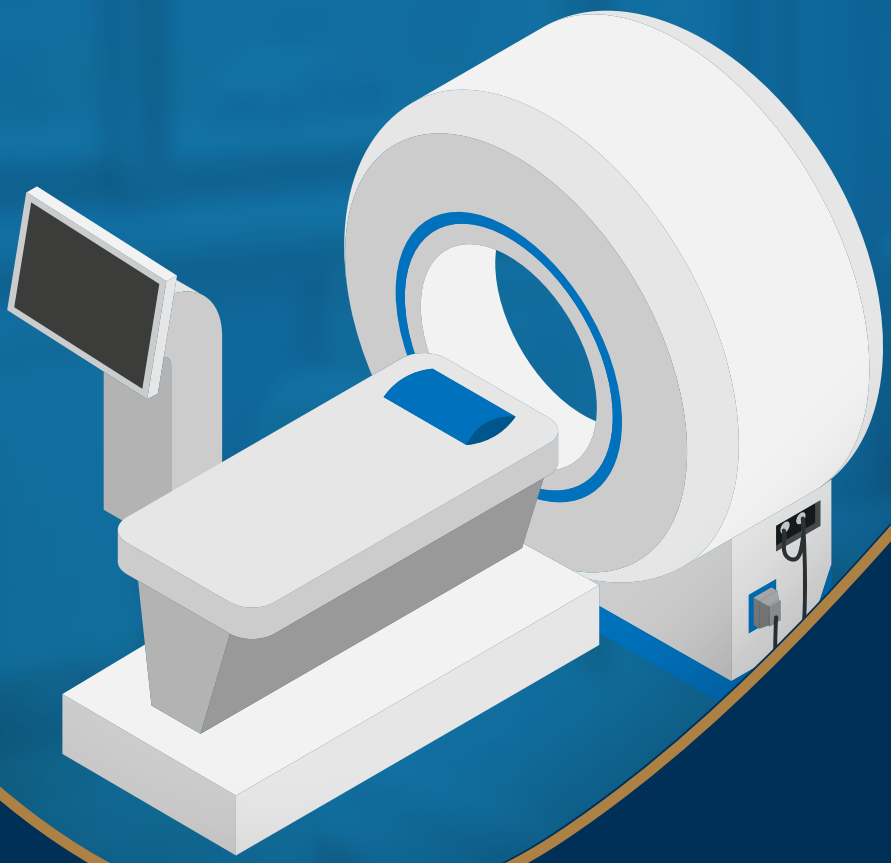
Georgia Tech Panama
Logistics Innovation & Research Center

Regional hub for
Medical Devices



# Navigating the Medical Device Ecosystem: An Overview of Essential Types

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# Navigating the Medical Device Ecosystem: **An Overview of Essential Types**

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# I. Overview

Medical devices are essential to modern healthcare, improving patient outcomes, enabling less invasive treatments, and facilitating continuous health monitoring. Medical devices are used in many diverse settings—by laypersons at home, by paramedical staff and clinicians in remote clinics, by opticians and dentists, by healthcare professionals in advanced medical facilities for prevention and screening and in palliative care.

Today, there are an estimated 2 million different kinds of medical devices on the world market, categorized into more than 7000 generic device groups.[1] This is an important market, with a 2023 worth of USD 600.21 Billion, and is forecasted to grow at a CAGR (Compound Annual Growth Rate) of 5.8% during the forecast period, reaching USD 996.93 Billion by 2032.

Medical devices cover a broad field, ranging from ordinary materials such as dressings, to medical imaging, implantable devices and revolutionary technologies, such as the *artificial heart.*[2] Devices are becoming more sophisticated, compact, and personalized.[3] The development of innovative medical devices will continue to transform patient care and expand medical possibilities.[4]

In the realm of healthcare, the effective distribution of medical devices is a cornerstone of patient safety and well-being. Logistics hubs are key components in the global supply chain for medical devices. These hubs serve as key production centers and distribution points.

The geographic distribution of the medical device supply chain is centered around several major logistics hubs. These hubs enable efficient production, global distribution with multimodal transportation, and cost reduction by bringing together multiple stakeholders across continents, including manufacturers, suppliers, distributors, and healthcare professionals and patients.

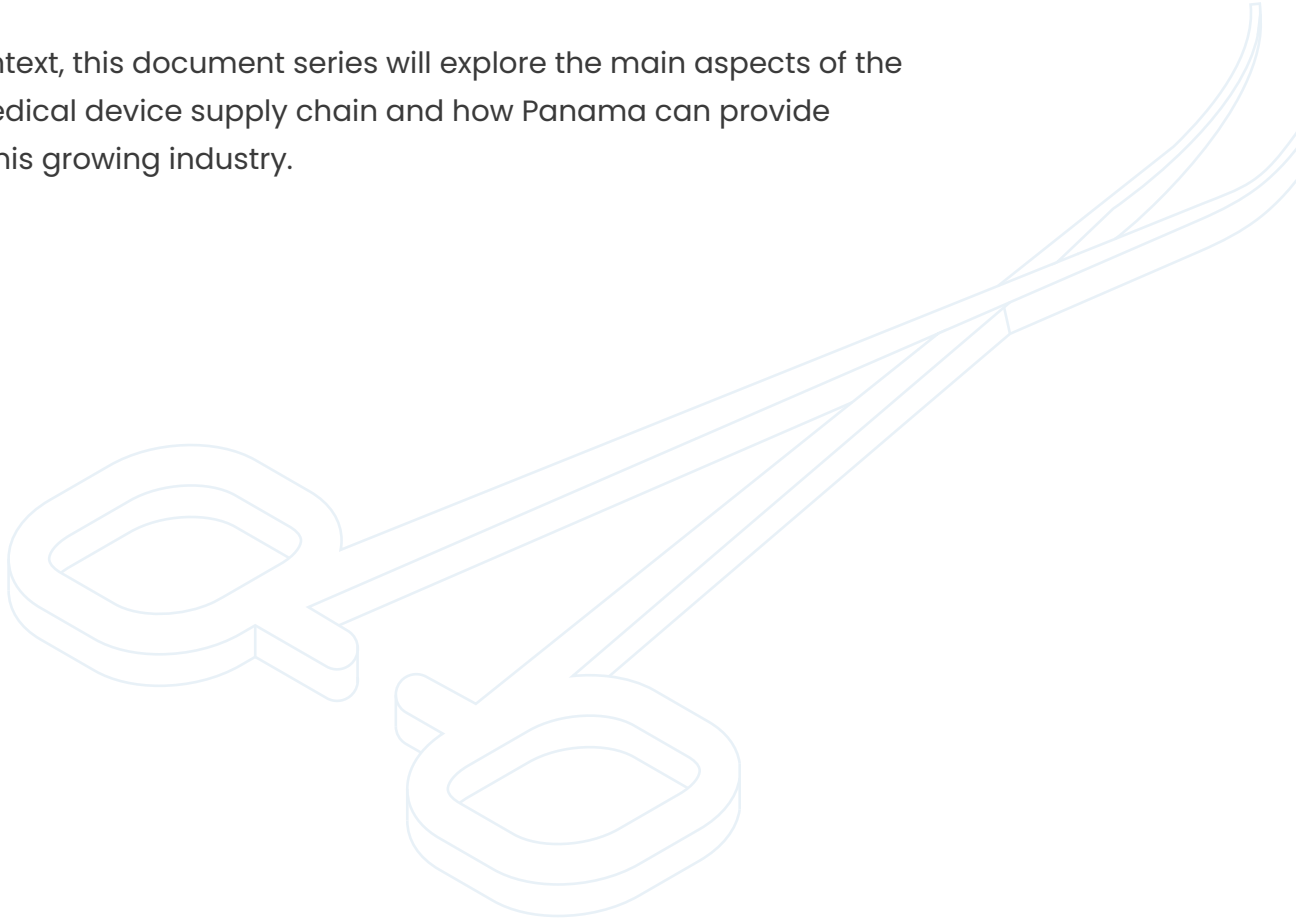
Advancements in global logistics and supply chain management have significantly improved the availability, quality, and pricing of medical

devices worldwide. However, supply chain disruptions caused by factors such as trade law changes, transportation difficulties, and geopolitical tensions can lead to shortages or delays in accessing essential medical devices.

