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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

Materials
- Performance Plastics for Food, Pharmaceuticals and Medical Devices

Manufacturing & Quality
- PFAS in Single-Use Systems for Biopharmaceutical Manufacturing
- Sizing Catheters for Angiography: Quality Problems

Dr. Priyabrata Pattnaik
Chief Executive Officer (CEO)
Ami Polymer Pvt. Ltd.

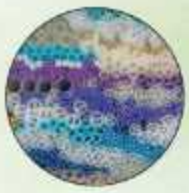
Medical Plastic Tubings
- Configurations, Applications & New Techniques for Manufacturing

Product Gallery: Medical Tubings
- Advanced Medical Grade Silicon Tubing
- Precision Multilayer Tubing for Interventional Catheter Innovation
- Striped and Multi-lumen Precision Tubings and Components

Dr. Prujal Parekh MBBS, MS
General & Minimal Access Surgery Surgeon and Founder, "ASPIEL"

Medical Device Industry Innovations:
- The Aspiel Syringe: Innovation Born in the Operating Room

Global Trends & Global Market
- Advances in Micro-extrusions and Importance of Catheter Liners
- European Union Medical Devices Market



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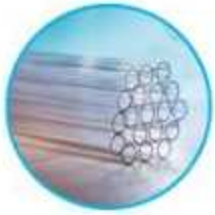
Process Flow
Feeding → Melt Extrusion → Multi-stage Sizing → Haul-off(Puller) & Cutter → Quality Inspection & Packaging (Optional)



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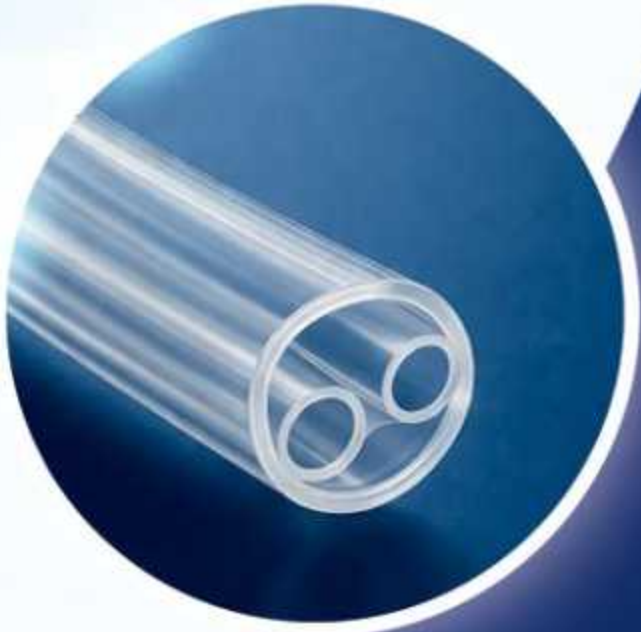

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- **Tests for Irritation**
  ISO 10993-23
- **Implantation Test**
  Different routes viz. SC/IM/bone in rodents & nonrodents • ISO 10993-6
- **Hemocompatibility Testing**
  Direct/Indirect Hemolysis Test, PTT, Hematology, Platelet Count, Complement Activation Test etc. • ISO 10993-4
- **Pyrogen Test**
  USP/IP/BP, etc. • ISO 10993-11
- **Skin Sensitization Test**
  GPMT & Buehler test • ISO 10993-10
- **Bacterial Endotoxin Test**
  IP, USP, ISO 11737-3
- **Microbial Limit Test**
  IP, USP
- **Sterility Test**
  IP, USP, ISO 11737-2
- **Bioburden Test**
  USP, ISO 11737-1
- **Ethylene Oxide / Chlorohydrine / Glycol**
  Residual Analysis • ISO 10993-7
- **Chemical Characterization Testing**
  ISO 10993-18
- **Toxicological Risk Assessment**
  ISO 10993-17
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PA6/66 - NOVAMID® Care
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- Validated Clean Room Environment

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PHARMADOCX CONSULTANTS

9996859227

PHARMADOCX

CDSCO LICENSE

CDSCO MANUFACTURING LICENSE - MD5, MD9

DOCUMENTS REQUIRED

Aadhar card, MOA/AOA, Rent Agreement, Device Master Files, Plant Master File, Quality Management System Manual, Fire NOC, Pollution NOC etc.

GOVT FEES

- Class A Non-Sterile Non Measuring - No Fees
- Class A Sterile / Measuring & Class B - ₹5,000 per site, ₹500 per product
- Class C & D - ₹50,000 per site, ₹1,000 per product

CDSCO IMPORT LICENSE - MD15

DOCUMENTS REQUIRED

Free sale certificate, CE Certificate, ISO-13485, Manufacturing License, Power of Attorney, Whole Sale License, Declaration of Conformity etc.

GOVT FEES

- Class A Non-Sterile Non Measuring - No Fees
- Class A Sterile/ Measuring - $1,000 per site, $50 per product
- Class B - $2,000 per site, $,1000 per product
- Class C & D - $3,000 per site, $1,500 per product

DOCUMENTATION

- Device Master Files / Technical Files
- Essential Principles Checklist
- Risk Management File
- SOPs, Formats, Quality Manuals as per ISO 13485
- and more...

PLANT DESIGN

- Civil Design
- Electric Design
- Plumbing Design
- HVAC Design
- and more...

REGULATORY SERVICES

MANUFACTURING LICENSE	US FDA 510(K)
IMPORT LICENSE	CE MARKING (MDR, IVDR)
TEST LICENSE	CANADA MDL & MDEL
FACTORY DESIGN	CLEAN ROOM DESIGN
ISO 13485	QMS IMPLEMENTATION
TECHNICAL FILE	FREE SALE CERTIFICATE

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- 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


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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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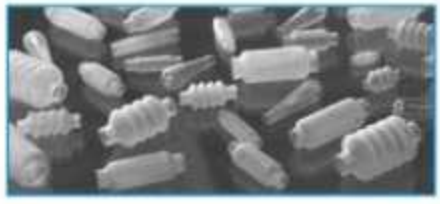


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- DIN EN ISO 13485 Quality management for medical devices
- DIN EN ISO 14001 Environmental management
- Cleanroom EG-GMP-guideline Annex 1 cleanroom class D & ISO14644-1 (class 8)

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MEDICAL PLASTICS
DATA SERVICE
SINCE 1994

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

Flashback

MEDICAL PLASTICS DATA SERVICE

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- HUSKY Innovations For Precision Medical Products Manufacturing Mr. Rajendra Kasi, VP (South Asia), Husky Injection Molding Systems (India) Pvt. Ltd. Hot runner systems can optimize your system's performance through better balance, faster color changes and minimal parts variation for superior finished part quality. Their wide operating window gives you maximum processing flexibility... (July-August 2023)

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The Role Of Biodegradable Materials In Reducing Medical Plastics Waste. (July-August 2023)

GLOBAL MARKET : MEDICAL DEVICES Myanmar : Medical Devices Market Mr. Amit Dave, M. Pharm, MBA, Former CEO – Brazil operations/ Vice President Export - Zydus Cadila Claris Lifesciences Myanmar Food & Drug Administration regulates the registration of medical devices in Myanmar. In 2019, the system was overhauled, and an online registration system is implemented for import registration, saving time, and reducing the risks of influence. (July-August 2023)

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- Govt To Bring Recruitment Rules For Appointment Of MD Inspectors To Implement New MD Regime From October 1. (July-August 2023)

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- ICMR Issues List Of Technologies Supported Under ICMR- MDMS To Foster Indigenous Manufacturing Of Medical Devices
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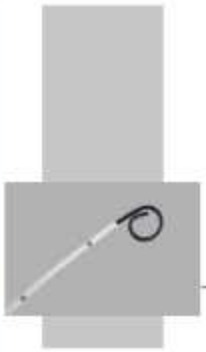

Did You Know?

About Quality problems with sizing catheters used in angiography

Catheters are widely acknowledged to be an invaluable tool for physicians in the diagnosis and treatment of cardiovascular disease.

Sizing catheters are intended for use in angiographic procedures by physicians trained and experienced in angiographic techniques. Sizing catheters have marker bands that can be used to properly orient the device within the anatomy. These catheters are for use in angiographic procedures and available in a variety of lengths (70 and 100 cm) and tip configurations (straight, PIG, and VCF).

As reported by USFDA, a leading global medical device company identified that the marker bands on impacted products may be at an increased risk of cracking/breakage.

Quality problems with sizing catheters used in angiography involve structural defects, calibration inaccuracies during quantitative imaging, and handling limitations. Recent regulatory actions highlight severe manufacturing defects, while technical studies point to inherent measurement challenges in vessel sizing.

Structural and Manufacturing Defect Risks

- **Device fragmentation:** Material degradation or structural flaws can cause parts of the catheter to break off inside the vascular system.
- **Vessel injury:** Broken fragments, sharp edges, or separation of components risk tearing or damaging blood vessels.
- **Prolonged procedures:** Dealing with faulty or breaking equipment forces medical teams to spend extra time retrieving fragments or replacing tools.
- **Regulatory warnings:** Agencies like the U.S. Food and Drug Administration have issued alerts and removals for specific centimeter sizing catheter lines due to material separation risks.

Quantitative Imaging and Calibration Errors

- **X-ray attenuation variance**
- **Dimension overestimation**
- **Lack of standardization**

Handling and Performance Limitations

- **Poor torque control**
- **Suboptimal imaging**

In a Nutshell....

"Medtech startups rarely fail bacause of weak technology. They fail because the commercial model was never built up to win."

- Aaron Tutwiler
CCO / VP of Biz Dev.

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From the Editor's Desk

The growing adoption of high-performance polymers and adherence to international standards presents a favourable outlook for plastic tubing usage in the Asia Pacific region.

As per a recent study by a leading market research agency, Asia Pacific is projected to be the fastest-growing regional market for medical plastics tubing during 2026 to 2031. Due to the ongoing expansion of the region's healthcare infrastructure, high growth of healthcare expenditures, and the rapid expansion of the medical device, biotechnology, and pharmaceutical sectors.

This issue focuses on important technical and marketing aspects of medical plastic extrusions including micro-extrusion as well as various types of medical plastic tubings and extrusions. It includes important configurations, applications as well as recent trends in medial plastic tubing manufacturing.

As introduced in the "Global Trends" column, **miniaturization is an ongoing trend in medical technology, and one of the enabling manufacturing processes is micro-extrusion,** which is used to produce ultra-thin, precision tubing. The process enables the fabrication of single-lumen, multi-lumen, and multi-layered catheter liners typically required for minimally invasive medical devices.

The "Global Trends" column highlights various **manufacturing innovations.** These advances have had a profound impact on patient care.

For the benefit of Medical Device Industry, the "Did You Know" column in this issue also shares **"Quality problems with sizing catheters** used in angiography" as reported by USFDA. It includes risks because of structural and manufacturing defects.

We are pleased to mention that in order to support indigenous manufacturing of critical care medical devices, **some of the Indian and multi-national companies have already initiated manufacturing of various different types of extruded tunings and products.** Under the "Product Gallery" Column, we have introduced thre such leading companies namely "Suresh Enterprises", "Tekniplex Materials Science Solutions" and "Lubrizol Advanced Materials India" .

Two important technical articles cover high-performance polymeric materials. Dr Priyabrata Pattnaik , CEO, Ami Polymers Pvt ltd , in an very detailed analytical article introduces "PFS in Single-Use Systems for Biopharmaceutical Manufacturing". PFS (Per- and polyfluoroalkyl substances) are widely used in the form of fluoropolymers and fluorinated processing aids within single-use systems (SUS), including bioprocess bags, tubing, filter assemblies, connectors, gaskets, diaphragms, seals, and membrane technologies.

As mentioned earlier, the medical grade polymers have contributed immensely in pushing the boundaries of medical technology. **Following two recent innovations highlight this contribution as covered in this issue:**

Dr Prujal Parekh, General & Minimal Access Surgery Surgeon and Founder," ASPIEL" has innovated a novel syringe designed to simplify aspiration during high-risk injections while allowing the clinician to maintain better control of the device.

This issue also covers our other regular columns like "Global Markers", Regulatory & Industry News etc.

D L Pandya

Medical Plastic Tubings: Configurations, Applications and New Techniques for Manufacturing

Plastic tubing plays a pivotal role in many advanced medical procedures, such as vascular catheters, conduits for acquiring biopsy samples, and holders for stents being implanted into heart arteries.

Minimally invasive techniques such as angioplasty drove the need for tubing with small diameters and thin walls, temperature control became critical for maintaining tight dimensional tolerances.

