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Medical Devices: Wearable and Implantable

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1. Abstract

The healthcare system is experiencing a critical shift from the conventional hospital-centered system to an individual-centered system due to the increased prevalence of chronic diseases, an ageing population, and continuously rising healthcare expenses. A wide range of therapeutic tools used to modulate or restore organ function make up medical devices. Devices are used to administer a variety of therapies, such as medications, electrical stimulation, laser, and thermal energy, provide mechanical support, and restore sensory functions. They may be implanted or activated temporarily or permanently. This essay aims to examine several implantable and wearable medical technologies. Using a combination of multiplexed bio sensing, microfluidic sampling, and transport systems coupled with flexible materials and body attachments for increased wearability and simplicity, wearable technology has gradually advanced. The ability of these wearable's to provide patients with feedback and a deeper understanding of the relationships between analyte concentrations in blood or non-invasive bio fluids is promising and crucial for the prompt diagnosis, treatment, and management of medical disorders. The sorts of wearable's devices for biological fluids for disease prevention and real-time monitoring of human health are covered in the current review. Since the first implantation pacemaker was developed, implantable medical devices have made incredible strides in the treatment of the most difficult diseases. The ageing population and rising incidence of chronic diseases

are driving an increase in the demand for innovation in both current and new implanted devices. We have discussed various IMD kinds in this work, including orthopedic and cardiovascular implants.

2. Introduction

A medical device is officially defined by the World Health Organization as "any instrument, apparatus, implement, machine, appliance, implant, reagent for in vitro use, software, material, or other similar or related article, intended by the manufacturer to be used, alone or in combination, for human beings, for one or more specific medical purposes".

Medical tools come in many different forms, including prosthetics and systems that can provide medications, electrical stimulation, laser, mechanical, or chemical sensors, among other sorts of therapy. Medical technology has grown significantly in importance over the last few decades as a tool for curing sickness and extending life.

The intricacy of medical devices varies widely, from implantable life-sustaining devices like pacemakers and defibrillators to simpler "devices" like bedpans and gloves. Several device accessories, including plastic tubing and computer software, as well as some human tissues, such as heart valve allografts, are governed as devices.

Wearable biosensors are currently receiving a lot of attention due to their potential for personalized medicine and human health monitoring. In vivo sensing, data collection, and calculation utilizing mobile or portable devices are made possible by wearable biosensors (WBSs), which are portable electronic devices that integrate sensors into or with the human body in the form of tattoos, gloves, clothing, and implants. WBSs are renowned for fostering two-way communication between doctors and patients. These tools also make it possible to non-invasively and in real time quantify several biochemical markers in bodily fluids like saliva, perspiration, tears, and skin.

With surgical placement, IMDs are brought close to the target organs, greatly enhancing the sensing or stimulation efficiency. To ensure constant implant operation over many years, these devices are constructed from strong and biocompatible materials. These implants work well in general, however they contain non-resorbable metallic and polymeric materials, which might lead to infections if exposed to the implant material for an extended period of time. Due to bio fouling and the inflammatory reaction, periodic renewal or extraction procedures are therefore common. This eventually increases the expense of the treatment and causes patient suffering.

3. Wearable

The healthcare system is experiencing a critical shift from the conventional hospital-centered system to an individual-centered system due to the increased prevalence of chronic diseases, an ageing population, and continuously rising healthcare expenses. Wearable sensors have become increasingly common in healthcare and biomedical monitoring systems since the turn of the 20th century, enabling continuous measurement of vital biomarkers for tracking disease progression and health, as well as medical diagnostics and evaluation in bodily fluids like saliva, blood, and sweat. The focus of recent advancements has been on electrochemical and optical biosensors, as well as improvements in the non-invasive monitoring of biomarkers, germs, hormones, and other substances. Using a combination of multiplexed bio sensing, microfluidic sampling, and transport systems coupled with flexible materials and body attachments for increased wearability and simplicity, wearable technology has gradually advanced. These wearable's show promise and have the potential to provide patients with more information about the relationships between analyte concentrations in blood or non-invasive bio fluids, which is crucial for the quick diagnosis, treatment, and management of medical disorders. However, in order to support the clinical acceptability of wearable biosensors, cohort validation studies and performance evaluation are required.

