

MEDICAL PLASTICS DATA SERVICE

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



Dr. Renjith S
Biomedical Technology Wing,
SCTIMST, Trivandrum

• Medical Polymers

- New Developments
- Performance Plastics & Their Applications
- Performance Plastics :
Global Markets & Growth Potential

• Medical Device Packaging

- Materials & Design of Sterile Barriers
- Innovations in Polymer Films for Medical Packaging
- Misconceptions about Medical Device Packaging



Asim Datta
Consultant Faculty, Indian Institute of Packaging
& NIPPER Chandigarh



Quality Testing of Syringes & Needles

Medical Device Industry Markets

Global Markets : Chile Medical Devices Market

Domestic Market : India's Push Shows
Promising Growth



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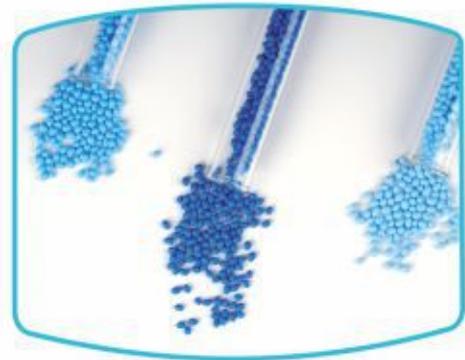
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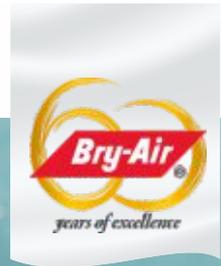
Optional materials: TPU, TPE, PE, PP, PA, PEBA, PVC, PC, PETG, PS, FEP, PVDF, PFA, PTFE, ETFE, PEEK, PPSU;

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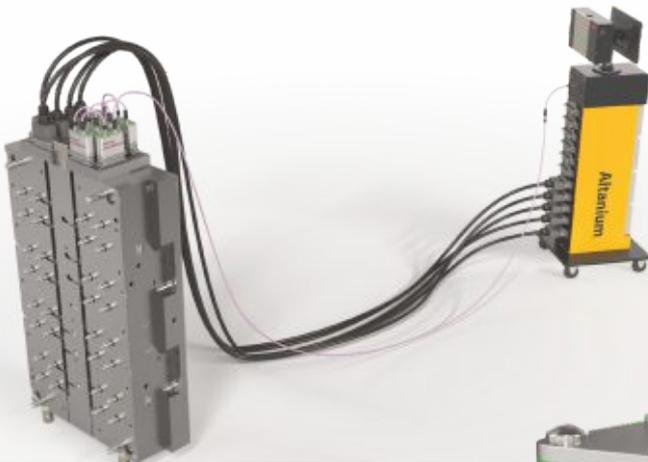


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- 3-Way Extension Line
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- Dial Flow Regulator
- I. V. Set With Flow Regulator
- Codan Set

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- ECG Paper & ECG Accessories
- Patient ID Belt
- Oxygen Flow Meter
- Caution Pencil

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- Urine Bag With Urometer
- Hemodialysis Catheter Kit
- Neltan Catheter
- Blood Tubing Set
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- DJ Stent - All Type

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- Ryles Tube
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- Kher T Tube
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Sai-45P	45 MM	26:1	15 HP AC	2mm-10mm	L-11M X W-2M X H-3M
Sai-50P	50 MM	26:1	20 HP AC	2mm-12mm	L-12M X W-2M X H-3M
Sai-65P	65 MM	28:1	30 HP AC	3mm-20mm	L-14M X W-2M X H-3.5M
Sai-80P	80 MM	28:1	60 HP AC	5mm-40mm	L-16M X W-2.5M X H-3.8M
Secondary Extruder	Available For Lining, 20mm/25mm/30mm on Demand				

Our Product Range



IV Canula Medical Tubing Extrusion Line



Winder



Caterpillar

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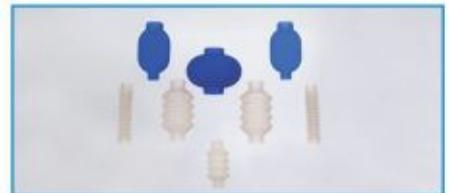
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- Acute Systemic Toxicity Test (ISO 10093-11)
- Material Mediated Pyrogen Test (ISO 10093-11)
- Sub-Acute Systemic Toxicity Test (ISO 10993-11) Sub-Chronic Toxicity Test (ISO 10993-11)
- Chronic Toxicity Test (ISO 10993-11)
- Implantation Test (IM/SC/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



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



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5. Packaging Testing & Transport Validation Study



6. Stability Testing Services



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Our 32nd Year of Publication

MEDICAL PLASTICS DATA SERVICE

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

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• **Medical Device Sector Needs Government Support**

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Dr. Gijo Raj
 Scientist, Biomedical Technology Wing, SCTIMST, Trivendrum

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- Plastic Additives and Role of Plasticizers in Medical Devices
- Plasticizers for Medical Grade PVC Applications: Safe Alternatives.
- Use of Radiopaque Fillers in Medical Material Manufacturing

• **MedTech Regulations in India**

• **Healthcare Plastic Waste Management**

• **Argentina Medical Device Market**

• **Plastics For Cardiovascular Devices**

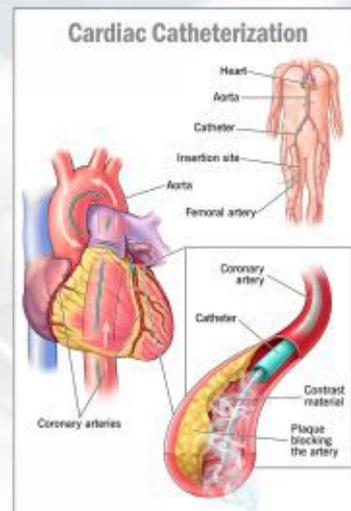
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- Cardiovascular System & Structure
- Cardiovascular Device Applications & Markets
- Polymeric Materials / Plastics Used
- Classifications of Polymers Used
- Regulatory Perspective
- New Technologies & Innovations
- Catheter Tubes For Cardiovascular Devices



- **Shape Memory Polymers For Medical Applications**
- **Chemical Characterization Of Medical Devices**
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- **Optimal Hospital Plastics Recycling**
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“100 Benefits of Plastics in Medical Devices”
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Shri Himanshu Baid

Managing Director, Poly Medicure Ltd., Faridabad

Thanks for sharing the online version of the publication. I always find it very informative and learn a lot of new things from the Advertisements and the articles. Wishing you very best of health and success. I look forward to receiving from time to time all future editions.



Dr. JK Sharma

MD & CEO, AMTZ & Advisor, Health & Med. Tech., Govt. of A.P., Visakhapatnam

Congratulations and looking forward to the 50th year of publication Thank you



Jitesh Shah

Director, Suru International Pvt. Ltd., Mumbai

Congratulation sir and I wish you many more successes !



Dr. S. S. Murugan PhD, Safety Toxicologist,

Managing Director, GLR Laboratories Pvt Ltd., Chennai

Congratulations! We are happy to know that Medical Plastics Data Service magazine is entering into the 29th year of Publication. It is our pleasure to extend our support in future also. Also, thanking you for your continuous support.



Anil Jauhari (ex-CEO, NABCB), New Delhi

Congratulations for such a feat of sustaining the magazine into 29th year. I would be happy to support in whatever way you may wish. I keep posting educational pieces on Linked in etc and you are free to reproduce any of them should it interest you.



Rajnikant Shah

Director Marketing - MRK Healthcare Pvt. Ltd. and Nulife Global Medical Devices Pvt.Ltd., Mumbai

Arrangement of dais and compare and order of event was excellent. Food and beverages were well arranged. The volunteers were very courteous and active. Whole atmosphere was like a international conference



Kishore Khanna

Managing Director, Romsons Group of Industries, & Joint Co-ordinator, Medical Consumables Products Segment, Association Of Indian Medical Devices Ind. Agra, India.

The exhibition and presentations of the papers were vey useful for SME industry.



Brian Reilly

Marketing & Sales Director, Nusil Silicone Tech., USA.

There was a good blend of vendor booths, technical presentations, academic and professionals from healthcare device industry.

Rajiv Nath

Managing Director, Hindustan Syringes & Medical Devices Ltd & Forum Coordinator. Association of Indian Medical Device Industry (AiMeD)



We appreciate Medical Plastic Data Service endeavor in creating awareness about Medical Device Industry in India



and the insights and quality literature articles as well as your wonderful initiative for holding the technical conferences and technology show exhibitions for the benefit of Medical Device Industry.

Congratulations to Medical Plastic Data Service for completing 32 years of its publication journey, coming out with the Medical Devices Report mapping the growth of this sector for India to become the leading Manufacturing Hub of Medical Devices and suggesting the way forward by capturing the Govt. of India's 'Make in India' and 'Develop in India initiatives by relaying the feedback from the Medical Device Manufacturers for achieving the vision of India as Top 5 Manufacturing Hub of Medical Devices. This sector can achieve 100,000 crore Rs of exports in next 5 to 7 years from current level of 32,000 crore with appropriate Policies & Strategies to support the Entrepreneurs and Investors.

We wish to offer our gratitude to Mr. D L Pandya and Team @ MPDS for their sincere and selfless efforts in creating awareness by their publications and technical and technology show exhibitions for enabling the manufacturing growth of Indian Medical Device Sector over last 3 decades.

With Best Wishes

Dr. Roy Joseph

Scientist G (Sr. Grade) Division of Polymeric Medical Devices / Central Analytical Facility, SC, Biomedical Technology Wing, (SCTIMST) Trivandrum



I have seen the Medical Plastics Data Service since its inception. The magazine has evolved over the years, and I find it a good source of information for raw materials, medical devices, processing and shaping machinery, and relevant articles on medical devices. I wish all the best for the magazine and the team behind it.

Dr. Renjith S

Scientist C, Central Analytical Facility (CAF) Dept. of Technology and Quality Management Biomedical Technology Wing, (SCTIMST) Thiruvananthapuram



....the magazine plays a crucial role in connecting the R&D people with industry benefiting in understanding the recent trends in the polymer industry and other related aspects. The conferences also wonderful opportunities to interact with the industry and share our knowledge and understanding with them. Being an analytical chemist working in the field of I hope to be part of your future endeavors as well.

Tim Galekop

TIGAMED, Global Consultancy Infection Prevention, Belgium

For me this was the first time that I, in India, spoke on a conference dealing with Medical Plastics. It was for me extremely useful to network and meet interesting people.



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Argentina Medical Devices Market

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

Stable economy with a strong political history , High per capita healthcare spending, more than two-thirds population covered by the Government Insurance, Easy import rules.

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Did You Know?

3 Common Misconceptions About Medical Device Packaging

Misconception #1: Medical device packaging is one-size-fits-all.

Every medical device is unique, both in terms of design and indications for use. Manufacturers will need to consider the design and functionality of the device.

By considering important device attributes like Sterilization methods, intended use, end-users, transportation and storage conditions, self life etc, manufacturers can avoid issues like failed packaging tests, product launch delays, and regulatory submission issues.

Misconception #2: Medical device packaging only needs to be tested and validated once

For new devices, there are three primary categories of package validation testing: Integrity, or the characteristics preventing the growth of microorganisms; Strength, or the strength/force needed to open the packaging; and Microbial Barrier, or confirmation that the chosen, porous materials provide an adequate microbial barrier. There are multiple tests used to evaluate a pass or fail for the packaging.

At any changes made to existing products require revalidation and additional testing. These changes could be major, such as the intended use or an all-new design; they could also be internal directive shifts, like environmental sustainability initiatives. In fact, even a slight change in raw materials for previously-validated packaging materials could result in further revalidation for years.

Misconception #3: Packaging can happen after design and development
When design of packaging for medical devices is left to final hour, often to save time and money can increase the risk of noncompliance. Instead, during this process different sterile barrier systems can be evaluated and manufacturing methods evaluated to best meet needs and characteristics of a particular device.