AS per a recent study by "Markets and Markets", Asia Pacific is projected to be the fastest-growing regional market for medical plastics tubing during 2026 to 2031. Due to the ongoing expansion of the region's healthcare infrastructure, high growth of healthcare expenditures, and the rapid expansion of the medical device, biotechnology, and pharmaceutical sectors.

Chronic diseases are increasing globally, particularly with an aging population, driving up the use of medical plastic tubing in devices like catheters, IV systems, drug delivery systems, and dialysis equipment.

The rise in single-use or disposable devices to prevent healthcare infections further boosts the demand for medical plastics. The growing adoption of high-performance polymers and adherence to international standards presents a favourable outlook for plastic tubing usage in the Asia Pacific region.

Important Configurations, Applications, Innovations as well as Important Developments in Medical Tubing Manufacturing are given below:

1. **Medical Tubing Configurations**
   Medical Tubes are categorized mainly by following types according to Different Configurations:

A. **According to the structure:** Single-Lumen, Double-Lumen, Multi-Lumen, Two-Row, Multi-Row etc.

B. **According to the performance:** High-Pressure Tube, UV Protection Tube, Flame Retardant Tube Antimicrobial Tube, Gamma Ray Protection Tube.

C. **According to the usage:** High-Transparent Tube, Tube with Colour Line (One or Multi-Lines), Radiopaque Tube (One of Multi-Lines or Whole), Micro-Flow Tube, Intravascular Tube, Balloon Tube, High-Pressure Tube.

2. Medical Tubing: Materials & Respective Applications

Sr. No.	Materials	Common Applications
1	Polyvinyl Chloride PVC	Containers used for blood and blood components for urine or for ostomy products and tubing used for blood taking and blood giving sets, catheters, heart-lung bypass sets, haemodialysis set etc.
2	Polytetrafluoroethylene PTFE	Catheter liner, Electrical Insulation, Fluid transfer. Telecommunication
3	Fluorinated Ethylene, Propylene, FEP	IV catheter, Regional Anesthesia, Vascular access
4	Ethylene Tetra-fluoroethylene, ETFE	Fluid transfer, IV catheter, Electrical insulation
5	Perfluoroalkoxy, PFA	Fluid transfer, In Vitro diagnostics
6	NYLON, 6, 11, 12	Angiography, Choloecstectomy, Epidural catheter, Laparoscopic instruments, Radiology
7	Polyether Block Amide, PEBA	Angiography, Cholangeography, Epidural Catheter, Radiology
8	Polycarbonate PC	Laparoscopic instruments, IV therapy, Laparoscopic cannulae, Tube packaging, Microtubes
9	High Density Polyethylene LDPE	Embolectomy, Guidewire dispensers, Introducers, Protective tubes, Thrombectomy, Sheaths and dilators for introducers, Coextruded perfusion tubing, Aspirator tips
10	Low Density Polyethylene LDPE	Embolectomy, Guidewire dispensers, Introducers, Protective tubes, Throbectomy
11	Polyurethane PUR (Aliphatic)	Angiography, Cardiac catheters, Central Venous catheters, Dialysis, Epidural catheters, IV catheters, Epidural probes, Catheters, High-pressure lines
12	Polyurethane PUR(Aromatic)	Angiography, Cardiac catheters, Central Venous catheters, Dialysis, Epidural catheters, IV catheters
13	Polypropylene PP	Guidewire dispenser tubes and Protective tubes
14	Ethylene Vinyl Acetate EVA	Endotracheal, Embolectomy, IV therapy, Suction catheter
15	ACETAL	Laparoscopy, Gulding catheter

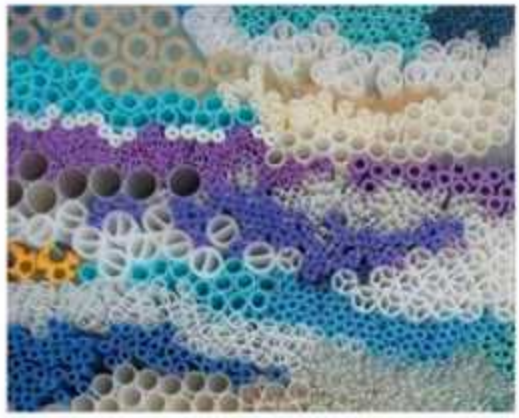
3. About Innovations and Techniques in Medical Tubing Manufacturing*

Different processing options have led to ground-breaking ways of producing tubing in order to optimize the performance and usability of medical devices. It helps to improve patients 'quality of life with better function and integrity, and by enabling the incorporation of APIs.

Some of such Tubing technologies include the following:

- High-precision, microextrusion, and thin-walled tubing for minimally invasive surgical devices.
- Platinum-cured silicone for use in implants.
- Multi component extrusion featuring radiopaque stripes for visibility in an x-ray or fluoroscope.

- Reinforced and kink-resistant tubing used to keep fluid paths open.
- Extruded ribbon and film used in diaphragms to support seals in devices such as pacemaker generator housings.
- Jacketed wires and cables used to power implantable heart pumps.
- Twisted extrusions for applications in which implanted power or sensing cables require strain relief from repeated flexing and bending, as with pacemaker leads.
- Custom profiles used to seal housing assemblies and repair heart valves.
- Bump tubing applied to plastics and elastomers, including silicone.
- Bonded or over moulded stops typically added to peristaltic pumps for infusion, internal feeding, laboratory equipment, diagnostic equipment, and fluid transfer.
- Formed extrusions used to fit tortuous anatomy or spiral shapes that might be used to soften contact within the bladder.
- Multilumen extrusion for catheters, electric medical devices, analytical equipment, fluid transfer, drug delivery, and medical instrumentation.
- Geometric transitioning extrusion applied to custom applications with precision tolerances.
- Geometric transitioning single lumen for custom-end assemblies, such as accommodation of connectors, fittings, and peristaltic pumps.
- Drug-eluting silicone extrusions that help prevent infection.
- Foam extrusion that provide additional cushion space.



References:
** (https://www.medicaldesignbriefs.com/component /content/article/mdb/pub/f In a Nutshell.... MEDICAL PLASTICS DATA SERVICE features/articles/39646)*

Advanced Medical Grade SEVITSIL® Silicone Tubing

SEVITSIL®
SOLUTIONS IN SILICONE

With over 51 years of expertise in silicone engineering, SEVITSIL® continues to advance the development of high performance medical-grade silicone tubing for the global healthcare and medical device industry. Designed for precision, reliability, and biocompatibility, our tubing solutions are engineered to meet the demanding requirements of critical medical applications while supporting OEMswith customized, application-specific products.

Materials & Special Features

(Anti-Microbial Tube - Image by Sevitsil (Suresh Enterprises))

SEVITSIL® medical-grade tubing is manufactured using advanced biocompatible, platinum-cured silicone compounds that offer exceptional purity, non-toxic properties, and very low extractables. For long-term medical applications, our portfolio includes specialized innovations such as **Anti-Microbial** Tube, developed with a dedicated antimicrobial additive to enhance implant compatibility and support advanced wound care applications.

(Image left to right: AnekSil® Tubing, J-Sil® Tubing, Radio-Sil®)

Our engineering capabilities extend to complex tubing geometries required for next-generation medical devices. This includes **AnekSil® Tubing,** offering up to 12 lumens for custom catheter designs; **J-Sil® Tubing,** specifically developed for hemodialysis catheters with smooth-bore flow characteristics; and **Radio-Sil® Products,** radio-opaque silicone tubing designed for clear visibility under X-ray and fluoroscopy. Across the portfolio, our tubing solutions provide excellent flexibility, kink resistance, chemical resistance, and compatibility with standard sterilization methods.

Healthcare Application

(Image left to right: SiliDrain, SiliBreath)

Trusted by medical device manufacturers worldwide, SEVITSIL® medical-grade tubing is used across a wide range of healthcare applications. These include hemodialysis and urology, where biocompatible tubing supports smooth-bore flow in dialysis catheters, urological catheters, and multi-eye drainage systems such as **SiliDrain**. Our solutions also serve cardiac and surgical devices requiring precision-engineered silicone components for life-saving therapies. In IV infusion systems and laboratory equipment, SEVITSIL® tubing delivers high-clarity, contamination-free fluid transfer, while **SiliBreath** tubing provides flexible, durable, latex-free solutions for ventilator and respiratory care systems.

Quality, Compliance & Certifications

Quality is integrated into every stage of manufacturing through a comprehensive four-stage verification process. As a trusted OEM manufacturing partner, SEVITSIL® operates with CDSCO Approved Product, ISO 13485-aligned quality systems alongside ISO 9001, ISO 14001, IATF 16949:2016 -certified processes, ZED Gold ensuring consistent quality, complete traceability, validated manufacturing, and reliable packaging for global medical device manufacturers.

Head Office & Factory

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"Precision Multilayer Tubing for Interventional Catheter Innovation

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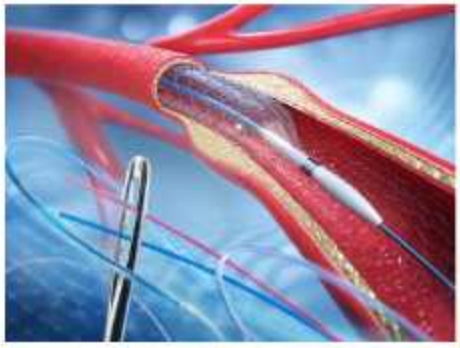

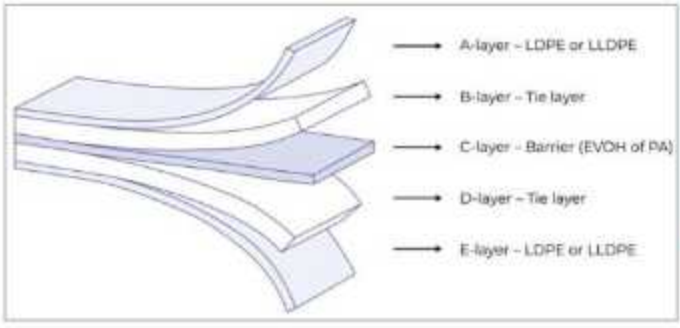

Interventional device performance is decided at the layer level. TekniPlex Healthcare applies decades of materials science and precision co-extrusion expertise to small-diameter, thin-wall multilayer catheter tubing, helping device designers balance guidewire movement, catheter construction, wall thickness, and application-specific performance in a single extrusion.

Tri-layer construction

The company's tri-layer inner tubing pairs polyamide (nylon) or polyether block amide copolymer (PEBA) outer layers with a high-density polyethylene (HDPE) inner layer, joined by an extremely thin adhesive tie layer. The HDPE inner layer reduces friction on the guidewire for smoother tracking and navigation. The outer layer is bondable to balloon catheter tubing of similar materials, simplifying downstream assembly. Inner and outer layer thicknesses are customized to suit the target application, allowing designers to tune lubricity, stiffness, and bondability without adding secondary operations.

Precision at scale

PTA/PTCA balloon catheter tubing for coronary and non-coronary angioplasty is produced across balloon sizes from 1 mm to 30 mm, manufactured to tolerances of ± .0005 in. with concentricity above 90 percent. A controlled elongation rate delivers blown balloons with uniform wall thickness, improving yield and substantially reducing burst risk. Tubing is produced and extruded in ISO-certified cleanrooms using medically certified raw materials.

Design flexibility

Capabilities extend to single-lumen diameters from 0.008 in. to 0.480 in., multi-lumen constructions, and tapered profiles. Multi-lumen tapered tubes extruded from Pebax® polymer for endoscopic biliary procedures carry guidewire, contrast, and balloon inflation lumens along a 2,050 mm length while transitioning from 2.45 mm proximal to 1.72 mm distal, with lumens as small as 0.4 mm held to consistently tight tolerances. An experienced technology team engages with customers from concept through commercialization, supported by a global manufacturing network built for security of supply.

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TekniPlex Healthcare
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Advancing India's MedTech Ecosystem Through Local Manufacturing of Medical Device Components

Lubrizol

India's medical device industry is poised for significant growth, driven by increasing investment, innovation, and manufacturing expansion. To fully realize this potential, greater focus on localized production of high-value components, including precision medical tubing, will be essential. While progress is being made, many advanced tubing solutions used in sophisticated medical devices continue to be imported, highlighting an opportunity to strengthen the domestic supply chain. This dependency can create challenges around lead times, supply assurance, customization, and cost competitiveness, especially as demand rises across India and global healthcare markets.

