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Industry Mapping and Value Chain Analysis of Medical Devices Companies in Penang

By Lee Siu Ming



10, Brown Road, 10350 George Town Penang, Malaysia **T** +604 228 3306 **F** +604 226 7042 **E** enquiry@penanginstitute.org

Industry Mapping and Value Chain Analysis of Medical Devices Companies in Penang

Lee Siu Ming¹

Executive Summary

This study analyses the medical devices industry value chain and mapping in Penang. In particular, the objectives are: (1) to identify and classify the companies in Penang's medical device industry ecosystem based on their different product segments (in the categories of Disposables, Surgical Instruments, Therapeutic Devices, Diagnostic, Parts and Others); (2) to map the business activities over time, and the positioning of medical devices companies in the value chain in Penang; (3) to identify the opportunities and challenges for Penang's medical devices upgrading; and (4) to provide recommendation for the medical devices industry development in Penang.

Penang is soon marking its half-century industrial development experience since the establishment of Bayan Lepas Free Trade Zone in 1972. Electrical and electronics (E&E) continue to remain a major driver of the state's investments (54% of total approved investments in 2014-2018) and industrial activities, and the state has experienced diversification in its industrial activities, with one major segment being the medical devices manufacturing. Six of the world's top 25 medical devices manufacturers² have operations in Penang, and Penang has established itself as a destination of choice for the orthopaedics and cardiovascular product segment.

On this note, identification and understanding of the current state of the manufacturing value chain in medical devices industry, and of how this industry evolves become necessary. Therefore, it is important to provide better clarity on the stage of the value chain in Penang's medical devices industry, where this will impart useful information to current and future industry players on the ecosystem available in Penang.

In terms of analytical framework, medical devices companies in Penang are identified from the International Trade Centre (ITC) data. The Harmonized Commodity Description & Coding System (HS) codes are used to identify the medical device products based on classification by Bamber and Gereffi (2013) and Torsekar (2018). HS codes used by Malaysia External Trade Development Corporation (MATRADE) for the identification of medical devices trade were obtained and compared.

Companies which are only involved in trading activities and do not manufacture, trading companies, and medical suppliers are filtered from this study, based on systematic tracking on industry directories (MIDA, AMMI) and company websites. Following the identification of companies within the medical devices industry, these companies are grouped according to the product segments and value chain involvement. This mapping allows a view on the companies in each sector and their clustering.

¹ The author was a Senior Analyst at Penang Institute at the time of research and writing.

² Lead firms with a global presence account for more than half of the world's market share (Bamber and Gereffi, 2013) while the ten largest medical device companies account for approximately 40% of total sales in the industry in 2018 (Vara (2019) based on data from GlobalData).

One major drawback in this study is the limited state-based firms and industry data on trade and manufacturing. To gather information on Penang's medical devices upgrading within the value chain, expert interviews were conducted to understand the opportunities and challenges within the industry. Some anecdotal evidences were used to support stakeholders' opinion where state-level data are scarce and inadequate.

Penang is undeniably an important medical devices manufacturing hub in Malaysia, contributing about 77% of the total gross output for the manufacture of irradiation, electro medical and electrotherapeutic equipment, and about 22% of the total gross output for the manufacture of medical and dental instrument and supplies, respectively.

Around 30 companies are identified from International Trade Centre (ITC) data. Large concentration of firms is in the product categories of disposables, surgical instruments and therapeutics. High foreign firms' concentration was observed in the surgical instruments and therapeutic segments. Meanwhile, there is more observable concentration of local firms for disposables largely due to the presence of firms in the latex-based industries (makes up about 33% of the firms in disposable category). Some products that are not in Penang's manufacturing landscape includes product segments in in-vitro diagnostic (IVD) (HS Codes 3821, 3822). Many Penang companies are also involved in medical devices contract manufacturing, especially in terms of plastic-based and metal-based products.

It is noticeable that similar to the investment promotion and industry development of other industries in the state in general, Penang adopts a FDI-driven export-oriented strategy for the medical devices industry.

The beneficiaries of the economic spillovers of medical devices firms' investments in Penang include suppliers in terms of metal, plastic and chemicals, contract packaging, contract sterilization, medical trading companies, and other related electrical and electronics companies involved in medical devices manufacturing industry.

The highest concentration of companies in Penang are involved in components manufacturing, assembly and production (described as low value-added segment). Companies such as B. Braun and Ambu have established their centre of excellence (COE) while Vigilenz and CCB Medical Devices have established R&D capacity (described as high value segment). With more global OEMs focusing on investment in innovation and advanced technologies, specialized contract manufacturers in Penang can gain traction through engineering capabilities and the ability to scale capacity. Localisation by multinationals to local suppliers appears to be relatively more challenging than other industries due to the stringent medical devices standard and capability to scale by local companies.

A major consensus among stakeholders is that the state should look into further solidifying medical devices industry in Penang given its resilience to economic uncertainty and less cyclical nature of the industry. Tapping on Penang and Malaysia's accumulated experience and residual intelligence in the industry, Penang continues to show potential for growth as the medical devices sector destination of choice. However, at the same time, the state is facing increased competition from other investment destinations, slower upgrading of firms in product and process, and increased challenges in the hiring of industry-ready talent.

Some policy recommendations for Penang's medical devices industry moving forward includes (1) Product upgrading and diversification, (2) Process upgrading, (3) Trade and technology promotion, (4) Promotion of further backward and forward linkages within the industry, (5) Flow and clarity of information, and (6) Academia-industry dialogue and collaboration.

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Chapter 1: Introduction

1.1 Background of study

Penang is soon marking its half-century industrial development experience since the establishment of Bayan Lepas Free Trade Zone in 1972. Electrical and electronics (E&E) industry continue to remain a major driver of the state's investments (54% of total approved investments in 2014-2018) and industrial activities, and the state has experienced diversification in its industrial activities, with one major segment being the medical devices manufacturing. Penang has established itself (not limited to) as a destination of choice for orthopaedics and cardiovascular product segment.

This study analyses the medical devices industry value chain and mapping in Penang. In particular, the objective of this study is: (1) to identify and classify the companies in Penang's medical device industry ecosystem based on their different product segments (in the categories of Disposables, Surgical Instruments, Therapeutic Devices, Diagnostic, Parts and Others); (2) to map the business activities, and the positioning of medical devices companies in the value chain in Penang; (3) to identify the opportunities and challenges for Penang's medical devices upgrading; and (4) to provide recommendation for the medical devices industry development in Penang.

On this note, identification and understanding of the current state of the manufacturing value chain in medical devices industry, and of how this industry evolves become necessary. Studies on the medical devices value chain in Malaysia are relatively scarce, at a time when better clarity is needed on the stage of the value chain in Penang's medical devices industry, and can impart useful information to current and future industry players on the ecosystem available in Penang.

A medical device is defined by the Medical Device Authority (MDA) to mean any instrument, apparatus, implement, machine, appliance, implant, in-vitro reagent or calibrator, software, material or other similar or related article for human beings for the purpose of diagnosis, prevention, monitoring, treatment or alleviation of disease, in general (Refer Table 1 for specific purposes by MDA (2014)).

Table 1: Specific purposes of medical devices

i.	diagnosis, prevention, monitoring, treatment or alleviation of disease;
ii.	diagnosis, monitoring, treatment, alleviation of or compensation for an injury;
iii.	investigation, replacement or modification, or support of the anatomy or of a
	physiological process;
iv.	support or sustaining life;
v.	control of conception;
vi.	disinfection of medical device; or
vii.	providing information for medical or diagnostic purpose by means of in-vitro
	examination of specimens derived from the human body, which does not achieve
	its primary intended action in or on the human body by pharmacological,
	immunological or metabolic means, but that may be assisted in its intended
	function by such means.

