



Medical sealing capabilities

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Your Partner for Sealing Technology

Serving the world's medical device industry

Trelleborg Sealing Solutions has been solving the world's most demanding sealing and bearing applications for over 50 years. We proudly offer a broad line of polymer products providing exceptional chemical and thermal resistance. Our product offering is extensive, and we have more than 2,000 material compounds available to produce seals, bearings, hoses, tubing and custom shapes for static, dynamic, reciprocating or rotary applications.

Sealing and bearing solutions must cope with the extremes of aggressive media, temperature, pressure and motion found in today's medical devices. In addition, chemical cleaning agent and steam sterilization resistance are often key requirements as more and more medical devices are designed for reuse.

We work closely with our customers to find the seal and bearing materials and designs that will provide unfailing performance of their equipment. Working together at the early stages of design provides our customers with shorter product launch times and improved quality and manufacturability.

Trelleborg Sealing Solutions proudly provides sealing solutions to all original equipment manufacturers and processors in the medical, pharmaceutical and biotechnology industries for applications including:

- Catheters
- Centrifuges, blood separators
- Diagnostic equipment
- Dialysis equipment
- Drug delivery systems
- Enteral feeding pumps
- Fiber optic sets
- Fluids transfer
- Home care oxygen compressors
- Orthopedic products
- Processing equipment
- Pumps (blood, infusion, HPLC)
- Respirators
- Sanitary fluid transfer
- Surgical saws and drills
- Surgical trays
- MRI machines



MRI tables

This bearing assembly is specifically designed without metal components so it will not interfere with the MRI imaging process.



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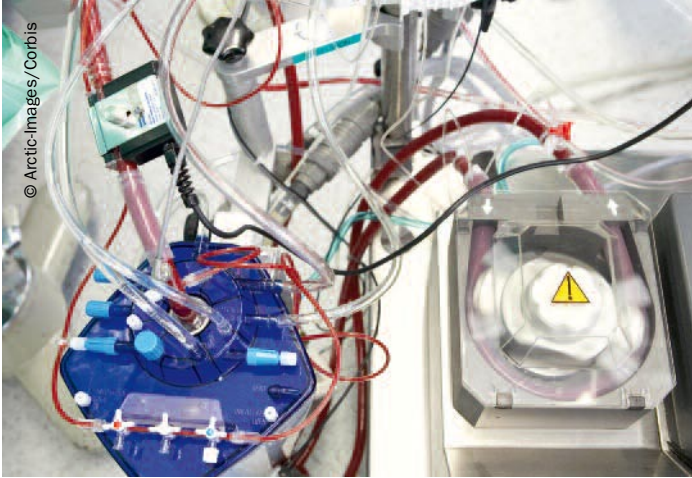
Engineered solutions

Trelleborg Sealing Solutions has the capability to bond elastomers and Turcon® to plastics and metals to create unique solutions such as these specialty valve components.



Hospital beds

Patient comfort is of extreme importance in the design of hospital beds. Seals and bearings from Trelleborg Sealing Solutions offer quiet, smooth operation with minimal friction and stick-slip.

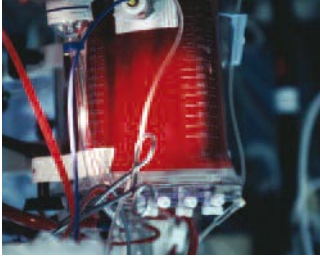


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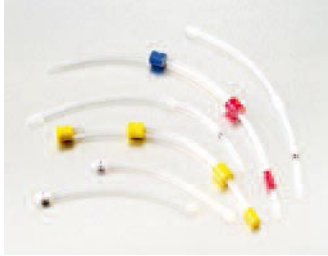
Medical pumps

Trelleborg Sealing Solutions offers a variety of high-performance products, for oxygen pumps to HPLC pumps to peristaltic pumps, to ensure leak-free sealing, long-lasting performance and solvent resistance.



