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Medical technology industry in India Riding the growth curve



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Foreword from CII

The opening up of the Indian economy during the early nineties heralded an era of unprecedented industrial growth in India. The growth rates seen match those of the fastest growing economies. A confident and resurgent Indian Industry is making forays into almost all the sectors of economy. Lately, the huge opportunities for growth within the domestic and global healthcare sector have attracted the attention of Indian industry.

The Indian Healthcare system has notched up several significant achievements over the last 50 years particularly in terms of life expectancy, infant mortality rate and success in dealing with various dreaded diseases. However, easy accessibility of quality healthcare and affordability to the citizens at large are key concerns.

Technology in the last two decades has revolutionized the way healthcare is delivered worldwide. It has greatly aided patients and providers alike by enhancing the quality of delivery, reduction in turnaround time of workflows and thus the overall cost, besides bringing in higher accountability into the system. Advancements in medical technology are playing a positive role in saving lives. The influence of medical technology is all pervasive - its positive impact is not only limited to the upper

crust of society but has also helped the poorer lot e.g. reduction in IMR/MMR due to usage of right technology e.g. incubators, warmers, better OT equipments.

The Confederation of Indian Industry (CII) being a stakeholder in the growth of the Indian economy, has taken some major initiatives in the field of Healthcare and Medical Technology. CII has formed the National Committee on Healthcare and CII Medical Equipment Division which give a sharper focus to the Sector since last several years.

CII, through its Medical Equipment Division, works towards the development of the Medical Technology Industry by providing a nodal point of reference for the Industry, providing a forum for dialogue with the customers & government and formation of appropriate regulatory structure.

We hope that this report will enable the domestic and the global Medical Technology companies to understand the emerging business opportunities and the health-care ecosystem in India. Further, this will help major companies to understand the Indian capabilities for making investments in India in this sector.

Preface from Deloitte

The Indian healthcare market was estimated at US\$ 35 billion in 2007, and has been witnessing double digit growth rates in recent years. However, this growth is largely fuelled by demand from major cities. India's healthcare system is paradoxical - on the one hand, it boasts of 'best in class' healthcare delivery attracting medical tourists from across the world, and on the other, it is characterised by a near absence of accessible, affordable quality health services for a large part of its population. Existing infrastructure, especially in smaller towns/ rural areas, is inadequate to meet the evergrowing needs of the Indian population. Less than 10% of the population is covered under health insurance, and India has less than 1/3rd doctors per capita compared to China, and almost one hundredth compared to that of USA.

Adding infrastructure and medical professionals alone will not be able to solve India's huge unmet needs in healthcare. It needs to be supported by technology. An effective and innovative use of medical technology, supported by ICT, has the potential of increasing access, significantly reducing the burden of disease and the load on healthcare delivery services through early diagnosis, better clinical outcomes, less invasive procedures and shorter recovery times.

Currently, the market for medical technology in India is small, but rapidly expanding. It is nascent and highly fragmented with limited indigenous manufacturing imports constitute over 75% of the estimated US\$2.75 billion market.

A transforming medical technology landscape, improving healthcare delivery and financing mechanisms, and changing patient profile are driving growth in the medical technology industry. However, the industry has been stifled by some key impediments to growth.

The foremost among these is the lack of - affordability, accessibility, awareness and availability. A key question, therefore, is how to increase penetration of medical technology to improve health outcomes in India?

The answer lies in innovation. Medical technology innovation can be the tool to make modern care accessible, available and affordable to all by lowering the cost of the product or delivery. Innovation need not only be restricted to products. Business model innovation across the value chain (manufacturing, distribution, marketing etc.) and frugality can often generate significant benefits to all stakeholders, including patients/end users.

For innovation to make an impact, collaboration between the stakeholders in the medical technology ecosystem is a key success factor. The industry must move from 'company-centric' innovation, towards 'co-creation'. All stakeholders – government, industry, academia, healthcare and insurance providers - need to co-ordinate/ strategise and move in step for their actions to resonate and bring about lasting change. Apart from this, there is also what can perhaps be the biggest opportunity for improvement - an ambiguous regulatory framework with no distinct legal status for the medical technology industry, which has been acknowledged as a key constraint for the industry.

CII's 3rd Medical Technology Conference is an ideal forum to discuss the way forward in addressing these challenges, and Deloitte is privileged to collaborate as the knowledge partner for the conference.

Charu Sehgal

Lifesciences and Healthcare Leader Deloitte in India

Introduction

Medical technology extends and improves life, alleviates pain, injury and handicap. Incessant medical technology innovation enhances the quality and effectiveness of care. Billions of patients worldwide depend on medical technology at home, at the doctor's, at hospital and in nursing homes.

What is Medical Technology?

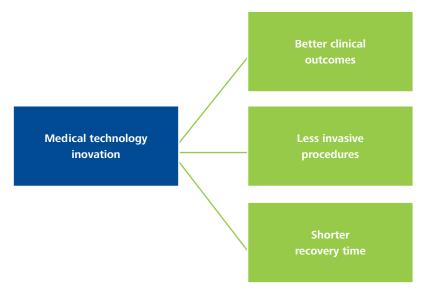
There are varied definitions of what constitutes 'medical technology'. For the purpose of this report, the term medical technology encompasses a wide range of healthcare products (devices, equipments as well as consumables/ supplies) that are intended by its manufacturer to be used specifically for diagnostic and/or therapeutic purposes. It encompasses any instrument, apparatus, appliance, implant, in vitro reagent, software, material or other article, which is

- used, alone or in combination, for the following purposes:
 - diagnosis, prevention, monitoring, treatment or alleviation of disease
 - diagnosis, monitoring, treatment, alleviation of or compensation for an injury
 - investigation, replacement, modification or support of the anatomy or of a physiological process
 - supporting or sustaining life
 - control of conception
 - disinfection of medical devices
 - providing information for medical or diagnostic purposes by means of in vitro examination of specimens derived from the human body
- and, which does not achieve its primary intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its intended function by such means.

