

ENHANCING THE COMPETITIVENESS OF PAKISTAN'S SURGICAL INSTRUMENTS INDUSTRY



APRIL 2022

A Joint Study By

The Pakistan Business Council (PBC) The Engineering Development Board (EDB) Surgical Instruments Manufacturers Association of Pakistan (SIMAP)





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DISCLAIMER

The findings, interpretations and conclusions drawn in this Study are those of the author(s) and do not necessarily reflect the views of the Board of Directors and Members of the Pakistan Business Council, or the companies they represent. Similarly, the findings, interpretations and conclusions drawn in this Study do not necessarily represent the views of the Engineering Development Board or the Government of Pakistan. Although every effort has been made to cross-check and verify the authenticity of the data used, the Pakistan Business Council, or the author(s), do not guarantee the data included in this work. All data and statistics used are correct as of 11th August, 2021 and may be subject to change.

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THE PAKISTAN BUSINESS COUNCIL: AN OVERVIEW

The Pakistan Business Council (PBC) is a business policy advocacy platform, established in 2005 by 14 (now 89) of Pakistan's largest private-sector businesses and conglomerates, including multinationals. PBC businesses cover nearly all sectors of the formal economy. It is a professionally-run organization headed by a full-time chief executive officer.

The PBC is a not-for-profit entity, registered under Section 42 of the Companies Ordinance 1984. Though it is not required under the law to do so, the PBC follows to the greatest extent possible, the Code of Corporate Governance as applicable to listed companies.

The PBC is a pan-industry advocacy group. It is not a trade body nor does it advocate for any specific business sector. Rather, its key advocacy thrust is on easing barriers to allow Pakistani businesses to compete in regional and global arenas. The PBC conducts research and holds conferences and seminars to facilitate the flow of relevant information to all stakeholders in order to help create an informed view on the major issues faced by Pakistan.

The PBC works closely with relevant government departments, ministries, regulators and institutions, as well as other stakeholders including professional bodies, to develop consensus on major issues which impact the conduct of business in and from Pakistan. The PBC has submitted key position papers and recommendations to the government on legislation and other government policies affecting businesses. It also serves on various taskforces and committees of the Government of Pakistan as well as those of the State Bank, the SECP and other regulators with the objective to provide policy assistance on new initiatives and reforms.

THE PBC'S FOUNDING OBJECTIVES

- To provide for the formation and exchange of views on any question connected with the conduct of business in and from Pakistan.
- To conduct, organize, set up, administer and manage campaigns, surveys, focus groups, workshops, seminars and fieldwork for carrying out research and raising awareness in regard to matters affecting businesses in Pakistan.
- To acquire, collect, compile, analyze, publish and provide statistics, data analysis and other information relating to businesses of any kind, nature or description and on opportunities for such businesses within and outside Pakistan.
- To promote and facilitate the integration of businesses in Pakistan into the World economy and to encourage in the development and growth of Pakistani multinationals.
- To interact with governments in the economic development of Pakistan and to facilitate, foster and further the economic, social and human resource development of Pakistan.

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THE PBC'S MEMBER COMPANIES

ARCHROMA





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International Industries Ltd.



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Bata

AkzoNobel

Artistic Milliners

Coca:Cola

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Jubilee















TAPAL

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Martin Dow

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PARISTAN TOBACCO COMPANY

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PAKISTAN STOCK EXCHANGE LIMITED

ROOMI FARRICS LIMITED

SICPA























SIEMENS













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1. BACKGROUND

The Surgical Instruments industry contributes 1.6% to Pakistan's exports. Being one of the five designated export sectors, the Surgical Instruments industry is an important contributor to Pakistan's exports with a potential to increase its contribution to the country's overall exports. It is felt by the industry's major players that the industry will be able to achieve its full potential if it is provided with a policy framework which allows it to compete on a level-playing field with its global competitors – in other words if the policy framework supports enhancing the industry's competitiveness.

To help improve the competitiveness of various sub-sectors of the engineering industry – including the Surgical Instruments sector, the Pakistan Business Council (PBC) and the Engineering Development Board (EDB) have entered into an MOU to jointly carry out sector competitiveness studies. This study on Pakistan's Surgical Instruments industry is the second joint study carried out by the two organizations.

2. OBJECTIVES

As per the terms of the PBC-EDB MOU, the objective of this study is to establish a general framework to facilitate cooperation between all stakeholders to promote development of the Surgical Instruments Sector of Pakistan. To accomplish this objective, this Study proposes – in consultation with all industry players, and a detailed review of literature, a set of policy recommendations aimed at making Pakistan a competitive hub for the manufacture of Surgical Instruments.

3. METHODOLOGY

A joint team from the PBC and EDB conducted a series of field interviews of the major players in the Sialkot cluster to obtain first-hand knowledge about the current state of the Surgical Instruments industry in Pakistan. Exporters were also encouraged to share their views on global trends and emerging competitors. The fieldwork was supplemented with desk research to better understand the strategies being followed by other countries for promoting their Surgical Instruments industries.

The Engineering Development Board (EDB) was established in 1995 with the primary objective to promote growth of Pakistan's engineering sector. The primary mandate which is assigned to the Board is policy formulation and putting in place a mechanism for implementing these policies. The objective being facilitating and encouraging the development & growth of Pakistan's Engineering Industry.

The EDB is organized under four operational groups: Tariff Group, Policy Development Group, Sector Development Group and Business Development Group. The key objective as stated above is to formulate and implement strategies for developing the engineering sub-sectors. This objective is planned to be achieved by integrating Pakistan's engineering sector into global supply chains by focusing on tariff rationalization, promoting indigenization, vendor development, giving international exposure to industry, handholding of industry, creating a comprehensive databank of industry capabilities through benchmarking, trainings etc.

EDB provides policy advice and technical support to Ministry of Industries and Production. It also engages with the Ministry of Finance / FBR on fiscal policy, the Ministry of Commerce / NTC for tariff rationalization, and with the Ministry of Science & Technology for standards, testing and quality.

EDB maintains an export directory of local engineering companies for dissemination of information. It also identifies local manufacturing capabilities in each sector and verifies manufacturing capabilities / facilities through field visits.

Regular sector studies are carried out by the EDB to identify sectoral needs for technological upgradation, especially for entering export markets. As part of this function, the EDB in collaboration with the PBC, has carried out this study on the competitiveness of Pakistan's Surgical Instruments Sector which in 2020 provided export revenues of USD 360 Mn.

The process followed in conducting this sector competitiveness study consisted of collection of secondary data from the Pakistan Revenue Automation (Pvt) Limited (PRAL), the Pakistan Bureau of Statistics (PBS), the International Trade Centre (ITC), a detailed review of previous studies conducted on the sector along with physical interviews of major stakeholders in the sector.

| PRE-PROCESSING DATA | DATA ANALYSIS | EVALUATION |
|---|---|---|
| Data integration Data filtering Field visits Industry interviews | Exploratory data analysis Containerizing qualitative analysis Theme identification Insight discovery Contextual reasoning | Selected dimensions of industry improvement |

4. EXECUTIVE SUMMARY

Surgical instruments are one of the many sub-sectors that fall under the umbrella of medical instruments and appliances. These include a wide assortment of products ranging from electrical and electro-mechanical items such as X-ray machines and CT scanners to non-electrical hand-held items such as forceps, scalpels, scissors etc. The US FDA has classified medical devices into three categories: Class I, Class II and Class III depending on their risk and criticality. Examples of Class I devices are tongue depressors, bandages, gloves, bedpans, and simple surgical devices. Examples of Class II devices are wheelchairs, X-ray machines, MRI machines, surgical needles, catheters, and diagnostic equipment. Class III devices are used inside the body and include heart valves, stents, implanted pacemakers, silicone implants, and hip and bone implants.

Pakistan's Surgical Instrument manufacturers mainly produce Class I and some Class IIb instruments. Surgical Instruments can also be classified under two major usage categories: disposables and non-disposables. Examples of non-disposable devices include machines and instruments, diagnostic equipment, surgical and dental instruments, prostheses, and implants.

Most of the world's surgical instruments are made by firms in selected cities & towns in Europe and Asia—these locations include Tuttlingen (Germany), Sialkot (Pakistan), Penang (Malaysia), Debrecen (Hungary), and Warsaw (Poland).

The Surgical Instruments industry of Pakistan is a highly fragmented industry with approximately 3,900 units (as per records of SIMAP¹) operating in the city of Sialkot, in the Punjab province of Pakistan. The industry consists of a multitude of small and medium sized manufacturers with a few large units. The market is characterized by a high degree of fragmentation as well as a strong export orientation. The industry operates on an OEM (Original Equipment Manufacturer) model. Orders and specifications are received from buyers, mostly from Germany and the USA. Local manufacturers construct the product according to specifications and export these to the overseas buyers who mostly brand the instruments and supply them to distributors overseas. The industry follows the Pareto principle with roughly 80 percent of the industry's revenue being contributed by 20 percent of its players. Pakistan's market share of surgical instruments has remained nearly static at 0.7% over the last 10 years suggesting a strong correlation of 0.96 with world demand.





The Sialkot cluster reportedly manufactures over 25,000 different types of instruments including precision instruments. These instruments are mostly made from medical grade stainless steel, and are used in surgical, dental and veterinary work. Items produced by the surgical sector includes various types of scissors, forceps, scalpels, needle holders, surgical knives, specula, stethoscopes, clamps, retractors etc. The instruments are categorized into two distinct quality differentiated market segments: higher quality reusable 'operation theatre' instruments and lower quality disposable 'floor' instruments used mainly for clinical purposes. The sector in Pakistan remains mostly restricted to the low technology end of the medical instruments segment with a few firms having the capacity to produce high-technology, precision-based, electromechanical instruments. There has been very low product or process innovation in the Sialkot cluster in the last 5 years. The surgical instruments manufactured in Pakistan are required to be compliant with the regulations of its main customers, namely the US and the EU. Pakistan needs to initiate efforts to comply with the new EU Medical Devices Regulations (MDR).

As can be seen from Table 1 below, Pakistan's surgical industry is highly competitive at the lower end of the technology scale due to its low labor costs.

| Country | Electricity cost USD per kWh | Labor cost USD per hr. |
|----------|------------------------------|---------------------------|
| Germany | 0.235 | 43.15 (EU average = 27.4) |
| USA | 0.121 | 39.09 |
| Pakistan | 0.163 | 0.809 |
| China | 0.103 | 4.11 |
| Vietnam | 0.077 | |

Table 1 Comparative costs of electricity and labor

The German SME surgical instrument manufacturers, who are the world leaders in surgical instruments, have mostly outsourced the lower technology intermediate and end products to the Sialkot cluster. While Pakistan's surgical instruments industry remains competitive in the low-tech end of the product scale, its exports are highly concentrated in a few geographical areas primarily because of established supply chains and the difficulties in entering new markets.

There are four distinct channels through which Sialkot's producers currently export their products:

- Foreign buyers who purchase both floor and theater instruments and supply medical wholesalers, retailers and medical end-users in the European, North American and East Asian markets. These also include large US 'kit-packers'.
- Foreign, particularly German, producers who subcontract all or part of their production of instruments to Sialkot based firms.
- Independent foreign-based Pakistani buyers, especially in the US market, these deal primarily in low quality floor instruments.
- Foreign sales offices of Sialkot manufacturers. These nominally independent concerns, usually managed by family members, purchase instruments from the parent firm in Sialkot and sell to specialized wholesalers, retailers and hospitals.

Majority of firms operating in the sector are family-owned. Some specialize in certain instruments or a particular branch of surgery. The vast majority are small firms employing less than 20 people. Larger firms have contracts mostly with German SMEs who outsource the manufacturing process to them. Small firms subcontract all but the final stages of production while large firms internalize most activities, using specialist subcontractors only for specific tasks and specialized items.

The top 3 destinations for Pakistan's surgical instruments are the USA, Germany and the UK. Nearly 80% of surgical instruments made in Pakistan are exported to only 15 countries. This limits Pakistan's export potential and increases concentration risk.

A recent development i.e., the advent of 3D printing is set to revolutionize many industries. 3D printing brings the ability to manufacture anything at a fraction of the current cost. Once commercialized, it is expected to change the face of industry as we know it. 3D printing has begun to play a significant role in the field of medical devices. The Pakistani Surgical Instruments manufacturing industry remains competitive due to its low labor cost. Currently the developed economies are using 3D printing for prototyping only. While Pakistan remains a global OEM supplier for the time being, the industry might face an existential risk in the future if commercial applications of 3D printing significantly reduce the cost of the final product negating Pakistan's labor cost advantage.

There is some evidence of minor growth in exports due to support given to the sector under various SROs. From 2016 to 2018, the exports of surgical instruments increased at a CAGR of 7.3%. This was in line with Pakistan's overall growth in exports which increased at a CAGR of 7.6% during the same period. Impact from support under SRO 578(I)/2016, "Product Development Incentive Order", saw an increase of 1.4% in CAGR for exports of surgical instruments. It may be noted that this CAGR was also impacted by other factors such as demand variation in global trade. After SRO 578 came into effect in 2016, the CAGR of surgical instruments exports grew from 5.9% to 7.3%.

There is intense competition within the sector. A majority of the local producers cite other domestic producers as their major competitors. Although local rivals claim to compete on the basis of product quality, the primary basis of competition appears to be price. This has been fueled by the growth in the number of manufacturers in Sialkot since the early 1980s and through competition between Pakistani sales agents in the USA. Firms try to obtain their rivals' price quotes, and the practice of 'poaching' foreign clients from competitors is not uncommon.

Sialkot has numerous service providers including printers who publish sample brochures and product catalogs. The manufacturers also often take part in foreign exhibitions. Apart from that, there is little marketing activity.

Buyers in the Middle Eastern market prefer to buy Pakistani instruments from US or European suppliers but not directly from Pakistan. This is because of their trust in European and American brands. Industry players in Sialkot need to appreciate the importance of brand building which can allow them to charge a premium. In addition to strong brands, country-of-origin association between Pakistan and Surgical Instruments will also facilitate Pakistani suppliers to enter new markets.

Manufacturers cite hurdles to online sales such as those associated with using PayPal and Amazon Pay. In both PayPal and Amazon Pay, buyers have the option to cancel payments within 7 days if they feel the delivery does not meet expectations. PayPal protects buyers therefore buyers trust the PayPal mechanism.

The Pakistani Surgical Instruments industry will face a new challenge in the form of the Medical Device Regulation (MDR) to be mandatorily introduced in the EU beginning 2024. All instruments destined for the EU will have to be compliant with the new European regulations on biocompatibility. The new regulations are expected, at least in the initial period to hinder exports of Surgical Instruments to the EU.

Sialkot suffers from infrastructure deficiencies. It is plagued with bad roads, inadequate power supply & distribution and poor communication links. In addition, increasing energy costs are making firms uncompetitive by squeezing margins and profitability.

