the Indian Certification of Medical Devices (ICMED), the country's first indigenously developed quality assurance system for medical devices mandatory for all medical devices marketed within the country.
- The certification scheme being launched has two certification options, ICMED 9000 certification (an International Organization for Standardization (ISO) 9001 plus additional requirements) for low-risk medical devices and ICMED 13485 (an ISO 13485 plus additional requirements) for medium and higher risk devices.
- This certification is a joint initiative of the Association of Indian Medical Device Industry (AIMED), Quality Council of India (QCI) and the National Accreditation Board for Certification Bodies (NABCB). NABCB is an accrediting, certifying and inspecting body and its accreditation programmes are internationally equivalent, placing it on par with European and American accreditation bodies. This equivalence would help the acceptance of an ICMED certification in the international market[8].
- AIMED, acting on the long standing demand of the industry of an independent but indigenous certification, took the initiative and collaborated with QCI and NABCB to come up with the certification.
- Intertek, a leading Total Quality Assurance provider to industries worldwide, has been approved as India's first certification body for the ICMED scheme.[9]
- AIMED strongly advocated the requirement of ICMED certification as the scheme will be able to fill a regulatory vacuum in the quality certification space for medical devices in the country. This will also enhance the competitiveness and profitability of the Indian medical device industry, increase pateint safety and confidence amongst the buyers.

8. http://www.pharmabiz.com/NewsDetails.aspx?aid=95101&sid=1
9. http://indiaeducationdiary.in/Shownews.asp?newsid=39232

Government initiatives

Medical Device Parks

Domestic manufacturing received a boost by dedicated medical device parks being set up in two states while more are in progress. With these parks having common facilities for manufacturing and testing, the set-up and manufacturing cost are expected to reduce, resulting in better quality and affordable products.

The objective is to create an ecosystem for medical device manufacturing, reduce imports and eventually export domestically manufactured devices to other countries.

Many states have been planning to set up medical device parks and a few states, namely Andhra Pradesh (AP), Maharashtra and Gujarat, have already announced India's first dedicated medical device parks.

Andhra Pradesh Medical Device Park

- The park is coming up near Visakhapatnam (Vizag) and is spread over 226 acres. The AP government suggests that the medical device park will attract an investment of over INR 200 billion from medical device companies and the ecosystem built to cater to it.
- The government of AP has laid the foundation of India's first medical device manufacturing park, Andhra Pradesh Medical Technology Zone (APMTZ) on 19 August 2016 in the Nadupur village of Pedda Gantyada Mandal in Vishakhapatnam[10]. The AP government formed a Special Purpose Vehicle (SPV)[11] for the medical device park.
- AMTZ was incorporated on 30 April 2016[12] and received formal registration[13]. It was funded by the state government on 1 June 2016.[14]
- AP health minister Kamineni Srinivas, along with a delegation, visited the Shanghai International Medical Zone to study the practices in the medical device manufacturing industry in China. The visit was made to ensure that AMTZ had the best practices and high-calibre infrastructure from the initial stages of development.
- The park will provide manufacturers with a one acre build plot for a monthly rent of INR 100 thousand and they will use common facilities and pay on a per-unit manufactured basis, bringing down the cost of production by 40-50%. All the necessary approvals will be in place before the manufacturer steps thereby reducing the time taken to begin commercial production.

10. http://www.pharmabiz.com/NewsDetails.aspx?aid=96731&sid=1
11. http://timesofindia.indiatimes.com/city/visakhapatnam/State-to-form-special-purpose-vehicle-for-medical-devices-park-in-Vizag/articleshow/50677866.cms
12. https://www.zaubacorp.com/company/ANDHRA-PRADESH-MEDTECH-ZONE-LIMITED/U85190AP2016SGC103153
13. http://www.pharmabiz.com/NewsDetails.aspx?aid=94934&sid=1
14. http://www.pharmabiz.com/NewsDetails.aspx?aid=95533&sid=1

Maharashtra Medical Device Park

- Maharashtra announced that the second dedicated medical device park will come up at Mihan Special Economic Zone (SEZ) in Nagpur. Mihan is strategically located at the geometrical centre of the country and is easily accessible by road, rail and air. It is currently the only multi-product SEZ adjacent to an existing international airport and is spread over an area of more than 1300 hectors. Mihan Park, like Vizag Park, will also be spread over approximately 200 acres in and adjacent to the Mihan SEZ.

