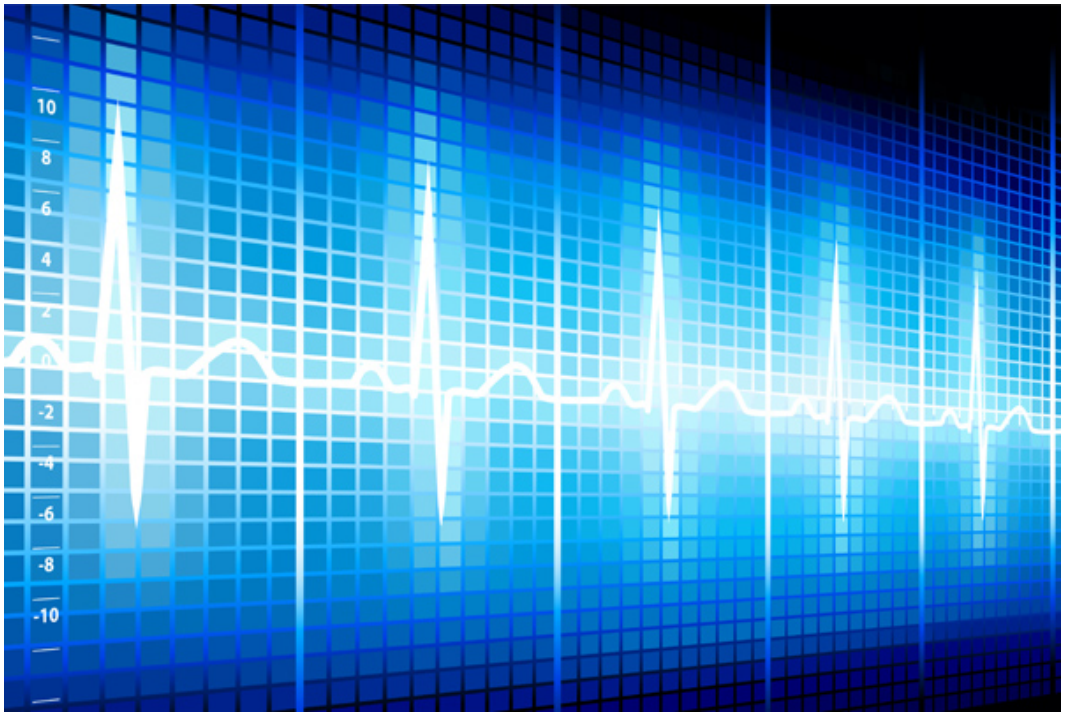
CHAPTER 2

Costa Rica in the Medical Devices Global Value Chain

OPPORTUNITIES FOR UPGRADING



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Acronyms

BS	Boston Scientific
CAGR	Compound Annual Growth Rate
CONARE	Consejo Nacional de Rectores
EU	European Union
E-O	Ethylene Oxide
FTZ	Free Trade Zone
GE	General Electric
GVC	Global Value Chain
HS	Harmonized System
INA	Instituto Nacional de Aprendizaje
IT	Information Technology
IV	Intravenous
J&J	Johnson and Johnson
M&A	Merger & Acquisition
MNC	Multinational Corporation
MRI	Magnetic Resonance Imaging
MRO	Maintenance, Repairs and Operations
NAFTA	North American Free Trade Agreement
NB	Notifying Body
NQAI	National Qualifications Authority of Ireland
OEM	Original Equipment Manufacturer
R&D	Research and Development
SINAES	Sistema Nacional de Acreditación de la Educación Superior
STEM	Science, Technology, Engineering and Mathematics
US	United States
WHO	World Health Organization

1. Introduction

Over the past two decades, Costa Rica has emerged as an important regional actor in the global medical devices industry. Since Baxter and Abbott (now Hospira) established operations in the country in the 1980s and 1990s respectively, Costa Rica's medical devices production has grown significantly. With a compound annual growth rate (CAGR) of 24% since 1998, exports reached US$1,284 million in 2011, making it the second largest medical devices exporter in Latin America. During this time, the products manufactured and exported from Costa Rica have become increasingly complex and today, multinational corporations (MNCs) export several sophisticated product lines, including bovine heart valves and intravenous pumps, and cover a number of market segments, including drug delivery systems, cardiovascular and orthopedic devices. Several firms, including Baxter, Boston Scientific and Hospira, are also performing a growing number of engineering processes locally.

Growth has been driven primarily by export-oriented strategies of large MNCs, several of which are top 10 global firms, which established operations in the country to take advantage of competitive labor, favorable trade and investment regimes and proximity to the United States (US). These firms employed approximately 12,500 people by 2011. Many foreign firms have expanded and upgraded both their manufacturing processes and the products they export from the country. Local firms, on the other hand, have been less successful in entering the industry, and primarily participate in low-value packaging functions. In order to continue to support growth, foster further upgrading and increase the value captured from participating in this industry, Costa Rica must focus on increasing the coordination and collaboration of the industry and financing to strengthen linkages between MNCs and suppliers. In addition, it must make important human capital advances in improving the quality of its engineering graduates, increasing the number of PhDs and encouraging business graduates to provide the workforce required for upgrading into higher-value segments of the value chain.

The report uses the global value chain (GVC) framework to analyze Costa Rica's position and potential for upgrading in the medical devices GVC. GVC analysis examines the full range of activities that firms and workers around the globe perform to bring a product from conception to production and end use. It examines the labor inputs, technologies, standards, regulation, products, processes and markets in specific segments and international locations, thus providing a holistic view of the industry both from the top down and the bottom up (Gereffi & Fernandez-Stark, 2011). Understanding how value is generated and controlled in the industry and analyzing the potential to shape domestic resources for use in the industry provide developing country policy makers useful information to identify trajectories for entry, growth and upgrading along that chain.

The report is structured in the following way. First, there is an overview of the medical devices value chain and a discussion of the key segments. This section presents the governance structure, upgrading and workforce development aspects of GVC analysis. Understanding the manner in which the industry operates at a global level is essential to be

able to determine how Costa Rica may be able to grow in the future. The next section examines the upgrading experience of Baja California and Ireland in the GVC for lessons to inform the Costa Rican policy development and identify potential upgrading trajectories for the country. Section four provides an analysis of Costa Rica's current contributions to the global medical devices sectors and the country's position in the GVC, highlighting significant trends in the evolution of the industry in the country. Finally, challenges that could potentially undermine attempts to upgrade and grow further are also discussed.

2. The Medical Devices Global Value Chain

2.1. The Global Medical Devices Industry

Covering a broad spectrum of products from inexpensive bandages, to technology-intensive hearing aids and tissue heart valves, to high-cost items such as magnetic resonance imaging (MRI) machines, the medical devices sector has been identified as a strong, global growth industry.[1] Estimates of the size of the market in 2010 range from US$164 billion (Markets and Markets, 2011) to Johnson and Johnson (J&J)'s estimate of US$350 billion (Seligman, 2012).[2] Total global exports in 2011 reached US$161 billion (see Table 2, UNComtrade, 2012).[3] An aging population with means to pay and advances in science and technology continue to push the boundaries of how devices can improve the quality of life for millions of people around the world. Future sales are expected to be strong. Developed country markets are mature, with low but steady growth rates, and they account for over 90% of global demand. Developing countries, on the other hand, represent an important new growth opportunity as the result of increasing expenditure on healthcare in emerging economies and double-digit growth rates that are expected to continue as overall income levels rise (Araujo et al., 2011).

The production of these devices is concentrated in a relatively small number of companies. Lead firms with a global presence account for more than half of the world's market share. Although the supply side of the market is consolidated, there is also an important degree of price pressure. Faced with rising health care costs, governments and health care organizations have begun to experiment with different procurement and reimbursement[4] models to gain

[1] According to the World Health Organization (WHO), there are approximately 1.5 million different device types that can be categorized in 10,000 generic device groups. These include "all instruments, appliances and materials that are designed for diagnostic and/or therapeutic purposes to monitor, treat, prevent or alleviate disease, injuries or handicap and that do not strictly achieve their action by pharmacological, immunological or metabolic means" (WHO, 2010b, p. 8).

[2] Estimates differ based on the products included in the classification of the sector.

[3] The products included in this measure are detailed in Appendix 6.1.

[4] Reimbursement procedures, whereby both public and private health insurance organizations agree to finance particular procedures, interventions or the use of particular devices and equipment, can act as a barrier to entry for new products. Due to their high prices, many medical devices are beyond the reach of

leverage with suppliers (Graves, 2011). As a result, over the past two decades, the medical devices sector has begun to focus on global production networks in order to improve economic efficiencies, target key growth opportunities in emerging markets and harness qualified human capital around the world. This offshoring of production provides important opportunities for developing countries with available skilled labor to leverage cost arbitrage and a favorable location to participate in this potentially lucrative sector.

The following sections present the global value chain, discuss the global geographic distribution of demand and supply, examine the leading firms in the sector and the manner in which the chain is governed through public and private standards as well as provide an overview of differing human capital needs in different parts of the chain. By analyzing the global dynamics of the industry, these discussions can provide a "blue print" for Costa Rican policy makers as the country develops its strategic plan for future growth.

2.2. Mapping the Medical Devices Global Value Chain

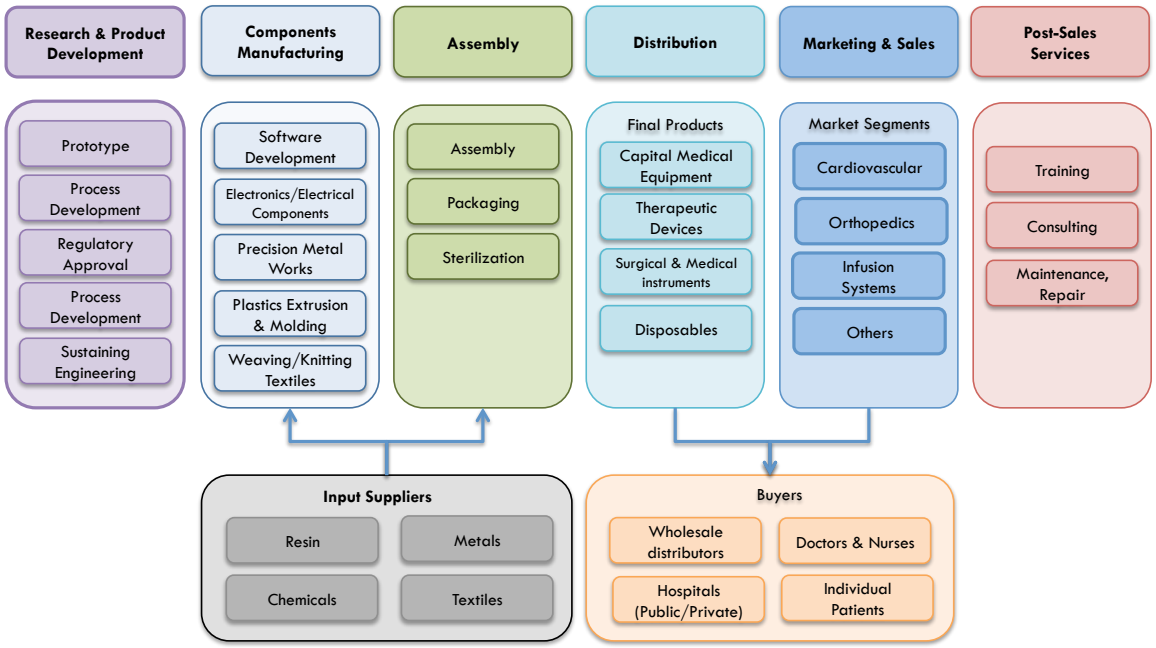
First, an overview of the medical devices global value chain is provided. Each stage of the chain is discussed, in addition to detailing the key product and market segments included in this industry. Breaking down the value chain to this level of detail allows us to more accurately determine where in the value chain Costa Rica participates, and identify specific opportunities for the country to upgrade.

In the GVC literature regarding medical devices, while several articles discuss the potential for "moving along the value chain," (Ciravegna & Giuliani, 2008; Fennelly & Cormican, 2006) there have been limited attempts to date to provide a detailed chain mapping (Producen, 2007; Puri et al., 2011; Rana & Gregory, 2012).[5] This probably stems from the large number of different products that can be categorized as medical devices, and a very wide value range of end products whose prices vary from a few cents to hundreds of thousands of dollars. As Costa Rica participates in a broad range of product segments, the value chain map provided is comprehensive, covering the sector as a whole (see Figure 1), rather than limiting this to a particular product line.

individual patients if they are not covered by their health insurance. Insurers can require additional proof of the effectiveness of a device beyond that required by the regulating agency before they agree to finance it.

[5] Burns, R.L. (2002). The Health Care Value Chain: Producers, Purchasers and Providers. New York: Wiley includes medical devices under the broader health care value chain.

Figure 1. Medical Devices Global Value Chain



Source: Authors.

The **highest value segment** of the chain is **research and product development (R&D)**. During this stage, new products are conceptualized, prototypes are produced and tested and potential manufacturing capabilities are assessed. Following initial concept tests, the product is then registered for regulatory approval in the desired market(s). This step alone can take up to six years, depending on the risk category of the device and clinical trials required, and the total time for a new device to come to market can be as long as eight years. Process development—that is, establishing the manufacturing parameters—takes place in conjunction with input from the engineers at the manufacturing plants to determine the most efficient means of production. Inputs and production processes must be validated by the firm's quality assurance department to obtain regulatory approval. At this stage, both a firm's internal production capacity and the availability of potential vendors can influence production decisions. The initial product price is determined and potential for reimbursement is assessed. Once the device enters production, a team of engineers continues to improve upon the production process (*sustaining engineering*). These engineers work in close contact with the product development teams. Increasingly, lead firms are acquiring new products through mergers and acquisitions (M&As) rather than undertaking the product development process internally (Simoens, 2009). This provides an opportunity for smaller firms to enter the market.

The **production segments, components manufacturing and assembly, are typically the lowest value-added segments** of the chain and are comprised of several different functions depending on the final product.

- **Components manufacturing**. Knitting, weaving and cutting are used for products such as compression socks and mastectomy bras; extrusion and molding are essential processes for producing plastics components for products such as intravenous drug delivery catheters; precision metal works are required for stents and pumps; while electronics components and software development are needed for a range of products from small therapeutic devices such as pacemakers and neuromodulators to large equipment such as X-ray and ultrasound equipment. These components may also require coating, electroplating or polishing prior to assembly to protect them from chemical, electrical and environmental corrosion. The value added for each of these components depends on the inputs used (such as resins, precious metals, etc.) and the complexity of the production process.
- **Assembly.** This may be done either manually or by automation, depending again on the final product. Products such as infusion pumps have as many as 500 different components and require up to 200 different assembly processes, parts of which can be automated, others which must be done by hand; other products such as bovine tissue heart valves must be assembled very carefully by hand. Once final assembly is complete, the product must be labeled, packaged and sterilized before distribution. Labeling and inserts are important parts of the production process, since incorrect information regarding use attached to a medical device can have fatal consequences.
- **Sterilization.** Once packaged, most products are then sterilized using one of three types of sterilization: E-beam (electrons are accelerated through the product); ethylene-oxide (E-O) (product is sterilized by gas); and gamma ray sterilization. While gamma ray sterilization is required for dense products, such as those containing liquids, most other products can either undergo e-beam or E-O sterilization. However, due to high costs of validation, usually one method is selected for regulatory approval per product.

Distribution, Marketing and Sales: Medical devices producers may distribute through wholesale distributors, such as Cardinal Health, or directly to their end clients via internal distribution centers. End clients may be hospital or clinic administrators, those responsible for direct patient care such as doctors, nurses and specialists, and through retail directly to the patient themselves, such as with gauze, adhesive bandages and plastic syringes. Distribution channels depend on the type and value of particular products. Lower-value products tend to be distributed through wholesale distributors, while high-value products are likely to be sold directly to hospital administrators.

In the face of rising health care costs, buyers are beginning to take initiatives to improve their negotiating positions. Measures include establishing purchasing groups, moving individual doctors' practices under the umbrella of hospital administrations to benefit from economies of scale, introducing tendering processes and reducing their overall number of suppliers (Seligman, 2012). Increased competition to become selected suppliers means that medical devices manufacturers spend significantly on direct marketing and building relationships with

clients. For example, it is estimated that in Europe, 56% of the cost base for a product is spent on marketing and sales (Frost & Sullivan, 2010).

Finished products can be classified into four categories:[6]

(1) *Disposables or high-volume commodities* include products such as bandages, surgical gloves, plastic syringes, catheters and needles. These are "low tech," generally single-use products that are cost driven. Manufacture of these products requires less medical expertise than other product categories, but producers must comply with specific quality standards for medical devices.

(2) *Surgical and medical instruments* include products such as forceps, medical scissors and dental drills, as well as specialized surgical instruments used in cosmetic and endoscopic surgery. These are generally multi-use products that are sterilized between uses with different patients. Some instruments may be electrically powered. The production of many surgical and medical instruments is increasingly cost-driven.

(3) *Therapeutic devices* include both implantable and non-implantable devices to help people manage physical illness or disability. For example, hearing aids, pacemakers and prosthetics are considered therapeutic devices. These products are directed towards specialists. Due to their prolonged use inside the body, the production of implantable devices requires considerable expertise, particularly with respect to bio-compatibility, and obtaining regulatory approval for implantable devices is a costly process. This increases the value of each device considerably.