The Surgical Instruments industry is a labor-intensive industry, heavily dependent on highly skilled labor to deliver outputs. However, recent years have witnessed a rapid de-skilling of labor in the sector. The phasing out of child labor from Pakistan has resulted in the collapse of the conventional ustad-shagird (apprentice) system, resulting in a dearth

of a trained and skilled workforce. Several attempts have been made to resurrect formal training programs, but the industry does not appear satisfied with the quality of trainees, citing that the nature of the skills is such that they have to be acquired at a young age.

The Export Processing Zone in Sialkot was set up at Sambrial on the Sialkot-Wazirabad Road in 2002. Despite the scale of the Zone, the adoption of the facility has been limited because of its distance from the current locus of manufacturing, which lies within the city. Manufacturers claim that the EPZ is too far from Sialkot and it would not be feasible for the stakeholders currently operating in the industry. Another factor for dissuasion to moving to the EPZ is the location of vendors and contractors who are mostly in the vicinity of existing units. Finally, manufacturers cite that raw materials and in-process semi-finished instruments would have to be moved in and out of the gated EPZ on a continuous basis as these are sent to sub-contractors for any number of processes.

The industry stated that they required a 'Common Facility Centre' (CFC) which would provide a common processing facility for manufacturers. The Surgical Instruments Manufacturers Association of Pakistan (SIMAP) has proposed that the CFC may be run by the Association itself thus ensuring the provision of advanced high-tech facilities on cost basis to firms. It should be noted that a CFC already exists in the form of the Metal Industries Development Centre (MIDC) in Sialkot. It is a government-established CFC with complete setup for all processes involved in manufacturing Surgical Instruments.

Surgical Instruments manufacturers also proposed that the government establish a 'Surgical City' at a prime location for all manufacturers to pool their production processes. The "City" is intended to house all manufacturing units of Surgical Instruments. However, the problems of fragmented vendors and outsourced sub-contractors being away from the proposed Surgical City remain. The provision of a new Common Facility Centre within the Surgical City can increase the attractiveness of the new location.

Other issues identified during the course of this Study include a deteriorating business climate, low managerial capacity, and lack of technology and modernization.

Our findings indicate that the surgical industry, despite being in existence for a long time, is not performing to its full potential. Compounded Annual Growth Rate from 2016-2020 was 2.6%. Despite the lack of fiscal space, the Government of Pakistan has been giving incentives to the industry to grow, however, the full development and export potential of the industry is yet to be realized. It is becoming increasingly clear that the government and industry need to come up with a joint strategy which encompasses product and process innovation if the industry to going to achieve its potential.

Pakistan's market share in the global trade for surgical Instruments is 0.7%. The low market share in terms of value appears to be primarily due to the absence of continuous product & process innovations aimed at producing products which fetch higher prices in global markets.

The primary raw material used in the manufacture of surgical instruments in Sialkot is imported medical grade stainless steel. The industry is unable to source quality steel locally making it dependent on imports. The quality of the imported steel varies depending on the source. Imports of prime steel are expensive, and for the SME sector time consuming. A few of the bigger players are supplied steel directly from Germany in an effort to ensure both delivery time and quality. Though the industry claims to be supplying most of the world's Surgical Instrument requirements, data shows that their top customers are buying a bulk of their requirements from other countries. As an example, the USA is buying a majority of its requirements of HS-901890 Surgical Instruments from Mexico while Germany is buying the bulk of its requirements from China. Evidence from Chinese videos posted on YouTube also shows that the Chinese are engaged in the manufacture of surgical instruments.

The local industry is having difficulties in moving into higher value electromechanical instruments such as EEG, ECG,

and other sophisticated equipment. Since buyers only give orders for low-end instruments such as scalpels, scissors, forceps etc., the industry is manufacturing those items. There have been no significant orders for new items in the last 5 years, clearly indicating that suppliers in Sialkot lack technology and capacity to produce high precision instruments – both these factors can be addressed through close industry – government linkages.

Since Pakistan's surgical instrument industry works at the low end of product sophistication, the market is characterized by intense price competition among the suppliers. In the absence of product differentiation, branding or a country-of-origin advantage, most exports don't carry a Make-in-Pakistan marking. With narrow margins, the industry is hoping to offset its future expenses e.g., upcoming MDR compliance expenditure through public funding.

On the positive side, the industry has made some marginal progress. Recently exports grew to USD 405mn in 2019 but a global slowdown in trade due to COVID-19 saw a slump in Surgical Instruments exports to USD 361.3mn in 2020. Government facilities, such as MIDC for the training of skilled workers and SIMTEL, are present for entrepreneurs and small manufacturers who cannot afford in-house production like the larger manufacturers. With its current product mix and near saturation in existing markets, the next logical step for the industry is to explore new products and new markets.

Major Issues Confronting the Industry & Some Recommendations:

| Issue | Industry Proposal | PBC recommendation |
|--|---|--|
| Only a few new products of any major export significance have been developed in the last five years. | Some of the larger players are concerned about this stagnation and suggest Joint Ventures with China for knowledge and technology transfer. | There is potential for Pakistani manufacturers to enter into JVs with German or Chinese firms. The country has a population base of 220 million and approximately 2,000 hospitals, which offer a potential market for 17 million surgeries per year, these JVs can rapidly build, scale and enter export markets. |
| Upcoming MDR compliance: Surgical Instruments exports into the EU will face a new challenge in the form of the requirement for compliance with Medical Devices Regulation (MDR) beginning 2024. All instruments entering the EU will have to be compliant with new European regulations on biocompatibility. The new regulations are expected to hinder exports of Surgical Instruments from Pakistan to the EU. | The industry recommends hiring foreign consultants for 3 to 5 years for MDR compliance. They also suggest that a lab be setup for testing biocompatibility as per the Medical Devices Regulations and that the government should bring in foreign certification bodies to provide test reports acceptable to foreign buyers. | The Government may bring in foreign consultants for a limited time period to assist in MDR compliance. Any cost of hiring consultants, building a lab etc. should be reflected in the pricing of the instruments that need compliance with MDR. If prices don't reflect the costs associated with compliance with MDR, the Pakistani taxpayers might end up subsidizing consumers in the EU. |
| Inconsistent Product Quality Impacting Exports. | The industry is concerned about the damage done to its image when sub-par instruments are supplied at extremely low prices quoted by some manufacturers. Some propose ISO9000 standards compliance as a way to ensure consistent quality. | The industry will need to self-regulate. Some options could include: provision of raw materials from a central SIMAP warehouse, SIMAP approved certification requirements for exporters, lobbying with the government to ensure that minimum export prices reflect costs of inputs etc. |

| Issue | Industry Proposal | PBC recommendation |
|--|---|--|
| Minimum Export Prices for disposable instruments are a hindrance. | Some players in the Surgical Instruments industry feel that the minimum export price imposed on instruments is hurting the disposable instruments industry as disposable instruments cost less than non-disposable ones. | The minimum export price may only be reduced for disposable instruments, not reusable ones. To prevent misuse of the proposed change, one option could be the implementation of Global Devices Medical Nomenclature (GMDN) for identification of instruments. GMDN is a system of internationally agreed generic descriptors used to identify all medical device products. |
| Absence of Made-in-Pakistan on export products, no major Pakistani Brands & hence no Country-of-Origin advantage. | Industry is of the view that if government mandates a Made-in-Pakistan requirement their buyers will stop buying from them. | Pakistan could learn valuable lessons from the Turkish "TURQUALITY" Program through which the Turkish government has been funding the development of 10 worldwide Turkish brands. A "PAKQUALITY" initiative may be promoted under the Public Private Partnership model to ensure that Pakistani brands also become regional global icons. The industry does not seem to appreciate that the segment that they operate in – low technology, low price, has no major competitors to Pakistani suppliers. |
| Concentration Risk: Exports are highly concentrated in markets of the EU & USA. | The industry's view varies on potential markets. Suggestions have been made including Russia, African nations and China. | PBC has identified that the East African nations and South Africa are potential markets where TDAP may look to hold more exhibitions. Other potential markets include Canada and the ASEAN region. EDB needs to work with the Association to create awareness regarding compliance requirements in new markets, and help manufacturers comply with these requirements. |
| Common Facility Center (CFC) | The Surgical Instruments industry is proposing that the government build a new Common Facility Centre equipped with the latest machinery that manufacturers cannot afford on their own. | A CFC in the form of MIDC already exists from where many manufacturers get part of their processes done. PBC proposes upgradation of the existing Common Facility Center. |
| Expansion is a major issue due to shortage of land in existing clusters. | The SMEs of the industry suggest construction of a 'Surgical City' which will be closer to Sialkot and will have a raw materials storage facility along with all other facilities in the existing cluster. | The same problems that impeded the Sialkot EPZ might also be present in the case of the proposed Surgical City. The challenge will be to ensure that the outsourced processes are also made available in the new cluster. |

5. PARAMETERS OF COMPETITIVENESS

Competitiveness is a broad concept and there is no definitive agreement on how to measure it precisely. However, there is more or less a consensus on which measures could be used to assess competitiveness (Pedraza, 2014).

At the firm level, the OECD (1992) defines firm level competitiveness as the "capacity of firms to compete, to increase their profits, and to grow". It is based on cost, prices, technology, quality and performance of products.

At the sectoral level, the European Commission cited Momaya's (1998) definition of sectoral competitiveness as "the extent to which a business sector offers potential for growth and attractive returns on investment".

At the economy-wide level, the European Commission defines the economy-wide or macroeconomic level of competitiveness as "an economy is competitive if its population can enjoy a high standard of living and high rates of employment while maintaining a sustainable external position".

Competitiveness can be looked at from 2 angles:

a) Price Competitiveness: price competitiveness refers to comparable export performance in terms of value. This is affected by a number of factors including relative inflation, the real effective exchange rate, and input costs.

b) Quality Competitiveness: Two broader notions here are the structure of an industry (such as the structural composition of the manufacturing sector which can be broken down into value addition, input sophistication, etc.) and its capabilities, for instance, innovation and the supporting players such as the education system, logistics system and government. The quality of non-price competitiveness includes a variety of aspects including product quality & design, R&D, brands, effective marketing, dynamic efficiency of the industry, labor productivity and others.

Measuring Competitiveness:

This study compares other countries with Pakistan on various metrics such as export value, revenue per unit of export, quantity etc. as well as metrics at the industry level such as Profit Analysis and Cost-Benefit analysis on subsidies. Since most surgical instruments manufactured in Pakistan don't have any comparable industry in other parts of the world, this study focuses on interviewing manufacturers and aggregating their inputs at the industry level, with the aim of finding out why the industry has not yet corporatized.

6. THE GLOBAL SURGICAL INSTRUMENTS INDUSTRY

Surgical instruments are one of the many sub-sectors that fall under the umbrella of medical instruments and appliances. These include a wide assortment of products ranging from electrical and electro-mechanical items such as X-ray machines and CT scanners to non-electrical hand-held items such as forceps, scalpels, scissors etc. Medical devices are classified into three categories: Class I, Class II and Class III depending on their risk and criticality. Examples of Class I devices are tongue depressors, bandages, gloves, bedpans, and simple surgical devices. Examples of Class II devices are wheelchairs, X-ray machines, MRI machines, surgical needles, catheters, and diagnostic equipment. Class III devices are used inside the body. Most implants are Class III devices, examples include heart valves, stents, implanted pacemakers, silicone implants, and hip and bone implants.

Devices that are characterized by complexity and technological sophistication and includes capital equipment (e.g. computed tomography scanners and magnetic resonance imaging devices).

Therapeutics

Devices of varying complexity that can be implantable (e.g. cardiac pacemakers and orthopedic implants) or non-implantable (e.g. ventilators and infusion pumps). This category also includes intravenous diagnostic kits.

Surgical Instruments

Devices that assist in various surgical procedures, such as cosmetic and endoscopic surgeries. Examples include forceps, scissors and dental drills.

Disposables

The lowest tech category of devices. These goods are mostly hospital supplies, such as bandages and rubber gloves, but also basic intravenous diagnostic technologies.

Figure 2 Medical Device categories and their relative technological complexity Source: (Torsekar, 2018)

Pakistan's Surgical Instrument manufacturers mainly produce Class I and some Class IIb instruments.

Surgical Instruments can be classified into two major usage categories: disposables and non-disposables. Examples of disposable devices include bandages, gloves, blood bags, colostomy bags, catheters, syringes, IV kits and tubing. Examples of non-disposable devices include machines and instruments, diagnostic equipment, surgical and dental instruments, prostheses, and implants. Materials used in non-disposable applications typically must meet long-term durability and stringent physical and mechanical properties. They may need to have chemical and/or lipid resistance, be resistant to specific sterilization methods, and may need to be biocompatible and nontoxic.

Disposable instruments are increasing in demand in the US markets, and as such Pakistani manufacturers are beginning to see increasing orders coming in for disposable or 'single-use' instruments.

Reusable instruments such as scissors are sterilized after each usage and periodically sharpened. This allows for multiple-use cycles during their 3-to-5-year operating lives. Single-use instruments are shipped in a sterile packaging. They are meant for one-time usage, especially in environments where re-sterilization is unavailable, e.g., emergency ambulances, military and disaster aid etc. Due to a significant price differential, there is also a competition between single-use and multi-use products for regular hospital applications as single-use instruments have a significantly lower price.

High tech

Medium tech

Low tech

Enhancing The Competitiveness Of Pakistan's Surgical Instruments Industry

Figure 3 shows the Life Cycle Assessment of Single-use vs multi-use instruments as determined by a Joint German-Australian Research Group in Sustainable Manufacturing who tracked the two sets of instruments throughout their entire lifecycle.



Figure 3 Life Cycle Assessment of Single-use vs multi-use instruments as tracked by researchers Source: (Schulz, et al., 2011)

Historically, surgical instruments were manufactured in regions that traditionally forged and worked metals, particularly knives, swords, weaponry and then stainless-steel products. The range of distinct production tasks within the industry promoted a division of labor whereby small firms began to flourish and local cluster began to emerge.

Sialkot is one of the five major global hubs for surgical instruments manufacturing. The other four being, Tuttlingen (Germany), Penang (Malaysia), Debrecen (Hungary), and Warsaw (Poland) (Bhutta, 2006).



Figure 4 Major Global Surgical Instruments Manufacturing Clusters

Of these, Tuttlingen and Sialkot are the largest centers of production. Companies in Tuttlingen represent manufacture of surgical instruments in the developed world, these firms rely on specialist technologies to produce endoscopes and implants in addition to more traditional instruments.

Companies in Sialkot represent manufacturing of surgical instruments in the developing world, a practice that stems from the production of swords in the Punjab during the Mughal era. Production methods are more traditional and labor intensive with most instruments manufactured and finished by hand.

Trade of surgical instruments fall under Chapter 90 of the Harmonized System (HS) codes. HS codes are the standardized classification of all items traded under World Trade Organization (WTO) rules.

The majority of Pakistan's exports of surgical instruments are covered under the 6-digit HS code: 901890 - Instruments and appliances used in medical, surgical or veterinary sciences, not elsewhere specified. The global trade for this HS code category was worth USD 58.1bn in 2020, of which Pakistan's exports were approximately USD 361.3mn, indicating a market share of 0.7%. While most manufacturing occurs in the clusters mentioned above, trading of surgical instruments takes place all across the world.