Medical technology improves health outcomes

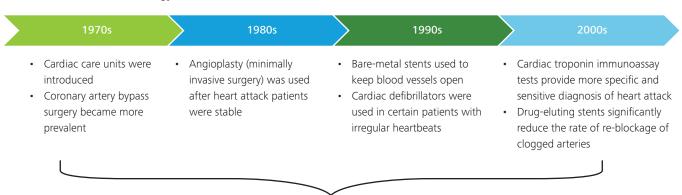
Medical technology plays a strategic role in fostering the change of health care delivery towards better health outcomes. According to EUCOMED (the European medical technology industry association) "Medical technology extends and improves life. It alleviates pain, injury and handicap. Its role in healthcare is essential. Incessant medical technology innovation enhances the quality and effectiveness of care. Billions of patients worldwide depend on medical technology at home, at the doctor's, at hospital and in nursing homes. Wheelchairs, pacemakers, orthopaedic shoes, spectacles and contact lenses, insulin pens, hip prostheses, condoms, oxygen masks, dental floss, MRI scanners, pregnancy tests, surgical instruments, bandages, syringes, life-support machines: more than 500,000 products (10,000 generic groups) are available today."

With the convergence of many scientific and technology breakthroughs, the pace of medical invention is accelerating, resulting in better clinical outcomes, less



invasive procedures and shorter recovery times, and thus improving overall health of people. Heart disease and its consequence, heart attack, is a good example of how new technology has changed the treatment and prevention of a disease over time. The following exhibit depicts the advancements in medical technology pertaining to cardiac care in the U.S.

Innovations in Medical Technology – Cardiac Care in the U.S



From 1980-2000, the overall mortality rate from heart attack fell by almost half, from 345.2 to 186.0 per 100,000 persons

Source: AdvaMed, The Value of Investment in Health Care: Better Care, Better Lives (January 2004)

Another example of how advances in technology have changed health outcomes over time is in the treatment of pre-term babies, for which very little could be done in the U.S in 1950. But by 1990, changes in medical technology, including special ventilators, artificial pulmonary surfactant to help infant lungs develop, neonatal intensive care etc., helped decrease mortality

At the high end, India has worldclass doctors, clinics and technologies, and attracts international medical tourists in growing numbers. However, even today, majority of India's population cannot afford anything better than basic healthcare.

to one-third its 1950 level, with an overall increase in life expectancy of about 12 years per low-birth-weight baby.

Need for Medical Technology in India

There can be no better example than India to illustrate the need for medical technology for improving healthcare delivery. In the second most populous country of the world, the supply of healthcare services falls significantly short of the demand. Existing health care delivery mechanisms are inadequate to meet the evergrowing needs of the Indian population, especially in smaller towns/ rural areas. The limited healthcare facilities available in the country are skewed more in favour of the affluent category of population. At the high end, India has world-class doctors, clinics and technologies, and attracts international medical tourists in growing numbers. However, even today, the majority of India's population cannot afford anything better than the most basic healthcare. Low health insurance coverage (estimated at less than 10% of population) makes matters even worse. Accessibility is restricted by shortage of healthcare facilities and professionals. For every 10,000 Indians, there are 6 doctors while China has 20 doctors for every 10,000 people, Australia has 249, UK has 166 and US has 548. Further, while



majority of the population resides in rural areas, doctors and hospitals are largely concentrated in cities. Poor healthcare infrastructure, along with a large population and high poverty levels has resulted in a dismal status of people's health. This is illustrated by the following facts:

- Of the 536,000 women who died during pregnancy or after childbirth in 2005 globally, India accounted for 117,000 (or 22%).
- IMR (Infant Mortality Rate) for India is 58 per 1000 births, which is more than double that of China (23 per 1000 births) and even higher than Bangladesh (54 per 1000 births).
- India has the highest burden of communicable diseases in the world, with malaria and tuberculosis among the leading causes of death.
- Growing non-communicable diseases (NCDs) highest number of diabetics in the world.

Good quality private healthcare is out of reach for majority of India's people. Government support/ subsidies alone are not enough to cater to the healthcare needs of this segment of the population. There is a need to use medical technology effectively to address the yawning gap between demand and supply of healthcare services in India. Innovative products and business models are needed to make healthcare affordable and accessible to a larger percentage of the population.

Demographics

- 2nd most populous country
- 70% population in rural areas
- 27.5% of population below poverty line

Health status

- High MMR and IMR
- Highest burden of communicable diseases in the world
- Growing NCDs diabetes capital of the world

Need for innovative medical technology solutions to bridge the demand-supply gap

Healthcare infrastructure

- 80% of doctors, 75% of dispensaries and 60% of hospitals situated in urban areas
- Number of beds, nurses, and doctors per 1,000 people in India, is the lowest in the world
 - 0.8 beds / 1000 people
 - 0.6 doctors/ 1000 people

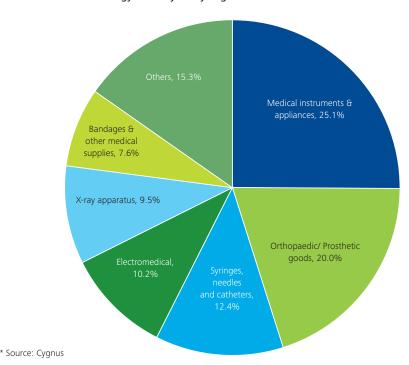
Market size and structure

A nascent market with double digit growth rates

The medical technology market in India was valued at US\$2.75 billion* in 2008, a growth of approximately 14% over 2007. The market is estimated to reach US\$5 billion* by 2012 with an annual growth rate of nearly 15%. However, this industry has not been well documented in the Indian context, and estimates of industry size and growth vary significantly across different sources. Other estimates of the market size range from US\$1.9 billion in 2009 to US\$3 billion in 2010. While a wide range of medical products are covered under the medical technology industry, classification of key segments differs widely across the industry. The key segments based on product application are depicted in the chart given below.

