

Tubing, Hose and Sheet

FOR HEALTHCARE & MEDICAL APPLICATIONS





Engineered Solutions for Healthcare & Medical

Trelleborg Healthcare & Medical develops, manufactures and supplies innovative engineered solutions for demanding medical, biotech and pharmaceutical applications in thermoplastics, silicone and other elastomers. We develop and manufacture components and complete medical devices as a contract manufacturer for leading OEMs and end users around the world.

Our engineers partner with customers to design, prototype, produce, test and assemble medical components and devices using state-of-the-art tools. As an extension of our customers' development teams, our engineers strive to meet the most demanding needs of Healthcare & Medical customers with innovative solutions. We measure our success by how fast we can help our customers introduce new technologies to market and by ensuring a reliable, consistent supply of the highest quality product, once our customers are in the market.

Trelleborg Healthcare & Medical has 6 global, dedicated facilities to support the business. Additionally, Trelleborg has an international network of over 70 facilities worldwide including over 20 manufacturing sites, strategically-positioned research and development centers, material and development laboratories and locations specializing in design and applications. Our manufacturing sites, in collaboration with our logistics centers, fulfill challenging service requirements, supplying standard parts in volume or a single custom-manufactured component to customers worldwide.

Facilities are certified to ISO 13485. Trelleborg Healthcare & Medical is backed by the experience and resources of Trelleborg Group, one of the world's foremost experts in polymer technology.

ISO 9001:2008

ISO/TS 16949:2009

ISO 13485:2016

The information in this brochure is intended to be for general reference purposes only and is not intended to be a specific recommendation for any individual application. The application limits for pressure, temperature, speed and media given are maximum values determined in laboratory conditions. In application, due to the interaction of operating parameters, maximum values may not be achieved. It is vital therefore, that customers satisfy themselves as to the suitability of product and material for each of their individual applications. Any reliance on information is therefore at the user's own risk. In no event will Trelleborg Sealing Solutions be liable for any loss, damage, claim or expense directly or indirectly arising or resulting from the use of any information provided in this brochure. While every effort is made to ensure the accuracy of information contained herewith, Trelleborg Sealing Solutions cannot warrant the accuracy or completeness of information.

To obtain the best recommendation for your specific application, please contact your local Trelleborg Healthcare & Medical experts. This edition supersedes all previous brochures. This brochure or any part of it may not be reproduced without permission.

* All trademarks are the property of Trelleborg Group. The turquoise color is a registered trademark of Trelleborg Group. © 2017, Trelleborg Group. All rights reserved.

Contents

04 Introduction

06 The Complete Toolbox

08 Cleanroom Production

10 Sterilization

14 Material & Product Testing

16 Silicone – Elastomer with Unique Capabilities

18 Product Range

22 Drug-Eluting Tubing & Sheeting

24 Tight Tolerances

26 Premium Grade Implantable Silicone Tubing

27 Platinum-Cured Single Lumen Tubing

28 Braided Silicone Hose

30 Custom Silicone Extrusion

32 Wrapped Hose

33 Silicone Sheeting Solutions

34 Sheeting & Film Products

Pioneering Innovations

MAKING AN IMPACT

At Trelleborg Healthcare & Medical, we help pharmaceutical and medical device companies improve patient quality of life. We do this by forming lasting partnerships with customers who seek our expertise to accelerate innovation and ensure reliable, high-quality product supply.

PARTNERING EVERY STEP OF THE WAY

Because medical devices perform critical functions, we value strong partnerships with our customers to develop innovative solutions and ensure the best possible outcome. Customers can approach us with their ideas for innovative medical components and devices and our Healthcare & Medical experts partner with them at every step of the way to turn these ideas into reality.

Trelleborg engineers and R&D teams have decades of experience in specifying solutions and tailoring them specifically to meet your application needs. Our fully integrated solutions, from first concept through to serial production, device assembly and beyond, cover a complete range of services tailored to your requirements.

ACCELERATING YOUR BUSINESS

Bringing new medical devices to market faster means we can make an impact on more patients' lives. At Trelleborg Healthcare & Medical, our engineers collaborate closely with customers to move as fast as possible through the design, testing and validation, and commercialization phases of product development so that our customers' patients can benefit. And once our customers' solutions are on the market, we strive to provide consistent, reliable supply to the quality standards upon which our customers and we agreed.

Spanning the globe, our Healthcare & Medical experts act as an extension of our customers' R&D teams to deliver the knowledge and capabilities needed.



Innovative Online Tools

Read the Book. See the Movie.

Now that you have the brochure, why not check out the film on our Healthcare & Medical capabilities! www.tss.trelleborg.com/en/healthcare/tools-and-media/film



Apps at the Slide of a Finger

Check out our latest engineering tools for smartphones:

- Healthcare Materials
- Tubing & Hose Selector



www.tss.trelleborg.com/en/healthcare/tools-and-media/mobile-apps

Online Services and Tools at the Click of a Mouse

Trelleborg Healthcare & Medical offers a range of cutting-edge online services and tools on our website.

www.tss.trelleborg.com/en/healthcare/tools-and-media

- Full range of catalogs and brochures
- Whitepapers on drug-device combination products
- Tools to support Healthcare & Medical design engineers

Our network of facilities offers:

- Product and material development support, including testing and qualification
- Extensive manufacturing and processing capabilities, such as cleanroom facilities and quality control systems
- Special packaging and sterilization services, medical device assembly and advanced delivery options to ensure the product is where you want it and ready to use

This unique set of service capabilities allows us to act as a business accelerator and help you bring an optimum product to market faster.

INNOVATIVE ENGINEERING

Innovative medical devices require thinking outside the box. At Trelleborg Healthcare & Medical, our vast engineering experience enables us to reliably manufacture complex designs to tight tolerances, optimize designs for ease of manufacturing, automate manufacturing processes and develop novel solutions to your unique challenges.

MANUFACTURING & QUALITY EXCELLENCE

At Trelleborg Healthcare & Medical, we bring leading edge technology and in-depth understanding of the challenges our customer must overcome to reliably develop and manufacture medical components and devices.

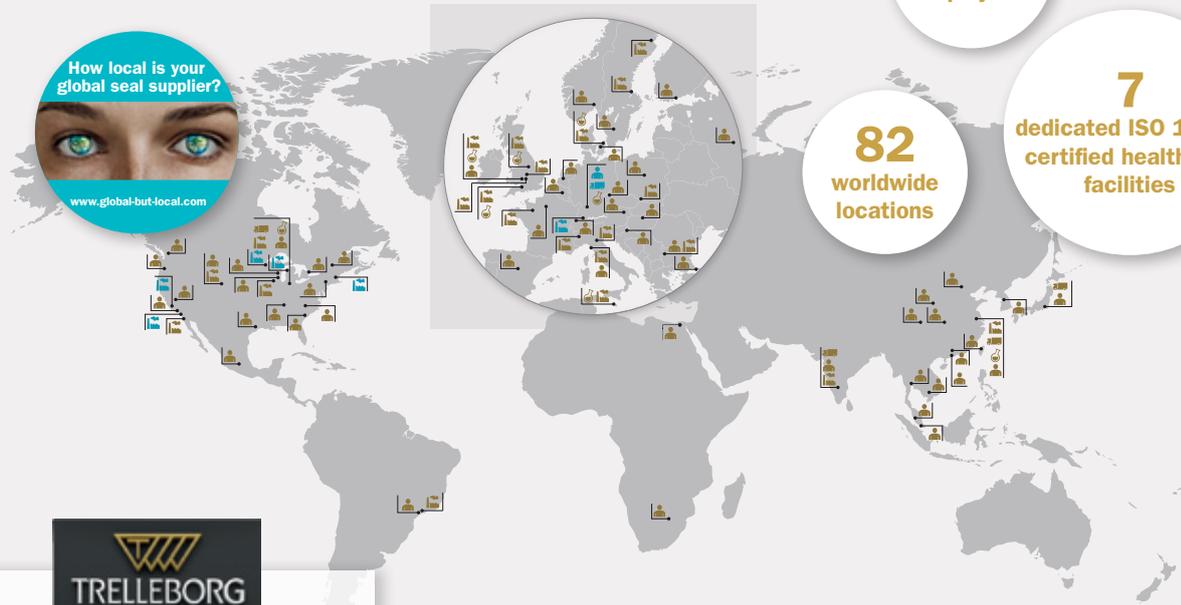
- Full range of testing capabilities to ensure both the material and the component meet application and manufacturing requirements
- State-of-the-art manufacturing capabilities to produce innovative and reliable precision components
- Complete suite of post-fabrication services to deliver products according to customer-specific requirements

MATERIAL EXPERTISE

When designing new medical devices, material selection is crucial. Materials must meet functionality requirements, withstand cleaning and sterilization regimes and comply with standards and regulations.