For long-lasting success, manufacturers need to thoroughly define the requirements of the unique device's packaging system much earlier in the product development process. Prequalification will only save money, time, and labor in a variety of ways.

Medical device packaging may be last thing on an engineer's mind, but thinking ahead will only help in a device's progress as it moves downstream.

<https://www.greenlight.guru/blog/medical-device-packaging-misconceptions>

In a Nutshell....



“New technologies and shifting healthcare work flows are driving the pace of medtech devices faster than ever before.”

-PHILIP REMEDIOS
Principal CFO & Director of Design and Development, BlackHagen Design

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ASST. EDITOR

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Cancer & Reconstructive Surgeon

PUBLISHED BY :

Classic Computer Services

B-4, Mandir Apartment, Opp. Jodhpur Char Rasta
BRTS Bus Stop, Ahmedabad-15, India
Phone : +91 79-26754867

E-mail: info@medicalplasticsindia.com

Website : www.medicalplasticsindia.com

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From the **Editor's**
Desk



Medical Packaging: Materials (Films), Design and Innovations

Medical Device Packaging plays vital role in safety and quality of Medical Devices. Stringent regulatory requirements for effective packaging of medical devices have led to development and innovations in the medical polymer films which can protect against outside influences and cause deleterious effect on the product.

Under the "Cover Story" as well as "Global Trends" columns, some of the research work carried out for various films including cross-linked biodegradable films, polymer-ceramic composites for skeletal tissue engineering, and elastomeric copolymers with tenable degradation profiles.

As explained by Mr Sanjay Shah, MD, Unikal Consultants, "for the Medical Device Packaging is vital to the safety and performance of healthcare products. Manufacturers must keep pace with advancements in sterilization technologies, sustainability, and material science to optimize product-self life and meet stringent regulatory demands."

While we had earlier covered the subject few years back, to match with the cover story of his issue, "Did You Know" column in this issue explains few of the misconceptions about medical device packaging.

High Performance Medical Polymers : Applications and Markets

One more focus of this issue is on High Performance Medical Polymers. Mr Asim Datta, Consultant Faculty, Indian Institute of Packaging, in his well-researched article has introduced few important performance polymers and their applications. High performance plastics markets have shown robust growth in recent years. Key statistics including market trends and segments as mentioned in a recent survey are also enlisted. This issue also covers some developments from recent research focusing on polymers that can be manufactured consistently at scale while meeting specific clinical requirements.

Quality Testing Of Medical Devices

From our last issue, we have initiated technical write-ups of various medical device products. The last issue highlighted various essential aspects related to need and testing requirements as well as methods for "Medical Examination Gloves". This issue highlights a very in-depth article on "Testing of Syringes and Needles" by Dr Renjith S of "biomedical Technology Wing, Sree Chitra Tirunal Institute for Medical Sciences and Technology" Trivandrum. The article highlights main evaluation methods of needle-based injection systems to ensure functional competence and the absence of toxic residues.

Welcome to Shri Amit Agrawal as the new Secretary of the Department of Pharmaceuticals. Shri Amit Agrawal was the CEO of the Unique Identification Authority of India (UIDAI). He takes over the position from Shri Arunish Chawla, IAS.

About Medical Device Industry in India and Global Markets

As per "Industry News" column, India's Medical Devices Sector is pushing for self-reliance with promising growth. While import dependency is still high, the Disposables, Consumables and Implants sub-sectors is on path to achieving self-reliance. Mr Amit Dave in his regular "Global Market" column highlights important features of "Chile Medical Devices Market".

This issue also covers news related to "Aimed", events, press releases along with an "Article Index" listing all important articles covered in out magazine in the year 2024.

D.L. Pandya

Innovations in Polymer Films for Medical Packaging

Medical Device Packaging plays vital role in safety and quality of Medical Devices. The package has to undergo harmful conditions during distribution chain, including extreme temperatures, humidity, contact with water and exposure to contaminants and microbes.

The stringent regulatory requirements for effective packaging of medical devices have led to development and innovations in the medical polymer films which can prevent protect against outside influences and cause deleterious effect on the product.

Many of the new developments in medical packaging films have taken place by better understanding and subsequent modification of molecular structures to improve the properties. This is done by introducing new manufacturing techniques for flexible films as well as use of newly developed additives including those with properties to give protection against radiation.

Under "Global Trends" column in this issue of magazine, some of the research work carried out for various films including crosslinked biodegradable films, polymer-ceramic composites for skeletal tissue engineering, and elastomeric copolymers with tenable degradation profiles. These and other approaches focus on developing materials that can be manufactured consistently at scale while meeting specific clinical requirements.

Plastics that can now tolerate radiation sterilization have created a market for a multitude of polymer formulations for products such as rigid and semirigid thermoforms and films with thicknesses from 0.5 to 10.0 mil.

Film structures combined with additives can be designed to be self-supporting and flexible, allowing them to be folded or creased without inducing a structural weakness in the film. Many of the newer film structures comprise fluoropolymers that are modified polychlorotrifluoro-ethylene. This material is converted to a film by melt extrusion, which requires special handling procedures because of its very high melt viscosity. Properties of such films include good tear strength, superior dimensional stability, and resistance to water vapor and to most chemicals. The films can stand up to steam, ethylene oxide, or radiation sterilization without being degraded.

FILM STRUCTURES

Among the types of film products available are single films, laminations, and co-extrusions. Properties that can be manipulated include barrier characteristics, clarity, stability in hot and cold environments, tensile strength, thermoformability, sealability, and radiation and chemical resistance. Compliance with new environmental regulations for disposal and recycling is also an important consideration.

BLISTER PACKAGING APPLICATIONS

Blister Packaging : The ability to precisely control film specifications for blister packaging enables this technique to be used to make specialized products such as child-resistant packaging. The technology for creating child-resistant packaging involves using seals, custom plastic banding, and container closures that must be pressed, twisted, or mechanically manipulated for entry. Foil webs require push-through or puncture to gain entry, and complete plastic tubes are used to totally enclose a package. Various combinations of polymer films, foils, and paper plies are employed in this type of packaging. Medical applications of blister packaging include surgical

instruments, medical pouches, implantable devices, diagnostic test kits, and disposables.

The other important applications of blister film includes Push-Through Lidding and Peel able Lidding.

Medical Packaging: Innovative Features

With more and more advancements in the healthcare and medical device industry, medical packaging with innovative features will transform the way medical products are packed and distributed. Some of the important advancements are listed below:

- Smart Packaging Technologies
- Anti-Counterfeiting Measures
- Sustainable Packaging Solutions
- Personalized Packaging for Patient Adherence
- Nanotechnology in Packaging
- Interactive Packaging for Improved Patient Education
- 3D Printing for Customized Packaging Solutions
- Improved Accessibility and Ease of Use
- Integration of Biometrics for Authentication
- Regulatory Considerations and Standards

Ref : <https://www.mddionline.com/3d-printing/innovations-in-polymer-films-for-medical-packaging>
<https://www.packaging-labelling.com/articles/the-future-of-medical-packaging-innovations-shaping-healthcare>



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Medical Device Packaging: Material And Design Of Sterile Barriers

Sanjay Shah
Director, Unikal Consultant

Medical device is a critical product, and its safety and efficacy are critical for patient and the user. At the same time, maintaining the efficacy and device life is important.

Medical Device is well defined in international definitions as per US FDA, EU MDR 1977/745, Indian MDR 17 and others.

MDR compliance means following the rules set out in the European Union Medical Device Regulation 2017/745 (EU MDR 2017/745) for companies making medical devices.

MDR 17 is compliance as per CDSCO guidelines.

ISO 13485 is a globally accepted standard for developing a Quality Management System (QMS) for companies that manufacture and market medical devices.

In the medical device industry, packaging plays a critical role in ensuring the safety, efficacy, and sterility of medical devices.

Thus, Medical Device packaging is a critical component and is well regulated as it is input for the final Medical Device. If the device is to be supplied in Sterile condition, its importance becomes critical.

One of the most crucial components of medical device packaging is the sterile barrier system, which is designed to maintain the sterility of a product from the time it is sterilized until it is used by healthcare professionals. The choice of material and design of this barrier system directly impacts the safety, usability, and regulatory compliance of medical devices.

Packaging material and design based on its usage and specific purpose in packaging a medical device; requires expertise and focused model. To select and design it requires regulatory insight, flexibility, and comprehensive validation study.

These will deliver compliant solutions that ensure quality and efficiency in packaging engineering output.

In this article, we will explore the importance of sterile barrier systems in medical device packaging, the materials used, and the key design considerations that ensure the integrity of medical devices.

The Role Of Sterile Barrier Systems

Sterile barrier systems are specifically engineered to:

- **Protect the device from contamination:** These systems safeguard medical devices from microbial contamination, dust, moisture, and physical damage throughout storage, handling, and transport.
- **Preserve sterility:** The primary function of sterile barriers is to maintain the sterility of the device until it is used, preventing any microbial ingress.

- **Facilitate easy access and usability:** The design of the packaging should allow easy opening without compromising the integrity of the sterile barrier.
- **Comply with regulations:** Medical device packaging must adhere to stringent regulations set by agencies such as the FDA (U.S. Food and Drug Administration) and ISO (International Organization for Standardization) to ensure both the device's safety and effectiveness.

Medical device packaging must meet several standards to ensure the safety and effectiveness of the device:

- **ISO 11607**
This standard from the International Standards Organization (ISO) covers the materials and design of sterile barriers for medical device packaging. It requires that packaging materials are:
 - Non-toxic, odorless, and non-leaching
 - Made from known and traceable materials
 - Intended for medical device use only
 - Free of defects like holes, tears, and thinning
- **Quality System Regulation (QSR) standards**
These standards outline general controls for the design, manufacturing, packaging, and distribution of medical devices.
- **FDA guidance**
The FDA requires that medical device packaging:
 - Prevents microbial ingress
 - Protects the device from damage
 - Provides an unambiguous method of presentation at the point of use
 - Is designed and constructed to protect the device from alteration or damage during processing, storage, handling, and distribution

Packaging designs must also be consistent with the intended use of the product. This includes considering the physical characteristics of the packaging and its suitability for the intended use. Medical device packaging must also undergo testing to ensure it meets its intended purpose:

- **Distribution testing**
Simulates hazards seen in the shipping environment, such as drop vibration and compression
- **Sterile barrier tests**
Ensures that the sterile barrier remains intact, and the device is able to be used without risk of infection

Materials Used in Sterile Barrier Packaging

The choice of materials for sterile barrier systems is dictated by

the need for physical protection, microbial resistance, and compatibility with sterilization methods. Common materials used in sterile barrier packaging include:

1. Medical-Grade Paper

Medical-grade paper is one of the most commonly used materials for sterile barrier packaging. It is often used in combination with other materials such as plastic films. The key benefits of medical-grade paper include:

- **Breathability:** It allows the passage of sterilizing agents, such as steam or gas, which is crucial for sterilization processes like autoclaving or EO (ethylene oxide) sterilization.
- **Durability:** The paper is designed to withstand handling without compromising its integrity or the sterility of the device.
- **Cost-effectiveness:** Paper is relatively inexpensive, making it a popular choice for packaging a wide variety of medical devices.

2. Plastic Films

Plastic films, such as polyethylene (PE), polypropylene (PP), and polyester (PET), are commonly used for packaging medical devices. These materials are often combined with medical-grade paper to create multi-layer systems that offer enhanced protection. The benefits of plastic films include:

- **Moisture and gas barrier:** Plastic films provide an excellent barrier against moisture and gases, which is critical for the longevity of certain medical devices.
- **Durability:** These materials are resistant to punctures and tears, which helps to maintain the integrity of the packaging during transportation and handling.
- **Transparency:** Clear plastic films allow for easy inspection of the device, ensuring that it remains visible and identifiable.