To mitigate these risks and challenges, the medical device industry is exploring strategies such as localized production (friendshoring and nearshoring), supply chain diversity, and digitization to improve resilience. Logistics providers are also adapting by investing in cold chain capacities, high level service, direct-to-patient delivery models, supply chain optimization, inventory optimization, and digital technologies.

Logistics hubs are critical to the efficient and reliable supply of medical devices globally. By leveraging these hubs and implementing strategic solutions, the industry can ensure a resilient and sustainable supply chain that meets the evolving needs of patients and healthcare systems worldwide.

In this context, this document series will explore the main aspects of the global medical device supply chain and how Panama can provide value to this growing industry.



## Brief overview of the medical device supply chain

The medical device supply chain is a critical and intricate component of the healthcare industry. This chain encompasses all activities required to bring a medical device from concept to patient use, including design, research and development (R&D), manufacturing, testing, packaging, and distribution. Ensuring the smooth operation of this chain is paramount as any disruption or mismanagement can compromise product quality, directly impacting patient safety and treatment outcomes. Technological advancements and innovation have facilitated better tracking and management of products throughout this process, from raw materials to delivery.

Key components of the medical device supply chain include sourcing and procurement, manufacturing, distribution and logistics, and customer service. Sourcing and procurement involve more than just acquiring raw materials and components; it requires finding suppliers who maintain high-quality standards and can consistently fulfill demand.

Precision, innovation, and strict adherence to regulatory standards are imperative in the manufacturing of these devices to ensure functionality, reliability, and patient safety. Distribution and logistics play a pivotal role in ensuring the timely and intact delivery of devices, particularly for temperature-sensitive or sterile items, by maintaining product integrity through proper storage and shipping conditions.

**Regulatory compliance** and **quality assurance** are equally crucial, ensuring adherence to evolving standards and allowing for adaptability to maintain production and transportation efficiency.

Customer service is also very important, providing support through troubleshooting, training, managing returns, and addressing concerns to enhance the value of the products and foster trust and reliability among healthcare professionals. A robust supply chain strategy must anticipate and meet the current and future needs of customers, ensuring seamless and reliable delivery of life-saving medical devices.

# II. Understanding Medical Devices

## A. What are medical devices?

Medical devices include a wide range of health technologies such as instruments, apparatus, implements, appliances, software, machines, implants, in vitro reagents, or other similar articles (except for vaccines and medicines) required for prevention, diagnosis, treatment, monitoring, rehabilitation and palliation (WHO). They are indispensable for universal health coverage, monitoring wellbeing and addressing outbreaks or emergencies. Some medical purposes can include:[1][5][6][7]

- Diagnosis, prevention, monitoring, prediction, prognosis, treatment or alleviation of disease,
- Diagnosis, monitoring, treatment, alleviation of, or compensation for, an injury or disability,
- Investigation, replacement or modification of the anatomy or of a physiological or pathological process or state,
- Providing information by means of in vitro examination of specimens derived from the human body, including organ, blood and tissue donations,

Medical devices range from basic hand tools to complex computer-controlled machines. These include simple devices like wound dressings and scalpels; durable devices like wheelchairs and dentist chairs; devices for the control or support of conception; implantable devices like cardiac pacemakers and monitors, prosthetic limbs and prosthetic joints; life-supporting devices like respirators and lung ventilators; sophisticated, software-controlled devices like Computed Tomography scanners and Magnetic Resonance Imaging machines; and in vitro diagnostic reagents and test kits or blood glucose meters. Medical devices also include radioactive material and electronic items [8].

Initially, in vitro self-diagnostic devices were included within the broad category of medical devices. Over the years, regulatory bodies realized

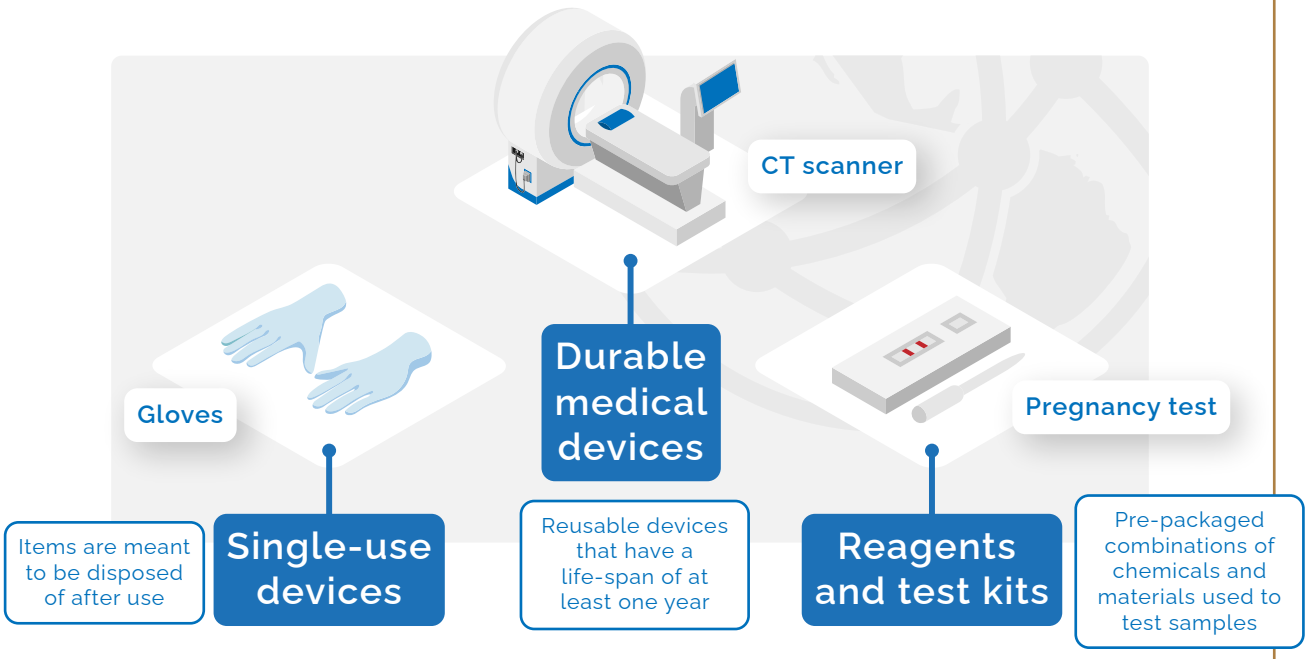
that the nature of these medical devices was different because, for diagnostic purposes, they do not come into direct contact with the human body, but indirectly through clinical samples such as blood, urine, joint fluid, among others. This fact determines that internationally they are assigned a definition and rules different from general medical devices.[9]

## B. Categories of Medical Devices

Medical devices are commonly categorized into risk classes according to the associated risks. Nonetheless, there are alternative approaches to enhance the precision of medical device classification.

