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MEDICAL PLASTICS DATA SERVICE

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

- **Medical Polymers & Medical Device Industry**
  - Polyurethanes as Biomaterials
  - Importance of Change Management for Regulatory Compliance
  - Ultra Engineered Polymers (UEP) for the Medical Device industry
- **Medical Device Sector Needs Government Support**
  - Himanshu Baid
- **Quality**
  - Ensuring the safety and performance of latex medical examination gloves

Himanshu Baid
Chairman, National Medical Technology Forum, CII

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Business Development Manager, PEAK Performance Compounding, LLC. USA

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Mn Solutions, New Delhi

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

- **Additives For Medical Grade Plastics**
  - 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**

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  - Plastic Materials & Components Used

Developing from Concept to commissioning

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- **Medical Device Sector : Comparing with Pharmaceuticals**
- **Book Reviews**
  - Applications of Polyurethanes in Medical Devices
  - Plastics For Cardiovascular Applications

A Tribute to Prof. M S Valiathan
The Pioneer of Medical Devices Development in India

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Now Our 32nd Year of Publication

MEDICAL PLASTICS
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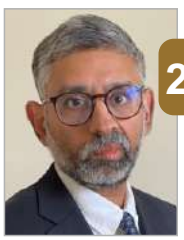

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MEDICAL PLASTICS DATA SERVICE

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  - Mr. Amit Dave, M. Pharm, MBA, Former CEO Brazil operations/VP Export – Zydus Cadila, Claris Lifesciences (March - April 2022)
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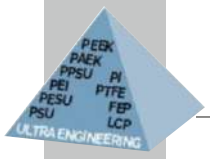


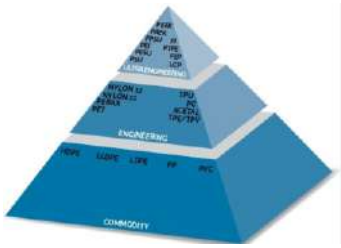
Did You Know?

About Ultra Engineered Polymers (UEP) for the Medical Device industry?

There has been a profound shift in the medical industry where procedures have aimed to become more minimally invasive, quicker and more effective. This requires medical devices and their components to use updated and advanced, high performance polymers.

There are a wide range of these ultra-engineering high temperature polymers but many of them are somewhat new to the plastics industry and some are relatively uncommon. Many of these advanced materials fall under the general description of high heat polymers.

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



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

Ultra-engineering polymers have very good chemical resistance which makes them ideal for the hospital environment and the many harsh chemicals and drugs that plastics can be exposed to. The physical properties of ultra-engineering polymers also out perform all other standard engineered polymers in the areas of tensile strength, flexural strength and impact resistance.

All of these ultra-engineering materials require specialized extrusion equipment, purpose designed tooling and the knowledge of unique processing methods.

In a Nutshell....

"The gift of knowledge is a far higher gift than that of food and clothes, it is even higher than giving life to a man, because the real life of man consists of knowledge"

-SWAMI VIVEKANANDA

MEDICAL PLASTICS
DATA SERVICE

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MEDICAL PLASTICS
DATA SERVICE

From the Editor's Desk

Medical Polymers & Medical Device Industry

Polymers and Modern medical Devices are like "made for each other". Many medical device applications would not be feasible without extensive collaboration of Polymer technology and Medical discipline.

The cover story explains how Change Management is crucial for maintaining regulatory compliance and ensuring product quality for suppliers of medical polymers. The key objectives include reducing operational risks, ensuring product safety, and maintaining compliance with industry standards.

Polymer Additives

Various types of additives are used to improve processability, to ensure stability against deterioration due to heat during processing and to visible and ultraviolet light, to prevent fire, and for other functions of plastic materials along with biocompatibility.

This issue covers two important additives, Plasticizers & Radiopaque Fillers especially commonly used Poly vinyl Chloride (PVC)

A plasticizer is a substance that when added to a material, usually a polymer, makes it flexible, resilient, and easier to handle. The editorial research article introduces plasticizers used in a variety of PVC-based medical devices as well as the new and safe alternatives.

As explained in another very well researched article by Mr Joseph Wilson, Business Development Manager, PEAK Performance Compounding LLC, USA , Radiopaque fillers are a revolutionary addition to medical polymer manufacturing and contribute to the vast growth and success of the Minimally Invasive Surgical Market. Their ability to provide device visibility, while also maintaining biocompatibility makes them a cornerstone of modern medical engineering. The article introduces various materials used as fillers and critical medical device applications requiring use of these materials.

Polyurethanes as Biomaterials in Medical Devices

The lead article by Dr Ajay Padsalgikar, a pH.D. Technical Director, Bioling, USA highlights important aspects related to Polyurethanes in Medical Device applications. Polyurethanes, in many cases, form the core of these medical devices. The article highlights important properties and applications of Polyurethanes in critical care Medical Devices.

Ultra Engineered Polymers (UEP) in Medical Devices

Procedure in Medical industry have become more minimally invasive, quicker and more effective. This requires medical devices and their components to use updated and advanced, high performance polymers. The "Did You Know "column introduces wide range of ultra-engineering high temperature polymers , the major ones being PEEK, PPSU, PSU, PESU and PEI. They have added a level of performance to plastics that was relatively unknown until not that long ago.

Quality Testing & Regulations

Dr Gijo Raj, Scientist, Division of Polymeric Medical Devices, SCTIMST, Trivandrum explains the test method to ensure safety & performance of latex examination gloves in accordance with related quality standard. An article by Dr B N Nagpal, Mn Solutions, New Delhi covers a comprehensive overview of MedTech regulations in India.

This issue also includes our regular columns on Association & Industry News, Product Gallery and more.

D L Pandya

Medical Grade Polymers: Importance of Change Management for Regulatory Compliance

In industries like pharmaceuticals or medical devices, a change management plan is crucial for maintaining regulatory compliance and ensuring product quality. The key objectives include reducing operational risks, ensuring product safety, and maintaining compliance with industry standards such as FDA regulations.27 Sept 2024

A **change management plan** is a structured approach to handle modifications in processes, products, or policies within an organization. The primary objective of this plan is to ensure that changes are implemented efficiently while minimizing disruptions.

It is important to maintain stable and consistent product quality over lifetime of a Medical Device Product for the safety and comfort of the patients. This requires stable and consistent quality of the materials / components used in the manufacturing of the Medical Devices.

Selection of appropriate material / polymers for medical application products at the beginning of the development process is very important.

As defined in the VDI 2017 document, " Polymeric plastics and refined plastic preparations and formulations (masterbatches, blends, compounds) are called "Medical Grade Plastics" (MGP) when they are intended for use by a given manufacturer in the manufacture of finished products in the following application areas :

01 Medical Devices in accordance with regulatory requirements.

02 In-vitro Diagnostics in accordance with regulatory requirements

03 Primary Packaging for Medical Devices / Pharmaceuticals and other medical application products as specified in VDI 2017.

As on now , no US or EU guidelines or standards exist for clearly defining the medical grade plastics.

The materials have to meet design needs such as mechanical, thermal ,chemical as well as biocompatibility requirements. It is also important to have safety of long term supply with constant quality.

The consistency of a formulation is regarded as the essential requirement for constant properties. It also includes consistency in components and raw material suppliers as well as consistency in the material manufacturing process.

The material suppliers may be required to share documentation on formulation consistency with the customer on request. Information transfer has to be covered by corresponding non -disclosure agreements.

Polymer grades inevitably undergo changes but they should be kept to minimum. The process of change has to follow a prescribed approach

The material manufacturer should first evaluate changes that affect consistency particularly those with respect to possible impact on product properties.

In such cases, corresponding information has to be given to the customer along with a change notification.

The customer has to evaluate the changes with respect to impact on his product and takes up activities necessary to implement the change for his product. It means verification of the product properties affected by the change.

During this period, the security of supply by material that has not undergone change yet has to be provided by the manufacturer.

The installation of change management process is another requirement for Medical Grade Plastics.

The material supplier can provide supply guarantee either by installing a secondary production line or simply providing safety stock that can be used in case of stop of material production. The quantity of safety stock has to be agreed upon between supplier and customer.

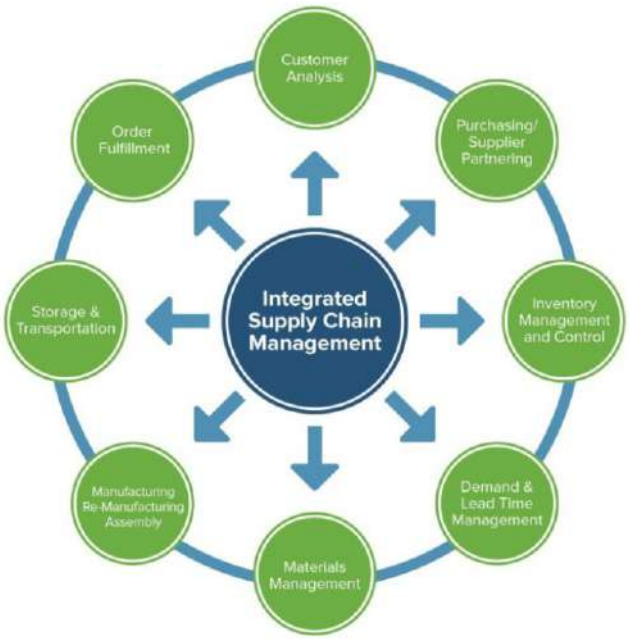
How to Manage Change for Medical Devices?

Managing change in the medical device industry comes with unique challenges. The US FDA's requirements for medical device changes emphasize the importance of documenting every step in the change control process.

Examples of common changes in medical devices include design modifications, software updates, or material substitutions. A strong change management plan ensures these changes are implemented without compromising product safety or performance.

Why Do You Need One?

Developing, coordinating, and implementing a change management plan is valuable for many reasons. With a proper plan, you can:



- **Avoid Regulatory Non-Compliance and Fines:** No more worries about non-compliance or the costly fines associated with it when you can manage change efficiently and smoothly.
- **Mitigate Risks and Ensure Product Safety:** With a structured approach, organizations can reduce risks that could compromise product safety.
- **Improve Overall Operational Efficiency and Reduce Costs:** A change management plan streamlines processes, reducing delays and associated costs.
- **Enhance Stakeholder Communication and Collaboration:** It ensures

clear communication with stakeholders, leading to smoother transitions and more aligned teams. By addressing these areas, a change management plan becomes essential for both compliance and business success.

Benefits of a Change Management Plan

Having a well-structured change management plan drives multiple benefits, including:

- **Increased Product Quality and Reliability:** It ensures that changes are carefully evaluated, reducing errors and enhancing product performance.
- **Improved Patient Safety and Satisfaction:** Especially in healthcare sectors, a robust change management system safeguards patients by minimizing risks associated with product changes.
- **Enhanced Organizational Reputation and Trust:** Organizations that consistently meet regulatory standards are seen as reliable, earning the trust of customers and partners.
- **Stronger Regulatory Compliance and Market Access:** A solid change management process helps companies avoid compliance issues, allowing smoother market access.

What are the Key Elements of a Change Management Plan?

An effective change management plan consists of several essential components:

1. **Change Control Process:** A clear procedure for evaluating, approving, and implementing changes to ensure all stakeholders are aligned.
2. **Impact Assessment:** Conduct a thorough impact assessment to understand the impact on product, process, people and technology.
3. **Risk Assessment and Mitigation:** Identifying and mitigating potential risks associated with each change to minimize disruption and ensure safety.
4. **Communication and Stakeholder Engagement:** Keeping all stakeholders informed about changes and their potential impact to ensure smooth transitions.
5. **Documentation and Record keeping:** Comprehensive documentation is required to maintain regulatory compliance, from initial change requests to final approvals.
6. **Monitoring and Evaluation:** Regularly assessing the outcomes of implemented changes to ensure they meet quality and compliance standards.

These elements work together to ensure changes are managed in a controlled and compliant manner.

Ref :
01 VDI 2017 – Medical Grade Plastics (MGP)
02 Article on "Stability and Continuity" by S.Roth as published TPE Magazine- 3/2019
03 https://www.qualityze.com/blogs/fda-change-management-plan

Plastic Additives and Role of Plasticizers in Medical Devices

Plastic additives are chemical substances that are intentionally added to plastic materials to achieve a physical or chemical effect during processing of plastic or in the final material or container. They may consist of a single chemical substance, a polymeric substance, or a defined mixture of different components.