Enhancing The Competitiveness Of Pakistan's Surgical Instruments Industry

Figure 5 Pakistan's Surgical Instruments Top Destinations Source: (International Trade Center, 2020)

7. PAKISTAN'S SURGICAL INDUSTRY

Majority of the instruments manufactured are of mechanical nature and only few instruments are of electro-mechanical nature with very basic electrical components.

The surgical industry of Pakistan is a highly fragmented industry with the Surgical Instruments Manufacturers Association reporting more than 3,500 units clustered in the city of Sialkot. The industry consists of a multitude of small and medium sized manufacturers with a few large units. The sector is characterized by a high degree of fragmentation as well as a strong export orientation. The industry operates on an OEM (Original Equipment Manufacturer) model. Orders and specifications are received from buyers, mostly from Germany and the USA. Local manufacturers construct the product according to the OEMs specifications and hand it over to the buyer who then does quality assurance, branding, repackaging and then supplies the product to his distributors.

The industry follows the Pareto principle with roughly 80% of the industry's revenue being generated by 20% of the firms. The bigger players are mostly descendants of Mr. M.F. Elahi who managed to secure orders from German buyers. The largest players, who are running on full-capacity are operating on the OEM model. Their orders and specifications come from international buyers along with technical assistance when required; the smaller players however are in need of marketing and technical support if Pakistan is going to significantly increase exports from the sector.

A pictorial representation of some of the types of instruments manufactured in Pakistan is given in Figure 6. Majority of the instruments manufactured are of a mechanical nature and only a few instruments are of an electromechanical nature with very basic electrical components.



Figure 6 Types of Surgical Instruments Manufactured in Pakistan Source: Surgical Instruments manufacturers' online catalogs

Pakistan's Surgical Instruments industry has witnessed modest growth over the last 5 years, as shown in Figure 7.





A cursory analysis of Surgical Instruments exports reveals that Pakistan's market share of the global surgical equipment market has remained static at 0.7% over the past 10 years suggesting a strong correlation with world demand.



Analysis of data over the last 10 years for world exports of HS-901890 Surgical Instruments and Pakistan's exports of the same revealed a correlation of 0.96. This means Pakistan's exports of surgical instruments increase or decrease at almost the same rate as the world's exports of surgical instruments. When the world demand for surgical instruments moves up or down, Pakistani manufacturers receive their orders accordingly.

| Exports of HS-901890 Surgical Instruments | | | | | | | | | | | | |
|---|----------|----------|----------|----------|----------|----------|----------|----------|----------|----------|----------|----------|
| Value in USD Mn | 2009 | 2010 | 2011 | 2012 | 2013 | 2014 | 2015 | 2016 | 2017 | 2018 | 2019 | 2020 |
| World | 34,126.5 | 36,883.9 | 41,192.9 | 42,414.5 | 45,181.5 | 47,765.0 | 45,796.2 | 47,605.5 | 50,005.7 | 54,619.2 | 57,825.3 | 58,112.2 |
| Pakistan | 233.0 | 219 | 271.7 | 291.4 | 296.8 | 319.5 | 332.6 | 326.0 | 361.1 | 375.5 | 405.5 | 361.3 |
| %age share of Pakistan | 0.7% | 0.6% | 0.7% | 0.7% | 0.7% | 0.7% | 0.7% | 0.7% | 0.7% | 0.7% | 0.7% | 0.6% |

Table 2 Surgical Instruments exports of World and Pakistan with market share

Source: (International Trade Center, 2020)

This finding indicates that while exports of surgical instruments from Pakistan have grown at a higher CAGR than overall national exports, Pakistan has been unable to increase its global market share.

Looking at the quantity-wise data as shown in Figure 8, it is evident that the quantity of items exported peaked in 2014 at over 238 million units and then saw a dip in volume in 2015, 2017 and 2019. The decline in 2015 can be attributed to a decline in global trade during the year. While the global trade recovered in 2017, Pakistan's exports of surgical instruments in volume terms declined during the year.



Source: (UN Comtrade, 2020)

This also shows that while the dollar-value of exports of Pakistan's surgical instruments have been crawling upwards, the quantity of items exported have been declining post-2014.

Pakistan's Exports of Surgical Instruments - Quantity wise

8. ITEMS PRODUCED BY PAKISTAN'S

SURGICAL INDUSTRY

8.1 EXISTING PRODUCTS

The Sialkot cluster is capable of manufacturing over 25,000 different types or surgical instruments; however, majority of trade is in approximately 2,000 SKUs. Surgical instruments produced in Sialkot are mainly produced from medical grade stainless steel, and are used in surgical, dental and veterinary work.

Items produced by the surgical sector include various kinds of scissors, forceps, scalpels, needle holders, surgical knives, specula, stethoscopes, clamps and retractors. Most instruments are differentiated by function (e.g., incision scissors, operating scissors, stitch scissors, neuro-scissors, epistome scissors, eye scissors, tonsil scissors, uterine scissors etc.). Further differentiation is done on the basis of by size, metal composition and end-user requirements.

The instruments are widely categorized into two distinct quality differentiated market segments: higher quality reusable "operation theatre" instruments and lower quality disposable "floor" instruments used only for clinical purposes.

The sector in Pakistan remains restricted to the low technology end of the medical instruments sector with only a few firms having the capacity to produce high-technology, precision-based, electromechanical instruments.

Manicure and pedicure products are included under cutlery; however, they are exported as surgical instruments. Their annual export value is estimated at 50-60 Million USD.

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8.2 PRODUCTS AND TECHNOLOGY

There have been few significant product or process innovations in the industry in the last 5 years. Manufacturers work on the OEM (Original Equipment Manufacturer) model similar to the textile industry. Orders are obtained from foreign buyers along with specifications and requirements. Local manufacturers make the instruments with little or no branding of their own and sell to buyers at competitive prices.

The surgical instruments industry today is at a crossroads. The shortage of labor, coupled with the increasing cost of energy, necessitate productivity and efficiency improvements in the sector.

The desire to climb up the value chain will open doors to new and exciting areas such as orthopedic and orthodontic devices and instruments, beauty and cosmetic instruments, and electro-mechanical medical devices and instruments. However, to materialize these opportunities that will open up, it will require considerable investments in capacity, technology, and training and very few firms (no more than 10 to 25) are currently in a position to make such investments.

Creating higher quality surgical instruments will require investments in automation through the deployment of CNC lathes and other advanced machinery, such as multi-axis machining centers, and 3D printers and plotters. The move will also require an investment in the forging and steel industry, to allow for better quality local steel to be available as an input for the final products.

8.3 INTERNATIONAL STANDARDS COMPLIANCE

To ensure the safety of users/patients, Surgical Instruments must conform to certain standards. There are several regulations in force for testing depending on the markets for which the instruments are destined. There are differences in the regulatory systems and the required documentation for registration in different countries. There are around 60–65 countries which have implemented regulations for medical devices including Surgical Instruments or will be doing so soon (Ramakrishna, Charlene, Tian, Liao, & Teo, 2015). The local manufacturers identify their target markets and comply with the regulations accordingly. For example, a medical device that has been approved by the US FDA may not be able to enter the Chinese market without the CFDA's approval, even though it has undergone the most stringent procedures in the world as mandated by the US FDA.

Surgical instruments manufactured in Pakistan are required, at the minimum to be compliant with regulations of its main customers namely the US and the EU. Pakistani manufacturers depending on requirements need to comply with either CE marking, GMP, ISO 9001, ISO 13485, and ISO 10993. In 1994, the US imposed restrictions on the import of surgical instruments from Pakistan by requiring compliance with FDA regulations. This forced the industry to improve its manufacturing and management systems along with acquiring certifications, such as GMP, ISO, and CE.

Recently the European Union has enacted the Medical Devices Regulations (MDR) with which Surgical Instruments imported in the EU will have to eventually comply with. Pakistani manufacturers are currently in the process of complying with the requirements of the new MDR regulations.

9. PAKISTAN'S SURGICAL INDUSTRY COMPETITIVENESS

Pakistan's surgical industry is highly competitive at the lower end of the technology scale e.g., forceps, scissors, clamps, stethoscopes etc. due to its low manufacturing and labor costs. In fact, German SMEs in the surgical sector have outsourced most of these low technology products to the Sialkot cluster (Jacobsson, Klutsch, Kang, & Probst, 2017). The German companies now focus on continuous innovation, broadening of product portfolio within the existing field of mechanical surgical instruments and on looking for an increased global footprint. They have formulated their own business strategies and have moved towards product innovation and sophistication.

While Pakistan's surgical instruments industry remains competitive in the low-tech end of the product scale, their exports are highly concentrated within a few geographical areas because of established supply chains and a difficulty in identifying and entering new markets.

10. PAKISTAN'S COMPETITIVE EDGE

Pakistan's competitive edge lies in its low cost of production. The average price of a surgical instrument depends on the type and category. Average unit prices for exports range from USD 0.5 to USD 7.0 (derived from PBS data).

10.1 SURGICAL GOODS MANUFACTURING IN PAKISTAN

To minimize overhead costs, most of the production process is subcontracted. Most firms subcontract the initial production of instruments to workers employed in small workshops or working from their own homes, with finishing and quality checking of the product being in-house.

Electricity costs are lower in China but labor costs are lower in Pakistan. Since low level instruments have a large labor component especially in polishing, Pakistan is able to produce instruments at a cheaper cost than China. China meanwhile focuses more on Class III instruments.

Table 3 Comparative Electricity and Labor Costs

| Country | Electricity cost USD per kWh | Labor cost USD per hr. |
|----------|------------------------------|---------------------------|
| Germany | 0.235 | 43.15 (EU average = 27.4) |
| USA | 0.121 | 39.09 |
| Pakistan | 0.163 | 0.809 |
| China | 0.103 | 4.11 |
| Vietnam | 0.077 | |

Source: (www.GlobalPetrolPrices.com, 2021) (International Labor Organization, 2021)

Specialist subcontractors generate economies of scale for local producers with savings on cost, space and skills in capital intensive processes, such as forging and heat treatment. This spares smaller firms from investing in expensive machinery (such as mechanized drop and pneumatic hammers, high temperature forges, eccentric presses, die-making equipment, dies, and vacuum heat furnaces).

In labor-intensive and product-specific tasks, the sub-contractors ensure that firms do not need to maintain large pools of specialized labor. Before the product is exported, quality is checked against the European Union or US standards.

There are benefits derived from Sialkot being a surgical instrument cluster. Clustering generates agglomeration economies and facilitates vertical and horizontal linkages between local participants. This enhances possibilities for local cooperation and raises the prospect of cluster-wide gains (Sengenberger & Pyke, 1991). Clusters offer the following potential gains:



Figure 9 Advantages of clusters

Joint action within vertical linkages, including backward ties with suppliers and subcontractors and forward ties with traders or buyers allows for the ability to absorb and transmit skills and knowledge within vertical production chains. This joint action promotes competitiveness, accelerates innovation and enhances prospects of growth for the cluster.

The concentration of highly skilled labor within the cluster generates further advantages for Sialkot based firms. Firms are able to find skilled workers at short notice within the cluster. Similarly, labor is able to seek work with little difficulty. This is facilitated by the easy availability of information within the cluster on the employment history and credentials of specific artisans.

The skill base is reinforced by the traditional pattern of informal apprenticeship (the ustad-shagird system), a common basis of training in the sector. This results in the skills associated with the industry remaining concentrated in Sialkot. The presence of large numbers of skilled workers and subcontractors ensures competition. Wages and process task rates for each activity are well known and uniform across the cluster.

All these advantages are particularly crucial for SMEs who despite their more limited resources are able to produce a wide range of products and compete in the same global markets as larger firms.

For a sector largely dependent on imported raw materials and producing almost exclusively for distant foreign markets,

Sialkot is poorly located. Although it has its own international airport, and is in proximity to Lahore International Airport, surgical instruments made in Sialkot are normally shipped using shipping lines to keep freight charges low. It is over 1,000 km from the nearest seaport, and also does not lie on Pakistan's main north-south road and rail artery.

There have been attempts by some investors in the past to shift the sector to Karachi, however they have not fared well. One unit tried to move to the port of Karachi, Pakistan's industrial and commercial hub, in the mid-1950s in search of lower transport and trading costs. Shifting to Karachi, however, meant operating in isolation. The firm in relocating to Karachi, lost access to the specialized labor market and the sector specialized support network taking shape in Sialkot. It tried to entice skilled artisan labor from Sialkot to Karachi with the prospects of higher wages. Some moved, but most returned to Sialkot where living expenses were lower, a greater volume of work was available and family support networks were present. Unable to compete with Sialkot based producers, the firm ceased producing surgical instruments in the late 1960s.

11. VALUE CHAIN ANALYSIS

There are four distinct channels through which Sialkot's producers trade in global markets:

- Foreign buyers who purchase both floor and theater instruments and supply medical wholesalers, retailers and medical end-users in Europe, North America and the East Asian markets. These also include large US "kit packers".
- Foreign manufacturers, particularly German manufacturers who subcontract all or part of their production of particular instruments to Sialkot based firms.
- Independent foreign-based Pakistani (usually from Sialkot) buyers, especially in the US market, who deal predominantly in low value floor instruments.
- Foreign sales offices of Sialkot manufacturers. These nominally independent concerns, usually managed by family
 members, purchase instruments from the parent firm in Sialkot and sell to specialized wholesalers, retailers and
 hospitals.



Figure 10 Logistics Chain Mapping

| Core process | | | ۲ ک | | | | | |
|--------------|---|---------|----------|-----|---------|---------|----------|---------|
| | | warde | Compa | | ier | Bank | gent | ustoms |
| | | ght For | irance (| AP | go Carr | orter's | ıring Aş | istan C |
| | | Frei | Insu | SIM | Carg | Exp | Clea | Pak |
| 1. Buy | | | | | | | | |
| 1.1. | Conclude sales contract and trade terms | | | | | х | | |
| 2. Ship | | | | | | | | |
| 2.1. | Arrange transport | х | | | х | | | |
| 2.2. | Obtain cargo insurance | х | | х | | | | |
| 2.3. | File Goods Declaration | | | | | | х | х |
| 2.4. | Prepare cargo for shipment | х | | | | | | |
| 2.5. | Transport cargo | х | | | | | | |
| 2.6. | Customs clearance of cargo and loading | х | | | | | х | х |
| 2.7. | Prepare documents required by importer | х | | | | | | |
| 3. Pay | | | | | | | | |
| 3.1. | Establish payment guarantee | | | | | х | | |
| 3.2. | Claim payment for goods | | | | | х | | |

Figure 11 Core Processes and Responsibilities in the Logistics chain

It takes, on average, 13 days for stakeholders to fulfill commercial and regulatory requirements of Surgical Instruments export business processes (Trade Related Technical Assistance (TRTA II) Programme, 2016).