Source: Medical Device Authority (2014)

1.2 Analytical framework

Firstly, the Harmonized Commodity Description & Coding System (HS) codes are used to identify medical device products based on classification by Bamber and Gereffi (2013) and Torsekar (2018). In addition to the codes used by Torsekar (2018), HS codes used by Malaysia External Trade Development Corporation (MATRADE) for the identification of medical devices trade were obtained and compared. Taking local Malaysian medical devices into consideration, several slight changes (inclusion and removal of codes) were made for computation and identification of firms. The HS codes used in this study are listed in Table 13 in Appendix.

Following that, medical devices companies in Penang are identified from the International Trade Centre (ITC) data. ITC data provides a list of companies that exports products under the Harmonized Commodity Description & Coding System (HS) codes with data provided on the city of the company which the company is located in. The cities for the companies located in Penang identified in this study are Bayan Lepas, Bukit Mertajam, Nibong Tebal, Perai, George Town, Gelugor, Nibong Tebal, Butterworth and Sungai Jawi. Occasionally, the author noted that the data would list Pulau Pinang and Penang as a city as well.

Companies which are only involved in trading activities and do not manufacture, trading companies, and medical suppliers are filtered from this study, based on systematic tracking of industry directories (MIDA, AMMI), Penang Institute database, and company websites. Following the identification of companies within the medical devices industry, these companies are grouped according to the product segments and value chain involvement. This mapping allows a view on the companies involved in each sector along with their clustering.

This study adopts a two-pronged approach in looking at the medical devices industry value chain in Penang (and to a larger extent in Malaysia), which is through (1) a product-based approach where companies in their respective product segments are analysed and from which the technology required for such products are deduced; and (2) analysis of Penang companies in the industry in their respective supply and value chain.

To gather information on Penang's medical devices upgrading within the value chain, expert interviews were conducted. Reference of interview questions are from the National Institute of Economic and Social Research et al. (2017) and Kimelberg and Nicoll (2012). Some anecdotal evidences were used to support stakeholders' opinion where state-level data are scarce and inadequate.

1.3 Scope of study

One major limitation in this study is the limited state-based firms and industry data on trade and manufacturing. This required the author to analyse national-level data and to make some state level inference, where possible.

The identification of companies was also conducted using the companies listed in the International Trade Centre data, which may not cover the entire population. However, to the best of the author's knowledge, this is among the best possible dataset for the purposes of this research.

Companies that are only involved in trading activities and do not manufacture, are filtered from this study, based on systematic tracking on industry directories (MIDA, AMMI) and company websites. In addition, also excluded from the scope of this study are trading companies and medical supplies shops (pharmacies, etc).

While life sciences industry, biotechnology and the pharmaceuticals industries are often included in the discussion of the medical devices industry, this study emphasises that the scope of study is on medical devices only, referenced against products covered by the Medical Devices Authority (MDA).

Chapter 2: Global Medical Devices Industry

2.1 Global medical device manufacturing investments and lead firms

Lead firms with a global presence account for more than half of the world's market share (Bamber and Gereffi, 2013). Vara (2019) noted that based on data from GlobalData³, the 10 largest medical device companies account for approximately 40% of total sales in the industry, estimated at USD515.16 billion in 2018.

Investments in the medical devices segment as a part of the healthcare industry has become increasingly more important and are irreplaceable in diagnostics, prevention, monitoring, and medical treatment of diseases (Maresova et al., 2015). Costa Rican Investment Promotion Agency (CINDE) stated that in terms of industry growth, the medical devices sector growth is very stable (Lo, 2018). Within medical devices manufacturing, the cardiovascular and orthopaedic product segments are the two largest market segments (Markets and Markets, 2011).

The majority of the top 15 leading firms are headquartered in the United States, the prominent regional clusters being at California, Massachusetts and Minneapolis-Saint Paul (Kimelberg & Nicoll, 2012). This fact is supported by the list of top 25 medical devices companies globally ranked by revenue in 2018 (see Table 2). 13 of the 25 companies are headquartered in United States, four in Japan, three in Germany, and one each in Ireland, Netherlands, France, Switzerland, and the United Kingdom

	Company Name	Revenue	Market Capitalization	Country
				-
1	Medtronic plc	30,378	122,163	Ireland
2	Johnson & Johnson	27,300	346,109	United States
3	Fresenius Medical Care AG & Co. KGaA	19,845	19,935	Germany
4	General Electric Company	19,701	65,845	United States
5	Abbott Laboratories	16,811	127,036	United States
6	Becton, Dickinson and Company	15,983	60,713	United States
7	Siemens AG	15,976	94,622	Germany
8	Cardinal Health, Inc.	15,659	13,288	United States
9	Stryker Corporation	13,276	58,654	United States
10	Royal Philips NV	12,669	32,748	Netherlands
11	EssilorLuxottica SA	11,595	53,885	France

Table 2: Top 25 medical devices companies globally, by revenue (USD million),2018

³ GlobalData is a data and analytics provider listed on the London Stock Exchange.

12	Baxter International Inc.	11,030	35,026	United States
13	Boston Scientific Corporation	9,820	48,904	United States
14	Zimmer Biomet Holdings, Inc.	7,936	21,156	United States
15	B. Braun Melsungen AG	7,671	Private ownership	Germany
16	Novartis AG	6,925	217,442	Switzerland
17	Olympus Corp.	6,127	10,542	Japan
18	3M Company	5,985	110,949	United States
19	Terumo Corporation	5,275	21,543	Japan
20	Smith & Nephew plc	4,888	16,306	United Kingdom
21	Canon Inc.	4,502	36,482	Japan
22	Dentsply Sirona, Inc.	4,018	8,281	United States
23	Edwards Lifesciences Corporation	3,634	32,020	United States
24	Intuitive Surgical, Inc.	3,570	54,693	United States
25	Hoya Corporation	3,307	22,998	Japan

Note: Author has included BBraun based on 2017 annual report, which was not in QmeD's original list

Additional notes by QmeD: Johnson & Johnson - Revenue include only the Medical Devices segment; General Electric Company - Revenue include only the Healthcare segment; Abbott Laboratories - Revenue include only the Diagnostics and Cardiovascular & Neuromodulation segments; Siemens AG - Revenue include only the Healthcare segment; Cardinal Health, Inc.-Revenue include only the Healthcare segment; Royal Philips NV - Revenue exclude the Personal Health segment; EssilorLuxottica SA - Essilor and Luxottica completed their merger on October 3, 2018. Revenue include Essilor's Lenses & Optical Instruments and Equipment segments, and Luxottica's Wholesale segment; Olympus Corp. - Revenue include only the Medical Systems and Imaging Systems segments; Novartis AG - Revenue include only the Alcon segment; 3M Company - Revenue include only the Healthcare segment; Canon Inc. - Revenue include only the Medical Systems segment; Hoya Corporation- Revenues include only the Life Care segment.

Source: Compiled by author based on QmeD, Medical Device and Diagnostic Industry and company websites

International Trade Administration (2016) noted that due to United States medical device companies' innovations and high-technology products, there is high regard for these companies globally. United States companies are expected to continue to play an important role in medical devices research and development. According to PricewaterhouseCoopers Innovation Scorecard released in 2010, the United States is considered the global leader for medical device innovation. Other countries in the top 10 includes Germany, United Kingdom, France, Japan, Israel, China, Brazil and India.

Other than the United States, Germany, France, Italy and the United Kingdom are home to important R&D and manufacturing hubs. R&D and new product development primarily takes place in the global headquarters⁴ (Bamber and Gereffi, 2013).

2.2 Medical devices product segment

In terms of medical devices by product segment, previous literature such as Bamber and Gereffi (2013) and Torsekar (2018) have sorted the products into four main categories: (1) disposables, (2) surgical instruments, (3) therapeutics, and (4) diagnostic equipment. Another two product segments are parts and others not within these categories.