Majority of the Indian medical technology market is dominated by medical instruments and appliances used in specialties such as ophthalmic, dental and other physiological classes. This segment accounts for 25% of the total market, followed by orthopaedic / prosthetic goods segment accounting for 20% of the total market. The 'other' segment includes endoscopy equipment, cardiovascular control equipment and healthcare IT equipment etc.

Indian Medical Technology Industry - Key Segments*



Estimated growth rates for the key market segments during 2008-12 range between 14-20%*, with the 'other' segment witnessing the highest growth. Though not identified as a separate segment in the above pie chart, diagnostic kits represent one of the fastest growing segments of the medical technology industry in India, enjoying an annual average growth rate of over 30%.

Competitive market- presence of MNCs as well as domestic firms

The Indian medical technology industry is highly competitive and fragmented, with domestic firms primarily manufacturing low technology products such as disposables/ medical supplies, and MNCs primarily importing high end medical equipments. However, in recent years, some domestic firms have expanded local manufacturing operations to produce cost effective, medium end, medical devices. Most MNCs are involved in distribution of medical technology products, though some of them have set up manufacturing operations in India. MNCs seeking to enter the industry typically form joint ventures with local manufacturers, establish subsidiaries or employ local agents to distribute their products. However, increasingly these companies are moving away from the practice of importing through local agents and setting up subsidiaries. According to industry sources, in 2007, over 25 foreign medical device companies received licenses to import medical devices in India through their subsidiaries.

High imports

High end medical technology products are largely imported into India. Infact, imports constitute about 75% of the Indian medical technology market. Key categories* of items that are imported into India include imaging equipment, pacemakers, orthopaedic and prosthetic appliances, breathing and respiration apparatus, and dental equipment.

It is interesting to note that while India's medical technology industry is primarily import dependent, at the same time, nearly 60% of what's being manufactured is being exported. In fact some companies derive as much as 75% of their revenue from exports. However, the exports of high quality, high tech Indian products are very low compared to other developing countries.

Key growth drivers

The rapid growth of the medical technology industry in India has been driven by the changing medical technology landscape, improving healthcare delivery and financing, and changing patient profile.

Key Growth Drivers for Medical Technology Industry in India

Changing Medical Technology Landscape

Faster upgradation of existing technology and global new product innovation

Evolution of India as a medical tourism hub leading to demand for world class equipments

Growing awareness amongst providers & consumers on advancements in medical technology

Improving Healthcare Delivery & Financing

Increasing competition with the advent of large private sector healthcare providers

Increasing trend of seeking accreditation leading to rise in technology investments

Rising health insurance leading to increased coverage of high cost treatment

Changing Patient Profile

Increased life expectancy and aging population

Increasing incidence of lifestyle / non communicable diseases

Rising purchasing power / disposable income

Changing medical technology landscape

Faster upgradation of existing technology and global new product innovation

Availability of advanced and sophisticated medical technology has created new markets/ applications, which have expanded demand. For instance, new implant materials and improved surgical techniques for joint replacement (e.g. hybrid replacement technique used in hip replacement surgery) are driving growth in the orthopaedic segment. Advent of new and reliable diagnostic technology has also forced the medical community to increase their reliance on diagnoses. Further, introduction of latest techniques also lead to rapid obsolescence of existing medical technology, thereby creating demand for replacement/ upgradation of these products.

Evolution of India as a medical tourism hub

Medical tourism is being promoted by the government and stimulated by the corporate boom in medical care. As a result, India is fast emerging as a medical tourism hub for patients from across the world. International tourists coming to India for medical treatment demand high quality care and world class devices/ equipments. This has also driven private care providers to upgrade their medical technology infrastructure.

Growing awareness among providers and consumers on advancements in medical technology

The Indian consumer, especially in the urban areas, is increasingly becoming more aware about latest medical technologies available in the market, and consequently demanding the same. At the same time, awareness among providers is also increasing due to training and education workshops/ seminars etc. being conducted by industry members. This has driven up demand for new medical technologies.

Improving healthcare delivery and financing

Increasing competition with the advent of large private providers

Industry estimates suggest that India will need as many as 1.75 million additional beds by 2025, and the public sector is expected to contribute only 15–20% to this

investment. Several private providers are entering the healthcare delivery space to cater to this huge additional demand. For instance, the Medanta group has established the Medicity in Gurgaon. The Sahara group plans to set up a 1,500-bed multi super-specialty, tertiary care hospital at Aamby Valley City, and some more multi-specialty hospitals across the country. International healthcare providers, such as Malaysia based Columbia Asia, are also entering India. Entry of new players has made the private healthcare space extremely competitive. As a result, demand for medical technology is coming not just from new entrants, but also from existing providers such as Apollo Hospitals, Fortis Healthcare, and Max India who are upgrading infrastructure and building new hospitals equipped to Western standards to compete effectively in the market.

Increasing trend of seeking accreditation

Private care providers in India are increasingly seeking accreditation of hospitals to cater to the booming demand for quality healthcare and growth of medical tourism. This trend is further accelerated by expanding insurance penetration, and insurers requiring accreditation by hospitals. These factors have resulted in upgradation of medical technology by hospitals to comply with the accreditation requirements.

Rising health insurance

Growth in health insurance in the country has led to increased coverage of high cost medical procedures, enabling a larger part of the population to demand quality healthcare. This in turn has driven up demand for medical technology.

