

INVEST-IN-PENANG BERHAD

STUDY ON THE MEDICAL DEVICE INDUSTRY IN PENANG

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December 2013

1) Introduction

The term medical device refers to medical technology, supplies and equipment which encompass a wide array of healthcare products use in diagnosis, prevention, monitoring or treatment of healthcare illness or handicap but exclude drugs (Medical Device Authority, MDA).

Medical device manufacturing is a sub-sector of life-sciences that encompasses supporting infrastructure such as research universities, hospitals, medical laboratories and venture-capital firms, making it one of the most knowledge-intensive sector within the Malaysian economy.

Developments in medical device applications and demographics favour sustained growth of the medical device industry. The market for medical devices is driven by growing population, longer life expectancy, increasing consumer awareness, new quality / technology products, higher living standards, availability of skilled manpower and low production costs. Growing importance of electronics, the convergence of devices, pharmaceuticals, biotechnology and development of new treatments are especially matched Penang's strengths in electrical and electronics to become a substantial player in the medical device industry.

The Malaysian government has attempted in recent years to encourage domestic manufacturers to expand production into more technologically advanced products and develop services such as Information and Communications Technology and other support related services. Medical devices industry is also targeted for further development and promotion under Third Industrial Master Plan 2006-2020.

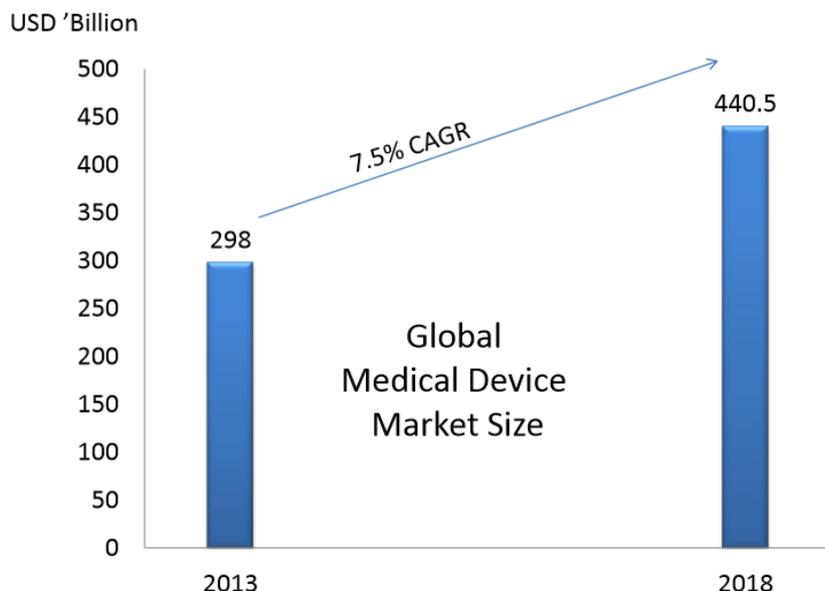
The Association of Malaysian Medical Industries (AMMI) members of Malaysian medical device industry directly support over twenty-five thousands of jobs and pays above-average wages. (AMMI Industry Survey 2012) Medical device industry is an emerging driving force for Penang's global economic competitiveness.

2) Medical Device Market

Overall Global Medical Devices Market

Global medical devices market is expected to reach US\$ 350 billion by 2016 with global annual average growth of 5% from 2011 to 2016. Global medical devices market is expected to reach US\$ 440.5 billion by 2018 with global annual average growth of 7.5% from 2013 to 2018. BRIC countries have large patient base, estimated to bring 1 billion new patients to the world's healthcare system in the next three to five years (*Espicom*).

Figure 1: The Global Market for medical devices in 2013



Source: Espicom, AMMI

There is significant medical device and instrumentation manufacturers of Penang to total Malaysian production of these products. Among the top 30 medical device manufacturers in 2012, multinationals mainly American companies such as Cardinal Health, B. Braun and St. Jude Medical have been operating from Penang.

