



Saint-Gobain
Life Sciences –
Medical Components

An alternative to phthalate-based PVC.

This tubing is not made with phthalate.

C-Flex® Tubing for Medical Device Manufacturers

C-Flex® Thermoplastic Elastomer Medical Tubing

C-Flex® offers a wide range of formulations, sizes and opaqueness for all of the medical device manufacturer's needs. All products are also available in custom sizes, lengths and packaging.

Characteristics

C-Flex® combine the processing advantages of thermoplastics with the properties of vulcanized rubber. When heated, thermoplastic elastomers melt and can be extruded or formed into complex shapes using standard thermoplastic melt processing equipment. As solids, thermoplastic elastomers are soft, flexible and resilient like rubber and can reground and reprocessed without significant property loss.

C-Flex®'s patented formulations range in hardness from 5 Shore through 95 Shore A and can be extruded as tubing along with custom profiles. C-Flex® is not made with any latex rubber, polyvinyl chloride, silicone rubber or polyurethane, and it is not made with DEHP.

Biocompatibility

C-Flex® formulations are made from raw materials tested for biocompatibility and are formulated to meet the rigorous testing standards of the medical device industry and meets the requirement of the USP <88>, Plastic Class VI .

Features / Benefits

- Significantly fewer TOC extractables than PVC
- Not made with materials of animal origin
- Tested for Biocompatibility
- Silicone alternative
- Not made with DEHP
- PVC alternative
- Clear and opaque formulations

Typical Applications

- Fluid Transfer Tubing



Typical Physical Properties of C-Flex®

| Property | Reference | FORMULATION | | |
|---|------------|-------------|-------------|---------|
| | | 374 | 082 | 072 |
| Appearance | - | Translucent | Translucent | Opaque |
| Durometer, Shore A | ASTM D2240 | 60 | 60 | 60 |
| Tensile Strength, psi | ASTM D412 | 1190 | 1106 | 1196 |
| Elongation, % | ASTM D412 | 915 | 874 | 862 |
| Tensile Modulus, @100%/300%, psi | ASTM D412 | 244/385 | 256/400 | 247/389 |
| Tensile Set @ 300% Stretch | ASTM D412 | 24 | 29 | 26 |
| Compression Set Constant Defl., "B" (22hrs @ 70°C), % | ASTM D395 | 83 | 89 | 86 |
| Brittle Point, °C | ASTM D746 | -65 | -64 | -66 |
| Low Temperature Flexibility @ -45°C | ASTM D380 | Pass | Pass | Pass |

| 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
- Radiation - 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 through 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

4451 110th Avenue North
Clearwater, FL 33762
Tel: (727) 531-4191
Fax: (727) 530-5603

Saint-Gobain Performance Plastics

La Mothe-aux-Aulnais
F-89120 Charny, France
Tel: (33) 3-86-63-78-78
Fax: (33) 3-86-63-77-77

www.medical.saint-gobain.com

Important: "This Saint-Gobain product is a medical component intended for processing or use in the manufacture or assembly of medical devices before the finished medical device is packaged/labeled; it is intended to be included as part of the finished, packaged, and labeled device [21CFR820.3(c)]. Please refer to our Medical Products Disclaimer at www.medical.saint-gobain.com/resources/regulatory-and-quality/medical-product-disclaimer.

Caution: For manufacturing, processing or repacking"

IMPORTANT: It is the user's responsibility to ensure the suitability and safety of Saint-Gobain Performance Plastics products for all intended uses and that the materials to be used comply with all applicable medical regulatory requirements. Saint-Gobain Performance Plastics 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 Performance Plastics 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 thereof.

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