

Pakistan in the Medical Device Global Value Chain

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Acronyms

ADOZONA	<i>Asociación Dominicana de Zonas Francas</i> (Dominican Association for Free Trade Zones)
AMMI	Association of Malaysian Medical Industries
ATC	Apprentice Training Center, Pakistan
CAFTA-DR	Central American Free Trade Agreement
CARIFORUM	Forum of the Caribbean Group of African, Caribbean and Pacific States
CMC	Community Manufacturing Center
CNC	Computer Numeric Control
CNZFE	<i>Consejo Nacional de Zonas Francas de Exportación</i> (National Council of Export Processing Zones)
EAP	East-Asia Pacific
EGFSN	Expert Group on Future Skills Needs
E-O	Ethylene-Oxide
EPZs	Export Processing Zones
EU-15	European Union
FDA	Food and Drug Administration, United States
GVC	Global Value Chains
HAI	Hospital Acquired Infections
ILO	International Labor Organization
IMDRF	International Medical Device Regulators Forum
M&As	Mergers and Acquisitions
MDA	Medical Device Act (Malaysia)
MFN	Most Favored Nation
MIDA	Malaysia Industrial Development Authority
MIDC	Metal Industries Development Center, Pakistan
MMDA	Malaysia Medical Device Association
MNCs	Multinational Corporations
MRI	Magnetic Resonance Imaging
NB	Notifying Bodies
PSQCA	Pakistan Standards and Quality Control Authority
R&D	Research and Product Development
SCCI	Sialkot Chamber of Commerce and Industry
SIMAP	Surgical Instruments Manufacturers Association of Pakistan
SIMTEL	Sialkot Material Testing Laboratory
SMEs	Small and Medium Sized Enterprises
T&A	Textiles and Apparel
TDAP	Trade Development Authority of Pakistan
TEVTA	Technical Education and Vocational Training Authority, Pakistan
UID	Unique Identification
UK	United Kingdom
US	United States of America
WHO	World Health Organization

I Introduction

Pakistan is a long-established actor in the medical devices global value chain (GVC), a multi-billion global dollar industry covering a wide spectrum of products from inexpensive, single use items such as bandages and dressings, to high-cost, state of the art capital equipment, such as magnetic resonance imaging (MRI) machines. For years, Sialkot, Pakistan has been a traditional global cluster for export-oriented contract manufacturing of precision metal instruments used in general surgery. Success to date has been based on decades of production experience passed down generation to generation, combined with low-cost labor supply. However, changing dynamics in the global medical device industry mean that past drivers of competitive advantage are becoming less relevant. Pakistan has seen its medical devices exports plateau in recent years as new products and competitors have entered the market. In order to sustain its participation in the industry, Pakistan needs to adopt a specific growth strategy based on improved efficiencies, entry into new markets and diversification of production.

Since the turn of the century, the global medical devices industry has experienced considerable growth, reaching US\$360B in 2017, as populations have expanded and aged, diseases spread and health care coverage increased. This growth has created new opportunities but it has also been accompanied by significant changes in the industry that have important implications for Pakistan's sustained participation. First, technological advancements in surgical techniques and production capabilities have become to shift the demand away from traditional surgical instruments to new, smaller and smarter tools that reduce patient risk and recovery time. Second, high health care costs and regulatory requirements have led to the restructuring of the value chain around fewer, larger and more diversified firms; this has created considerable barriers for entry in established markets. Third, in response to these pressures, lead firms are consolidating production in select locations with strong capabilities in a diverse range of products, from surgical instruments to highly regulated implantable devices. Opportunities for growth still exist in emerging markets, where healthcare expenditure is increasing, however, this window will be limited as lead firms seek to gain market share in these growth regions. As a result, as has occurred in multiple globalizing industries, small, less innovative firms struggle to maintain their positions in key markets and are often pushed down the chain into low-margin contract manufacturing activities.

While Pakistan's exports have grown steadily along with global industry trade in the past decade to reach US\$355M in 2016, Pakistan remains a small-scale exporter globally of surgical instruments and recent years show a notable slowdown as new products and competitors have entered the market and internal human capital deficiencies and inefficient production practices have stifled the industry. In order to sustain its position in the industry, Pakistan needs to adopt a specific growth strategy that engages both public and private sector actors towards common goals. Specifically, Pakistan should upgrade production processes to increase productivity, diversify its product portfolio and strengthen ties with emerging markets. The country's past success in textiles and apparel also offer an opportunity for the country to become a more significant player in the medical textiles industry. Policies supporting these upgrading trajectories will need to capitalize on strengths of the industry, including its reputation as a low-cost supplier and existing geographical concentration of firms while also addressing human capital, institutionalization, and production challenges.

Numerous reports have documented Pakistan's production of precision metal surgical instruments over the past two decades. However, these reports fail to consider the broader forces that are changing the medical devices industry as a whole, which will have important implications for Pakistan's continued participation in the industry. This report therefore seeks to situate Pakistan's

production of surgical instruments into the broader medical devices GVC. This GVC framework will allow policymakers to better understand how the global medical device industry is evolving, assess Pakistan's current position in the chain and identify opportunities for economic upgrading. Research on Pakistan is aided by field research conducted in September 2018. In total, 15 interviews with key stakeholders across three cities (Sialkot, Lahore, and Karachi) were completed. Private sector actors of varying sizes accounted for the majority of interviews (73%) and 85% of all participants were located in Sialkot. Interviews were further aided by firm level data based on Pakistan Custom's Authority data provided by the World Bank.

The report is structured as follows: It first provides an overview of the medical devices GVC to present a clear understanding of the scope of the industry, how markets are structured and how changing distribution of demand and supply destinations and lead firm organization alter structural dynamics in the chain. It then analyzes the domestic industry within Pakistan, first detailing the country's position in the chain as well as recent trends and the internal organization of the industry. After assessing the advantages and constraints observed in Pakistan, it looks to the Dominican Republic and Malaysia for comparative case studies, detailing the lessons learned for Pakistan. The report concludes by outlining potential upgrading strategies to enhance the country's competitiveness.

2 The Medical Device Global Value Chain

Key Takeaways

- The global medical device industry is a US\$360B industry and covers a wide spectrum of products from inexpensive bandages, to technology-intensive hearing aids and high-cost items such as magnetic resonance imaging (MRI) machines. Surgical/Medical instruments, the largest segment, represents 28% of exports.
- A few select locations have been prioritized by device companies, particularly for lower cost products in disposables and surgical instruments; these sites are now shifting into higher value orthopedics and implantables products.
- The use of hand-held precision instruments for general surgery has dominated the healthcare market for decades, in recent years the emergence of new, less invasive surgical techniques has begun to drive demand for a new set of tools.

2.1 The Global Medical Device Industry

Surgical/Medical instruments are part of a broader global medical devices industry. Covering a wide spectrum of products from inexpensive bandages, to technology-intensive hearing aids and high-cost items such as magnetic resonance imaging (MRI) machines, the medical devices sector is a strong, global growth industry.¹ The global market reached an estimated US\$360B in 2017 (BMI Research,

¹ 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, 2017).

2018a), while trade in 2016 at US\$203B (UN Comtrade, 2018).² Surgical instruments represent an important share of global medical device industry trade, accounting for approximately 27-30% over the past two decades and US\$56B in 2016 (UN Comtrade, 2018).

Advances in science and technology, surgical techniques, an aging global population and increased access to more advanced medical care around the world, continue to drive demand in the industry and foster the development of new products. Developed country markets are mature, with low but steady growth rates, but they still remain the most valuable accounting for over three-quarters of the global market share (Frost & Sullivan, 2017). Recently, however, developing countries have emerged as key growth opportunities thanks to rising incomes, aging demographics, and government increases in per capita healthcare expenditure, particularly an expansion of healthcare beyond major cities (BMI Research, 2018a; CFRA, 2018).

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. At the same time, nonetheless, faced with rising health care costs, governments and health care organizations have begun to apply coordinated procurement and reimbursement³ models to gain leverage with suppliers (BD, 2018; Boston Scientific, 2018; Medtronic, 2018). As a result, the medical devices sector has begun to focus on global production networks to improve economic efficiencies, and harness qualified human capital abroad.

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 lucrative sector. Numerous countries from Latin America (Brazil, Costa Rica, Dominican Republic, Mexico) and Asia (China, India, Malaysia, Singapore, Taiwan) have developed industrial policies to attract this global expansion, targeting both foreign direct investment and domestic firms alike (Bamber & Frederick, 2018; BMI Research, 2018a; Field Research, 2018b; World Bank, 2011).

The following sections present the medical devices GVC, 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 these global dynamics, these sections provide a “blue print” for Pakistan policy makers as the country develops its strategic plan for future growth.

Three major trends have shaped the global medical devices industry in general, and the instruments sector specifically in recent years: (1) demand has been growing for minimally invasive surgical instruments; (2) shifting regulatory environment; and (3) rise of select offshore locations. Each is discussed below.

² The products included in this measure are detailed in Table A- 1 of the Appendix. Trade data was analyzed for the period 2006-2016. 2016 was the latest available comprehensive data at the time of publication. 2017 trade data was incomplete and therefore misleading.

³ Reimbursement procedures, whereby health insurance organizations agree to finance particular procedures, can act as a barrier to entry for new products. Due to their high prices, many medical devices are beyond the reach of 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.

Growth in demand for minimally invasive surgical instruments. While the use of hand-held precision instruments for general surgery has dominated the healthcare market for decades, in recent years the emergence of new, less invasive surgical techniques has begun to drive demand for a new set of tools. Minimally invasive or ‘keyhole’ surgery has grown in popularity in advanced healthcare markets thanks to the reduction in recovery time and hospital stays, and overall reduced risk. Large surgical instrument manufacturers have invested considerably in bringing new laparoscopic and endoscopic devices to market, training surgeons and encouraging a shift to these new tools. This tendency has combined with the demand for single-use instruments as health care providers seek to manage per-patient costs and reduce potential liability from hospital-acquired infections.

Increasingly strict regulatory environment. The regulatory environment is changing globally due to changes in the European Union (EU-15), the withdrawal of the United Kingdom (UK) from the EU-15, the adoption of new frameworks by emerging markets, as well as a revision of the requirements of the Food and Drug Administration (FDA) in the United States. Regulators maintain that these changes are designed to improve the safety and efficacy of products on the market, as well as to stimulate innovation. However, these changes – such as the new European Union requirements for re-registration of all products – raise costs and uncertainty for manufacturers of medical devices around the world. These changes will be particularly challenging for small and medium sized enterprises (SMEs) to withstand and supportive policies must be considered.

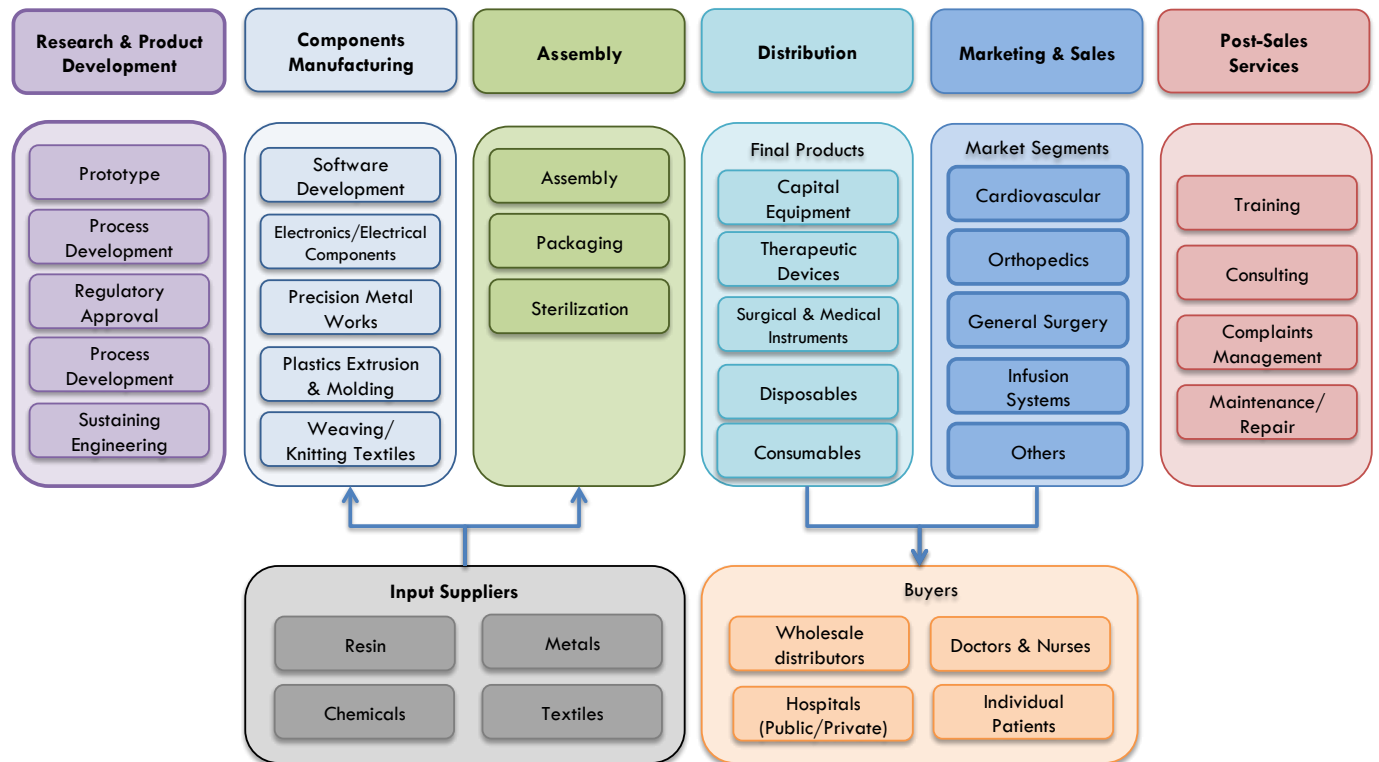
Consolidation of select offshore production locations. Albeit slower than other manufacturing industries (Brocca et al., 2017), medical devices producers have launched offshore production strategies to help reduce their costs and access new markets. Overall, a few select locations have been prioritized by device companies, particularly for lower cost products in disposables and surgical instruments; these include Ireland, Mexico, Singapore, Costa Rica, Dominican Republic and Malaysia. ‘Medtech’ has become a prioritized sector in these countries and clusters of foreign and local firms have emerged. These countries are steadily consolidating their share of, and ranking in, global exports (see Table 3) favored for their combination of capable workforce, geographic location for access to market, supportive export policies, and oversight in intellectual property protection (Bamber & Frederick, 2018; Bamber & Gereffi, 2013; BMI Research, 2018a; Giblin & Ryan, 2012). While these sites began in lower cost product segments, the fastest growth segment over the past decade are in higher value orthopedics and implantables (i.e. therapeutics; see Table 4).

2.2 The Medical Devices Global Value Chain

First, an overview of the broader medical devices GVC is provided followed by more specific stages involved in the development of medical and surgical instruments in particular, such as precision metal works. 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 policy makers to more accurately map Pakistan’s current and potential opportunities in this global industry as a whole, rather than taking a monoscopic approach focused solely on surgical instruments. Due to the growing overlap in ownership, production, distribution and buyer behavior across the range of products in the medical devices sector, understanding trends and changes in the surgical and medical instruments sector is best understood by analyzing them in their broader context.

This report utilizes the medical devices GVC defined by Bamber and Gereffi (2013) to provide the broader context of the industry (see Figure 1).

Figure 1. Medical Devices Global Value Chain



Source: Authors based on Bamber and Gereffi (2013)

Note: For simplicity and relevance for Pakistan categories such as respiratory devices are not displayed.

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 can be a lengthy process, depending on the market's regulatory approach, the risk category of the device and clinical trials required. Generally, inputs and production processes must be validated 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. Lead firms often acquire 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. In recent years, R&D in the medical and surgical instruments category has focused on the development of minimally invasive devices.

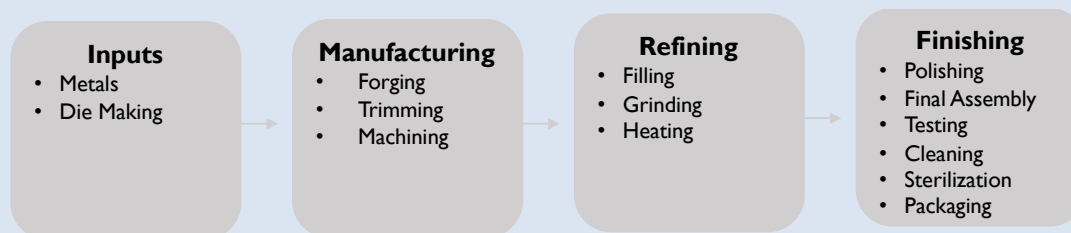
The **production segments, components manufacturing and assembly, are typically the lowest value-added segments** of the chain and are comprised of several different functions

depending on the final product. Box 1 details the production stages of precision metal instruments. Finally, 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 takes place using one of several methods: E-beam (electrons are accelerated through the product); ethylene-oxide (E-O) (product is sterilized by gas); and gamma ray sterilization are amongst the most commonly used. 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. Sterilization in production locations allows for direct sales shipments.

Box 1. Production of Precision Metal Medical and Surgical Instruments

Precision metal medical and surgical instruments are used in a variety of procedures. While several instruments exist, the production process is similar for all of these products (see Figure 2).

Figure 2. Production Stages for Precision Metals



Source: Authors.

Raw materials: Consist primarily of metal inputs; the specific metal used varies by buyers' needs. The most common metal used is stainless steel but other materials such as titanium and tungsten carbide may also be used. Within stainless steel, magnetic and non-magnetic steel categories are used depending on the specific instrument being produced. Quality of inputs is an important consideration and buyers may specify the precise origin of metal inputs and the grade of the metal to be used.

Manufacturing: This is labor intensive and involves a series of complex steps, several of which can be geographically separated: First, a die is made for the instrument, followed by *forging* when hot metal is placed into the die-casting and struck to forge the shape needed. This can be done mechanically or manually depending on the firm's level of sophistication; mechanical processes allow for higher volumes and reduced waste. The instrument is then trimmed and machined to achieve the desired shape. Maintaining a constant temperature of the forge ensures better quality by reducing stress and softening the product for further processing. Refining then occurs where joints and grooves are fashioned and the desired edges produced. The instrument is then re-heated to harden the metal. Throughout production, a constant temperature must be maintained (*annealing*) to avoid brittleness and guarantee quality.

Finishing: Polishing, cleaning and packaging of the instrument. Tests are performed to insure against environmental and chemical corrosion and devices are cleaned using an ultrasonic cleaner to remove dust particles.

Sources: Field Research (2018a); Liaqat (2013)

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

or catalogues. 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. 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. Products might also be sold as *integrated solutions*, which combine medical devices, training, consulting and other post purchase services. Sales channels for medical and surgical instruments vary by type; disposables are often sold in surgical kits packaged with items such as surgical drapes while reusable instruments such as forceps and retractors are sold through direct orders (Field Research, 2017).

