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MEDICAL PLASTICS DATA SERVICE

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A TECHNO-ECONOMIC NEWS MAGAZINE FOR MEDICAL PLASTICS, MEDICAL DEVICES, DIAGNOSTICS AND PHARMA INDUSTRY

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- Next-gen Circular Medtech Frontier : The Rise of Smart & Sustainable Plastics
- Polytetrafluoroethylene (PTFE) in Medical Applications: Properties, Developments, and Clinical Relevance
- Understanding Thermoplastic Polyurethane: An Adaptable Material for Medical Devices
- Engineering Polymers & Ultra Engineered Polymers (UEP) for Medical Device Industry
- Bioabsorbable Polymers for Implantable Medical Devices

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- Shape Memory Polymers: Emerging Applications & Global Markets
- Malaysia Medical Devices Market

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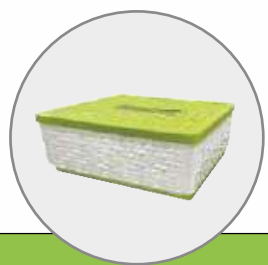

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- Skin Irritation (ISO 10993-23)
- ETO Residue (ISO 10993-7)
- Biological Reactivity (USP 87)

Microbiological Testing: Control contamination risk and meet hygiene standards.

- Bioburden Testing
- Sterility Testing
- Bacterial Endotoxin (Pyrogen) Testing

Material Characterization: Gain insights into the properties of medical plastics.

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- Acute Systemic Toxicity Test (ISO 10093-11)
- Material Mediated Pyrogen Test (ISO 10093-11)
- Sub-Acute Systemic Toxicity Test (ISO 10993-11)
  Sub-Chronic Toxicity Test (ISO 10993-11)
- Chronic Toxicity Test (ISO 10993-11)
- Implantation Test (IM/SC/Intraocular/Intra-biliary/ Intra- arterial) (ISO 10993-6)
- Genotoxicity Tests (AMES, CHA, MNT) (ISO 10993-3 & ISO 10993-33)
- Hemocompatibility Tests (ISO 10993-4)
- Carcinogenicity Test (ISO 10993-11)
- Reproductive / Developmental Toxicology (ISO 10993-11)
- Degradation Testing (ISO 10993-9, ISO 10993-13, ISO 10993-14 & ISO 10993-15) Toxicokinetic study of Degradation Products (ISO 10993-16)
- In-vitro Skin Irritation Test (ISO 10993-23)
- In-vitro Skin Sensitization Test (ISO 10993-10)
- Mucosal Membrane Irritation Test (Oral, Ocular, Penile, Vaginal & Rectal) (ISO 10993-11)
- Biological Evaluation Plan (BEP) & BER
- Toxicological Risk Assessment (TRA)


1. Biocompatibility Testing of Medical Devices (As per ISO 10993-1:2018)


2. Chemical Characterization /Extractable & Leachable Testing (ISO 10993-18 & ISO 10993-17)


3. Biological Testing of Raw Material of Plastics, Rubber, Silicon, Polymers, etc.


4. Microbiological Testing Services


5. Packaging Integrity Testing


6. Stability Testing Services & Transport Simulation Testing


7. Mask, PPE, Gloves & Textile Performance Testing


8. Performance Testing of Medical Devices


9. Performance Testing of Rapid In Vitro Diagnostic Kits


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- ISO 10993-13: Identification and quantification of degradation products from polymeric medical devices
- ISO 10993-14: Identification and quantification of degradation products from ceramics
- ISO 10993-15: Identification and quantification of degradation products from metals and alloys
- ISO 10993-17: Toxicological Risk Assessment (TRA) of medical devices, packaging materials and CCS
- ISO 10993-18: Chemical characterization of medical device. (Exaggerated/Exhaustive extraction studies and study designing).
- E&L for Pharma, Packing and Medical devices as per ICH, PQRI, USP <1663> & <1664>, ISO 10993-12 &18 etc.
- ISO 11979-5: IOLs; Physicochemical tests like Extractables, Leachables, Hydrolytic Stability, Photo Stability and Insoluble Inorganics.
- ISO 11981 & ISO 11986: Soft Contact Lenses; Physicochemical tests
- 21 CFR 177.1500 Chemical Testing of Nylon Resins and Polymers
- EN 1186 Migration Study
- ISO 18562-2: Emission of Particulate Matter from Gas Pathways
- ISO 18562-3: VOCs from Gas Pathways
- ISO 18562-4: Condensate Leachables from Gas Pathways
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- Raw material and finished products testing
- Ink Migration and Glassware Delamination Studies.
- Toys testing for nitrosamines and phthalates as per EN 14350:2020, EN-71-12, EN-73-14
- REACH Study as per regulation (EC) No.1907 etc.
- BS EN 455-3 and ASTM D5712: Aqueous Extractable Protein Test
- ASTM D6499: Antigenic Protein tests.
- ASTM D7558: Extractable Chemical Dialkyldithiocarbamate, Thiuram, and Mercaptobenzothiazole Accelerators Test.
- TOC, THC as per ISO 19227:2018; BS EN 1484:1997
- Particulate Matter as per USP <788> and EP 2.9.19, ISO 19227:2018
- Syringe Tests as per ISO 7886-1
- Nitrosamines and NDSRIs Method development and Validation
- USP <661> Plastic Packaging Systems and Their Materials of Construction
- Unknown peak identification and characterization
- Forced degradation Study
- Residual solvents analysis
- Heavy metal analysis.
- Elemental analysis as per ICHQ3D & USP<233>

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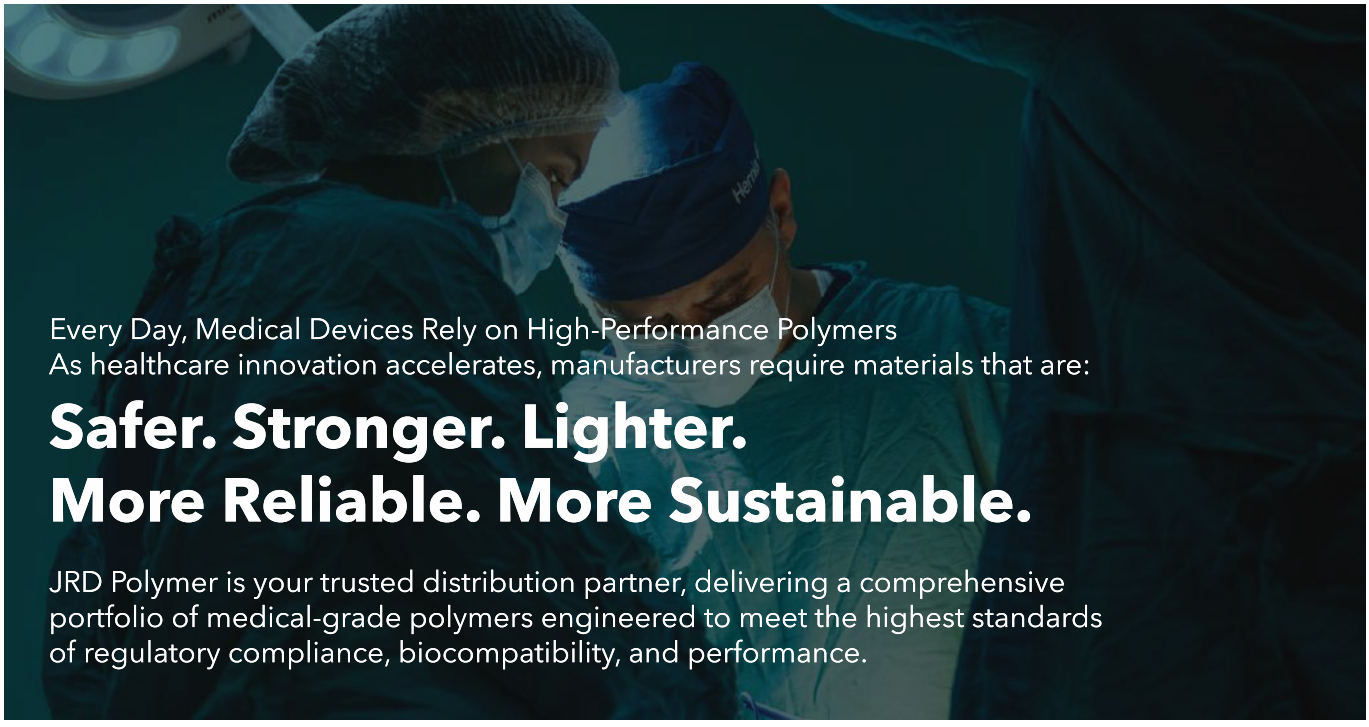

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March-June 2023

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About Innovations and Techniques in Medical Tubing Manufacturing Different processing options have led to ground-breaking ways of producing tubing in order to optimize the performance and usability of medical devices… (March-April 2023)

COVER STORY

IMDI 2023 : 21st National Conference And Technology Exhibition on Medical Devices (Plastic Disposables & Implants) Industry : Manufacturing, Quality & Regulatory - Challenges & Opportunities Pioneer & The Only Event For Medical Plastic Disposables & Implants Industry In India Workshop on " Biocompatibility for Medical Devices, Biomaterials & Polymeric Materials" : Interlinking Chemical Characterization • Includes Facility Tour • Limited Seats (40 Nos) on first cum first basis (May-June 2023)

COMPLIANCE

Need For Medical Devices Industry To Align With Global Norms In Conjunction With : Technology Display show 2023 EXHIBITION Mr. Anil Jauhri, Ex CEO – NABCB, The National Accreditation Board for Certification Bodies (NABCB), Delhi. The Indian medical device market is relatively smaller than other overseas markets but holds significant growth potential. To fully capitalize on this potential, it is crucial to assess the country's compliance with global standards… (May-June 2023)

QUALITY

- The Biocompatibility and Biostability of the Materials Chosen for Your Device will Affect its Clinical Success The biocompatibility and biostability requirements of a particular medical device are dependent upon its application-specific design and performance requirements. The article explains key application-specific biocompatibility and biostability factors to consider… (May-June 2023)
- Dry Lubrication Coating Improves Lifetime & Performance of Medical Device S.M. Kanakaraj, Managing Director, Mark TechPro & Consultants Pvt. Ltd. Dry Lubrication Coating is one of the techniques used to reduce friction of components and increase its life as well. This coating enables reduction in friction between two surfaces during sliding between each other with or without the need for a liquid medium…(May-June 2023)

Did You Know?

About Bioabsorbable Polymers for Implantable Medical Devices

Bioabsorbable polymers degrade and disappear at predictable rates, making them an ideal material for parts of implantable devices that could otherwise impair healing or create an ongoing risk of injury or infection.

Bioabsorbable sutures made of glycolide/lactide polymers, first developed in the 1970s, are strong and flexible enough to hold tissue together to promote healing.

But unlike synthetic sutures which stay in the patient long after a wound has healed, bioabsorbable sutures do not create a long-term risk of foreign-body reactions or require a second intervention to remove.

Bioabsorbable materials have also allowed the development of devices that must be rigid when they are initially implanted, but become flexible as the natural tissue heals around them.

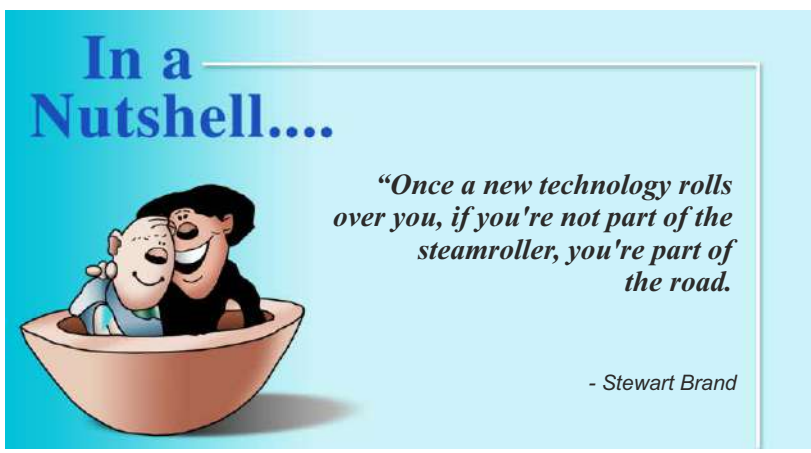
Bioabsorbable polymer materials can also create a scaffold to promote the regeneration of the patient's own cells into new tissue, such as a living, growing heart valve that replaces a defective valve.

Bioabsorbability can also require a compromise on strength or weight.

Bioabsorbable orthopaedic Implants:

The use of bioabsorbable implants in orthopaedic surgical procedures is becoming more frequent. Advances in polymer science have allowed the production of implants with the mechanical strength necessary for such procedures. Bioabsorbable materials have been utilized for the fixation of fractures as well as for soft-tissue fixation. These implants offer the advantages of gradual load transfer to the healing tissue, reduced need for hardware removal, and radiolucency, which facilitates postoperative radiographic evaluation.

Ref :
https://www.medicaltubingandextrusion.com/absorbable-polymers-bioresorbable-bioabsorbable-implantable-medical-devices/
https://pubmed.ncbi.nlm.nih.gov/11575907/



MEDICAL PLASTICS
DATA SERVICE

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MEDICAL PLASTICS
DATA SERVICE

From the Editor's Desk

With this Jan. – Feb. 2026 issue of magazine, **"MEDICAL PLASTICS DATA SERVICE" IS NOW IN 34TH YEAR OF PUBLICATION.** We feel proud to mention that **Looking to 33 years' of Service to the Indian Medical Devices and Medical Plastics Industry, the Grand Jury Panel awarded 16th MT INDIA HEALTHCARE AWARD 2026 to "MEDICAL PLASTICS DATA SERVICE" The Title of "Most Promising Company in Training & Capacity Building"** Presented by Medgate Today International Magazine, in association with Medical Fair India and Medicare Asia.

