Vol.32 No. 2 Mar. - Apr. 2024

Our 32nd Year of Publication

MEDICAL PLASTICS DATA SERVICE

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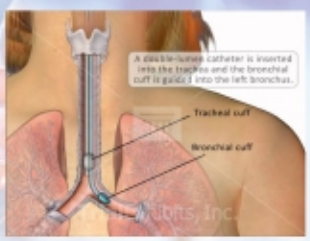
A TECHNO-ECONOMIC NEWS MAGAZINE FOR MEDICAL PLASTICS, MEDICAL DEVICES, DIAGNOSTICS AND PHARMA INDUSTRY

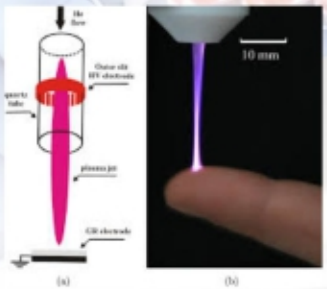
Medical Devices Sterilization

- Microbiological Contaminants
- Sterility Assurance Levels Required
- Sterilization Methods
- Ethylene Oxide Alternatives For Sterilization
- Process Validation & Other Challenges



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.

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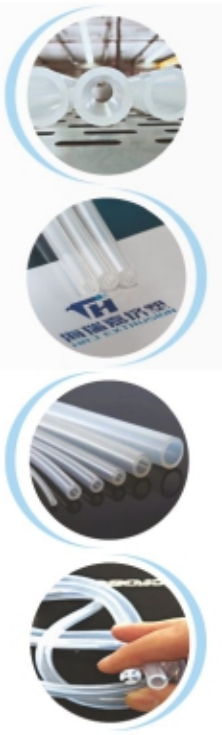

Model	Screw Diameter	L/D	Main Power	Product Standred	Floor Space
HRJSJ-50	50mm	14:1	15KW	Φ1.5mm-10mm	L13M*W1.5M*H4.0M
HRJSJ-65	65mm	14:1	22KW	Φ3.0mm-25mm	L15M*W1.5M*H4.0M
HRJSJ-90	90mm	14:1	45KW	Φ5.0mm-40mm	L18M*W1.5M*H4.0M

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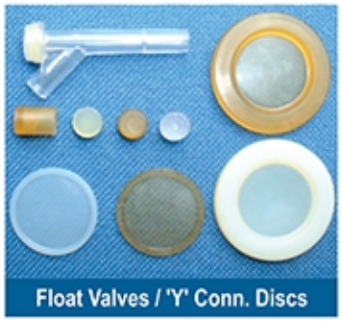
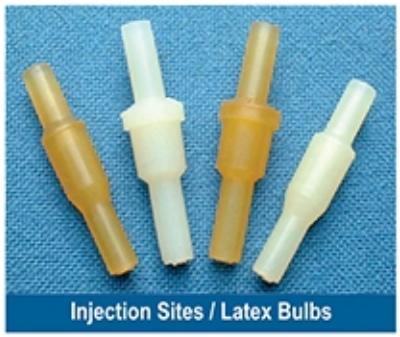
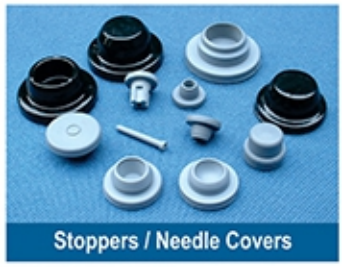

Float Valves / 'Y' Conn. Discs


Injection Sites / Latex Bulbs


Syringe Gaskets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- Breathing Filter - All Type
- 3 Ball Spirometer
- Ambu Bag - Adult / Paed / Neo
- Ventilator Circuit - All Type
- Bain Circuit - Adult / Paed
- Endotracheal Tube Plain & Cuf fe
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- 3-Way Extension Line
- Measure Volume Set
- Dial Flow Regulator
- I. V. Set With Flow Regulator
- Codan Set

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

UROLOGY & NEPHROLOGY
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- Urine Bag With Urometer
- Hemodialysis Catheter Kit
- Neltan Catheter
- Blood Tubing Set
- AV Fistula Needle
- DJ Stent - All Type

GASTROENTROLOGY
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- Infant Feeding Tube
- Ryles Tube
- Stomach Tube
- Kher T Tube
- Levins Tube
- Selum Sump Tube

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- Suction Catheter
- Thoracic Drainage Catheter
- Abdominal Drainage Kit
- Close Wound Suction Set
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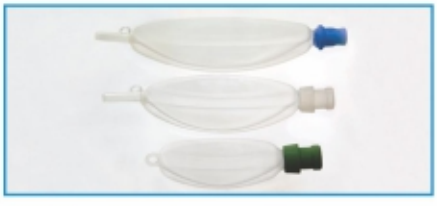
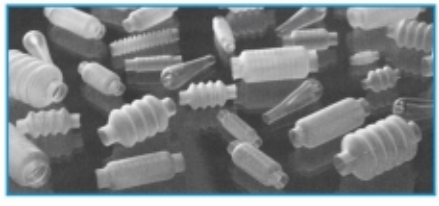
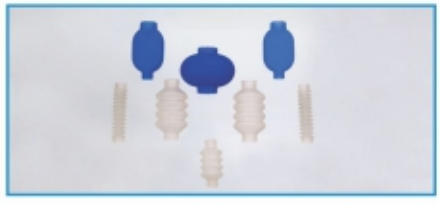

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- DIN EN ISO 13485 Quality management for medical devices
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- Hemocompatibility Tests (ISO 10993-4)
- Carcinogenicity Test (ISO 10993-11)
- Reproductive / Developmental Toxicology (ISO 10993-11)
- Degradation Testing (ISO 10993-9, ISO 10993-13, ISO 10993-14 & ISO 10993-15) Toxicokinetic study of Degradation Products (ISO 10993-16)
- In-vitro Skin Irritation Test (ISO 10993-23)
- In-vitro Skin Sensitization Test (ISO 10993-10)
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6. Stability Testing Services

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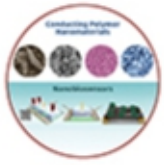
9. Performance Testing of Rapid In Vitro Diagnostic Kits



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11. Clinical Study (CER)

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- Important Thermoplastics
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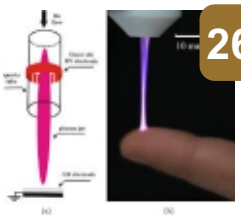

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DATA SERVICE

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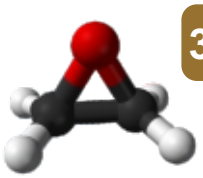

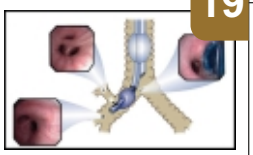

Flashback

MEDICAL PLASTICS DATA SERVICE

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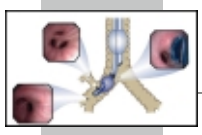
Sept. 2020 to Jan 2021

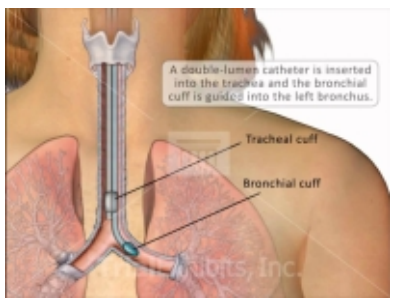


Did You Know ?

About Importance Of Precise Placement Of Double – Lumen Tube During Anesthesia And Surgery

A double-lumen tube (DLT) is an endotracheal tube designed to isolate the lungs anatomically and physiologically. Double-lumen tubes (DLTs) are the most commonly used tubes to provide independent ventilation for each lung.

One-lung ventilation (OLV) or lung isolation is the mechanical and functional separation of the 2 lungs to allow selective ventilation of only one lung. The other lung that is not being ventilated passively deflates or is displaced by the surgeon to facilitate surgical exposure for non-cardiac operations in the chest such as thoracic, esophageal, aortic and spine procedures. It can also be used during minimally invasive cardiac surgery and in disease processes.



DLT is an essential equipment for thoracic anesthesia and its precise placement is particularly important for anesthesia and surgery.

Incidence of DLT malposition remains high and it leads to lung isolation failure and hypoxemia during one-lung ventilation.

In one such incidence, the Supreme Court directed Manipal Hospital to pay Rs 10 lakh compensation to the widow of a patient who developed hoarseness in his voice as a result of faulty insertion of a double lumen tube while administering anaesthesia. While the operating surgeon had assured the patient that the patient could regain his voice within 6-8 months with nebulization and voice therapy, the patient's voice was not restored and remained hoarse all through. The patient had virtually lost his voice.

Doctors opined that there was subluxation of the left arytenoid process, which happened due to wrong intubation during the anaesthesia procedure. It was found to be on account of the trauma caused leading to the paralysis of the vocal cord.

https://medicaldialogues.in/pdf_upload/supreme-court-rs-10-lakh-compensation-232650.pdf
https://www.ncbi.nlm.nih.gov/books/NBK535366/

MEDICAL PLASTICS
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MEDICAL PLASTICS
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From the Editor's Desk

Medical Devices Sterilization:
In most of the applications, medical devices have to be sterile. Sterility is a hygienic standard and its understanding had been developed for decades in the twentieth century. It is important to understand the need of sterility and its problems within the medical device industry.

Each sterilization procedure needs to be accessed for technical viability. The method should be as fast and reliable as possible and should have no impact on plastic materials. The cover story includes: nature of microbiological contaminants, product wise sterility assurance levels required, various sterilization methods used, process validation & other challenges as well as possible alternatives for Ethylene Oxide.

SPE INDIA Medical Plastics Division
We are happy to announce launching of Society Of Plastics Engineers India (SPE INDIA) Medical Plastics Division. SPE, founded in 1942 is spread over 84 countries with more than 60,000 stakeholders helping Plastic Professionals worldwide succeed and strengthening their skills through networking, events, training and knowledge sharing. The Medical Plastics Division (MPD) exists to encourage the interchange of technical and regulatory information on the polymer materials / components used in medical devices among the scientists and engineers who are working in medical device and related industries.

Medical Device Industry Technology Eco-system in India
We have been introducing various reputed Institutions either in Government Sector of Private Sector supporting growth of Medical Device Industry. One such Institute introduced in this issue is **Facilitation Centre of Industrial Plasma Technologies (FCIPT)** under Institute for Plasma Research (IPR), (an autonomous Institute of Dept., of Atomic Energy, Govt. of India) devoted to research in plasma science, technology and applications. Along with industrial applications, FCIPT is working on many biomedical applications under cold plasma techniques for surface modification and sterilization. It includes Plasma Sterilization of Medical Equipment, Plasma – surface modification for preventing bio-film formation, Plasma Pyrolysis for Safe Disposal of Biomedical waste, Atmospheric Pressure Plasma Jet which can be used for a large number of biomedical applications.

Innovations in Medical Polymers Revolutionizing Medical Device Industry
As per a very well researched article contributed by " Lubrizol Life Science " , leading medical device manufacturers are in race to develop new devices that are smarter , minimally invasive and capable of delivering better patient outcomes. The article includes three important trends that will define the future of Medical Device Design. It explains variety of factors important to consider . One such widely used material highlighted is Thermoplastic Polyurethanes (TPUs) .

One more article contributed by " Shriram Polytech Limited" highlights emerging trends in PVC Medical Devices.

A very important aspect related to "adverse effects is "importance of Precise Placement of Double-Lumen Tube during Anaesthesia and Surgery explained in "Did You Know" column. It describes how malposition can lead to lung isolation failure and hypoxemia.

As always, this issue also includes other columns like Industry and Regulatory News, Global Market Trends, Events etc.

D L Pandya

Sterility Assurance Levels Required For Medical Devices & Sterilization Methods

Many of the procedures and applications require devices to be in temporary or permanent contact with a patient's skin, tissue, blood, or other parts of the body. Such devices should not cause infection to the patient from microbiological contamination or residues. **Contamination from microorganisms can come from various sources that could include the raw material from suppliers, the manufacturing process and the storage, handling and distribution processes.**

Many devices need to be packaged and sterilized, either before distribution or before use. Examples of such devices are surgical gloves, clean room garments, specimen cups, wound care products, sutures, needles, syringes, catheters, drain bags, IV bags, fluid delivery systems, dialysis equipment, implants, surgical instruments, dental instruments, surgery supplies, and combination products. Devices for such applications should be sterile before use to ensure that the microbiological contamination is minimized. **The purpose of sterilization is to inactivate the microbiological contaminants and thereby transform the nonsterile medical devices into sterile products.** Fig below lists some of the different types of microorganisms and their resistance to disinfection and sterilization.

