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MEDICAL PLASTICS DATA SERVICE

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

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- Medical Plastic Extrusions: Applications, Process & Innovations
- Multi-Layer Extruded Tubing for Medical Devices
- The Engineer's Guide to Medical Device Luer Connection Selection
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Services

- ISO 10993-1: Biological Evaluation Plan (BEP) and Biological Evaluation Report (BER)
- ISO 10993-7: Ethylene oxide sterilization residuals Analysis
- ISO 10993-13: Identification and quantification of degradation products from polymeric medical devices
- ISO 10993-14: Identification and quantification of degradation products from ceramics
- ISO 10993-15: Identification and quantification of degradation products from metals and alloys
- ISO 10993-17: Toxicological Risk Assessment (TRA) of medical devices, packaging materials and CCS
- ISO 10993-18: Chemical characterization of medical device. (Exaggerated/Exhaustive extraction studies and study designing).
- E&L for Pharma, Packing and Medical devices as per ICH, PQRI, USP <1663> & <1664>, ISO 10993-12 &18 etc.
- ISO 11979-5: IOLs; Physicochemical tests like Extractables, Leachables, Hydrolytic Stability, Photo Stability and Insoluble Inorganics.
- ISO 11981 & ISO 11986: Soft Contact Lenses; Physicochemical tests
- 21 CFR 177.1500 Chemical Testing of Nylon Resins and Polymers
- EN 1186 Migration Study
- ISO 18562-2: Emission of Particulate Matter from Gas Pathways
- ISO 18562-3: VOCs from Gas Pathways
- ISO 18562-4: Condensate Leachables from Gas Pathways
- ASTM D7823-18: Residual Phthalate Testing
- Raw material and finished products testing
- Ink Migration and Glassware Delamination Studies.
- Toys testing for nitrosamines and phthalates as per EN 14350:2020, EN-71-12, EN-73-14
- REACH Study as per regulation (EC) No.1907 etc.
- BS EN 455-3 and ASTM D5712: Aqueous Extractable Protein Test
- ASTM D6499: Antigenic Protein tests.
- ASTM D7558: Extractable Chemical Dialkyldithiocarbamate, Thiuram, and Mercaptobenzothiazole Accelerators Test.
- TOC, THC as per ISO 19227:2018; BS EN 1484:1997
- Particulate Matter as per USP <788> and EP 2.9.19, ISO 19227:2018
- Syringe Tests as per ISO 7886-1
- Nitrosamines and NDSRIs Method development and Validation
- USP <661> Plastic Packaging Systems and Their Materials of Construction
- Unknown peak identification and characterization
- Forced degradation Study
- Residual solvents analysis
- Heavy metal analysis.
- Elemental analysis as per ICHQ3D & USP<233>

Accreditations

ISO 9001:2015

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

Microbiological Testing: Control contamination risk and meet hygiene standards.

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

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

- Physical & Chemical Analysis (FTIR, SEM, Micro CT)
- Thermal Properties (DSC/TGA)
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- 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)


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


4. Microbiological Testing Services


5. Packaging Integrity Testing


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March 12 & 13, 2026.

Highlights

Medical Device Definition & Classification, Materials Characterization & Material Properties Evaluation, Biocompatibility, Biological Safety & Risk Assessment (ISO 10993), Testing (Physico-chemical, Chemical, Thermal, Mechanical and Morphological), Pre-Clinical Efficacy, Clinical Evaluation, Product Release Studies, Product Development – Concept to commercialization, Emerging Trends & Innovations.

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KMTC Kerala Medical Technology Consortium

The process of medical device development is complex and need inputs from varied disciplines of science and technology. Hence biomedical technology and allied areas requires extensive learning.

Biomedical Technology Wing, SCTIMST : The Biomedical Technology Wing (BMT Wing) located at the Satelmond Palace at Poojappura, Trivandrum has been instrumental in establishing a medical device industry base in India by successfully developing and commercializing technologies of a number of devices and implants. Some of the commercialized technologies include blood bag, membrane oxygenator, hydrocephalus shunt, artificial heart valve, dental materials, hydroxyapatite-based materials and implants.

Medical device industry being at a budding stage in India and various start ups emerging, the Institute recognises that the expertise and experience that has been gained through the years are to be shared with the medical device industry, the researchers and students.

SPE INDIA Medical Plastics Division (SPE INDIA MPD) exists to encourage the interchange of technical and regulatory information on polymer materials / components used in Medical Devices among scientists and engineers who are working in Medical Devices and related industries.

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March 12 & 13, 2026.

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Highlights

Medical Device Definition & Classification, Materials Characterization & Material Properties Evaluation, Biocompatibility, Biological Safety & Risk Assessment (ISO 10993), Testing (Physico-chemical, Chemical, Thermal, Mechanical and Morphological), Pre-Clinical Efficacy, Clinical Evaluation, Product Release Studies, Product Development – Concept to commer- cialization, Emerging Trends & Innovations.

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Did You Know?

About Medical Plastics Micro-Moulding

Medical plastics micro-molding is a high-precision manufacturing process for creating tiny, intricate plastic components for medical devices, using specialized equipment to achieve micron-level tolerances, enabling miniaturization in areas like drug delivery, diagnostics, catheters, and implants, requiring strict material biocompatibility and rigorous validation.

This process enables miniaturization for minimally invasive procedures and advanced diagnostics, meeting stringent medical regulations.

Key Aspects:

- **Precision & Scale:** Produces parts weighing less than a gram with features measured in microns (thousandths of a millimeter).
- **Applications:** Essential for minimally invasive surgery tools, micro-pumps, diagnostic chips, catheters, implantables (e.g., punctum plugs), and hearing aid components.
- **Materials:** Uses medical-grade, biocompatible, and sterilizable plastics (like PE, PP, PVC), sometimes multi-material systems, ensuring safety and performance.
- **Technology:** Involves advanced micro-machining, EDM, and specialized tooling with high-resolution positioning for mold building, plus cleanroom environments.
- **Challenges:** Requires expertise in material science, tool design, process control (addressing material behaviour at micro-scale), and extensive regulatory validation.

Why it's Crucial:

- **Enables Innovation:** Allows for the creation of devices impossible with traditional molding, driving advancements in diagnostics and treatment.
- **Improves Patient Care:** Supports minimally invasive surgery and portable health monitoring by making components smaller and more precise.
- **Meets Demands:** Addresses the growing need for complex, tiny parts in next-generation medical technology.

In essence, it's a specialized injection molding niche meeting extreme accuracy needs for advanced healthcare solutions.

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From the Editor's Desk

Importance of Plastic Components - For Safe Medical Devices : Not only for regulatory compliance (like ISO 13485), **quality plastic components are the foundation for creating medical devices** that are safe, effective, compliant, and trusted, making it a non-negotiable necessity, not just a best practice, for medical device manufacturers. It reduces costly recalls, and building essential trust with healthcare providers and patients.

This issue focuses on two major segments – **Plastic Injection moulded Components and Extruded Tubes.**

The lead article by the Company, "Qosina" focuses on one critical category of **components- luer connectors – having wide range of applications from IV therapy to** diagnostic equipment serving as the interface between components and systems. The article provides an extremely useful comprehensive overview of the various of the various types with considerations for engineers during the design and selection process. It includes types of connects, raw materials used, application specific relevant quality standards as well as design and compatibility considerations.

The column "Did You Know" highlights key aspects of **Medical Plastics Micro-Moulding** – a high precision manufacturing process creating tiny, intricate plastic components for medical devices. The "Global Trends" article covers **Global Medical Injection Moulding Markets including current trends.** Asia Pacific region has the largest share of the Global Medical Injection Moulding Market.

Another important component largely required for medical devices are extruded tubes. The editorial research article **"Understanding Medical Plastic Tube Manufacturing: Process, Applications & Innovations"** covers very elaborate information on medical tubing from the basics of medical extrusions, extrusion process challenges and ways to meet the challenges as well as various medical tubing configurations with respective medical applications. It highlights innovations and emerging techniques in the medical plastic extrusion process.

One important emerging technique in medical extrusions is **manufacturing of multi-layer extruded tubing** using co-extrusion process where multiple-polymer layers are simultaneously extruded into a single tube. It creates a composite structure with distinct functions for each layer. These tubing extruded by combing materials are critical for medical devices for better performance, biocompatibility and specific properties. It includes benefits of multi-layer tubes, common applications, possible material-combinations and likely processing challenges.

Another very well researched article by Mr Sanjay Shah covers one very important trend regarding **use of Artificial Intelligence (AI) and Machine Learning (ML) in Contract Manufacturing & Medical Device Industry.** It explains how are AI and ML transforming Medical Device Industry.

World Health Innovation Forum (WHIF) 2025 @ Andhra Pradesh MedTech Zone (AMTZ), held between Dec.11 – Dec 13,2025, the only global event – was participated by **over 60 countries** spanning governments, healthcare systems, industry, academia, and global health organisations.SPE INDIA Medical Plastics Division led a special session on **importance of materials science in shaping the next generation of medical devices.**

The "Global Market" column in this issue covers **Indonesia Medical Devices Market.** It includes our regular columns of Industry, Association and Regulatory related developments.

D L Pandya

Understanding Medical Plastic Tube Manufacturing: Process, Applications & Innovations

Global medical tubing market size was estimated at USD 11 billion in 2023 and is anticipated to reach USD 19.5 billion by 2030, growing at a CAGR of 8.5% from 2024 to 2030. (Ref. Grand View Research) Key Market Trends include:

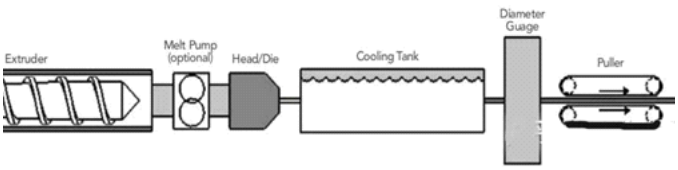
- North America led the market and accounted for a revenue share of 35.5% in 2023.
- Asia Pacific is estimated to be the fastest-growing regional due to the rising demand for better healthcare products.
- Based on application, the bulk disposable tubing segment led the market and accounted for a revenue share of 34.5% in 2023.
- In terms of product, the polyvinyl chloride (PVC) segment held the largest revenue share of 30.7% in 2023 in the market.

Medical Tubing Manufacturing

Extrusion is a basic processing operation carried out for manufacturing of medical tubes manufactured with the help of an extruder.It is a continuous process. It involves melting a medical-grade polymer and shaping it into a tube through a die.This continuous process ensures uniform wall thickness, precise diameter, and consistent quality, meeting stringent standards for patient safety and device reliability.

An extrusion line combines several pieces of equipment, including a resin drying system, an extruder, a die, a cooling tank, a take-up unit (wire puller) and a cutter or winder.

