

# Your Partner for Life Changing Technologies



# Your Partner for Innovative, Reliable Engineered Solutions

The trend to miniaturize wearable, digital and implantable medical devices offers new and life changing benefits to patients. It also brings about novel challenges to the design and manufacturing processes required for these advanced therapies. Add to this the increasingly strict regulations around medical devices, as well as a constant desire to accelerate time to market, and it is evident that the medical device industry requires innovative partners.

As a critical supplier to medical device manufacturers, this makes it more important than ever that we offer robust, flexible manufacturing capabilities built on proven processes to enable fast adaptation to an ever-changing medical landscape.

Global  
Sales &  
Technical  
Support

Regional  
R&D  
Centers

7  
Logistics  
Centers

ISO 13485  
Manufacturing  
Sites

## PARTNERS IN ENGINEERING

At Trelleborg Medical Solutions, we help medical device companies negotiate the development process from concept to commercialization. We form lasting partnerships with customers to design, develop, manufacture, and bring to market innovative engineered solutions for demanding medical device, biotech, and pharmaceutical applications.

Customers rely on Trelleborg to accelerate time to market through development of engineered processes, prototyping and validation, rapid scale-up, adherence to the strictest quality standards, and more. Once in market, our robust processes ensure a reliable, high-quality supply.

## OUR GLOBAL NETWORK



## DESIGNED TO BENEFIT OUR CUSTOMERS

The design and setup of our manufacturing network centers on flexibility. Each site specializes in multiple capabilities with versatile floor plans that enable rapid rearrangement. Our easily adaptable production areas, combined with the use of custom-built equipment and in-house tooling, results in an efficient and consistent manufacturing process.

- Proprietary materials and in-house R&D labs enable us to work concurrently with manufacturing, reducing time to market.
- Flexible floor designs allow rapid scale up to meet changing production requirements.
- Multiple manufacturing sites, specializing in different technologies, are designed to quickly adapt their production capabilities to support our customers' ever-changing needs.
- In-house tool rooms enable our team to develop, inspect, and quickly repair tools to ensure high-quality parts with high yields, while also ensuring components reliably meet each customer's specifications.
- Automation and quality checks assure quality and consistency in production runs, increase product yield, and reduce total cost of ownership.

# Manufacturing Excellence

State-of-the-art manufacturing solutions and decades of experience support our customers' ambitions.

## PARTNERS IN MANUFACTURING

Dedicated facilities ensure global development, production and supply of high-performance elastomer and engineered-plastic sealing solutions. Reduced supply chain complexity is a key asset of our comprehensive offering, while partnering with customers early in the design process enables us to tailor our flexible production capabilities to meet each customer's specific needs.

A collaborative approach enables our experts to explore possible processing methods and materials, ensuring products are designed for manufacture and scale up. Regardless of the project, our wealth of knowledge is at our customers' disposal.

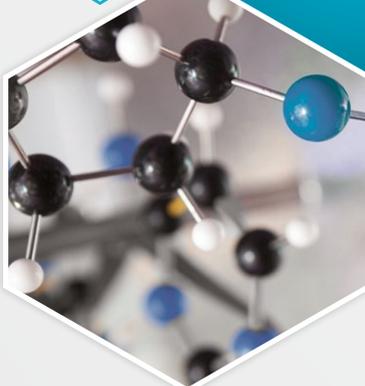


### DESIGN OF PRODUCT

- Development partnerships to meet customer specifications
- Design for Manufacturing
- Quality in mind

### MATERIAL

- Partnerships with the world's leading material developers
- Application and processing experts



### CLEANROOM AND ADVANCED PRODUCTION

- ISO 13485
- ISO 14644-1
- Class 7 (Class 10,000) and
- Class 8 (Class 100,000)
- Ultra lean and clean

# Manufacturing Excellence



### PROCESS

- ISO 13485
- Lean manufacturing
- Flashless and wasteless principles
- Robust APQP process



### TOOLING

- From prototype to complete multi-cavity production tools
- Innovation-driven
- In-house tool room



### QUALITY

- Robust quality management system
- In-process quality control
- Zero-Defect quality culture
- Expertise in validation



### TECHNICAL SKILLS

- Our biggest asset
- Tradition of apprenticeship, training and continuous improvement
- Outstanding skill levels



### AUTOMATION

- State-of-the-art equipment
- Customized, fit-for-purpose solutions for the highest efficiency and quality



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# Expertise at Your Service

As an extension of your team, our dedicated resources are focused specifically on serving global healthcare and medical markets, which enables Trelleborg to deliver value through a strong set of core capabilities.