Table 1: Top 30 Medical Device Manufacturers in 2012

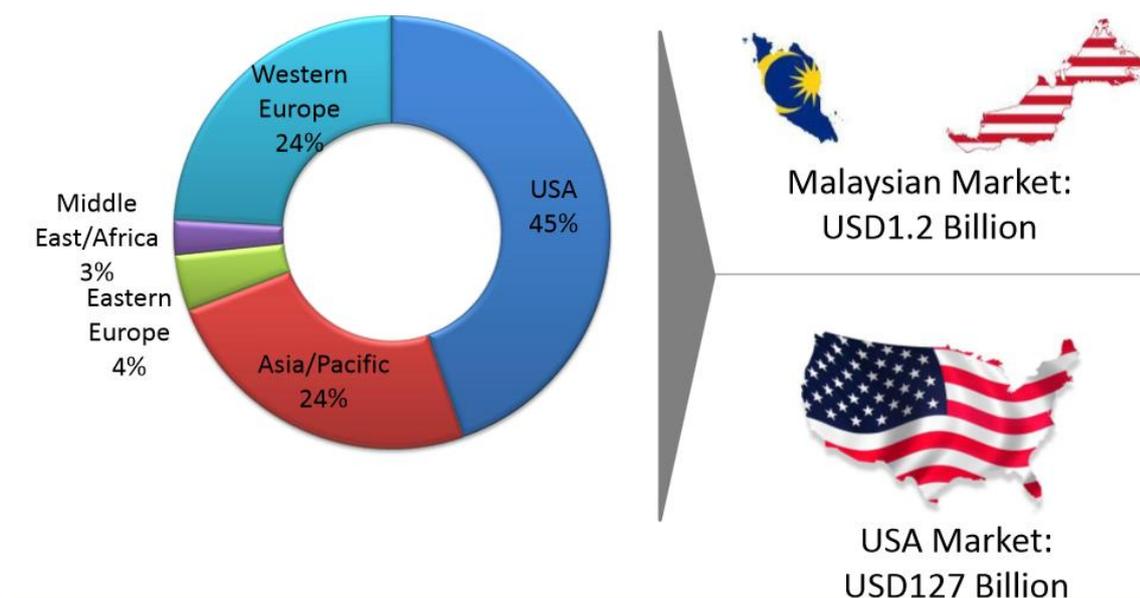
Rank	Company	Country	Rank	Company	Country
1	Johnson & Johnson		16	St. Jude Medical	
2	GE Healthcare		17	Novartis (Alcon)	
3	Siemens Healthcare		18	3M Healthcare	
4	Medtronic		19	Zimmer	
5	Baxter International		20	Terumo	
6	Philips Healthcare		21	Olympus Medical	
7	Covidien		22	Smith & Nephew	
8	Abbott Labs		23	Hospira	
9	Cardinal Health		24	Toshiba Medical	
10	Stryker		25	Getinge Group	
11	Danaher		26	CareFusion	
12	Becton Dickson		27	Bayer	
13	Boston Scientific		28	Fresenius Medical Care	
14	B. Braun		29	C.R. Bard	
15	Essilor		30	Dentsply	

16 4 3 2 1 1 1 1 1

Source: Medical Product Outsourcing (MPO) 2013

World medical devices market is 45% accounted in United States (US) (US\$127 billion), while APAC market contributed 24% and Malaysia's medical devices market worth 1% of US market valued at US\$1.2 billion (Espicom)

Figure 2: Medical Device Market – By Region



Source: Espicom, AMMI

Medical devices industry is identified as one of the seven new Entry Point Projects (EPPs) under the Healthcare National Key Economic Area (NKEA). Healthcare NKEA is one of the cores of Economic Transformation Program. From 2011 to 2015, annual average growth more than 8%, and Malaysia medical devices market value is expected to reach \$1.6 billion by 2015 (MIDA, 2011)

Table 2: Malaysia’s Medical Devices Sales Indicators 2007-2015 (USD billions)

	2009	2010	2011f	2012f	2013f	2014f	2015f
Medical devices sales	0.936	1.091	1.253	1.371	1.464	1.580	1.692
Medical devices sales % of GDP	0.5	0.5	0.5	0.5	0.5	0.5	0.5
Medical devices sales % of total healthcare sales	9.70	9.79	9.83	9.93	9.96	10.13	10.27

Source : Business Monitor International, March 2011
f=forecast

The future of medical devices is good for continuously aging population in major OECD country, new and significant emerging economies, increasing awareness and improving health infrastructure in emerging economies, increasing income and expenditures in developing countries, and the inelastic demand for healthcare. Malaysia is among the top medical devices exporting countries globally and has shown commendable export performance with continuous positive trade of balance.