State	Particulars
Andhra Pradesh	Manufacturing of medium to high-end electronics and equipment related to medical devices.
Maharashtra	Cluster of companies manufacturing consumables, orthopaedic implants and surgical instruments.
Gujarat	Manufacturing of disposables and consumables.

Dedicated Medical Device Testing Labs

- The quality of medical devices manufactured in India has always been in question. However, with the new indigenous quality certification and dedicated testing labs, the government intends to improve the quality. Although two testing labs for approximately 14,000 products is insufficient, it should be seen as a positive first step being taken.
- Based on the recent approval from the Department of Commerce, the two dedicated medical device testing labs will come up at Vadodara in Gujarat and at Noida in Uttar Pradesh.

Gujarat – Vadodara

- Gujarat is coming up with the first medical device testing lab which will be the only dedicated biomaterials and implants lab in the country.
- It will be under the guidance of H.G. Koshia, Commissioner, Foods, Drugs And Cosmetics Act (FDCA), Gujarat and INR 150 million has already been earmarked for the same.[15]

Uttar Pradesh - Noida

- The lab at Noida will be set up primarily for testing electrical and electronic medical devices in the country.
- This type of testing lab will help manufacturers overcome deficiencies in their products and would complement the government's Make in India initiative by accelerating industrial growth.

Electronics Development Fund (EDF)

- The Ministry of Electronics & Information Technology (MEITY) launched the Electronics Development Fund (EDF)[16] in February 2016 which is a structured initiative as a 'Fund of Funds' to participate in 'Daughter Funds' which in turn will provide risk capital to companies developing new technologies in the area of electronics, nano-electronics and Information Technology (IT).
- The supported Daughter Funds will promote innovation, R&D and product development within the country in the specified fields of electronics, nano-electronics and IT. This R&D in turn is expected to reduce the dependence on foreign technology for our medical devices and the funds can also be used to acquire a company/technology that might be the future of medical devices.

Materiovigilance Programme of India (MvPI)

MvPI will monitor the safety of medical devices in India and has been approved for commencement by the Ministry of Health & Family Welfare. The MvPI was formally launched in July 2015 at the Indian Pharmacopoeia Commission (IPC), Ghaziabad by the Drugs Controller General of India (DCGI).

EDF has already disbursed funds worth INR 1.69 billion to four Daughter Funds. This is a welcome step from MEITY that will create and enable an ecosystem which provides capital for R&D to the industry and academia.

15. http://www.pharmabiz.com/NewsDetails.aspx?aid=95513&sid=1
16. http://meity.gov.in/content/shri-ravi-shankar-prasad-honble-minister-cit-formally-launched-electronics-development-fund-

MvPI was launched due to the significant number of cases of medical device breakdown or serious adverse events (SAE) occurring due to a medical device. Although the programme was launched last year, it started gathering pace recently. NHSRC under MoHFW provides the technical support and acts as a resource centre. The key objectives of this programme are to:

- Monitor Medical Devices Associated Adverse Events (MDAEs) in Indian population.
- Create awareness amongst healthcare professionals about the importance of MDAE reporting in India.
- Evaluate the risk-benefit profile of medical devices.
- Generate independent evidence-based suggestions on the safety of medical devices.
- Support CDSCO for formulating safety related regulatory decisions relevant for medical devices.
- Communicate findings with all key stakeholders (manufactures, regulators, etc.)

The industry suggested that the current format should provide clarity of the complaint reported so as to not treat each and every complaint as an SAE. The industry also presented its views on:

- standard procedures for receiving, documenting and investigating complaints;
- developing a robust reporting structure;
- determining when complaints are reportable;
- the manner of report generation;
- the methodology for closing the complaint and updating the risk management file; and
- how to avoid duplicity of a reported event.

MvPI is unique as it requires inputs in biomedical engineering unlike medicines where the mechanism is different for reporting of Adverse Drug Reaction (ADR) reporting.

National Health Innovation Portal (NHInP)

- NHInP is an initiative taken under the National Health Mission and falls under the jurisdiction of the MoHFW. It was launched at the National Summit on Healthcare Innovations at Shimla[17] in July 2015.
- It is a public platform to facilitate the collection and dissemination of good practices and innovations which are innovative and are replicable in nature. The innovative solutions have either demonstrated abilities to address healthcare delivery challenges in identified contexts.