TYPICAL MEDICAL TUBING EXTRUSION LINE



Extrusion Process Breakdown

1. **Material Selection:**
   Medical-grade polymers, such as PVC, polyethylene, or silicone, are chosen based on the specific application and required properties like flexibility, biocompatibility, and chemical resistance.
2. **Melting and Extrusion:**
   The selected polymer is fed into an extruder, where it's heated and melted by screws and heaters. The molten plastic is then forced through a die, which shapes it into the desired tube profile.
3. **Cooling and Sizing:**
   The extruded tube is cooled, often in a water bath or cooling tank, to solidify its shape. It may also pass through a sizing mechanism to ensure precise dimensions.
4. **Cutting and Packaging:**
   The finished tube is then cut to the required length and prepared for further processing or packaging.
5. **Quality Control and Sterilization:**
   Throughout the process, quality checks are performed to ensure the tubing meets strict medical standards. This includes dimensional accuracy, material properties, and freedom from contaminants. Finally, the tubes are sterilized before use in medical settings. Key aspects of medical tube extrusion include:

Key aspects of medical tube extrusion

Precision:
The process requires high precision to achieve the tight tolerances and consistent dimensions needed for medical devices.

Cleanliness:
Medical tube extrusion often takes place in cleanroom environments to minimize the risk of contamination.

Material Properties:
The choice of polymer and the extrusion process parameters are carefully selected to ensure the tubing possesses the necessary properties for its intended use.

Specialized Dies:
Dies with specific shapes and dimensions are used to create the desired tube profiles, including multi-lumen tubes, tapered tubes, and other complex geometries.

Post-processing:
Various post-processing steps, such as tipping (shaping the end of the tube), bonding, and surface treatments, can be applied to further enhance the tubing's functionality and performance.

Medical Plastics Extrusion Challenges

Degradation during the extrusion process can greatly affect the performance of end-use medical tubing.Polymers are very large molecules that derive their unique and useful properties from their size (molecular weight). Degradation is the breakdown of these large molecules and can lead to changes in properties such as tensile strength, brittleness, flexibility, and discoloration.This variation is mainly due to the effect on the chemical composition of the polymer.

Another cause of degradation during extrusion is the multiple melting process steps. For example, some materials used to make medical tubing must be pre-mixed, where the base material is melted and mixed with other materials such as colorants, radiopaque fillers, stabilizers, processing aids, etc on plastic extrusion process steps.

This is usually done in a separate extrusion operation to ensure proper dispersion and distribution of the components. Compounding is usually performed in twin-screw or single-screw extrusion processes.

Most medical tubing extrusion specifications include tubing drawings with materials, dimensions and tolerances. Specifications rarely include other tubing properties or process parameters associated with tubing production.

A common misconception is that as long as a batch of tubing is made from the correct material and meets dimensional requirements, it will be the same or equivalent to another batch of tubing made by the same or a different supplier. While this may be true, it is quite possible that the two batches of tubing may be different. These differences are not always obvious or easy to identify, even when checked by the incoming QC. The process parameters and equipment used to medical tubing extrusion are usually as important, if not more important, than the actual size of the tubing.

The design of the extrusion screw is critical to achieve uniform melting of the polymer and pumping without over processing (over shearing) the material. Different materials require different screw designs to optimize the extrusion process.

Many tube manufacturers use a generic screw design and try to

run all materials with the same screw. This can lead to over-shearing and degradation of some materials, and improper melting and gelation of others.

Medical tubing extruder tool (Die) is located at the end of the extruder and is where the polymer enters the cooling tank. The die forms the initial shape of the tube. The tool typically consists of 2 main components: a mandrel or tip that forms the inner diameter of the tube; and a tool or ring that forms the outer diameter of the tube.

The design of these components plays a key role in the extrusion process and the ability of the extruder to produce accurate dimensions and maintain proper physical properties of the material.

Very small diameter medical tubing with very thin walls may be difficult to extrude thin walls tube through a standard extrusion head/die.

When extruding thin-walls tubing, specially designed heads are often required to produce high quality thin tube without degradation, gels, black spots or undesirable residual stresses. The extrusion cooling process is the next critical step. Cooling is critical for many polymers, and different cooling conditions can lead to significant changes in physical properties and morphological structure.

Many medical extrusion lines come with very small, undersized cooling tanks that may not be well suited for long production runs, extruding large diameter and/or thick-walled tubing, or extruding small thin-walled tubing at higher line speeds, without enough time in the tank to properly cool the tubing.

Medical Tube Exttrusion : Managing the Challenges

Some of the major problems that can impact quality and resulting in rejections are : Melt fracture, Pressure control, Gels

Melt Fracture :

Melt fracture is surface roughness (sharkskin appearance), a common issue when small tooling gaps are used with some polymers. . Some of the resins that are most susceptible to melt fracture are HDPE, LLDPE, polycarbonate, fluoropolymers, and higher- viscosity thermoplastic urethanes. Common approach to avoid melt fracture is to utilize larger tooling gaps, which means making the tubing with a larger drawdown. GELs

Gels are seen as bumps on the tubing surface. Their size depends on the source. .The thinner the tubing wall, the more obvious the gels typically become. Some of the polymers that seem to be gel-prone are flexible PVC, TPU, and some other TPEs.

Gels can come from a number of sources, including material inconsistencies, degradation, cross-linked particles, and contamination. Gels in flexible PVC are typically the result of PVC resin particles that have not absorbed enough plasticizer, causing them to “float” along with the melt.

To solve the problem, a high-shear screw with elevated barrel temperature settings is used to see if the gel level can be reduced by shear and temperature. If the gels are not reduced noticeably— unfortunately the usual case—it can be assumed that the screw won’t solve the problem. The options then are to either find a way to filter out the gels with a fine-mesh and large-area filter, or have the gels removed prior to extrusion.

Challenges Of Meeting Standards for Medical Tubing

One important standard for medical tubing is non-adhesiveness. On- adhesiveness is achieved by making the surface of the tube’s inner wall as smooth as possible.While some level of roughness is needed to prevent air bubbles from forming in the tube, the roughness must not interfere with the tube’s transparency. Manufacturers must quantify the roughness of their tube’s inner surface to ensure they meet the standards. Wall thickness is another critical specification for medical tubing products, and there are often tight tolerances that need to be met. However, measuring wall thickness can be difficult as tubing becomes increasingly miniaturized for non-invasive procedures.

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 Color Line (One or Multi-Lines), Radiopaque Tube (One of Multi-Lines or Whole), Micro-Flow Tube, Intravascular Tube, Balloon Tube, High-Pressure Tube.

Multi-lumen

Extrusions with multiple lumens are commonly used to carry multiple wires or fluids to, or within, the body.

Such tubes typically have four to five lumens but have been manufactured with 20+ lumens. The lumens are often symmetrical within a round tube. But they can also be asymmetrical, varying in size and position within the extrusion.

Inspection methods become more critical as lumen numbers increase and as the number of inspected dimensions multiplies to include all walls between lumen and between lumen and OD. This is especially true in smaller, increasingly more complex implanted smart devices, such as those incorporating power, sensors, and/or drug delivery.

Micro-extrusion

Silicone tubes in diameters as narrow as 0.014 in. OD and 0.007 in. ID can be produced to accommodate precise drug delivery. They can also be used as scaled-down devices for neonatal applications. Measurement methods become especially critical for these products and often require custom innovations to

measure ever-shrinking sizes and tolerances with accuracy.

Reinforced

Silicone tubes can be made kink-resistant by reinforcing them with nylon monofilaments in a double-helix configuration.

The monofilaments are embedded in the tube wall to add radial strength and reduce the likelihood the tube will compress.

Reinforced tubes are ideal for long-term implantable devices because they allow fluid to flow from the device into the body, or between implanted components, regardless of bodily movement. The tube remains open when muscles flex, ensuring consistent fluid transfer in all positions.

Medical Tubing: Critical Applications

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.Other Examples of tubing applications include high-pressure catheter tubing, stent-delivery catheters & balloons etc. Examples of markets that rely heavily on tubing technology include the following:

- Neurovascular (e.g., treatment of stroke).
- Cardiovascular (e.g., angioplasty, stenting, cardiac ablation, and mitral valve repair).
- Peripheral interventions (e.g., stent grafts, venous therapy).
- Endoscopic and renal denervation applications
- Implants (e.g., inferior vena cava filter, and prosthetics valves).

Medical Tubing: 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	Polytetrafluoroethyl ene, PTFE	Catheter liner, Electrical Insulation, Fluid transfer, Telecommunication
3	Fluorinated Ethylene, Propylene, FEP	IV Catheter, Regional Anaesthesia, Vascular Access
4	Ethyleme Tetrafluoroethylene, 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, Guiderwire dispensers, Introducers, Protective tubes, Thrombe-tomy, Sheaths and dilators for introducres, Coextruded perfusion tubing, Aspirator tips
10	Low Density Polythylene 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, Dailysis, 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, Guidingn catheter

Innovations and Emerging Techniques

- 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 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 molded 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.
- Millilumen 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 provides additional cushion space.

FAST FACTS

Global Medical Plastic Extrusion Market Size is valued at USD 4.3 Bn in 2024 and is predicted to reach USD 7.5 Bn by the year 2034 at a 6.4% CAGR during the forecast period for 2025 to 2034.

The catheters category held the largest share in the Medical Plastic Extrusion market in 2024 because the performance, comfort, and safety of catheters are largely dependent on extruded polymer tubing.

(https://www.insightaceanalytic.com /report/medical-plastic-extrusion-market/3358)

The Engineer's Guide to Medical Device Luer Connection Selection

(By QOSINA)

In the world of medical device design, few components are as ubiquitous—or as critical—as luer connectors. Found in a broad range of applications from IV therapy to diagnostic equipment, luers serve as the interface between components and systems, ensuring secure, leak-free fluid and gas transfer. Selecting the right luer connection is paramount for safety, performance and regulatory compliance. This guide provides a comprehensive overview of the various luer types available and offers key considerations for engineers during the design and selection process.

Understanding Luer Basics

Luer connectors are standardized small-bore fittings used widely in the medical and laboratory fields. They come in two primary configurations: luer slip and luer lock (or taper). Both are defined by ISO 80369, which replaced the older ISO 594 standard to improve patient safety by reducing the risk of misconnections between different delivery systems.

- **Luer Slip:** Also known as luer taper, these connectors rely on friction to hold mating components together. They are quick to connect and disconnect, commonly used in low-pressure applications.
- **Luer Lock:** These connectors add a threaded mechanism to secure the connection, preventing accidental disconnection and improving pressure resistance. This type is often used in applications requiring higher security and reliability.

Both male and female variants exist, and engineers must consider both the gender and the method of engagement when selecting components.