(4) *Capital equipment* includes single-purchase equipment that can be used repeatedly over a number of years. These products require ongoing account management for accessories, services and parts. This product category covers equipment used in patient monitoring, diagnostics and imaging, and ranges from infusion pumps and blood pressure monitors to considerably large investments such as MRI equipment or computed tomography. Equipment requiring these large, long-term investments generally requires multiple decision-makers.[7]

In addition, there are two new emerging sets of products: *integrated solutions*, which combine medical devices, training, consulting and other post purchase services; and *convergence products*, which are devices that combine important contributions from the

[6] Detailed definitions of each of these product categories by trade codes are available in Appendix 6.1. For the purposes of this study, "medical devices" are limited to those products that are designated strictly for use in dental, medical, surgical or veterinary practices. For example, surgical gowns are considered general apparel products. Medical and surgical furniture, such as hospital beds, were not included in this study. These products do not require specific medical expertise.

[7] Medical device manufacturing firms may categorize their production divisions by intervention type, such as patient monitoring and imaging and diagnostics. Siemens Medical, GE Healthcare and Philips Healthcare are the leading producers within this category.

medical devices, information technology (IT) and/or pharmaceutical sectors, such as drug-eluting stents. Medical IT systems, for example, include information systems used in the administration of laboratories and hospitals, as well as software interfaces used with different therapeutic devices, monitoring and diagnostic equipment (McCaffery et al., 2004; McHugh et al., 2012). Due to the lack of specific data on these cutting edge products, they are not analyzed in this paper.

End market segments are generally divided according to the body system they are used to treat. These segments include cardiovascular health, orthopedics, respiratory issues, anesthesia, neurology and spinal health, renal health, urology and reproductive health, hematology, dentistry, ophthalmology, biomaterials and tissue generation, as well as specific treatment types, such as oncology, diabetes management and advanced wound treatment. Cardiovascular and orthopedics are the two largest market segments (Markets and Markets, 2011).

Due to the level of expertise and innovation required in the production of each device, manufacturers tend to specialize in one or more **specific end market (**Simoens, 2009). For example, St. Jude Medical and Medtronic are leaders in cardiovascular devices, while Hospira, Baxter and Carefusion are leading suppliers of intravenous drug delivery systems. Each of these end markets may require all, or a subset of, the product categories described above. For example, in the treatment of cardiovascular conditions, gloves and catheters may be used for a transfusion (disposable), a pacemaker for cardiac rhythm management (therapeutic), surgical instruments such as clamps and forceps during heart surgery (surgical instruments) and a patient monitor during recovery (capital equipment), as well as IT systems to remotely monitor a patient's progress and adjust their pacemaker.

Finally, **post sales services** include training on equipment and consulting as well as account management for the supply of accessories, maintenance and repairs (Ghemawat, 2007). This is considered to be a key emerging differentiator in this competitive sector.

2.3. Geographic Distribution

Global Demand

Demand, to date, has been led by developed countries. The United States, Europe and Japan in particular are the most important markets, together accounting for over 85% of global demand for medical devices (WHO, 2010b). These are large, mature markets with low annual growth rates of around 2–2.5% (Business Insights, 2010). While developing countries currently account for just a fraction of the market, they represent an important growth opportunity for the sector. In particular, demand is beginning to grow in large emerging economies, including Brazil, China and India, where growth rates are higher than 10% as a result of a expanding and aging middle class populations, more health insurance and increased national healthcare expenditures (Business Insights, 2010). In Asia, after Japan, China is the largest market for medical devices, followed by India (Business Insights, 2010).

Russia is also expected to contribute to global demand due to the need to update obsolete medical equipment. In Latin America, Brazil is the largest market for medical devices, followed by Mexico, and the region as a whole is considered to have important growth potential (Araujo et al., 2011). Chile, for example, while a smaller overall market, has strong demand for more sophisticated high technology solutions. Table 1 indicates the estimated demand for medical devices in Latin America in 2012.

Table 1. Estimated Demand from Key Latin American Markets

	Estimated Market Size (US$ Million)
Brazil	$4,034.0
Mexico	$3,500.0
Colombia	$863.9
Venezuela	$595.3
Chile	$495.4
Peru	$317.9

Source: Espicom Business Intelligence Ltd, 2012.

Among these emerging markets, demand is most notable in four main categories: imaging, patient monitoring, cardiovascular and orthopedic technologies (Business Insights, 2010). The type of product required for these emerging markets is also important. For example, it is estimated that in 2000, due to shortage of trained and qualified medical staff and challenges as simple as translating instructions, as many as 52% of medical devices in Mexico's public healthcare system went under- or unutilized (Brady et al., 2001).

Global Supply

While developing countries are beginning to play an increasingly important role in production for the sector, supply continues to be dominated by developed countries. The majority of the top 15 leading firms are headquartered in the US, within which there are important regional clusters in California, Massachusetts and Minneapolis-St. Paul (Kimelberg & Nicoll, 2012). Each of these three clusters covers all aspects of the value chain, performing cutting edge R&D as well as manufacturing, marketing and sales functions. Some estimates place the US production market share as high as 51% (Producen, 2007).[8] Germany, France, Italy and the United Kingdom are home to important R&D and manufacturing hubs in Europe.[9] R&D and new product development primarily takes place in global headquarters (see Box 1).[10]

[8] Measuring market share using international trade data is complicated due significant intra-firm transfers whereby a product may be exported by a subsidiary into the US as an unfinished product, sterilized and then re-exported as a finished product. Furthermore, a significant portion of medical devices is consumed within the United States without being exported.

[9] Two firms are headquartered in Germany, one in the Netherlands, and one firm shares its corporate headquarters between the US and Ireland.

[10] By 2005, GE Healthcare had located 60% of its manufacturing capacity in low cost countries (Ghemawat, 2007).

Box 1. Research & Development: Challenges for Offshoring

A functional upgrading trajectory into R&D is often the primary goal of industrial development policy for developing countries. However, this goal is often misaligned with both Original Equipment Manufacturer (OEM) firm strategies and the capabilities of the country. Understanding how R&D decisions are made and the factors that drive this is essential for adequate policy formulation. This box discusses these challenges for offshoring of R&D in the medical devices sector.

The industry is characterized by a very high rate of innovation, resulting in short production cycles and a need for continuous improvements to existing products making use of cutting edge scientific and technological advances (Simoens, 2009). The average life cycle of a product in this sector is about 18 months (Chatterji et al., 2008). It is estimated that 80% of profits in the industry originates from the products developed within the past 5 years and that 50–70% of device portfolios consist of products launched in the past 3 years (Frost & Sullivan, 2006 as cited by (Simoens, 2009)). The life cycle of a product can be divided into two phases: radical innovation and incremental innovation.

Radical innovation for a device involves three steps: discovery, development, and dissemination (Chatterji et al., 2008). Small- and medium-sized firms have been found to be twice as likely to launch radical innovations to the market as new firms. These new innovations require close relationships with academic institutions and end users (Brown et al., 2008; MacPherson, 2002). These innovations also depend on the availability of venture capital with expertise in the sector to provide the significant financing involved in bringing a new medical device from conception through compliance to production (Forfás, 2009; McCaffery et al., 2004). This process can take numerous years with compliance costs alone up to US$100 million. It is not uncommon for a large firm to acquire these smaller innovative firms once they have obtained regulatory compliance in order to control these disruptive new technologies.

Due to the potential value of these innovations, the intellectual property is closely guarded by firms and new product development is generally carried out in a firm's headquarters. Thus the origin of a firm could be seen as a strong determinant of the location of radical innovations. Indeed, in Ireland, despite the large number of multinational medical devices manufacturers in the country and the maturity of the sector, most of the firms engaging in new product development are actually small, Irish start-ups (Forfás, 2009).

Incremental innovation, on the other hand, involves constant improvement to the product and the development process as patents expire and new substitutes enter the market. These incremental improvements and changes to a product can be used to expand the devices market to include both new market segments and key end markets. Of particular importance to developing countries with growing manufacturing capabilities is the need to adapt medical devices for emerging markets. The World Health Organization (WHO, 2010b) notes that the majority of medical devices designed for high-income countries are not appropriate for low-to-middle income country needs as they are too complicated to use, particularly in settings where there is shortage of trained staff. Proximity to end market users and interactions with medical staff using these products thus provides developing country manufacturing facilities with a core competitive advantage. Emerging economies are already starting to host a rising number of R&D centers (Barbella, 2012).

Sources: Barbella, 2012, Brown et al., 2009; Chatterji,et al., 2008; Forfas, 2009, McCaffery, et al., 2004, McPherson, 2002, WHO, 2010b.

Establishing captive production plants abroad and building regional production capacity through foreign acquisitions have been common practices in the industry for a long time. Foreign investments, however, were often driven by specific "market-seeking" initiatives to capture local demand. Over the past decade, this approach has been combined with a tendency to relocate certain manufacturing operations to cheaper destinations in order to cut costs and improve competitiveness. In the last five years, 56% of new or expanded

manufacturing facilities for the major medical devices companies were outside of the United States (AdvaMed, 2011 cited in (Puri et al., (2011)). The resulting global production networks of firms now combine lower-cost, foreign talent to support demand from local emerging markets and, at the same time, provide more cost-effective products for developed countries (Ehrenberg, 2012). In addition, two dynamics are also likely to drive the shift of global production further towards developing countries: the first is rising tariffs and complex regulations and reimbursement in key emerging markets, such as Brazil and China; and the second is reform of the US health care system, which places an additional 2% excise tax on all medical devices manufactured and sold in the US (Axendia, 2012; BMI, 2012; Seligman, 2012).

Globally, firms may operate sister plants, whereby two or more global operations produce very similar product groups allowing for redundancy and facilitating risk management, or they may operate under a model whereby one global manufacturing plant is charged with production and inventory development and a small portion of manufacturing capability is maintained in the home country. Location selection for these global production facilities varies based on a variety of factors, including presence of qualified human capital, cost, established presence of supply chain actors and distance to market, among others, depending on the product category (Ehrenberg, 2012; Fennelly & Cormican, 2006; Field Research, 2012; Kimelberg & Nicoll, 2012). For example, low-value, high-commodity products such as surgical gloves and bandages are produced in low-cost countries such as Thailand and Malaysia (Business Insights, 2010), while many medical devices production facilities that use electronics components are often based in Asia, close to the electronics supply chains.

Table 2 highlights the leading exporters in each of the four key product categories. As can be seen, Europe and the United States are the leading exporters in all categories, and Japan is also a top five exporter in three of the four categories. Mexico has become an important exporter of disposable products and surgical instruments (see Section 4). Japan, China and Korea are leaders in the capital equipment product segment, which draws heavily on the electronics value chain.

Table 2. Top Five Global Exporters of Selected Products, 2011 (US$ Millions)

Exporter	Disposables		Capital Equipment		Therapeutics		Instruments		Total [(a)]	
	Value	Share %	Value	Share %	Value	Share %	Value	Share %	Value	Share %
World	26,652		41,593		44,729		48,333		161,307	
EU-15	12,405	46.5	20,246	48.7	24,883	55.6	21,690	44.9	79,223	49.1
USA	6,140	23.0	9,669	23.2	8,546	19.1	11,848	24.5	36,202	22.4
Switzerland	--	--	--	--	6,226	13.9	2,288	4.7	9,534	5.9
Japan	866	3.2	3,615	8.7	--	--	1,702	3.5	6,279	3.9
China	1,307	4.9	2,449	5.9	756	1.7	--	--	5,877	3.6
Mexico	2,319	8.7	--	--	--	--	2,072	4.3	5,421	3.4
Singapore	--	--	--	--	775	1.7	--	--	3,410	2.1
Israel	--	--	919	2.2	--	--	--	--	1,594	1.0
Top Five	23,036	86.4	36,897	88.7	41,186	92.1	39,600	81.9	140,720	87.2
Rep. Korea	155	0.6	840	2.0	204	0.5	415	0.9	1,613	1.0
Costa Rica	543	2.0	32	0.1	289	0.6	262	0.5	1,127	0.7
HS96 Codes	90183		90181, 90182, 9022		9021		90184, 90185, 90189			

Source: UNComtrade, 2012

(--): indicates country is not in the top five exporters for the product category in 2011

Note (a): Total includes the country's exports for all four product categories. With the addition of South Korea and Costa Rica, the table represents the top ten overall exporters in 2011.

In the Americas, Baja California (Mexico), Costa Rica, Puerto Rico and the Dominican Republic—all strategically located close to the United States—host important export-oriented medical devices clusters. There are approximately 67 firms operating in Baja California, 67 in Costa Rica and more than 30 firms in Puerto Rico (Medical Product Outsourcing, 2011; Producen, 2007). Several of the top 10 global firms, including J&J, Cardinal Health, Baxter, B.Braun and Hospira, have also established production facilities in the Dominican Republic. Exports from these countries include both low-value and higher-value product categories and are primarily destined for the United States. Brazil also plays a significant role in the fabrication of medical devices; however, the large number of multinational firms in the country, including Baxter and GE Healthcare, tends to be more focused on producing for the domestic market than driving export growth.

2.4. Lead Firms and Governance

The industry is highly consolidated with a very small number of multinational firms dominating the sector. The four leading firms, J&J Medical Devices, GE Healthcare, Siemens Medical and Medtronic, control approximately 40% of the global market (Datamonitor, 2011). An additional 40% of the market is divided amongst approximately 10 firms, including St. Jude Medical, Cardinal Health and B.Braun. The remaining 20% is highly fragmented and includes a large number of small- and medium-sized firms (Datamonitor,

2011; Seligman, 2012). As a result of mergers and acquisitions, the top 10 firms today cover a broad range of market segments, from cardiovascular and orthopedics to diabetes management, and product categories, such as endoscopic surgical instruments and diagnostics and imaging equipment. However, there are also firms like Kaiser Permanente and Fresenius Medical Care A.G. that focus on one specific market, offering specialized hospital facilities and services in addition to manufactured devices. Table 3 highlights the top 10 global firms in the sector by revenue.

Table 3. Top 10 Global Firms in the Medical Devices Industry, by Revenue 2011

	Global	HQ Location	Core End Markets	Revenue (FY 2011) US$ Billion	Employees (2011)
1	J&J Medical Devices & Diagnostics	USA	Diagnostics and imaging	25.8	Est. 51,000
2	GE Healthcare	USA	Diagnostics and imaging	18.1	46,000
3	Siemens Medical	Germany	Diagnostics and imaging	16.1	51,000
4	Medtronic	USA	Cardiovascular & Neurological	15.9	43,000
5	Baxter*	USA	Anesthesia & Hematological	13.9	48,500
6	Covidien*	Ireland	Cardiovascular	11.6	41,300
7	Phillips Healthcare	Netherlands	Diagnostics and imaging	11.5	37,000
8	Stryker	USA	Neurological & Orthopedics	8.3	21,242
9	Boston Scientific*	USA	Cardiovascular, Women's Health Gastroenterology	7.6	24,000
10	Becton Dickinson	USA	Diagnostics, Anesthesia	7.6	29,369

Source: Company Websites, One Source, Hoovers.

Note: In 2005, GE Healthcare, Siemens Medical and Phillips Healthcare accounted for 75% of the diagnostics-imaging market (Ghemawat, 2007). *Indicates the firm has operations in Costa Rica.

Many firms still prefer to maintain their operations in-house to protect their intellectual property (Forfás, 2009). As a result, firms are highly vertically integrated, and often perform all activities in the value chain from R&D, through components manufacturing processes such as extrusion and molding to assembly, labeling, packaging and distribution of their products. Some firms even produce the raw materials, such as resin, for their plastic products. Offshored production facilities may carry out any subset of these processes. Nonetheless, the sector is slowly adopting outsourcing strategies to focus on core competencies, and a growing number of contract manufacturers are entering the sector to provide plastic and metal components. Extrusion, specialized injection molding, and precision metalwork and machining, as well as some automation and assembly, are beginning to be outsourced to external vendors.

Quality assurance is the most important concern in this outsourcing. New regulatory changes place the burden of quality and supplier compliance for any part of the manufacturing process on the OEM firm (McHugh et al., 2012). Selection of suppliers thus occurs early in the

product development process. Rigid and sophisticated qualifications apply to ensure quality and suppliers must comply with complex documentation requirements to ensure that the final product meets regulatory demands (Weber et al., 2010).[11] Usually several iterations of sample testing and improvements are made with suppliers before they are qualified (Weber et al., 2010). Switching costs for components thus can be very high and the process can be complicated and time consuming (Fennelly & Cormican, 2006).

In addition to quality concerns and liability, the large scale of the lead firms means that vendor decisions are primarily made within the corporate headquarters. Raw material contracts are negotiated for global supply due to leverage for large orders, quality assurance and guarantees for on-time delivery. Although global production facilities may be required or allowed to provide supplier recommendations regarding major inputs, they typically only have autonomy over non-essential inputs, such as maintenance and repairs supplies (MROs). Furthermore, all decisions regarding the global distribution of the firm supply chain, such as the location of the production of different product lines and activities, are made at the corporate level. Global production facilities must compete based on cost, quality and proven capabilities to drive growth and upgrading (Fennelly & Cormican, 2006).