Trelleborg silicone and medical polymer experts work directly with customers to determine the best material compound for their application. We find innovative solutions to customer challenges through our understanding of the interactions of materials, the manufacturing environment and the customer's application.

OUR GLOBAL RESOURCES



	9	Research & Development Centers
	54	Marketing Companies
	5	Logistics Centers
	28	Manufacturing Sites
		including ISO 13485 certified sites

The Complete Toolbox

Providing the right solution for an application can be challenging. At Trelleborg Healthcare & Medical we employ a complete toolbox of skills and expertise to make sure that the best result is achieved every time.



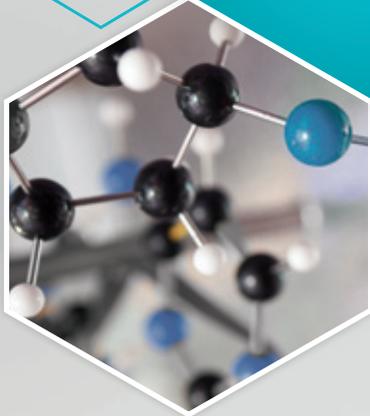
DESIGN OF PRODUCT

- To customer specification development partnership
- Robustness in manufacturability
- Quality in mind



MATERIAL

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



CLEANROOM OR STANDARD PRODUCTION

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



Quality by Design



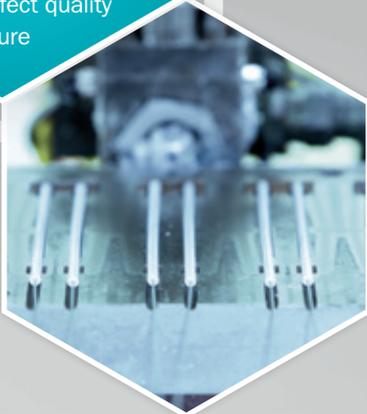
TOOLING

- Precision manufacture of die and mandrel
- From prototype to complete multi-cavity production tools
- Innovation-driven



PROCESS

- ISO 13485
- Lean
- Flashless and wasteless principles
- Robust APQP process
- In-process quality control
 - Zero-Defect quality culture



EXTRUSION

- Long standing experience in extrusion of silicone hoses & tubes
- Patented special processes such as GeoTrans™



TECHNICAL SKILLS

- Our biggest asset
- Tradition of apprenticeship, training and continuous improvement
- Outstanding skill levels based on extensive technical experience



AUTOMATION

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





KEY BENEFITS

- Produced in a Class 8 (Class 100,000) environment
- Double-bagged in a Class 7 (Class 10,000) environment
- Capable of handling lots from several thousand up to millions of pieces/ meter of tubings
- Site certifications to ISO 9001, ISO 14001 and ISO 13485:2016

Cleanroom Production

Components for the healthcare, medical and pharmaceutical industries require the highest levels of cleanliness at all steps of production to meet stringent hygienic standards. The need for germ- and contaminant-free components and environments is ever increasing, and as parts become smaller, they are even more sensitive to airborne particles. When superclean products are a requirement for your application, Trelleborg Healthcare & Medical offers cleanroom services to ensure this.

To serve customers globally Trelleborg Healthcare & Medical has installed high-tech cleanrooms conforming with ISO 14644-1 in the Americas and Europe. These work to a set of stringent internal technical and operating standards in order to guarantee the utmost level of quality, cleanliness, hygiene and process control. If cleanroom manufacturing is not needed, standard production is available.

SPECIAL REQUIREMENTS

In addition to cleanroom operations, Trelleborg Healthcare & Medical offers a wide range of special finishing operations and services including:

- Special washes, such as acetone washes
- Product coatings and surface modification
- Product sterilization
- Special customized packaging
- Reduction or elimination of secondary operations, such as:
 - Assembly
 - Cutting-to-length
 - Overmolding

The majority of our tubing is manufactured in a controlled environment in Class 8 (Class 100,000) conditions. As a standard, we monitor ambient temperature, humidity and particulate counts.



Sterilization

WITHSTANDING SEVERE CLEANING REGIMES

Healthcare & Medical devices and products are required to stand up to demanding environments. Tubing, hoses and sheeting must not only be compatible with system media, but also with stringent cleaning regimes.

Modern cleaning procedures support production efficiency, prevent toxic and microbial contamination of products and minimize contamination during the process. However, aggressive media used in automated **CIP (Cleaning in Place)**, **SIP (Sterilization in Place)** and disinfection procedures can shorten tubing and hose life.

Complex formulations of chemicals can rapidly cause severe damage to plastics and elastomers, especially in applications with high load and pressure. With high temperature and steam sterilization, deterioration can be dramatically accelerated.

As hygiene requirements increase, more cleaning agents and disinfectants are being used. To extend equipment life, it is vital to work with a supplier that understands materials and processes critical to maximizing efficiency and reducing total cost of ownership.

Trelleborg Healthcare & Medical supports you every step of the way in specifying the right specialized elastomer grades to ensure products withstand emerging CIP and SIP procedures.



SILICONE: THE OPTIMUM CHOICE FOR STERILIZATION PROCESSES

When designing new medical devices, selecting the correct materials and processing techniques are fundamental considerations. Not only must the materials meet functionality requirements and carry a number of certificates and approvals, but they must also cope with destructive cleaning media.

With multidrug-resistant microbes causing potential infections, the sterility of medical devices and instruments is a vital necessity. A single-use device only needs to withstand one cycle of sterilization, while multi-use devices have to cope with the repeated impact of these highly aggressive treatments. There are a number of different sterilization methods used in practice, ranging from radiation to steam and EtO, but most of them involve high energy to ensure aggressive pathogens are killed.

With elastomers, high levels of energy result in changes at the molecular level. Unwanted crosslinking or chain scissoring can lead to deterioration over time and a loss of important physical properties, such as flexibility and tensile strength. Trelleborg Healthcare & Medical has developed specialized compounds with proven compatibility and resistance to sterilization processes. Our product and material experts aid in selecting the ideal compound, thereby preventing failures which could result in risks to a patient's wellbeing.

MATERIAL SELECTION

Take an elastomer product with small holes, inherent to the function of the component. Due to high energy sterilization regimes involving radiation, the holes could 'heal' over, resulting in a total loss of functionality. When deciding on a material for this kind of application, it is important to work with an experienced supplier who understands the physical effects of sterilization on polymers. In this instance, due to its biocompatibility and resistance to aging, temperature and many chemicals, special silicone grades would be used, as it frequently is for the modern medical device market.

Steam Sterilization at +134 °C for 5 minutes

A steam autoclave is commonly used to sterilize reusable medical devices. This will most likely have little effect on the physical properties of silicone because of its moisture and heat resistance.

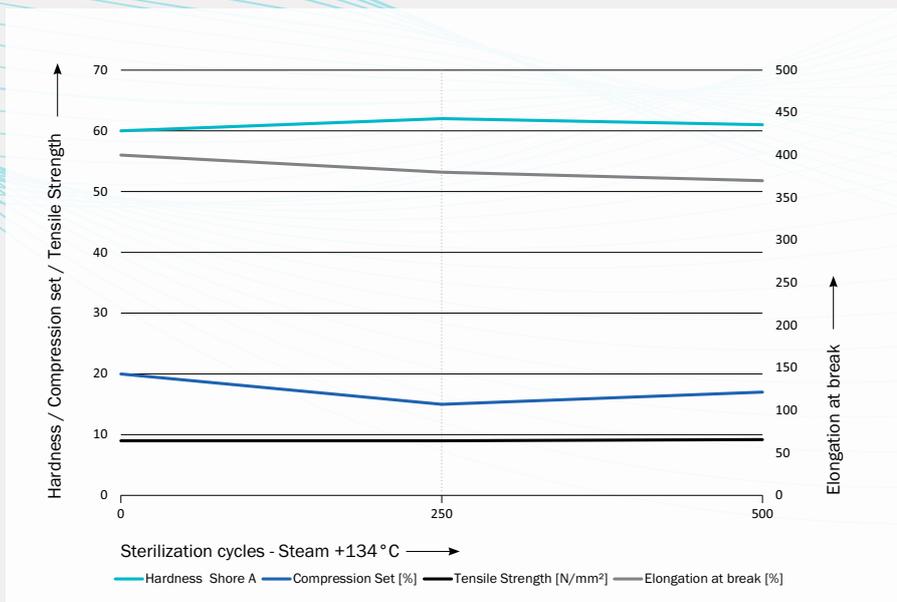


Figure 1: Physical behavior of silicone during steam sterilization. The physical properties of silicone are not significantly impaired by steam sterilization.