Peristaltic pump tubing

Peristaltic pumps are widely used in medical applications because the pump never comes in contact with the fluid. Custom durometers and wall thicknesses can be developed for specific applications.



Innovative material formulations

Material compliance

Trelleborg Sealing Solutions develops and formulates materials in-house and engages in ongoing development of applied material technology. We offer over 90 materials that are fully compliant with the FDA CFR 21. Since the FDA only approves systems and units, our compliance with this norm ensures that our seals will not be the limiting factor for our customers to receive FDA approval for their systems. In addition, we offer compounded materials compliant to USP Class VI and ISO 10993 Cytotoxicity. Certificates on material conformance to these standards are available upon request.

Turcon® – a PTFE-based material

Our Turcon® PTFE products have very good slide properties with low friction and no stick-slip, provide high sealing efficiency and a long service life, meet demanding service conditions and provide high flexibility for easy installation. Our wide variety of Turcon® formulations ensures that we will have just the right material to meet the specific needs of our customers' applications.

Isolast® – a perfluoroelastomer material

Seals made of our Isolast® material operate in temperatures ranging from cryogenic up to +325 °C / +617 °F and seal effectively under pressure or in a vacuum. They provide nearly universal chemical resistance to withstand aggressive fluids such as acids, bases, solvents, gases and autoclaving solutions. Their FDA- and USP Class VI-compliant material formulations help reduce downtime and improve production efficiency by extending seal life, while minimizing the risk of contamination and bacterial ingress, which ensures product purity. Isolast® seals are available in black, white and clear.

Silicone material

We extrude, liquid injection mold and overmold products using specialized silicone materials to provide custom-engineered solutions for a variety of medical device, healthcare, biotechnology and pharmaceutical applications. Our silicone products maintain high pressure ratings, have excellent flexibility, are sterilizable and autoclavable, impart no taste or odor, are available in bulk or assemblies and operate under a wide temperature range.

Silicone inherently inert to bacteria, mold and fungi

Silicone materials are ideal for use in bioprocessing, medical and pharmaceutical production due to their inherent inertness to bacteria, mold and fungi. Trelleborg Sealing Solutions provides materials that give excellent heat resistance, cold flexibility and dielectric properties. They are especially good where exposure to ozone and oxygen is likely and have operating temperatures from -60 °C / -76 °F to +200 °C / +392 °F. Also, their exceptionally low surface energy means they will not adhere to counterparts. Demonstrating low long-term compression set, silicone materials are suitable for use in hot water, animal and plant fat, some lubricants and glycerin. However, care should be taken if specifying in acids, alkalis, ketones, esters and steam.



Engineered thermoplastics

Ideal for applications where wear resistance and low friction is required, a variety of high-performance PEEK and polyimide materials are offered which withstand high temperatures, have excellent chemical resistance and low out-gassing.

Industry Material Standards

Compliance with strict standards

The Life Sciences and Biotechnology industries, as well as the Pharmaceutical and Food and Beverage industries, provide a multitude of sealing challenges for critical processing components. These processes and applications require that sealing materials be manufactured from a variety of materials compliant with various national and international approvals and standards listed in the table below.