2.5. Standards

The medical devices sectors is governed by a combination of public and private standards that are closely related and are designed principally to ensure a safe, quality product for the health of the patient using the device. Failure of a medical device can have severe and fatal consequences. Regulatory controls may include technical documentation, clinical trials and testing of the biocompatibility of materials, among others. In addition to regulatory controls, criteria laid out by public and private healthcare insurers in major markets regarding which devices are eligible for reimbursement can also affect which products survive from the prototype stage to market. These insurers can often require more rigorous clinical evidence of effectiveness than required by regulatory controls (Lin et al., 2010). Due to their significant market shares, these standards set by the United States, the EU and to a lesser extent, Japan, control the development and commercialization of new products in this sector. Table 4 includes the key regulatory bodies in the global industry.

Generally, medical devices are categorized by perceived risk to the patient and whether the new device is subject to general controls (basic), special controls (more specific), or requires clinical trials. An important difference between regulation in the United States versus in the EU is that in the US, the product must be deemed safe and effective, while in the EU, the product must demonstrate that it is safe and performs consistently with intended use (Kaplan et al., 2004). Approval for use of medical devices in the United States thus continues to be more complex and takes longer than in the EU (Puri et al., 2011). Due to the shorter approval

[11] These findings were based on the analysis of the Siemens Healthcare supplier management in both developed and developing countries.

times, the European market is often used as a launch pad for products that will later be sold to the US market. Data from patient use in Europe can also help contribute to FDA approval (Business Insights, 2010); however, reimbursement processes in the EU, which is struggling under the burden of an aging population and public debt, can be very demanding and can add a further barrier to entry. There are initiatives underway by the Global Health Task Force[12] to harmonize these standards, but compliance for multiple markets still requires significant time, financial and intellectual resources, and is considered one of the most significant challenges to business success in the sector (Axendia, 2012). As a result, these standards create considerable barriers to entry into the medical devices market, particularly for small- and medium-sized companies (McCaffery et al., 2004).

Table 4. Regulatory Bodies for Medical Devices in Major Markets

Market	Consumption Market Share (2009)	Regulatory Body
United States	40.7%	Food and Drug Administration (FDA) Center for Devices and Radiological Health.
European Union	35% (Largest markets: Germany, 8.1%; France, 3.8%, Italy 3.6%, UK, 3.4%)	Notifying Bodies (NBs) appointed by each member state. NBs are private organizations with the right to approve new medical devices for sale in their member states. Each medical device manufacturer may choose the NB to evaluate their device, leading to competition between NBs for evaluations, and they tend to respond more quickly that the FDA in the US.
Japan	10.1%	Pharmaceuticals and Medical Devices Agency (PDMA), which Operates under the Ministry of Health, Labor and Welfare (MHLW).

Source: (McHugh et al., 2012; WHO, 2010b).

Undoubtedly, the United States and EU are generally the more attractive and highest value markets for medical devices; yet, selling to these market segments has important challenges, and switching to less rigorously regulated markets can provide important alternative entry points for new product groups and/or new firms from developing countries. Indeed, many developing countries do not have the institutional framework to implement and enforce medical devices regulations, nor do they have strong healthcare insurance operators. The World Health Organization (WHO) estimates that one-third of all countries, and 40% of low-income countries, do not have an adequate system to ensure the safety of a device for the practitioner and the patient (WHO, 2010a). The European CE Mark, which is relatively easy to obtain compared to FDA approval, is often the minimum requirement set by non-US countries for imports of medical devices. The CE Mark thus facilitates product expansion into other emerging markets, many of which are leading growth in demand.

[12] The Global Healthcare Task Force is a voluntary organization of regulators seeking to harmonize regulatory and quality standards globally.

Private Standards

In addition to the public standards described above, there are two additional private standards that are central to the manufacturing and sourcing stages of the value chain in particular: quality management and cleanroom operations. Medical devices manufacturers, like most businesses, have based the core of their quality system on the ISO 9000:2000 family of standards (McCaffery et al., 2004). This ISO standard is complemented by the industry specific standard: ISO 13485:2003, Medical Devices, Quality Management systems. The ISO 13485 standard is aligned with the FDA regulations for good manufacturing practices in the medical devices sector (FDA, 2012b) and this standard applies to all medical devices manufacturing firms, regardless of size. The primary objective of ISO 13485:2003 is to "facilitate harmonized medical devices regulatory requirements for quality management systems" (ISO, 2012). The ISO 13485, although a voluntary standard, has been widely adopted in the sector. By 2010, close to 20,000 firms had been certified under this standard. In 2010, with 15% CAGR, it was the third highest growth area among ISO standards. Growth was led by the US, Germany and Italy (American Society for Quality, 2012).

In addition to the ISO 13485 standard, medical devices manufacturing also requires different degrees of cleanroom standards. A cleanroom is an environment, typically used in manufacturing or scientific research, which has a controlled level of pollutants such as dust, airborne microbes, aerosol particles and chemical vapors. Cleanrooms are classified by the number of particles per cubic meter at a specified particle size. Cleanroom facilities are essential in the manufacturing process of medical devices to avoid contamination of sensitive, often life-saving equipment.

2.6. Upgrading Trajectories

In this section, we discuss the different upgrading trajectories that can occur for firms or firm networks operating in the medical devices sector for a given territory. While Costa Rica has already successfully entered and upgraded in the value chain, unpacking each of these global upgrading trajectories is important to understanding the manner in which Costa Rica's participation in the chain has evolved, as this can shape future growth potential.

Table 5. Upgrading Trajectories in the Medical Devices Global Value Chain

Entry into the value chain (subsidiary)	New subsidiaries typically enter the value chain with one or two product lines and must ramp up to meet productivity requirements within the allotted time frame. The transfer of a new product to a production facility takes approximately 24 months. For the first 12 months, the facility must produce "as is;" no modifications can be made to the production process during this time. Operations must obtain the appropriate certifications prior to the first production run.
Process upgrading	Production can be shifted from manual to automated assembly, barcodes can be introduced to track inventory and the plant layout can be improved to facilitate improved productivity. In addition, plants may adopt certification processes such as Six Sigma and lean manufacturing to improve just-in-time delivery, reduce down time, etc.

Product upgrading	Product upgrading can take place within one product family, such as moving from simple catheters to complex IV tubing, or it may involve moving into production of a completely new and more complex product family, such as the shift from a Class I to a Class II or III device, with considerably more complexity and increased need for quality control due to the life sustaining nature of the product.
Functional upgrading from manufacturing to R&D	Initially a production facility may receive instructions from headquarters or another firm regarding the exact characteristics of the product to be fabricated and the manner in which it must be done. The facility functionally upgrades when it is able to perform these design and engineering functions internally. While product design R&D may take place in the headquarters, the process by which that product is fabricated is developed by a local engineering team.
Vertical Integration and Backward and Forward Linkages in Production	Developing forward and backward linkages in the value chain helps to reduce the time and cost of inventory in transit. By vertically integrating production sites, facilities can avoid lost time caused by unforeseen delays in the logistics pipeline, such as port strikes, weather delays, as well as allowing the firm to adjust production specifications quickly during early manufacturing stages. At a territorial level, vertically integrating (backward linkages) to add extrusion, molding or precision metalworks increases the domestic component of production, the value captured by the production site, and increases employment for a less educated segment of the workforce. Similarly, providing sterilization capabilities close to the production operations (forward linkages) allows firms to distribute their products directly to end clients. By avoiding shipment of finished products for sterilization, firms can save the equivalent of up to one month of inventory in transit with important cost saving implications. This is also an essential step towards functionally upgrading into the distribution stage of the chain.
Chain upgrading	There are two opportunities emerging for leveraging the knowledge developed in one sector to enter another value chain: (1) Drug-device convergence products; and (2) IT-device convergence products (Forfás, 2009). An increasing number of devices incorporate the knowledge of both the pharmaceutical and nanotechnology segments to improve the efficacy of treatment, such as drug-eluting stents. On the IT side, more devices are incorporating sophisticated electronics systems to operate machines, facilitating automation of treatment and rapid diagnostics, among others. These devices all require software systems.
Geographic end market upgrading	Entering into new higher-value end market segments. For example, as noted earlier, the FDA regulations make the US market a particularly complex one to enter; however, the country also accounts for over 40% of global market share, making it a particularly attractive target market. Countries can also seek to "downgrade" to serve regional developing markets. This downgrading move can simultaneously drive functional upgrading as distribution center capabilities are developed locally.

Source: Authors.

2.7. Human Capital & Workforce Development

Achieving these upgrading trajectories requires the availability of an appropriately qualified workforce for each stage (Gereffi et al., 2011). Globally, this workforce is comparatively small; although they account for over half of the global market share, the top 10 firms together employ just 500,000 people globally (see Table 3). However, due to the fatal consequences of human error and the potential for liability suits, the quality of the human capital involved in production of medical devices is essential to business success. Indeed, human capital has been identified in certain cases as the single most important factor driving site selection in the medical devices manufacturing sector (Field Research, 2012; Kimelberg

& Nicoll, 2012). In this section, we present a brief overview of workforce requirements for both lower and higher levels of the value chain. Understanding the human capital needs for these different segments of the value chain is important for assessing which of the upgrading trajectories described above are feasible for a relatively small labor force such as that of Costa Rica and the human capital development policies that must be put in place to support that upgrading.

The experience and skill level of the workforce differs depending on the stage of the value chain (Gereffi et al., 2011). Lower-value segments of the chain such as components manufacturing and assembly require a large number of unspecialized labor and technicians performing labor-intensive operations, while higher-value segments of the chain such as R&D require a more specialized workforce, including researchers and product designers with industry experience, venture capitalists and a large number of engineers. For example, in Baja California where the industry is primarily focused on assembly functions, just 19% of the labor force has tertiary degrees. In comparison, approximately 40% of the medical devices workforces in both Ireland and Massachusetts, areas with a focus on the manufacturing and R&D portions of the value chain, have tertiary education degrees (Fennelly & Cormican, 2006; Kimelberg & Nicoll, 2012).[13] Furthermore, in Massachusetts, which has a stronger focus on R&D, 12% of the workforce have graduate or professional degrees (Kimelberg & Nicoll, 2012). Table 6 highlights the key employees required for select segments of the value chain.

[13] In Massachusetts, 30.4% had a Bachelor's degree or higher and 9.2% had an Associate's Degree (2 year). In Ireland, this figure refers to "third level qualifications", that is, all university degrees as well as a higher level or advanced certificate. The latter refers to completion of 2-year programs at a recognized higher education institution, including Institutes of Technology. Graduates of this level are expected to have both specialized vocational skill sets as well as supervisory training (NQAI, 2012).

Table 6. Employee Profile for Select Segments of the Value Chain

Value Chain Stage	Professional Labor with Tertiary Education	Technicians and Operators
R&D	Clinicians (incremental & radical innovation) Engineers (incremental innovation) (mechanical, Electronic, biomedical, electrical, chemical, industrial, process) Product designers PhDs with industry experience and capacity in applied research Government & regulatory affairs officers Risk capital specialists (angel investors, venture capitalists)	Highly skilled technicians (prototypes)
Components	Engineers (chemical, electrical, electronic, industrial, mechanical, automation) Validation engineers Quality assurance Microbiologists	Mechanics Electricians Technicians Machine operators Manual assemblers
Assembly	Engineers (chemical, electrical, electronic, industrial, mechanical, automation) Validation engineers Quality assurance Microbiologists Compliance officers (lawyers, documentation clerks)	Mechanics Electricians Technicians Machine operators Manual assemblers
Marketing & Sales	Government & regulatory affairs officers Health economics specialists Reimbursement specialists Marketers Product specialists	

Source: Araujo et al., 2011, Forfás, 2009, Expert Group on Future Skills Needs, 2008.

3. Lessons Learned from the Baja California and Ireland Medical Devices Clusters

In order to help define the potential upgrading of Costa Rica's medical devices sector, the experiences of two other clusters, Baja California, Mexico and Ireland, are examined. These two cases were chosen for analysis due to their similar characteristics to Costa Rica. For one, these clusters are both located in areas with small labor forces; in 2009, Baja California's labor force reached 1,350,000 (OECD, 2011), while in Ireland, in 2012 this figure was 2,200,000 (The World Bank, 2012b). Both regions have also pursued export-oriented economic development models through FDI. Due to the multilevel, decentralized regulatory environment in Mexico, regional governments such as that of Baja California have the autonomy to develop and enforce their own industrial policies (OECD, 2011). This allows for a more realistic comparison based on size between Baja California and Costa Rica.

These two regions illustrate different strategies for growth. In Baja California, sector development has been driven to a large degree by its proximity to the United States, and the

southern California medical devices clusters in particular that relies on the North American Free Trade Agreement (NAFTA), the maquila regime and relatively cost-effective labor. Baja California has primarily achieved process and product upgrading supported by an expansion of the sector's workforce. Ireland provides an example of functional upgrading into higher-value segments of the value chain, while shedding some activities focused on cost arbitrage of labor, allowing these activities to move to less expensive destinations.

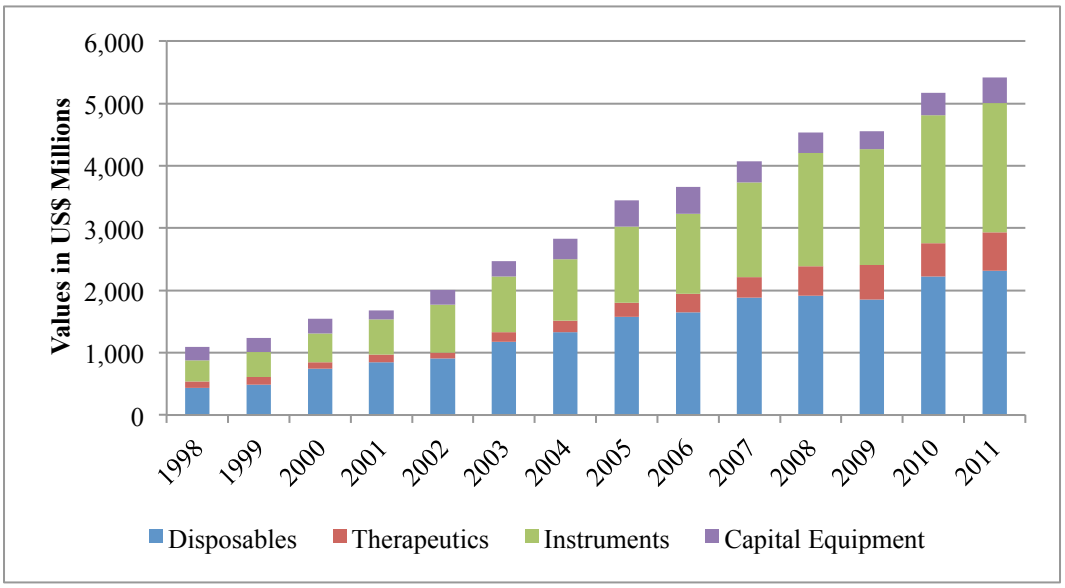
3.1. Baja California, Mexico

The medical devices sector in Baja California has developed over the past 25 years. During this time, primarily US medical device manufacturers have established operations in the region to take advantage of low-cost opportunities for labor intensive processes within very close proximity to the California medical devices clusters (Producen, 2007).[14] The maquila import-export regime (IMMEX) and Mexico's entry into NAFTA were also important drivers of the sector. Despite Mexico's large internal demand for medical devices, this is an export-oriented industry. In 2005, 95% of medical devices production in the region took place under the preferential tax regime for assembly operations, and in 2011, 92% of production was exported. By 2012, there were 67 plants operating in the medical devices sector, employing approximately 42,000 people.

FDI continues to be mostly of US origin (Producen, 2007). The plants in the region are principally focused on manufacturing and assembly, and little progress has been made in upgrading into R&D functions beyond some process engineering at the manufacturing level (Carillo, 2009). Products produced in the region are predominantly disposables and surgical instruments, and are mature products; that is, they have been on the market for considerable time and thus have lower intellectual property protection concerns (Producen, 2007). Exports from these plants account for over 50% of Mexico's total medical devices exports (PROMEXICO, 2011). Figure 2 highlights the evolution of these exports since 1998 by product category.

[14] In 2007, 28 of the plants operating in Baja California had corporate offices or operations in southern California (Producen, 2007).

Figure 2. Mexico's Medical Devices Exports, By Product Category: 1998–2011



Source: UN Comtrade, 2012.

From a policy perspective, the development of the medical devices sector in Baja California prior to 2005 was primarily supported by transversal policies focused on attracting foreign direct investment. Plants were concentrated in Tijuana under the IMMEX program and were supported by industrial parks and the non-profit Tijuana Economic Development Corporation; however, it was not until 2005 that specific policies were undertaken to support the industry. The 2005 Law of Competitiveness and Economic Development of Baja California empowered the state government to establish industrial policies to support economic growth. That same year, a multi-stakeholder initiative brought together industry, government and educational institutions to articulate a vision for the medical devices sector, one of 15 high-potential clusters identified by the government.

Producen, a branch of the Secretariat of Economy (SEDECO) acting as a facilitator between these different actors, helped to establish a strategy for fulfilling that vision. Shortly after this, an industry association was established formally, bringing together private sector stakeholders. Efforts were also made to improve the business environment, with the adoption of the federal system to reduce the time required to set up a new business (Sistema Apertura Rápida Empresarial). By 2007, with 34,500 employees, Tijuana had become the largest medical devices manufacturing cluster in the Americas by employment.