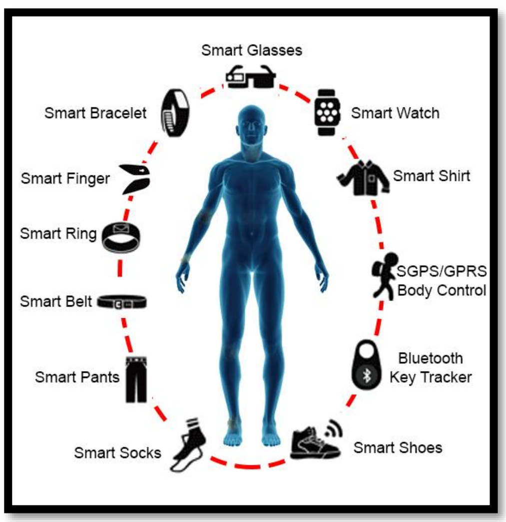


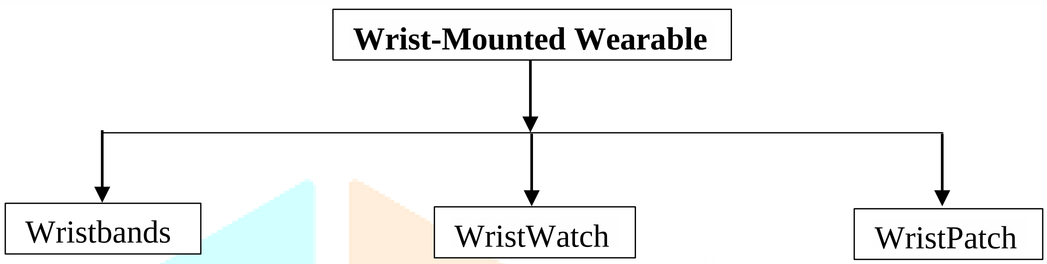
Fig:- Wearable Device

3.1. On The Basis of Their Design or Utility

From the dawn of the twenty-first century, the use of wearable technology into personalized health care has drawn considerable attention. Wearable gadgets can be divided into four categories: wearable bands (like watches and gloves), wearable fabrics (like t-shirts, socks, and shoes), wearable gear (like glasses and helmets), and sensory devices for tracking one's health. Wearable biochemical sensors have become firmly ingrained in our daily lives as a result of technological breakthroughs in wireless communication, microelectronics, and integrated miniature devices.

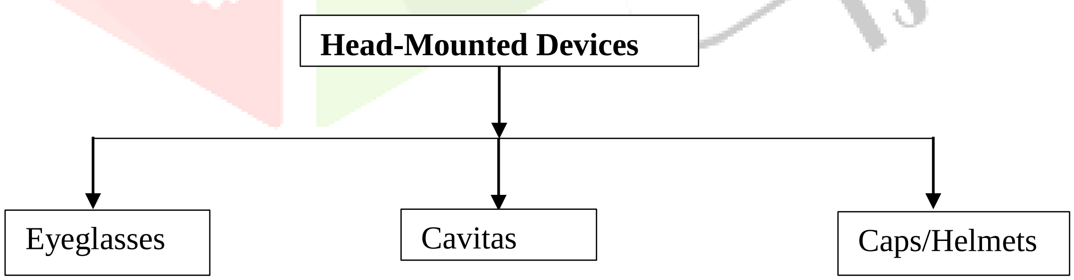
3.1.1. Wrist-Mounted Wearable

Wrist-Wearable Devices (WWD) are worn on the wrist, as the name suggests. With the benefit of providing downsizing and an increase in battery longevity, WWDs for the monitoring of physiological parameters have been created. They convert raw signals into real-time interpretable data. Wearable's that attach to the wrist, such smart watches and fitness bands, have recently evolved from simple accelerometer-based models (like pedometers) to ones that incorporate biometric sensing. Smart watches or wristbands are the only wrist-worn gadgets now utilized commercially for non-intrusive human monitoring.



