BioPharmaPro™

SINGLE-USE SOLUTIONS FOR FLUID PATH SYSTEMS

Pioneering Innovation

SOLUTIONS FOR THE BIOPHARMACEUTICAL INDUSTRY

The biopharmaceutical industry plays a critical role in the healthcare ecosystem, developing innovative treatments and therapies for a variety of diseases and conditions. New solutions require efficient drug discovery, the ability to quickly scale-up production, and the competency to adapt to an ever-changing world. To ensure patients receive the therapies they need to improve their lives, technology to develop more effective biopharmaceuticals and optimize the efficiency of manufacturing processes is required.

Decades of innovation have enabled the biopharmaceutical industry to expand and diversify:

- Cell lines maximize efficiency and safety
- Process media continuously improves
- Equipment, such as bioreactors, filters, chromatography systems and preservation equipment, optimizes the manufacturing process
- Fill and finish processes deliver medicines to patients as quickly as possible

Single-use components are being widely adopted, since they enable therapy producers to safely change equipment after batch runs and thereby ensure equipment is free of contamination from previous usage.

Trelleborg Medical Solutions supports biopharmaceutical companies with its BioPharmaPro™ line to improve patient quality of life with safe, effective, and timely, biological therapeutics.

THE BioPharmaPro™ PORTFOLIO

Accelerate the Advancement of Life-Changing Therapies
BioPharmaPro™ from Trelleborg Medical Solutions is a family of innovative products, materials and services for fluid path single-use equipment. These solutions are created using a vast portfolio of materials, including thermoplastics, silicones, and composite materials, which can be manufactured into tubing, custom molded components, processing columns, filters, full assemblies, and much more.

FEATURES AND BENEFITS

- Solutions range from individual single-use components to assemblies and full biopharmaceutical systems
- Full portfolio of polymer materials, which meet functionality, cleaning and sterilization, and regulatory requirements
- State-of-the-art equipment and processes deliver a consistent supply of high-quality products
- Advanced manufacturing technology produces innovative and reliable precision components and assemblies
- Systems can be produced in ISO 7 and ISO 8 cleanrooms
- Components meet purity, cleanliness and biocompatibility requirements
- Integrated solutions, including full assemblies, packaging, and kitting, enable supplier consolidation

OUR GLOBAL NETWORK

4
Customer Solution Centers

14
ISO 13485 Certified Manufacturing Sites

4
Innovation Centers

Backed by additional Trelleborg resources

55+ Customer Solution Centers
35+ Manufacturing Sites
15+ R&D Centers
7+ Logistics Centers SCM

Spanning the globe, our experts act as an extension of our customers' R&D teams to deliver the knowledge and capabilities needed. Our network of facilities offers:

- Product and material development support, including testing and qualification
- Extensive manufacturing and processing capabilities, including cleanroom facilities and quality control systems
- Special packaging and managed sterilization services, full assembly and advanced delivery options

With this unique set of capabilities, we act as a business accelerator and help you bring your product to market faster.

CONTACT US
Do you need support with your biopharmaceutical equipment projects? Reach out to Trelleborg Medical Solutions to learn how we can support you.

Expertise at Your Service

ACTING AS AN EXTENSION OF YOUR TEAM, OUR DEDICATED RESOURCES DELIVER VALUE THROUGH A STRONG SET OF CORE CAPABILITIES.

Because single-use systems perform critical functions, we value strong partnerships with our customers to develop innovative solutions and ensure the best possible outcome. When customers approach us with their ideas for innovative components and devices, we collaborate with them at every step to turn these ideas into reality.

INNOVATIVE ENGINEERING

Trelleborg Medical Solutions engineers work closely with customers to design and develop solutions ranging from individual single-use components to assemblies and full biopharmaceutical systems. Collaboration early in the development process accelerates the timeline from prototype to scale-up.

We combine custom engineering with Design for Manufacturing (DfM) to test designs and materials using the latest simulation techniques. Our expertise ensures the right selection of material and design for a functional integrated solution and improves future production yields.

POLYMER MATERIAL EXPERTISE

When designing new single-use systems, material selection is crucial. Materials must meet functionality requirements, withstand cleaning and sterilization regimens, and comply with standards and regulations. Trelleborg has decades of experience developing, testing, and qualifying materials for use in biopharmaceutical systems.