In the face of rising health care costs, buyers are improving their negotiating positions by 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 (Medtronic, 2018; Seligman, 2012). Increased competition to become selected suppliers means that medical devices manufacturers spend significantly on direct marketing and building relationships with clients. As early as 2010, it was estimated that in Europe, 56% of the cost base for a product is spent on marketing and sales (Frost & Sullivan, 2010).

Finished products: Surgical and medical instruments are one of a number of product categories in the medical devices sector. For this report, the following categories are used: (1) Consumables;⁴ (2) Disposables; (3) Surgical and Medical instruments; (4) Therapeutic Devices; (5) Capital Equipment; and (6) Other Devices (Bamber & Gereffi, 2013; Sturgeon et al., 2015). These are detailed in Table I.⁵

⁴ Consumables can also be considered a medical supply rather than device; nonetheless, they are becoming increasingly sophisticated and potential substitutes for medical devices including sutures and thus are included in the analysis.

⁵ Detailed definitions of each of these product categories by trade codes are available in Table A-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. Medical and surgical furniture, such as hospital beds, were not included in this study.

Table I. Medical Devices Categories based on Use, Characteristics and Production Expertise

Product Category	Examples	Characteristics	Production Capabilities/Medical Expertise
<i>Consumables</i>	Bandages and dressings	Highly cost driven	Compliance with cleanroom standards; generally, not subject to regulatory controls/standards
<i>Disposables</i>	Plastic syringes, catheters and needles, sutures	Single-use products; highly cost driven	Compliance with specific medical devices standards
<i>Surgical and medical instruments</i>	Forceps, medical scissors and dental drills, as well as specialized minimally invasive surgical instruments	Multi-use products sterilized between uses; single-use versions of the same instruments; cost-driven	Compliance with specific medical devices standards
<i>Therapeutic devices</i>	Hearing aids, pacemakers and prosthetics	Implantable and non-implantable devices to help people manage physical illness or disability; quality and skill driven	their prolonged use inside the body, the production of implantable devices requires considerable expertise, particularly with respect to bio-compatibility
<i>Capital equipment</i>	Ranges from infusion pumps and blood pressure monitors to considerably large investments such as MRI equipment or computed tomography	Single-purchase equipment used repeatedly over a number of years; large, long-term investments	Medical and electronics expertise
<i>Other Devices</i>	Breathing devices, oxygen therapy devices, gas masks, massage equipment	Multi-use products for single users; single-use products;	Compliance with specific medical devices standards

Source: Authors.

Each of these product categories represents a wide range of products. The surgical and medical instruments category, for example, represents thousands of distinct devices (Box 2). Variation among products is common depending on specific use and material used in production. Instruments are further classified by their use, which is often determined by the quality of inputs and the quality of production; these classifications include:

- **Surgical Operation Room Quality** - this is the highest quality of instruments using the best grade steel input for forging and with high expectations for quality shaping and grinding.
- **General medical use** - these instruments are reusable instruments but have a slightly lower quality than operation room grade
- **Single use instruments**⁶- these use lower quality steel inputs and are designed for single use. This category is growing in popularity in developed markets because they eliminate the need for sterilization and remove risk of contamination across patients (Field Research, 2018a).

⁶ Defined by the FDA as “intended for use on one patient during a single procedure . . . and is not intended to be reprocessed (cleaned, disinfected/sterilized) and used on another patient (FDA, 2015).”

Box 2. The Shifting Nature of Surgical and Medical Instruments

Traditionally, this product segment has been considered mature with little product differentiation beyond branding and cost. Well-established products include forceps, retractors, surgical scissors, needle holders and scalpels, measuring instruments amongst others. Over the past two decades, however, two major trends have begun to shift the dynamics of this segment.

First, notable technological and medical advances have made surgeries easier and faster to perform, improved outcomes and reduced both surgical and post-op complications. These include advances in powered devices, minimally invasive instruments and surgical robotics. This has been driven by significant R&D activity; globally, close to 60,000 patents have been filed in the past ten years for endoscopic devices alone. Although adoption has been uneven, applications of these tools cover most major fields, including neurosurgery, cardiovascular, orthopedic, plastic and reconstructive surgery.

Second, demand has grown for single-use surgical instruments to manage hospital acquired infections (HAI) resulting from improper or inadequate sterilization of multi-use devices, and to increase responsiveness to pricing requirements from healthcare insurers (Freedonia, 2016). Some growth estimates suggest that demand for single-use products is expanding at twice the rate of reusable products.

These trends vary by market. The shift to minimally invasive instruments has been particularly important in high-income countries (which account for the bulk of medical devices spending), while middle- and low-income countries have been slower to shift. Between 2010 and 2015, there was a notable increase of minimally invasive instruments for surgical procedures in the EU for the most common surgeries, including laparoscopic appendectomies and hysterectomies.

Although lower-income countries face challenges in sterilization of reusable instruments, the demand for these instruments continues to be stronger than for single-use versions as healthcare providers seek to contain costs in the face of small budgets. North America leads demand for single-use instruments with an estimated 33% of the market in 2018, followed by Europe with 26%.

Sources: (BCC Research, 2014; Eurostat, 2017; WIPO, 2018). **Note:** Search parameters for WIPO database were A61B, endoscope & endoscopic, AD: 2007-2018.

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 have been the two leading market segments for most of the past decade (Frost & Sullivan, 2017; Markets and Markets, 2011).

While large firms today have become highly diversified in the end markets they serve, due to the level of expertise and innovation required in the production of each device, smaller and medium size manufacturers tend to specialize in one or more **specific end market** (Field Research, 2017; Simoens, 2009). 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).

Finally, **post sales services or post-market services** include training on equipment and consulting, account management for the supply of accessories, maintenance and repairs as well as regulatory requirements such as *adverse events or complaints handling* (Ghemawat, 2007; WHO, 2017). As embedded software and sensors grow in their importance in the industry, post sales analytics and corresponding services are becoming increasingly important differentiators amongst firms (Frost & Sullivan, 2017).

2.3 Global Trade in the Medical Devices Global Value Chain⁷

Global trade in medical devices has expanded considerably since 2000 in response to growing populations, increased access to healthcare and efforts to increase production efficiencies. Between 2002-2016, trade more than doubled, and growth remained robust – albeit, slowing – following the global economic crisis in 2008. Trade is generally in final products as many companies operate vertically integrated production sites.⁸

Demand is highest amongst high-income groups but it is growing fastest amongst upper middle and lower middle-income group countries. The EU-15, led by Germany, remains the strongest source of both demand and supply, yet, its shares of the global markets have declined since 2006. China has steadily gained market share; indeed, Chinese growth rates in demand and supply have outstripped all other countries since 2002. On the supply side, in absolute terms, export value has grown in almost all locations. Fewer than 5 of the leading 50 exporters in 2016 have experienced a decline in exports since 2006 (e.g. UK, Indonesia, and Sweden). Growth rates, however, vary across countries as several production locations have consolidated their position within the value chain (e.g. Mexico, Singapore, Ireland), and new sources of demand have emerged in response to increased spending on healthcare (e.g. East Asia & Pacific, South Asia and Latin America and the Caribbean).

This section analyses these major global trends to provide a broader context for Pakistan's potential growth trajectories, in addition to analyzing the evolution of the surgical/medical instrument segment.

2.3.1 Global Demand

Global demand is driven by high-income countries, which accounted for 81% of all medical devices imports in 2016. Middle-income countries, however, are emerging as new markets. In 2002, these absorbed just 12% of imports; by 2016, these had reached a combined 19% (Table 2), representing approximately US\$39B in healthcare imports.

⁷ Global trade analysis is based on the following six product categories: Disposables, Instruments, Therapeutics, Capital Equipment, Consumables and Respiratory Devices. The details for each of these categories can be found in Table A-1 in the Appendix.

⁸ The capital equipment segment is a notable exception as many of the components are sourced from specialized suppliers within the electronics GVC. Although there is considerable flow in raw materials across borders, due to their application in multiple sectors basic trade statistics cannot isolate these.

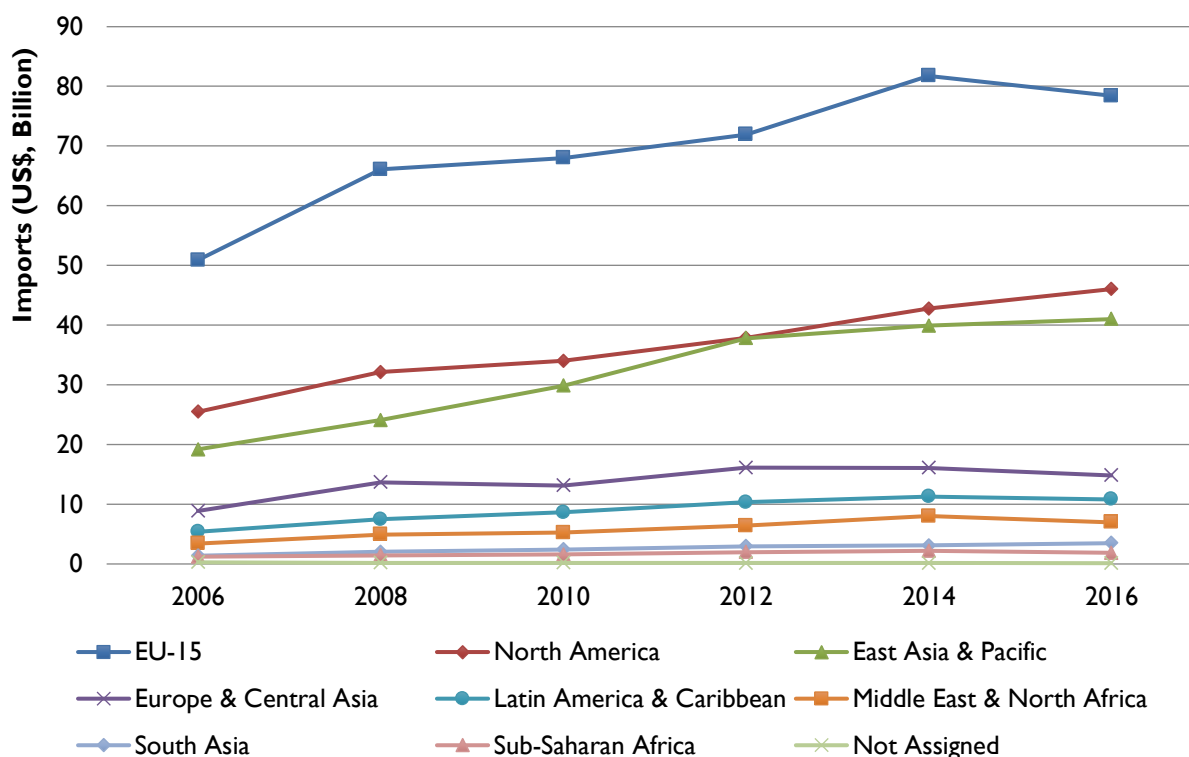
Table 2. Global Medical Devices Imports, by Income Level Group 2002-2016

Income Group	Share of Imports (%)								Growth Rates	
	2002	2004	2006	2008	2010	2012	2014	2016	2002-2016	2006-2016
High Income	87	87	85	83	82	80	80	81	203	66
Upper Middle Income	10	10	11	13	14	16	15	15	382	133
Lower Middle	2	3	3	3	4	4	4	4	454	130
Low Income	0	0	0	0	0	0	0	0	262	81
World	100	100	100	100	100	100	100	100	227	75

Source: UN Comtrade (2018) Based on HS-2002 product categories defined in Table A-1; all exporters; downloaded 27/08/2018. **Note:** Income group level based on World Bank classifications (See World Bank, 2017).

With a large population, and high healthcare expenditure, the EU-15 leads the demand for global imports of medical devices (Figure 3). EU-15 demand is dominated by the top five importers (Germany, Netherlands, Belgium, France, and the UK). North America and East-Asia Pacific (EAP) follow, with similar market shares (23% and 20% respectively in 2016). North American demand is led by the US, while EAP demand is more diversified amongst several countries (e.g. China (30%), Japan (25%), Australia (10%) Rep. of Korea (7%), Singapore (7%). Nonetheless, the fastest growing markets globally are Asian; EAP and South Asia grew at 114% and 153% over the past decade (compared to global 75%). Low health care spending, however, in several countries in South Asia (BMI Research, 2018a), including Pakistan and Bangladesh, underscores the uneven demand across the region.

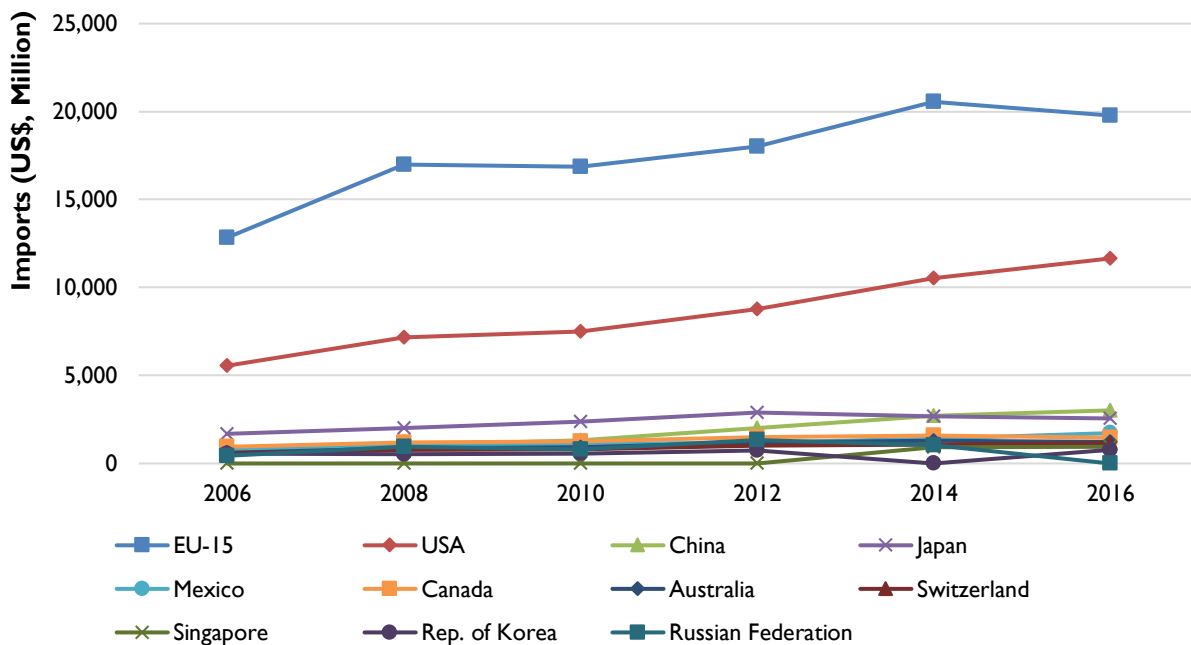
Figure 3. Imports of Medical Devices by Geographic Region (US\$, Billion), 2006-2016



Source: UN Comtrade (2018). Based on HS-2002 product categories defined in Table A-1; all exporters; downloaded 27/08/2018.

In 2016, surgical/medical instruments category accounted for the largest share of trade by value (28%), followed by therapeutics (25%) and capital equipment (21%) (see Table 3). The category has grown at a slightly higher than the average rate of 81% (2006-2016). The mature, low value and low weight and general use characteristics of these products makes them highly tradable. While the EU-15, led by Germany, accounts for the strongest share of demand for instruments (35%), this has declined by approximately 6% over the past decade. The UK represents just 10% of EU-15 demand and 3.6% of global demand, valued at just under US\$2B in 2016. Of the leading importers, China is by far the highest growth market, growing at 365% (2006-2016), followed by Mexico at 117% (Figure 4). All leading markets experienced considerable growth in absolute terms; the slow redistribution of market share is thus indicative of the rising demand for healthcare products in emerging markets rather than a decline in demand in traditional markets.

Figure 4. Top Ten Global Surgical/Medical Instruments Importers (US\$, Million), 2006-2016



Source: UN Comtrade (2018). Based on HS2002: 90184, 90185, 90189, Retrieved 7/27/18

2.3.2 Global Supply

The industry is dominated by mature manufacturing locations in the US and EU-15; these two origins accounted for close to two-thirds of all exports in four of the six product categories analyzed, and over half in the two remaining product segments (Table 3). Once a strong third contributor, Japan's share of global supply has declined; a leading exporter in 2002 in all categories, by 2016, it was only a top five exporter in the more specialized capital equipment product segment. Within the EU-15, Germany is the most important exporter, growing at 204% between 2006-2016, almost three times the rate of the global average.