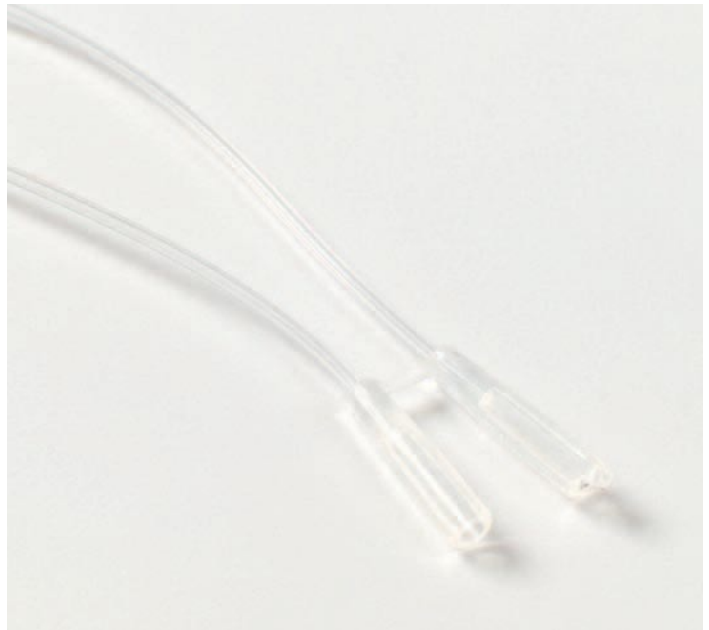
Standard authority	Regulations applicable to seals
<p>FDA</p> <p>The Food and Drug Administration (FDA) is a government agency within the US Department of Health and Human Services and is responsible for enforcing the Federal Food, Drug, and Cosmetic Act to ensure consumers' health and safety. It is mandatory that seals conform to this standard when in contact with food or pharmaceuticals in processing systems.</p>	<p>Elastomer seals must comply with standards detailed in paragraph 21 CFR 177.2600 "Rubber articles intended for repeated use" and FFKM elastomers with 21 CFR 177.2400.</p> <p>Polyurethane based elastomers must conform to FDA 21 CFR 177.1680.</p> <p>Perfluorocarbons (PTFE products and compounds, FEP and PFA resins) must comply with 21 CFR 177.1550, olefin based resins must conform to FDA 21 CFR 177.1520.</p>
<p>3-A</p> <p>3-A Sanitary Standards, Inc. (3-A SSI) is an American organization that formulates sanitary standards and accepted practices for design, fabrication, installation and cleanability of dairy and food equipment or systems used to handle, process and package consumable products. Its goal is to protect consumable products from contamination and ensure that all product surfaces can be cleaned. A prerequisite for 3-A approval is that the seal material already fulfills the FDA requirements.</p>	<p>Elastomer seals must comply with standard number 18-03, which covers Multiple-Use Rubber and Rubber-Like Materials that come into contact with production media.</p> <p>Perfluorocarbons (PTFE products and compounds, FEP and PFA resins) must comply with standard 20-25, which covers Multiple-Use Plastic Materials Used as Product Contact Surfaces.</p>
<p>USP</p> <p>The United States Pharmacopoeia (USP) is an independent, science-based public health organization. It is the official public standards-setting authority for all prescription and over-the-counter medicines, dietary supplements and other healthcare products manufactured and sold in the United States. The USP is considered one of the most technologically advanced and respected pharmacopoeias in the world.</p>	<p>USP Class VI testing Part 88 is referenced for sealing products and components, designed to evaluate plastics and elastomeric materials for use in drug processing equipment. It consists of a four-part evaluation involving animal testing, to test the biological reactivity in vivo.</p> <p>USP testing according to Part 87, also called cytotoxicity, is a complimentary in vitro test that measures the quality of the test substrate to be toxic to cells.</p>
<p>NSF</p> <p>NSF is a non-profit organization known worldwide for providing certification services in the areas of health and safety.</p> <p>NSF registration assures inspection officials, consumers and end users that products are safe to use in and around food processing and storage. The evaluation process includes a toxicological review of the ingredients, accuracy of labelling and material safety data sheet. In some cases, toxicology testing may be required.</p>	<p>NSF/ANSI Standard 51 "Food equipment materials". This standard provides minimum food protection and sanitation requirements for the materials used in the construction of commercial food equipment. No physical testing is required but a formulation review is performed.</p> <p>NSF/ANSI Standard 61 "Drinking water systems components Health effects." In order to comply to this standard, sealing materials have to undergo a third-party certification process which requires the recipe to be fully disclosed and toxicology tested and reviewed by the NSF organization.</p>
<p>KTW</p> <p>The Deutsche Vereinigung des Gas und Wasserfaches (DVGW) is an independent organization sharing expertise for self-regulation in the gas and water supply industry in Germany and Europe.</p>	<p>The KTW certificate is applied to polymers exposed to cold, warm and hot drinking water. The approval contains an extraction test and taste test, as well as a register of permitted ingredients.</p>
<p>WRAS</p> <p>The Water Regulations Advisory Scheme (WRAS) is the UK Water Industry's approval scheme. Products are approved by the scheme with tests for compliance carried out in accredited laboratories.</p>	<p>Suitability of non-metallic products for use in contact with water intended for human consumption with regards to their effect on the quality of the water is specified in BS6920:2000. It requires a formula review, microbial test, extraction test and test in hot water.</p>
<p>ACS</p> <p>Accréditation de Conformité Sanitaire (ACS) is a French sanitary standard relevant for potable water systems.</p>	<p>The standard is used for rubber and plastic materials in contact with potable water systems. The applicable criteria are laid down in the French Standard AFNOR XP P41-250, Part 1-3.</p>
<p>BfR</p> <p>The German organisation Bundesamt für Risikobewertung (BfR) is employed to evaluate plastics material used in the food and beverage industry.</p>	<p>In section XXI, the recommendations for rubber based articles for daily use are specified. Depending on the type of application, contact media and contact time, different test are required.</p>