Our team of silicone and medical polymer experts works directly with customers to determine the best material compound for their application. We excel at finding innovative solutions to customer challenges through our understanding of the interactions of materials, the manufacturing environment, and the application.

ADVANCED MANUFACTURING PROCESSES

At Trelleborg Medical Solutions, we have an in-depth understanding of the challenges our customers must overcome. This enables us to reliably develop and manufacture components and assemblies for single-use biopharmaceutical systems using:

- A full range of testing capabilities to ensure both the material and the system meet application and manufacturing requirements
- State-of-the-art manufacturing capabilities to produce innovative and reliable precision components and assemblies
- A complete suite of post-fabrication services to deliver products according to customer-specific requirements

QUALITY & VALIDATION

Maintaining consistent quality is essential for single-use systems. At Trelleborg Medical Solutions, we utilize state-of-the-art equipment and processes to deliver a consistent supply of high-quality products. Our facilities are optimized for biopharmaceutical manufacturing, and systems can be produced in ISO 7 and ISO 8 cleanrooms. Benefits include:

- Robust change control process and philosophy supports full traceability and proactive communication to customers
- Lower cost and higher yields for our customers
- Strict quality systems accelerate time to market
- In-house labs ensure consistent and reliable products prior to validation
- Quality Management System ensures quality requirements are met
- Automation for consistent results throughout every product run
- Products are of the highest quality, verified using Machine Vision Inspection

BioPharmaPro™ Products & Capabilities

Trelleborg Medical Solutions supports biopharmaceutical companies with a full range of products, from single-use tubing and tubing sets and custom molded parts to full assemblies for filtration or chromatography equipment with advanced composite columns. Our facilities utilize automation, in-house tooling, state-of-the-art processing equipment, and cleanroom production to deliver effective, safe, high-quality products and solutions.

BioPharmaPro™ SILICONE TUBING

BioPharmaPro™ silicone tubing is manufactured using platinum-cured silicone, to achieve the highest level of purity. Extended extractable and leachable studies following the BioPhorum Operations Group (BPOG) testing protocol reflect the outstanding cleanliness of BioPharmaPro™ silicone tubing. It comes with United States Pharmacopeia (USP) 87, USP 88 Class VI compliance and can be sterilized with the latest gamma and X-ray sterilization methods to achieve the standards needed in today's single-use systems.

Available in 25 ft/7.62 m, 50 ft/15.24 m, and 100 ft/30.48 m coil lengths, our standard sizes (inner diameter) for non-braided, silicone tubing are:

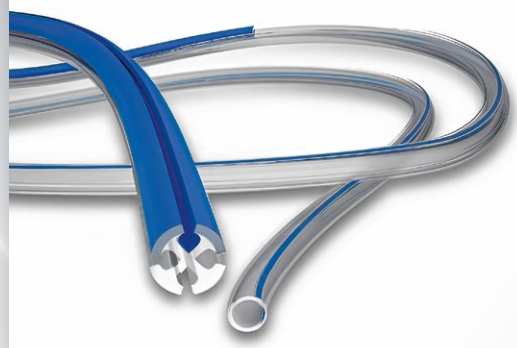
0.187"/4.75 mm	0.312"/7.92 mm	0.500"/12.70 mm	0.750"/19.05 mm
0.250"/6.35 mm	0.375"/9.53 mm	0.625"/15.88 mm	1.000"/25.40 mm

BioPharmaPro™ BRAIDED, REINFORCED HOSE

BioPharmaPro™ braided, reinforced silicone hoses are designed for demanding medical applications, which undergo repeated sterilization-in-place (SIP) and cleaning-in-place (CIP) cycles. They are designed for high-pressure applications and withstand extreme temperatures while maintaining flexibility at temperatures from -80 °F to 500 °F/-62 °C to +260 °C. Our braided, reinforced hoses are manufactured with the same platinum-cured silicone as used for our BioPharmaPro™ silicone tubing.