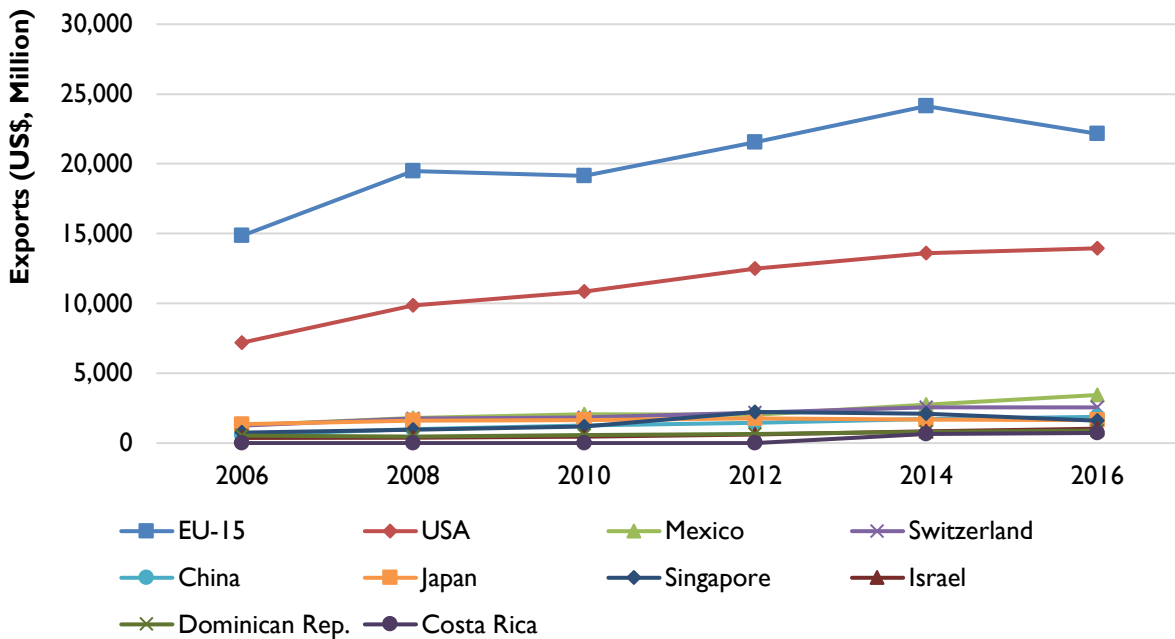
Table 3. Top Five Global Exporters by Product Category, 2016

Exporter	Disposables		Capital Equipment		Therapeutics		Instruments		Consumables		Other	
	Value	Share (%)	Value	Share (%)	Value	Share (%)	Value	Share (%)	Value	Share (%)	Value	Share (%)
World	34,944	17.2	41,704	20.5	51,375	25.2	56,074	27.5	7,275	3.6	12,240	6.0
EU-15	15,734	45.0	17,807	42.7	27,969	54.4	22,176	39.5	3,608	50%	3,533	28.9
USA	7,359	21.1	9,372	22.5	9,308	18.1	13,951	24.9	709	10%	2,733	22.3
China	1,989	5.7	3,129	7.5	1,387	2.7	1,879	--	1,295	18%	2,733	22
Switzerland	--	--	--	--	6,110	11.9	2,555	4.6	--	--	--	--
Mexico	2,889	8.3	--	--	--	--	3,443	6.1	--	--	--	--
Japan	--	--	3,624	8.7	--	--	--	--	--	--	--	--
Singapore	--	--	--	--	1,633	3.2	--	--	--	--	838	6.8
Rep. of Korea	--	--	1,190	--	--	--	--	--	--	--	--	--
Costa Rica	1,142	--	--	--	--	--	--	--	--	--	--	--
Australia	--	--	--	--	--	--	--	--	--	--	672	5.5
Czechia	--	--	--	--	--	--	--	--	306	4%	--	--
Top Five	29,112	80.0	35,122	81.4	46,407	90.3	44,004	75.1	5,918	81	10,509	86
EU-15+US	23,092	66.1	27,179	65.2	37,277	72.6	36,126	64.4	4,317	59	6,266	51
HS02 Codes	90183*		90181*, 90182*, 9022, 841920		9021*		90184*, 90185*, 90189*		300590, 300510		9019, 9020	

Source: UN Comtrade (2018). Based on HS-2002 product categories defined in Table A-1; all exporters; downloaded 27/08/2018.

Surgical and medical instruments, regionally, is led by the EU-15 and the North America, although two key countries, the US (US\$13.9B) and Germany (US\$7.7B) dominate supply, accounting for 53.2% of exports in 2016 (Figure 5). While a large share of this output is manufactured in these countries, firms do also undertake final branding, labeling, repackaging and sterilizing of products produced in other locations. The EU-15, however, has steadily lost close to 10% of the market share since 2006; France, Sweden, Spain and the UK have all seen their exports of these instruments decline in absolute terms during this period.

Figure 5. Top Ten Exporters Surgical/Medical Instruments, by Year 2006-2016



Source: UN Comtrade (2018). Based on HS2002: 90184, 90185, 90189, Retrieved 7/27/18

Several emerging sites have joined mature manufacturing locations and steadily consolidated their positions within the medical devices value chain. These include China, Mexico, Singapore, Republic of Korea, Costa Rica and Malaysia. Newcomers China, Malaysia and Costa Rica, in particular, have grown very fast - three to four times (227%, 300%, 296% respectively) the global average over the last decade. These locations generally entered global trade through one product category and have either gained export share in that category, diversified into multiple categories or both (see Table 4). The fastest growing product category for the majority of these countries today is the therapeutics segment. Surgical/Medical instruments, nonetheless, is a key product category for these locations; Mexico, China, Singapore, Dominican Republic and Costa Rica have all joined the top ten global exporters in this category since 2002. With the exception of China, with few local lead firms of their own, exports of these countries are dominated by multinational corporations (MNCs) and the strengthening of these exporters is illustrative of the industry's general strategy to protect its intellectual property and quality by offshoring to a select number of strategic locations.

Table 4. Growth of Selected Offshore Production Locations

Country	Total Exports, 2016		Leading Product Category, 2016			Fastest Growth Product Category, 2016	
	Value (US\$ millions)	Growth Rate 2006-2016 (%)	Category	Share (%)	Growth Rate 2006-2016 (%)	Category	Growth Rate 2006-2016 (%)
China	12,411,200,713	227%	Capital Equipment	25%	245	Therapeutics	361
Ireland	11,254,566,441	123%	Therapeutics	48%	92	Consumables	625
Mexico	8,822,991,749	120%	Surgical/Medical Instruments	39%	170	Therapeutics	228
Singapore	5,773,677,403	164%	Therapeutics	28%	168	Other	1,124
Rep. of Korea	2,603,829,215	180%	Capital Equipment	48%	162	Therapeutics	664
Costa Rica	2,507,955,659	296%	Disposables	46%	151	Capital Equipment	9,744
Israel	2,069,763,000	77%	Surgical/Medical Instruments	50%	179	Therapeutics	1,460
Malaysia	1,843,212,496	301%	Surgical/Medical Instruments	36%	262	Therapeutics	852
Dominican Republic	1,060,869,130	85%	Surgical/Medical Instruments	85%	72	Therapeutics	9,251

Source: UN Comtrade (2018). Based on HS-2002 product categories defined in Table A-1; all exporters; downloaded 27/08/2018.

2.4 Lead Firms and Governance

The global medical devices industry is highly consolidated and dominated by a small number of MNCs. Traditionally, these firms focused on leadership in niche markets, but this has changed over the past decade in response to increased buyer power. Increasingly larger buyers -- including public health programs,⁹ consolidated hospital networks and insurers' and group purchasing organizations -- seek lower prices, and fewer, but larger, vendors to cope with rising healthcare costs.¹⁰ As a result, lead firms have developed capabilities to serve a broad range of market segments, from cardiovascular and orthopedics to diabetes management, and product categories, such as minimally invasive instruments and diagnostics and imaging equipment as well as provide global coverage. Over the past decade, there were 300 M&A completed valued at over US\$100M in the industry.¹¹ With large R&D and acquisition budgets and regulatory offices, these lead firms play a major role in

⁹ For example, in China, regulations require public hospitals to utilize centralized provincial procurement systems (BMI Research, 2018b).

¹⁰ Many of these programs limit the number of vendors which can participate in their procurement systems. Vendors with the greatest breadth of products therefore benefit (Medtronic, 2018).

¹¹ Medtronic, Stryker and Boston Scientific have been amongst the most active acquirers during this period, collectively acquiring some 80 firms. Medtronic has also been the highest spender with close to US\$50B in acquisitions (Zephyr, 2018).

shaping the evolution of the global industry. Table 5 highlights the top 10 global firms in the sector by revenue.

Table 5. Top Ten Global Firms in the Medical Devices Industry, by Revenue 2017

Firm (HQ)	Primary Specialties	Revenue (US\$ Billion, 2017)	Employment (2017)
Medtronic (Ireland/USA)	Cardiovascular, Neuromodulation, Diabetes, and Surgical Technologies.	29.71	102,688
Johnson & Johnson (USA)	Surgery, Orthopedics, Cardiovascular	26.6	134,000
Abbott Laboratories (USA)	Branded Generic Drugs; Medical Devices; Diagnostic Assays; Nutritional Products	20.85	99,000
GE Healthcare (USA)	Medical Imaging; diagnostics	19.1	52,000
Danaher Corporation (USA)	Environmental & Applied Solutions, Life Sciences, Diagnostics, and Dental	16.88	67,000
Siemens Healthineers (Germany)	Medical Imaging; diagnostics	13.8	45,000 (2016)
Cardinal Health (USA)	Medical, Surgical, Cardiovascular	13.5	49,800
Becton, Dickinson and Company (USA)	Medical Devices, Instrument Systems, and Reagents	12.48	41,900
Phillips Healthcare (Netherlands)	Personal Health; Diagnostics and Treatment; Connected Care & Health Informatics; HealthTech; Legacy Items	12.3	71,000
Stryker Corporation (USA)	Ortho, Medical & Surgical, Neuro	11.33	33,000

Source: Company Websites, One Source, Hoovers.

The **surgical instruments segment** is more fragmented than other product segments, with a number of smaller, independent producers participating in the industry (BCC Research, 2014). Nonetheless, four of the top ten lead firms are important players in this segment, with their instruments divisions generating multi-billion dollar revenue in 2017: Medtronic (US\$5.5B), Stryker (US\$5.5B), BD (US\$3.5B) and Boston Scientific (US\$3.4B).¹² These firms are pushing a strategy to shift surgeons towards the minimally invasive procedures, for which they have been developing new tools over the past decade and which now account for a considerable share of revenue. Medtronic

¹² Based on annual reports. Medtronic is a leading player in surgical instruments; its Minimally Invasive Therapies division earned US\$5.5B in 2017 (Medtronic, 2018). Stryker's Medical and Surgical instruments net US\$5.58B in 2017; around US\$1.6B in endoscopic tools (Stryker, 2018).

refer to this as their ‘open-to-minimally invasive strategy’ (Medtronic, 2018), that is, gaining a reputation in open surgery tools as a means to shift surgeons towards less invasive ones. This includes training surgeons to use their instruments; surgeons tend to favor products they were trained on. The growth strategies of these lead firms include a keen focus on emerging markets in general, and Asia-Pacific in specific (BD, 2018; Boston Scientific, 2018; Medtronic, 2018). This marks a potentially important threat to independent, traditional tools manufacturers in the region.

The medical devices GVC is typically highly vertically integrated to protect important investments in intellectual property creation, contract manufacturing is growing (Brocca et al., 2017), particularly in the production of mature precision metal surgical and medical instruments, as well as in precision metal implantable devices. Contract manufacturing in these product segments occurs across the globe with major clusters found in Germany, Hungary, Malaysia, Pakistan and Poland. Quality assurance is typically the most important concern in this outsourcing, followed by cost. Regulations generally place the burden of quality and supplier compliance for any part of the manufacturing process on the branded firm (Bos, 2018; McHugh et al., 2012; Sethuraman, 2018).¹³ Rigid and sophisticated qualifications thus generally apply to ensure quality and suppliers comply with regulatory demands (Weber et al., 2010). However, unlike other medical device products where suppliers are locked in for long time periods by these regulations (Fennelly & Cormican, 2006), switching costs for mature products like traditional surgical instruments, are relatively low as equivalence is easily illustrated and regulatory oversight is lower (Brocca et al., 2017).

In addition to quality concerns and liability, the large scale of the lead firms means that vendor and contractor 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 supplying less demanding emerging markets opens up avenues for contract manufacturers to source locally. Although global production facilities or contract manufacturers 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. 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.

Lead firms have generally limited production to a handful of locations over which they have significant oversight. Further, due to their dominance in the market, the investment decisions of large lead firms have resulted in notable trends in the emergence of new offshore locations – including in Galway (Ireland), Baja California (Mexico), Singapore, Santo Domingo (Dominican Republic) and Penang (Malaysia). These locations are generally prized for progressive skills development capabilities, geographic and regulatory proximity to key markets, intellectual property protection, and increasingly cost. Global production facilities must compete based on cost, quality and proven capabilities to drive growth and upgrading (Brocca et al., 2017; Fennelly & Cormican, 2006). Most firms begin their new locations with a few, existing products in low risk categories, ramping up as sites improve their capabilities (Bamber & Gereffi, 2013).

¹³ As private label production increases in this sector, regulators are acknowledging that the final brand may not be engaged in the design, development or manufacture of the product and are thus adapting regulations focused on the final company placing the product on the market (MHRA, 2017).

2.4.1 Regulation and Public and Private Standards

The medical devices sector 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 vary by the type of device, but 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 regarding which devices are eligible for reimbursement can also affect which products survive from the prototype stage to market (BMI Research, 2018b; Medtronic, 2018). These insurers can often require more rigorous clinical evidence of effectiveness than required by regulatory controls (Lin et al., 2010).

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. Globally, the majority of surgical instruments fall under either general controls or special controls. Traditional instruments dedicated to open medical and surgical procedures have typically been classified as low risk products (i.e. Class I); classification approaches for minimally invasive instruments diverge, with some regulatory agencies applying additional scrutiny (BMI Research, 2018b; Sethuraman, 2018).

Due to their significant market shares, the standards set by the US, the EU-15 and to a lesser extent, Japan, have to date controlled the development and commercialization of new products in this sector (see Table 9). While varying in design and application, the regulatory requirements of these have generally been considered the global gold standard, and many other countries will fast-track devices with FDA, CE or Japanese approval. Of the three, with slightly less rigorous requirements and faster approval times,¹⁴ devices have often been first launched in Europe and the European CE Mark has thus been considered the basic requirement for entry into many emerging markets without their own regulatory frameworks (Medtronic, 2018; Puri et al., 2011).

Recent developments, however, may shift this status quo. These include:

- 1. More emerging markets are adopting medical device regulatory frameworks of their own (BMI Research, 2018b; Boston Scientific, 2018; WHO, 2017; Wong & Tong, 2018).** The guidelines developed by the World Health Organization's (WHO) Global Harmonization Task Force (GHTF) between 1993 and 2012 have provided the foundations for many of these new regulatory systems. By 2016, over half of WHO member states (113/194) had established some regulatory system. There has been considerable activity in the Asia-Pacific region, Singapore (2007/2010),¹⁵ India (2017/2018), and Malaysia (2012/2018), have all rolled out new programs, while the ASEAN group have all agreed to the ASEAN Medical Device Directives (2015) largely aligned with GHTF (Sethuraman, 2018). While these countries have followed the approach taken by the GHTF founding members, they are increasingly beginning to develop their own regulation from the ground up. Africa and the Middle East are the least regulated regions (WHO, 2017).

¹⁴ In the EU, Notifying Bodies or (NB) are used 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.

¹⁵ Singapore's regulatory agency has even found itself in the forefront in having to roll out regulations for products not yet regulated by the FDA/ EU-15 (Sethuraman, 2018).

- 2. The new Medical Device Regulation entered into force in the EU-15 in 2017 replacing the existing Medical Devices Directives.** This creates standardized, and higher requirements on all EU member states in allocating the European CE mark (see Box 3 for further information). Traceability through Unique Identification (UID) numbers and centralized registration is a central change, and all devices must be listed in EUDAMED, a new centralized database. Industry response is that this will significantly increase the burden for compliance in Europe and drive innovation towards the US (Boston Scientific, 2018; Lowe, 2017; Medtronic, 2018). This is further complicated by the pending withdrawal of the UK from the EU-15 in 2019 and whether or not a deal is reached. A “no deal” exit will result in all devices with CE marks provided by UK Notifying Bodies having to reapply or contract with a EU-15 member state NB (European Commission, 2018).
- 3. In 2018, the FDA announced that it will also reform the requirements for the approval of medical devices in the US.** The goals include streamlining processes, to encourage manufacturers to develop safer products to replace existing devices, and to require cyber security measures for vulnerable devices (“Inside FDA’s new plan to bolster medical device safety,” 2018). The US will also be requiring UID.

Despite these changes, both regional and international initiatives continue to work towards standardizing national and industry medical device regulations and requirements, removing barriers to entry and ensuring new innovative, life enhancing and saving technologies can reach patients in need. These include the International Medical Device Regulators Forum (IMDRF), which is made up of the EU, the US, Australia, Brazil, Canada, China, Japan, Russia, Singapore, South Korea, and the WHO. The Asian Harmonization Working Party has been working towards harmonizing requirements for the growing Asian market, specifically and emerging markets in general¹⁶. Initiatives are primarily focused on information sharing and the development of regulatory capabilities.

¹⁶ As Asia-Pacific emerges an alternative market, its regulatory frameworks are now more important for firms. The general tendency in the region has been to lower the regulatory requirements for low risk devices helping to increase access and lower costs, increase those for high risk devices and, at the same time, establish fast track channels for innovative devices with high potential market demand (Field Research, 2018b). Table A- 5 in the Appendix presents the key changes in medical devices regulation in the region.

Box 3. New Medical Devices Regulation in Europe

In May 2017, the new Medical Devices Regulation entered into force in the EU-15 replacing the existing Medical Devices Directives with a three-year phase in period. The goal of the regulation is to strengthen the safety of medical devices in the regional market and update existing legislation from the 1990s allowing it to be more responsive to forthcoming challenges in the sector. All devices, even existing ones on the market, will be required to comply with the new legislation by 2020, requiring all products to be re-registered affecting every company operating in the medical devices sector in Europe.

Changes include increasing safety and efficacy requirements; the creation of a EU-wide database EUDAMED containing all medical devices approved by the region's notifying bodies intended to increase transparency; new traceability mechanisms; financial mechanisms for protecting the consumer from defective devices. An important part of this is presenting a standardized set of requirements for all EU-member countries.

The legislation also introduces new equivalence requirements for avoiding lengthy medical trials; in this case, a second device manufacture must have significant supporting documentation of equivalence – essentially a contract with a competitor on access to their data. This is anticipated that it will slow down the release of new products on the market, and potentially make the launching of new products in Europe more onerous than that in the US. The ultimate result is that the EU-15 may be replaced as the launch point for many products.

To remain in the market, firms will need to allocate both financial and human resources to achieving European compliance. Allowances have been made for SMEs to help reduce the additional costs of compliance.

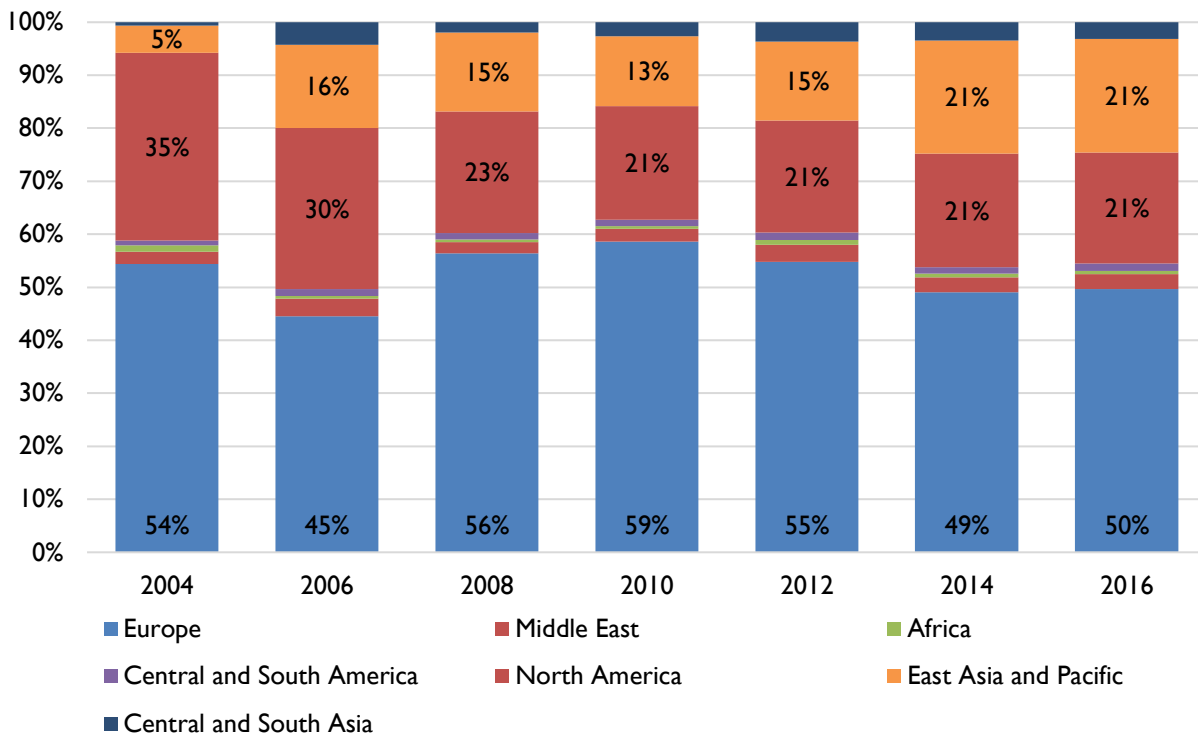
Source: Lowe (2017); Monitor (2017).

