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- Material Mediated Pyrogen Test (ISO 10093-11)
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- Chronic Toxicity Test (ISO 10993-11)
- Implantation Test (IM/SC/ Intraocular/ Intra-biliary / Intra- arterial) (ISO 10993-6)
- Genotoxicity Tests (AMES, CHA, MNT) (ISO 10993-3 & ISO 10993-33)
- Hemocompatibility Tests (ISO 10993-4)
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- In-vitro Skin Sensitization Test (ISO 10993-10)
- Mucosal Membrane Irritation Test (Oral, Ocular, Penile, Vaginal & Rectal) (ISO 10993-11)
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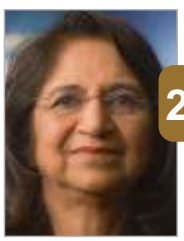

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- **Markets :** Go to Market Strategies for Medical Device Start-ups and Entrepreneurs in India (March - April 2021)
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  - Kamalnain Kurra - Director – Innovative Performance Plastics
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- **Cover Story :** Significant Contribution by Polymer Based Disposables & Consumables In Medical Devices for IVD / Diagnostics Sector (May – June 2021)

Did You Know ?

About Evaluating Microbial Barrier Qualities of Medical Device Packaging

Medical device packaging requirements include all aspects of device packaging, including labelling, sterilization, and package materials. Microbial challenge testing plays a crucial role in the assessment of medical devices and pharmaceutical packaging. Its primary objective is to determine the packaging's ability to prevent the entry of microorganisms, thereby maintaining the sterility and integrity of the products throughout their lifecycle.

ASTM F1608-16 "Standard Test Method for Microbial Grade of Porous Encasement Materials (Exposure Chamber Method) " is used to determine the passage of airborne bacteria through porous materials intended to Encasement sterile medical apparatus. This test method is designed to test materials under test conditions that result in detectable passage of bacterial spores.

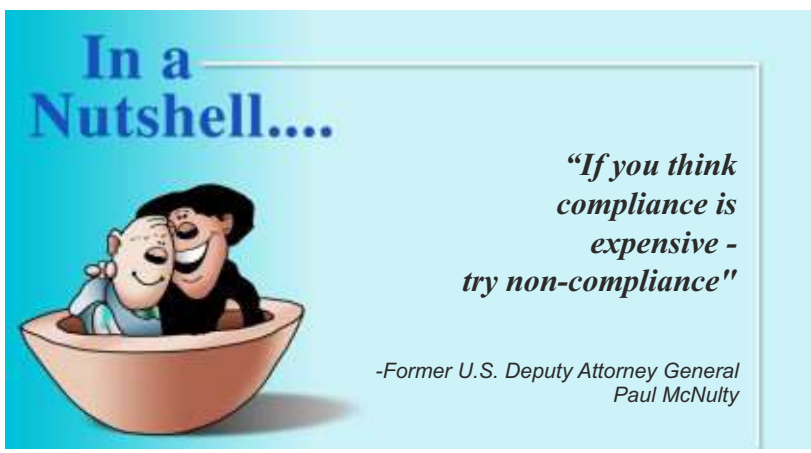
Maintenance of sterility in a specific packaging application depends on many factors, including but not limited to the following:

1. Bacterial challenges (number and type of microorganisms) encountered by the packaging during distribution and use. This may be affected by factors such as shipping method, expected shelf life, geographic location and storage conditions.
2. Packaging design, including factors such as: adhesion between materials, presence of secondary and tertiary packaging, and the nature of the equipment within the package.
3 Rate and volume exchange of air encountered in porous packaging during distribution and storage. This can be affected by factors including the amount of free air within the package and pressure changes due to transportation, handling, weather or mechanical influences such as room door closures and HVAC systems.
4. Under different airflow conditions, the microstructure of porous materials will affect the relative ability to adsorb or retain microorganisms or both.

The ASTM F1608 method was designed to compare and rank materials. To detect differences in barrier performance, a high flow rate was included to create ingress through materials not seen under real world conditions. Any spores that penetrate the material are captured on a filter and enumerated. The log reduction value (LRV) is calculated by comparing the log of the positive control (no material) to the log of the test result.

One source of published data on LRV values shows that medical grade papers typically demonstrate 1-3 LRV, whereas high-density polyethylene options normally fall between 4-6 LRV

(https://www.packagingdigest.com/medical-packaging/what-is-the-minimum-acceptable-lrv-for-medical-packaging-36124)



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From the Editor's Desk

Medical Device Packaging

It is undoubtedly clear now that packaging for a medical device is almost as important as the device itself. It plays a key role in safely delivering specialized treatment to patients. Most single use, sterilized medical devices can be opened with a high degree of confidence that it has remained sterile throughout storage, handling and transportation.

Regulatory authorities also recognize the critical nature of sterile barrier or primary package by considering them components or accessories to the medical device. Some of the important aspects regarding medical device packaging highlighted under cover story in this issue include:

- Development and Manufacturing of Primary Packaging For Medical Devices
- Innovations In Medical Device Packaging
- Thermoforming Automation for Medical Packaging

One of the important aspects is about evaluating microbial qualities of Medical Device Packaging. The "Did You Know" column discusses various factors responsible for maintaining the sterility.

One more article under "Global Trends "describes how **antimicrobial Packaging** is transforming the healthcare industry.

Circular Economy

The International Federation of Pharmaceutical Manufacturers And Associations (IFPMA) have commitment to create globally harmonized plastic regulations. They believe that these regulations are important for driving innovative changes while also ensuring that plastic materials and components are safe and effective for medical applications. The Global Trends Column discusses various case studies showing how some leading pharma / medical product companies are proactively addressing its environmental footprint by reducing plastic waste and are working towards circular economy.

A very well researched article by Mr Falgun Jani, Business Head, India Region, Freudenberg Medical highlights, **"Recent Advances In Medical Plastics"** including introduction to new application areas as well as future market potential.

SPE INDIA MEDICAL PLASTICS DIVISION COLLABORATES WITH AMTZ.

As mentioned in our last issue, SPE INDIA MEDICAL PLASTICS DIVISION was virtually inaugurated by Mr Conor Carlin SPE President 2024 during his visit to India recently. **Being one of the pioneer and the largest MedTech Zone in India with a cluster of 120 companies executing over 600 Projects and hundreds of Medical Devices being produced at one place , SPE INDIA has decided to collaborate with AMTZ** and a formal inauguration of a centre will be inaugurated shortly. Mr Santosh Kumar Balivada , AMTZ Co-ordinator for SPE INDIA MEDICAL PLASTICS DIVISION & CEO , Additive Manufacturing at AMTZ has in his article detailed various production processes for manufacturing of Medical Plastic Components being carried out at AMTZ.

"Technology" column introduces new materials including innovation regarding "Nano Composite Dental Material" by a US based scientist of Indian Origin, Ms Sumitra Mitra". It also gives details about tie up between IIT Roorkee & UnivLabs for commercialising technology related to Ureteral Stents as well as introduces a new material, Polylactic Acid (PLA) biopolymer.

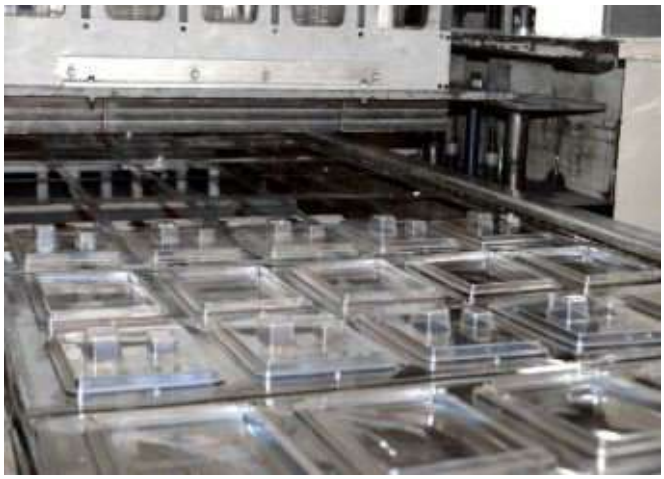
This issue also covers columns including Government, Regulatory & Industry News, Global Markets, Product Gallery , Events & More.

D L Pandya

Development and Manufacturing of Primary Packaging and Medical Devices

Packaging plays a critical part in the pharmaceuticals and medical devices industries and is developed with its own set of security standards for the safety of consumers.

The conceptualisation, development and manufacturing of primary packaging in the pharmaceutical industry require a meticulous and multi-disciplinary approach to ensure that the products meet the highest standards of safety and efficacy.



The role of primary packaging has extended beyond the primary objectives of sterility, physical and chemical protection, and security. The packaging should also offer increased ergonomics to patients and medical personnel, such as ease of extraction of the product from the packaging and directing the user with specific marking and sequence to identify and use multi-component sets.

Explore the top companies in the development and manufacturing of primary packaging and medical devices

Pharmaceutical Technology has listed some of the leading companies in the development and manufacturing of primary packaging for pharmaceuticals and medical devices based on its intel, insights, and decades of experience in the sector.

The list includes companies that offer various solutions and services, including but not limited to primary packaging design and optimisation for pharmaceuticals and medical devices, production process development, customised medical devices development, packaging process validation, sterile barrier packaging, accessories assembly, sterilisation, test stripes packaging, security and connectivity, such as traceability and anticounterfeit, child resistant, tamper evidence, as well as smart packaging solutions, such as near-field communication (NFC) label application, hidden watermarks and augmented reality features.

The list also contains companies providing regulatory services, validations, package design verification testing, quality and microbial testing as well as different products, such as sterile barrier pouches and rigid trays for sterile implants, blister packages, strip packages, vials, ampoules, caps, bottles, desiccants and more.

The information contained within the download document is intended for packaging executives, packaging engineers, medical device product managers, decontamination technicians, packaging technologists, process scientists, plant operators, regulatory experts, quality assurance personnel and any other individual involved in the development and manufacturing for primary packaging and medical devices.

The document contains detailed information on the providers and their product offerings, alongside contact details to aid your purchasing or hiring decision.

Primary packaging materials for pharmaceuticals

Pharmaceutical primary packaging materials are used for a wide range of products, including oral solid dose forms such as tablets and capsules, parenteral products such as injections and infusions, topical products such as creams and ointments, and inhalation products such as sprays and powders. The choice of the primary packaging material for pharmaceuticals is influenced by factors such as the product's physicochemical properties, stability, route of administration, and regulatory requirements.

With constantly evolving primary packaging pharmaceutical products are being offered with improved safety, efficacy, and convenience to patients and healthcare professionals. Pre-filled syringes, for example, offer numerous advantages over traditional vials and ampoules, while the use of advanced materials, such as cyclic olefin copolymer (COC), for primary packaging provides superior barrier properties and chemical resistance compared to traditional materials.

Technological advancements in the primary packaging of medical devices

The use of the Internet of Things (IoT), such as integrating radiofrequency identification (RFID) in packagings such as prefilled syringes, growth in the implantable device market, and improved efforts for developing counterfeit prevention mechanisms are driving the growth of the medical device packaging market. Furthermore, the rising demand for sustainable packaging solutions is gradually opening a new avenue in the primary packaging market.

Companies are continuously evolving to develop more intelligent and interactive packaging for pharmaceuticals and medical devices, which can effectively communicate between providers and consumers by tracking the package, recording the dosing activity, and proving the prescription information of a patient.

Role of regulatory compliance

Primary packaging can influence the quality, safety, compatibility, traceability and activity of a product, accentuating the role of regulatory affairs, which not only advises on the regulations but also understands and helps in implementing continuous updates during the development of the product.

The primary packaging is subject to stringent regulations, including the EU Medical Device Regulation (MDR), US Food and Drug Administration (FDA) regulations and other regulatory requirements, in different countries.

Regulatory experts help packaging companies in procedural compliance, translating regulatory requirements into actionable items and balancing compliance within the regulatory timeline, failure to which can result in severe consequences.

https://www.pharmaceutical-technology.com/buyers-guide/primary-packaging-medical-devices/

Innovations in Medical Device Packaging: Meeting Industry Demands

Introduction: Top Medical Device Packaging Trends

Medical device packaging is a critical component of the healthcare industry, providing protection, sterility, and information for a wide range of medical devices. With advancements in technology and increasing demands for safety and efficiency, the landscape of medical device packaging is constantly evolving. In this blog, we will explore seven key trends shaping the Medical Device Packaging Market.