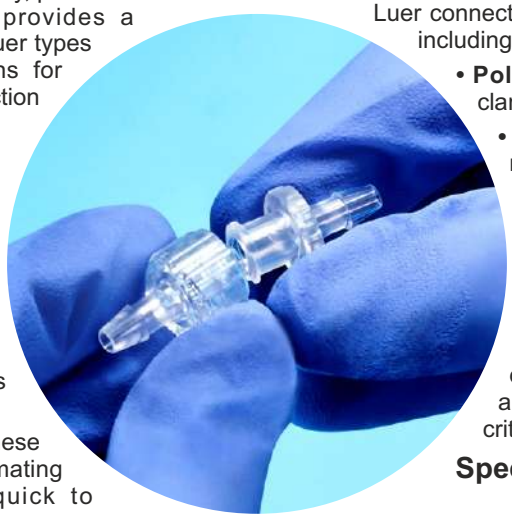
A variety of precision-engineered luer connectors, highlighting the range of styles available for medical device applications.

Standard vs. ISO 80369 Series

To improve patient safety, the ISO 80369 series breaks out luer-like connectors by application to prevent cross-connection. For example:

- **ISO 80369-2:** Respiratory and driving gas applications
- **ISO 80369-3:** Enteral applications
- **ISO 80369-4:** Urethral and urinary applications
- **ISO 80369-5:** Limb cuff inflation applications
- **ISO 80369-6:** Neuraxial applications
- **ISO 80369-7:** Retains the traditional luer standard for intravascular and hypodermic connections, with more rigorous required testing

For engineers, this means paying close attention to the intended application and ensuring compliance with the correct subset of the ISO 80369 family.



Luer fittings connect with a secure, reliable seal—designed for performance in critical fluid management applications.

Material Selection

Luer connectors are available in a range of materials, including (but not limited to):

- **Polycarbonate (PC):** High strength and clarity; can be suitable for gamma sterilization
- **Polypropylene (PP):** Good chemical resistance and cost-effective
- **Acrylic (PMMA):** Offers optical clarity for visual inspection
- **Copolymers (e.g., COC/COP):** Low extractables and suitable for a variety of sensitive biological applications.

Material choice affects compatibility with drugs and sterilization methods (such as autoclave, EtO or gamma), making it a critical factor in the design process.

Specialty Luer Variants and Applications

While standard luer lock and slip types meet the needs of many devices, several specialized options exist to address specific use cases:

- **Valved luers:** Include an internal check valve to prevent fluid backflow—useful for IV systems and diagnostic testing.
- **Color-coded luers and luer rings:** Facilitate line identification and reduce cross-connection risk.
- **Swivel and spin luers:** Designed to freely rotate during connection for ease of alignment, then lock securely into place once fully engaged.
- **Rotating male luers:** Enable free rotation while fully connected, reducing stress on tubing and devices.
- **Custom/OEM luers:** Tailored solutions for proprietary systems, often requiring close collaboration with component suppliers like Qosina.

Design and Compatibility Considerations

When integrating luer connectors, engineers should evaluate:

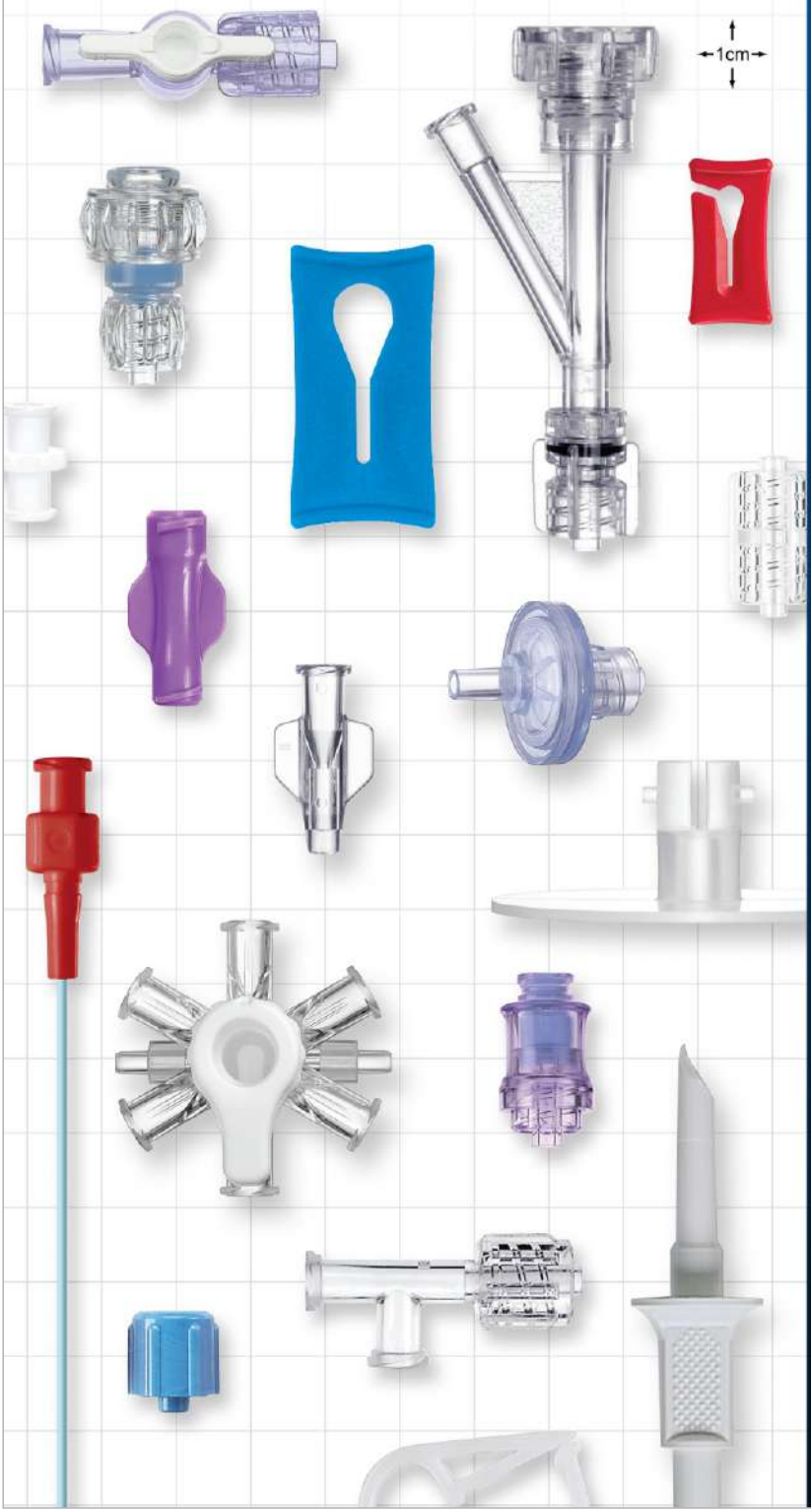
- **Mating compatibility:** Ensure tight tolerances and smooth engagement between components, especially when sourcing from different vendors.
- **Pressure ratings:** Match the connector to the pressure demands of the application to avoid leaks or disconnections.
- **Sterility and cleanroom requirements:** Evaluate the application's needs for sterilization compatibility and cleanroom-grade packaging.
- **Regulatory compliance:** FDA and ISO standards necessitate that connectors meet biocompatibility, material traceability and dimensional criteria.

Partnering with the Right Supplier

Given the complexity of connector selection, partnering with a

QOSINA

Thousands of Stock Components



For nearly 45 years,

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

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

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

Log on to **qosina.com** today to see our full product offering.

knowledgeable supplier is paramount. At Qosina, we offer one of the industry's largest selections of off-the-shelf luer components—more than 1,000 styles in stock—and provide engineering support to help customers identify the best solution for their specific application. Whether it's a standard ISO 80369-7 luer lock for a drug delivery system or a custom valved configuration for diagnostic equipment, we help engineers streamline development while meeting critical regulatory and performance requirements.

Conclusion

Choosing the right luer connector is more than just picking between a slip or lock—it's a decision that impacts safety, usability, manufacturability and compliance. With a thorough understanding of connector types, standards and design considerations, engineers can ensure robust system integration and optimal performance in their medical devices.

For more information or to request luer samples, visit www.qosina.com.

Manufacturing Multi-Layer Extruded Tubing for Medical Devices

Co-extruded multilayer medical tubing uses a process where multiple polymer layers are simultaneously extruded into a single tube, creating a composite structure with distinct functions for each layer, like inner lubricity for drug flow and outer strength for handling. This advanced tubing is crucial for modern medical devices, enabling complex catheters (angiography, pain therapy), micro-tubes for diagnostics, and high-pressure balloons by combining materials for better performance, biocompatibility, and specific properties not possible with single-layer tubes.

Key Features & Benefits

- **Multi-Functional:** Each layer offers specific benefits (e.g., inertness for drug contact, flexibility, bonding, strength, colour, or lubricity).
- **Complex Designs:** Allows for intricate designs like multi-lumen tubes or tapered profiles for advanced catheters.
- **Advanced Materials:** Combines various polymers (similar or dissimilar) with different hardness (durometers) and properties.
- **Micro-Scale:** Enables production of tiny tubes for minimally invasive procedures and diagnostics.
- **Customization:** Can be made DEHP-free, PVC-free, and compatible with sterilization methods (ETO, Gamma).
- **Multilayer extrusion of up to four layers**
- **Exceptional compatibility with body and the flow medium**
- **Application-specific distribution of layer thickness**
- **Multiple colour and x-ray contrast stripes can be embedded**
- **Integration of functional layers, e.g. for light protection properties or gas barrier.**
- **Use of bonding agents prevents delamination of incompatible polymers.**

Common Applications

- **Drug Delivery:** Insulin delivery, pain therapy catheters.
- **Cardiovascular:** Angiography, stent delivery balloons.
- **Diagnostics:** Miniature tubing for sample collection.
- **Surgical Devices:** Complex catheters for minimally invasive surgery.

The Co-Extrusion Process

1. **Multiple Extruders:** Two or more extruders feed different polymer resins.
2. **Single Die:** Materials are combined and pushed through a single die head.
3. **Simultaneous Formation:** Creates one tube with distinct, bonded layers.
4. **Micro-Extrusion:** Specialized machines handle very small throughputs for micro-tubing.

Materials Suitable for Multi-layer Tubes:

- Polyethylene (PE), Polypropylene (PP), Polyvinyl chloride (PVC), Ethylene vinyl acetate (EVA), Polyamide (PA), Polyurethane (TPU), More thermoplastic elastomers (TPE)

Typical Material Combinations (inner/middle/outer)

- PE / EVA / PVC – Your all-rounder in oncology and pain management: inert & light-absorbing
- TPE / Soft-PP / TPE – Connector tubes for infusion and dialysis bags: flexible & cost-efficient
- PE / PUR – Your reliable companion for insulin treatment: minimal loss of active ingredients

Challenges

Co-extruding Dissimilar Polymers

Multilayer coextrusion poses some challenges, particularly in creating uniform wall thicknesses. Differences in the viscosities, melt temperatures and velocities of dissimilar polymers may cause problems, including delamination.

Dissimilar polymers have different chemistries with low levels of interlayer adhesion and are subject to wave like instabilities at the layer interfaces. This is compounded when polymers with low surface energies are used in the multi-layer structures. As a result of the chemical incompatibility, these different grades of polymers do not form strong bonds with each other during coextrusion, and thus, tubing comprising layers of dissimilar materials tend to be subject to delamination.