3. Tyvek® (Polyethylene Terephthalate)

Tyvek is a high-density polyethylene material that is widely used in the medical device industry due to its excellent microbial barrier properties. It is often used for packaging devices that need to remain sterile for extended periods. The advantages of Tyvek include:

- **High strength-to-weight ratio:** Tyvek is strong yet lightweight, offering superior tear resistance and puncture resistance.
- **Breathability:** Like medical-grade paper, Tyvek allows the sterilizing agents to penetrate during the sterilization process, but it also prevents microbes from passing through after sterilization.
- **Compatibility with various sterilization methods:** Tyvek can withstand autoclaving, EO sterilization, and gamma radiation, making it a versatile choice for sterile barrier packaging.

4. Foil Materials

Aluminum foil or foil-laminated materials can also be used for sterile barrier packaging. These materials are particularly beneficial for devices that are sensitive to light or moisture, as they provide a complete barrier against these elements.

- **Superior barrier properties:** Foil materials offer an exceptional barrier against light, moisture, and oxygen, making them ideal for sensitive medical devices.
- **Durability:** Aluminum foil is highly resistant to tearing and puncturing.

Design Considerations For Sterile Barrier Systems

While material selection is essential, the design of the sterile barrier system is just as critical in maintaining sterility and usability. Several factors must be taken into account when designing a sterile barrier for medical devices:

1. Sealing Integrity

The seal is the most important aspect of the sterile barrier

system. A reliable seal prevents the ingress of contaminants and ensures that the device remains sterile. The design must incorporate appropriate sealing techniques, such as:

- **Heat sealing:** Commonly used for plastic-based sterile barriers.
- **Sterile ultrasonic sealing:** Uses ultrasonic vibrations to bond materials without the need for heat, which is especially useful for sensitive materials.

The strength of the seal must be tested rigorously to ensure that it can withstand the pressures and stresses of transportation, storage, and handling without breaking or weakening.

2. Ease of Opening

A sterile barrier should be easy to open by healthcare professionals in a sterile environment. Packaging should allow for a one-handed opening process, minimizing the risk of contamination. Common design features include:

- **Peelable pouches:** Pouches made of flexible materials that can be easily peeled open without compromising sterility.
- **Tear notches:** Pre-designed tear points that allow for easy and clean opening of the package.

3. Sterilization Compatibility

Different sterilization methods, such as steam (autoclaving), ethylene oxide (EO) gas, gamma radiation, and electron beam (e-beam) irradiation, require different packaging materials. A good sterile barrier design will ensure that the materials used are compatible with the chosen sterilization method. For example:

- **Autoclaving:** Materials like medical-grade paper and Tyvek are designed to withstand high heat and moisture during steam sterilization.
- **Gamma radiation:** Packaging must be made of materials that can withstand the radiation process without degradation or loss of strength.

4. Barrier Performance and Testing

The integrity of the sterile barrier system is assessed through rigorous testing, which may include:

- **Burst testing:** To evaluate the strength and durability of seals.
- **Microbial barrier testing:** Ensures that the material used can effectively prevent microbial ingress.
- **Shelf-life testing:** To determine how long the sterile barrier will maintain its protective qualities under various storage conditions.

5. Sustainability Considerations

With growing concerns about environmental impact, sustainable packaging solutions are becoming increasingly important in the medical device industry. Manufacturers are looking into biodegradable or recyclable materials, as well as reducing the overall packaging size and weight to minimize waste.

Conclusion

Medical device packaging, particularly the design and material selection of sterile barrier systems, is vital to the safety and performance of healthcare products. The choice of materials, from medical-grade paper and Tyvek to plastic films and foil, must balance protection, sterilization compatibility, and cost-effectiveness. Additionally, packaging design must ensure ease of use, sealing integrity, and rigorous testing to meet regulatory standards.

As the medical device industry continues to evolve, manufacturers must keep pace with advancements in sterilization technologies, sustainability, and material science to provide packaging solutions that enhance patient safety, optimize product shelf-life, and meet stringent regulatory demands.



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

Asim Datta

Consultant Faculty, Indian Institute of Packaging & NIPPER Chandigarh



ABC

Acquaintance, Behaviour & Consumption

Introduction

The definition of plastics and their categorization is known to everyone. All the plastics so far produced have been subdivided broadly into three categories as shown in the plastic pyramid and they are defined as follows

- Commodity Plastics at the base: Commonly used for their cost-effectiveness.
- Engineering Plastics in the middle: Renowned for their enhanced mechanical and thermal properties.
- High-Performance Plastics at the apex: Reserved for specialized applications requiring their exceptional durability, thermal and mechanical shock resistance.

Now let us focus our attention on the apex of the plastics pyramid, I mean, on the high-performance plastics. Such glamorous designation awarded to this category of plastics is due to their excellent performance even in a very harsh, unfavorable and extreme environmental condition. Such praiseworthy capability of the members of this family (High performance) is due to their unique inherited properties like Strength and durability, very high temperature resistance, Electrical properties, processing flexibility etc.

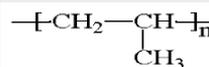
Now without having any doubt and displeasure in mind I just want to put an effort to bring all the members of the plastic world under one umbrella and name this umbrella as "Performance plastics" just by deleting the word "High" from the statement "High performance plastics". To make my intention clearer and intelligible to all let me concentrate the most vital, demanding and precious word "Performance"

Definition and characteristics of the word "Performance": It is the ability of a person, process, material to meet specific functional requirements for achieving a predetermined target. In this case it is the plastic material of any of the category. Performance is measurable, quantifiable and comparable. Except natural polymers, Plastics are man-made and also tailor made to suit a specific need. Therefore, each plastic performs well in its specific area of application for which it is made and selected.

With this understanding and philosophical interpretation, I think, it won't be unethical to bring all the plastics under one umbrella and call each member as a performer.

Now let us focus on the main topic. In this write-up I will capture few important plastics from each category and briefly highlight their properties and areas of applications.

Polypropylene (PP / cPP)



KEY PROPERTIES

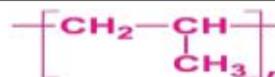
- High clarity, high heat resistant
- Good barrier for moisture
- High chemical resistant
- Good rigidity and unbreakable
- Density- 0.905 gm/cm³

Polypropylene is a favoured option for medical devices because of its unique properties as follows.

- Chemical resistance
- Steam sterilization feasibility
- Dimensional stability
- Machinability &
- Recyclability



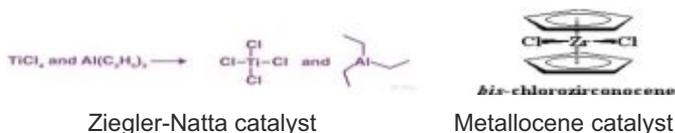
Example of Medical Device with Medical Grade Plastics



Polypropylene(PP) is currently one of the fastest growing polymers. Polypropylene is prepared from the polymerization of propylene gas in the presence of a catalyst system, usually Ziegler-Natta or metallocene catalyst.

Types of Polymerization: Gas Phase, Bulk, and Solution Processes are adopted to prepare PP polymer. Polymerization conditions (temperature, pressure and reactant concentrations) are controlled to prepare a particular grade of the polymer to be produced.

Polypropylene is produced by the chain-growth polymerization of propylene. Polymerization proceeds at 60 to 80 °C and 30–40 atm are applied to keep the propene in the liquid state.



MEDICAL-GRADE POLYPROPYLENE: A VERSATILE SOLUTION FOR HEALTHCARE NEEDS

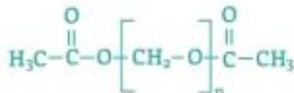
MAJOR PACKAGING APPLICATIONS

- PP bottles and closures are used in food and pharma packaging
- Polypropylene is a cost-effective, versatile, and durable plastic that's used in many medical devices like IV bottles & bags, contact lens packaging, centrifuge tubes
- PP is also used in the fields of Prosthetics & Orthodontics, Polypropylene is used to manufacture disposable syringes, connectors, Catheters etc.



Polypropylene Disposable Iv Cannula,

Polyoxymethylene- POM



The global medical polyoxymethylene market size was estimated at USD 118 million in 2023 and is projected to grow at a CAGR of 6 % from 2024 to 2030.

This remarkable anticipated growth potential of POM polymer in the healthcare industry is due to its unique features such as superior mechanical quality, biocompatibility, and resilience to chemicals and sterilization processes.

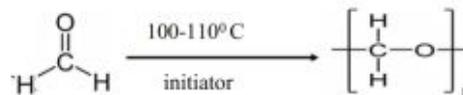
Polyoxymethylene, also known as acetal, polyacetal, and polyformaldehyde, is an engineering thermoplastic used in precision parts requiring high stiffness, low friction, and excellent dimensional stability. POM polymer containing repeating formaldehyde units.

POM is characterized by its high strength, hardness and maintains its rigidity even at -40 °C. POM is intrinsically opaque white, due to its high crystalline composition, but it is available in many colors. POM has a density of 1.410–1.420 g/cm³. POM continues to be widely used and appreciated for its durability, reliability, and versatility in numerous industrial applications.

Typical applications for injection-molded POM include high-performance engineering components such as small gear wheels. POM is used in a variety of medical applications, including artificial heart valves & hip joints, pumps, inhalers, syringes, surgical instruments, implants, drug delivery system, Dental devices, Catheters and tubing, insulin pen etc.

Polyacetal Homopolymer

Acetal Homopolymer is produced from anhydrous, monomeric formaldehyde.

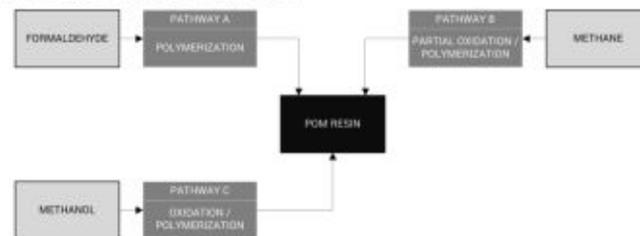


➤ Polymerization occurs readily below 110^o C

- The principal method is by reaction of the aqueous formaldehyde with an alcohol to create a hemiformal,
- dehydration of the hemiformal/water mixture (either by extraction or vacuum distillation) and release of the formaldehyde by heating the hemiformal.
- The formaldehyde is then polymerized by anionic catalysis and the resulting nascent polymer stabilized by reaction with acetic anhydride.

For the production of POM homopolymer & co polymer different routes can be followed and they are related to different sources of raw materials. Both POM homopolymers & copolymers are produced using cationic, anionic and coordination catalyst. Types of catalysts used for initiating the polymerization process entirely depends on the production pathways and the types of monomers used for producing POM.

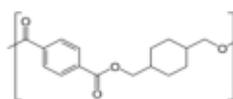
Polyoxymethylene Production Pathways Diagram



Medical devices and components made of POM



PCTG - Poly Cyclohexylene dimethylene Terephthalate glycol-modified



Polycyclohexylene dimethylene terephthalate (PCT) is a thermoplastic polyester formed from the polycondensation of Terephthalic acid

and Cyclohexanedimethanol. Its chemical structure is similar to that of polyethylene terephthalate (PET), with which it shares properties like dimensional stability and chemical resistance. PCTG is an advanced form the original PET polymer. To create the successor, ethylene glycol in the molecular chain with a larger monomer will blend with cyclohexane dimethanol, which will play a key role in stopping the crystallization.

Materials

It is produced utilizing a two-step melt-phase polycondensation process. It's a simple but effective process combining two monomers with the help of a small release of water. PCTG is a family of transparent polymeric material with a very wide range of applications, e.g. injection moulding, blow moulding as well as extrusion. PCTG provides excellent transparency, very high impact strength and chemical resistance. PCTG complies with the EU directive 10/2011 and FDA approved so it can be used for different types of applications as a food contact material.