(a) Orthopedic Segment

World orthopedic market is expected to grow 10% from 2009-2012 (from \$32 billion to \$42 billion), while APAC orthopedic market is expected to grow at 5% CAGR from 2011 to 2015. (Frost & Sullivan, 2012)

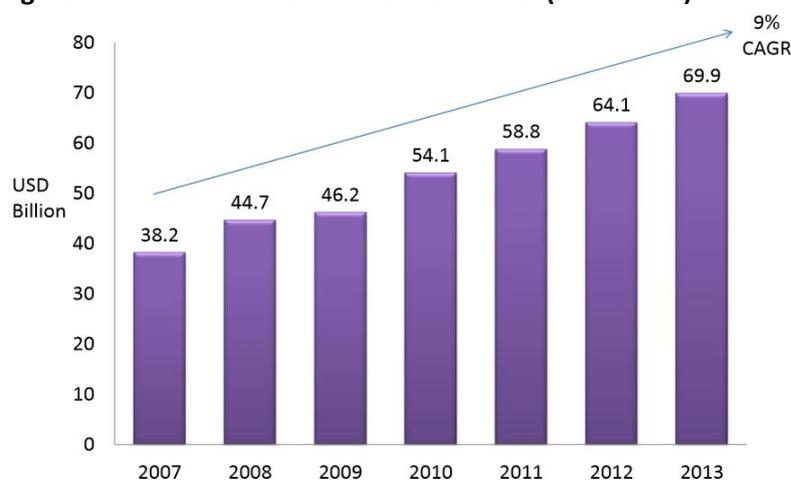
(b) Cardiology Segment

The global cardiovascular monitoring and diagnostic devices market is expected to grow at 8.8% CAGR for 2010 to 2016 (PR Newswire). The expectation of Axis Research Mind (2011) on Global Cardiac Pacemakers market is even higher that was expected to \$5.1 billion by 2015 at 11% CAGR from 2009 to 2015. APAC cardiology market is expected to reach \$18 billion by 2015 (Frost & Sullivan, 2012). APAC Cardiac Pacemakers market is the fastest growing region. Grow at 13.3% CAGR and the market value is expected to reach US\$1.3 billion by 2015. (Axis Research Mind, 2011)

Asia Pacific

From 2007-2013, medical device market in APAC are expected to grow at 9% CAGR to US\$69.9 billion (Espicom). From 2012-2015, healthcare expenditure in APAC will increase by 75%. In 2015, 35% of healthcare sales are to Asia. APAC healthcare expenditure will increase by 151% by 2020. Asia medical devices revenues are expected to grow at 14% CAGR from 2011-2015 (from US\$82.8 billion to US\$140 billion). Asia growing at more attractive rates compared to matured medical devices markets due to strong medical devices import growth and steading rising health expenditure (Frost & Sullivan, 2012).

Figure 3: Asia Pacific Medical Device Market (2007-2013)



Source: Espicom, AMMI

Local

An expectant for this sector is the anticipation of increase aging in population in Malaysia. By 2010, Malaysia has a population of 19.3 million i.e. 67.6% of which falling in the bracket of 15-64 years. In 2010, Malaysia's population is 28.6 million and is projected to increase by 10 million (35.0%) to 38.6 million in 2040. During this period, the population aged 65 years and over is projected to increase more than three folds to 4.4 million of the 2010 population of 1.4 million. The increase will lead Malaysia to become an aging population in 2021 when the population aged 65 years and over reach 7.1 per cent.

Table 3: Population projection by age group, Malaysia, 2010–2040

Tahun Year	0–14 ('000)	%	15–64 ('000)	%	65+ ('000)	%	Umur penengah Median age
2010	7,822.1	27.4	19,341.4	67.6	1,425.1	5.0	26.3
2015	7,733.4	25.4	20,971.9	68.8	1,779.9	5.8	28.2
2020	7,780.7	24.0	22,445.9	69.2	2,214.6	6.8	29.9
2025	8,009.5	23.4	23,533.4	68.6	2,751.3	8.0	31.5
2030	8,087.9	22.5	24,542.0	68.2	3,335.7	9.3	33.0
2035	7,893.4	21.1	25,606.1	68.5	3,889.9	10.4	34.5
2040	7,537.2	19.6	26,615.6	69.0	4,405.1	11.4	36.0

Source: Population Projection, Malaysia 2010 - 2040

Malaysia has increased the life expectancy consistently over the past few years i.e. the anticipation of increase aging in population.

