SAINT-GOBAIN MEDICAL

BIO-SIL® PRECISION

Tubing for Medical Device Manufacturers

Bio-Sil® Precision silicone tubing has been uniquely formulated by the material experts at Saint-Gobain Medical, and was developed specifically for medical pumping applications. Bio-Sil products are the result of decades of material science expertise and state-of-the-art manufacturing processes.

CHARACTERISTICS

As part of our family of silicone products, Bio-Sil Precision has been formulated to optimize the pumping characteristics of silicone, while providing a level of repeatability and consistency that is not found in other pump tubings. The material formulation is tightly controlled to reduce variation in the physical properties of the material.

CONSISTENCY AND PERFORMANCE

Produced using the Compass Technology® extrusion process, Bio-Sil Precision provides best in class tolerance control on both material physical properties and tubing dimensions. The result is greater consistency in the product and less variation in its performance in your application.

Compass Technology for silicone tubing offers optimized formulations tailored to your specific application, ensuring precision tolerances for critical dimensions and fluid system modeling for product design. This technology platform delivers premium parts that consistently perform across manufacturing runs. Additionally, our in-process data collection capability helps control dimension tolerances and enhance quality control and documentation standards, expediting your validation process.

FEATURES/BENEFITS

- Sterilizable
- Consistent material performance
- Bio-Sil Precision has met Plastic Class VI, as described in USP <88> (2022) requirements

TYPICAL APPLICATIONS

- Diagnostic sample handling
- Infusion therapy
- Insulin delivery
- Oncology treatment

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.

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BIO-SIL® PRECISION TUBING

BIO-SIL® PRECISION TUBING MANUFACTURED SIZES

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

BIO-SIL® PRECISION TUBING TYPICAL PHYSICAL PROPERTIES*

Property	ASTM Method	Value or Rating
Durometer Hardness, Shore A, 15 sec.	D2240	53
Tensile Strength, psi (MPa)	D412	1,500 (10.34)
Ultimate Elongation, %	D412	750
Modulus at 100% Elongation, psi (MPa)	D412	230 (1.59)
Tear Strength, ppi (kN/m)	D1004	190 (0.02)

* 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.

BIO-SIL® PRECISION TUBING CHARACTERISTICS

Bio-Sil Precision has met the following test requirements:

- Plastic Class VI, as described in USP <88> (2022)

BIO-SIL® PRECISION TUBING STERILIZATION METHODS

Physical properties are not significantly impacted by the following 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.

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BIO-SIL® 1350

Tubing for Medical Device Manufacturers

Bio-Sil® 1350 platinum-cured silicone tubing is engineered for ultrapure fluid transfer in medical applications where flexibility, precision, and pump performance are essential. With a Shore A hardness of 50, it combines high compressibility with resilience, supporting stable flow rates in peristaltic pump systems. The formulation minimizes wear over extended use, helping maintain dimensional integrity and functional performance through repeated pump cycles.

BIOCOMPATIBILITY CHARACTERISTICS

Bio-Sil 1350 is manufactured from raw materials that meet the requirements of USP<88> and can be classified as USP Plastic Class VI. Finished tubing is tested to ISO 10993 standards for genotoxicity (ISO 10993-3), hemolysis (ISO 10993-4), and cytotoxicity (ISO 10993-5). Testing is conducted on tubing sterilized by ethylene oxide (EtO), gamma irradiation (25–40 kGy), and steam autoclaving at 121°C to confirm compatibility with common medical sterilization methods.

IDEAL CHOICE FOR MEDICAL APPLICATIONS

The 50 Shore A durometer provides a balance of flexibility and compressibility for consistent pumping performance. The smooth bore and low friction surface reduce mechanical stress on pump components, while the material's resilience supports extended tubing life. These characteristics make Bio-Sil 1350 suitable for hemodialysis systems, anesthesia delivery, respiratory therapy devices, and diagnostic instruments requiring accurate, repeatable fluid control.

Manufactured in France, Bio-Sil 1350 is ideally positioned to support the European medical device market with localized production and supply chain advantages.