Various types of additives are used to improve processability, to ensure stability against deterioration due to heat during processing and to visible and ultraviolet (UV) light during use, to prevent fire, and for other functions of plastic materials.

Plasticizers In Medical Devices

A plasticizer is a substance that when added to a material, usually a polymer, makes it flexible, resilient, and easier to handle. There are more than 300 different types of plasticizers described of which between 50 and 100 are in commercial use. The most commonly used plasticizers are phthalates. In Western Europe, about one million tons of phthalates are produced each year, of which approximately 900,000 tons are used to plasticize PVC. The most common are dioctyl terephthalate (DEHT), di-iso-nonyl phthalate (DINP) di-iso-decyl phthalate (DIDP), and di(2-ethylhexyl) phthalate (DEHP). Plasticizers are used in a variety of PVC-based products.

Softness and flexibility are key properties of medical devices. This is, for example, crucial for tubing that goes inside the body, which must be as soft as possible for optimum patient treatment and comfort. In order to make PVC medical devices soft and flexible, a plasticizer is added to the PVC compound.

Plasticisers play a key role in sensitive applications such as medical tubing and other device components by imparting the flexibility, durability and elasticity required to resist kinking and other failure modes. Plasticisers are selected for their ability to meet critical application requirements while maintaining biocompatibility and enhancing clarity. Plasticisers are essential to maintaining a medical device's long-term functionality.

Producers now offer non-phthalate products that contain ISCC-certified recycled content (including content derived from molecular recycling), plus bio-derived inputs.

A wide range of plasticizers for medical applications are now included in the European Pharmacopoeia, which sets Europe's legal and scientific standards for delivering high-quality medicines in Europe and beyond.

Plasticizers are not chemically bound to PVC and may therefore leach (leak, migrate) into the surrounding environment. The biological properties of the phthalate plasticizers used in PVC, especially DEHP, have been the subject of a very substantial amount of research.

As a consequence, concerns have been raised about the implications for human health and to the environment of three particular properties of DEHP observed in experimental animals/other experimental systems, namely, the potential to cause: reproductive and developmental effects, endocrine disruption and testes toxicity, peroxisome proliferation in the liver and thereby increase the incidence of liver cancer in rodents.

DEHT is main plasticizer used in PVC-based medical devices.

Medical Device manufacturers across the industry face increasing pressure from regulators, governments and consumers to produce more environmentally friendly products.

(Ref : https://www.medicalplasticsnews.com/news/teknor-apex-to-deliver-more-sustainable-polymers/)

Plasticizers for Medical Grade PVC Applications: Safe Alternatives.

The phthalate DEHP used to be the main plasticizer in medical PVC due to its technical properties and low cost. The substance has been under increasing scrutiny by regulatory and medical authorities, and in the EU its continued use in high-risk medical devices after 31 December 2027 and in low-risk medical devices after 31 December 2028 require robust justification.

As part of their commitment to innovation, continuous improvement of safety, performance and cost-efficiency, companies within the medical PVC value chain have progressively made available a wide range of alternatives to DEHP plasticiser for medical applications, which are approved by the European Pharmacopeia. T

PVC is the single most used plastic for disposable medical devices such as masks, tubing and bags. Most of the PVC-based medical devices are soft, which requires that a so called plasticiser is added to the compound. For many years the plasticiser of choice was the phthalate DEHP. Based on its toxicological profile the substance has been under increasing scrutiny by regulatory and medical authorities.

Under the EU Medical Device Regulation, the continued use of DEHP in medical devices after 31 December 2027 for high-risk devices and 31 December 2028 for medium- and low-risk devices requires a **justification** according to the latest relevant scientific committee guidelines. Under the EU's chemical regulation **REACH,** the use of DEHP in the remaining applications will have to be terminated by 14 December 2024, or in medical devices by 1 July 2030.

The plasticiser industry has invested more than €6 billion in developing safe alternatives. For medical applications, the **European Pharmacopoeia** lists since 2016 the following plasticisers as replacements for DEHP: DINCH, BTHC, TOTM (TETHM) and DEHT (DOTP/DEHTP). These plasticisers can replace DEHP in virtually all instances, also in blood bags.

Not all Plasticizers are alike

A main concern related to plasticisers is that they can migrate, leach, or evaporate from the products as they are not chemically bound to the PVC matrix. Medical treatment can lead to high exposure to DEHP. Though they can all make PVC soft, not all plasticisers are alike. The observed adverse effects of DEHP and other low molecular weight (LMW) phthalates are caused by their specific molecular structures. As the molecular structure of the DEHP substitutes are very different, they migrate far less and do not show the adverse effects like LMW phthalates.

The producers have thoroughly tested their new substances. Please note that the development of these alternative plasticisers started years ahead of REACH! Now, under the EU chemicals regulation REACH – which is seen as the strictest in the world – it is up to industry to prove that a substance is safe. REACH requires chemical manufacturers to register substances with the European Chemicals Agency if they are used on the market.

The REACH system ensures that for any plasticiser currently produced safe use can be demonstrated. Regarding medical devices, which are regulated specifically by the Medical Device Regulation, the safe use and benefit-risk analysis in the intended applications need to be provided by the medical device industry. The data used for these safe use determinations for medical devices comprise acute toxicity, skin and eye irritation, sensitisation, repeat dose toxicity, genotoxicity, carcinogenicity, reproductive and developmental toxicity, and endocrine disruption. As all these chemicals are dual use materials, the whole environmental hazards are covered by the REACH information requirements.

The four plasticisers used in medical devices as listed in the European Pharmacopeia (DINCH, BTHC, TOTM and DEHT) have been used for more than 20 years. No adverse effects have been observed. In addition to the studies undertaken to satisfy the REACH information requirements, DINCH, BTHC and DOTP have been subject to repeat dose toxicity testing on the intravenous route – for a time period that is sufficient to do a safety assessment for medical applications.

About replacing PVC altogether to avoid plasticisers?

Plasticisers are among the world's most researched substances. Some LMW phthalates have shown to exhibit adverse effects on health and environment, other plasticisers have not. The chemical industry has developed safe alternatives which are based on their comprehensive toxicological profiles safe for all the intended uses. These alternative plasticisers have substituted LMW phthalates nearly to 100% in Europe.

To avoid plasticisers, some are calling to phase out PVC with other materials that do not require plasticisers to be softened. However, just because a plastic material does not need plasticisers, it does not mean it is free from additives that may migrate into the body with possible adverse effects. Today, 10,000 substances are used to provide different properties to different plastics. According to a recent study, nearly 25% of these chemicals have been identified as substances of potential concern because they meet EU's persistence, bioaccumulation and toxicity criteria. Thus, if PVC

as such is merely replaced by other plastics, regretful substitution cannot be ruled out.

As mentioned by PVCMed, following third-party bodies have assessed the safety of the DEHP substitutes :

- The substitutes are not classified as hazardous according to the **CLP Regulation**
- DINCH and DEHT were subject to **PACT and REACH** compliance checks by ECHA. For some other substances minor formal requirements need to be completed to comply with increase production volumes under REACH
- Listed for medical applications by the **European Pharmacopoeia**
- Meet requirements of the **EU Medical Device Regulation**
- Evaluated by the European Food Safety Authority (EFSA)
- Evaluated by the **French Agency for Food, Environmental and Occupational Health & Safety (ANSES)**
- Evaluated by the **Danish Environmental Protection Agency**
- Evaluated by the **Swedish Chemicals Agency**
- Evaluated by European Commission's **Scientific Committee on Emerging and Newly-Identified Health Risks (SCENIHR)**
- Toxicity Reviews by US Consumer Product Safety Commission
- Assessment by the Australian Inventory of Chemical Substances (AICS)
- Peer-reviewed publications by the US NSF (health advisory board chaired by the US EPA)

(Ref : https://pvcmed.org/healthcare/plasticisers-for-medical-applications/)

Polyurethanes as Biomaterials In Medical Devices

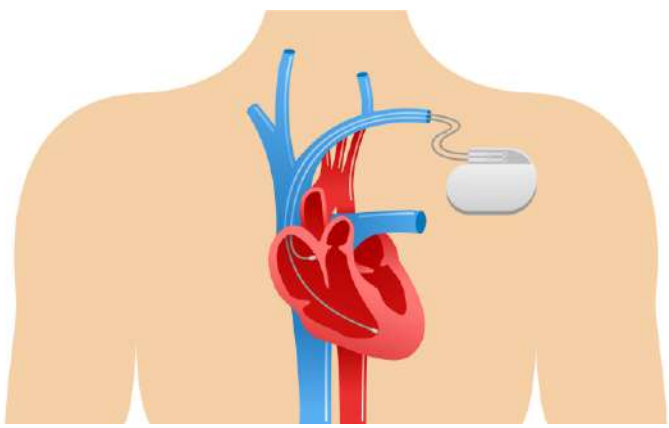
Dr. Ajay D Padsalgikar
Ph.D., Technical Director, Biolinq Inc. USA

The complex nature of the human body is inherent in its structure, from the smallest building block of the cell to their collection as tissues, the formation of organs from tissues and the contribution of organs to their particular system and ultimately to the entire body. It is important to note that all these processes are interrelated and thus no part of the body, whether it is the smallest cell or a complex body system, works in isolation from each other. It is this fine-tuned balance that results in homeostasis and is important in the maintenance of health. Disease, on the other hand, is the disruption of this balance or homeostasis.

Medical Devices and Polymers

Medical science continues to advance in both disease treatment strategies and the understanding of medical conditions. Management of the diseased state of the body is frequently done using medical devices. Concurrently with the advances in health care, there is an increased use of medical devices targeted to treat several conditions. Plastics constitute an important part of medical devices. Plastics have an inherent advantage over traditionally used materials, such as glass and metals, in medical devices. Plastics are lightweight, inexpensive and often compatible with bodily fluids. Most plastics are also comparable in density to the body and thus are easier to incorporate into the body. They, for the most part, also have a high degree of resistance to chemicals, both natural and synthetic, that make them suitable for being used in medical applications. The role of nature and properties of plastics in the correct functioning of a device is critical. Very often the selection of the plastic can dictate the efficacy of the device and the treatment of the disease.

Many medical devices are implantable systems. These devices are implanted inside the human body and perform critical functions in the regulation of some bodily functions. Polymers form the core of many of these devices, and the properties of the polymeric material allow greater functionality of the device. The implantable devices are further divided into short term implantable and long-term implantable devices depending on the duration of the dwell time of the implantable device inside the body. Most devices shorter than a 90-day dwell time are classified as being short-term implants.



Polyurethanes as Biomaterials

Polyurethanes are a class of polymers that are prominently used in various medical device applications. Polyurethanes are a widely researched class of polymers and find applications in numerous technical areas, with their properties ranging from hard plastics to soft gels and applications ranging from furniture foam to shoe soles to surface coatings. The polyurethane group of materials is characterized by the presence of the urethane bond; the urethane bond is formed by the reaction of the end groups of isocyanate and hydroxyl on the reacting molecules. Since the existence of the urethane bond describes the polyurethane polymer, this implies that the molecules on either side of the end groups could take on many different forms. This flexibility implies that polyurethanes can possess a wide spectrum of properties. Depending on the polyurethane formulation, materials can be made soft or hard, elastomeric or rigid, thermoplastic or thermoset etc.

For polyurethanes to be used in medical applications, the property of biocompatibility is critical. A material is said to be biocompatible when the material does not elicit any undesirable response from the host upon coming in contact with the elements of the hosts' body. Therefore, by not generating any negative responses from the cellular or tissue structures, the material then allows the appropriate function of the implanted device that the material either makes up or supports.

Different characterization techniques exist to assess the biocompatibility of a material. The tests depend on the duration of the implant and its function of the material in the device. Some of the basic tests of biocompatibility include quantification and identification of any substances that leach out from the material under conditions that mimic the conditions that the material experiences inside the body. The response of the cells in contact with the material (cytotoxicity) and the response of the genes in contact with the material

(genotoxicity) form the basic tests for biocompatibility.

Polyurethanes can also be formulated as biologically stable or biologically degradable systems. A biologically stable formulation is one that can resist the action of body fluids and not lose any functionality over time; this property makes them suitable for the construction of long-term implants. A biologically degradable formulation, on the other hand, can be broken down into easily digestible and harmless elements over time. This degradation can be programmed to occur either at a specific time or upon a specific action. This property makes biodegradable polyurethanes attractive options in areas such as drug-device combinations and regenerative medicine.