Changing patient profile:

Increased life expectancy and ageing population

Higher standards of living and technological advances in medicine have led to a sharp increase in life expectancy at birth from 58.2 years in 1990 to 63.7 years in 2008. As a consequence, longer-lived individuals will pose demands for increased aggregate healthcare services over a longer period of time. Additionally, the proportion of aged population is increasing, creating upward pressure on demand for healthcare. It is expected that the population above 65 years will increase from 5% of the population in 2005 to 15% in 2030.

Rising purchasing power/ disposable income

A booming economy has resulted in an increase in

personal disposable income and overall standard of living. India's per capita income doubled during 2000-2008, and the share of healthcare expenditure in household consumption has increased. As a result, a larger number of people are now able to afford better quality of healthcare services. An increasingly affluent population in major cities is driving up demand for latest and advanced medical technologies.

Increasing incidence of lifestyle/ non-communicable

Non-communicable diseases (NCDs) have emerged as a major public health problem in India. Aging population, sedentary lifestyle, high stress levels etc. has led to an increase in lifestyle/ non-communicable diseases in India, such as diabetes (India has the highest number of diabetics in the world), cancer, cardiovascular diseases etc. The steep increase in non-communicable/ lifestyle diseases is driving demand in some key segments of the medical technology industry. For example, a sedentary lifestyle, characterized by a lack of physical exercise, has led to a high incidence of back pain and joint afflictions being recorded in India, driving demand for spinal implants, joint implants and associated products. Similarly, rise in the number of cancer cases is driving demand for cancer diagnostic and treatment equipment.

India is fast emerging as a global medical tourism hub with international patient base growing in double digits year on year. This rising trend has resulted in an increase in investments by healthcare providers in installing best in class medical equipments, upgrading technology and seeking quality accreditation.

Key challenges

Low penetration

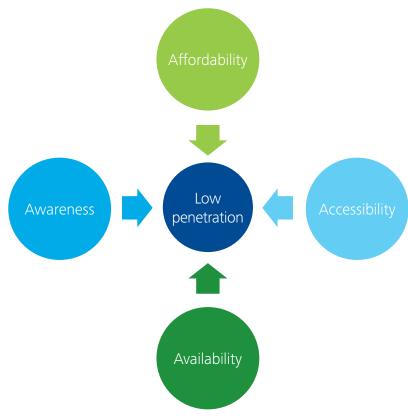
Despite the strong growth of the Indian medical technology market in the last few years, the industry is plagued by low penetration. The per capita spend on medical technology in India is approximately US\$2, as compared to US\$5 for China and US\$231 for Germany. One example to illustrate low penetration is sales of pacemakers. At 18,000 units per year, India's pacemaker penetration is just 1% of western levels. According to Dinesh Puri, CEO, MediVed, India should be selling a million pacemakers a year, considering heart disease is a major killer in India. The challenge is to expand the market. While the medical technology industry is growing rapidly in India, demand comes primarily from major cities. Penetration in smaller cities/towns/rural areas remains low, owing mainly to lack of affordability, accessibility, awareness and availability.

Affordability

Since most of the country' population cannot afford to pay for healthcare, providers in turn pay careful attention to costs in making their purchasing decisions. For example, while big hospitals in Tier I cities are typically driven by quality while purchasing medical devices and equipments, most smaller hospitals, particularly those in Tier II and III cities and rural areas, opt for cheaper products. Many of them do not have high end products as they cannot afford it.

Accessibility

Inequitable access to healthcare delivery has been a key issue with the Indian healthcare system. Public health infrastructure is inefficient and inadequate too, with low investments in medical infrastructure, including devices and equipments. As a result access to healthcare is inadequate or absent in rural India. Consequently, distribution of medical technology in these areas becomes a challenging task.



Availability

Lack of innovation has resulted in scarcity of cost-effective products and solutions in the medical technology industry. At present, there are a limited number of such options available, and that too in select pockets of the country. There is a huge gap between the needs of the Indian consumer and what is available in the market.

Awareness

While there is growing awareness towards health related issues in the major cities, a large part of India's population remains ignorant about the latest advance-

Indian medical technology sector is growing but the per capita spend of US\$2 is significantly lower than not just the developed countries but also the other emerging economies. Demand in India is predominantly driven from the major cities and penetration in smaller cities/town/rural areas has remained low due to lack of the 4 A's (Affordability, Accessibility, Awareness and Availability)



ments in medical technology. For example, the concept of Self Monitoring Blood Sugar (SMBG) is still not well-known in India as compared to the West. In India a meagre 0.3% of diabetics use SMBG as opposed to almost 22% in developed countries. Lack of awareness regarding complication of diabetes and benefits of regular monitoring are key factors for this.

Ambiguous regulatory environment

The regulatory environment for medical technology in India is ambiguous, complex and lacks transparency. There are two key issues pertaining to regulation of the medical technology industry in India:

No distinct status for the industry

The medical technology industry in India has no separate legal status. It is currently regulated by the drug controller general of India (DCGI) of the Central Drugs Standard Control Organization (CDSCO), Department of Health. The limited regulation that has been introduced to date covers 14 medical devices (e.g. cardiac stents, catheters, orthopaedic implants etc.) under the Drugs and Cosmetics Act 1940 and subsequent amendments. Application of the Drugs and Cosmetics Act has resulted in redundant rules for medical devices and equipments in India. In certain cases, product registration and manufacturing standards intended for drugs are applied to the manufacture of devices – e.g. it is insisted that an expiry date be given on certain medical devices, whereas this is not required for such products.

Complex rules and guidelines

Absence of specific regulation for the industry, and coverage under the Drugs and Cosmetics Act has resulted in lack of clarity and transparency about the regulations. There are problems pertaining to multiple levels of government authority involved in enforcing the guidelines, as well as inconsistent interpretation and application of the regulatory guidelines by customs officials at the ports, state drug controllers, and officials within CDSCO. This results in a prolonged and cumbersome regulatory pathway, especially for new products.