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.

FEATURES/BENEFITS

- Tubing has met ISO 10993-3/4/5 criteria
- Bio-Sil 1350 raw material has met USP <88> Class VI criteria
- Compatible with EtO, gamma (25–40 kGy), and steam sterilization
- Designed and manufactured without the intentional addition of animal-derived materials
- Custom sizes available

TYPICAL APPLICATIONS

- Diagnostic and analytical instruments
- Dialysis and blood filtration
- Drug delivery and infusion therapy
- Peristaltic pump systems
- Respiratory and anesthesia equipment

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BIO-SIL® 1350 TUBING MANUFACTURED SIZES

Part Number	I.D.		O.D.		Wall Thickness		Length	
	inches	mm	inches	mm	inches	mm	feet	m
BS1350-0076-0165	0.03	0.76	0.065	1.65	0.018	0.44	50	15
BS1350-0079-0239	0.031	0.79	0.094	2.39	0.032	0.80	50	15
BS1350-0102-0216	0.04	1.02	0.085	2.16	0.023	0.57	50	15
BS1350-0147-0196	0.058	1.47	0.077	1.96	0.010	0.24	50	15
BS1350-0160-0241	0.063	1.60	0.095	2.41	0.016	0.41	50	15
BS1350-0160-0318	0.063	1.60	0.125	3.18	0.031	0.79	50	15
BS1350-0198-0318	0.078	1.98	0.125	3.18	0.024	0.60	50	15
BS1350-0239-0396	0.094	2.39	0.156	3.96	0.031	0.79	50	15
BS1350-0264-0488	0.104	2.64	0.192	4.88	0.044	1.12	50	15
BS1350-0318-0478	0.125	3.18	0.188	4.78	0.032	0.80	50	15
BS1350-0318-0635	0.125	3.18	0.25	6.35	0.063	1.59	50	15
BS1350-0335-0465	0.132	3.35	0.183	4.65	0.026	0.65	50	15
BS1350-0396-0556	0.156	3.96	0.219	5.56	0.032	0.80	50	15
BS1350-0478-0635	0.188	4.78	0.25	6.35	0.031	0.79	50	15
BS1350-0478-0795	0.188	4.78	0.313	7.95	0.063	1.59	50	15
BS1350-0478-0953	0.188	4.78	0.375	9.53	0.094	2.37	50	15
BS1350-0478-1113	0.188	4.78	0.438	11.13	0.125	3.18	50	15
BS1350-0635-0795	0.25	6.35	0.313	7.95	0.032	0.80	50	15
BS1350-0635-0953	0.25	6.35	0.375	9.53	0.063	1.59	50	15
BS1350-0635-1113	0.25	6.35	0.438	11.13	0.094	2.39	50	15
BS1350-0635-1270	0.25	6.35	0.5	12.70	0.125	3.18	50	15

Custom hardness and dimensions available.

BIO-SIL® 1350 TUBING STERILIZATION METHODS

Physical properties are not significantly impacted by the following sterilization methods:

- Autoclavable (30 min at 250°F/121°C)
- EtO (Ethylene Oxide)
- Gamma irradiation (up to 4 Mrad (40 kGy))

BIO-SIL® 1350 TUBING TYPICAL PHYSICAL PROPERTIES*

Property	ISO	Value or Rating
Durometer Hardness, Shore A (+/-3)	48-4	53
Color	Translucent	
Tensile Strength, psi (MPa)	37	1427 (9,84)
Ultimate Elongation, 100%	37	923
Tear Resistance, Die B, ppi (kN/m)	34-1	166 (27,27)
Specific Gravity	1183	1.13

* 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.