Engineering

Manufacturing

Material  
Expertise

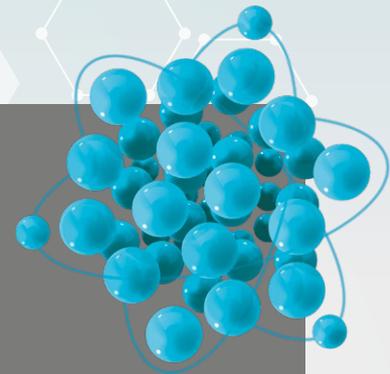
### POLYMER MATERIAL EXPERTISE

Trelleborg has decades of experience developing, testing and qualifying materials for use in medical devices. Knowledge of how materials can be utilized, such as silicone for drug-elution, is invaluable during the design process. An expert team is available to assist with selecting the ideal material based on its function and environment.

Whether you need assistance with leachables or extractables, cleaning or sterilization, durometer, opacity, or any other physical requirement, our team has the experience to guide your decision-making process. Beginning the design process with the correct material is essential to accelerate the time to market.

### EXTENSIVE EXPERIENCE MANUFACTURING USING:

- Silicone
- Thermoplastics
- Technical Plastics
- Liquid Silicone Rubber (LSR)
- High Consistency Rubber (HCR)
- Other Medical-Grade Elastomers

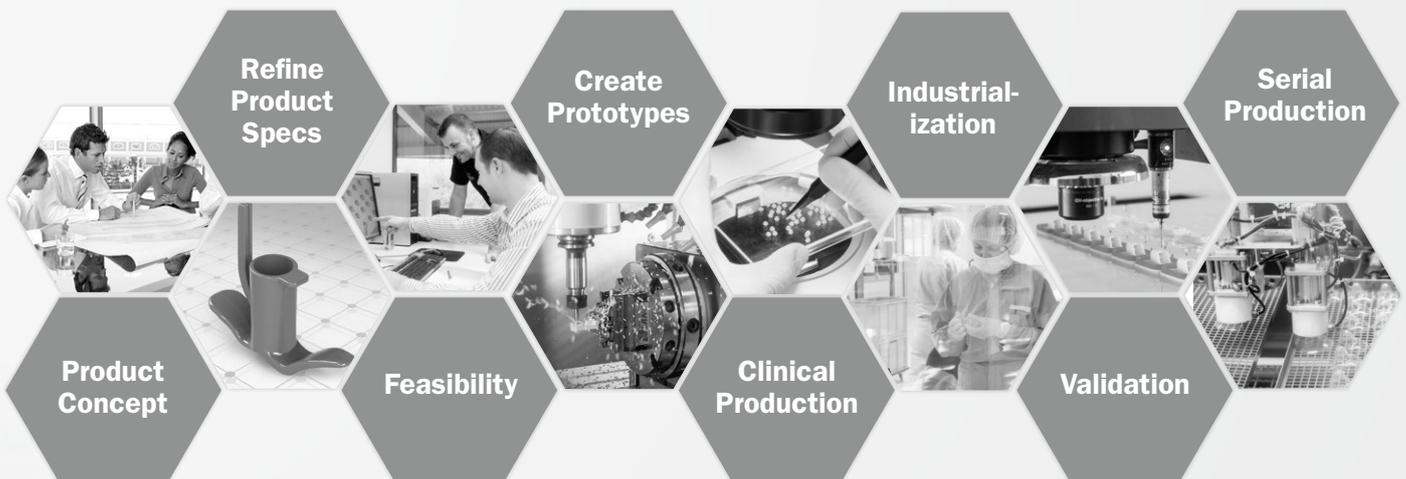


### ENGINEERING EXPERTISE

Involving Trelleborg early in the development process helps accelerate the timeline from prototype to scale-up. To speed the process, we combine customized design with Design for Manufacturing (DfM) to test designs and materials using the latest finite element analysis (FEA) techniques. Our comprehensive array of engineered solutions improves future production yields and simplifies our customers' supply

chains. Whether rapid tooling and prototyping, scaling up for production, or automation is required, we custom fit the process to our customers' needs. Working closely with customers enables Trelleborg to identify and, when required, engineer the ideal production method to support the success of the product.

### FROM CONCEPT TO SERIAL PRODUCTION WITH A FOCUS ON QUALITY AND TOTAL COST



### QUALITY & VALIDATION

Maintaining consistent quality is essential for the successful manufacturing of medical devices. Our established process of utilizing state of the art equipment and processes results in a consistent supply of high-quality products. All Trelleborg Medical Solutions facilities are ISO 13485 compliant, and products can be produced in ISO 7 and ISO 8 cleanrooms.