Most resistant

Most resistant

- Prions
- Bacterial spores
- Mycobacteria
- Small, nonenveloped, nonlipid viruses
- Gram-negative bacteria
- Fungi
- Large, nonenveloped, nonlipid viruses
- Gram-positive bacteria
- Vegetative bacteria
- Medium-sized lipid enveloped viruses

Least resistant

Adapted from Favero MS, Bond WW Chemical Disinfection of Medical and of Medical and Surgical Material. In: Disinfection, Sterilization and Preservation, 5th Edition Phila: Lippincott Williams & Wilkins 2001 pp. 881-917

ISO 11139 details sterilization process standards and provides a vocabulary of terms used in sterilization of medical devices.3 EN 556-1 is the harmonized European standard specifying requirements for designating a terminally sterilized device as sterile.4 It has also been adopted in a number of countries outside Europe, for example, Australia and China. EN 556-1 specifies that a probability of a viable microorganism on a device of 10-6 or less (e.g., 10-7) has to be achieved in order to designate a terminally sterilized medical device as sterile. EN 556-2 is the harmonized European standard specifying requirements for designating an aseptically processed device as sterile.5

The sterility of any product is defined by the probability of a viable microorganism on the product after it has been sterilized. This probability is referred to as a Sterility Assurance Level (SAL) which is defined as the probability of a single viable microorganism occurring on an item after sterilization.3 The SAL is normally expressed as 10-n and is quantitative value to assume sterility. SALs of 10-3 or 10-6 are the most frequently used values for sterilization. The lower the SAL, the higher the sterility of the medical device or material. The probability of a single viable microorganism occurring on an item after sterilization can never be reduced to zero (i.e. 100% assurance level).

Sterility Assurance Level (SAL)

Types of Medical Devices requiring different levels of Sterility Assurance levels (Either 10-6 and 10-3)

Illustrative List Of Products with Sterility Assurance Level (SAL), SAL = 10-6 0r less

A Products and materials intended to come into contact with breached skin or compromised tissue:

- Catheters
- Cannulas
- Wound dressings
- Prefilled syringes
- Incise drapes
- Surgical Instruments
- Ventilators

B Invasive Products and materials that come into contact with sterile tissue:

- Lead extraction devices
- Surgical instruments
- Ultrasound probes
- Biopsy probes
- Endoscopes
- Bronchoscopes

C Products and materials that come into contact with sterile fluid pathways:

- Fluid delivery administration sets
- IV tubing
- Dialysis tubing
- Syringe needles; syringes
- Blood collection devices
- Endoscopes

D Surgically implanted devices:

- Stents
- Cardiac Leads
- Implanted infusion pumps
- Implanted orthopedic devices
- Sutures
- Intraocular lenses
- Surgical meshes

E Cell-based and tissue-based devices

Illustrative List Of Products with Sterility Assurance Level (SAL), SAL = 10-3

A Products not intended to come into contact with breached skin or compromised tissue:
- Blood collection tubes, specimen containers, culture media devices
- Surgical drapes and gowns,
- Medical equipment

B Products incapable of achieving an SAL 10-6 by any sterilization method:
- Porcine heart valves

Methods used to sterilize medical devices include moist heat (steam) or autoclaving, dry heat, radiation, EtO gas, vaporized hydrogen peroxide, and other sterilization methods like chlorine dioxide gas, vaporized peracetic acid, and nitrogen dioxide. EtO sterilization comprises 50% of the global sterilization market, followed by gamma radiation (40.5%), e-beam (4.5%), and other methods of sterilization like steam autoclaving, hydrogen peroxide, etc., (5%).

Sterilization procedure includes always some disadvantages due to the simple fact that there is a certain amount of energy necessary to destroy living germs, even those, which are specialized on harsh living conditions. On the other hand, a sterilization procedure should be as fast and reliable as possible and has no impact on plastic materials as well. Interesting emerging technologies for medical device sterilization might be:

- Plasma beam sterilization
- Hydrogen beam sterilization
- X-ray beam Sterilization
- Electro-beam sterilization

Medical Device Ethylene Oxide (ETO/EO) Sterilization: Validation and other challenges

Mr. Sanjay Shah
Director, Unikal Consultants

What is a medical device? A definition is referred in article in this Issue.

Why there is an emphasis on medical device with right quality and performance?

This is to elevate the focus of all medical device stakeholders from baseline regulatory compliance to sustained, predictive practices that advance medical device quality and safety to achieve better patient outcomes.

Quality standards which are established should be treated as base line and not the ceiling of quality.

We are consistently talking of Make in India and export to the world with acceptable quality. We must also work on make for India. We should expect and demand same quality of healthcare products; medicines and medical devices, that is available in the developed world. We must get the same treatment with our experienced medical fraternity, in the environment and, with healthcare products of world class quality.

In medical device field, it must be designed with the latest technology and made of the material accepted all over. More on this and where we are lacking can be the content of a separate article. Today we are talking of specific requirements and challenges of EO sterilization process and validation.

Why some medical devices need to be sterilized?

A sterile medical device is one that is free of viable microorganisms. Medical devices produced under standard manufacturing conditions in accordance with the requirements for quality management systems (EN ISO 13485 and acceptable under MDSAP); might, prior to sterilization, have microorganisms on them, albeit in low numbers. Such medical devices are non-sterile. The purpose of sterilization is to inactivate the microbiological contaminants and thereby transform the non-sterile medical devices into sterile ones.

The kinetics of inactivation of a pure culture of microorganisms by physical and/or chemical agents used to sterilize medical devices can generally best be described by an exponential relationship between the numbers of microorganisms surviving and the extent of treatment with the ethylene oxide (EO); inevitably this means that there is always a finite probability that a microorganism might survive regardless of the extent of treatment applied.

Challenge is to reduce the same to a level acceptable in the current scenario. To do so, not only the equipment, methodology and sterilant used is appropriate, a validation of the process and equipment needs to be done. Basis for this article arises from these requirements.

For a given treatment, the probability of survival is determined by the number and resistance of microorganisms and by the environment in which the organisms exist during treatment. It follows that the sterility of any one medical device in a population subjected to sterilization processing cannot be guaranteed and the sterility of a processed population is defined in terms of the probability of there being a viable microorganism present on a medical device.

What are the challenges: To achieve certain level of acceptable sterility level, many factors need to be considered. Type of materials the medical device is made from, manufacturing process, packaging line, packing material compatibility, and bio load on the medical device; final application, or use of the medical device is a critical factor as well.

Challenges start in finding right sterilization method, which is effective, cost effective, safe to use, has long history of use, and handling of the sterilant and equipment is acceptable.

Why Is Ethylene Oxide Used to Sterilize Medical Devices?

Ethylene oxide sterilization is an important sterilization method that manufacturers widely use to keep medical devices safe. Learn more about sterilization methods in the Submission and Review of Sterility Information in Premarket Notification (510(k)) Submissions for Devices Labeled as Sterile Guidance. (ref - FDA Guidelines)

Literature shows that about fifty percent1,2,3 of all sterile medical devices in the U.S. are sterilized with ethylene oxide. The types of devices that are sterilized with ethylene oxide range from devices used in general health care practices (for example, wound dressings) to more specialized devices used to treat specific areas of the body (for example, stents).

For many medical devices, sterilization with ethylene oxide may be the only method that effectively sterilizes and does not damage the device during the sterilization process. Medical devices made from certain polymers (plastic or resin), metals, or glass, or that have multiple layers of packaging or hard-to-reach places (for example, catheters) are likely to be sterilized with ethylene oxide.

ISO 11135 describes requirements that, if met, will provide an ethylene oxide sterilization process intended to sterilize medical devices, which has appropriate microbicidal activity. Furthermore, compliance with the requirements ensures that validations conducted following this International Standard will

provide products that meet the defined requirements for sterile products with a high degree of confidence.

The globally harmonized standard, that provides guidance for completing such a validation is ANSI/AAMI/ISO 11135:2014, "Sterilization of health care products – Ethylene oxide – Requirements for development, validation, and routine control of a sterilization process for medical devices".

Amendment 1: Revision of Annex E, Single batch release (ISO 11135:2014/Amd 1:2018). This document modifies EN ISO 11135:2014 with a revised European Foreword and European Annexes ZA, ZB and ZC, and additional European Annexes ZD and ZE as per MDR 1975/745.

Challenges in carrying out special processes:

The standards for quality management systems recognize that, for certain processes used in manufacturing or reprocessing, the effectiveness of the process cannot be fully verified by subsequent inspection and testing of the product. Sterilization is an example of such a process. For this reason, sterilization processes are validated for use, the performance of the sterilization process monitored routinely, and the equipment maintained.

Since process is defined as a special process; it needs to be operated by qualified operators as per SOP guidelines, operators need to be well trained by qualified personnel in the EO Sterilization process and operating EO Sterilizers.

Exposure to a properly validated, accurately controlled sterilization process is not the only factor associated with the provision of reliable assurance that the product is sterile and, in this regard, suitable for its intended use.

Attention is therefore given to number of considerations including:

- — the microbiological status of incoming raw materials and/or components.
- — the validation and routine control of any cleaning and disinfection procedures used on the product.
- — the control of the environment in which the product is manufactured or reprocessed, assembled and packaged.
- — the control of equipment and processes.
- — the control of personnel and their hygiene.
- — the manner and materials in which the product is packaged.
- — the conditions under which product is stored.

Here we have attempted to give an overall view of what is equipment and process validation and steps involved like DQ, IQ, OQ & PQ. Specifically for Ethylene Oxide (EO) sterilization.

- An Ethylene Oxide (EO) Sterilization Validation is designed to assist the manufacturer in the development of a sterilization process that delivers the appropriate sterility assurance level and ensures repeatability for each product type developed.

Describing detailed processes, documentation and re-validation will require much bigger platform.

So, queries in implementation, interpretation and report preparation may be addressed to the author. We will make best efforts to resolve them.

Validation

EtO Sterilization is a low-temperature process (typically between 37 and 63°C) that uses Ethylene Oxide gas to reduce the level of infectious agents. EtO is used in gas form and is usually mixed with other substances, such as CO2 or steam. It is mainly used for products that cannot withstand the heat of typical autoclave sterilization such as plastic. The main physical parameters to be monitored are temperature and relative humidity.

The total length of the process can vary depending on the goods that are being sterilized, but typical cycles are between 36 and 48 hours. There are two main ways to divide the cycle; a three-phase cycle and a five phase cycle. The difference being that a three-phase cycle does factor in the pre and post exposure phases.

Three phases of EtO Sterilization

A typical three phase EtO sterilization cycle can be summarized as follows:

Preconditioning:
Provides temperature and humidity conditions to entice infectious agents to come out of hibernation

Sterilization / Conditioning:
Exposure to the sterilizing agent at the specified temperature, RH% and pressure levels

Aeration:
Et0 gas is removed using changes of air in the sterilization chamber removing any EtO particles. This process is usually taking place in a separate chamber or room. Time and temperature are monitored.

Validation Stages – definition / explanation

Validation – Is a process where documented evidence is generated to demonstrate that the equipment, product and/or process do what it purports to do.

INSTALLATION QUALIFICATION (IQ)

- Generally, Equipment specific Activities conducted to demonstrate that equipment has been installed or modified as designed.

In health care facilities, process and equipment characterization are generally the responsibility of the sterilizer manufacturer. The management of the health care facility should have controls in place to ensure that the equipment it purchases conforms to national, regional, and local regulations and is suitable for use to sterilize products that require EO sterilization. Sensors, data loggers and other monitoring equipment forms critical part of IQ

The management of the health care facility should ensure that the facility has the infrastructure necessary to correctly operate the sterilizing equipment and to achieve effective sterilization of medical devices.

Software and it's validation. Software used to control and/or monitor the process shall be prepared and validated in accordance with the elements of a quality system that provides documented evidence that the software meets its design specification.

OPERATIONAL QUALIFICATION (OQ)

- Product, Process or Equipment
- Activities conducted to demonstrate that changes in an existing product/process, piece of equipment, new product/process scale-up or new installations operate as designed.

VALIDATION OR PROCESS QUALIFICATION (PQ)

- Product or Process
- Activities conducted using the specified product / process / equipment, i.e., one that has been "qualified", to demonstrate that the system (product/process/equipment) does what it purports to do consistently and reproducibly.
- PQ consists of both microbiological and physical performance qualification and is performed in the equipment used to sterilize the product.

Most often, the validation of an EO cycle follows the half-cycle or "over-kill" method using Biological Indicators (BI's) and product. This method demonstrates that the resistance of the microbiological challenge test system is equal to or greater than

the product bioburden.

An Ethylene Oxide (EO) Sterilization Validation is designed to assist the manufacturer in the development of a sterilization process that delivers the appropriate sterility assurance level and ensures repeatability for each product type developed.
Standard ISO 11135:2014 covers following, with referred clause numbers:

6 Process and equipment characterization

6.1 General

The purpose of this activity is to define the entire sterilization process and the equipment necessary to deliver the sterilization process safely and reproducibly.