2.4.1.1 Private Standards

The primary private standard is the ISO standard for medical device manufacturing, ISO 13485 Medical Devices, Quality Management Systems.¹⁷ Launched in 2003, certifications in this standard grew globally at a CAGR of 26% to 29,585 by 2016. The evolution of certification by region over the past decade further illustrates the growing importance of the Asia Pacific region in global manufacturing, as the region's capabilities have grown and awareness has spread regarding the need for certification. East Asia & Pacific and Central and South Asia have outpaced established sites during this period; accounting for just over 5% of certifications in 2004, the region held an equal share of certifications as the US by 2016 (Figure 6).

¹⁷ There are several additional standards regarding supporting activities such as cleanrooms, sterilization (ISO 11135-1 Ethylene-Oxide Sterilization and ISO 11137-1-2- Radiation Sterilization).

Figure 6. ISO 13485 Certification, by Region 2004-2016



Source: ISO, 2018

These private quality standards have begun to overlap with public standards as harmonization efforts continue. In particular, ISO 13485 is increasingly being used by regulatory agencies as a proxy for quality audits (BMI Research, 2018b; Sethuraman, 2018). This is due to its proximity to regulatory requirements of multiple countries; in addition to US and EU, its supports firms for compliance with Australia, Canada and Taiwan, and is comparatively similar to Japanese requirements (Bos, 2018). The 2016 revision of the standard further increases alignment with both FDA and pending EU MDR regulations for good manufacturing practices (Bos, 2018; FDA, 2012). ISO 13485:2016, raises the requirements for suppliers and contract manufacturers, increasing the likelihood of unscheduled audits from regulatory agencies (Bos, 2018).

2.5 Human Capital, Workforce Development and Gender

Globally, the workforce is small, estimated at 1.5-2M in total (UNIDO, 2016). Leading exporters such as the US, Germany and China employ 308,000 (BLS, 2018), 178,000 (Eurostat, 2015) and 409,500 workers respectively; Mexico is one of the world's leading offshore production locations by workforce size with 116,000 (INEGI, 2018), with others such as Malaysia and Singapore are much smaller by comparison with approximately 31,000 and 14,800 workers respectively (AMMI, 2016). Table 6 provides a comparative perspective illustrating employment growth between 2008-2015.

Table 6. Employment in Medical Devices Sector, Select Leading Countries 2008-2015

Country	Employment		Share of Global Employment		Growth Rate
	2012	2015	2012	2015	2012-2015
World	1,667,468	1,776,018			7%
EU-15*	428,238	437,240	26%	25%	2%
Germany	184,354	197,974	11%	11%	7%
China*	365,465	409,457	22%	23%	12%
USA	358,713	325,067	22%	18%	-9%
Mexico	98,661	111,796	6%	6%	13%
Japan*	90,363	90,363	5%	5%	0%
Brazil	50,626	58,221	3%	3%	15%
India*	46,559	50,835	3%	3%	9%
Korea*	5,707	37,601	0%	2%	--
Switzerland	22,528	23,860	1%	1%	6%
Turkey	18,425	22,242	1%	1%	21%
Malaysia	14,372	19,594	1%	1%	36%
Vietnam	14,190	17,721	1%	1%	25%
Poland	14,455	17,096	1%	1%	18%
Costa Rica	11,882	16,290	1%	1%	37%
Hungary	11,593	13,616	1%	1%	17%
Czechia	12,770	12,962	1%	1%	2%
Singapore	9,844	11,422	1%	1%	16%
Other Countries	93,077	100,635	6%	6%	8%

Note: ^a based on 90/97 countries with reported employment in ISIC 2660 Irradiation/ electromedical equipment and 3250 Medical and dental instruments and supplies /total. ^b EU-28 total sourced from EUROSTAT, 2018. Individual European countries listed from UNIDO INDSTAT ISIC Rev 4. 4 digits.

Source: UNIDO (2016); Eurostat (2018)

While small, the global workforce is growing as demand for medical devices continues to rise around the world, increasing some 58% between 2008-2015. Growth has been modest (<10%) in more mature production locations during this period,¹⁸ with the exception of Germany, where employment grew by 20%. Non-traditional manufacturing hubs such as Singapore, Brazil, and Malaysia grew the fastest, with their sector workforces each growing by over 50% in the same period,¹⁹ as medical devices firms have expanded into new destinations to lower costs, tapped into contract manufacturing operations and access new markets (Brocca et al., 2017). Even Mexico's large medical devices workforce grew an additional 24% between 2010-2015. This growth offers developing countries a small, yet important opportunity for job creation.

Keeping up with this growing demand is challenging, however, as the workforce typically consists of skilled and semi-skilled labor. Consequently, support by an adequate set of education and training institutions is needed. 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). Thus, remaining competitive and upgrading in the medical devices

¹⁸ The US workforce contracted by 1% during this period.












¹⁹ Malaysia growth rate measured for 2009-2015, as 2008 data not available. This was approximately 70%.

industry requires the availability of an appropriately qualified workforce for each stage (Bamber & Gereffi, 2013; Gereffi et al., 2011).

The experience and skill level of the workforce differs depending on the stage of the value chain (Table 7) (Gereffi et al., 2011). Understanding the human capital needs for these different segments of the value chain is important for assessing feasible growth trajectories for Pakistan's medical instruments sector and the human capital development policies that must be put in place to support that upgrading. Lower-value segments of the chain such as components manufacturing and assembly require a large number of semi-skilled 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. The majority of the roles in the industry are in production together with a handful of bottleneck positions. Using the US medtech labor force as an example, the leading occupations are production (52%), office & administrative (13%) and engineering (8%). Healthcare practitioners and life sciences professionals (e.g. chemical and biology technicians) account for just 2.2% of roles in the industry.

Approximately one third of manufacturing roles require either a two-year degree, technical or vocational training plus experience in addition to up to two years of on the job training, while the remaining two-thirds require a minimum of high school and a few months to a year of on the job training (BLS, 2018; O*Net OnLine, 2018). Germany has similar requirements for its workforce, with the industry association also citing current high demand for regulatory professionals in response to the major shifts in global regulation in the sector (BVMed, 2018). Overall, the dependence on primarily high school and technical education makes the industry well suited for growth in developing countries.

Table 7. Select Job Profiles in the Production Segment of the Medical Devices GVC

Position	Job Description	Formal Education Requirements	Training/ Experience	Skill Level
Components Production & Assembly				
Grinding, Polishing, Buffing Equipment Operators	Grind, sand, polish using hand-held electrical tools or machines following basic instructions to provide final product according to set specifications.	High school diploma/ technical education	Min: On the job training Max: 1 years Experience	
Molding, Coremaking, and Casting Machine Operators	Set up, operate, or tend metal or plastic molding, casting, or coremaking machines to mold or cast metal or thermoplastic parts or products.	High school diploma/ technical education	On the job training for up to 1-2 years	
Machinists	Operate machine tools to produce precision parts and instruments	Technical education	On the job training	
Assemblers	Assemble components of medical devices into final products	High school diploma/ technical education	Experience: Need of speed and accuracy skills	
Packaging Equipment Operators	Operate or tend machines to prepare industrial or consumer products for storage or shipment.	High school diploma/ technical education	Experience: Need of speed and accuracy skills; understanding of traceability systems	
Transportation and Material Moving Occupations	Physically move materials or operate industrial trucks or tractors equipped to move materials around a warehouse, storage yard, factory, construction site, or similar location.	High school diploma/ technical education	Experience; on the job training	
Line Leaders & Production Flow Supervisors	Supervisory roles; oversee the pace of the work and ensure stoppages are minimized, monitor production levels, train new workers, and manage constant problem solving.	Technical education/ Bachelor's degree	Management skills	
Quality Control	Maintain final quality prior to distribution of product, monitored by buyers.	Technical education	Knowledge of quality systems	
Industrial Engineers/ Engineers	Design, develop, test, and evaluate integrated systems for managing industrial production processes, including human work factors, quality control, inventory control, logistics and material flow, cost analysis, and production coordination. Other engineering roles can include mechanical, chemical, biochemical and electrical/electronic depending on the product mix.	Bachelor's Degree	Management skills	
Microbiologists	Investigate the growth, structure, development, and other characteristics of microscopic organisms, such as bacteria, algae, or fungi..	Bachelor's degree	Specialized knowledge in microbiology	
Regulatory Compliance Officer	Undertakes audits of products to ensure they meet regulatory compliance of target markets.	Bachelor's Degree	Specialized knowledge in regulations of specific markets	

Source: Authors based on BLS (2018); O*Net OnLine (2018) and extensive firm interviews.

Furthermore, unlike other sectors such as textiles and apparel and electronics which are highly feminized (Bamber & Staritz, 2016), the medical devices GVC is characterized by greater gender equity in overall employment numbers and lower variation as product composition changes. Many of the leading exporters of these products have similar shares of male and female employment. In

2015, 47% of the US workforce was female (BLS, 2018); in China, 50% (UNIDO, 2016), while in Mexico, the share was slightly higher with 59% (INEGI, 2018). The female share of the workforce tends to be higher in production as compared to the overall manufacturing sectors (US: 27%; China: 40%; Mexico: 35% (INEGI, 2018), although with a lower share of senior management and ownership roles.

3 Pakistan in the Medical Device Global Value Chain

Key Takeaways

- Pakistan's historic position as a surgical instrument producer is insufficient to maintain participation in a changing global medical device industry.
- Pakistan is a small player in the medical device GVC with exports totalling US\$355M in 2016; 98% of exports are in surgical/medical instruments.
- The industry is comprised mainly of micro-small firms that rely on historic production methods. Only 85 firms reported exports above US\$1M in 2016. These firms account for over 60% of exports.
- Pakistan has several organizations and institutions to support the industry but there is overlap in activities and all focus almost exclusively on surgical instruments.
- The industry is struggling to retain a skilled workforce and invest in needed

Pakistan is a small, niche actor in the medical devices GVC with US\$355M exports in 2016 (0.1% of industry exports) (UN Comtrade, 2018). The country's participation in the medical device GVC is centered on precision metal instruments and is concentrated primarily in one city, Sialkot. The nation has a long history in the production of these devices, dating back to the 1940s. Following local demand by missionary hospitals in the 1920s, Pakistan began exporting during World War II and currently exports to 110 nations globally (PCA, 2018).²⁰ The combination of a historical supplier of precision metals and its low-cost labor supply have contributed to its current participation in the chain. However, the changing dynamics of the global industry – including in the mature surgical instruments niche - mean that these past drivers of competitive advantage are becoming less relevant. Pakistan has seen its medical devices exports plateau in recent years as new competitors and products have entered the market. In order to sustain its position in the industry, Pakistan needs to upgrade its processes to increase productivity, diversify its products portfolio and strengthen the industry's ties with emerging markets. The country's past success in textiles and apparel also offer an opportunity for the country to become a more significant player in the medical textiles industry. This section discusses Pakistan's participation in the medical device value chain and current trade dynamics as well as the internal industrial organization of the industry. The country's strengths and weaknesses as a participant in the medical devices GVC are also examined to determine the viability of growth.

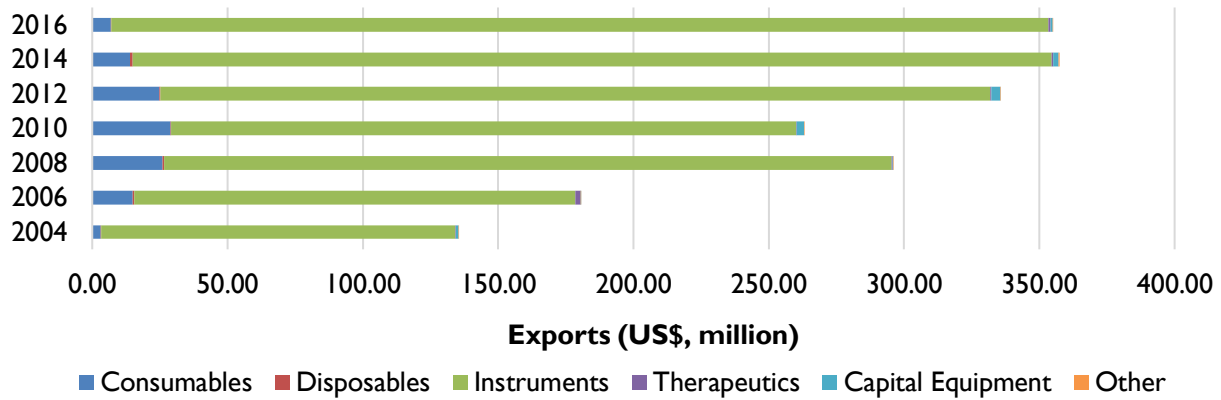
3.1 Pakistan's Current Participation in the Medical Device Global Value Chain

Pakistan's exports in the medical device GVC are primarily concentrated in precision metal instruments (Figure 7). Metal Instruments account for close to 98% of Pakistan's medical device

²⁰ Firm level data is based on Pakistan Custom's Authority data provided by the World Bank.

exports in 2016 while consumables (e.g. bandages) account for just 2% (UN Comtrade, 2018). Exports of medical devices have consistently grown over the last decade, increasing 97% since 2006, outpacing the global average of 75% (UN Comtrade, 2018).

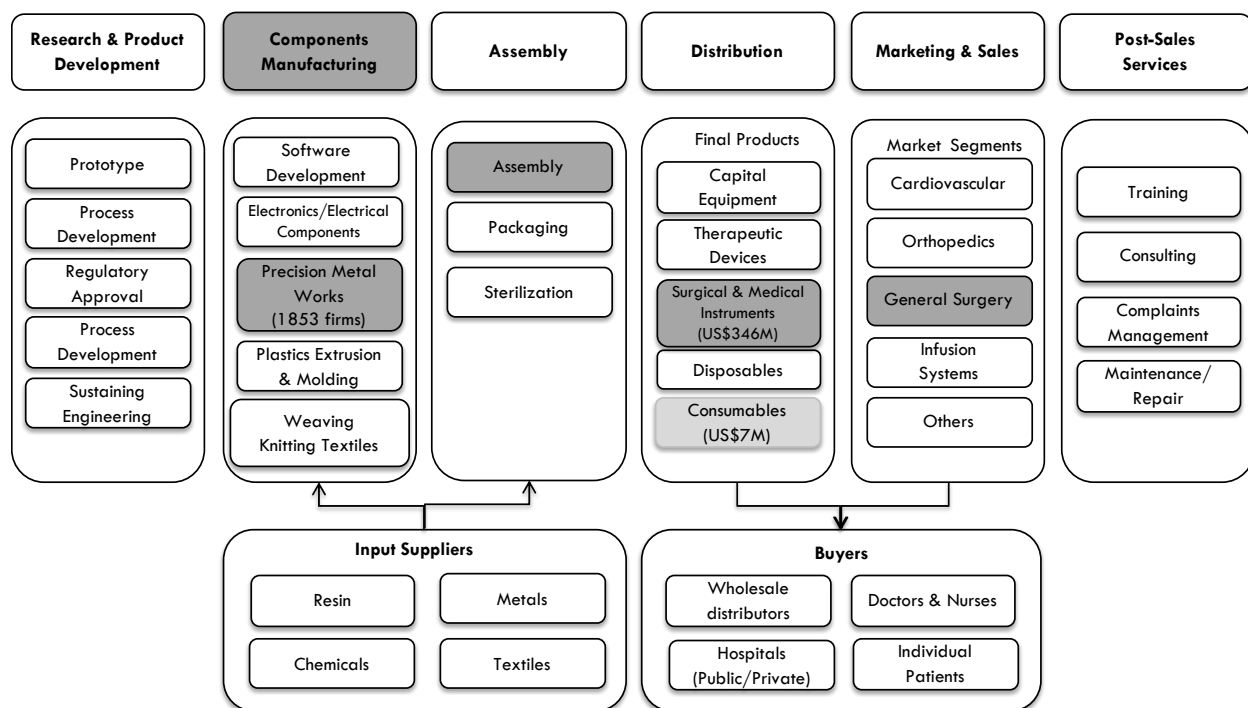
Figure 7. Pakistan Export by Medical Device Sector, 2004-2016



Source: UN Comtrade (2018). Based on HS-2002 product categories defined in Table A-1; Pakistan exports; downloaded 27/08/2018.

Analysis of exporter firm data indicates that exports have plateaued between US\$350-380M between 2014 and 2017 (PCA, 2018). Following steady growth, the industry began stalling in 2014 as more nations entered the precision metal instrument product category and Pakistan found its niche threatened. Further, as buyers in established markets shifted more towards single use instruments, buyers exerted downward pressure on prices, further squeezing producers and stalling industry growth.

Figure 8. Pakistan in the Medical Devices Global Value Chain



Source: Authors using PCA, 2018 data

Pakistan’s involvement in the medical device is concentrated in the Components Manufacturing and the Assembly segments; most products are sent on to other destinations for final packaging and branding (Figure 8). Using both domestic and imported steel (PSDF, 2016), production occurs primarily in Sialkot (PCA, 2018). This is an almost exclusively export-oriented sector, with over 95% of production exported, to over 100 markets. In the 2016/2017 fiscal year, 1,853 firms reported exports. Despite the size of the population, domestic demand is low as a result of very low healthcare expenditure (BMI Research, 2018a).²¹ As a result, even micro-firms in the industry focus on export-oriented activities.

Virtually all activity is focused on the production of precision metal instruments with little activity occurring in other product segments; instruments account for 98% of all sector exports. The top 20 medical device exporters (by value) participate exclusively in instruments (PCA, 2018). These devices are primarily mature surgical instruments classified as Class I (FDA), however, a small number of firms are also producing more advanced endoscopic instruments and accessories (FDA, 2018b). Finally, in addition to the medical sector, these products are destined to dental, veterinary and manicure/pedicure industries which have similar needs for metal products (SIMAP, 2018), although with varying regulatory requirements.