3.1.2. Head-Mounted Devices

Visual tools with hands-free functionality, head-mounted tools are typically mounted on the user's head. The most research-related wearable's fall into this category, which includes items like caps, spectacles, and helmets. These devices are currently used in modelling, imaging, and surgery; nevertheless, the commercial head-mounted wearable's appear to be less developed than wrist-worns at this time.



3.1.3. Smart Clothing

Intelligent or smart materials that can sense various environmental variables and react to stimuli like thermal, chemical, or mechanical changes are the basis for smart clothing (also known as "E-Textiles"). These fibers and filaments are made up of conductive tools that can interact with the environment and the human body, as well as clothing that is sewn or attached to these tools. E-textiles, which combine sensors like electrodes sewn into fabric and these integrated biosensors are used to evaluate bio fluids, providing a neurological system to detect signals. Electrocardiogram (ECG) and acceleration signals are measured using a smart shirt-based biosensor for continuous and real-time health monitoring. The typical design of the shirt includes an electrode-covered piece of conductive fabric and a sensor for real-time monitoring of health data. These wearable sensors are made to be small enough to fit into a shirt and have low power requirements, which reduces the size of the battery. In order to achieve a clear ECG signal while jogging or engaging in physical activity, an adaptive filtering approach in the proposed shirt was developed and tested to cancel the artefact noise from the electrodes made up of conducting fibers.

3.1.4. Chest-Mounted Devices

For careers or healthcare professionals, the monitoring of falls and postural impairment are their top priorities. There are two commercially available alarm systems for safety monitoring: the Life Alert Classic from Life Alert Emergency Response Inc. and the AlterOne medical alert system. The push button on these gadgets is embedded into the pendant, and pressing it sends the message wirelessly to a distant location. In addition, the Wellcore system makes use of cutting-edge microprocessors and accelerometer meter units to track postural movement. This gadget can communicate further with a distant center and distinguish between normal and fall-related bodily motions. Another chest-worn gadget for monitoring the heart rate, sleep pattern, temperature, and other parameters is MyHaloTM by Halo MonitroingTM. As a result, a gadget with an integrated system on a mobile device that is outfitted with a balance sensor and initiates automated dialing on an emergency contact in the event of a fall will be extremely helpful.

3.2. Bio-Multifunctional Smart Wearable Sensors (WSs)

One of the key elements in creating WSs that imitate the bio-functions is choosing nano-materials that are mechanically compatible. Key considerations include monitoring several biological signals such as physical, electrophysiological, and gait abilities as the critical sign of existing catastrophic disorders. The development of wearable health monitoring technology over the past few decades has made it possible to identify these crucial biological signals early on. The wearable sensor's performance and wear resistance can be improved, and its usefulness can be increased, if the suitable material is available. The many bio-functional materials utilized in wearable sensors will be covered in this section.

3.2.1. Self-Healing Flexible Wearable Sensors

Due to the biosensor components' proneness to damage, which alters their functionality and further lowers their performance, shelf-life, and electronic qualities, wearable medical devices are restricted in their resilience. An ideal bio-multifunctional wearable biosensor is an intelligent sensor that not only maintains its electronic operations but also has the ability to self-repair slight micromechanical damage to its internal physical qualities. Wearable electronic devices that are in contact with the skin must have the ability to repair themselves without the need for external stimulation (such as heat). There have been studies on a number of flexible self-healing sensors based on conductors and polymers. Only a few self-healing polymeric materials have been applied to flexible wearable electronics, despite the field's rapid progress. To develop self-healing capability, a variety of composite materials are packed with conductive particles or capsules that contain healing agents.

3.2.2. Biocompatible Wearable Sensor

As wearable biosensors are in close contact with the human body, there shouldn't be any new health risks for people. So, in order to prevent the formation of an immune response, it is crucial for the wearable biosensor to be biocompatible, which makes biocompatible materials the preferred materials for smart wearable sensors. Bioresorbable silicon-based multifunctional electronic brain sensors have recently been developed. Moreover, the development of an implantable pressure-strain sensor made of biocompatible conductive polymer. This sensor can distinguish between the pressure caused by a salt (12 Pa) and a strain of 0.4% without interference by using two vertically isolated devices to measure pressure and strain separately.