Single-Use Product Capabilities

Trelleborg Sealing Solutions single-use products serve the Life Sciences industry in healthcare, bioprocessing and pharmaceutical applications.

Trelleborg Sealing Solutions offers a complete line of disposable products for the Life Sciences industry. Applications ranging from patient care, bioprocessing and pharmaceutical processing require systems that will provide first-time, one-time quality results. Researchers and healthcare providers are assured the highest quality of single-use products through our SF Medical product line. Trelleborg Sealing Solutions has long been known for their PharmaSil® premium medical-grade silicone tubing. The PharmaLim® liquid injection molded (LIM) products also offer a wide range of stoppers and bottle top assemblies. By combining these two market-leading products, Trelleborg Sealing Solutions is able to provide the Life Sciences industry with a complete line of premium first-time, one-time quality products such as:

- Tubing
- Stoppers
- Bottle Top Assemblies
- Unions such as Y and T connectors
- Custom Gaskets & Molded Components
- Custom-Designed Manifold Systems



PharmElast™ sheeting

Trelleborg Sealing Solutions also provides a complete line of silicone sheeting. PharmElast™ Sheeting is a translucent or radiopaque silicone elastomer material designed for applications demanding the ultimate compatibility in healthcare and other biological-related applications. PharmElast™ is available as a solid silicone sheet or with polyester tricot reinforcement. A complete line of color tinting is available, as well as clear.

Multi-lumen and custom design capability

Trelleborg Sealing Solutions can work with your engineers to develop custom tubing sub-assemblies such as these tubing sets designed for use in vascular & cardiac surgery. Our tubing is used in a variety of catheter designs for various medical specialties.

Innovative engineered product solutions

Our leading-edge sealing solutions for the medical device industry include a broad range of custom and standard seal options based on engineered plastic and metal technologies. Some of our solutions include:

- Variseal® spring-energized PTFE seals – providing the highest level of system integrity in extreme gas, fluid and pasty media handling applications.
- Varilip® PDR rotary shaft seals – a hydrodynamic sealing lip in a specially formulated grade of Turcon® PTFE that provides high sealing integrity and a low level of power consumption. Varilip® low friction/low wear seals are designed to provide a good seal even when in contact with oils with low surface tension and are compatible with most chemicals over an extremely wide temperature range.
- Bearings – We manufacture two types of bearing designs – HiMod® / Turcite® bearings (generally known as journal, sleeve, flange and thrust bearings or bushings) and Durobal® bearings (generally known as polymeric rolling element bearings).
- Diaphragms – providing the world's most advanced diaphragm solutions, from homogeneous designs to highly-engineered, deep drawn, fabric-reinforced, coated and bonded diaphragms.
- Hose – providing sanitary hose for a variety of medical applications including pumps; pharmaceutical processing; chemical, acid, vessel, tank or bulk transfer; cell cultures and load cells.