1. Sustainable Packaging Solutions

One of the most significant trends in the Medical Device Packaging Market is the shift towards sustainability. As environmental consciousness grows, manufacturers are seeking sustainable materials and designs. Biodegradable plastics, recyclable paper-based materials, and compostable options are becoming more prevalent. Companies are also exploring ways to reduce packaging waste, such as minimizing unnecessary materials and using eco-friendly inks and adhesives.

2. Innovative Smart Packaging

Smart packaging technologies are revolutionizing medical device packaging. RFID tags, NFC, and QR codes are being integrated into packaging to provide real-time tracking and monitoring. This allows healthcare providers to easily access information like expiration dates, batch numbers, and usage instructions. Smart packaging enhances supply chain visibility, improves inventory management, and ensures regulatory compliance.

3. Customization for Diverse Devices

The trend towards customization is growing in the Medical Device Packaging Market. Medical devices come in various shapes, sizes, and specifications, requiring tailored packaging solutions. Companies are offering customizable packaging options to meet the specific needs of different devices. This includes packaging that accommodates different sterilization methods, provides protection for delicate devices, and meets the branding and labeling requirements of manufacturers.

4. Enhanced Safety Features

Ensuring the safety and sterility of medical devices is paramount, and packaging plays a crucial role. Advanced packaging materials with barrier properties protect devices from contamination and external factors. Tamper-evident seals and indicators are being integrated to provide visual assurance of product integrity. Additionally, packaging is designed to withstand the rigors of transportation and storage, maintaining the quality of devices until they reach the end-user.

5. Regulatory Compliance and Quality Standards

There are stringent quality standards and regulations in place, and the market for medical device packaging is exceptionally regulated. Manufacturers of packaging are required to comply with a variety of regulatory criteria, including FDA guidelines, ISO standards, and others. In order to guarantee compliance and ensure that safety and performance standards are met, quality control procedures, which may include testing and validation, are taken into action. Compliance with regulations not only guarantees the safety of the product but also contributes to the development of trust with both patients and healthcare providers.

6. Innovative Materials and Technologies

In the field of medical device packaging, innovation is being driven by developments in both materials or technologies. These antimicrobial coatings are being utilized to prevent the growth of bacteria, which is necessary for maintaining the sterility of the device. The shelf life of a product can be extended by using barrier films and foils, which protect against moisture and oxygen. Static charges, which could potentially cause damage to sensitive electrical devices, are prevented using anti-static materials. Not only do these advances improve the protection of devices, but they also result in an improved user experience and increased reliability.

7. Global Market Expansion

The Medical Device Packaging Market is experiencing significant growth and expansion globally. Emerging markets in Asia-Pacific and Latin America are witnessing increased demand for medical devices. This expansion presents opportunities for packaging companies to enter new markets and adapt to local regulations and preferences. Collaborations between packaging manufacturers and medical device companies are also on the rise, leading to the development of tailored packaging solutions for specific market needs.

https://www.verifiedmarketreports.com/blog/top-7-trends-in-medical-device-packaging/

Medical Packaging And Thermoforming Automation

Automation of the thermoforming process has been embraced in the medical packaging industry quicker than in other markets.

Originally driven by stringent quality requirements and the need for high levels of repeatability, automation has brought other benefits to medical packaging producers, including facilitating higher and more predictable throughput and addressing the challenges of attracting, training, and retaining a quality manufacturing workforce.

What's different about medical packaging?

Thermoformed medical packaging is designed to protect items ranging from implantable medical devices to surgical instruments. The selection of materials and the forming and sealing processes ensure the integrity of the sterile barrier system is maintained during shipping and handling until the product is opened.

Packaging must protect products from damage during shipping by securely holding each item in place and separating multiple items packaged together from damaging each other. For sharp objects, such as needles, screws, and drills, the packaging must protect the safety of the people handling the package.

Material selection

Polyethylene terephthalate glycol modified (PETG) and high-impact polystyrene (HIPS) are often selected for medical packaging applications. PETG is created by adding a glycol modifier to PET making it slightly softer for tighter seals and more suitable for withstanding high-temperature sterilization processes. HIPS plastics are impact-resistant and clear and have hygienic qualities.

Strong flange, complex geometries

The entire package must withstand temperature and pressure extremes of the sterilization process. The flange must have the thickness, rigidity, and smooth surface to accept and maintain a hermetic seal to the Tyvek lid, and the sidewalls must have the strength and thickness to prevent cracking and leakage during transport.

The most challenging aspect of medical packaging design is often isolating individual items into separate compartments and locking them in place. When properly designed and manufactured, undercuts allow each part to be snapped into place and held securely.

Elimination of airborne particulates

Most medical packaging applications call for enclosing the thermoforming machinery in a protective enclosure to minimize exposure to airborne particulates that can cause gaps during the hermetic sealing process. It's imperative to eliminate static that can attract particulates and ensure the cutting process doesn't generate particulates that can migrate to the product.

Isolating the system from ambient air and temperatures that cause fluctuations in the heating of materials and in the air pressure of pneumatic components is also important.

Increasing automation

The special requirements for medical packaging have led to the wide-scale adoption of form/cut/stack thermoforming systems. Simpler, less costly contact heat systems are suitable for a small fraction of medical packaging applications because they lack plug assist capabilities required for complex geometries and higher clamping forces that form/cut/stack systems offer. Contact heat systems are primarily used for simple package designs and low production volumes.

Form/cut/stack systems are usually enclosed, protecting the process and product from airborne particulates and ambient temperature and humidity. They can be more fully automated and therefore more precisely controlled, especially machines with 100% servo motors and drives.

Investment in automation offers advantages in medical packaging manufacturing. More precision and control results in higher repeatability, which means higher quality products, fewer defects, and less waste. The process improvements achieve faster cycle times and predictable output, for higher throughput and scalability.

Precise control and repeatability are critical to the calibration and production consistency required by standards and government regulations for medical packaging, such as ISO 11607:2019 and Title 21 CFR Part 11. Automation may also include vision systems and other inspection technology that provide automatic, continuous real-time quality control.

Workforce management

Medical packaging manufacturing faces the same workforce challenges as all industries. The operation of earlier generations of thermoforming equipment was often known as more of an art than a science, with operations acquiring a feel for what works after decades of experience. Veterans of the industry are moving on to other roles or retiring, and it's difficult to transfer these skills to new equipment operators, especially when employee turnover rates are high.

Ease of operation

Automated systems are less labor-intensive because instead of requiring one or more operators per production line, a single operator can cover multiple lines. This requires machines to autonomously perform forming, cutting, and stacking processes with little or no hands-on engagement by the operator. For high volume production, robotics is employed to automatically perform downstream packaging and palletizing functions.

The procedures for changing tooling between SKUs and replacing roll stock also need to minimize human error and effort. Right tooling needs to be installed in exactly the right way for every production run, and roll stock can weigh up to 1,500 lb. Thermoforming equipment should be designed with procedures and tools for streamlining these processes and preventing errors with ergonomic aids for lifting and correctly positioning heavy objects.

Intuitive HMI

The human-machine interface (HMI) must be designed to be easy-to-learn for new employees while also being efficient during production every day. The latest HMI systems employ large high-resolution displays that support multitouch gestures, taking advantage of skills new employees universally bring with their years of smartphone experience. Like smartphone apps, new interfaces should require little training and no paper documentation.

Looking forward

The whole concept of a form/cut/stack thermoforming machine is integrating and automating multiple functions in a single system. Medical packaging manufacturers have been at forefront of trend toward automation, initially driven by the need for high quality, repeatability, and traceability. Automation also increases scalability and throughput. Third driver of automation is need to address labor shortages and high turnover by making processes more productive, less labor-intensive, and easier to learn.

https://www.todaysmedicaldevelopments.com/news/automation-thermoforming-medical-packaging/

SPE INDIA Medical Plastics Division

AMTZ Collaborates With SPE INDIA Medical Plastics Division

Santosh Kumar Balivada,
AMTZ Co-ordinator for SPE INDIA
MEDICAL PLASTICS DIVISION
& CEO, Additive Manufacturing, AMTZ

SPE INDIA MEDICAL PLASTICS DIVISION was virtually inaugurated by Mr. Conor Carlin SPE President 2024 during the SPE INDIA board meeting held in Mumbai on March 12, 2024. An Off-line inauguration of SPE INDIA MEDICAL PLASTICS DIVISION will be shortly done at Andhra Medical Technology Zone (AMTZ), Visakhapatnam.

The board meeting also selected Mr. D. L. Pandya as the Vice President, Medical Plastics Division, SPE India

This initiative is for the benefit of Indian Medical Device Industry as well as Plastic Industry Professionals.

About Society Of Plastic Engineers

84 Countries

60,000+ stakeholders

We unite plastics professionals

SPE was founded in 1942 as the Society of Plastics Engineers. In 2018, SPE introduced the tagline "Inspiring Plastics Professionals" to encompass all plastics professionals no matter their role in the industry.

84 countries and 60,000+ stakeholders strong, we unite plastics professionals worldwide—helping them succeed and strengthening their skills through networking, events, training, and knowledge sharing.

AMTZ is known globally as the largest premier medical technology park equipped with the world class scientific laboratories and state-of-the-art assembly lines for large scale production. With a cluster of more than 120 companies executing over 600 projects, AMTZ has built and demonstrated, a sustainable capacity of indigenous manufacturing in the most needed and ever expanding landscape of modern healthcare. Enriching through its array of shared facilities for Rapid prototyping, Electromagnetic Compatibility Testing to Gamma Sterilisation and Superconducting Magnets, AMTZ has harnessed the power of an integrated eco-system to be exemplified as the most techno-commercial viable set-up for national and international investors.

AMTZ is the only place in the world to have WTC and WHO Centres beside each other in one campus.

Of the hundreds of Medical Devices produced in AMTZ, plastic engineering and design plays a major role in all of them. The strength of regulatory teams and testing facilities at AMTZ contribute to successful innovations translating to market.

Plastic Production & Testing at AMTZ

- **Production Processes**

  Extrusion-plastic tubing weather stripping, and cable insulation.

  Injection Molding- Automotive parts – dashboards, bumpers, grilles. Electronic components-electrical -connectors, enclosures, protective sleeving. Medical devices – syringes, valves, dishes.

  Blow Molding- for manufacturing bottles, containers, and other hollow objects.

  3DPrinting (Additive Manufacturing)-Ideal for prototyping, custom parts, and complex geometries that are difficult to produce with traditional methods.

- **Testing Laboratories**
  1. Mechanical testing - Tensile , Impact & Hardness
  2. Chemical & Thermal Testing -Chemical Resistance Testing, Spectrometric & Calorimetric Analysis

Quality Assurance & Regulatory at AMTZ

- ISO 13485 and ISO 9001 Certified facilities and Centers

No matter where you work in the plastics industry value chain-whether you're a scientist, engineer, technical personnel or a senior executive-nor what your background is, education, gender, culture or age-we are here to serve you.

About SPE Medical Plastics Division

Innovations in medical plastics and associated applications are rapidly advancing in exciting ways. Concurrently, the medical device and healthcare industries face several new and evolving challenges related to materials, regulatory requirements, product design, and materials characterization and validation in order to ensure better outcomes for patients while being mindful of plastic wastes in the environment and focusing efforts on sustainability.

The Medical Plastics Division (MPD) exists to encouragethe Interchange of technical and regulatory information on the polymer materials/components used in medical devices and in device containers among the scientists and engineers who are working in medical device and related industries.

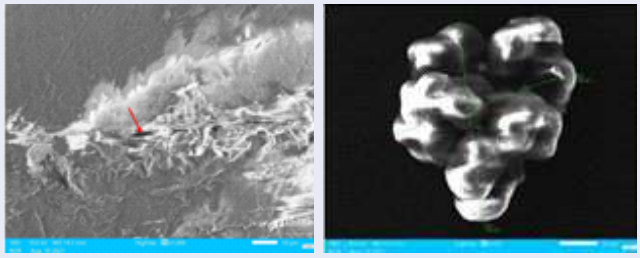
With over several hundred webinars, newsletters and conferences arranged every year, MPD allows opportunity to establish deep connections within the plastics community.

- **Biomaterial Characterisation**
  Biocompatibility Testing - As per ISO 10993 part 1-23 are used to assess the compatibility of plastic materials with biological tissues. This is especially important for medical devices, implants, and any plastic product that will be in contact with the human body.
- **Sterilization Facilities**
  Ethylene Oxide (EtO) Sterilization: Uses ethylene oxide gas to sterilize at lower temperatures, suitable for heat-sensitive plastic materials.
  Applications: Ideal for medical devices, electronics, and components with complex geometries.
  Gamma Radiation: Uses high-energy gamma rays to break down microbial DNA, effectively sterilizing the material.
  Applications: Widely used for single-use medical devices, syringes, and food packaging.