- Robust change control process and philosophy
- Lower cost & 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
- Automation for consistent results throughout every product run
- Machine Vision Inspection

# Core Manufacturing Capabilities

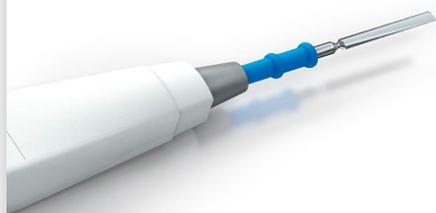
**Trelleborg's facilities utilize automation, in-house tooling, state-of-the-art equipment, and cleanroom production to deliver high-quality, cost-effective products and solutions.**



## SILICONE AND ELASTOMER MOLDING

Molding with Liquid Silicone Rubber (LSR) results in flashless, wasteless production and provides the highest consistency in dimensions, precision, and overall quality due to lean manufacturing processes. LSR also enables the highest volume production as a result of short cycle times due to the material's fast-curing nature. Elastomers like EPDM, FFKM, FKM or Butylrubber serve critical environments in terms of media, temperature and pressures to ensure long lifetimes of machines and equipment.

Trelleborg relies on in-house tooling and sophisticated process engineering to improve quality and ensure the consistent achievement of tight tolerances. Designing for manufacturing helps to avoid potential pitfalls when transitioning from prototype to production.



## SILICONE DIPPING AND COATING

With more than 30 years of silicone dipping experience for medical device applications, our experts understand and control the many variables that contribute to the quality and reproducibility of each part. Dip molding provides a cost-effective alternative to silicone molding and can be used for rapid prototyping of complex, thin-walled shapes.

Process validations include evaluation of mandrel surface finish, immersion and withdrawal angle and speed, dispersion viscosity and temperature, ambient manufacturing conditions, and vulcanization parameters.



## PLASTIC INJECTION MOLDING

Trelleborg's in-house tooling, engineering expertise, and ability to scale to production are at the core of our approach to plastic injection molding. Our specialized equipment is suited for manufacturing high-temperature, engineering-grade resins, including implantable polyether ether ketone (PEEK). We also offer soft touch overmolding, high-volume insert overmolding through automation, and value-added services, including laser scribing and pad printing. Trelleborg's plastic injection molding capabilities fit each of our customer's unique needs.



### SILICONE SHEETING

Our silicone 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 sheeting needs to be vulcanized, unvulcanized, reinforced, non-reinforced, pigmented, rolled or cut to purpose, our capabilities deliver what is required.



### SILICONE EXTRUSION

Our extrusion processes can be tailored 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.

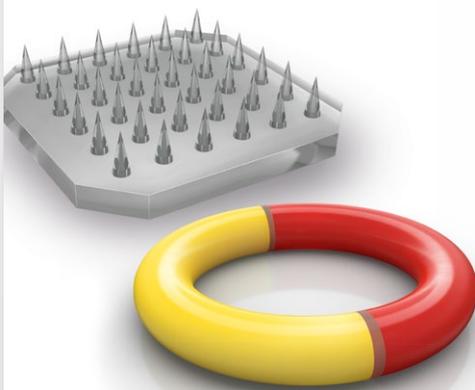
Our GeoTrans™ technology is used for custom applications with precision tolerances, enabling the cross section of silicone tubing to be changed during the extrusion process to eliminate molding and secondary bonding steps. This patented technology promotes hygienic design and eliminates significant costs associated with secondary operations and inspections. Our team precision manufactures the die and mandrel using in-house tool rooms, translating to high-quality and consistent supply for our customers.



### MULTICOMPONENT LSR

The use of multicomponent LSR technology provides designers with the latitude and flexibility to enhance their applications. Designers can integrate multiple components into one fully-bonded solution, increasing cleanliness and reducing risks associated with secondary assembly. Multicomponent technology can also lower costs by reducing the number of components in the supply chain.

We are at the forefront of tool, process, and automation technology for multi-component liquid injection molding. In a fully automated and closed loop system, either a combination of thermoplastic and LSR or two dissimilar grades of LSR are co-molded into a bonded component.



### DRUG-ELUTING AND COMBINATION PRODUCTS

A wealth of engineering and materials expertise enables us to perform complete product development and manufacturing of drug-eluting combination products using silicone and bioresorbable materials.

Active Pharmaceutical Ingredients (APIs) infused in silicone present solutions for wound care, reduction of swelling post-device implantation, and other innovative treatment options. The controlled release of an API, as opposed to bolus-type delivery, facilitates consistent API concentrations over an extended period while minimizing adverse side effects.

We deliver comprehensive support to innovators in both the pharmaceutical and medical device industries, spanning from design assistance, feasibility and prototyping to scale up.

# Developments Through Partnership

When customers involve Trelleborg early in the design process, our team is able to determine the ideal manufacturing method to ensure success from prototype to scale-up, ultimately leading to a reliable, high-quality supply.

## 1 LONG-TERM UROLOGICAL IMPLANT

### Requirements

To ensure unobstructed passage of fluid, especially while a patient is moving, tubing must not kink or fail. The solution needs to also prevent an interior filament from protruding through the silicone.