Biological stability, often referred to as biostability, can be defined as the ability of a material to withstand the biological environment within the human body without degradation. It is seen that upon the implantation of a medical device inside the body, the body's immune system immediately responds to the new object and treats it as a foreign object. As a result, different active species aided by enzymes attack the foreign object with an aim to destroy the foreign object. In addition, the material also has to withstand the environment within the body that is mainly hydrolytic in nature. The response of the material to these environments determines the degree of biostability of a material. The biostability of a polyurethane formulation determines the suitability of a material to be used in implantable medical devices.

The best measure of biostability for any polyurethane used in a medical device is the actual data coming from clinical use. However, before the actual application in the clinic there needs to be a test that will indicate how the polyurethane formulation will behave under the conditions of the bodily environment. Animal trial is one method to ascertain material performance in in-vivo conditions. An appropriate animal model is chosen for the trial and either the finished device or the polyurethane on its own is implanted. Several researchers have also worked on the development of a representative laboratory or in-vitro test to replicate the in-vivo conditions. Many methods also try to accelerate the tests in order to get confidence of the long-term performance of the material in the body. It has been frequently noted that in-vitro tests in general and accelerated in-vitro tests in particular do not correspond to results from in-vivo conditions and this has been attributed to the complexity of body environment and the inadequacy of in-vitro models in successful replication.

Applications of Polyurethanes in Medical Devices

Major bodily systems, cardiovascular, orthopedic, neurological, urinary, digestive etc. have been treated through the use of medical devices for their functional disorders. Polyurethanes, in many cases, form either the core of these medical devices or assist in the device functionality. Some examples of their current commercial usage are listed below.

Polyurethane formulations have been used in the space of cardiac surgery, cardiology, cardiovascular and structural heart for decades. One area of polyurethane use is in the field of cardiac arrhythmia. Cardiac arrhythmia is the disruption of the electrical activity of the heart that results in the irregular beating of the heart. Implantable devices can address the issues of a fast-beating heart, tachycardia (heart beats > 100 beats/min) or a slow beating heart, bradycardia (heart beats <60 beats/min).

Pacemakers are designed to treat bradycardia whereas Implantable Cardioverter Defibrillators (ICDs) are used to treat tachycardia. Pacemakers and ICD devices consist of a metallic can and wires that go along the blood stream inside the heart muscle (Figures 1 and 2). The can is implanted subcutaneously, usually below the collar bone. The metallic can, usually made from titanium, houses the main electronic circuit and the battery for the operation of the circuit. A plastic cap is joined on to the top of the can, this cap also known as the header acts as the link and connects the electrical signals from the wires to the electronics in the can and vice versa. The wires, also referred to as leads, have metallic conductor coils made out a Nickel – Titanium alloy, and these are covered with an insulation.

The header of a cardiac device needs to have a certain hardness and be transparent. These properties are essential as the connectors from the wires are metallic. A hard header is required to be relatively inflexible with respect to the inserted conductors. Transparency is desirable to visually ensure the correct placement of these conductors. In many devices, the header is made from a hard grade polyurethane. Polyurethane headers are injection molded and joined to the cans using both mechanical interlocks and silicone adhesives.

The materials used for the insulation of pacing leads are a very important component of the pacemaker or defibrillator device. Any issues with the material in the application can lead to failure of the lead to sense and regulate the current flowing through it and subsequently lead to device failure with serious consequences. The medical device industry has used, for decades, polyurethane materials for lead insulation. There were issues early on concerning the biostability of the insulation, however, with the use of greater biostable polyurethane compositions, made comprising either polysiloxane or polycarbonate-based materials, the longevity of the devices has remarkably improved. The leads with greater biostability have shown longevity of up to 20 years.

Heart failure is a major affliction affecting millions of people across the world. Heart failure causes an insufficient supply of blood to the body, this causes a volumetric expansion of the left ventricle in order to keep up with the requirements of the body. This volumetric expansion weakens the heart muscle and further increases the size of the left ventricle. A ventricular assist device (VAD) is a mechanical pump that's used to support heart function and blood flow in people who have ventricles that have significantly weakened and can no longer provide adequate blood supply to the entire body (Figure 3). Polyurethanes have been used in the construction of pump housing and flexing components. Here the advantages of blood compatibility and mechanical properties of the polyurethanes are utilized.

In all the implantable devices, accurate placement is of paramount importance. Using the properties of biological and blood compatibility, flexibility, toughness and robust mechanical properties, polyurethanes are frequently used as delivery catheters.

There is widespread use of polyurethanes in neurological applications, especially in neurostimulators. Neurostimulation therapies employ approaches that apply electromagnetic energy to specific anatomical targets to induce neuromodulation of the corresponding neurological network. Many fundamental design concepts of neurostimulators are very similar to cardiac

pacemakers and defibrillators, this is because the requirements of both technologies are similar. Polyurethanes are widely used in neurostimulation devices as the insulators for leads and extenders, they are also used in the fabrication of headers on the top of stimulators. Many of the requirements, like the use in cardiac pacemaker and ICD devices, need the polyurethanes used to demonstrate excellent biostability and mechanical properties.

With the range of structural possibilities in polyurethanes offering a wide spectrum of physical properties, polyurethane formulations have always been of great interest in orthopedic applications. Polyurethanes are considered as alternative materials for hard-on-soft bearings in artificial joints. Polycarbonate-based polyurethane is used in a cushion-bearing system as an acetabular socket (Active Implants, LLC Memphis, TN). The same material was also used to develop a meniscal implant for knee joints. A polyurethane formulation based on biodegradable polycaprolactone and butane diisocyanate used to develop meniscal implants. Clinical outcomes showed favourable outcomes with the implant (Actifit® from Orteq) demonstrating promotion of meniscal regeneration.

Another aspect of polyurethane material properties is to act as selective membranes allowing permeability of desired species. This property is used effectively in continuous glucose monitoring (CGM) devices. CGM devices are used for monitoring glucose levels continuously by people with either type I or type II diabetes. A continuous glucose monitor takes a reading on set intervals with a small electrode placed under the skin and held in place by an adhesive. A transmitter attached to the electrode sends data to a separate receiver. CGM devices, based on the glucose oxidase enzyme, require the transmission of oxygen and glucose to the enzyme in a fixed ratio. The ratio is decided mostly by the specific design features of the device and is obtained by the fine tuning of the composition of the polyurethane membrane that surrounds the enzyme.

Emerging Applications

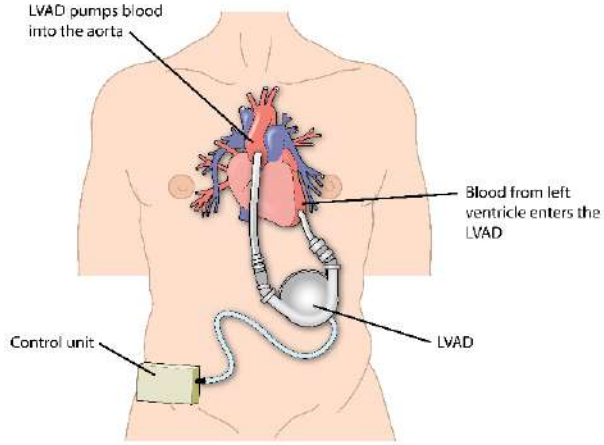
The use of polyurethane formulations in different areas of medical devices is well established, however, given the versatile nature of these materials combined with their inherent biocompatibility, newer application numerous areas are emerging, a few of these are noted below.

Polyurethanes can be effective drug carriers or excipients, and drug delivery devices is a growing area for fabrication with polyurethanes. Drug and device combinations can be designed in coordinated strategies to elicit mutually reinforcing effects and provide, in certain circumstances, significant medical advantages over administering both the drug and the device in their conventional, separate forms. Formal regulatory recognition and development of the combination device design motif worldwide is relatively new, with flexible performance feature and biotechnology both advancing on many contributing fronts, combination products represent a promising new opportunity for improving implanted prosthetic device performance and associated quality of life issues. Drug delivery occurs mainly through diffusion of the drug through the polymer matrix. Since drugs can be both hydrophilic and hydrophobic, the ability of the polyurethanes to accommodate the differing polarity of the drug is an important aspect.

In the cardiac space, aortic valve replacement is seen as the therapy for severe cases of aortic stenosis. Aortic valve replacement is mostly done using a surgical procedure with either a mechanical or a tissue valve. Traditional heart valve replacement devices are either animal tissue based or are metal based mechanical devices. A combination of favorable physical and chemical properties combined with its flexibility in processing techniques have been the main attractions for the use of polyurethanes in fabricating heart valves leaflets. Issues of oxidative stability, hemocompatibility, thrombosis and calcification have slowed down the use of polyurethanes as heart valve leaflets in commercial devices. Thrombogenicity and biostability have been addressed by two different groups Strait Access Technologies and Foldax Inc. and their versions of TPU heart valves, both surgical and TAVR, are in clinical trials.

The use of polyurethanes in biosensors relies upon the selective nature of permeation of polyurethane membranes. This selective nature is dependent on the chemical formulation as well as the morphology of the material. The wide range of formulations that polyurethanes are capable of, enable materials to be developed that allow permeation of molecules of interest while blocking other species. This property is used in the development of sensors that have the ability to analyze analytes of interest.

In summary, the expanse of properties of polyurethanes, stemming from their versatile chemical and morphological nature, make them attractive for use in different applications areas of medical devices. The areas include well-established ones and newer ones emerging.



Biography of Ajay D Padsalgikar

Ajay graduated with a degree in Polymer Engineering from the University of Poona, India in 1990. He then completed a PhD from Clemson University, SC, USA in 1996. Ajay has worked different companies, Huntsman Polyurethanes in Belgium, AorTech Biomaterials in Australia and Abbott in Minnesota, DSM Biomedical, Pennsylvania. He has been involved with different aspects of polyurethane chemistry, morphology and processing of polyurethanes for medical devices.

Ajay joined Biolinq Inc. in July 2022 as a Technical Director, where he is working on a range of material solutions for biosensors.

Ajay has more than 30 published scientific papers and 10 patents. He has also authored two books, 'Plastics in Medical devices for Cardiovascular Applications' was published by Elsevier. 'Applications of Polyurethanes in Medical Devices' was published in June 2022 also by Elsevier.

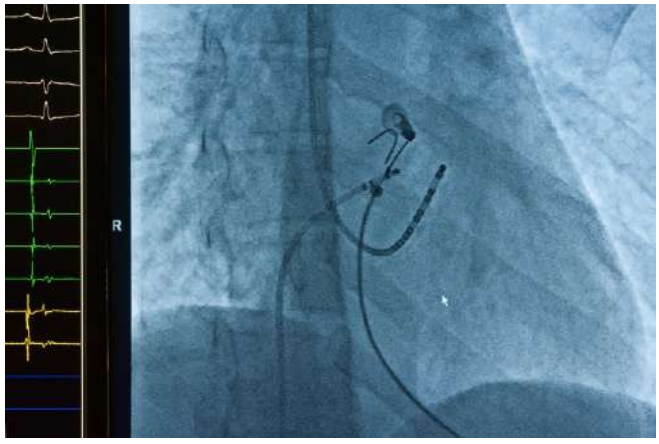
The Use Of Radiopaque Fillers In Medical Material Manufacturing

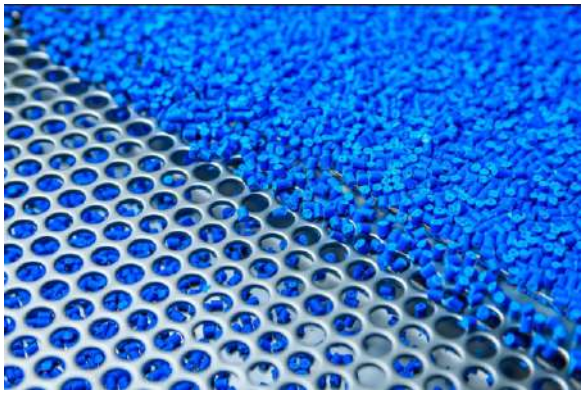
Joseph Wilson,
Business Development Manager
PEAK Performance Compounding, LLC.