Coming to the focus of this issue, development of new polymeric materials leads to development of new range of medical devices.

The lead article by Mr Falgun Jani, Business Head – India, Freudenberg very elaborately introduced history and evolution of Medical Grade Plastics. The article starts with a historical timeline of polymers and plastics, charting key discoveries and commercial milestones from 1830 to 1970 and goes on to emphasis on circular economy. AS rightly mentioned in his article, "circular Medtech economy requires a commitment to high value, affordable healthcare. By prioritizing innovative product design, responsible manufacturing, and re use strategies, the industry can safeguard supply chains, reduce environmental impact, and build a sustainable healthcare future.

Various technical articles cover polymeric materials including Polytetra-fluoroethylene (PTFE), Thermoplastic Polyurethane as well as Shape Memory Polymers, Bioplastics, Smart Plastics etc.

The Cover Story introduces a range of materials under Engineering and Ultra-Engineering categories.

As per a very elaborate and well researched article by Dr Anandakrishnan and Mr Anupam Gogoi from Application Development Centre-FP, SRF Ltd, Polytetrafluoroethylene (PTFE) has played a foundational role in medical device engineering due to its biocompatibility, chemical inertness, and durability. Its clinical relevance has expanded from early vascular grafts to modern smart materials and drug eluting systems. Recent regulatory assessments continue to confirm its safety in medical applications. The article starts with explaining basic properties, covers various quality aspects, current and future applications and markets.

One more article by Mr Surendra Kumar Pandey, Technical Sales Manager, TPU, Lubrizol Advanced Materials India Pvt. Ltd. Explains how Thermoplastic Polyurethane is an adaptable material for medical devices.

The "Global Trends" column introduces one more critical application material under the category of Shape memory polymers. These polymers will "remember" their original shape when deformed, and flip back to the initial shape when exposed to an external stimulus.Due to the shape memory effect, the medical devices based on SMP can be implanted into body through minimally invasive surgery in contraction or folded state and recovered to their requisite original shapes at target position.

Another category of Medical Polymers introduced in this issue in the "Did You Know" column is Bioabsorbable Polymers which degrade and disappear at predictable rates. The use of bioabsorbable implants in orthopaedic surgical procedures is becoming more frequent since it also helps production of implants with mechanical strength necessary for such procedures.

As always, this issue includes, Global Trends, Industry News, Events and more.

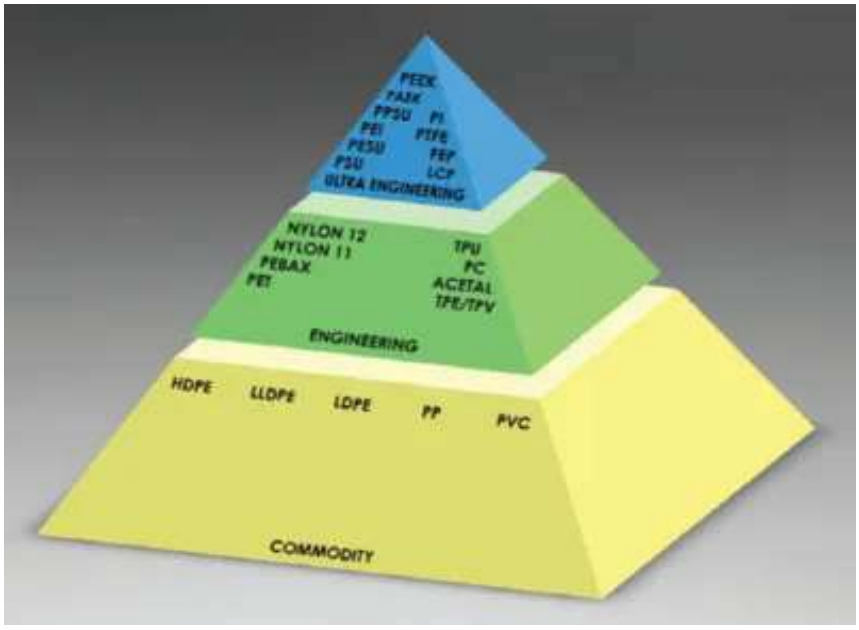
D L Pandya

Engineering Polymers & Ultra Engineered Polymers (UEP) for Medical Device Industry

There are many different types of polymers that can be used in the manufacture of medical components. Commodity thermoplastic materials are starting to be replaced with engineering polymers that can offer better performance qualities and increased stability.

These polymers have greater engineering properties than commodity materials but are more difficult to process. The end result is in terms of the quality and stability they bring to medical components.

Key properties like biocompatibility, strength, durability, and resistance to sterilization make them suitable for these uses.



Specific medical applications

- **Implantable devices:** Used for devices like knee and hip replacements, spinal fusion cages, and heart valves due to strength, durability, and biocompatibility.
- **Surgical instruments:** Used for handles, grips, and internal components that must withstand repeated sterilization.
- **Drug delivery systems:** Used to manufacture precision components for syringes, IV connectors, and inhalers.
- **Diagnostic and imaging equipment:** Used for the casings and internal components of machines like X-ray and MRI machines.
- **Hospital equipment:** Used for components in ventilators, hospital beds, and other equipment that require chemical resistance and light weight.
- **Prosthetics:** Used for artificial limbs and other aids, focusing on strength, fatigue life, and often cosmetic appearance.
- **Packaging:** Used for packaging pharmaceuticals and sterile medical devices due to excellent barrier properties that prevent contamination.
- **Laboratory supplies:** Used for test tubes, beakers, and other containers.

Common engineering plastics and their uses are:

- **PEEK (Polyetheretherketone):** Used for spinal implants, orthopaedic trauma fixation, and replacement joints due to its high strength, biocompatibility, and ability to withstand sterilization.
- **(PMP) Polymethyl Pentene:** TPX (PMP) is a transparent polymer with a very high melting point. It is the lightest polymer available, has low moisture absorption and is chemical and heat resistant so is ideal for medical instruments and laboratory equipment that need to be sterilised or autoclaved. Other applications include optical components containing lenses and windows.
- **Copolyester:** Copolyesters are versatile, transparent resins that are impact and chemical resistant, retaining their mechanical properties when exposed to aggressive chemicals such as medical disinfectants and oncology drugs that would affect other polymers. Copolyesters perform well throughout the plastic injection moulding process and are suited to high speed, high volume production. Medical applications include IV components and connectors.
- **Polybutylene terephthalate (PBT):** PBT has consistent mechanical properties, low moisture absorption and produces parts that have good dimensional stability. It performs particularly well during the injection moulding process allowing for faster cycle times. Applications include valves and connectors, clamps, clips, handles and sleeves for surgical, diagnostic and drug delivery devices as well as housings for monitoring equipment.
- **Polyethylene terephthalate (PET):** PET is a lightweight but exceptionally strong material with excellent mechanical and thermal properties combined with resistance to abrasives and chemicals. It is an inert material that promotes tissue growth and is anti-microbial so can be used for surgical implants.
- **Polyamide (PA) Nylon:** Polyamide (PA) Nylon is a lightweight polymer that is strong and durable with exceptional resistance to corrosion and abrasion. It is heat and chemical resistant to oil, grease, solvents and detergent so is ideal for laboratory equipment, medical device components, tubing and surgical instruments that require frequent or repeated sterilisation.
- **Polyoxymethylene (POM or acetal):** Known for its dimensional stability, POM is a rigid, hard and strong engineering polymer that is low friction and has good electrical insulation. It is a highly crystalline thermoplastic that is ideal for complex components due to its strength and machining ability. It offers excellent wear resistance and chemical resistance particularly to alkalis, disinfectants and solvents. Ideal applications include precision parts for drug delivery equipment, medical devices and orthopaedic instruments.
- **Polycarbonates (PC):** Polycarbonates have high temperature and impact resistance which makes them easy to process without cracking or breaking. PC is transparent, lightweight and robust which makes it ideal for instruments used during surgical procedures. It is also resistant to gamma radiation and can handle tough sterilisation processes. Other devices PC is

suited to include endoscopic equipment and dialysis components.

- **Polycarbonate/Acrylonitrile Butadiene Styrene (PC/ABS):** PC on its own has poor chemical resistance. It is the acrylonitrile that provides the chemical resistance in ABS. PC/ABS produces a material that has the best of both worlds.

A lot of hospital electrical equipment and devices rely on the use of PC/ABS, PC, and ABS for the outer housing due to its glossy appearance and good impact strength.

Ultra Engineered Polymers (UEP) for the Medical Device industry

With a drive within the medical industry to improve patient outcomes using minimally invasive, quicker procedures, traditional materials have not been able to meet the necessary requirements. Due to their unique performance attributes, UEPs can work in environments and applications in which common engineering polymers would fail. From high temperature exposure, exhaustive sterilization requirements, aggressive chemistry handling, high tensile strength/flexural modulus needs, or excellent dielectric properties, I-JEPS allow for solutions in the most challenging of applications.

There is a wide range of I-JEPS and many are described also as "high-heat" polymers due to their required high temperature processing conditions and heat resistance — the major ones being PEEK, PPSU, PSU, PESU and PEI. They have added a level of performance to plastics that was relatively unknown until not that long ago.

These materials are crucial for medical innovation, as they can withstand demanding environments and multiple sterilization cycles, meeting the requirements for both current and future minimally invasive procedures

Key characteristics and benefits

- **High performance:** I-JEPS possess high tensile and flexural strength, and excellent impact resistance, allowing for the creation of strong and durable parts.
- **Chemical resistance:** They resist aggressive chemicals, solvents, and cleaning agents, making them ideal for use in hospital environments and fluid-handling components.
- **Sterilization compatibility:** Many UEPs can withstand repeated high-temperature sterilization methods like autoclaving and gamma radiation, which is critical for reusable medical devices.
- **Biocompatibility:** UEPs are often biocompatible, making them suitable for medical implants and long-term patient contact.
- **Dielectric properties:** Some UEPs have excellent dielectric properties, which is beneficial for the electronic components found in many medical devices.

An important requirement before using an ultra-engineering material is to find a processor that has the knowledge, skills, and experience necessary for converting them to extruded or injection moulded components. All of these materials require specialized equipment; purpose designed tooling and the knowledge of unique processing methods.

(Ref : Spectrum Plastic Group White Paper).

Next-gen Circular Medtech Frontier : The Rise of Smart & Sustainable Plastics

Falgun Jani
Business Head India Region, Freudenberg Medical

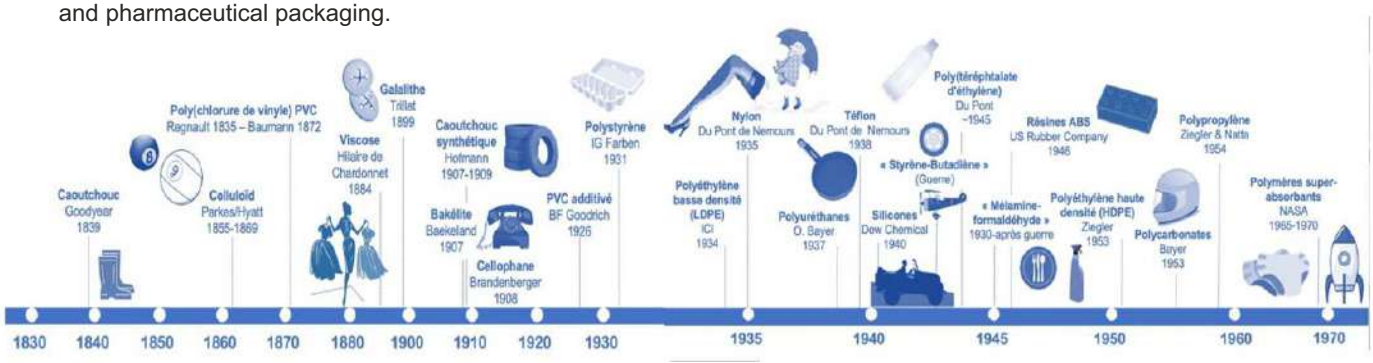
Modern medicine would be unthinkable without plastics. They are used in a wide variety of forms and textures and not only save many lives, but also make the everyday lives of medical staff much more comfortable and efficient.

History & Evolution of Medical Plastics :

Historically, the term "plastic" in a surgical context ("plastic surgery") dates back to **1816–1838** (derived from the Greek **plastikos** meaning “to mold”).

The specific term **"medical plastics,"** referring to synthetic polymers used in medicine, came into common usage around the **mid-20th century.**

In the modern age, **Medical Plastics** (or "medical-grade" plastics) are referred to the specialized polymers engineered and manufactured for use in healthcare applications, ranging from surgical tools and implants to diagnostic equipment and pharmaceutical packaging.



This image is a **historical timeline of polymers and plastics,** charting key discoveries and commercial milestones from 1830 to 1970. It highlights the evolution from natural and semi-synthetic materials to the sophisticated synthetic polymers that define modern industry.

The evolution of medical plastics from 1970 to the present has transitioned from simple, **single-use disposables** to high-performance, **biocompatible polymers** and **3D-printed** solutions. This journey has been driven by the need for infection control, patient safety, and advanced surgical outcomes.