Available in 25 ft/7.62 m, 50 ft/15.24 m, and 100 ft/30.48 m coil lengths, our standard sizes (inner diameter) for braided, silicone hose are:

0.250"/6.35 mm	0.375"/9.53 mm	0.625"/15.88 mm	0.875"/22.23 mm
0.312"/7.92 mm	0.500"/12.70 mm	0.750"/19.05 mm	1.000"/25.40 mm



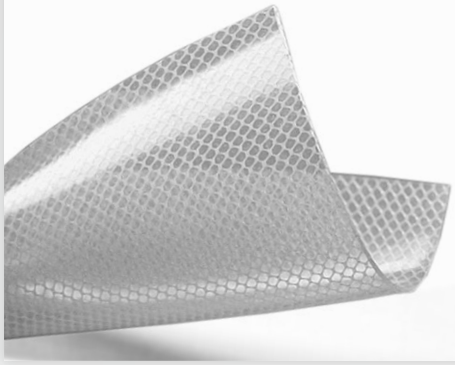
BioPharmaPro™ ADVANCED EXTRUSION

We tailor our extrusion processes to meet our customers' needs, no matter how complex. Capabilities include overmolding, multi-lumen, inside and outside diameter variation, twisted lumen, reinforced tubing, extremely thin walls and more.

Our GeoTrans™ technology is used for custom applications with precision tolerances. The process allows for silicone tubing to change cross section during extrusion, which eliminates molding and secondary bonding steps. This patented technology facilitates hygienic design and lowers overall device costs. Our team precision manufactures the die and mandrel using in-house tool rooms, translating to high-quality and consistent supply for our customers.

BioPharmaPro™ FITTINGS

Customized to each application, BioPharmaPro™ fittings can be manufactured in a range of metal, silicone or thermoplastic materials. They can be supplied as single molded products or together with overmolded silicone tubing, single-braided hose, and double-braided hose. They are suitable for use as sanitary fittings or connectors combined with our BioPharmaPro™ tubing and hose, providing an integrated solution for fluid path and biopharmaceutical applications.



BioPharmaPro™ SHEETING

Our BioPharmaPro™ sheeting solutions are designed and manufactured with the highest level of quality and compatibility. We work closely with customers to design components that meet their precise requirements, whether vulcanized, unvulcanized, reinforced, non-reinforced, pigmented, rolled or cut to purpose.

BioPharmaPro™ THERMOPLASTIC MOLDED COMPONENTS

Trelleborg's in-house tooling, engineering expertise, and ability to scale to production are at the core of our plastic injection molding capabilities. Our specialized equipment is suited for manufacturing molded components in high-temperature, engineering-grade resins, polysulfone (PS), polycarbonate (PC) and polyether ether ketone (PEEK). Components can be enhanced with soft touch overmolding, high-volume insert overmolding through automation, and value-added services, including laser scribing and pad printing.

BioPharmaPro™ SEALING SOLUTIONS

Seals perform critical functions in biopharmaceutical equipment. By eliminating dead space, they protect the product from contamination, and prevent leakage to the outside environment. They must withstand harsh environments and be suitable for use with biopharmaceuticals. We offer a broad range of high-performance sealing solutions, from the versatile O-Ring to complex multi-faceted geometries. Our portfolio includes seals for static and dynamic applications in a wide range of materials, including silicone and other elastomers, engineered plastics and metal technologies.

BioPharmaPro™ LSR MOLDED COMPONENTS

We produce liquid silicone rubber (LSR) molded components in a state-of-the-art, flashless, wasteless production process, which provides the highest consistency in dimensions, precision, and overall quality. Our lean manufacturing processes can produce almost any design, ranging from micro-sized components to large-scale pieces. LSR molding enables high-volume production with short cycle times, due to the material's fast-curing nature.

Our in-house tooling and sophisticated process engineering ensure the highest quality and consistently achieved tight tolerances. By utilizing DfM principles, we facilitate a smooth transition from prototype to production.

BioPharmaPro™ MULTICOMPONENT SOLUTIONS

The use of multicomponent LSR technology provides designers with increased latitude and flexibility in design solutions. Multiple components can be integrated into one fully bonded solution, increasing cleanliness and mitigating risks and costs associated with secondary assembly.

Our in-house team of experts is at the forefront of tool, process, and automation technology for multicomponent liquid injection molding. In a fully automated and closed loop system, either a combination of thermoplastics and LSR or two dissimilar grades of LSR are co-molded into a single bonded component.

