

Elastomers (Rubbers)

To assure consistent quality for medical device and pharmaceutical applications, elastomers from Dow Corning are manufactured, packaged, and tested at the Healthcare Industries Materials Site utilizing principles of GMP guidelines for both Active Pharmaceutical Ingredients (APIs) and Medical Devices.

Regulatory Status			
Ph. Eur. (EP) Monograph 3.1.9. Silicone Elastomer for Closures and Tubing	Volatile Matter Substances Soluble in Hexane		
Technical File			
FDA Regulation 21 CFR 177.2600 (Food Grade)			
Biocompatibility Tests			
Cytotoxicity			
Mutagenicity/Genotoxicity			
Hemolysis			
Skin Sensitization			
Pyrogenicity (USP)			
90-day Implant (exceeds USP Class VI)			
30-day Implant (exceeds USP Class VI)			
USP Class V and VI			
BioMedical Grade High Consistency Rubber			
Description	Typical Applications		
One-part, enhanced tear-resistant silicone elastomers; peroxide initiator selected by customer and added at point of use	<ul style="list-style-type: none"> Fabrication of medical/surgical/diagnostic devices and components Fabrication of extruded parts 		
Two-part (1:1 by weight), platinum-catalyzed, enhanced tear-resistant silicone elastomers	<ul style="list-style-type: none"> Balloons, molded and extruded parts Fabrication of medical/surgical/diagnostic devices and components Fabrication of extruded parts 		
Class VI Elastomers			
One-part, enhanced tear-resistant silicone elastomers; peroxide initiator selected by customer and added at point of use	<ul style="list-style-type: none"> Fabrication of medical/surgical/diagnostic devices and components Fabrication of extruded parts Implantation applications ≤29 days 		
Two-part (1:1 by weight), platinum-catalyzed silicone elastomers	<ul style="list-style-type: none"> Fabrication of medical/surgical/diagnostic devices and components Fabrication of extruded parts Implantation applications ≤29 days 		
Class VI Enhanced Elastomers			
Dow Corning® C6-350 LH Elastomer			
Typical Properties [†]			
Relative Density			
Tear Strength, Die B			
Elongation			
Tensile Strength, Die C			
Durometer Hardness, Shore A	MPa (psi)	%	kN/m (ppi)



AV06479

[†] Specifications Writers: These values are not intended for use in preparing specifications. Please contact your local Dow Corning sales office prior to writing specifications on these products.

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