For India to build a more resilient medical device ecosystem, the next step is to advance local manufacturing with technology, quality systems, and engineering capabilities aligned with global standards. Precision medical tubing sits at the center of this transformation, supporting applications ranging from minimally invasive neurovascular and cardiovascular devices to fluid management systems and advanced catheter technologies.

Recognizing this need, Lubrizol, a global specialty chemicals leader,, has expanded its investment in India through a new advanced medical component manufacturing facility in Chennai, developed in collaboration with Polyhose, a leading manufacturer in fluid conveyance systems. The expansion brings globally proven extrusion expertise, rigorous quality standards, and advanced manufacturing capabilities closer to Indian medical device manufacturers through its ISO 13485-certified facility in Chennai. This investment represents an important step in strengthening India's capabilities in high-value medical components and expanding access to locally manufactured tubing solutions.

Enabling more advanced tubing designs remains a key area of focus for Lubrizol. Building on its extrusion expertise, the company now manufactures precision striped tubing in India with integrated 3-, 4-, and 6-stripe configurations, supporting the development of increasingly advanced medical devices These designs help improve tube identification, orientation, and procedural efficiency, while providing device manufacturers greater flexibility in product design and customization.

Lubrizol's Chennai facility also supports multi-lumen tubing configurations, enabling multiple fluid pathways or functionalities within a single tube, an increasingly important requirement for complex minimally invasive devices. Beyond striped and multi-lumen constructions, the facility produces high-precision tubing using a broad portfolio of materials including Pebax®, polyamides, nylon, polypropylene, polyethylene and medical-grade TPU. Capabilities extend across single- and multi-lumen extrusion, balloon tubing, braiding, and tri-layer tubing, allowing manufacturers to source advanced solutions from a local facility supported by Lubrizol's global technology network.

As India advances as a global MedTech manufacturing hub, local production backed by world-class technology will be essential. Through its advanced extrusion capabilities in Chennai, Lubrizol is strengthening supply resilience, enabling innovation, and supporting the development of medical devices that improve patient outcomes in India and beyond.

Qosina Expands Beyond Components with Launch of Regulatory Services

QOSINA

New offering connects Qosina's component and supply-chain expertise with regulatory strategy, submissions, quality systems and compliance services

RONKONKOMA, N.Y., August 18, 2026 — Qosina, a global supplier of single-use components for the medical device and life sciences industries, today announced the launch of Qosina Regulatory Services. The new offering supports customers from early pathway planning through submissions and ongoing compliance.

Led by Bryan Brosseau, Qosina's Regulatory and Quality Strategist, the new services address the regulatory and quality requirements that follow a product from development through market. From startups mapping their first regulatory pathway to established manufacturers working through complex compliance challenges, Qosina provides experience-driven guidance tailored to each organization's needs.

"The regulatory issues that cost our customers the most time aren't the ones they saw coming," said Lee Pochter, CEO of Qosina. "A supplier change or a material substitution that seemed routine during development turns into a documentation problem much further down the road. Regulatory Services exist to catch that at the front end, so customers can make sourcing decisions with the right information in hand."

Qosina Regulatory Services span quality systems, including QMS audits and gap analyses, audit preparation and remediation, and eQMS support. Submission work covers regulatory pathway planning, FDA and international submissions, CE-marking support and UDI implementation. Technical support includes design controls, risk documentation, biocompatibility, design verification and validation, supplier management and auditing, and training.

Brosseau will discuss the regulatory challenges that shape a medical device's path to market at MEDevice Boston, August 26-27, 2026.

For more information about Qosina Regulatory Services or to schedule a discovery call, visit https://bit.ly/Regulatory_Services.

About Qosina

Qosina is a leading global supplier of 7,000+ components to the medical and pharmaceutical industries. For more than 45 years, Qosina has helped medical device and life sciences companies accelerate product development and commercialization through an extensive component portfolio, technical expertise, quality documentation and supply-chain support. Qosina provides customers with the flexibility to source, sample and evaluate components while reducing the time and complexity involved in bringing products to market. Qosina Regulatory Services further extend that support, helping organizations navigate regulatory strategy, submissions, quality systems and compliance. For more information, visit https://bit.ly/QosinaPR.

Contact : Rachelle Morrow, Senior Manager, Communications, Qosina Corp. QOSMEDIX

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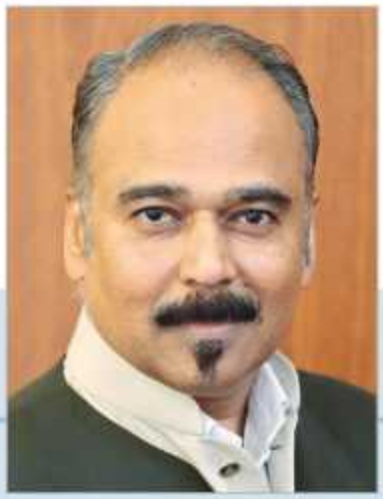

PFAS in Single-Use Systems for Biopharmaceutical Manufacturing: Regulatory Crossroads, Extractables & Leachables Risk, and the Path Forward

Dr. Priyabrata Pattnaik
Chief Executive Officer (CEO)
Ami Polymer Pvt. Ltd.

Executive Summary

Per- and polyfluoroalkyl substances (PFAS) have emerged as one of the most consequential chemical classes facing the biopharmaceutical industry today. While PFAS are often discussed in the context of contaminated drinking water, firefighting foams, or consumer products, their role in bioprocessing is less visible but highly significant. PFAS are widely used in the form of fluoropolymers and fluorinated processing aids within single-use systems (SUS), including bioprocess bags, tubing, filter assemblies, connectors, gaskets, diaphragms, seals, and membrane technologies. Their exceptional chemical inertness, thermal stability, low extractables profile, and compatibility with sterilization processes have made them indispensable to modern biologics manufacturing.

However, the global regulatory landscape is rapidly evolving. Regulatory agencies in Europe and North America are increasingly treating PFAS as a class of concern due to their environmental persistence, bioaccumulation potential, and associations with adverse human health outcomes. Proposed restrictions under the European REACH framework, U.S. EPA actions, and growing customer expectations regarding sustainability are creating unprecedented uncertainty for suppliers and users of single-use technologies.

For biopharmaceutical manufacturers, PFAS regulation is not merely an environmental issue; it is a strategic business issue that directly affects supply chain resilience, product quality, process validation, regulatory compliance, and long-term manufacturing economics.

Why PFAS Matters to Bioprocessing

The rise of single-use technology has transformed biopharmaceutical manufacturing over the last two decades. Disposable bioreactors, bags, tubing manifolds, filters, and fluid transfer assemblies have enabled unprecedented manufacturing flexibility, reduced cleaning validation requirements, accelerated facility construction, and lowered contamination risks.

Many of these systems depend on fluorinated materials. PFAS represent a broad family of more than 10,000 fluorinated compounds characterized by highly stable carbon-fluorine bonds. These bonds are among the strongest in organic chemistry, conferring exceptional resistance to heat, solvents, acids, bases, oxidation, and biological degradation. Because of these properties, PFAS-containing fluoropolymers such as polytetrafluoroethylene (PTFE), polyvinylidene fluoride (PVDF), fluorinated ethylene propylene (FEP), perfluoroalkoxy alkane (PFA), ethylene tetrafluoroethylene (ETFE), fluoroelastomers (FKM, FFKM), have become essential materials in pharmaceutical manufacturing and medical technologies.

Historically, fluoropolymers were considered low-risk because they are high-molecular-weight, relatively insoluble materials. However, increasing scientific scrutiny has revealed that fluoropolymer production often relies on PFAS processing aids, residual monomers, oligomers, surfactants, and degradation products that may remain within finished materials and potentially contribute to environmental contamination or extractables and leachables (E&L) concerns.

Where PFAS Exist in Single-Use Bioprocess Systems

PFAS-containing materials appear throughout modern bioprocessing operations.

1. **Tubing Systems:** Fluoropolymer tubing is widely used in buffer transfer, media transfer, product harvest, chromatography skids, fill-finish operations, etc. FEP, PFA, and PTFE tubing offer extremely low adsorption, high chemical compatibility, excellent cleanability, and resistance to gamma irradiation and sterilization
   These attributes are particularly valuable for high-value biologics, vaccines, viral vectors, and cell therapy products.
2. **Filtration Systems:** PVDF membranes remain among the most common membrane materials used in sterile filtration, vent filtration, virus filtration, clarification processes, etc. PVDF provides high protein recovery, low extractables, excellent mechanical strength, and broad chemical compatibility.
3. **Single-Use Bags:** While most bag films consist primarily of polyethylene-based multilayer structures, PFAS-containing materials may be present in ports, connectors, weldable fittings, internal components, barrier layers, and manufacturing additives.
4. **Gaskets, O-Rings and Seals:** Fluoroelastomers such as FKM and FFKM are used extensively because they resist aggressive CIP chemicals, organic solvents, high temperatures, and repeated sterilization cycles.
5. **Manufacturing Processing Aids:** Perhaps the least visible PFAS source is fluorinated processing aids used during polymer manufacture. Historically, compounds such as perfluorooctanoic acid (PFOA), perfluorooctanesulfonic acid

(PFOS), genX-related substances, and fluorinated surfactants have been used to facilitate polymerization processes. Although many legacy substances have been phased out, concerns remain regarding residuals, byproducts, and replacement chemistries.

PFAS and Extractables & Leachables (E&L): The Scientific Concern

For the biopharmaceutical industry, the primary concern is not the bulk fluoropolymer itself, but what can migrate from it, specifically extractables and leachable.

Extractables are compounds that can be forced from materials under aggressive laboratory conditions. Potential PFAS-related extractables include residual monomers, oligomers, polymerization aids, fluorinated surfactants, processing impurities, and degradation products.

Leachables are compounds that migrate into process streams under actual manufacturing conditions. Potential risk factors include long contact times, elevated temperatures, organic solvents, surfactants, high pH solutions, and repeated irradiation exposure.

Although fluoropolymers generally exhibit low extractables compared with many alternative polymers, regulators increasingly expect manufacturers to understand whether fluorinated compounds may appear in process intermediates or final drug products. This concern becomes particularly relevant for monoclonal antibodies, vaccines, cell therapies, gene therapies, and mRNA products where patient safety margins can be extremely narrow.

Recent literature also highlights concerns regarding trace PFAS migration from medical devices and fluid-contact materials, emphasizing the need for further quantitative assessment of fluoropolymer-associated exposure pathways.

Why Regulators Are Concerned

The scientific rationale behind PFAS regulation rests on three fundamental characteristics.

1. **Extreme Environmental Persistence**
   PFAS are frequently referred to as "forever chemicals." The carbon-fluorine bond resists hydrolysis, photolysis, microbial degradation, and oxidative degradation. As a result, PFAS can persist in soil, groundwater, surface water, and living organisms for decades. Scientific reviews consistently identify environmental persistence as a primary regulatory driver.
2. **Bioaccumulation**
   Certain PFAS compounds accumulate in blood, liver, kidney, and breast milk. Human biomonitoring studies also demonstrate widespread exposure globally.
3. **Toxicological Concerns**
   Growing evidence links specific PFAS compounds with immunotoxicity, endocrine disruption, reproductive toxicity, developmental toxicity, liver dysfunction, metabolic disorders, certain cancers, etc. The International Agency for Research on Cancer (IARC) classified PFOA as carcinogenic to humans (Group 1) and PFOS as possibly carcinogenic. These findings have fundamentally changed regulatory attitudes toward PFAS-containing materials.

Current Global Regulatory Landscape

European Union

The most significant regulatory development is the proposed PFAS restriction under REACH. In January 2023, Germany, Denmark, Sweden, Norway, and the Netherlands submitted a broad PFAS restriction proposal covering manufacture, use, and market placement of PFAS-containing materials. The proposal is expected to progress toward implementation around 2029–2030, although exemptions may be granted for essential uses.

The proposal adopts a class-based approach rather than regulating individual compounds. This is particularly important because fluoropolymers may fall within PFAS definitions, suppliers may need to justify essential use exemptions, and customers may demand PFAS-free alternatives even when exemptions exist. The EU has also implemented stringent PFAS limits in drinking water under Directive EU 2020/2184.

United States

The U.S. EPA has intensified PFAS oversight. Recent actions include designation of PFOA and PFOS as hazardous substances under CERCLA, drinking water limits of 4 ppt for PFOA and PFOS, expanded TSCA reporting obligations, and increased PFAS disclosure requirements. While medical devices and pharmaceutical manufacturing materials currently remain largely exempt from direct restrictions, the regulatory direction is clear.