Decade	Key Developments and Milestones	Primary Materials
1970s	Introduction of **first flexible plastic IV bag** (1970), enabling closed transfusions. **Polycarbonate** became widely used for its toughness and PEEK was first prepared (1977)	PVC, Poly-carbonate, PEEK
1980s	First artificial heart made primarily with **Polyurethane** implanted (1982). Rapid expansion of **high-performance plastics** for complex medical tools	Polyurethane, HDPE
1990s	Use of artificial arteries made of **Teflon** (1994). Introduction of **Polylactic Acid (PLA)** as a commercially successful **Bioplastic** (1990s)	PTFE (Teflon), PLA
2000s	Rise of **Nanotechnology** in medical polymers. Advanced prosthetic devices offering greater flexibility and comfort became common	Nanocomposites, Bio-Polymers
2010s to 2020s	Dominance of **3D Printing** for personalized implants and surgical guides. Shift towards **sustainable Biopolymers** and **anti-microbial** varieties.	Bio-based resins, Engineered Plastics

Healthcare Plastic 'OR' Medical Plastic ?

Since both these terms are commonly used interchangeably in recent times, It is important to understand the difference between them.

Healthcare plastics is a broader term encompassing all plastic materials used within a healthcare environment, including non-medical applications like cafeteria utensils, packaging, and office supplies

Medical plastics are specialized, biocompatible polymers engineered to meet strict regulatory, sterilization, and safety standards for direct patient contact, such as implants, tools, and drug delivery systems.

Feature	Healthcare Plastic	Medical Plastic
Primary Scope	Broad use across hospitals and clinics including support activities	Specialized polymers for diagnostic and treatment devices
Common Uses	Cafeteria trays, administrative tools, Janitorial supplies and non-sterile packaging	Syringes, Catheters, Implants, Surgical tools, IV Delivery systems
Biocompatibility	Typically not required for non-clinical applications	Mandatory : must pass ISO 10993 or USP Class VI testing
Sterilization	Standard cleaning with mild disinfectants	Must withstand autoclaving, gamma irradiation or EtO (Ethylene Oxide) sterilization
Material Origin	Often standard commercial or industrial grades	Medical grade materials specifically engineered for high purity & stability
Regulatory Risk	Low, Often classified as non-medical	High, strictly regulated by different agencies like FDA depending on risk to the patient
Examples	Industrial grades of PP, PE, PVC, PC, PS, PET, ABS	Medical grades of Silicones, PVC, PEEK, PP, UHMWPE, PMMA, TPU, PSU, PES, PPSU

Linear Economy Vs Circular Economy :-

Linear economy operates on a **"take-make-dispose"** model, extracting raw materials to create products that are discarded as waste, leading to resource depletion.

Circular economy focuses on **"reduce-reuse-recycle,"** designing products for longevity and keeping resources in use to eliminate waste and regenerate natural systems

Circular Economy Strategies for Medical Plastics :-

Circular economy strategies for medical plastics focus on reducing, reusing, and recycling, transitioning from linear "take-make-dispose" models to closed-loop systems.

Key strategies include designing for recyclability, utilizing sterilization for safe reuse, implementing advanced recycling techniques (pyrolysis, depolymerization), adopting bio-based materials, and employing Extended Producer Responsibility (EPR).

Key Circular Economy Strategies:

Design and Material Substitution: Redesigning medical devices to allow for easier, safer sterilization and reuse instead of single-use. Substituting conventional plastics with bio-based, biodegradable, or recyclable alternatives.

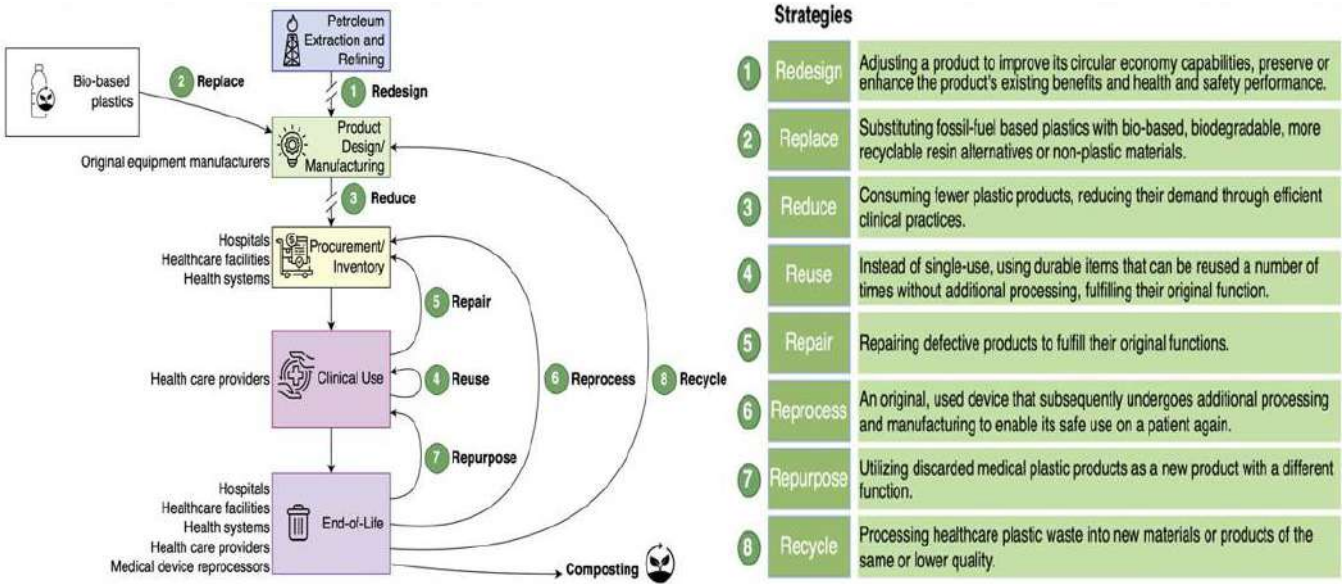
Safe Reuse and Reprocessing: Establishing systems for cleaning, testing, and re-sterilizing medical instruments, which can significantly reduce waste and costs.

Advanced Recycling (Chemical/Mechanical): Utilizing technologies like pyrolysis to break down complex medical plastics into raw materials (e.g., oil) for new product manufacturing, avoiding downcycling.

Waste Segregation and Management: Implementing rigorous, hospital-level waste sorting, such as distinguishing clean, recyclable packaging from infectious plastic, and utilizing autoclave chemical techniques.

Extended Producer Responsibility (EPR): Mandating that manufacturers take responsibility for the entire lifecycle of their products, encouraging sustainable design and take-back programs.

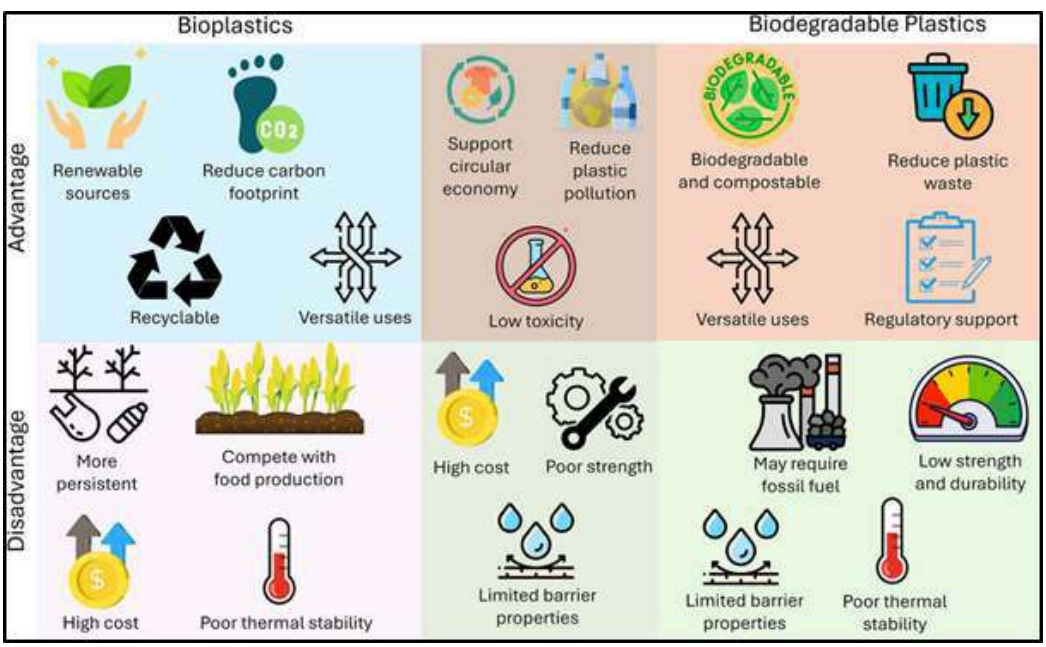
Digital Tracking: Utilizing AI-driven sorting and blockchain to enhance traceability and efficiency in managing and recycling medical plastic waste.



Difference between BioPlastics and Biodegradable plastic :-

Bioplastics are derived from renewable resources (like corn, sugarcane, or cellulose), while **biodegradable plastics** are designed to break down into natural elements by microorganisms, regardless of their source.

A key distinction is that not all bioplastics are biodegradable (e.g., Bio-PE), and not all biodegradable plastics come from renewable sources.



Bioplastics Examples (Bio-based, not always biodegradable)

These focus on the source of the material (biomass).

PLA (Polylactic Acid): Derived from fermented plant starch (corn/sugarcane); used in food packaging and cutlery.

PHA (Polyhydroxyalkanoates): Produced by microorganisms, often used in medical devices and food packaging.

Bio-PET (Polyethylene Terephthalate): Made from bio-ethanol, used in beverage bottles (e.g., Coca-Cola's PlantBottle).

Bio-PE (Polyethylene): Derived from sugarcane, used in plastic bags and bottles. Starch-based plastics: Often blended for films and packaging

Biodegradable Plastics Examples (Decomposable, not always bio-based)

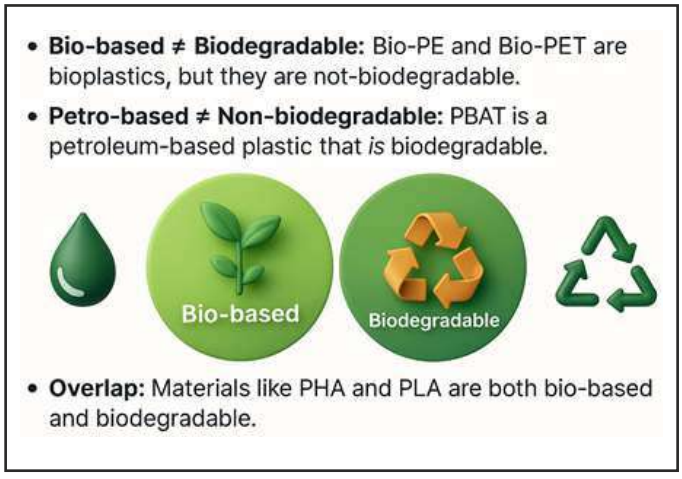
These focus on the disposal method (breaking down by microbes).

PBAT (Polybutylene Adipate Terephthalate): Petroleum-based but fully biodegradable; often used in compostable bags and agricultural mulch films.

PCL (Polycaprolactone): Petroleum-based, used for long-term biodegradability, such as in biomedical applications.

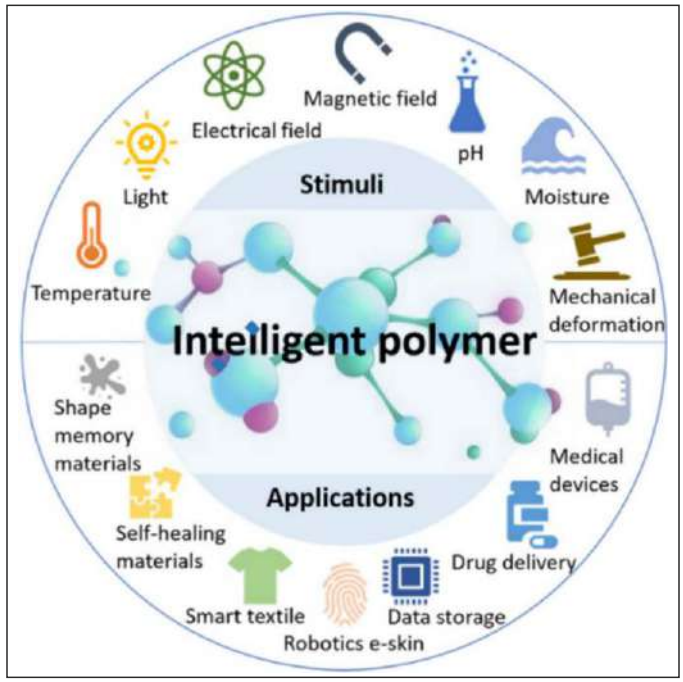
PBS (Polybutylene Succinate): Can be bio-based or petro-based; used for food packaging and films.

PHA/PLA Blends: Frequently used to increase durability while remaining compostable.

