Bioimplants and Devices

Wellness, By Design

Anurag Mairal

Bioimplants and devices sector, also known as the medical device sector, is a key part of the healthcare industry worldwide. The sector covers a wide spectrum of devices including diagnostics, imaging, dental, surgical, ocular, wound care, orthopedic and cardiovascular devices. Although the $250-billion medical device sector is substantially smaller than the $750-billion pharmaceutical industry, it is growing 6-8% annually compared to 2-4% growth rate of the global pharmaceutical market.

The faster growth in the device sector is driven in large part due to the substantial clinical needs that have remained unaddressed by drugs. The growth is substantially higher over 10% in the emerging markets as they become increasingly affluent and adopt technologies widely accepted in the developed markets. As the pharmaceutical industry growth slows down, large healthcare companies looking for growth have increasingly turned their attention to medical devices. In fact, 2009 saw a number of large mergers and acquisitions in the device sector, despite the global economic slump.

Structure of and Evolution within the Medical Device Sector

Medical device sector, much like the pharmaceutical industry, is dominated by some very large players who have market leadership in a number of segments within the sector. While these large companies have internal product development teams, the thousands of start-ups funded by venture capital form the backbone of device innovation, contributing a majority of new products in the market. The entrepreneurial culture of the device industry is widely recognized and well-supported by all the stakeholders in the medical device eco-system, including large device companies, investors, inventors, clinicians, vendors and service providers, academia, and the government. Most of these start-ups are acquired by large companies after the concept or the technology has been validated through animal and early clinical trials. Large companies then take over the later stages of product development, perform more extensive clinical trials, seek regulatory approval and insurance coverage, and carry out product commercialization. Substantial capabilities of large companies in these areas built through heavy investment of resources create a barrier to entry for any new entrant. The select few companies that do grow to become a mid-size enterprise (say, >$100 million in sales) often get acquired in large acquisition deals.

Leading device companies are active in multiple therapeutic areas (see table on page 4 for a list of largest global medical device companies and their device sales figures. Many of these also have substantial presence in the pharmaceutical industry). ▶▶

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Top Medical Device Companies and Areas of Activity

Rank	Company	Home Country	Revenue	Primary Device Sector Segments
1	Johnson and Johnson	U.S.	$23.1B	Orthopedic, cardiovascular, surgical instruments, diabetes
2	GE Healthcare	U.S.	$17.4B	Medical imaging, diagnostics, patient monitoring systems
3	Siemens	Germany	$16.1B	Diagnostic imaging, diagnostics, hearing instruments
4	Cardinal Health	U.S.	$13.7B	Surgical products to pharmacies and hospitals
5	Medtronic	U.S.	$13.5B	CRM, cardiovascular, neuromodulation, diabetes, and surgical
6	Baxter International	U.S.	$12.3B	Blood management, immune disorders, renal, infection
7	Philips Healthcare	Netherlands	$10.7B	Diagnostic/treatment in cardiology, oncology, critical care
8	Covidien	Ireland	$8.9B	Surgical devices and supplies, airway and ventilation
9	Boston Scientific	U.S.	$8B	Cardiovascular, CRM, neuromodulation, neurology, endoscopy
10	Abbott Laboratories	U.S.	$7.2B	Cardiovascular, diabetes, neurology, hospital care
11	Becton, Dickinson & Co.	U.S.	$7.2B	Diagnostic and laboratory tools and instruments
12	Stryker	U.S.	$6.7B	Orthopedics
13	B. Braun	Germany	$5.3B	Surgical equipment
14	St. Jude Medical	U.S.	$4.3B	CRM, structural heart, neuromodulation
15	3M Healthcare	U.S.	$4.2B	Casting and Splinting, Diagnostics, woundcare
16	Zimmer Holdings	U.S.	$4.1B	Orthopedic devices, dental implants
17	Toshiba	Japan	$3.9B	X-ray, CT, MRI
18	Smith & Nephew	U.K.	$3.8B	Orthopedic devices, endoscopy, advanced wound care
19	Hospira	U.S.	$3.6B	Medication management systems
20	Danaher	U.S.	$3.3B	Medical instruments and tools
21	Olympus Medical Systems	Japan	$3.3B	Endoscopy
22	Synthes	U.S.	$3.2B	Trauma, surgical power tools, biomaterials for bone defects
23	Beckman Coulter	U.S.	$3.1B	Laboratory instrumentation
24	Terumo	Japan	$3B	Needles, syringes, catheters, blood collection devices
25	Alcon	Switzerland	$2.9B	Opthalmology
26	Fresenius Medical	Germany	$2.8B	Medical supplies, renal
27	Biomet	U.S.	$2.4B	Orthopedic, dental implants, supplies
28	C. R. Bard	U.S.	$2.4B	Vascular, urology, oncology, and surgical supplies
29	Dentsply International	U.S.	$2.2B	Dental products and instruments
30	Agfa Healthcare	Belgium	$2.7B	Diagnostic imaging, healthcare IT clinical applications