### Situation

The customer's initial supplier of kink-resistant tubing generated a 75% scrap rate due to visual and dimensional defects, including particulates, bubbles, and reinforcement pitch inconsistencies.

### Trelleborg Solution

Trelleborg engineers designed a proprietary manufacturing process from start to finish, using custom-built equipment and tooling to ensure a consistent, high-quality product that reliably achieves up to 99% yield from 100% inspection under 10x magnification.

## 2 LONG-TERM INTRAUTERINE IMPLANT

### Requirements

The device must remain in place and elute a small dose of an active API over an extended period with a high degree of consistency.

### Situation

A device manufacturer relied on Trelleborg to develop a prototype, complete engineering studies, and manufacture the product.

### Trelleborg Solution

Through a combination of materials expertise and in-house prototyping, Trelleborg identified the ideal silicone consistency to provide a continually controlled elution rate. After designing the prototype and scaling up to production, Trelleborg now manufactures multiple components and assembles the final device.

### 3 OCULAR IMPLANT

**Requirements**

The miniscule inner diameter of the tubing must reliably facilitate the flow of fluid. Tight tolerances are required during manufacturing, and the quality must be verified through microscopic levels of inspection.

**Situation**

Complexity in the customer's supply chain resulted in procurement inefficiencies and inconsistent product quality.

**Trelleborg Solution**

Trelleborg partnered with the customer to develop the manufacturing process. By owning and managing the supply chain, including manufacturing, sterilization, packing and labeling, Trelleborg delivered a turnkey solution for the customer to go to market.

### 4 LONG-TERM ORTHOPEDIC IMPLANT

**Requirements**

Production of an extremely small, less than 0.38 millimeters (0.015 inches), co-extruded silicone product with a unique additive that elutes after implantation.

**Situation**

Unsure of how to manage the additive preparation process, and in need of a partner that could manufacturer a very small co-extruded product with tight tolerances, the customer aligned with Trelleborg.

**Trelleborg Solution**

Trelleborg invited the customer onsite to its in-house R&D lab, bringing about the development of a proprietary process for introducing the additive to the silicone. Trelleborg also developed a co-extrusion process and inspection method to measure both silicone components, ultimately yielding a unique and innovative product.

### 5 HEMOSTASIS SEAL

**Requirements**

A bonded joint must maintain a watertight seal under an applied load. A consistent manufacturing process to ensure the quality of the critical-to-performance shutoffs is required.

**Situation**

The customer was experiencing issues with the quality of final products due to the inconsistencies in a supplier's rigid polymer product, resulting in flashing and negatively impacted yields.

**Trelleborg Solution**

Trelleborg took over manufacturing of the thermoplastic to ensure consistent quality through the automated assembly of components, while also reducing the complexities of the customer's supply chain. An engineered solution reduces scrap rate and costs, while improving functional performance and ease of doing business.

### 6 LIQUID SILICONE RUBBER SHEETING

**Requirements**

An LSR microfilm 0.051 to 2 millimeters (.002 to 0.08 inches) thick is needed that can consistently hold tight tolerances throughout the width and length of the roll.

**Situation**

Producing very thin layers of silicone sheeting had been accomplished via casting or dip coating; both of which are costly and time consuming. A more cost-effective, time-efficient process was needed to produce thin silicone sheeting.

**Trelleborg Solution**

Modifications to in-house equipment enabled Trelleborg to produce and cure the LSR sheeting precisely to the specified thickness. The LSR microfilm is rolled onto spools at up to 50.8 centimeters (20 inches) wide and can be cut or punched to an infinite range of custom sizes and shapes.

### 7 COSMETIC SILICONE IMPLANT

**Requirements**

Using silicone dipping, created a niche implant that performs similarly to longstanding products on the market, while offering improved function and safety.

**Situation**

The customer was experiencing quality issues due to bond failures.

**Trelleborg Solution**

Trelleborg assumed responsibility for product assembly, using remaining inventory from the previous supplier until in-house equipment and manufacturing processes could be set up and validated. This provided the customer with product while the customer and Trelleborg collaborated to make product improvements. To ensure consistent visual and thickness criteria, Trelleborg utilized automated inspection equipment.

### 8 BLOOD GLUCOSE MONITORING SYSTEM

**Requirements**

A clear, molded tubing with a silicone body needed to be combined with conductive silicone traces.

**Situation**

Trelleborg's rapid tooling and automation capabilities gave the customer confidence in Trelleborg's ability to solve the design issues and scale up.

**Trelleborg Solution**

A viable tubing design was established through a collaborative prototyping process. Trelleborg quickly developed bridge tooling to assist the customer in manufacturing for clinical trials. After successful trials, flexible manufacturing cells and automation supported rapid scale up to the production of parts in the tens-of-millions.

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](http://www.trelleborg.com/medical/contact-us)