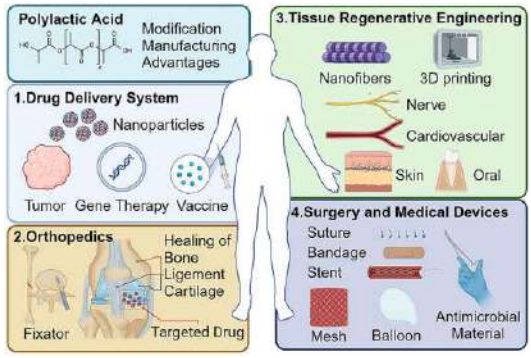


Rise of Smart & Sustainable Plastics :-

- Smart plastics, also known as intelligent or active plastics, are a type of plastic material engineered to respond to external stimuli like heat, light, or pressure.
- They are sophisticated materials with embedded sensors, actuators, and even data processing capabilities.
- This allows them to interact with their environment, monitor conditions, and potentially change their properties or behaviour in response.
- The term 'bioactive materials' was defined by Hench et al. (1971) as "a bioactive material is one that elicits a specific biological response at the interface of the material, which results in the formation of a bond between the tissues and the material."

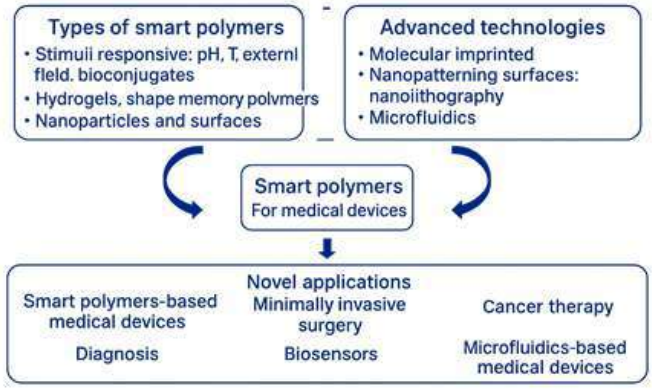


Bioplastics are increasingly used in the medical field for biocompatible, biodegradable, and sustainable applications, including drug delivery, tissue engineering, and temporary implants like stents or sutures. Common types include PLA, PCL, and PHA, which offer advantages like controlled resorption in the body, reducing the need for secondary surgeries.



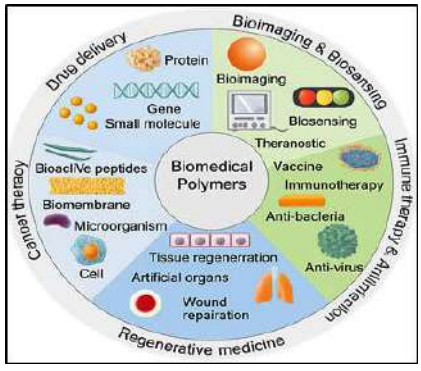
Here is a structured overview of smart polymers and their expanding role in medical device innovation.

This graphic emphasizes how the synergy between cutting edge polymer science and enabling technologies is driving a new generation of medical devices with improved responsiveness, adaptability, and therapeutic precision.



It highlights two foundational pillars that enable the development of these advanced materials:

1. **Types of Smart Polymers,** including stimuli responsive polymers (triggered by pH, temperature, or external fields), hydrogels, shape memory polymers, and nanoparticle based systems.
2. **Advanced Technologies** that enhance their functionality, such as molecular imprinting, nanopatterned surfaces using nanolithography, and microfluidics.



Conclusion & Key Takeaways :-

Transitioning to a **circular Medtech economy** requires a commitment to high value, affordable healthcare. By prioritizing innovative product design, responsible manufacturing, and re use strategies, the industry can safeguard supply chains, reduce environmental impact, and build a sustainable healthcare future.

FAST FACTS

The term plastic comes from the Greek word "plasticos", meaning capable of being molded or shaped. This property refers to the ability of these materials to be formed into a variety of shapes.Another commonly used term for plastics is polymers – also derived from Greek language where "poly" is many and "mer" is a unit or part. Therefore a material thant can be shaped in various forms and is composed of a long chain of many repeating units is defines as a plastic.

Press Release

Qosina and Informa Markets Launch Student Education Initiative to Empower the Next Generation of MedTech Engineers

RONKONKOMA, NY—January 21,2026— Building on more than four decades of collaboration, Qosina, a leading global supplier of OEM medical device components, and Informa Markets today announced the launch of a new Student Education Initiative designed to empower future medical technology engineers through hands-on industry exposure, professional networking and real-world learning opportunities.

The initiative introduces students to the medical device ecosystem by connecting academic learning with live industry environments, including leading manufacturing and medtech trade shows. Through curated educational programming, in-booth engagement, student-focused surveys and video interviews, the partnership highlights the critical role that quality components, trusted suppliers and professional relationships play in both successful academic projects and long-term careers.

"This initiative reflects Qosina's long-standing commitment to education and to the future of the medical device industry," said Lee Pochter, CEO of Qosina. "By working alongside Informa, we're helping students move beyond the classroom and into the real-world environments where innovation happens, showing them how supplier quality, industry knowledge and networking directly impact patient outcomes and career success."

The Student Education Initiative will be activated before, during and after key Informa Markets manufacturing events, including MD&M West taking place February 3-5, with touchpoints designed to maximize student engagement and insight. Planned activities include pre-show student surveys, in-booth educational signage announcements within student education tracks and on-site video interviews capturing student perspectives.

As part of the initiative, MD&M West 2026 will also feature Workforce Connect, a career panel and networking program connecting students with employers, including a session hosted in collaboration with Dr. P. K. Shukla, The Shah Family Endowed Chair in Innovativeness at Chapman University, and Tim Engel, President of the Society of Manufacturing Engineers (SME) – Los Angeles Chapter.

"Students are the future of manufacturing and medtech, and it's critical that they understand how the industry truly works," said Adrienne Zepeda, VP, Growth Portfolio Leader at Informa Markets – Manufacturing. "By partnering with Qosina, we're creating meaningful opportunities for students to engage directly with suppliers, engineers and industry leaders, helping them build confidence, professional skills and a clearer path from education to employment."

Together, Qosina and Informa aim to strengthen the bridge between education and industry—ensuring the next generation of medtech professionals is informed, connected and prepared to innovate.

About Qosina

Qosina is a leading global supplier of OEM single-use components to the medical and biopharmaceutical industries. With over 45 years of experience, Qosina offers one of the world's largest selections of stock components—including connectors, fittings, valves, tubing and other critical parts—to help companies accelerate innovation and reduce time to market. In addition to its extensive catalog, Qosina provides custom sourcing, molding and assembly solutions. Headquartered in Ronkonkoma, New York, with a European office in Milan, Italy, Qosina serves customers worldwide with a commitment to quality, compliance and innovation.

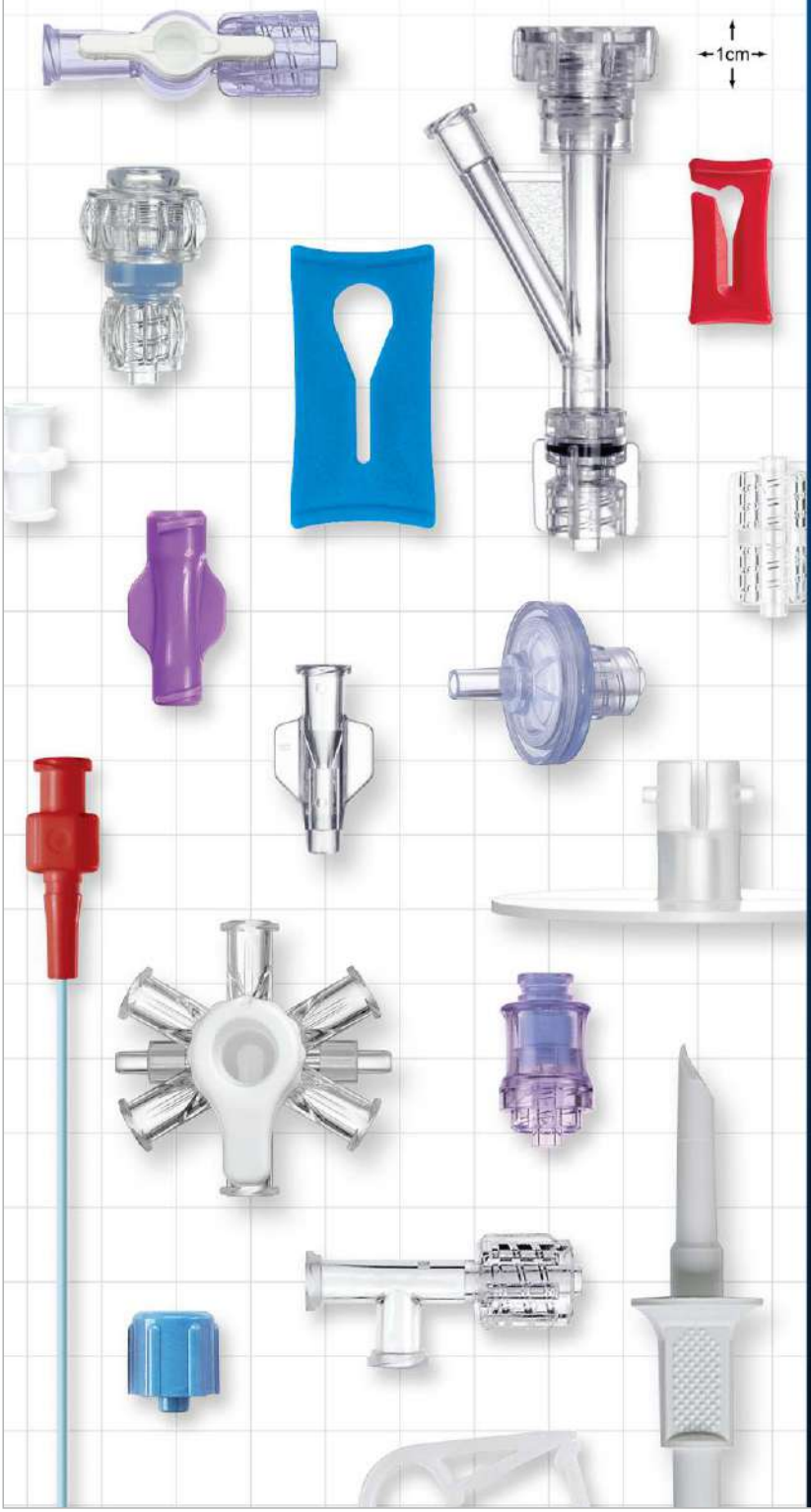
FAST FACTS

Improving Recyclability and Market Value

- Avoid multiple material types used within one product
- Avoid paper tapes or labels attached directly to products
- Avoid metalized plastics and paper/film packaging combinations
- Allow for the identification and removal of product residue
- Minimize the use of pigments in products

QOSINA

Thousands of Stock Components



For nearly 45 years,

Qosina has been a trusted partner to medical device engineers, providing thousands of in-stock components and innovative solutions to meet the industry's evolving needs. Qosina delivers high-quality components and practical support.

Serving diverse applications, Qosina's extensive product portfolio includes over 5,000 components across 25+ categories. With same-day shipping, flexible order quantities, and an ISO 8 Class 100,000 cleanroom for repackaging, Qosina ensures timely, customized solutions that meet your project's unique demands.

Whether you're in the design or development phase, Qosina is here to support you with practical, reliable solutions at every step.

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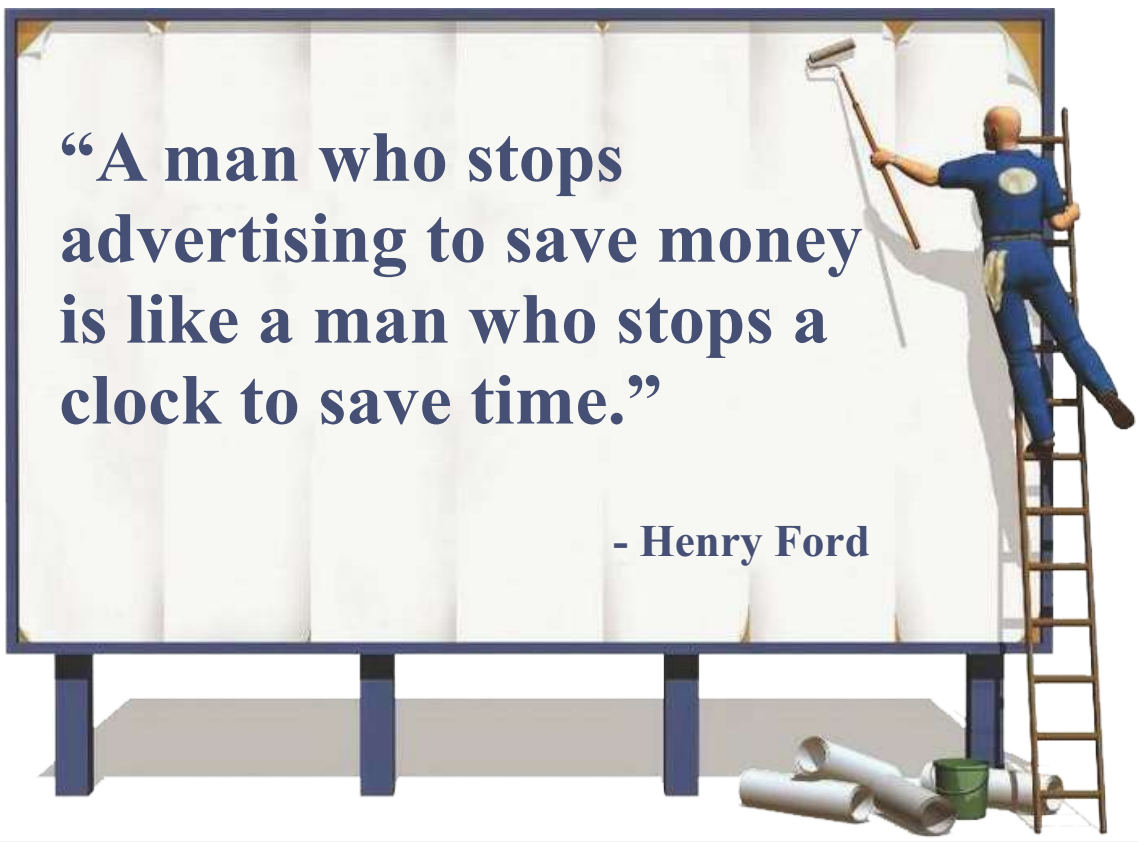