Figure 1: Summary of medical devices product segment



Source: Author's compilation based on Bamber and Gereffi (2013) and Torsekar (2018)

The disposables product segment usually consists of low-tech, single-use products. Manufacturing of these products requires relatively less medical expertise. Some examples of the products (not exhaustive include bandages, gloves, plastic syringes, catheters & needles). For the surgical instruments product segment, this category involves devices that assist in surgical procedures and specialized surgical instruments used in cosmetic and endoscopic surgery. Examples of the products include forceps, medical scissors and dental drills, and specialized surgical instruments used in cosmetic and endoscopic surgery.

Next, for the therapeutics segment, higher medical standards are usually applicable as the products in this category involve implantable & non-implantable devices, some which may be in the human body for a long time, such as hearing aids, pacemakers and prosthetics. The final product segment is diagnostic equipment, which involves relatively the highest use of technology. The products in this segment ranges from infusion pumps, blood pressure monitors to large equipment such as magnetic resonance imaging (MRI) equipment or computed tomography.

⁴ This view, however, is not fully agreed during interviews with stakeholders conducted in this study.

2.3 Medical devices value chain

Meanwhile, Figure 2 shows the global value chain for medical devices manufacturing. There are five main processes in the value chain: (1) research and development (R&D), (2) components manufacturing, (3) assembly/production, (4) distribution and marketing, and (5) post sales services.

According to Bamber and Gereffi (2013), the research and development (R&D) stage is the highest value segment. This stage involves prototype production, process development, regulatory approval, and improvement in the production process. R&D is costly and may take several years for the medical device to be put up in the market. Simoens (2009) observed that there is an increasing trend for lead firms to acquire new products via mergers and acquisitions (M&A).

Figure 2: Global value chain for medical devices manufacturing



Source: Adapted from Bamber and Gereffi (2013)

Assembly and manufacturing are usually the lowest value-added segments in the value chain. The functions differ depending on the final product. In terms of distribution, marketing and sales, there are usually two channels in this process: (1) directly to end users such as hospitals and medical facilities through the firm's central distribution centre; or (2) through distributors. Lower value products are usually sold through wholesale distributor while higher value products are sold directly to end users (Bamber and Gereffi, 2013). The final segment in the value chain is the post-sales service, which may include training on equipment and consulting as well as account management for the supply of accessories, maintenance and repairs (Ghemawat, 2007).

Chapter 3: Medical Devices Industry in Penang and Malaysia

3.1 Malaysia's medical devices trade and investment

There is continued approved inflow of medical device manufacturing investment between RM1.8 billion and RM2.2 billion in the five-year period. Table 3 shows the export and approved manufacturing investment data for Malaysia for the period 2014-2018. The proportion of foreign direct investment (FDI) compared to domestic investment is higher in 2016 and 2017, but lower in the years of 2014, 2015 and 2018.

Table 3: Malaysia's Medical Devices Trade and Approved Medical DevicesManufacturing Investment

Year	2014	2015	2016	2017	2018
Medical	13.4	15.5	15.8	19.8	23.0
Devices					
Export					
(RM billion)					
Approved	2.2	1.8	2.9	2.2	2.1
manufacturing					
investment					
(RM billion)					
FDI	1.0	0.6	1.6	1.6	0.6
Domestic	1.2	1.2	1.3	0.6	1.5

Note: Approved manufacturing figures does not includes latex-based medical devices investment

Source: Ministry of International Trade and Industry, MATRADE, MIDA

Malaysia recorded a Compounded Annual Growth Rate (CAGR) of 14.5% for medical devices export for 2014-2018. from RM13.4 billion in 2014 to RM23.0 billion in 2018. According to MATRADE, Malaysia's medical device export continues to grow steadily, with the composition of gloves and non-gloves to be of almost equal proportion. According to MATRADE, the growth of non-glove medical devices export outpaced the growth of glove medical devices export. In 2013-2018, the export growth rate of non-glove medical devices export stood at 15.2% as compared to glove medical devices export growth rate of 9.4%.

Growth in exports is mainly driven by intravenous catheters and orthopaedic products in recent years. With a relatively small domestic market⁵, manufacturers of medical devices in Malaysia activities are mainly for the export market. This is in contrast to the historical trend of setting up in China with the common objective to cater to local market demand.

⁵ In terms of the government review of Pharmaniaga's contract, stakeholders interviewed expressed that there may be opportunities for other interested companies (likely via a tender process) at the end of Phamaniaga's 10-year contract period in November 2020.

Figure 3 shows the changing Malaysia's medical devices export composition for 2014-2018. There is a high concentration of exports in disposables, between 73.9% and 75.8%. This figure is largely due to Malaysia's strength in export of medical examination and surgical gloves. There is a slight fluctuation in the composition of export of disposables in the past five years, but disposables export composition still remains above 70%. In terms of diagnostic equipment, there is a decline from 5% in 2014 to 2.8% in 2018. For the product segment IVD, it is still largely a small proportion (between 0.2% and 0.3%) but in terms of value it is still growing healthily.

Malaysia's surgical instruments and therapeutic export made almost equal contribution to the national total medical devices export in the past five years. In 2018, the export composition for surgical instruments and therapeutic stood at 11.8% and 10.8%, respectively. Diagnostic medical devices export showed lower contribution to total medical devices export, from 5.0% in 2018 to 2.8% in 2014.



Figure 3: Malaysia's Medical Devices by Product Category (%), 2014-2018

Note: Product segment composition may differ among sources due to differences in HS codes categorization Source: Author's compilation based on categorization by Bamber and Gereffi (2013) and Torsekar (2018)

In the national context, there are also four noticeable Malaysian companies in the top 115 medical devices companies globally (Refer to Table 11 in Appendix). These companies are Malaysia's four largest rubber medical devices companies, which are mainly in the medical examination and surgical gloves manufacturing industry. Stakeholders interviewed agree that the gloves firms in Malaysia have reached a relatively significant mature stage. Stakeholders also agree that the large glove companies in Malaysia have continued to acquire technology in their industry and their growth has become relatively sustainable. Today, the glove manufacturing (medical and non-medical segment) and other rubber medical devices industries are among Malaysia's most successful resource-based manufacturing industries.

Bank Negara Malaysia (BNM) Annual Report 2018 highlighted four segments where, despite global technology down cycle, increased capacity allows firms to tap into global demand for growing product segments. Of the four, two are related to the medical devices industry, which are (1) products used in the medical devices segment spurred by semiconductor use in medical devices, and (2) rubber products (gloves, sheath contraceptives and catheters) used in the medical industry. In terms of geographic concentration, Klang Valley and Penang and northern Malaysia are two of the major medical devices manufacturing hubs in Malaysia.

3.2 Medical devices manufacturing economic contribution in Penang

Penang is undeniably an important medical devices manufacturing hub in Malaysia. Based on the manufacturing census conducted in 2015 (Table 4 and Table 5), Penang contributes about 77% of the total gross output for the manufacture of irradiation, electro medical and electrotherapeutic equipment, and about 22% of the total gross output for the manufacture of medical and dental instrument and supplies, respectively. The notion of Penang as a leader in non-latex medical devices industry in Malaysia is also relevant, with at least 80% of gross output and value added in the manufacture of irradiation, electro medical and electrotherapeutic equipment contributed by companies based in Penang in 2015.