Source: http://www.mpo-mag.com/articles/2009/07/still-on-target and company websites

The global medical device industry can in fact be classified in terms of the disease segments or treatment areas. (see figure on top of page. 5 for an overview of the top-10 device segments in terms of their contribution to the total market in the U.S).

Globalization in the Medical Device Sector

A remarkable shift is taking place in the medical device sector. This shift has been in the making for much of the last decade. As the healthcare costs have skyrocketed in the U.S. and are projected to account for one-fifth of the entire GDP, there has been a vigorous debate about ways to control the costs. Aging population, inefficiency in the complex healthcare system, and rising cost of therapies have been among the many reasons cited for the rise in costs. A growing number of healthcare experts are pushing for prevention as a cost-effective alternative to more expensive treatment-and-management paradigm. This has made the device industry rethink its product development approach. For decades, the medical device industry developed increasingly complex technologies to treat a range of conditions from blocked arteries to arrhythmia and obesity. With the increase in the sophistication and complexity of the technology, the cost of therapies also went up. As FDA demands more rigorous, expensive trials before approval and insurance companies tighten their reimbursement ▶▶

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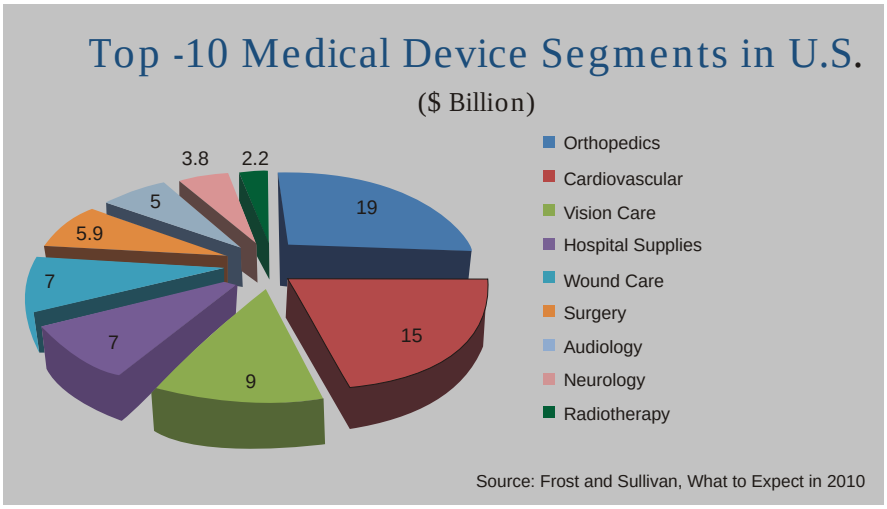


policies, the medical device industry is reevaluating its product strategy.

