



ITALIAN TRADE AGENCY

ICE - Agenzia per la promozione all'estero e
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Market Overview of Iran's Medical Devices Sector

November 26, 2015

in cooperation with Plan Be

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Demographics and Healthcare Infrastructure of Iran

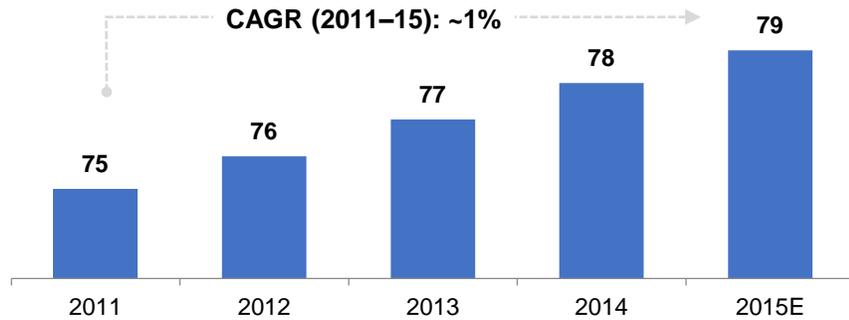
Demographics & Healthcare Spending

Healthcare Infrastructure & Medical Tourism

Increasing population in higher age groups and steadily rising healthcare spending per capita to drive Iran's medical devices sector

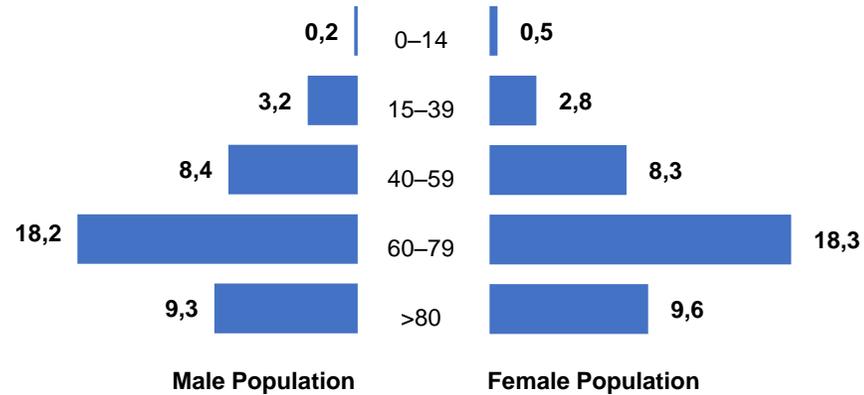
Iran's Population

2011–15E | Figures in Million



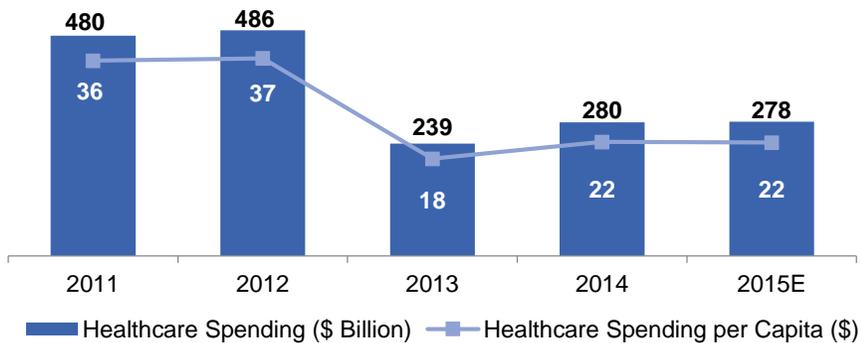
Iran's Population Pyramid

2015E | Figures in Million



Iran's Healthcare Spending

2011–15E

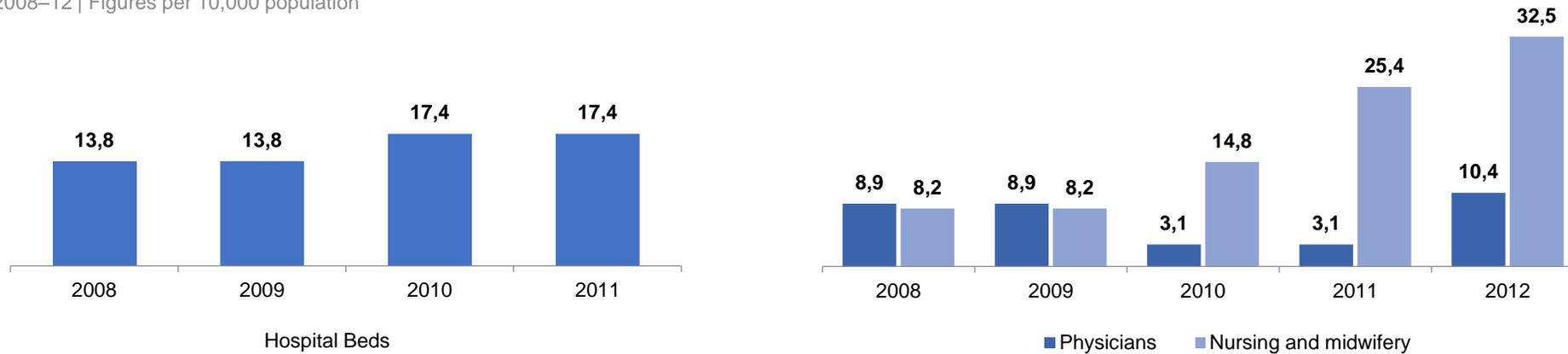


- Over 67% of Iran's population falls within the age group of 40–80 years; this category faces high health risks
- To address this issue, Iran's government contributes about 40% to total healthcare expenditure
- Growing population in the high-health-risk age group and steadily rising healthcare spending per capita are major factors driving growth in Iran's medical devices sector