Products Range at AMTZ

- **Medical Consumables**
  Connectors: Polymers are used in connectors for medical devices like catheters, IV sets, and tubing.
  Cannula: Polymers provide lightweight, flexible, and biocompatible designs for vein puncture and tracheotomy procedures.

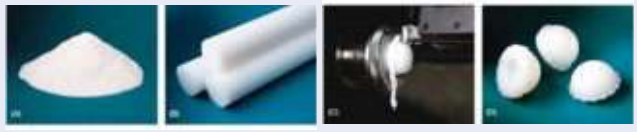
Orthoplatics -Ultra High Molecular Weight Polyethylene

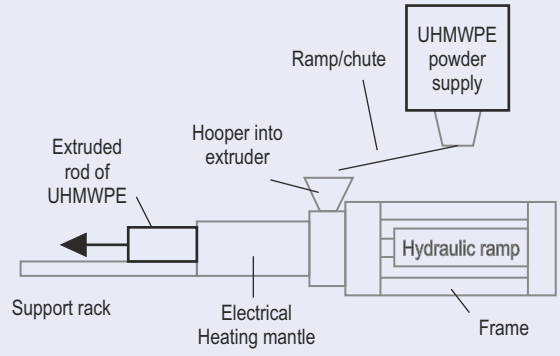


Unfused areas have been observed, which can be correlated with broad peak observed in Raman analysis & The size of each UHMWPE granule is about 100µm and polyhedral in shape.

UHMWPE and its production machinery were developed domestically at AMTZ. It shows potential as a biomaterial for medical use, passing biocompatibility tests per ISO 10993 standards. Tests on guinea pigs and rats, including skin sensitization, intracutaneous reactivity, and 90-day systemic toxicity, showed no adverse effects, indicating its safety.

Polymerization & Ram Extrusion of UHMWPE-





Trays: Medical trays made from PP and polycarbonate store and transport instruments, ensuring hygiene and organization.

Cassettes: Polymer cassettes offer durable, chemical -resistant solutions for specimen storage and processing in labs.

Cartridges: Polymers like PMMA and PE are used in drug delivery cartridges for insulin pens and prefilled syringes, ensuring safe medication administration.

Syringes: Made from PP and PE, syringes are essential for medication delivery and fluid aspiration, providing a cost -effective, disposable solution for healthcare providers.

Radiological equipment Consumables

Polymers are employed in detectors for medical imaging technologies like MRI and CT scans, offering durable and nonreactive components that contribute to accurate diagnostics.

SPE INDIA MEDICAL PLASTICS DIVISION
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Recent Advances in Medical Plastics

Falgun Jani
Business Head
India Region, Freudenberg Medical

What are Medical Plastics :

By definition, Medical plastics can be referred to those plastic materials or polymers that are either used **'as-is' in their original form** 'OR' **specifically designed and customized** to produce different types of medical products in the healthcare industry. These plastic polymers have become essential components in the modern-day healthcare system.

These plastics can be either
Rigid types like ABS (Acrylonitrile Butadiene Styrene), PC/ABS Blend, PC blends, PC (Polycarbonate), PS (Polystyrene) with styrene copolymers of ABS and SAN, PP (Polypropylene), PET (Polyethylene Terephthalate), PETG (Polyethylene Terephthalate Glycol), PMMA (Polymethyl Methacrylate), PEEK (poly-etheretherketone), etc.

'OR'

Soft types like Silicone, TPE (Thermoplastic Elastomers), TPU (Thermoplastic Polyurethane, TPO (Thermoplastic Polyolefin), PVC (Poly Vinyl Chloride), PE (Polyethylene), PA (Polyamides both traditional nylons and amorphous nylons), PTFE (Poly Tetra Fluoro Ethylene). etc.

Application areas of Medical Plastics :

- Medical Tubings & Disposables
- Molded & Micro-molded Components & Parts
- Medical Implants
- Prosthetics & Orthodontics
- Drug Delivery Devices
- Surgical tools & devices
- Wearables, Sensors & Monitoring Devices
- Medical Equipments & housings
- Diagnostics Devices
- Protective & Rehabilitation equipments
- Blood Bags & Transfusion devices

Developmental Advantages of Medical Plastics :

- Lower cost compared to metals
- Can be re-used without sterilization for non-critical applications
- Easy processing with adaptability to various different manufacturing techniques : Extrusion, Co-Extrusion, Compression Molding, Injection Molding Over-molding, Calendaring, Sheeting, 3D-printing etc.
- Mechanical versatility : Tough and Rigid 'OR' Soft and Flexible, Abrasion Resistance, Impact Strength, Thermal stability, Good Optical properties & Clarity, Good Chemical Resistance or inertness
- Proved history of usage into medical and healthcare applications due to broad range of Biocompatibility
- Adaptability to various sterilization techniques : Autoclave, ETO, Gamma, X-Ray

Past & Present of Medical Plastics :

The medical device industry has roots in the foundation materials of glass intravenous (IV) bottles, rubber tubings, and metal operating room instruments. The development of plastics in the 1930s, 1940s, and 1950s enabled the development of medical devices that overtook and eventually replaced the foundation materials with newer and better materials such as polyvinyl chloride (PVC) for IV bags and tubing, silicone tubing for catheters and balloons, polyolefins for trays and bottles, and fluoropolymers for IV catheters.

Recent Advances in Medical Plastics :

Innovative applications of medical plastics and elastomers continue to emerge, showcasing their versatility and potential impact on healthcare.

- **Shape-Memory Plastic Polymers :** Researchers are developing shape-memory plastic polymers for minimally invasive surgical (MIS) tools that can change shape in response to temperature or light stimuli, enabling precise maneuvers within the body.

- **Plastic Meniscus :** In 2015, surgeons implanted the first plastic meniscus in U.S. as a part of an FDA-approved clinical trial (it's already in use in Europe). This minimally invasive alternative- made possible by plastics-has been helping avoid major knee replacements.
- **Plastics to Prevent Bleeding :** Researchers are developing an injectable plastic designed to curb the bleeding caused by Trauma. A first responder to medical emergency carrying a pre -loaded syringe can inject this plastic into the patient on site to improve blood clotting and prevent excessive bleeding.
- **Disappearing Plastic Stent :** The FDA panel in 2016 approved a resorbable plastic heart stent that also delivers targeted drugs. The stent helps in opening a blockage in the arteries by delivering the medication and then disappears over time. This device is already used in Europe.
- **3D printed Eyes :** 3D-printed prosthetic eye produced in a fraction of the time compared to the time taken by the conventional process, looks more realistic. Such Prostheses is now being fitted in patients for the first time in a clinical trial at Moorfields Eye Hospital in London.
- **3D printed Plastic Vertebrae :** Researchers have developed a 3D-Printed plastic vertebrae using biocompatible plastics. The FDA has already approved such device. Such plastic vertebrae mimics mechanical properties of bone, enabling the body to adapt to the implant.
- **3D printed Brain Tissue :** In a path-breaking scientific endeavour, researchers have created the world's first 3D -printed brain tissue that behaves like a natural brain tissue. This is being considered a major leap towards the development of advanced solutions to neurological and neurodevelopmental disorders.
- **3D printed heart replica :** Engineers at Massachusetts Institute of Technology have developed a 3D printed heart replica that pumps & looks like Human heart by using polymer based bio-ink.
- **Temporary Artificial Heart :** Artificial hearts made of special medical plastic with long-term durability and high fatigue resistance are helping extend patient's lives.
- **Skin Grafts and Skin for Prosthetics :** When combined with skin stem cells, plastics cab be used as skin grafts to heal burns and ulcers. Researchers are also studying 'Self-healing' polymers that can repair themselves after being cut.
- **Neuromodulation Devices :** In neurostimulation / neuromodulation applications, accuracy is paramount. Electrically conductive silicone enables precise delivery of electrical signals to specific neural pathways, helping to modulate neural activity with high precision.

One of the example of such unique & innovative smart medical device is 'ExCiteOSA' : a daytime sleep apnea therapy device' from Signifier Medical Technologies which recently received USFDA approval. Working with Freudenberg Medical, Signifier Medical Technologies developed a neuromuscular tongue training device. Controlled with a smartphone app, it is used 20 minutes a day in the oral cavity to stimulate the tongue muscle with slight electric pulses.

The device's mouthpiece was manufactured by Freudenberg Medical in Kaiserslautern. Its material consists of electrically conductive silicone that Freudenberg improved specifically for Signifier Medical Technologies. :

Watch the video here :
https://www.youtube.com/watch?v=--jcKy3EmAw

- **Wearable Monitoring Device :** One of the example of such unique & innovative smart medical device is 'Bambi Belt' : an innovative wireless neonatal vital sign monitoring system. The Bambi Belt replaces cumbersome monitoring with electrodes and wires, substituting a silicone belt that is kind to the infant's skin. It consists of a flexible strip conductor encased in various silicones. The sensors are built-in. This especially soft belt can be put on and taken off painlessly. The sensors inside capture the vital functions of the preemie through the skin. In 2023, Bambi medical received CE mark for this device.

In this video, see how Freudenberg Medical teamed up with Bambi Medical to develop and manufacture the Bambi Belt passionately and enthusiastically to address an unmet need.

Future of Medical Plastics :

With recent cutting-edge advances in polymer science, processing technologies & confluence of different scientific streams, the medical plastics are pushing the boundaries of what's possible in medical and healthcare. According to one of the research, Global medical plastics demand is expected to increase from US$ 25.6 billion in 2023 to reach US$ 41.2 billion at a CAGR (compound annual growth rate) of 10%.

Growing trends like..

- Increasing adoption of high-performance engineering polymers,
- Advances in bioresorbable polymers,
- Advanced recycling & upcycling of medical plastics (Greener medical plastics)
- Increasing investments & support from private & government sector

Etc. are helping to further propel the growth of medical plastics.

Advantages of using Freudenberg Medical as your partner for Medical devices

Freudenberg **is a 175 year old, family-owned, global technology group that is long-term oriented and responsible in its actions.**

As a **trusted & reliable** development partner to our customers, we set standards **in technology, innovation and quality** utilizing our **leading-edge technology products, solutions and services** & thereby making a valuable contribution to our customers' **long- term success & a sustainable future.**

Freudenberg Medical is part of The Freudenberg Group.

At Freudenberg Medical, we are a global CMO (contract manufacturing organization) / CDMO (Contract design & manufacturing organization) 100% focused on solutions that address the complex challenges of medical device and pharmaceutical industry.

All of our facilities are **ISO 13485 certified** and all manufacturing is conducted in either **Class 7 or 8 clean rooms.** 5 of our 11 facilities are **FDA certified.**

Our manufacturing capabilities range from high precision molding components and medical and biopharma tubing to drug coatings, finished devices, catheters shafts and hypotubes for minimally invasive, handheld and catheter-based devices.

Please feel free to visit www.freudenbergmedical.com 'OR' reach out to us at falgun.jani@freudenberg.in

Nanocomposite Dental Materials

Sumita Mitra

U.S. Patent Nos. 6,730,156; 6,572,693; 6,387,981
Inducted in 2018
Born Feb. 27, 1949

In the late 1990s, Sumita Mitra, a chemist at 3M Oral Care, the dental products division of 3M Company, invented the first dental filling material to include nanoparticles. The new composite filling material, called Filtek™ Supreme Universal Restorative, is a versatile material that could be used for restoring teeth in any area of the mouth; mimicked the beauty of natural teeth; had better polish retention; and exhibited superior strength than existing dental composites.

Mitra and her multidisciplinary team looked outside the realm of traditional dental materials technologies to develop the innovative material. They developed unique nanomeric and nanoclustered filler particles which they combined to generate a composite system that had excellent paste handling properties and, when cured, provided superior optical properties both initially and long-term, while exhibiting excellent mechanical strength and wear resistance. Filtek Supreme's improvements over standard composites included versatility of use due to its excellent lasting esthetics, ability to withstand fracture, low shrinkage during curing and extremely good resistance to wear. Tooth-colored composites provide the ability to preserve more of a patient's natural tooth structure and do not pose similar health and environmental concerns as with amalgam fillings containing mercury. Moreover, Filtek Supreme was attractive enough to fill front teeth, and strong enough for all teeth, even molars, which exert heavy chewing pressure.