Another factor that forces the medical device industry to chart a new path is the extraordinary growth rates of the device industry in emerging markets against the backdrop of maturation in the developed markets.

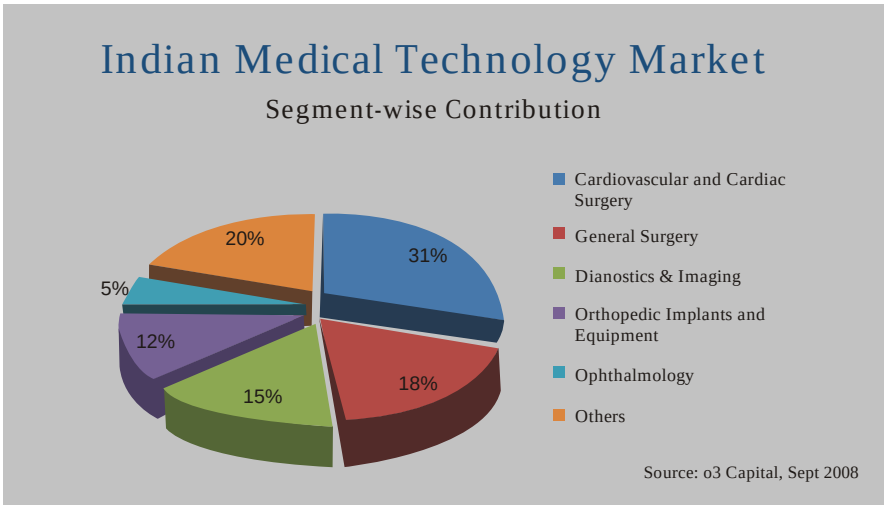
The outcome has been the emergence of a new model of reverse innovation, in which the emerging markets not only serve as promising future customer base but also as the breeding ground for cost-effective, disruptive innovation that can be brought ashore in the U.S. and Europe, reducing healthcare costs in these developed markets and offering new therapies for the global clinical needs. Indeed, a number of key players, including GE Healthcare, have already started to execute this new model.

