TRINSEO™

Engineered Materials | Medical

Manufactured for being human

Rigid and soft-touch plastics for medical devices

Connecting ideas with solutions

trinseo.com

Contents

Turning Ideas into Reality

ABOUT TRINSEO

Trinseo is a technology leader and innovator in performance plastics solutions. Our manufacturing, Research & Development (R&D) and testing facilities, located strategically across the globe, allow us to collaborate, develop and manufacture seamlessly across regions.

All our manufacturing facilities adhere to strict, disciplined processes. This allows us to offer materials with worldwide equivalency, consistency of quality, and assurance of supply. We hold ISO 9001, 14001, 16949 and 13485 certifications, and apply the standards at sites as applicable.

Trinseo uses carefully selected raw materials, combined with tightly controlled manufacturing processes to deliver product consistently, predictably, and sustainably across the globe.

$5.0 BILLION
REVENUE IN 2022

11
R&D FACILITIES GLOBALLY

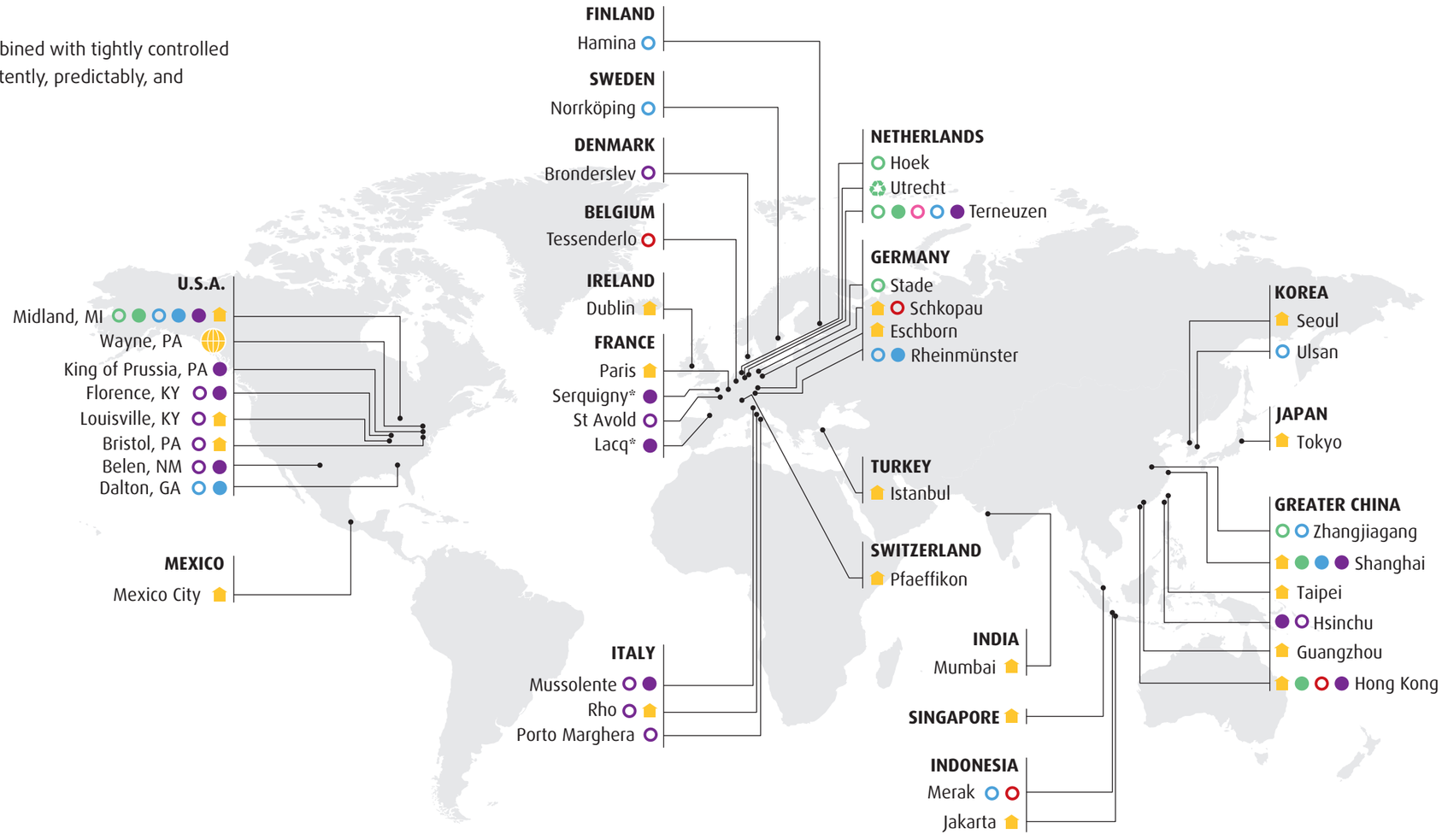
3,400
EMPLOYEES

24
MANUFACTURING SITES GLOBALLY

WIDESPREAD MANUFACTURING ASSETS

- Plastics Solutions
- Feedstocks
- Latex Binders
- Polystyrene
- Engineered Materials
- Corporate and Sales Offices
- Global Operating Center

○ = Manufacturing
♻ = Recycling Facility
● = R&D
* *R&D activity takes place at an external shared site*



Supporting the Medical Industry

Trinseo provides medical grade resins for single- and multiple-use devices, drug delivery systems, housings and enclosures, and medical wearables. We have provided resins to the medical industry for over 40 years. As a single-source supplier of rigid and soft-touch plastics, we specialize in high-performance material solutions. Our polymers can be used in applications alone, in combination with other polymer types, and even over-molded using co-injection or insert-molding technology. Our materials for medical devices include:

Rigid Plastics (Thermoplastics)

- CALIBRE™ Polycarbonate Resins
- CALIBRE™ MEGARAD™ Polycarbonate Resins
- EMERGE™ Advanced Resins
- MAGNUM™ ABS Resins
- PLEXIGLAS® Acrylic Resins (Americas)
- ALTUGLAS™ Acrylic Resins (Europe and Asia Pacific)
- STYRON™ Polystyrene Resins (available in certain markets)

Soft-touch Plastics (Thermoplastic Elastomers-TPE)

- MEGOL™ MED TPS-SEBS Compounds
- MEGOL™ SK TPS-SEBS Compounds
- RAPLAN™ MED TPS-SBC Compounds

Trinseo is a technology leader and innovator. Our involvement with medical devices has taken us from syringe barrels and luer locks to some of the most advanced applications that draw on cross-industry expertise. Among our achievements are radiation-stable polycarbonate with proprietary color compensation technology, animal-derivative-free product offerings, medical grade glass-filled resins with high stiffness, lubricated resins for reduced friction, and skin contact grades for wearable applications.

All Trinseo medical grade polymers are manufactured with heightened attention to quality and compliance.

Our manufacturing and compounding adhere to cGMP or ISO 13485 standards, and we offer cleanroom polycarbonate production for applications requiring special care. As a manufacturer of both rigid and soft-touch polymers, we have full control of substrates and overlays, providing optimal adhesion in finished products.

We distinguish ourselves by working with customers strategically, collaboratively, and confidentially to solve complex material challenges. We recognize the complexity of the regulatory landscape and have medical product stewards in each region. Our medical grades have been biocompatibility tested and selected products have US FDA Master Access Files.