Advanced medical devices are built on high-quality polymers, meticulously engineered through melt process compounding to deliver specialized, performance-boosting properties. The use of common metals, (also known as radiopaque fillers) in medical device manufacturing has become increasingly popular to enable the production of devices that are not only durable and biocompatible, but also detectable under X-ray imaging technology. This article explores the use of radiopaque fillers in medical device manufacturing, including properties, benefits, and market applications.

The Role of Radiopaque Fillers in Medical Plastics

Radiopaque fillers are mineral and metal powders incorporated into polymers to enhance their visibility under X-ray and fluoroscopy. These fillers provide contrast by absorbing radiation, making devices and instruments distinctly visible against surrounding bodily tissue. The use of radiopaque fillers enables healthcare professionals to monitor the placement, movement, or functionality of a medical device inside the body to deliver lifesaving therapies. This is critical for minimally invasive medical procedures, including cardiac catheterization, neurological catheterization, orthopedic surgery, endoscopy and postoperative monitoring.





Common Radiopaque Materials

The most commonly used radiopaque fillers include Barium Sulfate, Bismuth Subcarbonate, Bismuth Oxychloride and Tungsten. The use of one filler over another is determined based on a set of factors, including base resin, desired radiopacity, aesthetic color / appearance and cost.

Most fillers are highly biocompatible, making them safe for bodily contact, whether it be short term or even long-term implantation. Additionally common radiopaque fillers are highly customizable, allowing for formulation tailoring based on specific device requirements.

Barium Sulfate (BaSO4) is a high-density, white powder with excellent radiopacity and chemical stability. Barium Sulfate is highly compatible with a range of polymers, including those most commonly used in the construction of minimally invasive medical catheters, including Polyether-block Amide (PEBA), Nylon and Thermoplastic Polyurethane (TPU). Barium Sulfate is the most cost-effective radiopaque filler and commonly compounded at loading levels of 10-40% by weight, with some compounds requiring up to 60% loading.

Bismuth Subcarbonate (BI2O2CO3) is a higher cost filler that offers a high degree of radiopacity and can typically be used in smaller loading volumes when compared to Barium Sulfate. While Bismuth Subcarbonate can be used with a range of polymer types, it often results in processing challenges in some TPU grades of resins and yellowing can occur when processed at high temperatures.

Bismuth Oxychloride (BiOCl) offers excellent radiopacity, thermal stability and chemical resistance. It is highly compatible with a range of polymers, offering uniform distribution and dispersion when melt compounded. Bismuth Oxychloride also offers aesthetic benefits due to its pearl-like appearance and often yields surface finish enhancements for extruded and injection molded products, with slightly lower coefficient of

friction.

Tungsten (W) is known for its high density and excellent imaging properties. In high precision applications, such as marker bands and micro-sized catheters, Tungsten offers the ability to be added at very high loading levels (up to 90% by weight) for the highest degree of traceability. Tungsten also offers the highest degree of temperature resistance when compared to other radiopaque fillers and is compatible with a wide range of thermoplastics and elastomers.

Integration with Polymers

Radiopaque fillers are incorporated into polymer matrices using twin-screw compounding techniques. Filler dispersion ensures uniform radiopacity and preserves the mechanical properties and biocompatibility of the base polymer, while also minimizing surface imperfections.

Optimal results can be achieved through strategic equipment configuration, precise feeding controls, and tailored compound formulations. The polymer-to-filler ratio is highly customizable, depending on the desired radiopacity and performance characteristics of the final device, allowing for application-specific solutions. Additional additives, including colored pigments, polymer reinforcements, lubricants and processing aids can also be added.

Applications in Medical Device Manufacturing

Catheters, Stents & Tubing

Radiopaque compounds play a pivotal role in diagnostic and interventional procedures, particularly in cardiac and neurological catheterization. Applications include angiography catheters, angioplasty catheters, and stents, where radiopaque markers are strategically integrated along the length of the catheter to guide precise placement and deployment of therapeutic intervention. Similarly, stents enhanced with radiopaque markers ensure accurate positioning within blood vessels to effectively alleviate artery blockages. This innovation in minimally invasive surgical techniques has revolutionized cardiac care, significantly improving procedural accuracy while minimizing patient trauma and recovery time.

Guide Wires and Needles:

Radiopaque coatings and engineered compounds enable visibility of guide wires and needles during insertion and manipulation, thereby improving accuracy during biopsies and vascular access procedures.

Surgical Instruments

Metal-reinforced plastics are used to manufacture durable and lightweight surgical instruments. These radiopaque materials enhance the visibility of surgical tools, helping physicians accurately locate and manipulate instruments in real time.

Radiopaque polymers are often utilized in two forms, including instrument coatings and or embedded markers on tips and edges. Specific tools that utilize radiopaque compound technology include forceps, scissors, clamps and endoscopy instruments.

Implantable Devices

Implantable devices, including orthopedic screws and spinal implants often include radiopaque materials to facilitate placement and healing. Regulation is heightened for these applications, where contact with blood and bodily tissue extends beyond thirty days.

PEAK Compounding Expertise

PEAK Performance Compounding has extensive experience with formulating, processing and manufacturing radiopaque compounds for a variety of medical applications, including those in contact with the body for less than thirty days. Radiopaque formulations fall under the RADIENCE™ product line and are fully customizable.

RADIENCE™ Radiopaque Compounds are manufactured in a dedicated white room environment to provide the highest level of quality control. RADIENCE™ Radiopaque Compounds can be formulated using commodity resins (TPEs, Flexible PVC, PE, PP, PS and ABS), engineering polymers (TPU, PEBA, PA, 11/12, PET, PBT and PC) and high-temperature materials (PEEK, PAEK, PEKK, PSU, and PEI). Custom colors and other performance enhancements, including SYNNERGY™ Rx Low Friction Additives are also available upon request. Manufacturing is based in the United States with localized sales and engineering support in India.

Conclusion

Radiopaque fillers are a revolutionary addition to medical polymer manufacturing and contribute to the vast growth and success of the Minimally Invasive Surgical Market. Their ability to provide device visibility, while also maintaining biocompatibility makes them a cornerstone of modern medical engineering.

As technologies advance, the integration of these materials into innovative applications will continue to revolutionize the field, improving patient outcomes and expanding the possibilities of minimally invasive medicine. By addressing current challenges and exploring emerging trends, manufacturers and suppliers can harness the full potential of radiopaque fillers. Contact PEAK Performance Compounding to discuss your radiopaque compounding needs and to get started today!

Thank you,
Joe Wilson, Business Development Manager
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Medical Device Sector Needs Government Support

Himanshu Baid
Chairman, National Medical Technology Forum
CII

Highlights of Views Expressed By Mr Himanshu Baid on how Exports of India's med-tech industry could reach USD 20 bn by 2030

Synopsis

India's medical technology industry aims to achieve exports up to USD 20 billion by 2030. The sector requires extended government incentives and further ease of doing business to accelerate growth. Industry experts suggest expanding production linked incentive (PLI) scheme across products and improving export infrastructure to enhance competitiveness and reduce costs.

India's medical technology industry is expected to touch exports of up to USD 20 billion by 2030 but the sector needs more government incentives and further ease of doing business to accelerate overseas shipments, industry body CII said on Friday.

Highlights :

- "Today, we are importing almost 60 to 70 per cent of our medical equipment which are needed in the country. Whereas, our manufacturing is still very low as around 30 per cent is only manufactured in the country. Our imports are far exceeding our exports. Our imports are almost USD 8 billion and our exports are close to USD 4 billion,"
- In the existing PLI scheme for the medical devices sectors, only 28 companies were allotted. There was a budget of Rs 3,400 crore and only 10 to 20 per cent of the fund have been utilised. To enhance exports, the PLI for the medical devices sector needs to be extended to more products.
- The government should incentivise every manufacturing which is happening in the country to push for global markets.
- We are required to wait for two to three weeks to ship our containers out of the country, whereas in China, it takes may be two days or three days to ship the products out.
- We have the best potential to grow this industry to the next level, taking advantage of the world adopting the 'China plus one' strategy to reduce import dependence on one particular country.
- We have the talent it has in terms of software, hardware and low-cost of labour as compared to China.
- It is expected that by 2030 India's exports can reach around USD 15 billion to USD 20 billion dollar and our imports would reduce from USD 8 billion to USD 3 billion-USD 4 billion.
- The industry is looking for some more ease of doing business, (removal of) overlapping regulations and certain areas where they have put in QCO orders, which is impacting 'Make in India' and exports.
- Medical Devices Industry is currently governed under the Drugs and Cosmetics Act that regulates the pharma sector which needs a separate regulator. Drugs and pharma and medical devices are seen under the same lens. The Medical Device industry has the same regulator.
- Medical Device is a "very complex engineering industry" with electronic, mechanical and plastic parts with different standards. It is very different from pharma which is more about chemical and pharmacopeia with a defined formulations.
- Medical Device industry suppliers are small players, who don't have the wherewithal to go BIS and register themselves globally. So we are asking the government for exemption from quality control order (QCO) especially for med-tech industry.

(https://economictimes.indiatimes.com/industry/healthcare/biotech/healthcare/exports-of-indias-med-tech-industry-could-reach-usd-20-bn-by-2030-sector-needs-govt-support-cii/articleshow/115804851.cms?from=mdr)

Nov. 29, 2024

> **"Medical Devices Industry is currently governed under the Drugs and Cosmetics Act that regulates the pharma sector which needs a separate regulator. Drugs and pharma and medical devices are seen under the same lens. It is very different from pharma which is more about chemical and pharmacopeia with a defined formulation."**

Ensuring The Safety And Performance Of Latex Medical Examination Gloves

Dr. Gijo Raj
Division of Polymeric Medical Devices, Department of Medical Devices Engineering, Biomedical Technology Wing, Sree Chitra Tirunal Institute for Medical Sciences and Technology, Poojappura, Trivandrum, Kerala. PIN 695 012.

The quality of latex medical examination gloves is critical in delivering safe and effective healthcare in hospitals. They not only help ensure patient safety but also help protect healthcare workers from diseases that spread through cross-contamination. Medical examination gloves were also part of personal protective equipment that contributed to tackling global health pandemics such as COVID-19. This was mainly attributed to the non-permeable nature (less than 1%) of natural rubber latex gloves to viruses. They offer superior performance than gloves made from synthetic polymers such as polyethylene and polyvinyl chloride [1]. These properties of latex medical examination gloves indeed contributed greatly to tackling the pandemic situation by providing safety to patients and healthcare workers.

Before Covid-19, the import of latex medical examination gloves to India was estimated at USD 58 million [2]. However, during and post-pandemic years, the import of latex medical examination gloves has been ever-increasing. A major concern though is increasing reports of failure of latex medical examination gloves due to poor quality [3]. Thus, to ensure the quality, safety, and performance of medical devices, the Drugs Controller General (India) in its notice dated 13th September 2021 classified latex medical examination gloves as Risk Class A medical device. Hence import, manufacturing, distribution, and sales of medical examination gloves are regulated in India. Consequently, the office of the commissioner of customs (Import – II) in its public notice (no. 55/2023) issued on 21st March 2023, states that all Bills of entry containing medical devices including surgical and medical examination gloves can only be imported following the mandatory compliance. Thus, the medical device needs to confirm the standard laid down by the Bureau of Indian Standards or, in the absence of relevant standards by the former, the standard of International Organization for Standardization (ISO), or International Electro-Technical Commission (IEC), or by any other pharmacopeia standards.

ISO 11193-1:2020 standard, on Single-use medical examination gloves - Part 1: specification for gloves made from rubber latex or rubber solution, serves as a reference for evaluating the safety and performance of examination gloves made from natural rubber latex. However, there were only a few laboratories that offered testing of single-use medical examination gloves as per ISO 11193-1 standard. This prompted delays of several months, for clearing imported shipments of latex medical examination gloves, and the price of medical examination gloves in the market shot up to 40% [4]. Sree Chitra Tirunal Institute for Medical Sciences and Technology (SCTIMST), Trivandrum is a registered medical device testing laboratory under the Central Drugs Standard Control Organization (CDSCO) for testing and evaluation of medical devices on behalf of manufacturers under the Medical Devices Rules, 2017. During the crisis due to the large demand of testing imported latex medical examination gloves, SCTIMST offered testing of latex medical examination gloves as per standards laid down by ISO 11193-1. These tests included water tightness, physical dimension, and analysis of the mechanical properties of the gloves before and after aging conditions.