Healthcare infrastructure development and Iran's positioning as medical tourism destination to boost medical devices sector

Healthcare Infrastructure in Iran

2008–12 | Figures per 10,000 population



Medical Tourism Statistics of Iran

“ Annually 30,000 medical tourists visit Iran; moreover, the country hosts 200,000 health, wellness and spa tourists ”

“ Key target markets are Azerbaijan, Iraq, Turkmenistan, Afghanistan, Kuwait, Lebanon, Saudi Arabia and Turkey ”

“ Provinces of Tehran, Khorasan Razavi, Eastern Azerbaijan, Gilan, Ardabil and Fars are the major medical tourism destinations ”

“ Iran offers fertility treatment; stem cell treatment; dialysis; treatments for cancer related diseases; and heart, cosmetic and eye surgeries ”

02

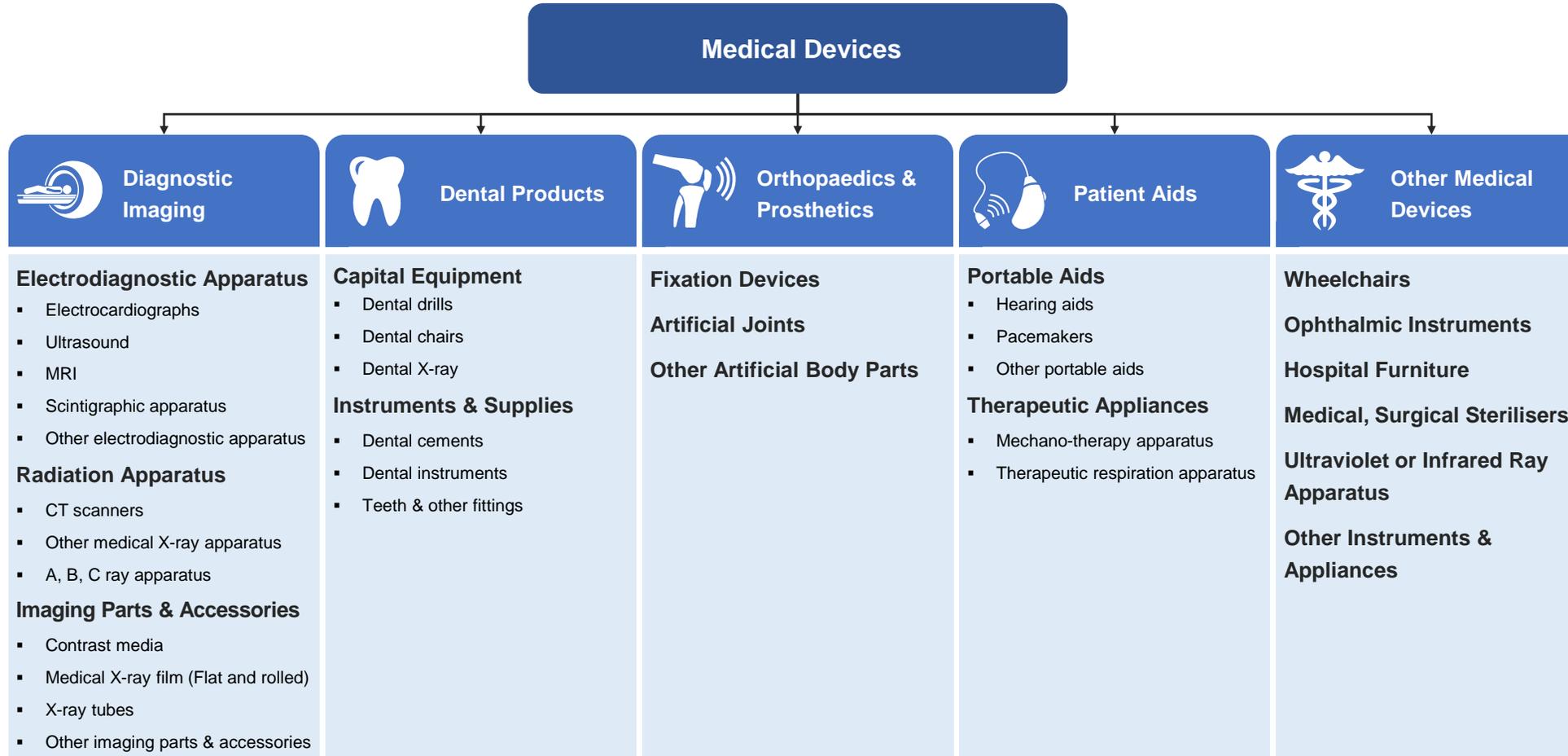
Overview and Value Chain of Iran's Medical Devices Sector