Table 4: Principal manufacturing statistics of medical devices in Penang based on Malaysia Standard Industrial Classification (MSIC)

Ι	MSIC 266 - Manufacture of Irradiation, Electro Medical and Electrotherapeutic Equipment						
Year	Number of Establishments	Value of gross output (RM'000)	Value of intermediate Input (RM'000)	Value added (RM'000)	Total employment	Salaries & wages paid (RM'000)	Fixed assets (RM'000)
2010	6	1,054,088	612,059	442,029	5,176	167,585	558,656
2015	12	3,485,125	2,227,897	1,257,228	10,642	406,796	1,748,529
	MSIC 3	25 - Manufac	ture of Medica	al and Dental	Instrument an	d Supplies	
Year	Number of Establishments	Value of gross output (RM'000)	Value of intermediate Input (RM'000)	Value added (RM'000)	Total employment	Salaries & wages paid (RM'000)	Fixed assets (RM'000)
2010	10	31,957	23,559	8,398	136	3,155	20,729
2015	25	289,436	226,953	62,483	1,397	44,923	213,926

Source: Unpublished data from Department of Statistics, Malaysia

For both industry products (MSIC 266 and 325), Penang has shown steady growth in total employment and salaries and wages paid in 2015 as compared to 2010. For MSIC 266, employment grew by 105.6% to reach 10,642 employees in 2015 as compared to 5,176 in 2010. Meanwhile for MSIC 325, total employees employed grew by 9.3%, from 136 persons to 1,397 persons. It is interesting to note that while Penang showed healthy increase of total employment for MSIC 266 as compared to the total employed for whole country at 81% in 2015 (2010: 70%), there is remarkable

growth total employment for MSIC 325 as compared to the total employed for whole country at 21% in 2015 compared to only 3% in 2010.

Table 5: Penang's total as compared to the national total for medical devices manufacturing

MS	MSIC 266 - Manufacture of Irradiation, Electro Medical and Electrotherapeutic Equipment						
Year	Number of Establishments	Value of gross output (RM'000)	Value of intermediate Input (RM'000)	Value added (RM'000)	Total employment	Salaries & wages paid (RM'000)	Fixed assets (RM'000)
2010	55%	77%	77%	77%	70%	85%	75%
2015	29%	81%	80%	83%	81%	82%	83%
MSIC 325 - Manufacture of Medical and Dental Instrument and Supplies							
	MSIC 325	- Manufacti	ire of Medical	and Dental	Instrument an	d Supplies	
Year	Number of Establishments	- Manufactu Value of gross output (RM'000)	Value of intermediate Input (RM'000)	Value added (RM'000)	Total employment	Salaries & wages paid (RM'000)	Fixed assets (RM'000)
Year 2010	Number of Establishments	- Manufactu Value of gross output (RM'000) <u>6</u> %	Value of intermediate Input (RM'000) 8%	and Dental Value added (RM'000) 4%	Total employment <u>3%</u>	Salaries & wages paid (RM'000) 4%	Fixed assets (RM'000) 17%

Source: Unpublished data by Department of Statistics, Malaysia based on Economic Census (Manufacturing) conducted in 2010 and 2015

3.3 Major medical devices companies in Penang and Malaysia

Table 6 shows the major foreign medical devices companies based in Penang. Three are headquartered in the United States while there is one each from Germany and Denmark respectively. This is largely in line with Penang's overall investment inflow host country demographics where the United States is the largest FDI contributor followed by EU countries.

Company	Products	Headquarter
B. Braun Medical	Infusion and transfusion sets, sutures, intravenous cannula,	Germany
Industries	large volume parenterals, hemodialysis concentrates,	
	peritoneal dialysis solution, bloodlines, surgical	
	instruments, hypodermic needles, spinal needles, AV	
	fistula epidural	
	anaesthesia sets	
St. Jude Medical	Cardiac rhythm management e.g. pacemakers, defibrillators	United States
Operations	and leads	
Symmetry	Medical sterilising cases, medical instruments and	United States
Medical	orthopaedic implants	
Malaysia		
Ambu Sdn. Bhd.	Disposable medical electrodes	Denmark
Haemonetics	Whole Blood Devices &	United States
Malaysia Sdn.	Apheresis Devices	
Bhd.		

Table 6: Major medical devices companies in Penang

Note: Haemonetics did not appear in ITC's data for HS codes as classified by

Source: Adapted from Ministry of International Trade and Industry

Five of the world's top 25 medical devices manufacturers (Table 7) have operations in Penang. These are Abbott Laboratories, Cardinal Health, Boston Scientific, B. Braun and Canon Inc.. Out of these, four operate in the Bayan Lepas Industrial Park, while Boston Scientific (officially opened in February 2018) operate at Batu Kawan Industrial Park. Furthermore, Haemonetics Corporation which ranks 65th, with revenue at 939 million USD) officially opened also at Batu Kawan. in February 2015.

Table 7: Companies in top 25 medical devices companies global list with operations in Penang

Rank	Company Name	Revenue	Country	Operating location
		(USD million)		In Penang
5	Abbott Laboratories	16,811	United States	Bayan Lepas
8	Cardinal Health, Inc.	15,659	United States	Bayan Lepas
13	Boston Scientific Corporation	9,820	United States	Batu Kawan
15	B. Braun Melsungen AG	7,671	Germany	Bayan Lepas
21	Canon Inc.	4,502	Japan	Bayan Lepas

Note: See Table 2 for full list of the top 25 medical devices companies globally, by revenue, 2018 Source: Compiled by author based on QmeD, Medical Device and Diagnostic Industry and company websites Based on the same reference from MITI, there are two major local medical devices companies in Penang, which are Straits Orthopaedics (Mfg) Sdn. Bhd. and Vigilenz Medical Devices Sdn. Bhd. Straits Orthopaedics is mainly involved in contract manufacturing of orthopaedic products while and Vigilenz Medical Devices is involved in the manufacturing of sutures & disposable articles for surgeries. In terms of product range, there is a mix of low- and high-value items across the segments of disposables, surgical instruments, parts of various products, therapeutic, and diagnostic equipment.

Nonetheless, industry stakeholders view that the government should continue to enhance the ecosystem for medical devices manufacturing with lesser concern on the final product manufactured. Industry stakeholders opine that firms may continue to upgrade product manufactured in Penang/Malaysia once the decision to established a plant here is made. This definitely has to be balanced with the decision to attract strategic investment projects centered at the thrust of high-technology, high-income projects.

Japan Lifeline has also announced that its first factory outside Japan involves a RM70 million investment in Penang Science Park. This will be manufacturing medical devices for cardiac rhythm management, electrophysiology or ablation and cardiovascular surgery for Japanese markets such as balloon catheters, electrophysiological catheters, ablation catheters and open stent grafts. MIDA has also publicised an investment by PENTAX Medical, a Japanese-headquartered medical devices company. According to MIDA, PENTAX is one of the top three endoscopic and surgical system manufacturers in the world. The estimated investment is RM76 million, which will provide employment for 193 employees at first, with an expected increase to 440 employees by 2021.

Figure 4 shows the timeline of investments by major medical devices companies, and re-investment announcements in Penang. It is estimated that the largest medical devices company in Penang (measured by total accumulated investment) is B. Braun. As of 2018, B. Braun has invested a total of RM4.75 billion in Penang. In addition to the fact that B. Braun is the earliest medical devices company to set up in Penang, it might be relevant to note that there was a slight time gap before other medical device firms chose to set up in Penang post late-1980s.





Source: Company websites, MIDA

BOX 1: B. Braun in Penang

B.Braun's presence in Malaysia started in 1972, around the same period that Penang started its industrialization process. B. Braun Medical Industries in Penang is B.Braun's first manufacturing site in Asia Pacific region and is one of the largest B.Braun manufacturing sites for the group outside Europe. In 2018, the company celebrated its 45th year in Penang and Malaysia, and announced that since its establishment in Penang in 1972, the company has invested over RM4.75 billion.

B.Braun Malaysia has more than 7,700 employees (based on announcement in April 2018). The company's Penang plant is among the largest manufacturers of medical, surgical and pharmaceutical products in Malaysia and in the region.

The company has also established their Center of Excellence for Intravenous Access Products. B. Braun Medical Industries was also awarded the International Procurement Centre (IPC) status by the Malaysian Investment Development Authority (MIDA), which allows procurement and sale of raw materials, components and finished products to companies within the region. Products manufactured in B. Braun Medical Industries Penang are exported to the US, Japan, Germany and several major markets around the world.

The company also provides reasons for choosing Penang and Malaysia as their investment location of choice, which include the talent know-how, competency, and dedication to the company's production and innovation.

Source: B. Braun Melsungen AG. (n.d.). B. Braun Malaysia. Retrieved September 27, 2019, from <u>https://www.bbraun.com.my/en/company/b-braun-malaysia/organizations/company-bmi.html</u>.