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January 2025 to December 2025

January-February 2025

March-April 2025

Target Readers
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Dr. R. A. Mashelkar
Former Director General
Council of Scientific & Industrial Research & Secretary, Government of India
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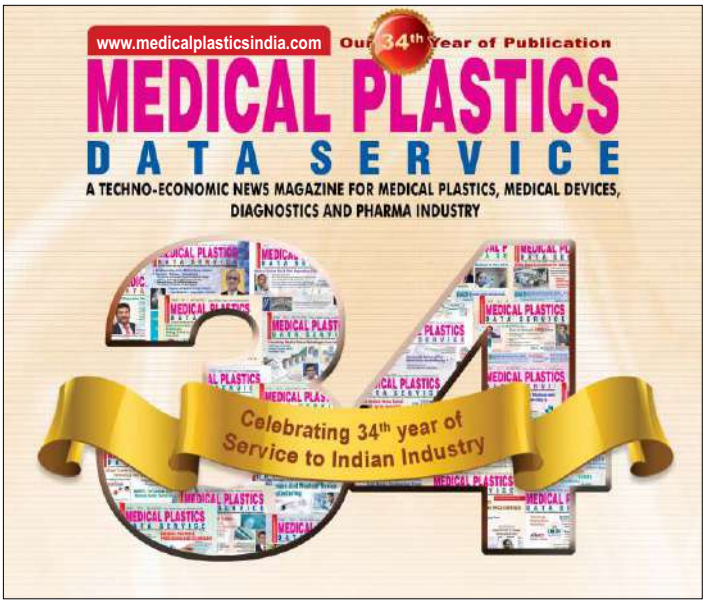

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Polytetrafluoroethylene (PTFE) in Medical Applications: Properties, Developments, and Clinical Relevance

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Application Development Centre-FP, SRF Ltd

Abstract
Polytetrafluoroethylene (PTFE) has played a foundational role in medical device engineering due to its biocompatibility, chemical inertness, and durability. Its clinical relevance has expanded from early vascular grafts to modern smart materials and drug eluting systems. Recent regulatory assessments continue to confirm its safety in medical applications.

1. Introduction

Polytetrafluoroethylene (PTFE) is one of the most influential synthetic polymers of the modern industrial and medical era. Discovered accidentally in 1938 by Dr. Roy J. Plunkett at DuPont, PTFE rapidly transitioned from a laboratory curiosity to a material of global significance due to its exceptional chemical stability, thermal resistance, and friction reducing characteristics [7]. Its commercial introduction as Teflon in 1945 marked the beginning of its widespread industrial use, catalyzing applications in aerospace, electronics, chemical processing, and later, the medical sector.

PTFE had emerged as a transformative material in medical technology, first being used in vascular grafts—a breakthrough that reshaped cardiovascular surgery [8]. Throughout the following decades, its role expanded into surgical tools, implantable devices, coatings, and diagnostic instrumentation. The development of expanded PTFE (ePTFE) further enhanced its functionality, introducing controlled porosity for better tissue integration and enabling new possibilities in reconstructive and regenerative medicine [8].

In the contemporary world, PTFE's unique combination of properties—chemical inertness, biocompatibility, hydrophobicity, and thermal stability—has made it indispensable across industries. Today, PTFE is integral to minimally invasive medical devices, high performance electronics, advanced manufacturing, and energy technologies. The medical industry, in particular, relies heavily on PTFE for catheters, stents, grafts, surgical implants, and microfluidic systems due to its low friction and long term stability [6].

Additionally, regulatory evaluations continue to solidify its place in modern healthcare. In 2025, the U.S. FDA reaffirmed that fluoropolymers such as PTFE remain safe for continued use in medical devices, following extensive review of clinical data and decades of real world performance [2]. With ongoing advancements in nanotechnology, biofunctional coatings, and smart materials, PTFE continues to evolve, maintaining its status as one of the most essential polymers shaping modern scientific and industrial progress [8].

Evolution of PTFE in Medicine:

Early Adoption (1960s–1980s)

PTFE's entry into vascular graft applications during the 1960s revolutionized cardiovascular surgery. Advances in the 1970–80s improved PTFE's porosity and biocompatibility, leading to ePTFE. [1]

Diversification (1990s–2010s)

PTFE use expanded to dental implants, orthopaedic components, surgical coatings, and microfluidic diagnostic devices, supported
by nanotechnology-driven surface engineering. [1]
Modern Innovations (2010s–present)
Recent developments include:

- PTFE composite biomaterials
- Drug eluting PTFE structures
- Surface biofunctionalization
- Nanostructured PTFE for regenerative medicine [1]

2. Material Properties Relevant to Medicine

2.1 Biocompatibility and Safety

PTFE is biologically inert and does not trigger inflammation or adverse tissue reactions. This quality makes it ideal for implants and long term medical devices [1].
The U.S. FDA further confirmed in 2025 that fluoropolymers, including PTFE, show no evidence of patient-care issues, reinforcing its necessity and continued use [2].

2.2 Chemical Resistance and Durability

PTFE maintains its structural integrity even when exposed to bodily fluids, chemicals, and aggressive substances used in hospitals. This ensures reliability in implants, catheter coatings, and surgical instruments [3].

2.3 Extremely Low Friction Surface

PTFE has one of the lowest friction coefficients of any solid material. This lubricity is essential for medical devices that must glide through the body [4]. PTFE enables smooth passage of catheters, guidewires, stents, etc. It also reduces irritation, while its non stick surface prevents tissue adhesion—important in wound dressings and surgical instruments. [5]

2.4 Porous ePTFE Enhances Tissue Integration

Expanded PTFE (ePTFE) has controlled porosity that supports tissue ingrowth, making it critical for vascular grafts, patches, and reconstructive implants [1]. It also enhances tissue integration and healing, especially in vascular grafts and reconstructive grafting.

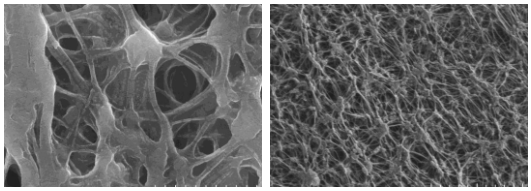

Fig-1, Porous structure of Expanded PTFE

2.5 High Thermal Stability Supporting Sterilization

PTFE withstands autoclaving, gamma irradiation, and other sterilization techniques without degradation. This makes it suitable for reusable surgical tools and diagnostic components [4]

2.6 Chemical and Biological Inertness

PTFE is highly resistant to bodily fluids and does not react with tissues, minimizing risks of inflammation or rejection—key requirements for implants and long term medical devices. [5]

3. Purification required in PTFE

Polytetrafluoroethylene (PTFE) does not naturally exist in a form suitable for medical devices. It must undergo a series of engineered processing steps to achieve the required purity, mechanical properties, porosity, biocompatibility, and shapes needed for implants, catheters, grafts, and diagnostic tools. The transformation from raw polymer to medical grade PTFE involves polymerization, purification, molding/extrusion, controlled expansion, and surface modification.

3.1 Polymerization and Raw Material Formation

PTFE originates from the polymerization of tetrafluoroethylene (TFE), where the TFE monomers link into long chains to form PTFE. This reaction was first observed during the accidental discovery in 1938, laying the foundation for controlled industrial synthesis today [1].

The polymerization process produces PTFE resin in forms such as:

- Fine powder
- Granular resin
- Aqueous dispersion

These grades then serve as feedstock for medical processing lines [4].

3.2. Purification to Meet Medical Grade Requirements

PTFE used in medical devices must meet extremely high purity standards to ensure biocompatibility, chemical stability, and long term safety when placed inside the human body. These requirements come from regulatory findings confirming the importance of fluoropolymers' safety and inertness in clinical environments [2], as well as the known biological inertia of PTFE essential for implants and long-term device use [3].

3.2.1. Removal of Residual Monomers and Processing Aids

PTFE is produced through polymerization of tetrafluoroethylene (TFE). After polymerization, the raw PTFE contains residual monomers, surfactants, catalysts, and emulsifiers, all of which must be removed to achieve medical-grade purity.

Key Purification Steps

- Thermal outgassing to evaporate and remove volatile monomers.
- Repeated washing and filtration to eliminate emulsifiers and polymerization residues.
- Vacuum drying to ensure no moisture or processing contaminants remain.

These steps are critical because PTFE's medical value comes from its non-reactive nature and resistance to bodily fluids, which depends entirely on proper purification [3].

3.2.2. Particle Purification and Size Control

Medical PTFE must have precisely controlled particle size and molecular weight to ensure predictable extrusion and molding behaviour.

Methods Used

- Mechanical sieving to ensure narrow particle size distribution.
- Centrifugal purification to remove ultra-fine particles and aggregates.
- Chemical neutrality testing confirming absence of reactive species.

These refinements ensure the mechanical reliability of PTFE medical products such as catheters and grafts, which depend on smooth extrusion and structural consistency. PTFE's beneficial properties, such as low friction used in catheters, rely on this precision [4].

3.2.3. Removal of Extractables and Leachables

Extractables and leachables refer to chemicals that may migrate from the material into the patient's body.

Purification Techniques

- Hot solvent extraction (using high purity alcohols).
- High-pressure deionized water flushing.
- Thermal vacuum cycling to drive off trace chemicals.

These steps are necessary because recent FDA reviews of PTFE medical devices confirm that patient safety is tied to ensuring no harmful substances leach out of fluoropolymer components [2].

3.2.4. Purification During ePTFE Production

Expanded PTFE (ePTFE), essential for vascular grafts and surgical implants, requires further purification during and after expansion.

Steps Include

- Controlled stretching to create microporosity.
- Complete removal of lubrication oils used during extrusion.
- High temperature sintering to stabilize structure.

The tissue integration ability of ePTFE, which makes it invaluable for grafts and patches, depends on achieving a clean, uniform porous structure free of residues [1].

3.2.5. Final Surface Cleaning and Biofunctional Preparation

Before being incorporated into medical devices, PTFE components undergo:

Final Cleaning Procedures

- Plasma cleaning to remove organic residues.
- Ultrapure water rinsing to remove particulates.
- Cleanroom drying and packaging to maintain sterility.

Recent developments in PTFE medical technology, including nano engineered and bio-functional surfaces, rely on the polymer being free of contaminants so that advanced coatings or drug eluting layers can bond properly [1].

3.2.6. Required Purity Levels for Medical Grade PTFE

Although exact values vary by manufacturer and device type, the industry generally follows stringent thresholds consistent with FDA expectations:

Parameter	Medical Grade Requirement
Residual monomers	Non detectable
Surfactants/emulsifiers	Non detectable or <1 ppm
Lubrication oils	0 ppm detectable
Particulates ≥10 µm	Very low (cleanroom standard)
Heavy metals	Below toxicological limits
Endotoxins	Below medical device regulatory limits

These purity controls align with the FDA's fluoropolymer safety review, which confirms PTFE remains safe when manufactured according to stringent purification and processing standards.

3.3. Forming PTFE into Medical Device Structures

3.3.1 Compression Molding & Sintering

PTFE powder can be molded and sintered into:

- Surgical instrument coatings
- Solid components
- Seals and gaskets

The high thermal stability of PTFE allows it to retain structural integrity through sintering, which is crucial for sterilizable products [3].

3.3.2 Paste Extrusion for Tubes & Catheter Liners

Medical grade PTFE tubes for catheters, guidewires, and vascular devices are produced through paste extrusion. This method creates:

- Ultra-thin, smooth-walled tubing
- Low-friction catheter liners

PTFE's lubricity is critical in minimizing friction and improving patient comfort. [3][5].

3.3.3 Film Stretching & Skiving

For wound dressings, membrane filters, and implantable patches:

- PTFE blocks are skived into thin films
- Films may be stretched to adjust porosity

This ensures a non-stick surface, reducing tissue adhesion during healing [5].

3.3.4 Expansion to Create ePTFE (Expanded PTFE)

A breakthrough was the development of expanded PTFE (ePTFE), which is produced by stretching PTFE under controlled heat and tension. This creates:

- A microporous structure
- Tunable pore sizes
- High flexibility
- Tissue integrative surfaces

ePTFE is widely used in vascular grafts, soft tissue patches, and reconstructive implants, where porosity promotes tissue ingrowth [2].

3.3.5 Surface Modification & Biofunctionalization

Modern medical applications require PTFE surfaces to perform specific biological functions. Techniques include:

- Plasma treatment to improve cell adhesion
- Chemical grafting for improved tissue compatibility
- Nanostructuring to mimic natural biological surfaces

Recent advances even include smart PTFE devices capable of controlled drug release and responsive behaviour in the body [2].