Global Trends

CAS analysis of the global PFAS landscape demonstrates increasing regulatory activity across United States, European Union, China, Japan, South Korea, Australia and New Zealand. The regulatory environment is becoming increasingly fragmented, creating compliance complexity for multinational pharmaceutical operations.

India

India's regulatory framework for PFAS remains at an early stage compared with the European Union and the United States. As of 2026, India does not have a comprehensive national PFAS management program, PFAS-specific drinking water standards, environmental discharge limits, or broad restrictions on the manufacture and use of PFAS across industrial sectors. Environmental oversight of PFAS currently relies on general provisions under the Environment (Protection) Act, 1986, the Water (Prevention and Control of Pollution) Act, 1974, and related hazardous chemical regulations, none of which specifically address PFAS as a chemical class. India is, however, a signatory to the Stockholm Convention on Persistent Organic Pollutants (POPs), which requires controls on certain PFAS compounds such as PFOS, PFOA, their salts, and related substances that have been listed under the Convention.

The most significant recent regulatory development is the action initiated by the Food Safety and Standards Authority of India (FSSAI). In October 2025, FSSAI published the Draft Food Safety and Standards (Packaging) Amendment Regulations, 2025, proposing a complete prohibition on the use of PFAS in food-contact materials and packaging. The proposal was subsequently notified to the World Trade Organization (WTO) and reflects growing concern regarding the migration of "forever chemicals" into food products and their potential impact on human health. The draft regulation aligns India with emerging international trends and signals the government's increasing willingness to regulate PFAS-containing materials where human exposure is considered significant. However, as of mid-2026, the proposal remains under regulatory review and has not yet evolved into a broader national PFAS restriction framework.

For the biopharmaceutical industry, this means that PFAS-containing fluoropolymers used in single-use systems, filters, tubing, gaskets, and processing equipment are not currently subject to specific Indian restrictions. Nevertheless, Indian

manufacturers supplying global markets must closely monitor developments in Europe and North America because regulatory requirements imposed by international customers and health authorities will likely influence material selection, extractables and leachables assessments, and supply-chain qualification practices long before comparable regulations emerge domestically. Consequently, while India presently follows a relatively permissive PFAS regulatory model, the direction of travel suggests increasing scrutiny, enhanced disclosure requirements, and eventual adoption of risk-based controls consistent with global regulatory trends.

Implications for Single-Use System Suppliers

SUS suppliers face several challenges. Customers increasingly requesting material disclosure covering PFAS inventories, material composition declarations, and supply chain transparency. Historically proprietary formulations may now require disclosure.

Global suppliers are investing heavily in reformulation focusing on finding alternative polymers, non-fluorinated membranes, PFAS-free elastomers, and new manufacturing routes. However, many alternatives do not yet match fluoropolymer performance.

The challenge is regulatory qualification costs. Every material substitution requires extractables studies, toxicological risk assessments, process validation, stability studies, and regulatory filings. The costs can be substantial.

Business Impact on Biopharmaceutical Manufacturers

The PFAS issue extends far beyond environmental compliance. The biggest impact is the supply chain risk. A major PFAS restriction could affect availability of filters, tubing, gaskets, sensor components, connector systems, etc. Even temporary shortages could disrupt manufacturing campaigns.

There will be change control burden. Substituting a fluoropolymer component may require process characterization, comparability assessments, product impact studies, and regulatory submissions. For commercial biologics, this can involve years of work.

There will be potential increase in cost of goods. Alternative materials often cost more, have shorter operating life, and may require additional qualification. All these cause manufacturing costs to increase significantly.

Advanced therapies frequently depend on highly specialized SUS components.

Regulatory uncertainty could slow cell therapy scale-up, gene therapy manufacturing, ad continuous bioprocessing adoption.

It is likely to have investor and ESG Pressure. Investors increasingly will evaluate environmental sustainability, chemical stewardship, and supply chain resilience. PFAS management is becoming an ESG issue as much as a regulatory one.

CAS industry analysis highlights that sectors such as medical devices, aerospace, and advanced technologies face substantially greater technical challenges in PFAS replacement compared with consumer-facing industries. Biopharmaceutical manufacturing belongs firmly within this technically challenging category.

Are Fluoropolymers Really High Risk?

A critical scientific debate remains unresolved. Many toxicological concerns arise from PFOA, PFOS, and small PFAS molecules, rather than high-molecular-weight fluoropolymers themselves. Some scientists argue fluoropolymers should be treated separately because they are less bioavailable, they exhibit lower mobility, and they generally show lower toxicity. Others argue that production processes still generate PFAS emissions, end-of-life disposal remains problematic, and degradation pathways are incompletely understood. This debate will likely shape future regulations.

Mitigation Strategies for the Biopharmaceutical Industry

Rather than waiting for regulations to force change, manufacturers should adopt proactive strategies.

1. **PFAS Material Mapping:** Conduct comprehensive inventories of tubing, bags, filters, gaskets, membranes, and sensors. Identify both direct PFAS materials and hidden fluorinated processing aids.
2. **Supplier Engagement:** Request PFAS declarations, regulatory roadmaps, alternative material strategies, and extractables data packages. Transparency will become increasingly valuable.
3. **Expand E&L Programs:** Future E&L studies should include targeted PFAS screening, high-resolution mass spectrometry, and non-targeted analysis. Traditional E&L programs may miss emerging PFAS species.
4. **Risk-Based Prioritization:** Not all PFAS-containing components carry equal risk.
   It is important to prioritize product-contact materials, long-duration exposure systems, and high-surface-area components.
5. **Alternative Material Evaluation:** It is worth to investigate polyolefin elastomers, thermoplastic elastomers, silicone technologies, advanced polyethylene membranes, and ceramic filtration systems. However, performance equivalence must be demonstrated rigorously.
6. **Lifecycle Thinking:** Assess environmental impacts from raw material sourcing, manufacturing, use phase, and disposal. Circular economy approaches and sustainable procurement strategies are increasingly recommended by regulatory and scientific communities.

The Future of PFAS in Bioprocessing

PFAS are unlikely to disappear from biopharmaceutical manufacturing overnight.

The technical reality is that fluoropolymers continue to provide performance characteristics that remain difficult to replicate chemical inertness, sterilization resistance, protein compatibility, and mechanical reliability.

Regulators recognize these challenges and are likely to permit transitional exemptions for essential uses. Nevertheless, the direction is unmistakable. The industry is moving toward greater transparency, enhanced E&L scrutiny, reduced PFAS dependency, and sustainable material innovation. The organizations that begin preparing today will be best positioned to navigate future regulatory requirements without compromising product quality or supply continuity.

Conclusion

PFAS represent one of the most complex challenges facing modern biopharmaceutical manufacturing. Fluoropolymers and fluorinated processing aids have enabled the growth of single-use technologies by delivering unmatched performance in bags, tubing, filters, membranes, seals, and fluid management systems. Yet the same chemical properties that make PFAS valuable—persistence, stability, and resistance to degradation—also underpin growing regulatory and societal concern.

For extractables and leachables specialists, the focus must shift from viewing PFAS solely as materials science issues to

understanding them as integrated product-quality, patient-safety, environmental, and business-risk issues. Regulatory restrictions under REACH, EPA actions, and emerging global policies will increasingly influence material selection, supplier qualification, E&L programs, and lifecycle management strategies.

The winners in this transition will not simply be companies that eliminate PFAS first. They will be organizations that combine scientific rigor, proactive risk assessment, supplier collaboration, and strategic innovation to ensure uninterrupted delivery of life-saving biologics while adapting to a rapidly changing regulatory landscape.

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ABC Of Performance Plastics & Their Applications In Food Pharmaceuticals And Medical Devices

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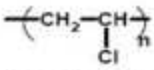
This is in continuation to my last writeup published in MPDS magazine volume 33 (Jan-Feb 2025). Let us explore few more important performance plastics which are in use in the field of Food, Pharmaceutical & Medical devices

ABC

Acquaintance, Behaviour & Consumption

of PERFORMACE PLASTICS & their applications in food pharmaceuticals and medical devices Food, Pharmaceuticals & Medical device

Polyvinyl chloride (PVC)

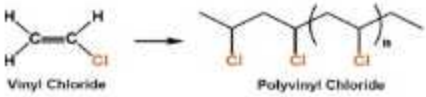


KEY PROPERTIES

- High clarity
- Moderate barrier for gas and moisture
- Hard and rigid.
- Excellent thermoforming property
- Density - 1.35-1.38 gm/cm3

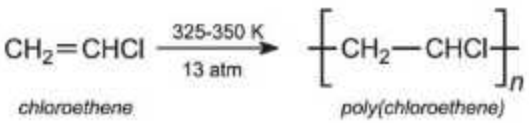
MAJOR PACKAGING APPLICATIONS

- Blister packaging in pharmaceuticals.
- Packaging of meat,cheese
- Medical bag / kit
- Shrink film / sleeve



PVC is produced by polymerization of vinyl chloride monomer (VCM). The main polymerization methods include suspension, emulsion, and bulk (mass) methods.VCM is then sent through a reactor containing a catalyst where polymerization occurs. This process links the vinyl chloride molecules together to form PVC chains. The resulting PVC is a white powder.

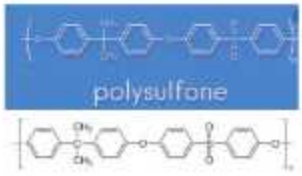
About 80% of production involves suspension polymerization. First, the raw material VCM is pressurized and liquefied, and then fed into the polymerization reactor, which contains water and suspending agents in advance. Next, the initiator is fed into the reactor, and PVC is produced under pressure Pressure (13 atm) at 40 – 60°C.



In suspension polymerization an initiator, an organic peroxide is used, which is soluble in chloroethene. After the reaction, excess monomer is removed and the polymer is separated, by centrifuging and drying.

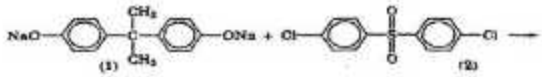
PVC is used for many life-saving and healthcare products like

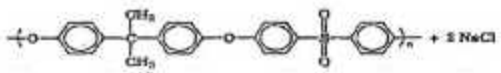
- Blood and plasma transfusion sets
- Catheters and cannula
- Blood bags
- intravenous solution giving sets
- Surgical and examination gloves
- Mattress and bedding covers
- Blister packs for pharmaceutical solid dosage medicines



Polysulfones are a family of high performance amorphous thermoplastics.

These polymers are known for their toughness and stability at high temperatures. Aromatic polysulfones can be produced by the polycondensation reaction of bisphenol salts with 4,4-dichlorodiphenyl sulfone (4,4-DCDPS) Reactions are carried out in high- boiling polar solvents like dimethyl sulfoxide (DMSO), and N-methyl pyrrolidone (NMP) at temperatures ranging from 130 to 160°C





Polysulfone polymer is known for its unique properties like:

Implantable polysulfone port

- Transparency
- Sterilizability.
- High impact resistance
- Chemical resistance .
- Flame retardancy & and good electrical properties (Good Insulator)
- High creep resistance and thermal stability
- Biocompatibility

Examples of medical devices that use polysulfones are : Implants, surgical instruments, and diagnostic equipment like MRI machines, CT scanners, X-ray machines,Medical fittings and connectors

Polysulfone Membrane Blood Dialyzer

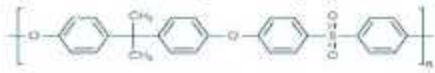
Polysulfone Surgical Storage Containers

Polycondensation reaction

Aromatic polysulfones can be produced by the reaction of bisphenol salts with 4,4- dichlorodiphenyl sulfone (4,4-DCDPS) (Figure 8.2). Reactions typically are conducted in high-boiling polar solvents like sulfolane, dimethyl sulfoxide (DMSO), and N-methyl pyrrolidone (NMP) at temperatures ranging from 100 to 250°C This reaction involves diphenoxide and bis(4-chlorophenyl)sulfone (DCDPS). The diphenoxide is produced in situ from a diphenol and sodium hydroxide. The polymerization is carried out in a polar, aprotic solvent, such as dimethyl sulfoxide, at 130–160°C

Polysulfone is used in medical devices, such as synthetic membranes, hemodialysis, blood circulation, and implant materials.

The bisphenol monomers and a salt forming agent react to form bisphenolate. The bisphenolate and 4,4'-dihalodiphenyl sulfone undergo polycondensation to produce polysulfone.