Typical applications

- Transparent consumer articles
- Extrusion sheets
- Food packaging, e.g. drinking bottles & food containers
- Toys

Benefits and features

- Transparency
- High impact strength
 - Very good chemical resistance

Asim Datta

Consultant Faculty, Indian Institute of Packaging & NIPPER Chandigarh

A packaging professional having more than 30 years of industrial experience in converter (Flexible packaging), FMCG, Food & Pharmaceutical industries

Some past & present assignments as a Consultant :

- Inventia Health care Ltd. - Mumbai, India
- SK+F Dhaka, Bangladesh
- ACME Laboratories Ltd. - Dhaka, Bangladesh
- Beximco Pharmaceuticals Ltd. - Dhaka, Bangladesh
- Intertek - Plc (As a technical advisor for Food Safety Audit & certification)

Associated as a faculty with following reputed Institutes in India

- Indian Institute of Packaging (IIP) - An autonomous body under the ministry of commerce & Industries
- Delhi Institute of Pharmaceutical Sciences and Research (DIPSAR-Delhi)
- National Institute of pharmaceutical Education & Research (NIPER-Chandigarh)

FAST FACTS

New research and innovations play a major role in the field of medical devices where newer materials are required for better performance. To develop effective and safe devices, design engineers and manufacturers must have access to precise information on material properties. Several new materials with enhanced properties have been introduced.

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The medical device industry in India is one of the fastest-growing sectors in the country and plays a critical role in the healthcare ecosystem. As India's healthcare needs grow due to its large and diverse population, rising income levels, and an increasing focus on quality healthcare, the medical device industry is poised for significant expansion. We depend on imports for about 70-80% of our huge medical device demand.



To ensure the quality and performance of the medical devices, the testing and evaluation of medical devices and the biomaterials used are inevitable. The **Central Analytical Facility (CAF) at the Biomedical Technology Wing of Sree Chitra Tirunal Institute for Medical Sciences and Technology (SCTIMST)** offers test services to evaluate the physicochemical properties of biomaterials and medical devices as per international standards. All testing activities of CAF are in line with ISO 17025:2017. Two tests offered by CAF, viz. compositional analysis of materials using thermogravimetric analysis (TGA), and determination of transition temperatures and corresponding enthalpy changes of materials using differential scanning calorimeter (DSC) are NABL accredited. The testing services of CAF are open to all customers through the customer service cell (CSC).



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- Extractable & leachable analysis
- Drug estimations
- Molecular weight estimation of polymers
- Corrosion analysis
- Crush resistance of devices
- Compression characteristics of devices
- Compression characteristics of dental materials
- Adhesiveness of patches
- Muco-adhesion of wound dressings
- Peeling force of adhesives
- Injectability/syringeability of bio-inks
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- Raman chemical mapping, etc.



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Testing of Syringes and Needles

Dr. Renjith S

Biomedical Technology Wing, Sree Chitra Tirunal Institute for Medical Sciences and Technology, Poojappura, Trivandrum 695012.

Syringes are one of the most widely used medical devices. They have been used to infuse medicines for treatment or diagnosis and to draw blood for diagnostic or transfusion purposes. They are also required for vaccination purposes. Syringes function through piston technology to draw blood or to deliver medicines. Disposable, insulin type, medical, glass, and hypodermal are some of the different categories of syringes being deployed in the healthcare sector. As the healthcare sector advances day by day, the demand for syringes and needles also increasing steadily. The growing number of lifestyle diseases like diabetes further increases the requirement for syringes. The global market for syringes and needles is estimated to have a value of 29.85 billion USD in 2023 and is expected to reach 47.20 billion USD by 2029 at a compound annual growth rate of 7.93 %. As per recent statistics, India is Asia's fourth-largest medical device market. Production of good quality syringes and needles meeting the standard requirement is essential to meet the growing demand of our country.



Testing of the syringes is one of the critical steps in the development of needle-based injection systems. When a needle-based injection system is to be evaluated all the functional aspects of the system should be thoroughly checked. Polymeric/glass cylinder, plunger, and needle are the major parts of the injection system. They have to be evaluated to ensure functional competence and the absence of toxic residues. The main evaluation methods of needle-based injection systems are listed below.

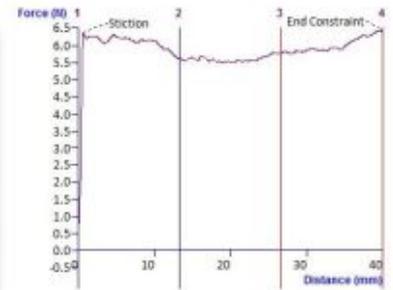
1. Syringe break loose force (ISO 8537): It is an important test for medical syringes. This test measures the force required to move the plunger from its resting position. This force is called break loose force. This test ensures the ease of handling the syringe when filled with test liquid. Normally the break loose force is measured in newtons. This test is mandatory to assess the easiness or comfort of using a syringe when filled with liquids like drugs. This test is used for the performance

validation of syringes by checking the easiness of piston movement, leakage of filled liquids, etc. This test also ensures the compliance of the syringe with ISO 8537 and USP382.



- 2. Glide force test (ISO 8537):** The glide force test is similar to the break loose force test. This test is mainly performed to study the resistance experienced by the piston when it moves through the entire length of the syringe barrel. This test also functions as a validation test for the fresh batch of syringes and to ensure the smooth usage of syringes in drawing or dispensing test liquids or body fluids. The test will ensure the compliance of the syringe as per ISO 8537.
- 3. Needle penetration force (ISO 11040):** This test measures the force required by a syringe needle to penetrate through polymeric films similar to human skin. The ease of penetration of the needle depends on the sharpness of the needle, strength of the needle, and its angle of contact with the polymer film or skin. In this test, the uncapped syringe is fixed in the upper grip and lowered to the film secured in the bottom grip, and the force required to penetrate the film was measured. The syringe that pierces the skin with minimal force and time will be more comfortable for the patient than the one that takes more time and force. This test can be used to check the compliance of syringes, compare the syringes of different batches, and choose the right syringe for specific purposes.
- 4. Strength of the needle bonding (ISO 11040):** This is another important test of syringes that measures the strength with which the needles are bound to the syringe. The syringe is fixed in the bottom grip of the testing equipment, and the needle is secured in the upper moving pneumatic grip and the force required to pull out the needle from the bonding is measured.

5. Break resistance of injection needles (ISO 9626): This test is an important quality evaluation test for injection needles. This test is generally performed using a two-point or three-point flexure setup. In the two-point setup, the needle housing is secured at one end, and the other end is bent at an angle using a wedge to measure the break resistance of the needle. In the three-point setup, the needle is placed on the supports, force is applied at the midpoint using the wedge probe, and the break resistance is measured. This test will give the strength of the needle and the quality of the needle housing.



6. Injectability and syringeability of gels or formulations: This is another important test involving syringes. It could be used for evaluating the quality of syringes as well as the suitability of hydrogels to be used as inks for 3D printing, 3D bioprinting, etc. Injectability measures the restriction to the inward flow of gels or formulations to the syringe whereas the syringeability measures the frictional forces operating when the gels or formulations are dispensed from a filled syringe.

Syringeability often considered as the ability of a certain product or formulation to be successfully administered using a specific syringe and needle. The administration of the product and its receipt under the skin depends on the tracking of the syringe piston within the syringe barrel. By testing the ease with which the injectable solution is administered, the manufacturers can optimize the usability and patient comfort. It could also be a quality control method to validate the manufacturing. Here the filled syringe is secured in the testing platform and force is applied to the piston to measure the force required to dispense the product or formulation from the syringe. The graph will give the frictional forces operating during the piston movement as Stiction, plateau force, and end constraint.

7. Residual ethylene oxide content (ISO-10993-7): All surgical equipment is supplied after sterilization. Ethylene oxide sterilization is a potent and feasible method for sterilizing polymeric medical devices like syringes. As the sterilant used, ethylene oxide is a known carcinogen, its residual amount should be evaluated before usage. As per ISO 10993-7 one should ensure that the residual content of ethylene oxide is below the threshold level for safe usage. We have been employing headspace gas chromatography as a tool for the estimation of residual ethylene oxide content in medical device extracts for the past six years.

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<https://www.arizton.com/market-reports/syringe-needle-market>.
2. ISO 8537
3. ISO 11040
4. ISO 9626
5. ISO 10993-7

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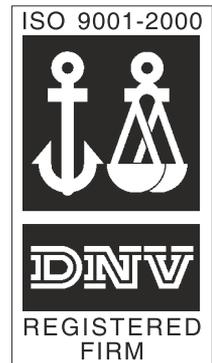
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MEDICAL PLASTICS

DATA SERVICE

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Soaring Growth in High Performance Medical Plastics Market

High Performance Medical Plastics Market

The global high-performance medical plastics industry continues to boom, driven by the growing demand for minimally invasive procedures and biocompatible materials.

The high performance medical plastics market has experienced a robust growth trajectory in recent years. Here are the key statistics:

- The market size was \$1.03 billion in 2024.
- It is projected to grow to \$1.11 billion in 2025, reflecting a compound annual growth rate (CAGR) of 8.1%.
- Market growth is influenced by increased demand for minimally invasive procedures, regulatory compliance, advancements in healthcare infrastructure, and the rising prevalence of chronic diseases.
- The market size is foreseen to reach \$1.62 billion in 2029, with a promising CAGR of 9.9%.
- This future growth can be credited to expansion in emerging markets, growing emphasis on sustainability, rising demand for biocompatible materials, a shift towards home healthcare, and advancements in material biocompatibility.

Growth Drivers

Growing healthcare expenditure in emerging economies is expected to spearhead the growth of the high-performance medical plastics market. Countries like India and China are escalating their healthcare spending in response to the necessity to improve healthcare infrastructure, augment public health, and tackle the recent COVID-19 pandemic. Elevated spending facilitates the population to opt for implants and prosthetic procedures made from high-performance medical plastics, thereby increasing the demand for medical plastics and propelling the market forward. A survey of global medical insurers conducted by Willis Towers Watson Public Limited Company, revealed that healthcare benefit costs rose from 8.2% in 2021 to 8.8% in 2022, and is predicted to surge again in 2023 to a high global average of 10%. This growing health expenditure in emerging economies has become a significant growth driver for the High-performance medical plastics market.

Some of the Global Key Players :

BASF SE, • DuPont de Nemours, Inc. • Solvay S.A.
 • Eastman Chemical Company • Celanese Corporation
 • 3M Company • Covestro AG • SABIC (Saudi Basic Industries Corporation) • RTP Company • Victrex plc
 • PolyOne Corporation • Evonik Industries AG
 • Mitsubishi Chemical Corporation • Momentive Performance Materials Inc.

Key Market Trends :

- Advancements in nanotechnology
- Focus on sustainability
- Customization and personalization
- Trends in precision medicine

Market Segments :

01 Type:

Fluoropolymers (FP), High Performance Polyamides (HPPA), Polyphenylene Sulfides (PPS), Polyetherimide (PEI), Other Types

02 Raw Material:

Polycarbonate, Polypropylene, Polysulfone, Polytetrafluoroethylene, Polyphenylene Sulfide, Other Raw Materials

03 Applications:

Medical Equipment And Tools, Medical Supplies, Drug Delivery, Prosthesis And Implants, Therapeutic System, Other Applications

Which Region Leads The High Performance Medical Plastics Market?

North America dominated the high-performance medical plastics market in 2024. However, the prospect of robust growth in Asia-Pacific is predicted to dominate the landscape of the high performance medical plastics market in the coming years. The report covers regions such as Asia-Pacific, Western Europe, Eastern Europe, North America, South America, Middle East, and Africa.

<https://www.openpr.com/news/3822468/soaring-growth-in-high-performance-medical-plastics-market-an>

Medical Polymer Materials Development for Healthcare Applications

Medical polymers face demanding challenges in biocompatibility, mechanical properties, and degradation control. Current materials must maintain structural integrity under physiological loads while degrading at precise rates—often between 3-24 months—and their breakdown products must remain below cytotoxic thresholds, typically under 10 mg/L in surrounding tissues.

The fundamental challenge lies in simultaneously controlling mechanical properties, degradation kinetics, and biological responses while meeting strict regulatory requirements for medical-grade materials.