- 1.1 Conclude sales terms and contract
- 1.2 Arrange transport
- 2.2 Obtain cargo insurance
- 2.3 File Goods Declaration
- 2.4 Prepare cargo for shipment
- 2.5 Transport cargo to Airport
- 2.6 Customs clearance and loading of cargo
- 2.7 Prepare documents required by the importer
- 3.1 Establish payment guarantee
- 3.2 Claim payment for goods

Other countries such as the US and Germany offer complete supply chain management with streamlined distribution and warehousing. Some of the bigger exporters in Germany store their goods in bonded warehouses or Free Trade Zone (FTZ) warehouses. In Bonded warehouses, no duty is collected until the products are withdrawn for sale. If the importer cannot find a buyer, goods can be re-exported without paying duty. In FTZ warehouses, goods do not go through an official Customs entry process when first stored in the warehouse. Goods can be inspected, repaired and repacked within a FTZ warehouse. This allows a business to remove damaged products and withdraw them before going to market. Merchandise can remain in a FTZ warehouse indefinitely, whereas bonded warehouses have a five-year time limit.

Figure 13 shows the key elements of the Sialkot surgical instruments sector that interact with the Surgical instruments manufacturers in the value chain process.



Figure 13 Key elements of Surgical Instruments sector

Key process activities in the manufacturing process include:



Figure 14 Key processes in the manufacturing process

Most of the firms are family-owned. Some specialize in particular instruments or a particular branch of surgery. The vast majority are small firms employing less than 20 people. Surrounding Sialkot's producers are an array of satellite units including suppliers of inputs and machinery, specialized subcontractors and ancillary service providers.

Manufacturers face an efficient market for supplies in which prices are well known and products and services standardized and easily available. Relations with suppliers, despite being long-term, are essentially arms-length in nature. Ties between producers and input suppliers are rarely anonymous, with majority of the firms using the same suppliers for the past 5 years. Suppliers assist when problems arise and seek technical advice and suggestions from manufacturing enterprises. Yet dialogue with input suppliers is largely centered on price, availability and source of inputs.

Where quality concerns are paramount, the industry as a whole has successfully exerted pressure on local suppliers to upgrade. for example, disposable surgical instruments are usually manufactured from locally available medical grade steel. Quality issues led to Pakistani surgical instruments being barred from the US market in 1989. Following that crises, Sialkot's producers, particularly their trade body, successfully pressurized local medical grade steel suppliers to improve quality.

The industry is highly labor intensive with over 20 stages in production, each requiring distinct skills and tools. Some subcontractors are product as well as process specialists. In addition to suppliers and subcontractors, there are a number of public and private institutions geared to meet cluster needs. These include the government-run Trade Development Authority of Pakistan (TDAP) which specializes in exhibitions and the technology support and common services facility of the Metal Industries Development Centre (MIDC) operated by the provincial government; the privately run Sialkot Dry Port Trust provides Customs and Port handling facilities locally and there are representative trade bodies such as the Surgical Instruments Manufacturers Association of Pakistan and the Sialkot Chamber of Commerce and Industry.
11.1 RAW MATERIALS

Important raw materials for surgical instruments manufacturing include stainless steel, processing chemicals etc. A specialized laboratory, SIMTEL (Sialkot Material Testing Laboratory), has been established since 2000 to test the quality of raw materials and finished products. SIMTEL, however, needs upgradation as it lacks facilities for wet analysis.

Wastage of raw material can be up to 75% depending on which part is used

Medical Grade Stainless steel: Steel is the most important raw material required for the production of surgical instruments. Imported steel is used in the manufacture of Surgical Instruments to conform to health standards, particularly in the case of reusable surgical instruments. Fluctuating prices of steel in the international market makes it difficult for manufacturers to accurately forecast their cost of production.





Wastage of raw material can be up to 75% depending on quality of steel used [data derived from: (Engineering Development Board, 2020)]. The wastage is however recycled. Average fault rate is 30% vs Germany's average fault rate of 4% indicating that either the local craftsmen are not as skilled as advertised, or there are issues with the materials or processes.

Processing Chemicals: Most chemicals used are available locally or can be imported easily. The application of these chemicals, mostly acids, on the instruments being manufactured requires skilled labor to obtain the desired results.

Titanium: Because it is biocompatible (non-toxic and not rejected by the body), titanium is used in a number of medical applications including surgical implements and implants, such as hip balls and sockets (joint replacement) which can stay in place for up to 20 years. Titanium is often alloyed with about 6% aluminum and 4% vanadium. In Pakistan, since the import of titanium is banned, most of the required metal is acquired from ship breaking.

Other metals: A number of other metals and alloys are required by the industry for their properties. However, in Pakistan, there is a severe scarcity of expertise and technology linked to metallurgy (Trade Related Technical Assistance (TRTA II) Programme, 2014).

Ceramics: Some instruments such as scalpels are ceramic coated to make them chemical resistant and add stiffness and thermal stability. Ceramics also have excellent wear resistance. Examples of ceramic materials include oxides of aluminum and zirconium, inorganic carbides, nitrides, borides, silicide, phosphates, and some zirconates and titanates.

Plastics: Some Surgical Instruments may be coated with plastics or made entirely from plastics. The increased use of disposable devices is leading to an increased use of plastics over metals, ceramics, and glass. With an increase in infectious diseases around the world, disposables are becoming the product of choice to prevent the spread of infections. Shorter hospital stays and an increase in home healthcare have also increased the use of disposables. The changes in sterilization technologies from steam sterilization to radiation and high-energy sterilization has increased the use of plastics, since these are more amenable to gamma and electron beam radiation sterilization.

11.2 THE ROLE OF SIMTEL

Sialkot Material Testing Laboratory (SIMTEL) is a venture of the Export Development Fund (EDF) to assist manufacturers in the testing of raw materials used in making surgical instruments. Manufacturers can get their stainless-steel sheets tested and graded by SIMTEL and Surgical Instruments exporters can then show this certification to buyers to assure them that quality steel has been used. The most frequently used grades of Stainless Steel are SS Alloy 304, 410 and 420. SIMAP has however reported that SIMTEL is not fully operational and that SIMTEL's certification is normally not acceptable to international buyers.

11.3 MACHINERY

Machinery is sourced from outside Sialkot. Smaller manufacturers mostly use machinery from the 1950s era, while larger manufacturers use machinery from the 90s and 2000s. Most machinery used is second-hand / reconditioned. Some machines such as CNC laser cutters are newer but these are only affordable by the bigger players. Sialkot also has service providers such as machinery repair units. The 5-axis CNC machines cannot be used in Pakistan due to its role in making weapons, hence, the most Pakistani manufacturers can use are 4-axis and (usually) 3-axis CNC machines.

The government-run institution MIDC also provides machining services for smaller manufacturers. Smaller manufacturers can outsource production jobs to MIDC which then utilizes its own on-site machinery to produce the end product for the manufacturer to export.

11.4 PROCESS

The process of producing a surgical instrument comprises of an array of small steps, meticulously performed over a small piece of metal as it moves from one process to another. The process usually relies on extensive human interaction and involvement. Even with many of the steps being automated, the overall process is manual, making this an extremely labor-intensive method of production, and thus not easily amenable to automation. Figure 16 illustrates an approximate production flow diagram. The steps involved for manufacturing reusable instruments are larger in number compared to those required for disposable instruments (Trade Related Technical Assistance (TRTA II) Programme, 2014).



Figure 16 Processes in making Surgical Instruments

11.5 THE ROLE OF THE TECHNICAL EDUCATION & VOCATIONAL TRAINING AUTHORITY (TEVTA)

TEVTA is an initiative of the Government of Punjab to provide free-of-cost technical education to the workforce and to help create skilled labor for the industrial sector. In essence, it provides apprenticeships thereby replacing old ustad-shagird (master-apprentice) system of the foregone era. By providing apprenticeships to a larger number of people, it reaches out to a larger audience. In Sialkot, TEVTA has 2 functions:



Figure 17 Functions of TEVTA

Institute of Surgical Technology (IST) provides the academic part of the technical training. There are different courses available each with its own duration. The course details obtained from TEVTA are given below:

| S.N. | Name of Course | Duration | Entry Level |
|------|--|----------|---------------------|
| 1 | Machinist (Specialization in Surgical) | 2 years | Matric with Science |
| 2 | Industrial Electronics | 2 years | Matric with Science |
| 3 | Fitter General (Die Maker) | 2 years | Matric |
| 4 | Draftsman / AutoCAD | 1 year | Matric |
| 5 | Inspection & Quality Control | 1 year | Matric with Science |
| 6 | Material Testing & Heat Treatment | 1 year | Matric with Science |
| 7 | Post Diploma CNC Machinist | 6 months | DAE (Mech) |
| 8 | Forging & Press Work | 6 months | Middle school pass |

Source: (Shehzad, 2021)

Metal Industries Development Centre (MIDC) provides on-the-job training to students. The MIDC section of TEVTA has all the machines and processes required to manufacture instruments. It also provides end-to-end services for entrepreneurs who bring in the raw materials (e.g., stainless steel) and MIDC does all the manufacturing jobs thereby creating the finished products in their facility.

The Common Facility Centre provided by MIDC greatly eases the manufacturing process for manufacturers who do not have sufficient capital to purchase expensive machinery or hire labor. They can easily outsource all the manufacturing processes to MIDC and sell the finished product to their own buyers.

Figure 18 shows that the number of process jobs at MIDC has declined since 2018, suggesting maybe a move towards greater in-house production as entrepreneurs become more established and prefer to have more control over the production processes. The decline in exports and process jobs in 2020 are attributed to the global slowdown due to the COVID-19 pandemic and lockdown.



Source: (MIDC, 2021)

It is however worth mentioning that SIMAP members, during the course of this Study, mentioned that neither TEVTA nor the government institutes launched any training programs aimed specifically towards meeting the needs of the surgical industry.

11.6 FINANCIAL & FINANCING FACILITIES

Sialkot has banks and leasing companies to provide ancillary and financial services. Manufacturers have access to SBP's Export Refinance Facility (ERF) and Long-Term Finance Facility (LTFF). ERF is regularly used whereas LTFF is rarely used due to small manufacturers not being able to meet the eligibility criteria as well as due to lack of awareness (Asad, 2021). According to SBP, loan default is almost nil for ERF. Letters of Credit (L/Cs) are also availed from banks and discounting facilities are easily available to exporters.

Manufacturers also provide assistance to subcontractors by offering credit, advance payments, transport, lending/repairing of machinery, training of workers and helping organize production.

11.7 LOGISTICS

Various agents facilitate exports. These include global couriers that ensure firms can send samples and small consignments safely and rapidly to existing and potential buyers, haulage firms which provide transportation to ports and airports, and cargo handling agents who undertake shipping arrangements and customs handling formalities. Prior to the mid-1980s, Sialkot's exporters had to travel to Lahore or Karachi to handle customs formalities, a costly and time-consuming exercise, especially for smaller firms. To offset this, leading exporters from all major sectors in Sialkot resolved to 'bring the port to Sialkot'. Based on their efforts, and initial investment, the Sialkot Dry Port Trust (SDPT) was set up in 1985 as a self-financing private trust to provide a range of trade-related services. It serves as a customs collectorate undertaking customs valuations and levying import duties, which ensures that all customs formalities and disputes are handled within Sialkot. It also provides cheaper warehousing for both imports and exports and a more reliable haulage service for transporting goods to and from airports and seaports. Running costs are met through handling charges and transport services.

Table 4 Volume handled by Sialkot Dry Port Trust 2018-20

| | 2018 | 2019 | 2020 |
|--------------------|--------|--------|--------|
| Containers handled | 3,938 | 6,848 | 6,293 |
| Value (PKR M) | 19,319 | 34,182 | 24,431 |
| Weight (MT) | 8,482 | 10,558 | 9,038 |

Source: (Sialkot Dry Port Trust, 2021)

12. TOP EXPORT DESTINATIONS



Figure 19 shows the top destinations of Pakistan's exports of HS 901890 Surgical Instruments from 2016 to 2020.

The top 3 export destinations for Pakistan's surgical instruments are the USA, Germany and the UK with average annual exports for the last 5 years being USD 103.8mn, USD 50.9mn and USD 33.3mn respectively. Figure 19 reveals the concentration risk of Pakistan's exports as Surgical Instruments exporters are providing a majority of their supplies to a limited number of countries. Table 5 shows the average Surgical Instruments exports of Pakistan to its top 20 destinations, the percentage share of each destination in total exports and the CAGR for the 2016 to 2020 period.

| Countries | Average PK Exports of Surgical Instruments in USD Mn over last 5 years | % Share of Pakistan's total SI Exports | CAGR (%) 2016-2020 |
|----------------------|---|---|--------------------|
| USA | 103.8 | 28.5% | -0.2% |
| Germany | 50.9 | 14.0% | 3.4% |
| United Kingdom | 33.3 | 9.1% | -1.2% |
| China | 17.5 | 4.8% | 19.1% |
| France | 13.4 | 3.7% | -2.8% |
| United Arab Emirates | 9.9 | 2.7% | 23.9% |
| Brazil | 8.9 | 2.5% | 4.6% |
| Japan | 8.5 | 2.3% | 5.9% |
| Australia | 7.7 | 2.1% | 1.5% |
| Italy | 7.4 | 2.0% | 7.9% |
| India | 6.7 | 1.8% | -75.8% |
| South Africa | 5.2 | 1.4% | -1.6% |
| Netherlands | 5.1 | 1.4% | 10.7% |
| Russian Federation | 5.0 | 1.4% | 12.1% |
| Rep. of Korea | 4.8 | 1.3% | 1.0% |
| Mexico | 4.7 | 1.3% | 6.6% |
| Belgium | 4.6 | 1.3% | -2.1% |
| Turkey | 4.5 | 1.2% | 4.8% |
| Poland | 2.8 | 0.8% | 22.4% |
| Philippines | 2.7 | 0.7% | -2.4% |

Table 5 Pakistan Surgical Instruments Exports, market share, CAGR 2016-20

Source: data derived from (UNComtrade, 2020)

13. ANALYSIS OF CONCENTRATION RISK

One of the possible reasons for Pakistan's low exports of surgical instruments could be Pakistan's continued reliance on a limited number of export destinations. Nearly 80% of surgical instruments made in Pakistan are exported to only 15 countries. This limits Pakistan's export potential and increases concentration risk. TDAP sponsored trade fairs and exhibitions continue to be held primarily in the USA and the EU countries. Although there have been limited attempts in recent years to hold exhibitions in a few African countries.

Figure 20 shows the quantity-wise exports of Pakistan's surgical instruments.



Figure 20 Quantity-wise exports of Surgical Instruments from Pakistan 2016-2020 Source: (UN Comtrade, 2020)

The data of quantity-wise exports of surgical instruments also reveals the concentration risk, with a majority of surgical items going to the USA, Germany, the UK and France. Pakistan's lack of diversified destinations also hinders its ability to achieve a higher per-unit price.