A device can be categorized based on the following criteria:[10]

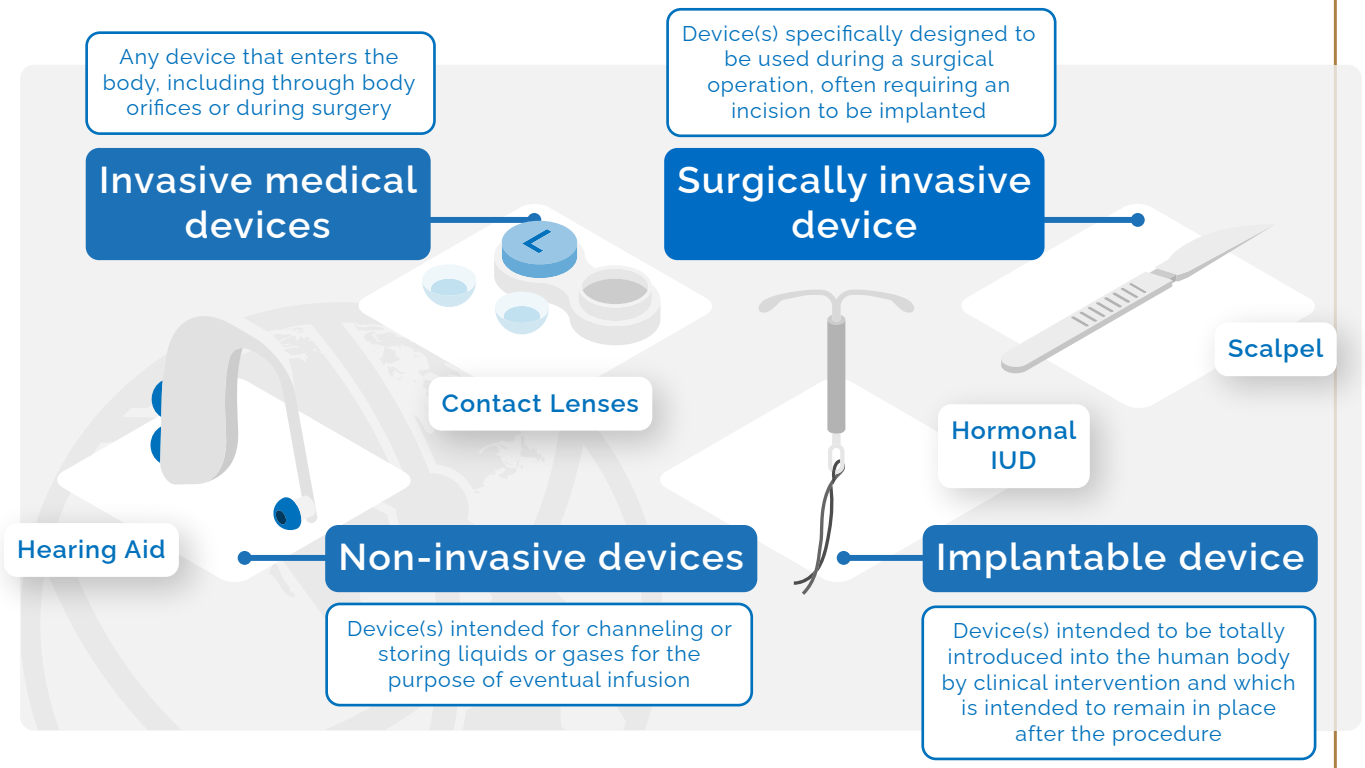
### Intended use [11]




- **Single-use devices** are used in general medical treatments and normally not high-tech. The items are meant to be disposed of after use. Examples include syringes, hypodermic needles, tubes, catheters, cannulas, disposable gloves and some items used in dentistry or ophthalmology.

- **Durable medical devices** normally have a lifespan of at least one year. Examples include first aid kits, wheelchairs, medical beds, technical equipment used in medicine, surgery and dentistry, electrical diagnostic tools, and x-ray machines.
- **Reagents and test kits** include equipment used to diagnose illnesses and conditions and chemical kits used to test samples drawn from patients. For example, to test for blood type before dialysis, pregnancy tests, and to detect HIV infection.

## Degree of invasiveness



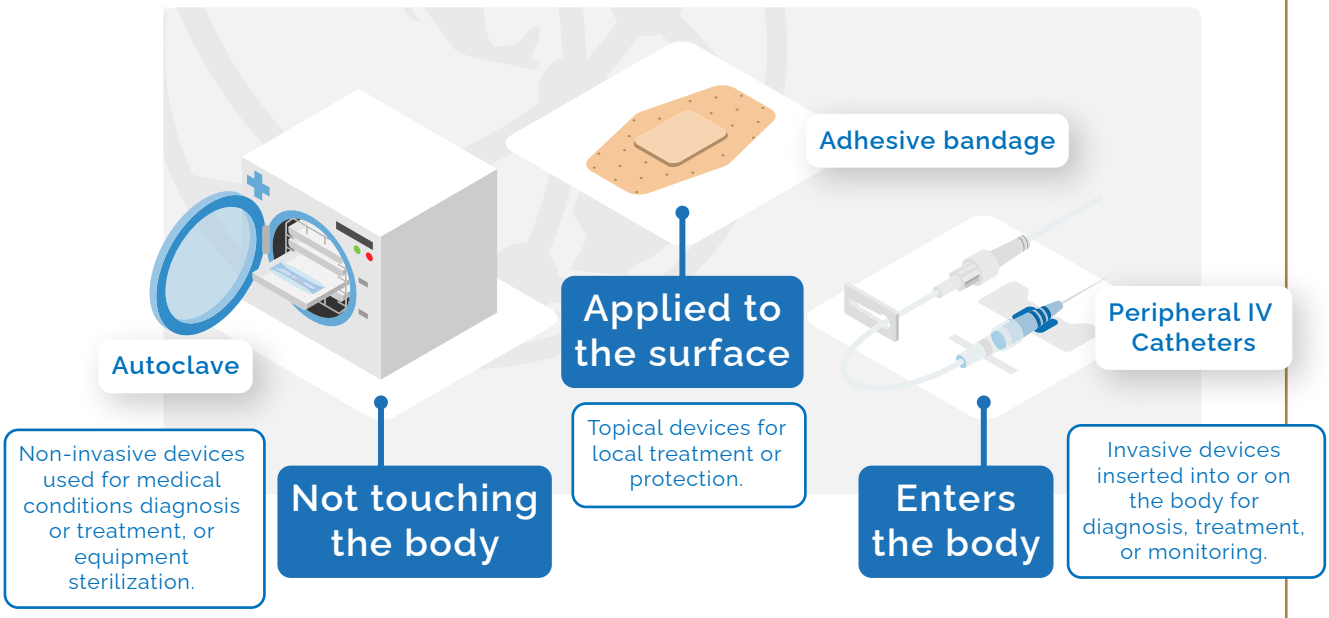

- **Non-invasive devices.** Do not touch the patient or contact only intact skin, and that are intended for channeling or storing liquids or gasses for the purpose of eventual infusion, administration or introduction into the body (e.g. hearing aids, external splints, bandages, wheelchairs, casts).[12] [13]

- **Invasive medical devices.** Any device which, in whole or in part, penetrates inside the body, either through a body orifice or through the surface of the body, including through mucous membranes of body orifices with the aid or in the context of a surgical operation. A device that administers energy to the body should not be considered as invasive if only the energy it emits penetrates the body and not the device itself. Some examples are contact lenses, examination gloves, enemas, needles, cardiovascular catheters.[10]

- **Implantable device.** Any device, including those that are partially or wholly absorbed, which is intended to be totally introduced into the human body by clinical intervention and which is intended to remain in place after the procedure.

- **Surgically invasive device.** Those that penetrate inside the body through the surface of the body, including through mucous membranes of body orifices with the aid or in the context of a surgical operation; and a device which produces penetration other than through a body orifice. In this last case, it implies that it enters through an artificially created opening (often large) such as a surgical incision, or it can be a pinprick opening made by a needle.