BIO-SIL® 1350 TUBING CHARACTERISTICS**

Method Description	Reference Standard	Result
USP Class VI (raw material)	USP <88>	Meets Criteria
Genotoxicity (Ames)***	ISO 10993-3	Meets Criteria
Hemolysis (direct and indirect)	ISO 10993-4	Meets Criteria
Cytotoxicity (L929)	ISO 10993-5	Meets Criteria

**After gamma, steam and EtO sterilization.
***EtO results in progress.

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BIO-SIL® 1360

Tubing for Medical Device Manufacturers

Bio-Sil® 1360 platinum-cured silicone tubing is engineered for high-purity fluid transfer in demanding medical applications. With a Shore A hardness of 60, it offers enhanced flexibility while maintaining excellent strength and durability. Designed for peristaltic pump performance and long-term reliability, Bio-Sil 1360 is ideal for applications requiring biocompatibility, sterilization compatibility, and consistent mechanical properties.

BIOCOMPATIBILITY CHARACTERISTICS

Bio-Sil 1360 is manufactured from raw materials that meet the requirements of USP<88> and can be classified as USP Plastic Class VI. The finished tubing has been tested and validated to meet ISO 10993 standards for genotoxicity (ISO 10993-3), hemolysis (ISO 10993-4), and cytotoxicity (ISO 10993-5). These tests were performed on tubing sterilized via Ethylene Oxide (EtO), gamma irradiation (25–40 kGy), and steam autoclaving at 121°C, ensuring compatibility with common sterilization methods.

IDEAL CHOICE FOR MEDICAL APPLICATIONS

The physical and chemical characteristics of Bio-Sil 1360 tubing—particularly its 60 Shore A durometer, platinum-cured formulation, and ISO 10993 testings—make it an excellent choice for a wide range of medical applications. Its flexibility and durability support consistent performance in various applications.

Manufactured in France, Bio-Sil 1360 is ideally positioned to support the European medical device market with localized production and supply chain advantages.

FEATURES/BENEFITS

- Tubing has met ISO 10993-3/4/5 criteria
- Bio-Sil 1360 raw material has met USP <88> Class VI criteria
- Compatible with EtO, gamma (25–40 kGy), and steam sterilization
- Designed and manufactured without the intentional addition of animal-derived materials
- Custom sizes available

TYPICAL APPLICATIONS

- Dialysis and blood filtration
- Drug delivery systems
- Infusion and IV therapy
- Peristaltic pump systems
- Respiratory and anesthesia equipment

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.

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BIO-SIL® 1360 TUBING MANUFACTURED SIZES

Part Number	I.D.		O.D.		Wall Thickness		Length	
	inches	mm	inches	mm	inches	mm	feet	m
BS1360-0076-0165	0.03	0.76	0.065	1.65	0.018	0.44	49.2	15
BS1360-0079-0239	0.031	0.79	0.094	2.39	0.032	0.80	49.2	15
BS1360-0102-0216	0.04	1.02	0.085	2.16	0.023	0.57	49.2	15
BS1360-0147-0196	0.058	1.47	0.077	1.96	0.010	0.24	49.2	15
BS1360-0160-0241	0.063	1.60	0.095	2.41	0.016	0.41	49.2	15
BS1360-0160-0318	0.063	1.60	0.125	3.18	0.031	0.79	49.2	15
BS1360-0198-0318	0.078	1.98	0.125	3.18	0.024	0.60	49.2	15
BS1360-0239-0396	0.094	2.39	0.156	3.96	0.031	0.79	49.2	15
BS1360-0264-0488	0.104	2.64	0.192	4.88	0.044	1.12	49.2	15
BS1360-0318-0478	0.125	3.18	0.188	4.78	0.032	0.80	49.2	15
BS1360-0318-0635	0.125	3.18	0.25	6.35	0.063	1.59	49.2	15
BS1360-0335-0465	0.132	3.35	0.183	4.65	0.026	0.65	49.2	15
BS1360-0396-0556	0.156	3.96	0.219	5.56	0.032	0.80	49.2	15
BS1360-0478-0635	0.188	4.78	0.25	6.35	0.031	0.79	49.2	15
BS1360-0478-0795	0.188	4.78	0.313	7.95	0.063	1.59	49.2	15
BS1360-0478-0953	0.188	4.78	0.375	9.53	0.094	2.37	49.2	15
BS1360-0478-1113	0.188	4.78	0.438	11.13	0.125	3.18	49.2	15
BS1360-0635-0795	0.25	6.35	0.313	7.95	0.032	0.80	49.2	15
BS1360-0635-0953	0.25	6.35	0.375	9.53	0.063	1.59	49.2	15
BS1360-0635-1113	0.25	6.35	0.438	11.13	0.094	2.39	49.2	15
BS1360-0635-1270	0.25	6.35	0.5	12.70	0.125	3.18	49.2	15

Custom hardness and dimensions available.