Sealing product range

- O-Rings
- Diaphragms
- Cup seals
- Turcite® Slydrings
- Varilip® PDR
- Molded elastomer seals
- Variseal®
- Metal seals
- Gaskets



Bearing product range

- HiMod® Bearings
- Turcite® Bearings
- Durobal® Bearings
- Composite Bearings

Hose product range

- PharmaSil® Sanitary Hose
- PharmElast™ Silicone Sheeting
- PharmaLim® products

Product Design

Rapid Prototyping

Succeeding in today's extremely competitive Life Sciences and Biotechnology industries requires much more than creative concepts and the development of advanced sealing solutions. Winning in these markets with their continually reduced product development times demands the ability to design, communicate and deliver a cost-effective design in a fraction of the time of traditional design and production cycles. While many product development organizations gauge design cycles in months, today's competitive Life Sciences and Biotechnology industries are moving at such a rapid rate that potential suppliers are expected to complete concepts and samples for presentation to potential customers before even securing the business.

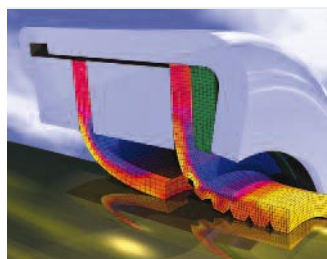
Trelleborg Sealing Solutions is a leading manufacturer of tubing, hoses and sealing solutions for the Life Sciences industry. To gain a competitive advantage, we utilize Liquid Injection Molding (LIM) technology within a clean room environment. However, the fast moving health care market is placing greater demands on suppliers within this industry to reduce lead times on not only delivery of manufactured products, but also delivery of quoting and samples of design. The time and cost to deliver such samples to secure new business is many times not possible due to the tooling utilized for LIM manufacturing.

Trelleborg Sealing Solutions has made a strategic investment in advanced design, prototyping and production technologies to gain a competitive edge. The company began investigating rapid prototyping technologies as part of an effort to shorten design cycle, reduce prototype development costs, streamline production, improve customer presentation and capture new business. Prototype samples which used to take weeks and months and cost thousands of dollars now can take hours and cost as little as \$10. Prototype samples produced are available in a number of different material systems to satisfy a variety of modeling needs. While some companies may use the more rigid snap-to-fit epoxy-based binder material, we incorporate the elastomeric material to create parts with rubber-like properties.

This technology has already found its way into the world's best-known R&D facilities. In a short lead-time competitive quoting situation, Trelleborg Sealing Solutions is able to provide potential customers with multi-colored samples to hold and touch instead of line drawings or CAD models.

Extensive test facilities

FEA modeling techniques are also used in conjunction with test rigs at our fully-resourced design and application centers to prove the effectiveness of our seal, bearing and custom solutions.



FDA-approved location

The manufacturing facility that produces our silicone tubing product line is registered with the FDA and undergoes regular audits by key customers to maintain approvals.

Bone Drill



This bone drill design uses an oiler cartridge to keep the drill tip cool during operation. A seal is needed to contain the oil and keep contamination out. This static application operates at 0.414 MPa/60 psi, +135°C/+275°F and is exposed to air, mineral oil and autoclave sterilization. The original design utilized an O-Ring that prematurely failed due to excessive wear and leakage.

Solution: Variseal® M with Turcon® T17 seal material with medium load V-spring

Result: The seal met all operating requirements and provided improved wear resistance, which resulted in extending the service life.