Components manufacturing. All manufacturing processes, from die casting to final components is undertaken in Pakistan, although due to the complexity of the process (Box 1; see section 2.2) only the largest firms perform all activities, with smaller firms sub-contracting different stages to

²¹ Pakistan has the lowest per capita healthcare expenditure of the Asia-Pacific region and its large rural population further complicates the profitability of the domestic market. Pakistan’s medical device sales per capita are US\$4.1 compared to a global average of US\$50 and an average of US\$39.9 in the Asia-Pacific region (BMI, 2018).

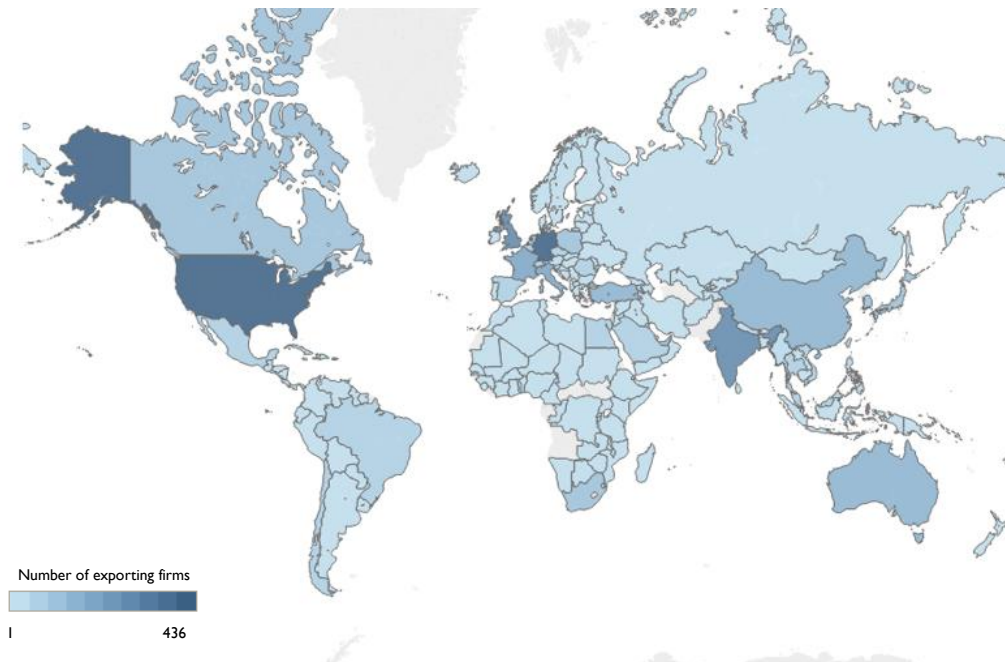
more specialized vendors in the country (Chaudhry, 2010, 2011; Field Research, 2018a). For example, most firms subcontract heat treatment and hardening process locally, with one firm undertaking approximately 90% of national orders (Field Research, 2018a).

Assembly. Assembly, packaging and sterilization activities are undertaken, although to varying degrees. Assembly and final packaging for export is limited primarily to larger firms, which provide final products for their buyers. Local sterilization is very limited, with most only using ultrasonic cleaning. Products are sterilized when they reach their final destination, before use by the end consumer. Single use or disposable instruments are an exception to this rule; these products undergo a more extensive cleaning and sterilization process prior to packaging. However, even these devices are often exported to other markets for final sterilization and packaging before being sent to the end consumer (Field Research, 2018a).

3.1.1 Pakistan’s Medical Device Exports

Pakistan exports medical instruments across the globe, reaching 107 nations in 2017 (PCA, 2018). Despite this wide scope in export destinations, total exports are concentrated among a small group of nations, including the US, the UK, and Germany. Further, firm size is closely related to export destinations with larger firms being most active in established markets. Market penetration into lower value export destinations is low; approximately half of these destinations is served by five or fewer Pakistani firms (FY2016/2017), while 19 nations imported medical devices from just one Pakistani firm (Figure 9). Firms exporting to new markets are often smaller in size, reflecting a limited focus on market diversification in the country (PCA, 2018).

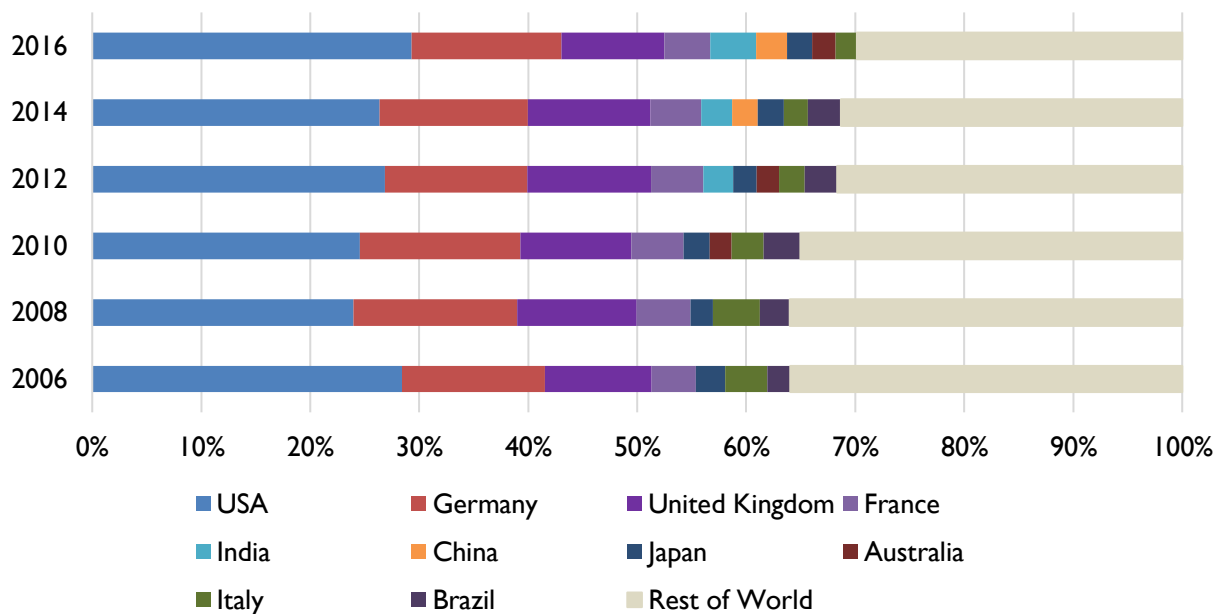
Figure 9. Pakistan's Medical Device Exports (US\$) by Exporters per Destination, 2016/2017



Source: PCA, 2018

While select markets remain the most important export destinations for Pakistan, recent shifts to regional and developing markets suggest this strong dependence on select markets may be changing (Figure 10). Traditional export markets remain key export destinations. However, new actors are rising in prominence. The US, Germany and the UK are the largest export markets for Pakistan; In 2016, the US accounted for 29% of exports while Germany and the UK accounted for 14% and 9% respectively. The share of total exports among these nations remained relatively stable over the past decade, with export value increasing to US\$101.5M in 2016 for the US, a 164% increase between 2004-2016. Germany grew 148% during the same period while the UK rose 242% (UN Comtrade, 2018).

Figure 10. Pakistan’s Medical Devices Export Destinations (% of total exports), 2006-2016



Source: UN Comtrade (2018). Based on HS2002: 90184, 90185, 90189, Retrieved 7/27/18

While the traditional export destinations remain stable buyers for Pakistan, the emergence of trade partners in regional markets and developing economies suggest future growth markets. For example, exports to India have grown significantly in the last decade. Prior to 2012, no surgical instrument exports were reported to India from Pakistan but by 2016, it accounted 4% of total exports, US\$14.5M. Similarly, China, with no Pakistani imports prior to 2014, accounted for 3% of total surgical instrument exports from Pakistan in 2016 (UN Comtrade, 2018). These new markets are growing faster than the country’s traditional partners; from 2014-2017, the growth rate of exports to China was 69% and India 19% compared to 4% in the US and an overall export growth rate of 3% (PCA, 2018).

Pronounced differences exist in market orientation based on firm size. Exports from larger firms are overwhelmingly represented in US–destined exports, while smaller firms are seen serving the

EU market. Of the leading export firms²² from 2014-2017, 96% exported to the US while 81% exported to Germany and 70% to the UK. Nearly half of the exports of the largest exporters (>US\$5M) were destined to the US in 2016 (PCA, 2018). Smaller firms focused more on EU and smaller regional markets where regulations have been less stringent and lower economies of scale are required. Export destinations for smaller firms are also less concentrated, with the top three markets comprising 31% of all exports for firms under US\$500K (Table 8).

3.2 Industry Organization

The medical instruments cluster in Pakistan consists of a few medium sized firms and several micro and small, family owned firms. The majority of firms are small with minimal participation in the GVC. In the 2016/2017 fiscal year, only 11 firms reported exports greater than US\$5M while 74 reported exports above US\$1M. These firms account for nearly 60% of exports (Table 8). Two thirds of firms had exports above US\$10,000 but less than US\$100,000 for the same year (PCA, 2018).

Medium firms are able to meet stringent regulations of international buyers and meet larger volume demand. They also have invested in new technologies and have machinery onsite. These firms tend to be structured and employ outside workers, using modern machinery, compared to smaller firms which are frequently family operations with multigenerational histories in the industry. Some of the largest firms, such as QSA Surgical have sophisticated operations due to their historic partnership with global firms in the 1990s (Field Research, 2018a; Nadvi, 1999).

Nonetheless, even smaller firms are well established with annual exports. 61% of firms exporting in 2016/2017 also registered exports in the previous two years and these firms account for 94% of all exports. The average exports for firms in FY2016-2017 was US\$251K; however, the median exports that same year was just US\$50,250, illustrating the prevalence of small exporters (PCA, 2018).

Table 8. Firm Characteristics, 2016-2017

Firm Size by export value (US\$)	Number of Firms (% of firms)	Share of Exports	Key Markets (% of exports)
Exports Over US\$5M	11 (<1%)	22%	United States (48%) United Kingdom (12%) Germany (10%)
Firms Between US\$1M<x<US\$5M	74 (3%)	37%	United States (30%) Germany (17%) United Kingdom (8%)
Firms Between US\$500K<x<US\$1M	134 (7%)	11%	United States (26%) Germany (13%) United Kingdom (11%)
Exports Under US\$500K	1686 (90%)	29%	Germany (12%) United States (11%) United Kingdom (8%)

Source: PCA, 2018

²² Leading export firm is defined as being one of the top 20 exporters by value for any one year during the three-year period between 2014 and 2017. In total, 27 firms meet this threshold.

Due to their role as small contract manufacturers and with a limited domestic market, firms in Pakistan's medical device sector are largely captive to global lead firms and buyers. Power in the chain is concentrated among large global brands and these brands often partner with larger firms in Pakistan who can meet both quality and quantity expectations for export destinations. Even these firms, however, have limited power and often must comply with buyer demands in terms of inputs and production specification. Further, producers report facing downward pressure on prices from many buyers with unit prices declining over the last few years as buyers capitalize on a competitive local market (Field Research, 2018a). This is further exacerbated by an expanding global supply of producers.

Despite efforts to improve the quality and reputation of surgical instruments in Pakistan, the nation remains a supplier of unbranded instruments. Instead, products are exported abroad for final branding, limiting the value that Pakistan receives from GVC participation. While the cost of Pakistani surgical instruments is considered to be very competitive, for a variety of reasons such as perceived lower quality, many firms are unable to directly market their product. As a result, intermediaries, frequently in Tuttlingen, Germany buy and sell Pakistani products at a high markup. One firm reported that once exported, distributors sold instruments produced in Pakistan at over 100 times the price they paid to Pakistani firms. The price markup was attributed to marketing and branding which was largely absent among domestic producers (Field Research, 2018a).

Currently, there are no global firms operating in Pakistan. This is due not only to quality concerns, but difficulties doing business in the country. Previously, Becton, Dickinson and Company had operations in Lahore, but closed its facility in 2016. As a result, the industry lacks the MNC presence seen in major offshore production locations. This has limited Pakistan's potential to boost upgrading into other product segments beyond its historical position as a precision metals supplier as has happened in other countries in the industry.

Beyond firms, several public and private institutions, most based out of Sialkot, provide support to the industry, albeit limited (see Table 9). The most prominent institution is the industry association, Surgical Instruments Manufacturers Association of Pakistan (SIMAP); SIMAP works to help promote the industry domestically and internationally. In addition to providing a list of members, which serves as a potential sourcing directory, it promotes trade and the industry abroad and handles trade disputes among members. It recently opened a Community Manufacturing Center (CMC) to help small producers overcome major productivity challenges (see Box 4 for more detail). Finally, it provides the final quality control of all exports produced in Sialkot, via its Sialkot Material Testing Laboratory (SIMTEL) established in 2001; SIMTEL ensures the correct steel is used and the instrument meets minimum specification (Field Research, 2018).

In addition, the Sialkot Chamber of Commerce and Industry (SCCI) also supports the industry by serving as a liaison between government and businesses, as well as promoting the local industry. In order to export, firms must be affiliated and registered with at least one of these bodies with most firms registering with both SIMAP and SCCI (SCCI, 2016). Additionally, the Metal Industries Development Center (MIDC) supports producers via training programs that focus on quality control. It also has a history as a monitor of quality within the nation though it is not currently functioning in this capacity.

Table 9. Key Industry Stakeholders in the Medical Device GVC

Actor	Description	Role
Surgical Instruments Manufacturers Association of Pakistan (SIMAP)	Industry Association founded in 1958 to promote the industry; in 2018, SIMAP had 3,600 members	Promotes industry domestically, operates training programs and oversees quality among members
Sialkot Chamber of Commerce and Industry (SCCI)	Established in 1982, the Chamber represents export-oriented industries in Sialkot; 2241 medical devices members	Serves as a liaison between members and the government relating to business issues
Metal Industries Development Center (MIDC)	Center charged with helping promote quality control in the surgical instruments industry	Oversees community manufacturing center and provides training as needed
Trade Development Authority of Pakistan (TDAP)	Government authority that oversees global trade and export promotion	Helps promote exports of all industries, including surgical instruments
Pakistan Standards and Quality Control Authority (PSQCA)	Pakistani Authority that oversees standards in the country	Certifies firms ISO 13485 in Pakistan and communicated international standards to local actors
Technical Education and Vocational Training Authority (TEVTA)	Punjab regional workforce development body	Develops and administers a curriculum to train workers in surgical instrument field
Institute for Surgical Technology	Institute to help train workers in the surgical instruments sector	Provides training on activities critical for the surgical instruments sector such as die making, heating, and machining
Sialkot Material Testing Laboratory (SIMTEL)	SIMAP ran laboratory that test metal composition of instruments	Performs chemical analysis of metals for all exported instruments to ensure it meets industry standards and provide analysis to consumer

Source: Authors.

3.3 Upgrading and Industry Evolution in Pakistan’s Medical Device Global Value Chain

Pakistan has been an exporter of surgical instruments since the 1940s. It solidified its place as a global cluster for metal instruments manufacturing but has since made only modest advancements in the introduction of mechanized processes, the manufacture of other products categories or upgrading into new stages of the value chain.

Key progress is beginning in several areas of the industry: (1) improved access to technology for small firms, (2) process upgrading through increased certification, and (3) entry of high performing firms into more complex products within the surgical instrument category, as well as in therapeutics.

Strides have been made to increase access to new technology among smaller firms. Most notable of these is the Metal Industries Development Center (MIDC) and other community manufacturing centers (CMC) that help smaller firms gain access to machinery and technology (Box 4).

Box 4. Community Manufacturing Centers

A key development to assist micro and small firms producing surgical instruments in Pakistan is the use of CMCs. The growing global requirements for production using higher technologies, coupled with limited ability of firms to access the finance needed to invest in capital technologies the region has led to the creation of CMCs to empower firms. CMCs are community centers where firms can access the necessary machinery for production, allowing them to accept larger and more sophisticated orders. These facilities help firms to overcome funding challenges while encouraging the growth of the local cluster.

Several CMCs are active in Sialkot. Notably, the MIDC operates a CMC at its facilities where machines are available for firm use as well as for training. These machines cover many production processes and include advanced technology, including computer numeric control (CNC) machines for large volume or technical orders. In September 2018, SIMAP opened a new CMC facility to provide members an additional resource to meet the needs of global buyers and remain competitive.

Source: Field Research (2018)

Along with increased access to technology, process upgrading is occurring as more firms earn internationally recognized certifications. 421 local firms held ISO 13845 certifications for medical devices in 2016, a required threshold for exporting to developed markets (ISO, 2017). The number has grown consistently over the last decade increasing 205% since 2006 (ISO, 2017). The increase in ISO certification indicates a growing number of firms see value in meeting global standards and show potential for GVC participation.

Finally, with over 70 years of experience in the industry, Pakistan is tentatively expanding into new product categories of the medical device GVC and related supplies. Several firms export medical textiles and disposables while some firms are moving into more sophisticated surgical instruments, such as laparoscopic and endoscopic devices. The rise in specialty instruments is the result of two factors: established participation in the industry allowing firms to expand into new, more sophisticated production; and the formation of specialized sub-clusters within Sialkot. Villages around Sialkot often focus on select subsectors of the industry, allowing for specialized knowledge creation and the development of advantages allowing firms in these areas to operate in niche production. Finally, some large firms are entering into implantable devices based on their long history in the industry, entering into a higher value product segment. While limited to a few firms, with low exports, the move to implantable devices demonstrates some product upgrading is occurring.

3.4 Human Capital

Human capital in Pakistan's medical device sector is primarily semi-skilled workers who perform various production tasks for surgical instrument manufacturing. Entry into the workforce requires basic education, below completion of high school, and development of metalworking skills. With a few notable exceptions, most of the estimated 150,000 of workers received initial training at home with family members training young workers on basic skills, additional skills are then learned at the job site. Capacity building for surgical instruments is a lengthy process. Historically the primary transfer of knowledge occurred among family members and began at a young age. This model, known as the *shagirdi* system, centered on skilled workers imparting knowledge on the craft among younger workers for up to ten years (Ilias, 2006). Training occurred within the factories and most entering the workforce had low levels of formal education.

In the 1990s, pressure from the International Labor Organization (ILO) and others to stop child labor spurred a move away from this traditional training model and human capital development has become increasingly institutionalized. Most notably, actors such as the Technical Education and Vocational Training Authority's (TEVTA) Apprentice training center (ATC) and curriculum from the MIDC have helped to formalize education, a crucial step to ensuring long term growth.