The first generation Filtek Supreme Restorative was launched in 2002, followed by the second generation in 2005. In 2012, 3M Oral Care launched the third generation, Filtek Supreme Ultra. The Filtek Supreme product line has been highly successful commercially and has been used in over 600 million restorations worldwide since its initial launch.

Mitra holds 98 US patents and their international equivalents. Her inventions have led to a number of breakthrough dental technologies, including nanocomposites, resin-modified glass ionomers and dental adhesives. Other products that have resulted from her innovations include Viteremer™ and Vitrebond™ Resin-modified Glass Ionomers, RelyX™ Luting Cements, Scotchbond Multipurpose™ Adhesive and APC™ Orthodontic Bracket Adhesive. She earned her B.S. in chemistry from India's Presidency College, her M.S. in organic chemistry from the University of Calcutta, and her Ph.D. in organic/polymer chemistry from the University of Michigan. Mitra retired in 2010 after more than 30 years with 3M, and now runs Mitra Chemical Consulting LLC with her husband. A former Science Coach for the American Chemical Society, she also maintains a close relationship with the Minnesota Dental Research Center for Biomaterials and Biomechanics at the University of Minnesota of which she was Industrial Director for nearly ten years.

https://www.invent.org/inductees/sumita-mitra

IIT Roorkee & UnivLabs Tie Up For Commercialising Technology Related To Ureteral Stents

The Indian Institute of Technology (IIT), Roorkee and Gurugram-based UnivLabs Technologies Private Limited have signed a Technology Transfer Agreement and a Memorandum of Agreement (MoA) for translating research findings into real-world applications.

The tie up e130nhances the potential for success in developing and commercialising the technology related to ureteral stents developed by a team of researchers from IIT Roorkee and resources with UnivLabs Technologies Private Limited. The title 'A biodegradable polymeric composite with enzymatic degradation for ureteral stent and its methods of preparation,' has been patented in the country.

This patented technology is based on the Ureteral stents, often used to maintain fluid drainage from the kidney to the bladder when the ureter is obstructed due to many clinical reasons, such as kidney stones, tumors, blood clots and post-operative swelling and infection. The stents are required to be in place for a maximum of four months in general.

However, the currently used ones being non-degradable, needs a surgery to remove them and are often associated with discomfort leading to pain, urinary tract infection, stent migration, fragmentation of breakage, and very importantly sedimentation on them, known as encrustation. The clinical stents available in the market at present are made up of silicone and polyurethane polymer.

A team of researchers Prof. Debrupa Lahiri, Prof. Partha Roy, Gunjan Kaushik from IITR and Dr. Anil Mandhani from Univ Labs and Fortis, Gurgaon have developed materials for a total biodegradable stent with required degradation profile and mechanical integrity for an ideal ureteral stent, which will reduce biofilm formation and encrustation, while also ensuring that the stent disappears completely without the need for a second surgery for its removal.

Dr Anil Mandhani, director, UnivLabs Technologies, said, “the development of a total biodegradable ureteral stent addresses several key challenges associated with conventional stents, offering significant benefits in terms of patient comfort, reduced complications, and improved clinical outcomes.”

Prof. Akshay Dvivedi, Dean Sponsor Research and Industrial Consultancy (SRIC), IIT Roorkee, said that the potential of this technology being transferred from IIT Roorkee holds great promise for revolutionizing healthcare practices, particularly in the field of urology with the development of biodegradable ureteral stents.

"This innovation has the potential to improve patient outcomes, reduce complications, and enhance overall quality of life for individuals requiring such medical interventions. We look forward to seeing that this collaboration represents a promising advancement in the field of urology and medical device technology," said Dvivedi.

Prof. K.K. Pant, director, IIT Roorkee, said that the research is a catalyst for positive change, driving progress and shaping the trajectory of human civilization. Its impact extends far beyond academia, touching every aspect of society and paving the way for a brighter tomorrow.

"We believe that the innovation of biodegradable ureteral stents holds great promise for advancing healthcare practices in urology. It represents a promising advancement that underscores the importance of research and collaboration in driving innovation in healthcare," added Pant.

UnivLabs Technologies, an integrated, research-based medical devices manufacturing company, works on a wide range of medical devices in the field of surgical vision, urology consumer products and wearable infusion pumps for slow and accurate long term medicine delivery. It has also launched its flagship 4K endoscope tower and is in the advanced stage of developing a flexible endoscope. It has two patents and nine more in process, said the company.

April 25, 2024
https://www.pharmabiz.com/NewsDetails.aspx?aid=168749&sid=1

PLA a Prescription for Sustainable Healthcare Packaging

Innovative Bottles’ pill vial and specimen packaging relies on TotalEnergies Corbion’s Luminy PLA biopolymer as a healthier choice for the environment.

At a Glance

- Innovative Bottle’s healthcare packaging uses PLA from TotalEnergies Corbion.
- Bioplastic vials and medical containers reduce energy use and greenhouse gas emissions.
- Industrial composting option is an alternative to landfilling of single-use plastics.

Rare is the market that can’t benefit from a sustainable packaging improvement and that includes unexpected applications in healthcare.

Exemplary of that effort is Innovative Bottles, which has pioneered a range of biopolymer vials and specialized medical packaging. The company’s products offer environmental benefits by replacing fossil-fuel based polymers with polylactic acid (PLA). Its two flagship products are ECOVial brand PLA vials for pharmaceutical and veterinary markets and specimen containers for medical. These products present an industrial composting option that can help customers lower single-use plastic waste.

Bio-based packaging is an on-trend offering, according to Joseph Salerno, CEO. "By combining innovative technology with renewable materials, we are addressing the urgent need for sustainability in the healthcare sector and paving the way for a greener future.”

The market has responded favorably to bioplastic packaging. “Our packaging complements today’s sustainability programs that [are] flourishing,” Salerno notes. “Our patented design has all the form, fit, and functionality of plastic without its eco-destructiveness. Our products are [better] for the environment — reduction of [conventional] plastic is one of the signature environmental initiatives of our time.”

The PLA vials are available in six sizes and four colors, amber, green, blue, and black. He tells us black is a popular choice for cannabis.

The clear sterile specimen container, used for urine or blood samples and shown below, is 3.5 ounce/110 cc and is marked in 10 mL increments. The leak-proof, screw-on lid is also made of plant-based material.

Asked about costs versus standard plastic packaging, Salerno responds that “the vials and specimen containers are a high-end products that are near cost parity with similar high-end petroleum-based products.”

He defines “high end” as domestic products versus cheap but low-quality packaging imported from China.

PLA lowers energy use and carbon emissions.

Salerno sees PLA’s primary benefit as fossil-fuel reduction, but there are other advantages as well. “For example, we use 32% less energy in production and emit 42% less greenhouse emissions, which lowers the carbon footprint.”

That’s a strong business case for sustainably minded companies to consider a bioplastic alternative; even if landfilled as all conventional plastic vials and specimen containers are, that environmental advantage is already built-in to PLA packaging.

FAST FACTS

About Heart Surgery

Progress in heart surgery has been rapid. The first pacemaker, developed in 1952, was the size of a television, but the first to be implanted beneath the skin appeared just six years later. Less than a decade later, in 1957, Christian Barnard carried out the first human heart transplant.

INNOVATIVE BOTTLE

Some months back the Cerritos, CA, company was compelled to change PLA vendors when the prior supplier discontinued a grade of PLA. NatureWorks referred the company to TotalEnergies Corbion, which produces Luminy brand PLA. Salerno attended NPE2024 the week of May 6 and visited the TotalEnergies booth where Innovative Bottle's PLA packaging was displayed.

PLA drives healthy growth and opportunities.

The company's market reach starts in the US and spreads across the globe. And it's growing.

"Our line of eco-friendly prescription vials and single-use specimen containers are available in the US and across the globe," Salerno says. "We have an international customer in The Bermuda Diabetes Association and are selling in England via KVP International."

Appropriately, business is healthy across all markets.

"KVP International has been aggressively promoting and selling our products to customers in the veterinary sector as we continue to make penetration into pharmaceuticals," says Salerno. "US Plastic, Premium Vials, Inc., and Value Drug have recently come on board, and our products are on their websites. We are also on Medline."

Salerno has an eye on one market that holds compostable promise.

"Specimen containers are an especially exciting market because they never leave the customer facility, leading to a closed-loop process and zero-waste opportunity," he suggests.

If there's one thing that's lacking, it's downstream where more infrastructure would be welcome.

"The backend of collection and industrial composting is still maturing," Salerno admits, "but there are 4,700 industrial composting sites across the US, albeit each does different things."

May 16, 204
https://www.plasticstoday.com/packaging/pla-a-prescription-for-sustainable-healthcare-packaging

IFPMA Supports Plastic Materials And Components For Safe And Effective Medical Production Along With Circular Economy

The International Federation of Pharmaceutical Manufacturers and Associations (IFPMA) supports the UN Global Plastics "Instrument" because it could help create globally harmonized plastic regulations. The IFPMA believes that these regulations are important for driving innovative change while also ensuring that plastic materials and components are safe and effective for medical production.

The innovative pharmaceutical industry is proactively addressing its environmental footprint and embracing sustainable initiatives. For instance, several leading pharmaceutical companies are committed to reducing the impact of plastic waste through the adoption of recyclable and biodegradable packaging materials

Importance of medical and medicinal products for Human Health:

Medical and medicinal products are pivotal in maintaining public health and well-being, driving healthcare outcomes, and supporting economic growth. They prevent disease, alleviate symptoms, cure illnesses, and enhance the quality of life for billions worldwide. From antibiotics and innovative biologics to the COVID-19 vaccines and cutting-edge medical devices, medical and medicinal products represent the pinnacle of scientific achievement and medical progress.

Access to medical and medicinal products underpins global health equity and social justice and, therefore, any requirements related to use and disposal of plastics must not jeopardize the uninterrupted availability of medical and medicinal products even considering the laudable objective of minimizing the negative impact of plastics on planetary and human health. The best way to do so under the Instrument is to establish targeted extended compliance periods for medical and medicinal products to assure the availability of appropriate alternatives that meet the quality, safety and access requirements needed by our patients while alternatives are developed and implemented. Exceptions to limitations on plastic use in healthcare applications must be permitted when no safe or effective alternatives are available. Throughout this process, engagement of regulators will be critical as most changes to manufacturing processes and packaging will need to be approved before being allowed to be marketed.

Plastics[1] in medical product manufacturing and packaging:

Plastic materials and components are indispensable in every stage of the pharmaceutical lifecycle, and are crucial for medicine production, quality, and safety. The use of plastics, like any material employed in drug development and manufacturing processes, follows comprehensive and intensive benefit-risk analyses, which are reviewed by experts at health authorities worldwide. Currently, plastic materials and components cannot easily be replaced by other materials while ensuring the same levels of patient and healthcare practitioner safety. For example,

- In drug development, plastics facilitate the synthesis, purification, and formulation of active pharmaceutical ingredients (APIs), enabling precise dosing and controlled release mechanisms.
- Plastics are used in lieu of fiber based materials to minimize contamination due to fiber particulate in pharmaceutical operations.
- Plastics play a crucial role in the healthcare sector due to their unique properties such as versatility, durability, transparency, sterilizability and biocompatibility. In addition, they enable aseptic and sterile environments during manufacturing of biologics and sterile injectables (for example biobags, tubing, and filters).
- Plastic packaging ensures the integrity, stability, and sterility of medicines, safeguarding their potency and safety during storage and transportation. Whether in the form of vials, blister packs, or infusion bags, plastics offer versatility, reliability, and cost-effectiveness in pharmaceutical packaging that is not easily replicable with other materials.

Broadly speaking, the use of plastics in manufacturing provides a number of important benefits:

(I) facilitates installation and qualification of equipment, especially in low-income countries; (ii) reduces the amount of electricity and water needed; (iii) increases productivity and scalability; and, (iv) facilitates production in more diverse locations, especially in lower-income countries.

Conscious of the negative impacts that plastic use has on the environment and human health, many companies committed to and are already working to reduce or eliminate the amount of plastic waste as well as supporting more sustainable alternatives, such as recycling and longterm circularity (see Annex).

Positive efforts by the pharmaceutical industry towards environmental sustainability

The innovative pharmaceutical industry is proactively addressing its environmental footprint and embracing sustainable initiatives. For instance, several leading pharmaceutical companies are committed to reducing the impact of plastic waste through the adoption of recyclable and biodegradable packaging materials. Furthermore, innovative technologies such as green chemistry and continuous manufacturing hold promise for reducing plastic usage and minimizing environmental impact throughout the pharmaceutical supply chain.