Blood Separator



This device separates platelets from blood, which can later be used to speed the healing process of wounds or supply hemophiliacs with clotting factor. A bearing is used to provide rotary fluid exchange between the collection tray and the separator unit. The bearing operates at room temperature and rotates at 1,680 rpm without coming into direct contact with the blood. The existing bearing was too costly and experienced unacceptable field failures.

Solution: A Durobal® bearing design consisting of PET inner and outer portions with a PET compounded cage and 302 stainless steel balls

Result: Significant cost savings were achieved by going to a near net molded part versus the fully machined original. The product has been in production since 2001 and has resulted in reduced service costs and field failures.

Oxygen Pump

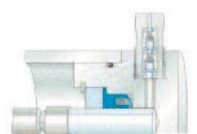


This 5-stage pump is the key component for the filling of oxygen tanks in the home in a safe, compact manner. Oxygen, created with an integrated oxygen concentrator, must be charged to approximately 15.17 MPa/2,200 psi in order to ensure adequate volume within the tank to last for many hours. To safely do this, the oxygen is fed through each of the five stages, with each stage yielding a higher pressure until it finally reaches the tank at 15.17 MPa/2,200 psi.

Solution: Each stage incorporates a piston with one Variseal® M, a V-spring-energized piston seal made from Turcon® T07 and two wear sleeves made from QD8. This combination allows for an efficient charging of the oxygen with low power consumption.

Result: The seals passed all testing and have provided excellent service life.

HPLC Pump



Plunger pumps used in analytical chemistry systems handle a wide range of solvents as well as abrasive saline solutions. The seal needed to be leak-free while sealing on a very smooth sapphire plunger, be compatible with numerous solvents and provide consistent friction and long life. The seal reciprocates with a 0.64 mm/0.25 inch stroke at 41.40 MPa/6,000 psi. Operating temperatures vary from +4°C/+40°F to +49°C/+120°F.

Solution: Custom Variseal® FW with extended heel, Zurcon® Z80 seal material and a heavy load slantcoil spring

Result: The specified seal, made from UHMWPE, provides excellent wear resistance and long life while the slantcoil spring imparts the force necessary to create a consistent, leak-free seal with consistent friction.

Bioprocessing Flow Tubing



Due to the volume of a large volume bottom outlet disposable biobag, a high flow rate discharge was required. A standard peristaltic pump would not achieve the desired flow rate, so a rotary lobe style pump was selected. Standard 0.32 mm/0.125 inch wall tubing was collapsing due to the large suction pressure caused by the rotary lobe style pump, and the desired flow rates were not being achieved.

Solution: The tubing wall was increased to 0.48 mm/0.1875 inch while maintaining the same ID. This improvement would prevent the tube from collapsing under the higher pump suction.

Result: The thicker wall tubing has proven to be a successful solution to the problem, and the specified flow rates are being met.

Medical device sealing and bearing capabilities

Quick Disconnect Coupling

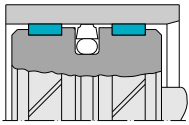


This coupling is used for portable oxygen units that convert liquid oxygen into a breathable form. The portable unit is recharged by a larger, home-based container. This seal must withstand cryogenic temperatures, be FDA-compliant, leak-free, durable and exhibit low friction while being engaged and disengaged repeatedly.

Solution: Standard Variseal® FM with a Turcon® T01 jacket and medium-load V-spring

Result: The specified seal meets all of the application requirements and has helped make portable oxygen units easier to use and operate. The seal's durability also provides an added measure of reliability.

Hospital Bed Cylinder



Today's powered hospital beds utilize electronically controlled hydraulic cylinders to move patients into different positions. The patients are often too weak or immobilized, but must be moved to conduct various procedures. Patient comfort is of extreme importance, and due to the side loads, minimal friction and stick-slip are required.