Following are some of the solutions from recent research—including crosslinked biodegradable films for post-surgical applications, polymer-ceramic composites for skeletal tissue engineering, and elastomeric copolymers with tunable degradation profiles. These and other approaches focus on developing materials that can be manufactured consistently at scale while meeting specific clinical requirements.

1. Bio-Based Degradable Polyurethane with Specific Mechanical Properties and Tailored Composition

NATIONAL DONG HWA UNIV, NATIONAL DONG HWA UNIVERSITY, 2024

High-strength and high-elasticity bio-based degradable polyurethane for applications like biodegradable plastics. The polyurethane has properties like breaking strength over 75 MPa, elongation at break over 1200%, elastic modulus between 50 and 600 MPa, and toughness between 100 and 150 MJ/m³.

2. Injectable Hydrogel Composed of Modified Polyethylene Glycol Diacrylate with Amino Acids and Glycerol Incorporating Platelet-Rich Plasma

SICHUAN NORMAL UNIVERSITY, 2024

A high-strength, high-toughness injectable hydrogel for preventing adhesions in the uterus after surgery. The hydrogel is made by modifying the chemistry of polyethylene glycol diacrylate (PEGDA) hydrogels. The hydrogel forms quickly in the uterus, blocks adhesions, and releases growth factors from the PRP to promote regeneration of the endometrium.

3. Antibacterial Thermoplastic Polyurethane Elastomer with Hydrazide Modifier and Silver Ion Stabilization

WANHUA CHEMICAL GROUP CO LTD, 2024

Color-change-resistant antibacterial thermoplastic polyurethane elastomer (TPU) with improved discoloration resistance compared to conventional TPUs containing silver ion antibacterial agents. The TPU can be prepared by reacting the

components and has applications in fields like automotive, medical, electronics, etc.

4. Injectable Copolymer Composition of Poly(3-hydroxybutyrate) and Monomethoxypolyethylene Glycol with Specific Weight Ratio, Molecular Weight, and Particle Size

JEON HYEON JIN, 2024

Composition for tissue repair injection that contains a copolymer made from poly(3-hydroxybutyrate) and monomethoxypolyethylene glycol. The copolymer has a weight ratio of 1:1 to 1:5 of poly(3-hydroxybutyrate) to monomethoxypolyethylene glycol, a molecular weight of 2,000 to 20,000 g/mol, and particle size of 50 microns or less. The composition can be injected into the body to promote collagen production for tissue repair. The copolymer has biocompatibility and can be used as an alternative to synthetic polymers like PCL or PLA. The copolymer's properties allow it to be easily injected and stimulate collagen production after injection.

5. Self-Healing Bio-Based Polyurethane with Diamine-Induced Hydrogen Bonding Network

FOSHAN UNIVERSITY, UNIV FOSHAN, 2024

A self-healing bio-based polyurethane with rapid self-repair capability without external stimuli. The hydrogen bond content can be adjusted by composition to control polyurethane properties.

6. Biocompatible Polymer Composition with Sub-10,000 nm Polyhydroxyalkanoate Particles

CJ CHEILJEDANG CORP, POSTECH RES AND BUSINESS DEVELOPMENT FOUNDATION, POSTECH RESEARCH AND BUSINESS DEVELOPMENT FOUNDATION, 2024

Medical composition with biocompatible polymer particles for tissue adhesion, hemostasis, wound healing, and bacterial infection inhibition. The composition contains polyhydroxyalkanoate (PHA) particles with a specific size range of 10,000 nm or less. The PHA particles have high tissue adhesion, hemostatic efficacy, wound healing potential, and bacterial infection inhibition ability. They can be used in medical applications like wound closure, hemostasis, and infection prevention due to their biocompatibility and tissue bonding properties. The particles are prepared by dispersing PHA in solvent, passing through a membrane, and solidifying.

7. Biocompatible Medical Composition with Sub-10,000 nm Polyhydroxyalkanoate Particles

CJ CHEILJEDANG CORP, POSTECH RES AND BUSINESS DEVELOPMENT FOUNDATION, POSTECH RESEARCH AND BUSINESS DEVELOPMENT FOUNDATION, 2024

Biocompatible medical composition with improved hemostasis, wound healing, tissue adhesion, and bacterial infection prevention. The composition contains polyhydroxyalkanoate (PHA) particles with a specific size range of 10,000 nm or less. The small particle size allows the PHA to bond effectively to biological tissues without causing immune reactions. The composition can be used for hemostasis, wound healing, tissue adhesion, and inhibiting bacterial infection in applications like surgical adhesives, wound dressings, and hemostatic agents.

8. Hydrogel Composition with Histone-1 Peptide in Decellularized Porcine Matrix for Dental Implant Integration

BEIJING BIOSIS HEALING BIOLOGICAL SCIENCE & TECH CO LTD, BEIJING BIOSIS HEALING BIOLOGICAL SCIENCE & TECHNOLOGY CO LTD, 2023

Medical hydrogel composition for promoting tissue healing around dental implants. The hydrogel contains histone-1 (Hst1) peptide to enhance epithelial attachment and soft tissue sealing

around implants. The Hst1 is sustained-release from the hydrogel matrix made of decellularized porcine small intestinal submucosa. The hydrogel improves tissue adhesion and prevents peri-implant inflammation compared to bare implants.

9. Injectable Tissue Repair Composition with Hydrophilic and Hydrophobic Biocompatible Polymer Copolymer

ROSE LAB CO LTD, 2023

Composition for tissue repair that has excellent effects and physicochemical properties, including a hydrophilic biocompatible polymer and a hydrophobic biocompatible polymer copolymer. The composition has temperature sensitivity, injectable properties in vivo, and collagen regeneration effect, providing excellent tissue healing. The composition can be used as a restorative injection infusion. It has properties like small particle size, decreasing viscosity with temperature, and biodegradability within weeks after injection. The composition contains a copolymer of methoxypolyethylene glycol and polycaprolactone at specific ratios and molecular weights.

10. Method for Synthesizing Biodegradable Polyurethane Foam via Aldehyde-Containing Polyols and Amine Catalysts

SHANGHAI JIAO TONG UNIVERSITY, 2023

Preparation method for biodegradable slow rebound polyurethane foam with improved biocompatibility. The foam is made by reacting polyisocyanate with a specific blend of polyols, catalysts, and foaming agents. The polyols contain aldehyde groups that react with lysine to form a biodegradable polyurethane main chain. The foaming catalysts are amines that enable foaming while maintaining biocompatibility. The foam has slow rebound properties like memory foam but can degrade naturally under environmental conditions.

Source

11. Medical Device Surface with Urethane Resin Coating Comprising Polycarbonate Polyol and Aliphatic Isocyanate Units with Urea Bonds

DAI ICHI KOGYO SEIYAKU CO LTD, DAI-ICHI KOGYO SEIYAKU CO LTD, KYUSHU UNIV NATIONAL UNIV CORP, 2023

Modifying biocompatibility to a surface of a medical device. The modification includes a urethane resin having a structural unit derived from a polycarbonate polyol and a structural unit derived from an aliphatic isocyanate, and having at least 1 urea bond or more.

More List of Patents can be available @ following weblink : <https://xray.greyb.com/packaging/medical-polymer-materials>

FAST FACTS

AI Becomes Standard, Not Just a Novelty

By the end of 2025, all major Medtech companies will have AI-enabled products. What was once a cutting-edge novelty is becoming table stakes, driven by intensifying competition and the pressure to innovate, AI will no longer be reserved for start-ups, experimental products, or niche applications; it will be embedded into devices across diagnostics, treatment planning, and patient monitoring.

But the rush to integrate AI comes with strings attached. Manufacturers aren't just racing to develop these tools—they're under immense pressure to ensure AI systems are safe, effective, secure, and compliant with increasingly complex regulations. Companies that fail to address these foundational challenges first will never be able to harness the power of AI in medicine.



Chile Medical Devices Market

Mr. Amit Dave

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



Country Profile

Chile, a country in western South America, is the southernmost country in the world. Chile is the country closest to Antarctica. Chile is a narrow strip of land (with an average width of 110 km) between the Andes Mountains and the Pacific Ocean, with a wide variety of climates, like a desert (northern part) and cold subantarctic regions (in the south).

Like many other Latin American countries, Chile was colonized by Spain, with a Spanish influence. Typically, the old society had a small group of elite with most of the land and the wealth. One important point here is that in the later years, Chile progressed into an economy with a manufacturing base instead of depending heavily on agriculture and mining (unlike many Latin American countries). Chile is one of the more urbanized Latin American societies, with a large and growing middle class. Most of the urban cities are in the central part, including the capital, Santiago de Chile. Also, unlike many Latin American neighbouring countries, Chile has a long history of democratic government. Chile has a population of very close to 2 crore people and has been considered by the World Bank as a "high-income economy" for the last more than ten years. That makes the country interesting. With a high index of human development, low corruption and a stable economy, Chile is one of the high prosperity LATAM countries. Chile has been granted a credit rating of A from S&P.

Chile has signed free trade agreements with a whole network of countries, including an FTA with the United States that was signed in 2003 and implemented in January 2004.

Regulatory Framework and Product Classification

In Chile, "ANDID" (National Agency for Medical Devices, Innovation, and Development) is the agency that regulates, monitors and controls medical device registration, including in vitro diagnostic medical devices.

The classification for registration is in line with many European countries.

Class I: Low-risk devices (Examples- Bandage, Surgical camera; Electric

operating table)

Class II: Low - Moderate risk devices (Examples -Pregnancy self-testing, Electric Hospital Bed, Surgical Lamp, Surgical Mask)

Class III: High - Moderate risk devices (Examples - Blood glucose self-testing, ECG, X-ray Unit, Syringe)

Class IV: High-risk devices (Example -Stent, Intraocular lens, Defibrillator, Pacemaker)

The approval process is quite simple. After appointing a local authorized representative in Chile, access the GICONA system and click on "request registration", fill in the details, attach the documents asked for and also, arrange for the payment. "Authorized Representative" needs to be given a written mandate in the form of a power of attorney or signed contract from a legal manufacturer. A notification will be sent via email indicating that the application is resolved if everything is in order. Registration follows this message but may take some more time. Once granted, the license is perpetual unless there is some change in the application or laws.

A bit old but still relevant presentation in a PDF format is available on the website mentioned below.

<https://ahwp.info/sites/default/files/Annex%202012%20Chile.pdf> and readers will find this interesting. Also, by searching ANDID, a very detailed webpage with an English option opens which is also recommended for more details.

Chile Highlights

- A stable economy with a strong political history
- High per capita healthcare spending
- More than two-thirds of the population covered by the Government Insurance
- Easy import rules

Chile Medical Devices Market

Market size estimation is about 2 bn USD for devices. Cardiac devices make up the largest proportion. Newer diagnostic equipment and telemedicine solutions are also growing significantly. Per capita expenditure in Chile is the highest in Latin America though the market size is small due to the smaller population. The growth rate is around 7% which is better than many

other countries or even the world growth rate. The government-run healthcare insurance system (FONASA) covers 69% of the population. 23% of people subscribe to private sector insurance and 3% are covered under defence or military insurance. This means the majority of the population need not have to worry about healthcare expenditure. Healthcare spending is more than 5% of the country's GDP. Many Chilean physicians have U.S. post-graduate degrees and are in regular touch with important U.S. healthcare institutions, giving the US an advantage, which needs to be noted.

Life expectancy is 82 years for women and 75.7 years for men, and these older populations will naturally need higher healthcare services. Chile has a favourable import climate and that makes the country an attractive export destination. Local manufacturing of devices is very low and import dependence is very high for the sector. The United States (close to 40%), Germany (23%) and China (10%) are the major sources of imports of devices. The majority of supply is to the Government sector, and so, price sensitivity is high for the exporters.

Opportunities and Challenges

Higher life expectancy and so, elderly population in the country provide a good market opportunity. Heavy import dependence and simpler import processes, with the least corrupt system, also give an easy entry. Registration processes are smoother too, as we saw.

A stable economy ("A" rank by S&P) and a predictable political environment (long-standing democratic system) are also favourable in general compared to many other LATAM countries. The challenges are language, price sensitivity of the market, the competition from the US and distance from India.