However, as mentioned above, plastics are used for a number of different purposes and at different points in the manufacture, distribution and use of medical and medicinal products. The specific function and point at which plastics are used strongly influences the feasibility of replacement of these materials. Specifically, the different quality and safety requirements between primary packaging, secondary packaging and plastics used in production processes affect the ability of manufacturers to replace or reformulate such plastics.

Case studies

Plastic materials which have been in contact with certain drug product process streams present some unique challenges from a waste management standpoint as they can be considered regulated medical waste. Some pharmaceutical companies have been working with waste and materials vendors who are able to treat and recycle this material to produce plastic lumber.

Necessary components are often shipped to pharmaceutical manufacturers in plastic boxes instead of fiber-based boxes to reduce potential contamination of pharmaceutical operations due to particulate. While the material (i.e. polypropylene) typically

used is recyclable, suppliers servicing our industry are starting to change the material to 100% recycled polypropylene which reduces greenhouse gas emissions, contributes to demand of recycled material and is also recyclable.

Industry efforts at reducing plastic waste and working towards a circular economy[5]

ASTRAZENECA

From single use to reusable thermal packaging

Each year, Astra Zeneca sends 60,000 products to hospitals and clinics for clinical trial distribution. It involves a huge amount of packaging. The original process used a box the size of a small table, each containing 15kg of packaging that had to be thrown away after delivery with recipients being responsible for its disposal. AstraZeneca decided to work with its distribution partner to develop a new approach involving a returns process and make it workable. Some simple ideas like using the brightest coloured paper for returns instructions – a pink envelope gets more attention than just a white sheet of paper. After a pilot, the initiative was rolled-out across 35 countries. **The results: 98% return rate and reduced packaging waste equivalent to the weight of a 747-jumbo jets.**

SANOFI

Eco-design – Plastic-free packaging for Vaxigrip® vaccine

The new Vaxigrip® packaging has been designed to be plastic-free, thanks to a complete cardboard packaging. This new packaging halves the size of the box, which optimizes its storage and reduce its environmental footprint: - 30% reduction of the number of transportations needed (air, sea and road) - 50% reduction of CO2 per box - 25 to 50% reduction of environmental impacts according to the indicator

BOEHRINGER INGELHEIM

Eco-design - Switch from single use to re-usable inhaler

Respimat® re-usable is the result of patient feedback, providing an inhaler with enhancements such as simplified handling and an easy-to-read dose indicator, and significantly reduced impact on the environment. It reduces waste and product carbon footprint (PCF) can be used with up to six medication cartridges before needing replacement. Respimat® is also propellant-free, meaning its CO2 emissions are 20 times lower than those of commonly used pressurized metered-dose inhalers. **By 2025, it is expected that 776 tons of plastic waste and 14,300 tons of CO2 emissions will be prevented as a result.** 776 tons of plastic waste equals more than 77.6 million 0.5-liter PET bottles.

GSK

Complete the Cycle

73 million respiratory inhalers are prescribed every year in the UK and not disposing of them correctly can be harmful to our environment. GSK created an inhaler recycling scheme, Complete the Cycle, which was the first of its kind for respiratory inhalers in the UK. 2 million inhalers had been collected by 2019 and the scheme led to a wider discussion on how a national inhaler return scheme could be created in conjunction with the wider health care system. By working together with patients, pharmacies and healthcare professionals, we can all help to reduce waste and greenhouse gases, moving towards a more environmentally sustainable treatment of respiratory disease.

CHIESI

Take back pilot - Take Action for Inhaler Recycling

Chiesi launched the Leicestershire Take AIR (Take Action for Inhaler Recycling) pilot scheme in January 2021, to enable inhaler users to recycle their empty, unwanted or out of date inhalers safely and effectively through the post. Any inhaler, brand and type, is accepted. The pre-paid, pre-addressed envelopes are provided by community pharmacies within the area.

The scheme is funded by Chiesi and supported by University Hospitals of Leicester NHS Trust and Leicestershire and Rutland Local Pharmaceutical Committee (LPC).

Inhalers are sent through the postal system, directly to a waste management company, where the component parts of pressurized metered dose inhalers are recycled, and non-recyclable inhalers are disposed of using the most environmentally appropriate process. Through the scheme, the aluminum canisters are crushed and recycled. The plastic components are recycled into the plastic supply chain and any remaining propellant gas is extracted and reused in the refrigeration and air conditioning industry. Non-recyclable materials are converted into energy through a process called energy-from-waste by high temperature incineration.
Scheme data as of 11th April 2022:

- 147 pharmacies and 3 hospitals participated
- Patients have returned 6,491 envelopes, containing 24,469 inhalers and
- 144 tons of CO2e have been captured

The results from the pilot are being evaluated including quantitative and qualitative analysis, lessons learnt and recommendations for potential upscale through system-wide collaboration. This enables the findings to be shared with relevant stakeholders to support the development of a future sustainable recovery and recycling process for inhalers

(Abstracted from : https://www.ifpma.org/publications/our-position-on-the-global-plastics-instrument/#:~:text=Ahead%20of%20negotiations%20on%20a,creates%20globally%20harmonized%20plastic%20regulations.)

How Antimicrobial Packaging Is Transforming The Healthcare Industry

The use of antimicrobial packaging in the healthcare industry is further fuelling product sales. Rising awareness of consumers on hygiene and packaging of medicines is aiding the market growth.

The healthcare industry has been experiencing growth in recent years which will directly amplify product sales in the forecast period.

Antimicrobials are primarily used as packaging agents to prevent the growth of microorganisms and guarantee product safety. These antimicrobial agents are used while packaging any item so that they can work by a slow release on surfaces or can also be used in vapour form.

The growing importance to maintain storage temperature is further augmenting growth in the market. The growth of potential microbes is dependent on the element of storage temperature. For this reason, a properly designed antimicrobial packaging system is employed to prevent medical illnesses from healthcare packaging by maintaining moderate storage temperature and distribution systems.

Nowadays, hospitals are becoming a breeding ground for growth of algae, bacteria, and fungus which in turn causes harmful effects on consumers and also on plastic medical devices. For this purpose, antimicrobial additives are added in antimicrobial packaging to restrict microbial growth and to improve the hygienic factor among patients.

Also, healthcare equipment manufacturers have been developing innovative products comprising effective microbe-resistant properties which maintain the aesthetic value of hospitals and also stop the growth of infectious agents in the hospitals. This factor is expected to drive market growth by escalating product sales.

Driving Demand for Antimicrobial Packaging?

Over the past decade there has been a major shift in lifestyle of people. There has been a sizeable increase in the number of health conscious consumers which is driving the demand for packaged products with antimicrobial properties.

Asia Pacific Antimicrobial Packaging Market Outlook

It has been projected that in next five years healthcare spending in Asia Pacific is poised to grow by ~40% expanding at the rate 2x the world average.

These positive trends along with increased production of packaging in the region is projected to propel the demand and sales of packaging materials with antimicrobial properties.

North America Antimicrobial Packaging Market Outlook

Between the period 2012-2016 consumption of packaging rose by ~10% in the region and was further expected to rise by ~20% by the end of 2022. Increased consumption of packaging along with demand for safe and microbial free packaged products is projected to drive the market in the long run.

Moreover, high government spending on healthcare especially in the US has provided a surge in demand for packaging for with antimicrobial properties. These above mentioned factors along with high disposable income among consumers is projected to drive the antimicrobial packaging industry in North America.

https://www.medicalplasticsnews.com/medical-plastics-industry-insights/medical-plastics-packaging-insights/how-antimicrobial-packaging-is-transforming-the-healthcare-i/
22 JUNE 2023

Venezuela Medical Devices Market

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

Country Profile

Venezuela was born from the collapse of Gran Colombia in 1830 (along with Ecuador and Colombia).

Venezuela possesses one of the largest oil deposits in the world. Venezuela is one of the largest oil exporters and an influential member of OPEC outside the Gulf countries also. One of the world's largest deposits of coal is in Venezuela. The country also has large deposits of iron ore, bauxite and gold. The export of all these natural resources earning good foreign currency, along with the absence of local manufacturing, makes the country an attractive export destination. The country has a socialistic political system and a major part of the money earned out of these exports is being spent for the public systems including healthcare infrastructure. Venezuela, however, struggles with unabated high inflation, unemployment and poor infrastructure. Non-availability of essential goods including medicines and devices is a perennial feature. The government has inadequately provided for the supply needs of the free public healthcare system and restricted international aid from other nations. On multiple occasions, the country has refused international aid, including medical supplies.

With about 3 crore population, Venezuela is one of the most urbanised countries in Latin America, with Caracas (the capital city) being the centre of the major commercial activities. A tussle with the USA has also been going on for years, with commercial restrictions and sanctions off and on. The country is involved in a long-running border dispute with neighbouring Guyana.

During many visits to Venezuela by the author, it was clear that this very beautiful country has a very high crime rate also. However, a clear positive feeling for India (and very high regard for Mahatma Gandhi) also exists. The country always has very powerful bureaucrats from India in the Embassy who are not only experienced but astute diplomates maintaining a well-balanced relationship with the country. This is a positive factor.

The official (and the most common) language is Spanish.

Regulatory Framework Outline and Product Classification

Regulatory Authorities are Servicio Autónomo de Contraloría Sanitaria (SACS) and Instituto Nacional de Higiene Rafael Rangel (INHRR). Both are part of the Ministry of Health known as MPSS (Ministerio del Poder Popular para la Salud) and are controlled by MPSS. There is a fair degree of ambiguity in the rules and regulations for medical devices, along with corruption, making it a challenge to sail through the rules for medical devices. The role of a strong and reliable local partner becomes crucial here. There are very good and highly reliable parties in the market (almost all in Caracas, the capital city) with branch offices in Europe or the USA (Miami, Florida, mainly). This agency representative business is a big revenue earner in Venezuela. To get a good partner, thus, is not a major issue.

Venezuela Highlights

- A HIGH RISK-HIGH REWARD market
- Very high import dependence for medical supplies
- The key to success – the right local partner

Classification of medical devices –

- Class I
- Class II
- Class III
- Class IV

While the classification scheme for medical devices looks the same as in many other countries with four classes, this classification is different from that in Brazil (ANVISA Classification). Instead of a degree of risk, which applies commonly to the classification categories, in Venezuela, the classification is based on the use of devices. For QMS, ISO 13485 and ISO 9001 are applicable. A local Authorized Representative is essential legally. Registration Timeline can range between 1 to 12 months!! This depends on good follow-up and a good agent. Once granted, the license is valid for 5 years. Since the official language is Spanish, documentation must be submitted in Spanish.

Venezuela Medical Devices Market

The healthcare system in Venezuela comprises both public and private sectors. The private sector medical system is not only operating but is thriving. It must also be noted that due to currency rate fluctuations, import reimbursement restrictions and political changes, many large healthcare companies have booked losses frequently. India is, however, in a favourable position but that does not mean total risk mitigation.

Product realizations are extremely good for healthcare products, in a way to compensate for the country and currency risks. To put it in clear words, Venezuela is a HIGH RISK-HIGH REWARD market overall.

While lower-end products like syringes, surgical wear, and hospital furniture are made locally, most of the other products are imported. In the absence of developed local industry, in the medical sector also, there is high import dependence. A specialized rate of currency reimbursement applies to such imports. Management of this rate effectively depends highly on the local agent.

Medical Devices imports are mainly from the USA, Cuba, Mexico and Brazil. Indian suppliers certainly have an opportunity with cost-effective supplies. Fresenius, Medtronics, Coloplast, Abbott, and Hoffman-La Roche are some leading names of the companies operating in the country.

Opportunities and Challenges

Venezuela is a HIGH RISK-HIGH REWARD market because of good realization but complex systems and higher country risk. Local agent's role is quite crucial and the key to success is selecting an influential local partner. There are many Indians based locally and they can be of help for an exploration of the market.

Govt Revisiting Standards For Medical Devices Considering Evolving Technology In Medical Sciences

The new norms will ensure harmonized regulation in the medical device sector. Discussions are going on with the Department of pharmaceuticals, NITI Aayog and the Union health ministry.

As per an CDSCO official , given evolving technology in medical sciences, the Union government is now evaluating standards of medical devices for safety and performance.

Currently, there are around 1,500 standards for different pharmaceutical items available in the country. There are approx 6,000 medical devices in the country. However, CDSCO has classified around 3,000 medical devices in different categories based on their usage.