Sampling for testing gloves was in accordance with inspection levels and acceptance quality limits (AQLs) specified for each test characteristic. For example, for physical dimensions (width, length, and thickness) Inspection level of S2, and an AQL of 4.0 was used. For water tightness, an Inspection level of G-1, and AQL of 2.5 was used. Finally, for force at break, and elongation at break (before and after aging conditions), an Inspection level of S-2 and an AQL of 4.0 was used.

The length measurement of the glove was taken by hanging the glove on a suitable mandrel with a tip radius of 5mm. While width measurement was made by placing the glove on a flat rigid surface. The double wall thickness of an intact glove was measured at specified locations and thickness of the glove is reported as half the measure of double-walled thickness. Physical dimension of gloves shall confirm to the values indicated for different size codes ranging from 6 and below to 9 and above.

A water tightness test is performed using a circular hollow mandrel having a minimum external diameter of 60 mm. The mandrel should have an adequate length such that when the glove is attached, it can hold 1 litre of water. The glove is securely attached up to a distance of 40 mm from the free end of the mandrel. 1 L of water at a temperature of maximum 36 °C is introduced into the hollow mandrel. The glove is raised so that the whole of the glove, excluding the 40 mm part from the cuff end, is tested. Water tightness is an effective test in immediately detecting defects such as pinholes, cuts, tears, and punctures that significantly compromise the safety of medical examination gloves.

The mechanical property of medical examination glove is evaluated from Tensile properties measured in accordance with ISO 37 standard before and after accelerated aging conditions. Using a pneumatic die cutter, three type 2 dumbbell test specimens are punched from the back or palm region of the gloves. Median values of Force at break and elongation at break from UTM analysis are reported as test results. For accelerated aging conditions, either the glove or test specimen was placed in a hot air oven at 70 °C for 7 days. In the case of the former, test pieces were punched from the aged gloves samples. For gloves

made from natural rubber latex, the minimum force at break before and after accelerated aging should be 7 N and 6 N respectively. The minimum elongation at break before and after accelerated aging should be 650 % and 500 % respectively. Compliance with medical examination gloves to the laid down standards would ensure the safety of millions of patients as well as healthcare workers across the country.

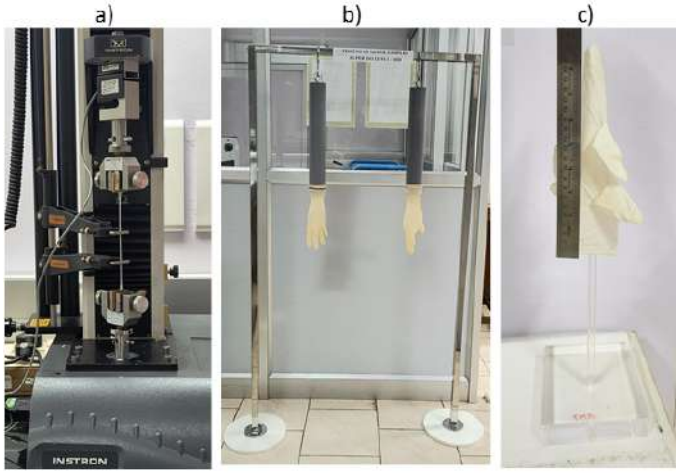

Figure 1: Testing of single use latex medical examination gloves as per ISO 11193-1:2020 standard. a) Mechanical testing of ISO 37 type 2 dumbell specimen of the glove in UTM, b) Water tightness test setup, and c) measuring length of the glove in physical dimension test.

Acknowledgement: GR wish to acknowledge Er. Saurabh S. Nair for support in the design of Water tightness test setup, Mrs. Jasmin Joseph and Mr. Adarsh A.B. for accelerated aging studies, and Dr. Roy Joseph for fruitful discussions.

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Quality in a service or product is not what you put into it. It is what the client or customer gets out of it.

- Peter Drucker

Navigating the Regulatory Landscape: A Comprehensive Overview of MedTech Regulations in India

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Mn Solutions, New Delhi
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The MedTech industry in India plays a vital role in providing innovative healthcare solutions to millions of people across the country. From diagnostic equipment to life-saving devices, the sector encompasses a wide array of products aimed at improving patient outcomes and quality of life. However, operating within the MedTech space requires a thorough understanding of the regulatory framework governing the industry. In this article, we delve into the current regulatory scenario for MedTech companies in India, exploring the key regulations, compliance requirements, and recent developments shaping the landscape. At the forefront of regulating the MedTech sector in India is the Central Drugs Standard Control Organization (CDSCO), operating under the purview of the Ministry of Health and Family Welfare. The CDSCO is responsible for overseeing the approval for import of all risk classes (A, B, C & D) and manufacturing of Class C & D devices in the country. It formulates and implements regulations to ensure the safety, efficacy, and quality of medical devices available in the Indian market.

The Medical Device Rules, 2017, serve as the cornerstone of the regulatory framework for the MedTech industry in India. These rules provide a comprehensive set of guidelines for the registration, classification, import, manufacturing, and distribution of medical devices. They define the regulatory pathways and requirements that MedTech companies must adhere to in order to bring their products to market. Medical devices in India are classified into four risk-based categories: Class A, B, C, and D. The classification is risk based classification and is determined based on the factors such as intended use, potential risk to patients, and mode of action. Class A includes low-risk devices such as tongue depressors and bandages, while Class D comprises high-risk devices like implantable devices and life-supporting equipment. Each class is subject to different regulatory requirements, with higher-risk classes necessitating more stringent scrutiny and documentation.

MedTech companies operating in India are required to obtain registration or licensing from the CDSCO for importing, manufacturing, distributing, or selling medical devices. The licensing process entails the submission of detailed technical documentation, testing reports, and evidence of compliance with quality management system (QMS) standards such as ISO 13485 or the Vth Schedule of MDR 2017. Additionally, manufacturers must provide evidence of conformity with relevant Indian standards and specifications. Compliance with QMS standards is a fundamental requirement for regulatory approval in India. Medical device manufacturers must establish and maintain a robust QMS that ensures the consistent quality, safety, and performance of their products. Certification to ISO 13485 though not mandatory as per MDR 2017, is an internationally recognized standard for QMS in the medical device industry, demonstrates adherence to best practices in design, manufacturing, and distribution processes.

The CDSCO regulates clinical investigations of medical devices conducted within India. MedTech companies seeking to conduct clinical trials must obtain approval from the Central Ethics Committee (CEC) and the Central Drugs Standard Control Organization-Technical Advisory Board (CDSCO-TAB). Clinical data generated from these trials are crucial for assessing the safety and efficacy of medical devices and are integral to the regulatory approval process. Ensuring the safety and performance of medical devices post-market is paramount to protecting public health. MedTech companies are required to establish robust post-market surveillance systems to monitor adverse events, track device performance, and implement corrective actions when necessary. Timely reporting of adverse events and continuous monitoring of device-related risks are essential components of post-market surveillance efforts.

Import and export of medical devices are subject to specific regulations outlined by the CDSCO and other relevant authorities. Importers must obtain necessary licenses and comply with labelling requirements, customs regulations, and import duties. Similarly, exporters must adhere to export control regulations and ensure compliance with destination country requirements.

The regulatory landscape for MedTech companies in India is dynamic and multifaceted, reflecting the diverse nature of the industry and the evolving healthcare needs of the population. Navigating this complex regulatory environment requires a thorough understanding of the applicable rules, standards, and procedures. By adhering to regulatory requirements, maintaining high standards of quality and safety, and embracing innovation, MedTech companies can contribute to advancing healthcare delivery and improving patient outcomes in India.

> **"The Medical Device Rules, 2017, serve as the cornerstone of the regulatory framework for the MedTech industry in India."**

Healthcare Plastic Waste Management Challenges & Opportunities : Case Study

Introduction

In 2020, over 32 billion pounds of healthcare plastics were produced globally, and is expected to grow to 48 billion pounds by 2025. This continued growth will bring with it increases in healthcare plastic waste.

Most of this hospital waste is being disposed of in landfills or is incinerated. However, 85% of the hospital waste generated is non-hazardous, meaning it is free from patient contact and contamination. This combined with the high-quality of the plastic waste results in strong potential for recycling.

The Healthcare Plastics Recycling Council (HPRC) undertook a qualitative study to understand the barriers that exist for recycling plastics within healthcare facilities today, focusing on hospitals in Europe. Four hospitals were selected to take part in the study. The hospitals were based in the Netherlands (Linz, Utrecht), UK (Northampton) and France (Santeon). They are all public hospitals, with capacity varying from 700 to 5000 beds. The majority of hospitals were recycling waste for approximately 2 years, along with one hospital that was only starting to implement a waste management programme.

Interviews with sustainability or waste leaders were conducted between September 2023 and April 2024. The interview process was conducted via a questionnaire with guided interviews afterwards, using predetermined questions. Responses were aggregated to the following categories:

- **Materials and Products**
- **Sorting**
- **Program Implementation**
- **End of Life**
- **Economics**

Insights

After completing the interviews, compiling the results, and analyzing the findings, summarized the key insights from each category below.

Materials s Products Healthcare plastics sent for recycling as shown in **Figure 1** include a range of items such as single-use plastics, shrink wrap, sterile barrier, general packaging materials and irrigation bottles.
However, the consistency of what is categorized as recyclable varies; for instance, irrigation bottles and plastic films are often disposed of as regular waste. Among these, recycling of sterilization wrap from the operating room is the most prevalent practice.

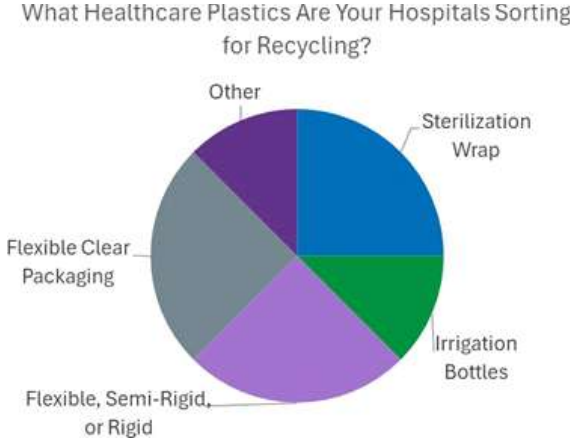

Figure 1: Types of Plastic Materials Being Collected in Hospitals

Sorting

Hospitals are making a concerted effort to encourage staff to sort materials for recycling. This sorting often occurs at the point of use, which involves some of the hospital's most costly staff. The feedback we received stated that this method is considered the most effective for waste separation. In most hospitals, waste segregation takes place primarily in the Operating Room, although some facilities have dedicated waste management rooms.

Primary challenges to effective sorting include physical time constraints and limited personnel availability.

Program Implementation

Starting off with pilot schemes paired with widespread training are the most common approaches to implementing recycling programs. In order to shift mindsets and behaviors towards waste separation, frequent information sharing and continued encouragement during meetings is essential. Successful implementation is particularly noticeable in certain hospital areas, with effective infrastructure and training in the Operating Room being critical. Anesthetists have been identified as key influencers in this process.

The main obstacles to maintaining successful programs include sustaining discipline and participation over time. Improvements such as clearer recycling labels, dedicated waste management spaces, and a new business model for handling small volumes of recyclable waste could enhance success. Hospital staff are mainly driven by the desire to make a positive environmental impact and compliance with regulations, rather than sustainability targets.

Hospitals that were interviewed are open to benchmarking against others, viewing it as a way to improve results through collaborative learning and information sharing.

End of Life

Recycling protocols stipulate that hazardous waste must be completely separated from recyclable waste streams, with no hazardous materials allowed in recyclables.