Ethylene Oxide Sterilization (EtO)

EtO penetrates microbial cells, destroying nuclear cell components. Silicones generally have a high permeability to gases compared to most elastomeric materials, enabling the EtO molecules to diffuse through the polymer network, sterilizing throughout the entire polymer matrix.

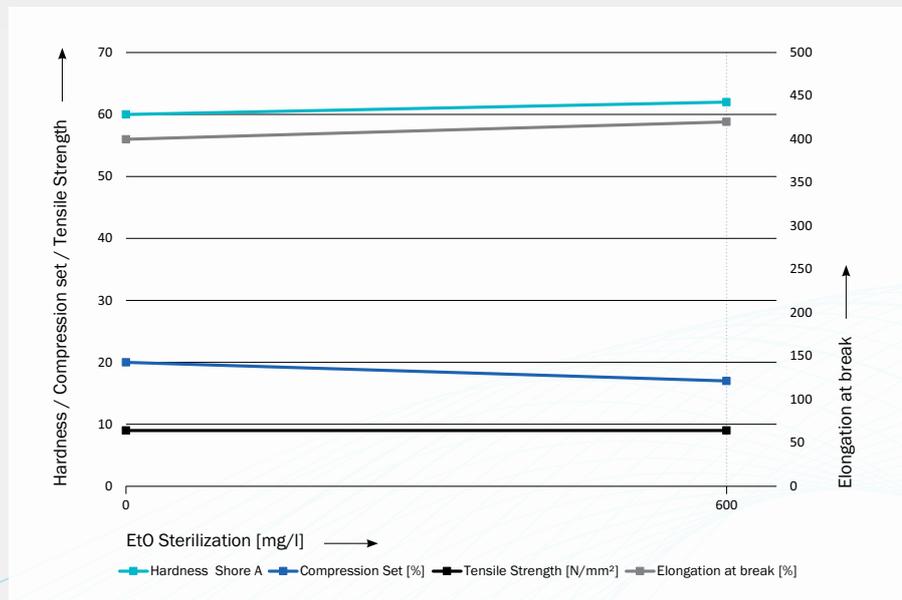


Figure 2: Physical behavior of silicone during EtO sterilization, which is not significantly impaired.

Gamma Sterilization

Gamma radiation and e-beam processing are alternative sterilization methods for heat sensitive devices and devices that are not permeable to gasses used in chemical sterilization. A major concern for many device manufacturers is that radiation may damage or degrade polymeric materials.

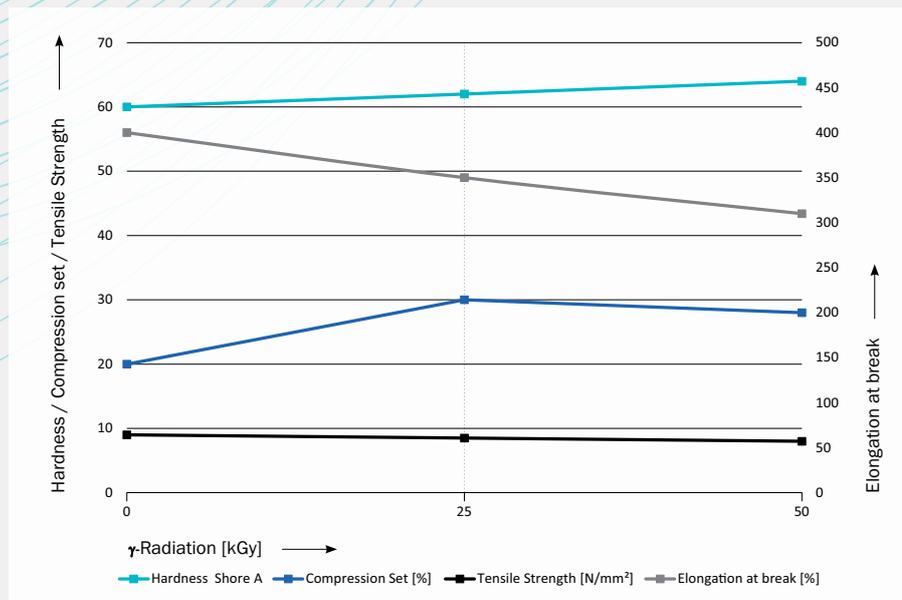


Figure 3: Physical behavior of silicone during Gamma sterilization. Changes at physical properties can occur due to Gamma Sterilization.

Material & Product Testing

Products designed for medical purposes must be safe for patients, especially when these products come into contact with a patient's body, and even more so when products are implanted for long-term use.

With the new EU Medical Device Regulation and revisions to the ISO 10993 series of standards, stringent regulatory requirements have been put into place to ensure the safety and performance of medical devices.

To support customers with the development of new medical devices, Trelleborg Healthcare & Medical experts can perform a range of tests to determine the suitability of materials and products for patient use and confirm regulatory compliance.

BIOCOMPATIBILITY TESTS

To protect patients from potential biological risks from the use of medical devices, biocompatibility of those devices must be assured. This can be done by evaluating the risk of the product and performing essential biocompatibility tests.

To support our customers in this process, Trelleborg Healthcare & Medical offers various materials which have been tested for biocompatibility according to the standards set by the United States Pharmacopoeia National Formulary (USP), as well as ISO 10993. Selected materials can also be used for long-term implants.

EXTRACTABLES & LEACHABLES

Since risks are high in the Healthcare & Medical industry, strict regulations and monitoring requirements are applied to quality, hygiene and biocompatibility. One particular area, which can affect 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 individuals and have possible long-term effects on the human body.

To ensure that our products can be used for high risk applications, such as drug-delivery devices, combination products or long-term implants, Trelleborg Healthcare & Medical experts conduct extensive testing.

Tests have been performed to determine whether substances can be extracted under different conditions. Results show that Trelleborg tubing and hose meet the highest standards and demonstrate outstanding purity levels.

Measuring method	Substance	Amount [$\mu\text{g}/\text{cm}^2$]	Amount [$\mu\text{g}/\text{g}$]	pH-value
HS-GC-MS	Isopropanol	1,2	2,85	3,0 (KCl)
HS-GC-MS	Isopropanol	1,93	4,62	9,0 (Hydrogen phosphate buffer)
Measuring method	Substance	LOQ [ng/g]	Amount [ng/g]	pH-value
ICP-MS	Ni	0,521	0,911	3,0 (KCl)
ICP-MS	Pt	0,154	0,226	3,0 (KCl)

BIOBURDEN

The population of viable microorganisms is a crucial parameter for medical products and device components like sheeting or tubes. Several different factors can contribute to the bioburden, including raw materials, manufacturing environment and processes, manufacturing and assembly aids, and cleaning and packaging of the finished products.

To monitor the bioburden and ensure product quality, testing is conducted: microorganisms are extracted from the sample and cultivated to determine the degree of contamination. This is done according to EN ISO 11737-1:2006. Microorganisms are measured in CFU, colony forming units.

Trelleborg Healthcare & Medical performs bioburden tests to meet customer needs in accordance with standards and regulations.

ENDOTOXINS & LAL TESTING

Residues of bacteria killed in the sterilization process are known to cause problems for patients. These bacterial endotoxins, components from gram-negative bacterial walls, can function as pyrogens and cause fever. As they are neither destroyed by high temperature nor by other sterilization methods it is important to monitor them.

To check for endotoxins on medical device products or medical device components the Limulus Amoebocyte Lysate (LAL) test is performed. This test is often conducted for products designed for implantation or as external communicating devices. The LAL test determines the presence of endotoxin generated from gram negative bacteria, for example E. coli.

The test is based on EN ISO 10993, USP30- NF25 <85> and E.P 6th edition <2.6.14>.

At customer request, Trelleborg Healthcare & Medical can perform LAL testing.