Table 6 shows the countries where 80% of Pakistan's exports go in unit terms.

| | Countries | Average SI Quantity of last 5 years (units) | % of Total |
|----|----------------------|---|------------|
| 1 | USA | 53,698,285 | 29.1% |
| 2 | Germany | 26,098,057 | 14.1% |
| 3 | United Kingdom | 18,456,013 | 10.0% |
| 4 | China | 9,743,043 | 5.3% |
| 5 | France | 6,186,695 | 3.4% |
| 6 | Brazil | 4,703,828 | 2.5% |
| 7 | Australia | 4,297,800 | 2.3% |
| 8 | United Arab Emirates | 3,852,115 | 2.1% |
| 9 | India | 3,514,353 | 1.9% |
| 10 | Japan | 3,197,247 | 1.7% |
| 11 | Italy | 3,061,128 | 1.7% |
| 12 | South Africa | 2,805,416 | 1.5% |
| 13 | Turkey | 2,652,817 | 1.4% |
| 14 | Belgium | 2,631,765 | 1.4% |
| 15 | Russian Federation | 2,608,157 | 1.4% |

Table 6 Countries which receive 80 percent of Pakistan's Surgical Instruments Exports – in unit terms

Source: derived from (Pakistan Bureau of Statistics, 2019)

Exporters also do not appear to be keen on exporting to other countries new markets, citing difficulties in finding leads, travel costs, difficulties with local languages, registration of their products, obtaining L/Cs, payment guarantees etc. However, this doesn't fully explain the reluctance of exporters regarding exports to countries such as Japan, Turkey, Singapore etc.

14. DOLLAR PER UNIT VALUE ANALYSIS

According to the data on export values and quantities from PBS, the highest per-unit price is fetched from African countries such as Malawi, Suriname, Mali and non-African countries such as Macao, Luxembourg and Cyprus.

The map below shows the per-unit price obtained from different markets.



Figure 21 Map of dollar-per-unit obtained via exports 2016-2020 Source: (UN Comtrade, 2020)

The lowest per-unit price obtained in the last 5 years was USD 1.4 per item and the highest was USD 9.2 per item. Taking into consideration, average per-unit price, it appears that the highest value, per-unit wise, is achieved in exports to African countries.

The table below shows the top 20 per-unit prices fetched from exports to various countries.

Table 7 Top 20 countries that fetch highest dollar-per-quantity

| Countries | Avg unit price USD |
|------------------|--------------------|
| China, Macao SAR | 9.223 |
| Malawi | 8.016 |
| Dominica | 7.438 |
| Luxembourg | 7.308 |
| Suriname | 7.016 |
| Sierra Leone | 5.923 |
| Тодо | 5.525 |
| Mali | 5.502 |
| Cyprus | 5.445 |
| Botswana | 5.164 |
| Aruba | 5.045 |
| Gabon | 5.002 |
| Angola | 4.899 |

East African nations fetched the highest in terms of per-unit dollar value while China, Canada and Sub-Saharan Africa fetched the lowest per-unit dollar value. The map also shows that Pakistan's supply of surgical instruments to the rest of the world is at a low price.

Table 7 Top 20 countries that fetch highest dollar-per-quantity

| Countries | Avg unit price USD |
|--------------------|--------------------|
| Niger | 4.840 |
| Cameroon | 4.835 |
| Côte d'Ivoire | 4.786 |
| Bosnia Herzegovina | 4.706 |
| Somalia | 4.695 |
| Namibia | 4.650 |
| Burkina Faso | 4.561 |

15. INTERNATIONAL COMPETITORS

Most of the world's surgical instruments are made by firms in towns in Europe and Asia—Tuttlingen (Germany), Sialkot (Pakistan), Penang (Malaysia), Debrecen (Hungary), and Warsaw (Poland).

In developed countries, most of the production processes are mechanized. Another important feature is that surgical instruments production in developed countries does not form an isolated industry, constituting, instead, a small part of the much larger medical equipment industry.

Developed countries have achieved considerable advances in metal-related technologies, thereby guaranteeing uninterrupted availability of specific materials. Research and development are a continuous process for them, innovative materials, with augmenting properties, are researched and tested in collaboration with the surgical instruments industry. Moreover, quality raw materials are locally available. Availability, and use, of superior raw materials gives German instruments a long and trouble-free usage cycle.

In places like Germany, most of the designing is done using CAD (Computer Aided Design) techniques. These drawings are then fed to the Computer Numerical Control which automates the entire manufacturing process. CNC machines are equipped with several tools for manufacturing highly sophisticated instruments, including:

- Laser or plasma cutters
- High pressure forging
- Milling machines
- Induction hardening machines
- Surface grinders
- Cylindrical grinders
- 3D printing
- Knife cutting

With the availability of these tools, the CNC machines can manufacture high-tech products in large numbers, without requiring a great deal of human intervention.

The CNC machines are integrated with fully automated tools that clean and polish the manufactured products. These tools clean manufacturing residues using customized brushes, polish metal surfaces using polishing pastes, and sterilize instruments by using radiation.

15.1 GERMANY

Germany is considered a global powerhouse in the manufacture of all types of engineering products including surgical instruments. German surgical instruments are associated with features such as precision, accuracy and performance. Large investments in business sophistication are key drivers of this preeminent position. Since the 19th century, Germany has been a hub for research and innovation in medical technology (MedTech). The German surgical instruments cluster consists mostly of SMEs as well as some well-known global surgical manufacturers such as Aesculap, Karl Storz, KLS Martin and Smith & Nephew. For German SMEs, competition has intensified mostly from low-cost clusters such as Sialkot.

Germany leverages its GI (Geographical Indication) "German Engineering" to great effect. Germany is known for exceptional quality and precision engineering. In addition, German firms have worked to shorten lead times to streamline their supply chains.

Germany enjoys a 12.5% share in the global exports of HS-901890 Surgical Instruments, including those products originally made in other countries such as Pakistan, Malaysia, and Poland. Most of its industry is concentrated in the South Western town of Tuttlingen, which serves as a global manufacturing and marketing hub for surgical instruments. The three major types of instruments being exported from Germany are:

a) Reusable Stainless-Steel Instruments: Most of these instruments are manufactured by German firms based in Tuttlingen using high-quality stainless steel. German firms also operate in Malaysia or have subcontractors based in Pakistan, Poland and Hungary. These instruments are expensive with a lifespan of several years.

b) Disposable Stainless-Steel Instruments: Pakistan enjoys a near monopoly in the manufacture of high-quality, disposable surgical instruments made from stainless steel. German firms subcontract or import these instruments from Pakistan, and after testing them for quality, sell them under their own brand names. China produces a large number of such disposable units at cheaper prices, however, reportedly because of quality issues, they have failed to obtain significant market shares in developed markets.

c) Disposable Plastic Instruments: These instruments are manufactured mostly by German companies operating in Malaysia, and then sold, either directly or via Germany, to end users. These instruments have demonstrated a potential for their reusability and eco-friendliness (Trade Related Technical Assistance (TRTA II) Programme, 2014).

A pictorial representation of some of the instruments manufactured is given in Figure 22 for a better understanding. These are manufactured in Germany for use in surgical and operation theaters.



Figure 22 Pictorial representation of Surgical Instruments made by Germany

Some of the instruments such as electro-mechanical appliances are made in Germany and these are normally branded.



Figure 23 Branding Example by German Manufacturer

Even in high-quality equipment, some low-end items such as stainless-steel clamps and forceps are outsourced to Pakistani manufacturers to save costs. German companies do the designing and then outsource manufacturing to Pakistani suppliers. After the basic shaping is done in Sialkot, quality inspection and assurance will usually be done in Germany. Batch sizes are small as surgical equipment are highly specialized. The Tuttlingen cluster relies on specialization and sophisticated supporting industries:



Figure 24 Tuttlingen cluster value chain mapping

| Importing country | Germany HS-901890 avg exports 2018-20 (USD Mn) | Pakistan HS-901890 avg exports 2018-20 (USD Mn) |
|----------------------|---|--|
| USA | 1,225.6 | 107.8 |
| China | 510.5 | 20.8 |
| Netherlands | 386.6 | 5.6 |
| France | 383.9 | 13.5 |
| Italy | 322.2 | 7.3 |
| Switzerland 297.5 2. | | 2.4 |
| Russian Federation | 274.7 | 5.8 |
| United Kingdom | 261.9 | 33.6 |
| Spain | 212.9 | 1.5 |
| Japan | 171.5 | 9.1 |
| Austria | 162.7 | 0.8 |
| Belgium | 148.5 | 4.5 |
| Poland | 147.6 | 3.4 |
| Czechia | 113.3 | 2.5 |
| Sweden | 107.5 | 0.5 |
| India | 100.9 | 3.8 |

Table 8 HS-901890 Surgical Instruments Exports - Major Destinations: Germany vs Pakistan 2018-20

| Importing country | Germany HS-901890 avg exports 2018-20 (USD Mn) | Pakistan HS-901890 avg exports 2018-20 (USD Mn) | |
|-------------------|---|--|--|
| Rep. of Korea | 94.7 | 4.8 | |
| Turkey | 88.7 | 4.7 | |
| Saudi Arabia | 84.5 | 1.1 | |
| Brazil | 84.3 | 9.9 | |

Table 8 HS-901890 Surgical Instruments Exports - Major Destinations: Germany vs Pakistan 2018-20

Source: (UN Comtrade, 2020)

Table 8 above shows Germany's Surgical Instruments average exports to their top destinations, from 2018-20, compared to Pakistan's Surgical Instruments exports during the corresponding period for the same destination markets.

15.2 CHINA

Local specialized markets and industrial clusters have been a driving force in China's transition from a rural to a market economy. These local clusters have provided a means for small local producers to access domestic and international markets.

China has not focused on developing its Surgical Instruments industry in the same way as Pakistan has, however manufacturing plants do exist that make many different instruments.



Figure 25 A Surgical Instruments manufacturing plant in China

Since China's shift towards more eco-friendly industries, the pollution causing work of making Surgical Instruments has been reduced. However, suppliers from China still exist and trade in large volumes especially with the EU market. China promotes its products based on quality certifications, advanced production standards, facilities based on Corporate Social Responsibility (CSR) and compliance with Environment Health & Safety (EHS) standards along with an experience of complying with Food & Drug Administration (FDA) audits.

Table 9 shows China's Surgical Instruments average exports to their top destinations, from 2018-20, compared to Pakistan's Surgical Instruments exports during the corresponding period for the same destination markets.

| Importing country | China HS-901890 avg exports 2018-20 (USD Mn) | Pakistan HS-901890 avg exports 2018-20 (USD Mn) |
|----------------------|---|--|
| USA | 746.3 | 107.8 |
| Germany | 198.5 | 53.1 |
| Japan | 125.1 | 9.1 |
| China, Hong Kong SAR | 120.1 | 1.5 |
| India | 65.5 | 3.8 |
| United Kingdom | 62.8 | 33.6 |
| Netherlands | 59.2 | 5.6 |
| Brazil | 59.0 | 9.9 |
| Italy | 56.5 | 7.3 |
| Russian Federation | 55.5 | 5.8 |
| Rep. of Korea | 50.0 | 4.8 |
| Singapore | 36.7 | 1.9 |
| France | 36.6 | 13.5 |
| Turkey | 34.3 | 4.7 |
| Australia | 29.3 | 7.8 |
| Iran | 24.6 | 0.2 |
| Poland | 24.6 | 3.4 |
| Indonesia | 24.2 | 1.8 |
| Spain | 22.3 | 1.5 |
| Mexico | 22.1 | 4.9 |

Table 9 HS-901890 Surgical Instruments Exports: China vs Pakistan 2018-20

Source: (International Trade Center, 2020)

15.3 MALAYSIA

The medical devices industry in Malaysia is dominated by companies engaged in the production of medical gloves, other disposable products, as well as several high value-added items. Malaysia continues to maintain its position as the world's leading producer and exporter of medical gloves and catheters, catering to 60 and 80 percent of the world's demand for gloves and catheters respectively (Trade Related Technical Assistance (TRTA II) Programme, 2014). Currently, there are more than 180 medical device manufacturers in Malaysia, including some major MNCs who are involved in the production of high value items such as orthopedic products, dialyzers, surgical instruments, medical electrodes, catheters, diagnostic radiographic equipment, safety intravenous cannula, sutures, and ophthalmic lenses. A German MNC has set up a plant in Malaysia to manufacture disposable surgical instruments from plastics and reusable stainless-steel instruments.

Table 10 shows Malaysia's Surgical Instruments average exports to their top destinations, from 2018-20, compared to Pakistan's Surgical Instruments exports during the corresponding period for the same destination markets.

| Importing country Malaysia HS-901890 avg exports 2018-20 (USD Mn) | | Pakistan HS-901890 avg exports 2018-20 (USD Mn) | |
|--|-----------|--|--|
| USA | USA 312.5 | | |
| Germany | 96.5 | 53.1 | |
| Belgium | 81.2 | 4.5 | |
| Netherlands | 68.0 | 5.6 | |
| Japan | 66.5 | 9.1 | |
| China | 34.3 | 20.8 | |
| Australia | 32.2 | 7.8 | |
| Singapore | 31.9 | 1.9 | |
| Ireland | 12.8 | 0.6 | |
| Hungary | 8.2 | 1.3 | |
| Rep. of Korea | 8.0 | 4.8 | |
| Indonesia | 6.4 | 1.8 | |
| India | 6.4 | 3.8 | |
| France | 6.3 | 13.5 | |
| Thailand | 5.5 | 2.4 | |
| Philippines | 3.6 | 2.5 | |
| Viet Nam | 3.4 | 2.3 | |
| Switzerland | 3.0 | 2.4 | |
| China, Hong Kong SAR | 2.9 | 1.5 | |

Table 10 HS-901890 Surgical Instruments Exports: Malaysia vs Pakistan 2018-20

Source: (International Trade Center, 2020)

15.4 POLAND

The major export products manufactured by the Polish medical equipment industry includes bio-electronic apparatus, operation theatre equipment, rehabilitation equipment, furniture for medical facilities, surgical instruments and devices using medical imaging technologies. One of the most thriving branches of the industry consists of producers of bio-electronic equipment which is used for 'vital functions monitoring' (including patient monitors; defibrillators with the function of monitoring and transmitting data; ECG equipment; Holter recorders; and spirometers). Most of the raw materials, such as stainless-steel forgings etc., are imported from Germany to manufacture high-quality health grade instruments. These are then either sold directly to end consumers or to German firms in Tuttlingen.

