

SAINT-GOBAIN MEDICAL

BIO-SIL[®] 1450

Tubing for Medical Device Manufacturers

Bio-Sil[®] 1450 platinum-cured silicone tubing is the next generation in ultra-pure silicone tubing for the medical market. This high performance pump tube is available in 50 Shore A durometer and is ideally suited for medical applications where strength, durability, pump performance and biocompatibility are of primary importance.

BIOCOMPATIBILITY CHARACTERISTICS

Bio-Sil is a highly biocompatible silicone material designed specifically for medical applications. Bio-Sil silicone tubing is manufactured and tested to USP <88>, Plastic Class VI criteria and is non-toxic, non-hemolytic and nonpyrogenic.

BIO-SIL[®] 1450 TYPICAL PHYSICAL PROPERTIES*

Property	ASTM Method	Value or Rating
Durometer Hardness, Shore A, 15 sec.	D2240	52
Color	—	Translucent
Tensile Strength, psi (MPa)	D412	1,293 (8.91)
Ultimate Elongation, %	D412	719
Tear Resistance, Die B, ppi (kN/m)	D624	164 (50.1)
Specific Gravity (g/cm ³)	D792	1.14
Tensile Modulus, at 200% Elongation, psi (MPa)	D412	241 (1.38)

* Unless otherwise noted, all tests were conducted at room temperature (73°F). Values shown were determined on 0.075" thick extruded strips, 0.075" thick molded ASTM plaques or molded ASTM durometer buttons.



FEATURES/BENEFITS

- Ultra-low extractables
- Fully sterilizable
- Bio-Sil 1450 has met the criteria of various ISO 10993 and USP test
- Custom sizes available

TYPICAL APPLICATIONS

- Blood analysis
- Drug delivery
- Peristaltic pumps

Product recommendations are based on a combination of industry knowledge, material science expertise, and/or material testing data. Contact Saint-Gobain Medical for further tubing recommendation information.



BIO-SIL® 1450 TUBING MANUFACTURED SIZES**

Part Number	I.D.		O.D.		Wall Thickness		Length feet
	inches	mm	inches	mm	inches	mm	
BS1450-012-025	0.012	0.305	0.025	0.635	0.007	0.178	25
BS1450-020-037	0.020	0.508	0.037	0.940	0.009	0.229	25
BS1450-020-083	0.020	0.508	0.083	2.108	0.031	0.794	50
BS1450-025-047	0.025	0.635	0.047	1.194	0.011	0.279	50
BS1450-030-065	0.030	0.762	0.065	1.651	0.018	0.457	50
BS1450-031-094	0.031	0.794	0.094	2.381	0.031	0.794	50
BS1450-040-085	0.040	1.016	0.085	2.159	0.023	0.584	50
BS1450-058-077	0.058	1.473	0.077	1.956	0.010	0.254	50
BS1450-063-095	0.063	1.588	0.095	2.413	0.017	0.432	50
BS1450-063-125	0.063	1.588	0.125	3.175	0.031	0.794	50
BS1450-078-125	0.078	1.981	0.125	3.175	0.023	0.584	50
BS1450-094-156	0.094	2.381	0.156	3.969	0.031	0.794	50
BS1450-104-192	0.104	2.642	0.192	4.877	0.044	2.642	50
BS1450-125-188	0.125	3.175	0.188	4.763	0.031	0.794	50
BS1450-125-250	0.125	3.175	0.250	6.350	0.063	1.588	50
BS1450-132-183	0.132	3.353	0.183	4.648	0.026	0.660	50
BS1450-156-219	0.156	3.969	0.219	5.556	0.031	0.794	50
BS1450-188-250	0.188	4.763	0.250	6.350	0.031	0.794	50
BS1450-188-313	0.188	4.763	0.313	7.938	0.063	1.588	50
BS1450-188-375	0.188	4.763	0.375	9.525	0.094	2.381	50
BS1450-188-438	0.188	4.763	0.438	11.113	0.125	3.175	50
BS1450-250-313	0.250	6.350	0.313	7.938	0.031	0.794	50
BS1450-250-375	0.250	6.350	0.375	9.525	0.063	1.588	50
BS1450-250-438	0.250	6.350	0.438	11.113	0.094	2.381	50
BS1450-250-500	0.250	6.350	0.500	12.700	0.125	3.175	50
BS1450-313-438	0.313	7.938	0.438	11.113	0.063	1.588	50
BS1450-313-500	0.313	7.938	0.500	12.700	0.094	2.381	50
BS1450-313-563	0.313	7.938	0.563	14.300	0.125	3.175	50
BS1450-375-500	0.375	9.525	0.500	12.700	0.063	1.588	50
BS1450-375-563	0.375	9.525	0.563	14.288	0.094	2.381	50
BS1450-375-625	0.375	9.525	0.625	15.875	0.125	3.175	50
BS1450-500-625	0.500	12.700	0.625	15.875	0.063	1.588	50
BS1450-500-688	0.500	12.700	0.688	17.463	0.094	2.381	25
BS1450-500-750	0.500	12.700	0.750	19.050	0.125	3.175	25
BS1450-625-875	0.625	15.875	0.875	22.225	0.125	3.175	25
BS1450-750-1000	0.750	19.050	1.000	25.400	0.125	3.175	10
BS1450-1000-1250	1.000	25.400	1.250	31.750	0.125	3.175	10