Initiatives at the regional level were driven by strong public-private collaboration with a clear focus on goals and responsibilities (Carillo, 2009). This collaboration was institutionalized through Producen, which officially took on the role of stakeholder coordination and strategy development. Emphasis was placed on expanding the growth of the sector through the development of human capital and the support for local suppliers. In 2007, the Consejo de

Desarrollo Económico de Tijuana funded a competency analysis of the medical devices, plastics and metal mechanics sectors to better understand the medical devices industry's human capital needs. The state, which spends more on education than any other in Mexico (Tijuana Economic Development Corporation, 2012), has six accredited university engineering departments, which annually graduate approximately 680 engineers with degrees relevant for the medical devices sector (Tijuana Economic Development Corporation, 2012). In addition, technical schools were established in the region where the workforce is trained according to the industry needs (Tijuana Economic Development Corporation, 2012).

The medical devices cluster also signed an agreement with the Universidad Autónoma de Baja California in order to streamline the flow of information between the private sector and educational institutions regarding both the industry's current and future needs, as well as to promote internships and work experience opportunities for students. A similar agreement was signed with Ceyts University in 2012 to support professional development within the cluster. The state government also focused on driving research in human capital formation.

With respect to the supporting local suppliers, domestic inputs accounted for an estimated 8.2% in 2005, and increased to 9.5% in 2007 with existing textile and electronics suppliers entering the sector (Producen, 2007); this was also supported by well established subsidiaries in the sector gaining autonomy in decision-making regarding suppliers (Carillo, 2009; Producen, 2007). In 2008, the industry association began an annual suppliers day; by 2012, 230 Mexican and 35 foreign companies participated in this event (PRWeb, 2012). In addition, through SEDECO, the state government initiated a number of policies to support the development of domestic SMEs. These included access to financing to support certification to supply MNCs,[15] financing for the creation of five new incubators to provide start-up firms with legal support and business plan development, as well as funds for marketing and staff training. These funds were available through competitive bids and were open to companies with up to 250 employees. Furthermore, Axis Consulting (a spin-off from Producen) conducted analysis of industry input requirements in 2012 in order to identify key market opportunities for local suppliers, finding that plastics accounted for 61% of firm requirements, metallic components or sub-contracting 17% and packaging supplies 6% (Axis, 2012). The cluster's newly formulated strategic plan for 2012–2020 aims to increase local content to 20% over the next eight years.

An improved business environment and access to a supply of managers and engineers with experience working in export-oriented MNCs, combined with an increase in available world class manufacturing space for rent in industrial parks since 2008, have helped to support the state's competitiveness in the sector. Growth appears to have been principally the result of increased capacity and an increase in the number of product lines at existing operations, rather than the result of upgrading into higher-value segments of the chain, despite federal programs to support R&D initiatives (Carillo, 2009). Analysis of the number of firms

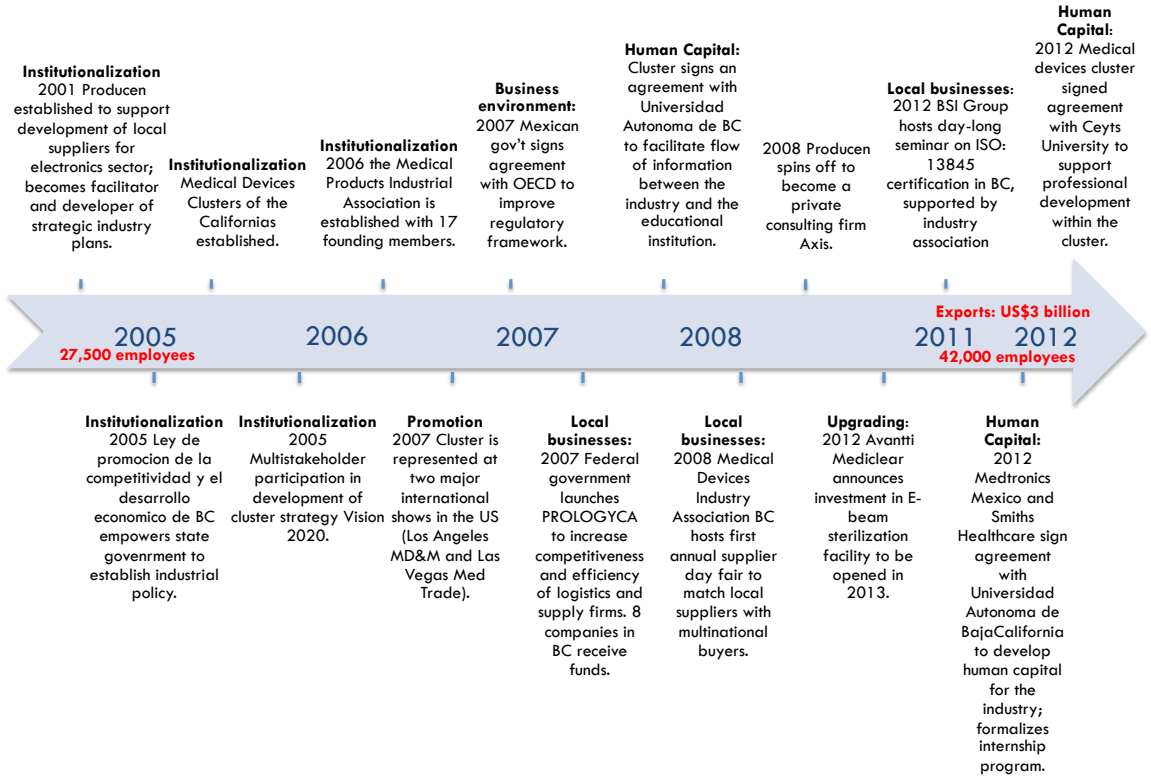
[15] BSI Group, a Mexican subsidiary of the English certification company, offers ISO 13845 training and certification to the over 140 firms exporting medical devices from Mexico.

operating in the medical devices sector indicates, however, that new FDI has been relatively slow since the cluster policies were established. Approximately 10 firms have established operations since 2005, but the majority of these, including Welch Allyn and United Plastics Group, were established by 2007 (Producen, 2007). Employment, nonetheless, has increased by about 14,000 during that same period. This suggests that growth has been driven by labor-intensive operations and by expansion programs.[16]

Indeed, approximately 80% of the operations in Baja California are large-sized, with over 500 employees (PROMEXICO, 2011). In 2012, for example, Medtronic, Covidien and DJO Global respectively employed 3,300, 3,500 and 2,000 employees each in their Baja California plants. Medtronic's expansion plan has included adding some 250 employees annually over the last decade (PROMEXICO, 2012). Expansion has been facilitated by significant internal migration into Baja California from other parts of Mexico. 6% of the population arrived in the region within the past five years, while 45% of the population was born in a different Mexican town (Rhoda & Burton, 2010). Nonetheless, the recent announcement of the establishment of Avantti Mediclear's new e-beam sterilization plant (Cervantes, 2012) is likely to support Mexico's upgrading into the distribution segment of the value chain. Figure 3 highlights milestone policies and events in the development of the sector.

[16] Expansion plans of existing firms in 2007, estimated the addition of 1,600 new jobs in the sector (Producen, 2007).

Figure 3. Evolution of the Baja California Medical Devices Sector, Milestones and Select Policies



Source: Authors.

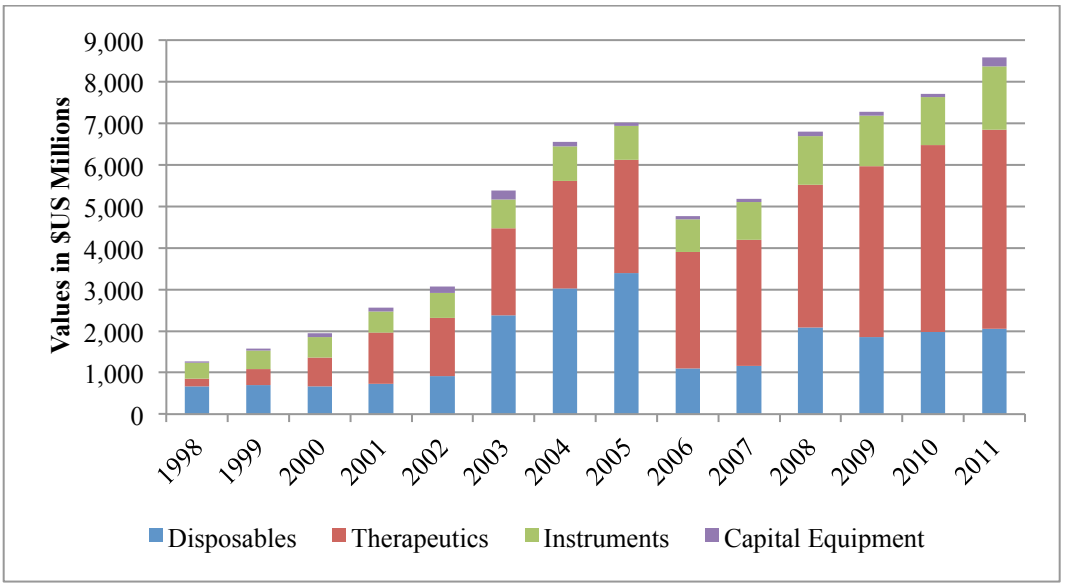
3.2. Ireland

Ireland entered the medical devices GVC as a manufacturing center in the early 1990s. The country's initial success was based on its ability to attract and maintain large FDI from the world's leading medical devices firms thanks to proximity and tariff-free access to the European market, regulatory ease,[17] and relative cost competitiveness. The majority of FDI for the sector was from the United States, using Ireland as a platform for the European market; in 1998, 65% of its production was exported to European countries (Fennelly & Cormican, 2006). By 2006, the country was home to 18 of the top 25 medical devices manufacturers (Advantage Business Media, 2011; Fennelly & Cormican, 2006) and by 2011, medical devices accounted for 8% of Irish exports (products) at US$8.6 billion (Irish Medical

[17] Once CE Mark has been awarded in Ireland, the device can be sold anywhere in Europe. The Irish Medicines Board is a Notified Body for Class 1 CE devices, while the National Standards Authority of Ireland can award the CE Mark generally. Certification agencies present in the sector offer certification for the US/EU and Japanese markets.

Devices Assoication, 2012).[18] The cluster had also developed strong areas of expertise in cardiovascular and cardio rhythm management devices, orthopedics, diagnostics and ophthalmology. In 2011, 33% of the world's contact lenses were manufactured in Ireland. Employment also grew steadily, reaching 25,000 by the end of the decade (Irish Medical Devices Assoication, 2012). Furthermore, the country made strong progress in developing backward linkages, and today, Ireland's components and contract manufacturing sector consists almost entirely of Irish-owned firms (Irish Medical Devices Assoication, 2012). Figure 4 shows the evolution of medical devices exports from the country. The growth of therapeutic devices exports is notable.

Figure 4. Ireland's Medical Devices Exports, By Product Category: 1998–2011



Source: UNComtrade, 2012.

The country offered other important benefits, including an English speaking labor force, a conducive business environment (ranked 15th in the 2013 World Bank's *Doing Business* rankings (The World Bank, 2012a)), strong intellectual property protection (International Property Rights Index, 2012) and a proactive and supportive foreign investment promotion agency, IDA. Importantly, by the early 2000s, there was also a consolidated supply chain for the sector in the country, helping to improve cost competitiveness. This was partly the result of strong government support for development of local suppliers and the formation of backward linkages with MNCs in the early stages of FDI manufacturing investment in the country, supported by the IDA and later Enterprise Ireland. Among other reasons, building

[18] Using the same methodology to determine the value of exports as used in the evaluation of Costa Rica, Ireland exported US$8.6 billion in 2011.

linkages was motivated by need to root FDI in the country by connecting them with strategic suppliers. The Entrepreneurship Development Program was initiated in 1978 and targeted managers, professionals and academics to establish high-potential start-ups. These firms, in sectors such as machining and toolmaking, electronics and medical devices, received support including loan guarantees from the government.

Nonetheless, in the early 1980s, policy makers conceded that by improving supply side alone, Irish suppliers were not successfully creating links with the MNCs. IDA thus established the National Linkages Program through which it actively sought to connect established and high-potential domestic suppliers with foreign firms operating in the country. The program researched the needs of the MNCs, identifying feasible areas in which domestic companies could participate, targeting potential 'winners' and providing these domestic suppliers with assistance in upgrading and quality standards; it also provided financial incentives to multinationals creating local linkages.[19] A key factor in the success was the strict selection criteria of local firms to participate in the program. By placing emphasis first on reliable quality suppliers, they were able to leverage the demonstration affect of these role models for other linkages (Condron, 2007). Linkages were more prominent amongst small- and medium-sized foreign firms than with large firms with global footprints where scale made it inefficient to use local suppliers (Gorg & Ruane, 2000; Görg et al., 2009). Smaller firms tended to have neither the internal capacity nor the global networks to source from global suppliers.

Despite this strong positioning, in 2006 rising business costs and overloaded infrastructure began to undermine the country's competitiveness. As a result, Irish subsidiaries came under increased pressure from other low-cost locations (Forfás, 2009). As shown in Figure 4, in 2006, there was clear decline in the export of lower-value disposable products from the country, with exports falling by approximately two-thirds. This was accompanied by a series of plant closures. Abbott Laboratories closed its Galway plant in 2007, laying off just under 500 employees (Kennedy, 2007). Allergan, closed its Irish plant in 2008 and expanded its operations in Costa Rica (Castillo Nieto, 2008). Boston Scientific also reduced and consolidated its Irish operations in 2009 after opening its plants in Costa Rica (RTE News, 2009). Covidien followed a similar strategy in 2011. The continued competitiveness of the country thus required a consolidation of product upgrading away from disposables and into the higher-value therapeutics product segment and upgrading into higher-value activities, such as R&D.

Upgrading into R&D segments of the value chain began in the mid- to late 2000s. This upgrading has been led by multinational companies relocating process R&D, moving them closer to their manufacturing operations, accompanied by an emerging indigenous R&D sector focused on clinical R&D. Ireland faced several challenges, however, in functionally upgrading into this and the sales and marketing segments of the value chain. First, there was

[19] Although Gorg et al., (2009) find that there was no direct effect of the financial subsidies on linkage uptake amongst European and US firms, there was a positive effect from other parts of the world.

insufficient interaction between medical devices manufacturers in Ireland and clinicians while the relatively low corporate tax rate did not incentivize R&D spending (Fennelly & Cormican, 2006). Second, there was little experience in marketing and sales in the medical device sector in the country. In 1998 there were approximately 100 people directly employed in sales and marketing roles, less than 1% of the total workforce (IMDA, 1998). The marketing deficiency of the industry "reduced the ability of any proposed product development function to engage with customers' [sic] and to satisfy their needs" (Fennelly & Cormican, 2006). In 2007, they thus performed an analysis of the human capital required for the future growth of the sector, as described in Box 2 below.

Box 2. Identifying the Workforce for the Future

In 2007, the Irish Expert Group on Future Skills Needs (EGFSN) began analyzing future human capital requirements to support ongoing growth of the Irish medical devices sector. Although led by the public sector, this initiative emphasized multi-stakeholder contributions, requesting input from a full range of industry, academic and government actors in the industry. In an effort to prepare a workforce to support upgrading into the next stage of the value chain, the group examined human capital demands and development programs in the leading clusters in the United States, including California, Minneapolis and Massachusetts. Two needs trajectories were examined: one scenario based on continued rapid growth of the sector, and a second more conservative scenario that assumed a slow down in growth. In addition, they identified key trends in the evolution of the sector in the country, including the relocation of low-cost, labor-intensive operations to cheaper destinations outside of Ireland and the emergence of local, innovative start-ups.

Through this analysis they identified three important high-demand areas for labor: engineering, technicians and management familiar with particular industry issues such as regulation. Under the rapid growth scenario, the EGFSN predicted an increase in the annual demand for engineers and scientists from 240 in 2007 to 384 in 2012; for technicians, 178 to 280 and management from 106 to 146. Four future high-demand engineering skills sets were identified: Product development, process and manufacturing engineering, validation engineering and the design of automated production systems. They found that the country's engineering programs were sufficiently developed to supply the required numbers of engineers, but that they needed to focus their content a little more towards biomedical engineering. The core challenge for the sector would rather be developing adequate numbers of technicians to meet future demand, and thus the group developed a strategy to "upskill" the existing labor force and to recruit technicians from other industries.

This industry-specific analysis was later combined in a transversal study to identify common workforce development opportunities.

Source: (Expert Group on Future Skills Needs, 2008).

Policies to support upgrading into the R&D segments of the value chain were thus driven on several fronts, with simultaneous efforts to improve upgrading into the marketing and sales segment of the chain. IDA Ireland launched a new campaign in 2009, "Innovation Comes Naturally," and refocused their promotion strategy to high-value manufacturing and R&D

with life sciences as the top priority for FDI in 2010. Since 2009, IDA has offered R&D and innovation grants to encourage both current and potential FDI to engage in R&D in the country. These include grants for assessing the feasibility of pilot research projects and training grants for "up-skilling" staff to perform the research. Grants can be up to €250,000 (US$327,000)[20] or 50% of the costs. Funding available for industrial research can cover up to 40% of the costs, as high as €7.5 million (US$9.8 million), or higher if EU approval is granted. Employment and capital grants for training and investments in new equipment are also available, although they are linked to locations in the Border, Midland and Western (BMW) regions (Deloitte, 2009). Enterprise Ireland also upped its efforts to drive domestic innovation in 2007. It has become the largest seed capital fund in the country, and works with four seed capital and seven venture capital funds, with combined resources of just under US$1 billion to invest in the commercialization of cutting edge research from early stage through late stage development. In 2011, the MedTech Accelerator Fund was launched together with the National University of Ireland Galway and the University of Limerick as investors, to provide smaller investments (Advantage Business Media, 2011).