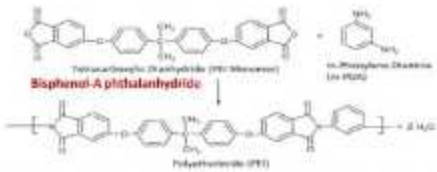


polysulfone

POLYETHERIMIDE (PEI): AN UNIQUE & RELIABLE POLYMER FOR MEDICAL DEVICES

Polyetherimide(PEI) is an amorphous, transparent engineering thermoplastic. The unique polymer offers an exceptional combination of high heat resistance, flame retardancy, and chemical resistance. PEI can maintain its mechanical strength & dimensional stability across a wide range of temperatures. PEI is also sterilizable through autoclaving, radiation, chemical methods therefore it is very useful and a favoured option for medical devices.

PEIs are made through a polycondensation reaction, which is a reaction consisting of two or more monomers, each containing one or more functional groups, which in this case are a dianhydride and a diamine.



Synthesis of PEI between bisphenol-A phthalanhydride and a diamine

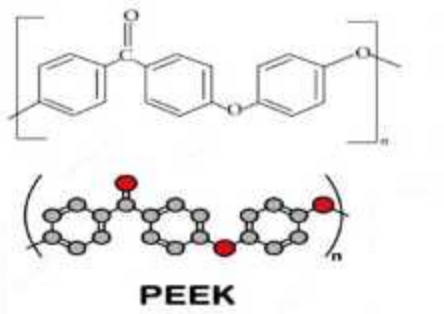
PEI is used in many medical devices

- Surgical instruments like the handles, forceps, and retractors of surgical instruments.
- Implantable devices like orthopedic implants, cardiovascular devices, and dental implants.
- Diagnostic equipment like blood analyzers, imaging devices, and diagnostic reagent containers.
- Medical tubing due to its strength characteristics, thinner walls, and larger inner diameter requirements.

surgical devices made from medical grades PEI maintain properties after repeated autoclave cycles. Polyetherimide (PEI) Compression Spring

PEEK (Polyether ether ketone) Plastic

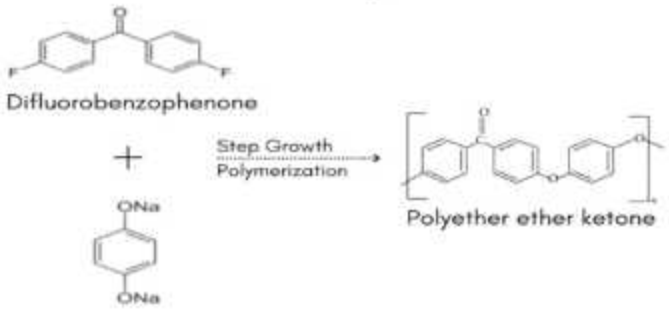
Chemical Structure



PEEK

PEEK belongs to polyaryletherketone (PAEK) family of polymers.

PEEK Plastic Polymerization



Disodium Hydroquinone

Polyetheretherketone (PEEK) is a high-performance polymer that is produced through a step-growth polymerization process: 4,4'-difluorobenzophenone is reacted with the disodium salt of hydroquinone in a polar aprotic solvent, such as diphenyl sulfone.The sodium phenoxide attacks the fluorine atoms in the difluorobenzophenone, forming ether linkages and longer polymer chains.

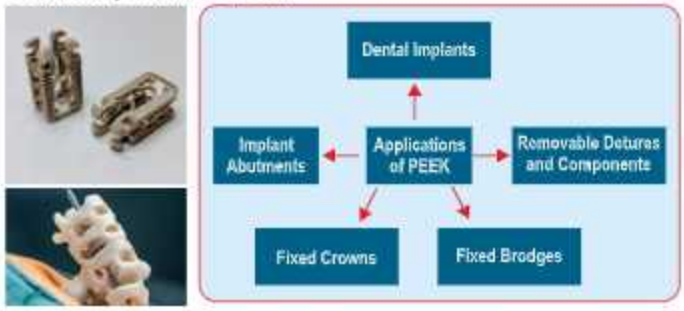
PEEK is a semicrystalline polymer with a rigid aromatic backbone that gives it a high glass transition and melting temperature. It has excellent mechanical properties and chemical resistance, and can be used conveniently at temperatures up to 240°C

PEEK® is an organic thermoplastic polymer that offers excellent mechanical and chemical resistance properties because of its chemical make-up. PEEK® is short for polyether ether ketone, which means it's a member of the polyaryletherketone family. These polymers are notable for their phenylene rings and oxygen bridges, which result in resilience, durability and strength.

Many medical device manufacturers now use PEEK® as a way to improve the biocompatibility of load bearing implants. PEEK® is increasingly becoming the new standard biomaterial across a range of medical, orthopedic, and dental applications.

Polyetheretherketone (PEEK) is a thermoplastic polymer with many uses, including: Medical implants. Polyetheretherketone provides cost-effective, innovative parts with excellent wear, heat, electrical and chemical resistance. Its applications in healthcare industry mainly in the area of dental instruments, endoscopes and dialyzers

PEEK polymers maintains outstanding mechanical strength, excellent stress cracking resistance and hydrolytic stability in the presence of hot water, steam, solvents and chemicals. This plastic offers improved biocompatibility of load bearing implants.PEEK is used in medical implants like bone replacement materials, screws, and plates for spinal surgeries and cranial implants. PEEK is biocompatible and has a modulus of elasticity similar to bone.

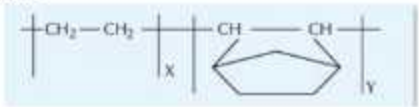


High Precision, PEEK, Thermoplastic Medical Spinal Implant Component

Polyetheretherketone (PEEK) in dentistry.

PEEK has been established as a biocompatible material, meaning it is safe for use in vivo (within the living body). Extensive research has shown that PEEK exhibits no signs of cytotoxicity, genotoxicity, or immunogenicity. Studies spanning more than 20 years have demonstrated its effectiveness in various applications, including spinal fusion cages, orthopedic implants, and dental devices COC (Cyclic olefin copolymer).

It is an amorphous transparent copolymer possessing a cyclic olefin structure.



KEY PROPERTIES

- Low Density
- Highly transparent
- Good water vapour resistant
- Very good acid and alkali resistant
- Density –1.02 gm/cm3

MAJOR PACKAGING APPLICATIONS

- Blister packaging material
- COC Vials replace the glass vials.
- Co-extruded film & laminates used for food & pharmaceutical packaging
- Pre filled syringes.

Cyclic olefin copolymer (COC) is a plastic material that is widely used in medical devices and packaging applications due to its unique properties COC is used in a variety of medical devices, including:

- Laboratory and diagnostic devices: Syringes, vials, ampoules, cuvettes, microtiter plates, test tubes, petri dishes, and pipettes
- Needleless injectors, injector pens, and inhalers: COC is used in the development of drug- delivery systems
- Blister packs: COC is ideally suitable for the production of blister packs due to its good thermoformability

COC is a good choice for medical devices because of its:

- Clarity: COC is highly transparent and clear, which ensures accurate results in assays

- Biocompatibility: COC is biocompatible with the tissues and proteins used in assays
- Heat resistance: COC can withstand high temperatures during the manufacturing process and sterilization through autoclaving
- Chemical resistance: COC is resistant to solvents like alcohol
- Sterilization compatibility: Most COC grades can undergo sterilization by gamma radiation, steam, or ethylene oxide
- Low water absorption: COC has a low water absorption value of less than 0.01% Norbornene or norbornylene or norcamphene is a highly strained bridged cyclic hydrocarbon. It is a white solid with a pungent sour odor.

The molecule consists of a cyclohexene ring with a methylene bridge between carbons 1 and 4. The molecule carries a double bond which induces significant ring strain and significant reactivity.

Ethylene/norbornene content within cyclic olefin copolymer (COC) is well known to affect the chemical and physical properties of the copolymer, such as the glass transition temperature (Tg) and transparency.

TOPAS® COC is manufactured by TOPAS Advanced Polymers GmbH and sold by Polyplastics in the Americas, Japan and Asia Pacific.

Norbornene

TOPAS® COC (cyclic olefin copolymer) is a glass-clear and extremely pure plastic for healthcare, packaging, and electronics applications. From insulin delivery, to food contact films, TOPAS® COC is the high-performance material of choice.

The broad global regulatory compliance of TOPAS® COC can make your next development a simpler task.

TOPAS® COC is manufactured by TOPAS Advanced Polymers GmbH and sold by Polyplastics in the Americas, Japan and Asia Pacific.

Raw ingredients and production method

TOPAS® COC is a cyclo olefin copolymer (COC) copolymerized from norbornene and ethylene using a metallocene catalyst. Comonomer content determines the glass transition temperature, so TOPAS® COC grades with high cyclic olefin content have higher heat resistance.

The ASPIEL Syringe: Innovation Born in the Operating Room

Dr. Prujal Parekh
MBBS, MS
General & Minimal Access Surgery Surgeon and Founder, "ASPIEL"

The story of how a surgeon's clinical experience led to the development of the Aspiel Syringe for safer high risk injections.

Every innovation begins with a simple question. For me, that question was, **"Can this be done better?"** As a practicing General and Minimal Access Surgeon, I have spent years performing procedures where precision is everything. In the operating room, even the simplest instruments can influence patient safety. Among these instruments, the syringe is probably the most familiar. It has remained largely unchanged for decades, despite being used millions of times every day. I often found myself wondering whether this simple device could be be improved to make certain procedures safer without changing the way clinicians work.

That question became the beginning of this journey.

High risk injections are performed every day in operating rooms, emergency departments, pain clinics and many other healthcare settings. These include peripheral nerve blocks, local anaesthetic infiltration during trauma and emergency care, and several other procedures where the needle is placed close to important blood vessels and nerves. During these injections, clinicians follow several recognised safety practices to reduce the risk of unintentionally injecting medication into a blood vessel.

One of these safety practices is aspiration. Before injecting the medication, the clinician gently pulls back on the syringe plunger to check whether blood enters the syringe. If blood is seen, the needle may be inside a blood vessel and can be repositioned before the medication is administered. This simple step has been an important part of clinical practice for many years.

However, aspiration is not a perfect test. A negative aspiration, where no blood is seen, does not always guarantee that the needle tip is outside a blood vessel. Medical literature has described situations in which **false negative aspiration** can occur. This may happen because the opening of the needle is blocked by the vessel wall, the blood vessel temporarily collapses when suction is applied, or the needle position changes slightly during the procedure. For this reason, clinicians rely on aspiration as one important safety measure while also using careful technique, anatomical knowledge and, where appropriate, imaging guidance.

Apart from these recognised limitations, aspiration itself can sometimes be technically challenging. During many high risk injections, the clinician must keep the needle steady while simultaneously pulling back on the plunger and watching for blood. This often requires excellent hand coordination, and even slight movement of the needle may be undesirable. Watching these challenges repeatedly in daily practice made me ask another simple question.

Could the syringe itself make aspiration easier while allowing the clinician to maintain better control?

The Aspiel Syringe is a novel syringe designed to simplify aspiration during high risk injections while allowing the clinician to maintain better control of the device. At the heart of the device is a patented mechanical concept that separates the process of aspiration while preserving the familiar handling and operation of a conventional syringe. Rather than introducing a completely new way of performing injections, the design builds upon techniques that clinicians already know. The intention is not to replace clinical judgement or established safety practices. Instead, it is designed to support clinicians by making animportant safety step easier and more intuitive.

One of the guiding principles throughout development was simplicity. Healthcare professionals work in demanding environments where new devices must be easy to understand and easy to use. A device that requires extensive retraining is unlikely to become part of routine practice. For this reason, Aspiel was designed to feel familiar in the clinician's hand while incorporating an innovative mechanism that assists during aspiration.

Developing the device was a journey that required patience and persistence. The original concept evolved through numerous sketches, prototypes and design refinements. Every version taught us something new. Some concepts worked well clinically but were difficult to manufacture consistently. Others were easy to manufacture but did not provide the performance we were looking for. Achieving the right balance between clinical function, ease of use and manufacturability took several years of continuous refinement.

Engineering played an equally important role throughout this journey. A successful disposable medical device must be more than an innovative idea. It must be capable of consistent

manufacturing, efficient assembly, reliable sterilisation and rigorous quality control while remaining commercially practical. Every stage of development was guided by these considerations, ensuring that the final design could be translated from an idea into a product suitable for large scale production.

Feedback from fellow clinicians was invaluable throughout the development process. Their experience helped refine the ergonomics, improve usability and ensure that the device remained practical in everyday clinical settings. This collaboration between clinicians and engineers became one of the greatest strengths of the project. Clinicians understand the problems that need solving, while engineers provide the expertise to transform those ideas into reliable medical devices.