Chapter 4: Supply Chain and Value Chain Analysis of Medical Devices Industry in Penang

4.1 Medical devices companies in Penang by product segments

For this study, around 30 companies were identified from International Trade Centre (ITC) data., along with several medical devices companies in Penang (identified initially from ITC's data) which have undergone merger and acquisitions (M&A) or have common shareholders. These are:

Aesculap and B. Braun

Accelent, Lake Region and Integer

ABio Orthopedics and Straits Orthopedics which is owned by common substantial shareholder Straits Apex Sdn Bhd. Straits Apex Sdn Bhd is a full subsidiary of Apex Healthcare Berhad and owns 40% of ABio Orthopedics and 40% of Straits Orthopedics, respectively.

A large concentration of firms is in the product categories of disposables, surgical instruments and therapeutics. High foreign firms' concentration was observed in the surgical instruments and therapeutic segments. Meanwhile, there is more observable concentration of local firms for disposables largely due to the presence of firms in the latexbased industries (makes up about 33% of the firms in disposable category). Some products that are not in Penang's manufacturing landscape includes product segments in in-vitro diagnostic (IVD) (HS Codes 3821, 3822).

Disposables	Surgical Instruments	Therapeutic
Latex-based	Alliance Contract Manufacturing Sdn.	Alliance Contract Manufacturing
Alliance Rubber Products Sdn. Bhd.	Bhd.	Sdn. Bhd.
Central Elastic Corporation Sdn. Bhd.	Ambu Sdn. Bhd.	B Braun Surgical Sdn Bhd
Concept Rubber Products Sdn Bhd	B Braun Surgical Sdn Bhd	Boston Scientific (Malaysia) Sdn.
Dongkuk Techco Rubber Industries	B. Braun Medical Industries Sdn Bhd	Bhd.
Sdn Bhd	B. Braun Pharmaceutical Industries	Knowles Electronics (Malaysia) Sdn. Bhd.
Gaw Rubber Products Sdn Bhd	Sdn Bhd	Orthomedic Innovations Sdn.
Kai Sik Towa Rubber Products Sdn Bhd	Boston Scientific (Malaysia) Sdn. Bhd.	Bhd.
Mapa Gloves Sdn. Bhd.	Knowles Electronics (Malaysia) Sdn. Bhd.	Straits Orthopaedics (Mfg) Sdn. Bhd.
Nastah Industries Sdn. Bhd.	Lake Region Medical Sdn. Bhd.	Symmetry Medical Malaysia Sdn
Profound Rubber Industries Sdn Bhd	Orthomedic Innovations Sdn. Bhd.	Bhd
Non latay	St. Jude Medical Operations	UWC Healthcare Sdn Bhd
<u>INOII-latex</u>	(Malaysia) Sdn. Bhd.	Vigilenz Medical Devices Sdn.
Alliance Contract Manufacturing Sdn. Bhd.	Straits Orthopaedics (Mfg) Sdn. Bhd.	Bhd.
		1

Table 8: Medical devices companies in Penang by product segments

Ambu Sdn. Bhd.	Symmetry Medical Malaysia Sdn Bhd	Visco Technology Sdn. Bhd.
B Braun Surgical Sdn Bhd	Vigilenz Medical Devices Sdn. Bhd.	Woodridge Life Sciences Sdn
B. Braun Medical Industries Sdn Bhd	Visco Technology Sdn. Bhd.	Bhd
B. Braun Pharmaceutical Industries Sdn Bhd	Woodridge Life Sciences Sdn Bhd	
Boston Scientific (Malaysia) Sdn. Bhd.		
CCB Medical Devices Sdn Bhd		
Engineered Medical Systems Malaysia Sdn. Bhd.		
Haemonetics Malaysia Sdn Bhd		
Knowles Electronics (Malaysia) Sdn. Bhd.		
Lake Region Medical Sdn. Bhd.		
Orthomedic Innovations Sdn. Bhd.		
St. Jude Medical Operations (Malaysia) Sdn. Bhd.		
Straits Orthopaedics (Mfg) Sdn. Bhd.		
Symmetry Medical Malaysia Sdn Bhd		
UWC Healthcare Sdn Bhd		
Vigilenz Medical Devices Sdn. Bhd.		
Woodridge Life Sciences Sdn Bhd		
Diagnostics Equipment	Parts	Others
Alliance Contract Manufacturing Sdn. Bhd. Canon Medical Systems Polar Electro Malaysia (M) Sdn. Bhd.	B Braun Surgical Sdn Bhd	

Source: Author's compilation based on ITC data according to classification in Bamber and Gereffi (2013) and Torsekar (2018)

Note: The names of the individual companies within the same group of companies may appear several times in Table 8 as the individual companies may be producing different products within the same segment and/or different segments.

Many Penang companies are also involved in medical devices contract manufacturing, especially in plastic-based and metal-based products. These include Straits Orthopaedic, Alliance Contract Manufacturing, CCB Medical Devices, and Accelent (now Lake Region). In a speech by former Penang Chief Minister Lim Guan Eng in 2015, he highlighted that 44% of companies in Penang are contract manufacturers of electronic components for medical equipment, while another 25% are orthopaedic and supporting companies.

Duff and Phelps (2018) noted that cost-cutting measures by OEMs to decrease their number of suppliers have positioned contract manufacturers in a position to benefit from downstream pressure, as they offer a wider range of capabilities and help reduce costs. Besides that, in view of OEMs' more focused investment in innovation and advanced technologies, specialized contract manufacturers can gain traction through engineering capabilities and the ability to scale capacity. Contract manufacturers in Penang are well-positioned to gain traction since the largest medical devices market segment are cardiovascular and orthopaedic (Markets and Markets, 2011).

Concentrations of medical device players in Penang include Bayan Lepas Industrial Park (B. Braun, Abbott, Canon Medical, Knowles, Lake Region, Mapa), Batu Kawan Industrial Park (Boston Scientific, Haemonetics, UWC Healthcare), Prai Industrial Park (Straits Orthopedic), and Bukit Minyak (Vigilenz, CCB Medical Devices). Given the demographics of Penang, the author infers that companies are not particularly concerned with specific locations when setting up (choice of different industrial parks) in Penang.

Beneficiaries of the economic spillovers of medical devices firms' investments in Penang include suppliers of metal, plastic and chemicals, contract packaging, contract sterilization, medical trading companies, and other related electrical and electronics companies involved in medical devices manufacturing industry. The medical devices companies also utilize the services of supporting companies from neighbouring states. For example, sterilization process is usually procured from Steris in Kulim, and raw materials for rubber medical devices from neighbouring states with rubber production.

4.2 Value chain activities of medical devices companies in Penang

In terms of activities within the medical devices industry value chain (see Figure 5), the highest concentration of companies in Penang are involved in components manufacturing, assembly and production (described as lower value-added segment). Specific details of companies with activities within the assembly/production segment is provided in Figure 5.

Due to Penang's industrial strength in E&E and backend semiconductor, there is a large number of companies involved in electronics development within the components manufacturing segment, such as Flex, Sanmina, Celestica, Jabil, Plexus, UWC, Venture, KLS Martin, Epsilon Medical Devices, Coraza, and Paramit. The deepening of capabilities for this sub-segment may be worth further exploration, given Penang's industrial linkages in the E&E industry.



Figure 5: Value chain activities of medical devices companies in Penang

Source: Author's computation, basic conceptual diagram adapted from Bamber and Gereffi (2013)

Over the years, several medical devices companies in Penang have upgraded their capabilities in Penang with R&D function, including one with a centre of excellence. Companies such as B. Braun have established a centre of excellence (COE) while Ambu and Vigilenz have established R&D capacity in Penang (described as high-value segment). Table 9 provides further details on the medical devices companies and their R&D activities in Penang.

