

# BIO-SIL<sup>®</sup>

## 1465

### Tubing for Medical Device Manufacturers

Bio-Sil<sup>®</sup> 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<sup>®</sup> 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.




Bio-Sil<sup>®</sup> 1465

#### 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

# BIO-SIL® 1465 TUBING

## BIO-SIL® 1465 TUBING MANUFACTURED SIZES\*\*

Part Number	I.D.		O.D.		Wall Thickness		Length feet
	inches	mm	inches	mm	inches	mm	
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
BS1465-750-1000	0.750	19.050	1.000	25.400	0.125	3.175	10
BS1465-1000-1250	1.000	25.400	1.250	31.750	0.125	3.175	10

\*\*Custom sizes also available

## BIO-SIL® 1465 CHARACTERISTICS

Method Description	Reference Standard	Result
Genotoxicity	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>	USP <87>	Meets Criteria
Biologic Reactivity Tests, <i>In Vitro</i> : As Manufactured Irradiation Samples	USP <88>	Meets Criteria
Biologic Reactivity Tests, <i>In Vitro</i> : Post-Gamma Irradiation Samples	USP <88>	Meets Criteria
Biologic Reactivity Tests, <i>In Vitro</i> : 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)

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.