BIO-SIL® 1360 TUBING STERILIZATION METHODS

Physical properties are not significantly impacted by the following sterilization methods:

- Autoclavable (30 min at 250°F/121°C)
- EtO (Ethylene Oxide)
- Gamma irradiation (up to 4 Mrad (40 kGy))

BIO-SIL® 1360 TUBING TYPICAL PHYSICAL PROPERTIES*

Property	ISO	Value or Rating
Durometer Hardness, Shore A (+/-3)	48-4	63
Color	Translucent	
Tensile Strength, psi (MPa)	37	1389 (9,58)
Ultimate Elongation, 100%	37	896
Tear Resistance, Die B, ppi (kN/m)	34-1	155 (27,16)
Specific Gravity	1183	1.15

* 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.

BIO-SIL® 1360 TUBING CHARACTERISTICS**

Method Description	Reference Standard	Result
USP Class VI	USP <88>	Meets Criteria
Genotoxicity (Ames)	ISO 10993-3	Meets Criteria
Hemolysis (direct and indirect)	ISO 10993-4	Meets Criteria
Cytotoxicity (L929)	ISO 10993-5	Meets Criteria

**After gamma, steam and EtO sterilization.

NOTE: The information provided pertains only to product manufactured at the Saint-Gobain Saint-Quentin-Fallavier facility (France). Saint-Gobain Performance Plastics France ("Saint-Gobain") products that are used as components in the manufacture of medical devices (as defined by Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices) are sold by Saint-Gobain only and exclusively to medical devices manufacturers for use in the manufacture, assembly or distribution of their medical devices. This product is not a finished medical device and is not intended for direct use by end users, consumers or patients. Medical device manufacturers, to whom Saint-Gobain acts as a supplier or a subcontractor for finished products, are solely responsible for determining whether their finished products qualify as a medical device and for ensuring compliance with the appropriate certifications and registrations, or other regulatory requirements relevant to their intended markets.

This document provides information to help you assess whether the product generally meets your application needs; it 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; other factors in your use and application may impact such values. No medical, therapeutic, or performance claims are made regarding this product as supplied or delivered.

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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^2)	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.

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BIO-SIL® 1450 TUBING MANUFACTURED SIZES**

Part Number	I.D.		O.D.		Wall Thickness		Length
	inches	mm	inches	mm	inches	mm	feet
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, In Vitro: MEM Elution Test	USP <87>	Meets Criteria
Biological Reactivity Tests, *In Vivo*: Agar Diffusion Test	USP <87>	Meets Criteria
Biological Reactivity Tests, *In Vivo*: Direct Contact	USP <87>	Meets Criteria
Biologic Reactivity Tests, *In Vivo*: As Manufactured Samples	USP <88>, Class VI	Meets Criteria
Biologic Reactivity Tests, *In Vivo*: Post-Gamma Irradiation Samples	USP <88>, Class VI	Meets Criteria
Biologic Reactivity Tests, *In Vivo*: 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.

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BIO-SIL® 1465

Tubing for Medical Device Manufacturers

Bio-Sil® 1465 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 65 Shore A durometer and is ideally suited for medical applications where strength, durability, pump performance and biocompatibility are of primary importance.