Today, Aspiel Syringes has progressed from an idea conceived in the operating room to a clinically evaluated medical device. Before entering clinical use, the device successfully completed preclinical biocompatibility testing to demonstrate that the materials used are safe for their intended medical application. It subsequently received regulatory approval from the Central Drugs Standard Control Organisation (CDSCO) for marketing in India. Clinical evaluation demonstrated encouraging results together with positive feedback from users, providing further confidence in the practical application of the device.

The scientific basis along with the randomized controlled trial of the innovation has also been published in **BMJ Innovations** one of the leading peer reviewed journals in the field of medical innovations. Publishing the work allowed the concept to be independently evaluated and shared with the wider medical community. Alongside these scientific and regulatory milestones, a strong intellectual property strategy has been pursued. The invention is protected by granted and pending patents in multiple jurisdictions, supporting its future global development and providing a strong foundation for commercial partnerships. Although these milestones are important, they represent only the beginning of the journey. The true success of any medical device lies in its ability to improve patient care and become a practical tool for healthcare professionals around the world. Achieving that goal requires strong partnerships in manufacturing, regulatory affairs, quality systems and global distribution.

Looking back, the Aspiel Syringe began with a simple observation made during routine clinical practice. Looking ahead, the vision remains equally simple: to provide clinicians with a better tool for performing one of the most important safety steps during high risk injections. Innovation does not always come from complex technology or sophisticated electronics. Sometimes it begins with recognising a problem that others have accepted, asking whether it can be improved, and working patiently to transform that idea into a practical solution.

The best innovations are not always the most complicated. They are often the ones that solve a real problem in the simplest possible way. That philosophy continues to guide the journey of Aspiel.

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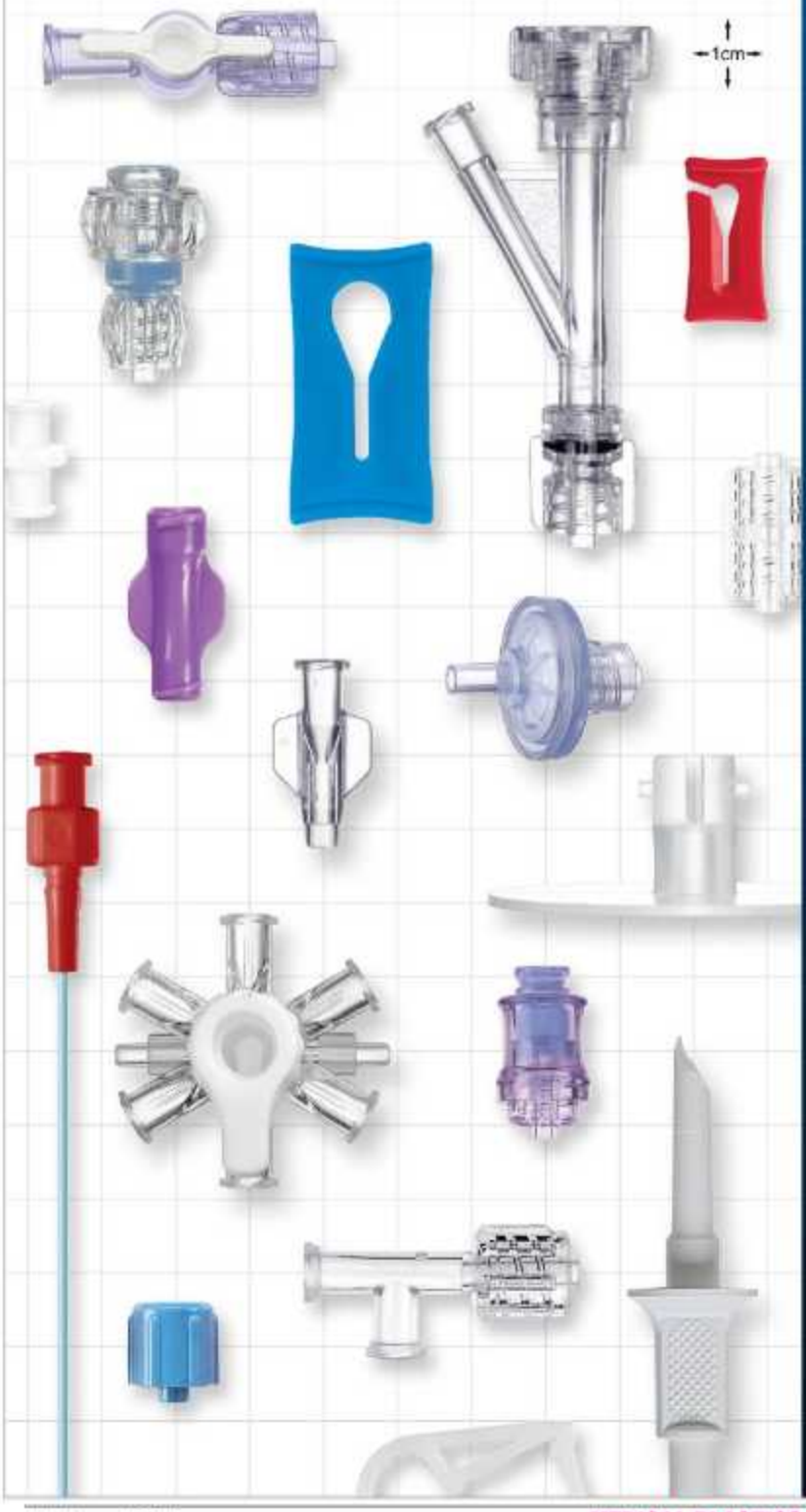

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Advances in Micro-extrusions and Importance of Catheter Liners

Miniaturization is an ongoing trend in medical technology, and one of the enabling manufacturing processes is microextrusion, which is used to produce ultra-thin, precision tubing. The process enables the fabrication of single-lumen, multi-lumen, and multi-layered catheter liners typically required for minimally invasive medical devices.

Innovations in micro-extrusion, material processing, and surface modification have allowed for the development of ultra-thin, high-strength, and chemically resistant liners that enhance procedural efficiency and patient safety.

Recent advances in micro-extrusion for medical catheters focus on ultra-thin wall profiles (under 0.005 inches), micron-level lumen concentricity, and real-time AI defect detection. These manufacturing improvements allow microcatheters to safely navigate winding, microscopic blood vessels for targeted neurovascular and cardiovascular procedures.

Micro-extrusion is a critical enabling technology for the production of these devices. Advances in this technology, the materials that can be processed, and surface treatment techniques continue to push the boundaries of medical technology.

Key Manufacturing Innovations

- **AI-Driven Monitoring:** Real-time sensor systems detect structural micro-defects during production.
- **Multi-Layer & Multi-Lumen Co-extrusion:** Advanced dies combine variable polymers (like PEBA, PTFE, and TPU) in a single continuous process.
- **Tight Tolerances:** Wall thicknesses shrink below 0.005" while maintaining structural integrity and high burst pressures.
- **Embedded Micro-Sensors:** Integration of flex circuits and micro-sensors directly within the extruded shaft walls. [1, 2, 3, 4, 5]

Material and Design Improvements

- **Enhanced Trackability:** Improved pushability and torque transmission for distal vessel access.
- **Advanced Surface Modalities:** Incorporation of micro-textured patterns or hydrophilic matrices directly via advanced compounding and co-extrusion.

These advances have had a profound impact on patient care. Reduced trauma and vascular injury is one of the key benefits, as low-friction liners significantly minimize resistance during catheter insertion. This reduces mechanical stress on delicate blood vessels, lowering the risk of endothelial damage, which can lead to serious complications such as thrombosis or restenosis."

- Microextrusion enables fabrication of catheter liners required for minimally invasive medical devices
- Thin-walled, high-precision components provide properties such as lubricity, structural integrity, and biocompatibility
- AI-driven extrusion monitoring systems detect micro-defects in real time

Importance of catheter liners

Catheter liners are ultra-thin inner tube layers used inside medical catheters and delivery sheaths. Made mostly from low-friction materials like PTFE or FEP, they create a smooth interior path. This slick surface helps doctors pass tiny wires, balloons, or stents smoothly through blood vessels.

Catheter liners play a foundational role in the performance of minimally invasive medical devices. The thin-walled, high-precision components act as inner layers within catheters, providing essential properties such as lubricity, structural integrity, and biocompatibility. "Their function is particularly crucial in neurovascular and cardiovascular interventions, where the precision of guidewire tracking and catheter flexibility determines the success of complex procedures.

Advanced liners prevent material degradation and leaching, which is essential for maintaining the performance of chronic catheterization devices and controlled drug delivery systems. By enhancing both the short-term and long-term outcomes of catheter-based interventions, these innovations are significantly improving patient care and procedural efficiency."

precision liners that enhance guidewire and catheter navigation have improved procedural success rates. "This is particularly critical in complex procedures such as stroke interventions, cardiac ablations, and stent placements, where even minor resistance or misalignment can compromise patient outcomes."

Key Functions

- **Low Friction:** Offers a non-stick, slippery inner surface so medical tools glide easily.
- **Space Saving:** Features very thin walls to keep the overall catheter small and flexible.
- **Strength:** Helps the catheter keep its round shape when pushed through tight or twisted pathways.

Common Materials

- **PTFE (Polytetrafluoroethylene):** The gold standard for inner liners due to extreme slickness and durability. Often chemically etched on the outside so outer jacket layers can glue or bond to it safely.
- **FEP (Fluorinated Ethylene Propylene):** Another slick fluoropolymer used to line guiding tubes and multi-lumen shafts.

Moreover, precision liners that enhance guidewire and catheter navigation have improved procedural success rates. This is particularly critical in complex procedures such as stroke interventions, cardiac ablations, and stent placements, where even minor resistance or misalignment can compromise patient outcomes.

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European Union Medical Devices Market

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After covering the Asia Pacific markets and important LATAM markets, we will now understand the basics of the European market in this series of articles. As the learned readers know, this market is far more complicated in its nature and dynamics. It is proposed, therefore, to understand the broader aspects of this market, the structure of this market in some detail, and also to brush up on some market strategic aspects (though some of these will be a repetition of your knowledge during your entrepreneurial journey).

Close to 30% of India's medical device export of India is to the European market, and this export has a growth rate of approximately 7.5%. This also makes the European market important.

Centre for the Promotion of Imports from Developing Countries (CBI)

A fairly long time ago, the Centre for the Promotion of Imports from Developing Countries, hereinafter referred to as CBI (not the conventional denotation of the Indian agency CBI!!), had implemented an earnest effort to facilitate exports of Indian medical devices to European countries. This Centre for the Promotion of Imports from Developing Countries (CBI) deserves some more detailing here. CBI is sponsored and funded by the Netherlands government, with its main aim being to strengthen the social, economic and environmental sustainability of Small and Medium-sized Enterprises (SMEs) in low- and middle-income countries by connecting SMEs to European and regional markets, as its webpage highlights (https://www.cbi.eu/). The Netherlands Ministry of Foreign Affairs established CBI in 1971. With more than 50 years of experience in successfully helping sustainable economic development through exports, more than 10,000 SMEs from 70 countries have been supported by CBI, connecting them to buyers or partners in the European market, raising awareness and building capabilities through training and knowledge-sharing. Some of the material which we will present here is from CBI training sources.

European Union – Basic Structure

The European Union, conventionally known as the EU, comprises 27 countries. The EU was formed in 1993. These 27 countries act as a single economic and political block for the policies related to these areas. 19 of these 27 countries have a common currency, the Euro (while 8 EU members have their own currency). The list of the 27 EU countries is: Austria, Belgium, Bulgaria, Croatia, Cyprus, Czechia, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, and Sweden.

Unlike the United States of America, the EU is not a federal state. The EU is a group of countries/territories based on treaties. The policies of the EU cover the three main areas, namely, the Community pillar, Common Foreign and Security Policies, and the Justice & Home Affairs area.

The Euro Area Outline

Many of the member countries of the EU have replaced their national currencies with the single currency – the euro. These Member States together are known as the Euro Area or Eurozone. In 1999, the Euro was introduced; the euro area comprised 11 Member States. Many countries gradually joined the EU as well as the Euro Area. Today, the euro area numbers 20 EU Member States. These are Austria, Belgium, Croatia, Cyprus, Estonia, Finland, France, Germany, Greece, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, the Netherlands, Portugal, Slovakia, Slovenia, and Spain. The remaining 7 non-Euro area countries are Bulgaria, Czechia, Denmark, Hungary, Poland, Romania, and Sweden. However, gradually, these countries may also become part of the Euro area.