Absence of quality standards

Lack of regulation of the industry has resulted in products of sub-standard quality being brought into the market, creating wider gaps of quality and cost within the same category of products. There have been some cases of illegal/ counterfeit products also – e.g. illegal reprocessing and re-packaging of used syringes for re-sale. This creates significant risk for the consumer.

Low indigenous manufacturing

India has not been able to develop itself as a strong manufacturing base for medical technology. The industry remains dependent on imports for meeting its domestic requirements. There are two key factors contributing towards this trend, as described below.

Lack of incentives

The government has not been proactive in encouraging the development of a domestic manufacturing industry. There are no specific incentives in place to attract local or foreign companies to set up a production base in India. Further, the current duty structure for medical devices and equipments favours imports, reducing the competitiveness and growth potential of the local medical technology industry. Unlike China, which encourages manufacturing of medical devices and equipments, Indian laws indirectly reward trading by charging higher duties on raw materials than on finished goods. For instance, titanium sheet/ rod imported for making implantable pacemakers attracts a total import duty of 23.89%, while import of the pacemaker itself attracts a duty of 9.36%. As a result, in many cases, cost of a finished product manufactured within the country remains higher than an imported product.

High capital requirement

Medical technology is capital intensive, and setting up a manufacturing plant requires significant investment. While the industry is on a high growth trajectory in India, the overall market remains small due to low penetration. As a result, volumes are low and do not provide economies of scale for most manufacturers. Pune based manufacturer of catheterisation labs (where stenting is done), Alpha X-Ray (acquired by Philips) is a case in point. Alpha X-Ray began making its own path labs from scratch less than seven years ago at less than half the price of an imported one and expanded access to many districts in Maharashtra. Yet Alpha's promoters sold out, since it was struggling for funds, according to P.V. Gopal, a co-founder.

Burning need: Frugal innovation

Innovation across the value chain in areas of product, process, business model, service delivery, technology etc., keeping frugality in mind will help the medical technology players create new markets in the lower income segments and leapfrog to the next level of growth

The medical technology industry in India needs to innovate in order to address the challenge of low penetration and meet the healthcare needs of all income segments. In a country like India, where resources are scarce but needs are great, solutions have to be affordable, reliable, resilient, easy to distribute, and easy to use. Consequently, frugal innovation is the way to go. Companies need to squeeze costs so they can reach more customers, and consequently exploit economies of scale. Frugal approaches to innovation are particularly critical in the Indian medical technology industry to make modern care accessible, available and affordable to all. Existing demand for medical technology in India is concentrated in big cities. Innovation will help medical technology players create a new market in the lower income segments, primarily, smaller towns and rural areas, and leapfrog to the next level of growth.

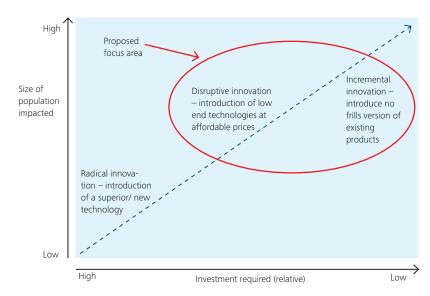


Smaller towns/cities/ rural areas - largely untapped disruptive/ frugal innovations are required to improve access, availability, and affordability



In an emerging economy like India, disruptive and incremental innovations that are capable of lowering the cost of product/ delivery are more suited in the short-run, than radical innovations which introduce advanced technologies that may be sometimes more than what the consumers need or demand. Indian medical technology industry needs "low-end disruptions" which target customers who do not need the full performance valued by customers at the high end of the market, as well as incremental innovations that make changes to existing products to launch no-frills or lower end versions. These innovations have the capability to impact a larger segment of the population which is price conscious and driven by affordability.

In recent years some companies have developed costeffective products specifically for the Indian market. One such innovation is GE's Mac series, an ultra-portable electrocardiogram (ECG) machine. The device was conceptualized, designed and manufactured in India according to the requirements of the domestic market. With the Indian market in mind, the MAC 400 is priced at one-third that of imported ECG systems of similar quality. To deal with power outages in many parts of India, the MAC 400 is battery-operated. Moreover the device is designed to be easy to use so that it can be used by general physicians as well as cardiologists. Customers in the health care field wanted the machine to be portable so they could reach more patients; hence, it is lightweight. To ensure easy serviceability (especially in remote areas) and to lower costs, it comes with commercially available components instead of



customized and proprietary parts. The MAC 400 has been very successful, and has been sold in over 100 countries since its launch in India. Infact, in November 2009, GE Healthcare India released its latest ECG device: the MAC I. Smaller than a laptop and with a price tag of Rs 25,000 (\$535), the MAC I will reduce the cost of delivering an ECG bill to just Rs 9 - six times lower than prevailing ECG rates.

Some Indian companies are also channelling their technological and medical talent towards frugal approaches. A few examples are given below.

Company	Product	USP	
MediVed	Pacemaker	Cost is Rs. 20,000 to 25,000 below the comparable pacemakers produced by international companies	
Bigtec Labs	MicroPCR	 A miniaturized, no-frills and portable version of the bulky PCR (polymerase chain reaction) machine Costs Rs 1 lakh compared to a conventional PCR's price tag of Rs 15 lakh 	
Perfint Healthcare	PIGA-CT	 Uses robotics to make image-guided, soft-tissue biopsies simpler, safer and more accurate At Rs 15 lakh a machine, it is less expensive than other imported alternatives — such as fluoroscopes - which are double the cost 	
Skanray	X-ray imaging systems	High-frequency digital X-rays with radiation leakage controlCost is a fraction of the imported equipment	

Given the criticality of ensuring safety and quality in the case of medical devices and equipments, appropriate regulation and quality control processes will be a prerequisite for frugal innovation to foster and sustain.