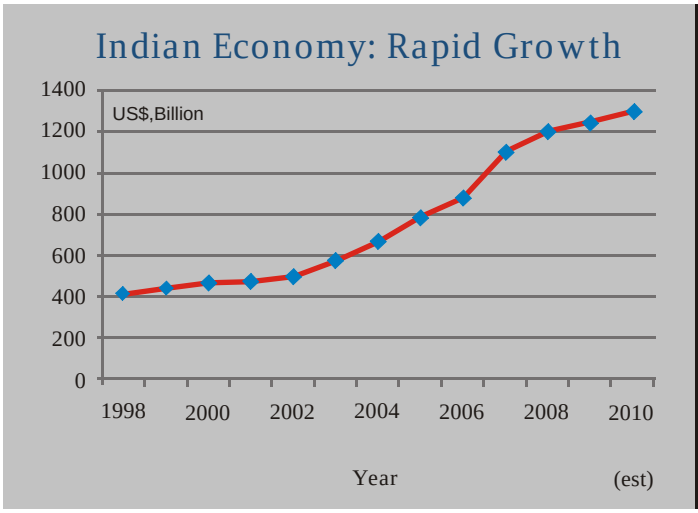
Why Reverse Innovation Makes Sense

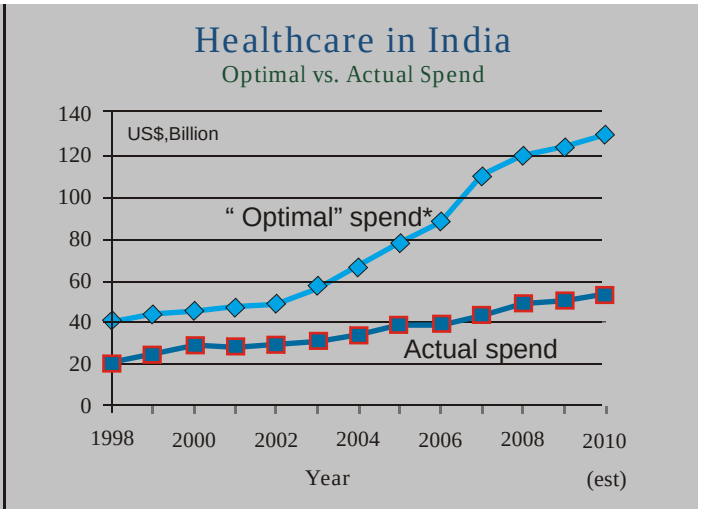
Medical technology has come a long way since the early 1900s. The innovation in the medical device industry has broadly mirrored the overall technological progress in the society. However, much of this innovation has been focused on the needs of the richer, developed markets. Unlike the pharmaceutical industry, where emerging markets see new drugs introduced and adopted very quickly, the medical device industry has not managed to get the emerging markets to adopt the advances in technology until very recently. Even recent upswing in adoption in these new markets of leading-edge technologies in drug-eluting stent, cardiac rhythm management and spinal fusion have been limited to the affluent, large cities.

While there are several reasons for poor penetration of medical technology in emerging markets, chief among them is the lack of innovation both in terms of business models and engineering and design that is specific to the needs of the local population. These markets require products that are easy-to-use, robust, and cost effective. Advanced features that may provide a marketing advantage in the U.S. market often prove to be a hindrance, both from ease-of-use and pricing perspective, in India and China.

With a return to basics in healthcare, driven in part due to the looming healthcare cost crisis and aided further by the current macroeconomic environment in the U.S., medical device industry must adapt. Reverse innovation will not only allow the industry to finally address the healthcare needs of an untapped market but also provide a ▶▶







Optimal spend calculated as 10% of the GDP, comparable to the level of spend by best managed national healthcare systems in the world.

pipeline of technologies that meet the needs of a redefined healthcare market in the West. The timing in uncanny countries like Brazil, Russia, India, and China (the BRIC countries) are growing economically and can afford to seek new therapies for their growing healthcare burden.

India: A Booming Economy and Disease Burden

India is in the midst of a major economic growth, and has more than doubled in GDP in the last decade. Most economists project India to be one of the top three economies, after United States and China, within the next three decades. (see figure above on the left)

However, as the country has become more affluent, the clinical burden in India has shifted gradually from infectious diseases to the lifestyle conditions such as coronary heart disease and diabetes. India is now home to the largest population of heart disease and diabetes patients. The country spends just over 4% of its GDP on healthcare, substantially less than the allocation by most developed nations. Most of this spending is borne by the private payers; government contributes less than 20% to the healthcare tab of the nation. India must increase its healthcare spending substantially to meet its needs (see figure above, on the right, for current and historical spend and the optimal level for a well-run healthcare system).

Medical Device Industry in India

India's medical device industry is estimated at $2.5 Billion and is expected to cross $4 Billion by 2012; growing at more than 15% annually (see figure on page 5 for contribution of the various therapeutic areas to the total market). While most of the device volume comes from non-implantable devices (classified as Class I medical devices), much of the revenues come from lower-volume Class II and Class III devices, many of which are implantables such as the stents and pacemakers (see table below for types of devices that comprise the various device segments).

Changing Face of Indian MedTech Industry

Until recently most indigenous manufacturers of medical devices focused on supplying low-cost devices such as tubing and syringes, whereas large global players dominated the high-end medical equipment and device segment. In the last decade, however, a new generation of device companies has ▶▶

(Contd. on page 21)

Types of Devices Comprising Device Segments in India

Device Segment	Device
Cardiovascular and Cardiac Surgery	stents, cardiac surgery tools, pacemakers
General Surgery	sutures, surgical tools
Diagnostics and Imaging	CT, MRI, X-Ray, diagnostic kits
Orthopedics	screws, artificial knees and hips
Ophthalmology	devices and surgical tools

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(Contd. from page 7)

Representative list of International and Domestic Medtech Companies Active in India.