6.2 Process characterization

Process characterization, at a minimum, shall include:

a) identifying the phases that are necessary for an EO sterilization process;
b) identifying the process variables for each phase; and
c) documenting the process variables

6.3 Equipment characterization

The specification for the equipment to be used shall be developed and documented. This specification shall include:

a) the preconditioning area (if used);
b) the sterilizer; and
c) the aeration area (if used)

9 Validation

9.1 General

The purpose of validation is to demonstrate that the sterilization process established in the process definition (see Clause 8) can be delivered effectively and reproducibly to the product within the sterilization load. Validation consists of several identified stages: installation qualification (IQ), operational qualification (OQ), and performance qualification (PQ). Testing shall not commence until the procedures and/or protocols have been approved.

9.2 Installation qualification, IQ

9.3 Operational qualification, OQ

9.4 Performance qualification, PQ – Microbiological & Physical

9.5 Review and approval of validation

The purpose of this activity is to undertake and document a review of the validation data to confirm the acceptability against the approved validation procedures/protocol for the sterilization process and to approve the process specification.

10 Routine monitoring and control

The purpose of routine monitoring and control is to demonstrate that the validated and specified sterilization process has been delivered to the product.

When validating an EO sterilization process, it is necessary to perform a mapping of the chamber and monitor temperature and relative humidity to evaluate the performance of EO sterilization. Both empty and loaded chamber tests are required.

It is important that patient safety be addressed by minimizing exposure to EO and its by-products during normal product use. ISO 10993 7 specifies limits for EO and ethylene chlorohydrin (ECH); however, no exposure limits are set for ethylene glycol (EG) because risk assessment indicates that when EO residues are controlled, it is unlikely that biologically significant residues of EG would be present.

Author's observations during validation / re-validation process – challenges:

Use of wireless data loggers can make validation process more accurate and easier

Use of EO concentration monitor probe is recommended. This is expensive but can be very reassuring for validation data.

BI strips used per cycle is substantial in number and cost of testing post the cycle is substantial, especially when their results need to be validated from third party (independent test facility).

These and other time and cost consuming processes make the validation very assuring for manufacturer, healthcare person and of course the patient.

Acceptable and beyond Quality of device; assurance of its safe and effective use should be kept in mind while carrying out these validations faithfully and diligently.

Some extracts from FDA guidance documents:

How Does the FDA Help Ensure that Medical Devices Sterilized with Ethylene Oxide Are Safe?

Before most sterile medical devices are on the market, the FDA reviews premarket submissions to determine if the sterility information (for example, the method the manufacturer is choosing to sterilize their device and validation activities used to show that the device can be effectively sterilized) is in accordance with internationally agreed upon voluntary consensus standards that the FDA recognizes. An important element of our regulatory framework is a robust standards program. The FDA encourages medical device manufacturers to use FDA-recognized voluntary consensus standards in their submissions, as conformity to relevant standards streamlines regulatory review and fosters quality. Learn more about the

FDA's Recognized Standards Program.

For ethylene oxide sterilization, voluntary consensus standards (ANSI AAMI ISO 11135:2014) describe how to develop, validate, and control ethylene oxide sterilization processes for medical devices and the acceptable levels of residual ethylene oxide and ethylene chlorohydrin left on a device after it has undergone ethylene oxide sterilization. These standards help ensure levels of ethylene oxide on medical devices are within safe limits since long-term and occupational exposure to ethylene oxide has been linked to cancer. Learn more about the risks of ethylene oxide on the National Institutes of Health web page on ethylene oxide.

The FDA also inspects industrial facilities that sterilize medical devices and medical device manufacturing facilities to make sure that they have validated sterilization processes that meet FDA -recognized standards.

EPA's Role in Ethylene Oxide Sterilization

The U.S. Environmental Protection Agency (EPA) reviews and enforces the Clean Air Act regulations for sterilization facilities that emit ethylene oxide to ensure that they protect the public from significant risk. Learn more about the EPA's Regulations for Ethylene Oxide on EPA's website.

Note: In preparation of this article author acknowledges he has referred and quoted from ISO 11135 narratives and FDA guidance documents. He is grateful to them.

FAST FACTS

The global ethylene oxide sterilization services market size was valued at USD 4.4 billion in 2022 and is projected to expand at a compound annual growth rate (CAGR) of 10.7% from 2023 to 2030.

- Grand View Research

Facilitation Centre for Industrial Plasma Technologies

Institute for Plasma Research **(IPR),** (an autonomous Institute of Dept. of Atomic Energy, Govt. of India) is exclusively devoted to research in plasma science, technology and applications. India's first high temperature plasma device "Aditya Tokamak, built at IPR, produces plasmas at 5 million degrees temperature - comparable to that of the sun. An advanced fusion device with superconducting magnets, capable of steady state operation is under fabrication. IPR is also active on a broad front of fundamental studies. It has engineering groups skilled in technologies of Superconducting Magnetic, Ultra High Vacuum, Pulsed Power, Microwave and RF, Computer-based Control and Data Acquisition. Theory and computer simulation complement experimental programmes.

FCIPT infrastructure with State-of-art R&D setup, manufacturing and testing/characterization facilities

FCIPT

The Facilitation Centre for Industrial Plasma Technologies (FCIPT) as a unit of IPR, links the Institute with the industries and commercially exploits the IPR knowledgebase. FCIPT interacts closely with entrepreneurs through the phases of development, incubation, demonstration and delivery of technologies. Complete package of at broad spectrum of plasma-based industrial technologies and facilitation services is offered.

FCIPT offers services, equipment supply, technology transfer in the following fields:

- **Surface Engineering:** Technologies like Plasma nitriding, Plasma ion implantation, Plasma Enhanced Chemical Vapour Deposition, Plasma Metallizing, Aluminizing for performance enhancement of engineering goods in wear/corrosion resistance, hardness etc. applicable to industrial sectors like Textile Processing, Plastic industry, automobile, Die and Mould/ Tooling industry, power plant, aerospace & defence sectors.
- **Mineral Processing:** Thermal plasma technology for value addition to mineral smelting of ores of Titanium, Zircon etc. Emerging needs of advanced Ceramics can be met by thermal plasma route. Thermal plasma techniques can also be utilized for metallurgical smelting and refining, space craft re-entry simulation etc.
- **Biomedical applications: Cold plasma techniques for surface modification and sterilization have been developed at FCIPT. Novel biomedical applications using pencil torch are being explored.**
- **Environmental applications & Alternate Energy:** Gas phase corona reactor has been developed and installed at IPCL, baroda for treatment of VOCs. Plasma Pyrolysis Technology has been developed at FCIPT for waste disposal and energy recovery from waste has been proved and widely appreciated. Atmospheric plasma treatment for sterilization of spices is also taken up at FCIPT for development & transfer.
- **Textile applications:** Atmospheric pressure plasma processing, non-thermal plasma pencil torch systems, dielectric barrier discharge systems etc. are being used for novel textile processing applications.
- **Nanotechnology applications:** The knowhow on plasma technology has been successfully utilized to develop nanotechnology applications such as nano-patterning of surfaces for solar applications, nano powder synthesis etc.

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Plasma Pyrolysis Technology for Safe Disposal of Biomedical Waste

Plasma pyrolysis is a thermal disintegration process where organic mass is fragmented into hydrogen, CO and lower hydrocarbon in oxygen starved environment. Graphite based Plasma torch is used to produces high temperature (plasma core temperature >5000 deg C) in the primary chamber by converting electrical energy into thermal energy in an efficient manner. Almost 99% of organic mass gets converted into combustible gases in this process. These combustible gases are useful fuel for heating application and can also be used for power generation. Unlike conventional incinerators, toxic molecules such as dioxins, furans, poly-aromatic hydrocarbons etc. are completely eliminated in Plasma pyrolysis. Hence; it is an environment friendly process for safe disposal of biomedical waste. Plasma pyrolysis is approved under the Gazette of India for safe disposal of BMW.

Salient features

- Thermal disintegration of waste at high temperature and in oxygen starved environment, plasma core temperature is more than 5000 deg C.
- All emissions are within the limit set by US-EPA and CPCB/MoEF&CC.
- Environment friendly process.
- MoEF&CC/CPCB approved home grown technology.

Applications

- Plasma pyrolysis is approved for safe disposal of biomedical waste under BMW management rules 2016.

Atmospheric Pressure Plasma Jet

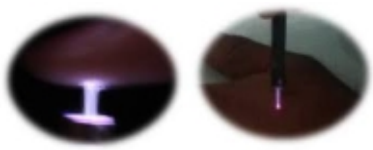
Atmospheric Plasma Jet is a simple apparatus to form plasma at atmospheric pressure. The plasma produced is touchable by bare hands and can be used for bio-medical, agricultural and surface modification application.

Salient features

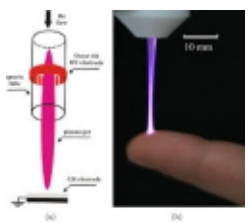
- Simple apparatus to produce plasma at atmospheric pressure.
- Operates on 24 V batteries for bio-medical application.
- Plasma apparatus is portable.
- Plasma is touchable for bio-medical applications.

Applications:

Bio-medical application:



- Blood coagulation.
- Skin treatment.
- Dental cleaning.
- Treatment of certain types of cancers.



- Hair treatment for dyes.
  Sterilization of hands.

Agricultural applications:

- Sterilization of vegetables.
- Sterilization of seeds.
- Increasing the germination rate of seeds.

Surface modification:

- Increasing the surface energy of the polyester film for some coatings.
  Sterilization of bio-films.

http://www.plasmaindia.com/Pyrolysis.html
http://www.plasmaindia.com/Plasma_jet.htm

EVENT REPORT

ONE DAY SEMINAR ON

Plasma Technologies for Purification and Sterilization

ABOUT THE THEME OF SEMINAR

PTPS-2024 showcased plasma based technologies developed indigenously in the field of air and water purification as well as sterilization of medical components for the benefit of medical device companies, medical practitioners, bio-technologists, researchers, pharmaceutical companies and industrialists. It was participated in large numbers by Researchers and representatives from Medical Devices & Health sectors alongwith those in Dairy industries, MSMEs, Environment Sector, Packaging and Textile industries.

TOPICS COVERED

- Plasma sterilization of medical equipment
- Prevention of bio-film formation by plasma surface modification
- Inactivation of micro-organisms using plasma-activated water
- Non-thermal plasma for purification of ambient air containing microorganisms
- Atmospheric plasma jet for hand sterilization
- Exhaust gas treatment using plasma
- Advanced oxidation process for industrial wastewater treatment

Smaller, Smarter and Sustainable: Trends that Will Define the Future of Medical Device Design

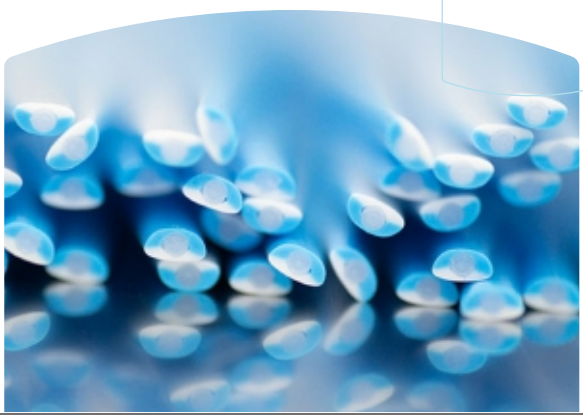
There's never been a bigger moment for innovation in the healthcare industry than right now. Leading medical device manufacturers are in a race to develop new devices that are smarter, minimally invasive and capable of delivering better patient outcomes. But without a trusted polymers partner to offer the materials knowledge and testing capabilities necessary to give your device the performance characteristics it needs — your innovation may not be realized.

LUBRIZOL LIFE SCIENCE

Trend 1: MINIMALLY INVASIVE DEVICES

Patient comfort is one of the highest considerations when developing a medical device. Manufacturers are constantly striving to make their devices less invasive. The first thing that comes to mind when we think of "minimally invasive" is size. Because these types of devices are introduced into the patient's body through incisions that need to be kept small, device designers know it is critical for them to have the thinnest possible walls to allow the largest possible delivery channel without compromising on outer diameter (gauge).

Thin walls require materials with the appropriate physical properties that provide a combination of strength, kink resistance, friction reduction and extrusion processability. Thermoplastic polyurethanes (TPUs) are a widely used material due to the strength they impart in minimally invasive devices, allowing manufacturers to bring designs for optimal patient outcomes to life.



Trend 2: DEVICES WITH SMART TECHNOLOGY

An emerging trend in medical device design is utilizing new technology to make devices smarter. For example, by incorporating additional sensors into a catheter, you are also able to measure flow, pressure and other factors during an examination that help physicians to optimize the treatment for a better patient outcome.