Co-extruding Similar Polymers

Super high-pressure balloon tubing may have a wall with at least three coextruded layers of similar polymers such PA12, with varying durometer ranges for each layer. After the multilayer tubing (preform) is reheated and formed via a stretch blow moulding process into a biaxially oriented balloon, the burst performance of the multi-layer balloon is much greater than that of a traditional single-layer non-compliant dilatation or stent delivery balloon. The super high-pressure multi-layer balloons are considered, in addition to cutting balloons and rot ablation, for procedures where coronary lesions are difficult to dilate due to significant calcification.

When designing a multi-layer balloon tubing extrusion of similar polymers, it is important to understand the durometers of each layer. Lower durometer polymers have an increased elongation (lower flex modulus) therefore the combined elongation should not be greater than that of the harder durometer material. The blow ratios i.e. Radial Ratio and Stretch Ratio should be designed closer to the harder durometer polymer as excessive stretch during the forming process will create delamination between the layers. Each layer is designed separately taking into consideration its position Outer/Intermediate/Inner.

Medical Device and Extrusion Polymer Selection

Multi-layer tubing suitable for percutaneous transluminal catheters used to deliver an angioplasty balloon or stent to a

calcified lesion in an artery may require a lubricious polymer on the inner layer such as high-density polyethylene (HDPE) to facilitate advancement of the catheter over the guidewire. The adhesive middle layer could be made of a modified linear low density polyethene (LLDPE) and the outside may be a soft "bondable" layer such as polyether block amide (PEBA) for bonding a polyamide (PA12) or polyester (PET) non-compliant balloon to the catheter shaft. Percutaneous transluminal catheter tubing contains ultra-thin individual wall thickness down to 25 microns with internal diameters designed to support 0.014", 0.018" and 0.035" guidewire delivery platforms. From an extrusion standpoint, viscosity is the most important flow property in multi-layer polymer selection. Typically, the inner layer has the highest viscosity and the outer layer has the lowest viscosity as the low viscosity melt can encapsulate the high viscosity melt while flowing through the die head and tooling channels.

Polymers with compatible glass transition temperatures (Tg) and melt temperatures (Tm) should also be chosen for consistent layer distribution.

When designing a co-extruded multi-layer tube for an intravascular application, the final physical properties of the polymers used are not the only factor. For optimal extrusion and device performance, it is also important to consider the effects of the viscosity, the polymers' melt temperatures and durometers, and their placement in the structure.

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Application of Artificial Intelligence (AI) and Machine Learning (ML) In Contract Manufacturing & Medical Device Industry

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Contract Manufacturing In Medical Device Industry

Medical Device or Medical Device Component contract manufacturing (MDCM) is when a company (OEM) hires a specialized third-party firm (Contract Manufacturer) to produce all or parts of a medical device, handling complex tasks like precision machining, assembly, sterilization, packaging, and regulatory compliance (FDA, ISO standards).

The purpose may be specialized knowledge/ expertise of third party, or to allow the OEM to focus on R&D, or reducing costs, and speeding up time-to-market or all of the above.

How it Works

- Outsourcing: An Original Equipment Manufacturer (OEM) pays a CM to manufacture devices or components.
- Specialization: CMs often have specific expertise, such as molding, electronics, or complex machining, and specialized facilities/labs.
- Scope of Services: Can range from producing a single component to full product assembly, sterilization, labeling, and managing supply chains.
- Quality & Regulation: CMs must adhere strictly to FDA and ISO quality standards, ensuring devices are safe and effective.

Key Benefits for OEMs

- Cost Savings: Lower labor/overhead, established supplier networks, better material pricing, large production facility
- Focus on Innovation: Frees up resources for R&D and design.

What if one uses AI for R&D and design? While AI can process vast amounts of data and perform complex calculations, it cannot replace the creativity, critical thinking, and ethical judgment that humans bring. Maintaining a human-centric approach ensures that AI serves as an assistive tool, complementing human capabilities rather than replacing them. Users are responsible for ensuring the quality and appropriateness of the data used, appropriately managing risk in high-stakes applications, and ensuring the privacy and security of user data.

- Expertise & Quality: Access to specialized skills, equipment, and regulatory knowledge.
- Scalability: Easier to scale production up or down for prototypes or mass market.
- Faster Time-to-Market: Streamlined processes get products out quicker.

Examples of Services Provided by Cms

- CNC Machining & Plastic Molding
- Assembly & Sterilization
- Prototyping
- Packaging & Labeling
- Supply Chain Management

Combining contract manufacturing with AI/ML capabilities / applications

What is AI/ML

AI (Artificial Intelligence) is the big idea of machines mimicking human intelligence, while ML (Machine Learning) is a specific way to achieve AI, using algorithms to learn from data to find patterns and make decisions, improving without being explicitly programmed for every task, making ML a core subset of AI. Think of AI as the entire field of smart machines, and ML as a powerful tool within that toolbox, enabling systems to learn and adapt from experience.

How Are Artificial Intelligence and Machine Learning (AI/ML) Transforming Medical Devices?

AI/ML technologies have the potential to transform health care by deriving new and important insights from the vast amount of data generated during the delivery of health care every day. Medical device manufacturers are using these technologies to innovate their products to better assist health care providers and improve patient care. One of the greatest benefits of AI/ML in software resides in its ability to learn from real-world use and experience, and its capability to improve its performance.

What benefits does AI bring to the medical device industry?

AI brings transformative benefits to the medical device industry by optimizing processes, enhancing decision-making, and achieving unprecedented levels of efficiency with minimal infrastructural costs.

Here's a closer look at these benefits:

1. Process Optimization; Improve Decision-Making; Cost Savings; Improve Patient Care and outcomes.
2. Quality & Compliance
   - Automated Inspection; Real-time Process Control.
   - Predictive Quality: Predicts product quality attributes in real-time, supporting faster release testing and identifying root causes of defects.
3. Efficiency & Optimization
   - Predictive Maintenance:
   - Digital Twins: Creates virtual models of the factory floor to simulate changes, identify bottlenecks, and optimize

workflows without disrupting real production.
- Workforce Augmentation: Frees skilled staff from routine tasks, shortens training times, and helps co-pilot complex programming (like PLCs).

4. Design & Development
   - Design for Manufacturability (DFM): AI analyzes CAD designs to identify potential production inefficiencies early.
   - Rapid Prototyping: Generative AI rapidly iterates designs by analyzing material performance and testing scenarios virtually.
5. Supply Chain & Planning - Demand Forecasting; Inventory Optimization:
   - Risk Management: Identifies potential supply chain disruptions and suggests proactive interventions.
6. Regulatory & Cost - Cost Management; Compliance Support

Usefulness of using AI/ML in Contract Manufacturing of Medical Devices (MDCM)

Medical device contract manufacturing (MDCM) comprises a significant portion of the $657 billion the global medical device market is projected to reach by 2028. Regulatory frameworks from the FDA and ISO standards mandate strict compliance, placing additional pressure on manufacturers to adopt advanced technologies to ensure product safety, efficacy, and regulatory adherence while meeting the growing demand for personalized medical devices with greater customization, and a shorter time-to-market.

AI is useful in medical device contract manufacturing by optimizing production, ensuring quality, streamlining design, and improving supply chains through predictive analytics, computer vision, and automated adjustments, leading to faster cycles, lower costs, better compliance, and enhanced patient safety in highly regulated environments. It enables "self-healing" processes, predicts maintenance needs, identifies microscopic defects, and optimizes material use, transforming manufacturing from reactive to proactive.

AI is transforming the contract manufacturing industry by automating processes, reducing human error, optimizing production efficiency, and enhancing product quality, enabling manufacturers to meet increasingly complex market demands.

AI-Driven Automation in Manufacturing Robotic Process Automation (RPA)

AI-driven RPA automates repetitive tasks like assembly, quality testing, and packaging. RPA ensures that tasks are completed with the accuracy and consistency required in medical device manufacturing. For instance, robotic arms equipped with AI algorithms can assemble micro-scale devices far more efficiently than human workers, significantly improving throughput while reducing the risk of error.

Predictive Maintenance

AI algorithms analyze data from machinery and production lines in real-time, allowing companies to predict potential equipment failures. This reduces unexpected downtime, extends the lifespan of expensive machinery, and minimizes repair costs. Predictive maintenance can reduce downtime by up to 50% and significantly lower maintenance costs.

Case Study:

A global medical device contract manufacturer implemented AI-driven predictive maintenance tools across multiple production lines. The system used machine learning algorithms to monitor equipment conditions and predict potential failures before they occurred. As a result, the company reduced equipment downtime by 25%, extending the operational life of its machinery and saving substantial amount.

Quality Control and Inspection

Machine Vision

AI-powered machine vision systems are used to inspect medical devices for defects. This is particularly useful in detecting micro-defects such as irregularities in shape, texture, or material in high-precision devices like stents, catheters, or pacemaker components. Machine vision systems can increase defect detection rates by 30-40% and reduce inspection times by 50%.
Data-Driven Process Control

AI can identify patterns or anomalies that might compromise product quality. By continuously learning from the data, AI systems can recommend adjustments to the manufacturing process, proactively preventing quality issues before they escalate.

Case Study:

A U.S.-based contract manufacturer specializing in precision surgical instruments implemented machine vision systems powered by AI to improve its quality control process. With AI, the company increased its defect detection rate by 40%, resulting in a significant reduction in product recalls and improving customer satisfaction. The system also reduced human inspection time by 50%, allowing for faster throughput while maintaining stringent quality standards.

Supply Chain Optimization

Optimized Inventory Management

AI tools can analyze past trends, current demand signals, and external factors such as geopolitical shifts or supply chain disruptions to forecast demand more accurately for leaner inventory management.

Supplier Risk Mitigation

AI can assess suppliers' performance based on past delivery times, quality of materials, and financial stability, allowing manufacturers to make informed decisions on sourcing. AI-enabled supply chain management helped some manufacturers improve on-time delivery rates by 15% and reduce costs by 10% during the COVID-19 pandemic.

Case Study:

A medical device contract manufacturer with global operations used AI to optimize its supply chain management. By analyzing real-time data from suppliers and logistics providers, the AI system identified bottlenecks and recommended alternative routing for materials. The company improved its on-time delivery rate by 15%, reduced shipping costs by 10%, and decreased overall supply chain disruptions, even during periods of global instability.

Product Design and Development

Simulation and Modeling

AI-powered simulations allow for digital prototyping, drastically reducing the time and costs involved in physical prototyping by simulating thousands of iterations, helping manufacturers bring products to market faster.

Design for Manufacturability (DFM)

AI analyzed CAD designs can check for production efficiency without requiring complex tooling or unnecessary production steps.