The MvPI is meant to enable safety data collection in a systematic manner so that regulatory decisions and recommendations on the safe use of medical devices for India could be based on data generated in India.

The National Health Innovation Portal will foster a culture of innovation and technology among Indian entrepreneurs.

- It will also serve as a gateway to introduce innovation to mainstream healthcare and thereby bring transformative improvements in healthcare delivery.
- The portal will help in escalating products and programmes which are successful and solve issues of the masses.
- Even though the portal was launched last year, awareness of the portal has been low. The portal is running in a time bound manner and once an innovation is submitted to the portal, the NHSRC has to report on its usability for public health care programmes to the MoHFW within 90 days. A decision is taken accordingly by the ministry.
- Innovators are rewarded for their products or programmes as NHSRC will hold patent auctions for the commercialisation of the same. They also receive 60% of the auction proceeds. The NHInP will not only provide innovative products and technology for the healthcare industry but also to other sectors as well.

17. http://www.financialexpress.com/article/healthcare/happening-now/mohfw-launch-of-national-health-innovation-portal/115293/

Duty structure

The medical devices sector has been plagued with an inverted duty structure for many years (i.e. finished goods are cheaper to import than raw materials for domestic manufacturing). This structure has particularly hampered industry growth leading to imports dominating with 70% of market share.

However, one of the associations, NATHEALTH, is of the view that the Government of India should come up with a plan to encourage domestic manufacturing and, in the interim, reduce the import duty so that health care delivery remains unaffected.

Budget 2016

Duty	Previous	Current
Basic Custom Duty on certain Medical Devices	5%	7.5%
Basic Custom Duty on Raw Materials	N.A.	2.5%
Additional Custom Duty	Exempt	N.A.
Special Additional Duty on certain medical devices	-	4%
Overall Impact	**17-18%**	**27-28%**

- The medical device industry had high expectations from the budget as the government was planning to focus on the development of this sector. The industry's representative body, AIMED, was very hopeful and had even come up with its wish list for the Budget. However, there were no policy changes proposed in the Budget for the medical device industry except the introduction of the National Dialysis Programme (NDP).
- According to Finance Minister Arun Jaitley, every year in India, approximately 4,950 dialysis sessions take place. A dialysis machine costs is in the range of INR 700-800 thousand and each session of dialysis costs an average of INR 25,000. These high costs could be drastically reduced if the machines were manufactured in India. However, no domestic company is currently capable of this. As a consequence, due to the high costs of these sessions, only half of the patient requirements get fulfilled.
- Under the NDP, the Finance Minister proposed to cut duties for certain yet-to-be-identified parts for the dialysis equipment. Although the 2016 Budget did not meet the expectations of the medical device industry, Finance Minister Jaitley reduced the BCD on the yet-to-be-identified parts of a dialysis machine to increase domestic production and bring down the cost of each session. However, the industry is of the opinion that merely reducing BCD will not bring costs down as session providers are not obliged to pass on the cost benefit to the patients.

Schedule M III for medical devices

- Schedule M is part of the Drugs and Cosmetic Act, 1940. Schedule M includes good manufacturing practices (GMP) for premises and materials and requirements of good manufacturing practices in the pharmaceutical industry in plant and equipment. Schedule M III is more specific to GMP and requirements of premises, plant and equipment for medical devices and in-vitro diagnostic kits and reagents.
- Earlier, Schedule M consisted of GMP for both the pharmaceutical and medical device industry. Based on strong recommendations from the industry, the central government agreed to align Schedule M III with ISO 13485 by delinking it from Schedule M of pharmaceuticals
- The government released the much-anticipated revised Schedule M III which contains its own set of requirements for quality management systems pertaining to all notified medical devices and IVDs, plus appendices covering device master files and site master files.
- With this notification of Schedule M III, the sector will now be able to explore new business opportunities as it will be more open for investments that will help develop the manufacturing of medical devices in India.[18]

18. http://www.pharmabiz.com/NewsDetails.aspx?aid=96177&sid=1

Transactions

Kedaara Capital buys 13% in Bengaluru-based surgical equipment-maker Sutures India

- Private equity fund Kedaara Capital bought 13% of CX Partners' stake in the Bengaluru-based surgical equipment-maker Sutures India for INR 4 billion. The key rationale for the investment was the company's expansion plans into the international market and expected healthy growth in revenue.[19]
- The company's equity value is INR 30 billion. Post-investment, the majority stake of 52% is held by TPG Growth, followed by 30% by promoters. CX Partners have retained 7% by selling 13% of their stake to Kedaara Capital.