However, innovations in products alone won't suffice to tap the unique needs of the growing Indian market. There is a need to rethink and redesign the entire business model. Medical technology industry needs to evolve from merely supplying devices and equipments to the healthcare industry, to providing integrated solutions for improving health outcomes.

Communication, Technology) presents an opportunity for universal access to medical technology at very low cost, and it should be used in creative, new ways to support innovation in medical technology. ICT also aids in developing models that address the problem of physician/ technician shortage in the country For instance, Intel's Active Management Technology allows IT professionals to proactively monitor remote medical equipment systems for issues and install software patches and upgrades to keep the equipment operating under field conditions. Medical technology companies need to leverage the offerings of such providers to create business processes and models that enable efficient distribution of products in remote areas.

Innovative business models - some examples Financing options Medical technology Continue to offer which offer the company takes on low end version buyers an option to the role of a service of products which pay in installments, provider as well and may not have latest or procure medical offers to operate the technology but equipment on lease medical equipment for provide the required a healthcare provider treatment/ diagnosis

The examples stated above provide affordable options to healthcare providers for purchasing medical technology and will increase market penetration. Another significant opportunity for developing innovative business models is to partner with technology and communication providers. ICT (Information,

Telemedicine on mobile

Maestros Mediline, a medical equipment manufacturer, has launched an application in collaboration with Blackberry, where doctors can check their patients' ECG on their mobile handsets. This application of mobile ECG would enable the doctors to monitor the heart performance of their patients accurately even from a distance.

Remote monitoring for cardiac devices

Sorin Group, a global medical device company and a leader in the treatment of cardiovascular diseases, and Orange Business Services, the leading global communications solutions integrator, entered into an agreement in 2009 to develop and service a remote monitoring solution for patients implanted with cardiac rhythm management (CRM) devices.

The four pillars of innovation

While innovation is the need of the hour for the Indian medical technology industry, there are certain key enablers that will facilitate and drive the process of innovation. These enablers, or the four key pillars of innovation, together create the right environment, including resources and incentives, needed for companies to innovate. These four pillars of growth are – funding, talent, supportive regulation and indigenous manufacturing.

Funding

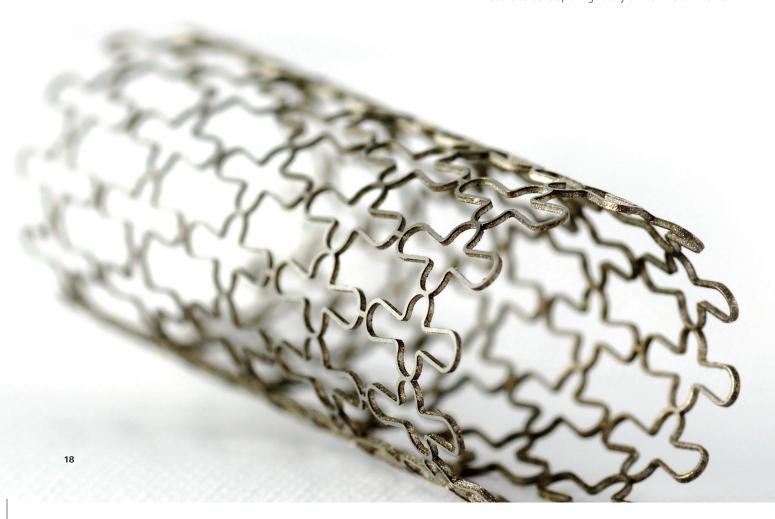
While many of the MNCs have access to sufficient capital for investment in R&D, most Indian firms do not enjoy such status and are unable to innovate due to lack of funding. While several PE and venture capital firms have started taking interest in the Indian medical technology sector, access to capital for most domestic firms remains restricted. The government can play a key role here by providing some financial support to medical technology companies with innovative business proposals and by encouraging private investment in the sector.

Talent

While India has a large base of technical manpower with basic qualifications, it lacks trained and experienced professionals to undertake high end research and development in the field of medical technology. This is a result of the fact that medical technology has not received enough attention as a field for higher education. Medical and engineering streams have been kept apart in India till now. The IITs, for example, in their B.Tech curriculum are primarily mathematics driven. However, IIT is now expanding into medical programmes. A good example of amalgamation of medical and engineering streams is the Stanford Biodesign programme, as part of which AIIMS and IIT, Delhi are working together. The industry needs to work together with the government and academia to ensure availability of the right talent pool for innovation.

Supportive regulation

A sound regulatory framework is a key enabler for growth of the medical technology industry, and will accelerate the pace of innovation. The most immediate need is to develop a regulatory environment which is



Four Pillars of Medical Technology Innovation

Innovation

Funding

financial support to sustain the required research and development activities over a long period

Talent

relevant and experienced skill base for carrying out design and development of innovative products

Supportive regulation

distinct and simplified regulation for the industry, harmonized with global standards

Indigenous manufacturing

Incentives for local manufacturing to support development of low cost products

Medical Technology

not only pro-growth, but also harmonized with global standards in medical technology. Some movement has started on this front - the Government of India is in the process of developing a separate legal framework designed to ensure the quality, safety and performance of medical devices. The framework will take into consideration international standards (e.g. GHTF - Global Harmonization Task Force). Approval of revised guidelines under Schedule M-III represents India's first systematic attempt at regulating medical devices as a separate sector from drugs, and calls for stricter oversight on both the manufacturing and import of medical devices. Further, there has been a move towards more collaboration and interaction between the DCGI and the industry in the recent past. However this needs to be institutionalised and improved in order for a workable regulatory system to be established.

Indigenous manufacturing

Until the constraints to manufacturing are taken care of, innovation will not yield the desired impact on the industry. Local manufacturing will enable production of cost-effective devices and provide the volume needed to increase penetration. A few companies are already focusing on producing low-cost medical devices/ equipments for the Indian market. For instance, a GE baby warmer that was imported at US\$30,000 now sells for less than US\$3,000 without "bells and whistles". What has helped keep the production cost low, apart from world-class research, is the company's policy of manufacturing not just the finished products in India, but also many of the components that go into it.