Overview of Iran's Medical Devices Sector

Value Chain Analysis

Iran's medical devices sector broadly categorised into five product segments

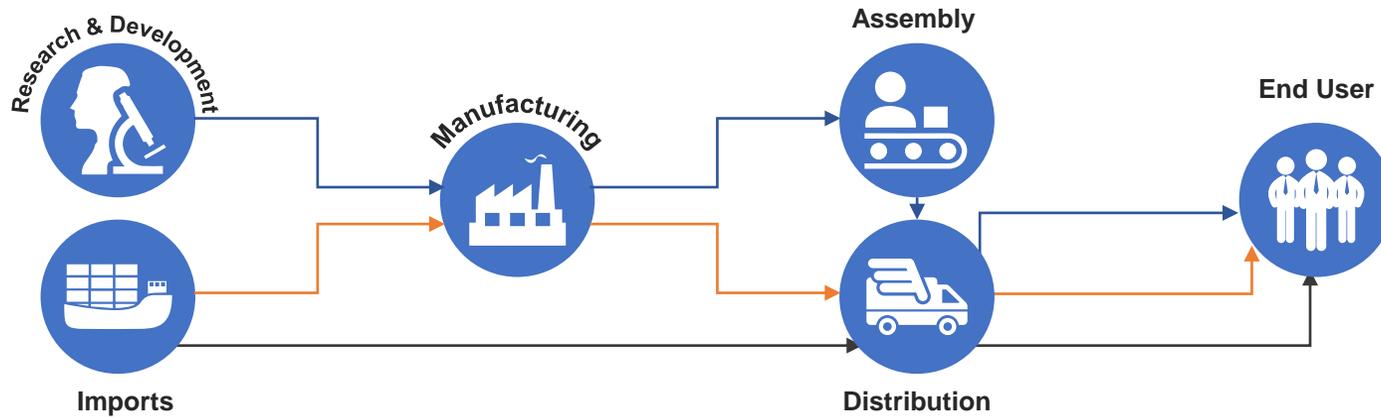
Overview of Iran's Medical Devices Sector



Source: BMI

Major importer of medical devices with an extensive distribution network; manufacturing capabilities for medical devices relatively low

Value Chain of Iran's Medical Devices Sector



Research & Development	Imports	Manufacturing	Assembly	Distribution	End User
<ul style="list-style-type: none"> Very few companies with R&D capabilities Reliance on research institutes such as Iranian National Centre of Laser Science and Technology for R&D 	<ul style="list-style-type: none"> Import dependency for specialised medical devices Countries in the European Union (EU) are major import partners 	<ul style="list-style-type: none"> About 300 manufacturers Companies mostly into manufacturing of medical supplies (syringes, needles, infusion sets) Limited manufacturing of high-tech medical devices such as MRIs and CT scanners 	<ul style="list-style-type: none"> Assembly includes packaging and sterilisation of devices 	<ul style="list-style-type: none"> Distribution of medical devices largely done through agents or wholesale distributors Some local companies, including Tajhizat Pezeshki Pishrafteh, use direct-selling model 	<ul style="list-style-type: none"> Public and private hospitals Clinics Individual patients Doctors Nurses