Products Available for Medical Applications

	CALIBRE™	CALIBRE™ MEGARAD™	CALIBRE™ (Glass-filled)	EMERGE™	MAGNUM™	PLEXIGLAS® (Americas) ALTUGLAS™ (EU & AP)	MEGOL™	RAPLAN™
Polymer Family	PC	PC	PC-GF	PC/ABS	ABS	PMMA	TPS-SEBS	TPS-SBC
Features	· Transparent · Opaque · Custom colors available · Biocompatibility · High flow	· Transparent · Gamma & e-beam radiation resistance · Biocompatibility	· Opaque · High rigidity · Biocompatibility	· Excellent processability · Ignition resistance · Limited biocompatibility	· Superior natural whiteness · Pre-colored resins for selected products · Excellent lot-to-lot consistency · Ethylene oxide sterilization biocompatibility	· Exceptional biocompatability · Chemical resistance · Exceptional clarity · Gamma, e-beam, ethylene oxide, and UV sterilization	· Elastic and soft · Translucent, opaque and/or colored · Bond on polar (PC, ABS, PC/ABS) and non-polar (PP) materials	· High transparency · Non-halogenated · Chemical resistance · Welding · PVC substitute
Application								
Caps and closures							✓✓	
Connectors	✓✓	✓✓				✓✓		
Dialysis cassettes						✓✓		
Digital displays and screens						✓✓		
Drug delivery devices: injectors, inhalers, etc.	✓				✓✓	✓		
Drug and fluid delivery: syringes, stopcocks, trocar, luers, etc.	✓✓	✓✓				✓✓		
Equipment housings: imaging, respiratory, etc.				✓✓		✓		
Filter housings						✓✓		
Infusion drip chambers								✓✓
Lenses, cuvettes, light pipes	✓					✓✓		
Monitoring devices: housings & covers	✓			✓✓		✓		
Oxygen masks	✓✓						✓✓	
Portable device housings: diabetes management equipment, glucose meters, pumps, insulin pens, etc.	✓				✓✓	✓		
Renal care: blood filter housings, dialyzer housings, etc.		✓✓				✓✓		
Specula, endoscopes						✓✓		
Surgical devices	✓✓	✓	✓✓		✓	✓		
Surgical device handles & housings	✓✓		✓✓		✓			
Surgical tool handles	✓✓		✓✓		✓		✓✓	
Tracheotomy patches							✓✓	
Valves	✓	✓				✓✓		

✓✓ = Best Suited ✓ = Suitable

Sustainable Solutions

At Trinseo, we've made it our goal to advance sustainability across a variety of applications. We're exploring advanced chemical recycling methods as well as designing for circularity and material substitution. We offer several grades of our MAGNUM™ ABS Resins with renewable content. These products provide a convenient solution to further your sustainability efforts. Materials are derived from a combination of fossil-based and sustainable raw materials resulting in a bio-based composition.

Following are the BIO offerings of our MAGNUM™ ABS Resins.

MAGNUM™ CO_2NET™ 3325MT BIO60

MAGNUM™ CO_2NET™ 3325MT BIO60 is a medium heat ABS. Its inherent low gloss combined with a high flow makes it specifically suitable for unpainted interior automotive applications.

Benefits	• Lot-to-lot consistency, allowing for optimal machine parameters settings from the start • Self-coloring, enabling cost reduction by using less pigment and lowering logistics cost • Low VOC, providing a better interior air quality • Heat stability during wide range of processing temperatures, allowing enhanced part design freedom • High scratch and mar resistance for an improved aesthetic durability of the parts • Easier recyclability of unpainted parts
Certification	• Credited with 60% ISCC+ bio-based feedstocks through mass balance certification
Available Location	• Available in North America
Applications	• General injection molding applications • Non-patient contact applications

MAGNUM™ CO_2NET™ 8391 BIO80

MAGNUM™ CO_2NET™ 8391 BIO80 combines an excellent glossy appearance with high flow and medium impact performance. The mass continuous polymerization process technology ensures an ABS resin that combines excellent processability with a stable light base color that is ideal for self-coloring.

Certification	• Credited with 80% of ISCC+ bio-based feedstocks through mass balance certification
Available Locations	• Available in North America, EMEA, and Asia Pacific
Applications	• Drug delivery devices • Portable device housings • Surgical device handles

MAGNUM™ CO_2NET™ A371 BIO80

MAGNUM™ CO_2NET™ A371 BIO80 combines high impact and good processability, and is designed for injection molding and extrusion applications. Its stable light base color makes it an ideal candidate for self-coloring process.