Table 11 shows Poland's Surgical Instruments average exports to their top destinations, from 2018-20, compared to Pakistan's Surgical Instruments exports during the corresponding period for the same destination markets.

| Importing country Poland HS-901890 avg exports 2018-20 (USD Mn) | | Pakistan HS-901890 avg exports 2018-20 (USD Mn) | |
|--|------|--|--|
| Germany 208.7 | | 53.1 | |
| USA | 40.4 | 107.8 | |
| Ukraine | 27.3 | 1.1 | |
| France | 26.0 | 13.5 | |
| United Kingdom | 23.1 | 33.6 | |
| Russian Federation | 20.6 | 5.8 | |
| China | 14.0 | 20.8 | |
| Switzerland | 12.3 | 2.4 | |
| Romania | 8.8 | 1.0 | |
| Australia | 7.3 | 7.8 | |
| Netherlands | 7.1 | 5.6 | |
| Denmark | 6.8 | 2.6 | |
| Mexico | 6.8 | 4.9 | |
| Italy | 6.4 | 7.3 | |
| Spain | 6.0 | 1.5 | |
| Austria | 5.8 | 0.8 | |
| Tunisia 5.6 0.4 | | 0.3 | |
| Estonia | 5.3 | 0.1 | |
| Czechia | 4.8 | 2.5 | |
| Hungary | 4.7 | 1.3 | |

Table 11 HS-901890 Surgical Instruments Exports: Poland vs Pakistan 2018-20

Source: (International Trade Center, 2020)

16. THE EMERGING CHALLENGE FROM 3D PRINTING

Recent developments in the field of 3D printing promises to revolutionize many industries. 3D printing brings the potential ability to manufacture anything at a fraction of the current cost. Once commercialized, it can potentially change the face of manufacturing as we know it.

3D printing has begun to play a significant role in the field of medical devices. The Pakistani surgical instruments manufacturing industry currently remains competitive primarily due to its low cost of production.

While Pakistan remains a global OEM supplier at the current time, the local industry may become redundant in the future if the commercial application of 3D printing leads to the production of surgical instruments at competitive prices in the developed world.

3D printing is opening the doors to a new approach in the production of medical devices, which allows the complexity of their designs to be pushed to the limit. With 3D printing technology, a computer-aided design (CAD) model can be directly transformed into a 3D object, built layer-by-layer, in a relatively short time and with a low cost, avoiding the long processes of conventional fabrication methods.

Figure 26 shows the classification of medical fields where 3D printing has been applied.



Figure 26 Application of 3D printing in medical fields

These includes drug delivery systems, laboratory equipment, customized cutlery, implants and medical equipment for diagnostics and surgery (Culmone, Smit, & Breedveld, 2019). 3D printing has been used to create both conventional and non-conventional instruments. Conventional instruments are devices where the basic design is based on traditional instruments used in diagnostics and surgery such as surgical tweezers. Non-conventional instruments are those where a completely new design is made using CAD (Computer Aided Design) before manufacturing. Examples of 3D printed instruments are shown in Figure 27.



Figure 27 Examples of 3D printed instruments

17. PAKISTAN'S CURRENT POLICIES REGARDING SURGICAL INSTRUMENTS

The following government policies have an impact on the surgical instruments sector.

17.1 MANUFACTURING BOND SCHEME

Manufacturing Bond Scheme provides warehousing facility without payment of import duty, sales tax, FED, WHT on import of raw materials required for the manufacture of export goods.

The scheme allows manufacturers-cum-exporters to import duty free inputs for subsequent export of value-added products.

The Licensee is required to operate in a licensed customs bonded area and is required to obtain a certificate called "Analysis Certificate" which allows him to import duty free inputs as per the product's Analysis Certificate. Application for this certificate is filed online and similarly approval is granted online.

To further facilitate exporters under this scheme, up to 40% of manufactured goods can be sold in the local market after payment of duties and taxes.

Customs has the option to check at any time the status of the imported materials, balance quantities and the quantity of goods already exported.

17.2 DUTY AND TAX REMISSION FOR EXPORTS (DTRE) SCHEME

DTRE Scheme provides refund of import duty, sales tax, FED, WHT on acquisition through import and local purchase of input goods required for the manufacture of output goods meant for exports.

This facility is available on imported inputs, locally purchased duty/tax-paid goods and taxable/excisable services including gas, electricity, diesel, furnace oil, coal.

This scheme can be availed by a wide range of businesses i.e., Sales Tax registered exporters, commercial exporters, contracted vendors of foreign manufacturers and persons engaged in value-addition in export goods, supplies made against international tenders, EPZs, projects entitled to duty/tax-free inputs and supplies made by indirect to direct exporters.

17.3 EXPORT ORIENTED UNITS (EOU)

EOU scheme provides exemption from payment of customs duty, sales tax, FED, WHT on imports and local purchase of raw materials required for the manufacture of export goods as well as plant & machinery, equipment, apparatus & capital goods used solely in the manufacture of goods for export. Licensing of the applicant is required to avail the facility. The utilization period for raw materials is 24 months and the retention period for the machinery / spares is 5 years in the EOU. The unit is required to export at least 60% of its annual production, another 20% in the form of indirect exports against securities or on payment of duty / taxes and the remaining 20% can be sold in the local market on payment of duty / taxes.

EOU scheme is most frequently availed by manufacturers cum exporters. This scheme, not only allows import of duty free and tax-free input materials but also allows duty free and tax-free import of plant, machinery, equipment, apparatus, including capital goods.

All types of input and output ratios are made available online, resultantly credit and debit of material is also online which greatly facilitates exporters at the time of import/export.

Exporters can supply their goods to other exporters availing other export facilitation schemes like EOU, Manufacturing Bond and DTRE.

17.4 DUTY AND TAX REMISSION FOR EXPORTS (DTRE) SCHEME

DTRE Scheme provides refund of import duty, sales tax, FED, WHT paid on the acquisition through import and local purchase of input goods required for the manufacture of output goods meant for exports.

This facility is available on imported inputs, locally purchased duty/tax-paid goods and taxable/excisable services including gas, electricity, diesel, furnace oil, coal.

This scheme can be availed by a wide range of businesses i.e., Sales Tax registered exporters, commercial exporters, contracted vendors of foreign manufacturers and persons engaged in value-addition in export goods, supplies made against international tenders, EPZs, projects entitled to duty/tax-free inputs and supplies made by indirect to direct exporters.

17.5 TEMPORARY IMPORTATION SCHEME

This scheme entails suspension and exemption from duties and taxes for the import of accessories used for manufacture of exportable goods.

This facility is also available for duty-free imports of components and sub components for assembly of machinery, electrical equipment, bicycles, aluminum, steel ware, kitchen utensils, surgical instruments, toys, decorative items, stationery items meant for exports etc.

17.6 EXPORT PROCESSING ZONES

Export Processing Zones have been established with the objective of boosting industrialization and augmenting the country's exports by creating facilities for investors to enable them to set up export-oriented units which would create job opportunities, bring in new technology and expertise and attract foreign investment.

All types of goods including machinery, equipment, materials can be imported duty and tax free. Local sales of up to 20% has also been allowed.

Investors at EPZ can avail facilities of vendors in the tariff area (Sustainable Development Policy Institute, 2019).

17.7 MINIMUM EXPORT PRICE

Surgical Instruments are subject to a minimum export price due to intense competition in the Sialkot cluster which was leading to price wars with manufacturers apparently selling below cost of production to secure international buyers. The table below lists the minimum export price for surgical instruments. The Association worked closely with the Ministry of Commerce to revisit the minimum export price for single use surgical instruments and these have now been exempted from MEP provided they are clearly marked as "single use" and have been certified by SIMTEL.

| | Name of Items | HS Codes | FoB prices in USD |
|----|--|----------|-------------------|
| 1 | Adson Dressing Forceps 4 ¾" | 9018 | 0.45 |
| 2 | Adson Tissue Forceps 1*1 4 ¾ " | 9018 | 0.45 |
| 3 | Allis Tissue Forceps 6" 4*5 teeth | 9018 | 1.50 |
| 4 | B.P. Handle Number 3 and 4" | 9018 | 0.35 |
| 5 | Dressing Forceps 4 1/2 to 5 1/2 " | 9018 | 0.50 |
| 6 | Dressing Forceps 5 ½ " | 9018 | 0.50 |
| 7 | Dressing Scissor 4 ½ "S/B – B/B | 9018 | 0.55 |
| 8 | Dressing Scissor 5 ¼ "S/B – B/B | 9018 | 0.70 |
| 9 | Iris Scissors 4 ½ " | 9018 | 0.50 |
| 10 | Kelly/Crile/Rochester Pean/Artery Forceps 5 ¼ "Mosquito Forceps 5" | 9018 | 0.75 |
| 11 | Lister Bandage Scissors 5 ½ " | 9018 | 0.75 |

| | Name of Items | HS Codes | FoB prices in USD |
|----|--|----------|-------------------|
| 12 | Lister Bandage Scissors 7 ½ " | 9018 | 1.25 |
| 13 | Mayo Hegar Needle Holders 5" – 6" | 9018 | 1.0 |
| 14 | Mayo Scissors | 9018 | 0.85 |
| 15 | Probes & Explorers, Scalars/Filing Instruments, Excavators | 9018 | 0.60 |
| 16 | Speculum Grave Large Cusco Medium Small | 9018 | 2.50 |
| 17 | Sponge Holding Forceps 7" | 9018 | 2.00 |
| 18 | Sponge Holding Forceps 9 ½ "Forceps/Ramplay/Bozeman Uterine/Dressing/Teneculm | 9018 | 2.50 |
| 19 | Stitch Scissors 4 ½ " | 9018 | 0.65 |
| 20 | Tooth Extraction Forceps S/Joint, B/Joint | 9018 | 3.5 |
| 21 | Towel Clamp 3 ½ "to 5 ¼ " | 9018 | 0.90 |
| 22 | Webster Needle Holders 5" to 6" Baumgartner Needle Holder 5 ½ " | 9018 | 1.0 |

Source: (Ministry of Commerce, Government of Pakistan, 2020)

Update: As per SRO 1275(I)/2021 dated 30th September 2021, Minimum Export price has been revoked and now there is no MEP applicable on the aforementioned items.

17.8 EXISTING SROS

| SRO | Department | Policy |
|-------------|------------|---|
| 211(I)/2009 | FBR | Repayment of custom duties on importation of raw materials used in manufacture of scheduled goods including surgical instruments |
| 711(I)/2018 | МоС | DLTL. Was applicable June 2021. 50% drawback without condition of increment in exports. Remaining 50% drawback to be provided if the exporter achieves annual increase of \geq 10% in exports. The finance minister has recently announced continuation of this scheme. The EDB has requested that the DLTL scheme be continued beyond June 2021 and the rate be increased from 3 to 5% |
| 492(I)/2009 | МоF | Exemption of custom duty and sales tax on temporary importation of goods for subsequent export of components for assembly of surgical instruments. |

| SRO | Department | Policy |
|--------------|------------|---|
| 578(I)/2016 | MoC | Product Development Incentive Order to provide 50% matching grant up to a max of PKR 5mn for specified plant and machinery |
| 579(I)/2016 | МоС | Brand and Certification Development Support. Government to provide matching grants on intellectual property registration, including trade and services marks certification and accreditation. According to SIMAP, this SRO never came into effect. |
| 582(I)/2016 | МоС | DLTL. Remained in force till June 2018. Superseded by SRO 711(I)/2018. |
| 1065(I)/2005 | MoF | Exemption of custom duty and sales tax on temporary importation of goods for subsequent export of components for assembly of surgical instruments. Superseded by 492(I)/2009. |
| 580(I)/2016 | MoC | Technology Upgradation Fund. 20% investment support up to max of PKR 1Mn per annum per company available for import of new plant and machinery. 50% markup support on upgradation of technology provided for import of new plant and machinery subject to max PKR 1mn per annum per company. The industry has requested that this SRO be revived to help boost investment in the sector |

18. PERFORMANCE UNDER SROS

There is some evidence of minor growth due to the support given to the sector under various SROs. From 1st July 2016 to 30th June 2018, the export of surgical instruments increased at a CAGR of 7.3%. This was in line with Pakistan's overall exports which increased at a CAGR of 7.6% during the same period.

Table 12 CAGR of Pakistan's SI exports vs Pakistan's total exports

| Value in USD Mn | 2015 | 2016 | 2017 | 2018 | 2019 | |
|---|----------|----------|----------|----------|----------|--|
| PK Total Exports to world | 22,089.0 | 20,533.8 | 21,911.6 | 23,778.6 | 23,818.8 | |
| CAGR of Total Exports- 2016-18 | 7.6% | | | | | |
| Surgical Instruments Exports from PK to world | 332.6 | 326.0 | 361.1 | 375.5 | 405.5 | |
| CAGR of SI Exports – 2016-18 | 7.3% | | | | | |

Impact of support from SRO 578(I)/2016, Product Development Incentive Order, was an increase of 1.4% in CAGR for export of surgical instruments. It may be noted that this was impacted by other factors as well, such as demand variation in global trade.

After SRO 578 came into effect in 2016, the CAGR for surgical instruments exports increased from 5.9% to 7.3%.

CAGR of Surgical Instruments' exports from 2013-15 (Before SRO 578): 5.9%

Figure 28 CAGR before and after Product Development Incentive Order

MAJOR FINDINGS

German suppliers have sourced instruments from Pakistan for several years. Historically, contractual relationships were developed whereby the German firms would use one Pakistani manufacturer. This achieved mutual benefit. For the Pakistani firm it guaranteed regular work and (arguably) a fairly negotiated price for its goods, whereas for the German supplier there was the security that the quality of instruments would be up to the standard stipulated in the contract.

Whereas under this system there may still have been questions over the fairness or otherwise of prices that were paid to Pakistani firms, the situation was complicated by new US legislation in 1994 requiring surgical instruments that were imported into the US to comply to international quality standards (a requirement subsequently endorsed by the EU). Manufacturers complied with these standards to remain in business, but this created a shift in their relationships with suppliers in the developed world.

Now that the buyers knew that all surgical instruments would be manufactured to comply with international standards, they were free to award short term contracts based on the cheapest price without the need to continue with one manufacturer.

This eventually drove down profits for manufacturers in Pakistan and resulted in cost-cutting in labor costs and safety standards. Furthermore, in such a competitive environment, buyers of instruments can stipulate unreasonable terms within their contracts.

Manufacturers rely on subcontractors to meet delivery schedules and quality stipulations, while the latter need manufacturers to provide them a continuous stream of work. Closer technical ties between the two has increased the possibility of improvements in products and processes.

Small firms subcontract all but the final stages of production, while large firms internalize most activities, using specialist subcontractors only for specific tasks and specialized items. Subcontracting lowers costs but implies a loss of control over the monitoring of quality. This trade-off determines both the extent of subcontracting and the relationship

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that a firm maintains with a subcontractor. The quality of forging, filing, polishing and heat treatment is particularly important to the overall quality of the finished instrument. Where the stages are subcontracted, firms need to ensure that subcontractors meet the necessary quality standards.

Subcontractors rarely receive support for the supply and upkeep of machinery and tools, or for labor training. However, most manufacturers frequently make advance payments for working capital, and regularly assist subcontractors through detailed discussions and feedback on manufacturing processes, product quality and production organization. Help in organizing production, along with technical and quality related feedback, is especially important in the quality critical processes.

Despite the relative closeness of such ties, there is little sign of process or product innovation. Where firms move up the value-added chain, such advances often lead to the internalization of key processes. This ensures stricter quality control and limits the leakage of valuable technical knowledge. Moreover, where product innovation has occurred, it is usually the result of collaboration in forward linkages. Product innovation in surgical instrument-making requires close interaction with end-users - surgeons and health care professionals. Most instruments are developed on the basis of requests, suggestions and feedback from the medical profession. In Sialkot, where few producers have direct links with end users, product designs are specified by external buyers or they follow widely accepted international specifications.