Table 4: Life Expectancy by Gender, 2000, 2005, 2010 and 2013

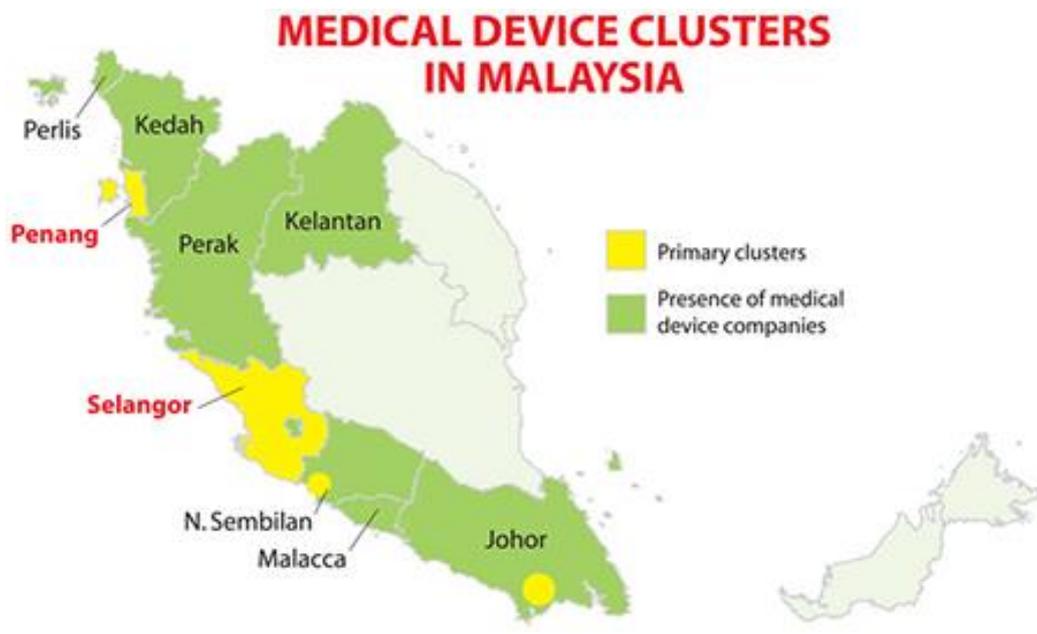
Gender	2000	2005	2010	2013e
Female	74.6	76.2	76.8	77.2
Male	70.0	71.4	71.7	72.6

Source: Department of Statistics, Abridged Life Tables Malaysia

In 2010, the highest per capita expenditure on healthcare is Singapore (US\$2005), followed by Malaysia (US\$368) in ASEAN (WHO World Health Statistics 2013). The higher-income countries are ahead in terms of allocation of resources, availability of medical talent, access to healthcare and quality of care. The healthcare systems in these countries are also compared to the quality of healthcare in the US and UK. High standards and quality of healthcare have also led to a growing healthcare travel industry in the region. Singapore and Malaysia have developed competitive advantages and are the region's leading exporters of healthcare services. (Source: Healthcare, Network ASEAN Forum 2013) The medical tourism revenues are expected to reach USD 1,692M in Singapore and USD 1,309 M in Malaysia by 2016 (Source: Frost and Sullivan, 2012)

Main industrial states Penang and Selangor are hosts to primary medical device clusters in Malaysia, while states located in the West Coast of the Malaysia Peninsular namely Johor, Malacca, Negeri Sembilan, Perak, Kedah, Perlis and the East Coast state of Kelantan have been identified with the presence of medical device companies.

Figure 4: Medical Device Clusters in Malaysia



Source: Site Selection (September 2013)

The AMMI comprises 45 member companies which collectively account for more than 50% of the country's total export revenue for medical devices. The industry recorded sales of RM6.5bil last year, based on the AMMI's survey on 67% of its members. According to the survey, Malaysia's medical device exports in 2012 totalled RM12.9bil, with RM5.9bil coming from AMMI members. The association expects exports to increase to RM13.7bil this year. Medical gloves and catheters made up RM9.8bil of the total value last year while instruments for medical, surgical and dental practices, electro-mechanical devices, contraceptives, ophthalmic lenses, radiation devices and orthopaedic implants made up RM3.1billion (Source: MIDA). AMMI forecasted that export of medical devices from Malaysia to grow 6% to RM13.7 billion in 2013.

3) Industrial Players in Penang

The medical devices manufacturing in Penang is focused in surgical and medical instruments, and electro medical and electrotherapeutic instruments. Table 5 depicts the Industrial Players in Penang. There is increasing importance in linkages that exist between medical device manufacturers and the manufacturers of electronics, producers of precision metal components, and plastics manufacturers.

