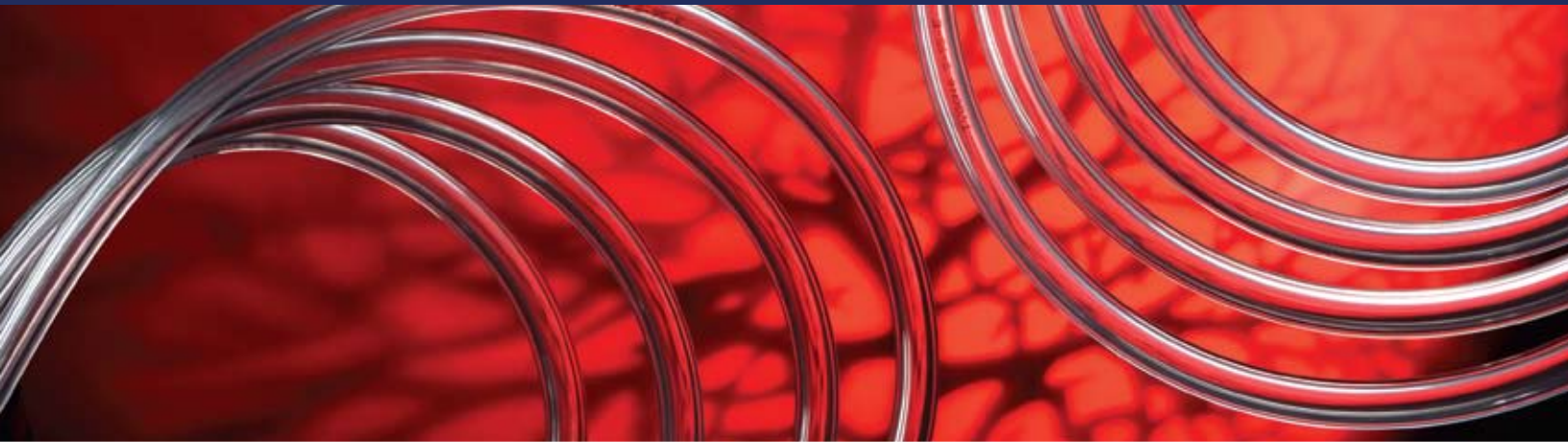


TYGON®

Non-DEHP S-95-E Tubing



Medical Products

The Tubing Standard for ECMO Procedures

Features/Benefits

- Superior peristaltic pump life
- Non-DEHP formulation
- Ideal for contact with blood
- Meets USP Class VI, European Pharmacopoeia 3.1.1.2 and FDA criteria
- Meets ISO 10993 standards
- Withstands both EtO and gamma sterilization
- Registered with the FDA under Master File MAF106

Typical Applications

- Extracorporeal membrane oxygenation (ECMO) pumps
- Kidney dialysis pumps
- Peristaltic pumps
- Blood and IV solutions

TYGON® Non-DEHP S-95-E Tubing

TYGON® S-95-E is a medical-grade, clear, non-DEHP polymer tubing offering superior peristaltic pump life and exceptional flexibility. TYGON® S-95-E is specifically designed for Extracorporeal Membrane Oxygenation (ECMO) and other critical care procedures, including kidney dialysis.

Characteristics

With its longer pump life, TYGON® S-95-E saves time and money by reducing the number of tubing changeovers needed. TYGON® S-95-E features extremely low extractables and is ideal for use in all peristaltic pumping applications involving blood transfer. The standard of the industry for life-saving ECMO procedures, TYGON® S-95-E tubing provides high quality and consistent performance that's unmatched by any other product on the market today.

Biocompatibility

TYGON® S-95-E is made from a biocompatible polymer material developed specifically for medical applications. It meets USP Class VI, ISO 10993 and European Pharmacopoeia 3.1.1.2 standards.

TYGON® S-95-E Typical Physical Properties*

Property	ASTM Method	Value or Rating
Durometer Hardness, Shore A, 15s	D2240-02	66
Tensile Strength, psi (MPa) (at break)	D412-98	2,000 (13.8)
Ultimate Elongation, %	D412-98	390
Tear Resistance, lb-f/inch (kN/m)	D624-91, Die C	130 (22.7)
Specific Gravity	D792-02	1.16
Color	n/a	Clear

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

TYGON® S-95-E Relative Chemical Resistance Properties**

Acids	Bases	Salts	E
concentrated F	concentrated E		
medium E	medium E	Alcohols	F
weak E	weak E	Ketones	U

E=Excellent, F=Fair, U=Unsatisfactory

** All tests conducted at room temperature

TYGON® S-95-E Product Characteristics

ISO 10993 – Cytotoxicity	Pass
ISO 10993 – Hemocompatibility	Pass
ISO 10993 – Pyrogens	Pass
ISO 10993 – Sensitization	Pass
ISO 10993 – Irritation	Pass
ISO 10993 – In Vitro Hemolysis	Pass
ISO 10993 – Genotoxicity	Pass
USP Fungistasis	Pass
USP Physicochemical Testing for Elastomeric Closures	Pass
USP Class VI	Pass
European Pharmacopoeia 3.1.1.2	Pass
C3a Complement Activation Assay	Pass

TYGON® S-95-E Sterilization Methods

Autoclavable	Yes
Gas	Yes
Radiation	Yes (2.5 MRad)

TYGON® tubing is not intended for use as an implant material.

TYGON® is a registered trademark.



Saint-Gobain Performance Plastics

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IMPORTANT: It is the user's responsibility to ensure the suitability and safety of Saint-Gobain Performance Plastics tubing for all intended uses. Laboratory and clinical tests must be conducted in accordance with applicable regulatory requirements in order to determine the safety and effectiveness for use of tubing in any particular application.

For a period of 6 months from the date of first sale, Saint-Gobain Performance Plastics Corporation warrants this product to be free from 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. User assumes all other risk, if any, including the risk of injury, loss or damage, direct or consequential, arising out of the use, misuse, or inability to use, this product. THIS WARRANTY IS IN LIEU OF THE WARRANTIES OF MERCHANTABILITY, FITNESS FOR PARTICULAR PURPOSE, AND ALL OTHER WARRANTIES, EXPRESSED OR IMPLIED. No deviation is authorized.

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