BioPharmaPro™ ADVANCED COMPOSITES

Advanced composites solutions are lightweight, high tolerance-controlled, non-reactive products. They are ideal for use in bioprocessing equipment, for example in chromatography applications. Our BioPharmaPro™ advanced composite columns are designed to replace stainless steel or acrylic, multi-use columns. Produced with polypropylene thermoplastic materials, the columns can be recycled, offering a more sustainable single-use solution.

Our advanced composite products are manufactured using advanced fiber placement technologies, which give these components their unique properties. The continuous E-glass fiber reinforced polypropylene material is thin and lightweight, while able to withstand very high pressures. Components are designed to meet customer requirements, which can include the addition of machined features to promote ease of assembly.

Find out more about our solutions for chromatography equipment on page 15.

Fully Assembled

FROM CONCEPT TO SERIAL PRODUCTION

Trelleborg Medical Solutions takes the BioPharmaPro™ product and solution portfolio a step further by delivering value-added fluid path assembly solutions.

How our integrated solutions help:

- Custom solutions designed to meet unique customer needs
- Integrated solutions range from tubing sets for single-use applications to full equipment assembly, such as chromatography systems
- Support from the earliest development stages through to full serial production
- Our design and material expertise, paired with simulation technology, facilitates the development of the best design for functional solutions
- Supplier consolidation reduces risk in the supply chain
- Saves costs through bundled purchasing processes and consolidated audits, shipping and logistics
- Rectifies design and manufacturing issues before a product goes to the market
- In-house assembly and testing in ISO 7 and 8 cleanrooms ensure consistent high-quality
- Time and money savings enable you to focus on your core competencies and remain agile for the future

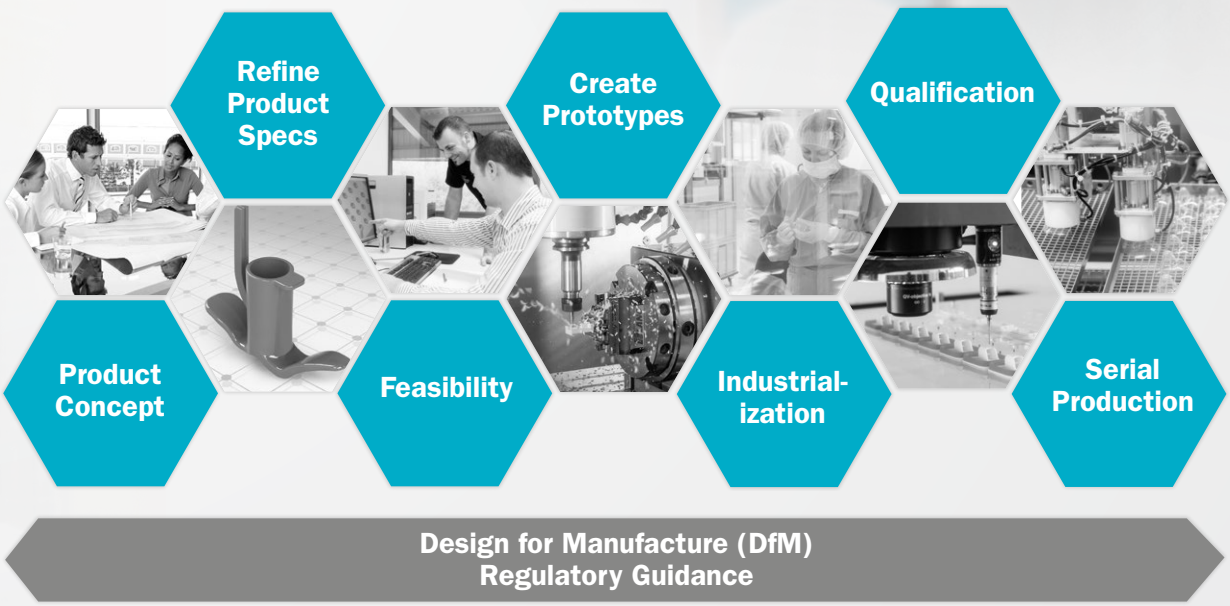
Integrated Solutions

In the fully integrated solution, different services, such as cut-to-length tubing, marking, gluing, overmolding and various assembly processes are combined. Assemblies are packed, labelled and, if needed, sterilized. When required, documentation covering regulatory compliances and information on testing and validation accompanies the assembly.

Find examples on page 15.