## Contact with the patient's body [14][15]




### Not touching the body.

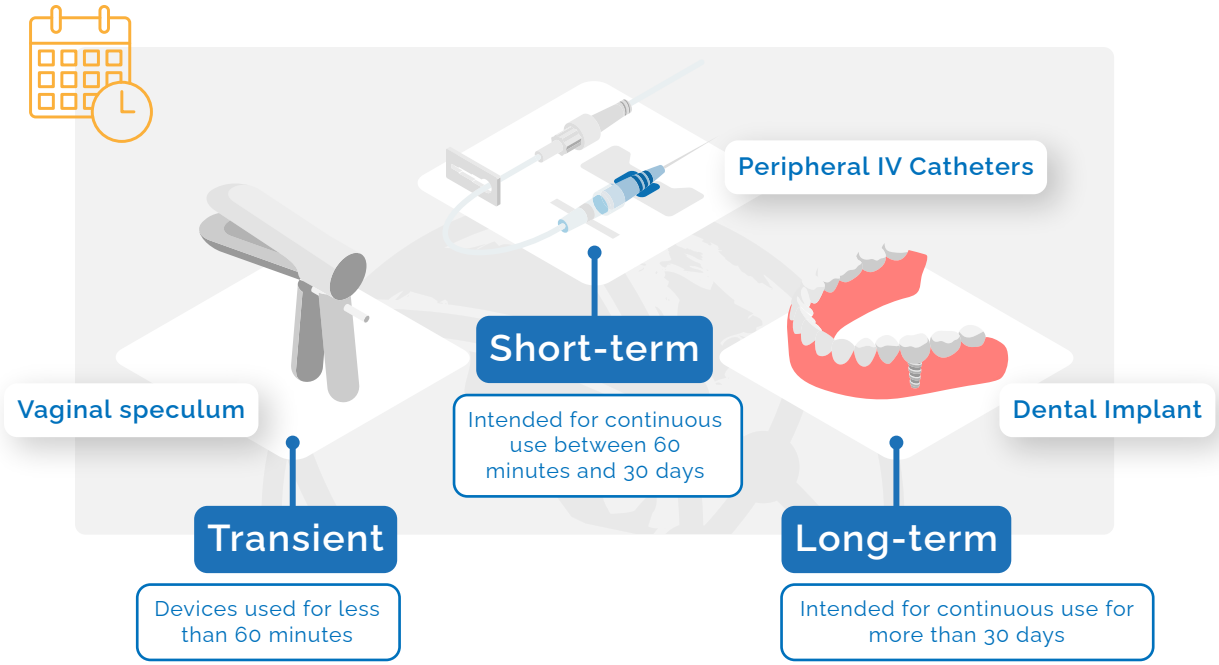
- Accessory (e.g., surgical gloves, sterilization containers, surgical instrument cases and trays).
- Associated with biological samples (e.g., specimen collection containers, microscope slides, petri dishes).
- Acting on the patient (e.g., infusion pumps, dialysis machines, ventilators, anesthesia machines.
- External patient support (e.g., hospital beds, wheelchairs, walkers and crutches).

### Applied to the surface.

- Not attached to another device (e.g., bandages and dressing, wound closure strip).
- Attached to another device (electrical, e.g., medical electrode).

- **Enters the body.**
  - Through an orifice (e.g., nasogastric tubes, urinary catheters, ear tubes).
  - Through the surface (e.g., intravenous catheters, chest tubes, epidural catheters).
  - Implanted (e.g., pacemakers and implantable cardioverter-defibrillator, artificial joints, breast implants, intrauterine devices-IUDs).

## Duration of use/of contact with the body [10][15]

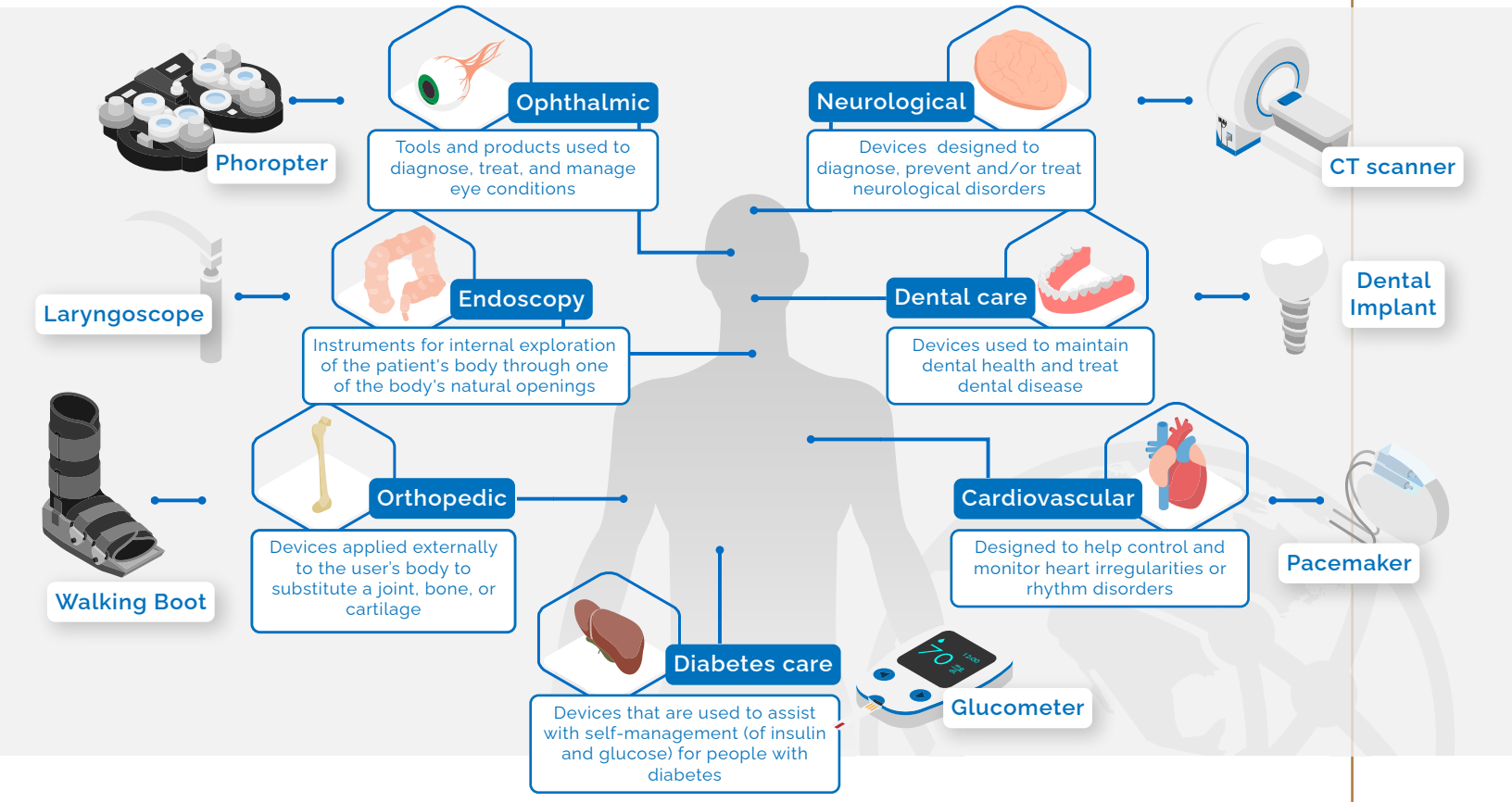



- **Transient.** Transient devices are intended for continuous use for less than 60 minutes (e.g., needles, scalpels, syringes).

- **Short-term.** Short-term use devices are intended for continuous use between 60 minutes and 30 days (e.g., catheters, hearing aids, short-term contact lenses).

- **Long-term.** Long-term use devices are intended for continuous use for more than 30 days (e.g., pacemakers, prosthetic heart valves, surgical mesh, breast implants).

## Part of the body affected by the use of the device




There are a lot of different types of devices according to the body part affected. Some of the most common are:

- **Cardiovascular.** Pacemakers, implantable cardioverter defibrillators (ICD), vascular stents and intra-aortic balloon pumps are designed to help control and monitor heart irregularities or rhythm disorders. Some are permanent implantable devices for long term control while others are portable temporary monitors.[16][17]

- **Orthopedic.** It encompasses all devices applied externally to the

user's body to substitute a joint, bone, or cartilage due to damage or deformity (orthosis) – such as from breaking a leg, losing a limb (prosthesis), or a congenital defect. Some medical devices used for orthopedic applications include screws, wares and pins, spinal implants, splints and bone lengthening and fracture fixation devices.[18][19][20]

- **Diabetes care.** Used to assist with self-management, ranging from lifestyle modifications to glucose monitoring and therapy adjustments for people with diabetes. Diabetes care devices are divided into two main categories: insulin administered by syringe, pen, or pump, and glucose as assessed by blood glucose monitoring (BGM) or continuous glucose monitoring (CGM).[21]