Since medical devices perform a wide range of functions, purity and quality requirements vary from case to case. Get in touch with our medical experts to discuss materials and testing for your specific application under www.tss.trelleborg.com/en/healthcare/contact-us



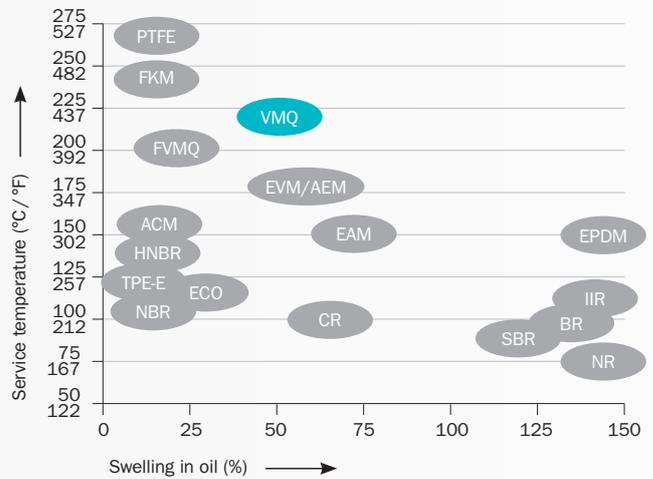
Silicone – Elastomer with Unique Capabilities

BENEFITS OF SILICONE

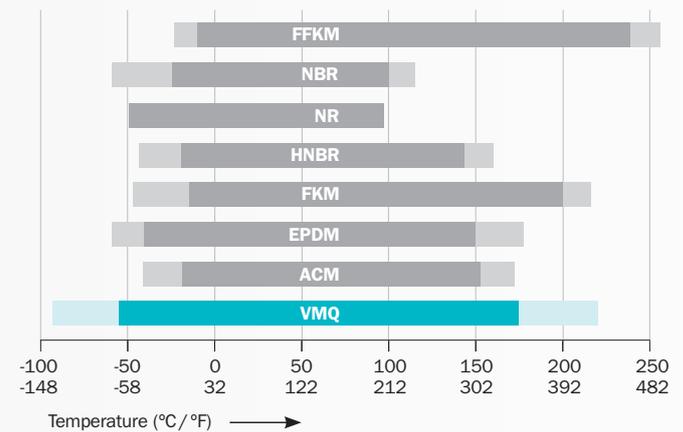
Silicone is an extremely versatile material that lends itself to a broad range of application conditions. Silicone offers advantages in processing that make it an optimal choice for technical components.

- Available in hardnesses
 - LSR Silicone: 5-90 Shore A
 - HCR Silicone: 20-80 Shore A
- 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
- Outstanding electrical insulation and available in UL94 listed types
- Biologically inert and therefore first choice for long-term implants
- Master files available for long-term implantable silicones (applications greater than 29 days)
- Special grades that meet material requirements of MDR
- Specific to biomedical and pharmaceutical applications:
 - Biocompatibility to ISO 10993 and USP Class VI
 - Compliant with European Pharmacopoeia 3.2.9
 - Compliant with FDA
 - Withstands common sterilization methods such as dry heat, steam, gamma radiation, EtO

Media resistance of silicone (VMQ) in special test oil



Working temperature range of silicone (VMQ) against other elastomer types



BENEFITS OF THERMOPLASTIC ELASTOMERS (TPE)

TPEs are copolymers or mixtures of rubber and plastic, exhibiting properties of both materials. The material consists of a hard and a soft segment. The hard segments are responsible for the hardness and stiffness of the material. The soft segments give the materials their flexibility and elasticity. They require virtually no compounding, reinforcing agents, stabilizers or curing agents, providing consistent batch-to-batch properties, leading to consistent performance in application.

PROPERTIES:

- Temperature range -50°C / -60°F to +135°C / +275°F
- Hardness 60 Shore A
Translucent, flexible and resists kinking, making it ideal for pumping and fluid transfer
- Weldable and heat sealable
- Recyclable
- Low permeability silicone
- Can be sterilized with gamma radiation or in an autoclave

The absence of any natural ingredients in the formulation leads to a very pure material, free from any allergens or other natural impurities.

Compliances

USP Class VI, FDA

Elastomer Physical Properties

	ASTM Method	Typical Values
Hardness Durometer A	D-22406	60
Tensile strength psi	D-412	1275
Elongation %	D-412675	625
Tear Resistance Die B ppi	D-624	1.15
Compression set % (22 hours at +350°F)	D-395	40



Product Range

ADVANCED ENGINEERED TUBING

Trelleborg Healthcare & Medical manufactures tubing and hose for critical applications. Our range of standard and customized tubing solutions is designed to meet all your application needs.

SILICONE TUBING AND HOSE

High purity, performance and biocompatibility

Key Benefits

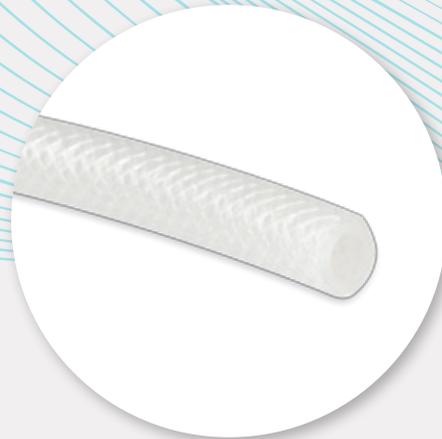
- Platinum-cured for highest level of purity
- Extended post-cure for lowest levels of extractables and leachables
- Biocompatible, inert and non-reactive with other elements per systemic testing
- Odorless, tasteless, non-toxic: for use in medical, food, drug, personal care, and deionized water applications
- Sterilizable by radiation, EtO, steam
- Resists temperature extremes and retains flexibility: -60 °C to +200 °C / -76 °F to 392 °F
- Color striping for custom process control identification

BRAID-REINFORCED HOSE

Suitable for demanding applications, withstands cleaning, sterilization and high pressure

Key Benefits

- High pressure ratings
- Sterilizable and autoclavable
- Platinum-cured
- Resists extreme temperatures and retains flexibility: -60 °C to +200 °C / -76 °F to 392 °F
- Pigmented tubing available
- Available in bulk assemblies



To discuss a specific application, please contact your local Trelleborg Healthcare & Medical marketing company or reach out to us at www.tss.trelleborg.com/en/healthcare/contact-us

SPECIAL TUBING STYLES

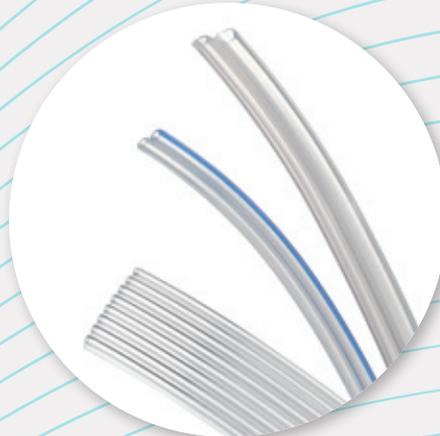
Tubing and hose can be produced in a variety of styles to adapt to specific applications or to add benefits in addition to those of the material chosen.

MULTI-LUMEN TUBING

Multiple channels for separating fluids or wires in one tube

Key Benefits

- Numerous lumens or channels with differing diameters
- Over-molded onto connector to separate lumen into individual tubes
- Allows multiple, discrete paths within a single extrusion
- Precision assemblies facilitated by compact spacing of lumen
- Available in translucent for visual monitoring, and colored for fast identification

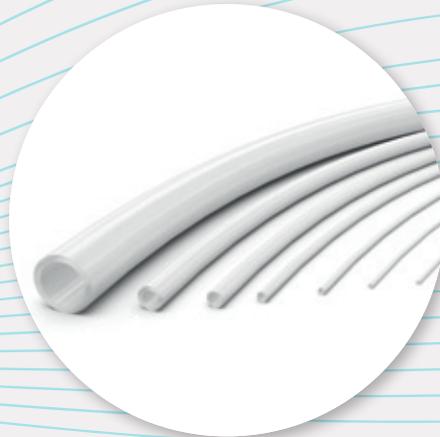


THIN WALL TUBING

Lower space requirements while retaining benefits

Key Benefits

- Less invasive for devices that will be inserted into human body, such as catheters and endoscopes
- Allows reduction in size of medical devices



CORRUGATED TUBING

Permitting bending while preventing pinching

Key Benefits

- Ideal for respiratory and anesthesia applications
- Corrugated outer diameter (OD) with smooth inner diameter (ID), allowing greater bending than regular tubing without pinching



Product Range

CUSTOM PERISTALTIC PUMP TUBING

High performance silicone pump solutions

Key Benefits

- Designed to meet specific application needs
- Consistent long-term flow rates
- Offered in flexible and chemically resistant silicone tubing
- Helps pump achieve consistent flow rates while reducing the effects of hysteresis and spallation
- Stops can be added using bonding or overmolding for increased hygiene and performance



CO-EXTRUDED TUBING

Multiple materials within the same tube

Key Benefits

- Simultaneously extruded, providing similar integrity to standard tubing
- Accounts for differing material properties and media interactions
- Combinations such as silicone inner diameter (ID) for compatibility with drugs, while having different exterior materials



To discuss a specific application, please contact your local Trelleborg Healthcare & Medical marketing company or reach out to us at

www.tss.trelleborg.com/en/healthcare/contact-us



HOSE FITTINGS

Reducing assembly costs and improving application performance

Key Benefits

- Maximum 15Ra mechanical finish
- Assembled Type 316 stainless steel sanitary fitting (Table 1)
- Leakage and pressure testing of all tubes with assembled fittings
- Exceeds Class VI standards for internal smoothness and in compliance with 3A
- Fully seals transition from hose to fitting
- Interlock between crimp collar and insert fitting eliminates any possibility of fitting blow-off
- Unique barb configuration offers end-to-end fully sealed crimps
- Alternative: Silicone molded tri-clamp, metal free with hygienic design (Table 2)