Source: Plan-Be Research & Analysis

03

Overview of Iran's Medical Devices Sector

Market Size: Total & Segments

Market Segmentation by Sub-product

Trade Overview

Regulatory Overview

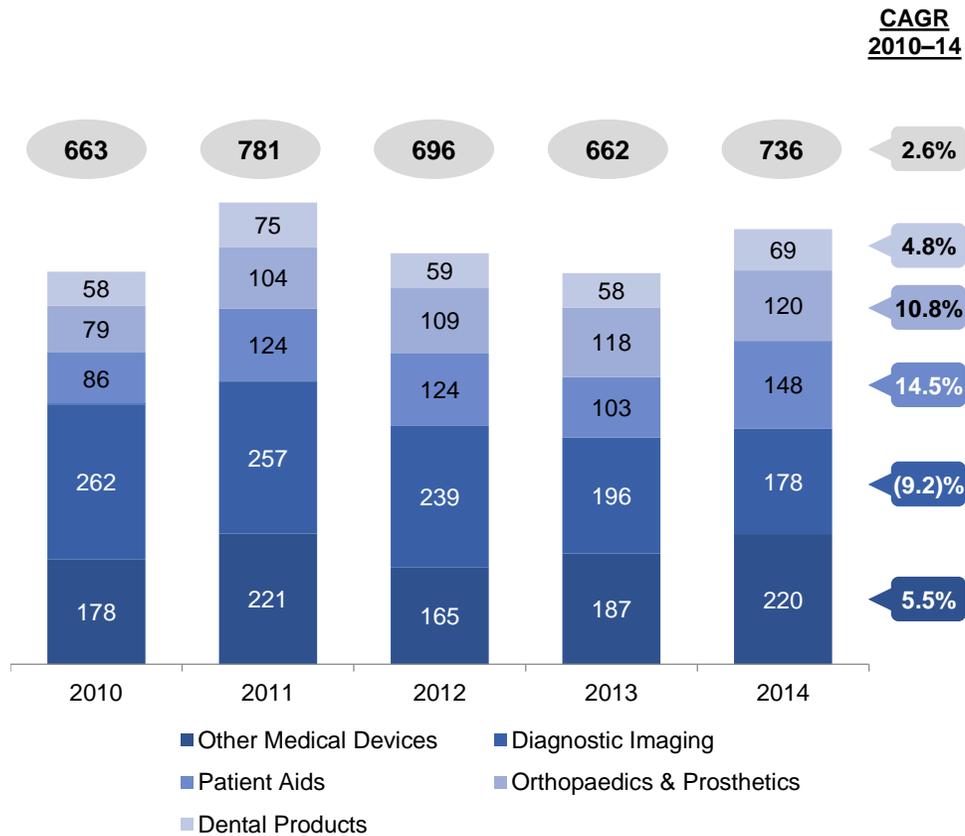
Trends & Developments

Key Drivers & Challenges

Iran's medical devices sector valued at \$736 million in 2014; other medical devices segment largest contributor

Size of Iran's Medical Devices Sector – Total and Segments

2010–14 | Figures in \$ Million



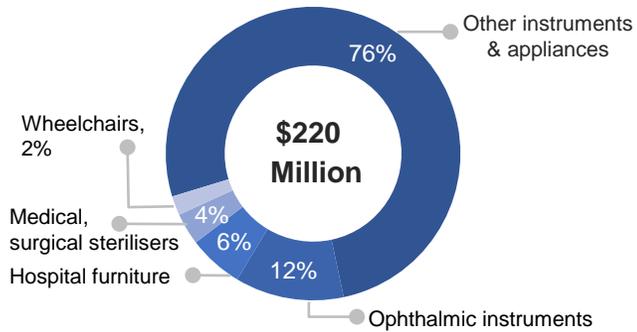
- Although international sanctions have had an impact on Iran, the medical devices sector expanded at a gradual CAGR of 3% over 2010–14
 - This growth can be largely attributed to various initiatives undertaken by the government to improve the country's healthcare infrastructure for locals as well as medical tourists
- Iran's medical devices sector is currently the fifth-largest in the Middle East and Africa (MEA) region, as the country has the highest number of hospitals in the region; the sector accounts for 3.3% of total health expenditure and 0.2% of Iran's GDP
- The other medical devices segment, which includes ophthalmic instruments and hospital furniture, is the largest contributor (with 30% market share) to the sector
- Patient aids is the fastest growing segment due to high prevalence of cardiovascular diseases in the country, resulting in increased demand for pacemakers
- The medical devices sector is expected to increase at a CAGR of 4% until 2019, as relaxing of sanctions is expected to open the sector to foreign investment
- The goals of Iran's government to increase the number of hospital beds, raise immunisation rates, improve senior care, prevent non-communicable diseases, restructure state-sponsored health insurance/welfare and attract foreign investors are anticipated to boost the medical devices sector's growth

High demand for electrodiagnostic apparatus, portable aids, dental instruments and artificial body parts in Iran

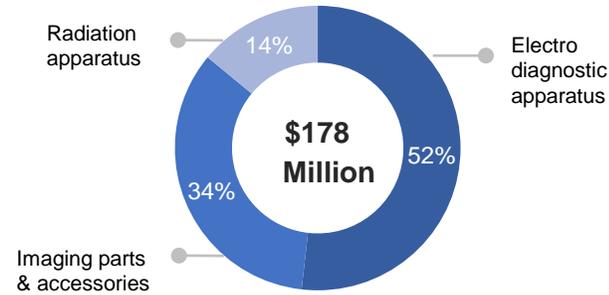
Break-up of Iran's Medical Devices Sector by Sub-products