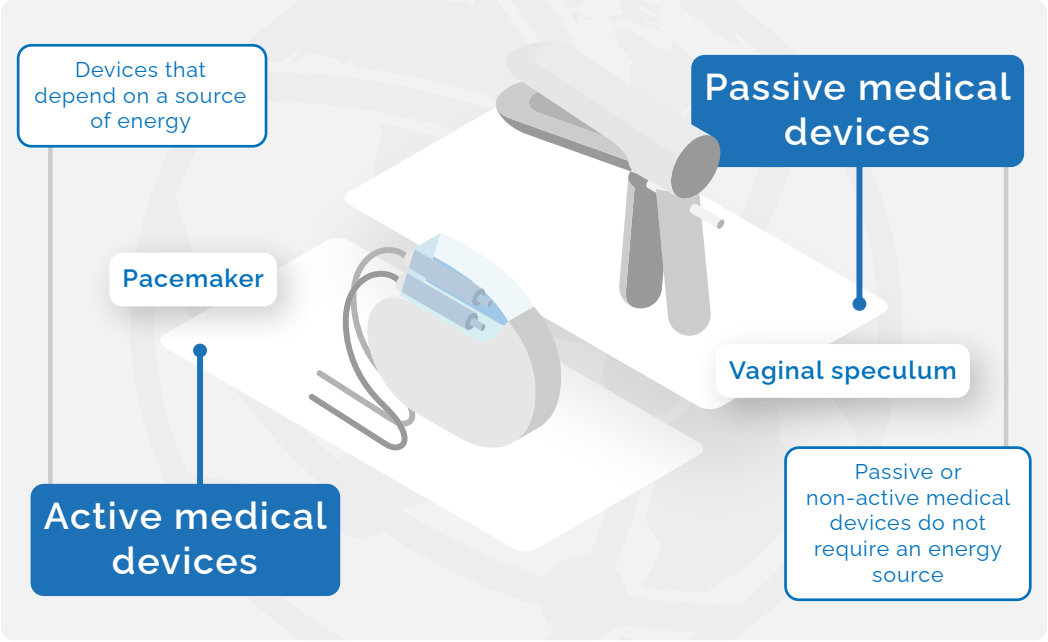
- **Dental.** Used to maintain dental health and treat dental disease. The most common dental apparatus is dental amalgam, which is used to fill cavities caused by tooth decay. Besides dental amalgam, dental devices also include acrylic polymers, crowns, plates, screws, wires, dental and facial implants, braces, and various devices for oral and facial reconstruction.[22]

- **Endoscopy.** Used to examine the interior of a patient's body, that are usually inserted through one of the body's natural openings, such as the mouth, urethra or anus.[23] There are differents endoscopy devices, according to organ to be inspect, including laryngoscope (larynx), gastroscope (stomach), esophagoscope (esophagus), angioscope (blood vessels), nephroscope (kidney), cystoscope (urinary tract) and some others.[24]

- **Ophthalmic.** A device that serves a medical function in optometry and ophthalmology. These devices include non-invasive instruments for diagnostic purposes, invasive items like contact lenses and their care products, and implantable devices such as intraocular lenses. Additionally, surgical systems like lasers, phacoemulsification machines, and various surgical tools also fall under this category.[25]

- **Neurological.** Neurological devices can help diagnose, prevent, and treat a variety of neurological disorders and conditions such as Alzheimer's disease, Parkinson's disease, major depression, epilepsy, spinal cord injury, and traumatic brain injury. Examples of neurological devices include neurodiagnostics (Computed Tomography scanner, Magnetic Resonance Imaging scanner, Positron Emission Tomography scanner), neurointerventional (embolization coils, carotid stents, intracranial stents, neurovascular thrombectomy), and neurostimulation devices (spinal cord stimulation, cochlear implants).[26]

## Categorization based on the energy source of devices

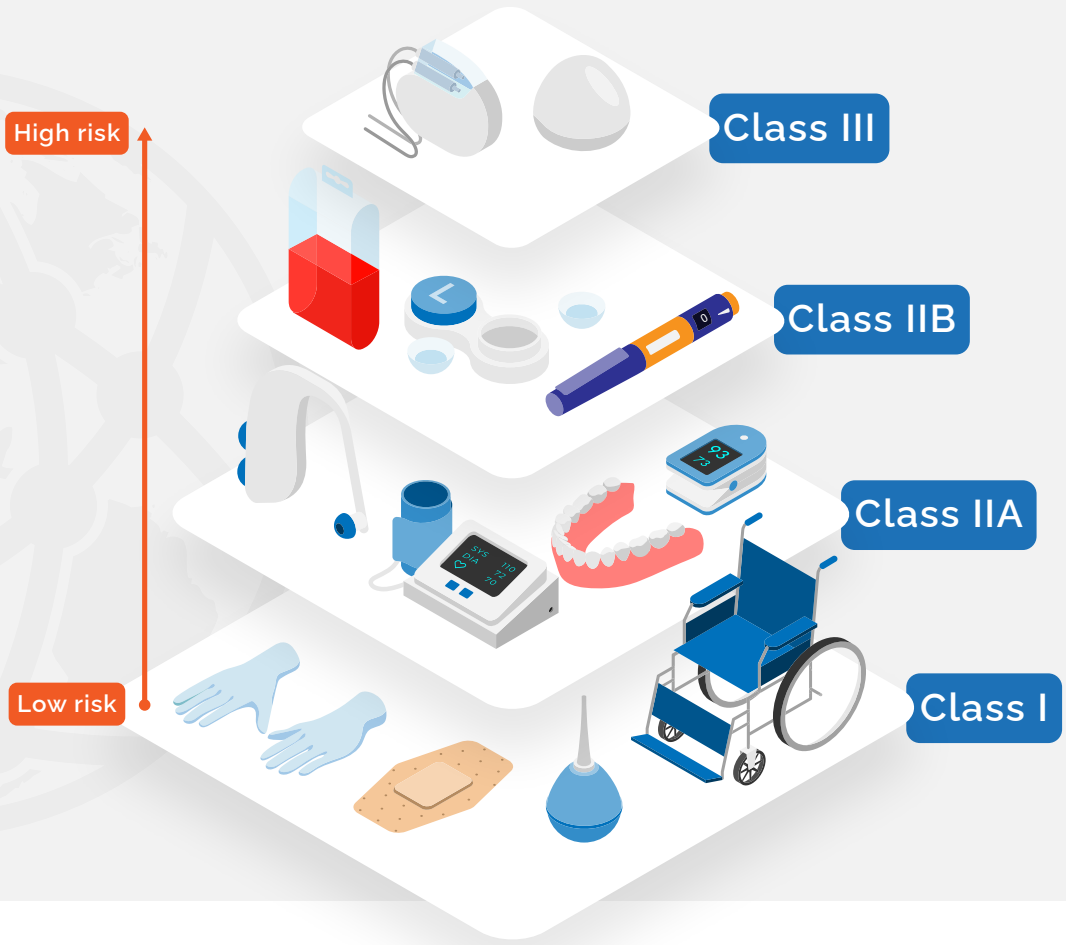



- **Active medical devices.** The operation depends on a source of energy other than that generated by the human body for that purpose, or by gravity, and which acts by changing the density of or converting that energy. Devices intended to transmit energy, substances or other elements between an active device and the patient, without any significant change, shall not be deemed to be

active devices. This type of device often involves more complex technology and ongoing monitoring, maintenance, or calibration to ensure their proper functioning and safety. This category includes X-ray equipment, insulin pumps, pacemakers.[10]

- **Passive medical devices.** Passive or non-active medical devices do not require an energy source. They rely on physical or mechanical properties, such as gravity, elasticity, or the body's natural processes, to perform their intended function. These devices are simple and low maintenance. Passive devices are often used for supportive, protective, or corrective purposes in various medical settings, and are considered safer and more straightforward than active devices.[27]

## Categorization based on the level of risk on patients and users



Medical devices are divided into 4 risk classes ranging from low to high. Each category has specific evaluation and control rules associated with it: [13][28][29][30]

- **Class I (lowest risk class)**, which includes, for example, corrective glasses, vehicles for disabled people, crutches, etc.;
  - **Class Ia** – Non-sterile or no measuring function (low risk)
  - **Class Ib** – Sterile and a measuring function (low/medium risk). This class is complemented with three subclasses addressing specific features:
    - **Class Is** – devices that are delivered sterile
    - **Class Im** – devices with a measuring function
    - **Class Ir** – devices that are reprocessed

For this, an authorized entity must be involved in the conformity assessment of the parts related to sterilization, measuring function, and reusability.