While AI can process vast amounts of data and perform complex calculations, it cannot replace the creativity, critical thinking, and ethical judgment that humans bring. Maintaining a human-centric approach ensures that AI serves as an assistive tool, complementing human capabilities rather than replacing them. Users are responsible for ensuring the quality and

appropriateness of the data used, appropriately managing risk in high-stakes applications, and ensuring the privacy and security of user data.

Regulatory Compliance and Documentation

Automated Documentation

AI can automate the creation of regulatory documentation, reduce errors and speeding up the approval process.

Regulatory Monitoring

AI-driven platforms monitor global regulatory changes in real-time, ensuring that contract manufacturers remain compliant, even as regulations shift across regions.

The Future of AI in MDCM

AI-Driven Personalization of Medical Devices

AI will play a critical role in the personalization process of medical devices, such as customized implants or prosthetics by analyzing patient-specific data to design devices tailored to individual anatomy or physiology. AI-driven 3D printing technologies are particularly suited for creating patient-specific devices with a high degree of accuracy and customization.

Blockchain for AI-Enhanced Traceability

Blockchain technology can ensure compliance with supply chain traceability required across regulatory bodies, optimizing the flow of immutable and auditable-data.

Human-AI Collaboration

AI systems can enhance the power of human operators by providing real-time insights, predictions, and recommendations for faster innovation, fewer errors, and more efficient processes. One example includes supporting engineers and technicians in monitoring production lines or diagnosing equipment malfunctions. Human-AI collaboration will become more seamless, resulting in smarter manufacturing environments combining human judgment with AI precision.

AI has introduced significant efficiencies in MDCM by automating repetitive tasks, enhancing quality control, and optimizing supply chain management.

Ai's role in MDCM is set to continue to grow, particularly in areas such as personalized medical devices, blockchain-enhanced traceability, and human-AI collaboration. However, manufacturers must offset the benefits against high implementation costs, regulatory complexities, and workforce reskilling. Despite these challenges, the industry appears to be unanimous that these are a worthy price for the advantages and opportunities that AI provides.

How can users ensure reliable outcomes when utilizing AI?

Ensuring the quality and appropriateness of data used to train AI models is essential for responsible use. Developers must carefully select and validate data to ensure it is accurate, relevant, and free from biases. This involves rigorous data management practices and transparency about sources, storage, and usage.

Artificial intelligence (AI) and machine learning (ML) technologies have the potential to transform health care by deriving new and important insights from the vast amount of data generated during the delivery of health care every day. Medical device manufacturers are using these technologies to innovate their products to better assist health care providers and improve patient care. The complex and dynamic processes involved in the development, deployment, use, and maintenance of AI technologies benefit from careful management throughout the medical product life cycle.

Global Medical Injection Moulding Market Size

The **Global Medical Injection Moulding Market** size is expected to be worth around **USD 42.0 Billion** by 2034, from **USD 24.8 Billion** in 2024, growing at a **CAGR of 5.4%** during the forecast period from 2025 to 2034. In 2024 **North America** held a dominant market position, capturing more than a **44.9%** share, holding **USD 19.6 Billion** in revenue.

Medical injection moulding is a precision manufacturing process that forms plastic or silicone into complex, high-quality components for healthcare by injecting molten material into a mold. The medical injection molding market is driven by the increasing demand for high-precision medical devices and equipment, which require materials such as plastics for their versatility, cost-efficiency, and ease of sterilization.

The Asia Pacific region plays a dominant role in the market due to its advanced manufacturing capabilities and cost advantages. Despite challenges, such as compliance with evolving quality norms, the market is expected to grow in the near future.

Key Takeaways

- The global medical injection moulding market was valued at **USD 24.8 billion** in 2024.
- The global medical injection moulding market is projected to grow at a **CAGR of 5.4%** and is estimated to reach **USD 42.0 billion** by 2034.
- Based on types of product, medical devices & equipment dominated the medical injection molding market, constituting **45.8%** of the total market share.
- Based on the material, plastic dominated the medical injection molding market, with a substantial market share of around **73.7%.**
- Among the systems, hot runner held a major share in the medical injection molding market, **67.8%** of the market share.
- In 2024, the Asia Pacific was the most dominant region in the medical injection molding market, accounting for **46.5%** of the total global consumption.

Plastic Material Dominated the Medical Injection Moulding Market.

- On the basis of material, the medical injection molding market is segmented into plastic, metals, and rubber. Plastic material dominated the medical injection molding market, comprising **73.7%** of the market share. It is the most commonly used material in medical injection molding due to its versatility, cost-effectiveness, and ability to meet stringent regulatory standards. Plastics such as polypropylene, polycarbonate, and polyethylene can be molded into complex shapes with high precision, making them ideal for producing a wide range of medical components such as syringes, diagnostic devices, and surgical instruments.
- Additionally, plastic materials can be sterilized easily, ensuring compliance with healthcare hygiene standards. In addition, the lighter weight of plastic compared to metals makes it ideal for disposable items, reducing shipping costs and improving patient comfort. While metals and rubber are used in specific applications, plastic offers superior flexibility, easier integration with other materials, and faster production cycles.

Hot Runner Systems Held a Major Share of the Medical Injection Molding Market.

- Based on the system, the medical injection molding market is segmented into hot runner and cold runner. Among the systems, **67.8%** of the medical injection molding is manufactured by hot runner systems. Most medical injection molding systems use hot runners instead of cold runners due to their ability to improve efficiency, reduce material waste, and enhance part quality. In hot runner systems, the plastic is kept molten throughout the entire molding process, which ensures a consistent flow of material into the mold cavities.
- This eliminates the need for additional material that is usually discarded with cold runners, reducing waste and improving cost-effectiveness, especially in high-volume production. Additionally, hot runners allow for faster cycle times, as the material is always at the ideal temperature, leading to better flow control and less risk of defects such as short shots or incomplete fills. These advantages are particularly crucial in the medical device sector, where precision, quality, and efficiency are paramount. Similarly, hot runners support the molding of complex designs with minimal scrap, which is vital for producing the intricate, high-precision parts required in medical devices.

• Demand for Diagnostic Equipment Creates Opportunities in the Medical Injection Molding Market.

- The growing demand for diagnostic equipment presents significant opportunities for the medical injection molding market, driven by the increasing need for accurate and rapid diagnostics in healthcare. As medical technologies evolve, devices such as blood glucose monitors, pregnancy tests, and portable ultrasound equipment require advanced plastic components that can be produced with high precision and reliability through injection molding. For instance, according to the International Diabetes Federation, by 2023, nearly **589 million adults** lived with diabetes globally (1 in 9), with over 250 million unaware of their condition, leading to **3.4 million** annual deaths.
- This prevalence creates the demand for glucose monitoring systems whose components, which include sensors, casings, and connectors, are often manufactured using injection molding. The increasing adoption of point-of-care diagnostic devices, designed for home use or in outpatient settings, further fuels the demand for lightweight, durable, and cost-effective molded parts. As healthcare providers focus on providing faster, more accessible diagnostics, the ability to efficiently produce these complex devices in large quantities supports the expansion of the medical injection molding sector.

• Trends

- **A Focus on Automation in the Medical Injection Molding.**
- The ongoing trend towards automation in the medical injection molding sector is transforming the production of medical devices, enhancing efficiency and precision. Automation technologies, including robotic arms, automated material handling systems, and integrated inspection systems, are increasingly being employed to streamline the manufacturing process. For instance, robotic arms are used for tasks such as part removal, assembly, and packaging, significantly reducing manual labor while ensuring higher production speeds and consistent product quality.
- In addition, automated inspection systems are capable of performing high-precision quality checks, ensuring that parts meet stringent medical standards. This focus on automation is particularly critical in the production of high-volume, high-precision products such as surgical instruments, IV components, and diagnostic devices, where error-free manufacturing is essential. By minimizing human intervention, automation reduces the risk of contamination, improves

throughput, and lowers production costs, which are crucial factors in the highly regulated medical industry.

- **Geopolitical Tensions Are Reshaping the Dynamics of the Medical Injection Molding Market.**

- The geopolitical tensions are significantly impacting the medical injection molding market. Trade disruptions, particularly between major economies such as the U.S. and China, have led to supply chain uncertainties. Tariffs on raw materials and components used in the injection molding process, such as specialized polymers and metals, have increased production costs for manufacturers.
- Additionally, the Israel-Hamas war had sabotaged trade routes in the Red Sea and the Suez Canal, which led to delays for an outgoing trip from Asia to Europe. Similarly, the conflict revolving around the South China Sea had restricted deliveries of semiconductor products, essential in molding machines and medical devices, to other countries, such as the US.
- In contrast, countries in South Asia, such as Vietnam and India, are increasingly becoming key players in medical device manufacturing, offering a more stable and cost-effective alternative. Additionally, rising concerns about healthcare security amid geopolitical instability are driving governments to invest in local manufacturing capabilities, creating new opportunities for injection molding suppliers. Despite the challenges, these factors are likely to reshape the market dynamics and foster regional growth in the medical injection molding sector.

Asia Pacific Held the Largest Share of the Global Medical Injection Molding Market.

- In 2024, the Asia Pacific dominated the global medical injection molding market, holding about 46.5% of the total global consumption. The region holds the largest share of the global medical injection molding market, driven by a combination of factors such as a large manufacturing base, lower production costs, and increasing demand for medical devices.
- According to the India Brand Equity Foundation, healthcare spending accounted for 3.3% of India's GDP in 2022 and is expected to rise to 5% by 2030. Countries such as China, India, and Japan are prominent players, leveraging their advanced manufacturing capabilities and growing healthcare infrastructure. For instance, China has become a global hub for the production of medical devices, including disposable syringes, catheters, and diagnostic equipment, all of which are produced via injection molding.
- The region's strong emphasis on cost-efficiency, coupled with an expanding middle class and aging population, has significantly boosted the demand for both domestic and international medical devices. Japan has the world's most rapidly aging population, with nearly 30% of its people over 65, and a median age of 49. Furthermore, the Asia Pacific's regulatory environment has evolved to accommodate international standards, making it an attractive region for foreign investments in medical manufacturing.

(Ref : https://market.us/report/medical-injection-molding-market/)

Indonesia Medical Devices Market

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We will continue our journey in the Asian region for market exploration. We will visit the market of Indonesia in this issue, after exploring Vietnam in the last issue.

Country Profile

Indonesia has the highest population in Southeast Asia and is the fourth most populous country in the world. The country has an estimated population of about 28 crore. Indonesia is now the world's third most populous democracy and the world's largest Muslim-majority nation. Before the country was christened "Indonesia", it was known as the Dutch East Indies because it was occupied by the Dutch till 1945. The capital city of Indonesia is Jakarta. There are close to 17,000 islands which make up Indonesia. 7,000 of these are uninhabited. Close to 70% of the country's land is covered by the islands of Sumatra, Java, Kalimantan, Sulawesi and Papua. Indonesia has the largest number of active volcanoes today.