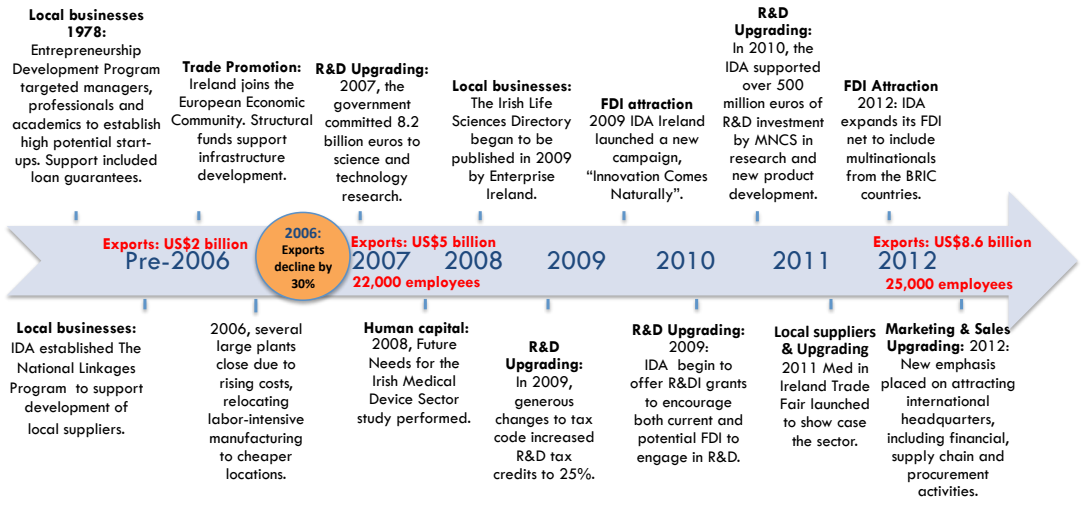
Furthermore, in 2007, the government committed €8.2 billion (US$10.7 million) to science and technology research over a five-year period, funding research centers including the Biomedical Diagnostics Institute focused on the development of next generation devices. These research centers not only bring together industry and academia, but they also provide further education opportunities at the graduate level. In 2009, generous changes to tax code increased R&D tax credits to 25%, while for qualifying patents, up to €5 million (US$6.5 million) can be exempt from income tax. Overall, these initiatives ensure that all firms, from small-scale domestic start-ups to large, established MNCs, including Medtronic, Stryker and Boston Scientific, are incentivized to engage in R&D while also providing access to the human capital to do so. These policies are already reaping rewards. In 2010, the IDA supported over €500 million (US$654 million) of R&D investment by MNCs in research and new product development. Between 2007 and 2012, a US$3 billion increase in exports was supported by the addition of just 3,000 employees to the workforce.[21]

Figure 5 highlights key milestones and policies that have helped to support the upgrading of the Irish medical devices sector since 2006.

[20] All euro to US$ conversions are based on the exchange rate of US$1.30 to €1.

[21] Comparatively a US$1.5 billion expansion of exports in Baja California was accompanied by an increase in the labor force of over 14,500 employees.

Figure 5. Evolution of the Irish Medical Devices Sector, Milestones and Select Policies



Source: Authors.

4. Costa Rica and the Medical Devices Global Value Chain

In 2012, approximately 50 firms were participating in the medical devices supply chain in Costa Rica, with an additional 16 firms providing packaging and support services. Over half (60%) of these firms were of US origin and less than 30% of these firms were Costa Rican. The remaining firms come from six countries, with one firm each coming from Colombia, Germany, Ireland, Japan and Puerto Rico. Firms are concentrated in the production segments of the value chain, manufacturing components and assembling final goods (70%). A small number of OEM firms perform additional manufacturing R&D focused on improving the production process (sustaining engineering) and establishing the new production process for new products (process development) to be launched directly from Costa Rica. Costa Rican-owned firms contribute principally in the labeling and packaging segments of the value chain as well as support services. This section examines how the industry has evolved and upgraded over time and where in the value chain the country is currently positioned. Potential constraints to upgrading are then analyzed.

4.1. The Development of the Costa Rican Medical Devices Sector

The Costa Rican medical devices industry is relatively young. The industry began with the establishment of Baxter's operations in 1985. To understand the industry's evolution, we analyzed the types of firms entering the sector over four periods: Pre-2000 (inclusive), 2001–2004, 2005–2008 and 2009–2012. One quarter of firms existed prior to 2000, while the most significant growth in number and variety of firms and the value of the key products they are manufacturing has occurred within the past three years (2009–2012). Table 7 details the characteristics of firms in each of these stages.

Table 7. Overview of Medical Device Firms in Costa Rica, by Entry Year

Entry Year	Firm Characteristics	Main Product Export Category	Core Market Segments	Product Examples (FDA Class)	Select Firms
Up to 2000 24 firms: 8 US 15 CR 1 German	4 OEMs 8 Components 1 Input distributor 7 Packaging 1 Finishing 3 Support services	Disposables	Drug delivery; Women's health	Intravenous tubing (I) Mastectomy bra (I)	Hospira; Baxter; Amoena; Corbel
2001–2004 13 firms: 9 US 3 CR 1 Colombian	3 OEMS 6 Components 1 Finishing 1 Logistics provider 2 Support services	Instruments	Endoscopic surgery	Biopsy forceps (II)	Arthrocare; Boston Scientific; Oberg Industries
2005–2008 8 firms: 7 US 1 Puerto Rico	2 OEM 4 Components 1 Packaging 1 Finishing	Therapeutics	Cosmetic surgery; Women's health & urology	Breast implants (III) Minimally invasive devices for uterine surgery (II)	Allergan; Tegra Medical; Specialty Coating Systems
2009–2012 21 firms: 16 US 1 CR 1 Ireland 1 Japan 2 Joint ventures (US-CR)	5 OEMS 7 Components 2 Non-OEM assemblers 1 Input Distributor 2 Sterilization 2 Packaging	Therapeutics Disposables Instruments	Cardiovascular Drug delivery	Heart valves (III) Dialysis catheters (III) Guide wires (III) Compression socks (I)	Abbott Vascular St. Jude Medical Covidien Moog Synergy Health Volcano Corp.

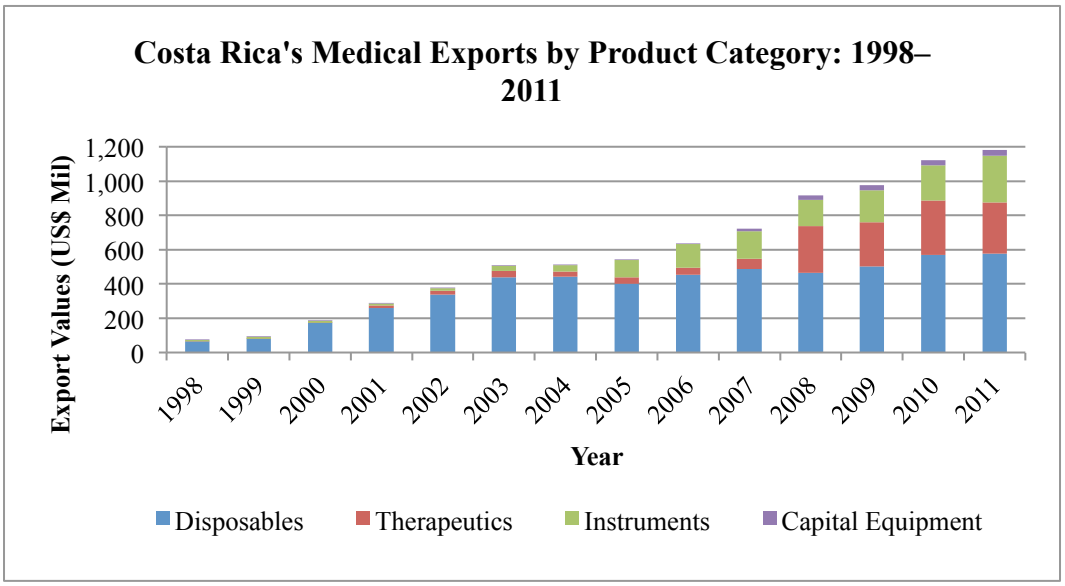
Source: Authors.

Key Trends & Highlights

- **Growth driven by export-oriented strategies**: Costa Rica's medical devices sector has been shaped by efficiency-seeking strategies of multinational medical devices lead firms of US origin establishing operations in the country to take advantage of its strategic location, skilled human capital and political and economic stability (Field Research, 2012).[22] Between 2001 and 2012, US firms accounted for 30 of the 37 market entrants, and 12 of the 16 OEM firms in the country are of US origin.
- **Initially a low-cost center:** OEMs were initially attracted to Costa Rica as a low-cost destination for manufacturing: the firms that set up operation pre-2000 were focused on lower-value disposable products, such as IV tubes (see Figure 2). This perspective has changed over time. Interviews revealed that, today, the presence of human capital with experience in the sector was ranked as more important in attracting firms to establish operations in the country than cost. Indeed, several firms noted that both labor and non-labor costs in Costa Rica are considerably higher than in other potential locations.
- **Rapid expansion & process upgrading:** Once they determined the capacity of Costa Rica's labor force to adapt to new demands, OEM firms in particular quickly began to expand activities performed in their production plants in the country (e.g. Hospira, Boston Scientific, Covidien). Today, many manufacturing operations of OEM firms are completely vertically integrated, with firms receiving raw materials and performing activities including extrusion, molding and assembly of final goods (Field Research, 2012). Several firms indicated they had adopted lean manufacturing practices, and had Six Sigma Black and Green Belt trainers on staff.
- **Product upgrading:** There has been a general increase in the complexity of products fabricated in Costa Rica. Figure 6 below shows the evolution of medical devices exports by product category since 1998. Exports began to diversify in 2005, with increased exports in the instruments product categories, and then in 2008 with an increase in exports in the therapeutics export category. Exports in capital equipment products continue to be limited. In addition, there has been an increase in the number of Class III products fabricated in the country, indicating a growing confidence in the capabilities of Costa Rican plants to follow strict regulatory protocols. The shift in product upgrading is the outcome of two factors: existing firms increasing the sophistication of product lines (e.g. Hospira, Boston Scientific) and the recruitment of firms with devices in more complex product categories (e.g. St. Jude Medical, Covidien).

[22] This is consistent with general findings regarding FDI in Costa Rica (Ciarli & Giuliani, 2005).

Figure 6. Costa Rica Medical Exports by Product Category, 1998–2011



Source: Authors based on Procomer data (1998–2011).

Note: See tables in Appendix for detailed information on exports by product category from 2002 to 2010.

- **Market segment diversification.** Early firms to begin operations in Costa Rica focused on drug delivery (e.g. Hospira and Baxter) products. In the early 2000s, firms establishing operations began to diversify with the introduction of products for endoscopic and cosmetic surgeries. Four of the five OEM firms to enter Costa Rica between 2009 and 2012 focus on the cardiovascular segment (e.g. St. Jude Medical, Covidien & Abbott Vascular). The cardiovascular segment is the largest and most lucrative of the medical devices industry. This market diversification indicates that the Costa Rican medical devices manufacturing operations are maturing.
- **Local suppliers have gained market share as MRO suppliers, but not for key inputs.** Costa Rica Provee indicates that by 2012, there were 364 local suppliers of the medical, chemical and pharmaceutical sector (Dobles, 2012). However, data gathered during the interviews[23] and supported by the import data of firms in the sector[24] suggested that these suppliers are mostly in packaging and non-production functions (see Table 8). Packaging supplies accounted for approximately 75% of the value of all local purchases (Zolezzi, 2012). Seven of the 11 firms in the packaging segment of the value chain are local firms and each supplies a number of the large OEM firms. Local firms providing specific

[23] All firms interviewed indicated that local suppliers were used only for packaging and MRO supplies and not for key inputs. One firm indicated that local suppliers were used for overflow tooling requirements.

[24] Based on the data for the same 28 firms referenced above.

production functions, such as raw material and component suppliers, have overall not been able to enter the chain.

Table 8. Domestic Firm Direct Participation in the Medical Devices GVC

Firm activity	No. of firms
OEM Manufacturing	1
Packaging & Labeling	7
Metal components finishing	2
Plastics components	2
Total	15

Source: Authors, based on interviews and analysis of all firms identified in the sector.

Note: This list does not include firms that provide MROs, cleaning suppliers or support services such as calibration services.

Between 2008 and 2010, medical devices manufacturers reported subcontracting operations such as assembly and molding of plastic parts from local suppliers worth approximately US$600,000,[25] yet total exports for the sector during that same period reached US$3 billion.[26] Interviewees highlighted that key problems potential suppliers faced were limited scale, financial capital and expertise (Field Research, 2012). These findings are consistent with those of Paus & Gallager (2008), Guiliani (2008) and Patton & Moore (2012). Guiliani (2008) also found that electronic and medical devices firms in Costa Rica in 2004 were unlikely to contribute to the upgrading of local firms, rather they expected these firms to develop the required competencies without their support as globalization increasingly enabled them to use experienced suppliers from around the world.

These limitations are also similar to those faced by small- and medium-sized local firms in other global value chains (Fernandez-Stark et al., Forthcoming; Humphrey & Schmitz, 2008), and derive from market failures, including imperfect information and coordination failures (Paus & Gallagher, 2008). Nonetheless, local suppliers have developed sufficient capabilities to operate according to the quality standards required by multinational firms in non-production activities. Non-production activities include general support functions such as construction of buildings, cleanrooms and MROs.

- **Foreign suppliers have begun to enter the country to supply forward and backward linkages.** In order to continue to foster growth, OEMs have pushed their global suppliers

[25] Figure calculated from an analysis of FTZ data from PROCOMER. All conversions between the Costa Rican colon and the US dollar are based on the exchange rates noted in Table A.17 in the Appendix.

[26] Figured based on FTZ data from PROCOMER. Firms are required to report all sub-contracting relationships within the country each fiscal year. These include transactions with firms in both the FTZ and beyond. Several firms report working with the same local firms on an ongoing basis (year on year).

to establish operations in the country.[27] Indeed, over half of the firms interviewed indicated that the presence of global suppliers and other OEM firms in the sector was one of the key factors in their decision to establish operations in Costa Rica. Foreign suppliers based in the country provided approximately US$7,47 million[28] in subcontracting services during the 2008–2010 period (over 10 times that of local suppliers which was US$600,000 for this same period). In 2011, foreign suppliers provided US$27,5 million in subcontracting services in 2011, largely due to one large OEM engaging a foreign supplier for sub-assembly work. Strong and significant linkages across the sector have not yet emerged. One supplier, for example, established operations to meet the demand of a single client in 2006, and, despite having existing global relationships with other OEMs present in Costa Rica, the supplier has not been able to expand its customer base in Costa Rica (Field Research, 2012). While anecdotal evidence suggests an uptake of linkages in 2012, Table 9 illustrates that by 2011, just three firms subcontracted less than three percent of their total production.

Table 9. Medical Devices Assembly Firms Engagement in Subcontracting

	2007	2008	2009	2010	2011
Number of Firms Engaged in Subcontracting	1	0	2	2	3
Total Value Subcontracted ($US Millions)	0.145		1.78	5.69	5.54
Total Value of All Production ($US Millions)	156.9		150.0	169.2	192.8
Average Share of Production Subcontracted by Subcontracting Firms	0.09%		1.18%	3.36%	2.87%

Source: Procome, 2012.

Note: One OEM firm reported US$21.8 million in sub-assembly in 2011, however, they reported this as a local input rather than a subcontracting operation and thus it is not included in the data above.

- **Spillovers and spin-offs.** Significant knowledge transfer to the country has occurred over the past decade due to the presence of several leading global medical devices manufacturers. For example, senior management at all firms interviewed was Costa Rican (Field Research, 2012). Two of the more established firms in the sector indicated that they were "universities for the sector," due to the common practice of former

[27] The practice by which a multinational corporation attracts its existing suppliers to co-locate operations close to its global production sites is known as follow sourcing (Humphrey, 2003). Pre-existing inter-firm relationships reduce search costs, ensure quality standards and reliability within the supply chain, and facilitate information flow through the chain (Posthuma, 2001). Adhering to these design and quality requirements is essential in the highly regulated medical device sector where OEMs have the responsibility to ensure compliance of their suppliers (McHugh et al., 2012). The establishment of foreign supplier operations can thus rapidly deepen a country's participation along the global value chain, technological know-how is quickly transferred to the host nation and total employment in the sector increases. Humphrey and Memedovic (2003) argue, however, that this practice can crowd out the development of local suppliers in developing countries and ultimately constrains potential positive spillovers to the local economy.

employees moving on to work in management levels of other medical devices firms in the country. Labor mobility between firms appears to have been more effective in transferring industry knowledge than the generation of new, entrepreneurial endeavors. After 12 years of industry experience, only one significant domestic OEM firm, Establishment Labs, had been established in the country.