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| IEC 62304:2006 | : Medical device software — Software life cycle processes |
| EU MDR | : European Union Medical Device Regulation |
| QMSR | : Quality Management System Regulation |
| (As release by USFDA) | |
| MDSAP | : Medical Device Single Audit Program |
| Schedule – M | : As per drugs and cosmetics act 2024 (Good Manufacturing Practices for pharmaceuticals) |
| SEDEX | : Supplier Ethical Data Exchange |



Contact: **Mr. Bhupesh Sood**

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UIDAI CEO Amit Agrawal Appointed As New Pharmaceuticals Secretary In Major Bureaucratic Reshuffle

In a significant bureaucratic reshuffle, Amit Agrawal, the Chief Executive Officer (CEO) of the Unique Identification Authority of India (UIDAI), has been appointed as the new Secretary of the Department of Pharmaceuticals. He takes over the position from Arunish Chawla, a 1992 batch Indian Administrative Service (IAS) officer from the Bihar cadre. This move is part of a series of high-level administrative changes carried out by the Centre on Wednesday.

Amit Agrawal, in his new capacity as Pharmaceuticals Secretary, will play a crucial role in shaping the country's pharmaceutical

<https://voiceofhealthcare.org/updates/>

Union Budget 2025, Disappointing Budget for Medical Devices Industry

- Overall right push to macro-economic and policy direction in the Budget 2025
- No investment promotion measure for the 70% imports dependent Medical Devices Sector in Budget speech is disappointing

Rajiv Nath, Forum Coordinator, Association of Indian Medical Device Industry (AiMeD)

Mr. Rajiv Nath appreciated the overall macro-economic and policy direction measures announced in the Union Budget 2025. There are many key features in the Budget announcements that will strengthen the economy and propel the GDP growth.

Some of the important steps that are in the right direction are setting up of Manufacturing Mission and support measures for the MSMEs & Startups. The measures to boost R&D and innovation in the domestic industry are also a welcome move. Government's intention to have a trust-based light regulatory mechanism and decriminalisation of several laws further is also a correct and much-needed approach.

Mr Nath, on behalf of the medical devices industry, expressed disappointment over the fact that there is no mention of any investment promotion measures for the imports dependent sector in the main speech and had hoped that there will be some measures to boost the sector in the fine print.

He said, "The Industry is disappointed that expectations of the Medical Devices sector and many of which had been supported by Dept of Pharmaceutical too as an investment enabler under the National Medical Device 2023 policy finds no mention in the speech. We were hoping to see the finance minister speak about Medical Devices as make in India enabler and address the 70% import dependence due to inadequate tariff protection with duties at zero to 7.5% in most cases and an ever-rising imports bill that is expected to cross 75000 Cr Rs this year.

The Indian Medical Devices Industry's expectations were:

1. Increase in Custom Duty to a nominal 10% to 15% (and as a Predictable Tariff Policy).
2. Correction of Inverted Duty by levying Health Cess of 5% custom duty on balance Medical Devices (In 2020 this was applied to only 5 of the 4 Digit HS Codes and balance 22 HS Codes are pending).
3. Trade Margin Capping by monitoring MRP of Imports (if found over 10 to 20 times of CIF price).
4. Income Tax benefits for CAPEX and R&D investments in Medical Devices.
5. The government can consider standardising the GST rate of 12% across all medical devices as it would simplify the tax structure, ensuring consistency and ease of doing business.

AiMeD Seeks Monitoring Of MRP Of Imported Medical Devices Against Import Landed Cost

New Delhi, 10 Jan 2025: Monitoring of maximum retail price (MRP) of imported medical devices into India has been demanded by medical device manufacturers to provide truly affordable rates to the Indian consumers. In its Pre-budget memorandum to the Finance Ministry, Association of Indian Medical Device Industry (AiMeD) has highlighted that reduction of import duty on devices is an effort of the government that going in vain since the consumers/patients are paying 10-30 times of the import landed price of the devices. There is no gain to the consumers from NIL duty as affordability is linked to MRP labelled on product as that is what has been charged to them. Thus, the device manufactures have asked for withdrawal of Concessional Duty Notification that reduce Duty to 0-7.5% and seek 5% - 15% duty on imports of medical devices.

"As assured by you in your earlier Budget speech there is a need

to remove NIL Duty Exemption notifications (and we recommend even Concessional Duty Exemption notification that reduces duty to 7.5%) which have made it non-viable to manufacture and motivated many manufacturers to become importing traders or pseudo manufacturers" said **Mr Rajiv Nath, Forum Coordinator, AiMeD** in a letter to the Finance Minister Ms Nirmala Sitharaman recently.

The current duty structure is also incongruent to the "Make in India" approach of the government. Nominal tariff protection is needed for medical devices that are being manufactured in India as a predictable tariff policy so if capacity is added by a domestic manufacturer, there's assured nominal protection. To promote domestic medical device industry that will also enable exports and subsequently reduce India's heavy reliance on import, the current basic import tariff of 0-7.5% is not enough. The imports



are consistently above Rs 61,000 crore for the past three consecutive years and even jumped 13% in the last fiscal (2023-2024) to reach Rs 69,000 crore, AiMeD said.

AiMeD has emphasized that Indian manufactures have the ability to cater to 1.4 billion people, and can have enough domestic production but sadly there is 70% import dependence in the field of medical devices. This dependence can be completely avoided if there is some reasonable protection for the domestic industry as provided for the Mobile Phone Industry. The current Basic Import Tariff of 0-7.5% is required to be hiked to 5% - 15% for medical devices and on their components to be at least 5%. The tariff for components needs to be 7.5% for the next two years as a PMP Make in India enabler. Concessional Duty on raw material (including packaging materials of sterile disposables) may be retained at 2.5% for now, for next three years.

The current scenario is against Indian manufacturers in every way. After GST, imported devices became cheaper by 11% and the Indian manufacturers have been challenged to compete with foreign imports in government tenders.

Indian manufacturers are forced to become importers as it is cheaper and more convenient to import. Importers avail GST input credit which they were not availing in the pre-GST period. There is 6% CVD and 4% SAD now but no such credit was earlier

available to a trader. Department of Pharmaceuticals has stated that indigenous manufacturers have a disability of 12-15% on account of various factors like lack of adequate infrastructure, high cost of finance, inadequate availability of power, limited design capabilities, low focus on R&D and skill development, etc and have supported AiMeD request to Finance Ministry for Recall of NIL / Concessional Duty Notification for the Medical Devices that are being made in India and where adequate capacity exists.

There is no mechanism to address these disabilities in the manufacturing of medical devices in India as compared to other major economies. The Department of Biotechnology, NITI Aayog and the office of Principal Scientific Advisor to the Prime Minister have been working to create an ecosystem for nurturing startups and incubators. But once they create a commercial product and have to graduate to MSME entrepreneurs, the real challenge comes for these startups to survive and cope with the 12-15% disabilities as well as being stonewalled by buyers who do not seek lower costs but seek higher MRP based Trade Margin chargeable to their Patients/Clients.

AiMeD has requested the government to take care of these factors and protect Ethical Manufacturers and Importers to help India achieve medical security and provide employment to a larger section of the population.

Medical Device Manufacturers Hail CDSCO Move On Stopping Import Of Used Medical Devices

- **India Inc backs CDSCO on stopping import of pre-owned Medical Devices**
- **India's compromised healthcare security with 70% imports dependence begins to get addressed**

New Delhi, 17 Jan 2025: Medical device manufacturers have hailed the clarification by the Central Drugs Standard Control Organization (CDSCO) that current law does not provide for granting of licenses for import of refurbished devices. Pointing out that the healthcare security of the country is already compromised with about 70% of the current medical device requirements being met through imports, the Association of Indian Medical Device Industry (AiMeD) said that ongoing import of used medical devices without any regulatory controls had further jeopardized it as nearly 60% of the Rs 40,000 Cr of imports of medical electronic equipment were estimated to be of pre-owned equipment being dumped into India. That is one of the main reasons why domestic manufacturers have been seeking regulations of this sector to enable a level playing field. All medical devices had come under regulations in Feb 2020 and a transition time had been provided thereafter for importers and manufacturers to get licensed under Medical Devices Rules of D&C Act.

“A stop to import of refurbished medical equipment is a true policy intervention that will guard the domestic industry against dumping of equipment with uncertain quality and will also help the patients in receiving appropriate medical care thereby bringing the best value of cost for them and for the payers, including insurance agencies. This is a welcome and much awaited long due intervention”, said Dr Jitendra Sharma, Managing Director, AMTZ, Visakhapatnam.

At a time when the domestic industry is already grappling with issues like negligible import tariff of 0 to 7.5% on medical devices

in India, allowing import of refurbished devices had further acted as a deterrent to the entrepreneurial spirits of the domestic manufacturing industry making India severely imports dependent, pointed out Mr. Rajiv Nath, Forum Co-Ordinator, AiMeD.

“We welcome MNCs to invest in India and make high technology equipment and make these affordable to the Indian patients as is being done in Mobile phones and the automobile sector. A healthy competition is welcome,” said Mr. Nath.

“There is a Policy review of the need for imports underway and we have sought related regulations for refurbished or remanufactured Indigenous medical equipment that has lived beyond the extended warranty terms, with adequate and additional patient safety safeguards to bring in the necessary discipline “ and Mr. Nath hoped that the guidelines issued by the Ministry will be in consonance with the National Medical Devices Policy 2023 to make India a leading hub of manufacturing of medical devices globally.

Confusion arose after a notification by the Ministry of Environment, Forest, and Climate Change (MoEFCC) allowed the import of certain second-hand medical devices and equipment in India

Mr. Nath has pointed out that while (MoEFCC) may be right in addressing the concerns regarding e-waste management, other regulators like CDSCO must diligently carry out their duties in addressing the high-risk patient safety concerns. He also highlighted the fact that, many-at-times, the import of new medical devices is resulting in end-users paying 10-30 times of



the import landing price of the devices because of absence of trade margin rationalization measures. This is where the Ministry of Health, Dept. of Pharma, together with the Ministry of Finance, must play its part in regulating the MRP of the devices in a rational manner so that ethical manufacturers and marketers as well as consumers gain.

India's import bill for medical devices is going up every year, with a 13% jump in 2023-24 alone. India currently imports a staggering Rs 69,000 crore worth of devices.

"The circular issued by CDSCO regarding refurbished medical devices imported into India has shown Modi 3.0 is awake and ready to listen to a common consumer. Now our next logical step should be to recall all such illegally imported medical devices from every corner of the country and destroy them in the interest of 'Patient Safety', said Prof Bejon Kumar Misra, Founder of Patient Safety and Access Initiative of India Foundation.

As per industry insiders a lot of domestic businessmen have become pseudo manufacturers and importers because of the meager import duties and genuine manufacturers are being

pushed out of the business due to prevalent nonconductive duty structures presently.

AiMED has demanded the import duties to be in the range of 10-15% for medical devices to provide a level playing field to the domestic manufacturers.

"We applaud the CDSCO in removing the confusing signals we had been getting as on one side we had been supported by Gol excellent PLI scheme to manufacture high end Cath labs & imaging equipment in India but were despondent when we had to compete against low-priced second-hand imports. The Medical Device rules do need a provision for extra safeguards needed for refurbishing or re-manufacturing of equipment beyond extended warranty period and the existing informal sectors that had been repairing and refurbishing imported pre-owned equipment can now use their skills to do so for the indigenously produced equipment. With a growing market expected from a stable and competitive domestic manufacturing, this sector will also have ample opportunities to grow as a support to the healthcare industry, explained Mr Gaurav Aggarwal, Managing Director, Innvolution Healthcare.

MoHFW To Establish An Expert Committee To Monitor Adverse Effects Caused By Medical Devices.