ACCELERATING YOUR BUSINESS

Bringing new fluid path systems to market faster means we can make an impact on more patients' lives. At Trelleborg Medical Solutions, our engineers collaborate closely with customers to move as fast as possible through the design, testing and qualification, and commercialization phases of product development, while paying attention to quality and costs. And once our customers' solutions are on the market, we strive to provide consistent, reliable supply to the agreed upon quality standards.



BioPharmaPro™ Materials

CONFORMING WITH STRINGENT BIOPHARMACEUTICAL REQUIREMENTS

Products designed for biopharmaceutical purposes must fulfill the highest requirements in terms of purity, cleanliness and biocompatibility. Components must be suitable for use with aggressive media and sterilization processes and be inert and non-reactive with cell cultures and media used in drug production.

To support customers with the development of new single-use systems, Trelleborg Medical Solutions experts can perform a range of tests to determine the suitability of materials and products.

EXTRACTABLES AND LEACHABLES

Since risks are high in the pharmaceutical industry, strict regulations and monitoring requirements are applied to quality, hygiene and biocompatibility. One area of risk that can impact a material´s performance is extractables, or substances that might be unintentionally extracted from polymer materials. An interaction of extractables with drugs or other media can be harmful to patients and potentially have long-term effects on the human body.

Our material development experts conduct extensive tests to ensure that our products can be used for biopharmaceutical applications, especially for the transport of media. Tests are performed to determine whether substances can be extracted under different conditions. Results show that our tubing and hose meet the highest standards and demonstrate outstanding purity levels according to BPOG and USP 665.

BIOCOMPATIBILITY TESTS

To ensure products have no harmful influence on cell cultures, the final drug or the patient, biocompatibility must be assured. Trelleborg Medical Solutions conducts essential tests to evaluate the risk of materials.

BioPharmaPro™ materials have been tested for biocompatibility according to the standards USP 87, USP 88 Class VI and ISO 10993.

STERILIZATION PROCESSES

The cleanliness of biopharmaceutical products is vital. When designing single-use systems, selecting the correct materials and processing techniques are fundamental considerations. Not only must the materials meet functionality requirements and carry several certificates and approvals, but they must also cope with destructive cleaning media and harsh sterilization methods.

There are several different sterilization methods used in practice, including gamma radiation, steam, X-ray and EtO. These high-energy processes ensure aggressive pathogens are killed. Commonly used sterilization methods can cause molecular changes to polymer materials, resulting in accelerated deterioration and changes to physical properties, such as flexibility and tensile strength.

OUTSTANDING MATERIALS FOR DEMANDING REQUIREMENTS

Specially engineered for the most challenging environments, Trelleborg Medical Solutions BioPharmaPro™ materials can be used in a wide range of biopharmaceutical processing applications. Compounds demonstrate proven compatibility with aggressive media and sterilization processes and do not affect cell cultures or patients.

BioPharmaPro™ materials are typically used in single-use systems, especially within the fluid path, and are often in direct contact with the media. The materials can be used in combination or as single components for a full biopharmaceutical system.

BioPharmaPro™ SILICONE ELASTOMER WITH UNIQUE CAPABILITIES

Silicone is an extremely versatile material that lends itself to a broad range of application conditions, and the advantages in processing make it an optimal choice for biopharmaceutical components.

- Available in various hardnesses:
  - LSR: 5-90 Shore A
  - High consistency silicone rubber (HCR): 20-80 Shore A
- Most flexibility in geometry and size
- Highest level of purity with platinum-curing
- Excellent low and high-temperature resistance
- Resistant to ozone, weather and UV rays
- Hydrophobic
- Excellent mechanical damping properties
- Biologically inert
- Biocompatible according USP 88 Class VI, USP 87 and chapters of ISO 10993
- Compliant with USP 381
- Suitable for use with common sterilization methods such as dry heat, steam, gamma radiation and EtO
- BPOG and USP 665 studies available

CONTACT US

Do you need support with material selection or want a detailed validation report? Please contact Trelleborg Medical Solutions.