3.2.3. Biodegradable Flexible Sensors

A sensitive and effective wearable pressure monitor for monitoring the heart that uses biodegradable conducting polymers. The developed sensor can be integrated for continuous cardio-vascular monitoring, such as the recording of blood pulse signals, due to its higher sensitivity and quicker response time. In order to prevent surgical interventions, it may also be employed in biomedical applications. Flexible biosensor design and construction strategies principally call for a tactical approach to fine-tune materials for biomedical use. Using photolithography, it is simple to create sensors made of poly (3,4-ethylenedioxythiophene):poly(styrene sulfonate) that are completely biodegradable and flexible. The biosensor demonstrated outstanding electrochemical activity and stability over a few days in the detection of dopamine and ascorbic acid with increased sensitivity thanks to the conductivity of micro patterns as the working electrode. Yet, an enzymatic response has the potential to attack these sensors. The development of a wearable sensor with great performance using cellulose Nano fibers.

3.3. Microfluidic-Integrated Wearable Biosensor

3.3.1. Colorimetric-Based Wearable Sensors

The real-time sensing platform needs to be straightforward, user-friendly, quick, and affordable. Rapid detection of the target molecule is made possible by the appearance of a color change following a chemical reaction between the analyte and the recognition site, as in colorimetric-based sensing systems. It has already been established that colorimetric biosensors are useful for detecting ions (H+, Na+, K+, Ca2+, Cl), single molecules, microorganisms, and proteins. Recently, it has been possible to do colorimetric detection using both the built-in high-definition cameras of smartphones and conventional spectrophotometry equipment. Moreover, this system can be combined with textile components to be used as textile-based fluid handling platforms, collecting and analyzing the sample for real-time analysis and doing away with the requirement for mechanical micro pumps. This is the first instance of a colorimetric wearable biosensor built on a microfluidic platform and incorporated onto a polyester/lycra textile. It has qualities for transporting fluids and is affected by the density and the proportion of the two materials. The pH sensor on fabric was created using functionalized fabric microfluidic pH dye sensors with excellent fluid-transport properties. A different strategy used a cotton thread-mounted microfluidic system to further enhance sweat transport, quantify pH changes in sweat samples in real time, and include an LED-based detecting system.

3.3.2. Electrochemical-Based Wearable Sensors

An alternative to colorimetric sensors, which are intrinsic with the properties of increased sensitivity and selectivity for a large range of metabolites, is a new electrochemical-based bio sensing platform. Electrochemical biosensors now have better sensitivity and detection limits thanks to developments in nanotechnology, polymer science, and the integration of inorganic materials. Sweat analysis is made possible by combining an electrochemical bio sensing platform with a pilocarpine iontophoresis mechanism in the absence of microfluidic technology. However, because sweat is not secreted at rest, these approaches are not appropriate for sweat analysis.

4. Implantable Medical Device

Devices that replace or function as a portion or the entire biological structure are referred to as implants. Implants are currently employed in a wide range of body parts for a variety of purposes, including orthopedics, pacemakers, cardiovascular stents, defibrillators, neural prostheses, and drug delivery systems. In the modern world, people are living longer, but there are also more age-related ailments. As a result, there is a greater demand for innovative therapies, implants, prostheses, and long-term medication use, as well as for extending the lifespan of existing approaches. One example of how medical treatment requirements are changing is joint disease. Cardiovascular conditions are another illustration. Coronary stents have evolved into a new angioplasty technique standard. Alone exceeded the quantity of drug-eluting stents placed. The majority of tissue hyperplasia, which mostly develops where the stent struts make contact with the artery wall, is the cause of in-stent restenosis. Sub-acute thrombosis is a less frequent but bothersome consequence that is not completely prevented by current stent placement methods and antiplatelet medications. Drug-eluting stents offer a remedy to the aforementioned issues by containing a coating or medication aimed at the local thrombotic or hyperplastic reactions. These implantable devices can be roughly categorized into three classes based on their intended use: cardiovascular implants, orthopedic implants, and implants for other uses. A new angioplasty technique standard is now nary stents.