The new norms will ensure harmonized regulation in the medical device sector. Discussions are going on with the Department of pharmaceuticals, NITI Aayog and the union health ministry.

“We are in the process of framing the standards for all kinds of medical devices available in the country. Already, BIS has limited standards, so we are sort of revising the standards for all products. The device should have the essential principal checklist for safety and performance, so that manufacturers are given the liberty to choose the applicable standards for their devices. Therefore, it is compulsory for manufacturers to meet the standards for their product," said the official.

Standards help in many ways. They can facilitate trade and commerce, improve processes and make them more efficient, guide in consistent functioning and quality, simplify comparison of products & services, ensure health and safety, conserve resources and reduce impact on our environment and promote technological developments.

“Review of medical devices standards published by BIS is an ongoing dynamic process to align with latest ISO standards that have undergone or undergoing revisions as well as requests from stakeholders. We are very thankful to the government that in the last 5 years there’s been exemplary progress in publishing new standards for medical devices by adopting ISO standards. This helps manufacturers and procurement professionals get aligned to seeking the right quality of performance specifications," said Rajiv Nath, Forum Coordinator, Association of Indian Manufacturers of Medical Devices (AiMeD).

(https://www.livemint.com/news/india/govt-revisiting-the-standards-for-medical-devices-considering-evolving-technology-in-medical-sciences-11716270947819.html)
21 May 2024

Govt Launches Meditech Stackathon To Give Big Push To Medical Devices Manufacturing

New Delhi, May 8 (IANS) The government on Tuesday launched the Meditech Stackathon 2024 in collaboration with apex business chamber CII to give a big push to the domestic manufacturing of medical devices and reduce dependence on imports.

Addressing the gathering, Dr Arunish Chawla, Secretary, Department of Pharmaceutical, said that India’s MedTech industry holds immense potential, with projections estimating a growth rate of 28 per cent annually, reaching a size of USD 50 billion by 2030.

He said that currently, India is the 4th largest market for medical devices in Asia and among the top 20 globally. Net imports for 2022-23 stands at USD 4101 Million with an import coverage ratio of 0.45.

The Secretary said that the sector has witnessed a surge in imports, driven primarily by countries like the US, China, and Germany. However, India’s robust policy ecosystem presents opportunities for export boosts and reducing import dependence through domestic manufacturing.

He said that the Stackathon would deliberate in eight focused groups namely Cancer Therapy, Imaging, Critical Care, Assistive Medical Devices, Body Implants, Surgical instruments and Hospital Equipment, Consumables & Disposables, and IVD Instruments and reagents, each tasked with specific objectives including segment-wise identification of important medical devices, assessment of import-export dynamics, examination of duty structures, and their implications across the entire value chain.

Dr Chawla emphasised the importance of policymakers, and industry coming together to draw up a sturdy policy stack for the growth of the medical devices industry in the country.

He highlighted the critical need to focus on quality to ensure that India becomes globally competitive.

Exports overtook imports in consumables and disposables during last year, he said while urging the industry to continue with the momentum in other pillars of medi-tech sector.

Collaboration among stakeholders is essential to address these challenges and enhance both the ease and cost of doing business in the sector. By fostering partnerships, boosting investment in research and innovation, and streamlining value chain processes, we can achieve our shared goal of accessible and affordable healthcare for all, he added.

Through the Stackathon, participants will delve into the complexities of different product segments within the medical devices industry to gain insights into their unique challenges and opportunities, analyse and map value chains across various segments of the medical devices industry to identify key stakeholders, processes, and dependencies, identify critical issues hindering the development of the medical devices industry, such as import dependence, regulatory hurdles, and technological gaps, Dr Chawla said in his address.

Preceding this workshop, group leads and members have undertaken extensive virtual discussions and preparatory work. The challenges persist in the sector, including cost competitiveness, quality assurance, and regulatory hurdles.

Himanshu Baid, Chairman, CII highlighted a shared vision of collaborative excellence, wherein stakeholders unite to drive tangible outcomes and propel the MedTech industry towards unparalleled growth.

He said that with India's MedTech exports surpassing 4 billion dollars, the industry stands poised on a trajectory of remarkable expansion. However, he highlighted the need for enhanced data collation mechanisms to address gaps in product consumption and production within India.

He stated that India's MedTech landscape is brimming with promise, poised to capture 10 per cent of the global market share over the next decade.

https://www.sarkaritel.com/govt-launches-meditech-stackathon-to-give-big-push-to-medical-devices-manufacturing/ May 8, 2024

DCGI Emphasises Need For Sample Test For Standards For Medical Devices And Ivds

Drugs Controller General of India (DCGI) Dr Rajeev Singh Raghuvanshi has emphasised that the medical devices and in-vitro diagnostics (IVD) sold in the county should be tested for the standards prescribed by the Bureau of Indian Standards (BIS) for its quality and performance in the country.

The DCGI has issued a circular to all stakeholders in the sector, including all medical devices testing laboratories and manufacturing associations, elaborating the requirement for testing.

"...it may be ensured that the samples of the medical devices shall comply with the BIS standards for its quality and performance and accordingly the medical devices shall be tested with respect to the requirements as prescribed in the BIS standards," said the regulator.

"If no BIS standard is available, then only other standards as mentioned in Rule 7 of the MDR (Medical Devices Rules) may be applied," he added.

In order to ensure the quality, safety and performance of medical devices and IVDs, the Union ministry of health and family welfare has granted registration of laboratory for carrying out test or evaluation of medical devices on behalf of a manufacturer, under Chapter X of MDR, 2017 to strengthen the testing facility in the country.

Consequent to the implementation of MDR, 2017 with effect from January 1, 2018, the Drug Rules, 1945 are no longer applicable for medical devices and IVDs.

According to the Rule 7 of the MDR, the medical device shall conform to the standards laid down by the BIS established under Section 3 of the Bureau of Indian Standards Act, 1985 or as may be notified by the ministry of health and family welfare in the Central government, from time to time.

A second sub-rule adds that where no relevant standard of any medical devices has been laid down under the sub rule (1) regarding the BIS standards, such devices shall conform to the standard laid down by the International Organisation for Standardisation (ISO) of the International Electro Technical Commission (IEC), or by any other pharmacopoeial standards.

In case of the standards which have not been specified in these two sub-rules, the device shall conform to the validated manufacturer's standards.

"It has been observed that the medical devices which have BIS standards available, the testing of such devices are not being carried out as per BIS standards," said the drug regulator.

It may be noted that the central drug regulator has repeatedly requested private medical devices testing facilities in the past to come out and register themselves as Medical Devices Testing Laboratories (MDTL) on behalf of the manufacturers, in an effort to strengthen the MDTL network in tandem with the growing requirement for quality tests.

The Central Drugs Standard Control Organisation (CDSCO) is responsible for ensuring the quality, safety and performance of medical devices under the Medical Device Rules, 2017. With the implementation of two notifications on February 11, 2020, all medical devices have come under the Drugs and Cosmetics Act, 1940 and Medical Device Rules, 2017.

With more devices falling under the ambit of drugs, the requirement for more testing facilities for these medical devices has emerged, and the regulator has been in an effort to gather the infrastructure to test the products, both manufactured and imported to the country, on time without the industry meeting delays to reach the market.

So far, certain private testing labs have been registered under MDR, 2017 for testing and examination of certain medical devices in the country on behalf of the manufacturer, says the regulator.

In order to strengthen the private testing facility for medical devices in the country, the CDSCO is in the process of identifying the existing private labs having the facility to test the medical devices, so that these labs may be registered under MDR, 2017, said the DCGI in one such request earlier this year. The medical devices require various tests including physical, chemical, microbiology, mechanical and electrical, etc.

"... it is requested that you may kindly identify your facility for testing of the above tests for medical devices and submit the application in Form MD-39 along with the requisite information with fees as per MDR, 2017 for registration of testing laboratory on behalf of the manufacturer," added the DCGI in a communication to all stakeholders.

https://www.pharmabiz.com/NewsDetails.aspx?aid=169485&sid=1 May 31, 2024

Centre Launches DBT-Handbook On Bio-Design For Medtech; To Push Make In India

Union Minister of State (Independent Charge) Science & Technology; MoS PMO, Personnel, Public Grievances, Pensions, Atomic Energy and Space, Dr Jitendra Singh launches multi-disciplinary post-doctoral courses in Bio-Sciences to address global health challenges.

Delivering the key-note address at the launch of "i3c BRIC-RCB PhD Programme" in Biosciences in New Delhi, Dr Jitendra Singh announced that 1000 Ph.D. students will be enrolled in the next

five years to drive innovation in the critical healthcare sector.

The Minister said, this Ph.D. programme is designed on the four pillars of ideation, immersion, innovation and collaboration.

Addressing a gathering of esteemed scientists, researchers and students, Dr Jitendra Singh said, "This program will enable Indian students to embark on world-class research in fascinating and diverse fields of biotechnology and is aligned with Prime Minister's vision of enhancing & implementing transformative power of S&T for benefit of all".

Dr Jitendra Singh informed that along with a unique course curriculum, hands-on training on high-end facilities would be provided to all the research scholars. He said, a special on-field 'Immersion Fellowship' supported by Grand Challenges India would be provided to first-hand experience challenges and problems and derive motivation to address them through collaborative research in the DBT institutions. Additionally, the program will also induct and provide opportunities for non-biologists to undertake this Ph.D. program through special fellowships, the Minister added.

Dr Jitendra Singh informed that the Department of Biotechnology (DBT) has created a new Autonomous Body, Biotechnology Research and Innovation Council (BRIC) by subsuming the 14 autonomous research institutions. He said, BRIC will integrate multi-disciplinary research and innovation programs, capacity-building across the institutions synergistically and maximize biotech impact in the country.

The Minister also informed that the "Regional Centre for Biotechnology (RCB), an Institution of National Importance under the DBT, along with iBRIC (institutions of BRIC) has rolled out a globally competitive interdisciplinary Ph.D. program- "The i3c BRIC-RCB PhD Programme in Biosciences".

Speaking on the occasion Dr Rajesh S. Gokhale, Secretary, DBT remarked that, "All DBT institutions, i.e. iBRIC, RCB and ICGEB pioneers the cutting-edge, multi-disciplinary, immersive, collaborative research in biosciences and this programme will transform the Ph.D. research landscape in the country".

Dr Jitendra Singh also launched the DBT-Handbook on Bio-design for Med-Tech Innovations and licensed medical technologies developed by DBT-Bio-design fellows to the startups incorporated by them in the ceremony.

The DBT-Biodesign Program promotes and nurtures Med-tech innovators in the country. At present, six Biodesign Centers across the Country twining over 20 leading medical schools and technical institutions are providing the biodesign capacity building and indigenous med-tech innovations.

The Biodesign process is a '3-i' process i.e. - Identify, Invent, and Implement. The program provides on-site training on biodesign processes to aspiring medical technology innovators to identify unmet health-related needs and to invent health technologies. Overall aim is to address the unmet national needs and to prepare the innovators/entrepreneurs to translate the technologies into patient care through start-up incorporations.

Lauding the efforts of the DBT Bio-design Centres and their fellows, Dr Jitendra Singh said, "The technologies in Biomedical devices, diagnostics and therapeutics, developed by the DBT-Biodesign fellows will help us to provide Made-in India solutions for our unmet National Needs and will lead towards the Atmanirbhar Bharat".

The Minister mentioned that India's bioeconomy experienced robust growth in 2022, surging by 29% to reach a substantial value of around US$140 billion. It is projected to reach US$300 billion by 2030. India which ranked 81 in 2015, has risen to 40th rank out of 132 economies in the Global Innovation Index".

He added that the medical devices area in India has a great growth potential under the Make-In-India initiative.

https://www.medicalbuyer.co.in/centre-launches-dbt-handbook-on-bio-design-for-medtech-to-push-make-in-india/

Dop Launches Portal And Constitutes ICPMR For Implementation Of R&D Policy

The Department of Pharmaceuticals (DoP) has said that it has developed a portal for monitoring the implementation of the research and development (R&D) policy and has constituted the Indian Council for Pharmaceuticals and Medtech Research and Development (ICPMR), as envisaged in the National Policy on Research and Development and Innovation in the Pharma-Medtech Sector in India.

"R&D Policy envisages setting up of Indian Council for Pharmaceutical and Meditech Research and Development (ICPMR) which has been constituted vide DoP OM dated March 5, 2024 with the approval of the Hon'ble Minister of Chemicals and Fertilisers."