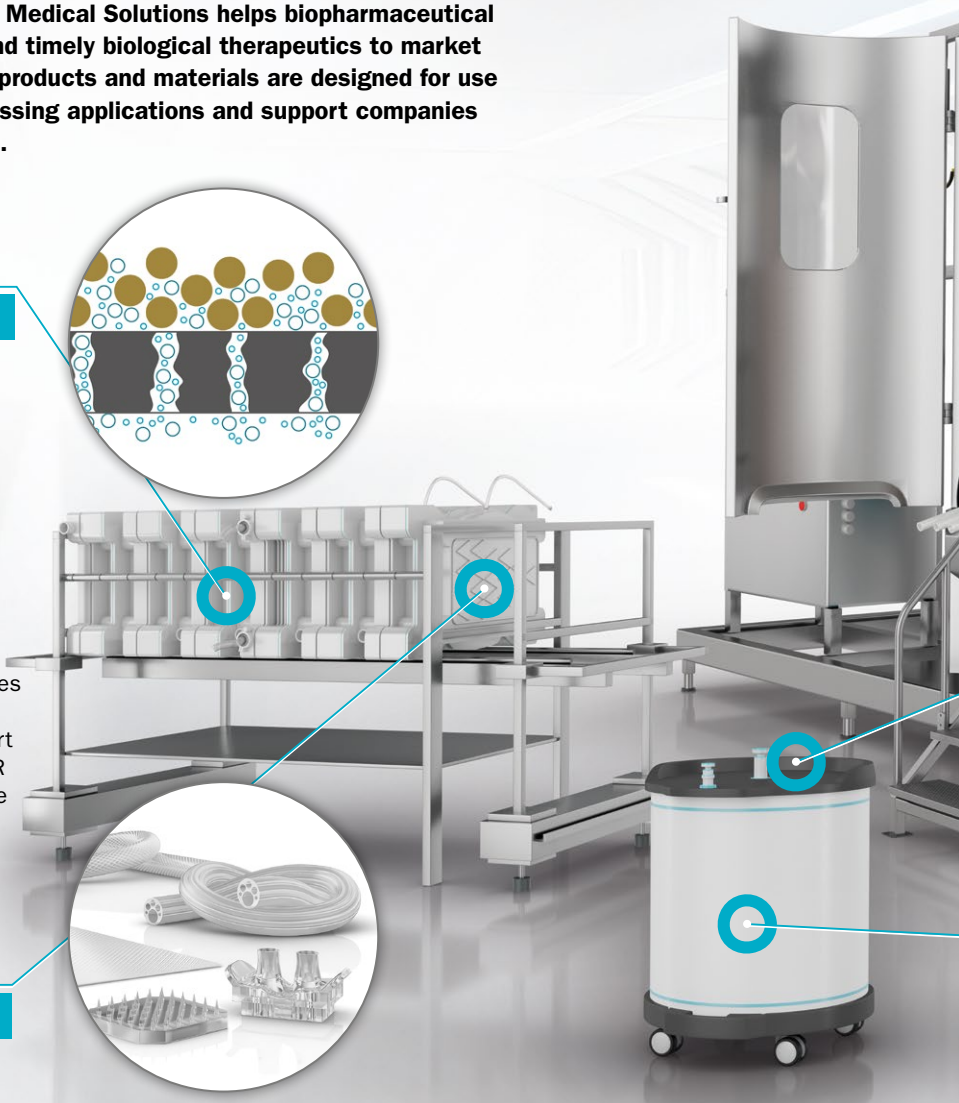
BioPharmaPro™ MATERIAL COMPLIANCE

Material Family	Product	USP 88 Class VI	USP 87	ADI free	Eur.Ph. 3.1.9	BPOG
Silicone	BioPharmaPro™ Extruded HCR	●	●	●	●	●
	BioPharmaPro™ LSR	●	●	●	●	
	BioPharmaPro™ molded HCR	●	●	●	●	
Ethylene propylene diene rubber (EPDM)	BioPharmaPro™ EPDM	●	●	●	n/a	
Fluoroelastomer (FKM)	BioPharmaPro™ FKM	●	●	●	n/a	
Perfluoroelastomer (FFKM)	Isolast® BioPharmaPro™	●	●	●	n/a	
Composite PP/glass fiber	BioPharmaPro™ Advanced Composites	●	●	●	n/a	
Polytetrafluoroethylene (PTFE)	Turcon® BioPharmaPro™ virgin PTFE	●	●	●	n/a	
Polysulfone (PS)	BioPharmaPro™ PS	●	●	●	n/a	
Polycarbonate (PC)	BioPharmaPro™ PC	●	●	●	n/a	
Polyether ether ketone (PEEK)	BioPharmaPro™ PEEK	●	●	●	n/a	

Biopharmaceutical Applications

SUPPORTING THE DEVELOPMENT OF LIFE-CHANGING TREATMENTS

With its BioPharmaPro™ portfolio, Trelleborg Medical Solutions helps biopharmaceutical companies bring innovative, safe, effective and timely biological therapeutics to market to improve patient outcomes. Our innovative products and materials are designed for use in numerous critical biopharmaceutical processing applications and support companies from small batch through to serial production.