Certification	• Credited with 80% of ISCC+ bio-based feedstocks through mass balance certification
Available Location	• Available in Asia Pacific
Applications	• Extrusion sheets • Profiles • General injection molding applications

MAGNUM™ CO_2NET™ A460 BIO80

MAGNUM™ CO_2NET™ A460 BIO80 is an ABS resin that can be used for both extrusion and injection molding applications. This grade combines high impact and medium-high heat resistance. The mass continuous polymerization process technology ensures a stable light base color ideal for self-coloring, low gel level, and high purity that makes MAGNUM™ A460 a suitable candidate or extrusion and alloy compounding applications.

Certification	• Credited with 80% of ISCC+ bio-based feedstocks through mass balance certification
Available Location	• Available in Asia Pacific
Applications	• High-end extrusion applications • ABS feedstock for PC/ABS compounds • General injection molding applications

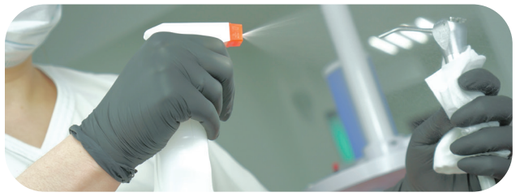
Understanding Your Material Needs

Trinseo distinguishes itself by taking the time to truly understand our customers' needs and expectations. We offer the expertise and knowledge needed for industry-leading, quality-focused solutions:

Biocompatibility

Physical, chemical, and toxicological testing is done according to ISO 10993 and/or USP standards to determine the biocompatibility of various resin grades and color combinations. Over the years, we have developed biocompatibility test data for a wide variety of our products.

Chemical Resistance



Trinseo has conducted in-house tests of our material solutions, to evaluate their reaction to chemicals, disinfectants, detergents, food products, cosmetic substances, oil, and grease.

Sterilization

Selected grades of CALIBRE™ PC Resins, MAGNUM™ ABS Resins, and PLEXIGLAS®/ALTUGLAS™ PMMA Resins have been specifically developed to handle a variety of sterilization processes and application requirements, including steam autoclaving, gamma or electronic beam (e-beam) radiation and ethylene oxide (EtO).

Enhancing Medical Device Usability

To meet the needs for soft-touch surfaces on rigid plastic substrates, Trinseo offers a complete portfolio of thermoplastic elastomers (TPEs) under the brands MEGOL™ TPS-SEBS and RAPLAN™ TPS-SBC Compounds. These compounds come with a full battery of biocompatibility testing specifically for medical applications and can be customized to meet the needs of a particular application.

Whether the interest is a non-slip surface, better grip potential, ergonomic design, or simply aesthetics, Trinseo experts at our overmolding lab in Mussolente, Italy can provide the solution. This facility — a state-of-the-art specialized center — focuses on the development, design, and processing of TPEs and rigid plastics in overmolding applications as well as measurement of overmolding adhesion according to the stringent VDI 2019 standards, which Trinseo helped to develop.

Regulatory Support & Quality Processes

Global regulations around medical resins are increasingly stringent and complex. To support customers in this area, Trinseo has a network of regional product stewards who assist customers by providing them with detailed information regarding our materials. This includes Regulatory Data Sheets (RDS) that include comprehensive global regulatory data to allow OEMs to determine the suitability of the materials for their intended use.

In addition, Trinseo has developed internal processes to meet the industry's stringent guidelines. We produce our medical grade resins under strict quality guidelines, controlled conditions, and validated processes. We hold ISO 9001, 14001, 16949, and 13485 certifications, and apply the standards at sites as applicable. Our multiple resin production sites provide an assurance of supply — consistently, predictably and sustainably.