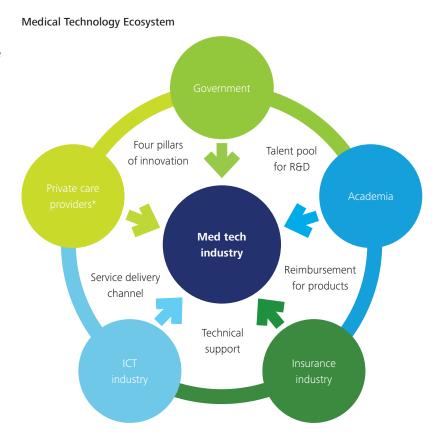
Collaboration – a key success factor

While some isolated examples of frugal innovation can be observed in the Indian medical technology industry, the challenge is to develop and implement cost effective and scalable models of delivering medical technology. However, it is practically impossible for the industry to achieve this alone. A collaborative approach towards innovation in the industry will help in overcoming this challenge and enable the medical technology industry to be the game changer in transforming the Indian healthcare scenario. A coordinated effort is required from all stakeholders, including the industry, academia, healthcare providers and the government to promote medical technology innovation in India. Each of these stakeholders must contribute towards strengthening the medical technology ecosystem, which will in turn improve healthcare delivery in the country.

The industry needs a platform to promote and celebrate innovations. Effective collaboration across the value chain is essential for managing innovation and new product introduction; managing the product portfolio; lowering development and support costs; delivering product to the marketplace faster; protecting the company's intellectual capital; and effectively and efficiently supporting the customer.

For instance, the academic research being carried out in the country remains mostly theoretical, with little practical application for product development in the medical technology industry. Greater interaction is required between the academia, government and the industry to conduct research that is relevant. The government, on its part, needs to realize that medical technology is a critical part of the healthcare delivery value chain, and provide avenues for new product development and commercialisation.

Similarly, collaboration with ICT companies is essential to develop innovative business models for micro-accessibility of affordable healthcare and medical technology. A



*Including diagnostic service providers

dialogue needs to be started with insurance companies as well, in order to design products for promoting sales of medical technology and effectively expand in areas like home care. Partnership with healthcare providers is undoubtedly critical since medical technology forms an important part of the healthcare delivery value chain. Care providers can offer the backbone for implementing innovative business models of medical technology companies.

A case in point - Israel

A key lesson to be learnt from Israel is the excellent collaboration that exists between education, R&D institutions, companies and entrepreneurs, both domestic and international. Israel is home to seven tech transfer organizations (TTO's) within the university system, and a further five from within its leading research hospitals. The TTOs provide a valuable forum for connecting Israeli researchers and early stage projects with investment, sponsorship and partnerships from multi-national companies eager to benefit from Israeli innovation. This cross-fertilization has bridged the once impenetrable gap between basic and applied science and has made it easier for innovative technology to come to fruition.

The government can play a pivotal role in stimulating growth of medical technology industry. For instance, China has set up high technology parks where duty exemptions are provided to the manufacturers. In

addition, significant funding support is provided to local manufacturers for carrying out R&D. Such proactive involvement of the government is critical for the growth of Indian medical technology industry and will go a long way in strengthening the four pillars of innovation.

PPP in medical technology

GE Healthcare: In Madhya Pradesh and Gujarat, GE Healthcare has set up diagnostic centres at select government medical colleges. The charges for the patients are unchanged, the centre and the equipment will be run by the company and its partners.

B Braun: The company, in partnership with the state government of Andhra Pradesh, has set up 11 centres equipped with 111 haemodialysis machines within medical colleges and hospitals in the state to provide treatment to patients suffering from chronic kidney diseases (CKDs).

PPP (Public Private Partnership) route to innovation

One important way in which the government can promote medical technology innovation is through PPPs. Both the parties can leverage each other's strengths to bring affordable healthcare within the reach of a large majority of the country's population. While such a model will provide good quality care to the masses, medical technology companies can gain by the increased patient volume and economies of scale. GE and B Braun are examples of companies that have partnered with state governments under the PPP route to provide affordable and accessible healthcare.

PPP- GE Healthcare, Government of Madhya Pradesh and Sanya Hospitals and Diagnostic Centre				
Key terms	• The company helped set up an advanced, diagnostic centre at the Netaji Subash Chandra Bose Medical College Hospital, Jabalpur			
Industry contribution	 The company installed a Lightspeed 16-slice CT and a Signa HDx1.5T MRI system Sanya Hospitals and Diagnostic Center provided diagnostic imaging services at an affordable cost. The Centre invested Rs 80 million on equipment and training professionals including doctors, nurses and technicians to the medical college hospital 			
Outcome	• The PPP model reduced diagnostic imaging costs for patients by approximately 30% and up to 50% for below poverty line patients			

PPP- B Braun and Government of Andhra Pradesh				
Key terms	 The company has committed to make an incremental investment of Rs 35 crores in a PPP project in Andhra Pradesh over seven years The scheme is a part of the state government's Arogyasri scheme meant to provide medical services at affordable rates for the poor 			
Industry contribution	• B Braun will set up 11 centres equipped with 111 haemodialysis machines within medical colleges and hospitals in the state to provide treatment to patients suffering from chronic kidney diseases (CKDs). Eight such centres were already operational as of March 2010.			
Outcome	• The dialysis treatment given under Arogyasri programme of the State Government is rendered free of cost to patients, with the state government paying Rs 1,080 per patient for treatment.			