In line with its population, Indonesia is the fourth-largest consumer market in the world. The fast-growing middle class of the country is a major force behind this boost to the consumer market. Consumers from the urban centres make up close to 60% of the buyers. For necessities of life, as well as discretionary and leisure items, this market is booming. The economy of the country is now among the world's top 10 in terms of purchasing power parity. Location and diversity of the landscape make Indonesia a tourist attraction, supporting economic growth. The famous temple of Borobudur in Central Java is a major attraction of Indonesia.

Medical Device Registration in Indonesia

Medical devices in Indonesia are regulated by the National Agency of Drug and Food Control (NADFC), which functions under the Indonesian Ministry of Health (MoH). Registration can be through a local Indonesian distributor, an agency (there are regulatory agencies that can do registration and then transfer them to an appropriate partner/s based on the decision of an overseas manufacturer) or by a subsidiary of the parent company.

This point is crucial because, being an important and large market, with difficulty in transferability of registration, a careful decision needs to be taken in this regard for a long-term model pertaining to registration ownership. Registration transfers are very difficult as this is possible only if the existing distributor gives a no-objection certificate, and rarely will an existing party be willing to give such a certificate.

The medical device classification system in Indonesia follows the four classes based on the risk involved, as seen in many other countries. Article 7 (1) of the devise law covers this classification. The same is summarised below-

Class A, low risk level;
Class B, low to moderate risk level;
Class C, moderate to high risk level; and
Class D, high risk level.

Once granted, the validity of the license is for 5 Years. Submission Format can be either online or through submissions of papers, and the language for documents can be either English or Indonesian. Interested readers are suggested to see the detailed document in English on the website https://regalkes.kemkes.go.id/informasi_alkes/Regulasi%20Lisensi%20Produk.pdf

Highlights

- A very large existing and future market for medical devices
- Imports make a large part of the device market
- Country has an inclination towards local manufacturing

The registration process is simple. After clarifying the class of the products under question, appropriate papers are to be submitted along with the payment. Either a provisional certificate is issued, or queries and questions on deficiencies are raised. Labelling requirements are also important, which should be noted. An average processing time for an application is between 45 to 60 days. For Class D products, processing may take 90 days. There is an announcement of

the applicability of Halal certificates also in the future, and an updated status from a local partner is advised for an exporter. Voluntary halal certification has already been proposed since 2021 for medical devices, but this certification will not be mandatory until 2026 onwards.

Medical Devices Market

Broad scenario:

Healthcare is a priority area for the Government. Upgradation of healthcare facilities is at a good pace. In spite of protectionist measures to boost local manufacture of medical devices, Indonesia continues to rely on imported products, and Imports make a large portion of the market. Demand for Diagnostics has grown much faster. 90 % of the population is covered under the healthcare benefit schemes. A major factor contributing to the market of upper-end devices is the growing private healthcare facilities. Out of about 3000 hospitals, around 63 per cent are privately managed. Domestic manufacture focuses on lower-end, simpler devices such as surgical gloves, bandages, orthopaedic products, and hospital furniture. Protectionist policies, however, have prompted some large MNCs like GE to start joint ventures in Indonesia to meet local content requirements. Medical equipment is subject to a 5% - 30% import tax, depending on the type, in addition to the standard 10% VAT. The country prohibits the import of used or refurbished medical equipment.

Market in numbers:

- Market size - a generally accepted estimate is 4.5 bn USD.
- Growth rate - About 6%, with the future projected GR of 8%.
- Import contribution - 65% of the total consumption (which is down from 80% earlier)
- Registration status (2025 numbers) - 16,777 locally made; 56,325 imported device registrations (This is in line with high import dependence)
- Import source Countries - China is number 1, with 20% imported devices, followed by Germany with 15%, and then the US, making up about 11.5%.

Opportunities and Challenges

A large and growing market with high dependence on imports and smoother registration processes makes the country quite attractive. India, as a country, has a very high regard in the local society, with a strong cultural influence. Reliable large distributors are not difficult to get for this market. The English language for commercial transactions is also an advantage for Indian exporters.

The challenges are quality and servicing. A fragmented geographical market (due to many islands) is also a challenge. Local manufacturing norms becoming stricter will be an important factor, too, in the future.

Parliamentary Panel Recommends Measures To Expedite Approvals And Innovation In Medical Devices Sector

The Parliamentary Panel on Health and Family Welfare has recommended to the Department of Health to ensure complete digitisation and automation of licensing process, and implement a single comprehensive query system and a time-bound conditional approval mechanism in the Central Drugs Standard Control Organisation (CDSCO) to expedite approvals and encourage innovation in the medical devices sector.

The Panel, in its 170th report on action taken by the government on its recommendations and observations in the 163rd report on Demands for Grants for the Department of Health for the year 2025-26, took note of various initiatives such as implementation of MD online portal, creation of a Medical Devices Vertical, establishment of testing laboratories and notified bodies and launch of MedTech Mitra platform to support innovators.

While these measures are commendable steps towards improving regulatory efficiency and transparency, the Committee observes that persistent industry concerns remain regarding delays, inconsistent timelines, and lack of end-to-end real-time tracking of licensing applications, it observed.

"The Committee, therefore, recommends that the Department must ensure the complete digitization and automation of the licensing process through a unified and integrated digital platform linking central and state licensing authorities, with mandatory public disclosure of application status, query logs, and processing timelines," said the Panel headed by Member of Parliament Prof. Ram Gopal Yadav in the report presented to the Rajya Sabha on December 11.

"The Committee further urges that a robust performance monitoring and accountability framework be instituted to track adherence to defined service timelines and penalize undue delays," it added.

Additionally, the Panel expressed its desire that CDSCO leverage AI-driven analytics to identify procedural bottlenecks, reduce manual interventions, and improve predictability in approvals so as to foster a globally competitive and innovation friendly medical device ecosystem in India.

With regards to the delayed query process and communication between the industry and the CDSCO, observed in its previous report, the Panel noted the steps taken by the Department and CDSCO to enhance transparency and reduce procedural ambiguities, including the introduction of tooltips on the MD Online portal, publication of updated FAQs and guidance documents, establishment of Public Relations Offices (PROs), and regular stakeholder consultations and open meetings by the Drugs Controller General of India.

However, the Committee observed that despite these initiatives, applicants - particularly startups and small-scale manufacturers - continue to face multiple and sequential queries, causing delays and uncertainty in approval timelines.

"The Committee, therefore, recommends the Department for implementing a single comprehensive query system to ensure that all observations are raised in one go, thereby minimizing repetitive communication and expediting approvals," said the report.

The Panel further recommended the adoption of a time-bound conditional approval mechanism, especially for products possessing recognized international certifications such as CE or US FDA, to promote ease of doing business and encourage innovation.

It also sought the CDSCO to establish a dedicated regulatory facilitation cell for startups within the MedTech Mitra framework to provide real-time query assistance and guidance, ensuring that India's regulatory environment becomes more predictable, responsive, and innovation-friendly.

https://www.pharmabiz.com/NewsDetails.aspx?aid=183018&sid=1, December 15, 2025

Licenses For Manufacturing And Importing Medical Devices Will No Longer Lapse After Five Years

The Centre plans to scrap expiry-based licences for medical devices and introduce perpetual approvals alongside uniform lab testing rules, according to two officials and a draft notification reviewed by Mint. The move aims to cut compliance burdens in a sector valued at $14-15 billion and projected to double by 2030.

Under the proposed changes, licences for manufacturing and importing medical devices will no longer lapse after five years but will remain valid indefinitely, provided companies pay periodic retention fees. At the same time, all registered laboratories will be required to submit test reports in a standardized format to address long-standing inconsistencies that have complicated reg ulatory oversight.

Together, the measures seek to simplify compliance, cut costs and improve product safety, while making India a more attractive destination for investment in medical devices.

"To keep these licences valid, companies will simply need to deposit a retention fee (at specified intervals), eliminating uncertainty and administrative hurdles associated with filing fresh renewal applications repeatedly," one of the officials said.

The current 5-year validity was introduced under the Medical Devices Rules, 2017, which came into effect on 1 January 2018; prior to that, medical devices were regulated under the broader Drugs and Cosmetics Rules, 1945, which did not have a distinct licensing structure for devices. Stakeholders and the public have been given 30 days to review the draft notification and submit comments. Queries sent to the health ministry remained unanswered.

Industry groups welcomed the move but flagged potential complications for exporters.

Rajiv Nath, forum coordinator at the Association of Indian Manufacturers of Medical Devices (AIMED), said that while perpetual licences improve ease of doing business domestically, overseas regulators often need certificates with a defined validity period, like three to five years, to approve imports. "We need a simple software option that allows us to print certificates showing these dates based on our fee payments, otherwise, our overseas distributors will struggle to register Indian products."

Alongside licensing reform, the draft notification lays out the

mechanics of standardized testing, introducing a single mandatory document that all registered laboratories must use for test reports.

"This standardizes the process, requiring laboratories to explicitly list critical details such as the device's batch number, date of manufacture, and expiry date, alongside specific results for physical, chemical, and biological tests. This creates a uniform language for quality assurance across the country, ensuring that a report from a lab in Mumbai looks exactly the same as one from Chennai," the official said.

"This is a very welcome step for all NABL (National Accreditation Board for Testing and Calibration Laboratories) accredited and CDSCO (Central Drugs Standard Control Organisation) recognized labs to have a standard format test reporting format. We look forward to the detailed template and hope it provides clear provision of ISO (International Organization for Standardization) and/or BIS (Bureau of Indian Standards) standard referenced accreditation to," Nath said.

https://www.pressreader.com/india/mint-chennai/20251219/281672556286281

AiMed Welcomes Comprehensive Economic Partnership Agreement (CEPA) with the Sultanate of Oman.

"AiMeD" wholeheartedly commended Prime Minister Narendra Modi and the Government of India for the successful conclusion of the Comprehensive Economic Partnership Agreement (CEPA) with the Sultanate of Oman. This landmark accord is a forward-looking step that will not only strengthen bilateral trade but also open new horizons for India's medical device industry.

The CEPA provides a framework for enhanced collaboration in healthcare and life sciences, enabling Indian manufacturers to expand access to high-quality, affordable medical technologies across Oman and the wider Gulf region. For sectors such as cardiac and dialysis care, syringes, and single-use disposable medical devices, this agreement will facilitate smoother market entry, predictable regulatory pathways, and greater trust in India's globally recognized manufacturing standards.

By fostering contract manufacturing partnerships and encouraging ethical procurement practices, CEPA will help ensure that patients in Oman benefit from safe, innovative, and cost-effective solutions while Indian companies gain new opportunities to scale and diversify. This is a win-win for both nations, reinforcing India's role as a reliable partner in advancing healthcare accessibility and resilience.

When Global Healthcare Innovation Met Science of Smart Materials

World Health Innovation Forum 2025 at AMTZ

With Special Session By

SPE INDIA Medical Plastics Division

In mid-December 2025, the city of Visakhapatnam witnessed a rare transformation — a coastal industrial hub turning into a truly global meeting ground for healthcare innovation. From **11 to 13 December, the World Health Innovation Forum (WHIF) 2025 unfolded at the Andhra Pradesh MedTech Zone (AMTZ),** drawing participants from **over 60 countries** spanning governments, healthcare systems, industry, academia, and global health organisations.