The use of subcontractors became common in the mid-1970s after a period of labor unrest and strikes. Subcontracting minimizes company overheads and lowers costs, but, because subcontractors are not employees of the company and competition is fierce, it drives down wages and health and safety standards.

Subcontracted manual labor has no job security or guarantee of income and no medical insurance or provision of education for their children. Nearly all subcontractors are forced to seek wages in advance from the firms that employ them, further disadvantaging these workers' position in arguing for a fair wage (Bhutta, 2006).

19. PRICE WAR

There is intense competition in Sialkot. The majority of local producers cite each other as their major international competitors. Although local rivals claim to compete on the basis of product quality, the primary basis of competition appears to be price. This has been fueled by a growth in the number of manufacturers in Sialkot since the early 1980s and because of competition among Pakistani sales agents in the USA. Subsequently, while manufacturers reported rising sales volumes over the past five years, most of them also reported that product prices had fallen in this period.

Local competition is also predatory. Firms try to obtain their rivals' price quotes, and the practice of 'poaching' foreign clients from competitors is common. Producers attempt to keep marketing and technological information as closely guarded secrets. Strategic information is often withheld from those within the firm, such as hired managers or key foremen, who could emerge as potential threats. The need to keep information from outsiders is even more important. Visits by producers to each other's units are rare, usually restricted to close friends or family members. Most of the producers do not allow others to see their production facilities.

20. NEED FOR INCREASED MARKETING AND BRANDING ACTIVITIES

Sialkot has numerous service providers including printers who publish sample brochures and product catalogs. The manufacturers also often take part in exhibitions arranged by the Trade Development Authority of Pakistan (TDAP). Apart from this, there is little marketing activity for promotion of exports. Very few manufacturers brand their instruments. Most Surgical Instruments are sold to foreign buyers who then use their own brand to sell at a premium in international markets. It is not known whether final buyers are aware of Pakistani manufacturers. German and American buyers buy from Pakistani manufacturers and ensure quality. After providing quality assurance, German and American importers sell within or in other countries.

Foreign buyers place emphasis on quality and provide access to technical knowledge. In contrast, independent Pakistani sales agents have weak quality standards, rarely provide technical feedback for support, and are highly price focused. Trading patterns and marketing channels vary by firm size. Large firms are more likely to trade with technically advanced foreign manufacturers, leading US kit packers or major international buyers. Small firms sell to less specialized and less quality-conscious foreign buyers and foreign-based Pakistani agents, foreign clients are the most important sources of technical and market related information. Many producers obtain technical insights and ability from visits to surgical instrument manufacturers abroad.

The industry is making all out efforts in cementing ties with foreign buyers, and in seeking out new clients in existing and new markets. Almost all manufacturers have been dealing with the same foreign buyers for over 5 years. Contacts are frequent. Buyers visit Sialkot regularly while local manufacturers make frequent trips abroad to consult clients and seek new buyers.

Requirement for maintaining quality comes primarily from buyers who also provide assistance to improve product quality and on new products and refinement to existing instruments. They send drawings and instrument specifications for producers to follow and give feedback on finished products.

In the mid-1980s, German firms began to subcontract to Pakistani firms. They sent metallurgical engineers to Sialkot to train partner firms on quality control and production engineering. This was followed by regular visits from technical advisory and inspection teams. In a few cases such collaboration led to joint ventures. In this more formal relationship, the foreign producer provides access to new technology, knowledge and markets, as well as stipulating production guidelines and quality control specifications with regular on-site inspections and training missions.

From the buyer's perspective, visits to Sialkot and close ties with particular firms help ensure punctual deliveries. Buyers are the leading conduit for new information on technologies and methods. They are also the key agents forcing producers to maintain and upgrade quality standards. Here again the relationship varies by firm size, larger producers are more likely to have ties with technically advanced buyers and foreign producers.

The industry cites its lack of advanced marketing and branding activities as a source of concern in selling its goods. Marketing is limited to exhibitions organized by TDAP and using sales brochures. Manufacturers own branding is practically non-existent. There are few large manufacturers who brand their instruments but most of them only put their label or 'Made in Pakistan' label on the packaging box and not on the instruments themselves.

Manufacturers seem to be reluctant in branding instruments, citing that only the USA asks for a 'Made in Pakistan' stamp due to their rules regarding Technical Barriers to Trade whereas other buyers e.g., Germany insist that Pakistani manufacturers not mark their instruments as 'Made in Pakistan'. Fearing loss of trade, Surgical Instruments manufacturers are subdued and readily comply with European buyers' demands. This is despite the fact that these manufacturers are the OEM suppliers for these Surgical Instruments.

While European buyers appear to have a good image of Pakistani Surgical Instruments manufacturers, buyers in the Middle East prefer not to buy directly from Pakistani suppliers. Middle Eastern buyers prefer to buy Pakistani manufactured instruments from US or European suppliers but not directly from Pakistan. This is because European and American buyers sell Pakistani-origin Surgical Instruments under their own well known international brands and this gives comfort to the buyers.

21. PERCEPTION ISSUES

Other than in its traditional markets, Pakistan's surgical instruments industry suffers from a perception issue in international markets. This phenomenon has more to do with the perception of Pakistan being a manufacturer of low-quality products especially engineering goods. As a result of this negative country perception, international buyers prefer to pay higher prices to middlemen/companies in the West who are willing to give an assurance regarding quality. The surgical instruments sector will have to replicate the model of the sport goods industry also based in Sialkot on how to ensure that their output also commands a premium price in international markets.

22. COMPLIANCE WITH NEW EUROPEAN RULES

The Pakistani Surgical Instruments industry will face a new challenge in the form of Medical Devices Regulation (MDR) compliance beginning 2024. All instruments manufactured will have to be compliant with new European regulations on biocompatibility. The new regulations are expected to impact exports of Surgical Instruments. The industry is asking the government to help with MDR compliance by providing consultants for five years who would help in meeting regulatory standards. They also want a publicly-funded testing lab established for the purpose of complying with these regulations.

23. INFRASTRUCTURE

Sialkot suffers from infrastructure deficiencies. It is plagued with bad roads, inadequate power generation and distribution and a poor communications network. The export boom has led to everyone purchasing private vehicles. This has led to an increase in traffic in Sialkot which the current narrow roads cannot bear. The lack of public transport services has also exacerbated the traffic problems of the city.

24. COST OF DOING BUSINESS

The increasing energy costs are making firms uncompetitive by compressing margins and profitability. The production of surgical instruments is an energy-intensive process, with sub-processes, such as annealing that uses specialized furnaces that run on gas, and rely on the continuous use of machines with heavy electrical loads. The industry, therefore, requires a reliable supply of electricity and gas at relatively cheap prices to remain competitive. The issue of rising energy costs has become a serious challenge in recent years, as the energy situation has been identified as a major reason for slowing down investments in the industry.

25. LABOR SHORTAGES

The surgical instruments industry is a labor-intensive industry, heavily dependent on skilled labor to deliver outputs. Sialkot has traditionally been endowed with a skilled workforce that operates much of the industry. However, recent years have witnessed a rapid de-skilling of the labor present in the sector. The phasing out of child labor, and rightly so, from Pakistan has resulted in the collapse of the conventional ustad-shagird (apprentice) system, resulting in a dearth of a trained and skilled workforce especially in the process of polishing. The visually dirty work does not appeal to the younger generations who prefer to work in relatively cleaner environments.

The disruption of the apprenticeship system has led to the drying up of the pipeline of relatively young people interested in undergoing a fairly long — at times 5 to 7 years — apprenticeship to acquire the skill-set required to produce surgical instruments.

Several attempts have been made to resurrect formal training programs (such as at the Sialkot Surgical Training Institute), but the industry does not appear satisfied with the quality of trainees, citing that the nature of skills is such that they have to be acquired at a young age. Another challenge in recent years has been the emergence of contracting as an alternate way of forming an association with a firm. Contractual agreements, which are partly the result of cost-cutting initiatives undertaken by larger firms, has resulted in the unintended consequence of the loss of affiliations with the workforce. Some critics also identify the lack of appropriate salaries (sometimes even lower than the minimum wage) as one of the key reasons as to why the industry is losing its appeal, especially with the next generation of workers in Sialkot.

26. EPZ POLICY

Efforts have been made to provide an incentive package to Sialkot through the establishment of an Export Processing Zone (EPZ). The Zone was set up at Sambrial on the Sialkot-Wazirabad Road in 2002 with an investment of around PKR 184 million, primarily from private entrepreneurs. The EPZ is spread over an area of 238 acres, with 881 plots ranging from 4 kanals to 10 marlas in size, and the land being priced at USD 5.21 per sq. meter. Despite the large size of the establishment, the adoption of the facility has been limited because of its distance from the current locus of manufacturing, which lies within the city. Repeated attempts by the Government, to encourage factory owners to establish new factories in this EPZ, have not yielded the kind of results that were expected. Manufacturers report that the EPZ is too far away from Sialkot and would not be feasible for the stakeholders in the industry. Employees also are reluctant to travel such long distances.

Another factor for dissuasion of moving to the EPZ is the location of vendors and contractors who are at a distance from the EPZ location. Manufacturers cite that raw materials and in-process semi-finished instruments would have to be moved in and out of the gated EPZ continuously as they are sent to sub-contractors for any number of processes.

27. COMMON FACILITY CENTER

The industry stated that they required a "Common Facility Centre (CFC)" which would provide a common processing facility for manufacturers. SIMAP proposed to the authors of this report that the CFC be run by the association and be able to provide advanced high-tech facilities on cost basis to the firms (which is a prohibitive investment that many firms are unable to undertake individually). A proposal was sent to the Export Development Fund (EDF) to establish the CFC. Since firms contribute to the EDF (0.25% Export Development Surcharge (EDS) is levied on all exports from Pakistan) run by the Ministry of Commerce, the industry is of the opinion that this is a common need for the sector and would help propel exports.

28. SURGICAL CITY

Surgical Instruments manufacturers are suggesting that the government construct a 'Surgical City' at a prime location for all manufacturers to gather their production processes. The Surgical City may have a tax holiday option for interested manufacturers. The "City" is proposed to house all manufacturing units of Surgical Instruments. However, the problems of fragmented vendors and outsourced sub-contractors being located far away from the Surgical City remains.

29. OTHER ISSUES

Finally, there are a host of other issues such as:

Cut Throat Competiton

There is a need to create a culture of cooperation and trust, agreeing upon a code of ethics to manage cut throat competition in the industry so that companies do not undercut each other needlessly

Low capacity

The firms are not large enough to achieve economies of scale and have the ability to offset their fixed costs.

Lack of innovation

Lack of access to quality universities and colleges, absence of international collaborations, shortage of research facilities and design units within organizations, and the inability to use multidisciplinary knowledge in order to graduate to higher value equipment (for example medical electronics or electro-mechanical devices).

Absence of modern machinery

Machinery in small firms is from the 70s and 80s era. Production processes are also outdated. In some cases, wastage can be as high as 75%.

30. DISCUSSION

So how does Pakistan fare in terms of competitiveness?

Our findings indicate that the surgical industry, despite being operational for a long time, is not performing to its full potential.

Compound Annual Growth Rate (CAGR) from 2016-2020 was 2.6%. CAGR for other industries is also given in Table 13 as a comparison.

Table 13 CAGR of exports of various industries in Pakistan

| CAGR of various industries in Pakistan 2016-2020 | | | | | | | | |
|--|---------|---------|------------|--------|-----------|------------------|--------------|--|
| Surgical Instruments | Bedwear | Leather | Auto parts | Cement | Chemicals | Electrical Goods | Sports Goods | |
| 2.6% | 3.1% | -1.6% | 0.4% | -3.4% | 5.9% | 14.6% | -5.2% | |

Government subsidies in the form of rebates has failed to move the industry to the next level of business development.



Pakistan's Exports of Surgical Instruments - Quantity wise



Pakistan's market share in global trade of surgical instruments is 0.7%. One of the reasons for this low market share is buyers buying Pakistani origin instruments at low prices and then selling these at higher prices to other countries by doing some value-addition as well as being guarantors of quality. The industry has yet to reach the "1-billion-dollar club", an informal term used for sectors that have reached the USD 1Bn mark in exports such as textiles, rice and ICT services. In fact, the industry has not even reached USD 500Mn in terms of exports.

The raw material used is medical grade steel and because the major source of this steel are commercial importers, it is very difficult to ensure consistency in steel quality. In the absence of a large domestic supplier of medical grade steel, consistency of steel will remain a problem for the industry. SIMAP should consider forming a consortium to buy medical grade steel directly from foreign steel mills and they sell to their members, this would at least address the issue of consistency. Some of the bigger players are supplied steel directly from Germany to ensure quality.

Though the sector's exporters claim to be manufacturing all of the world's Surgical Instruments, data shows that their

top customers are buying a majority of their instruments from other countries. The USA is buying a majority of HS-901890 Surgical Instruments from Mexico and Germany is buying the same from China.

Evidence from Chinese videos posted on YouTube also shows that Chinese firms are engaged in the manufacture of surgical instruments.



Figure 30 Surgical Instruments manufacturing plants in China

The local industry is so far not moving into electro-mechanical items such as the manufacture of EEG, ECG, and other sophisticated equipment. Since buyers only give orders for low-end instruments such as scalpels, scissors, forceps etc., the industry is only manufacturing those. There have been few significant orders for new items in the last 5 years.

Buyers mostly dictate prices in negotiations. The industry is embroiled in a price war where each seller is trying to get customers by quoting the lowest possible price thus leading to a lower aggregate number in sales value.

Sellers are not stamping / labeling their products as 'Made in Pakistan' which is hampering their marketing ability. Instruments are sold as a commodity, not as a category since there is no branding.

The industry states that moving to the EPZ is not feasible, therefore they are looking to negotiate with the government for a nearby location which will be designated as a 'Surgical City'. The industry is also looking to offset its future expenses e.g., upcoming MDR compliance expenditure through public funding.

On the positive side, the industry has made some progress. Recently exports grew to USD 405mn in 2019 but a global slowdown in trade due to COVID-19 saw a slump in Surgical Instruments exports, with exports clocking in at USD 361.3mn in 2020. Government facilities, such as MIDC and SIMTEL, are present for entrepreneurs and small manufacturers who cannot afford in-house production like the larger manufacturers.

The next step the industry needs to take is to increase its market share by exploring newer markets and venturing into new products.

31.1 FAIR TRADE IN BANANAS AND COFFEE; WHY NOT IN

SURGICAL INSTRUMENTS?

Issue: Manufacturing firms in Pakistan rarely have the infrastructure or marketing presence to allow direct trade with end users in the destination countries. Most therefore sell to suppliers and retailers in the developed world with a low profit margin. These "middle men" (mostly in Tuttlingen, Germany) then trade with end users, predominantly in the US or Western Europe, usually after adding a large mark up. Inadequate renumeration and labor standards compound the underlying problems of the absence of skilled labor.