Table 9: Selected medical device companies with centre of excellence/research and development activities in Penang

Company	R&D Activity
B. Braun	B. Braun Medical Industries in Penang is the global Center of Excellence for Intravenous Access
	(CoE IVA) products including R&D and production technology. The team, led by Dr. Juergen
	Schloesser, Senior Vice President Operations & CoE IVA, develops and manufactures safety
	products and systems like IV catheters (IVC), scalp vein sets (SVS) and hypodermic needles.
Ambu	In 2008, the company established its R&D department in Penang. Ambu's main innovation
	centres are located in Denmark and Malaysia (Penang) (Ambu, 2018). Ambu stated then that
	Malaysia and China will handle product updates and the development of new products within
	the existing product areas, with Malaysia being a centre for electrodes and electronic single-use
	products.
Vigilenz	The research within the company focuses on biomaterial for medical application, Urology and
	CVC products, Infection Control and wound management products.

Where distribution and marketing, and post-sales services are concerned, generally MNCs have central distribution to end customers (hospital, medical facilities) while local companies are mostly OEM that sells through distributors, or some directly to end users.

Meanwhile, localisation by multinationals to local suppliers appears relatively more challenging than in other industries due to the stringent medical devices standard and the capability to scale by local companies.

Chapter 5: Human Capital and Workforce Development

5.1 Workforce requirements

Table 10 shows the workforce needs for the medical devices manufacturing industry in the categories of (1) Professional labour with tertiary education, and (2) technicians and operators level adapted from Araujo et al. (2011) and Forfás (2009).

Table 10: Workforce requirement for medical devices manufacturing industry

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

Source: Adapted from Araujo et al. (2011), Forfás (2009).

Knowledge and skills transfer is one the anticipated benefits of FDI. Some stakeholders have opined that knowledge transfer may be taking place at a pace slower than expected in the case of Penang and Malaysia, with several saying that this is due to limitations in the capacity of local talent and industry.

However, stakeholders (government, association and industry members) have also voiced out that having an effective and industry-focused skill development centre in Penang is positive for the medical devices industry and other targeted industries in Penang. The Penang Skills Development Corporation (PSDC) is seen to be an important skills upgrading factor for talents in the industry in Penang. Based on PSDC's 2018 Annual Report, the only medical devices company involved in Malaysia Meister Program training is B. Braun Medical. The lack of other participating

companies in the programme provides motivation for the state government and PSDC to further promote the programme to medical devices companies.

In terms of labour adaptability among different product segments, stakeholders opine that it is dependent upon the type of activity the worker is involved in and the skills required in the new job. Stakeholders interviewed say that workers involved in production may be more mobile and if provided with training, more able to adapt the skills required at the production floor. For medical devices involving chemical and chemical products, chemists may also have the mobility to move between segments and companies.

For technician level staffing, there are requirements for specific skills for these talents in different product segments. For example, in the orthopaedics product segment manufacturing, machinist with specific skillsets and training are required for orthopaedic products.

However, in terms of regulatory and sales, there are certain limitations since some companies are involved in original equipment manufacturing (OEM) while other companies sell directly to end users (hospitals and medical facilities). Skill in registering different classes of medical devices (such as to the United States Food and Drug Administration (FDA), China FDA, Europe CE Mark) is useful, but stakeholders say that this requires more comprehensive skillsets from the workers involved in sales and regulatory.

According to various stakeholders, what is required to advance the medical devices industry in Malaysia is for talents that have experience to be involved in R&D, or with those that have training in R&D. Talents who have expertise in design and research in terms of product and process are required in COEs, and research and developments divisions. Stakeholders, especially industry members, state that they understand the government's efforts in promoting more COEs for medical devices in Malaysia but opine that there is a need for more talent to be involved in R&D.

It is understood that MIDA and MITI have undertaken a talent environmental scan study, and the study for the medical devices industry has been completed early 2019. There is a plan to undertake discussions with major universities on the requirement of the industry, to ensure that graduates are better equipped to be in the workforce.

5.2 Critical occupation list and medical devices industry

This section discusses the Institute of Labour Market Information and Analysis (ILMIA) and Talent Corporation's (TalentCorp) critical occupation list (COL) 2018/2019 list and its relationship with the medical devices industry. The author has shortlisted the occupations listed in Table 11 which makes specific reference to the medical devices industry in the report.

Table 11: Critical Occupation List related to Medical Devices Industry

Critical Occupation List related to Medical Devices Industry
Sales and Marketing Managers
Manufacturing Managers
Mechanical Engineers
Electrical Engineering Technicians
Mechanical Engineering Technicians
Manufacturing Supervisors

Source: ILMIA and TalentCorp (2018)

This list shows similarity with the discussion in section 5.1 (especially Table X and stakeholders' feedback). In particular, the COL report highlighted that Sales and Marketing Managers and Manufacturing Supervisors positions are difficult to fill in the non-consumable medical devices manufacturing segment. For Electrical Engineering Technicians, the surgical/medical gloves sub-sector particularly highlighted the need for talent to fill this position.

It is also a growing concern that some of the talents required are from the same talent pool required by other industries, including the E&E industry which is Malaysia's largest manufacturing contributor. E&E industry is also Penang's most significant manufacturing sector. These jobs (shown in Table 9) are Manufacturing Managers, Mechanical Engineers, Electrical Engineering Technicians, Mechanical Engineering Technicians (e.g. machinery technicians, maintenance technicians), and Manufacturing Supervisors. Industry stakeholders point out that institutions of higher learning (both public and private) should be aware of the prevailing scenario and should make necessary adjustments to the training that they offer.

Chapter 6: Conclusion

6.1 Opportunities and challenges

A major consensus among stakeholders is that the state should look into further solidifying the medical devices industry in Penang, given the former's resilience to economic uncertainty and the less cyclical nature of the industry. Tapping on Penang and Malaysia's accumulated experience and residual intelligence in almost 50 years of industrialisation, Penang continues to show potential for advancement as the destination of choice for the medical devices sector. However, at the same time, the state is facing increased competition from other investment destinations, relatively slower upgrading of firms in terms of product and process, and increased challenges in the hiring of industry-ready talent.

It is also observed that Penang will continue to adopt export-oriented FDI-driven strategy (as observed in Costa Rica and Baja California's case). The industry's contribution to national export is less than 3%, which exemplifies the vast space into which Malaysia can continue to expand, given with better facilitation for the medical devices industry.

This study has highlighted Penang's strength in orthopaedic, cardiovascular and related E&E product segments for the medical devices industry. Penang should take note of emerging markets while continuing to tap on the existing traditional markets. China could be the world's largest orthopedic device market within 10 years (Liu, n.d.). This may be another investment attraction for Penang, and export promotion destination for companies currently based in Penang and Malaysia.

The industry's wave of M&As may help, by exposing more companies to the country through acquisitions of firms with Costa Rican operations (Lo, n.d.). This is also in line with the continued M&As taking place globally for the medical devices industry. It is also important to remain cognisant of the fact that the production of medical devices is concentrated in a relatively small number of companies, and lead firms with a global presence account for more than half of the world's market share.

In terms of disposables, Malaysia has a comparative advantage in rubber medical devices. While Penang hosts some rubber medical devices companies, it is observed that none of top Malaysian medical devices companies have operations in Penang. Latex-based medical devices are also not in Penang's promoted industries. In view of the ongoing consolidation taking place in the industry in Malaysia for the past 10-20 years during which large rubber medical devices firms have been pursuing merger and acquisitions (M&A), the author does not rule out the possibility of smaller rubber medical devices firms in Penang being involved in such M&As in the future. In many cases, there is technology transfer and operations efficiency after a merger and acquisition has taken place.

Among the most well-discussed advantage and challenge for the industry in Penang is the talent pool and upgrading. This is one of the most important factors for companies when investing in Penang. It is important to note that competitor countries have also continued to nurture talent pool for the industry. Stakeholders continue to raise issues to upgrade local talents to be more industry-trained and also to request of policymakers to raise awareness among students on the potential of the medical devices industry.

