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FROM CONCEPT TO CLINICAL PRACTICE: A SYSTEMATIC REVIEW OF MEDICAL DEVICE DEFINITIONS

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Abstract: Medical devices play a pivotal role in modern healthcare, encompassing a wide range of instruments, apparatuses, implants, and software utilized in the diagnosis, treatment, monitoring, and prevention of diseases and medical conditions. This paper provides a comprehensive exploration of the definition of medical devices, considering various regulatory frameworks, classifications, and technological advancements shaping the field. By elucidating the multifaceted nature of medical devices, this paper aims to enhance understanding and foster discussion on the evolving landscape of healthcare technology.

Key words: medical devices, global medical device, instrument, apparatus, medical equipment, contrivance, implant.

Evolution of medical devices from ancient times to modern era.

The evolution of medical devices from ancient times to the modern era is a fascinating journey that reflects humanity's relentless pursuit of understanding and improving healthcare. Across civilizations and centuries, medical devices have evolved from rudimentary tools to sophisticated instruments, driven by advancements in science, technology, and medical knowledge. Here's an overview of the evolution of medical devices through key historical periods:

Ancient civilizations such as Mesopotamia, Egypt, Greece, and China developed some of the earliest medical devices. These included simple tools like scalpels, forceps, and probes used for surgical procedures, wound care, and basic diagnostic purposes. The Ancient Egyptians, for instance, crafted intricate surgical instruments from bronze, copper, and other metals, demonstrating remarkable skill and craftsmanship. In China, acupuncture needles and herbal remedies were utilized for therapeutic purposes, reflecting early forms of medical device innovation.

During the classical period, notable figures like Hippocrates and Galen made significant contributions to medical knowledge and practice. Their writings documented various medical instruments and techniques used for diagnosis and treatment. The ancient Greeks and Romans developed more specialized surgical tools, including bone drills, specula, and cautery devices, to perform procedures such as trepanation and amputation.

Medical device innovation during the Middle Ages was influenced by Islamic scholars who preserved and expanded upon ancient medical knowledge. Islamic physicians introduced new surgical techniques and instruments, including the use of anesthesia and the development of advanced surgical tools like retractors and hemostats. The Renaissance period saw a revival of interest in anatomy and medicine, leading to the refinement of existing medical devices and the invention of new ones. Leonardo da Vinci's anatomical drawings, for example, contributed to a better understanding of human anatomy and the design of medical instruments.

The Industrial Revolution marked a transformative period for medical device manufacturing, with the advent of mechanized production techniques and the use of new materials such as steel and plastics. In the 19th and 20th centuries, innovations in medical devices accelerated rapidly, driven by

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advancements in science, engineering, and medical research. The invention of the stethoscope, X-ray machine, syringe, and anesthesia apparatus revolutionized diagnosis, imaging, and patient care.

The latter half of the 20th century witnessed unprecedented progress in medical device technology, including the development of implantable devices such as pacemakers, artificial joints, and prosthetic limbs. Breakthroughs in electronics and miniaturization led to the creation of devices like defibrillators, insulin pumps, and hearing aids. In the modern era, medical device innovation continues to thrive, fueled by emerging technologies such as nanotechnology, robotics, and wearable sensors. Advances in digital health and telemedicine are reshaping the landscape of medical device usage and patient care, ushering in a new era of personalized medicine and remote monitoring.

Throughout history, the evolution of medical devices has been intertwined with the quest for better health outcomes, improved patient care, and enhanced quality of life. From ancient tools crafted by skilled artisans to cutting-edge technologies developed by interdisciplinary teams of scientists and engineers, medical devices have played a vital role in shaping the practice of medicine and shaping the future of healthcare.

The term medical devices cover a large number of instruments and appliances, from every day object such as sticking plasters, syringes, gloves, pregnancy test, wheelchairs, hearing aids, tongue depressor, stethoscope, sphygmomanometer to highly sophisticated computerized medical equipment such as MRI, CT-scan, life supporting machines, implantable devices such as heart valve and pacemakers, replacement joints for knee and hips. There are more than 10,000 types medical devices.

Medical devices are grouped into two categories. These are medical devices other than In-vitro diagnostics (IVD) and In-vitro diagnostic medical devices. The Ethiopian Food, Medicine, and Healthcare Administration and Control Authority (FMHACA) and the United States Food and Drugs Administration (FDA) use the same expression for medical devices other than In-vitro Diagnostics definition.