Table 1: Sanitary Fittings

ø ID	SF100HP			SF200HP		
	S0	SA	S1	S0	SA	S1
0.0625 in (1.588 mm)	–	–	•	–	–	•
0.1250 in (3.175 mm)	–	–	•	–	–	•
0.1870 in (4.750 mm)	•	•	•	•	•	•
Sizes up to 1.2500 in (31.75 mm)	•	•	•	•	•	•

S0 Sanitary Tri-Clamp
SA Sanitary Step-up
S1 Mini Sanitary

Table 2: Molded Silicone Tri-Clamps

ø Hose ID	Mini Tri-Clamp	Regular Tri-Clamp	2" Tri-Clamp
0.125 in (3.175 mm)	•		
0.187 in (4.750 mm)	•		
0.250 in (6.350 mm)	•		
0.312 in (7.925 mm)	•		
0.375 in (9.525 mm)	•	•	
0.500 in (12.70 mm)		•	
0.750 in (19.05 mm)		•	
1.000 in (25.4 mm)		•	
1.250 in (31.75 mm)			•

Drug-Eluting Tubing & Sheeting

ANTI-MICROBIAL TUBING

Reducing hospital acquired infections and transmission of germs.

Key Benefits

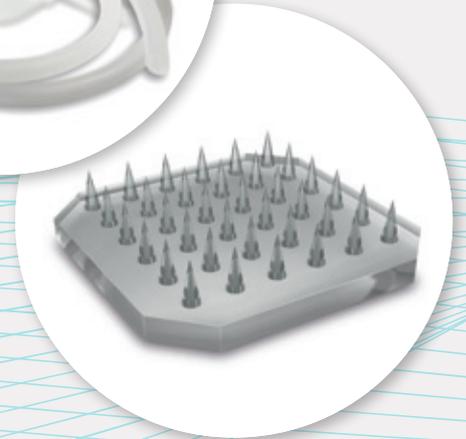
- Tubes with anti-microbial properties
- Elimination/Reduction of microbial growth and spread of germs
- No degradation of the silicone properties
- No additional processing steps necessary (e.g. coating)
- Design flexibility
- Available for standard and custom parts

DRUG-ELUTING SHEETING

Ideal for wound and burn treatment.

Key Benefits

- Breathable wound dressing
- Minimizes scarring, reduces risk of infection and accelerates healing
- Combined with antibiotics or decongestants



To discuss a specific application, please contact your local Trelleborg Healthcare & Medical marketing company or reach out to us at www.tss.trelleborg.com/en/healthcare/contact-us

APPLYING TO SILICONE

Silicone is often used for catheters, respirators or implants due to biocompatibility and biostability benefits. However, silicone is not immune to bacterial colonization. One option to prevent the tube from transmitting bacteria is to impregnate the vulcanized silicone with Active Pharmaceutical Ingredients (API). The silicone is immersed in drug solutions, which are absorbed into the material. Our immersion impregnation method has been thoroughly tested by our silicone and drug-device experts and offers advantages over conventional methods.

Key Benefits

- APIs do not interfere with the cure chemistry of the silicone
- The API is uniformly impregnated on the surface of the inner lumen
- No thermal degradation of the API due to immersion at room temperature
- Regular and precise drug elution at treatment area
- Lower dosage required therefore minimized side effects
- Improved patient compliance as many conventional medications are not used as prescribed
- Diverse processing possibilities in low and high volume
- Simplified treatments, fewer visits to the practitioner
- Numerous medications can be impregnated



Punctum plugs and infusion sleeve



Contraceptive ring



Want to learn more? Read our whitepapers for in-depth information:

- **Supporting the Advancement of Drug-Eluting Devices takes an in-depth look at methods to add APIs to silicone components.**
- **Fighting Hospital Acquired Infection discusses techniques for reducing bacterial colonization in silicone catheter tubing**

Download whitepapers now!
www.tss.trelleborg.com/en/healthcare/tools-and-media/technical-library



APPLICATIONS:

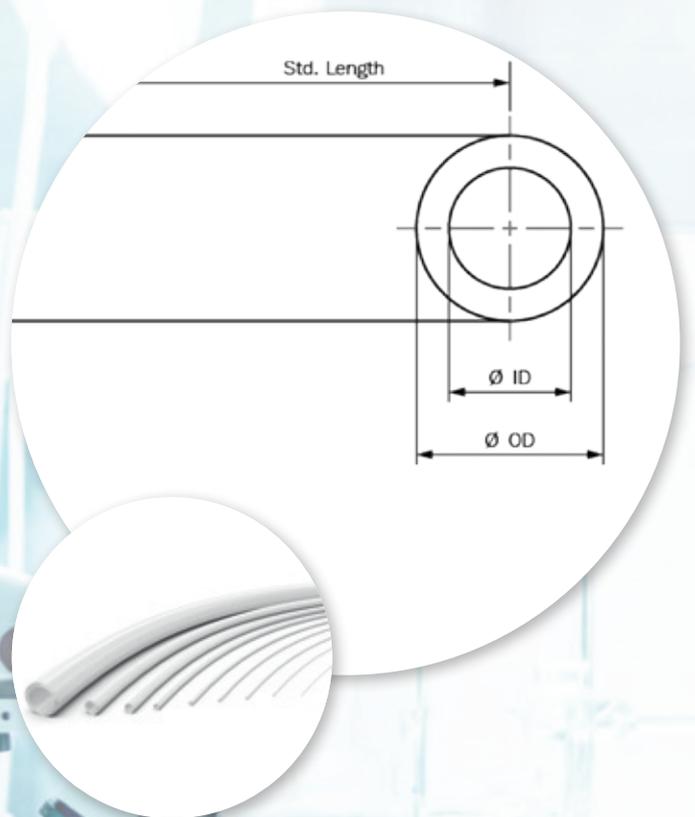
The immersion-impregnation technique to add APIs to silicone components can be effectively used not just on silicone tubing and sheeting, but also on molded components, which opens up drug-eluting devices to a wider range of applications.

Tight Tolerances

Many medical applications, e.g. for use in cardiology, neurological and other (long-term) implants, require tubing and hose with tight tolerances to guarantee the highest level of reliability and quality. Due to the critical nature of some medical devices, tight tolerances are essential to ensure optimum performance.

At Trelleborg Healthcare & Medical, our silicone tubing engineers work closely with you to meet your tight tolerance tubing needs.

Get in touch with us to discuss your custom tubing needs:
www.tss.trelleborg.com/en/healthcare/contact-us



	Smallest size	Largest size
ø ID	0.153mm (0.006 in)	9.5mm (0.375 in)
ø OD	0.331mm (0.013 in)	12.7mm (0.500 in)
Wall	0.076mm (0.003 in)	Dependent on tube size
Tolerances	+/- 0.025mm (0.001 in)	-

Different sizes upon request

Premium Grade Implantable Silicone Tubing

PLATINUM-CURED SINGLE LUMEN TUBES FOR LONG-TERM IMPLANTS

Medical tubing designed for long-term implantation must meet stringent quality and hygiene requirements.

We offer a selection of silicone tubing and hose solutions, which have been tested for implantation greater than 29 days. Master files have been submitted to the FDA.

Features & Benefits:

- Platinum-cured for the highest degree of purity
- Extended post cure for lowest level extractables
- Non-leaching plasticizers
- Biocompatible, inert, non-reactive with other elements
- Odorless, tasteless, non-toxic for use in medical, food, drug, personal care, and deionized water applications
- For use in sterile applications
- Sterilizable by radiation, EtO, steam – 30 psi / 2 bar at +123 °C / +253 °F
- Reusable
- Resists temperature extremes – flexibility retention: -54 °C to +204 °C / -65 °F to +400 °F; brittlepoint: -73 °C / -100 °F
- Translucent for visual monitoring
- Color stripe, tint for custom process control identification



**More details concerning Biocompatibility Tests
see Page 14**

Platinum-Cured Single Lumen USP Class VI FDA Master File

ADDITIONAL SERVICES AND FEATURES

- Available in custom lengths, bulk or cut to length*
- Multi lumen, radiopaque, striped, color coded available
- Custom sizes and standard sizes available
- Also available in peroxide cure