**Custom sizes also available

BIO-SIL® 1450 BIOCOMP TESTING

Method Description	Reference Standard	Result
Genotoxicity Test	ISO 10993-3	Meets Criteria
Hemolysis - Direct Contact	ASTM F756-00	Meets Criteria
Hemolysis - Indirect Contact	ASTM F756-00	Meets Criteria
Irritation and Skin Sensitization: Kligman Maximization Test	ISO 10993-10	Meets Criteria
Systemic Toxicity - Systemic Injection	ISO 10993-11	Meets Criteria
Biological Reactivity Tests, <i>In Vitro</i> : MEM Elution Test	USP <87>	Meets Criteria
Biological Reactivity Tests, <i>In Vivo</i> : Agar Diffusion Test	USP <87>	Meets Criteria
Biological Reactivity Tests, <i>In Vivo</i> : Direct Contact	USP <87>	Meets Criteria
Biologic Reactivity Tests, <i>In Vivo</i> : As Manufactured Samples	USP <88>, Class VI	Meets Criteria
Biologic Reactivity Tests, <i>In Vivo</i> : Post-Gamma Irradiation Samples	USP <88>, Class VI	Meets Criteria
Biologic Reactivity Tests, <i>In Vivo</i> : Post-Autoclave Samples	USP <88>, Class VI	Meets Criteria
Particulate Matter	USP <788>	<1 particle/ mL for each category
Bacterial Endotoxin	USP <85>	< 0.005EU/ mL
Systemic Toxicity: Rabbit Pyrogen	ISO 10993-11	Meets Criteria
Bacteriostasis & Fungistasis	USP <71>	Meets Criteria
Elastomeric Closures for Injection	USP <381>	Meets Criteria
Physicochemical Tests for Plastics	USP <661>	Meets Criteria
Test for Rubber Closure for Aqueous Infusions	JP 59	Meets Criteria
Silicone Elastomer for Closures and Tubing	EP 3.1.9	Meets Criteria
Total Extractables in Rubber Articles Intended for Repeated Use	21CFR Part 177.2600	Meets Criteria

BIO-SIL® 1450 STERILIZATION METHODS

- Autoclavable (steam 30 min at 15 psi, 250°F/121°C)
- EtO (Ethylene Oxide)
- Radiation (50 kGy/5.0 Mrad)

NOTE: The information provided pertains only to product manufactured at the Saint-Gobain Taunton, Massachusetts facility. Saint-Gobain Performance Plastics Corporation's Life Science ("Saint-Gobain") products that are used as components in the manufacture of any Medical Devices (as defined by the FDA) are sold by Saint-Gobain only and exclusively to Medical Device manufacturers for use in the manufacture, assembly or distribution of their medical devices. Medical Device manufacturers, to whom Saint-Gobain sells components or for whom Saint-Gobain acts as a subcontractor for finished products, are solely responsible for determining whether their finished products are a medical device and complying with the appropriate certifications and registrations.

This document is intended to provide information about the product to enable you to consider whether generally the Product meets your application need and is not intended to provide product specification. This document should not be considered a Product warranty or guaranty. To the extent this document mentions any tests done by Saint-Gobain, such tests are done under controlled laboratory circumstances and hence other factors in your use and application may impact such values.