Table 5: Industrial Players in Penang

	Company	Main Products/ Services
1	Aesculap, B. Braun, Karl Mueller Scientific, Lifecare Medical Devices	Surgical instruments
2	St. Jude Medical	Cardiac rhythm management
3	Ambu	Diagnostic instruments, cardiac electrodes
4	Alliance Contract Manufacturing	Health imaging equipment
5	Vigilenz	Sutures, cannulas
6	CCB, Epsilon	Cannulaes
7	ABio, Coraza Systems, Fizco, Kens Fine Med Tech, Orthomedic, Straits Orthopaedics, Symmetry Medical	Orthopedic
8	AT Systemisation, Frencken Group (FG) / Precicol	Medical equipment parts
9	Accellent	Special alloy components
10	GBC Scientific Equipment	Analytical instruments
11	Bezcon, Kobay, Leadman, NSEC, Prodelcon, RC, Tornos	Precision Tooling & Molding
12	Komax Systems, Lemtronics	Clinical pump
13	Pentamaster	Test & measurement
14	Plexus	Class III finished devices, CT, MRI, Therapeutic in Cardiology, Orthopedic, etc.
15	Polar Twin Advance (PTA)	Heart rate monitors
16	Texchem WazOne	Packaging
17	Flextronics, GMMI Texchem, Paramit, Sanmina-SCI, Venture	EMS for Medical Electronics
18	Enersol	Condom & Gloves testing
19	UWC Healthcare	Transfer medical bed
20	MechaMedic	Perianal support
21	Uchi	Control module
22	Escatec Medical, Alverix	Monitoring equipment
23	Knowles	Hearing aids
24	Agilent, NationGate	Instrumentation
25	Jabil	Electronics solutions
26	Allen Healthcare Products (AHP)	Rapid diagnostic products
27	Cardinal	Gloves
28	Haemonetics	Blood collection and separation technologies

**This list may not include all the industrial players in Penang.*

4) Regulatory

Malaysia concerns the quality of medical device products and has therefore has regulated the industry through Medical Device Act (MDA) 2012 as an integral part of the standards of medical device products. Since export of generics to the high growth emerging markets is to be a key strategy for growth, hence upgradation of SMEs to GMP standards would enable them to export their products. The regulations are aligned with the guidelines drawn up by the ASEAN Harmonisation Working Party (AHWP) and the Global Harmonisation Work Force (GHTF).

The scope of medical device regulatory system covers the life-cycle of a medical device calculated from its design and development to manufacture and its subsequent disposal. It can be divided into three common stages, namely pre-market, placement on-market and post-market. In addition to the device itself, the regulatory control also cover the representation of the device, the manufacturer or local authorized representative (of foreign manufacturer of imported device) and the users. The purpose is to protect the public health and safety to ensure that medical devices in Malaysia are of high quality, effective and safe. According to Association of Malaysian Medical Industries (AMMI), the standards under the Medical Device Regulations would help Malaysia be recognised as a reliable producer of medical devices in the global market.

5) Education Providers

In Penang, the education and training in the medical device sector are provided by public and private organisations such as University of Science Malaysia (USM), Penang Skills Development Corporation (PSDC) and Medsociety. Among the highly praised and received medical device sector training is the PSDC's MedTech Graduate Training Program which was designed based on input from the industry players.

6) Issues and Challenges

The main issues challenging the sector include increasing global price competition, inconsistent regulatory systems between countries, international reimbursement payment environments (reducing reimbursement rates, mandatory price reductions and establishing price ceiling), intellectual property right issues, insufficiency of R&D spending, and lack of sufficient university graduates with specific skills (EPU/The World Bank, 2011).

Therefore, Penang's continuous success in future will depend on her ability to create a business environment where high-growth economy zone and strategic location, high quality infrastructure and business services, high level skills and expertise, high-technology research and knowledge, competitive cost structure and value, are blended.

Useful Contacts

- Association of Malaysian Medical Industries (AMMI): <http://www.ammi.com.my/>
- Association of Private Hospitals of Malaysia (APHM): <http://www.hospitals-malaysia.org/>
- Malaysia Medical Device Association (MMDA): <http://www.mmda.org.my/>
- Ministry of Health (MOH): <http://www.moh.gov.my/>
- Medical Device Authority (MDA): <http://www.mdb.gov.my/>
- Penang Skills Development Centre (PSDC): <http://www.psdcc.org.my/>

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