Another example of smarter devices are wearables such as continuous glucose monitors (CGMs). Just as important as the sensors that are pushed through the skin to measure glucose levels in the body are the membranes that coat them. CGM sensor coatings are a unique part of the function of the device itself and are coated for multiple reasons including:

- Immobilization of glucose-related enzymes, which fuel the generation of electrochemical signals to the sensor.
- Exclusion of other dissolved substances that can interfere with sensor readings and reduce device sensitivity.
- Creation of a biocompatible interface within the body, including prevention of sensor fouling.

Materials suppliers can evaluate how best to incorporate and apply polymers as a coating. Suppliers can also modify existing polymers to develop these necessary membranes and provide critical protection to the device and to the patient.

Trend 3: DEVICES MADE WITH SUSTAINABILITY IN MIND

As the healthcare industry evolves, manufacturers are facing pressure from key stakeholders to produce devices that use environmentally sustainable materials, implement processes that reduce their carbon footprint, and produce more high-quality devices that are capable of lasting longer periods of time and meet evolving regulatory requirements. Partnering with a materials supplier who utilizes bio-sourced raw materials and optimized processing techniques is key to developing more sustainable devices.

HOW LUBRIZOL LIFE SCIENCE SUPPORTS INNOVATION IN MEDICAL DEVICE DESIGN

Device manufacturers looking to stay ahead of the curve and develop the next generation of medical devices will need to innovate in terms of size, smart technology and sustainability. Selecting the right materials and the right partner will enable them to do so.

At Lubrizol, we are experts in the relationship between the structure, processing, and performance of medicalgrade TPUs. Our team designs new TPUs to achieve specific mechanical properties that will allow medical device designers to create smarter and smaller devices, thereby making them less invasive, safer, and ultimately, more effective.

We also strive to create a more sustainable environment and reduce our carbon footprint by recycling materials and exploring reclaiming our Isoplast® ETPU during dental aligner manufacturing and reusing it in industrial applications. We are also considering utilization of sustainably bio-sourced raw materials. Furthermore, we help our customers develop more sustainable and more reliable medical devices, particularly in implant applications by producing high quality materials for long-term applications.

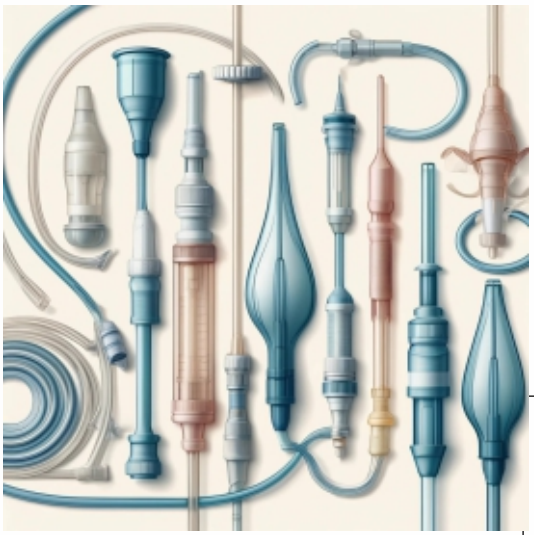
DELIVERING VALUE BEYOND THE DEVICE

To develop an innovative device, manufacturers must think holistically. It's important to consider a variety of factors including material selection, compatibility with other materials and equipment used during procedures, manufacturability, and how the device will be assembled, packaged, and sterilized. At Lubrizol, we consider all phases – from concept to commercialization to ensure the device can deliver the required clinical performance and desired patient outcome – **it's how we deliver value beyond the device.**

To learn more about how Lubrizol can bring your innovation to life, visit us at go.lubrizol. com/BYDBrief or contact Rajnish.Singh@Lubrizol.com for more information.

The Emerging Trends in PVC Medical Devices

Courtesy : Corporate Communications, Shriram PolyTech Limited (Group Company of DCM Shriram Ltd.)



Polyvinyl chloride (PVC) stands as a cornerstone in the realm of medical device manufacturing, revered for its versatility, cost-effectiveness, and compatibility with rigorous sterilization protocols. However, the landscape is evolving, with a spotlight on the polymer compounders who fuel this industry. Consumer behavior in the medical industry has shifted towards stringent industry specifications, placing responsibility for purchasing compounds on the device manufacturers from the polymer compounders who follow the specification or are in the process of doing so. Understanding these heightened standards not only provide valuable insights but also will evolve into the possibilities of circularity and premiumization of the Industry.

Let us try and understand the applications and why the medical industry is growing stricter with their standards while they chose a compounder:

Intravenous (IV) Tubing: PVC is commonly used in the manufacture of IV tubing due to its flexibility and compatibility with various medications. PVC formulations are increasingly used free from DEHP (di(2-ethylhexyl) phthalate), a plasticizer that has raised concerns about its potential health effects.

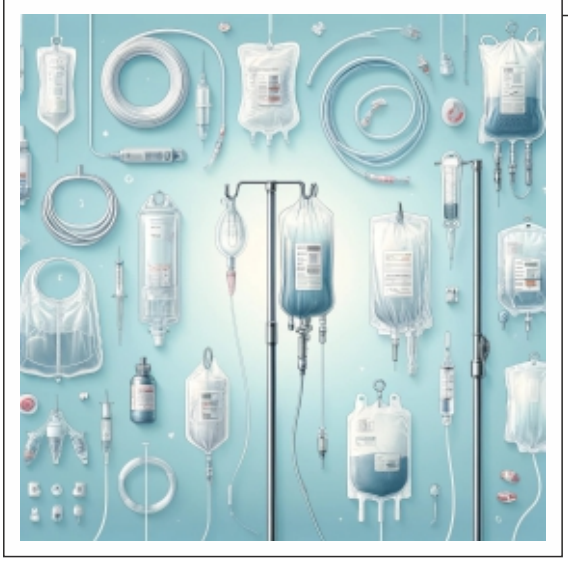
Blood Bags: PVC is also used to manufacture blood bags because it can withstand the storage and transportation of blood and blood products. PVC formulations are being developed with improved properties, such as increased durability and puncture resistance.

Catheters: PVC is a key material in producing urinary catheters, central venous catheters, and other types of catheters. Recent trends include the use of antimicrobial additives in PVC formulations to reduce the risk of infections associated with catheter use.

Medical Tubing: PVC is used in a wide range of medical tubing applications, including nasogastric tubes, respiratory tubing, and drainage tubes. Manufacturers are focusing on developing PVC formulations that meet stringent regulatory requirements for biocompatibility and safety.

Infusion Sets for delivering medications and fluids to patients, **Surgical Gloves** due to their flexibility and barrier properties, **Braces and Supports** in orthopedic supports due to their ability to provide support and immobilization, and **Medical Packaging** and pharmaceutical products due to their clarity and barrier properties.

Overall, PVC continues to be a valuable material in the medical device industry, and manufacturers are constantly innovating to improve the performance, safety, and sustainability of PVC medical devices. The focus on PVC formulations has shifted from concerns over plasticizer additives to innovation, aiming for health-safety formulations. This includes enhancing durability, puncture resistance, and antimicrobial properties. However, adherence to regulatory standards like ISO:13485-2016 and USP Class VI is crucial for Indian value players. Trust and transparency are paramount, and the choice of PVC compounders should transcend cost considerations. Industry stalwarts and conscientious consumers must navigate this landscape with integrity, ensuring every PVC compound for medical devices meets these standards.



Ehylene Oxide Alternatives For Medical Device Sterilization

Finding suitable ethylene oxide alternatives for medical device sterilization is more crucial than ever with the **EPA's new emissions rule** in light of **the chemical's health risks.**

Ethylene oxide (abbreviated as EtO or EO) is estimated to be used to sterilize of half of all medical devices, or about 20 billion units per year. It's primarily used for new, single-use and reusable devices and equipment. For example EtO is used to sterilize an estimated 95% of all surgical kits.

EtO alternatives include radiation sterilization (using gamma rays or electron beams) and heat, but there are currently no EtO alternatives for some products.

Of all sterilization methods, EtO is least likely to harm a medical device's materials or components. Other sterilization methods have limitations on material compatibility and scalability or lack accepted validation measures for sterility assurance.

"The absence of EtO for use on medical devices and equipment would cause widespread disruption to the availability of sterile medical devices including feeding tubes used in neonatal intensive care units, drug-eluting cardiac stents, catheters, shunts, and other implantable devices," the EPA said in its **2023 proposal for new EtO regulation.**

But there are some EtO alternatives available for a wide range of medical devices, and more may be on the way as the FDA works with the medtech industry to ensure the safety of patients, sterilization workers and neighbors of sterilization facilities.

Radiation sterilization: gamma ray and electron beam (e-beam)

The next most common methods of medical device sterilization after EtO are two forms of radiation sterilization: gamma irradiation and **electron beam (e-beam) irradiation.** Like EtO, these methods can penetrate product packaging, and can even go further into airtight compartments where EtO can't reach.

But radiation sterilization methods can damage semiconductors and degrade other electronics in medical devices. Radiation sterilization can also damage or otherwise change the properties of certain polymers and plastics, and discolors clear glass.

Vaporized hydrogen peroxide (VHP)

The FDA recognized vaporized hydrogen peroxide (VHP) as an Established Category A method of sterilization for medical devices in January 2024. (Other Category A sterilization methods include EtO, dry heat, moist heat and radiation.) Long used as a sterilant in its aqueous form, hydrogen peroxide (H O) kills microorganisms like those that cause infections by oxidizing amino acids and proteins. Under ISO 22441:2022, VHP (also referred to as VH O) can be used to sterilize medical devices at low temperatures in both health care and industrial facilities.

What about heat sterilization as an ethylene oxide alternative?

Heat sterilization is the least expensive method of sterilization for medical devices, and that means any device that can be sterilized with heat instead of EtO probably already is. The high temperature of heat sterilization — whether dry heat or steam — makes it suitable only for heat-resistant materials, and the moisture from steam is a deal-breaker for electronics.

Potential ethylene oxide alternatives in development

The FDA has worked with at least four companies to **identify new sterilization methods and technologies through its FDA Innovation Challenge,** which is also seeking ways to reduce emissions from continued EtO sterilization.

This process has already led the FDA to add VHP (described above) to its list of Established Category A sterilization methods.

Companies working directly with FDA on new sterilization methods and technologies focusing on following technologies:

- Supercritical carbon dioxide sterilization (NovaSterilis)
- Nitrogen dioxide sterilization (Noxilizer)
- Accelerator-based radiation sterilization (STERIS)
- Vaporized hydrogen peroxide-ozone sterilization (TSO3, a Stryker subsidiary)

The new sterilization methods that don't use EtO would not only need to be safe and effective, but also meet certain criteria for compatibility, scalability and high throughput.

The new approaches would need to be compatible with a large cross-section of materials used for medical devices, packaging and sterile barriers, particularly materials that are compatible with EtO sterilization.

The FDA also wants the new approaches to have the potential for scale and effective sterilization of large volumes of devices in order to fulfill some or all of the demand for EtO sterilization.

Another potential alternative is **chlorine dioxide gas,** developed by Johnson & Johnson. The FDA approved sterilant for contract sterilization of medical devices in 2021, and it's been used for implantable contact lenses, artificial joints, suture products, surgical kits, vial stoppers, endoscopes and electronic devices.

But EtO has so far held one or more advantages over chlorine dioxide and other potential alternatives, so the search continues.

www.medicaldesignandoutsourcing.com March 14, 2024

Society of Plastics Engineers
Medical Plastics Division

84 Countries

60,000+ stakeholders

We unite plastics professionals

About Society Of Plastic Engineers

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.

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 encourage the 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.

SPE INDIA Medical Plastics Division

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

MEMBER BENEFITS

SPE benefits and programs are designed by plastics professionals for plastics professionals. You get only the "good stuff," from experts working in the field every day. No "fluff," just substance!

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- connection to a **global** community
- live **technical** events
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Contact : SPE INDIA INTERNATIONAL COUNCILOR : Mr Rajiv Sanghavi, Satellite Plastic Industries,
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Email: dlpandya@gmail.com, M : 9825467563

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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.

Highlights of Virtual Inauguration

Board meeting coordinated by **Mr Rajiv Sanghavi,** International Councillor, SPE INDIA.