WHIF has steadily evolved into one of the most purposeful platforms in the global health-technology calendar. What distinguishes the forum is not only its international scale, but its practical orientation — focused on how innovation can move from concept to clinic, from laboratory to large-scale manufacturing, and from policy discussion to patient impact.

This year's edition reflected that maturity. Conversations were grounded, collaborative, and deeply human, centred on improving healthcare delivery while strengthening innovation ecosystems across geographies.

A Global Exchange with Local Roots

Across three days, WHIF 2025 hosted policymakers, clinicians, engineers, manufacturers, investors, and researchers in a shared dialogue on the future of healthcare. Delegates from multilateral organisations, including the World Health Organization, joined industry leaders and startups to discuss topics ranging from health equity and regulatory pathways to digital health and advanced medical manufacturing.

The setting itself added depth to the discussions. AMTZ — India's flagship integrated medical technology ecosystem — provided participants with a living example of how innovation, manufacturing, testing, skilling, and regulatory support can coexist in one location. For many international delegates, this was a tangible demonstration of India's growing role as a **global MedTech innovation and manufacturing partner,** not merely a consumption market.

SPE India at WHIF 2025

Among the many thematic sessions at WHIF, a special session on **Smart Materials for Medical Applications** drew particular attention. The session was led by **SPE India,** whose strong representation underscored the increasing importance of materials science in shaping the next generation of medical devices.

The SPE India panel comprised senior leaders from the society and industry: **Mr. Ramesh Parasuraman,** President, SPE India, **Mr. Rajiv Sanghavi,** International Councillor, SPE India, **Mr. D. L. Pandya,** Vice President, SPE India Medical Plastics Division and **Dr. Teja Maganti,** CEO, Medi Mold (AMTZ).

Together, the panel brought a balanced perspective — combining global materials expertise, industry leadership, international engagement, and hands-on medical manufacturing experience within India's MedTech ecosystem.

Rather than focusing on theoretical advances alone, the session explored how smart materials are being translated into real medical products, addressing clinical needs while remaining manufacturable, scalable, and compliant with regulatory expectations.

Understanding Smart Materials in a Medical Context

Smart materials are defined by their ability to **respond dynamically to external stimuli** — such as temperature, mechanical stress, electrical signals, moisture, or chemical environments. In healthcare, this responsiveness opens new possibilities for devices that can adapt to the human body, rather than remaining static components.

During the session, panellists discussed a range of smart material classes increasingly relevant to medical applications:

- **Shape-memory polymers and alloys,** capable of changing shape or stiffness in response to temperature or stress
- **Stimuli-responsive hydrogels** used for controlled drug release and tissue interaction
- **Advanced medical polymers and composites** with enhanced bio-compatibility, durability, and functional integration
- **Smart elastomers and surface-engineered plastics** used in catheters, tubing, wearables, and implantable components

The discussion highlighted a clear shift in medical device design — from inert materials to **materials that sense, respond, and interact** with their environment.

From Material Science to Patient Outcomes

A key theme emphasised by the SPE panel was the importance of linking material innovation directly to **clinical and patient outcomes.** While smart materials offer advanced functionality, their success ultimately depends on reliability, safety, and long-term performance in real healthcare settings.
The panel shared insights into how smart materials are enabling:

- **Minimally invasive devices** that can be delivered in compact forms and activated within the body
- **Improved implant performance,** with materials that better match biomechanical and biological conditions
- **Enhanced medical disposables,** offering better safety, usability, and infection control
- **Wearable and diagnostic devices** capable of continuous monitoring and data-driven care

Dr. Teja Maganti, drawing from his experience at Medi Mold within AMTZ, highlighted the importance of designing smart material solutions that align with manufacturing realities — including process repeatability, cost efficiency, and regulatory validation. He emphasised that materials innovation must be closely integrated with tooling, process engineering, and quality systems to achieve meaningful adoption.

Manufacturing, Regulation, and Scale

An important dimension of the discussion focused on the challenges that accompany smart materials in medical applications. Panelists acknowledged that advanced materials often face hurdles related to long-term biocompatibility, validation protocols, regulatory acceptance, and industrial scalability.

Mr. D. L. Pandya and Mr. Ramesh Parasuraman emphasised the role of professional bodies like SPE in bridging these gaps — by enabling knowledge exchange, standardisation dialogue, and collaboration between material suppliers, device manufacturers, clinicians, and regulators.

Mr. Rajiv Sanghavi, in his role as SPE India's International Councillor, reflected on global trends and how international collaboration can accelerate learning curves, particularly in emerging markets. He noted that harmonisation of material standards and testing methodologies will be critical as smart materials become more widely embedded in medical devices worldwide.

Why Smart Materials Matter for India

The relevance of smart materials is particularly significant for India's healthcare landscape. As domestic medical device manufacturing expands, there is a growing need for materials that combine **performance, affordability, and scalability.**

Smart polymers, advanced plastics, and hybrid materials offer pathways to develop devices that are not only clinically effective but also economically viable at large volumes. When supported by ecosystems like AMTZ, these innovations can move faster from concept to commercialisation.

The SPE India session underscored that India's strength lies in its ability to integrate **materials science, manufacturing engineering, and clinical insight** — positioning the country as a contributor to global healthcare solutions rather than a follower.

WHIF as a Platform for Collective Progress

Beyond individual sessions, WHIF 2025 served as a platform for collaboration and convergence. Informal discussions often extended beyond scheduled panels, leading to conversations on joint research initiatives, pilot manufacturing projects, and cross-border partnerships.

The forum demonstrated that healthcare innovation is inherently multidisciplinary. Progress depends not on isolated breakthroughs, but on ecosystems that encourage dialogue between policymakers, scientists, manufacturers, and clinicians.

AMTZ: An Ecosystem That Enables Innovation

Hosting WHIF at AMTZ reinforced the importance of integrated infrastructure in advancing medical technology. For global delegates, the visit offered a firsthand view of how India is building capacity across the entire MedTech value chain — from design and materials to testing, certification, and scale-up.

AMTZ's role as host was not merely logistical, but symbolic of India's commitment to creating sustainable, globally relevant healthcare manufacturing ecosystems.

Looking Ahead

As WHIF 2025 concluded, participants departed with renewed confidence in the power of collaboration and purpose-driven innovation. The discussions around smart materials highlighted a future where medical devices are more adaptive, patient-centric, and responsive to real-world conditions.

For **SPE India,** the forum reaffirmed the society's critical role at the intersection of **materials science and healthcare technology.** The insights shared by the SPE panel — **Mr. D. L. Pandya, Mr. Ramesh Parasuraman, Mr. Rajiv Sanghavi, and Dr. Teja Maganti** — reflected both global perspective and local relevance.

As smart materials continue to move from emerging concepts to essential components of medical devices, the conversations initiated at WHIF 2025 will help shape technologies that are not only innovative, but practical, scalable, and deeply human-centred.

Andhra Set To Become The 'Medical Device Capital Of The World' With Massive 500-Acre Expansion

How a 500-acre medical hub in Andhra is set to create thousands of high-value jobs & why global giants are now eyeing Visakhapatnam for manufacturing.

Can Visakhapatnam become India's next global hub for medical devices? Andhra Pradesh plans to launch a 500-acre Medical Devices Manufacturing Zone 2.0 in Vizag. The project aims to boost high-value medtech production, attract global companies, and strengthen India's self-reliance in advanced healthcare technologies.

Expanding medtech manufacturing in Vizag

The Andhra Pradesh government has announced plans to develop a 500-acre Medical Devices Manufacturing Zone 2.0 in Visakhapatnam (Vizag). The project is designed to expand the state's medical technology manufacturing capacity and draw interest from both domestic and international medical device companies.

The new zone builds on the success of the existing Andhra Pradesh MedTech Zone (AMTZ). It will focus on the production of high-value medical equipment, including advanced diagnostic tools, imaging technologies, and essential medical consumables. Officials expect the project to strengthen India's position in the global medtech supply chain.

Focus on self-reliance and investment

The proposed zone aims to reduce India's dependence on imported medical devices while supporting the country's broader healthcare and industrial goals. By creating a dedicated manufacturing ecosystem, the state hopes to encourage long-term investment and innovation in medical technologies.

Nara Lokesh, Minister for Information Technology and Industries, said, "By offering dedicated infrastructure and a strong manufacturing ecosystem, the Medical Devices Manufacturing Zone 2.0 will enhance India's self-reliance in high-end healthcare technologies and attract global manufacturers to invest in Vizag."

Jobs, exports and research growth

The Medical Devices Manufacturing Zone 2.0 is expected to generate employment, boost exports, and support research and development activities. The initiative also aligns with the central government's Make in India programme, which aims to promote domestic manufacturing and strengthen India's industrial base in critical sectors.

https://www.manufacturingtodayindia.com/andhra-plans-for-vizag December 19, 2025

Odisha Unveils Pharmaceutical And Medical Devices Policy To Bring Rs 25,000 Crore Investment By 2030

Chief Minister Mohan Charan Majhi launched the new policy here at the Odisha Pharma Summit-2025 in the presence of Industries Minister Sampad Chandra Swain and senior government officers.

Bhubaneswar: The Odisha government on Tuesday unveiled Pharmaceutical and Medical Devices Policy-2025, aiming to attract investment of Rs 25,000 crore and create 1 lakh jobs by 2030.

Chief Minister Mohan Charan Majhi launched the new policy here at the Odisha Pharma Summit-2025 in the presence of Industries Minister Sampad Chandra Swain and senior government officers.

Speaking on the occasion, Industries Department's Additional Chief Secretary Hemant Sharma said India imports about 85 per cent of medical devices from other countries, and there is a huge opportunity for this sector.

As a lot of units of pharmaceutical and medical devices are expected to come up in the next five years, Odisha must make an attempt to become a part of this endeavour, Sharma said.

Under the policy, the state offers a 50 per cent subsidy on concessional land cost for units employing more than 200 Odisha-domiciled skilled staff.

The government also offered a 30 per cent capital subsidy on eligible plant and machinery (disbursed up to 6 per cent per annum for 5 years), without any upper cap, while a 25 per cent subsidy (capped at Rs 1 crore) will be given for dedicated power infrastructure, another official said.

The objective of the new policy is to fast-track Odisha as the eastern hub for pharmaceuticals and medical devices through investment, jobs, innovation and green manufacturing, he stated. "The policy is expected to bring an investment of Rs 25,000 crore MoUs worth Rs 5,000 crore have been signed on Tuesday itself, the official said.

The policy also aims to attract investment and catalyse local entrepreneurship and MSME growth, while generating employment across skilled and semi-skilled segments.

Anchored in the state's Industrial Policy Resolution (IPR) - 2022, which identifies pharmaceuticals, bulk drugs and medical devices as a thrust sector, the policy promotes infrastructure readiness, research excellence, industry-academia collaboration for skilling and a facilitative regulatory environment to enable inclusive and sustainable industrial development, another official said.