Solution: Turcite® Slydring

Result: The Slydring prevents metal-to-metal contact between the piston and bore. Turcite® is a reinforced PTFE capable of handling moderate side loads while providing good frictional properties. The new Slydring added damping to the system and removed the stick slip, which provided the important performance the customer was requesting.

MRI Machine



Comfortably moving patients in and out of the MRI machine is of utmost importance. The bearings used on the movable table must provide low friction and be non-metallic due to the strong magnetic field generated by the MRI process. The table bearings operate at room temperature and allow for 360 degrees of slow, smooth motion.

Solution: Custom Durobal® bearing assembly with quiet smooth operation

Result: Trouble-free operation and a long service life

Cryogenic Storage System



This new biological sample storage and retrieval system required a seal that could accommodate both rotary (5rpm) and reciprocating (102mm/40inch stroke) motion under a 5mm/2inch Hg vacuum. Since the motors and drives are external to the tank, the cryogenic seal seals the feed port through which the manipulator arm places and retrieves samples in the storage unit. The seal was exposed to liquid nitrogen and ice. In addition, the seal would operate infrequently, 2 to 3 times a day, for 1 to 2 minutes and required low friction and stick-slip.

Solution: Variseal® M seal with Zurcon® Z80 seal material with two nested load V-springs

Result: The seal met all performance requirements and provided long operating life.

Peristaltic Pump Tubing



Consistent, long-term flow rate through peristaltic pump tubing is vital for use in critical healthcare applications. The flow rate can be negatively affected by hysteresis (a lagging effect or loss in elastic energy when a silicone is dynamically deformed and returned to its original shape) and spallation (dislodged particles on the interior wall of the tubing). Silicone tubing must deliver consistent fluid flow rates.

Solution: Development of silicone grades to achieve the best formulation to achieve repeatable, consistent flow rates while reducing the effects of hysteresis and spallation

Result: Silicone tubing endurance testing shows Trelleborg Sealing Solutions pump tubing meets the demanding requirements of these critical applications.

Developing partnerships to optimize application solutions

Trelleborg Sealing Solutions works with our customers to develop partnerships that will ultimately identify the best sealing and bearing solution for specific applications from a broad range of materials and shapes. We also develop unique formulations and products to meet specific industry or functional requirements. Our highly-engineered solutions are verified at leading edge test facilities and backed by independent test results through internationally-recognized institutes.

Total Technology

From medical devices to applications in aerospace, automotive and general industry, Trelleborg Sealing Solutions is a major international seals and bearings provider. Our direct experience with unique and challenging applications positions us well to offer custom design and industry-specific development services for sealing components. Strategically located material development laboratories and fully resourced design and application centers continually deliver the latest product innovations and customer-focused sealing solutions.

Proven Expertise

With over 50 years of experience in the design, development and application of sealing and bearing systems, Trelleborg Sealing Solutions engineering personnel bring their expertise directly to our customers. This includes project design management, prototyping, production, testing and installation. Our state-of-the-art design tools include customer-compatible CAD systems and leading edge Finite Element Analysis (FEA) systems.

Customer Commitment

We help our customers achieve cost-effective, durable solutions that are precisely matched to their specific system requirements and business needs. This includes our logistical support, which effectively delivers over 40,000 different sealing and bearing systems to our customers worldwide. Trelleborg Sealing Solutions is one of the world's foremost experts in polymer sealing and bearing technology. We develop, manufacture and market safety-critical polymer-based precision seals and bearings and associated systems.

Our Competitive Edge

- A complete polymer sealing range for the medical device industry
- 24-hour worldwide service and support
- Industry-leading design and materials expertise
- Best practice manufacturing
- Customized distribution capabilities
- Proven engineering excellence



Global manufacturing, customer support

Our worldwide resources include over 80 facilities in the Americas, Europe and Asia including manufacturing sites, materials and development laboratories and design and application centers.

Contact your local marketing company for further information:

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