Barriers to recycling include the presence of multi-material items, low volumes of waste in some cases, complex compliance requirements, and perceptions by waste collection companies that all hospital waste is contaminated, leading to limited recycling services **(Figure 2).**

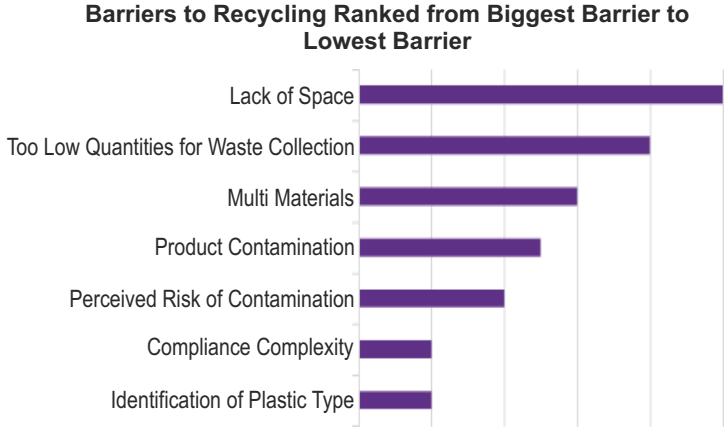

Figure 2: Barriers to Recycling Healthcare Plastics Ranked

Currently, decontamination of hazardous waste is outsourced by hospitals, as they lack in-house methods. However, advances are being explored, such as microwave heating for decontaminating waste to improve recycling rates. Some hospitals have found success recycled sterilization wrap collecting it with Greencycl to make CE certified product from it, signaling a shift from single-use plastics to reusables

Despite successes in recycling blue wrap and behavioral changes, hospitals have not seen notable improvements in the waste management stream.

Economics

The financial dynamics of healthcare plastic waste reveal that in 75% of cases, waste is either given away for free to recyclers or incurs a fee, raising questions about its financial value.

"As it stands today, the primary motivation to increase recycling of healthcare plastics is to make a positive impact, not financial gains."

-Clare Topping Head of Sustainability Northampton General Hospital The hospitals interviewed recycle between 50 and 200 tonnes of plastic waste annually, generating a modest income of €20,000 to €80,000.

Annually, over 900 tonnes of clinical waste and 550 tonnes of regular domestic waste are discarded by these hospitals. The calculation of recycling quantities is based on primary data, which includes universally available data and invoices from waste contractors.

Conclusion

All hospitals interviewed recognized the need to increase recycling and improve waste streams, driven by a strong purpose rather than economic incentives **(Figure 3).** There is a clear will and desire to do better. Implementing effective recycling programs involves change management, which requires discipline, training, and crucially, support from hospital management.

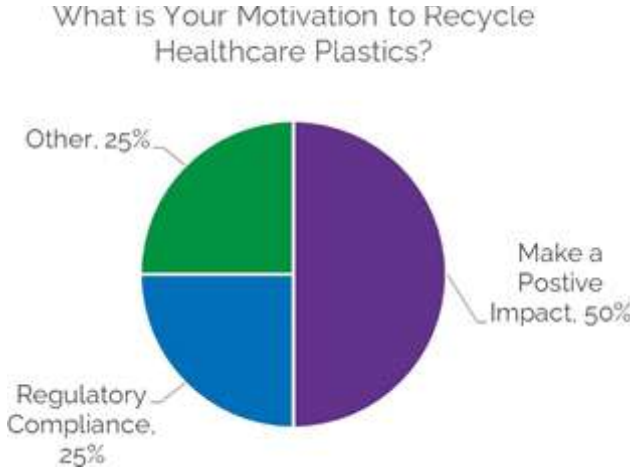

Figure 3: Motivations to Recycle Healthcare Plastics

Separation of waste, the first step in recycling, is occurring at the point of use. However, this often involves the most expensive medical staff and locations,

which are space, time and human resource constrained. Simplifying the process and identifying materials more clearly were highlighted as beneficial, along with providing increased space for separation and storage is as a key enabler. If recycling waste offered better financial value for hospitals, it could further help overcome some of these barriers.

The perceived risk and complexity associated with hazardous waste are believed to deter waste collection and recycling, even though such waste can be removed and is present at low levels. Education, proper separation, and in some cases, decontamination, are essential to addressing this issue.

This assessment identified high levels of awareness in hospitals and early progress in developing sustainable solutions. It also pinpointed several key areas requiring change to enable more widespread and effective recycling in hospitals.

HPRC extends its gratitude to the hospitals that contributed their insights.

ABOUT HPRC

HPRC is a private technical coalition of industry peers across healthcare, recycling, and waste management industries seeking to improve the recyclability of plastic products within healthcare. Made up of brand-leading and globally recognized members, HPRC explores ways to enhance the economics, efficiency, and ultimately the quality and quantity of healthcare plastics collected for recycling. HPRC is active across the United States and Europe working with key stakeholders, identifying opportunities for collaboration, and participating in industry events and forums.

Ref : https://www.3blmedia.com/news/european-hospitals-take-initiative-plastic-waste-new-hprc-case-study-explores-challenges-and

FAST FACTS

"U.S. healthcare sector is responsible for nearly 9% of the country's greenhouse gas emissions. Also, each day, a single patient can produce 30 pounds of medical waste including one-time use plastics. "

Argentina Medical Devices Market

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

Country Profile

The name Argentina comes from Argentum, the Latin word for silver.

Argentina is in the extreme south side of South America. Argentina covers most of the southern portion of South America and is the world's eighth-largest country in area. Argentina is larger than Mexico in size. The population of Argentina is 45.7 mn. Unlike many European economies, a fairly high percentage of the population is young. Argentina's national language is Spanish. However, Italian is also popular. (The readers will notice that except for Brazil, the rest of Latin America speaks Spanish.) More than 90 per cent of the people live in urban areas, with close to 30 % living in greater Buenos Aires alone. This high urbanization trend is also common in Latin America.

Argentina became independent in 1816 after three centuries of Spanish control. The country went to a military dictatorship in the 1970s. Argentina is a great source of valuable minerals (including Silver, Argentum). Also, Argentina is a major producer of livestock and cereals. The service industry makes up more than 60% of the GDP. Manufacturing makes up about 20% of total GDP. The national capital, Buenos Aires, is probably South America's most cosmopolitan and crowded city. It is compared with Paris or Rome for its architectural styles and lively nightlife. Argentina has one of the largest coastlines in South America and also, the Andean mountains.

Regulatory Framework and Product Classification

ANMAT (Administración Nacional de Medicamentos, Alimentos y Tecnología Médica) is the regulatory agency for Argentina. Regulatory classification for the devices is as below, which is in line with many other countries-

Class I: Low risk devices (Examples Simple surgical instruments, tongue depressors)

Class II: Low - Moderate risk devices (Examples Digestive catheters, infusion pumps, and powered wheelchairs)

Class III: Low - Moderate risk devices (Examples Dialyzers, and orthopaedic implants)

Class IV: High-risk devices (Example Coronary stent) IVDs (In-Vitro Diagnostics) are, again, classified into four classes-

Class A: Used for diagnosis of non-infectious or non- communicable diseases.

Class B: Used for diagnosis of infectious diseases except those belonging to Group C.

Class C: Used for diagnosis of sexually transmitted infectious diseases, or transmitted by blood or its derivatives, as well as for identification of blood groups.

Class D: Used for self-assessment

The prescribed procedure for registration of devices is fairly simple –

- Appointing a local authorized representative in Argentina
- Submitting all the details in the Declaration of Conformity
- Start loading files for the submission, all in PDF format and digitally signed by the Legal Representative and Technical Director

The processing time is about four months for Class I and II, and eight months for the higher classes. Once granted, a registration is valid for five years.

Readers may visit

https://www.imdrf.org/sites/default/files/2022-09/Argentina.pdf which has a small presentation uploaded by ANMAT in English giving a brief idea of their recent activities (though not related to the medical devices).

Argentina Highlights

- Heavy dependence on imports
- Very high healthcare spending by the country
- Easy regulatory regimen
- High future growth expectations

Argentina Medical Devices Market

Many versions float around the medical device segment size for Argentina. A reasonable average and logical number is 1.4 bn USD (and compare this with India's size, which is 11 bn with a population of 140 cr). The healthcare

budgets of Argentina are about 9 to 10 per cent of GDP, which is quite high comparatively. An important point is that 65-80 per cent of the total market size is catered by imported products, which is an opportunity. However, the regular trend of devaluation of the Argentine peso against the USD is a worry.

The healthcare system comprises three sub-segments namely, the public system, the system under social security, and the private market. The public system offers free healthcare to all citizens, and its funding is from the government. The Social Security sub-segment offers group health plans to workers and their families and is funded by money deposited by the workers. The private market attends to the higher-income patients and private insurance payers. The public hospitals make up more than 50% of the total hospitals. This is one of the largest in the region and has about 5 beds per 1,000 population, which is higher than many developed countries (Germany has 4.0 beds and the UK has 3.0). This explanation is needed to bring home the point that public tenders and government hospitals make the largest buyers of devices including equipment. As the readers know well, this segment is highly price-sensitive.

Opportunities and Challenges

Though a smaller market, overall high spending for healthcare by the country and high dependence on imports create a good opportunity. High demand and a simpler and faster regulatory approval timeline make Argentina a country worth exploring for the medical device business. The Argentina market is expected to grow at a CAGR of 12.4% from 2024 to 2030, which, again, is a positive. Wearables can be a good business avenue, as stated. Products from the US and Europe are regarded as very good, and the perception of India is not strong, unlike that in Brazil. This is a challenge. Devaluation and inflation are also possible issues.

DoP Releases Operational Guidelines For Strengthening Of Medical Device Industry Scheme

The Department of Pharmaceuticals (DoP) has released the operational guidelines for the newly announced central sector scheme for Strengthening of Medical Device Industry (SMDI), aiming at providing the much needed thrust to address the unmet needs of the medical devices industry in the next three years.

The highlights & background of the scheme as announced by DoP is as under :

Medical device is a sunrise industry in India, with double digit growth rate. Due to efforts of the government in the last decade in creating a suitable eco-system and incentivizing production of medical devices through PLI scheme, production of technology intensive medical devices such CT scan, MRI, C-arm etc. has started in India. However, the dependence on imports still continues to be about 70%.

Moreover, to deepen our manufacturing capability along the value chains of different segments of medical devices, it is essential to incentivize domestic manufacturing of key components/raw materials/accessories etc., along with Medical Devices under the list of medical devices for which exemption from the instructions of Department of Expenditure for Global Tender Enquiry are available owing to lack of domestic manufacturing to meet the requirement of procurement of central government hospitals, by providing support to industry in form of grant for marginal investment.

Another challenge faced by domestic medical device industry is high cost towards clinical investigations, which dissuades them from investing resources in R&D and manufacturing facilities, which can lead to newer product development, better safety and efficacy of devices, and enable access to markets abroad. As a nascent industry, the sector also requires support for awareness generation, knowledge sharing and promoting brand India. Availability of industry ready trained manpower is another constraint the industry faces.

To address these issues, after series of consultations and two Meditech Stackathons- a massive exercise involving about hundred manufacturers to identify industry issues and map value chains across eight medical device segments, the Department of Pharmaceuticals has formulated a scheme for strengthening of medical device industry. The scheme has five components, which are as follows –

(I) Common Facilities for Medical Device Clusters
(ii) Marginal Investment Scheme for Reducing Import Dependence
(iii) Capacity Building and Skill Development in Medical Device Sector
(iv) Medical Device Clinical Studies Support Scheme
(v) Medical Device Promotion Scheme

The scheme has an outlay of Rs. 500 crore and tenure of the Scheme is 3 years from Financial Year 2024-25 to FY 2026-27. In the next three years the scheme will provide the much needed thrust to address the unmet needs of the industry. The scheme is expected to have a multiplier effect in augmenting the domestic manufacturing capacities with significant reduction in imports, and promote - quality, human resource development, safety and efficacy of medical devices, and also enhance the depth of medical device value chains in the country.

Merger of existing Schemes

The following two sub-schemes were already approved in the Department of Pharmaceuticals (DoP) as part of scheme for Development of Pharmaceutical Industries:

(a) Assistance to Medical Device Clusters for Common Facilities
(b) Human Resource Development in Medical Device Sector 2

Now, the above schemes have become part of the single scheme – SMDI, with modification in the scheme guidelines and reduced financial outlay, as detailed in these guidelines.

(https://pharmaceuticals.gov.in/sites/default/files/Final%20guidelines%20for%20SMDI-8.11.2024.pdf)

Govt's New Medtech Scheme Will Help Domestic Players Give Up Pseudo Manufacturing & Restart Actual Production: AiMeD

• Medical devices exports growth exceeds imports, govt move will prove to be shot-in-the-arm

New Delhi, 11 Nov 2024: The Rs 500 crore MedTech scheme announced by the government on Friday will help the domestic players in the medical equipment industry to restart manufacturing and even become exporters. They had become mere traders and resorted to pseudo manufacturing due to the prevalent market compulsions and harsh realities.

