India has experienced significant growth in the health care sector in the past decade; however, it faces a constant challenge to make high quality health care affordable and accessible. Medical technology forms an important pillar in the health care system along with health care providers, pharmaceutical and health insurance industry in India, but is the least developed. It contributes only 8% of the total US$40 billion health care market in India and constitutes around 40% of the treatment, which is divided between equipment, diagnostics, consumables and devices (implants).

The medical technology market is dominated by imports, which account for more than 70% with few manufacturing initiatives in India. Most of the imported instruments have features more suited to the country of manufacturing and many of these features are not entirely relevant to the Indian context.

One of the key drivers for cost of health care is the lack of indigenous manufacturing and high import dependency. The Honourable Prime Minister of India, Shri Narendra Modi, during his recent speech on Independence Day, declared “Made in India” to be the slogan to boost manufacturing in India. With cognizance to this, as a long-term solution, there needs to be a clear directive to encourage and support innovation and manufacturing of medical technologies that makes health care affordable and accessible to the common man.

India has a considerable pool of intellectual capital that can be channelised for driving local innovation and manufacturing in the field of medical technology. However, issues of insufficient scale in India, cheap imports from countries such as China and prevalence of inverse duty structure are cited to be main reasons for lack of interest by local companies. The challenge around scale can be addressed by keeping global markets in view and thereby, creating quality products and solutions that are FDA/CE certified. Indian companies will have to focus on innovation, continuous improvement and local value addition to cater to the vast semi-urban and rural market. Mere indigenisation of imported devices may not provide differentiation, especially while comparing it with China.

Much has been spoken about developing India’s manufacturing capabilities, but there has been lack of clear policy direction. The trend must now change to create a world class manufacturing hub in India for medical technology products and rewrite India’s name in this domain as has been done in the areas of Information Technology and pharmaceuticals.

FICCI commissioned Ernst & Young LLP to develop the second edition of the paper Reinventing Affordable & Universal Health care through Innovation released last year in FICCI HEAL 2013. This year’s Paper titled Health care innovation and medical technology: reaching the unreached deep dives into the medical technology market, co-relates it to health care needs and innovation, analyses challenges around innovation and domestic manufacturing and recommends an enabling environment required to promote innovations and indigenous manufacturing of medical technology in India.

We would like to take this opportunity to thank the leaders from the industry and the Government who provided their valuable inputs and contributed to this knowledge paper.

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At the outset, we would like to thank FICCI for having provided this opportunity to collaborate in preparation of this Thought Leadership.

The Indian health care system has made significant progress in the last decade. However this is overshadowed by insufficient resources and poor clinical outcomes. With the government’s commitment to provide “universal health care” there is an urgent need for all key stakeholders to consult and develop a health policy that will bring us a step closer to providing accessible, affordable and “world class” health care to all irrespective of economic status and societal vulnerability.

India is a country of contrasts. On one hand the existing health care system is unequipped to meet the growing needs of the population; and on the other, our brilliance and talent in medicine and engineering sciences has forced the world to look eastwards to seek low cost high quality medical care and recognises us as the Information Technology hub of the world.

It is the innovativeness of use of technology in medical science that health care providers globally are able to provide effective and efficient health care through sensitive and specific diagnostic kits we are able to offer early diagnosis for precise and specific treatment and improve patient aid for better rehabilitation.

Awareness to its challenges in service provision, India is committed to provide impetus to medical technology from its current shape. Therefore, FICCI Health Care Sector has requested EY’s support in creating a white paper in the area of “Health care Innovation & Medical technology “.

Through our interactions with key stakeholders this Thought Leadership document has made an endeavour to understand the practical challenges, the inter-linkages, and barriers that have resulted in stunted growth of innovation in med-tech in India. The report is blended with sharp insights, perspectives addressing the unmet needs in the health landscape and potential bridge that health innovations and medical technologies can provide; and find appropriate solutions to build a vibrant ecosystem and an enabling environment:

- To address felt need of the end-user both nationally and globally, and improve access to effective and efficient high quality patient care services.
- Create a feasible, competitive, and sustainable market for medical technology
- To promote growth of Indian med-tech that is competitive globally in a frugal manner

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Executive summary
The goal of Universal Health Coverage is to ensure accessibility to affordable high quality health care. To ensure that this target is achieved, it is quintessential that the four pillars on which health care service delivery is founded on health care providers, the pharmaceutical sector, the health insurance sector and the medical technology grows in synchrony. At present, the growth of medical technology in India needs that fillip.

Improvisation in high quality precision devices to offer prolonged treatments for growing burden of chronic & lifestyle diseases such as cardiac, accident & trauma and geriatric diseases calls to improve the healthy adjusted life years of individuals’ technology has played a crucial role in rising cost of care. In order to have far reaching impact on the population in rural India and the poor urban settings, **all stakeholders must collaborate to encourage innovation, research and development (R&D), use technology in medicine that is affordable, accessible, sustainable and of high quality.**

This is an endeavor to understand medical technology market globally and in India, so as to localise the global learning. It further serves as a compendium of practical experiences of stakeholders in the value chain of med-tech for elucidating their role perceptions in the process of ‘co-creation’ of innovative medical technology; and to analyse what works/doesn’t work; what can make it work; challenges and barriers that have resulted in the stunted growth of the medical device industry in India; and how it will/can be made to work and concludes with a series of recommendations that can promote the growth of the industry to address the felt need of Indian people.

It is therefore important to understand that technology is innovative utilisation of science in medicine and therefore need not be frugal, but devices can be frugal. **The obfuscation of drugs and devices has curtailed the ability of the medical device sector to address health care needs.**

With the **Drugs & Cosmetic Bill (Amendment) 2013** currently tabled in the Rajya Sabha, medical devices are expected to be defined as per the erstwhile Global Harmonization Task Force (GHTF), International Medical Device Regulators Forum (IMDRF) and International organisation for Standardisation (ISO) that would bring a “harmonisation between India’s planned path forward and medical device manufacturers globally”.

The Indian medical devices market is among the top-20 in the world. India is among the top four emerging markets for direct investment by large medical device multinational companies after Japan, China and South Korea. India being a country with extra ordinary capabilities in terms of talent pool across various streams of science, engineering, medicine and designing must understand that we contribute significantly to the global burden of disease with 20% of the world’s population. So innovation must continue with or without R&D and become leading producers and exporters of low cost frugal med-tech similar to Ireland that has consciously capitalised its strengths to capture an export footprint of US$10bn worth of medical devices being far smaller country than India with far lesser disease burden. The changing geo-political situation in the US and China have created an environment conducive globally for Indian indigenous med-tech market to grow.