Surgical instruments, plasters, manual wheelchairs, thermometers, hospital beds, personal protection kits and endoscopes are some devices that fall into this category.

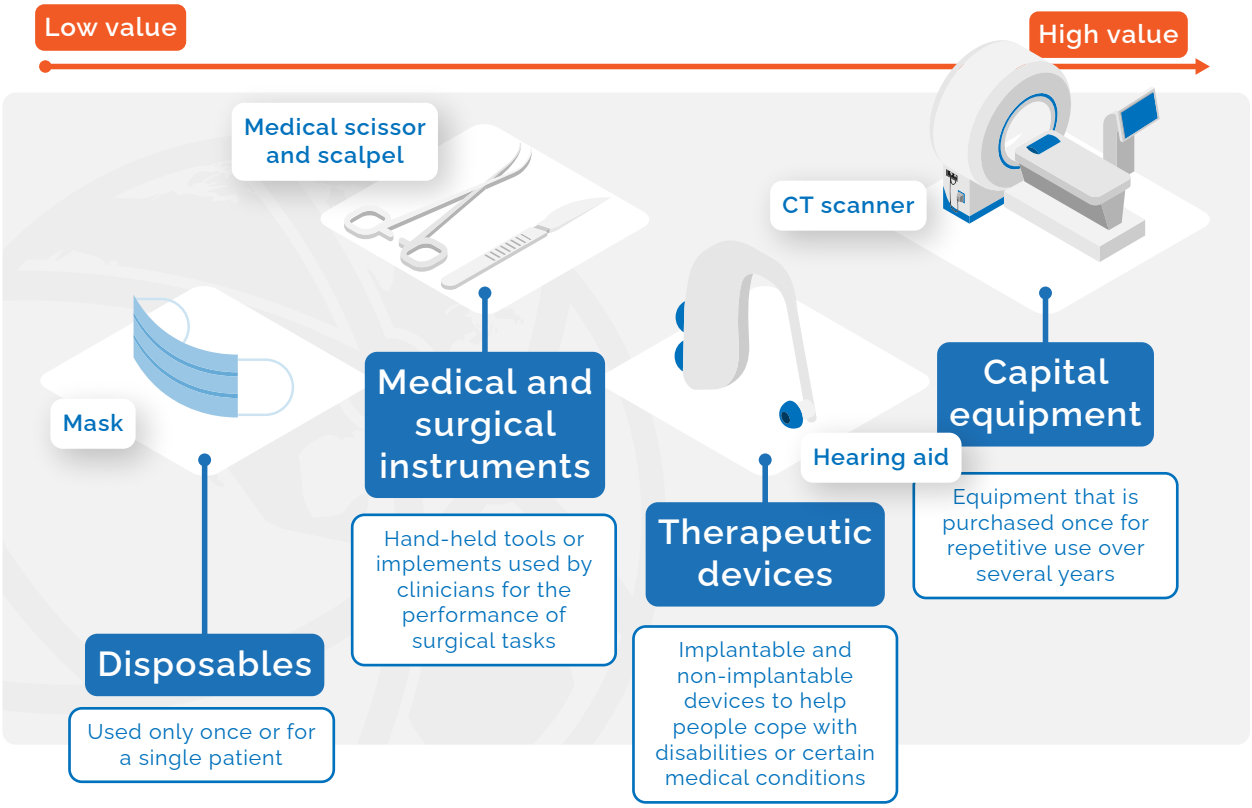
- **Class IIa (moderate/measured potential risk)**, are devices usually surgically invasive intended for transient and short-term use. Active medical devices used for diagnosis and monitoring also fall in this category. Some examples are contact lenses, ultrasound devices, dental crowns, ultrasonic diagnostic equipment.

- **Class IIb (high/significant potential risk)**, which includes in particular surgical lasers, lens disinfection products, blood bags, ventilators. Class IIb medical devices are usually implantable and long-term surgically invasive devices with greater impact on patient health than lower classes.

- **Class III (highest risk class)**, which includes for example breast implants, stents, hip prostheses, defibrillators and/or prosthetic heart valves. They are classified under this heading according to their sensitive anatomical location, the implantable nature of the medical device, the use of new technologies and/or the use of new materials. This category encompasses active implantable medical devices and long-term invasive medical devices that directly or indirectly support life.

There can be other considerations such as local vs systemic effect and potential toxicity. The manufacturer is responsible for classifying their device based on its intended purpose. To do this, the manufacturer relies on classification rules that are established, depending on the medical purpose that the latter claims for its product.

For the purposes of trade statistics the Inter-American Development Bank (IDB) has classified medical devices into four categories: [31]



- **Disposables.** These encompass single-use or single-patient-use items, such as needles, syringes, catheters, tubes, intravenous sets, bandages, surgical gloves, medical textiles, and masks.

- **Medical and surgical instruments.** Are hand-held tools or implements used by clinicians for the performance of surgical tasks. Includes medical scissors, dialysis devices, cardiac defibrillators, ophthalmological instruments, dental drills, instruments used in cosmetic or endoscopic surgery.

- **Therapeutic devices.** This category comprises both implantable and non-implantable devices designed to assist individuals in managing disabilities or specific medical conditions. Examples within this classification encompass hearing aids, pacemakers, and prosthetic components, which represent technologically advanced products characterized by high value, high margins, and relatively lower volume.

- **Capital equipment (diagnostic and imaging).** This category pertains to equipment procured for repetitive use over an extended period, typically spanning several years. It encompasses monitoring, diagnostic, and imaging equipment, including MRI (magnetic resonance imaging), ultrasound, X-rays, gamma rays, and beta rays. Notably, these items represent high-value, high-margin, and low-volume products.

This classification is important for two reasons:

→ Each category corresponds to products with increasing degrees of higher value added.

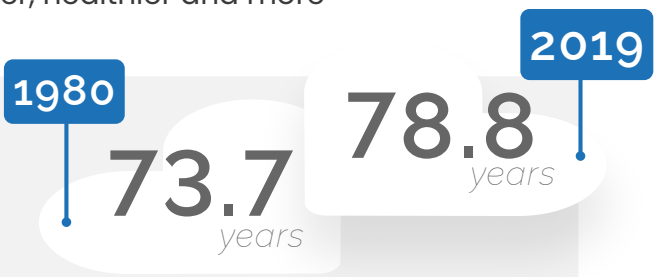
→ These categories are the basis for placing these products in the **Standard Industrial Classification** that guides the compilation of international trade statistics.

These same categories will be used throughout this document series to highlight certain trade statistics of medical devices.

## C. Benefits of Medical Devices on users (US)

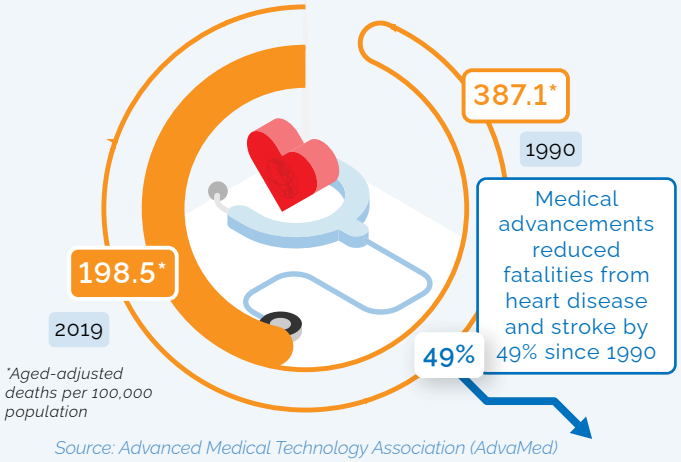
Medical devices allow people to live longer, healthier and more productive lives.