The Euro Area (Eurozone) Economy

For the Euro Area, projected GDP growth is 1.4% in 2027, higher than 2025 and 2026 GDP growth (in the range of 1.2-1.3%). Strengthening domestic demand and better private consumption will be the main reasons for this growth, it is predicted. Core inflation was at 2.4%, mainly due to inflation in the price of services. The euro has appreciated strongly against a basket of 41 currencies. A very useful website in this regard is of the Organisation for Economic Co-operation and Development, or OECD (https://www.oecd.org/en.html). The EU economy is the

second-largest economy in the world in nominal terms, after that of the United States.

In summary,

- Annual GDP Growth (EU): 1.5%
- Annual GDP Growth (Eurozone): 1.4%
- Q4 2025 Growth: 0.2% over the previous quarter in both the EU and Eurozone.
- Top Growth Countries: Ireland (12.3%), Malta (4.0%), and Cyprus (3.8%).
- Slowest Growth Countries: Germany (+0.2%), Finland (+0.2%), and Hungary (+0.4%)

Top EU Economies by Nominal GDP (2025 Projection)

- Germany: Projected to be the largest, with significant nominal growth (approx. $5 trillion+).
- France: The second-largest, holding a key position in European economic growth.
- Italy: Third-largest, with a nominal GDP estimated at around $2.5 trillion.

The Euro, the currency of the Euro Area, is stronger than the United States Dollar. In April 2026 end, the conversion rate was around 1.17 USD for each euro.

European Union –Understanding the Profile

After seeing the relative sizes of the economies of the EU and the Euro Area, a look at the population data of the top 10 countries may also be useful for making a judgment of the market sizes.

Rank	Country/Territory	Population 2026	Median Age	Urban Pop %	World Share
1	Germany	8,36,44,258	46	77%	1.01%
2	France	6,67,46,401	42	83%	0.80%
3	Italy	5,89,26,166	49	72%	0.71%
4	Spain	4,78,50,793	46	80%	0.58%
5	Poland	3,78,43,188	43	60%	0.46%
6	Romania	1,88,00,605	43	55%	0.23%
7	Netherlands	1,84,48,775	42	89%	0.22%
8	Belgium	1,17,74,642	42	99%	0.14%
9	Sweden	1,07,01,047	40	88%	0.13%
10	Czech Republic	1,05,27,781	44	76%	0.13%

Data from Worldometers (https://www.worldometers.info/)

The readers already know some clear observations of the past that the size of the economy and the population numbers have clear correlations. Also, the median age of between 40 and 50 shows "greying" of these countries (India's median age is below 30), and "greying" means health issues with a larger health market. Very high urban population density is also a clear observation.

Diversity in unity is the EU's main characteristic. One example of economic differences – London and Hamburg have double the per capita GDP compared to the average per capita GDP of the EU. On the other hand, Greece has half this number compared to the average per capita GDP of the EU. language and geography are also vastly different.

Some important social trends are – Religion (Christianity is followed by about 70%), a multicultural market, an ageing society, more leisure time, high single-person households, and households with both working members with no children.

Eleven Associations Seek Urgent Re-examination Of The "Draft Drugs, Medical Devices And Cosmetics Bill, 2026".

Eleven national associations representing manufacturers, traders, healthcare providers, hospitals, clinicians and patient advisory groups have jointly written to Union Health Minister J P Nadda, calling for an urgent re-examination of the Draft Drugs, Medical Devices and Cosmetics Bill, 2026.

The letter, dated August 8, 2026 and coordinated by the Association of Indian Medical Device Industry (AiMeD), was sent following a meeting with the minister on the sidelines of a Medical Devices Conference at Vigyan Bhawan the same day. The associations opened by congratulating Nadda on his leadership of both the Ministry of Health and Family Welfare and the Ministry of Chemicals and Fertilizers, saying his stewardship of both portfolios offered a historic opportunity to help India become a global medical device manufacturing hub, reduce import dependency from the current 70-80 per cent, and achieve exports exceeding Rs 1,00,000 crore within the next five to seven years.

Against that backdrop, the associations said the draft bill in its present form does not provide the regulatory foundation the sector needs to grow, innovate and compete globally, and that it runs contrary to the health ministry's own National Health Policy 2017, which had called for a separate regulator for medical devices. The draft, they said, continues to treat medical devices as an adjunct to pharmaceuticals despite clear scientific, engineering and regulatory distinctions between the two categories.

Key concerns raised

The letter lays out **seven specific objections** to the 2026 draft. It notes that the bill continues to use drug-centric terminology such as "adulterated," "spurious" and "misbranded," and applies pharma-style criminalisation to what are essentially engineering deviations, when **internationally, devices are regulated through risk-based conformity assessment, quality management systems, post-market surveillance, and recalls and corrective actions rather than imprisonment.**

The associations flagged that the bill imposes imprisonment of one to seven years for issues such as labelling errors, documentation lapses, licensing issues, post-market surveillance reporting mistakes and engineering defects, even when no harm has occurred, **a standard they say is not practised under the EU's Medical Device Regulation, the US FDA, Japan's PMDA, the UK's MHRA or Australia's TGA, where administrative enforcement is the norm.**

They also pointed to expanded arrest powers, immediate cessation orders and criminal procedure provisions for inspectors under the draft, which they called a major deterrent to investment and innovation, and noted that despite repeated recommendations, **the bill retains the existing drug-regulator framework instead of creating a dedicated, technically competent National Medical Devices Regulatory Authority.**

The letter further said **the draft omits essential device-specific concepts, including biocompatibility standards under ISO 10993, usability engineering under IEC 62366, software lifecycle safety under IEC 62304, provisions for accessories, remanufacturing and repackaging, and predicate equivalence pathways used under IMDRF, EU and US frameworks. It also applies uniform penalties across all device risk classes, from low-risk surgical instruments to high-risk implants,** rather than a risk-proportionate framework, and the associations said stakeholder consultation on the draft had been insufficient and inconsistent with the pre-legislative consultation process, despite repeated submissions from manufacturers, hospitals, clinicians, patient groups and engineering experts.

Backed by past recommendations

The associations said their position is reinforced by Parliamentary Standing Committee Reports 138 and 146, which explicitly recommended a separate law for medical devices, NITI Aayog's own Draft Medical Devices (Safety, Effectiveness and Innovation) Bill of 2019, which proposed a modern, engineering-aligned regulatory framework, and the World Health Organization's global principles for device regulation, which emphasise risk management, lifecycle safety and shared responsibility.

"Medical devices are engineering products, not pharmaceuticals. **India must adopt smarter, risk-proportionate regulation that safeguards patients while fostering innovation, and urge a dedicated Medical Devices Act,"** said Prof Bejon Kumar Misra, founder of the Patient Safety and Access Initiative of India Foundation.

Puneet Bhasin, president of the Surgical Manufacturers & Traders Association, said retaining medical devices under the same law as drugs would create complex compliance requirements, particularly for MSMEs, potentially hurting competition and innovation while increasing healthcare costs. "We urge the Government to establish a separate Act with an independent regulator," he said.

What the associations are asking for

Invoking the prime minister's vision of Atmanirbhar Bharat, Gati Shakti and Make in India, **the associations made six requests to the ministry.** They asked for the **constitution of a new expert committee** comprising engineering experts, clinicians, biomedical specialists, industry representatives, patient safety groups and regulatory experts, separate from the drug-regulator drafting group. They sought **enactment of a separate Medical Devices Act, modern and internationally harmonised,** aligned with the EU MDR, the US FDA device framework, IMDRF principles and NITI Aayog's 2019 draft.

They also **called for decriminalisation of non-mens-rea offences, with administrative enforcement** such as recalls, corrective actions and civil penalties replacing imprisonment for technical lapses, and for the establishment of a National Medical Devices Regulatory Authority with autonomy similar to TRAI or IRDAI, and clear oversight over state regulators and conformity assessment bodies, comparable to FSSAI. **Their remaining asks were for risk-proportionate, engineering-aligned regulation, with penalties, licensing, surveillance and enforcement based on device risk class and actual or potential harm, and for structured stakeholder consultation**

before the bill is finalised, to ensure it reflects the needs of manufacturers, hospitals, clinicians, patient groups and users.

The associations said they remain hopeful of stakeholder consultations with the Ministry of Health and Family Welfare, noting that both Minister Nadda and the ministry's secretary had assured them of a systemic redressal process when the matter was raised at the Medical Devices Conference.

"India's medical devices sector cannot be shackled by a pharma-centric law. Eleven national associations, backed by earlier recommendations from Parliamentary Committees, NITI Aayog, and WHO principles, urge the government to enact a standalone Medical Devices Act. Without this, India risks discouraging investment, innovation, and patient safety, undermining Make in India and Atmanirbhar Bharat," said Rajiv Nath, forum coordinator of AiMeD.

https://medicalbuyer.co.in/eleven-associations-seek-urgent-re-examination-of-the-bill/ (August 11, 2026)

Parliamentary Panel's Report On MedTech Roadmap to Shape Indian Industry

The Parliamentary Standing Committee on Health and Family Welfare's latest report reads less like a routine review and more like a blueprint for how India wants its medical technology sector to grow over the next decade. Taken together, the recommendations on procurement quotas, mandatory health technology assessment, the proposed Medical Innovations Development Acceleration Council, and a strengthened Patent Mitra framework point toward a shift from cheering innovation from the sidelines to actually building the plumbing that gets Indian-made devices into hospitals and clinics at scale.

The procurement quota idea is probably the most consequential piece of this. Indian MedTech has no shortage of promising innovation coming out of programs like MedTech Mitra, which has already mentored more than 400 innovators, and the seven IIT-based Centres of Excellence that have produced 43 technologies and 16 start-ups. What has been missing is a reliable first customer. Plenty of validated products die in what the committee calls the valley of death, the gap between a working prototype and an actual buyer willing to place a large enough order to justify manufacturing at scale. A dedicated quota within national health programs would effectively guarantee that buyer, and for cash-strapped start-ups and MSMEs, that kind of certainty tends to matter more than any subsidy. It changes the calculation for investors too, since a start-up with a guaranteed procurement channel is a fundamentally safer bet than one hoping a hospital network eventually notices its product.

The Medical Innovations Development Acceleration Council addresses a different, quieter problem: the diseases and health conditions that matter enormously to public health but attract almost no private investment because there's no real commercial upside. Neglected tropical diseases and regional outbreaks fall squarely in this gap. If MIDAC is properly capitalized and actually operationalized, rather than existing mostly on paper, it could become the funding mechanism that keeps Indian biomedical research from mirroring the same market failures seen globally, where research dollars chase the conditions with the biggest paying markets rather than the biggest public health burden.

The committee's push to link Model Rural Health Research Units and the Tribal Health Research Network directly into the MedTech Mitra ecosystem is a sensible complement to this, since it means new point-of-care tools like AI-enabled handheld X-ray devices and CRISPR-based diagnostic kits get tested in the exact underserved settings they're meant to serve, rather than being validated in a metro hospital and assumed to work everywhere else.

Patent Mitra is the piece that will determine whether any of this translates into products people can actually buy. Twenty-four patent applications and one successful technology transfer since March 2025 is a modest start, and the committee is right to flag that a patent by itself does nothing for public health if it never reaches manufacturing. The recommended fast-track mechanism connecting patent holders with PSUs and established private manufacturers, paired with financial incentives for companies that license and mass-produce these technologies, addresses a well-known failure point in Indian innovation policy, where research output has often outpaced the country's ability to commercialize it domestically.

If even half of this gets implemented with real budgets attached, the effect on the MedTech industry could be significant. Start-ups would gain a clearer path from prototype to procurement, established manufacturers would have new financial incentives to license domestic patents rather than import similar technology, and state governments would gain more say in which technologies actually reach their populations. The bigger question, as with most committee recommendations in India, is execution. CoEs, HTA nodes, and technology transfer mechanisms all require sustained funding and coordination across ministries, state governments, and premier institutions, and that kind of follow-through has historically been where good policy intentions in this sector have stalled.

Poly Medicure Bets on New Facilities, Products to Double Int'l Business: Himanshu Baid

Himanshu Baid
Chairman, National Medical Technology Forum, CII

Medical devices maker Poly Medicure is targeting to double its international business by FY30, backed by a strong innovation pipeline, new manufacturing capacities and deeper market penetration globally, managing director Himanshu Baid told ET in an exclusive interaction.