Despite this important step forward, the industry faces several challenges regarding human capital, primarily the shortage of skilled labor. Recruitment to the sector is challenged by concerns of the dangers of factory work, particularly in the polishing segment of production. Instead, young workers are entering into service sector jobs that are seen as more prestigious and safer. TEVTA mentions that many training facilities on their campuses remain inactive due to lack of demand. The result is a shrinking supply of labor for factories.

A second constraint to securing skilled labor is the shift towards global labor norms for the sector. This shift moves the organization of work away from traditional, family centric models towards factory models. Firms following global norms more frequently enforce minimum age regulations and also require minimum levels of education and training prior to beginning production (Field Research, 2018a).

Finally, social and cultural norms often limit employment opportunities to males (Field Research, 2018a). Overall, even though global employment in the industry is generally balanced between men and women, gender employment trends in Pakistan deviates as a result of cultural norms. The workforce is overwhelmingly male, a departure from other nations active in the GVC. At most, females comprise less than 5% of the workforce with many firms reporting no female workers (Field Research, 2018a). Furthermore, female participation is limited to select careers, such as packing, engineering and administration.

Several reasons are cited for the lack of female participation. First, female participation in the workforce in Pakistan is generally low, particularly in more culturally conservative cities such as Sialkot; females comprise only 25% of the labor force, even among women with high levels of education (Tanaka & Muzones, 2016). The social norm is for females to only enter into acceptable service-sector professions and because males are considered the primary breadwinners, employers should give priority to male applicants (Tanaka & Muzones, 2016). Second, the perceived danger of the factory work involved in surgical instrument production discourages female participation on the production line. Finally, when firms did introduce females into production lines, issues among male workers made such a shift difficult to sustain. As a result of these challenges, the industry in Sialkot will likely remain male dominated for the foreseeable future.

3.5 Advantages and Constraints

Pakistan's potential in the Medical Devices GVC in general, and the surgical/medical instruments product segment, in particular, depends on a set of structural strengths and weaknesses, elaborated in Table 10. These strengths allow for strategic opportunities that should be capitalized on. At the same time, the threats presented below must be addressed for the country to improve its position in the industry.

Table 10. SWOT of Pakistani Medical Device Industry

Strengths	Weaknesses
<ul style="list-style-type: none"> • Low cost labor • Wide range of instruments • Institutionalized capacity building • Geographically concentrated production 	<ul style="list-style-type: none"> • Low levels of industry coordination • Poor integration with global lead firms • Low productivity • Limited certification among firms • Quality Concerns
Opportunities	Threats
<ul style="list-style-type: none"> • Increased mechanization can boost productivity • Growing demand from emerging markets – particularly China • Upgrading into minimally invasive production • Expansion of medical textile and disposable activities • Several related industries with growing demand 	<ul style="list-style-type: none"> • Shift towards minimally invasive surgery • Increased regulatory compliance requirements in existing markets • Political uncertainty

Source: Authors

3.5.1 Advantages

Pakistan’s advantages in the medical device industry revolve around its capabilities to produce a wide range of instruments and its low-cost labor force. It also benefits from its established history in the industry as a niche supplier of precision metal instruments. Finally, the high level of customization helps distinguish it amongst competitors. The following sub-section expands upon these strengths.

1. **Low Cost Supplier.** Low cost is the main factor driving Pakistan’s competitiveness. Stakeholders often state that it is the cheapest producer globally of surgical instruments, making it attractive to many buyers. Low cost of production is closely tied to labor costs in the country. Pakistani per capita yearly earnings across various industries, including medical devices, is US\$1,870 (Lopez-Acevedo & Robertson, 2016). This is much lower than other Asia Pacific nations, such as Vietnam whose annual per capita manufacturing earnings are US\$3,340 or Malaysia’s per capita earnings of US\$8,030 (UNIDO, 2016).²³ Pakistan’s low-cost reputation is also tied to the small, cottage organization of the industry. However, it is important to note that the industry is stigmatized by a perception of child labor as a contributor to low costs.
2. **Wide Range of Instruments.** Pakistan is able to produce over 10,000 types of instruments, covering a large portion of the surgical instruments market (Chaudhry, 2011). Beyond the surgical instrument sector, these products are also used in the veterinary, dental and beauty sectors. As a result, the capability to cater to a wide product line attracts buyers from multiple industries.
3. **Institutionalized Capacity Building.** Pakistan has decades of experience in surgical instrument manufacturing. Recent efforts such as the MIDC and TEVTA’s ATC have begun

²³ Wage figures come from various sources and variation in data collection and analysis methods may skew reported wages.

to capture the lessons of this traditional family-based apprenticeship and formalized training to create a clear path for a better prepared and more sophisticated workforce.

- 4. Geographically concentrated production.** Sialkot is a strongly formed surgical instrument production hub. Virtually all participation in the medical device sector is located here, allowing for easier transfer of knowledge and institutionalization. At the same time, the emergence of sub-clusters around Sialkot focused on instruments for select specializations, such as optometry or neuroscience helps to strengthen the industry by allowing for pockets of specialized knowledge.

3.5.2 Constraints

Nonetheless, there are multiple challenges to Pakistan's potential to upgrade and grow in the sector; some of these have become particularly pronounced in recent years. A lack of integration with global lead firms combined perceptions of low-quality, impact the nation's competitiveness. Additionally, low productivity and lack of coordination undermine overall sector competitiveness while limited certification among firms and low levels of contract enforcement create issues for industry actors. Combined, these constraints have undermined the country's ability to develop a national brand and reputation.

- 1. Low levels of industry coordination.** Despite being an established cluster with an active industry association, the industry is not coordinated to optimize competitiveness. Contracts are often not enforced at the local level creating an absence of trust and stakeholder frequently cite poaching of clients as a problem. Further, despite compulsory membership, many producers cite that industry assistance offered by SIMAP privileges a narrow set of firms with limited impact on the majority of firms. As a result, actors do not work towards common goals within the industry.
- 2. Lack of integration with global lead firms.** Pakistan is not closely aligned with the global medical device firms. Prior to the 2000s some firms did form joint ventures with global firms, but these partnerships have since dissolved. As global firms increase their market share, this significantly impacts the country's potential to upgrade. Furthermore, Pakistan is often ranked low on measures of business-friendly policy environments. Pakistan currently ranks 147th out of 190 in the World Bank's Doing Business ranking, with scores consistently below the regional average (World Bank, 2018a). As seen in section 4.1 below, both Malaysia and the Dominican Republic have been able to attract investments by lead firms to help spur industry growth. Political uncertainty also presents a threat to attracting global firms.
- 3. Low productivity.** Productivity as a major constraint, with limited uptake of mechanization. Frequent electrical shortages and the inability to invest in modern machinery reduces the ability of producers to improve production processes and increase productivity. Access to equipment is further constrained by high import duties; some stakeholders cited import duties of up to 120% for select machinery.
- 4. Limited certification among firms.** Few firms in Pakistan have the certifications needed to export to key markets. Only 148 firms have FDA approval for export to the US; further, only 1/4 of firms have ISO 13485 certifications, a requirement for export to most markets

(ISO, 2017). It is crucial to help more firms earn the requisite certifications to participate in the global market.

5. **Quality concerns.** Pakistan's surgical instrument industry suffers from an image of lower quality products in the global market. As a result, buyers often prefer to source from other clusters. SIMAP does provide some quality control, but checks are often limited to verifying the type of metals used in production. No established quality control beyond this occurs by a third party prior to export.

4 Lessons for Pakistan's Upgrading in Medical Device from Global Experiences

For Pakistan to successfully establish a position for itself as an integrated player in the medical devices GVC, it needs to upgrade its current operations. By adopting new technologies, producing a new product or engaging in an entirely new set of activities, upgrading can also allow actors in the GVC to capture more value from their participation (Humphrey & Schmitz, 2002). These upgrading trajectories are frequently not only led by country governments, but also by firms. Table 11 summarizes the critical upgrading trajectories that have typically been pursued by countries in the medical devices GVC. While Pakistan has already successfully entered the value chain establishing itself as a player in the cost-driven, mature surgical instruments segment, unpacking each of these global upgrading trajectories is important to understand how the country's current participation in the chain can contribute to future growth potential.

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

<p>ENTRY INTO THE VALUE CHAIN</p>	<p>There are several paths to entry into this GVC: (a) host country to MNC subsidiaries (e.g. Dominican Republic), (b) through local suppliers becoming contract manufacturers to foreign firms (e.g. Pakistan, Malaysia), or (c) local firms entering directly into regional or global market (e.g. China). These pathways share a common characteristic; countries typically enter with one or two product lines and ramp up to meet productivity and market requirements over a fixed period of time. In (a) and (b), the transfer of a new product to a production facility can take up to 24 months. For the first 12 months, the facility must produce “as is;” no modifications can be made to the production process.</p>
<p>PROCESS UPGRADING</p>	<p>Production can be shifted from manual to mechanized or automated assembly, barcodes can be introduced to track inventory and output (e.g. identifiers for traceability) and the plant layout can be improved to facilitate improved productivity. Plants may adopt certification processes such as Six Sigma and lean manufacturing to improve just-in-time delivery, and reduce down time. Obtaining ISO 13485:2016 certification helps firms to align their operations and quality standards with a growing number of global markets, including US, EU, Japan, Australia, and Taiwan.</p>
<p>PRODUCT UPGRADING</p>	<p>Product upgrading can take place within one product family, e.g. from simple catheters to complex IV tubing, or it may involve moving into production of a new and more complex product family, e.g. from a Class I to a Class II or III devices, with considerably more regulatory and production complexity & increased need for quality control due to the life sustaining nature of the product. For example, as precision machining capabilities of US contract manufacturers in the surgical instrument segment grew, firms moved to metal implantable devices. These draw on the same manufacturing capabilities; however, they are subject to stricter regulatory controls.</p>
<p>FUNCTIONAL UPGRADING OEM TO OBM</p>	<p>A supplier develops capabilities in the product segment by manufacturing under contract for a lead firm brand. Over time, the firm identifies new opportunities to sell direct to market, hiring marketing and sales teams. This step requires not only establishing the firm’s new brand but also regulatory compliance in the market. This upgrading trajectory can bring a supplier into direct competition with its initial buyer. An alternative path is for the supplier to purchase or license the brand from their buyer. It also requires firms to establish numerous post-sales services, such as “complaints handling” which is critical for regulatory compliance.</p>
<p>VERTICAL INTEGRATION AND BACKWARD AND FORWARD LINKAGES</p>	<p>Developing forward and backward linkages 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. For example, the addition of labeling and packaging operations, along with sterilization facilities can help to shift into direct distribution. Costa Rica used this latter strategy to diversify its end markets.</p>
<p>CHAIN/ INTERSECTORAL UPGRADING</p>	<p>Using the capabilities developed in one sector to move into a new sector. For example, the Dominican Republic, a major textile and apparel exporter to the US in the 1990s, saw its market share begin to drop as sourcing shifted to Asia. Local and foreign firms tapped into the skills of workers in this segment to move into medical textiles, producing surgical drapes, slings and wraps amongst others, as well as sutures. By 2016, medical textiles generated 12% of the country’s exports.</p>
<p>GEOGRAPHIC END MARKET UPGRADING</p>	<p>Entering into new higher value or volume end market segments, resulting in increased returns for the firm. For example, the FDA regulations make the US market a particularly complex one to enter; however, the country also accounts for approximately 40% of global market share making it an attractive target market. As regulations change, countries can also seek to “downgrade” to serve regional developing markets that might have lower regulatory requirements but high volumes. This downgrading move can simultaneously drive functional upgrading as distribution center capabilities are developed locally.</p>

Source: Authors.

4.1 Case Studies

In analyzing different prospective paths for upgrading for Pakistan in the medical devices GVC, it is useful to look more in depth at specific examples from countries facing similar questions of how to add value to their domestic sectors. Two cases were selected for further examination:

- **Dominican Republic** offers a compelling display of growth via programs to strengthen the attractiveness of its export processing zones (EPZs), coupled with investments in workforce development to leverage its cost-competitive labor force. These initiatives drove investments by foreign and domestic firms, allowing the Dominican Republic to diversify its product mix and enter new markets.
- **Malaysia** provides an example of strong entry into the medical device GVC by capitalizing on lessons from other industries. Following a long history of supplying latex surgical gloves, Malaysia expanded into a variety of medical device products. Initiatives aimed at diversification were supported by a highly coordinated approach with several institutions supporting the industry.

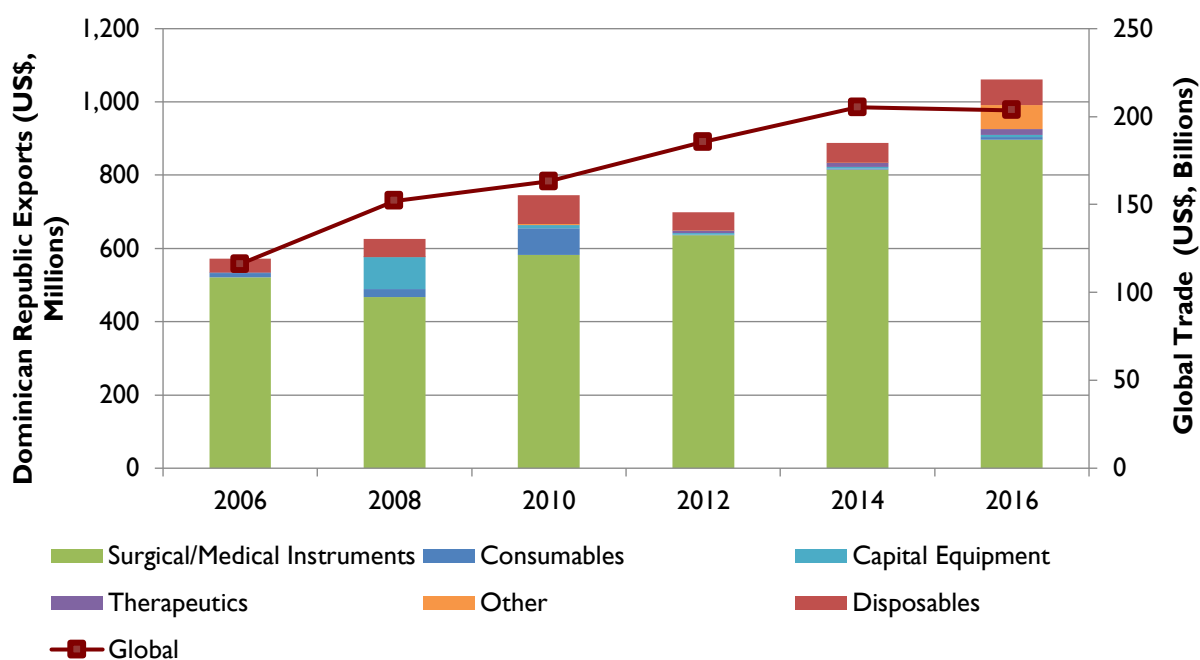
4.1.1 Dominican Republic

Over the past decade, the medical devices sector in the Dominican Republic has grown in importance to become one of the leading exports, worth over US\$1B in 2016, 0.5% of the global medical device market and 12% of national export basket (UN Comtrade, 2018).²⁴ Furthermore, exports have grown faster (85%) than the global average (75%) over the past decade (Figure 11). Insertion in the medical devices GVC marks a departure from the country's previous dependence on the comparatively volatile textile and apparel (T&A) industry. Medical devices production is one of the most advanced manufacturing industries in the country; while firms generally export devices in the surgical instruments product category, output covers a wide range of devices from sutures to ostomy bags and IV sets as well as parts for capital equipment. Activities primarily focus on labor-intensive assembly and packaging, with the more established firms carrying out sustaining engineering to support productivity improvements. Sectoral employment doubled between 2006-2016, reaching approximately 20,000. The majority of workers hold permanent contracts with access to social security and health care benefits.²⁵

²⁴ Based on an estimated US\$8.7B in exports (UN Comtrade, 2018).

²⁵ Export, employment and investment information in this project proposal is based on data published by the Dominican Republic *Consejo Nacional de Zonas Francas de Exportación (CNZFE)*.

Figure 11. Dominican Republic Exports in the Medical Devices GVC, 2006-2016



Source: UN Comtrade (2018). Based on HS-2002 product categories defined in Table A-1; DR exports; downloaded 27/08/2018.

This sector is exclusively export-oriented and driving this growth has been significant investment, from MNCs as well as a few domestic exporters. The Dominican Republic began exporting medical devices with the opening of Abbott’s plant in the late 1990s. However, the most significant growth has occurred since 2008 following considerable inflows of FDI. 72% of the sector’s US\$1.1B accumulated investment has entered since 2008 while the number of firms in the sector grew by 50% (CNZFE, 2003-2016). Larger plants are mostly controlled by North American divisions of global firms²⁶ and are part of large-scale, global networks with multiple production locations, including in Ireland, Mexico, and Malaysia. These include several lead firms such as Baxter, B.Braun, Becton, Dickinson and Company, and Medtronic. There are also numerous smaller niche firms, such as Oscar (US, cardiovascular) and Remington Medical (Canada, disposables). Investments have been very stable over time; during the past twenty years, there has only been one major closure. These almost exclusively foreign operations have leveraged the country’s relatively low-cost labor force and geographic proximity to assemble low value products for the U.S. market. Exports are concentrated on the US, which accounted for approximately 90% in 2016.