3.3.6 Quality Control and Regulatory Testing

Before PTFE can be used in medical devices, it undergoes:

- Biocompatibility testing
- Extractables and leachables analysis
- Mechanical integrity tests
- Long term stability evaluations

4. Clinical Applications of PTFE

4.1 Implantable Devices

4.1.1 Vascular Grafts

PTFE and ePTFE remain widely used in cardiovascular bypass and vascular reconstruction due to stability and hemocompatibility. [5]

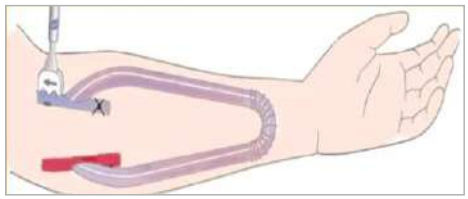

Fig-2, PTFE vascular Grafts in blood dialysis

4.1.2 Stents and Guidewires

PTFE is commonly used as a lubricious coating for cardiovascular and urological stents, supporting reduced tissue adhesion and improved delivery. [5]

Fig-3, PTFE guidewires

4.1.3 Orthopaedic and Dental Applications

PTFE composites are used in orthopaedic and dental reconstructive materials alongside PEEK and titanium-based systems. [5]

Fig-4, Guided bone regeneration using PTFE membrane

4.2 Interventional and Minimally Invasive Devices

4.2.1 Catheters

PTFE coatings are widely adopted for intravenous, urinary, and cardiovascular catheters due to its lubricity and patient comfort advantages. [5][6]

Fig-5, Guide catheters PTFE

4.2.2 Medical Tubing and Drains

PTFE serves as a durable, chemically resistant material for abdominal drains and chest tubes. [6]

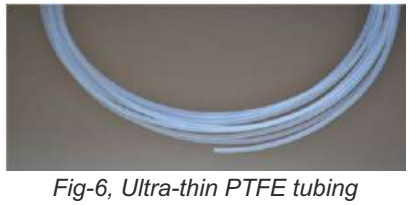

Fig-6, Ultra-thin PTFE tubing

4.3 Medical Instruments and Diagnostic Equipment

PTFE is used in:

- Surgical forceps, scalpels
- Syringe filters
- Mass spectrometer components
- Lab on chip microfluidic platforms [6]

5. Standards:

Standard	Purpose	Key Criteria Required
ISO 10993	Biological safety	No cytotoxicity, no irritation, no sensitization, no systemic toxicity, hemocompatibility [10]
ISO 13485	Quality management	Controlled manufacturing, traceability, contamination control [10]
FDA Regulations	Device & material safety	Biocompatibility, no harmful leachables, material master file, safety validation [2]
ASTM Standards	Mechanical & chemical performance	Tensile strength (D638), biological test method guidance (F748), mechanical reliability [7]
Industry Purity Standards	Medical-specific purity	Zero residuals, minimal particulates, high sterilization resistance [2][10]

6. Market Landscape

The global medical PTFE market was worth $3.9B in 2023 and is expected to reach $7.0B by 2033. Surgical applications account for 45% of usage, followed by cardiovascular (30%) and orthopedic (25%). [4]

7. Regulatory and Safety Assessment

In 2025, the U.S. FDA concluded that fluoropolymers including PTFE remain safe for medical device use, based on analysis of 1,800 healthcare providers and 1,750+ scientific publications. [2]

The U.S. FDA has reaffirmed PTFE's safety in medical devices after reviewing extensive clinical and laboratory data, ensuring it remains an approved and trusted material. Additionally, FDA's PTFE Material Safety Summary outlines decades of clinical evidence affirming PTFE's biocompatibility and safety profile. [3]

8. Future Directions

8.1. Shift Toward Smart, Drug Eluting, and Bioactive PTFE Systems

Smart PTFE materials, including drug eluting PTFE, biofunctionalized surfaces, and responsive coatings that adapt biologically after implantation. These developments aim to reduce thrombosis, enhance endothelialisation, and enable long term controlled drug delivery. [11], [15], [30]

8.2. Rise of Electrospun and Double Expanded PTFE for Next Gen Grafts

Electrospun PTFE membranes show superior hemocompatibility, while double – expanded PTFE (dePTFE) with hydrogel layers significantly improves compliance, burst pressure, and endothelialization—all essential for small diameter vascular grafts. [16], [15]

8.3. Industrial Scale Precision Processing Will Enable Uniform ePTFE Devices

New biaxial stretching techniques solve traditional issues of uneven thickness and porosity variation, allowing reliable industrial scale fabrication of uniform ePTFE membranes with validated biological performance. [14]

8.4. Regulatory Endorsement Supports Continued PTFE Use

FDA's 2025 evaluation concludes PTFE remains safe, irreplaceable, and critical for devices such as stents, grafts, pacemakers, and guidewires. This assures strong future adoption with innovations centered on surface and drug delivery enhancements rather than replacement. [12], [13]

8.5. Patents Reveal Next Generation Catheter Liners and Ultra Thin PTFE Structures

- Tie layer coated ePTFE liners for improved adhesion and lubricity
- Stretched PTFE liners with greater toughness and controlled friction
- Ultra thin (<0.001") PTFE catheter liners for deeper vascular navigation

These enable future catheters with higher flexibility, lower deployment force, and better navigability. [21], [22], [20]

8.6. Long Term Calcification

Studies highlight the need for anti-fouling coatings, endothelialisation strategies, and calcification resistant PTFE for long term graft success. Future work includes integrating biological layers and nanostructured surfaces to combat these issues. [17], [18]

8.7. Advanced Mechanical Modelling Will Accelerate Device Development

A new anisotropic constitutive model for ePTFE enables precise surgical simulations and accelerates the design of vascular grafts and stent grafts. Such models will integrate deeply in regulatory submissions and design cycles. [19]

8.8. MRI Safety Evidence Will Improve Clinical Use of PTFE Based Implants

Updated MRI guidance confirms safe imaging of PTFE covered grafts and stents at 3T, enabling seamless clinical workflows. This will encourage broader adoption of PTFE covered devices in high risk cardiovascular patients. [23]

8.9. Nanostructuring and Hybrid Composites Emerging as Surface Enhancement Tools

Nanostructured interfaces, supramolecular surface assemblies, and carbon/graphene composite enhancements are gaining interest for improving PTFE's biological interactions, wear properties, and cell responses. [25], [26]

8.10. Electrospun Stent Grafts and Drug Eluting ePTFE

Companies are actively commercializing electrospun PTFE membranes and launching drug eluting ePTFE stent grafts with clinical trials underway (DEScover Trial). This demonstrates a rapid shift from R&D to marketed advanced PTFE vascular devices. [28], [29], [30]

9. Conclusion

PTFE continues to be indispensable in modern medicine, supported by its biocompatibility, stability, and diverse applicability. With ongoing advances and regulatory validation, PTFE is set to remain a critical component in future medical device innovation.

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FAST FACTS

Benefits of Pre-Material Selection for Medical Devices

- Preselection is a valuable tool for helping product designers find materials that comply with safety standards.
- It greatly reduces time and cost associated with final end product testing, certification and development thereby speeding time to market. Also helps manufacturers maintain a competitive advantage in turnaround time.
- Allows product designers to determine the function of a component in the end product application.
- Selection is based on polymers meeting environmental and mechanical/physical requirements.

Understanding Thermoplastic Polyurethane: An Adaptable Material for Medical Devices

Surendra Kumar Pandey
Technical Marketing Manager, Lubrizol

Who is Lubrizol? Our Scale, Science, and Focus

Lubrizol's science is embedded in products people rely on every day—from personal and home care to transportation, electronics, and, importantly, healthcare. Our advanced materials enable performance in everything from medical catheters and dental aligners to the electric vehicles that support modern healthcare logistics. This breadth isn't incidental—it reflects deep, cross disciplinary expertise in chemistry, formulation, and application development, all of which directly strengthen the medical devices we help bring to market.

For nearly 100 years, Lubrizol has been at the forefront of innovation, delivering breakthrough solutions that enhance everyday life and make the modern world work better. With a heritage dating back to 1928, we've built a robust foundation of thousands of patents and an extensive product portfolio that continuously fuels our innovation pipeline. For medical device partners, this translates into unwavering reliability, strong regulatory discipline, and long term investment in the next generation of materials that enhance patient outcomes and elevate device performance.

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Thermoplastic Polyurethane (TPU) Fundamentals: Chemistry and Versatility

TPU is a segmented block copolymer built from hard segments—formed by diisocyanates and chain extenders—that provide strength, and soft segments—polyols—that deliver flexibility. This hard–soft architecture creates reversible crosslinks, giving TPU its hallmark combination of elasticity, toughness, and processability.

This chemistry can be tuned across polyether and polyester backbones to dial in properties like hydrolysis resistance, oxidative stability, and barrier performance. From a processing standpoint, TPU is thermoplastic—so you can extrude, injection mold, solvent cast, dip, spin, coat, 3D print, bond, or blow it. That breadth of processing methods empowers design teams to iterate quickly, integrate features, and reduce assemblies.

Is TPU the Right Material? Decision Criteria

Selecting TPU starts with the use case: the device's function and required properties; type and duration of body contact; mechanical profile—tensile, tear, kink resistance; chemical and thermal resistance; sterilization route; processing method; optical requirements; and whether you need radio-opacity.

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Why Medical TPU from Lubrizol

A medical grade TPU from Lubrizol is more than a material—it's a quality and regulatory partnership. You benefit from ISO 9001 manufacturing, strict change control processes, product integrity risk management, and strong medical device regulatory support backed by biocompatibility expertise and long term supply continuity planning.

TPU outperforms silicone in catheter and tubing applications with higher strength, thinner wall capability, and superior burst performance. TPU's unique softening behavior is a clinical advantage: stiffer at room temperature for trackability and placement and softening at body temperature to enhance patient comfort. As a thermoplastic with high melt strength, TPU also enables efficient secondary operations like tipping, reflow, thermal forming, and integrated features.

And with Lubrizol's customization capabilities—from hardness and clarity to lubricity, radiopacity, and more—you get a tailored TPU solution engineered to match your device's exact performance needs.

Lubrizol's Medical TPU Portfolio

Lubrizol's families cover the performance envelope required by today's devices:

- Pellethane®, Tecoflex®, Tecothane® TPU: Workhorse polyether grades for peripheral vascular and gastric

catheters—combining strength at thin walls, easy colorability for identification, patient-comfort softening, and compatibility with radiopacifiers for X-ray visibility.

- Isoplast® TPU: Aromatic TPU for high tensile and impact strength, dimensional stability, optical clarity, and excellent chemical resistance—ideal when solvents, lipids, or aggressive disinfectants are in play.
- Film-grade TPUs: Shore A aromatic polyether TPUs for IV dressings, wound-care and barrier films where breathability, conformability, and extrusion consistency are critical.

This portfolio allows engineers to choose the optimal balance of softness, resilience, clarity, chemical resistance, and processability for each component.

Latest Innovation in Medical TPU: Tolerathane™ TPU

Innovation is key to Lubrizol, through our strong backing of R&D we have introduced our newest offering for 2026.

For long-term implantable, Lubrizol introduced Tolerathane™—a new thermoplastic material designed exclusively for implanted medical devices. It delivers boosted biostability—superior tolerance to oxidative and hydrolytic attack—without sacrificing softness. Crucially, it maintains mechanical integrity at the softest durometers and scales on standard thermoplastic processes, enabling customization and fine-tuned performance.

Where does this matter? Think neuromodulation and cardiac pacing leads, structural heart implants, percutaneous catheters and cables, and implanted textiles. In each of these, designers are balancing chronic durability with flexible, low-profile constructions; Tolerathane opens new design space by coupling softness and strength with improved long-term stability.

India and US Market Relevance

India's MedTech industry is rapidly scaling, driving demand for high performance polymers that meet global standards while supporting local manufacturing. Lubrizol's upcoming Tamil Nadu facility brings precision TPU and advanced extrusion capabilities—such as tri layers, braiding, and balloon tubing—closer to Indian OEMs and multinational device makers. This local presence shortens lead times, reduces logistics risks, and accelerates validation.

Globally, Lubrizol's network of R&D centers, silicone and thermoplastic platforms, and device design hubs enables rapid prototyping in one region and seamless manufacturing scale up in another—all while maintaining consistent specifications, quality systems, and change controls.

Putting It All Together: What This Means for OEMs

- Faster concept-to-clinic: TPU's thermoplastic nature and Lubrizol's extrusion, molding, and secondary processes accelerate iteration.
- Risk reduction: Proven medical-grade governance—change control, audits, and biocompatibility support—stabilizes regulatory pathways.
- Performance tuning: From Pellethane®, Tecoflex®, Tecothane® to Isoplast® and Tolerathane™, you can tune for flow, kink resistance, clarity, chemical resistance, or chronic stability—within one partner ecosystem.
- Global-local execution: Design where it makes sense; manufacture where it's most efficient—leveraging Tamil Nadu and our global footprint.

Summary & Closing

Thermoplastic Polyurethane (TPU) is one of the most versatile material platforms used in modern medical devices. With nearly a century of materials science expertise, Lubrizol offers end to end medical capabilities and an industry leading TPU portfolio—ranging from reliable, proven catheter grades to advanced implantable solutions like next generation Tolerathane.

If you are developing a vascular access device, structural heart component, neurostimulation system, or an advanced wound care platform, partnering early can make a significant difference. Lubrizol can support you through material grade selection, device design considerations, component development, sterilization and process validation, and scalable manufacturing—both locally and globally.

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Note: This transcript aligns with content presented at the Medical Plastics Conference, Plastindia 2026, and the Lubrizol medical TPU portfolio overview.