Strict change management is another core element of our manufacturing process. To accommodate formal requirements and the need for documentation, Trinseo offers a Management of Change process that includes:

- Formulation Lock
- Notification of Change (NOC)
- Lot Traceability
- Extended Record and Sample Retention

Trinseo's regulatory expertise is recognized and appreciated globally, and we place a strong emphasis on maintaining this leadership position. Our goal is to provide end-to-end customer support.

Biocompatibility Testing

All Trinseo's Commercial Medical Grade products have been evaluated for their ability to successfully pass a standard battery of biocompatibility testing. These evaluations have been conducted by a third-party lab based on the guidelines of the International Organization of Standardization (ISO 10993). In addition, these biocompatibility studies were conducted in accordance with the provisions of the FDA Good Laboratory Practice (GLP) Regulations (21 CFR, Part 58). The table below lists the tests, with applicable test method, which Trinseo products must pass in order to be sold by Trinseo as a medical grade product.

Test	Method*
In Vitro Hemolysis: Extraction Method	ISO 10993 Part 4/Modified ASTM
In Vitro Hemolysis: Direct Contact Method	ISO 10993 Part 4/Modified ASTM
Cytotoxicity, Elution Method	ISO 10993 Part 5
Muscle Implantation – 1 week	ISO 10993 Part 6
Guinea Pig Maximization Sensitization	ISO 10993 Part 10
Intracutaneous	ISO 10993 Part 10
Systemic Toxicity	ISO 10993 Part 11
Physicochemical Test	USP <661>

* ISO = International Organization of Standardization 10993: Biological Evaluation of Medical Devices
* ASTM = American Society of Testing Materials
* USP = United States Pharmacopeia

These studies are performed on pellet samples of medical grade resin. The purpose of this testing is to ascertain whether the Trinseo materials cause any health effects. This testing is intended only as a preliminary qualification step and does not take into account processes or conditions of use by the customer; instead, the medical device manufacturer is responsible for evaluating its product based upon such factors as manufacturing processes and conditions of use. Trinseo LLC does not submit any finished devices or articles for testing.

Trinseo can provide detailed information with regard to biocompatibility testing and regulatory compliance for its products. New products may require additional time for the biocompatibility evaluation. Biocompatibility and compliance letters on new products will be provided upon request after final product testing and approval is completed. For information on specific grades, refer to the technical data sheet or contact your Trinseo representative.

Sterilization Techniques

Types of Sterilization Methods

Single-use medical devices (SUDs) and multiple-use medical devices (MUDs) that come in contact with human tissue or bodily fluids must be sterilized for patient safety. Determining a material's compatibility with the different methods of sterilization that are used for medical devices can be involved and complex. One must consider the effects of the sterilization process on both the physical integrity and the optical characteristics of the material.

Disposable or SUDs are commonly sterilized one time prior to being used. This sterilization is often done by the manufacturer on the fully assembled and packaged device prior to delivery to the customer. The typical methods are ethylene oxide (EtO) and irradiation sterilization. Irradiation may be done by gamma radiation (cobalt-60) or electron beam (e-beam) radiation. A common method of sterilization for reusable or MUDs is steam autoclave.

Gamma radiation, which involves exposure to photons from a cobalt-60 source, is widely used for the sterilization of medical devices. Gamma rays have no mass and are thus able to penetrate deeply into the material. As a result, they can easily penetrate most packaging materials, enabling the sterilization of devices in assembled and packaged form. A common gamma dosage for sterilization is 2.5 Mrad (25 kGy), although higher doses of 5.0 and 7.5 Mrad (50 and 75 kGy) are also used depending on application requirements. The process temperature is low, usually between 30 and 40 °C (86 and 104 °F). Sterilization cycle time is dependent on the level of gamma radiation required. Trinseo medical resins can tolerate typical doses of radiation sterilization and will maintain their physical properties. The radiation may affect the appearance of some materials in a negative way such as haze or yellowing, particularly with transparent polycarbonate. For transparent applications using radiation, we recommend CALIBRE™ MEGARAD Polycarbonate Resins or PLEXIGLAS® Acrylic Resins.