BIOCOMPATIBILITY CHARACTERISTICS

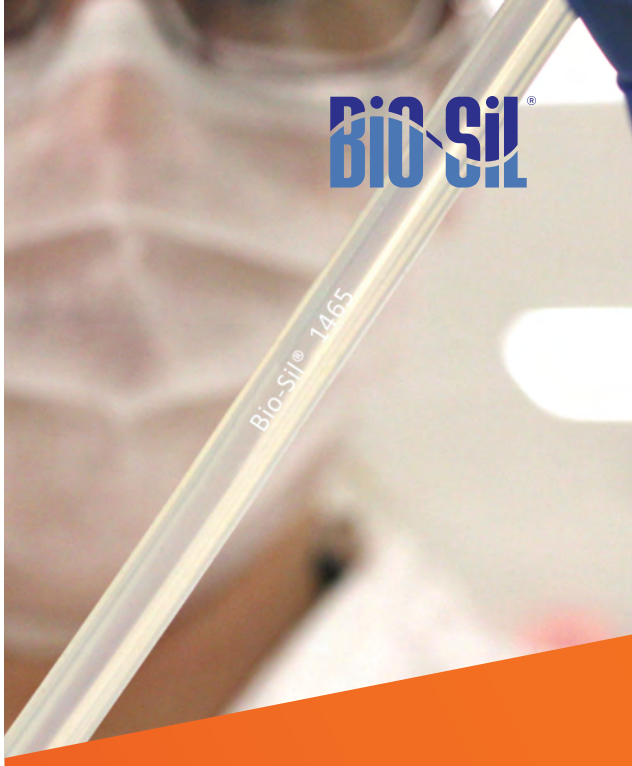
Bio-Sil 1465 tubing has been tested to various elements of ISO 10993 and United States Pharmacopeia standards including cytotoxicity, hemocompatibility, genotoxicity, and USP <88> Class VI plastic material. Bio-Sil 1465 is designed and manufactured without the intentional addition of animal-derived materials or DEHP.

BIO-SIL® 1465
TYPICAL PHYSICAL PROPERTIES*

Property	ASTM Method	Value or Rating
Durometer Hardness, Shore A, 15 sec.	D2240	65
Color	—	Translucent
Tensile Strength, psi (MPa)	D412	1,373 (9.47)
Ultimate Elongation, 100%	D412	608
Tear Resistance, Die B, ppi (kN/m)	D624	179 (31.3)
Specific Gravity	D792	1.17
Water Absorption, % 24 hrs. at 23°C	D570	0.10
Compression Set Under Constant Deflection, % at 158°F (70°C) for 22 hrs.	D395	60
Maximum Recommended Operating Temp.,°F (°C)	—	165 (74)
Brittleness by Impact Temp., °F (°C)	D746	-44 (-42)
Tensile Modulus, at 100% Elongation, psi (MPa)	D412	302 (2.08)

* 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.

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.



FEATURES/BENEFITS

- Bio-Sil 1465 has met the criteria of various ISO 10993 and USP tests
- Regular evaluations to ensure REACH compliance
- Platinum-cured silicone tubing
- Custom sizes available

TYPICAL APPLICATIONS

- Blood and IV solutions
- Chemotherapy drug delivery
- Dialysis equipment
- Peristaltic pumps
- Respiratory therapy