"The Department has developed a portal for monitoring the implementation of the R&D Policy that is operational since April 2, 2024," it added.

The Department identifies that in the regulatory framework, there are challenges including presence of multiple agencies with different mandates and expertise that an innovator firm has to navigate, and lack of regulatory capacity within the government in tandem with the latest advances in science and technology and dependence on ad-hoc external inputs.

"A mechanism will be explored by the government that will mandate all the regulators to work together to reduce process overlapping and establish timelines for requisite approvals. Data protection and time bound processing of regulatory approvals will be an important aspect to be followed by the regulators," said the policy.

"It will aim to bring down the current time taken for regulatory approvals for innovative products by at least 50% within the next two years," it added.

Various measures to strengthen the existing institutional capacity of the regulatory bodies, will be explored which would include building in-house expertise in respect of New Biological Entities and New Chemical Entities, Biologics, Imaging medical technologies, New Materials, tele-diagnostics, AI/ML based innovations, Sensors, etc.

National Pharmaceutical Pricing Authority (NPPA) would work to develop greater expertise in the pricing of new innovative products while pursuing affordability as an overall objective. Collaboration with relevant international regulatory agencies and capacity building of regulators will enable them to introduce benchmarked best practices, stay ahead of the curve and add

value to the expansion of the Pharma-MedTech sectors through Innovation.

"A review of the multiple legislation impacting research and development in pharmaceuticals and medical devices could be undertaken to identify areas of friction and design tenable solutions. Some of the areas indicated for such effort include differentiated handling of research in products that are cultured and cultivated artificially, increasing the number of bodies that can approve pre-clinical trials, enabling joint inspections and licensing mechanisms for traditional medicinal products," added the Policy notified by the Department.

The policy focuses on the provision of appropriate fiscal and non-fiscal incentives for pharmaceuticals/MedTech innovations by introduction of direct/ indirect funding support to promote India as an innovation hub. The interventions would be in compliance with multiple treaties with foreign countries wherein inter alia the Government of India has committed to non-discriminatory treatment of foreign investments in the country.

There is also a need to look at a range of interventions that would facilitate funding support for innovation such as schemes to support investments into R&D/innovation, reimbursement of R&D spending and appropriate fiscal incentives, review of scope of the patent box etc., it added.

Funding support can also be explored from the existing and future government programmes and schemes to aid R&D based innovation in the sector such as National Research Foundation (NRF) and Biotech Innovation Fund and leveraging the existing fund support available with various Ministries and departments for focused outcome-oriented Pharma and MedTech research. Thus, a compelling 'Discover in India' vision is to be created as a message to be actively disseminated across stakeholders.

The Policy will be supported by a ten-year Strategy and action plans that will spell out the policy and programmatic interventions required from time to time within the Policy, said the DoP during the time of notification.

https://www.pharmabiz.com/NewsDetails.aspx?aid=169353&sid=1
May 27, 2024

PLI Scheme For Medical Devices Attracts Investment Of Rs. 959 Crore Till April 2024

The production linked incentive (PLI) scheme for medical devices has reported commissioning of 17 manufacturing units till the end of April, 2024, with an actual investment of around Rs. 958.72 crore made by the industry.

The PLI scheme for promotion of domestic manufacturing of medical devices, launched in the year 2020, has witnessed actual investment going up almost Rs. 121.5 crore from Rs. 837.23 crore investments till March, 2023, to Rs. 958.72 crore by the end of April, 2024, according to official data.

The scheme has recorded actual production to the tune of Rs. 5,889.29 crore till April 30, 2024, offering employment to a total of 5,466 persons.

Under the PLI scheme for medical devices with a financial outlay of Rs. 3,420 crore, for the period 2020-21 to 2027-28. Total 26 applicants out of the 64 applications received, have been approved by the DoP in four rounds. The total number of products approved for these 26 applicants under the scheme is 138, according to the Department.

Under the scheme, financial incentive is given to selected companies at the rate of 5% of incremental sales of medical devices manufactured in India and covered under four Target Segments of the scheme, that is, cancer care equipment, imaging devices, critical care devices, and body implants.

The objective of this scheme is to establish domestic manufacturing capability of high-end medical devices under these four target segments.

The ministry of chemicals and fertilisers, under which the DoP operates, has in March, 2024, announced inauguration of 13 Greenfield manufacturing plants for medical devices under the PLI scheme. The projects inaugurated include Panacea Medical Technologies' linear accelerator (LINAC) and rotational cobalt machine in Karnataka, Philips Global Business Services' MRI Coils in Maharashtra, Siemens Healthcare's CT Scan and MRI production facility and Wipro GE Healthcare's CT Scan Cath lab and ultrasonography facilities in Karnataka, Trivitron Healthcare's X-Ray equipment, C-Arm, mammography and ultrasonography production facility in Maharashtra and Andhra Pradesh, Allied Medical's Anaesthesia related product range in Rajasthan, Microtek New Technologies' oxygen concentrators in Himachal Pradesh, among others.

The Ministry during the inauguration claimed that when the scheme was introduced, India imported 90 per cent of medical devices and after the introduction of the scheme, the net imports of medical devices decreased for the first time in 2023.

The Ministry said that with a wide base of scientists, biomedical engineers, and a growing innovation ecosystem in the country, the India MedTech sector is poised to grow rapidly. Indian manufacturers are continuously innovating. For instance, under the scheme, the country has indigenously developed cancer care equipment, such as Linear Accelerator for radiotherapy and evolved coronary stents.

It added that the medical devices being manufactured under the PLI scheme include high-end medical devices such as CT scan, MRI Coil, LINAC, C-Arm, Ultrasonography, Dialysis Machine, Intensive care ventilators, Knee implants, Hip Implants, Heart valves, Stents, Dialyzer etc. Some of these medical devices are being domestically manufactured for the first time in the country. Thus, the PLI scheme has paved the way for an ecosystem for domestic manufacturing of these high-end medical devices, said the Ministry.

The scheme encourages manufacturers to invest in R&D activities to develop innovative products and technologies. The scheme has enabled technology transfer in high-end medical devices enhancing capabilities.

The medical devices exports from the sector has been growing steadily at a CAGR of around 14% since FY 2019-20, said the Ministry. The market for the medical device industry in India is estimated to be of the size of $11 billion and it is expected to cross the $30 billion mark by 2050.

https://www.pharmabiz.com/NewsDetails.aspx?aid=169589&sid=1 June 6, 2024

Dialysis Firm Nephroplus Gets 8,50 Crore From Quadria

New Delhi: Singapore-based healthcare-focused PE firm Quadria Capital has announced an investment of $102 million (Rs 850 crore) in NephroPlus, Asia's largest dialysis network. Quadria will acquire a significant minority stake through a combination of a primary investment and purchase of ₹ shares from existing shareholders, a company statement said.

The transaction will support NephroPlus in serving growing demand for high quality, affordable dialysis services across India and other markets in Asia.

Founded in 2010, NephroPlus operates in sizeable, high-growth markets across Asia, with dominant leadership in India and a fast-growing footprint in the Philippines and other Asian countries. Demand for dialysis services in the company's target markets is expected to grow at a rate of over 11% annually over next five years.

Vikram Vuppala, founder and CEO of NephroPlus, said: "Our business has evolved tremendously over the past few years and today we are proud to be one of the fastest growing and most trusted providers of high-quality dialysis to around 30,000 patients. We look forward to expanding in India, our core market, while exploring further opportunities to bring our expertise and clinical excellence to more patients in other global markets".

https://timesofindia.indiatimes.com/business/india-business/dialysis-firm-nephroplus-gets-850-crore-from-quadria/articleshow/109897530.cms
May 7, 2024

India Poised To Benefit From US Tariff Hikes

Biden plan to levy high tariffs on a host of Chinese products, including electric vehicles (Evs), batteries, and medical supplies.

US President Joe Biden's plan to levy high tariffs on a host of Chinese products, including electric vehicles (EVs), batteries, and medical supplies, will likely benefit Indian exporters, government officials and trade experts believe.

Higher duties on Chinese face masks, syringes, needles, medical gloves and natural graphite could aid Indian exports of these products. By scaling up production and exports of these sough-after products, India stands to boost its presence in the US market, they said.

The White House on Tuesday hiked tariffs on Chinese EVs from 25% to 100%, the doubled levies on solar cells from 25% to 50%, and tripled the duty on certain steel and aluminium products from 7.5% or less to 25%.

Tariffs on non-lithium-ion battery parts shipped from China to the US will also increase from 7.5% to 25%. Previously untaxed Chinese items such as face masks, critical minerals, and ship-to-shore cranes will now be subject to a 25% tariff.

Washington has reportedly said that these tariffs will hit an estimated $18 billion worth of imports from China.

“It will certainly open gates for Indian products in the markets of developed economies," said a senior government official, who wished not to be named.

“The US is one of the major export markets for most Indian goods, such as diamonds, medical appliances and accessories, agricultural products, refined petroleum, rice, textiles, and apparel, among others."

That said, experts also cautioned about the possible dumping of Chinese goods in India. With the US and EU facing reduced imports of Chinese EVs due to tariff hikes, Beijing might divert these products to other markets, including India.

Opportunities for India

"Certain medical products, including PPE kits, syringes, gloves, and others, will enter the US market. India's position as the second-largest producer of PPE kits, masks, face masks, syringes, needles, and medical gloves will give us a significant advantage, allowing us to benefit from this opportunity," said Ajay Sahai, director general of the Federation of Indian Export Organizations (FIEO).

To be sure, India is not a leading manufacturer of every Chinese item now facing a tariff hike – China, for instance, is the world's largest manufacturer of EVs, whereas Indian EV production is negligible.

However, the story may be slightly different for some other items. In March 2024, exports of medical plastics, including syringes, catheters, cannulae, and spectacle lenses, surged by 10.4%, reaching $48.7 million from $44.1 million in March 2023.

India has the potential to ramp up its manufacturing capacities in certain segments to tap into opportunities resulting from the high tariffs imposed by the US on Chinese products, making them less competitive, Sahai said.

He also added there were potential export opportunities in aluminium and steel.

In FY24, Indian exports to the US saw a marginal decrease of 1.32%, totalling $77.5 billion compared to $78.54 billion in 2022-23. Simultaneously, imports from the US declined approximately 20%, amounting to $40.8 billion, according to data from the commerce ministry.

Implications of US-China trade tensions

“These proposed increases are a part of the US's broader strategy under Section 301 of the Trade Act of 1974, aimed at combating what it deems as unfair trade practices by China," said Ajay Srivastava, the founder of Global Trade Research Initiative (GTRI).

Katherine Tai, the US Trade Representative, emphasized that these measures are necessary to counter the flooding of global markets with low-cost Chinese products.

In 2023, the US imported goods worth $427 billion from China and exported $148 billion, highlighting a significant trade imbalance.

However, the GTRI said the proposed tariff increases exceed the US's bound duty commitments at the World Trade Organization, potentially violating WTO provisions. “The US has increasingly justified these increases under the rarely used National Security clause."

“Developed countries, including the US and EU, are increasingly embracing protectionist measures through routine tariff increases that exceed their WTO commitments and substantial subsidy programs aimed at boosting local production. This shift signals a prioritization of industrial policy over trade policy, reflecting a broader trend towards economic self-reliance," GTRI's Srivastava said.

“The new tariffs are another hit to supply chains as they try to manage ongoing risks and build resiliency. Whenever tariffs are increased, regardless of the rationale for doing so, the impact goes beyond cost increases to companies and consumers," said John Donigian, senior director of supply chain strategy at Moody’s.

Queries emailed to the commerce ministry remained unanswered till press time.

https://www.livemint.com/economy/competition-commission-of-india-to-soon-bring-new-set-of-merger-regulations-11716215222979.html
16 May 2024

NPPA Revises Ceiling Price Of Coronary Stents In Tune With WPI Growth

The National Pharmaceutical Pricing Authority (NPPA) has revised the ceiling prices of coronary stents with effect from the beginning of April, 2024, in tune with the Wholesale Price Index (WPI) change for the year 2023 over the previous year.

The Authority notified revised ceiling prices of 923 scheduled formulations with effect from April 1, 2024, in tune with the change in terms of the Wholesale Price Index announced for the preceding calendar year of 2023 over the year 2022. The prices have been revised to the tune of 0.00551 per cent from the beginning of April, 2024.

