

SILASTIC® Rx Medical Grade Tubing

FEATURES

- Excellent flexibility
- Easily sterilized
- Low extractable profile
- Contains no organic plasticizers, phthalates or latex additives
- No peroxide cure chlorophenyl or PCB by-products
- Non-wettable
- Custom profiles and tolerances
- Radiopaque options available
- Exceeds USP class VI plastic tests
- Meets ISO 10993 guidelines for body contact applications
- Meets EP monograph “Silicone Elastomer for Closures and Tubing”
- Manufactured to the principles of FDA 21 CFR 210/211 cGMPs for Pharmaceutical products
- Produced in an FDA-registered (CFN 1816403) and inspected healthcare facility

BENEFITS

- Make to order
- Custom sizes and tolerances
- Complete traceability
- Consistent performance
- Integrated supply chain
- Rigid change control

COMPOSITION

- Platinum-cured silicone tubing

Silicone tubing specifically designed for use in medical devices that is made from platinum-cured SILASTIC® BioMedical Grade Elastomer to ensure maximum biocompatibility

APPLICATIONS

- SILASTIC Rx Medical Grade Tubing is designed for use in medical devices anywhere an extruded silicone profile is needed.

TYPICAL PROPERTIES

Specification writers: These values are not intended for use in preparing specifications. Please contact your local Dow Corning sales representative prior to writing specifications on this product.

CTM ¹	Test	Unit	Result		
			Rx-50	Rx-65	Rx-80
0099	Durometer hardness ²	Shore A	50	65	78
0137A	Tensile strength at break, die D ³	MPa	9.6	9.0	7.1
		psi	1388	1301	1030
0137A	Elongation at break, die D ³	%	815	613	568
0137A	Modulus at 200%, die D ³	MPa	2.1	2.7	4.0
		psi	299	391	581
0159A	Tear strength, die B ²	kN/m	46	45	42
		ppi	263	257	240

1. CTM: (Corporate Test Method) corresponds to American Standard Test Methods (ASTM). Copies of CTM's are available upon request.

2. Typical properties for the elastomer.

3. Typical properties of the extruding tubing.

DESCRIPTION

SILASTIC Rx Medical Grade Tubing is a translucent silicone extrusion made from SILASTIC BioMedical Grade Silicone Elastomer. SILASTIC BioMedical Grade Silicone Elastomer is utilized to assure that this product meets stringent biocompatibility standards. These materials are available in 50, 65, or 80 Shore A hardness, and are specifically designed for use in medical device applications, or anywhere precision tolerances and/or custom sizes and geometries are needed from an extruded silicone profile.

SPECIAL NEEDS

Dow Corning has the capabilities to customize products to meet your specifications. Customization includes: sizes, tolerance, cut lengths, bulk packaging, multi-lumen, custom profiles and spooling. Please contact your local Dow Corning representative to discuss your specific requirements.

REGULATORY STATUS

SILASTIC Rx Medical Grade Tubing meets or exceeds:

- USP Class V extractables and Class VI plastics tests
- ISO 10993 guidelines for body contact applications
- European Pharmacopoeia Monograph 3.1.9 silicone elastomer for closures and tubing.

MANUFACTURING ENVIRONMENT

SILASTIC Rx Medical Grade Tubing is manufactured under strict quality-control guidelines. The Healthcare Industries Materials Site in Hemlock, MI, is dedicated to the production of silicone materials for healthcare applications. It is registered with the FDA (CFN 1816403) as a Drug Establishment. The site quality system is based on principles of current Good Manufacturing Practices for both Bulk Pharmaceutical Products and Medical Devices. Dow Corning is ISO 9001 registered globally with BSI.

QUALITY ASSURANCE

Dow Corning manufactures SILASTIC Rx Medical Grade Tubing in a totally integrated process from raw materials to the final extruded tubing. Our quality system, described above, ensures full documentation and complete traceability.

STERILIZATION CONSIDERATIONS

It is the user's responsibility to validate a sterilization process for silicone tubing. Common sterilization processes are listed below.

Autoclave (Steam Sterilization)

Silicone materials are more difficult to heat than materials such as thermoplastics because they have thermal insulating properties. However, silicone tubing can be effectively sterilized by steam in an autoclave. This has been accomplished in a standard gravity steam sterilization cycle (30 minutes at 1.03 bar/15psi and 121°C/250°F) and in a high-speed flash steam sterilization cycle (15 minutes at 2.07 bar/30psi and 132°C/270°F).

Gamma Radiation Sterilization

Gamma radiation studies of the effects on the physical properties of silicone elastomer have shown that doses of radiation up to 2.5 Mrad (25kGy) do not adversely affect durometer, elongation, modulus, tensile or tear strength. Repeated gamma sterilization or processing at higher doses of radiation may change some of the physical properties of the elastomer. The user should conduct testing if sterilization conditions vary and if minor property changes could affect application performance.