FMHACA defined medical devices other than IVD as “an instrument, apparatus, implement, medical equipment, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part or accessory that is:

- Recognized in a pharmacopoeia or any supplement to it;
- Intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or preventive of disease, in man or other animals, or;
- Intended to affect the structure or any function of the body of human being or other animal and which does not achieve any of its principals intend purpose through chemical action within the body of human being or other animals and is not dependent upon being metabolized for the achievement of any of its principal intended purpose.”

In-vitro diagnostics medical devices are used to identify diseases, infections, or tissue form the body and give true or false result to the individual or public health. Some examples of in-vitro diagnostic medical devices are pregnancy self-testing, glucose self-testing, HIV blood diagnostics, urine testing strips etc.

Overview of global medical device market

In 2017, the global medical device market was worth about USD 311 billion and it is estimated to reach around USD 435.8 billion in 2021. It will grow with an approximately 6.75 percent rate per year for the coming five years as illustrated in figure 1.1.

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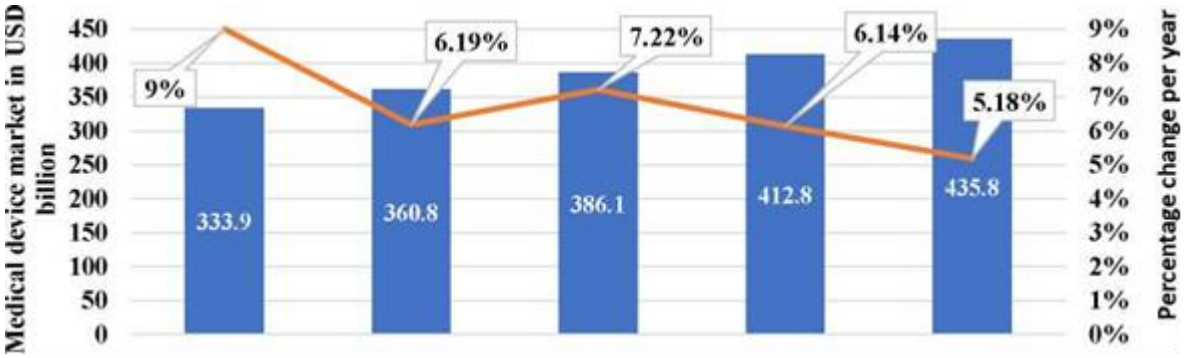


Figure 1.1 Global medical device market forecast from 2017 - 2021.

The United States (US) and European Union (EU) together accounted for 71 percent of the total with 42 percent and 29 percent respectively as shown in the table 1.1 [4,5].

№	Technical Fields	No. patent applications
1	Medical Technology	12,474
2	Digital Communication	10,762
3	Computer Communication	10,549
4	Electrical machinery, apparatus, energy	10,198
5	Transport	7,802
6	Measurement	7,727
7	Organic Fine Chemistry	6,414
8	Engine, pumps, and turbines	6,374
9	Biotechnology	6,048
10	Pharmaceuticals	5,884

Table 1.1 Medical device market share by countries in 2024.

The medical device technology is one of the most innovative and highly competitive market in the world. In 2019, there were more than 12,400 patent applications submitted to European Patent Office (EPO) in the field of medical devices that made up 7.8 percent of the total patent applications. From 12,400 patent applications, 40 percent of the applications were form European countries whereas 41% were from the US as shown in the table 1.1. In the same year (2019), there were approximately 30,800 medical device companies in the Europe and the US only.

In 2018, medical device for in-vitro diagnosis, cardiology, orthopedics and diagnostic imaging were the top four leading areas of medical technology accounted for 13%, 11.2%, 9.3% and 9.5% the total market shares respectively. In-vitro diagnosis, endoscopy, ophthalmic and cardiology will be the top four fastest growing area which sales will increase by 5.1%, 4.8%, 4.7% and 4.4% per annum respectively until 2020.

The global medical device demand will increase significantly due to a pronounced rise in the world aging population (aged 60 and over) and the number of aged populations are increasing faster

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than any age groups everywhere in the world. Globally, there were 901 million aged populations in 2015 and this is expected to increase by 56 percent and reach 1.4 billion by 2030. The aging population in Sub-Sahara Africa is also projected to increase by 64 percent between 2015 and 2030 with Rwanda the highest increase by 88 percent.

Japan, Germany, Italy and Finland were the top four most aged populated countries in the world which were represented by 33, 28, 28, and 27 percent of their total population respectively and China, India, the United States, Japan and Russia Federation accounted for 50 percent of the total aged 60 or above population in the world in 2015.

These growing aged population are exposed to several health-related problems and the most common generic problems related to aging are cardiovascular diseases, malignant neoplasms, respiratory diseases, sense organ diseases and neuropsychiatric and world health organization also identified the necessary medical equipment for such health problems.

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