Electron beam (e-beam) irradiation is the penetration of high-energy electrons throughout the material. Typical doses are in the 1 – 6 Mrad (10 – 60 kGy) range. The e-beam sterilization process is significantly faster than gamma sterilization. Parts need to be exposed only for minutes rather than hours. It should be noted, however, that the penetrating capability of e-beam radiation is not as good as that of gamma radiation and articles may need to be treated from multiple directions to achieve complete sterilization.

The effect of e-beam sterilization on the polymer is similar to that of gamma. Elastomer resins, however, are more negatively affected by e-beam and are not recommended for this use.

Ethylene Oxide (EtO) is another common form of sterilization for disposable medical devices or SUDs. The advantage of EtO sterilization is that compared to other sterilization methods, it is the least aggressive toward many thermoplastic materials. EtO can be used with materials that are sensitive to the heat of steam sterilization or that significantly degrade under irradiation. EtO sterilization is normally done at temperatures in the 50 – 60 °C (122 – 140 °F) range. Pure EtO is very flammable, toxic and explosive, so it is usually mixed with inert gas, such as carbon dioxide and some types of fluorocarbon gas. There are several variables for effective sterilization, including the exposure time, temperature, humidity and gas concentration. Other important considerations are the compatibility of the material with EtO gas and the permeability of the packaging material. EtO has minimal effect on the polymer, so most materials are compatible with this sterilization method.

A steam autoclave process is typically used to sterilize reusable or multiple-use medical devices (MUDs). However, single-use medical devices (SUDs) are also normally engineered to withstand 1 – 2 autoclave cycles in case a previously sterile package is believed to be compromised during shipping or handling. A steam autoclave unit uses high-pressure saturated steam in order to create an environment that effectively inactivates most bacteria, viruses, spores and fungi. Standard conditions for autoclave sterilization are 3 – 10 minutes at 132 – 134 °C (270 – 273 °F) and 3 – 30 minutes at 121 °C (250 °F). The high humidity and temperature create a harsh environment for plastics. Therefore, the polymer selected needs to have a glass transition temperature that exceeds the autoclave operating temperature in order to survive. As such, PMMA and ABS resins should not be used with steam sterilization. The number of sterilization cycles also needs to be evaluated for the resin durability. Materials such as polycarbonate can tolerate an autoclave but may show property degradation after multiple cycles.

For information on sterilization methods and their effects on Trinseo's material solutions, refer to our brochure Effects of Sterilization Methods on Medical Resins.

R&D, Quality, and Customer Service Support

Trinseo's research, testing, and development facilities for our plastics business are strategically located across North America, Europe and Asia Pacific. Our technical experts continuously work with our customers to understand ongoing requirements and ensure continuous improvement and innovation throughout our relationships.

All our manufacturing facilities adhere to disciplined quality processes to provide material consistently and reliably, according to specification.

In addition, our management system integrates the key elements of several external standards into its best practices, and all our medical manufacturing and compounding adhere to cGMP or ISO 13485 standards.

No matter where you are, our global customer service representatives are within reach. You can get immediate assistance through our customer service hotline for issues ranging from a general question about our product offerings to a request for a technical data sheet to a specific handling procedure for a particular product.

Corporate Social Responsibility

Trinseo is committed to managing its products in a safe and sustainable manner and we encourage our suppliers and customers to join our efforts to collaborate, innovate, and elevate industrial practices and expectations so that chemical products are managed safely throughout their lifecycle.

Trinseo has a robust Ethics and Compliance program and is a Responsible Care® company. As a signatory to the Responsible Care Guiding Principles, we are committed to continuously improving our company's performance related to health, safety, and the environment, and to communicate with stakeholders about our products and processes.