Ethylene Oxide Sterilization

Ethylene oxide has been used to sterilize silicone tubing with no degradation of physical properties. Sterilization by this method is only recommended if procedures allow sufficient time for complete out gassing of residual ETO and ETO by-products.

IMPORTANT INFORMATION

THE USER'S ATTENTION IS IN PARTICULAR DRAWN TO THE FOLLOWING STATEMENT:

It is the User's responsibility to ensure the safety and efficacy of this material for all intended uses. While this material has passed screening tests that are applicable to products intended to be implanted for up to 29 days, Dow Corning makes no end-use representation based on such testing. Nor does Dow Corning make any representation concerning the suitability of this product for applications of greater than 29 days of implantation in the human body.

ORDERING

SILASTIC Rx Medical Grade Tubing is available direct from Dow Corning. For ordering information, or to discuss specific requirements, please contact your local Dow Corning representative or call 1-800-248-2481.

HANDLING PRECAUTIONS

Product safety information required for safe use is not included. Before handling, read product and safety data sheets and container labels for safe use, physical and health hazard information. The material safety data sheet is available on the Dow Corning website at www.dowcorning.com. You can also obtain a copy from your local Dow Corning sales representative or Distributor or by calling your local Dow Corning Global Connection.

USABLE LIFE AND STORAGE

When stored in unopened original containers, this product has a usable life of 36 months from the date of manufacture. Dow Corning will guarantee the usable life of this product until the expiration date indicated on the packaging.

PACKAGING

To serve our customers better, Dow Corning has immediate availability of the most commonly used sizes of this product (see Table 1). Standard package is a 15 meter (50 foot) coil, double bagged in separately sealed polyethylene bags contained in a cardboard box.

HEALTH AND ENVIRONMENTAL INFORMATION

To support Customers in their product safety needs, Dow Corning has an extensive Product Stewardship organization and a team of Product Safety and Regulatory Compliance (PS&RC) specialists available in each area.

For further information, please see our website, www.dowcorning.com or consult your local Dow Corning representative.

LIMITED WARRANTY INFORMATION - PLEASE READ CAREFULLY

The information contained herein is offered in good faith and is believed to be accurate. However, because conditions and methods of use of our products are beyond our control, this information should not be used in substitution for customers' tests to ensure that Dow Corning's products are safe, effective, and fully satisfactory for the intended end use. Suggestions of use shall not be taken as inducements to infringe any patent.

Dow Corning's sole warranty is that the product will meet the Dow Corning sales specifications in effect at the time of shipment.

Your exclusive remedy for breach of such warranty is limited to refund of purchase price or replacement of any product shown to be other than as warranted.

DOW CORNING SPECIFICALLY DISCLAIMS ANY OTHER EXPRESS OR IMPLIED WARRANTY OF FITNESS FOR A PARTICULAR PURPOSE OR MERCHANTABILITY.

DOW CORNING DISCLAIMS LIABILITY FOR ANY INCIDENTAL OR CONSEQUENTIAL DAMAGES.

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Table 1. Standard tubing product sizes

(Values stated are typical values only, and are not intended for writing specifications).

<i>Standard sizes of SILASTIC Rx-50 Medical Grade Tubing</i>					
<i>Inside diameter</i>	<i>Dimension (mm)</i>		<i>Inside diameter</i>	<i>Dimension (inches)</i>	
	<i>Outside diameter</i>	<i>Wall</i>		<i>Outside diameter</i>	<i>Wall</i>
0.30	0.64	0.17	0.012	0.025	0.007
0.51	0.94	0.22	0.020	0.037	0.009
0.64	1.19	0.28	0.025	0.047	0.011
0.76	1.65	0.44	0.030	0.065	0.018
1.02	2.16	0.57	0.040	0.085	0.023
1.47	1.96	0.24	0.058	0.077	0.010
1.57	2.41	0.42	0.062	0.095	0.017
1.57	3.18	0.80	0.062	0.125	0.032
1.98	3.18	0.60	0.078	0.125	0.024
2.64	4.88	1.12	0.104	0.192	0.044
3.35	4.65	0.65	0.132	0.183	0.026
3.18	6.35	1.59	0.125	0.250	0.063
4.78	7.95	1.59	0.188	0.313	0.063
4.78	9.53	2.37	0.188	0.375	0.094
6.35	9.53	1.59	0.250	0.375	0.063
6.35	11.11	2.38	0.250	0.438	0.094
6.35	12.70	3.18	0.250	0.500	0.125
7.95	12.70	2.37	0.313	0.500	0.094
9.53	12.70	1.59	0.375	0.500	0.063
9.53	14.30	2.39	0.375	0.563	0.094
9.53	15.88	3.18	0.375	0.625	0.125
12.70	17.46	2.38	0.500	0.688	0.094
12.70	19.05	3.18	0.500	0.750	0.125
15.88	22.23	3.18	0.625	0.875	0.125