The country’s successful insertion into the medical devices GVC has been enhanced via three key upgrading trajectories: (1) product upgrading; (2) market diversification; and (3) inter-sectoral upgrading. Each of these trajectories is examined in further detail below:

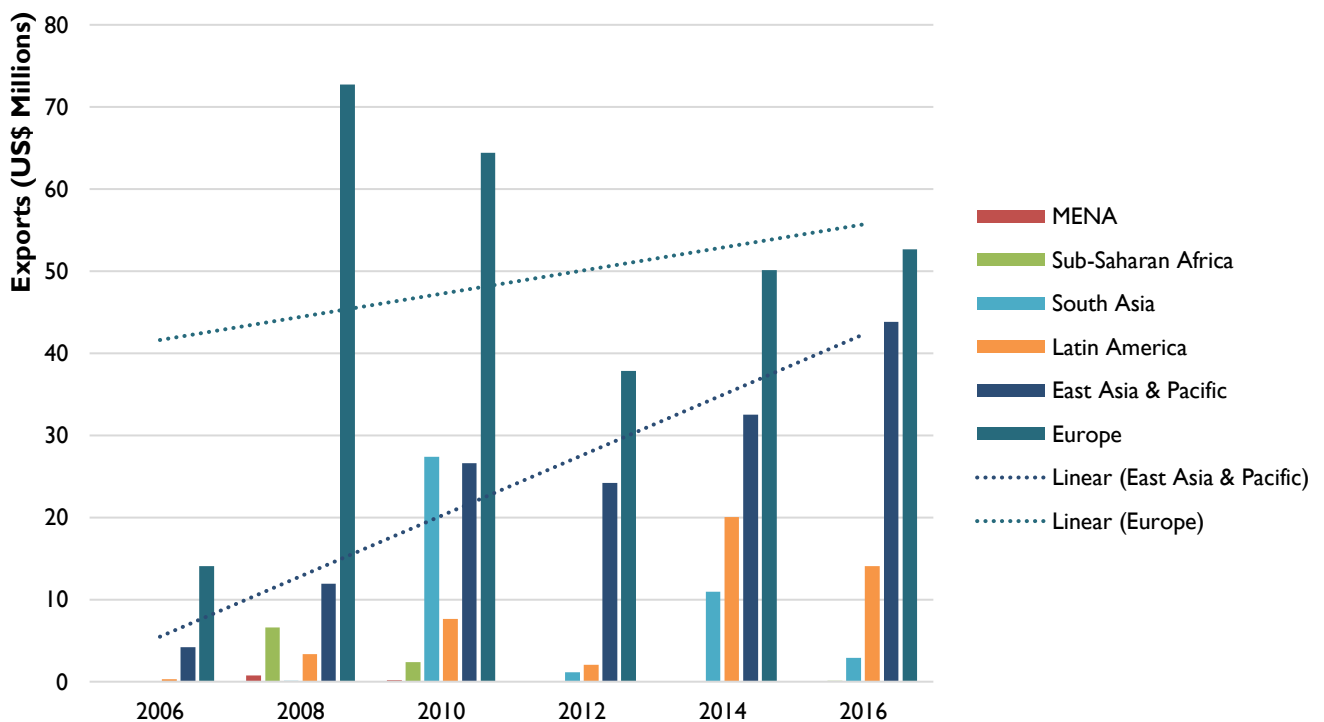
1. **Product Upgrading.** While the country’s exports are classified primarily in the surgical instrument category (HS02-901890), this obscures considerable product diversification. Firms generally started assembling one product and now produce multiple product families

²⁶ Exceptions include B. Braun, which is Germany by origin and Medtronic, which is now headquartered in Ireland. Nonetheless, the operations in the region are driven by the US divisions of these firms.

in their operations. The number of products registered with the FDA for manufacture grew close to 20% between 2017 and 2018 alone to 726 (FDA, 2018a). These products are typically high volume and the Dominican Republic plants are the exclusive global providers. Generally, the MNC operations in Dominican Republic are oriented towards lower risk products (Class I and Class II), but upgrading into new product categories has also increased in recent years as local capabilities have grown. Medtronic, in particular, notably increased the number of Class II products (FDA, 2018a) and the product segment with the highest growth rate over the past decade has been therapeutics (+9,000%).

- Market Diversification.** The US remains the country’s primary market accounting for the majority of exports (~90%). However, growth to new destinations has outpaced that to the US (114%; 2006-2016); these fast-growing locations include regional neighbors, Mexico and Colombia (LAC: 4,250%), European markets (274%; Germany, Belgium, Netherlands and Italy) and five key Asian markets (1,014%; China, Singapore, New Zealand, China Hong Kong, and Malaysia). Figure 12 shows the evolution of exports to select regions. Notably, East Asia & Pacific, led by China, Singapore and New Zealand, has become a major new growth destination for the country.

Figure 12. Dominican Republic Medical Device Exports, Select Regions 2006-2016



Source: UN Comtrade (2018). UN Comtrade (2018). Based on HS-2002 product categories defined in Table A-1; DR exports; downloaded 27/08/2018. Regional groupings based on World Bank classifications World Bank (2018b). Exports to the US excluded from graph for illustrative purposes. MENA: Middle East and North Africa.

- Inter-sectoral Upgrading.** In addition to expanding notably in medical instruments in recent years, Dominican Republic has seen a rise in medical textiles exports, leveraging the country’s considerable past experience in T&A (Burgaud & Farole, 2011). These include surgical gowns, bandages, straps, drapes and disposable medical bedding (FDA, 2018a). By

2016, the country was the third largest supplier of surgical drapes and towels to the US behind Mexico and China (US\$64M) (USITC, 2018). A small number of local and foreign investors export these, including lead firms in the segment, Cardinal Health and Ecolab (FDA, 2018a). This product segment typically has lower unit value prices, however, regulatory, quality and technical barriers to entry are lower.

Programs and Policies

Efforts in the Dominican Republic to support sector-specific growth are relatively incipient. Rather, the industry took root in the country organically, leveraging the country's cost-competitive labor; organized export processing zones (EPZ) with attractive fiscal incentives (World Bank, 2016); and the island's proximity to the US. EPZs in the Dominican Republic were established first for the T&A sector, however, they are not restricted; both foreign and domestic investors from any sector can take advantage of the host of fiscal incentives offered (World Bank, 2016). These include income tax holiday for 15 years (extendable), duty free imports of inputs and capital equipment and no local, land or other taxes, amongst others.²⁷ Initial efforts took advantage of the country's proximity to Puerto Rico, a former US manufacturing hub. During the 1990s, the Dominican Republic was used as a twin plant location for Puerto Rico operations, but as special tax provisions for Puerto Rican manufacturing were phased out, companies opted to concentrate production to their Dominican Republic plants (Marti, 2016). In recent years, however, as a result of its growing contributions to exports, employment and industrialization, the medical devices industry has been identified as a strategic sector for growth. In 2016, a Medical Devices cluster was formed as part of country efforts to develop an explicit strategy for upgrading.

Product Upgrading. While growth has been primarily organic, the success of existing firms has provided a strong demonstration effect for new investors. The commitment of these firms to long-term growth, in part, can be attributed to a strong supporting environment provided by a number of key stakeholders combined with a capable, cost-competitive workforce.

- **Strong institutional support from EPZ organizations.** The Dominican Republic is one of the world pioneers in the use of EPZs to promote inclusion in the global economy (Burgaud & Farole, 2011). Its first EPZs were launched in the 1960s and 1970s. The main institutions supporting these zones include the *Asociación Dominicana de Zonas Francas* (ADOZONA), an industry association representing all firms in the EPZs, and the *Consejo Nacional de Zonas Francas de Exportación* (CNZFE), a council which reports directly to the President's Office. These two organizations, along with the primarily privately-owned industrial parks, collaborate extensively in promoting investment, coordinating industry stakeholders and providing investors with extensive after-care services to facilitate their operations in country. In addition, CNZFE and ADOZONA have been instrumental in supporting the creation of the new Medical Devices Cluster. Other initiatives carried out by CNZFE include match-making events and certification support to help integrate local supporting firms such as packaging suppliers into the value chain (World Bank, 2016).
- **Workforce Development initiatives.** Much of the growth over the past decade has relied on the pools of available human capital with high school degrees, combined with a small

²⁷ These incentives, however, are on par with those of other regional locations such as Costa Rica, and thus are considered a necessary, but not sufficient condition for attracting firms to the industry (Field Research, 2017).

group of engineering and technical personnel and experienced management staff. Today, with over 15 years in the industry, an important share of senior management at the MNC plants is local.²⁸ Three key initiatives have helped streamline the supply of human capital to support industry needs:

- **Formal channels for EPZ operator employment.** Each industrial park operator maintains a list of approximately 200 qualified applicants for operator positions from which member firms are obligated to hire and salaries are consistent across firms. Park operators thus essentially serve as recruiters for their tenants.
- **Engagement by technical institutions to train operational staff.** While many companies run in-house training programs, a new Medical Devices Operator Program has been created by the national technical institution, INFOTEP,²⁹ in collaboration with human resources managers from medical devices firms. This 60-hour course focuses on issues of working in a cleanroom, documentation, working for an MNC, as well as technical skills such as materials handling. In 2017, approximately 150 students graduated from this course with very high initial placement rates in the industry.
- **Support to increase supply of highly qualified staff through allocation of scholarships and development of electives at the tertiary level.** Relevant subject areas for the medical devices industry are now eligible for graduate degree study abroad scholarships under a government-funded program (Ministerio de la Presidencia de la Republica Dominicana, 2017). In addition, in 2018, four new elective courses were developed at INTEC (*Instituto Tecnológico*) in collaboration with the new medical devices cluster for undergraduate engineering students., Firms provide employees to serve on the teaching staff. While these are new initiatives, these efforts have helped to signal to investing firms that the country is proactively managing human capital development for future upgrading needs, encouraging long term planning.

Market Diversification. The most relevant efforts towards market diversification have been transversal, focused on the country's inclusion in trade agreements with the US and the EU as part of broader regional blocs and ensuring lower tariff access to other markets. Although the medical devices sector varies in its reliance on preferential or free trade agreements (FTA) to provide tariff free enter into markets (Bamber & Frederick, 2018),³⁰ firms value the investment and business environment fostered as a result of having these agreements in place. This is particularly important for smaller companies with a limited global production portfolio. There was a notable increase in smaller operations investing around the time of the signing of the FTAs with the US (Central America FTA-Dominican Republic (2006)) and Europe (CARIFORUM-EU³¹ Economic Partnership, 2012) (Bamber & Frederick, 2018). These less globalized firms have a lower capacity to manage the risk associated with foreign investments, and thus tend to favor locations with additional institutional protection. Other efforts towards market diversification include participation in promotional activities such as the large industry trade fairs in the US and Germany and improving

²⁸ These managers have generally worked in the large MNC operations such as Baxter and Hospira.

²⁹ All firms in the country are required by law to contribute 1% of salaries into a common skills development fund; 35% of this fund is earmarked for training in the EPZs.

³⁰ Most favored nation (MFN) tariffs for many of these products are 0% in major markets including the US, EU, and China (WITS, 2018).

³¹ Forum of the Caribbean Group of African, Caribbean and Pacific States (CARIFORUM).

logistics. The country has two ports near Santo Domingo, providing redundancy for shipping operations; piloted single window customs operations; and launched a new logistics cluster (July 2017) improving support for a diverse number of shipping operations.

One notable, recent sector-specific initiative, however, is the attraction of third-party medical device sterilizer, Cosmed Group, that announced it will open operations in the same park as B.Braun, Becton, Dickinson and Company, Cardinal Health and Oscar (CZNF, 2018). This will support exports directly to market.

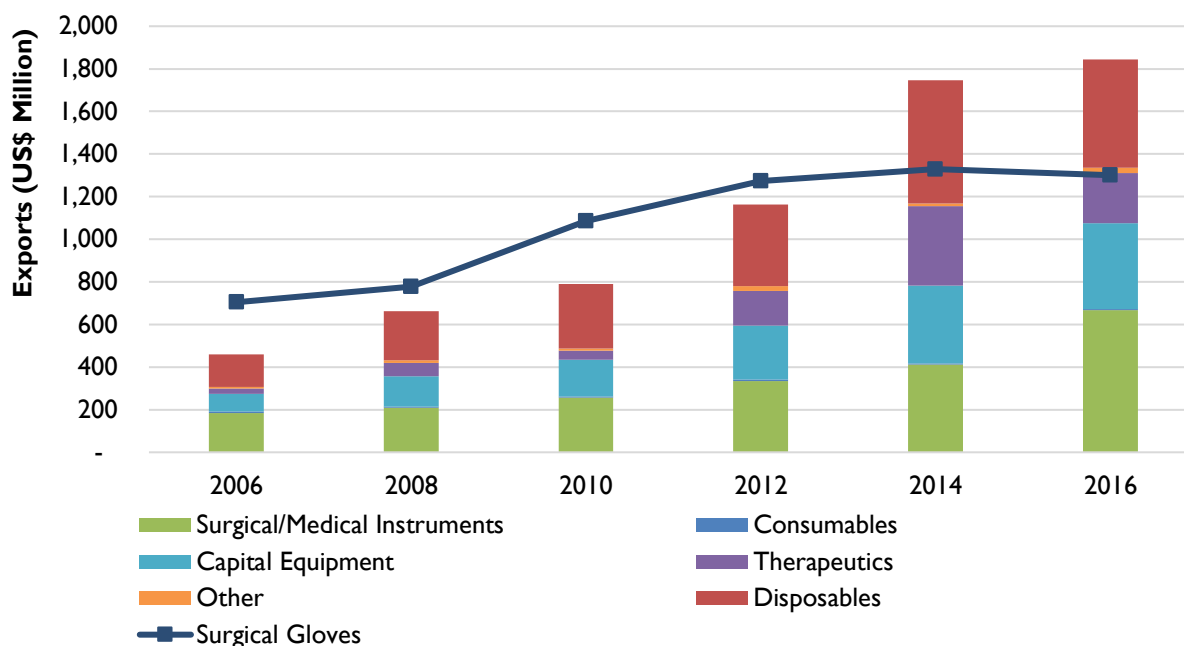
Intersectoral Upgrading. The decline of the apparel sector, which saw exports decrease by 50%, and employment to shrink from 120,000 to 44,000 between 2003 and 2016, put pressure on policymakers to identify new sources of export revenue generation and employment. This helped spur the creation of the medical devices cluster to help guide industry growth. However, there was no explicit policy for leveraging the capabilities honed in the T&A sector to drive medical textiles growth. This was rather opportunistic, facilitated by the geographic co-location of numerous T&A firms in the same EPZs as medical devices firms.³² When the former shut down, certain medical device firms saw an opportunity to hire the talented workforce with years of fabrication experience and leverage these for the medical textiles sector. Rather than have to teach operators how to sew, they only had to teach the specifics of the medical device products and how to operate under regulated conditions.

4.1.2 Malaysia: Leveraging Experiences in Related Industries

Malaysia is a growing producer of medical devices, exporting US\$1.8B in 2016, representing 1.1% of total global exports (AMMI, 2016; UN Comtrade, 2018), growing considerably faster than the Dominican Republic (85%) at 301% since 2006. Malaysia had its most notable growth in therapeutics, capital equipment and surgical instruments growing 852%, 383%, and 262% respectively between 2006 and 2016. This is compared to the more established medical supplies sector, surgical gloves, that grew only 85% in the same timeframe (Figure 13).

³² Park policy of maintaining a supply of qualified operators for all firms in their parks may have contributed to this labor mobility.

Figure 13. Malaysia's Medical Device Exports (US\$) by segment, 2006-2016



Source: UN Comtrade (2018). Based on HS-2002 product categories defined in Table A-1; Malaysia exports; downloaded 27/08/2018.

The industry is largely export-oriented with growth attributable to expansions in multiple product segments. Building on an established history and reputation in the rubber industry, several decades ago, Malaysia first leveraged its industry knowledge to transition into medical supplies, focusing on latex gloves. As Malaysia solidified its place as a global supplier of latex surgical gloves, it has also expanded into medical devices product categories. While surgical gloves, and more recent catheters comprises the bulk of medical-related exports (63%), other category exports are growing. These include surgical and dental instruments, orthopedic implants, and electro-mechanical devices, among others (AMMI, 2016; MITI, n.d.).

Malaysia's participation in the medical device industry is driven by 190 firms that can be divided into three categories (Table 12). The first group consists of local producers oriented primarily towards the domestic market. A second, growing body of firms function as contract manufacturers in the country, supplying global firms and exporters located in Malaysia. These firms are especially important for the country as they have the size needed to effectively enter into global markets, with the ability to secure the necessary technology and certifications to be competitive. Finally, a smaller group of firms are MNCs with facilities in the country and domestic exporters. Many of these firms are located in two major medical device clusters one located in the northern province of Penang and another in the central province of Selangor (Joshi, 2013) The clustering of firms in specific areas further aids in the transfer of knowledge and growth of the industry.

Table 12. Malaysian Medical Device Firms by Type

Firm Type	Number of firms	Key Features
Local SMEs	~109 firms	<ul style="list-style-type: none"> • Focus on Domestic Market • Often lack international certifications • Not integrated into the GVC
Local Larger firms	~47 firms	<ul style="list-style-type: none"> • Focus domestic and international • Each have >150 employees and >US\$6M in revenue • Often partner with MNCs to enter the GVC • Fully compliant with local and international standards
Multinational firms	~26 firms	<ul style="list-style-type: none"> • Primarily focuses on export • Account for highest percentage of export revenue • Fully compliant with local and international standards

Source: World Bank 2011; AMMI 2016

The medical devices industry in Malaysia is coordinated by several actors. Two industry associations, the Association of Malaysian Medical Industries (AMMI) and the Malaysia Medical Device Association (MMDA) both represent medical device firms in the nation. AMMI, consists of 67 firms who account for half of all medical device exports in Malaysia. Members include several local and international firms, such as 3M, Becton, Dickinson and Company, Boston Scientific, B. Braun, Johnson & Johnson, Terumo, among others (AMMI, 2016). MMDA, in contrast to the outwardly focus AMMI works to promote local operators and manufacturers who primarily serve the domestic market. Beyond industry associations, the government has aided the growth of the industry most recently by naming medical devices as a key sector in the Eleventh Malaysia Plan (RMK-11), established in 2016 and providing a strategic growth plan through 2020 (MITI, n.d.)

Malaysia's growth can be divided into two key trajectories: (1) Inter-sectoral Upgrading from medical supplies, primarily latex gloves, to medical devices; and (2) Product Upgrading through diversification into new medical devices segments such as therapeutics and capital equipment. Each of these upgrading paths is examined in further detail below:

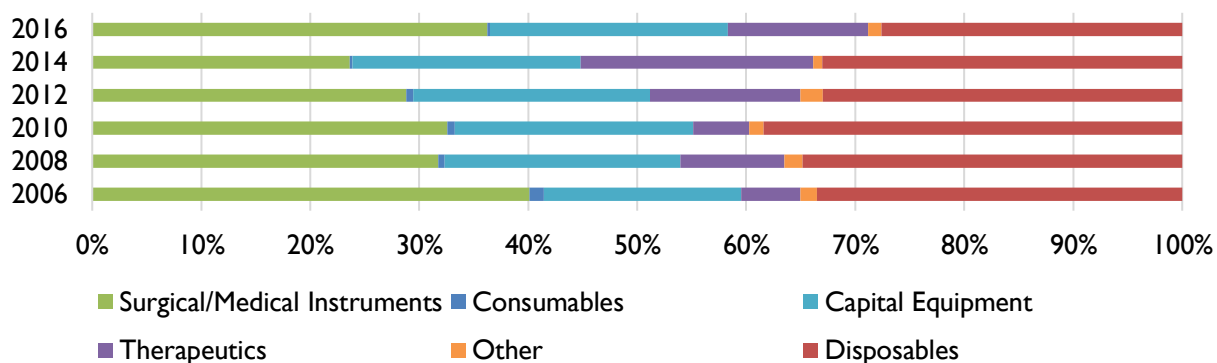
- 1. Inter-sectoral upgrading from surgical gloves to medical devices.** Malaysia's participation in the natural rubber industry helped to spur its participation in surgical gloves (Daly et al., 2017). After solidifying its position as a natural rubber exporter in the 1980s, Malaysia began to engage in manufacturing activities, producing latex gloves (RJA, 2011). Over time this industry grew with 105 firms participating in export-oriented latex glove production in 2014 (MIDA, 2014). Capitalizing on success in the surgical gloves industry, and the knowledge and capacities learned from surgical gloves, Malaysia shifted into the medical device industry. Initially, firms leveraged experience in latex rubber to move into other medical plastics, producing disposable kits and blood transfusion tubing, gradually moving from domestic use to export (World Bank, 2011).

