

# TYGON®

Saint-Gobain  
Life Sciences – Medical



## Tygon® Non-DEHP S-97-E Tubing for Medical Device Manufacturers

### The Tubing Standard for ECMO Procedures

Tygon® S-97-E tubing is made from a biocompatible polymer that is not formulated with DEHP. This tubing is crystal clear for easy visualization of fluid flow. The physical properties of Tygon S-97-E offer superior peristaltic pump life and exceptional flexibility.

#### Characteristics

Tygon S-97-E was formulated to meet the requirements of Regulation (EC) 1907/2006 on the Registration, Evaluation, Authorization and Restriction of Chemicals (REACH) and does not contain any reportable substances or chemicals of concern.

Saint-Gobain designed the Tygon S-97-E formulation to have extremely low extractables, long pump life, and excellent blood interaction with the intention of reducing changeovers needed during ECMO (extracorporeal membrane oxygenation).

Tygon ND S-97-E has met the requirements of Biological Test for Plastics Class VI, as described in USP <88>. Tygon S-97-E is not intentionally made or manufactured with animal derived material.

During the extrusion process, individual product dimensions are maintained and monitored through in-line micrometers and off-line verification with computerized imaging equipment. Consistent with many medical tubing market requirements, TYGON S-97-E material can be effectively bonded/welded using the following methods: heat, electronic (RF)/ultrasonic, solvent and adhesive. Factors to be considered when selecting the components include: security of the bond required, effect on the integrity of the Materials to be joined, and presence of residues or extractables that may affect biocompatibility. When bonding procedures are not used, mechanical clamps are recommended to provide secure attachment.

#### Features/Benefits

- Superior peristaltic pump life
- Non-DEHP formulation
- Tygon® S-97-E has met the requirements of various ISO 10993 tests and Biological Test for Plastics Class VI, as described in USP <88> (2014)

#### Typical Applications

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



## Tygon® S-97-E Typical Physical Properties\*\*

Property	ASTM Method	Value or Rating
Durometer Hardness, Shore A, 15s	D2240-02	64
Tensile Strength, psi (MPa) (at break)	D412-98	1,857
Ultimate Elongation, %	D412-98	410
Tensile Modulus, @ 100% Elongation, psi (MPa)	D412-98	977
Tear Resistance, lb-f/inch (kN/m)	D624-91, Die C	198 (25.9)
Specific Gravity	D792-02	1.17
Water Absorption, % 24 hrs. @ 23°C	D570	0.20
Compression Set % @ 158°F (70°C) for 22 hrs.	D395	46
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 strips, 0.075" thick molded ASTM plaques or molded ASTM durometer buttons.

## Tygon® S-97-E Tubing Relative Chemical Resistance Properties\*\*\*

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

E=Excellent, F=Fair, U=Unsatisfactory

\*\*\* All tests conducted at room temperature

## Tygon® S-97-E Tubing Characteristics

Tygon® S-97-E has met the following test requirements:

- Genotoxicity, as described in ISO-10993-3 (2003)\*
- Hemocompatibility, as described in ISO 10993-4 (2006)\*
- In Vitro Hemolysis, as described in ISO 10993-4 (2006)\*
- C3a Complement Activation Assay, as described in ISO 10993-4 (2006)\*
- Cytotoxicity, as described in ISO-10993-5 (2009)\*
- Irritation/Sensitization, as described in ISO 10993-10 (2002)\*
- Fungistasis, as described in USP <71> (2009)\*
- Plastic Class VI, as described in USP <88> (2014)
- Pyrogens, as described in USP <151> (2009)\*
- Physicochemical Testing/Elastomeric Closure, as described in USP<381> (2008)\*
- European-Pharmacopoeia-3.1.1.2 (2005)\*
- USP 10993 - C3a-Complement-Activation-Assay (2006)\*

\*Fluid path only

## Tygon® S-97-E Tubing Sterilization Methods

Autoclavable (Steam 30 min at 15 psi, 250°F / 121°C)	Yes
EtO (Ethylene Oxide)	Yes
Radiation	No

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