For more information about our sustainability achievements, please visit our website at www.trinseo.com/sustainability

Trinseo Medical Application Policy

Trinseo produces medical grade resins under stringent quality guidelines and controlled conditions. We strive to understand our customers' needs and expectations regarding patient safety, reliability, and compliance with regulatory requirements, and to provide biocompatible resins according to ISO 10993 standards. Additionally, Trinseo medical grade resins are subject to our "formulation lock" policy which ensures that components remain the same over time and that customers will have advanced notice in the rare cases where a formulation or process change is needed.

Based on Trinseo's interest in collaborating with its customers, Trinseo has developed a medical application approval policy and internal process for reviewing customer requests for use of ISO 10993-certified materials in certain medical applications. Our full medical applications policy is available upon request.

Through this review process, we determine whether or not Trinseo will support the use of Trinseo materials in the proposed medical application based on 1. Device Category, 2. Type of Body Contact, and 3. Duration of Body Contact utilizing the ISO 10933-1:2009 guidelines, Biological Evaluation of Medical Devices Part 1: Evaluation & Testing.

In no event will Trinseo support the use of Trinseo materials in medical applications classified as implant devices or birth control devices, defined as applications designed specifically to promote or interfere with human reproduction.

If customers, distributors, or resellers fail to comply with this Policy, and Trinseo becomes aware of said situation, then Trinseo business units shall take steps required to immediately preclude further sales to that end use.

Trinseo will exercise its business judgment and conduct appropriate assessments when forming supplier/customer relationships and supplying materials. Trinseo has not designed or tested its products with respect to all possible uses in medical applications. While we will commit to meet product specifications and quality standards agreed with the customer, it is the responsibility of the medical device or pharmaceutical manufacturer to determine the suitability of the parts and raw materials, including Trinseo products, used in final products to ensure safe, suitable, lawful and technical compliance for the intended end use.

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The principles of Responsible Care® and sustainability influence the production of printed literature for Trinseo PLC and its affiliated companies. As a contribution toward the protection of our environment, Trinseo's printed literature is produced in small quantities and on paper containing recovered/post-consumer fiber and using 100 percent soy-based ink whenever possible.

Product Stewardship

Trinseo and its affiliated companies have a fundamental concern for all who make, distribute, and use their products and for the environment in which we live. This concern is the basis for our Product Stewardship philosophy by which we assess the safety, health, and environmental information on our products so that appropriate steps may be taken to protect employee and public health and our environment. The success of our product stewardship program rests with each and every individual involved with Trinseo products – from the initial concept and research, to manufacture, use, sale, disposal, and recycle of each product.

Customer Notice

Customers are responsible for reviewing their manufacturing processes and their applications of Trinseo products from the standpoint of human health and environmental quality to ensure that Trinseo products are not used in ways for which they are not suitable. Trinseo personnel are available to answer questions and to provide reasonable technical support. Trinseo product literature, including safety data sheets, should be consulted prior to the use of Trinseo products. Current safety data sheets are available from Trinseo.

No freedom from infringement of any patent owned by Trinseo or others is to be inferred. Because use conditions and applicable laws may differ from one location to another and may change with time, the customer is responsible for determining whether products and the information in this document are appropriate for the customer's use and for ensuring that the customer's workplace and disposal practices are in compliance with applicable legal requirements. Although the information herein is provided in good faith and was believed to be accurate when prepared, Trinseo assumes no obligation or liability for the information in this document.

NOTICE REGARDING MEDICAL APPLICATION RESTRICTIONS

TRINSEO REQUESTS THAT CUSTOMERS REFER TO TRINSEO'S MEDICAL APPLICATION POLICY HTTPS://WWW.TRINSEO.COM/INDUSTRIES/MEDICAL BEFORE CONSIDERING THE USE OF TRINSEO PRODUCTS IN MEDICAL APPLICATIONS. THE RESTRICTIONS AND DISCLAIMERS SET FORTH IN THAT POLICY ARE INCORPORATED BY REFERENCE.

For more information on products, innovations, expertise, and other services available from Trinseo, visit www.trinseo.com, or in the U.S. contact us at +1-855-TRINSEO (+1-855-874-6736).

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