Mr Conor Carlin, President, SPE 2024 (Left) with
Mr Ramesh Parameswaran, President, SPE INDIA

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

Mr Conor Carlin, President, SPE 2024 (Left) with
Mr D L Pandya, Vice President, Medical Plastics Division SPE INDIA

50 Innovations: How Medical Polymers Revolutionized Pain Management in Diverse Medical Practices

Source : Society of Plastic Engineers Medical Plastics Division 2023-24 Winter Newsletter

Eliminating Pain Using Medical Polymers

1. **Robotic Surgery:**
   Robotic surgical instruments and devices incorporate precision plastic components for lightweight and precise control, enable minimally invasive procedures, reducing patient trauma and promoting quicker recovery.
2. **Intravenous (IV) Catheters:**
   These catheters, made of plastic materials, are used to deliver fluids, medications, or anesthesia directly into the bloodstream, reducing pain associated with repeated needle insertions.
3. **Vascular Stents:**
   Stents made from biocompatible plastics are used to open narrowed blood vessels, reducing pain caused by restricted blood flow and improving overall blood circulation.
4. **Insulin Pumps:**
   These devices, incorporating plastic components for tubing, reservoirs, and housing, deliver a continuous and customizable supply of insulin, providing diabetic patients with precise control over their blood sugar levels and minimizing the need for multiple injections.
5. **Wound Closure Strips:**
   These adhesive strips, often made of flexible plastic materials, offer a less painful alternative to sutures for closing small wounds, promoting faster healing and reduced discomfort.
6. **Intrathecal Drug Delivery Systems:**
   Using plastic components, these systems deliver pain-relieving medications directly into the spinal fluid, targeting pain receptors and minimizing systemic side effects.
7. **Intraocular Lenses:**
   These lenses, often made of plastic materials, replace the eye's natural lens during cataract surgery, improving vision and reducing postoperative discomfort.
8. **Pain Relief Cream Applicators:**
   Devices with plastic applicators are used to apply pain relief creams or gels topically, ensuring precise and mess-free application for localized pain relief.
9. **Nerve Block Catheters:**
   These catheters, made of flexible plastic tubes, deliver local anesthetics directly to nerves, providing prolonged pain relief after surgery or for chronic pain conditions.
10. **Pain Relief Orthoses:**
    Orthopedic braces and supports made of plastics provide stability and support to injured or painful joints, reducing discomfort and aiding in rehabilitation.
11. **Inhalers and Nebulizers:**
    Devices made with plastic components are used to deliver medications directly to the lungs, easing breathing difficulties and reducing discomfort for respiratory patients.
12. **Intragastric Balloons:**
    Utilizing plastic materials, these balloons are inserted into the stomach to aid in weight loss by reducing hunger and discomfort associated with overeating.
13. **Hemodialysis Catheters:**
    These plastic catheters are inserted into large veins to facilitate hemodialysis, reducing pain and discomfort for patients with kidney failure undergoing regular dialysis treatments.
14. **Pain Relief Compression Garments:**
    These garments, made of specialized elastic plastics, provide targeted compression to alleviate pain associated with swelling or circulation issues.
15. **Endotracheal Tubes:**
    These flexible plastic tubes are used to maintain an open airway during surgeries under anesthesia, ensuring proper breathing and reducing post-operative discomfort.
16. **Pain Relief Heat/Cold Packs:**
    Plastic-contained packs provide controlled application of heat or cold therapy, reducing pain and inflammation in specific areas of the body.
17. **Epidural Catheters:**
    These catheters are made with flexible plastic tubes and are used to deliver pain-relieving medications directly into the epidural space around the spinal cord. Plastics are used to ensure flexibility and comfort during insertion, minimizing discomfort for patients.
18. **Infusion Pumps:**
    These devices often incorporate plastic components to deliver controlled doses of pain-relieving medications or anesthesia directly into the bloodstream, ensuring a steady and pain-free administration.
19. **Nerve Stimulators:**
    Some nerve stimulators use plastic components in their electrodes or probes to precisely target and stimulate nerves, providing pain relief through electrical impulses without invasive procedures.
20. **Transdermal Patches:**
    These patches are made with plastic materials and contain pain-relieving medications that are slowly absorbed through the skin, providing continuous pain relief over an extended period.
21. **Orthopedic Implants:**
    Various orthopedic implants, such as joint replacements or plates, often use biocompatible plastics that mimic the properties of bone to reduce pain and improve mobility post-surgery.
22. **Cryotherapy Devices:**
    Some cryotherapy devices use plastic applicators to deliver cold therapy, reducing pain and inflammation by numbing nerve endings and constricting blood vessels.
23. **Dental Anesthesia Delivery Systems:**
    Plastic components in dental anesthesia delivery systems help in precise and comfortable administration of local anesthetics, minimizing pain during dental procedures.
24. **Ultrasound Devices:**
    Ultrasound machines often have plastic transducers that emit sound waves to create images of internal body

SPE INDIA Medical Plastics Division

Eliminating Pain Using Medical Polymers

structures, aiding in guided pain relief injections or diagnostic procedures.

25. **Continuous Glucose Monitoring Systems (CGMS):**
Some CGMS devices utilize plastic sensors inserted under the skin to monitor glucose levels, reducing the discomfort of frequent finger pricks for diabetic patients.

26. **Insulin Pumps:**
These devices incorporate plastic components for housing, tubing, and reservoirs to deliver insulin continuously, reducing pain associated with frequent injections for diabetic patients.

27. **Minimal Invasive Surgical Tools:**
Tools used in minimally invasive surgeries, such as laparoscopes and endoscopes, utilize plastic components for their lightweight and durable properties, reducing tissue trauma and post-operative pain.

28. **Nerve Conduction Study Devices:**
Some devices used for nerve conduction studies incorporate plastic electrodes, aiding in diagnosing nerve-related pain conditions by measuring electrical impulses.

29. **Pain Relief Eye Drops and Applicators:**
Plastic containers and applicators are used to deliver pain-relieving eye drops, ensuring precise and sterile administration for ocular discomfort.

30. **Plastic-based Neural Prosthetics:**
Prosthetic devices for nerve regeneration and pain management often use specialized plastics that interact with nerve tissue to mitigate chronic pain conditions.

31. **Pain Relief Injection Pens:**
Pens equipped with plastic components are used to administer pain-relieving injections with precision and minimal discomfort for patients with chronic conditions.

32. **Plastic-based Radiofrequency Ablation Probes:**
These probes use plastic materials to precisely target and ablate nerve tissues, providing long-term pain relief for certain chronic conditions.

33. **Pain Relief Electrotherapy Devices:**
Some electrotherapy devices incorporate plastic electrodes and pads, delivering targeted pain relief through electrical stimulation, minimizing discomfort.

34. **Plastic Splints and Braces:**
Used in the management of fractures and injuries, plastic splints and braces offer support and stability, reducing pain and aiding in the healing process.

35. **Pain Relief Laser Therapy Devices:**
Devices utilizing plastic components deliver low-level laser therapy to alleviate pain and inflammation, promoting tissue healing without causing discomfort.

36. **Pain Relief Massage Tools:**
Massagers made with plastic components help in relaxing muscles and reducing pain by providing targeted pressure and vibration therapy.

37. **Plastic-based Neurostimulation Implants:**
Implantable devices made with specialized plastics deliver neurostimulation to manage chronic pain conditions, providing long-term relief.

38. **Pain Relief Taping Systems:**
Elastic therapeutic tape with plastic components is used to alleviate pain by providing support to muscles and joints, enhancing movement without restricting mobility.

39. **Pain Relief Nasal Sprays:**
Nasal sprays containing pain-relieving medications in plastic containers offer quick relief from headaches and migraines.

40. **Insulin Pen Injectors:**
Insulin pen injectors, equipped with plastic cartridges and durable plastic bodies, provide a convenient and pain-free method for diabetic patients to self-administer insulin, offering precise dosage control and reducing the need for traditional syringes.

41. **Pain Relief TENS Unit Electrode Pads:**
These adhesive pads, typically made with conductive plastic materials, attach to the skin to deliver Transcutaneous Electrical Nerve Stimulation (TENS), easing various types of pain without invasive procedures.

42. **Plastic-based Pain Relief Traction Devices:**
Traction devices with plastic components aid in spinal decompression, alleviating back pain by gently stretching the spine and relieving pressure on nerves.

43. **Pain Relief Foot Orthoses:**
Customized orthotic insoles made from plastics offer support and alignment, reducing foot pain associated with various conditions such as plantar fasciitis.

44. **Plastic-based Percutaneous Neuromodulation Therapy:**
Devices employing plastic components provide pain relief by delivering electrical stimulation through the skin to modulate nerve activity, reducing chronic pain.

45. **Pain Relief Topical Patch Dispensers:**
These devices with plastic applicators facilitate the controlled application of medicated patches, providing localized pain relief for muscle or joint pain.

46. **Plastic-based Pain Relief Vibrating Massagers:**
Handheld massagers made with plastic parts and vibration mechanisms help in relaxing muscles, reducing pain, and improving blood circulation.

47. **Pain Relief Ultrasound Therapy Devices:**
asound devices with plastic transducers aid in pain management by delivering high-frequency sound waves to targeted areas, promoting tissue healing and reducing discomfort.

48. **Plastic-based Pain Relief Aquatic Therapy Equipment:**
Aquatic therapy tools made with specialized plastics offer low-impact exercise in water, reducing pain associated with movement and enhancing rehabilitation.

49. **Polymer-based Pain Relief Hot/Cold Water Bags:**
These bags made from durable polymers are filled with hot or cold water to provide temperature therapy, easing pain and promoting healing for various conditions.

50. **Microneedles:**
Microneedle patches, composed of biocompatible plastics, offer a minimally invasive and painless means of vaccine delivery by penetrating the skin's surface, enhancing vaccination efficiency

Brazil Medical Devices Market

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

Country Profile

While returning from the LATAM market during the recent tour, the author travelled through Brazil. Besides this, the author was instrumental in developing the Brazilian market for an MNC by staying there for many years in the recent past and thereby gaining first-hand experience with the Brazilian healthcare market dynamics. The article covers the observations from the recent visit as well as a gist of that past experience.

Brazil is the fifth largest country in the world by geographical area and also the sixth largest by population as per the latest data, with a population of 211 million inhabitants. Brazil ranks 10th in the world on GDP with a GDP value of USD 1.83 trillion. During earlier years, for almost over two years national unemployment rate was around 5% of the employable population, which, as per many experts, represents almost full employment. This also generated wage improvement, better consumption and strong credit growth. The capital city is Brasilia. Unlike rest of the Latin America, this country's official language is Portuguese (Brazilian Portuguese) and not Spanish. Brazil is also famous for Amazone, Iguazu waterfalls and, of course, Rio de Janeiro.

Regulatory Framework and Product Classification

Agência Nacional de Vigilância Sanitária, or ANVISA, is the responsible agency for registrations of devices. ANVISA has updated the earlier regulation with a new regulatory framework based on device risk classification, labelling requirements and instructions for medical devices and accessories.

The definitions section in No. 751/2022 is now expanded to include many terms not previously defined. Among the significant changes presented are the addition of definitions (and classification) for Software as a Medical Device (SaMD) and nanomaterials. This update closely aligns with the EU Regulation 2017/745, allowing for some degree of harmonization.

While the classification scheme for medical devices is the same as before (Classes I – IV), each class is now assigned a risk level:

- Class I – low risk
- Class II – medium risk
- Class III – high risk
- Class IV – maximum risk

As noted in previous articles, it is normal that in a geographical region, medical device product classifications are almost similar. As the readers will note, DR, Guatemala and Peru also have similar four classes for medical devices.

A simplified pathway for lower-risk devices is described under separate regulations covering Class I and Class II devices (resolutions under Regulation 751/2022). For Class I and Class II devices, submitting dossiers to ANVISA is not necessary, but a company should be prepared as the files might be reviewed during an audit. Documentary Repository of Medical Devices is also necessary, to be submitted on ANVISA's electronic portal. Registration, once granted, will be valid for 10 years very soon. All devices require a Medical Device Technical Dossier described under the law. Notification and registration activities are the responsibility of and are carried out by the "Brazil Registration Holder" (BRH, referred to as an "importer" earlier). ANVISA also offers a "Questions and Answers" FAQ on their website. Please note that this regulation does not apply to used, refurbished, custom-made, or in

Brazil Highlights

- Significantly large market for medical devices
- Regulatory Framework like the other LATAM counties
- Half of the market is catered by imported products

vitro diagnostic medical devices. Please copy and paste the below-mentioned link for a detailed document on the ANVISA website (the document is in PDF format in Portuguese).

http://antigo.anvisa.gov.br/documents/10181/5672055/RDC_751_2022_.pdf/37b2d641-82ec-4e64-bb07-4fc871936735

Brazil Medical Devices Market

Brazil is the largest medical equipment market in South America, and it is still growing. Positive factors driving the market growth for Brazil are –

- increase in purchasing power
- more people graduating to middle class
- readiness to pay for better healthcare services
- increasing elderly population

The International Trade Administration, USA website has mentioned the following numbers for the Brazilian medical devices market –

Total Brazilian medical devices market size 12.1 bn USD

Total imports 6.3 bn USD

The United States accounts for approximately 19% of the import market in Brazil, followed by China with 14% of the market and Germany with 13%.