"We are targeting to double our international business revenue by Fy30," Baid said.

In FY26, Poly Medicure's international business contributed ₹1,280.2 crore, accounting for nearly 68% of the company's total revenue of ₹1,875.3 crore. The company expects the next phase of growth to be supported by two upcoming manufacturing facilities, a pipeline of more than 50 products and a sharper focus on direct market operations across key overseas geographies.

The company launched 35 new products across domestic and international markets last year and expects to introduce over 50 new products over the next one to two years across critical care, cardiology, oncology and vascular access.

While the US and Europe currently account for about 35% of Poly Medicure's export revenue, Baid believes the biggest opportunity lies in emerging markets.

"The largest export potential for India would be the Global South," he said. "We have the Middle East as an important market, Southeast Asia, Africa and then also Latin America."

The company, however, has not yet experienced any material benefit from the global supply chain diversification away from China.

"At present, Poly Medicure has not seen any measurable increase in enquiries or orders specifically attributable to the China-plus-one strategy," he said.

Baid added that India had largely missed the first wave of manufacturing relocation. "Unfortunately, we have missed that first bus," he said, noting that much of the initial shift went to countries such as Vietnam, Indonesia and Malaysia where Chinese manufacturers themselves established production facilities.

However, he is of the view that the next phase could favour India as Europe seeks to diversify sourcing of medical devices. "Europe... has started looking beyond China. And I think that opens a good opportunity," he said. "Today, what has gone to Vietnam, Indonesia, or Thailand is mostly low-tech devices. India still has the potential to get high-tech and make high-tech products," he added.

On the domestic front, Baid expects India to outpace exports over the next few years. "India offers to be the most important market for us today in terms of growth strategy. In India, we aim to grow between 20-25% every year for the next four or five years. In exports, the growth should be between 15% and 20%, depending on how the market shapes out and how the situation changes over the next few months. But India will be a push-up compared to exports," said Baid.

Poly Medicure has identified renal care, critical care (oncology and neonatology) and cardiology as its biggest growth drivers. In dialysis, the company expects local manufacturing to lower treatment costs and accelerate the shift towards single-use dialyzers.

"The products were expensive because they were 100% import dependent. But with local manufacturing, the cost is coming down. We should all move to single-use because these devices are meant for single use," Baid said.

Baid said the company will continue evaluating inorganic opportunities where they help strengthen technology and regulatory capabilities. The company has earmarked over ₹200 crore of capital expenditure this year.

https://economictimes.indiatimes.com/industry/healthcare/biotech/healthcare/poly-medicure-bets-on-new-facilities-products-to-double-international-business-md/articleshow/132447336.cms?from=mdr (July17,2026)

Gujarat Aims To Become India's Biotechnology Hub By 2030.

Gandhinagar: Gujarat is steadily advancing toward becoming India's leading centre for biotechnology and bio-manufacturing by 2030, stated a report by Gujarat Rajya Institution for Transformation (GRIT). This push is backed by a strategy focused on building skilled talent, specialised education and industry-oriented capabilities, govt said on Sunday.

The report, titled 'Gujarat Bio-Economy 2030: Strategic Skill Architecture and Workforce Development', notes that India's bio-economy expanded from about $10 billion (Rs 94,360 crore approx) in 2014 to more than $150 billion (Rs 14 lakh crore approx) in 2024."Gujarat is poised to become one of the country's foremost states in the bio-economy space in the coming years. The state already accounts for around 40% of India's total pharmaceutical production and is also one of the country's major chemical manufacturing centres," an official statement said. Govt said that bio-pharma, with a share of 35%; the bio-industrial segment, with a 47% share; and bio-agriculture, with an 8% share, are driving growth in this sector.The statement said the Gujarat State Biotechnology Policy 2022-27 signals the state's intent to convert its industrial strength into bio-economy leadership.

"Gujarat's ambition goes beyond manufacturing generic drugs; it seeks to become a front-runner in the development of innovative biologics," the GRIT report said.A study of 23 institutions in Gujarat offering biotechnology and related programmes highlights the strength of the state's educational base and its significant potential, the report said. It also points out the scope of making academic programmes more aligned with emerging industry trends and preparing a future-ready workforce equipped for the evolving needs of biotechnology.

https://timesofindia.indiatimes.com/city/ahmedabad/gujarat-aims-to-become-indias-biotechnology-hub-by-2030-grit-report/articleshow/132057769.cms (29 June 2026)

Inauguration of SPE INDIA Student Chapter@CIPET:IPT Chennai

The **Inauguration of SPE INDIA Student Chapter@CIPET:IPT Chennai** was formally inaugurated on 20 August 2026 at the Video Conference Hall, CIPET: IPT Chennai, marking an important step towards strengthening students' technical knowledge, industry exposure, and professional development in plastics and polymer engineering.

The event was graced by Dr. K. Prakalathan, Director & Head, CIPET: IPT Chennai; Mr. Y. Hidayathullah, Manager (T), HOD – Plastics Technology and Faculty Advisor; Mr. Velladurai, HOD – Manufacturing Engineering; Ms. Udhayamalar, HOD – Testing; and faculty members of CIPET. From SPE India, Mr. Rajiv Sanghavi, SPE International Councillor, and Mr. D. L. Pandya, Vice President, Medical Plastics Division, joined the programme virtually.

The programme commenced with a welcome address by Mr. Anbumani S, Student President, who introduced the chapter and presented an overview of its objectives and planned activities.

The keynote addresses by Dr. K. Prakalathan and Mr. Y. Hidayathullah emphasized the importance of technical learning, professional engagement, and industry exposure for students.

During the online interaction, Mr. Rajiv Sanghavi and Mr. D. L. Pandya highlighted the support offered by SPE India through technical programmes, workshops, seminars, industry interactions, scholarships, and career and higher-study opportunities.

Mr. Rajiv Sanghavi
International Councilor,
SPE INDIA

Mr. D L Pandya
Vice President, SPE INDIA-Medical
Plastics Division

Inauguration under the guidence and virtual presence of Mr. Rajiv Sanghavi, SPE International Councillor and Mr. D. L. Pandya, Vice President, SPE INDIA Medical Plastics Division

The session also included discussions on upcoming technical workshops, seminars, industry-oriented programmes, and student activities planned for the academic year.

The inauguration marked the beginning of a renewed chapter dedicated to technical excellence, industry–academia interaction, professional networking, leadership development, and career advancement, creating greater opportunities for the students of CIPET: IPT Chennai.

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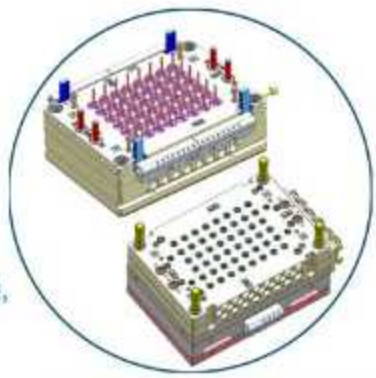

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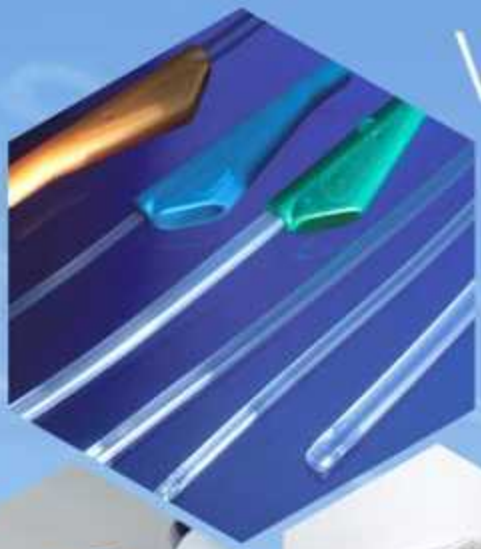

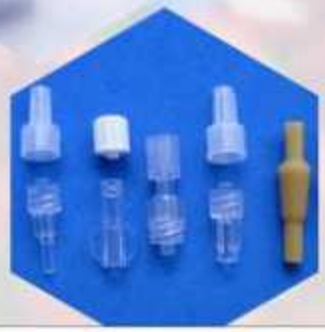

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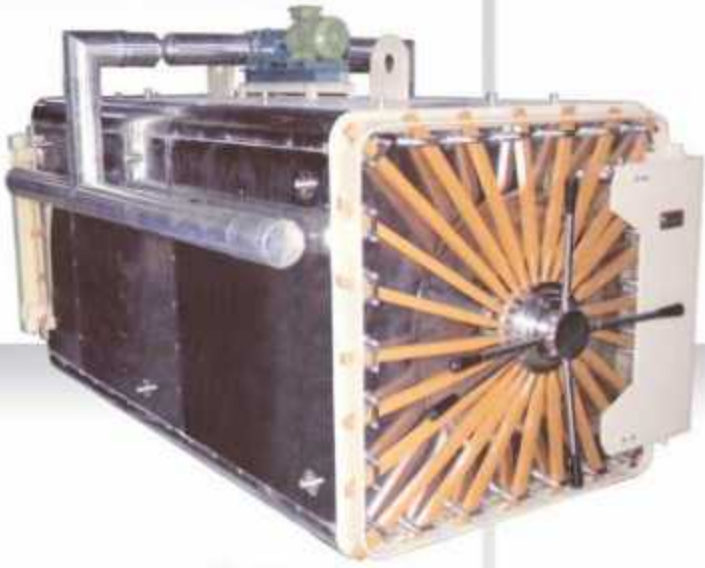

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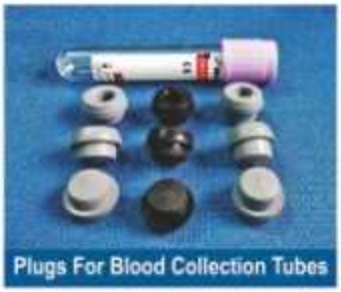
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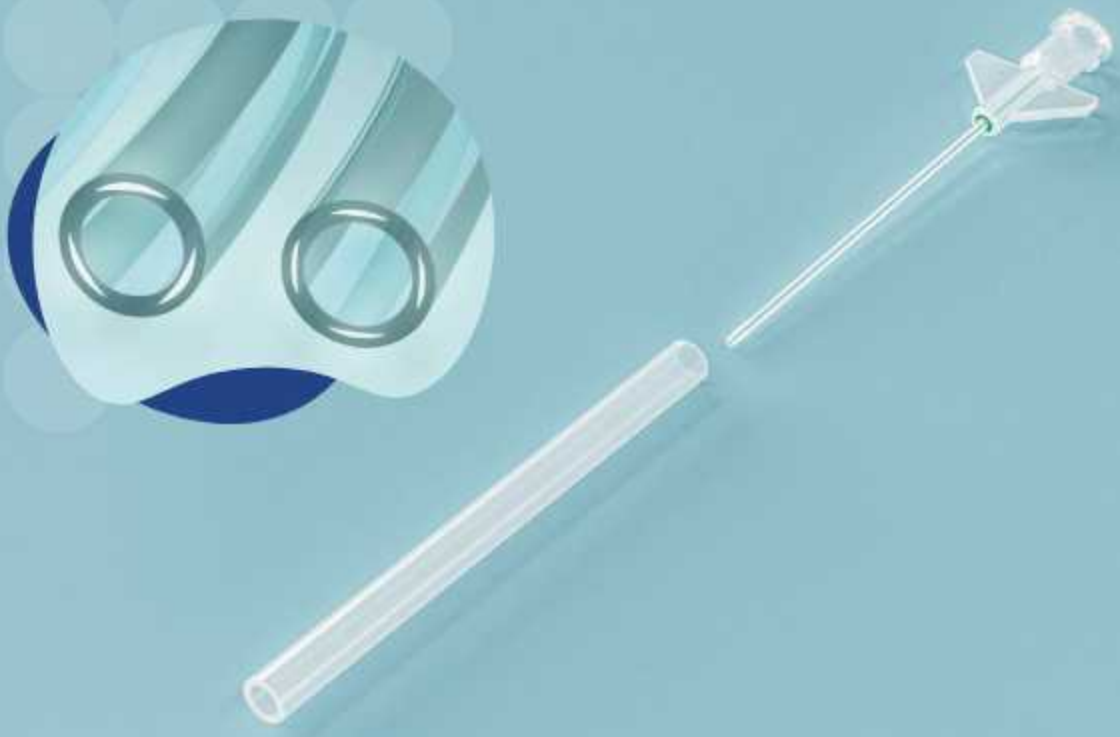

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- ISO/IEC 17025
- CDSCO MD40

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