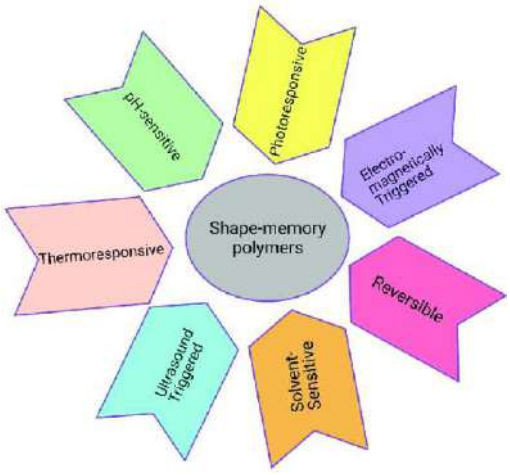
Disclaimer: "The author of this article serves as the Technical Sales Manager at Lubrizol Advanced Materials India Private Limited. The views and opinions expressed herein are solely those of the author and do not necessarily reflect the official policies or positions of Lubrizol or its affiliates."

Shape Memory Polymer Market Trends

These polymers (like shape-memory alloys) will "remember" their original shape when deformed, and flip back to the initial shape when exposed to an external stimulus.

The stimuli may be an electric field, light, changes in pH-value, or as most commonly, changes in temperature.

Due to the shape memory effect, the medical devices based on SMP can be implanted into body through minimally invasive surgery in contraction or folded state and recovered to their requisite original shapes at target position.



The global shape memory polymer market size was estimated at USD 927.66 million in 2022 and is expected to grow at a compound annual growth rate (CAGR) of 23.35% from 2023 to 2030. The growing use of shape-memory polymers (SMPs) in the medical industry is projected to drive the growth of the market. The U.S. market has experienced strong growth in recent years, with several factors leading to this expansion. The advancement and increase in R&D activities in numerous sectors in the U.S. are expected to drive the growth of the U.S. market. Shape-memory polymers are used in the aerospace and defense sectors in the U.S. for various applications, such as morphing aircraft components and self-healing materials.

The global shape memory polymer (SMP) market for medical devices is experiencing rapid growth, projected to exceed USD 5 billion by 2030, driven by the demand for minimally invasive, biocompatible, and intelligent, self-repairing materials. Key applications include smart stents, orthopedic scaffolds, sutures, and surgical tools that offer enhanced control and reduced trauma compared to traditional materials.

Market Growth and Trends

- **Key Drivers:** The surge is fueled by an aging population, rising demand for minimally invasive surgeries, and advancements in biomedical engineering.
- **Dominant Materials:** Polyurethane (PU) holds a dominant position, accounting for over 47% of the market due to its versatility and biocompatibility.
- **Medical Sector Dominance:** The biomedical segment is a major contributor, with SMPs allowing for devices that adapt to the individual shape of blood vessels or tissue.

Key Medical Applications

- **Cardiovascular Devices:** SMP stents, endovascular devices, and embolization devices that trigger at body temperature.
- **Orthopedic and Surgical Tools:** Self-tightening sutures, bone fixation, and tissue scaffolds.
- **Controlled Drug Delivery:** Smart polymers designed to release medication based on environmental trigger

Key Market Players and Regions

- **Top Players:** Major companies involved in the development of shape memory materials include BASF SECovestro AGEvonik Industries AGSMP Technologies Inc, and Cornerstone Research Group Inc.
- **Regional Dominance:** North America currently holds the largest market share (approx. 38.5%) due to high demand for advanced medical technologies and significant R&D.

The market is shifting toward materials that offer higher biocompatibility, precise recovery accuracy, and improved responsiveness, making them crucial for next-generation, patient-specific medical solutions.

https://www.grandviewresearch.com/industry-analysis/shape-memory-polymers-market-report

Malaysia Medical Devices Market

Mr. Amit Dave
M. Pharm, MBA
Former CEO – Brazil operations/ Vice President Export - Zydus Cadila Claris Lifesciences

Country Profile

Malaysia is composed of two land parts, which are not in contact with each other - West Malaysia (above Singapore) and East Malaysia (above Indonesia), with the South China Sea between them. Kuala Lumpur (KL), the capital city, is in West Malaysia (but the administrative centre is a new town called Putrajaya, about 25 km south of KL). Malaysia's population is 3.4 cr, and almost 80% of this is in West Malaysia. 75% population resides in urban centres. 64% population follows Islam (the official religion of the country) while about 6% are Hindus. The nation is quite young, as 70% population is below 44 years of age. Now the economy is highly diversified and is the fastest-growing in the region. Besides rubber, palm oil, petroleum, natural gas and commercial hardwoods are the main products for export. Exports contribute to over 60% of GDP. Electronics and electrical products also make up a large share of exports. China, the U.S., and Singapore are the major partners for trade. Kuala Lumpur has emerged as a regional financial hub. The tourism industry is a key contributor to employment.

Educated low-cost labour is a strong plus point of the country. NDP (New Development Policy) aims at a balance between economic growth and wealth redistribution, as well as to bring local Malays into focus. Privatisation of many public-sector activities like railways, airlines, telecommunications, and electricity companies is underway. The economy is projected to maintain steady growth because of its robust industrial base, strong trade links, and rising domestic consumption. Political instability and activities of the lower end in the value chain in manufacturing, however, are challenges.

Medical Device Registration in Malaysia

The Medical Device Act 2012 stipulates that MDA (Medical Device Authority under the Ministry of Health Malaysia (MoHM) is authorised to grant registrations for medical devices. The process of registration follows the ASEAN Medical Devices Directive (AMDD) standards. The classification of medical devices in Malaysia follows the standard four classes based on the risk involved -

- Class A (low risk)
- Class B (low-medium risk)
- Class C (medium-high risk)
- Class D (high risk)

Additionally, for combination devices, a fifth category is also prescribed. For Class A devices, review time is two months, while for other categories, it is 6 to 8 months. Applications are to be submitted through the MEDCAST system, which is online. Manufacturers and importers need an “establishment license”. Manufacturers with no local presence in Malaysia are also required to appoint a Malaysia Authorised Representative. Submissions are supposed to be made by this local company that acts as the license holder (Malaysia Authorised Holder, or MAH).

One very important point is the involvement of CAB. All the applications need a Certificate of Conformity from a Conformity Assessment Body (CAB) that is authorised by the ministry. However, medical devices with approval from specified reference countries are allowed a window of up to 5 years to submit this Certificate of Conformity under the fast-track system. Such applications will be issued a provisional registration for this period.

Highlights

- High dependence on Imports for higher-level products
- Predictable registration with documentation in English
- Outsourcing possibilities for gloves and catheters

Licenses are transferable from one Authorised Representative (AR) to another through an application on the same MEDCAST online portal, with all the necessary documents, along with a Termination Letter of the last AR and a Letter of Authorisation from the new AR.

The following Government website for medical device registration gives a very detailed description of the whole process in English, along with many links leading to the relevant subjects.

https://portal.mda.gov.my/index.php/industry/medical-device-registration/medical-device-registration-information

Medical Devices Market

Broad scenario:

More than 90% requirement of Malaysia's medical device market is catered by Imports and thus the export opportunity for medical devices is huge. The government's centralised procurement system is also a big opportunity. As a rubber manufacturer, Malaysia supplies 60% of the world's medical gloves and 80% of the world's rubber catheters. There can be an outsourcing opportunity for such products from Malaysia, on the other hand. Recent high tariffs on Chinese-produced rubber gloves by the USA for medical and surgical use are expected to help the manufacturers in Malaysia. The healthcare system of the country has two parts: a government-sponsored universal healthcare system and a high-quality private healthcare system with patients' payments or private insurance reimbursements. This private sector treatment is expected to grow with economic growth and rising incomes. Malaysia boasts one of the lowest medical fees in the world, which is about 40% lower than in the US and UK. This, along with the special visa systems for the elderly, makes Malaysia a potential health service hub, adding to the device market. The Government's efforts are to support products with high value and complexity instead of lower-end products in the value chain, which are labour-intensive. Some well-known Multinational Corporations have their APAC regional headquarters in Malaysia, along with research centres. The medical device sector is a priority sector for the Government, and ambitious Indian players may evaluate the joint venture possibilities in Malaysia.

Market in numbers:

Market size -The Malaysian medical device market size is estimated to be about 2.5 bn USD
Market growth rate – The medical device market growth rate is about 7.5% pa.
Import contribution - Imports make up around 95% of its need for medical devices for domestic consumption of medical devices.
Hospital bed density – For Malaysia, this is 2 beds/1,000 population (India Hospital bed density is 1.6 beds/1,000 population, both 2021 estimates)

Opportunities and Challenges

Fairly large and fast-growing market, along with heavy import dependence, makes Malaysia a good opportunity. Clear and predictable regulatory process, again, is a positive. English as a language of commerce also helps. Geographical distance being less adds to the ease of exploring this market.

Dr Rajeev Singh Raghuvanshi's Reappointment As Drugs Controller (India)

Synopsis

Dr Rajeev Singh Raghuvanshi will continue as Drugs Controller (India) at CDSCO. His reappointment is on a contract basis for one year starting March 1, 2026. This decision follows a proposal from the Department of Health and Family Welfare. Dr Raghuvanshi heads the CDSCO, responsible for drug quality and new drug approvals.

The Appointments Committee of the Cabinet has approved the reappointment of Dr Rajeev Singh Raghuvanshi as Drugs Controller (India) at the Central Drugs Standard Control Organisation (CDSCO). The decision follows a proposal from the Department of Health and Family Welfare.

According to an official notification issued by the Ministry of Personnel, Public Grievances and Pensions, Department of Personnel and Training, Dr Raghuvanshi will continue in his role on a contractual basis for one year from 1 March 2026.

"The Appointments Committee of the Cabinet has approved the proposal of the Department of Health and Family Welfare for the re-employment of Dr. Rajeev Singh Raghuvanshi as Drugs Controller (India), Central Drugs Standard Control Organization (CDSCO) on a contract basis for a further period of one year w.e.f. 01.03.2026, or till the appointment of a regular incumbent to the post, or until further orders, whichever is the earliest, by keeping the Recruitment Rules (RRs) for the post in abeyance," ..

The DCGI heads the Central Drugs Standard Control Organisation (CDSCO)which is responsible for ensuring quality drugs supply across the country. It also has authority to give approval to new drugs and regulating clinical trials.

Dr Raghuvanshi had joined the IPC as secretary-cum-scientific director on February 16, 2021.

Read more at:
https://economictimes.indiatimes.com/industry/healthcare/biotech/pharmaceuticals/acc-clears-dr-rajeev-singh-raghuvanshis-reappointment-as-drugs-controller-india/articleshow/128888994.cms?utm_source=contentofinterest&utm_medium=text&utm_campaign=cppst

AiMeD Welcomes CDSCO's Initiative To Boost Drug Factory Inspections via QCI-NABCB Accredited Bodies

"The Central Drugs Standard Control Organisation's (CDSCO) decision to enhance factory inspections for drug regulation compliance by engaging QCI's NABCB-accredited certification bodies is a commendable step toward integrating third-party certification.

Medical devices set this precedent, and it's high time Class C & D devices follow suit—as long recommended by the Association of Indian Medical Device Industry (AiMeD)—moving beyond a drug-centric approach.

For true success, however, notified bodies' work must be sample-supervised by regulators and NABCB, with regular feedback from stakeholders."

ICMR Launches "Medical Innovations Patent Mitra" to Support Biomedical Innovations

New Delhi, [8th March 2025] – In a significant move towards enhancing India's healthcare innovation ecosystem, the Indian Council of Medical Research (ICMR) has launched the Medical Innovations Patent Mitra initiative during the International Symposium on Health Technology Assessment (ISHTA). This program, developed under the guidance of NITI Aayog and in partnership with the Department of Pharmaceuticals (DoP), is supported by the Department for Promotion of Industry and Internal Trade (DPIIT). It aims to provide end-to end guidance and handholding support to innovators for patent filings and technology transfer of medical innovations to industry. The launch was followed by a panel discussion that brought together bureaucrats, industry leaders, investors, and public health experts to explore the challenges, opportunities, and strategies for enhancing patent filing and technology transfer in the context of translational research and medical innovation.

The Hon'ble Minister of Health and Family Welfare, Shri J.P. Nadda, launched this pioneering initiative. He said, "Medical innovation Patent Mitra is a testament of ICMR's commitment to advancing medical innovation. With the launch the launch of this initiative, our country is taking significant lead towards supporting our innovators. This platform will ensure that the ground breaking work done by our scientists & researchers is protected through patent and made available to public through seamless technology transfer. This visionary effort propels India towards the attaining the goal of Viksit Bharat."

Dr. Paul emphasized on the significance of the Patent Mitra initiative in directly contributing to the goals of Ayushman Bharat, ensuring that innovative technologies developed in India are reached in every corner of the country. Stressing on the need for building a self-reliant Innovation Ecosystem in the country, he stated, "India's journey towards becoming a self-reliant nation rests on our ability to innovate within our own borders. Through Medical Innovation Patent Mitra, we are creating an environment

where indigenous innovations in the biomedical field are not only encouraged but effectively protected, paving the way for a self-sustaining healthcare ecosystem."

For more information on the Medical Innovations Patent Mitra, visit patentmitra.icmr.org.in.

About ICMR: The Indian Council of Medical Research (ICMR), New Delhi, is the apex body in India for the formulation, coordination, and promotion of biomedical research. With a mission to improve health outcomes in India, ICMR plays a key role in fostering innovation and research that addresses critical public health challenges.