4.1. Cardiovascular implants

Cardiovascular implants offer a great potential to lower the overall cost of treating heart disease while also dramatically enhancing quality of life. The biggest sales increases for pacing devices will occur, mostly as a result of the expansion of cardiac resynchronization therapy. More pricing flexibility has emerged in a health care setting that is becoming more cost-conscious as a result of a focus on creating new generations of pacing devices that enhance patient outcomes and reduce mortality. Similar to the demand for pacing devices, there will be a high demand for cardiovascular stents and associated equipment. As more people use implantable monitors, ventricular assist devices, and heart valve technology progresses, structural implants will experience the quickest growth.

A variety of illnesses that affect the heart and blood arteries collectively fall under the wide category of cardiovascular disease. Cardiovascular implants made of polymer-coated and polymer-based materials are crucial components of contemporary medicine and will continue to be more significant as demographics shift towards an ageing population with higher rates of age-related morbidity. A number of characteristics of the envisioned next-generation of cardiovascular implants have been identified that could be satisfied by multifunctional polymers, based on the experiences with implants like coronary or peripheral stents, which are currently widely utilized in clinical care. To influence environmental cells and tissue, the challenge is to combine specialized mechanical qualities, fast endothelialization, and controlled drug release. Degradability and sensitivity to outside stimuli are also advantageous in a variety of applications. The haemocompatibility has a crucial role in clinical consequences. Degradable, multifunctional shape-memory polymers are presented as a potential class of functional polymers that meet a number of modern implant requirements and are highly relevant for cardiovascular applications (e.g. stent technology). Such multifunctional polymers serve as a technological foundation for induced auto-regeneration in regenerative therapies and future cardiovascular implants. Since they may expand on their own, shape-memory materials have been suggested for cardiovascular stents. Using self-expansion in the range of body temperature is the best technique to anchor a stent. Multifunctional shape-memory polymers are highlighted as a class of materials that combine biocompatibility and the capacity for stimuli-induced active movements for anchoring implants with a controlled degradation and drug release profile to enable functional tissue regeneration at the application site. The following are cardiovascular implants:

1. Pacing devices
   - Cardiac resynchronization therapy devices
   - Implantable cardioverter-defibrillators
   - Implantable cardiac pacemakers
   - Pacing accessories (pacing leads, pacing batteries)

2. Cardiac stents and related implants
   - Coronary stents (drug- eluting stents, bare-metal coronary stents)
   - Stent-related implants
     - Synthetic grafts (vascular grafts)
     - peripheral grafts (Vena cava filters)
3. Structural cardiac implants
   - Heart valves and accessories
   - Tissue heart valves
   - Ventricular assist devices

- Implantable heart monitors
  - Insertable loop recorders
  - Implantable hemodynamic monitors

