

Saint-Gobain Life Sciences – Bioprocess Solutions

SAINT-GOBAIN



C-Flex® TPE Tubing

for Biopharmaceutical Applications

C-Flex® sealable and weldable tubing

C-Flex® is the original patented thermoplastic elastomer tubing specifically designed to meet the critical demands of pharmaceutical and biopharmaceutical applications for fluid processing with excellent heat seal and sterile weld capabilities.

The material difference

For over 30 years, C-Flex® has been the thermoplastic elastomer tubing most widely used and validated by the world's leading pharmaceutical and biopharmaceutical companies. Each coil of C-Flex® tubing is extruded to precise ID and wall dimensions.

C-Flex® tubing is part of a family of TPE tubing offering the widest range of formulations and sizes in the industry including C-Flex® 082 and 374 translucent tubing for fluid flow visibility, and C-Flex® 072 opaque for peristaltic pump and light sensitivity applications. For applications demanding higher pressure, C-Flex® Braided combines a polyester fiber reinforcement with C-Flex® 082 material. C-Flex® tubing has a secure global supply chain with redundant manufacturing sites in the United States and Europe with validated manufacturing processes.

Biocompatible

C-Flex® tubing is manufactured from pharmaceutical-grade thermoplastic materials and tested to a variety of specifications including:

USP Class VI	ISO 10993-5 (Cytotoxicity, In-Vitro)
ISO 10993-3 (Ames Genotoxicity)	ISO 10993-11 (Systemic Toxicity, In-Vivo)
ISO 10993-4 (Hemolysis, Indirect)	European Pharmacopeia 3.2.9

For additional test data visit www.biopharm.saint-gobain to download the Validation Guide and the Regulatory Information Overview (RIO) or contact your customer service department.

Features / Benefits

- Sealable and weldable either pre- or post-sterilization
- C-Flex® 072 provides prolonged pump life
- Sterilizable by gamma irradiation and autoclave
- Product Validation Test Summaries available upon request
- Moldable, bondable and formable for single-use assemblies and overmolds
- Temperature range -67°C to 135°C (-85°F to 275°F)
- Significantly less permeable than silicone
- All formulas are Animal-Derived Component Free
- Multiple Manufacturing sites

Typical Applications

- Aseptic sealing disconnections
- · Aseptic welding connections
- Peristaltic Pump
- Ideal for use in single-use assemblies
- Buffer and media preparation
- Cell culture operations
- Single-use fluid transfer sets
- Tubing and bags manifolds



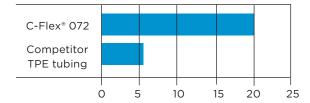
Typical physical properties of C-Flex®

A CTM Madde and	Formulations Value or Rating				
ASIM Method	374	082 072 Translucent Opaqu 60 60 1106 1196 874 862	072		
_	Translucent	Translucent	Opaque		
D2240	60	60	60		
D412	1190	1106	1196		
D412	915	874	862		
D412	244/385	256/400	247/389		
D412	24	29	26		
D395	83	89	86		
D746	-66	-67	-68		
	D412 D412 D412 D412 D395	ASTM Method 374 - Translucent D2240 60 D412 1190 D412 915 D412 244/385 D412 24 D395 83	ASTM Method 374 082 - Translucent Translucent D2240 60 60 D412 1190 1106 D412 915 874 D412 244/385 256/400 D412 24 29 D395 83 89		

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

Comparative opaque TPE peristaltic pump tubing life

The table below shows average hours until rupture of 1/4" ID x 3/8" OD (6.4 mm x 9.5 mm) tubing having undergone gamma irradiation. Samples were pumped using a 3-roller pump head operating at 300 rpm with 10 psi back pressure, at room temperature.



The performance of tubing in peristaltic pumping applications is affected by the conditions of use and equipmen utilized, along with size and all thickness of the tubing tested. The data above is presented for information only and should not be utilized for specification purposes.



C-Flex® comes in a wide variety of sizes and formulations.



One-piece overmolded C-Flex* manifold maintains inner bore diameters with superior reliability and product integrity.

Chemical resistance					
Acids, Dilute/Weak	Acceptable				
Acids, Strong/Concentrated	Acceptable				
Bases, Dilute/Weak	Acceptable				
Bases, Strong/Concentrated	Acceptable				
Salts	Acceptable				
High-purity Water	Acceptable				
Alcohol	Not recommended*				
Oil/Water Emulsion	Test before using				
Organic Solvent	Not recommended				

^{*}Brief or intermittent contact is acceptable.

NOTE: It is the users responsibility to insure the suitability and safety of C-Flex* for all intended uses/applications.

Sterilization Methods

Autoclavable	one time 30 minute cycle at 121°C
Gamma Irradiation	one time up to 40kGy

NOTE: C-Flex* tubing will deteriorate with repeated autoclaving. Radiation is the recommended method of sterilization for all C-Flex* thermoplastic materials.

Characteristics

The manufacturing process is carefully controlled from raw material compounding through finished production. Inspection and lot traceability information is readily accessible as batch numbers are assigned. All packages are identified by external labeling on both the bag and the crush-proof box.

Saint-Gobain Performance Plastics' manufacturing facilities have the ability to create a variety of sizes or coil lengths for your particular application needs. Contact us for a quote to meet your specific requirements.