The state will set up an Odisha Pharma Park and an Odisha MedTech Park (over 200 acres each) as integrated, good manufacturing practices (GMP)-ready clusters, he said.

The policy combines land, finance, skilled workforce, regulatory facilitation and R&D support to attract anchor investments across active pharmaceutical ingredients (APIs), formulations, vaccines, diagnostics, imaging, implants and wearables - positioning Odisha as a competitive, sustainable manufacturing and innovation destination.

It covers pharmaceuticals - APIs, bulk drugs, formulations, vaccines, biologicals and biosimilars, veterinary drugs and animal vaccines, nutraceuticals, and cosmetics classified as drugs; and Medical Devices - in-vitro diagnostics (IVD), implants, surgical consumables, instruments and apparatus, medical wearables, digital health devices and device software, the official added.

https://pharma.economictimes.indiatimes.com/news/policy-and-regulations/odisha-unveils-pharmaceutical-and-medical-devices-policy-to-bring-rs-25000-crore-investment-by-2030/126028732

Manufacturing And Innovation Of Medical Devices In India

The Production Linked Incentive (PLI) Scheme for Promoting Domestic Manufacturing of Medical Devices aims to promote domestic manufacturing of medical devices by attracting large investments for creation of domestic manufacturing capacity and incentivising domestic production. The list of high-end medical devices that are being manufactured in the country under the scheme is at Annexure. These medical devices are about 10% to 30% cheaper in comparison to imported products, thereby helping reducing domestic healthcare costs.

The setting up of a medical device park each in the States of Uttar Pradesh, Madhya Pradesh and Tamil Nadu, under the aforesaid scheme, is aimed at developing a highly competitive domestic manufacturing ecosystem by creating a state-of-the-art manufacturing ecosystem that offers plug-and-play facilities to greenfield units set up in these parks. Each park offers land at substantially subsidised rates, often coupled with exemptions or concessions on stamp duty, which significantly reduces initial capital outlay on land acquisition and project establishment. This upfront cost relief is particularly important for greenfield investors, as it allows a larger share of their capital to be directed towards plant and machinery, technology acquisition, automation and quality systems, rather than land costs and costs of establishing facilities that become available as common facilities.

A common feature of these parks is the development of robust common infrastructure facilities, which typically include centres for 3D design and printing, electronic assembly, electromagnetic interference and compatibility centre, moulding, sterilisation, biocompatibility testing, toxicology, electronic parts testing, component testing, gamma radiation facility and animal lab, especially for micro, small and medium enterprises (MSMEs). By providing such facilities on shared basis, the parks eliminate the need for individual companies to invest in expensive, capital-intensive infrastructure that is often under-utilised if set up in-house. This significantly reduces the per-unit cost of manufacturing, testing and validation, while also shortening product development timelines.

In addition, all three parks are structured around subsidised tariffs for key utilities, including power, water, warehousing and park maintenance. The combination of low cost of land, shared common infrastructure facilities and subsidised utilities improves both capital and operating efficiency. Collectively, these measures enable manufacturers to achieve economies of scale, enhance price competitiveness and position India as a strong global hub for medical device production.

The Capacity Building and Skill Development in the Medical Device Sector sub-scheme of the Strengthening of Medical Device Industry scheme is currently in the implementation phase. Under this sub-scheme, 18 applications have been approved for conducting two-year degree programmes and short-term courses in disciplines related to medical devices, with a view to address skilled manpower requirements of medical device industry and significantly enhance the availability of qualified technical personnel for the medical device sector. These approved programmes entail creation of a total of 750 training seats over the three-year period of the scheme, covering both postgraduate degree programmes and short-term skill development certificate courses. At present, a total of 187 candidates is enrolled in the first academic session.

The Promotion of Research in Pharma-Medtech Sector (PRIP) scheme has been launched by Department of Pharmaceuticals to provide financial assistance for research and development projects of industry, MSMEs and startups in priority areas, including novel medical devices. The strategies under the scheme to promote industry-academia collaboration for continuous innovation and next-generation MedTech development include the following:

I. With a view to help build specific research capacities in medical devices, tapping industry-academia linkage, institutional strengthening of research infrastructure and nurturing of talent pool has been undertaken through the setting up of a centre of excellence with advanced facilities at the National Institute of Pharmaceutical Education and Research (NIPER), Ahmedabad, which is an institute of national importance for imparting postgraduate and doctoral education and conduct high-end research in various specialisations in pharmaceutical sciences and medical technologies.

ii. Industry and startups are encouraged under the scheme to collaborate flexibly with reputed Government academic and research institutions specified in the Scheme guidelines to develop, translate and commercialise institutional intellectual property and to augment institutional research capacities in India.

Further, the NIPER Council has set up a NIPER Academia-Industry Coordination Committee as an institutional mechanism to promote strategic coordination between NIPERs and pharmaceuticals and medical devices industry by, among other things, facilitating greater synergies between NIPERs and industry and supporting research-driven growth, innovation, skilling and translation of academic research into industrial applications.

High-end medical devices being manufactured in India under the PLI Scheme

- Linear accelerator (LINAC), Laser ablation system, Rotational cobalt machine
- C-arm machine, Cath lab, CT scan machine, Mammography machine, MRI machine
- MRI coils, PET detector, Surgical X-ray C-arm, Ultrasonography, X-ray including fixed line frequency (LF) and high frequency (HF) X-ray product, X-ray panels, X-ray equipment
- Anaesthesia kits, Anaesthesia unit gas scavengers, Anaesthesia unit vaporisers
- Anaesthesia unit ventilators, Anaesthesia workstation, Automated external defibrillators (AED), Bi-phasic defibrillators, Defibrillators and AED, Dialysis machine, Emergency ventilators, Haemodialysis catheter, High flow oxygen devices, Intensive care ventilators Intreavascular lithotripsy catheter system, Micro-catheter tubing (neurovascular), Oxygen concentrators, Heart valves, Hip implants, Knee implants, PTCA balloon catheter, Stents

(This information was given by Union Minister of State in the Ministry of Chemicals and Fertilizers, Smt. Anupriya Patel, in a written reply in Rajya Sabha today.)

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Dec 12, 2025. 9.00 AM to 6.00 PM; Venue : The LaLit Ashok, Kumarakrupa, Bengaluru.

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EVENT REPORT

4th National Seminar On
Plastics For Medical Devices & Healthcare Industry : New Materials, Developments and Opportunities

Dec 12, 2025. 9.00 AM to 6.00 PM; Venue : The LaLit Ashok, Kumarakrupa, Bengaluru.

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Group Chairman
Manjushree Ventures

Mr. Sunil Khurana
Executive Chairman, BPL Medical Technologies Pvt Ltd

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Vice Chairman, Governing Council, IPI

Mr. Ramesh Parsuraman
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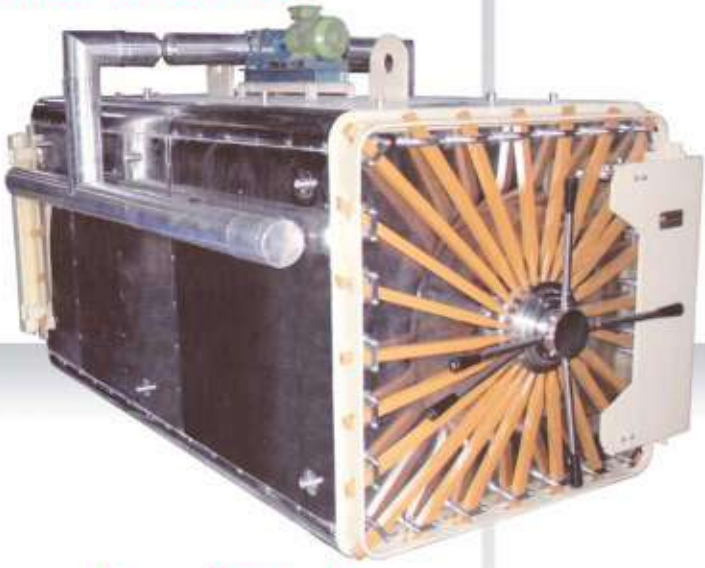

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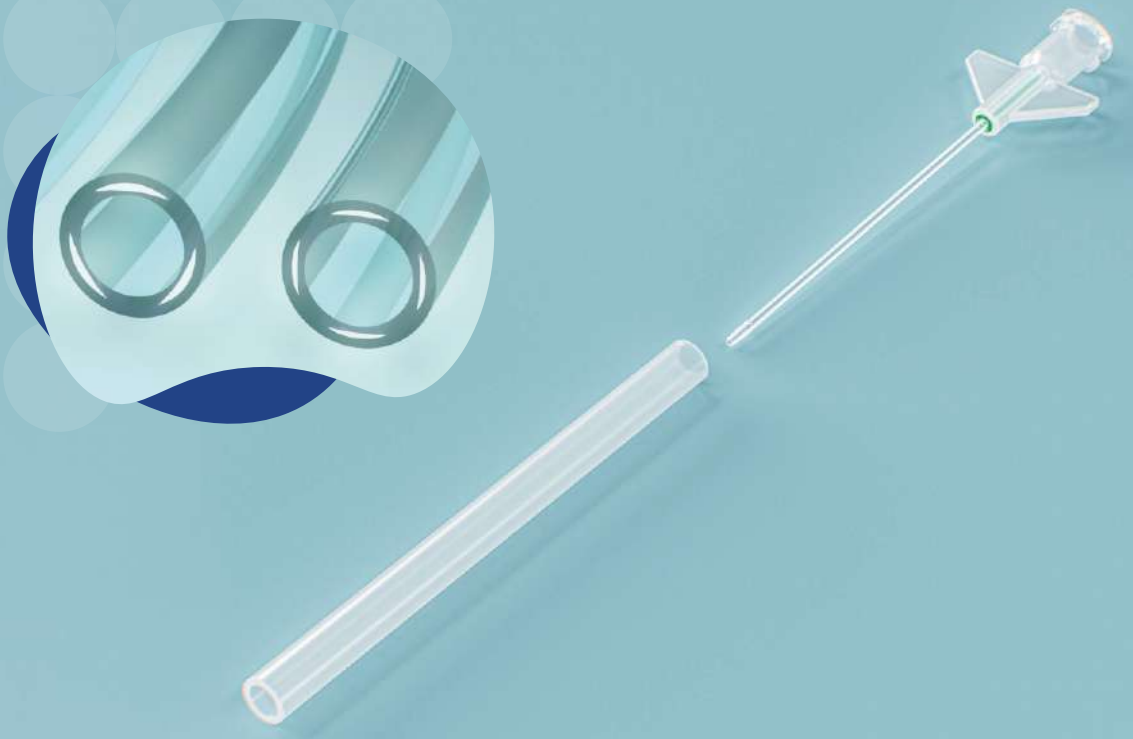

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