The domestic medical devices manufacturers have hailed the move by the government and said that the new Medtech scheme will provide the much needed fillip to address the skill shortage problem in the industry and also strengthen the export opportunities for these equipment and devices from India.

"We are delighted with the announcement made by Minister for Chemicals and Fertilizers Mr JP Nadda for giving impetus to manufacturing of medical devices. The domestic players who had become traders and importers and shifted to pseudo manufacturing will now be again motivated to become actual manufacturers and produce complete products and their components in house," said Mr Rajiv Nath, Forum Coordinator, Aimed.

The Budgetary allocation announced by the government this scheme may seem small and humble but this is ground breaking strategy will have a multiplier impact and it is a clever leverage to move the Indian Elephant in the direction to achieve Prime Minister's vision to make India the leading hub of medical devices manufacturing globally, as announced in the national medical devices policy to 2023, added Mr Nath.

The current export of medical devices from India stands at USD 3.7 billion, making India the fourth largest market in Asia. The current market size is USD 14 billion but the Medtech scheme introduced by the government will help the Indian manufacturers

to seize the potential to achieve a market size of USD 20 billion by 2026-2027.

The Medtech scheme introduced by the government encompasses key aspects of manufacturing of medical devices like skill development, clinical study assistance, establishment of shared infrastructure and promotion of the industry at national and international stages.

Minister Nadda described the scheme as a transformative initiative that will benefit the industry while promoting India's journey toward self-reliance in the medical equipment domain.

Under the scheme, the government will offer financial support to medical device clusters to establish common infrastructure like R&D labs and design and testing centers. It will also strengthen the Medtech supply chain by encouraging local manufacturing of essential components.

The scheme also offers financial assistance to industry associations and export councils to organize events like conferences and exhibitions.

The domestic medical devices manufacturing industry can offer really cost-effective and innovative products for both domestic and overseas markets. The medical devices manufacturing industry now comprises a wide range of products like consumables, disposables and even high-end diagnostic and therapeutic devices. The key segments of the product portfolio of the domestic manufacturing industry includes diagnostic imaging, consumables, patient aids, dental products and orthopaedic implants.

The growth of exports of medical devices by India has started to supersede the growth of imports. The annual growth rate of exports of medical equipment and devices for the last three years stands at an impressive 13.8% while the yearly growth rate of imports has fallen to -2.08% in the same time period.

With this new Medtech Scheme, the domestic manufacturers can even achieve a market size of USD 50 billion by USD 50 billion by 2030.

'India Fourth Largest Medical Devices Market After Japan, China And South Korea': Union Minister Anupriya Patel

India's medical device sector is recognised as a sunrise sector due to its growth potential driven by rising healthcare needs, technological innovations, government support, and emerging market opportunities, the union minister said.

NEW DELHI: India is the fourth largest medical devices market in Asia after Japan, China, and South Korea and among the top 20 global medical devices markets in the world, said Union Minister of State of Health and Family Welfare Anupriya Patel on Thursday.

Speaking at the 21st Health Summit of the Confederation of Indian Industry (CII), she said the medical device sector in India is recognised as a sunrise sector because of its immense growth potential driven by the country's increasing healthcare needs, technological innovations, government support, and emerging market opportunities.

"AI innovation is crucial within healthcare to create new methods for facilitating and tackling healthcare challenges and discovering new opportunities," she said.

Addressing the plenary session on Charting India's MedTech Revolution: MedTech Expansion roadmap to 2047, Patel said that the size of the Indian medical devices sector is estimated to be around USD 14 billion and it is expected to grow to USD 30 Billion by 2030.

She stressed that the MedTech industry is not just a component of healthcare but is the catalyst that links patients, payors, providers, and regulators to create a stronger and more equitable healthcare system.

"It is this unique positioning of MedTech that holds the promise of revolutionizing healthcare delivery and outcomes, both in India and globally," she said.

She highlighted that the government is trying to strengthen the medical device ecosystem by focusing on boosting domestic manufacturing, promoting research, enhancing skill development, and increasing India's share in the global market.

"Key policy decisions include allowing 100 per cent FDI under the automatic route and the approval of the National Medical Device Policy, 2023, which addresses regulatory streamlining, infrastructure development, R&D, investment attraction, and human resource development. This includes the establishment of Centres of Excellence, courses at NIPERs, and initiatives to strengthen MedTech education," she said.

The minister also noted that the government has taken steps to boost exports and industry collaboration, with the creation of the Export Promotion Council for Medical Devices (EPCMD) and the reconstitution of the National Medical Devices Promotion Council (NMDPC).

"These bodies aim to facilitate medical device exports, resolve regulatory challenges, and enhance the Ease of Doing Business, further promoting India's position in the global medical device market," she said.

She also informed about the launch of the Scheme for Promotion of Medical Devices Parks with a Rs 400 crore outlay, providing Rs 100 crore each to Uttar Pradesh, Tamil Nadu, Madhya Pradesh, and Himachal Pradesh for infrastructure development.

Additionally, the Promotion of Research in Pharma-Medtech Sector (PRIP) and the Scheme for Strengthening the Medical Device Industry with Rs 500 crore funding aim to foster innovation, enhance manufacturing capabilities, support skill development, and promote industry growth.

These efforts align with the vision of Atmanirbhar Bharat, focusing on self-reliance, innovation, and global competitiveness in the MedTech industry, she said.

Underlining that a healthy population fuels productivity, drives economic growth, and ensures social justice, Union Health Secretary, Punya Salila Srivastava said that "healthcare is not

just a social imperative but an economic necessity."

She noted that India's healthcare agenda focuses on making healthcare affordable, accessible, and inclusive for every citizen and stressed that the healthcare sector is a critical component of India's vision to become a developed country by 2047.

"The private sector plays a key role in transforming healthcare, particularly in Tier-2 and Tier-3 cities, through value-based care models and technological innovations. Public-private partnerships, preventive healthcare, and a focus on expanding the healthcare workforce will be critical in achieving Universal Health Coverage and positioning India as a global leader," she said.

"The goal is to transform India into a global leader in healthcare delivery by 2047, aiming for a healthier, stronger, and prosperous India. The private sector's role in shaping India's healthcare future is both a responsibility and an opportunity. By embracing this vision, quality healthcare will be provided to every Indian, driving economic growth and job creation," the health secretary said.

https://www.newindianexpress.com/nation/2024/Dec/19/india-fourth-largest-medical-devices-market-after-japan-china-and-south-korea-union-minister-anupriya-patel

Technology Development Board
Department of Science & Technology
Government of India

सत्यमेव जयते

CALL FOR PROPOSAL

ADVANCING TECHNOLOGY & INNOVATION IN INDIAN MEDICAL DEVICES AND ALLIED SECTORS

TDB-DST invites proposals from Indian Companies for development and commercialization of Indian Medical Devices and related components.

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- AI-driven devices for lifestyle and chronic disease detection & monitoring
- Anesthetic & Cardio-Respiratory devices: Catheters & Advanced Monitoring Systems
- Renal Care innovations for kidney health

THERAPEUTIC & PROSTHETIC DEVICES

- Cancer Care: Advanced Radiotherapy solutions
- Cutting-edge implants: Prosthetic limbs, organs, hearing aids, and ophthalmic prosthetics (e.g., artificial cornea, eye sockets)
- Specialized devices like voice prostheses for improved quality of life

REGENERATIVE THERAPY DEVICES

- Revolutionary cellular & immunomodulation technologies
- Tissue engineering innovations: Laboratory-grown organs and tissues

MEDICAL EQUIPMENT (CLASSIFIED DEVICES)

- Covering Class A (low-risk) to Class D (high-risk) medical devices
- Aligned with Medical Devices Rules, 2017 and Central Drugs Standard Control Organization guidelines

KEY FEATURES

- Financial Assistance to Indian Companies for Technology Commercialization
- Evaluation on the basis of Scientific, Technological, Financial and Commercial Merit
- Funding shall be in the form of Loan, Equity and/or Grants.

WHO ARE ELIGIBLE?

- Indian companies (as per Companies Act,1956 /2013)
- Start-ups with Recognition Certificate from DPIIT

For more Details, Funding Guidelines & Proposal Submission – tdb.gov.in
For additional info, please contact: richa.panwar@tdb.gov.in

LAST DATE TO APPLY- 16TH FEBRUARY, 2025

SMC Medical Manufacturing Pvt Ltd Receives CII Industrial Innovation Award 2024

SMC Medical Manufacturing Pvt Ltd, a subsidiary of SMC Ltd, US, has been honoured with the prestigious CII Industrial Innovation Award 2024. Recognized as one of India's Top 75 Most Innovative Companies, the award was presented at the CII Industrial Innovation Awards Ceremony held in New Delhi on 13th December 2024.

The selection process was comprehensive and rigorous, evaluating the company's innovation culture, management practices, investments in R&D and measurable outcomes.

Established in 1895, the Confederation of Indian Industry (CII) is a prominent non-government, non-profit organization committed to promoting India's economic growth, competitiveness, and sustainability.

ABOUT SMC

SMC (headquartered in U.S.A.) offers design, development and manufacturing services for single use diagnostic, drug delivery and other medical devices. We have nine design and manufacturing facilities in U.S.A., U.K., Costa Rica and India. With 1 million square feet dedicated to medical manufacturing, SMC provides full services from initial concept through final packaged device including program management, design and development, validation, product manufacturing, clinical manufacturing, electronics integration, kitting and packing, sterilization management as well as global sourcing and supply chain management.

In 2016, SMC acquired Oval Medical Technologies, a cutting-edge parenteral technology company based in Cambridge U.K. And in 2024, SMC acquired a new facility in Concord, North Carolina, USA, to offer sterile fill-finish services.

ABOUT SMC INDIA

SMC's India manufacturing facility in Bangalore is ideally located for domestic, developing and mature markets. SMC India's capabilities include component design, device design rationalization, tool design and build, prototyping, injection molding, finished device manufacturing, assembly, kitting and packing, sterilization management as well as quality and regulatory services.

SMC India's value proposition is as follows:

- SMC owned and operated 35,000 sq. ft. manufacturing facility located at Bangalore
- ISO 13485 certified, US FDA registered, MedAccred certified, ISO 14001 certified, accredited by Japan Health Ministry and Korean ministry of food and drug safety.
- Mature global quality management system
- Best in class new product development, engineering, validation, automation and sterilization service
- Tool design and build, injection molding, device assembly, kitting and packaging
- Manufacturing environment: ISO Class 7 and Class 8 clean rooms, air-conditioned room and white room
- High skill low-cost manufacturing
- Global sourcing and supply chain management capability
- Exports to mature and emerging markets

FAST FACTS

Simple Ways To Streamline Medical Devices Manufacturing Processes

1. **Simplify and Standardize Workflows**
   Identify and eliminate unnecessary steps, and standardize processes to reduce variability and errors. Implement visual management systems to track production, quality, and inventory.
2. **Implement Automated Quality Control**
   Invest in automated inspection and testing technologies, such as machine vision, robotics, and sensors. Automated quality control helps detect defects early, reduces waste, and improves overall product quality.
3. **Optimize Supply Chain and Inventory Management**
   Implement just-in-time inventory management, and optimize supplier relationships to reduce lead times and costs. Use data analytics to forecast demand, track inventory levels, and identify areas for improvement.

India's Homegrown E-beam Technology Sterilizes 5 Million Medical Devices.

India achieved a major milestone on Monday when the electron beam (E-beam) radiation technology developed by a premier institute of the Department of Atomic Energy completed sterilisation of 50 lakh medical devices.

Dr Ajit Kumar Mohanty, Secretary, Department of Atomic Energy and Chairman, Atomic Energy Commission, witnessed this achievement at the electron beam facility adjacent to Choithram Mandi in Madhya Pradesh's Indore, an official of Raja Ramanna Centre for Advanced Technology (RR-CAT) of the department said.

This achievement has put India in the select group of countries that use state-of-the-art indigenous radiation technology on a large scale, he said.

To make the memory of this moment everlasting, RR-CAT Director Unmesh D Malshe presented a memento to Mohanty, the official added.