The way forward

The government is the most important contributor in developing a conducive environment for growth of medical technology industry in India. At the same time, the industry members need to work hand-in-hand with the government to encourage innovation. There are certain expectations from both the government as well as the industry in order for the medical technology industry to achieve sustainable growth.

Way forward - Government

- Create a separate regulatory framework dealing with specific requirements of the medical technology industry
- Provide incentives for domestic manufacturing, such as tax holidays and low customs duties on imported raw materials
- Create and enforce quality standards in tune with the relevant global standards for medical technology
- Enter into public private partnerships with medical technology companies and healthcare providers for implementing cost effective models of healthcare delivery
- Encourage relevant R&D through:
 - Financial support to companies for product development and commercialisation
 - Development of local R&D capabilities e.g. establishment of research centres – and industry participation in the same
- Engage with the academia to develop relevant courses that will develop the required skill base for the industry, develop training institutes etc.
- Establish 'medical technology clusters' that will include not only industry members but also R&D centres, educational institutes etc. and will foster high levels of productivity and collaboration
- Create a central authority for holistic development
 of the medical technology industry in India the
 authority should look at non-regulatory / commercial
 aspects of the industry that will drive growth

Way forward - Industry

- Increase R&D activity geared towards developing products suited to the Indian market
- Collaborate with ICT companies to bring to fruition frugal approaches to innovation
- Partner with government and healthcare providers to reach out to the masses through affordable healthcare delivery models
- Engage with the government and academia to develop relevant courses that will develop required skill base for the industry, develop training institutes etc.
- Collaborate with healthcare providers to promote training and education of physicians and other technical personnel in the area of medical technology through continuing medical education (CME)
- Involve healthcare providers in the innovation process – e.g. associate with physicians for obtaining specific inputs on product development
- Strengthen industry network / association to promote awareness about innovations, share industry best practices and encourage of overall development of the industry
- Engage with insurance providers to expand health insurance coverage for medical technology products

Appendices

Appendix-I: List of People Interviewed

Name of Person	Designation	Name of Organization
Gautam Khanna	Executive Director	3M Medical
Dr Vinod Kohli	Managing Director	Allied Medical
Jaideep Gupta	Managing Director	Indraprastha Apollo Hospitals
Arun Mudgal	Business Unit Head- Pharmaceutical Projects	B Braun
Navin Sharma	Director, Government Affairs and Public Policy	Baxter
Manoj Gopalakrishna	Managing Director	Becton Dickinson
Rekha Khanna	Managing Director	Biomerieux
Vijay Simha	COO and Vice President	BPL Healthcare
Sunil Saigal	Managing Director	Consolidated Products Corp.
Arjun Sarker	Managing Director, Indian sub-continent	Covidien
R Asok Kumar	Head RA and QA, Indian sub-continent	Covidien
Dr. S Eswara Reddy	Assistant Drug Controller and Head of Medical Devices	Central Drugs Standard Control Organisation
Daljit Singh	President, Strategy and Organisational Development	Fortis Healthcare
A Vaidheesh	Managing Director	Johnson & Johnson Medical
Rohit Mehta	General Manager & Head – Medical Equipment & Systems	Larsen & Toubro Limited
Uday Puri	Business Manager	MediVed
Dheeman Vaidya	Head – Therapy Value Partnerships	Medtronic
Anjan Bose	Vice President	Philips Healthcare
Himanshu Baid	Managing Director	Poly Medicure
Dhirajlal Kotadia	Chairman	Sahajanand Medical Technologies
D. Raghavan	Cluster CEO of Healthcare Sector – South Asia Cluster	Siemens Ltd.
Yashdeep Kumar	Managing Director	Stryker
Ajay Pitre	Managing Director	Sushrut Surgicals
Suresh Vazirani	Founder	Transasia Biomedicals Ltd.
Dr GSK Velu	Managing Director	Trivitron Healthcare
Pavan Choudary	CEO and Managing Director	Vygon India
Sanjay Banerjee	Managing Director	Zimmer India

Appendix-II: References

- Cygnus
- Espicom
- AdvaMed (Advanced Medical Technology Association)
- Eucomed (European medical Technology Industry
- NIPER (National Institute of Pharmaceutical Education and Research)
- International Trade Administration
- Economist
- Business Standard
- Economic Times
- Financial Express
- http://medind.nic.in
- Express healthcare

About CII

The Confederation of Indian Industry (CII) works to create and sustain an environment conducive to the growth of industry in India, partnering industry and government alike through advisory and consultative processes.

CII is a non-government, not-for-profit, industry led and industry managed organisation, playing a proactive role in India's development process. Founded over 115 years ago, it is India's premier business association, with a direct membership of over 8100 organisations from the private as well as public sectors, including SMEs and MNCs, and an indirect membership of over 90,000 companies from around 400 national and regional sectoral associations.

CII catalyses change by working closely with government on policy issues, enhancing efficiency, competitiveness and expanding business opportunities for industry through a range of specialised services and global linkages. It also provides a platform for sectoral consensus building and networking. Major emphasis is laid on projecting a positive image of business, assisting industry to identify and execute corporate citizenship

programmes. Partnerships with over 120 NGOs across the country carry forward our initiatives in integrated and inclusive development, which include health, education, livelihood, diversity management, skill development and environment, to name a few.

CII has taken up the agenda of "Business for Livelihood" for the year 2010-11. Businesses are part of civil society and creating livelihoods is the best act of corporate social responsibility. Looking ahead, the focus for 2010-11 would be on the four key Enablers for Sustainable Enterprises: Education, Employability, Innovation and Entrepreneurship. While Education and Employability help create a qualified and skilled workforce, Innovation and Entrepreneurship would drive growth and employment generation.

With 64 offices in India, 9 overseas in Australia, Austria, China, France, Germany, Japan, Singapore, UK, and USA, and institutional partnerships with 223 counterpart organisations in 90 countries, CII serves as a reference point for Indian industry and the international business community.

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