PBC Proposal: The solution lies in final purchasers insisting on fair and ethical trade when sourcing instruments. Increasingly, people in the developed world consider ethical issues when they purchase groceries, clothing, and various other products. Yet they know relatively little of where and under what conditions medical commodities like surgical instruments are manufactured. The UK based NHS Purchasing and Supply Agency has developed a sustainable development policy. The stated aims of this policy include encouraging NHS (National Health Service) suppliers to ensure compliance with international labor standards and to act in an ethical business manner. Yet at present the health service is not meeting such obligations; there is no systematic assessment of the origin of the products it uses or the conditions under which they were produced. Similar to the purchase of agricultural products, the developed nations may move towards insisting on fair trade for purchase of surgical instruments as well. The issue of fair-trade practices in surgical instrument procurement may be discussed with the EU.

31.2 CONSULTANTS FOR MDR COMPLIANCE

Issue: Surgical Instruments exports into the EU will face a new challenge in the form of the requirement for compliance with Medical Devices Regulation (MDR) beginning 2024. All instruments entering the EU will have to be compliant with new European regulations on biocompatibility. The new regulations are expected to hinder exports of Surgical Instruments from Pakistan to the EU. Compliance with MDR is estimated to cost over 5% of annual sales (Yeo, 2020).

Industry Proposal: The industry suggests hiring foreign consultants for 3 to 5 years for MDR compliance. They also suggest that a lab should be setup for testing biocompatibility as per the Medical Devices Regulations and government should bring in foreign certification bodies to provide assurances to foreign buyers.

PBC Proposal: The Government may bring in foreign consultants for a limited time to assist in MDR compliance. Any cost of hiring consultants, building a lab etc. should be reflected in the pricing of the instruments that need compliance with MDR. If prices do not reflect the costs associated with ensuring compliance with MDR, the Pakistani taxpayers may end up subsidizing consumers in the EU.

31.3 JOINT VENTURES FOR INCREASING EXPORTS

Issue: Pakistan holds 0.7% market share in HS-901890 Surgical Instruments. The industry claims to be the OEM manufacturer of Surgical Instruments such as scissors, scalpels, forceps, clamps etc., which are shipped to the USA and European markets from where they are further sold to the rest of the world after quality assurance and some value-addition such as ceramic coating. Few new products of any major export significance have been developed in the Sialkot cluster in the last five years.

Industry Proposal: Some of the larger players are concerned about this stagnation and suggest Joint Ventures with Chinese companies for knowledge and technology transfer. The smaller players are content with the status quo of receiving continued orders for the same equipment.

PBC Proposal: Joint Ventures with firms in Germany and China will certainly help Pakistan in taking the next step towards evolution of the Surgical Instruments industry. Pakistani manufacturers can move from making simple stainless-steel instruments to complex machines used in EEG/ECG, radiology, CT scan and much more. As JVs with Germany helped the industry in upgrading production in the past, further technology and knowledge transfer with firms either in Germany or China can enable the industry to start creating complex engineering machinery that can bring in higher export revenues. The Government may look into the possibility of inviting Chinese or German FDI in this industry to enable knowledge transfer. Leveraging a domestic population base of 220 million and approximately 2,000 hospitals (Khan, 2019), which offer a potential market for 17 million surgeries per year (The Aga Khan University, 2019), these JVs can rapidly build, scale and enter export markets.



Figure 31 Market size for Surgical Instruments in Pakistan

31.4 A SURGICAL CITY AS PROPOSED BY SIMAP

Issue: The current location of the EPZ is not feasible for many manufacturers. Labor has to travel longer distances. The vendors are located far away and the nature of sub-contracting of processes will mean that there will be too much movement in-and-out of the EPZ for raw materials and semi-finished goods. Expansion is also a major issue due to shortage of land in existing clusters.

Industry Proposal: The industry suggests development of a 'Surgical City' closer to Sialkot and which will have a raw materials storage facility along with all other facilities in the new cluster.

PBC Proposal: A location closer to Sialkot may benefit workers and to ensure there is minimum disruptions in production, a Common Facility Centre for laboratory testing plus any outsourced production processes be setup within the Surgical City.

31.5 A NEW COMMON FACILITY CENTRE PROPOSED BY SIMAP

Industry Proposal: The Surgical Instruments industry is proposing that the government may either upgrade or build a Common Facility Centre which will contain latest machinery that manufacturers cannot afford on their own.

PBC Proposal: A CFC in the form of MIDC already exists from where many manufacturers already get part of their processes done. PBC proposes upgradation of the existing facility e.g., newer heat treatment furnaces, newer model CNC laser cutting machines etc., & if that is not possible in the existing setup a new CFC run by SIMAP may be set up.

31.6 ABSENCE OF MADE-IN-PAKISTAN ON EXPORT PRODUCTS

Issue: There is an absence of stamping of Made-in-Pakistan on export products, no major Pakistani Brands & hence no Country-of-Origin advantage. The industry is neither branding nor stamping instruments with the 'Made in Pakistan' label when exporting to Europe. Only instruments sent to the US are stamped because of US regulations. While exporting to Europe, exporters sometimes put the 'Made in Pakistan' label on the carton but not on the instruments. The industry, by and large, does not believe in its own strengths.

PBC Proposal: The reluctance to stamp 'Made in Pakistan' or their own brand name minimizes the potential to get a premium price or to sell to new markets. Pakistan could learn valuable lessons from the Turkish 'TURQUALITY' Program through which the Turkish government has been funding the development of 10 worldwide Turkish brands. A "PAKQUALITY" initiative may be promoted under the Public Private Partnership model to ensure that Pakistani brands also become regional / global icons.

Launched in 2005, TURQUALITY[®] is a scheme developed to promote Turkish brands. It is a project associated with bringing the concept of Turkey and Quality together. TURQUALITY[®] was initiated by the Ministry of Economy, Turkish Government, Turkish Exporters Assembly (TIM) and Istanbul Textile and Apparel Exporters Association (ITKIB).

31.7 PRODUCT PRESENTATION MATTERS

Issue: The current product mix is sold as orders come in and kit packers in the US and Europe create the kit packages before further selling.

PBC Proposal: Figure 32 shows what a kit package looks like. By assembling and creating kit packages themselves, Pakistani manufacturers can charge a higher price for being able to sell a ready-made solution.

China is able to clearly display all of its products at a one-stop shop, giving buyers the ease of shopping. This makes them want to buy from China. All hospital products are easily lined up for buyers making it a one-stop shop for all things used in a hospital.



Figure 32 A representation of Surgical Instruments toolkit



Figure 33 One-stop shops in China for all medical instruments

31.8 ENSURING QUALITY – STANDARDS

Issue: Inconsistent product quality is impacting exports, this is primarily due to the absence of standards

Industry Proposal: : The industry is concerned about the damage done to the industry's image when sub-par quality instruments are supplied at extremely low prices quoted by some manufacturers. Industry proposes ISO9000 standards compliance as a way to ensure consistent quality.

PBC Proposal: The industry will need to self-regulate and work for common minimum standards. Some options could include: provision of raw materials from a central SIMAP warehouse, SIMAP approved certification requirements for exporters, lobbying with the government to ensure that minimum export prices reflect costs of inputs etc.

31.9 EXPLORING NEW MARKETS

Issue: Currently exports are highly concentrated in markets of the EU & the USA. Concentration of exports in a few markets' limits revenue potential. This problem is hampered by the fact that every country has its own regulations regarding medical devices and instruments. US has its own FDA regulations, Europe has its own CE and the upcoming MDR rules, China has its own NMPA.

Industry Proposal: The industry's view varies on potential markets. Suggestions have been made including Russia, the African nations and China.

PBC Proposal: The problem is twofold and the solution lies with two government bodies. First, different countries have different regulations, complying with each countries regulations requires investments in product, production and processes. EDB needs to work with SIMAP to sensitize the industry regarding regulations as they apply to individual countries. Second, as this report identifies, there are potential markets which can be explored in the medium to long-term. TDAP needs to partner with SIMAP to hold exhibitions in these potential markets.

31.10 DISPOSABLE VS NON-DISPOSABLE ITEMS

Issue: Disposable Surgical Instruments are increasingly being used in the US market. The minimum export prices imposed on instruments are a hinderance for the disposable instruments industry as disposable instruments cost less than non-disposable ones and the industry is requesting for a review of the minimum export price mechanism.

Industry Proposal: Some of players in the Surgical Instruments industry feel that the minimum export price imposed on instruments is hurting the disposable instruments industry as disposable instruments cost much less than non-disposable ones.

PBC Proposal: The minimum export price should only be reduced for disposable instruments, not reusable ones. To prevent misuse of the proposed change, it is recommended that the Global Devices Medical Nomenclature (GMDN) may be used for identification of instruments. GMDN is a system of internationally agreed generic descriptors used to identify all medical device products.

31.11 USING E-COMMERCE PLATFORMS

Issue: Traditional channels are preferred by suppliers who either don't understand the e-commerce channel well enough or don't think that e-commerce can be a viable alternative to the traditional model.

PBC Proposal: Sellers in other countries such as China and Vietnam use e-commerce platforms such as Alibaba, Amazon etc. Use of alternative selling channels also reduces over-reliance on exhibitions and commercial counsellors, many of whom are not subject experts on Surgical Instruments when dealing with foreign buyers.



Figure 34 E-commerce platform to sell Surgical Instruments

Manufacturers may be made aware of the benefits of e-commerce channels. It would open new sales channels which can potentially lead to increased revenue.
31.12 REDUCE DOCUMENTARY COMPLIANCE

Issue: Currently Pakistan has one of the highest documentary compliance rules compared to other countries. The government also supports this practice in contrast to the rest of the world. Figure 35 shows an example of the complexity of documentation required by the Sialkot Dry Port Trust for export.



Figure 35 Process flow at Sialkot Dry Port Trust (SDPT)

PBC Proposal: Increased documentation hurts business and therefore revenues. This is the reason most countries have reduced documentation requirements to promote business-friendly environments. Figure 36 shows the cost of documentary compliance and export to GDP for Pakistan and other countries (Ahmed, 2017).



Pakistan needs to simplify its documentation process and do away with needlessly complicated bureaucratic procedures. Other nations require far less documentary compliance and as a result have export which less cost to promotes export-friendly an environment.

Figure 36 Comparative cost of documentary compliance

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33.1 PAKISTAN'S OVERALL COMPETITIVE POSITION

Figure 37 shows Pakistan's rankings in Doing Business indicators with an overall score of 51 out of 100. Its worst score is 25 out of 100 in ICT (information and technology) adoption and its best score is 71 out of 100 in Market size. Further details are given in Table 14 below.



Performance Overview 2019 Key \diamond Previous edition Δ Lower-middle-income group average \Box South Asia average

Figure 37 Pakistan's score in Doing Business Indicators

Pakistan made notable improvements in Doing Business Indicators 2020 (Schwab, 2019). With an overall rank of 110 out of 141 worldwide, Pakistan lacks international competitiveness. Figure 38 shows Pakistan's score and ranking for each pillar of the Doing Business Indicator.

| Global Competitiveness Index | Score /100 | Rank / 141 | Best Performer |
|-------------------------------------|------------|------------|----------------|
| Enabling environment | 49.3 | 118 | Singapore |
| 1st Pillar: Institutions | 47.7 | 107 | |
| 2nd pillar: Infrastructure | 55.6 | 105 | |
| 3rd pillar: ICT adoption | 25.2 | 131 | |
| 4th pillar: Macroeconomic stability | 68.7 | 116 | |
| Human capital | 48.5 | 119 | Switzerland |
| 5th pillar: Health | 56.3 | 115 | |
| 6th pillar: Skills | 40.8 | 125 | |

Table 14 Pakistan's score for each indicator

Table 14 Pakistan's score for each indicator

| Global Competitiveness Index | Score /100 | Rank / 141 | Best Performer |
|------------------------------------|------------|------------|----------------|
| Markets | 55.8 | 77 | United States |
| 7th pillar: Product market | 45.5 | 126 | |
| 8th pillar: Labor market | 51.3 | 120 | |
| 9th pillar: Financial system | 55.0 | 99 | |
| 10th pillar: Market size | 71.2 | 29 | |
| Innovation ecosystem | 49.5 | 70 | United States |
| 11th pillar: Business dynamism | 63.3 | 52 | |
| 12th pillar: Innovation capability | 35.8 | 79 | |

Pakistan Global Competitiveness Index



Figure 38 Pakistan's score on each pillar of the Global Competitiveness Index

Pakistan ranks very low in terms of Information and communications technologies (ICT) adoption (131st out of 141) as well as Innovation capability (79th out of 141) and high in terms of Market size i.e., the size of the domestic and foreign markets to which a country's firms have access (29th out of 141).

Pakistan ranks midway in Doing Business indicators (World Bank Group, 2020) with a rank of 108 out of 190 and Doing Business score of 61. Table 15 shows a comparative ranking of Pakistan along with its peers in the surgical instruments industry and its regional peers.

Table 15 Comparative economies' Doing Business score

| Rank | Comparative Economy | Doing Business score |
|------|---------------------|----------------------|
| 12 | Malaysia | 81.5 |
| 22 | Germany | 79.7 |
| 63 | India | 71.0 |
| 108 | Pakistan | 61.0 |
| 168 | Bangladesh | 45.0 |

33.1 LIST OF INTERVIEWEES

Table 16 List of interviews

| Company visited | Interviewee | Interviewee |
|----------------------------|-------------------------|-------------------------------|
| SIMAP | Sajid Mirza, M. Zeeshan | Vice Chairman, Chairman |
| Dental Devices | Waseem Yousaf | CEO |
| Medical Devices Pvt Ltd | Rizwan Khalid | Sales Manager |
| SITEC | Irfan Farooq | Director Sales & Marketing |
| TriMed | Gohar Iqbal | Director Sales |
| Surgical Sources Ind. | Rizwan Bajwa | CEO |
| Bullan Surgical Co. | Iftikhar Ahmad | CEO |
| Hilbro Instruments Pvt Ltd | Imran Ashraf | CEO |
| Moses Enterprises | Rohail Deura | Partner |
| TEVTA | Khurram Shahzad Awan | Project Director MIDC |
| Elmed Instruments | Hinan Humayun | Director International Sales |
| Hospimed | Aamer Mahmood | CEO |
| Tecno Instruments | Haseeb Bhatti | Marketing Director |
| CS Clinical Surgical | Khurram Iqbal | Managing & Marketing Director |
| NST Zone | Sajid Mirza | Partner |
| Polivitte International | Ayub Suddle | Managing Partner |
| Sialkot Dry Port Trust | Navid Iqbal Sheikh | Chairman |
| SBP BSC | Ansar Iftikhar Butt | Chief Manager |
| Richbolt Enterprises | M. Akbar | Partner |
| Mhay Industries | M. Ishfaque Mhay | Proprietor |
| ALM Surgicare | Fiaz Bukhari | Chief Executive |



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