2014 | Figures in \$ Million | X% | Share of segment in 2014

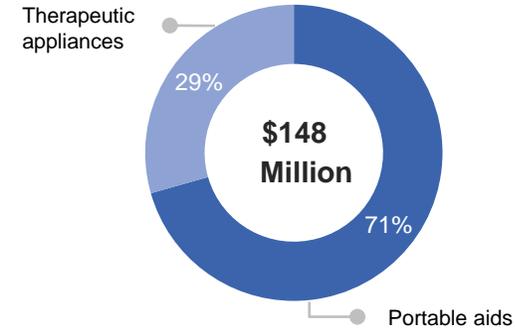
30% OTHER MEDICAL DEVICES



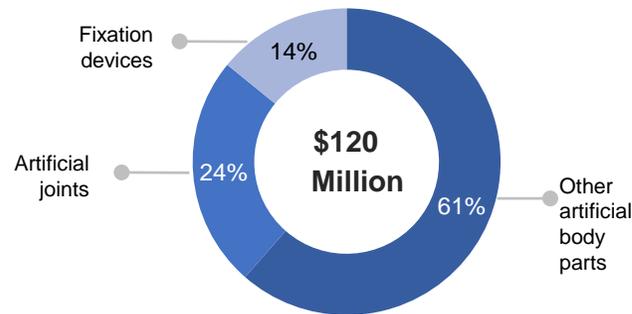
24% DIAGNOSTIC IMAGING



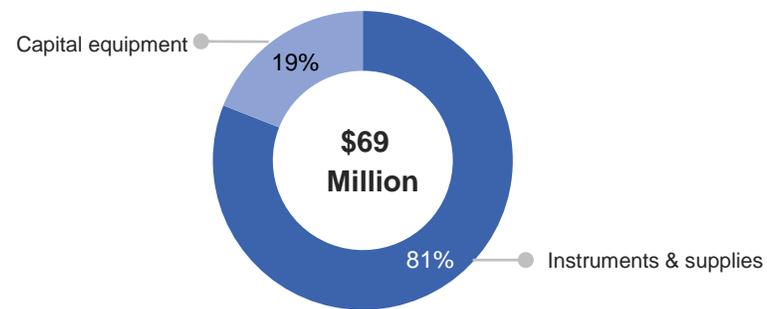
20% PATIENT AIDS



16% ORTHOPAEDICS & PROSTHETICS



9% DENTAL PRODUCTS

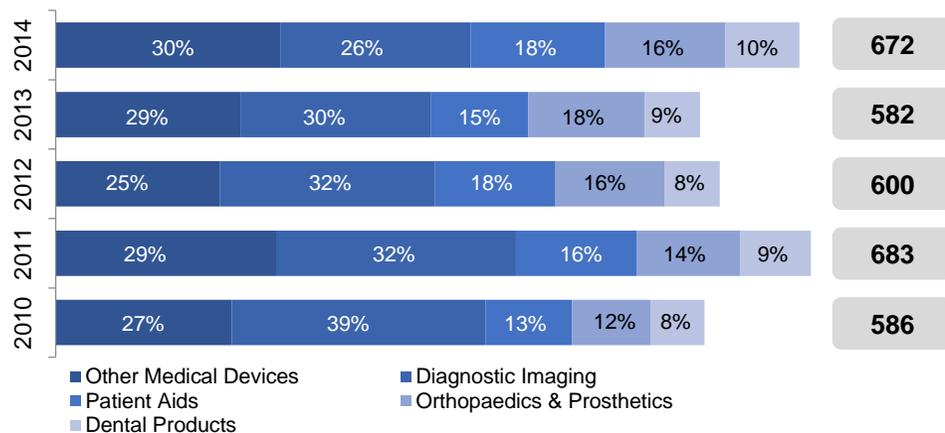


Source: BMI, News Articles

Imported medical devices cater to about 90% of total market; Netherlands, Germany and China account for nearly 50% of imports

Iran's Medical Device Imports

2010–14 | Figures in \$ Million



Top Five Import Partners

2014 | Figures in \$ Million

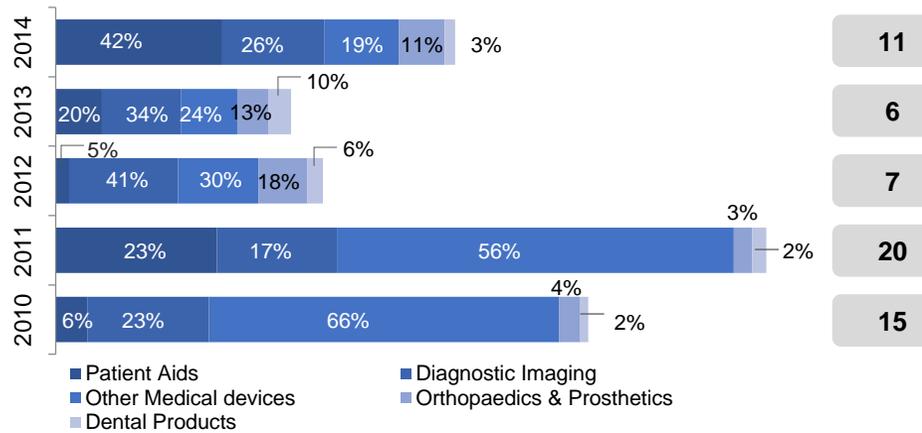
Partner Country	Import Value (\$ Million)	Share of Total Imports (%)
 Netherlands	179	22%
 Germany	122	15%
 China	90	11%
 South Korea	67	8%
 Belgium	60	7%

- Iran's medical devices sector is primarily import-driven, with imports accounting for nearly 90% of total sales in 2014. The country's import market for medical devices expanded at a CAGR of 3.5% during 2010–2014
- Although Iran specialises in the manufacture of syringes, needles and catheters, it largely depends on imports to meet its local demand for specialised machines
- The other medical devices segment, which includes wheelchairs, ophthalmic instruments, ultraviolet ray apparatus and hospital furniture, accounted for 30% of total imports in 2014; ophthalmic instruments constituted a significant share of the segment's imports
- The diagnostic imaging equipment segment, which includes CT scan, MRI and radiology machines, was the second-largest segment in terms of imports, as Iran still lacks the technology for domestic manufacturing of these products
- In 2014, the EU accounted for around 64% of total imports to Iran; the Netherlands and China were the leading import partners
- With the gradual lifting of sanctions, the import market for medical devices is expected to grow, with a significant increase expected in imports from the US (sixth-largest supplier of medical devices); this would provide Iran with high-technology products at competitive prices

Exports account for just 1.5% of total sales due to large domestic market for medical devices