C-Flex® tubing standard size

Part Numbers (1)	Standard Coil Length	ID x OD x Wall (inch)	ID x OD (inch fractions)	ID x OD x Wall (millimeters)	Average Working Pressure (psi): 66°F (19°C)					
					C-Flex® 072		C-Flex® 082		C-Flex® 374	
					psi	bar	psi	bar	psi	bar
xxx-031-1	50′ (15 m)	0.031 x 0.094 x 0.031	0.03 x 0.09	0.8 x 2.4 x 0.8	36	2.5	30	2.1	30	2.1
xxx-063-1	50' (15 m)	0.063 x 0.125 x 0.031	0.06 x 0.13	1.6 x 3.2 x 0.8	21	1.4	21	1.4	19	1.3
xxx-063-2	50' (15 m)	0.063 x 0.188 x 0.062	0.06 x 0.19	1.6 x 4.8 x 1.6	49	3.4	46	3.2	38	2.6
xxx-125-2	50' (15 m)	0.125 x 0.250 x 0.062	0.13 x 0.25	3.2 x 6.4 x 1.6	32	2.2	27	1.9	25	1.7
xxx-188-2	50' (15 m)	0.188 x 0.313 x 0.062	0.19 x 5/16	4.8 x 8.0 x 1.6	24	1.7	22	1.5	22	1.5
xxx-188-3	50' (15 m)	0.188 x 0.375 x 0.094	0.19 x 0.38	4.8 x 9.5 x 2.4	42	2.9	36	2.5	30	2.1
xxx-250-2	50' (15 m)	0.250 x 0.375 x 0.062	0.25 x 0.38	6.4 x 9.5 x 1.6	20	1.4	17	1.2	16	1.1
xxx-250-3	50' (15 m)	0.250 x 0.438 x 0.094	0.25 x 0.44	6.4 x 11.2 x 2.4	26	1.8	23	1.6	21	1.5
xxx-250-4	50' (15 m)	0.250 x 0.500 x 0.125	0.25 x 0.5	6.4 x 12.7 x 3.2	27	1.9	30	2.0	31	2.1
xxx-313-3	50' (15 m)	0.313 x 0.500 x 0.094	0.31 x 0.5	7.9 x 12.7 x 2.4	21	1.5	20	1.4	20	1.4
xxx-375-2	50' (15 m)	0.375 x 0.500 x 0.062	0.38 x 0.5	9.6 x 12.7 x 1.6	11	0.8	12	0.8	12	0.9
xxx-375-3	50′ 15 m)	0.375 x 0.563 x 0.094	0.38 x 0.56	9.6 x 14.3 x 2.4	19	1.3	16	1.1	18	1.2
xxx-375-4	50' (15 m)	0.375 x 0.625 x 0.125	0.38 x 0.63	9.6 x 15.9 x 3.2	24	1.6	21	1.4	20	1.4
xxx-500-3	50' (15 m)	0.500 x 0.688 x 0.094	0.5 x 10.69	12.7 x 17.4 x 2.4	14	1.0	13	0.9	22	1.5
xxx-500-4	50' (15 m)	0.500 x 0.750 x 0.125	0.5 x 0.75	12.7 x 19.1 x 3.2	17	1.2	15	1.1	16	1.1
xxx-625-4	50' (15 m)	0.625 x 0.875 x 0.125	0.63 x 0.88	15.9 x 22.2 x 3.2	16	1.1	13	0.9	14	0.9
xxx-750-4	15′ 4.5 m)	0.750 x 1.00 x 0.125	0.75 x 1	19.0 x 25.4 x 3.2	13	0.9	11	0.8	11	0.8
xxx-750-6	15′ (4.5 m)	0.750 x 1.125 x 0.188	0.75 x 1.13	19.0 x 28.3 x 4.8	16	1.1	15	1.0	20	1.4
xxx-750-8	15' (4.5 m)	0.750 x 1.250 x 0.250	0.75 x 1.25	19.0 x 31.7 x 6.4	21	1.5	19	1.3	20	1.4
xxx-1000-6	15′ (4.5 m)	1.00 x 1.375 x 0.188	1 x 1.38	25.4 x 34.9 x 4.8	13	0.9	11	0.8	15	1.0
xxx-1000-8	15' (4.5 m)	1.00 x 1.500 x 0.250	1 x 1.5	25.4 x 38.1 x 6.4	17	1.1	15	1.0	15	1.1

(1) FORMULAS: (xxx)

072 - Opaque

082 - Translucent

374 - Translucent

Working pressures are calculated at a 3:1 ratio relative to burst pressure using ASTM D1599 and ISO 7751

The values values listed for working and burst pressures are derived from tests conducted in laboratory conditions on unsterilized tubing. Many factors will reduce the tubing's ability to withstand pressure, including sterilization method, temperature, chemical compatibility, stress, pulsation and the attachment to fittings. It is imperative that the user conduct tests simulating the conditions of the application prior to specifying the tubing for use.



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IMPORTANT: It is the user's responsibility to ensure the suitability and safety of Saint-Gobain Life Sciences products for all intended uses and that the materials to be used comply with all applicable medical regulatory requirements. Saint-Gobain Life Sciences assumes no responsibility for any product failures that occur due to misuse of the materials it provides arising out of the design, fabrication or application of the products into which the materials are incorporated.

WARRANTY: For a period of 12 months from the date of first sale, Saint-Gobain Life Sciences warrants this product to be free of defects in materials and workmanship. Our only obligation will be to replace any portion proving defective, or at our option, to refund the purchase price there of.

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