Zimmer Biomet announces multi-year collaboration with Indo UK Institutes of Health

Zimmer Biomet Holdings Inc. will collaborate with the Indo UK Institutes of Health (IUIH) that will increase the capacity of India's healthcare infrastructure and will deliver affordable and accessible healthcare to India. The investment of more than INR 350 million is expected in The King's College Hospital in the Amaravati training and education centre over the period of three years, beginning in 2017.

- The first phase of the collaboration will be involving the establishment of the Zimmer Biomet Institute of India, a 30,000 square foot state-of-the-art medical training and education facility in the campus of King's College Hospital in Amaravati, Andhra Pradesh.[20]
- The Institute will be training more than 1,000 orthopaedic surgeons annually on the latest orthopaedic procedures and the safe and effective use of Zimmer Biomet medical technologies.

Trivitron buys 60% stake in Turkish firm for INR 372.3 million

- Medical technology firm Trivitron Healthcare has acquired a 60% stake in Turkish firm Bome Sanayi Urunleri Dis Tic Ltd Sti. The remaining 40% stake in IVD device manufacturing firm will be held by the promoters.
- Through this acquisition, Trivitron will acquire Bome's expertise in running low-cost new born screening programmes in public-private partnerships.
- Trivitron will now have access to produce IVD kits using Finnish and Turkish techniques in France, Turkey and India.[21]

US medical device-maker Alere Inc. sets up INR 1.5 billion manufacturing facility in India

- US-based portable molecular diagnostic products firm Alere Inc. has set up its first integrated manufacturing facility in Manesar, near Delhi. The unit will manufacture over 150 million cartridges which can be used for rapid tests for infectious diseases including malaria, dengue and HIV. The facility is spread across 180,000 sq. ft., which will generate 300 new jobs.
- With this new world class facility, the company believes that they would be able to provide affordable rapid diagnostics in India and throughout the Asia-Pacific region.
- The company is also working with state governments and institutions like the National Aids Control Organisation and Clinton Foundation.
- The new facility is part of the company's Asia-Pacific expansion plan, as it wants the Indian facility to cater to the growing demand for rapid diagnostics in the Asia-Pacific region.[22]

19. http://economictimes.indiatimes.com/markets/stocks/news/kedaara-capital-buys-13-in-bengaluru-based-surgical-equipment-maker-sutures-india/articleshow/53015261.cms
20. http://www.prnewswire.com/news-releases/zimmer-biomet-announces-multi-year-collaboration-with-indo-uk-institutes-of-health-to-deliver-affordable-and-accessible-healthcare-in-india-300300663.html
21. http://economictimes.indiatimes.com/industry/healthcare/biotech/healthcare/trivitron-buys-60-per-cent-stake-in-turkish-firm-for-5-million-euros/articleshow/53155595.cms
22. http://www.businesstoday.in/current/corporate/us-medical-device-maker-alere-sets-up-rs-150-crore-manufacturing-facility-in-india/story/235763.html

Innovative developments

The medical device industry across the globe is brimming with technological developments and innovation. The future of the industry depends on innovation and hence, all companies conduct R&D and bring new products to the market. Globally, the implants segment, which is one of the fastest growing segment, has witnessed substantial innovation and product development. Domestic players in this segment have capitalised by designing and manufacturing customised products for the Indian market.

3D-printed hip implant

- Global medical technology company Smith & Nephew (S&N) launched the new REDAPT™ Revision Acetabular Fully PorousCup[23] with CONCELOC™ Technology on 1 March 2016 at the American Academy of Orthopaedic Surgeons (AAOS) annual meeting in Orlando.
- The new REDAPT™ cup has been developed keeping in mind the revision of the compromised bone, making it difficult for implant fixation and stability. It gives improved stability and reduces micro motion after surgery by using the variable-angle locking screws.
- To allow bone in-growth and to secure the implant in place, usually external porous coatings such as sintered beads or fibre mesh, etc. is used. The CONCELOC Advanced Porous Titanium technology provides an alternative to the same.
- The company is also using 3D manufacturing technology to build these implants. Implants are only as successful as their integration, in terms of alignment and acceptance, with the patient's bone.