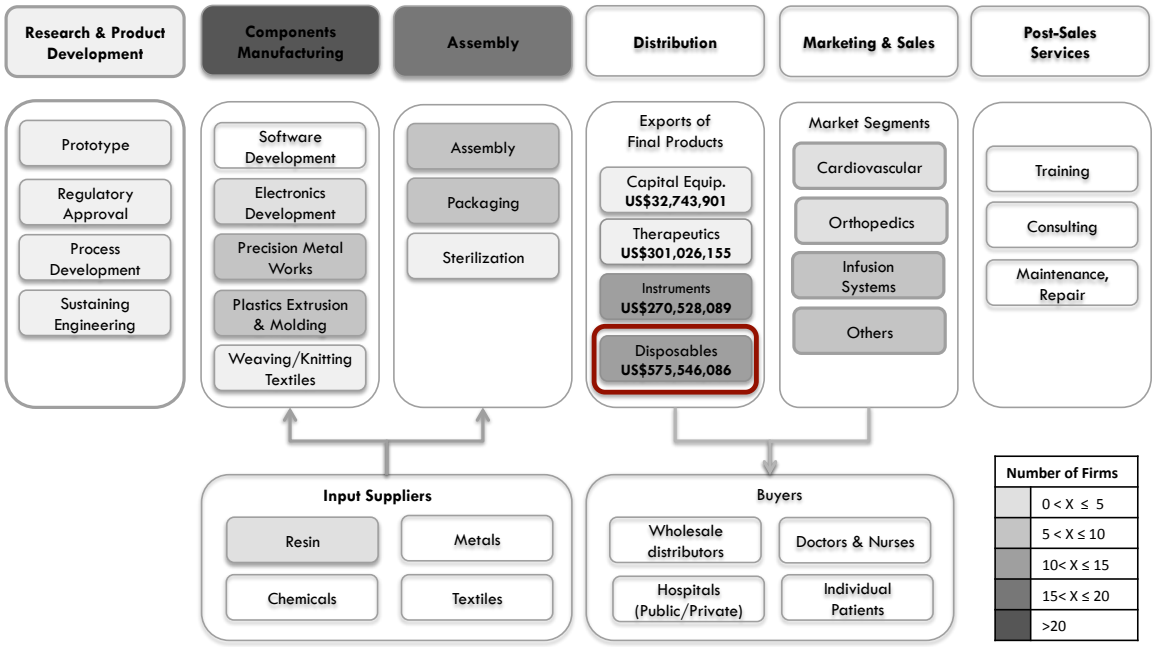
- **Institutional support**. Three organizations provide institutional support for the growth of the sector: CINDE, a non-governmental organization dedicated to promoting economic growth in Costa Rica through FDI attraction; PROCOMER, a public organization focused on promoting Costa Rican exports and COMEX, the Ministry of Foreign Trade, responsible principally for trade policy and negotiating trade agreements with other countries. In 2005, COMEX introduced the Directorate for Investment as the division responsible for advising on policy priorities and implementing investment promotion policy guidelines and defined by the Minister. Together CINDE, PROCOMER and COMEX have been instrumental in providing leadership for the continued development of the sector. CINDE, in particular, is a key facilitator, providing a forum for firms in the sector to come together and share their concerns as well as providing access to a range of other governmental and non-governmental actors to address specific challenges. These organizations have played a strong role in maintaining the country's commitment to the medical devices sector across different government administrations.

- **Centralization of operations in the Greater Metropolitan Area (GMA).** The medical devices sector is highly concentrated in the GMA region. Several factors including infrastructure, availability of qualified human capital and quality of life concerns have concentrated growth in the country's Central Valley. 66% of the labor force is located in this region.

4.2. Costa Rica's Current Participation in the Medical Devices Global Value Chain

Figure 7 highlights Costa Rica's current position in the medical devices GVC. No shading indicates that there are no firms participating in these segments of the chain, and progressively darker shading indicates areas where there is increased participation. While the majority of firms in Costa Rica are participating in the components manufacturing segment of the chain, OEMs making their own components and assembling final goods account for most of the exports. Approximately 16 firms export assembled medical devices products, primarily in three product segments: disposables, instruments and therapeutic devices. Assembled exports accounted for 93% of Costa Rica's total medical devices exports; the remaining 7% of total exports include components not listed under the HS Codes classified below as well as design services, which are not accounted for in the export trade database.

Figure 7. Costa Rica's Participation in the Medical Devices GVC



Source: Authors.

Note: Market segments reflect final products and do not include the exports of components for these market segments.

Total exports, including design services, for the sector reached US$1,283 million in 2011.[29] Disposable catheters and cannulae used in the intravenous delivery of drugs and nutritional substances accounted for 49% of all medical devices exports that year. Table 10 shows how these exports from Costa Rica in 2011 are divided between intermediate and final product categories.

Table 10. Costa Rica Medical Devices Exports, by Value Chain Segment (2011)

Description		HS Code	2011 ($US million)
Design Services [a]		NA	89.1
Components		Various	6.0
Assembled Products	Disposables	90183	575.5
	Therapeutics	9021	301.0
	Instruments	90184-9	270.5
	Capital Equipment	90181-2, 9022	32.7
	Other	6212100	8.6
Total			**1,284**

Source: Authors based on export data from Procomer, 2012.

[29] In addition to the products exported, the country exported approximately US$90 million in design services for medical device manufacturing (Procomer, 2012).

[a] Data for Design Services was calculated in colones at the exchange rate of 500 colones to US$1.

Each of the three product categories in which Costa Rica has significant exports is highly concentrated; together the two leading firms in each category, Baxter and Hospira (Disposables), Arthrocare and Boston Scientific (Instruments) and Allergan and St. Jude Medical (Therapeutics), accounted for 87% or more of exports in that category. These six firms together account for 89% of the medical devices exported from Costa Rica. Catheter exports are destined for the intravenous and urological markets, while non-catheter exports are principally destined for the cardiovascular, orthopedic, gastroenterology, urology and women's health markets.

Table 11 provides an overview of 2011 export destinations by product category. Between 2000 and 2010, 98% of exports were destined to markets outside of Central America. The majority of products in all categories (70%) are exported to the US. This can be explained by the proximity to the US, the US origin of the OEMs and component suppliers operating in Costa Rica and the fact that the US itself is the leading market for medical devices. For disposables, 14% are exported through Puerto Rico for further processing, such as sterilization, prior to being exported to the final destination. Therapeutics production serves a slightly more diversified market, with 25% shipped to Europe. Exports to the Asia-Pacific and Latin America regions are low at 3% and 4% respectively, despite the country's strategic location to access both markets.

Table 11. Leading Export Destinations by Product Category (2011) Values (US$ Million)

Country	Disposables (90183)		Therapeutics (9021)		Instruments (90184-9)		Capital Equipment (90181-2; 9022)		Medical Totals (All Categories)	
	Value	Share	Value	Share	Value	Share	Value	Share	Value	Share
Total	**575.5**		**301.0**		**270.5**		**32.7**		**1,179.8**	
United States	405.3	70.4	155.9	51.8	229.0	84.7	31.6	96.6	821.8	69.7
Puerto Rico	80.3	13.9	--	--	--	--	--	--	80.3	6.8
France	--	--	57.8	19.2		--	--	--	57.8	4.9
Netherlands	51.0	8.9	--	--	4.2	1.5	--	--	55.2	4.7
Belgium	--	--	14.8	4.9	27.2	10.1	--	--	42.0	3.6
Australia	--	--	16.6	5.5	2.6	1.0	--	--	19.2	1.6
DR	14.1	2.5	--	--	--	--	--	--	14.1	1.2
Canada	--	--	--	--	--	--	0.1	0.2	0.1	0.0
Brazil	--	--	11.2	3.7	--	--	--	--	11.2	1.0
Ireland	4.8	0.8	--	--	--	--	--	--	4.8	0.4
Argentina	--	--	--	--	2.4	0.9	--	--	2.4	0.2
Germany	--	--	--	--	--	--	0.5	2.1	0.7	0.1
Honduras	--	--	--	--	--	--	0.1	0.4	0.1	0.0
Denmark	--	--	--	--	--	--	0.1	0.2	0.1	0.0
Top Five	**555.5**	**96.5**	**256.2**	**85.1**	**265.4**	**98.1**	**32.6**	**99.6**	**1,109.7**	**89.6**

(--): indicates country not in the top five in 2011

Source: Procomer, 2012.

4.3. Workforce & Training

In 2011, the industry employed approximately 12,500 people. The largest 10 employers accounted for approximately 10,500 workers in 2011, with the top six accounting for over half of all employees in the sector. Engineering staff accounted for between approximately 10% and 20% of total employment in the firms interviewed, technicians between 10% and 15%, while direct labor accounted for between 60% and 82% of workers.[30] Slightly more than half (54.4%) of the workforce is female (CINDE, 2012).[31] All firms interviewed indicated that the majority of their workers (over 90%) are employed on permanent contracts. This was primarily due to the significant amount of training required for all levels of the workforce. For example, on average, line workers take six to eight weeks to reach full productivity, in addition to one- to two-week induction training and constant on-the-job supervision and development (Field Research, 2012).

Direct labor is mostly drawn from technical high school graduates (nine years primary and secondary, plus three years technical education). In some cases, firms also hired individuals with less than nine years of schooling. The percentage of qualified technicians per firm varied considerably. The majority of firms interviewed indicated that in addition to drawing on technical high school graduates, they worked with the Instituto Nacional de Aprendizaje (INA) to train line operators, material handlers and technicians. INA now offers a one-week introductory course to the medical devices sector, covering good manufacturing practices, working in cleanrooms and documentation. Instituto Tecnológico de Costa Rica and Universidad de Costa Rica were ranked by interviewees as the most important universities for supplying engineering talent including electrical, electronic, industrial, mechanical and chemical engineers. Microbiologists are recruited from the University of Costa Rica, which graduated approximately 86 graduates per year between 2001 and 2009. The number of graduates declined dramatically in 2010 to 47, but these numbers began to recover in 2011. Universidad Autónoma de Costa Rica recently opened a new program in microbiology, which should eventually help to balance demand and supply. Quality assurance and regulation compliance personnel tend to be more difficult to find in the local labor market.

Turnover rates for the industry as a whole have tended to be around 12–15% (CINDE, 2012), although approximately half of the firms interviewed indicated that attrition increased in the first half of 2012. Firms indicated that finding staff to fill positions was considerably easier than retaining staff, and several firm have recently launched strategies focused on staff retention. Key factors contributing to attrition include establishment of large new medical devices operations (particularly firms in the same parks), increased competition for engineering talent with high paying offshore services sector and female absenteeism. The

[30] The firms interviewed employed approximately 70% of the total workforce in 2011 (Based on interview responses, FTZ data and an estimate of total employment of approximately 12,500 at the end of 2011).

[31] This is consistent with FTZ data and interview findings.

latter is mostly attributed to childcare constraints and could be overcome with the provision of childcare facilities either at work or in the community. The average wage per employee has increased by approximately 50% since 2007, although it is not possible to determine whether this has been from a change in the profile of new recruits to the industry or upward pressure on wages.

4.4. Challenges for Future Expansion and Upgrading of the Medical Devices Sector in Costa Rica

As highlighted above, the medical devices manufacturing sector in Costa Rica has undergone important upgrading over the past 12 years, and the arrival of important OEM firms between 2009 and 2012 (e.g., St. Jude Medical, Covidien, Abbot Vascular) indicate that the number of increasingly complex products exported from Costa Rica is likely to increase significantly in coming years. Below, we outline several areas where improvements are required to facilitate continued growth of the sector and potential upgrading in the future. These include the increased institutionalization of the industry, quality of engineering programming, general business environment and presence of support services for the industry.

Coordination and collaboration among the industry stakeholders. While CINDE, PROCOMER and COMEX have together played an important coordination and leadership role, to date no formal, institutionalized frameworks exist to bring together industry stakeholders, and the private sector still lacks some cohesive organization such as an industry association which can represent their collective needs.

Quality improvements in engineering programming. Employment growth in the medical devices sector alone was approximately 2,000 jobs between 2010 and 2011. Assuming that between 10% and 20% were engineers and 10 to 15% were technicians, this suggests the demand for employees was 200–400 engineers and 200–300 technicians. In 2011, Costa Rica graduated 2,000 engineers and 510 technicians[32] in relevant fields for the medical devices sector (see Chapter 1, Tables 7 and 8), indicating that the current supply of human capital is adequate. With respect to engineering, there are already over 55 different engineering programs relevant to the medical devices sector offered at both public and private universities.[33] The quality of these programs varies significantly. The public system is well known for its quality, and the Consejo Nacional de Rectores (CONARE) has been an active proponent of the accreditation system to guarantee that quality.

Engineering, in particular, has been at the forefront of the higher education accreditation process in Costa Rica with a strong emphasis on quality at international standards. Engineering programs were the first to be accredited in the country, with the support of the

[32] Total number of graduating technicians fell by 28% between 2009 and 2010.

[33] This analysis is based on review of 57 public and private universities and 2 university colleges in Costa Rica.

Canadian Engineering Accreditation Board. Nonetheless, by 2012 only a few engineering programs had been accredited (approximately 20%), and the majority of these are at the public universities, Universidad de Costa Rica and Instituto Tecnologico de Costa Rica in particular. The accredited programs graduate approximately 400 students between them. Employers indicated that they prefer to only work with these two universities for quality reasons, creating an apparent shortage of labor. For example, one firm suffered attrition rates of 35% in 2011. Improving the quality of engineering education is therefore an important challenge Costa Rica must overcome. The government of Costa Rica, CONARE and SINAES have demonstrated their commitment to increasing both the quantity and quality of programming for high tech industries through the upcoming project with the World Bank (see Chapter 1, Box 1). Nonetheless, efforts are required to improve the quality of private engineering programs.

Improving the country's transportation infrastructure. Costa Rica's strategic location is an important factor of the country's competitiveness in this sector. However, this depends on an adequate transportation infrastructure, both for bringing in inputs from the ports to production facilities in the Central Valley, and for moving product to market. Low investments and maintenance over the past two decades have deteriorated the country's public infrastructure (The World Bank & Inter-American Development Bank, 2008). In 2012, Costa Rica was ranked 116th of 144 countries for infrastructure by the World Economic Forum's Global Competitiveness Report. Firms generally do not consider operating from other regions of Costa Rica due to lack of access, despite free trade zone (FTZ) incentives to do so, and this will likely continue to concentrate medical devices manufacturing in the Central Valley. Unemployment in the GMA region reached 6.9% in the Central Valley in 2012, but averaged close to 3% in the areas where the majority of FTZ parks are currently operating,[34] suggesting that labor market conditions are tightening in these areas. Yet, there is available labor for manufacturing in other areas around the country. Planned investments in a new container port in Limon-Moin—in addition to timely and effective implementation of the current administration's infrastructure plan, which committed US$2.66 billion to improve and modernize the country's airports, highways and rail network—will be key to future development.

Regulatory Uncertainty. While Costa Rica provides important advantages in terms of political and economic stability compared to neighbors such as Mexico and Dominican Republic,[35] uncertainty regarding FTZ regulation and unpredictability of permitting processes constrain investment and expansion plans. First, Costa Rica's free trade zones are an important asset for the country's medical devices sector: nearly 90% of foreign firms in this

[34] See Chapter 1, Table 5.

[35] The Political Instability Index published by the Economic Intelligence Unit shows the level of threat posed to governments by social protest. Ranked from 1 (most unstable) to 165 (most stable), for the 2009–2010 period, Costa Rica ranked 158th. By comparison, Dominican Republic ranked 16th and Mexico 79th (Economic Intelligence Unit, 2012).

sector operate under this regime. These zones offer attractive duty-free imports and exports and income tax benefits, lowering overall costs for firms. For example, in 2011, just 16% of all processing firms in the FTZ paid full income tax (30%). While all firms interviewed claimed that these tax benefits were not the main reason they had established operations in the country, they also stated that the uncertainty created around suggested changes to the free trade regime in 2010 had derailed investment decisions. Second, the lack of predictability of the permitting process and excessive bureaucratic procedures were repeatedly highlighted as constraints to growth by interviewees. The Costa Rican government has begun to work on improving the business environment through a technical assistance agreement with the World Bank, to address issues such as simplifying property transfer procedures, starting a business, obtaining construction permits and paying taxes (The World Bank & International Finance Corporation, 2011). Nonetheless, it will take some time to improve its relative competitiveness in these aspects as the country is still ranked 110th out of 183 countries in the World Bank's Doing Business ranking (The World Bank, 2012a).

Presence of core support services such as regulatory compliance certification to improve the cost of product and process upgrading. In the medical devices sector, product & process upgrading depends to a significant degree on the speed and cost of validation processes. As noted in Section 2.5, due to the potentially fatal consequences of manufacturing errors in medical devices, standards compliance is central to success, particularly for life-saving, higher-value, Class III products that are implanted in the body. The Latin American Headquarters of the FDA was established in San Jose in 2011 to facilitate access to regulations, as well as to work with local regulatory authorities, industry and academia (FDA, 2012a). While the US continues to be Costa Rica's key export destination, diversification into other markets requires a different, and less complex set of certifications—for example, the CE Mark for sale to regional markets. Time taken for CE certification is often considerably shorter than that for the FDA. No EU certifying bodies have a presence in Costa Rica.

Furthermore, there is limited support for firms with respect to ISO certifications. One firm offers ISO cleanroom certification services; however, there are no firms in Costa Rica accredited to provided ISO 13845 training and certifications, and firms must pay travel costs for trainers and auditors to come from the United States or the EU. Certification is essential for local firms to become approved suppliers for medical devices firms, particularly as changes in regulation now place the burden of quality assurance for suppliers with OEMs. The cost of ISO training and certification can prevent developing countries from accessing markets (Clougherty & Grajek, 2012). Given that there are two certifying bodies (INTECO and CIC) that are accredited to award a subset of international quality standards, including ISO 9001 and ISO 14000, and that the majority of firms operating in Costa Rica are subsidiaries of large multinational firms with access to capital to finance the training and certification process, the lack of an agency with ISO 13845 accrediting authority is likely the result of lack of economies of scale—that is, an insufficient number of firms requiring certification to justify the cost of developing the appropriate accrediting competencies.