Buntz and Newmarker (n.d.) noted that there is no single state that can claim to be the best location for all medical devices firm in the US case. This applies even to Malaysia., where different states have established the strength of attracting different segments of medical devices firms. The Klang Valley and Perak have a sizeable number of rubber medical devices companies while Penang has been receiving more medical devices companies that are manufacturing for orthopedic and cardiovascular purposes.

Key strengths, weaknesses, opportunities and threat for the industry is summarized in Figure 6.

Figure 6: SWOT analysis

Strength	Weakness	
Malaysia and Penang have well-developed	Local companies may not have the capacity or	
infrastructure and good ecosystem for the industry.	economies of scale to benefit from location activities	
Malaysia continues to be a destination of choice for	from industry MNCs.	
many medical devices companies. Industry members	Latex-based medical devices industry faces issues such	
opine that Malaysia continues to have a strong	as stability of water supply system and price of raw	
reputation among medical devices MNCs. Some of the	materials.	
companies that have chosen Malaysia for their first	Malaysian companies are more involved in	
overseas operations include B. Braun, Cochlear, St	consumables, and require relatively more support from	
Jude, and Japan Lifeline.	MATRADE. Local companies are also less involved in	
Multilingual talents and a relatively well-educated	therapeutic and surgical instruments product	
workforce is an advantage.	segments.	
Pioneering companies have provided cumulative		
industrial experience and residual intelligence for		
industries in Penang, including the medical devices		
industry.		
Investment promotion agencies such as MIDA and		
InvestPenang continuously encourage investors to		
bring in new technology, development programmes,		
and joint-venture collaboration to spur localization.		
Incentives are available for local vendors and suppliers		
to MNCs.		
Relatively good IP laws provide assurance to investors.		
FDI by MNCs, and domestic investment has led to		
export growth in the industry.		
Opportunities	Threat	
Potential M&As in rubber medical devices sector may	There is growing government support by competitor	
involve companies based in Penang and allow for	countries, and better incentive packages.	
technology transfer.	Malaysia needs to enhance the environment and its	
Penang's strength as a Global Business Services (GBS)	ecosystem towards a conducive R&D friendly	
destination of choice allows the state to attract medical	environment to spur innovation and move the	
devices companies looking to expand their GBS	economy higher up the value chain.	
functions.		

BOX 2: US-China Trade War Effect on Medical Devices Export

The US-China trade war has lasted about two years now (calculated from President Trump's memorandum to the US Trade Representative (USTR) instructing for an investigation on any of China's laws, policies, practices, or actions that may be unreasonable or discriminatory and that may be harming American intellectual property rights, innovation, or technology development.

The latest tariff imposition took place on 1 September 2019, but on September 11, China announced exclusion of 16 products (less than USD2 billion of US exports) from tariffs imposed in 2018. In addition, President Trump also announced plans to delay tariff increase on USD250 billion of Chinese imports from 25% to 30%, from 1 October to 15 October. On 20 September, the USTR announced that disposable electrocardiograph electrodes, certain X-ray and MRI components, otoscopes and anesthesia masks to be among medical device products exempted from tariffs on China.

Nevertheless, in general, the medical devices products continue to obtain exemption from tariff imposition in the ongoing trade war. However, for rubber gloves, United States has imposed a 15% tariff on Chinese-made medical and vinyl gloves effective Sept 1.

However, trade associations and industry players such as Advanced Medical Technology Association (AdvaMed) have concerns on the ongoing trade war. The parts and base materials exported from China form part of the supply chain and may complicate the cost and flow of components for the manufacturing of the final product in the medical devices industry.

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https://www.forbes.com/sites/brucejapsen/2019/09/24/despite-exemptions-medical-device-makers-leery-oftrumps-trade-war/#339991f2578e

6.2 Policy recommendations

The policy recommendation for the medical devices value chain in Penang involves: (1) product upgrading and diversification, (2) process upgrading, (3) trade and technology promotion, (4) backward and forward linkages, (5) flow of information, and (6) industry-academia dialogue.

Product upgrading and diversification

Initiatives should be intensified to attract investment and re-investment in higher value, high-tech product segments of therapeutic and diagnostic equipment. Re-investment promotion remains an important strategy, with historical data showing that Penang has high re-investment flows. Penang has already established its reputation in the cardiovascular and orthopaedics product segment and this can be an area of focus given its large market size.

On balance, stakeholders have also advocated for industry promotion to be more technology-based rather than keeping its major focus on product segment. Companies that find investing in Malaysia a preferable decision will eventually increase their investments into new product segments.

Process upgrading

Increased use of automation in assembly and manufacturing to increase productivity should be promotion, as part and parcel in the creation of an ecosystem for R&D activities and innovation. The government's Industry4WD programme should also be tapped upon to enhance upgrade, and increase the capacity of local firms to be more involved in localisations by MNCs.

In terms of both product and process upgrading, these recommendations can be further catalyzed with the promotion of more COEs for medical devices in Penang.

For both product upgrading and process upgrading, there should be promotion of a shared research and test facility similar to CREST with either process-based approach (pilot product and innovation) or process-based approach (shared facility for moulding, 3D printing, IoT).

• Trade and technology promotion

Stakeholders also propose for a technology-based medical devices exhibition and trade fair in Penang to showcase the latest innovation in the industry. This will further solidify Penang's image as an established hub for medical devices manufacturing and enhance the aspiration towards more innovation-led activities to take place in Penang.

Industry members opine that some previous exhibitions and conferences which had had a mix of local healthcare facilities, medical professionals, and rather broad range of suppliers in one same event in Penang could not achieve the objectives intended, especially for the medical devices manufacturing players. This is supported by the fact that most of the medical devices companies in Penang, if not all, are export-oriented and marketing and sales efforts are not particularly focused on local end buyers.

• Promote further backward and forward linkages within the industry

In this aspect, there is a need to encourage and further catalyze more COEs for medical devices in Penang. Penang has advantage in terms of component manufacturing and assembly, and existing companies should be encouraged to tap into other linkages within the value chain. The linkages should also not be limited to traditional manufacturing players, but also with emerging medical device trends companies (involved in wearables, health analytics, patient monitoring).

For contract manufacturers, with more global OEMs focusing on investment in innovation and advanced technologies, specialized contract manufacturers in Penang can gain traction through engineering capabilities and the ability to scale capacity. This definitely has to be accompanied with increase in capability and capacity by contract manufacturers in Penang.

The synergies should also be with existing players in neighbouring states. For example, Steris, which is involved in sterilization, is located in Kulim, Kedah. Also, some larger rubber medical devices players are in Perak. It is more idealistic to build a cluster of different specialisation in different states, tapping on the comparative advantage of each state, eventually to create a good cluster for medical devices in Malaysia.

• Flow and clarity of information

While export and investment promotion agencies (EPAs and IPAs) have produced quality data to assist in policy-making, there is still room to promote more well-structured data and information flows by publishing regular medical device approved investments and trade data. This allows for more enhanced initiatives to attract investments through better data clarity among policy makers, government agencies, industry members and potential investors.

For example, the release of medical devices industry-approved manufacturing investment data every quarter instead of once a year would be helpful. At the state-level, it will fill the gaps of knowledge currently found among state authorities (as approved investment data for state do not include the medical devices industry,

specifically). Better data clarity also allows investment promotion efforts to be implemented to further strengthen Penang and Malaysia as a medical device manufacturing location of choice.

• Academia-industry dialogue and collaboration

There is a need for further academia-industry dialogue and collaboration to increase the critical talent pool with R&D experience/training.

There should be more skills upgrading training to aid the medical devices industry. The involvement of medical devices companies in partaking the Malaysia Meister Program where tuition fees are subsidized by the Penang State government should also be further promoted.

Taking into consideration the high cost of development of products and R&D by local companies, there should be further promotion of university incubation programmes first before the spinning-off of successful ventures once the ventures are self-sustaining.