The use of 3D printing for devices will pave the way for manufacturing of affordable and high quality implants.

- S&N's 3-D printed implant provides the flexibility screws for the bone to grow internally post surgery. Fixed angled implants would hinder the internal bone growth and if the bone grew, the implants would not be as effective as they were intended to be.
- S&N solved the issue with clever engineering and also brought to light a new process of manufacturing which will eventually bring the costs of these implants down.

Miniaturising medical implants

- CerMet technology from Heraeus group is revolutionising the treatment of neurological and ophthalmic diseases with innovative medical technology. CerMet[24] is a blend of ceramic and metals which is also a bio-compatible material and is a combination of tiny platinum and aluminium oxide particles.
- CerMet technology could make an important contribution to the miniaturisation of medical implants used in the heart (pacemakers), brain (brain readers), eye (ocular prostheses) or ear (hearing aids).
- The miniaturisation is achieved due to small-scaled conductive paths with a diameter of only 0.15 mm (as fine as a piece of paper). New treatments require a higher level of integration of the electronics that are used and more electrical channels in the feed through. With CerMet technology, the size of the electrical interface of the implant that will be inserted can be reduced significantly.
- However, the technology is still new and will take a few years to mature. CerMet technology will significantly reduce the size of these implants and aids.

23. http://www.prnewswire.com/news-releases/smith--nephew-unveils-its-first-3d-printed-titanium-hip-implant-1-march-2016-300228331.html
24. http://www.med-techinnovation.com/News/home/news/1339/New+technique+for+miniaturizing+medical+implants+expands+treatment+options

New coating for bone bonding

- Scientists at the University of the West of England (UWE Bristol) have discovered a new way of making titanium implants bond better with bones.
- The effectiveness of the implant surgery depends on how good the bonding process is of the titanium with the patient's skeleton. When this bond forms properly, it is extremely strong. However, in some cases (around 10%), the patient's bone fails to join strongly to the titanium and the prosthesis loosens and eventually fails.
- Many implants used in surgery are made out of titanium including joint replacements, screws and plates for fixing broken bones and dental implants.
- UWE has found that they can coat titanium implants with a bioactive lipid called lysophosphatidic acid (LPA).[25] This novel coating also deterred the attachment of bacteria which means that manufacturers can have a potential dual-action titanium implant material. The coating is under the testing phase for robustness and stability under various scenarios. However, in the near future, it is very possible that all implants might be coated with this acid.

Stryker Corporation is in the process of commercialising a line of products branded 'System G', which is aimed at the mid-tier segment in India. System G forms one of Stryker's early line-up of devices, which is currently being pilot tested in Bangalore.

Mako - The new surgeon

- In the very near future, robots will be able to perform complicated hip and knee replacement surgeries.
- American medical device giant, Stryker Corporation, is set to woo the Indian market with its robot, Mako. The robot is equipped to perform knee and hip replacement surgeries. Mako, which costs between INR 100-130 million in India, is the only robot in the world that can perform joint replacement procedures. Stryker has already sold 300 Mako's across the globe.
- Stryker has established a huge R&D facility in India, housing 200[26] engineers and technologists, who assist in conceptualising, designing and developing no-frills power tools which can be used for cutting, drilling and shaping bones during joint replacement and trauma procedures.

Trivitron's NeoMass AAAC kit

- In January 2016, Trivitron Healthcare launched NeoMass AAAC Kit[27], a CE (Conformité Européenne) approved product, as part of its new-born screening device portfolio. It is the only kit in the market capable of detecting up to 50 disorders that a new-born baby might be having or might have without showcasing any symptoms or conditions.
- With this launch, Trivitron became a complete solution provider for NBS with modular systems, automated systems and kits for core panel screening and Tandem MS/MS.
- The testing process is fairly simple. The heel of a new-born baby is prickled to collect a blood sample on a filter paper within the first 72 hours of his life and test for the detection of life threatening disorders. The AAAC kit uses tandem mass spectrometry to screen for metabolic disorders allowing quick and accurate diagnoses of metabolic disorders.
- The kit, with patented methodology, detects deficiencies of all six enzymes involved in the urea cycle metabolic pathway. The urea cycle is a metabolic pathway occurring in the liver and kidney. Aberrant functions of the urea cycle enzymes lead to the build-up of ammonia.