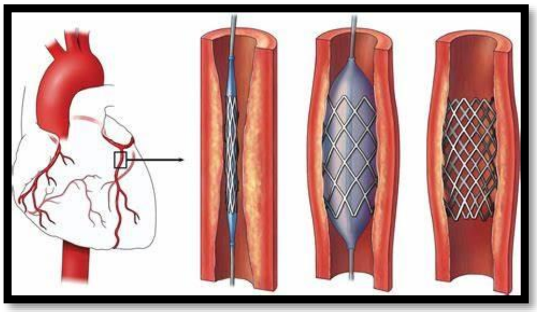


Fig:-Cardiovascular implants

4.2. Orthopedic Implants

The market value leader among implantable devices will continue to be orthopedic implants. Gains will also take into account the rising incidence of musculoskeletal degenerative illnesses and lifestyle modifications that increase the likelihood of sports and exercise-related injuries. The desire for new procedures rather than replacements will grow as products become more long-lasting and durable due to an increased patient population. Long-term challenges for this market segment will also come from improvements in pharmacological alternatives for treating arthritic problems. A solid foundation of insurance approvals for orthopedic implants, a reliable and well-funded medical delivery system, and product designs that enable minimally invasive surgeries will all be advantages for the market segment. Orthopedic implant devices are one of the most well-known uses for biomaterials. The structure of freely moveable (synovial) joints, including the hip, knee, shoulder, ankle, and elbow, is impacted by both osteoarthritis and rheumatoid arthritis. Such joints, especially weight-bearing joints like the hip and knee, might experience significant pain, which can have very negative impacts on ambulatory function. Since the invention of anaesthetic, antisepsis, and antibiotics, it has been able to replace these joints with prostheses, and hundreds of thousands of patients are familiar with the pain alleviation and restoration of movement. Orthopedic implants can be of the following types:

1. Reconstructive joint replacements
   - Knee replacements
   - Hip replacement implants
   - Other reconstructive joint replacements
     - Shoulder implants
     - Elbow implants
     - Ankle implants
     - Joint replacements
2. Spinal implants
   - Thoracolumbar implants
   - Intervertebral spacers
   - Motion preservation devices
   - Cervical implants
   - Implantable spinal stimulators
3. Orthobiologics
   - Hyaluronic acid
   - Bone substitutes

- Bone growth factors
- Bone cement

4. Trauma implants
   - Internal fixation devices
   - Craniomaxillofacial implants
   - Implantable trauma stimulators

Fig:-Orthopedic Implants

4.3. Other Implants

The advancement of cochlear implant technology has improved children's speech, hearing, and affordability. In children, binaural cochlear implantation has been used. Future fully implanted devices are anticipated thanks to the development of perimodiolar electrodes, implantable microphones, and rechargeable batteries. It has been researched to treat vitreoretinal disorders with prolonged intraocular medication release utilizing implanted devices. The disorders that could be targeted include those that can be treated with recurrent intraocular injections (cytomegalovirus retinitis, uveitis), those that need surgery (proliferative vitreoretinopathy), and chronic illnesses (macular oedema, retinitis pigmentosa). Hydrophobic or hydrophilic polymers can be implanted in the subretinal space, intrascleral space, vitreous space, peribulbar space, or at the pars plana in the form of a sheet, disc, rod, plug, or a bigger device. Osmotic mini-pumps, non-bioerodible and bioerodible drug-loaded pellets, configured capillary fibers, biodegradable scleral plugs, scleral discs, polymeric matrices, and scaffolds of various geometries with unique mechanisms of drug release have all been developed as solid biocompatible implantable devices for sustained or controlled intravitreal drug delivery to the posterior segment of the eye. Here are some other implants:

1. Otolaryngeal implants
   - Cochlear implants
   - Airway and oesophageal stents
   - Cosmetic implants
     - ➢ breast implants
2. Ophthalmic implants
   - Intraocular lenses
   - Glaucoma and other lenses
3. Gastroenterological implants
   - Gastric bands
   - Biliary stents
   - Urological implants
4. Gynecological devices

- Soft tissue repair
- Intrauterine devices

5. Drug implants
   - Hormonal implants
   - Brachytherapy products
   - Implantable drug pumps

5. Conclusion

This essay aims to examine several implantable and wearable medical technologies. Multiplexed bio sensing, microfluidic sampling, and transport systems have all been steadily incorporated into wearable technology, along with flexible materials and body attachments for better wearability and simplicity. These wearable's show promise and are capable of providing patients with feedback and a deeper understanding of the relationships between analyte concentrations in blood or other non-invasive bio fluids, which is crucial for the quick diagnosis, treatment, and management of medical disorders. The varieties of wearable biological fluid monitoring devices for illness detection and real-time health monitoring are covered in the current review. Since the first implantation pacemaker was developed, implantable medical devices have made incredible strides in the treatment of the most difficult diseases. The ageing population and rising incidence of chronic diseases are driving an increase in the demand for innovation in both current and new implanted devices. We have discussed various IMD kinds in this work, including orthopedic and cardiovascular implants.

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