Costa Rica-based suppliers. Firms in the Costa Rican medical devices sector largely operate with limited substantive linkages with other foreign firms within the countries, while local firms participate primarily in the packaging segment of the chain. While there are some preliminary indications that relationships are beginning to build across the sector,[36] such as an increase in the domestic component of production and initiatives to establish an industry association, strengthening inter-firm linkages remains a key development area for the country. Slow engagement with suppliers may be attributable to the governance structure of the value chain, although this can change over time. Consistent with hierarchical chains, most decisions regarding vendors are made in corporate headquarters and at scale to support manufacturing plants around the world. 78% of firms interviewed indicated they had either shared or no decision-making responsibility with respect to supplier selection for raw materials.

Paus & Gallagher (2008) note that this dynamic can change where local competencies mature to meet the needs of the OEM. For example, Baxter's plant in Singapore sources certain productive inputs from local suppliers as there is no difference between in-house quality and locally produced inputs. This occurs due to the potential cost savings the subsidiary can achieve by outsourcing. Grog et al. (2009) also find that the longer OEMs were embedded locally, the more linkages they were likely to establish, attributing this to the mitigation of information asymmetries by increased knowledge of the location. It may also be possible that this is due to the development of products in conjunction with established manufacturing subsidiaries where the procurement team is directly involved in selecting vendors (Weber et al., 2010).

Absence of local OEMs reduces potential opportunities for functional upgrading into R&D. Functional upgrading in the medical devices sector is challenged by the hierarchical nature of the chains. MNCs leverage global production networks to reduce their manufacturing costs, but they tend to maintain high-value R&D operations close to their corporate headquarters. Costa Rica has only one local firm engaged in developing new products for this sector, so upgrading into R&D in the near future will depend on foreign subsidiaries. In order to upgrade into R&D, local subsidiaries must compete based on capabilities and efficiencies. Subsidiaries must prove they have the capability to quickly learn new tasks and can achieve full productivity quickly and at a lower cost in order to upgrade.

Grants for R&D in medical devices can also help improve the competitiveness of these subsidiaries. R&D fiscal incentives are offered in numerous countries around the world, including strong competitors Ireland and Singapore; however, they are not available to firms in Costa Rica. Furthermore, the subsidiaries must have access to highly qualified personnel for R&D work. The two firms interviewed that indicated that they were hoping to upgrade into R&D noted that they believed it would be difficult to find the R&D talent locally. There

[36] Several new suppliers including Merrill's Packaging and Sterigenics opened operations in Costa Rica in 2012 and contract specifically to foreign OEMs operating in the country. These contracts would not be reflected in the 2011 dataset from firms operating in the FTZs.

has been a strong preference for social sciences amongst PhDs in Costa Rica in the past, with almost all doctoral degrees being awarded in these fields in 2002. Nonetheless, there are indications that more technology-related degrees are being pursued today, particularly in medical sciences (OECD, 2012), which could support this upgrading trajectory in the long term.

5. Potential Upgrading Trajectories for Costa Rica's Medical Devices Sector

The analysis in the Section 3 highlights Costa Rica's impressive performance as a new competitor in the medical devices global value chain, and there remains important potential for upgrading in the country. In this section, we highlight four potential upgrading trajectories.

1) **Product upgrading.** The country's medical devices exports have become increasingly diverse across the product categories, and therapeutics are likely to displace disposables as the leading category as newly established firms (e.g. St. Jude Medical, Covidien, Abbott Vascular*)* ramp up production. Nonetheless, production of capital equipment of any size is only taking place in a small number of firms and accounted for just US$32 million exports in 2011; yet these products are considerably more valuable than other product categories. For example, an infusion pump is a one-time purchase item and the value of this item is significantly higher than that of the IV sets used with it (as much as 1,000 times more). However, one pump requires 15–20 IV sets a month, thus driving complementary growth of an existing product in Costa Rica's portfolio. In addition, there are a growing number of convergent products that bring together information technology and medical devices. Given Costa Rica's strong IT presence, this could be a potential new product line to pursue.
2) **Process upgrading of local suppliers.** Continued growth in the number of firms operating in the country, combined with the small labor force emphasizes the long-term need to shift towards more capital-intensive rather than labor-intensive activities. Increased use of automated processes would facilitate long-term growth of the sector, with lower demand for labor per output while simultaneously creating higher paid employment (Sohn, 2009). There is also an opportunity for both local and foreign suppliers to provide services such as extrusion, injection molding, precision stamping, etc. Expanding the availability of these services at a high quality can allow OEMs to use existing capacity to maintain existing product lines and, at the same time, upgrade into new product lines. Product and process upgrading trajectories can help to increase the value added of the production, result in the transfer of new skills to the local operations or increase total employment in the sector in the country.
3) **Establish new backward & forward linkages.** Strengthen backward linkages of the value chain by attracting distributors that provide key resources for the medical devices sector. For example, inventory in transit is a key factor in this sector. By establishing

suppliers of key inputs in country, inventory in transit is decreased. This shifts the responsibility of managing key input inventory from the manufacturing firms to the suppliers, facilitates cash flow and improves the cost-effectiveness of manufacturing facilities in the country. In particular, strengthening the presence of resin distributors would improve the competitiveness of catheters, the country's key medical devices exports. Developing additional forward linkages, such as improving logistics operations for shipping and handling of products, while simultaneously improving transportation and port infrastructure could complement the presence of the new Synergy Health and Sterigenics sterilization facilities to support functional upgrading into the distribution segment of the value chain. By distributing products directly to end customer locations, Costa Rica would increase the value it captures from participating in the medical devices GVC.

4) **Diversify across geographic markets, in particular Latin America, to drive functional upgrading both in terms of incremental and clinical R&D and downstream marketing and sales functions**. While there is a growing interest among firms to co-locate manufacturing-related R&D functions with their production facilities, firms indicated that it would be unlikely that all R&D functions would be transferred to Costa Rica. The literature suggests that developing countries, such as Costa Rica, can contribute to incremental innovation and R&D for emerging markets (see Box 1). Supplying regional value chains provides opportunities for learning and skill development before targeting more sophisticated markets. Given its experience in medical devices manufacturing, cultural affinity with both the United States and Latin America, Spanish-language skills and awareness of the particular challenges developing countries face in health care provision, Costa Rica could potentially play a role in adapting developed-world products for emerging markets and marketing these to Latin American countries. Exports to Latin America currently account for only 4% of exports, while exports to other developing countries are negligible. Attracting companies that are looking to leverage Costa Rica for exports to the Latin American market could help facilitate upgrading into higher-value R&D, marketing and sales functions.

6. Appendix

6.1. Definition of Product Categories

Table A. 1. Medical Devices Product Categories, Based on Trade Data Classifications

Product Category	Product Examples	HS Code Aggregation	HS96 Codes 6-Digit (HS02-07 changes) and PROCOMER 10-Digit[37]
Disposables	Needles, syringes, catheters, tubing, IV sets, bandages, surgical gloves	90183 3005* 401511*	901831: Syringes, with or without needles 901832: Tubular metal needles and needles for sutures 901839: Needles, catheters, cannulae etc. (medical) (changes to Catheters, cannulae & the like in HS02) • 9018391010-90: Infusion equipment • 9018399010-20: Infusion and transfusion of serum • 9018399090: Other needles and catheters, cannulae and the like 3005: Wadding, gauze, bandages and similar 401511: Surgical gloves
Medical & Surgical Instruments	Dental Instruments, Forceps, Medical Scissors, Dialysis Devices, Defibrillators	90184 90185 90189	901841: Dental drill engines (expands to dental drill engines, whether/not combined on a single base with other dental equipment in HS02) 901842: Instruments and appliances, used in dentistry 901850: Ophthalmic instruments and appliances (expands to “” nes 90.18 in HS02) 901890: Instruments, appliances for medical, etc. science, nes (expands to Instruments & appliances used in medical/ surgical/veterinary sciences, incl. other electro-medical apparatus & sight-testing instrument, nes in 90.18 in HS02) • 9018900010-30: Surgical equipment for collection of semen and artificial insemination • 9018900090: Other medical devices
Therapeutic Devices	Artificial body parts, hearing aids, pacemakers, crutches, implants, prosthetics	9021	902111: Artificial joints (changes to 902131: Artificial joints HS02) 902119: Orthopedic/fracture appliances, nes (changes to 902110: Orthopedic/fracture appliances in HS02) 902121: Artificial teeth 902129: Dental fittings, nes 902130: Artificial body parts, aids, and appliances, etc. (changes to 902139: Artificial parts of the body other than teeth, dental fittings & joints in HS02) 902140: Hearing aids, except parts and accessories 902150: Pacemakers 902190: Orthopedic Appliances, nes (expands to appliances which are worn/carried/implanted in the body, to compensate for a defect/disability (excl. of 9021.10-9021.50) in HS02)
Diagnostic / Imaging Equipment	MRI, Ultrasound machine, X-rays, Patient Monitoring Systems, Blood Pressure Monitor	90181 90182 9022	901811: Electro-cardiographs 901812: Ultrasonic scanning apparatus 901813: Magnetic resonance imaging apparatus 901814: Scintigraphic apparatus 901819: Electro-diagnostic apparatus, nes (expands to “” used in medical/ surgical/dental/ veterinary sciences (incl. apparatus for functional exploratory examination/for checking physiological parameters), nes in 90.18) in HS02) 901820: Ultra-violet or infra-red ray apparatus (expands to “” used in medical/surgical/dental/veterinary sciences in HS02) 90221: Apparatus based on the use of X-rays, whether or not for medical, surgical, dental or veterinary uses, including radiography or radiotherapy 90222: Apparatus based on the use of alpha, beta or gamma radiations, whether or not for medical, surgical, dental or veterinary uses, including radiography or radiotherapy apparatus 902230: X-ray tubes 902290: Other, including parts and accessories

Source: Authors *indicates code is not included in statistics

[37] HS1996 definitions from UNCOMTRADE and HS02-07 from UN Statistics Division.

6.2. Top Exporters of Medical Devices By Product Category, 2002-2010

Product Category #1: Disposables

The disposables product category includes products beginning with HS code 90183. This has consistently been Costa Rica's top medical-related export category since 2002.

Table A. 2. Top Five Global Exporters of Disposables by Year

Exporter	Value ($US Millions)					Share of Global Exports (%)				
	2002	2004	2006	2008	2010	2002	2004	2006	2008	2010
World	9,193	15,027	16,935	22,079	23,934					
EU-15	4,198	7,850	7,732	10,767	10,933	45.7	52.2	45.7	48.8	45.7
USA	2,386	3,258	4,267	5,171	5,662	25.9	21.7	25.2	23.4	23.7
Mexico	908	1,329	1,652	1,910	2,219	9.9	8.8	9.8	8.7	9.3
China	--	--	520	878	1,064	--	--	3.1	4.0	4.4
Japan	346	467	496	595	770	3.8	3.1	2.9	2.7	3.2
Costa Rica	336	441	--	--	--	3.7	2.9	--	--	--
Top 5	**8,173**	**13,345**	**14,666**	**19,321**	**20,648**	**88.9**	**88.8**	**86.6**	**87.5**	**86.3**

Source: UNCOMTRADE, exports of HS1996: 90183; Retrieved 8/22/12

Table A. 3. Top Five Catheters and Cannulae Exporters by Year

Exporter	Value ($US Millions)					Share of World Exports (%)				
	2002	2004	2006	2008	2010	2002	2004	2006	2008	2010
World	7,095	12,044	12,973	17,013	18,600					
EU-15	3,038	6,259	5,805	8,261	8,351	42.8	52.0	44.7	48.6	44.9
USA	2,018	2,766	3,460	4,177	4,699	28.4	23.0	26.7	24.6	25.3
Mexico	801	1,189	1,425	1,623	1,842	11.3	9.9	11.0	9.5	9.9
China	--	--	--	548	626	--	--	--	3.2	3.4
Costa Rica	336	441	454	465	527	4.7	3.7	3.5	2.7	2.8
Singapore	--	--	405	--	--	--	--	3.1	--	--
Japan	190	271	--	--	--	2.7	2.2	--	--	--
Top 5	**6,382**	**10,925**	**11,550**	**15,075**	**16,044**	**89.9**	**90.7**	**89.0**	**88.6**	**86.3**
Top EU-15 Countries										
Netherlands	1,198	1,569	2,296	2,524	2,665	16.9	13.0	17.7	14.8	14.3
Ireland	706	2,814	928	1,898	1,776	10.0	23.4	7.2	11.2	9.5
Belgium	315	513	660	1,377	1,314	4.4	4.3	5.1	8.1	7.1
Germany	260	354	515	846	986	3.7	2.9	4.0	5.0	5.3
Denmark	207	374	488	587	557	2.9	3.1	3.8	3.5	3.0

Source: UNCOMTRADE; HS1996 Code 901839; Retrieved on 8/12/12. Note: Costa Rica's first largest medical export in 2010 (by value).

Product Category #2: Surgical (or Medical) Instruments

Table A. 4. Top Five Global Exporters of Surgical Instruments

Exporter	Value ($US Millions)					Share of Global Exports (%)				
	2002	2004	2006	2008	2010	2002	2004	2006	2008	2010
World	18,260	25,170	30,870	40,844	42,959					
EU-15	8,776	12,200	14,858	19,490	19,153	48.1	48.5	48.1	47.7	44.6
USA	4,527	5,663	7,194	9,851	10,858	24.8	22.5	23.3	24.1	25.3
Mexico	778	993	1,277	1,814	2,055	4.3	3.9	4.1	4.4	4.8
Switzerland	727	1,018	1,252	1,757	1,848	4.0	4.0	4.1	4.3	4.3
Japan	904	1,215	1,355	1,593	1,654	5.0	4.8	4.4	3.9	3.9
Top 5	**15,712**	**21,089**	**25,937**	**34,505**	**35,568**	**86.0**	**83.8**	**84.0**	**84.5**	**82.8**
Costa Rica	17	38	135	151	195	0.1	0.2	0.4	0.4	0.5

Source: UNCOMTRADE: HS1996: 90184, 90185, 90189; Retrieved 8/22/12

Table A. 5. Top Five Global Exporters of Other Medical-Related Instruments

Exporter	Value ($US Millions)					Share of World Exports (%)				
	2002	2004	2006	2008	2010	2002	2004	2006	2008	2010
World	15,316	21,174	25,846	34,252	36,536					
EU-15	7,279	10,100	12,128	15,968	15,925	47.5	47.7	46.9	46.6	43.6
USA	3,914	5,019	6,407	8,800	9,681	25.6	23.7	24.8	25.7	26.5
Mexico	753	957	1,234	1,781	2,030	4.9	4.5	4.8	5.2	5.6
Switzerland	--	--	752	1,063	1,147	--	--	2.9	3.1	3.1
Singapore	464	675	--	--	1,135	3.0	3.2	--	--	3.1
Japan	631	834	896	1,021	--	4.1	3.9	3.5	3.0	--
Top 5	**13,041**	**17,586**	**21,416**	**28,634**	**29,918**	**85.1**	**83.1**	**82.9**	**83.6**	**81.9**
Costa Rica	15	37	134	151	195	0.1	0.2	0.5	0.4	0.5
Top EU-15 Countries										
Germany	2,144	2,958	4,057	5,434	5,136	14.0	14.0	15.7	15.9	14.1
Belgium	575	962	1,173	1,928	2,159	3.8	4.5	4.5	5.6	5.9
France	936	1,259	1,410	1,981	1,797	6.1	5.9	5.5	5.8	4.9
Netherlands	657	1,109	1,159	1,354	1,648	4.3	5.2	4.5	4.0	4.5
United Kingdom	998	1,147	1,297	1,247	1,153	6.5	5.4	5.0	3.6	3.2
Ireland	577	812	779	1,155	--	3.8	3.8	3.0	3.4	--
Italy	534	714	815	1,071	--	3.5	3.4	3.2	3.1	--

Source: UNCOMTRADE; HS1996 Code 901890; Retrieved on 8/12/12. Full description: Instruments & appliances used in medical/surgical/veterinary sciences, incl. other electro-medical apparatus & sight-testing instruments, nes in 90.18. Note: Costa Rica's third largest medical export in 2010 (by value).