According to the official, the facility to sterilize medical devices in this unit started in October 2022 and so far 50 lakh medical devices of different companies have been sterilized in it. The AIC I-Hub, RRCAT's incubation centre, facilitates the provision of electron beam irradiation services to Indian industries at competitive prices when compared to conventional sterilization technology.

RRCAT's 10 MeV, 6 kW electron linear accelerator delivers precision-controlled irradiation doses ranging from a few Grays (Gy) (unit for measurement for absorbed radiation) to several Mega Grays (MGy) for a variety of applications, he said.

"Its versatility has enabled it to be used for commercial sterilization of medical devices, mutation breeding for improved crop varieties, colour modification of gemstones, creation of novel materials, modification of semiconductor properties, testing of ISRO components, and various other R&D applications for industries and academia," he informed.

Electron beam irradiation is gaining global recognition due to its eco-friendly, efficient, and secure nature, the official added.

This indigenously developed E-beam technology has the potential to position India as a global leader in medical device sterilization and other radiation-based applications, the official asserted. PTI

https://www.medicalbuyer.co.in/indias-homegrown-e-beam-technology-sterilizes-5-million-medical-devices/?utm_source=newsletter&utm_medium=email&utm_campaign=December1

New Material Designed For Medical Device Tubings Mimics The "Natural Behaviour Of Blood Vessels."

Researchers from the University of British Columbia (UBC) have developed what's being considered "a ground-breaking coating" that could make medical devices safer.

For millions of patients, this could mean reducing the risk of thrombosis (or blood clot formation) and dangerous bleeding, according to a UBC press release.

The new material, which is designed for tubing in various medical devices, mimics the "natural behaviour of blood vessels."

HIV-POSITIVE TRANSPLANTS NOW PERMITTED FOR LIVERS AND KIDNEYS

This allows for the safer use of blood-contacting devices, such as catheters, stents, blood-oxygenation machines and dialysis machines, the release stated.

The coating could prove especially helpful in cases where blood clots are a bigger concern.

Blood thinners are usually prescribed in high doses to prevent clots in machine users, but this can increase the risk of dangerous bleeding, according to the university.

"By designing a coating that mimics the body's natural approach to preventing clots, we've created a solution that could dramatically reduce the need for risky blood thinners before and after patients use these devices," the study author wrote in an email.

Dr Jayachandran Kizhakkedathu, professor of pathology and laboratory medicine at the University of British Columbia, shared with Fox News Digital that this discovery could be a "transformative step in the development of safer medical devices."

LEUKEMIA PATIENT RECEIVES FIRST-EVER BONE MARROW TRANSPLANT FROM DECEASED ORGAN DONOR

The research – which was published in the journal Nature Materials – confirmed that mimicking the body's own mechanisms, instead of repelling blood components, is "key to truly biocompatible device design," according to Kizhakkedathu.

Kizhakkedathu mentioned that there has been a "steady rise" in the use of blood-contacting devices over the past few decades, but noted that this has been limited by blood clot risk, which can be "detrimental to the health of patients."

"Since almost all synthetic materials activate blood upon contact, this is an enormous challenge," he went on.

Developing materials that can "inherently avoid coagulation activation" has been a long-term goal, according to Kizhakkedathu.

"There are no effective methods to prevent thrombosis and inflammation in devices, and little progress has been made over several decades in spite of significant efforts," he went on.

"However, our chemistry design allowed us to develop a non-toxic polycationic molecule and develop a surface that prevents blood clotting."

Kizhakkedathu mentioned that this development is still in the early stages and needs further research in more challenging cases and among other animal models.

"We hope this approach will also inspire and benefit other scientists in this field," he told Fox News Digital.

"For the general public, there is increased hope to create highly improved medical devices where thrombosis concern is no more."

https://www.wccsradio.com/rss/medical-devices-could-become-safer-with-this-new-breakthrough-experts-say/ , Nov 30, 2024 | 9:00 AM

Advanced Solution for Medical Polymers Treatment

(Courtesy: Bry-Air (Asia) Pvt. Ltd.)

Medical polymers such as polyethylene (PE), polypropylene (PP), polycarbonate (PC), polyvinyl chloride (PVC), polystyrene (PS), and other high-performance resins are the backbone of the healthcare industry. They are essential for producing various equipment and devices, including syringes, catheters, tubing, IV bags, and blood bags.

However, these polymers, valued for their excellent mechanical properties, are inherently hygroscopic, meaning they naturally absorb moisture from the atmosphere. Excessive moisture can lead to significant processing issues, such as

- Degradation of Mechanical Properties
- Undesired Hydrolysis
- Compromised Sterility

To effectively address these challenges, Bry-Air presents the Nano Dryer—a solution that offers unparalleled control over moisture content, ensuring the integrity of your materials.

Key Features:

High Precision Moisture Control: Maintains optimal moisture levels to prevent degradation.

Waterless Design: Efficient operation without the need for water.

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Ideal for Low Throughput: Perfect for medical plastics drying systems with a handling capacity of 6-12 kg/hr.

For more information about the Nano Dryer,
please contact our Airgineers® or write to us at bryairmarketing@pahwa.com.

Lee Pochter Appointed CEO of Qosina as Scott Herskovitz Becomes President and Chairperson of the Board

Lee Pochter
Executive Vice President

Scott Herskovitz,
formerly President, CEO and Chairperson of the Board

Ronkonkoma, NY – Qosina, a global leader in the distribution of medical components, is pleased to announce key leadership changes that will propel the company forward into its next chapter of growth and innovation.

Executive Vice President Lee Pochter has been appointed Chief Executive Officer. With a proven track record in driving strategic initiatives and fostering collaboration across all departments, Pochter is well-equipped to lead Qosina into a new era of growth.

“Lee has been an integral part of the Qosina team and has consistently demonstrated exceptional leadership, a deep understanding of our values and a commitment to our mission,” said Scott Herskovitz, President and Chairperson of the Board.

“I am truly honored to step into the role of CEO at Qosina,” said Lee Pochter. “Qosina’s unwavering commitment to innovation, quality and customer success inspires me every day. I am excited to lead our talented team as we embark on this next chapter, building on the strong foundation laid by Scott Herskovitz, and continuing to drive growth, excellence and meaningful impact for our customers and partners worldwide.”

Scott Herskovitz, formerly President, CEO and Chairperson of the Board, has transitioned into the role of President and Chairperson of the Board. In this new capacity, Herskovitz will provide leadership and guidance while focusing on advancing Qosina's strategic goals. As President, Herskovitz will engage with customers, partners and stakeholders, ensuring the company’s ongoing alignment with industry trends and fostering business development opportunities. His wealth of industry knowledge and relationships will continue to be instrumental as Qosina strengthens its position in the market.

About Qosina

Since 1980, 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. With offices in the United States and Europe, Qosina offers global reach with localized service. 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 at every step of the design process.

Rachelle Morrow
Senior Manager, Communications
Qosina Corp. QOSMEDIX
Email: rmorrow@qosina.com
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Medicall Kolkata 2025: East India's Largest & No.1 Medical Equipment Exhibition

Medicall Kolkata, India – South Asia's largest and most anticipated medical equipment and hospital needs expo, is set to make its grand return to Kolkata in 2025. Scheduled to take place from 15th Feb 2025 to 17th Feb 2025 at Hall B Biswa Bangla Mela Prangan, this 40th edition of Medicall promises an unparalleled showcase of innovation, technology, and networking opportunities for healthcare professionals, manufacturers, distributors, and other key stakeholders.

With its 2024 edition receiving record-breaking attendance, Medicall Kolkata 2025 is poised to surpass expectations. The event will host over 350+ exhibitors, including leading global medical device manufacturers, start-ups, and local innovators, across a sprawling exhibition space. Attendees will have the opportunity to explore cutting-edge medical technologies, hospital equipment, surgical devices, diagnostic solutions, and much more.

What to Expect at Medicall Kolkata 2025:

- **Exhibitions and Product Launches:** Discover the latest in healthcare innovation from world-class exhibitors.
- **Expert-Led Conferences:** Engage in thought-provoking discussions with industry leaders on the future of healthcare.
- **Networking Opportunities:** Connect with professionals from across the medical ecosystem, from hospital administrators to manufacturers.

Medicall Kolkata 2025 will also emphasize **sustainability and digital transformation in healthcare,** aligning with the evolving demands of the industry. A special focus on **omnichannel marketing** will provide participants with insights into bridging traditional and digital approaches in a post-pandemic world.

Dr. S. Manivannan, Founder & CEO of Medicall, stated, "Our mission is to bring the best of global healthcare innovation to the Indian market, empowering professionals with the tools and knowledge they need to drive excellence in patient care. Medicall Kolkata 2025 is more than an expo – it's a catalyst for progress in the healthcare industry."

Registrations for visitors are now open.
For more details, visit www.medicall.in or contact us at +91-7305 780 780.

About Medicall

Medicall, established in 2006, is South Asia's premier platform for medical professionals and businesses to explore the latest advancements in healthcare. With editions in multiple cities, it serves as a vital hub for networking, learning, and driving innovation in the medical industry.

Join us at Medicall Kolkata 2025 – where healthcare meets innovation!

Upcoming Editions

41th Edition / Hyderabad / 5, 6 & 7 April 2025

42nd Edition / Chennai / 25, 26 & 27 July 2025

43rd Edition / Delhi / 19, 20 & 21 September 2025

44th Edition / Mumbai / 12, 13 & 14 December 2025

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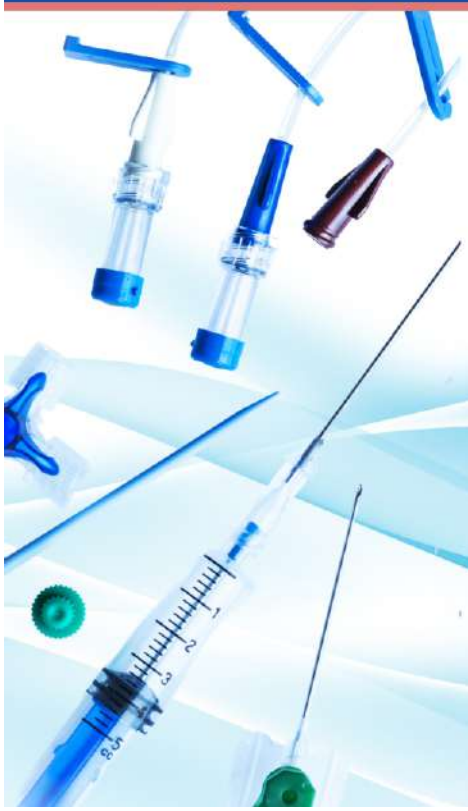

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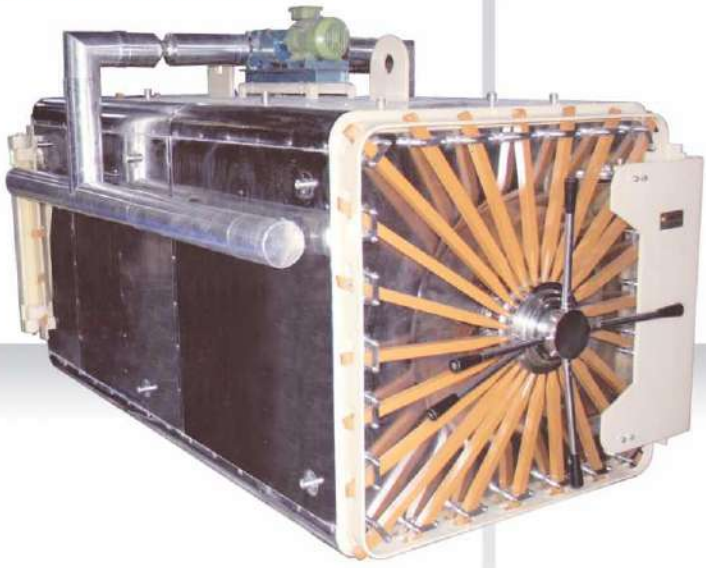

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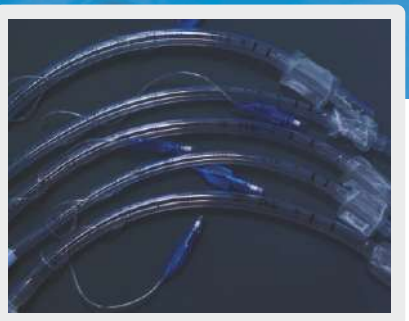

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