Leveraging capacities and knowledge of international certification requirements and regulatory requirements abroad, Malaysia moved further into surgical and medical instruments production. This transition was aided by both the entry of MNCs into the country and also the emergence of larger local firms who began as contract manufacturers for simple products and grew in capabilities to produce complex products, such as finished orthopedic devices (World Bank, 2011). While exports were minimal, they grew at a steady

pace across multiple categories. By 2014, Malaysia’s medical device exports surpassed surgical glove exports for the first time, indicating a successful chain upgrading.

2. Product upgrading by diversifying into surgical/medical instruments and capital equipment is notable. Beyond moving from surgical gloves to medical devices, Malaysia is also upgrading into more advanced product categories. For several decades, Malaysia has been a small, but consistent supplier of surgical and medical instruments. However, since 2006, Malaysia has consistently increased exports of therapeutics and capital equipment (Figure 14). In 2006, 5% of medical device exports were therapeutics, however, by 2016 it increased to 13% of total medical device exports, an 852% increase. Capital equipment export share also grew, albeit at a slower pace, increasing from 18% to 22% of total exports, growing 383% (UN Comtrade, 2018). This growth reflects strategic positioning and investments that allowed the country to learn from other industry activities to enter higher value product segments and improve its competitive position. The established activities in electrical components, such as semiconductors facilitated entry into medical capital equipment (Frederick & Gereffi, 2016).

Figure 14. Medical Device Export Share by Segment, 2006-2016



Source: UN Comtrade (2018). Based on HS-2002 product categories defined in Table A-1; Malaysia exports; downloaded 27/08/2018.

Product upgrading benefited from increased institutionalization via the establishment of a regulatory council and by the concentration of firms in select areas, which spurred cluster formation. Under the regulatory council, firms improve production processes and move towards international compliance, helping them better connect with global firms and integrate into the medical devices GVC.

Programs and Policies

Growth has been driven by specific programs and policies that increased both the scope and depth of participation in the medical device GVC. These policies were led both from the top-down and the bottom up. State-led programs from Medical Device Act (MDA) and the Malaysia Industrial Development Authority (MIDA) combined with the promotion of the industry by government agencies as a high growth sector further spurred growth. At the same time, AMMI and key private sector stakeholders provided strong support for growth. The major programs and policies implemented that facilitated this growth are detailed below.

3. Inter-sectoral upgrading into Medical Devices. Malaysia's established position in the surgical gloves industry provided a base for entry into the medical device GVC. By capitalizing on established abilities in latex rubber, and the subsequent move to surgical gloves, Malaysia was able to attract new investments in medical supplies. Further, attractive investment packages and the creation of EPZs helped bring demanding foreign firms into the nation, facilitating movement into medical devices. Specific program/policy the country used to help spur this movement include:

- To attract investments, Malaysia enacted the Promotion of Investment Act in 1986. Under the current iteration of the policy, foreigners are allowed to hold 100% equity in operations and are given additional tax incentives and investment tax allowances (Koty, 2017).
- In the mid-2000s Malaysia created investment programs specifically for medical devices. First, the creation of EPZs for major manufacturers, attracted surgical glove producers, and allowed local firms to expand operations. Most notably the Malaysian firm, Top Glove, expanded to 40 factories in country and abroad. It is now regarded as the largest producer of surgical gloves, which now produces additional medical supplies (Top Glove, 2018).
- The country also offered additional tax incentives for medical device and other high-tech manufacturers. These included tax allowances and exemptions of 100% for up to five year plus additional incentives after the five-year period for capital equipment investments and other reinvestments in the industry (MIDA, 2008).
- The AMMI works towards promoting Malaysia via participation in regional and global showcases and by forging links with foreign firms. Having one actor dedicated to this activity helps to streamline messaging and spur the development of a national brand (AMMI, 2016).
- Workforce development programs undertaken by public and private educational institutions cultivate a skilled workforce. These programs developed curriculum based on input from industry participants with a focus on developing firms capable of producing devices suitable for export (Hui-Nee, 2013).
- The certification and knowledge for these advanced medical supplies provided a base for firms to expand into other devices, such as catheters and simple medical instruments (World Bank, 2011).
- Investments in infrastructure and logistics helped improve efficiencies within the country and allowed for better integration into global supply chains. This includes investments in seaports, airports and telecommunications in major medical device producing regions (MIDA, 2008, 2014).

4. Product Upgrading by diversifying into multiple medical device product categories. Malaysia is growing into more sophisticated product lines, building its domestic capabilities as a medical device hub. This has allowed for advancement of domestic firms to supply MNCs and helped make Malaysia a more attractive location for global firms. Actions to help spur this growth included:

- The Eleventh Malaysia Plan (RMK-11), the strategic plan for economic growth in the country, prioritized the medical device sector as a high potential driver of economic growth. Under the program, public and private sector actors are investing US\$4.1B over four years to further growth and create 86,000 new jobs by 2020 (AMMI, 2016). Investments focus on R&D as well as improvements in education and new business ventures (MIDA, 2018).

- A tax incentive program established in the mid-2000s promoted investments in new equipment for all firms operating in the medical device sector to foster the adoption of more complex technologies, citing growing demand domestically and in key ASEAN nations, such as Singapore (Hui-Nee, 2013). Manufacturing companies receive special incentives to invest in new equipment and technologies. Firms, operating in the country can receive tax incentives totaling up to 60% of capital equipment investments (MIDA, 2008).
- The MDA strengthened patent and intellectual property right protection in the medical device field. By closely monitoring all production in the nation, it can better protect firm specific knowledge, an important consideration for many global firms. This was critical to upgrade into more advanced and innovative product categories.
- The establishment of a national regulatory council under the Medical Device Act helped to promote adoption of GMPs among local producers, creating opportunities for deeper GVC participation. Aligning with regional and global market regulations helped to strengthen linkages with foreign firms. Specific programs that helped achieve this upgrading include:
 - Stipulation that all medical device establishments register with the government and receive permission to participate in the industry. This safeguards manufacturing and quality standards (Gross, 2012).
 - Participation in the Asian Harmonization Working Party helped to align Malaysia with other regional markets in several industries, including medical devices. The voluntary working group aims to align members with best practices and facilitate sharing of knowledge towards a more standardized regulatory approach to industries. Malaysia, along with Singapore, are seen as having the most advanced regulatory environment of the ten nations in the ASEAN Medical Device working group (Field Research, 2018b).

4.2 Key Lessons for Pakistan

The Dominican Republic and Malaysia have both managed to drive their growth in an increasingly competitive GVC by using both diversification and intersectoral upgrading to enhance the economic benefits of chain participation. In both cases, valuable lessons exist for Pakistan if it is going to integrate into the medical devices GVC to a more significant degree.

1. **Establishment/use of EPZs to increase competitiveness and strengthen linkages with key global firms.** Global investors in the medical devices industry, in general, have come to expect EPZ benefits as a necessary condition for potential consideration (tax holiday, duty free imports and exports, no land /local taxes). Both the Dominican Republic and Malaysia have established strong EPZs with competitive terms to support both foreign and local firms alike. Benefits in both countries include tax holidays, capital investment promotion policies, national treatment and 100% foreign equity ownership. These EPZs have helped to support investor confidence in operating in unfamiliar business environments, and overcome constraints associated with operating in developing countries. This geographic clustering of firms has also helped to contribute to knowledge spillovers in Malaysia.
2. **Leveraging of related industries to enhance participation in the medical devices GVC.** While neither country entered the GVC based on a homegrown industry, their participation in the medical devices sector has notably drawn on capabilities developed in near-by industries. Malaysia was able to use regulatory and quality compliance and technical

experience in both rubber glove and electronics components manufacturing to launch into medical supplies and then capital equipment devices. The Dominican Republic leveraged its capabilities in the T&A sector combined with its regulatory knowledge of supplying low cost devices such as certain catheters to move into specialized medical textile products, tapping into a strong labor pool and deepening the product range offered.

- 3. Strong industry coordination and institutionalization facilitated articulation of industry growth strategy in Malaysia.** Malaysia's medical devices sector is well institutionalized through AMMI. The AMMI serves as a marketer of the industry, promoting industry growth and potential abroad and working to attract FDI. The agency works closely with the MDA to assure all actors meet minimum quality standards and helps better gauge industry activities and coordinate activities. The coordinated approach facilitates national branding initiatives and consistent messaging has led to the development of the nation's reputation as a global medical device supplier.
- 4. Workforce development has been identified as a critical element in driving product upgrading and growth.** Both countries have developed a range of programs to develop human capital for the industry, illustrating the importance of skilled personnel for the industry. These have been focused on the specific segments in which the countries are operating. The Dominican Republic has focused on operator programs combined with training a smaller number of professionals in select roles through study abroad programs and engineering electives.

5 Recommended Upgrading Trajectories for Pakistan

Opportunities for Pakistan to make strong headway into the medical device industry are limited in the short term by productivity challenges, technological and labor constraints, and limited existing capabilities beyond precision metal. These should be addressed before longer-term growth strategies are pursued. Pakistan's participation in the medical device GVC has benefited from inertia, yet changing dynamics such as shifting global demands and a declining workforce necessitate change in order for the industry to survive. Despite historical competitive advantages in surgical instruments, Pakistan is facing new challenges, with exports plateauing in 2016 and 2017 (UN Comtrade, 2018). In addition, important security concerns along with a difficult business climate make investments by MNCs an unlikely proposition in the short term. However, several upgrading trajectories in the short to medium term will help position the industry for growth in the long term. Recommended upgrading trajectories include:

Short term: Process upgrading to increase production efficiencies. The most pressing upgrading trajectory is to make investments in new technologies and training programs to increase the productivity of the industry. The surgical instrument industry is facing growing pressure to reduce cost and increase productivity while also facing labor shortages. Several stakeholders cited these issues as significant challenges to future growth in the industry. Currently, the industry is plagued by low levels of technology with manual production and slow production times. Investments in new technology can help increase production efficiencies in the industry. These investments should be determined based on a review of capabilities and where current bottlenecks exist in production. A shift towards more technologically advanced production also signals a greater demand for semi-skilled labor in order to use new machines and production tools. Training challenges are especially notable given the nature of production and the need for several years as an

apprentice before reaching full productivity in the production of precision metal instruments. By investing in training programs and curriculum to attract new workers and by continued investment in new technologies to increase productivity, Pakistan can increase the competitiveness of the industry.

Medium term: Market diversification into emerging markets with growing demand for medical devices. Despite exports to over 100 nations, Pakistan's exports remain concentrated with 52% of total exports going to the US, Germany, and the UK (UN Comtrade, 2018). Moving forward, Pakistan should seek to grow exports in emerging markets. Diversifying export market will help mitigate risk to increased regulatory changes and downward pressure on price from lead firms. Taking advantage of increasing economic partnerships and cooperation, China offers a growing market opportunity, especially considering the potential for increased economic cooperation under the Belt and Road Initiative. Other Asian markets like India, Singapore, and China Hong Kong also offer promising alternatives for Pakistan. These nations are raising healthcare expenditures, insurance coverage is expanding and demand is growing along with population. These markets also tend to have lower regulatory hurdles for entry, allowing smaller firms the chance to increase exports.

Long Term: Product diversification into new medical device segments, specifically disposables and therapeutics. The medical device GVC covers many products. Currently, Pakistan only participates on a large scale in one notable product category, surgical instruments. Successful medical device clusters around the world have consolidated their position by developing capabilities in a diverse base of products. In particular diversification into disposables, a labor-intensive segment that capitalizes on Pakistan's low-cost labor supply. A second segment, therapeutics, such as implantables, the fastest growing product segment globally. Initial upgrading into implantable devices is occurring in Pakistan among select firms but policies that help promote this trend on a larger scale will better position the nation in the medical device GVC. Pakistan should also pursue policies that encourage producers to cater to trends on the global market within the precision metal product category such as single use and minimally invasive instruments.

Intersectoral upgrading into related industries. Within Pakistan, several related industries, such as T&A and offshore services exist. Strategic partnerships can create new opportunities for deeper medical device GVC participation. Pakistan can encourage partnerships among textile and medical device firms to spur movement into medical textiles and with services exporters to provide medical IT services, such as transcription. Furthermore, given rising competition and high entry barriers for medical devices, one strategy for growth is to use the experience and knowledge from current participation in the industry to build strengths in other sectors, such as barber tools, manicure/pedicure supplies, and cutlery. This is advisable especially for firms struggling to comply with new regulatory standards and buyer demands in the medical device GVC. Further, unlike Pakistan, countries such as Malaysia, which are highly active in the medical device GVC have a strong domestic market that can support many smaller firms. Pakistan can leverage its capabilities from several generations in surgical instruments and its current activities in related fields to increase competitiveness in related metal instrument industries including potentially launching their own brands due to lower barriers to entry for new actors.

6 Appendix

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

Product Category	Product Examples	HS Code Aggregation	HS96 Codes 6-Digit (HS02-07 changes)
Disposables	Needles, syringes, catheters, tubing, IV sets, bandages, surgical gloves	90183	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
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)
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)
Capital Equipment	MRI, Ultrasound machine, X-rays, Patient Monitoring Systems, Blood Pressure Monitor	90181 90182 9022	841920: Medical, Surgical Or Laboratory Sterilizers 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
Consumables /Medical Supplies	Bandages and dressings	3005	300510: Dressings, adhesive; and other articles having an adhesive layer, packed for retail sale for medical surgical, dental and veterinary use. 300590: Wadding, gauze, bandages ad similar (excluding adhesive dressings) impregnated or coated with pharmaceutical substances, packaged for retail.
Other Appliances	Breathing devices and other mechano-therapy devices	9019 9020	9019: Mechano-therapy appliances; massage apparatus; psychological aptitude-testing apparatus; ozone therapy, oxygen therapy, aerosol therapy, artificial respiration or other therapeutic respiration apparatus; 9020: Other breathing appliances and gas masks (excluding protective masks having neither mechanical parts nor replaceable filters)

Source: Bamber & Frederick (2018) ; see also Bamber & Gereffi (2013) for another application.

Table A- 2. Top Five Global Importers by Product Category by Value (\$US Mil), 2016

Importer	Disposables		Capital Equipment		Therapeutics		Instruments		Consumables		Other	
	Value	Share (%)	Value	Share (%)	Value	Share (%)	Value	Share (%)	Value	Share (%)	Value	Share (%)
World	34,944	17	41,704	20	51,375	25	56,074	28	7,275	4	12,240	6
EU-15+US	22,506	64.4	20,100	48.2	33,282	64.8	31,435	56.1	4,568	63	7,025	57
EU-15	14,833	42	11,478	28	24,028	47	19,781	35	3,347	46	4,035	33
USA	7,673	22	8,622	21	9,254	18	11,653	21	1221	17	2,990	24
China	1,603	5	4,671	11	2,382	5	3,018	5	--	--	449	4
Japan	1,832	5	2,566	6	2,312	5	2,546	5	197	3	645	5
Mexico	940	3	--	--	--	--	1,726	3	209	3	--	--
Switzerland	--	--	--	--	1,753	3	--	--	159	2.2	--	--
India	--	--	943	2.26	--	--	--	--	--	--	--	--
China, HK	--	--	--	--	--	--	--	--	--	--	413	3
Top Five	26,881	77	28,280	68	39,729	77	38,725	69	5,134	71	8,532	70
Pakistan	96	0.3	97	1.6	45	0.1	111	0.2	7.99	0.11	21.43	0.18
HS2002	90183*		90181*, 90182*, 9022, 841920		9021*		90184*, 90185*, 90189*		300590, 300510		9019, 9020	

Source: UN Comtrade (2018). Based on HS-2002 product categories defined in Table A-1; all exporters; downloaded 27/08/2018.

Table A- 3. Leading Importers in East Asia & Pacific

	2002	2004	2006	2008	2010	2012	2014	2016
East Asia & Pacific (US\$, Million)	10,850	15,899	19,195	24,089	29,866	37,788	39,901	41,008
	Share of Regional Imports (%)							
China	14	16	15	19	21	25	28	30
Japan	43	39	36	34	33	31	27	25
Australia	10	11	11	12	11	10	10	10
Rep. of Korea	8	7	9	8	7	7	7	7
Singapore	5	7	7	6	6	6	7	7

Source: UN Comtrade (2018). Based on HS-2002 product categories defined in Table A-1; all exporters; downloaded 27/08/2018.

Table A- 4. ISO 13845 Certification by Region, 2004-2016

	Certifications							Global Share								Growth Rate
	2004	2006	2008	2010	2012	2014	2016	2004	2006	2007	2008	2010	2012	2014	2016	2004-2016
Europe	1307	3574	7463	11034	12232	12884	14705	54%	45%	54%	56%	59%	55%	49%	50%	1025%
Middle East	54	267	286	456	723	760	834	2%	3%	2%	2%	2%	3%	3%	3%	1444%
Africa	29	37	63	104	186	164	168	1%	0%	0%	0%	1%	1%	1%	1%	479%
Central and South America	23	106	164	219	320	316	423	1%	1%	1%	1%	1%	1%	1%	1%	1739%
North America	850	2444	3033	4040	4719	5631	6185	35%	30%	21%	23%	21%	21%	21%	21%	628%
East Asia and Pacific	123	1257	1966	2480	3328	5628	6329	5%	16%	18%	15%	13%	15%	21%	21%	5046%
Central and South Asia	16	341	259	501	809	897	941	1%	4%	3%	2%	3%	4%	3%	3%	5781%
World	2402	8026	13234	18834	22317	26280	29585									1132%

Source: ISO Survey, 2017

Table A- 5. Medical Device Regulation in Major Asia-Pacific Markets

Country	Authority	Most Recent Relevant Regulation
China	China Food and Drug Administration (Ministerial level since 2013)	2014: Regulations for the Supervision and Management of Medical Devices' (Decree No 650); Announcements No. 25 and No. 74 containing 186 new standards for medical devices
India	Central Drugs Standard Control Organisation & State Licensing Authorities	2017: Medical Device Rules
Japan	Pharmaceuticals and Medical Devices Agency	2014: Pharmaceuticals and Medical Devices Law
Malaysia	Medical Devices Authority, Ministry of Health	2012: Medical Devices Act
New Zealand	New Zealand Medicines and Medical Devices Safety Authority	1981: Medicines Act
Singapore	Medical Devices Branch, Health Sciences Authority	2010: Medical Device Regulation; 2013/14: Remote Health/Telemedicine Guidelines
South Korea	Ministry of Food and Drug Safety (High Risk Devices) and Medical Device Information & Technology Assistance Centre (low risk devices)	2003: Medical Device Act (Law 6909) & 2011: Amendment (Law 10564)

Source: Authors based on (BMI Research, 2018b).

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