International Manufacturers	Domestic Manufacturers
Abbott Laboratories (www.abbott.com)	Essel Propack (www.esselpropack.com)
Becton Dickinson (www.bd.com)	Invicta Meditek (www.imel.in)
Boston Scientific (www.bostonscientific.com)	Opto Circuits (www.optoindia.com)
GE Healthcare (www.gehealthcare.com)	Perfint Engineering (www.perfinttech.com)
Johnson & Johnson (www.jnj.com)	PolyMedicure (www.polymedicure.com)
Medtronic (www.medtronic.com)	Relisys (www.relisysmedicaldevices.com)
Philips Healthcare (www.philips.com)	RFCL (www.rfcl.in)
Roche Diagnostics (www.roche-diagnostics.co.in)	Sahajanand Medical Technologies (www.sahmed.com)
Siemens (http://w1.siemens.com)	Sushrut Surgical (www.sushrut.com)
St. Jude Medical (www.sjm.com)	Trivitron Medical Systems (www.trivitron.com)
Stryker (www.stryker.com)	Vascular Concepts (www.vascularconcepts.com)
Zimmer (www.zimmer.com)	

entered the market. These companies are started by determined entrepreneurs, often working closely with clinicians and investors, and have global ambitions. Although still small in terms of share of the high-end device market, the companies have demonstrated the viability of a domestic player in advanced technologies. Their initial success has sparked an interest in larger domestic corporations, catalyzing a flurry of investments, in particular in the diagnostics segment. Concurrently, multinationals like GE, Stryker, and Johnson & Johnson (J&J) have increased their efforts towards fostering innovation for meeting India's needs first, and for exporting it to the West in the longer term. For example, two years back, J&J developed a simple, inexpensive, and robust glucose meter for BRIC markets that was later introduced to the U.S. market with great success. The Table above shows the international and domestic medtech companies active in India.

Future of Medical Technology in India

A number of factors are coalescing to provide the necessary boost to the Indian MedTech Industry. With the increased focus on the potential of the industry, the government is actively formulating policies that create a conducive environment for the industry. In particular, the government is proposing a major overhaul of the regulatory framework governing medical device development, import, and sale. In addition, several federal and state agencies are supporting initiatives (including Stanford-India Biodesign and programs that fund entrepreneurs) to promote the domestic industry. The government is also in the process of rolling out an ambitious health insurance program that will cover hundreds of millions of people in rural India.

Concurrently, the health insurance industry is rapidly expanding coverage to urban population. Nearly 20% of India's population, up from 5% a decade back, has some form of coverage. Also expanding is the healthcare delivery infrastructure; high-quality private hospital chains are now exploring Tier II and Tier III cities, beyond the big-city India, for growth. Finally, as mentioned earlier, a pool of talented engineers and doctors are eager to engage in medical device innovation for India's needs.

Despite these significant factors supporting a potentially vibrant medical device industry, many challenges remain. For instance, the regulatory reform process has stalled over the last two years. India still does not have a critical mass of venture capitalists who would invest in very risky early-stage ideas of the eager entrepreneurs. Moreover, the army of smart engineers and designers is not experienced in the device industry, raising the bar for their success. Vendors providing prototyping, manufacturing, testing, regulatory, and commercialization services are few and far between. Such vendors have proven to be very valuable in facilitating medtech innovation in the West. Finally, the biggest challenge in creating a robust medtech industry in India is the lack of systematic market development. The country lacks a well-trained and organized device distribution infrastructure that is capable of educating patients and physicians alike, is able to navigate the complex medical devices through clinical adoption, and has deep penetration into all of India.

Yet the optimism in India's medtech industry is palpable. Leading industry groups such as CII and FICCI have both formed special interest groups to lobby on behalf of the medtech industry. Future of the device industry in India looks promising.■