Product Category #3: Therapeutic Devices

Table A. 6. Top Five Global Therapeutics Exporters by Year

Exporter	Value ($US Millions)					Share of Global Exports (%)				
	2002	2004	2006	2008	2010	2002	2004	2006	2008	2010
World	12,002	20,941	27,165	36,548	42,007					
EU-15	5,899	11,561	14,696	19,270	23,119	49.1	55.2	54.1	52.7	55.0
USA	3,204	4,531	5,646	7,774	8,420	26.7	21.6	20.8	21.3	20.0
Switzerland	2,037	3,001	4,228	5,511	5,772	17.0	14.3	15.6	15.1	13.7
Singapore	133	469	610	664	837	1.1	2.2	2.2	1.8	2.0
China	--	182	301	--	590	--	0.9	1.1	--	1.4
Mexico	--	--	--	481	--	--	--	--	1.3	--
Hong Kong	105	--	--	--	--	0.9	--	--	--	--
Top 5	**11,378**	**19,744**	**25,481**	**33,700**	**38,738**	**94.8**	**94.3**	**93.8**	**92.2**	**92.2**
Costa Rica	22	32	42	274	300	0.2	0.2	0.2	0.7	0.7

Source: UNCOMTRADE, exports of HS1996: 9021; Retrieved 8/22/12

Table A. 7. Top Five Artificial Body Parts, Aids, & Appliance Exporters by Year

Exporter	Value ($US Millions)					Share of World Exports (%)				
	2002	2004	2006	2008	2010	2002	2004	2006	2008	2010
World	**1,416**	**2,468**	**3,514**	**6,038**	**6,966**					
EU-15	888	1,632	2,117	2,892	3,364	62.7	66.1	60.3	47.9	48.3
USA	301	452	928	2,493	2,618	21.3	18.3	26.4	41.3	37.6
Switzerland	127	180	175	187	316	9.0	7.3	5.0	3.1	4.5
Costa Rica	--	--	--	--	203	--	--	--	--	2.9
Hong Kong	18	32	45	53	71	1.3	1.3	1.3	0.9	1.0
Mexico	--	--	--	56	--	--	--	--	0.9	--
Iceland	20	37	61	--	--	1.4	1.5	1.7	--	--
Top 5	**1,354**	**2,332**	**3,326**	**5,681**	**6,571**	**95.7**	**94.5**	**94.6**	**94.1**	**94.3**
Costa Rica	0	n/a	0	47	203	0.0	--	0.0	0.8	2.9
Top EU-15 Countries										
Netherlands	130	215	354	853	1,151	9.2	8.7	10.1	14.1	16.5
Belgium	244	425	529	620	738	17.2	17.2	15.0	10.3	10.6
France	116	189	212	360	524	8.2	7.7	6.0	6.0	7.5
Germany	159	326	444	429	374	11.2	13.2	12.6	7.1	5.4
United Kingdom	71	105	125	142	142	5.0	4.3	3.6	2.3	2.0
Austria	--	--	51	125	122	--	--	1.4	2.1	1.8
Italy	50	133	172	137	116	3.6	5.4	4.9	2.3	1.7
Sweden	--	--	64	95	95	--	--	1.8	1.6	1.4
Ireland	68	159	137	83	--	4.8	6.4	3.9	1.4	--

Source: UNCOMTRADE; HS1996 Code 902130; Retrieved on 8/12/12. (Note: this code switched to 902139 in HS2002). Note: Costa Rica's second largest medical export in 2010 (by value).

Table A. 8. Top Five Pacemaker Exporters by Year

Exporter	Value ($US Millions)					Share of World Exports (%)				
	2002	2004	2006	2008	2010	2002	2004	2006	2008	2010
World	2,830	5,386	5,852	6,163	6,819					
EU-15	1,702	3,974	3,917	4,446	4,871	60.1	73.8	66.9	72.1	71.4
Switzerland	800	882	1,248	1,044	1,261	28.3	16.4	21.3	16.9	18.5
USA	304	492	639	594	605	10.7	9.1	10.9	9.6	8.9
Hong Kong	18	24	29	45	63	0.6	0.5	0.5	0.7	0.9
Cyprus	--	5	8	23	8	--	0.1	0.1	0.4	0.1
Australia	1	--	--	--	--	0.04	--	--	--	--
Top 5	**2,825**	**5,377**	**5,842**	**6,150**	**6,808**	**99.8**	**99.8**	**99.8**	**99.8**	**99.8**
Top EU-15 Countries										
Ireland	840	1,518	1,189	1,523	1,510	29.7	28.2	20.3	24.7	22.1
France	27	912	1,307	1,170	1,238	1.0	16.9	22.3	19.0	18.1
Netherlands	479	1,166	979	1,017	845	16.9	21.7	16.7	16.5	12.4
Sweden	189	219	208	343	638	6.7	4.1	3.6	5.6	9.4
Germany	137	128	194	296	420	4.8	2.4	3.3	4.8	6.2
Italy	17	21	19	70	189	0.6	0.4	0.3	1.1	2.8
Belgium	4	--	--	--	18	0.1	--	--	--	0.3
United Kingdom	6	--	9	--	--	0.2	--	0.2	--	--
Austria	2	--	--	--	--	0.1	--	--	--	--

Source: UNCOMTRADE; HS1996 Code 902150; Retrieved on 8/12/12

Product Category #4: Capital Equipment (Diagnostic / Imaging Equipment)

Diagnostic equipment includes medical imaging machines, used to aid in diagnosis. Examples are ultrasound and MRI machines, PET and CT scanners, and x-ray machines.

Table A. 9. Top Five Global Capital Equipment Exporter by Year

Exporter	Value ($US Millions)					Share of Global Exports (%)				
	2002	2004	2006	2008	2010	2002	2004	2006	2008	2010
World	8,967	11,191	13,683	16,537	17,817					
EU-15	3,303	4,601	5,297	6,807	6,941	36.8	41.1	38.7	41.2	39.0
USA	3,140	3,388	4,399	5,030	5,484	35.0	30.3	32.2	30.4	30.8
Japan	1,215	1,545	1,631	1,886	1,786	13.6	13.8	11.9	11.4	10.0
China	--	--	--	674	980	--	--	--	4.1	5.5
Korea	--	--	366	477	501	--	--	2.7	2.9	2.8
Israel	213	258	374	--	--	2.4	2.3	2.7	--	--
Canada	193	281	--	--	--	2.2	2.5			
Top 5	**8,065**	**10,074**	**12,068**	**14,873**	**15,692**	**89.9**	**90.0**	**88.2**	**89.9**	**88.1**
Costa Rica	1	1	1	24	27	0.0	0.0	0.0	0.1	0.2

Source: UNCOMTRADE, exports of HS1996: 90181-2; Retrieved 8/22/12; Note: table does not include exports of 9022.

Table A. 10. Top Five Ultrasound Apparatus Exporters by Year

Exporter	Value ($US Millions)					Share of World Exports (%)				
	2002	2004	2006	2008	2010	2002	2004	2006	2008	2010
World	1,879	2,569	3,025	3,735	3,822					
EU-15	635	942	966	1,278	1,279	33.8	36.7	31.9	34.2	33.5
USA	443	545	748	856	905	23.6	21.2	24.7	22.9	23.7
Japan	452	639	613	644	580	24.1	24.9	20.3	17.2	15.2
China	--	--	163	313	433	--	--	5.4	8.4	11.3
Rep. Korea	102	136	228	293	295	5.4	5.3	7.5	7.9	7.7
Norway	71	75	--	--	--	3.8	2.9	--	--	--
Top 5	**3,581**	**4,906**	**5,744**	**7,119**	**7,313**	**90.6**	**91.0**	**89.9**	**90.6**	**91.4**
Top EU-15 Countries										
Netherlands	103	270	298	411	401	5.5	10.5	9.8	11.0	10.5
Germany	271	369	348	415	327	14.4	14.3	11.5	11.1	8.6
Austria	132	192	--	--	--	7.0	7.5	--	--	--

Source: UNCOMTRADE; HS1996 Code 901812; Retrieved on 8/11/12.

Table A. 11. Top Five MRI Exporters by Year

Exporter	Value ($US Millions)					Share of World Exports (%)				
	2002	2004	2006	2008	2010	2002	2004	2006	2008	2010
World	1,857	2,149	2,599	3,367	3,995					
EU-15	1,107	1,552	1,914	2,437	2,823	59.6	72.2	73.6	72.4	70.7
USA	492	334	426	441	614	26.5	15.5	16.4	13.1	15.4
Japan	211	203	159	222	245	11.3	9.4	6.1	6.6	6.1
China	22	28	67	157	200	1.2	1.3	2.6	4.7	5.0
Singapore	--	--	--	--	36	--	--	--	--	0.9
Dominican Rep.	--	--	--	58	--	--	--	--	1.7	--
Switzerland	11	13	18	--	--	0.6	0.6	0.7		
Top 5	**1,843**	**2,130**	**2,584**	**3,315**	**3,918**	**99.2**	**99.1**	**99.4**	**98.5**	**98.1**
Top EU-15 Countries										
Germany	728	871	1,101	1,246	1,318	39.2	40.6	42.4	37.0	33.0
Netherlands	271	536	685	982	939	14.6	25.0	26.3	29.2	23.5
United Kingdom	32	31	38	63	344	1.7	1.4	1.5	1.9	8.6
France	24	29	24	65	107	1.3	1.4	0.9	1.9	2.7
Italy	16	21	--	--	44	0.8	1.0	--	--	1.1
Belgium	--	--	--	--	43	--	--	--	--	1.1
Finland	20	36	26	--	--	1.1	1.7	1.0	--	--

Source: UNCOMTRADE; HS1996 Code 901813; Retrieved on 8/11/12.

6.3. Costa Rican Medical Device Firms and Exports

Table A. 12. Firms Operating in the Medical Device Value Chain in Costa Rica

	Firm Name	Origin	Year Est. in CR	Primary Categories
1	Abbot Vascular	USA	2010	Medical (Disposables)
2	Align Technology	USA	2001	Dental
3	Allergan	USA	2006	Medical (Therapeutics)
4	Amoena	Germany	1996	Apparel (Medical)
5	Arthrocare	USA	2002	Medical (Instruments)
6	Baxter Health	USA	1988	Medical (Disposables)
7	BeamOne (now Synergy Health)	USA	2009	Sterilization
8	Bentec Medical	USA	2009	
9	Boston Scientifc	USA	2004	Medical (Instruments)
10	Corbel	Costa Rican	1982	Packaging
11	Corrugados Alta Vista (Altavista)	Costa Rican	1992	Packaging
12	Covidien	Ireland	2012	Apparel (Medical)
13	Delfiplast	Costa Rican	1998	Plastic Components
14	DeRoyal	USA	1996	Electronic Components
15	Desarrollos LA de Metrología Integrada	Costa Rican	1998	Services (Calibration)
16	Electroplast	Costa Rican	1985	Manufacturing Equipment
17	Empaques Santa Ana	Costa Rican	1987	Packaging
18	Establishment Labs	Costa Rican/JV	2009	Medical (Therapeutics)
19	Etipres	Costa Rican	1985	Labeling
20	Expeditors	USA	2003	Logistics
21	FORTECH	Costa Rican	1994	Metal Finishing
22	Fotolit	Costa Rican	1956	Packaging
23	GW Plastics	JV/USA	2011	Plastic Subassembly/Components
24	Helix Medical	USA	2011	Plastic Subassembly/Components
25	Hologic Cytyc	USA	1999	Medical (Capital Equipment/ Medical Electronics)
26	Horizons International	Puerto Rico	2005	Medical (Instruments)
27	Hospira	USA	1999	Medical (Disposables)
28	Impresora Delta	Costa Rican	1972	Packaging
29	International Precision Molds	USA	2006	Manufacturing Equipment (Molds)
30	Keplac (PPC Industries)	USA	2001	Plastic Components/Medical
31	LAMBDA	Costa Rican	1986	Services (Microbiology Lab)
32	MedConx	USA	2007	Electronic Components
33	Merrill's Packaging	USA	2010	Packaging (Thermoform)
34	Met-Cal Engineering	Costa Rican	2003	Services (Calibration)
35	Micro Technologies	USA	1999	Electrical Components
36	Microfinish	USA	2002	Metal Finishing
37	MicroVention Inc	Japan	2011	
38	Moog	USA	2011	Medical (Disposables)
39	Nitinol Devices & Components	USA	2011	Medical (Instruments)
40	Oberg Industries	USA	2001	Metalwork for Instruments
41	Okay Industries	USA	2012	Subassembly/Components

42	Olympic Precision Machining	USA	1996	Metalwork Subassembly/Components
43	PolyOne	USA	2012	Resins
44	Precision Concepts	USA	1991	Medical (Disposables/Capital Equip./Medical Electronics/ Instruments)
45	Precision Wire Components	USA	2009	Metal Components
46	Prent	USA	2012	Packaging (Thermoform)
47	Proquinal	Colombian	2004	Plastic Components (Coated Fabric)
48	Resintech	Costa Rican	1970	Resins
49	SCM Metrología	Costa Rican	2002	Services (Calibration)
50	Sealed Air Corporation (ADT Thermoform)	USA	2011 (2005)	Packaging (Thermoform)
51	Serpimetal	Costa Rican	2001	Metal Finishing
52	SMC	USA	2011	Medical (Instruments/Disposables)
53	Smith Sterling	Costa Rican	1994	Dental
54	Source One	USA	2011	
55	Specialty Coating Systems	USA	2006	Metal Finishing (Coating)
56	St. Jude Medical	USA	2010	Medical (Therapeutics)
57	Sterigenics	USA	2012	Sterilization
58	SUPLILAB	Costa Rican	1993	Services (Microbiology Lab)
59	Tegra Medical	USA	2007	Metalwork Subassembly/ Medical (Instruments)
60	Vention Medical (ATEK & Medtech)	USA	2004	Medical (Disposables)
61	Verdiam (Point Technologies)	USA	2005	Electronic Subassembly
62	Volcano Corporation	USA	2012	Medical (Therapeutics)
63	West Star Medical (Estrella de Precision Tecnologica)	USA	2000	Metalwork Components/Subassembly
64	WestPort SA (Koros USA)	USA	2007	Medical (Instruments)
65	Wright Medical	USA	2010	
66	Yanber	Costa Rican	1953	Plastic packaging

Note: medical with a product category in parenthesis indicates that over 50% of exports in 2011 are in a category in the Appendix table (when it is listed first).

Table A. 13. Costa Rica Medical Devices Exports By Product Category, 2002-2010

Description	HS Code	Exports (Thousands, US$)					Share of Exports (%)				
		'02	'04	'06	'08	'10	'02	'04	'06	'08	'10
Disposables	90183	336,926	440,884	453,982	465,070	570,681	89	86	72	51	51
Instruments	90184-9	17,456	37,752	134,749	151,381	205,207	5	7	21	17	18
Therapeutics	9021	22,286	32,579	42,341	273,890	315,698	6	6	7	30	28
Capital Equipment	90181-2	1,104	1,335	1,272	24,673	28,266	0	0	0	3	3
Total		377,772	512,549	632,343	915,015	1,119,851	100	100	100	100	100

Source: Procomer, 2012

6.4. Regulation of the Medical Device Markets

Table A 14. Regulation of Medical Devices in Major Markets

US Regulations			
Device Classification	Risk Level	Control Type	Examples
Class I	Low risk	Subject to general controls regarding labeling, manufacturing, post-market surveillance and reporting.	Elastic bandages, examination gloves, hand-held surgical instruments
Class II	Moderate risk	General controls are insufficient to provide reasonable assurance of safety and effectiveness. Special controls may include performance standards, design controls and post-market surveillance programs.	Powered wheelchairs, infusion pumps, surgical drapes
Class III	High risk	General and specific controls are insufficient. These devices are either life sustaining or supporting, of substantial important in preventing impairment of human health, or present a high risk of injury/ illness.	Heart valves, silicone gel-filled breast implants
European Union[1]			
Device Classification	Risk Level	Type of Device Control	Example
Class I	Low risk	No notification required.	Blood pressure cuff
Class Is (sterile)		Conformity assessment	
Class Im (measurement)		Conformity assessment	Thermometer
Class IIa	Medium to high risk	Conformity assessment	
Class IIb		Conformity assessment	
Class III	High risk	Conformity assessment, Clinical investigation (specific controls)	Coronary stent
Japanese Regulations			
Device Classification	Risk Level	Type of Device Control	Example
Class I:	Extremely low risk	General medical devices.	X-ray film.
Class II	Low risk	Controlled medical devices.	Magnetic resonance imaging (MRI) scanners and digestive catheters
Class III	Medium risk	Specially controlled medical devices	Artificial bones and dialysers
Class IV	High risk	Specially controlled medical devices	Pacemakers and artificial heart valves

Note: [1]Following changes to the European regulatory system in 2010, software for use in the medical devices sector has been recognized as a stand alone device and is now subject to validation (McHugh et al., 2012).

6.5. Stakeholders Interviews

Table A. 14. Stakeholder Interviews

Organization	Individual(s) Interviewed
Non-Firm Actors Interviewed	
AZOFRAS	Alvaro Valverde, Executive Director
CINDE	Irving Soto, Director, Investment Promotion Douglas Sanchez, Deputy Director, Investment Promotion Carolina Umaña, Investment Promotion Manager, Advanced Manufacturing Sandro Zolezzi, Director of Research
Costa Rica – Provee	Rolando Dobles, Export Linkages Director
INCAE	Arturo Condo, President
Instituto Nacional de Aprendizaje	Ileana Leandro Gómez, Gestora Tecnologica Luis Alejandro Arias Ruiz, Jefe Nucleo Eléctrico
Ministerio de Comercio Exterior (Comex)	Francisco Monge
Ministerio de Educación Pública	Dirección de Educación Técnica y Capacidades Emprendedoras Fernando Bogantes Cruz, Director
Procomer FTZ Regimen	Laura Chaves, Analista de Informes Anuales Andrea Cespedes, Advisors Coordinator Andres Villalta, Coordinador de Regímenes
Procomer	Francisco Gamboa, Trade Intelligence Director

Table A. 15. Exchange Rate, Colones to US Dollar

	2002	2003	2004	2005	2006	2007	2008	2009	2010	2011
Colones to US$1	376.4	418.7	458.1	496.7	517.3	496.5	558.4	553.5	503.1	504.7

Source: www.xe.com 21/08/2012

Note: Based on December 31 of each year

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