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St Jude Medical brings ventricular assist technology to India

- The HeartMate 3 system is the first commercially approved centrifugal-flow left ventricular assist device (LVAD). It utilises the advance Full MagLev (fully magnetically-levitated) technology, in which the device's rotor is 'suspended' by magnetic forces. LVAD provides cardiac support option for advanced heart failure patients who are awaiting transplantation, not participants for heart transplantation or are in myocardial recovery.
- The design reduces trauma to the blood passing through the pump and improves the outcomes for patients. LVAD's are small implantable devices which perform the pumping function of the heart for patients whose hearts cannot perform the same on their own. St Jude obtained the CE mark in October 2015.

Trivitron launches Labsystems Diagnostics IVD factory

- The Trivitron group recently launched the Labsystems Diagnostics IVD Factory, an Indo-Finnish joint collaboration, at Trivitron Medical Technology Park, a medical technology park in SIPCOT (State Industries Promotion Corporation of Tamil Nadu Ltd) Industrial Park, Chennai, to house numerous factories manufacturing a variety of medical devices and equipment under one campus.

> The HeartMate 3 cardiac assist device brings benefit to patients suffering from heart failure and is a supportive solution, in particular, for those awaiting transplantation.

- Trivitron recently acquired a medical device company named Labsystems Diagnostics Oy. The company has also completed a 'technology transfer' from their Finnish company and developed a new facility capable of producing biochemistry/haematology/point-of-care diagnostics/immunoassay/mass spectrometry diagnostics kits and quality control sera in the Trivitron Medical Technology Park. This is the third manufacturing facility which will soon start commercial production within the park.

Indian medical device start-ups

- It is estimated that India has at least 150 start-ups at several stages of development with a major focus on ECG and patient monitoring as point-of-care screening and other diagnostic tools for haemoglobin, glucose, etc.

Sr.No.	Company	Product
1	Forus Health	Pre-screening ophthalmology device
2	Remidio	Fundus on Phone and Angio on Touch diagnostic imaging system – retina screening devices
3	Sattva Medtech	Sattva Medtech

- Remidio develops ophthalmic diagnostics technology and has launched two products i.e. Fundus on Phone and Angio on Touch diagnostic imaging system. A complete image of the retina requires a wide-field imaging camera that costs roughly INR 6.5 million whereas Remidio's Fundus on Phone, priced at INR 180,000, can connect to a smart phone camera to take pictures of the central part of the retina. This type of imaging assists in the early detection of diabetic retinopathy.
- Forus Health, Remidio and Sattva Medtech are a few of the start-ups who have developed revolutionary products which are high-quality and affordable. Sattva Medtech has developed a small, light and wearable device to detect fetal distress and notify the doctor via an SMS in case of emergencies. The price for the device will be two-thirds the price of similar devices manufactured by Philips and GE.

High concentration on medical device segments:

- ECG monitoring
- Patient monitoring
- Point of care screening and diagnostic tools for haemoglobin/glucose, etc.

Conclusion

The Indian medical devices sector is now developing quickly with the government, sectoral and industry initiatives. The sector is poised for significant growth over the next five years. The government, post declaring medical devices as a priority sectors, has undertaken many reforms to give the sector its due importance. With the medical device parks, the domestic industry will receive a boost and products manufactured there will become affordable for a population who largely cannot afford the imported devices.

The domestic industry is also venturing into traditionally import and MNC dominated categories like diagnostics, etc. and also conducting its own R&D to manufacture and sell products customised for the Indian market. This customisation is being led by start-ups who are redefining the healthcare delivery mechanism in India through the use of technology and addressing very specific healthcare needs in an efficient and affordable manner.

The opening up of FDI in both brownfield and greenfield will help in structuring the industry and also providing quality healthcare across segments, players and products. Despite the steps currently being taken, the sectors still encounters a variety of fundamental, environmental and ecosystem related hindrances that hamper the speed of the healthcare revolution in India.

It is imperative to be mindful of the fact that in spite of the present challenges, the Indian medical device industry is on the path of inclusive growth, technological innovation and most importantly, fulfilling the goal of providing healthcare services to every Indian.

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