Brazilian medical devices and equipment have the following segments with their breakup:

- Reagents for In Vitro Diagnostic, 20%
- Materials and Consumables, 19%
- Prosthesis, Implants and Parts, 15%
- Lab equipment, 14%
- Imaging equipment and consumables, 8%
- Dental Equipment, 3%
- Furniture, 2%
- Other, 19%

The Brazilian healthcare market is complex, asymmetric, fragmented, with high demand, and active government involvement.

São Paulo is the largest province with a 25% medical devices market share. The Second is Rio de Janeiro, and has 13% share. Belo Horizonte also has a large number of medical device market share. These three provinces combined have a 47% market share in the total Brazilian medical device industry.

Opportunities and Challenges

A significantly larger market size, driven by population size and other factors listed above offers a really good opportunity. Efforts to simplify the regulatory framework by ANVISA are in the right direction. However, the processes of ANVISA are complex and this can be a challenge. Bureaucracies of ANVISA are experienced by the author and this experience says that handling ANVISA can become a challenge, as mentioned.

Indian Embassy In Moscow Bats For Tapping Potential Of Indo-Russian Medical Device Industry Through Collaborative Efforts

- AiMeD and DRISP have joined hands to give a boost to bilateral medical device trade
- Future roadmap and emerging opportunities discussed in webinar
- MoU was signed between AiMeD and DRISP in November 2023

New Delhi, April 22, 2024: Given the enormous opportunities in the medical device industry for multifaceted bilateral engagements, experts from India and Russia have vouched for faster efforts to give a boost to collaborations to make the most of emerging opportunities in the areas of manufacturing and marketing lifesaving medical equipment and devices. AiMeD and DRISP had signed an MoU last year and are now moving ahead towards strengthening the bilateral relations through their collaborative efforts.

"The support extended by Indian Embassy in Moscow in our collective efforts to mutually cash in on emerging opportunities in medical device industry will go a long way in giving a further fillip to bilateral trade ties between two nations," said **Rajiv Nath, Forum Coordinator, Association of Indian Medical Device Industry (AiMeD).**

Nath informed that experts from India and Russia at a recently held webinar rightly stressed the need for a dynamic and multifaceted economic engagement, guided by shared interests and a commitment to further deepen bilateral cooperation and the two organisations will contribute in their own humble manner in line with that objective.

The online event was attended by over 70 Indian manufacturers and exporters alongside some key Russian investors.

"There is a huge scope for partnerships between Indian stakeholders and their Russian counterparts in the field of medical device industry. Centre for the Development of Russia India Strategic Partnership (DRISP) and AiMeD have joined hands to accelerate the pace of bilateral engagements, he said.

Ved Prakash, First Secretary, Embassy of India in Moscow, in his opening remarks, expressed gratitude for the organisation of the meeting on medical devices. Rohit Neema, Second Secretary, Indian Embassy in Moscow, promised his support for facilitating trade and cooperation in the medical device sector between India and Russia, recognising the sector's potential for economic growth and job creation.

Nath through his presentation of a comprehensive analytical document titled 'Medical Devices –The next big thing after IT and Pharma' showcased the latest trends and the year-on-year growth in exports and also introduced the audience to the domestic champions from various segments who have achieved great heights under the guidance of policies enacted by the Indian government.

Prasun Prakash, Founder, DRISP, alongside moderating the discussion, pointed out the right timing for the exchange of technology, critical data, knowledge base, human resource and expertise in the sector considering the latest geopolitical trends and the growing interest inside Russia towards establishing strategic partnerships with Indian manufacturers.

Denis Stepanov, General Director of CES Spine Medics, Russia, highlighted the potential for Indian medical device manufacturers entering Russia. He said that there are opportunities in the market, such as the interest from manufacturers and the need for high-tech and high-quality medical products. He also addressed the challenges, including the registration process, competition from Chinese and Turkish manufacturers, and the need for international collaboration.

Ashish Rangra from Invest India made a detailed presentation on the Indian medical devices sector, covering its current valuation, projected growth, key segments, import dependency, and the government's initiatives and incentives. He also discussed the upcoming manufacturing infrastructure, including the introduction of four new parks and success stories of companies investing in India.

About AiMeD

AiMeD is an Umbrella Association of Indian Manufacturers of Medical Devices covering all types of Medical Devices including Consumables, Disposables, Equipments, Instruments, Electronics, Diagnostics and Implants. With a Primary Membership of over 300 Manufacturers and additionally of over 200 Associate Members representing the interest of over 1200 Manufacturers of Medical Devices to address the manufacturer's problems.

The aim behind forming AiMeD is to allow the Indian Government to access a single point of contact and provide various services to the manufacturers like Advocacy on policy issues, Information services, Regulations for Medical Devices, Education and Training, services, Testing Assistance and guidance for Quality Certification (ISO, CE, GMP), advocacy and much more.

Ref : Website: *https://www.aimedindia.com/*

AiMeD Demands Separate Pricing Mechanism For Medical Devices Industry

The medical devices industry has reiterated that it needs a separate pricing mechanism and a separate regulatory framework from how drugs are regulated in the country, in the wake of the Department of Pharmaceuticals (DoP) constituting a committee to prepare a draft price control order for both drugs and medical devices.

"The domestic medical devices industry wants a separate regulatory framework and a separate pricing mechanism distinct from how drugs are regulated in the country," said Rajiv Nath, forum coordinator of Association of Indian Medical Devices Industry (AiMeD), the umbrella association of Indian manufacturers of medical devices covering all types of medical devices.

"Instead of price control, we have proposed price regulation based on trade margin monitoring and then a graded step by step non disruptive regulatory rationalisation at the first point of entry of goods into the supply chain where GST is initially charged on overseas and Indian manufactured medical devices," he added.

This could be applicable for imports and also ex factory prices. Indian manufacturers don't want to be equated with importers for foreign medical devices, we wish a level playing field with overseas manufacturers as importers are also distributors of overseas manufacturers, said Nath.

The DoP has constituted a Committee to reform the pricing framework for drugs and medical devices in the country and to prepare a draft Drugs and Medical Devices (Control) Order. The committee has to submit its report in three months.

The Committee will have three core members headed by Arunish Chawla, secretary, Department of Pharmaceuticals (DoP), with Kamlesh Kumar Pant, chairman of National Pharmaceutical Pricing Authority (NPPA) and Awadhesh Kumar Choudhary, senior economic advisor, DoP as members.

It will have two special invitees from the industry, one each from the Indian Pharmaceutical Alliance (IP Alliance) and Indian Drugs Manufacturers' Association (IDMA). The Committee will be free to invite anyone for seeking technical inputs or placing its views before the Committee.

The committee shall look into various aspects including the institutional reforms required for the NPPA, how to balance price and availability of essential medicines, while providing incentives to the industry to sustain growth and exports, how to design a price moderation framework for medical devices, while providing incentives to the industry to sustain growth and minimise imports, and how to design a price moderation framework for emerging and precision therapies to facilitate their timely reach to the needy patients.

The Committee is expected to come out with a draft Drugs and Medical Devices (Control) Order to achieve these objectives.

Recently the Department-related Parliamentary Standing Committee on Chemicals and Fertilisers has recommended the Department to take up the matter of price control for medical devices with the NPPA, for inclusion of medium and high-end medical devices which are used for critical care of patients, observing that the devices which are required for critical care to the patients should be listed under the National List of Essential Medicines (NLEM).

https://www.pharmabiz.com/NewsDetails.aspx?aid=166948&sid=1, March 14, 2024

India Changes Medical Device Application Processing System

On January 1, 2024, the Central Drug Standard Control Organisation (CDSCO) released a notice (ref. IT-13011(11)/1/203 link, pdf) regarding use of the Nation Single Window System (NSWS) portal. India's application processing system is changing to the NSWS, which will be replacing the old processing system, CDSCO MD Online. Initially, only three activities under MDR 2017 were developed and made operational on the NSWS portal January 1, 2024.

However, on January 16, 2024, the CDSCO expanded upon its activities and added more forms (link, pdf). The added forms are as follows:

1. Form MD-01 – Application for grant of Certificate of Registration of a Notified Body.
2. Form MD-12 – Application for grant of license to manufacture medical device for purpose of clinical investigations, test, evaluation, examination, demonstration or training.
3. Form MD-16 – Application for grant of license to import medical device for purpose of clinical investigations or test or evaluation, or demonstration or training.
4. Form CT-10 – Request for authority to manufacture new or experimental drugs for use in bioavailability or bioequivalence tests, clinical trials.
5. Form CT-12 – Request for approval to create a formulation with an unapproved active pharmaceutical ingredient for use in analysis, bioequivalence, clinical trials, or other studies involving bioavailability.
6. Form CT-13 – Application for permission to manufacture unapproved active pharmaceutical ingredients for clinical trials, formulation development, analysis, testing, and bioavailability and bioequivalence research.
7. Form CT-16 – Request for permission to import new or experimental drugs for testing, analysis, and inspection purposes, as well as for use in bioavailability or bioequivalence studies and clinical trials.
8. Form 12 – Application for license to import drugs for purpose of examination, test or analysis.

In the future, we envisage that all applications to CDSCO including Form MD-15 (application for a medical device Import License) will be processed through NSWS. Critically, the implementation of single-window pathways is expected to increase operation efficiencies, especially as the number of covered regulatory pathways increases to include import and manufacturing licenses for medical devices.

https://asiaactual.com/blog/india-changes-medical-device-application-processing-system/

CDSCO To Switch PSUR Submission Of Medical Devices And In-vitro Devices To Online System

As part of the ongoing efforts to digitise and streamline the regulatory submission procedure, the Central Drugs Standard Control Organisation (CDSCO) has switched the submission of Period Safety Update Reports (PSUR) related to marketing authorisation of medical devices and in-vitro devices to the online system. The offline mode of submission of these applications will be discontinued from April 1, 2024.

The drug regulator said that the system for submission of PSURs with regards to marketing authorisation of medical devices and in-vitro devices is functional now through the online system for medical devices portal.

"All applicants submitting PSURs' shall apply through Online System for Medical Devices as per checklist in the portal. The facility of offline submission of applications in hard copy or any other mode will not be available for processing from April 1, 2024," said Dr Rajeev Singh Raghuvanshi, Drugs Controller General (India).

It may be noted that in February, CDSCO has switched the

submission of Period Safety Update Reports (PSUR) related to marketing authorisation of new drugs and others to online system.

The drug regulator has been in an effort to switch various application and approval processes related to its office to online mode in recent years, as part of implementation of an e-governance mechanism in the organisation.

Last November, the CDSCO directed all stakeholders to submit the applications for Post Approval Changes (PACs) with regard to marketing authorisation for human vaccines and antisera through online system of Sugam Portal under Post Approval Changes, as it is stopping the offline submission process from December 1, 2023.

In the beginning of 2023, CDSCO switched the procedure for submission of form for test license for veterinary vaccines and drugs to online, stopping the facility of offline submission of applications in hard copy following this. In 2021, it has switched the applications for registration of centres for Bioavailability and bioequivalence (BA/BE) studies and application for PACs in BA/BE studies online.

The CDSCO launched the National Single Window System (NSWS) portal on January 1, 2024, initially offering three activities for the medical devices industry, in an effort to improve the ease of doing business to the industry.

NSWS is established by the central government with the objective to build a Single Window System which acts as a one-stop shop for all the approvals required by the investor and facilitates ease of doing business. The scope of NSWS includes all the approvals/licenses/clearances as acceptable.

The CDSCO has said that the portal for the drug regulator has been developed by Invest India through IT major Tata Consultancy Service (TCS) and this will be an independent portal from the existing SUGAM portal or the cdscomdonline portal, which is for the medical devices industry.

The drug regulatory organisation has also, in November, 2023, initiated efforts to set up a Digital Drugs Regulatory System (DDRS) as a unified digital ecosystem as a single window, single sign on and unified portal for all regulatory activities.

The proposed DDRS is aimed at building trust and confidence in the quality of drugs, medical devices, cosmetics, etc., in the domestic and global market, transparency and accountability in the regulation of the quality, effective enforcement of quality, safety and efficacy at the field level, and ensuring compliance to Indian pharmacopoeia & standards, according to the CDSCO.

https://www.pharmabiz.com/NewsDetails.aspx?aid=168101&sid=1 March 22, 2024

Health Regulator Seeks Private Labs for Quality Testing of Medical Devices

The health regulator agency of India is looking for private testing laboratories to test medical devices and create a mechanism of testing to ensure the quality and safety of medical devices sold in India, News18 has learnt.

Medical devices include blood pressure monitors, thermometres, glucose meters, ventilators and prosthetic limbs.

The Union government's health regulatory agency — Central Drugs Standard Control Organisation (CDSCO) — has advised eligible private laboratories to submit applications to its office to grant licenses.

As all medical devices are now regulated under the umbrella of Medical Devices Rules (MDR), 2017, the law provides an avenue for private testing laboratories to obtain licenses as government-approved facilities for testing medical devices and issuing required test certificates.