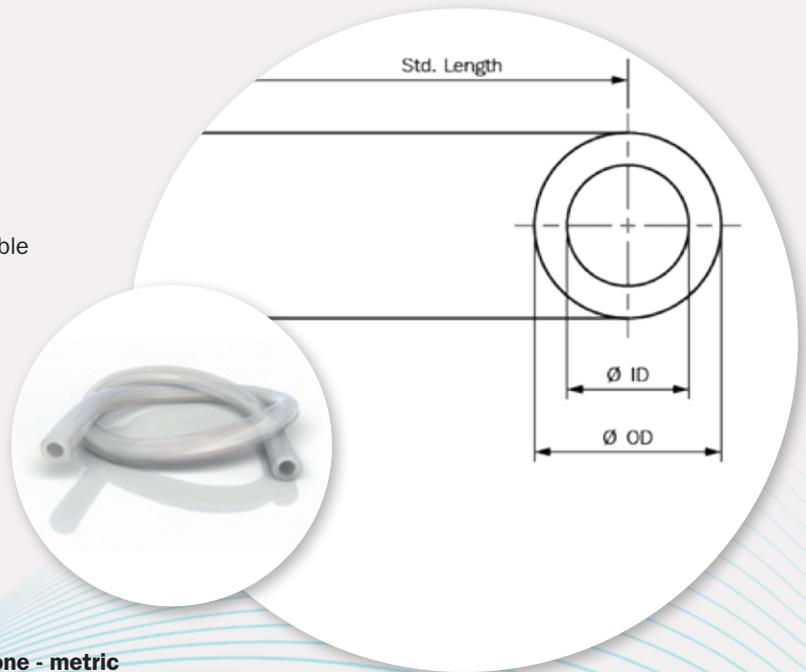


Table 1: Platinum-cured single lumen, Material: silicone - metric

ID (mm)	Tolerance** (mm)	OD (mm)	Tolerance* (mm)	ID (mm)	Tolerance** (mm)	OD (mm)	Tolerance** (mm)
1	+/- .200	1.5	+/- .250	9	+/- .350	11	+/- .350
1	+/- .200	2	+/- .250	10	+/- .350	12	+/- .350
1,5	+/- .200	2.5	+/- .250	11	+/- .400	13	+/- .350
2	+/- .200	3	+/- .250	12	+/- .400	14	+/- .350
3	+/- .200	4	+/- .250	13	+/- .400	15	+/- .350
4	+/- .200	5	+/- .250	14	+/- .400	16	+/- .350
5	+/- .250	6	+/- .250	15	+/- .400	17	+/- .400
5	+/- .250	7	+/- .250	40	+/- .700	50	+/- .700
6	+/- .250	8	+/- .250	42	+/- .800	52	+/- .700
7	+/- .350	9	+/- .250	44	+/- .800	54	+/- .700
8	+/- .350	10	+/- .250	48	+/- .800	60	+/- .700

Note*: Custom sizes available. Standard tubing on request, for common sizes tools are available. Contact Trelleborg Healthcare & Medical for other sizes.

**Tolerances to ISO 3302 E2

Table 2: Platinum-cured single lumen, Material: silicone - inch

Hose		Wall	OD	Standard Length	Burst
ID (in)	Tolerance (in)	(in)		(ft)	(psi)
0.012	+/- .003	0.007	0.025	50	25
0.020	+/- .003	0.009	0.037	50	25
0.025	+/- .003	0.011	0.047	50	35
0.030	+/- .004	0.018	0.065	50	45
0.031	+/- .004	0.063	0.156	50	70
0.040	+/- .004	0.023	0.085	50	45
0.058	+/- .005	0.009	0.077	50	30
0.062	+/- .005	0.017	0.095	50	40
0.062	+/- .005	0.032	0.125	50	44
0.062	+/- .005	0.063	0.188	50	65
0.078	+/- .005	0.024	0.125	50	40
0.104	+/- .005	0.044	0.192	50	43
0.125	+/- .005	0.063	0.250	50	43
0.132	+/- .005	0.025	0.183	50	30
0.187	+/- .005	0.063	0.312	50	29
0.187	+/- .005	0.094	0.375	50	43
0.250	+/- .006	0.063	0.375	50	21
0.250	+/- .006	0.094	0.437	50	31
0.250	+/- .010	0.125	0.50	50	43
0.312	+/- .007	0.063	0.437	50	17
0.312	+/- .007	0.094	0.500	50	25
0.375	+/- .010	0.063	0.500	50	14
0.375	+/- .010	0.094	0.562	50	20
0.375	+/- .010	0.125	0.625	50	29
0.500	+/- .010	0.063	0.625	25	11
0.500	+/- .015	0.094	0.687	25	16
0.500	+/- .015	0.125	0.750	25	22
0.625	+/- .025	0.125	0.875	25	18
0.750	+/- .025	0.125	1,000	25	15

Note*: Custom sizes available. Standard tubing on request, for common sizes tools are available. Contact Trelleborg Healthcare & Medical for other sizes.

Braided Silicone Hoses

100 HP SERIES

Platinum-cured Single Ply Polyester Braid Reinforced USP Class VI Silicone Hose

Features:

- High pressure ratings
- Excellent flexibility
- Sterilizable
- Autoclavable
- Imparts no taste or odor
- Available in bulk or assemblies
- Available in peroxide cured silicone
- Available in custom length
- Pigmented outer covers available
- Available in 25 ft, 50 ft, and 100 ft (7.6 m, 15.2 m and 30.4 m) lengths
- Temperature range: -80 °F to +500 °F/ -62 °C to +260 °C

Applications:

Pumps, pharmaceutical processing, vessel or tank transfer, cell cultures, load cells

Approvals:

Meets USP Class VI, FDA and USDA requirements

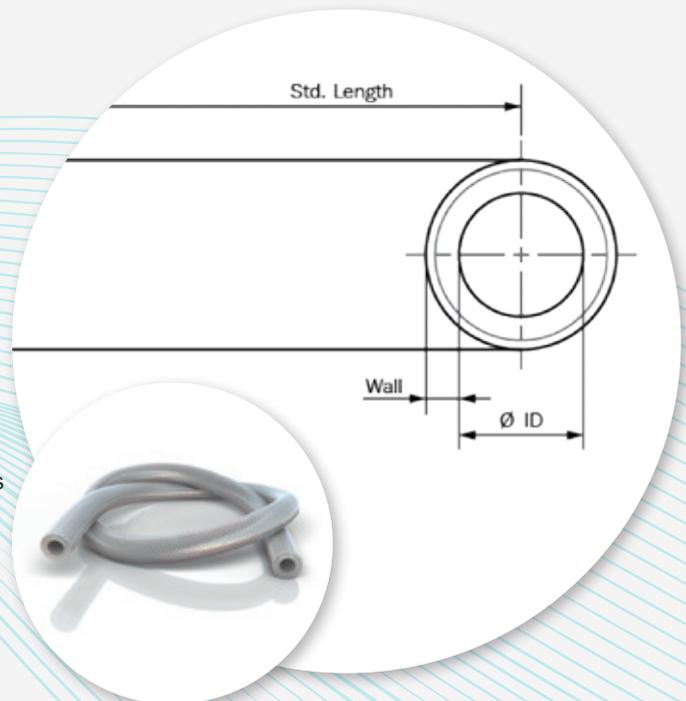


Table 3: Braided Silicone Hose, 100 HP Series - Inch

Hose		Wall	Recommended Working Pressure PSI at 68° F	Min. Burst Pressure PSI at 68° F	Min. Bend Radius
ID (in)	Tolerance (in)	(in)			(in)
0.0625	+ .030 / - .000	.115	175	700	1.00
0.125	+ .030 / - .000	.120	175	700	1.00
0.187	+ .030 / - .000	.130	165	650	1.25
0.250	+ .030 / - .000	.135	160	575	1.25
0.312	+ .030 / - .000	.140	140	550	1.75
0.375	+ .030 / - .000	.140	125	500	2.00
0.500	+ .030 / - .000	.150	130	425	2.50
0.625	+ .030 / - .000	.170	100	350	3.00
0.750	+ .030 / - .000	.175	85	275	3.50
0.875	+ .050 / - .000	.180	70	250	4.00
1.000	+ .050 / - .000	.180	65	225	5.00
1.250	+ .050 / - .000	.180	55	180	6.00

Note*: Custom sizes available. Standard tubing on request, for common sizes tools are available. Contact Trelleborg Healthcare & Medical for other sizes.

