



Healthcare
Solutions

Silicone Elastomers for Medical Device Applications

Application and Product Selection Guide

Proven. Performance.



Advancing healthcare through
material innovations

How can we help you today?

Dow Corning[®] and *Silastic*[®] brand silicone elastomers for medical device applications are dedicated to meeting your needs for specialty materials and innovative support.

Our rubber formulating experience and fabrication expertise, plus local market knowledge and collaborative problem solving help you make an informed choice. Learn more at dowcorning.com/healthcare.

Meeting your quality and regulatory needs

Our long-term experience in healthcare gives us broad expertise with global regulatory requirements. Depending on your need or application, you can call on our worldwide network of technology centers, our Product Stewardship organization, as well as our team of Product Safety and Regulatory Compliance specialists. We can provide material from an ISO-certified site or an FDA-registered facility to the appropriate level of GMPs. You can also benefit from our regulatory support that includes Pharmacopeial Certification, Drug Master Files, Material Application Files or Technical Files for select materials.

Meeting your safety needs


We are committed to ensuring that our products and services are safe and effective to use.

Silicones are one of the most extensively biotested materials used in the healthcare industry.

All *Dow Corning*[®] and *Silastic*[®] silicone elastomers for medical device applications are manufactured to ISO 9001 quality standards in accordance with the practices of *Responsible Care*[®] (ISO 14001).

Dow Corning has adopted the American Chemistry Council's *Responsible Care* program, which helps manage environmental, health and safety issues that could affect you.





Expertise meets Innovation

The past few decades have brought extensive advances in medical care. New and innovative technologies have helped find unprecedented ways to fight disease. Many of these technologies are the result of a visionary expansion in materials.

The diversity and versatility of *Dow Corning*[®] brand and *Silastic*[®] brand healthcare silicone elastomers help manufacturers of medical implants and devices around the world create innovative products to address critical medical needs. These silicone elastomers are suitable for a wide variety of medical device applications:

- Short-term and long-term implanted devices
- Medical/diagnostic devices and components
- Non-implant external devices

Dow Corning[®] brand and *Silastic*[®] brand silicone elastomers can help meet your need for quality, reliability and dependable performance:

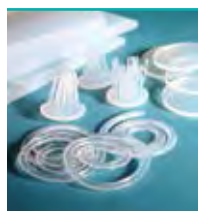
- Biocompatible, and FDA food grade compliant
- Consistent from batch to batch
- Available in a broad range of Shore A hardnesses
- Sterilizable (e.g., autoclave, gamma irradiation)
- Do not contain organic plasticizers, phthalates or latex additives
- Solventless, pigmentable and non-blooming in platinum catalyzed system, with high gas permeability compared to most thermoset elastomers and thermoplastics



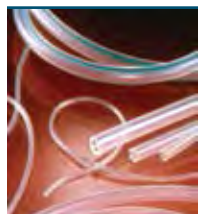
The right material for the right application

Dow Corning offers a broad range of uncatalyzed and platinum catalyzed silicones designed for the fabrication of medical devices and device components.

Use this selection guide to help you find the suitable material for your application.



Liquid Silicone Rubber (LSR) products are pumpable thermoset silicone elastomers that can be processed by molding equipment. They are ideal for intricate designs and close-tolerance parts.



High Consistency Rubber (HCR) products are millable thermoset silicone elastomers that can be extruded continuously to form a desired size and shape before curing, e.g. silicone tubing.

	Liquid Silicone Rubber				High Consistency Rubber		
	Dow Corning® QP1 LSR	Dow Corning® Class VI LSR	Silastic® BioMedical Grade LSR		Dow Corning® QP1 Elastomer	Dow Corning® Class VI Elastomer	Silastic® BioMedical Grade Elastomer
Uncatalyzed					●	●	●
Platinum Catalyzed	●	●	●			●	●
Applications							
Long-term implant*			●				●
Short-term implant	●	●	●		●	●	●
Medical insert	●	●	●		●	●	●
Non-implant	●	●	●		●	●	●
FDA 21 CFR 177.2600 (Food Grade)	●	●	●		●	●	●
Select European Pharmacopeia 3.1.9							
Substances soluble in hexane		●	●			●	●
Volatile matter		●	●			●	●
Biocompatibility							
Cytotoxicity	●	●	●		●	●	●
Mutagenicity/Genotoxicity			●				●
Hemolysis			●				●
Skin Sensitization		●	●			●	●
Pyrogenicity (USP)			●				●
90-day implant			●				●
30-day implant		●	●			●	●
7-day implant	●	●	●		●	●	●
USP Class V and VI	●	●	●		●	●	●
Production							
ISO 9001-2008	●	●	●		●	●	●
ISO 14001:2004	●	●	●		●	●	●
Produced in GMP facility		●	●			●	●
Change Notification (per ISO 9001)	●				●		
Change Control (per GMP)		●	●			●	●
Documentation							
US Drug Master File*			●				●
EU Technical File*			●				●

* Indemnification is required for long-term implant applications. Select *Silastic*® brand BioMedical Grade materials have US Drug Master Files and EU Technical Files.

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Contact Dow Corning

When you need innovation, Dow Corning can help. We are dedicated to meeting your needs for specialty materials, collaborative problem solving and innovation support. We have state-of-the-art application center laboratories in our facilities. Learn how we can help you at dowcorning.com/healthcare.

Your Global Connection

Dow Corning has sales offices and manufacturing facilities worldwide, as well as full-service, global technical support. Contact us today by visiting dowcorning.com/ContactUs.

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Dow Corning's sole warranty is that our products will meet the 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.

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We help you invent the future. is a trademark of Dow Corning Corporation.

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