Iran's Medical Device Exports

2010–14 | Figures in \$ Million



Top Five Export Partners

2014 | Figures in \$ Million

Partner Country	Export Value (\$ Million)	Share of Total Exports (%)
 Australia	2.1	16%
 South Korea	1.9	14%
 Ireland	1.3	10%
 Poland	1.0	8%
 Germany	1.0	8%

- Iran is not a major export market for medical devices, but for medical supplies such as syringes, needles and catheters; the export market for medical devices declined at a CARC of 7% over 2010–14
- In 2014, patient aids was the largest export segment, accounting for over 40% of total exports, with portable aids constituting nearly 67% of the segment's exports
 - The share of patient aids in total exports has been rapidly increasing, as manufacturers in Iran are using a new technology to produce a compact hearing aid with additional benefits, including high sensitivity and low power consumption
- Iran's top five partners accounted for about 56% of total exports in 2014; Australia, South Korea and Ireland were the top export destinations

Ministry of Health and Medical Education regulates Iran's medical devices sector; it lays down guidelines for registration, classification and imports

Regulatory Overview of Iran's Medical Devices Sector

Medical Equipment Department (MED) under Ministry of Health and Medical Education (MOHME)

Primary regulatory body for medical devices in Iran

Institute of Standards & Industrial Research of Iran (ISIRI)

Develops and designates official standards for products

Up to five years

Registration period for a medical device product

Certification

All products should have a CE certification and US FDA clearance/approval

Registration Process

Documentation

- The documentation required for registration is similar to that required for the US FDA's approval or EU CE marking; it follows the format of the Global Harmonization Task Force's Summary Technical Documentation (GHTF STED)
- The documents include CE and FDA certificates, supported by relevant ISO standards, quality management systems (QMS), test reports, declaration of conformity (Annex XII), application form (Annex XIII), submission summary dossier, technical details of medical devices, letter of authorisation, labelling according to article 42 and Central Office for Medical Equipment (COME)'s specifications

Classification of Medical Devices

- Medical devices are classified into four classes: A, B, C and D. Class A has the lowest and D has the highest level of risk.

Registration Number and Marketing Authorisation

- After the approval of application, a registration number and marketing authorisation are issued, which has a validity of five years

Laws Governing Medical Devices Sector

- The regulatory requirements for medical devices are outlined in the Medical Cure and Medical Education Act
- Used or refurbished medical equipment is prohibited in Iran, unless a special permission is obtained from MED
- US firms are required to obtain a license issued by the Office of Foreign Assets Control

Iran focusing on research & innovation and garnering interest from multinational companies

Trends and Developments in Iran's Medical Devices Sector



KEY TRENDS

FOCUS ON RESEARCH & INNOVATION

- Due to the need for better medical system and products to address its healthcare issues, Iran is focusing on research efforts to manufacture innovative devices
 - Iranian National Centre of Laser Science and Technology has invented lasers that find application in soft tissue dentistry surgeries
 - Isfahan University of Technology has created hydroxyapatite/alumina nanocrystalline composite powders by the sol-gel process, which are used in biomedical processes such as bone implants

GROWING FOREIGN INTEREST

- Due to the gradual easing of sanctions and increasing government initiatives for the healthcare sector, many foreign companies are interested in Iran's medical devices sector. The sector has recently seen investments by many multinational companies
 - Novo Nordisk announced plans to build a \$78 million manufacturing plant in Iran to manufacture its FlexPen prefilled insulin devices

Government's initiatives to improve healthcare services, support PPPs and position Iran as medical tourism hub to benefit the sector

Key Drivers for Iran's Medical Devices Sector



Government Support for Hospitals and Public-Private Partnership (PPP)

- Iran's government is focusing on increasing the number of hospital beds, improving senior care, restructuring state-sponsored health insurance and attracting foreign investments
- Many countries have expressed interest in helping Iran improve its healthcare sector, which is evident from the fact that a consortium of Korean organisations, including a builder, a medical equipment supplier and a university hospital, would be launching a large-scale general hospital construction project in Iran in 2016



Healthcare Initiatives and Packages for Citizens

- The government plans to establish more chemotherapy centres in Iran as part of its plan to address the rise of non-communicable diseases (NCDs) such as cancer
- The government launched health packages to promote personal care strategies; screen for early diagnosis and treatment; increase awareness on the risk factors of NCDs; improve child/maternal health, dental healthcare, and environmental and occupational health



Favourable Medical Tourism Destination

- Iran is an emerging medical tourism destination due to better geographic location and medical services than neighbouring Middle Eastern countries
- Iran aims to offer world-class medical facilities through PPPs; the country is a well-known destination for medical treatment among the neighbouring Persian countries

Existing sanctions, complex regulatory processes and corruption main areas of concern for the sector

Key Challenges for Iran's Medical Devices Sector



Political Climate

- The complex layers of sanctions imposed on Iran would take some time before they are completely removed. However, some sanctions linked to Iran, including human rights, would remain in place for a longer period of time
- Initially, companies may face difficulties to start a business and enter into partnerships in Iran. In addition, there is significant government involvement and widespread corruption, resulting in a challenging business environment



Exchange Rate and Oil Price Fluctuations

- Iran's economy is vulnerable to fluctuating exchange rates and oil prices. The current low prices of oil could impact government spending on healthcare
- Companies could not be willing to make large investments in Iran either as greenfield investments or partnerships until they are convinced of long-term durability of any agreement