Contacts Dr. Suchita Markan In-Charge, Innovation & Translation Research (ITR) Unit, Scientist-E & Mission In-Charge, Medical Device and Diagnostics Mission Secretariat (MDMS), Division of Development Research, Indian Council of Medical Research Email: suchita.markan@icmr.gov.in

Medical Devices Sector Hopes India-EU FTA To Be Beneficial To The Industry

Even as the India-European Union Free Trade Agreement (India-EU FTA), announced by India and European Union on January 27, is expected to eliminate tariffs of up to 6.7% across 99.1% trade lines, enabling cost-competitive entry in European markets for medical devices and testing instruments. The domestic medical devices industry has now expressed hope that the FTA would ensure level playing field for the domestic manufacturers and act as a catalyst for exports and innovation, while the research-based firms expect that it may help European companies to explore local manufacturing and R&D.

According to the ministry of commerce, India's medical instruments, appliances, and vital supplies built on cutting-edge manufacturing, innovation, and skilled talent are set for a quantum leap in the EU, following the FTA. The FTA enables preferential market access and unlocks opportunities in the $572.3 billion EU pharmaceutical and medical devices market.

"Tariffs of up to 6.7% eliminated across 99.1% of trade lines, enabling cost-competitive entry in European markets for lenses, spectacles, medical devices, measuring and testing instruments," while briefing the sector-wise gains under the FTA.

Rajiv Nath, forum coordinator, Association of Indian Medical Device Industry (AiMeD), said, "The India–EU FTA must ensure a level playing field for India's medical device manufacturers. With fair regulatory alignment and safeguards against predatory imports, especially from third countries, this agreement can unlock high-value collaboration, boost domestic manufacturing, and support India's ambition to become a top-five global MedTech hub".

He said that the goal should be mutual growth anchored in quality, transparency, and patient safety under a Mutual Recognition Agreement based on common ISO standards. AiMeD is looking forward to reviewing the fine print and the follow-on cooperation discussions.

Jatin Mahajan, president, Association of Diagnostics Manufacturers of India (ADMI), said that the Association views this agreement as a catalyst for exports, innovation, and global leadership for India's diagnostics companies.

Pavan Choudary, chairman, Medical Technology Association of India (MTaI), said, "We congratulate India and the European Union on concluding this landmark agreement, which is expected to open a new chapter in healthcare cooperation - where success will be measured not only in GDP, but in lives improved and saved".

If the fine print is in line with the announcements made, this FTA will enable India to strengthen its role as a reliable, innovation-driven partner by expanding exports of medical textiles, surgical instruments and disposables which India specializes in.

"European companies in India are hoping to benefit from lower duties, stronger participation in public procurement, and greater incentives for local manufacturing and R&D. Most importantly for patients, any eventual tariff reductions on medical devices should help improve affordability and access to advanced therapies, making this agreement a potential example of how ethical and equitable trade can reinforce health systems on both sides," added Choudary.

Elaborating ADMI's stand, Mahajan said, "The conclusion of the India–EU Free Trade Agreement marks a defining moment for India's diagnostics and in-vitro diagnostics industry. With preferential access for over 99% of Indian exports to the European Union, the FTA significantly strengthens the global competitiveness of Indian IVD manufacturers, particularly those driven by innovation, quality manufacturing, and regulatory compliance".

For the Indian IVD sector, the agreement goes beyond tariff liberalisation. Greater regulatory cooperation, transparency on technical barriers to trade, and streamlined customs and SPS procedures will help reduce the long-standing non-tariff challenges that diagnostic exporters face in EU markets. This creates a more predictable, rules-based environment for Indian companies to scale exports of rapid tests, ELISA, CLIA platforms, reagents, and diagnostic instruments.

Importantly, the FTA aligns strongly with the 'Make in India' vision by enabling Indian diagnostics manufacturers, including MSMEs, to integrate deeper into European value chains while continuing to invest in R&D, quality systems, and global certifications. As demand for reliable, affordable, and scalable diagnostics rises globally, the India–EU FTA positions Indian IVD companies as trusted partners in strengthening healthcare systems across Europe, opined Mahajan.

India and the European Union have on January 27, jointly announced the conclusion of the India-EU FTA, referred to as the 'mother of all deals', at the 16th India–EU Summit, held during the visit of the European leaders to India.

The European Union is India's one of the largest trading partners, with bilateral trade in goods and services growing steadily over the years. In 2024–25, India's bilateral trade in goods with the EU stood at Rs. 11.5 lakh crore ($136.54 billion) with exports worth Rs. 6.4 lakh crore ($75.85 billion) and imports amounting to Rs. 5.1 lakh crore ($60.68 billion). India-EU trade in services reached Rs. 7.2 lakh crore ($83.10 billion) in 2024.

https://www.pharmabiz.com/NewsDetails.aspx?aid=183856&sid=1

" MEDICAL PLASTICS DATA SERVICE" RECEIVES 16 TH MT INDIA HEALTHCARE AWARD 2026 AS "MOST PROMISING COMPANY IN TRAINING & CAPACITY BUILDING"

The 16th MT India Healthcare Awards 2026 concluded successfully on Jan. 30,2026 at the iconic Bharat Mandapam, Pragati Maidan, New Delhi, emerging as one of India's most authorative and internationally aligned healthcare recognition platforms. Presented by Medgate Today International Magazine, in association with Medical Fair India and Medicare Asia, the Awards ceremony unfolded on a grand scale with distinguished participation from India and overseas, rearming India's growing stature in global healthcare leadership.

Hosted on a world-class stage and attended by policy makers, eminent clinicians, hospital leaders, global industry captains, researchers and international dignitaries from Germany, the event went beyond celebration – positioning itself as a convergence of purpose, policy and progress. The awards honoured excellence across Doctors, Hospitals, Individual Personalities and organizations, recognizing contributions that are shaping resilient, ethical and future-ready healthcare systems.

Looking to 33 years of Service to the Indian Medical Devices and Medical Plastics Industry, the Grand Jury Panel awarded "MEDICAL PLASTICS DATA SERVICE" The Title of "Most Promising Company In Training & Capacity Building".

Fake ISO Certificates Claiming Safety And Quality Of Medical Devices Need To Be Verified: Experts

Experts have cautioned that fake International Organization for Standardization (ISO) certificates claiming safety and quality of medical devices need to be verified by the private and government hospital procurement and purchasing agencies in India. It has been learnt that cases of fake certificates have been reported by government healthcare institutions and agencies running healthcare schemes in India in the past few years.

"This has been happening due to lack of awareness around verification of these certificates and associated accreditation systems globally. ISO 9001 certificate for any sector including Pharma and Ayush or ISO 13485 certificate for medical devices can be verified at https://www.iafcertsearch.org/. These fake certificates are issued by certifying agencies not accredited under the international system operated by International Accreditation Forum (IAF) which is now known as Global Accreditation Cooperation Incorporated (GACI). It maintains a global database of certificates for some of the ISO standards including ISO 9001 and ISO 13485 which are extensively sought in the healthcare sector," informs Anil Jauhri, former CEO, National Accreditation Board for Certification Bodies (NABCB).

IAF CertSearch is the only global platform backed by the IAF, accreditation bodies, and certification bodies. It enables industry, regulators, and governments to verify some specific ISO certifications quickly and accurately.

From January 1, 2026, a new, single international accreditation organisation, GACI, has been established to bring together the work of the International Laboratory Accreditation Cooperation (ILAC) and the International Accreditation Forum (IAF). The formation of GACI will reduce duplication of efforts, harmonise accreditation policies and procedures and enable more consistent application of standards across sectors and borders.

There is a continuing risk of fake certificates on product quality flooding Indian medical devices market despite proper regulatory regime in place. A new medical device licensing regime- new Medical Device Rules (MDR)- 2017 has been implemented since October 1, 2023. While MDR, 2017 does not require ISO 13485 certificates and has instead prescribed its own quality management systems (QMS) vide Schedule 5, many manufacturers still go for ISO 13485 for its market value especially in global markets.

"Since the risk of fake certificates in India remains very high across sectors including for medical devices, the buyers or hospital procurement agencies should be careful while accepting any such certificates and verify them," advises Jauhri.

The MDR, 2017, introduced by the Central Drugs Standard Control Organization (CDSCO), have adopted a risk-based classification system for medical devices, which is in line with the guidelines of the Global Harmonization Task Force (GHTF). This system categorizes medical devices into four classes based on the potential risk associated with their use: Class A (low risk), Class B (low-moderate risk), Class C (moderate-high risk), and Class D (high risk).

Class A (Low Risk): Class A devices are non-invasive and generally do not come into contact with the patient or contact only the intact skin. Examples include devices like bandages, surgical masks, examination gloves, and tongue depressors.

Class B (Low-Moderate Risk): Class B devices are non-invasive

but come into contact with intact mucous membranes. Examples include devices like hypodermic needles, suction equipment, and aerosol nebulizers.

Class C (Moderate-High Risk): Class C devices are invasive, entering the body through a body orifice or making contact with the internal body fluid path. Examples include devices like bone fixation implants, heart valves, and intraocular lenses (IOLs).

Class D (High Risk): Class D devices are invasive and come into contact with the cardiovascular system, and central nervous system, or are intended for life support or sustenance. Examples include devices like pacemakers, defibrillators, and implantable stents.

The classification is based on several factors, including the degree of invasiveness, duration of use, potential for local or systemic adverse effects, and the risk associated with the device's intended use.

https://www.pharmabiz.com/NewsDetails.aspx?aid=183562&sid=1

Shape-Memory Polymers Redefine Heart Valve Implants

University of Akron researchers are developing fully polymeric, bioprintable heart valves that eliminate metallic components, utilize shape memory polymers, and integrate human cells for enhanced biocompatibility and environmental sustainability.

In a development poised to shift the paradigm in cardiovascular medicine, researchers are designing fully polymeric heart valves to replace traditional metallic implants. These valves, crafted from shape-memory polyester polymers, aim to enhance patient outcomes, reduce environmental impact, and eliminate the need for external interventions during implantation.

Hossein Ravanbakhsh, PhD, the project's lead researcher and an assistant professor of biomedical engineering in the College of Engineering and Polymer Science at the University of Akron in Akron, OH, explained the motivation behind this cutting-edge work.

"The idea is to get rid of the metallic meshes currently used in heart valves and replace them with fully polymeric valves," he said. "These materials are shape-memory polymers that can recover their original shape when exposed to body temperature."

The unique properties of these polymers allow the valves to be compressed outside the body and delivered through the femoral arteries. Once in place, they expand naturally when exposed to body heat.

"There's no need for any external intervention to open those heart valves up," Ravanbakhsh added. This eliminates the need for balloons or other devices traditionally used to deploy heart valves, making the procedure less invasive and potentially safer for patients.

The American Heart Association (AHA) recently awarded Ravanbakhsh a $200K research grant to develop these heart valve implants. The AHA's Institutional Enhancement Award provides two years of support in the university's BioEngineering for Translational Applications Laboratory (BETA Lab), which Ravanbakhsh leads. The lab focuses on functional biomaterials and biofabrication technologies for tissue engineering, regenerative medicine, and therapeutic applications.

https://www.plasticstoday.com/medical/shape-memory-polymers-redefine-heart-valve-implants

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Primary Packaging & Fluid Handling	ATEVA® G EVA CELANESE LDPE	Cryogenic Storage Bags, Medical Bags, Blow Fill Seal, Tubing and Extrusion Coating
Pharma Ingredients & Excipients	VITALDOSE® EVA VARIOUS OPTIONS	Controlled Release Excipient a custom solution for controlled release drug delivery Preservatives & Sweeteners

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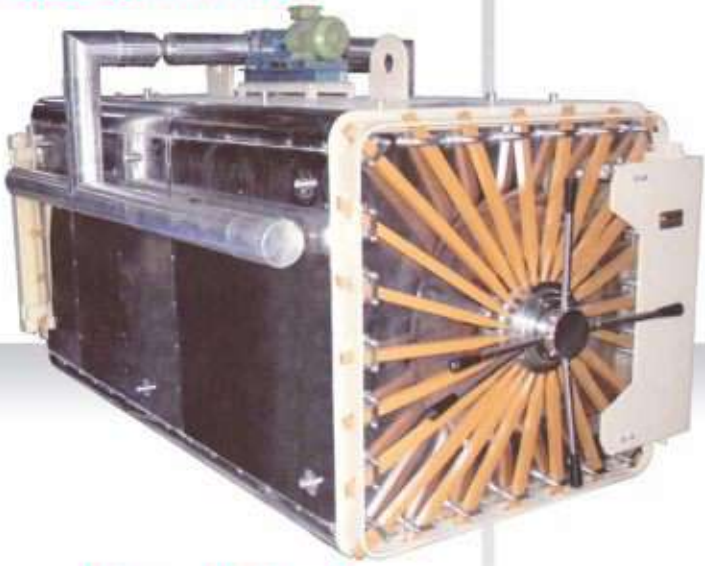

Auto - Sliding Door
Auto - Center Door
Manual Type Door

- ETO Sterilizer Plant
- 100 % ETO Sterilizer – Table Model
- Steam Sterilizer Plant - Auto Clave
- Dry Heat Sterilizer
- Multicolumn Distillations Plant
- Pharmaceutical Sterilizer Tunnel
- Pure Steam Generator
- CIP System
- SIP System
- Pressure Vessel
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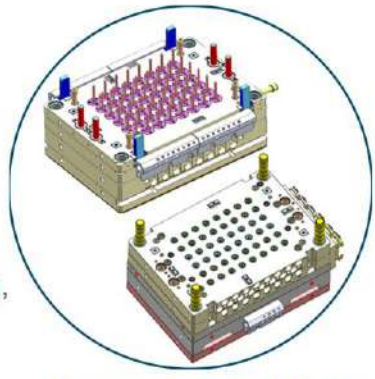

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