Medical advancements increased life expectancy by more than five years from 1980 to 2019.[32]




*Source: Advanced Medical Technology Association (AdvaMed)*

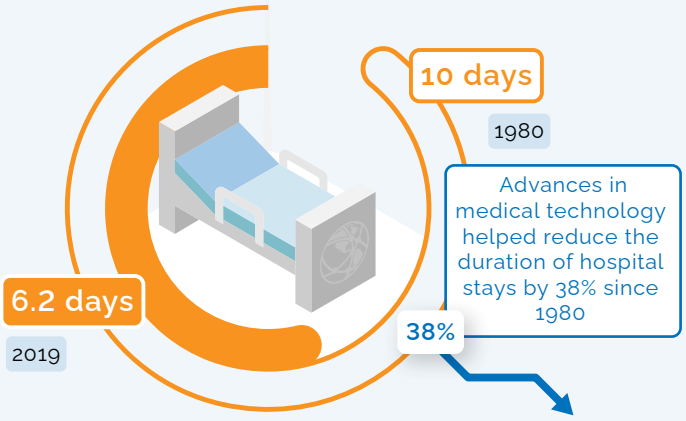
### Heart disease and stroke




**Aged-adjusted deaths per 100,000 population*

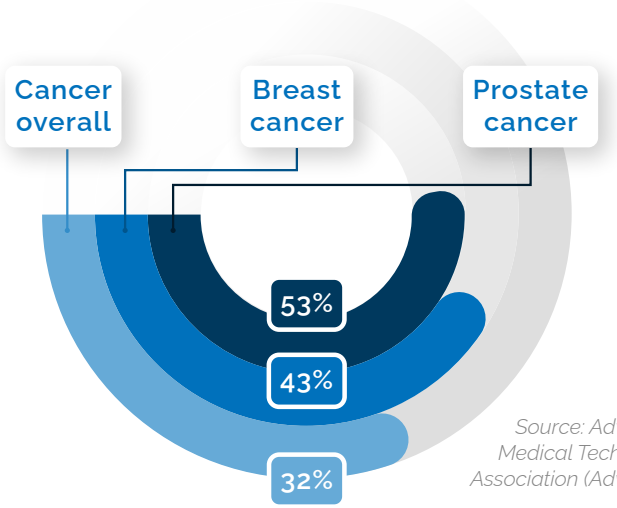
*Source: Advanced Medical Technology Association (AdvaMed)*

### Duration of hospital stays



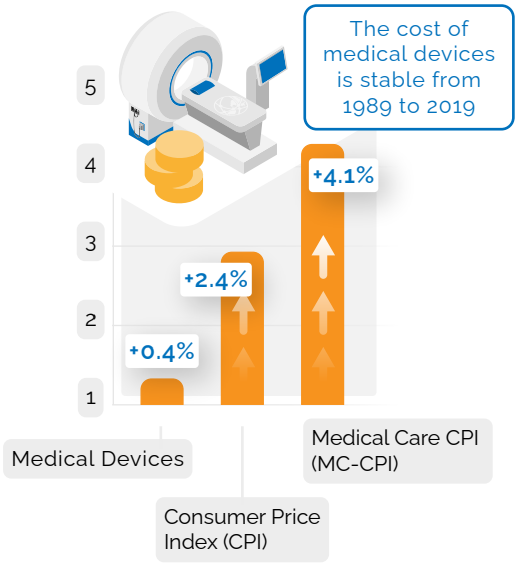

*Source: Advanced Medical Technology Association (AdvaMed)*

Screenings due to improved medical technology helped reduce deaths from:[34]

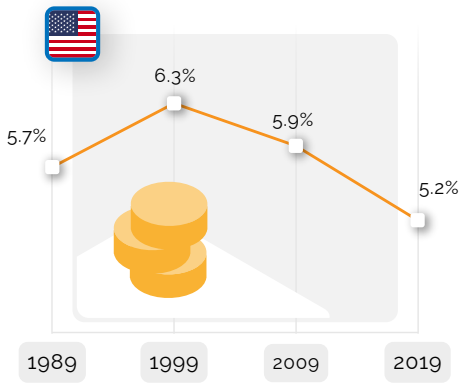



*Source: Advanced Medical Technology Association (AdvaMed)*

The cost of medical devices is stable from 1989 to 2019:[33]



Medical devices are a fraction of health spending:[35]

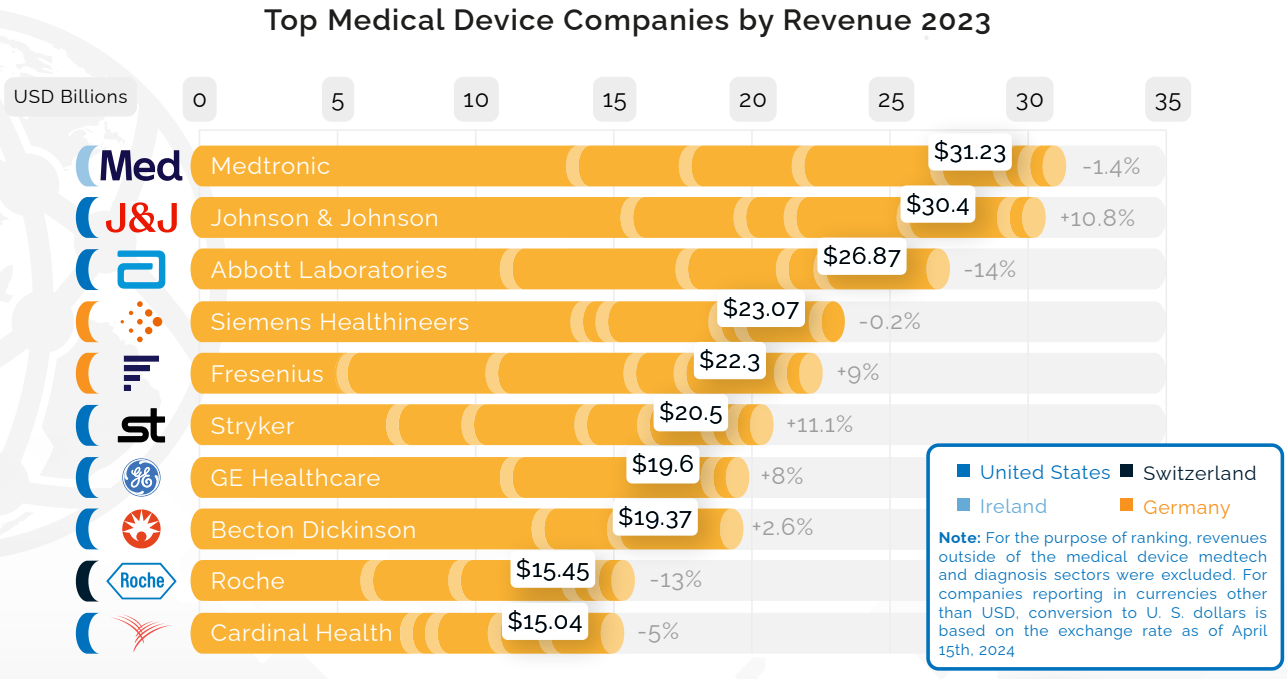



Share of medical devices in healthcare expenditure (USA)

## D. Top Medical Devices Players Worldwide

The growth of the healthcare industry is closely linked to the expansion of the medical device market, which is a crucial component of the global supply chain. Bringing innovation and technology to healthcare, the **MedTech** sector is growing rapidly and transforming the ways diagnosis and treatment are received.