According to recent reports, the Ministry of Health and Family Welfare (MoHFW) in India is establishing an expert committee specifically designed to monitor adverse effects caused by medical devices, aiming to improve patient safety by tracking, recording, and analyzing the root causes of such events; this committee will likely include specialists in fields like cardiology, gastroenterology, gynecology, neurology, and radiology to evaluate reported incidents and recommend corrective actions.

Key points about this committee:

• Function:

To monitor and analyze adverse events related to medical devices, including in-vitro diagnostics, to identify potential risks and suggest measures to mitigate them.

• Expertise required:

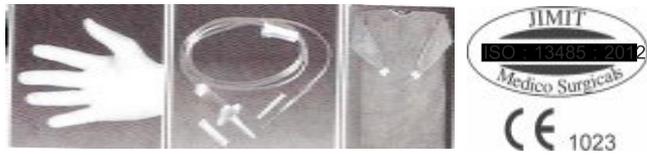
Specialists from various medical fields like cardiology, gastroenterology, gynecology, neurology, and radiology.

FAST FACTS

India's MedTech industry is transforming from import reliance to a global hub, driven by innovation, digital integration, and government initiatives.

• Underlying program:

This committee will operate under the "Materiovigilance Programme of India" (MvPI), which is managed by the Indian Pharmacopoeia Commission (IPC) under the MoHFW.



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India's Push For Self-reliance: Medical Devices Sector Shows Promising Growth

The data shows India's medical devices sector is gradually achieving self-reliance in consumables, implants, and electronic equipment, though import dependency remains high in some areas

To support the medical device industry, the government has launched a new scheme titled "Strengthening of Medical Device Industry," which aims to bolster manufacturing capabilities and skill development with a financial outlay of ₹500 crore.

Ministry of Chemicals and Fertilizers data shows significant export growth in the implants and consumables segments, reflecting a positive shift in India's manufacturing capabilities and global competitiveness. However, to achieve full self-reliance, there is a need to focus on local production of high-tech components and R&D investments in medical technology. The data shows a consistent increase in (in terms of values) exports across all segments over the three fiscal years. However, imports have shown mixed trends, with some segments witnessing a decline in import dependency while others continue to rely heavily on foreign markets.

The export growth indicates a positive shift driven by increased domestic production and government initiatives like the 'Make in India' campaign. However, the fluctuating imports suggest that certain high-tech equipment and consumables are still largely sourced from foreign suppliers.



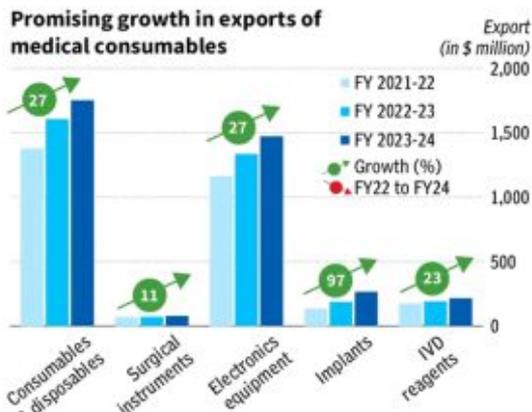
https://bl-i.thgim.com/public/incoming/866jmw/article69108403.ece/alternates/LANDSCAPE_1200/medical%20devices.jpg

of consumables and disposables. This trend is likely driven by increased domestic production capabilities, particularly in the post-pandemic period when demand for medical consumables surged globally.

Surgical Instruments and Electronics Equipment

Surgical instruments reported slow growth in both imports and exports. Overall (FY 2021-22 to FY 2023-24): Imports grew by 21.30 per cent, and exports grew by 11.26 per cent. The slow growth in exports suggests that India still faces challenges in scaling up the production of high-precision surgical equipment. Imports remain steady, indicating a dependency on foreign suppliers for high-tech surgical tools.

In electronics equipment overall imports slightly decreased by 0.61 per cent, while exports grew by 26.57 per cent. The electronics equipment segment consistently increases exports, reflecting India's growing capabilities in manufacturing medical electronics. However, the high import dependency remains a concern.



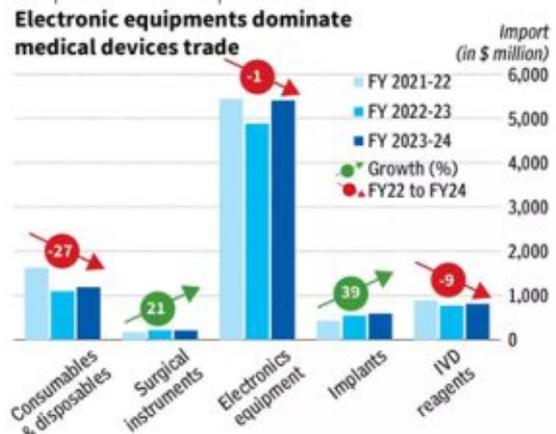
Source: Rajya Sabha December 2024

https://bli.thgim.com/public/books/reviews/ecx61x/article69110238.ece/alternates/FREE_730/BL18Jan_DF_Medical_Eqp_tra de2.jpg

• **Read: Walking the fine line between making and importing medical devices**

For consumables and disposables, overall (FY 2021-22 to FY 2023-24) imports decreased by 27.03 per cent (in terms of value), while exports grew by 27.14 per cent. The strong export growth and declining import dependency indicate that India is becoming a significant player in the manufacturing and export

Trends in medical devices import and export



https://bli.thgim.com/public/books/reviews/e4ynku/article69110222.ece/alternates/FREE_730/BL18Jan_DF_Medical_Eqp_tra de.jpg

• **Read more: Innovating in India — road ahead for medtech in 2025**

Interestingly implants have shown good export growth. Overall imports increased by 38.53 per cent, while exports almost doubled, growing by 97.03 per cent. The implants segment shows remarkable export growth, suggesting that India is emerging as a global supplier of medical implants. However, the steady increase in imports indicates domestic demand for implants still outpacing local production. This could allow manufacturers to further invest in high-quality,

affordable implants to reduce import dependency.

IVD Regents imports decreased by 8.95 per cent, while exports grew by 22.73 per cent. The gradual growth in exports of IVD reagents suggests that India is becoming more competitive in this segment. However, the stable import dependency indicates that key raw materials or advanced reagents are still sourced from foreign markets.

- **Read: Centre notifies National Medical Devices Policy 2023 New Scheme**

The Ministry recently told the Rajya Sabha that to provide support in critical areas of the medical device industry, covering manufacturing of key components and accessories, skill development, support for clinical studies, development of common infrastructure, and industry promotion, a new scheme, "Strengthening of Medical Device Industry" with five sub-schemes, was launched in November 2024 with a financial outlay of ₹500 crores.

<https://www.thehindubusinessline.com/data-stories/data-focus/indias-push-for-self-reliance-medical-devices-sector-shows-promising-growth/article69108290.ece>



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3. 3D printing & prototype product development
4. Plastic Processing, Assembly, Packaging/Design, Testing and Component Testing (Polymeric Material & Components)
5. Tool room, mold development lab and polymers development
6. Electromagnetic test (EMI/EMC), electrical safety, performance testing & calibration lab
7. Ethylene oxide sterilization (ETO)
8. PC Board manufacturing including component insertion and soldering for Electronics / instrumentation
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Following are the products allotted in the Medical Devices Park:

Radiotherapy workstation, Dental Implants, Orthopaedic Implants, Hip Implants, Trauma Implants, Pacemakers, ENT workstation, Cardiology Devices, Stents, Blood collection bags, Syringe, Catheter, Cannula, IV Infusion Set, ICU Monitor, ECG Machine.

Please contact

Principal Secretary
pscommind@mp.gov.in

Managing Director- MPIDC
md@mpidc.co.in

Principal Consultant
Dr. B.K. Doshi - Doshi Consultants

Principal Consultant of Madhya Pradesh Medical Devices Park
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For more information please visit <https://invest.mp.gov.in/>





Inauguration of New Pradhan Mantri Swasthya Suraksha Yojana (PMSSY) Building at SCTIMST

Inauguration of New Pradhan Mantri Swasthya Suraksha Yojana (PMSSY) Building at Sree Chitra Tirunal Institute for Medical Sciences and Technology.

The Sree Chitra Tirunal Institute for Medical Sciences and Technology (SCTIMST) proudly announces the inauguration of its new Pradhan Mantri Swasthya Suraksha Yojana (PMSSY) building. The state-of-the-art facility will be inaugurated by Dr. JP Nadda, the Hon'ble Cabinet Minister, Ministry of Health and Family Welfare and Ministry of Chemicals and Fertilizers and by Dr. Jitendra Singh, the Hon'ble Minister of State (Independent Charge), Ministry of Science and Technology and Ministry of Earth Sciences, Government of India, on 20.02.2025 at 10.00 am.

The ceremony will be conducted in the presence of Shri. Suresh Gopi, Hon'ble Minister of State, Ministry of Petroleum and Natural Gas and Ministry of State for Tourism; Smt. Veena George, Hon'ble Minister, Health, Woman and Child Development, Government of Kerala, Dr. Shashi Tharoor, Hon'ble Member of Parliament, Thiruvananthapuram, Kerala, Chairperson, Parliamentary Standing Committee, Dr. V.K Saraswat, Hon'ble Member NITI Aayog and Former President of the Institute, Shri. V. Muraleedharan, Former Minister, Minister for State for External Affairs & Parliamentary Affairs, Prof. Abhay Karandikar, Hon'ble Secretary, Department of Science and Technology, Government of India, Shri. Kadakampally Surendran, Hon'ble MLA, Thiruvananthapuram, and many other esteemed dignitaries.

SCTIMST is an Institute of National Importance under the Department of Science and Technology, Government of India. It is a leading tertiary care referral centre that provides world-class

medical care for patients with cardiac and neurological diseases. The institute's advanced facilities, experienced medical professionals, and multidisciplinary approach ensure that patients receive the highest quality of care. SCTIMST is also renowned for its cutting-edge medical research, innovative technologies, and commitment to providing high-quality, affordable healthcare. Dr. Kris Gopalakrishnan, former Chairman, Infosys, is the President of the Institute.

The new hospital building is a key project funded under the Prime Minister's Swasthya Suraksha Yojana (PMSSY). This initiative is being supported collaboratively by the Department of Science & Technology, Government of India and the Ministry of Health & Family Welfare, Govt. of

India.

The new PMSSY building represents a significant expansion of SCTIMST's infrastructure and its commitment to providing advanced healthcare services to the public. Spanning 9 floors and covering a built-up area of 270,000 square feet, this centrally air-conditioned building is equipped with 170 beds, including 130 beds dedicated to Intensive Care Unit (ICU) services. Additionally, 40 rooms will be allocated as pay wards to meet the increasing demand from patients. Once fully operational, this super-specialty facility will house several centres of clinical excellence, supporting 9 ultra-modern operating theatres, MRI & CT scan capabilities, 3 Cath labs, a sleep study unit, an echocardiography suite, a non-invasive cardiology evaluation suite, and other advanced neuro-cardiac care services. This hospital building will also feature modern wellness centres for patients, counselling rooms, and cafeteria.