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BIO-SIL® 1465 TUBING

BIO-SIL® 1465 TUBING MANUFACTURED SIZES**

Part Number	I.D.		O.D.		Wall Thickness		Length
	inches	mm	inches	mm	inches	mm	feet
BS1465-012-025	0.0120	0.305	0.025	0.635	0.007	0.178	25
BS1465-020-037	0.020	0.508	0.037	0.940	0.009	0.229	25
BS1465-020-083	0.020	0.508	0.083	2.108	0.031	0.794	50
BS1465-025-047	0.025	0.635	0.047	1.194	0.011	0.279	50
BS1465-030-065	0.030	0.762	0.065	1.651	0.018	0.457	50
BS1465-031-094	0.031	0.794	0.094	2.381	0.031	0.794	50
BS1465-040-085	0.040	1.016	0.085	2.159	0.023	0.584	50
BS1465-058-077	0.058	1.473	0.077	1.956	0.010	0.254	50
BS1465-063-095	0.063	1.588	0.095	2.413	0.017	0.432	50
BS1465-063-125	0.063	1.588	0.125	3.175	0.031	0.794	50
BS1465-078-125	0.078	1.981	0.125	3.175	0.023	0.584	50
BS1465-094-156	0.094	2.381	0.156	3.969	0.031	0.794	50
BS1465-104-192	0.104	2.642	0.192	4.877	0.044	2.642	50
BS1465-125-188	0.125	3.175	0.188	4.763	0.031	0.794	50
BS1465-125-250	0.125	3.175	0.250	6.350	0.063	1.588	50
BS1465-132-183	0.132	3.353	0.183	4.648	0.026	0.660	50
BS1465-156-219	0.156	3.969	0.219	5.556	0.031	0.794	50
BS1465-188-250	0.188	4.763	0.250	6.350	0.031	0.794	50
BS1465-188-313	0.188	4.763	0.313	7.938	0.063	1.588	50
BS1465-188-375	0.188	4.763	0.375	9.525	0.094	2.381	50
BS1465-188-438	0.188	4.763	0.438	11.113	0.125	3.175	50
BS1465-250-313	0.250	6.350	0.313	7.938	0.031	0.794	50
BS1465-250-375	0.250	6.350	0.375	9.525	0.063	1.588	50
BS1465-250-438	0.250	6.350	0.438	11.113	0.094	2.381	50
BS1465-250-500	0.250	6.350	0.500	12.700	0.125	3.175	50
BS1465-313-438	0.313	7.938	0.438	11.113	0.063	1.588	50
BS1465-313-500	0.313	7.938	0.500	12.700	0.094	2.381	50
BS1465-313-563	0.313	7.938	0.563	14.300	0.125	3.175	50
BS1465-375-500	0.375	9.525	0.500	12.700	0.063	1.588	50
BS1465-375-563	0.375	9.525	0.563	14.288	0.094	2.381	50
BS1465-375-625	0.375	9.525	0.625	15.875	0.125	3.175	50
BS1465-500-625	0.500	12.700	0.625	15.875	0.063	1.588	50
BS1465-500-688	0.500	12.700	0.688	17.463	0.094	2.381	25
BS1465-500-750	0.500	12.700	0.750	19.050	0.125	3.175	25
BS1465-625-875	0.625	15.875	0.875	22.225	0.125	3.175	25
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**Custom sizes also available

BIO-SIL® 1465 CHARACTERISTICS

Method Description	Reference Standard	Result
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Hemolysis - Direct Contact	ASTM F756-00	Meets Criteria
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Irritation and Skin Sensitization: Kligman Maximization Test	ISO 10993-10	Meets Criteria
Systemic Toxicity: Systemic Injection	ISO 10993-11	Meets Criteria
Biological Reactivity Tests, *In Vitro*	USP <87>	Meets Criteria
Biologic Reactivity Tests, *In Vitro*: As Manufactured Irradiation Samples	USP <88>	Meets Criteria
Biologic Reactivity Tests, *In Vitro*: Post-Gamma Irradiation Samples	USP <88>	Meets Criteria
Biologic Reactivity Tests, *In Vitro*: Post-Autoclave Samples	USP <88>	Meets Criteria
Particulate Matter	USP <788>	<1 Particle/ mL for each category
LAL Gel Clot Endotoxin	USP <85>	Meets Criteria
Systemic Toxicity: Rabbit Pyrogen	ISO 10993-11 & USP <151>	Meets Criteria
Bacteriostasis & Fungistasis	USP <71>	Meets Criteria
Bioburden Enumeration	ANSI/AAMA/ ISO 11737-1	19 CFU/ Device (Average)
Elastomeric Closures for Injection	USP <381>	Meets Criteria
Physicochemical Tests for Plastics	USP <661>	Meets Criteria
Rubber Closure for Aqueous Infusions	JP 59	Meets Criteria
Silicone Elastomer for Closures and Tubing	EP 3.1.9	Meets Criteria

BIO-SIL® 1465 TUBING STERILIZATION METHODS

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

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