Based on 2023 sales revenue, these are the top 10 medical device companies that are leading the charge in this rapidly evolving field:[36]-[45]

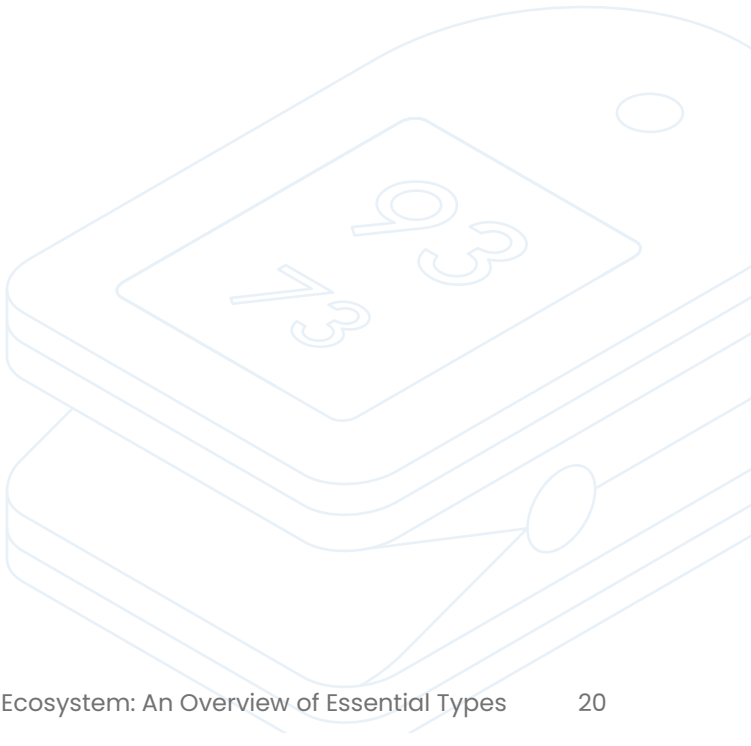


By 2023, Medtronic was the largest medical device manufacturer, having generated $31.23 billion, an increase of 1.4% in relation to the previous year. Its core products include those for cardiovascular, medical surgical, neuroscience and diabetes.

Johnson & Johnson is in second place in terms of revenue, with $30.40 billion during the same year, increasing 10.8% compared to 2022. The segments in which it moved the most were immunology, oncology, orthopedics, infectious diseases and neuroscience.

Abbott Laboratories ranked third in 2023, with revenue of $26.87 billion despite a 14% decline compared to the previous year. Abbott remains the market leader in diagnostic tests, instruments, and informatics systems, maintaining and developing within the sector with the use of artificial intelligence, having a greater impact in the segments of diabetes care, vascular, rhythm management and electrophysiology.

In addition to these three, other companies are important players in the industry thanks to the advances they are developing, including Siemens Healthineers, Fresenius, Stryker, GE Healthcare, Becton Dickinson, Roche and Cardinal Health.



# Closing

Medical devices are essential components of healthcare systems, playing a critical role in the safe and effective prevention, diagnosis, treatment, and rehabilitation of diseases. These devices are classified based on their risk, which is determined by various factors, including the duration of contact with the human body, the level of invasiveness, whether the device delivers medication or energy to the patient, whether it is intended to have a biological effect, and whether it is used alone or in combination with other devices. Understanding this classification is crucial for assessing the risk level associated with patient contact.

One of the primary reasons for classifying medical devices is to ensure their safety and effectiveness for users. The classification dictates the regulatory rules and requirements that manufacturers must meet before a product can be marketed.

A comprehensive understanding of the diverse categories of medical devices is crucial to understand the industry's supply chain, impacting procurement, inventory management, and distribution processes. This understanding empowers stakeholders to make informed decisions about resource allocation and technological investments.

As we continue expanding upon the medical device landscape, the next document in our series will explore **the global medical devices market and the industry's evolving regulatory requirements.**

# Notes

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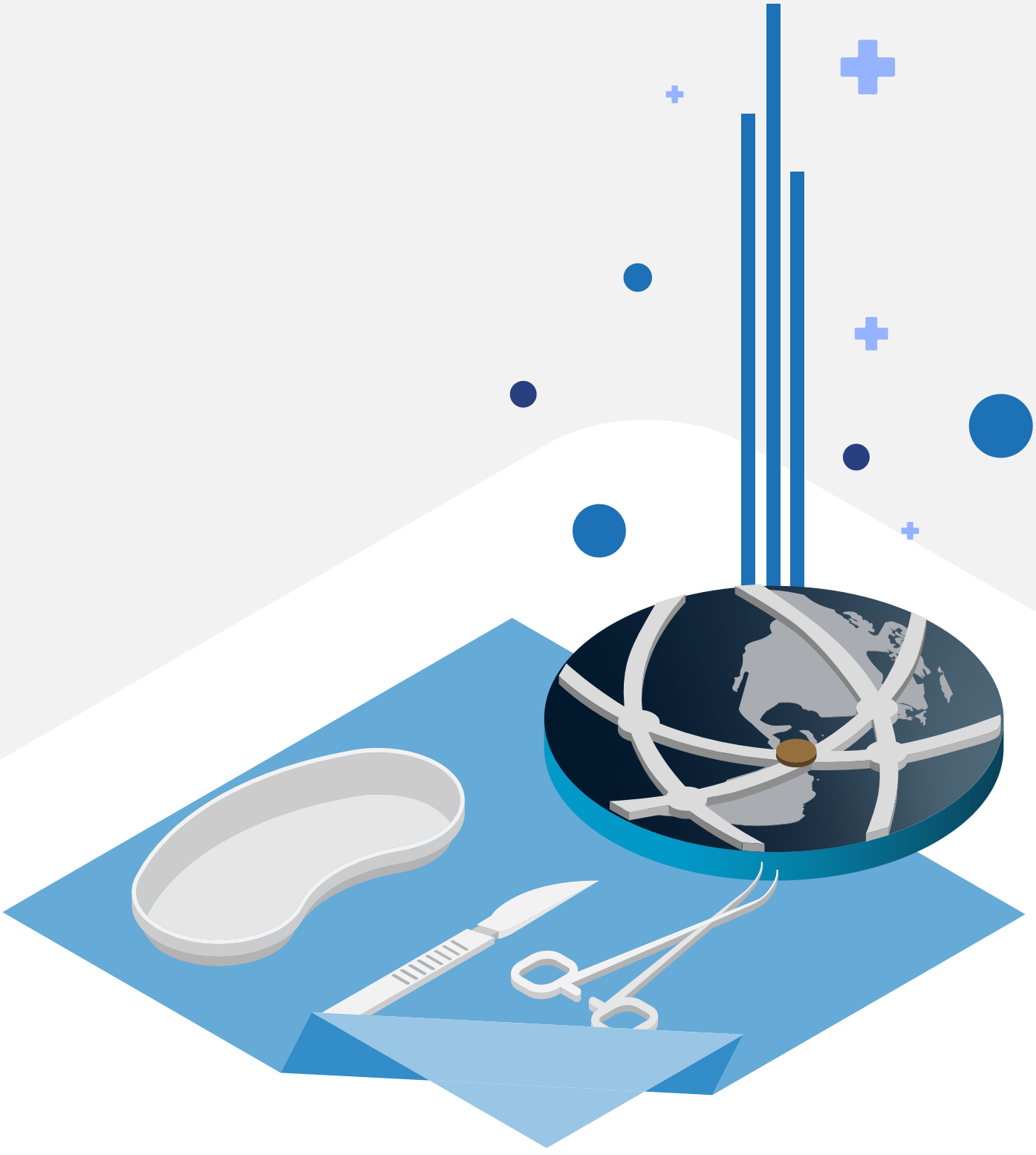

# About the **Why Panama** Program

In the current dynamic global landscape, it is clear that having access to high-quality insights is crucial when determining the optimal location for regional distribution in order to take advantage on the present structure of global value chains.

Georgia Tech Panama Logistics Innovation & Research Center recognizes the importance of key insights in the decision-making process, and works closely with companies seeking to assess their supply chains and how Panama can become a key part of their global logistics network.

The "Why Panama" program utilizes quantitative data and analytics to assess key variables and compare the costs, investments, and service benefits of setting up a distribution center in Panama. By conducting a thorough analysis, the program aims to provide businesses with valuable insights into the advantages of establishing a hub in Panama.

To know more you can contact Jeancarlos Chen at **jeancarlos.chen@gatech.pa** or Jorge Barnett at **jorge.barnett@gatech.pa**


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## About Us

The Georgia Tech Panama Logistics Innovation and Research Center is located in Panama City, Panama. It was launched in 2010 by an agreement between the Georgia Institute of Technology and the Goverment of Panama through the National Secretariat of Science, Technology and Innovation (SENACYT).



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Logistics Innovation & Research Center

An Innovation Center of:
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