A summary of the recommendations can be found in Table 12 in the Appendix.

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Appendix

Table 11: Malaysian	companies	among	the	Тор	115	medical	devices	companies
globally, by revenue,	2018							

Rank	Company	Revenue	Market Capitalisation	
		(USD million)	(USD million)	
58	Top Glove Corporation Bhd.	1,127	3,470	
91	Kossan Rubber Industries Bhd.	504	1,343	
92	Hartalega Holdings Bhd.	502	4,948	
113	Supermax Corp. Bhd.	256	573	

Source: Compiled by author based on QmeD, Medical Device and Diagnostic Industry

Table 12: Summary of the recommendations

Product	• Initiatives to attract investment and re-investment in higher value, high-tech product	
ungrading &	segments of therapeutic and diagnostic equipment - cardiovascular and orthonaedics	
diversification	segments of incrapeutic and diagnostic equipment - cardiovascular and of inopacules	
diversification	• Industry promotion to be more technology-based	
	71 07	
Process	 Promote increased advancement in assembly & manufacturing (tap on Industry4WD) 	
upgrading	Enhance ecosystem for R&D activities and innovation	
Promotion of a sha	red research and test facility similar to CREST with either process-based approach (pilot product	
and innovation) or	process-based approach (shared facility for moulding, 3D printing, IoT).	
Trada & tach	• Task a low bood we dial devices whili it on and two de fair in Denous to show one the	
I rade & tech	• rechnology-based medical devices exhibition and trade fair in Penang to snowcase the	
promo	latest innovations in the industry	
Backward &	• Further catalyse and promote more COEs for medical devices in Penang	
forward linkages		
	 Synergies – traditional players - & emerging medical device trends companies 	
	Dromate ungrading among contract manufacturers	
	• Promote upgrading among contract manufacturers	
Flow of	• IPAs, EPAs to promote more well-structured data and information flows - better data	
information	clarity	
Academia-	Industry-focused/supported courses	
industry		
dialogue	 Further enhancement to the current upskilling development programmes 	
0	• University in substice and succession	
	• University incubation programmes	

Table 13: HS codes used in this study

HS code	Description
900130	Optical Fibres And Optical Fibre Bundles; Optical Fibre Cables Other Than Those Of Heading 85.44;
	Sheets And Plates Of Polarising Material; Lenses (Including Contact Lenses), Prisms, Mirrors And Other
	Optical Elements, Of Any Material, Unmounted, Other Than Such Elements Of Glass Not Optically
	Worked.Contact Lenses
900140	Spectacle Lenses Of Glass
3005	Wadding, Gauze, Bandages And Similar Articles (For Example, Dressings, Adhesive Plasters, Poultices),
	Impregnated Or Coated With Pharmaceutical Substances Or Put Up In Forms Or Packings For Retail
200720	Sale For Medical, Surgical, Dental Or Veterinary Purposes.
300630	Pharmaceutical Goods Specified In Note 4 To This Chapter. Opacifying Preparations For X-Ray
200640	Examinations; Diagnostic Reagents Designed 10 Be Administered 10 The Patient:
300040	Bone Reconstruction Cements:
300691	Pharmaceutical Goods Specified In Note 4 To This Chapter. Other Than Sterile Surgical Catgut, Similar
	Sterile Suture Materials (Including Sterile Absorbable Surgical Or Dental Yarns) And Sterile Tissue
	Adhesives For Surgical Wound Closure; Sterile Laminaria And Sterile Laminaria Tents; Sterile
	Absorbable Surgical Or Dental Haemostatics; Sterile Surgical Or Dental Adhesion Barriers, Whether Or
	Not Absorbable, Blood-Grouping Reagents, Opacifying Preparations For X-Ray Examinations;
	Diagnostic Reagents Designed To Be Administered To The Patient, Dental Cements And Other Dental
	Fillings; Bone Reconstruction Cements, First-Aid Boxes And Kits, Chemical Contraceptive Preparations
	Based On Hormones, On Other Products Of Heading 29.37 Or On Spermicides And Gel Preparations
	Designed 10 Be Used In Human Or Veterinary Medicine As A Lubricant For Parts Of The Body For
	Instruments Appliances Identifiable For Octomy Use
3821	Prepared Culture Media For The Development Or Maintenance Of Micro-Organisms (Including
5021	Viruses And The Like) Or Of Plant, Human Or Animal Cells.
3822	Diagnostic Or Laboratory Reagents On A Backing, Prepared Diagnostic Or Laboratory Reagents
	Whether Or Not On A Backing, Other Than Those Of Heading 30.02 Or 30.06; Certified Reference
	Materials.
401511	Surgical Gloves
401519	Gloves, Other Thansurgical Gloves
8713	Invalid Carriages, Whether Or Not Motorised Or Otherwise Mechanically Propelled.
9019	Mechano-Therapy Appliances; Massage Apparatus; Psychological Aptitude-Testing Apparatus; Ozone
	Therapy, Oxygen Therapy, Aerosol Therapy, Artificial Respiration Or Other Therapeutic Respiration
	Apparatus.
902110	Orthopaedic Or Fracture Appliances
902121	Orthopaedic Appliances, Including Crutches, Surgical Belts And Trusses; Splints And Other Fracture
	Appliances; Artificial Parts Of The Body; Hearing Aids And Other Appliances Which Are Worn Or
	Carried, Or Implanted In The Body, To Compensate For A Defect Or Disability. Artificial Teeth And
000100	Dental Fittings:Artificial Teeth
902129	Other Dental Fittings
902131	Orthopaedic Appliances, Including Crutches, Surgical Belts And Trusses; Splints And Other Fracture
	Appliances; Artificial Parts Of The Body; Hearing Aids And Other Appliances Which Are Worn Or
	Carried, Or Implanted In The Body, 10 Compensate For A Defect Or Disability. Other Artificial Parts
002120	
902139	Other Artificial Parts Of The Body
902140	Orthopaedic Appliances, Including Crutches, Surgical Belts And Trusses; Splints And Other Fracture
	Appliances; Aruncial Parts OI The Body; Hearing Alds And Other Appliances which Are Worn Or Carried Or Implanted In The Body. To Components For A Defect Or Dischility. Hearing Aids
	Carried, Or Implanted in The Body, 10 Compensate For A Delect Or Disability. nearing Alds,

	Excluding Parts And Accessories
902150	Pacemakers Forstimulating Heartmuscles, Excluding Partsand Accessories
902190	Other Orthopaedic Applincl Appl Which Are Wornor Carried Or Implantedin The Body, To Compensatefor A Defect/Disability
902212	Computed Tomographyapparatus, Based On Theuse Of X-Rays
902213	Apparatus Based On Theuse Of X
902214	Apparatus Based On Theuse Of Xveterinary Uses
902221	Apparatus Based On The Use Of X-Rays Or Of Alpha, Beta Or Gamma Radiations, Whether Or Not For Medical, Surgical, Dental Or Veterinary Uses, Including Radiography Or Radiotherapy Apparatus, X- Ray Tubes And Other X-Ray Generators, High Tension Generators, Control Panels And Desks, Screens, Examination Or Treatment Tables, Chairs And The Like.Apparatus Based On The Use Of Alpha, Beta Or Gamma Radiations, Whether Or Not For Medical, Surgical, Dental Or Veterinary Uses, Including Radiography Or Radiotherapy Apparatus:For Medical, Surgical, Dental Or Veterinary Uses
902230	X-Ray Tubes
300650	Pharmaceutical Goods Specified In Note 4 To This Chapter. First-Aid Boxes And Kits
401410	Sheath Contraceptives
611510	Panty Hose, Tights, Stockings, Socks And Other Hosiery, Including Graduated Compression Hosiery (For Example, Stockings For Varicose Veins) And Footwear Without Applied Soles, Knitted Or Crocheted.Graduated Compression Hosiery (For Example, Stockings For Varicose Veins):
841920	Medical, Surgical Orlaboratorysterilisers