Complex Import Policies

- The money transfer procedures to import medical devices are extremely lengthy and negatively impact access to health technologies
- An increasingly complex import process has resulted in high procurement costs, thus affecting affordability of medical devices

04

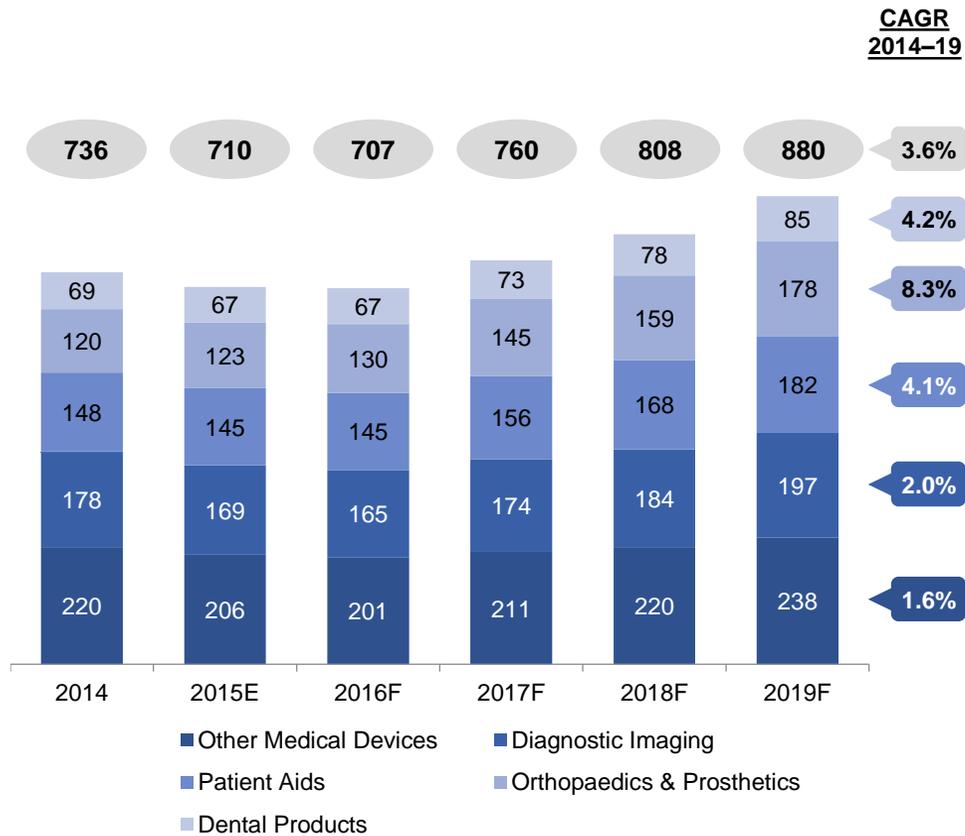
Forecast for Iran's Medical Devices Sector

Market Size: Total & Segments

Iran's medical devices sector to grow to \$880 million by 2019; orthopaedics & prosthetics to be fastest growing segment

Forecast for Iran's Medical Devices Sector – Total and Segments

2010–14 | Figures in \$ Million



Overall Market

- The medical devices market in Iran is expected to improve in the near term with the relaxing of sanctions
- With over 75 million people and significant government investment to improve healthcare, the consumption of medical devices is likely to increase
- Public-sector hospitals are being modernised and new facilities are being constructed, which would further boost the sector

Product Segments

● Orthopaedics & Prosthetics

- The orthopaedics & prosthetics segment is set to grow, driven by increasing government healthcare spending and investment in the sector, along with rising demand for new and more effective orthopaedic treatments and prosthetic limbs

● Patient Aids

- The government's commitment towards self-sufficiency and plans to increase investment for additional production would make patient aid kits more affordable to the general public of Iran and boost the sector

● Dental Products

- The dental products segment is anticipated to expand in the coming years, supported by overall economic growth and better income levels

05

Competitive Landscape

Manufacturing and Distribution Landscape

Key Players

The medical devices sector is fragmented, with around 300 manufacturers operating in Iran

Manufacturing Landscape of Iran's Medical Devices Sector

<p>~300 Medical device manufacturers</p>	<p>60% Medical device manufacturers with ISO 13485 certification</p>
<p>~600 Production units in Iran</p>	<p>~520 Different products manufactured</p>

Manufacturing Landscape

- The government places strong emphasis on self-sufficiency, which has resulted in increased manufacturing activity in Iran in recent years
- Companies are allowed to operate from the Kish Island Free Trade Zone, where 100% foreign ownership is permitted

Distribution Landscape of Iran's Medical Devices Sector

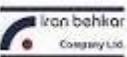


Distribution Landscape

- The most convenient method of doing business considered by foreign companies is to appoint a distributor that undertakes negotiations
- US-based companies find it difficult to operate due to tense relations between the two countries; thus, they distribute their products via agents or via neighbouring countries such as the UAE

Farafan Engineering and SOHA key domestic manufacturers; foreign players largely supply products through local distributors

Competitive Landscape of Iran's Medical Devices Sector (Key Players)