The price of bare metal stents, according to the revised order, will be Rs 10,509.79 per unit, while the drug eluting stents (DES) including metallic DES and bioresorbable vascular scaffold (BVS)/biodegradable stents will have the revised price of Rs. 38,267.18 per unit.

The Authority directed that all the existing manufacturers and importers of Coronary Stents having maximum retail price lower than the revised ceiling price (plus Goods and Services Taxes as applicable, if any), may revise the existing MRP of coronary stent, on the basis of WPI @ 0.00551% for the year 2023 over 2022 in accordance with the provisions of the Drugs Prices Control Order (DPCO), 2013.

As per Para 24(4) of DPCO 2013, every retailer and dealer shall display price list and the supplementary price list, if any, as furnished by the manufacturer or importers, on a conspicuous part of the premises where he carries on business in a manner so as to be easily accessible to any person wishing to consult the same.

"The manufacturers not complying with the ceiling price and notes specified hereinabove shall be liable to deposit the overcharged amount along with interest thereon under the provisions of the Drugs (Prices Control) Order, 2013 read with Essential Commodities Act, 1955," said the order.

It may be noted that the Union ministry of health and family welfare (MoHFW) has notified inclusion of the Coronary Stents in the National List of Essential Medicines (NLEM) 2015 and 2022, based on recommendations by the expert committee constituted to review and revise the list based on requirement.

The sub-committee which recommended the inclusion of coronary stents in the NLEM 2015, said that the inclusion was considering the high burden of coronary artery disease (CAD) in the country, which is associated with high morbidity and mortality, and that the coronary artery disease is a public health problem.

Although, medical devices are different from drugs in respect of their nature, mechanism of action, manufacturing, quality control, mode of administration/implantation, etc, coronary stents are among the categories of medical devices which have been notified by the government of India as “Drug" under the provisions of the Drugs and Cosmetics Act, 1940.

The NLEM 2022 was included in the Schedule I of the DPCO, 2013, following the release of the List, and the NPPA initiated measures from the end of the year 2022, to revise or fix the ceiling price of the drugs based on the revised Schedule.

https://www.pharmabiz.com/NewsDetails.aspx?aid=168886&sid=1
May 3, 2024

Kotak Alt To Invest Rs 400 Crore In Medical Device Maker Biorad Medisys

Synopsis

Kotak Strategic Situations India Fund II (KSSF II) managed by Kotak Alternate Asset Managers Limited (Kotak Alt) announced investing up to Rs 400 crore in medical device manufacturer Biorad Medisys. The investment will primarily facilitate a new manufacturing plant setup, debt repayment, and increased working capital.

Kotak Strategic Situations India Fund II (KSSF II), managed by Kotak Alternate Asset Managers Limited (Kotak Alt) on Tuesday announced an investment of up to Rs 400 crore in medical device manufacturer Biorad Medisys.

Biorad Medisys will primarily utilise the investment from KSSF II to set up a new manufacturing plant, repay existing debt and fund increasing working capital requirements.

Established in 1999, the company makes orthopedic implants for knee and hip and surgical and consumables focused on urology, gastroenterology and neuro- vascular intervention through its manufacturing facilities at Pune, and Bengaluru.

The company sells its products in India and countries across geographies like Latin America, Europe, Southeast Asia and Middle East.

“The Indian medical devices industry is at an inflexion point, with increasing demand for quality healthcare along with the Government’s support for domestic manufacturers through the ‘Make in India’ campaign, we believe that Biorad Medisys is well poised to capture this growth over the coming years,” said Eshwar Karra, CEO, KSSF.

“We will now strive to scale the business to newer heights through sustainable value creation and providing best-in-class quality and performance,” said Jitendra Hegde, MD, Biorad Medisys.

KSSF II is a $1.5 billion fund with focus on providing solution capital across growth and value creation situations.

https://economictimes.indiatimes.com/industry/healthcare/biotech/healthcare/kotak-alt-to-invest-rs-400-crore-in-medical-device-maker-biorad-medisys/articleshow/110119178.cms
May 14, 2024

Medtronic Appoints Mandeep Singh Kumar As Vice President Of Medtronic India

India Medtronic Private Limited on Friday announced the appointment of Mandeep Singh Kumar as the new Vice President and Managing Director of India Medtronic Pvt. Ltd., beginning May 2024.

According to the company's statement, he succeeds Michael Blackwell who has moved back to the US to pursue new opportunities. Assuming this position, he will oversee sales, marketing, and commercial operations for Medtronic's business in India.

"Mandeep Singh Kumar has extensive experience spanning over 25 years and has demonstrated agile leadership in driving successful growth and business transformations across healthcare, pharmaceutical and med-tech sectors. His expertise includes strategy development, ensuring successful execution, driving commercial excellence, and building winning teams across the globe," the company stated.

Mandeep's previous role was as Country Leader with Intuitive India where he led the development and implementation of plans to broaden patient access, build a holistic ecosystem for robotic assisted surgery, and drive successful customer robotic programs.

https://www.financialexpress.com/business/healthcare-medtronic-appoints-mandeep-singh-kumar-as-vice-president-of-medtronic-india-3507910/
May 31, 2024

Improving Medical Plastics Processing

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

In the field of medical plastics processing, ensuring the reliability of plastic materials is essential. However, one persistent challenge that plagues this sector is the management of moisture content in medical-grade plastics. Moisture absorption poses a significant threat, potentially compromising the quality and integrity of essential medical devices. This absorption can result in dimensional changes, reduced strength, and the onset of microbial growth, all of which pose risks to both product reliability and patient safety.

Effectively controlling moisture levels is therefore crucial in ensuring consistent quality and reliability throughout the processing of medical plastics. By implementing robust moisture control measures, manufacturers can mitigate these risks and optimise production efficiency.

Innovative solutions, such as advanced drying techniques, have emerged as valuable tools in combating moisture-related challenges. By integrating such solutions into their processes, manufacturers can uphold the highest standards of quality and reliability, ultimately delivering safer and more dependable medical devices to patients worldwide.

This focus on moisture management underscores the ongoing commitment of the medical technology industry to innovation and excellence, driving advancements that benefit patient care and safety.

Qosina Introduces New iDOT™ Single-Use Sensor Bag Ports from Polestar Technologies

Ronkonkoma, NY, USA, June 6, 2024—Qosina, a global supplier of OEM single-use components to the medical and pharmaceutical industries, has partnered with Polestar Technologies, a leader in optical sensing technologies since 1993, specializing in the monitoring of O2, CO2 and pH. Qosina is pleased to announce the addition of iDOT Single Use Sensor Bag Ports from Polestar Technologies to its extensive portfolio.

These integrated Disposable Optical Transducer (iDOT™) gamma-stable bag ports offer noninvasive monitoring and come pre-calibrated for plug-and-play use. Polestar's iDOT sensor configuration allows for simple integration of pH and dissolved oxygen (DO) monitoring to singleuse bags, including bioreactors. They feature a POE bag port with sensing film, using materials that meet USP Class VI requirements. These bag ports are designed to work with Polestar Technologies' DSP series optical process monitoring products, where the bag port would attach to a Polestar fiber optic cable. All products are made in the USA.

Qosina will market the iDOT bag ports to customers of all needs and sizes. Whether in R&D or full scale production. Qosina's ability to serve large and small customers, along with its high service levels, extensive product portfolio, sampling capabilities and technical expertise, will help fill an important supply chain and distribution role for Polestar Technologies.

Qosina is a one-stop source for single-use bioprocess components, with low minimum orders, a liberal sampling policy and bill of material kitting, all supported by regulatory documentation and backed by Qosina's assurance of supply.

Explore Qosina's single-use bioprocess component selection at www.qosina.com/bioprocess

About Qosina

Founded in 1980, Qosina is a leading global supplier of OEM single-use components to the medical and pharmaceutical industries. Qosina's philosophy is to address its customers' need to reduce time to market by providing thousands of stock components. The company's vast catalog features more than 5,000 products shown in full-scale illustrations on a one-centimeter grid. Qosina offers free samples of most items, low minimum order requirements, just-in-time delivery, modification of existing molds, and new product design and development. Qosina is ISO 13485, ISO 9001, ISO 22301, ISO 45001 and ISO 14001 certified, and operates in a 95,000 square-foot facility with an ISO-8 Class 100,000 Cleanroom. To learn about Qosina's full component offering, which includes the newest products, visit www.qosina.com or call +1 (631) 242-3000. Visit Qosmedix, Qosina's cosmetics division, at www.qosmedix.com. Qosmedix is a certified global supplier of beauty tools and accessories to the cosmetic, skincare, spa and salon industries.

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Qosina is a leading global supplier of more than 5,000 OEM single-use components to the medical and pharmaceutical industries. We offer free samples, low minimum order requirements, just-in-time delivery, modification of existing molds, and new product design and development.

Qosina is ISO 13485, ISO 9001, ISO 22301 and ISO 14001 certified, and operates in a 95,000 square-foot, climate-controlled facility that includes an ISO Class 8 Clean Room.

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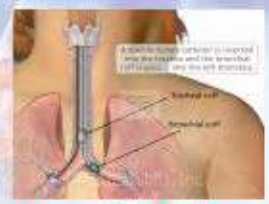
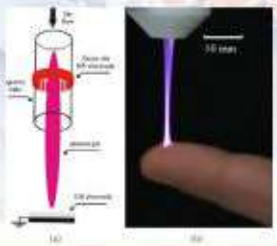


Technology

- Facilitation Centre For Industrial Plasma Technologies
- Plasma Technologies For Purification and Sterilization
- Plasma Pyrolysis Technology for Disposal of Biomedical Waste
- Plasma Jet : Biomedical Applications



Medical Polymers & Devices

- The Future of Medical Device Design
- 50 Innovations : How Medical Polymers Revolunize Pain Management in Medical Practices.
- PVC Medical Devices : Emerging Trends
- Importance of Precise Placement of Double –Lumen Tube during Anaesthesia & Surgery.

Medical Device Manufacturing

- Medical Device Manufacturing: Importance of Supply Chain
- Medical Device Sterilization
- US FDA :
  - Harmonization & Modernization of Regulations
  - Disposable Syringes : Quality Failures

Materials

- PVC Vs. Other Polymers In Medical Devices
- EU Report On Essential Role of PVC in Healthcare
- Adhesives For Medical Device Applications

Peru Medical Devices Market

Mr. Manoj Bhardwaj
Managing Director, SMC Ltd., Bangalore
Key Requirements of Contract Manufacturers

MedTech Innovations

- What Drives Innovation In India
- Top 100 Innovations
- Environmental Impact
- New Medical Device Policy 2023
- Gamma Radiation Sterilization
- Silicones : Life - Sustaining Applications
- Medical Devices : Dominican Market

- **Medical Device Design & Development Process :**
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Dr. Manoj Komath

- Catheter Tubing : Materials & Manufacturing
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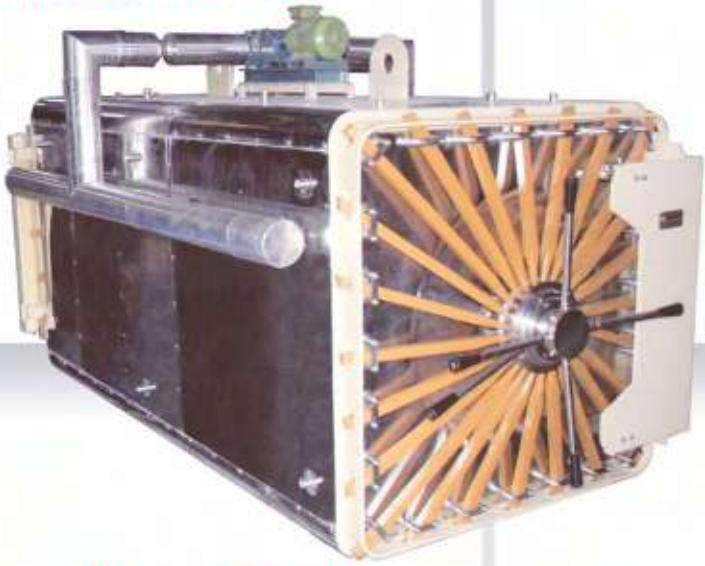

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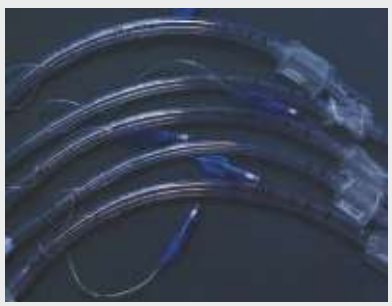

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