200 HP SERIES

Platinum-cured Double Ply Polyester Braid Reinforced USP Class VI Silicone Hose

Features:

- High pressure ratings
- Excellent flexibility
- Sterilizable
- Autoclavable
- Imparts no taste or odor
- Available in bulk or assemblies
- Available in peroxide cured silicone
- Custom lengths available
- Pigmented outer covers available
- Available in 50 ft. / 15.2 m lengths
- Temperature range: -80 °F to +500 °F / -62 °C to +260 °C

Applications:

Pumps, pharmaceutical processing, vessel or tank transfer, cell cultures, load cells

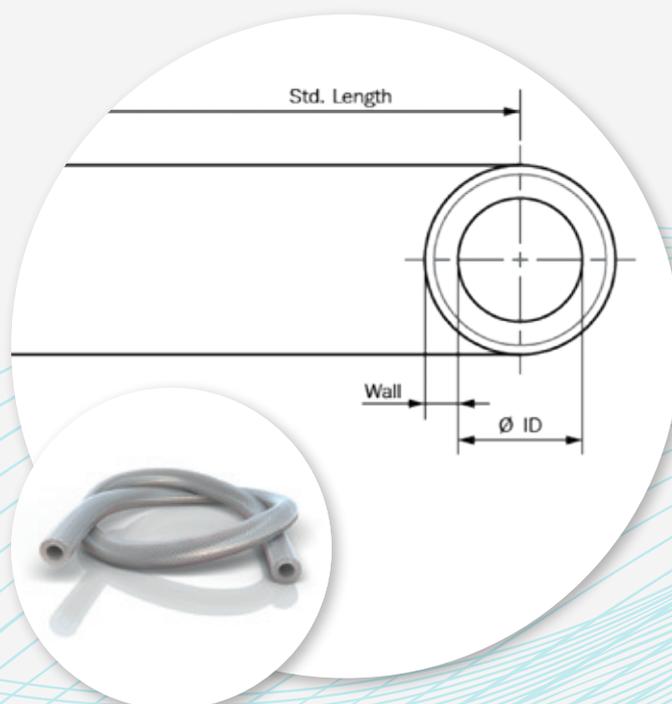
Approvals:

Meets USP Class VI, FDA, and USDA requirements

Table 4: Braided Silicone Hose, 200 HP Serie - Inch

Hose		Wall	Recommended Working Pressure PSI at 68° F	Min. Burst Pressure PSI at 68° F	Min. Bend Radius
ID (in)	Tolerance (in)	(in)			(in)
0.250	+ .030 / - .000	.135	200	800	1.75
0.312	+ .030 / - .000	.140	195	775	2.00
0.375	+ .030 / - .000	.140	190	750	2.25
0.500	+ .030 / - .000	.150	170	675	2.75
0.625	+ .030 / - .000	.170	150	600	3.25
0.750	+ .030 / - .000	.175	135	525	3.75
0.875	+ .030 / - .000	.180	125	500	4.00
1.000	+ .030 / - .000	.180	120	475	5.00
1.125	+ .030 / - .000	.180	115	460	6.00
1.250	+ .050 / - .000	.180	112	450	6.50

Note*: Custom sizes available. Standard tubing on request, for common sizes tools are available. Contact Trelleborg Healthcare & Medical for other sizes.



Custom Silicone Extrusion

Trelleborg Healthcare & Medical specialists offer a full range of extrusion capabilities to meet each customer's unique requirements. All silicone and GeoTrans™ extrusions are made from medical grade HCR, platinum-cured silicone.



Custom Extruded Tubing

Our tubing can be manufactured to custom specifications. Sizes as small as 0.20mm x 0.35mm and tolerances as low as +/- 0.025mm. Bump tubing and formed tubing capabilities are also available.



Multi-Lumen Tubing

Multiple fluid or wire paths can be customized with a range of shapes and sizes. Dimensional tolerances are possible to +/- 0.025mm (0.001 inch). Multilumen tubing can be produced with a continuous twist at a selectable pitch for applications requiring improved column strength, strain relief and electrical noise reduction when threaded with wires. Bump tubing capabilities are also available.



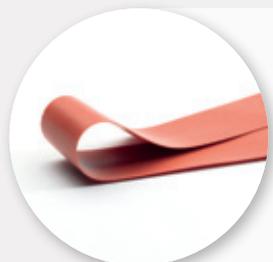
Silicone Foam

Close cell silicone foam offers custom mechanical characteristics by lowering effective durometer and providing additional cushion space. Silicone foam extrusion can be customized in a variety of sizes and cross sections with precision tolerances; pore size and foam density are adjustable.



Reinforced / Kink Resistant Tubing (KRT)

Silicone tubes and hoses can be reinforced in a variety of options, from polyester and stainless steel braids for expansion, elongation or burst resistance to spiral reinforcement with nylon monofilament for kink and crush resistance. Reinforcement is customizable and tubes can be made to precision tolerances.



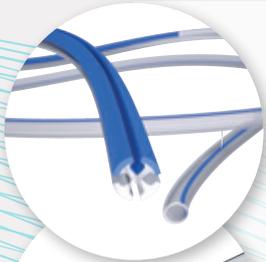
Extruded Ribbon

Silicone tape, sheet or ribbon can be extruded up to 152 mm / 6 inches in width and with a thickness down to 0.13mm (0.005 inches). Such ribbon can be supplied in spools with carriers and slip sheets or as punched seals or diaphragms.



Wire and Cable Jacketing

Wires and cable assemblies up to 5.08 mm / 0.2 inches can be jacketed with one or more layers of silicone to precision tolerances. Such products can be supplied on spools or cut to length.



GeoTrans™: Geometric Transition

Geometric transitioning allows for silicone tubing to change cross section during the extrusion process to eliminate molding and secondary bonding steps, allowing for a hygienic design. The technology is applied to custom applications with precision tolerances. Typical changes include:

- Changing of tube ID, OD or both to create a tube with two or more different cross sections
- Bifurcation or a dual lumen extrusion into two single lumen tubes
- Inclusion of channels to open internal fluid paths at locations along the extrusion length
- Stopping one of multiple lumen to avoid backfilling, such as when the lumen will be used for balloon inflation.



GeoTrans™ Extruded Balloons

Silicone balloons are common to many medical devices. A preformed balloon segment is typically bonded to a catheter shaft at a position where a small opening allows inflation by saline or air. GeoTrans™ balloons are formed in a single extrusion step as an integral part of a catheter shaft eliminating significant costs associated with secondary operations and inspections. They can be produced in a range of sizes and inflation pressures to fit specific requirements.



GeoTrans™ Single Lumen

Our GeoTrans™ Single Lumen technology, also called “Off-Ratio Bump Tubing” creates two distinct tube cross sections with near-step transition between. Tubing lengths are available in single transition (cross section A to B) or double transition (cross section A to B to A). Applications include custom end assemblies, such as accommodation of connectors or fitting, and peristaltic pumps.



TUBING & HOSE SELECTOR APP

Simplify the selection of tubing and hose for your application with our Tubing & Hose Selector App. Based on design parameters including material and pressure, you get instant suggestions without spending time searching through catalogs.

Download the app now!

www.tss.trelleborg.com/en/healthcare/tools-and-media/mobile-apps



Wrapped Hose

Platinum-cured Silicone Hose reinforced with Stainless Steel Wire & four layers of Polyester, USP Class VI

Features:

- High pressure ratings
- No risk of collapse under negative pressure
- No swelling under high pressure
- Sterilizable
- Autoclavable
- Imparts no taste or odor
- Temperature range: -76 °F to +338 °F / -60 °C to +170 °C
- Four layers of Polyester plus Stainless Steel Wire

Applications:

High pressure and vacuum applications, pharmaceutical processing, food contact applications, vessel or tank transfer

Approvals:

Meets USP Class VI, FDA, ISO 10993 sections 5,6,10,11, European Pharmacopoeia 3.1.9

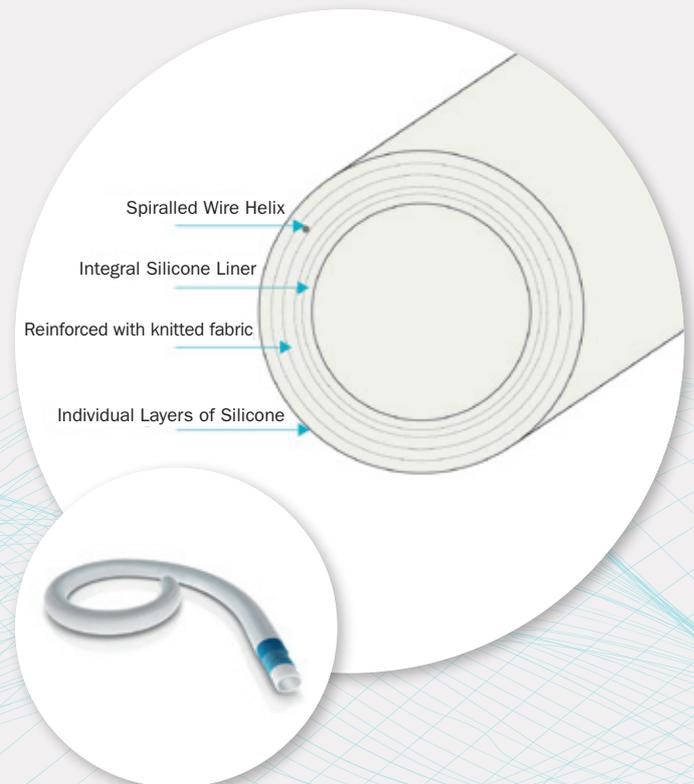


Table 5: Wrapped Hose - Metric

Hose		Wall	Recommended Working Pressure PSI at 68° F	Min. Burst Pressure PSI at 68° F	Min. Bend Radius
ID (mm)	Tolerance (mm)	(mm)	(mm)	(psi)	(mm Hg)
12.7	+0/- 0.400	5	50	450	700
19.05	+0/- 0.400	5	75	450	700
25.4	+0/- 0.400	5	90	450	700
38.1	+0/- 0.400	5	130	425	700
50.8	+0/- 0.400	5	200	425	700

Note: Custom sizes available. Standard tubing on request, for common sizes tools are available. Contact Trelleborg Healthcare & Medical for other sizes.