"To strengthen the private testing facility for medical devices in the country, this office 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 Medical Devices Rules (MDR), 2017," said the notice issued by the drug regulator of India, who heads CDSCO.

The notice, issued on April 3, highlighted that medical devices require multiple tests, including physical, chemical, microbiological, mechanical and electrical.

The regulator has requested laboratories to identify if their facility can run these tests for medical devices and submit the application for registration of testing laboratory on behalf of the manufacturer.

MOVE OVERDUE BUT NEEDED MORE DISCUSSIONS: EXPERTS

Experts say the move was overdue but needs a coordinated consultation approach between several authorities and departments.

Rajiv Nath, managing director, Hindustan Syringes & Medical Devices (HMD), hailed the move while adding that more discussions are required for a successful implementation.
Nath, who is also the forum coordinator of Association of Indian Medical Device Industry (AIMED) said they have been pushing the Union government for the same for over two years. "The move requires a coordinated consultation approach between Bureau of Indian Standards (BIS), Quality Council of India (QCI), National Accreditation Board for Testing and Calibration Laboratories and Indian Institutes of Technology (IITs), existing reputed private laboratories, government labs and manufacturers."

Dr PV Appaji, former director-general, the Pharmaceutical Export Promotion Council of India (Pharmexcil), called the move "a big opportunity for all existing labs". He said that the government in a "proactive measure" has encouraged eligible private laboratories.

https://www.news18.com/india/health-regulator-seeks-private-labs-for-quality-testing-of-medical-devices-8841835.html APRIL 06, 2024

FAST FACTS

In the field of medical devices, adhering to strict standards is not only a best practice but also a legal and ethical necessity.

AMTZ, Kyrgyzstan Govt Ink MoU For Supply Of Medical Equipment

Andhra Pradesh MedTech Zone (AMTZ) has inked a Memorandum of Understanding (MoU) with the Kyrgyzstan government for the supply of medical equipment.

Kyrgyzstan Federal Minister of Health visited Andhra Pradesh MedTech Zone Limited. He toured the production and research facilities of industry leaders including Transasia Bio-Medicals Ltd., Molbio Diagnostics, and Time Medical Systems, among other centers of AMTZ. An MOU has been signed with Kyrgyzstan for supply of medical equipment from AMTZ.

An enterprise under the Andhra Pradesh government, AMTZ is a 270-acre zone, dedicated to medical device and component manufacturers. The zone provides capital-intensive scientific facilities required by most medical device manufacturers and 250+ modern state-of-the-art independent manufacturing units.

https://www.medicalbuyer.co.in/amtz-kyrgyzstan-govt-ink-mou-for-supply-of-medical equipment/?utm_source=newsletter&utm_medium=email&utm_campaign=March3
March 18, 2024

AM Naik, Madhusudan Kela Invest In Medical Devices Company S3V Vascular Technologies

Mysore-based S3V Vascular Technologies Ltd, a medical devices manufacturing company focused on neurovascular devices to treat strokes, has raised a series B round of funding from investors including former L&T chairman AM Naik and veteran investor Madhusudan Kela, the company's founder told Moneycontrol in an interaction.

The company will use the funds to build a Rs300-crore integrated manufacturing facility for neurovascular devices at Mysore.

Badari Narayan, Promoter, Director and CEO – S3V Vascular Technologies, said that stroke is the fourth leading cause of death in India, affecting nearly 20 lakh individuals annually.

"The post-COVID era has witnessed a surge in stroke cases, especially among young adults," he said.

However, he added that the current treatment for acute ischemic stroke called mechanical thrombectomy, an interventional procedure performed in a cath lab to physically remove clots lodged in the brain's vessels, costs about Rs 5 lakh, thereby making it very expensive for most people in the country.

Narayan said that in comparison to mechanical thrombectomy, S3V's devices cost just around Rs 75,000, making the treatment more affordable.

Narayan said that the new manufacturing facility will be ready in 12 months and with the addition of the new facility the company will be able to produce around 60,000 to 70,000 devices per month.

"At peak production, we expect that we will be able to generate revenues of approximately Rs 500-600 crore," said Narayan.

The company plans to apply for US FDA (food and drug administration) and European approvals and plans to export its devices to various Asian, Middle East and East European markets.

Narayan said that he expects about 45% of the company's revenue to come from the domestic market with the rest coming from exports.

The company is also working on launching cardiology related medical devices.

Narayan said that the Indian market offers immense potential for advanced medical products as currently, around 90 percent of medical devices are imported, presenting an opportunity for growth in the sector.

"With a population of 1.4 billion, India is expected to conduct 5 lakh neuro interventions and 15 lakh cardiovascular procedures annually by 2030," he added.

https://www.moneycontrol.com/news/business/am-naik-madhusudan-kela-invest-in-medical-devices-company-s3v-vascular-technologies-12459901.html, MARCH 14, 2024

FAST FACTS

India's dependence on medical devices shipped from abroad grew significantly between November 2022 and October 2023 with imports jumping by 21 per cent to Rs 61,262.84 crore. The top suppliers of medical devices were the US, Germany and the Netherlands, according to the data from the Department of Commerce.

Concept Medical Receives USFDA IDE Approval For MagicTouch AVF Indication

AHMEDABAD: Gujarat based Concept Medical, a leading company in innovative medical device technology, has announced approval of an Investigational Device Exemption (IDE) for its US FDA breakthrough designated MagicTouch AVF for the treatment of stenotic lesions of Arteriovenous Fistula (AVF) in the Haemodialysis management of Chronic Renal Failure.

The Company has been granted four other US FDA IDE approvals for its MagicTouch product portfolio for different indications.

The latest IDE approval for the AVF indication is their 5th in quick succession.

This US FDA IDE approval allows Concept Medical to conduct pivotal clinical studies to gather safety and efficacy data for the Magic Touch Sirolimus Coated Balloon in A.V. fistula and support a future pre-market approval (PMA) application in the USA.

The multiple haemodialysis procedures necessary for the management of chronic renal failure patients often result in repeated blockages of the arteriovenous fistula used for the procedure. MagicTouch AVF is proposed for managing such stenotic lesions of arteriovenous fistula, offering a novel approach that could potentially enhance patient outcomes in haemodialysis, a life-sustaining treatment for those with renal failure.

Dr Manish Doshi, Founder of Concept Medical said, "This approval is not just a testament to our pursuit of innovation but also marks a pivotal moment in our journey to redefine the treatment landscape for haemodialysis patients. We look forward to MagicTouch AVF's positive impact on patient care and are excited about the upcoming clinical trials."

The Company anticipates initiating the AVF IDE clinical trial for MagicTouch SCB in the coming month and are on track to begin enrolment for the currently approved other IDE trials of the MagicTouch product in the US.

Concept Medical is headquartered in Tampa, Florida, and has a global presence with a manufacturing facility in Gujarat. It is engaged in developing innovative drug delivery technology for vascular and non-vascular diseases, utilizing a unique combination of technology and products with proprietary coating technology that delivers pharmaceutical agents across luminal surfaces of blood vessels.

https://timesofindia.indiatimes.com/city/ahmedabad/concept-medical-receives-usfda-ide-approval-for-magictouch-avf-indication/articleshow/108982543.cms Apr 2, 2024

Warburg Buys Majority Stake In Ophthalmic Device Company Appasamy

The latest deal follows Warburg Pincus acquiring about 67% stake in Coimbatore-based bath fittings brand Watertec India at ₹2,600-₹2,800 crore (about $340 million) valuation in 2023. The PE firm's other investments in the Indian healthcare sector include Meril Life Sciences, MedPlus, Laurus Labs, and Metropolis Healthcare.

New Delhi: US private equity firm Warburg Pincus has bought a majority stake in Chennai-based Appasamy Associates, India's largest maker of ophthalmic equipment and intraocular lenses (IOLs). Financial details of the transaction were not disclosed. Appasamy operates across the entire value chain of ophthalmic devices - diagnostic, surgical equipment, and IOLs, according to company statement.

ET was the first to report last July that Warburg Pincus was in advanced stages of talks to acquire Appasamy, having signed an exclusivity agreement, and started due diligence of the company.

Promoters of Appasamy were expecting a valuation of ₹3,000-₹3,200 crore, ET reported at the time. Warburg planned to buy a 60-70 per cent stake in the company and the business would continue to be run by the current management, ET reported. Post the deal, Appasamy will continue to be led by recently appointed CEO, Senthil Kumar who will drive the business going forward with support of the promoter family and in partnership with Warburg Pincus, according to the statement. Appasamy is also the exclusive distributor for Canon medical equipment in India.

"The promoters and the management team have a distinguished history of successfully running businesses in the ophthalmic industry. Senthil brings great strengths in building and scaling teams and products across geographies, and we are excited to collaborate with him in Appasamy's next phase of growth," said Narendra Ostawal, head of India private equity, Warburg Pincus.

Nuvama Investment Banking acted as the exclusive financial advisor to the transaction.

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Appasamy started operations in 1978 by introducing India's first low-cost cryo surgical equipment for ophthalmology at ₹1,800, compared to an equivalent imported unit costing ₹20,000.

"It is a matter of great pride for us to witness the evolution of Appasamy, from being just an idea of PSN Appasamy, the founder, to becoming a leading player in the Indian and global ophthalmic space, with remarkable growth over the last 40+ years," said Arvind Kasthuri, from Appasamy's promoter family.

The Indian intraocular lens market is dominated by global brands such as Alcon, Bausch Health, Biotech Healthcare Holding GmbH, Carl Zeiss AG, Hoya Holdings, Johnson & Johnson and French lens maker EssilorLuxottica SA.

Among Indian brands, Appasamy is the market leader with about 75 per cent market share.

https://health.economictimes.indiatimes.com/news/medical-devices/warburg-buys-majority-stake-in-ophthalmic-device-company-appasamy/109230863?utm_source=top_news&utm_medium=sectionListing, Apr 12, 2024

Industry News

Hindustan Syringes Launches Dispojekt To Reduce Needle Stick Injuries

Company aims to capture 60-70% of disposable syringes market in India

The Company Is Aiming To Initially Produce 200 Million Syringes And Needles Per Annum, For Which We Have Invested Approximately Rs 70 Crore In The First Phase

Hindustan Syringes and Medical Devices (HMD), one of the leading manufacturers of disposable and auto-disable syringes, on Thursday announced the launch of Dispojekt, an indigenous single-use safety syringe to reduce instances of needle stick injuries.

A needle stick injury (NSI) is an accidental skin-penetrating stab wound from a hollow-bore needle containing another person's blood or body fluid.

It can lead to the transmission of blood-borne diseases like Hepatitis B, C, and HIV among healthcare personnel.

“HDM is eyeing a 60-70 per cent market share in the next three years in the disposable syringes segment in India, which is estimated to be over 5 billion units per year and 5 to 6 billion needles,” the company said in a statement.

Sohail Nath, executive director of HMD said the company is aiming to initially produce 200 million syringes and needles per annum, for which we have invested approximately Rs 70 crore in the first phase.

https://www.business-standard.com/industry/news/hindustan-syringes-launches-new-syringe-to-reduce-needle-stick-injuries-124030700856_1.html, Mar 07 2024

Combatting Moisture Woes: Bry-Air's Wonder Dryer Leads The Way In Medical Plastics

Manufacturing medical plastics presents a myriad of challenges, with moisture management being a critical pain point. Nylon, Polycarbonate, ABS, and Polypropylene, known for their hygroscopic nature, readily absorb moisture from their surroundings. Meanwhile, Polyethylene and Polystyrene, though less prone to moisture absorption, can still carry significant moisture on their surfaces if not stored in dry environments during transit to manufacturing facilities.

This moisture infiltration poses a host of problems during processing. Improper drying of resins can result in defects such as low tensile strength, diminished impact resistance, surface cracking, internal defects, surface lines, bubbles, and silver streaking, ultimately leading to product rejection.

In addressing these challenges, Bry-Air's Wonder Dryer emerges as a transformative solution in combating moisture woes during medical plastics processing. Unlike conventional dryers, this innovative system operates without water, delivering a dew point of less than -40°C even at elevated return air temperatures. This capability addresses a range of moisture-related issues, ensuring superior product quality and reducing the risk of rejection.

Moreover, the Wonder Dryer's advanced honeycomb rotor technology not only slashes operational expenses but also offers unparalleled portability and convenience. Eliminating concerns about cooling connection water hoses and condensed water leakage, it streamlines the drying process for enhanced efficiency and reliability.

As medical plastics manufacturers strive for superior product quality and cost-effective production, Bry-Air's Wonder Dryer emerges as a beacon of innovation, promising accelerated ROI and substantial savings. In tackling the multifaceted challenges of moisture management, it heralds a new era of excellence in medical plastics processing.