CROSS-FLOW FILTRATION

Requirement: A filter unit which directs the fluid flow with its unique surface structure, while housing the filter and preventing contamination with a seal component.

Challenge: The development and production of the required surface structure for a filter system are complex, requiring material and design expertise.

Trelleborg Solution: Our material, design and manufacturing experts developed a filter unit consisting of four components. The surface structures for directional filtration are designed onto the thermoplastic part and onto the multicomponent part made of LSR and a thermoplastic. An additional LSR part keeps the system sealed. The filter layer can be integrated according to customer requirements.

DEPTH FILTRATION

Requirement: A high-performance fluid path and sealing component which supports critical and demanding filtration processes.

Challenge: Large filter systems must be designed to efficiently direct fluid through the series of chambers and withstand the pressure increases required to move the fluid through the filter membranes. These systems must also be effectively sealed to prevent contamination between the chambers.

Trelleborg Solution: Material and design experts developed a custom silicone seal matched to the filter cassette size and shape to ensure pure and clean separation and filtration of media. A set of plastic pipes and braided, reinforced hoses and connector components manages the media distribution.

BIOREACTOR DRIVE COUPLING

Requirement: The drive coupling must act as a sterile barrier and facilitate uniform mixing of the cell medium, which can be particularly challenging in large bioreactors.

Challenge: A typical drive coupling is not an adequate solution in large bioreactors. It cannot effectively maintain a sterile barrier and provide a sufficiently strong drive for uniform mixing of the cell medium.

Trelleborg Solution: Our materials and process experts at our manufacturing facilities developed a magnetic coupling that is powerful enough to apply sufficient torque to the stir bar and meets the sterile barrier requirement. The coupling can be provided as a fully assembled drive unit to streamline handling and ensure quality.

STERILE CONNECTOR

Requirement: A valve connector transports media from one filter to the next processing unit and must ensure a sterile working environment to prevent contamination of the medium.

Situation: Typically used in connectors, O-Rings are not without risk. Occasionally they are forgotten during assembly and the O-Ring groove is a typical haven for buildup of microorganisms.

Trelleborg Solution: A multicomponent part forgoes the need for an O-Ring. This fully bonded component eliminates dead space, thereby preventing bacterial growth and contamination Additionally, it streamlines the assembly process by combining the O-Ring and the housing into one single connector component.

CHROMATOGRAPHY EQUIPMENT

Requirement: A complete, light-weight solution for single-use, pre-packed chromatography systems.

Challenge: Chromatography systems come in a range of sizes and ideally are easy to move around to ensure optimal handling during the biopharmaceutical production process. Traditional stainless steel systems, which are used because of their robust performance profile and ability to withstand high pressures, are very heavy, requiring special tools to move, and are not suitable for large dimensions, which are needed when therapeutics are serially produced.

Trelleborg Solution: Advanced composite materials are ideal for chromatography columns, since they are uniquely lightweight, inert and robust. They can be manufactured in unlimited dimensions to meet a full range of size requirements. The columns can be combined with other BioPharmaPro™ capabilities to provide customers with a complete, pre-packed system, into which only the chromatography media needs to be added.

Trelleborg is a world leader in engineered polymer solutions that protect essential applications in demanding environments. Its innovative solutions accelerate performance for customers in a sustainable way.

Trelleborg Medical Solutions partners with the world's leading medical device and biopharmaceutical companies, collaborating from concept to commercialization to bring to market impactful solutions that improve patient quality of life. It leverages decades of design and manufacturing experience, in-depth knowledge of polymer materials to deliver pioneering, engineered solutions for transformative health technologies.

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If you'd like to talk to Trelleborg Medical Solutions, find your local contact at: www.trelleborg.com/medical/contact-us

Version no. 9900287GBGT0226