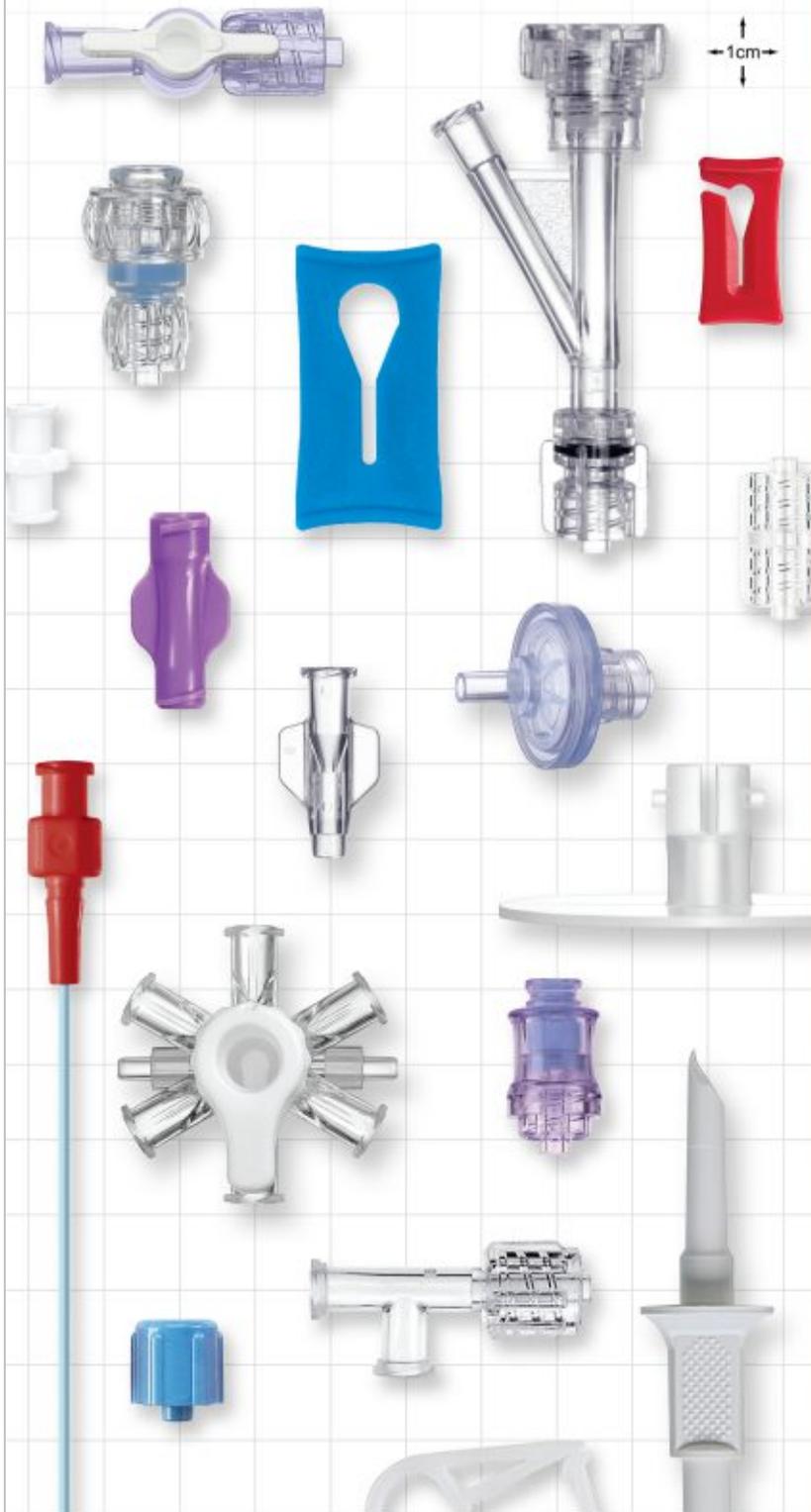
The newly established cath lab in the old building



The newly established neuroradiology cath lab in the old building

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Qosina Announces Collaboration with B. Braun, Expanding Access to Small-Quantity Purchases

Ronkonkoma, NY - February 4, 2025 - Qosina, a global leader in the distribution of medical components, is pleased to announce an exciting new collaboration with B. Braun Medical Inc. (B. Braun), a leader in smart infusion therapy and pain management. B. Braun customers can now purchase small quantities of their products directly through Qosina, providing increased flexibility for prototyping and small-scale production needs.

"Our collaboration with B. Braun represents a significant milestone for Qosina as we continue to expand our offerings and provide greater value to our customers," said Lee Pochter, CEO of Qosina. "By enabling small-quantity purchases of B. Braun's high-quality products, we're making it easier for engineers, designers and manufacturers to access the components they need to innovate and bring their projects to life. We're proud to collaborate with such a trusted leader in the healthcare industry and look forward to supporting our customers with this expanded portfolio."

As part of this collaboration, Qosina will showcase a dedicated section of B. Braun products at their booth (#3113) during the MD&M West trade show in Anaheim, CA, from February 4-6, highlighting the breadth of B. Braun components available through Qosina and giving engineers and designers hands-on access.

About Qosina

For 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.

About B. Braun

B. Braun Medical Inc. (B. Braun) is a leader in smart infusion therapy and safe and effective pharmacy products, patient and provider safety, and sustainable health solutions. Their purpose is to help providers constantly improve patient satisfaction and outcomes. With products and services created to help healthcare professionals focus on what matters most--their patients--B. Braun is uniquely positioned to help health systems succeed now and in the future. B. Braun is headquartered in Bethlehem, PA and is part of the B. Braun Group of Companies in the U.S., which includes B. Braun Interventional Systems, Aesculap(R) and CAPS®. The company employs 8,500 people at over 30 locations across North America.

Rachelle Morrow
Senior Manager, Communications
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Product Categories

01. Medical Disposables, Implants, Hygiene Products, Allied Medical Device..

02. Components, Raw Materials, Packaging Materials & Consumables..

03. Manufacturing Machineries, Equipments & Accessories..

04. Services: Testing, Quality Certifications, Consulting, Contract Manufacturing, Training, Others..

No	Company Name	Product Category	Website
1	Accuprec Research Labs Pvt. Ltd.	4	https://accuprec.com/
2	Advin Healthcare	1	
3	Alpha Medicare & Devices Pvt. Ltd.	1	www.alphamedicare.com
4	Alpha Therapeutics Pvt. Ltd.	1	www.atplworld.com
5	AMBICA MEDI FAB PVT LTD.	3	www.ambicasterilizer.in
6	Angiplast Pvt. Ltd.	1	www.angioplast.com
7	Beacon Plastics	2	www.beaconplastics.com
8	BRY-AIR (ASIA) PVT.LTD	3	www.bryair.com
9	Carclo Technical Plastics Pvt. Ltd.	1 & 2 & 4	http://www.carclo-plc.com
10	Celanese chemical	2	www.celanese.com
11	Cephas Medical Pvt. Ltd.	1 & 2 & 4	www.cephasmedical.net
12	Eewa Engineering Co. Pvt. Ltd	3	www.eewaengineering.com
13	ET Elastomer Technik India Pvt. Ltd.	2	www.elastormer-technik.com
14	GLR Laboratories Pvt Ltd	4	www.grlabs.com
15	HighRichJa Precision Extrusion Machinery Co., Ltd.	3	www.chinahrj.com.cn
16	Husky Injection Molding Systems (India) Pvt. Ltd.	3	www.husky.com
17	I-Kare Polyalloys Pvt. Ltd.	2	www.i-kare.in
18	Jain Rubbers Pvt. Ltd.	2	www.jainrubbers.com
19	Jimit Medico Surgicals Pvt Ltd	1	http://www.jimitsurgicals.com/
20	KLJ Polymers and Chemicals Ltd.	2	http://www.kljindia.com/
21	KSM Nanotech India	2	www.ksmnanotech.com
22	Lakshmi Electrical Control Systems Limited	2 & 4	www.lecsindia.com
23	LEELAVATHY MEDICAL DEVICES COMPANY	1	www.lmed.co.in
24	Life – O – Line Technologist	1	www.lifeoline.com
25	Lubrizol Life Science	2	www.Lubrizol.com/Health
26	MCPPP India Private Limited	2	www.mcppp-india.com
27	Medicall	4	www.medicall.in
28	Messe Duesseldorf India Pvt.Ltd. (Medical Fair India)	4	http://www.medicalfair-india.com/
29	Milliken Chemical and Textile (India) Co. Pvt. Ltd.	2	http://www.milliken.com/
30	Morrisons Lifecare Pvt. Ltd.	1	www.morrisonslifecare.com
31	Pharmadocx (rapid facto)	4	www.rapidfacto.com
32	Pharmadocx FDA Consultant	4	www.pharmadocx.com
33	PVC Colouring Compounding & Processing	2	www.pvclplastics.com
34	QOSINA	2	www.qosina.com
35	R R Patel Industrail Gases Pvt Ltd.	2	www.rapatelindustries.com
36	Raumedic Pte.Ltd	2	www.raumedic.com/pharma
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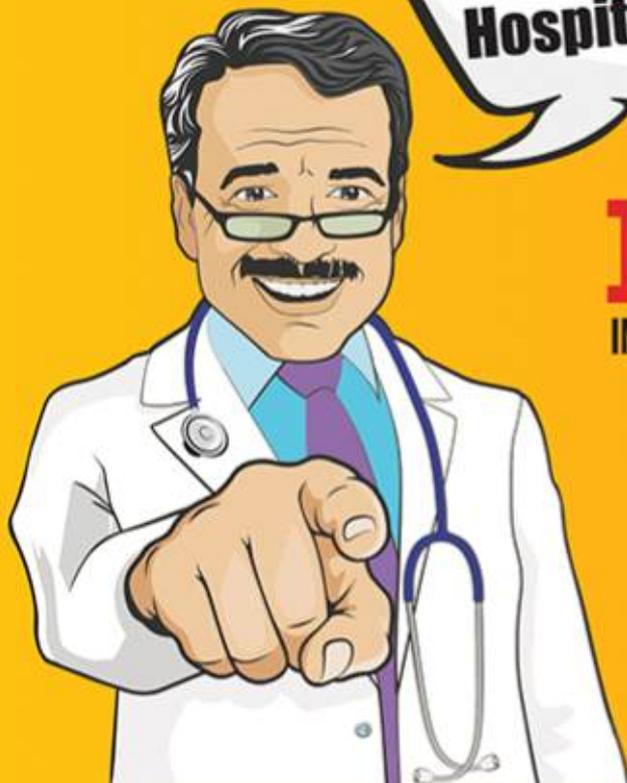
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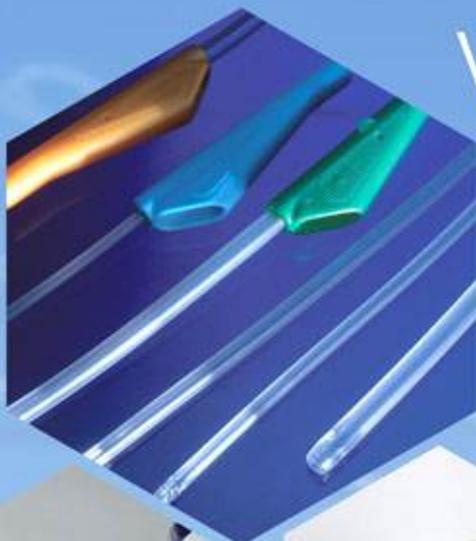
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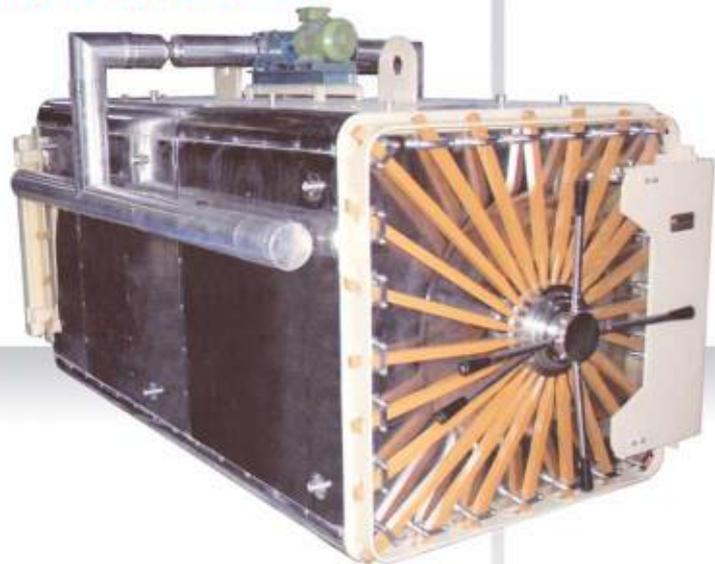
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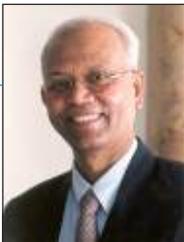
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