Bry-Air Knows Drying Best

Wonder Dryer
(Bry-Dry 80X Series)

Nano Desiccant Dryer

Qosina Introduces New Pharma+™ Tubing Retainers

Ronkonkoma, NY, USA, February 22nd, 2024—Qosina, a global supplier of OEM single-use components to the medical and biopharmaceutical industries, is pleased to introduce Pharma+™ tubing retainers to its extensive portfolio.

This new tubing retention solution for leak-free fluid transfer features a patent-pending lead-in ramp, creating a complete 360° compression. With an operating pressure of 80 psi (120 psi burst), these components are cleanroom-molded from polyketone (PK) and suitable for several sterilization methods including gamma radiation, X-ray and autoclaving. These tubing retainers work seamlessly with silicone, TPE and PVC tubing, making them a versatile choice for high-pressure bioprocess applications. They are installed using cable tie tension tools and are recyclable for easy disposal.

Learn more about Qosina's new line of Pharma+™ Tubing Retainers.

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 full line of securing clamps at https://www.qosina.com/securing-clamps.

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

Contact: Qosina Corp.
Rachelle Morrow, +1 (631) 242-3000
corporatecommunications@qosina.com

Qosina Welcomes New Representative in Korea

Ronkonkoma, NY, USA, March 21, 2024—Qosina, a global supplier of OEM single-use components to the medical and pharmaceutical industries, announces the addition of David Oh as the new representative for the Korean market.

David brings over two decades of invaluable experience to his new role, having been actively involved in the medical device industry since graduating from Penn State University in 2000. With a solid foundation in market analysis and sales forecasting, he has a proven track record of driving business growth and implementing effective sales strategies. Additionally, David has a keen eye for monitoring service quality, guaranteeing that Qosina's customers in Korea receive nothing short of excellence in all their interactions.

One of David's notable strengths lies in his ability to navigate regulatory matters, particularly with the Ministry of Food and Drug Safety (MFDS). His experience in developing policies to handle regulatory affairs will help the Qosina customer move towards compliance with standards and regulations. David is also well-versed in developing quality control strategies essential for maintaining MFDS approvals and advising customers on the requirements set forth by the Korea Medical Device Industry Association (KMDIA).

"We are thrilled to welcome David Oh to the Qosina family," said Jeff Cushner, Vice President of Sales at Qosina. "His extensive experience and expertise make him an invaluable asset to our team as we continue to expand our presence in the Korean market. We are confident that David will provide unparalleled support and solutions in Korea."

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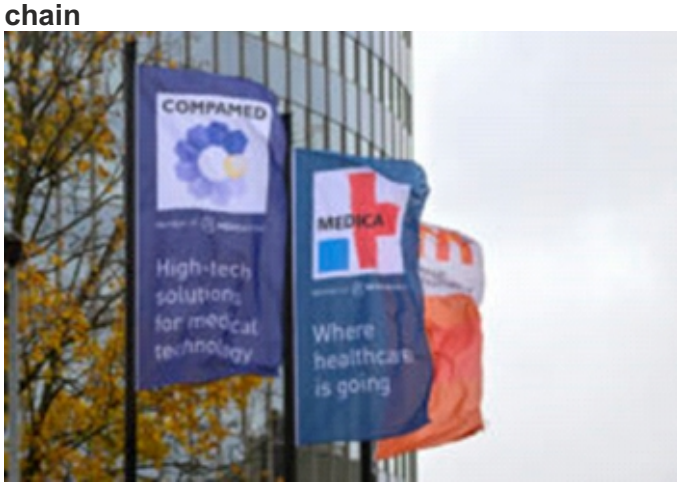

Photo: Strong trade fair duo for the entire value chain of the medical technology industry - MEDICA + COMPAMED in Düsseldorf (© Constanze Tillmann/ Messe Düsseldorf)..

The healthcare business and the medical technology sector are moving forward with vigour, driven by ever new technical developments. Innovative, digital and connected – this is how the sector persists against challenging framework and market conditions. And keeping pace with the industry, MEDICA and COMPAMED are also holding their own as a combination of globally unique platforms for business and information serving the entire added value chain of medical-technical systems and products – including manufacture and development. The number of registrations for both trade fairs this year puts expectations at a total of more than 6,000 companies from 70 countries exhibiting in Düsseldorf from 11–14 November 2024.

"With a volume of approximately 140 billion euros, the market for medical technology in Europe is extremely important for many of our exhibitors. Regardless healthcare policy debates, this is equally true for the German market, which alone accounts for 40 billion euros", says Christian Grosser, Director Health & Medical Technologies at Messe Düsseldorf, explaining why exhibiting companies benefit. With a view to the professional audience travelling to the events, Grosser also regards the date in 2024 as set: "In order to be fit for tomorrow's healthcare, it is critical to remain up-to-date by way of networking, knowledge transfer and innovations at the highest level. MEDICA in Düsseldorf has been providing excellent opportunities to do this for the better part of half a century."

At **MEDICA 2024,** there are **five worlds of experience** promising a comprehensive range of innovations for the treatment of outpatients and clinical use. For a first glimpse, see the database of companies and products at the MEDICA.de hub, which currently lists more than 12,700 products and services. The corresponding worlds of experience at the professional trade fair are: Lab Technology and Diagnostics, Medical Technology and Electromedicine, Commodities and Consumables, Physiotherapy and Orthopaedic Technology as well as IT Systems and IT Solutions.

Held in parallel to MEDICA as always, COMPAMED can look back on more than thirty years of success and has become an absolute hotspot for complex high-tech solutions. About 750 exhibiting companies will present their specialised knowledge as manufacturers and suppliers at **COMPAMED 2024,** also in **five worlds of experience:** Manufacturing & Devices (e.g., components, parts, manufacturing processes), Services & Advice (e.g., research, development, services), Materials (e.g., plastics, glass, ceramics, metals, composite materials, adhesives, packaging), Micro Tech (such as micro components, microfluidics) as well as IT in Tech (software development and maintenance for medical technology).

All trending topics of the year "live on stage"

Dominating market trends are currently causing a huge demand for information and plenty of issues for debate. MEDICA 2024 and COMPAMED 2024 will provide a corresponding superb stage programme with accompanying **forums** and **conferences** which bridge the content gap to exhibitors' presentations and topic-driven **special exhibitions,** for example the 'Wearable Technologies Show', the 'Hospital of the Future' or the MEDICA SPORTS HUB.

This year, the hot topics at MEDICA include the most recent **examples of AI application and robots and assistive systems** in day-to-day medical practice. Another focus is on the increasing **connectivity in healthcare provision,** specifically on innovations for the point of care, which means diagnostics and treatment in the immediate vicinity of patients (usually outpatients). This includes telemedical applications with the aim of providing optimised cooperation across all sectors by all persons involved in the treatment process.

Another top issue at this year's MEDICA is the **human factor.** The urgent lack of skilled professionals also affects almost all companies active in healthcare, leading them to search for solutions. These topics will be discussed in individual forums and at conferences which are appropriate to each target group.

Fresh ideas for the digital healthcare transformation

Some examples are the MEDICA HEALTH IT FORUM (for IT topics like big data, artificial intelligence or cybersecurity), the MEDICA TECH FORUM (trends and topics from science, politics and business with relevance for the medical technology industry) or the new **MEDICA INNOVATION FORUM.** This forum will

replace the former MEDICA CONNECTED HEALTHCARE FORUM. Because digital innovations are not limited to optimised connections between all healthcare players, the MEDICA INNOVATION FORUM will focus on the digital transformation of the healthcare industry in its entirety. The popular start-up competitions remain part of the programme and will shine a spotlight on fresh ideas and product solutions by the young start-up scene on the forum stage.

COMPAMED, too, promises excitement, information and open discussions. The agendas at the COMPAMED HIGH-TECH FORUM and COMPAMED SUPPLIERS FORUM reflect the top issues of the supply sector such as AI, robotics and automation, new trends in microtechnology and innovations in materials. And last but not least, there will be contributions and discussions about the best practices of international market cultivation. Supply chain management, questions of product approval and patent law are some of the relevant aspects.

Last year, MEDICA and COMPAMED recorded a total of 83,000 visiting professionals from more than 160 countries.

All information concerning events, services, topics, forum and conference programmes as well as participating companies is available online at: https://www.medica-tradefair.com / https://www.compamed-tradefair.com

The dates for all of the international medical trade fair events held by Messe Düsseldorf Group are available online at:https://www.medicalliance.global.

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FAST FACTS

IMPORTANT FOR MEDICAL DEVICE COMPONENT MANUFACTURERS

18. What is the regulatory expectation to ensure quality of components (raw materials which are to be used for further manufacturing of finished medical devices) under the valid licence for manufacturing?

? As regard to ensuring the quality of components/ raw materials to be used for further manufacturing of finished medical devices, it is required that manufacturer of these components need to qualify product standards and Quality Management System.

21. What is meant by a component of a Medical device?

? Component means any raw material, substance, piece, part, software, firmware, labeling, or assembly which is intended to be included as part of the finished, packaged, and labeled device.

(Ref: Central Drugs Standard Control Organization, (Medical Devices Division), Medical Devices, Frequently Asked Questions, Refer Doc No.: CDSCO/FAQ/MD/01/2024)

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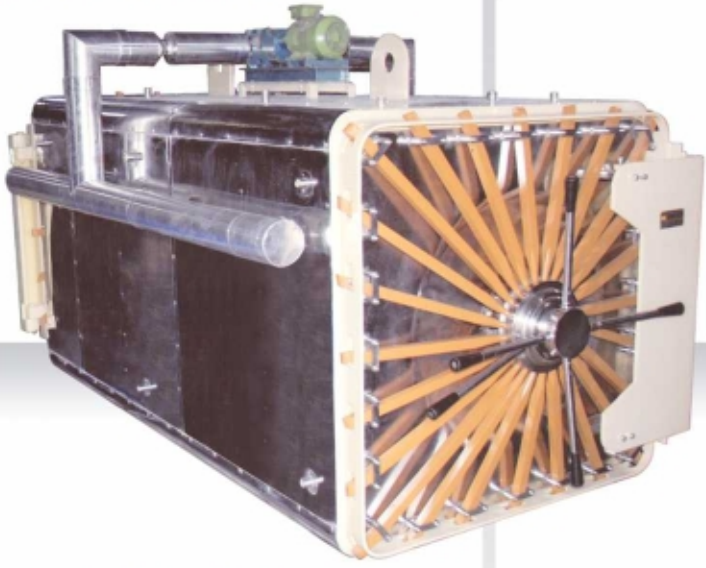

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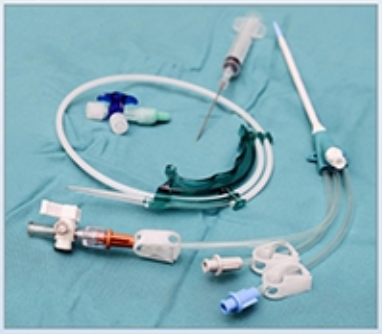

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Vessel volume in liters	35	130	210
Mixing tool motor capacity with dual/single speed motor	4-5/5 HP	16-20/15 HP	31-40/40 HP
Max. Mixing capacity Kg per batch/Output Kg per hr.	10/40-50	40/160-200	60/240-300

TWIST ENGINEERING WORKS
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Dr. S S Murugan PhD
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- ISO/IEC 17025
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600068
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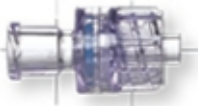
80303
Hemostasis Valve
Y Connector
Rotating MLL
FLL Sideport

80361
Luer-Activated
Valve FLL
Tubing Port

80135
T Connector with
Swivel ML and
2 FLLs



80129
Check Valve
FLL Inlet, MLL Outlet

61901
Female Hansen
Quick Disconnect Body
Barbed

80134
Needleless Injection Site

99780
1-Way Stopcock
FLL, MLS

80199
Check Valve
Tubing Port Inlet, MLL Outlet
Coated Stem

80330
Tuohy Borst
Adapter

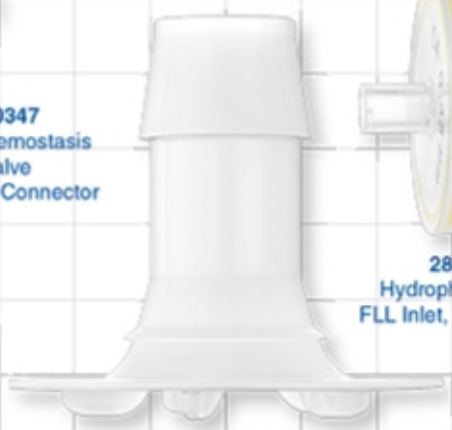
11607
Open-Ended Syringe

11560
FLL to Barb
Connector

91045
High-Flow
Check Valve

11499
Elbow
Connector
FLL, ML
with Spin Lock

80347
Hemostasis
Valve
Y Connector



61331
Bag Port Flange

28305
Hydrophilic Filter
FLL Inlet, MLL Outlet

57030
Flexible
Suction
Connector

97360
3-Part Torquer

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