Manufacturers		Distributors		
Logo	Company	Logo	Company	Foreign Suppliers
	Farafan Engineering		Ameco Medical Equipment	NIDEK, Biolase, Rayner, NETWORK, Rhein, Labtician, Scan Optics, ION vision, Optilasa, Fiso, MicroVision, Medicelage, Stereo Optical, EyeSys, John Weiss, Norwood, Dexta, Ziemer Ophthalmology
	Helal Iran Medical Devices (SOHA)		Andishmand Pardaz	Gifa, Ferno, Geomed, Treu Instrument, Samtronic, Schaerer Medical, S-CAPE
	Sifra		Pakhsh Razi	Ferring, CSL-Behring, Cenexi
	Exirsazan Hayat		Amoon Teb	Teknomed, IOSPL, VikingSpine
	Tajhizat Pezeshki Pishrafteh		Iran Behkar	China MEHECO Corporation, ELCON
	Navid Partonama		Exirsazan Hayat	KaWe, Sequel Medical
	Pantamed		Teb Tasvir	Hanau Med, Maquet, Medap, Merivaara, Micro Medical Devices, Wagner Medical, Laserscope, Dufner, ResMed, eVent, Laserex Technologies, EKU Elektronik, Unfors Instruments
	Iran Behkar			

Source: BMI, Company Websites, News Articles

06

Attractive Opportunities

Orthopaedics & Prosthetics

Dental Devices

Patient Aids

Increasing inflow of medical tourists in Iran due to low surgery costs and quality treatment to benefit the orthopaedics & prosthetics segment

Attractive Opportunities: Orthopaedics & Prosthetics

Key Facts

\$120 Million

Value of orthopaedics & prosthetics market in 2014

8.3%

Projected growth over 2014–19

Artificial Limbs

Fastest growing sub-segment

~850

Orthopaedists in Iran

Orthopaedics & Prosthetics

Key Drivers/Developments

- Iran is one of the top 10 countries globally in orthopaedics
- Due to cheaper and high-quality orthopaedic surgeries, patients from countries such as Azerbaijan, Iraq, Afghanistan and Qatar visit Iran for treatment
- Among the orthopaedic services, knee surgeries and replacements have significant demand
- Recent innovations in prosthetics include the development of a prosthetic hand, which is controlled by brain waves and commands, and an artificial vision system for a prosthetic ankle, which helps identify the ground profile

Competitive Landscape



- The segment has very few local manufacturers, but many foreign players, including Viking, TREU Instruments and Norwood Medical, operate in Iran

Rising number of dentists and private clinics to drive the dental products segment

Attractive Opportunities: Dental Products

Key Facts

\$69 Million

Value of dental products market in 2014

~80%

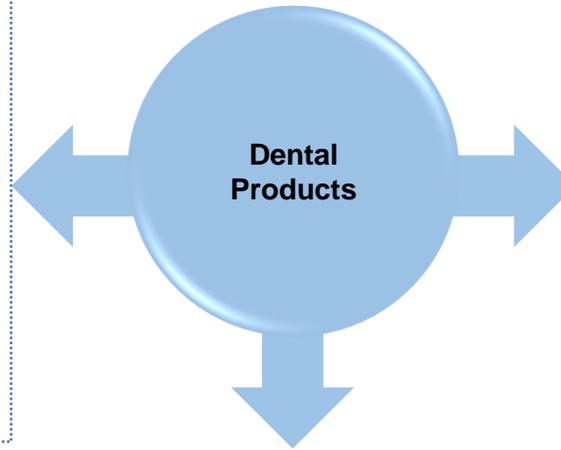
Share of dental instruments, teeth and other fittings

~26,000

General dentists and specialists in Iran

4.2%

Projected growth over 2014–19



Key Drivers/Developments

- The number of dentists per 10,000 people increased to 3.5 in 2013 from 1.9 in 2010
- Just 20% of dentists work in the public sector, while 80% have private practices
- On average, about 1,500 students are admitted to dental schools in Iran each year
- All these factors would result in an increase in the number of new clinics requiring more dental equipment and instruments, driving the dental products segment

Competitive Landscape



3M

SIEMENS

- About 200 companies operate in the dental products segment
- Both local and foreign players have presence in Iran, with MNCs such as Siemens licensing products to Iranian manufacturers

High prevalence of cardiovascular diseases and hearing disorders to aid growth in patient aids segment

Attractive Opportunities: Patient Aids

Key Facts

4.1%

Projected growth over 2014–19

Iranian Cochlear Implant Center

Tehran-based cochlear implant centre

Ranked 1st

For treatment of cardiovascular diseases in the Middle East

0 Death

Out of 25,000 angioplasty and heart pacemaker surgeries in the last 10 years

Patient Aids

Key Drivers/Developments

- A large section of Iran's population suffers from coronary artery disease (CAD); it was the cause for about 30% of total deaths in 2014
- About 7% of Iran's population suffers from hearing disorders, with hearing impairment being the most common disorder affecting 1 infant per 1000 born; this supports growth in the hearing aids market
- Iran provides the highest quality treatment for cardiac complications and best medical services surpassing global standards, driving its medical tourism industry

Competitive Landscape



- Many foreign players supply products (hearing aids and heart pacemakers) to Iran



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