Sheeting Solutions

Silicone sheeting and film serve a variety of medical uses, ranging from reinforced sheeting for artificial heart valves to adhesive silicone gel for wound management applications.

We offer a range of elastomer sheeting solutions designed for Healthcare & Medical applications demanding the highest level of quality and ultimate compatibility.

Trelleborg's silicone sheeting engineers work closely with customers to develop individualized solutions that meet all application requirements.

Silicone sheeting is available in the following sizes:

- Sheet sizes: 6 in x 8 in (152,4mm x 203,2 mm) and 12 in x 12 in (304,8 mm x 304,8 mm),
- Sheet thickness: can vary from 0.005 in (0,127 mm) to 0.12 in (3,048 mm).
- Custom sizes can be produced, maximum sheet size is 35 in x75 in (889mm x 1905 mm)

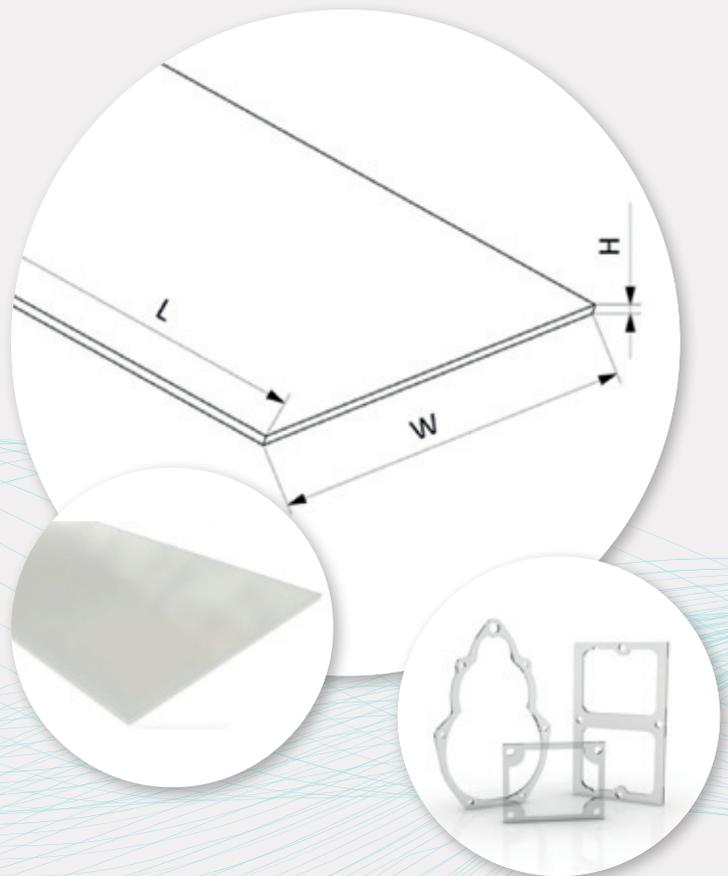
Special sheeting capabilities:

To meet the unique requirements of our customers, we offer a range of sheeting capabilities for custom solutions:

- Silicone Sheet Production
- Standard Silicone Sheeting
- Fabric-Reinforced Silicone Sheeting
- Micro Silicone Sheeting
- Gel Silicone Sheeting
- Unvulcanized HCR Silicone Sheeting
- Vulcanized Silicone Sheeting
- EPDM Sheet Production
- PTFE Sheet Production

Sheeting as a sealing material

By reinforcing sheeting and punching or cutting it into particular shapes, silicone sheeting can be used as a flat sealing element in Healthcare & Medical applications. Sheeting can be reinforced with various materials and can be punched or cut into any desired geometry. Punching offers the advantage of being a cost-effective production method.



Do you have specific requirements? Contact us!



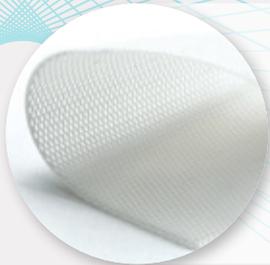
Sheeting & Film Products

SILICONE SHEET PRODUCTION



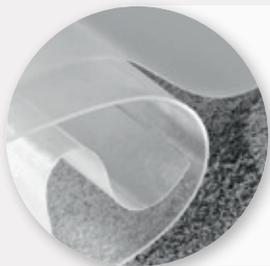
Standard Silicone Sheeting

Sheeting can be produced with different silicone elastomer materials in a variety of thicknesses for demanding applications.



Fabric-Reinforced Silicone Sheeting

Fabric is embedded between one or two layers of silicone sheeting and can be reinforced with a variety of woven and mesh fabrics made from materials such as polyester and nylon. Unvulcanized reinforced sheets are made from a High Consistency Rubber (HCR) peroxide cure system and can be supplied punched or cut to length on a protective carrier and cover sheet. Vulcanized reinforced sheeting is made from LSR or HCR platinum-cured silicone and can be supplied bulk spooled, punched, or cut to length on a protective carrier and cover sheet.



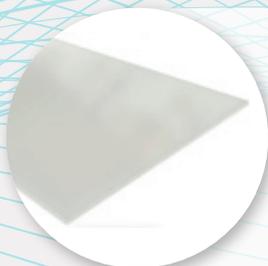
Micro Silicone Sheeting

Custom silicone micro sheeting can be supplied in thicknesses as low as 0.05mm/0.002 inch in usable widths up to 508mm/20 inch. Micro sheeting is available vulcanized and can be supplied bulk-spooled, punched, or cut to length on a protective carrier and cover sheet. Micro sheeting is made from LSR or silicone dispersion.



Gel Silicone Sheeting

Custom gel sheeting can be provided with a low, medium or high tack, ideal for applications such as scar and wound management. Gel sheeting can be supplied bulk spooled, or cut to length on a protective carrier and cover sheet. Gel sheeting is also offered coated on a layer of LSR sheeting or spandex fabric.



Unvulcanized HCR Silicone Sheeting

Custom silicone sheeting can be supplied in the uncured state for secondary assembly or molding operations. Unvulcanized sheets are made from HCR peroxide cure silicone and are supplied cut to length as flat sheets to prevent distortion, or punched on a protective carrier.



Vulcanized Silicone Sheeting

Custom vulcanized silicone sheeting is made from LSR or HCR platinum-cured silicone. LSR sheeting can be supplied bulk spooled, punched, or cut to length on a protective carrier and cover sheet. HCR sheeting can be supplied punched or cut to length on a protective carrier and cover sheet.

EPDM SHEET PRODUCTION



Himod® Flatseal EG

A new series of EPDM FlatSeal™ meets U.S. Pharmacopoeia (USP) Class VI certification. The new series meets the specific needs of pharmaceutical, medical and biotech equipment manufacturers who seek USP Class VI certified flat seals.

PTFE SHEET PRODUCTION



Himod® Flatseal 43 & 45

The HiMod® flat gasket range consists of products that will satisfy the requirements of the majority of gasket applications. Suitable for pharmaceutical and food contact, the gaskets offer improved performance compared to conventional polytetrafluoroethylene (PTFE) flat gaskets.

Trelleborg is a world leader in engineered polymer solutions that seal, damp and protect critical applications in demanding environments. Its innovative solutions accelerate performance for customers in a sustainable way.

Trelleborg Healthcare & Medical develops, manufactures and supplies innovative engineered solutions for demanding medical, biotech and pharmaceutical applications in thermoplastics, silicone and other elastomers. We focus on meeting the most demanding needs of Healthcare & Medical customers with innovative solutions.

WWW.TSS.TRELLEBORG.COM/HEALTHCARE



facebook.com/TrelleborgSealingSolutions
twitter.com/TrelleborgHM
youtube.com/TrelleborgSeals
linkedin.com/company/trelleborg-healthcare-&-medical

If you'd like to talk to a Trelleborg Healthcare & Medical expert, get in touch with us at: www.tss.trelleborg.com/en/healthcare/contact-us