

TYGON®

Saint-Gobain
Life Sciences –
Medical Components



Tygon® MPF-300+ Tubing for Medical Device Manufacturers

Tygon® MPF-300+ Tubing

TYGON® MPF-300+ Tubing is made from medical grade, clear non-PVC polymer available directly from Saint-Gobain. This TYGON® tubing formulation is made in an ISO Class 7 cleanroom to meet your medical application needs. This flexible tubing is designed to replace PVC in medical devices in which DEHP plasticizers and leachables are not desired. TYGON® MPF-300+ has excellent bonding strength and is ideally suited for fluid and oxygen administration applications.

Biocompatibility

TYGON® MPF-300+ Tubing is made with a biocompatible polymer material developed specifically for medical applications, that meets ISO 10993 and USP <88>, Plastic Class VI requirements. This tubing is non-pyrogenic and non-toxic in Systemic Toxicity, Intracutaneous Reactivity, Cytotoxicity, Hemocompatibility and Intramuscular Implant tests.

PVC Replacement Tubing – The Right Choice

Increasing concerns in Europe and North America regarding health hazards and environmentally friendly disposal of DEHP plasticizers led to the development of the MPF product line. These products are non-PVC and non-DEHP, and can be disposed of without harmful effects on the environment.

IMPORTANT: "Please refer to our Medical Product Disclaimer at www.medical.saint-gobain.com/resources/regulatory-and-quality/medical-product-disclaimers.

Saint-Gobain's medical products offer covers:

- **Medical Components** [21 CFR 820.3(c)], intended for processing or use in the manufacture or assembly of medical devices before the finished medical device is packaged/labeled; Medical Components are intended to be included as part of the finished, packaged, and labeled device [21CFR820.3(c)].
- **Finished Devices** [21CFR820.3(l)] made on behalf of medical device manufacturers [21 CFR 807.20(a)(2)] under contract-manufacturing agreement. In accordance with the United States' jurisdiction, Saint-Gobain complies with the FDA's requirements for contract manufacturers of finished devices."

Features/Benefits

- Made in ISO Class 7 Cleanroom
- PVC replacement
- Tubing is not made with plasticizers
- EtO and gamma sterilizable
- Meets USP <88>, Plastic Class VI Criteria
- Environmentally safe disposal
- Excellent bonding to plastic connectors

Typical Applications

- Fluid administration
- Oxygen administration



TYGON® MPF-300+ Typical Physical Properties*

Property	ASTM Method	Value or Rating
Durometer Hardness (Shore A), 15 sec.	D2240-02	83
Tensile Strength, psi (MPa) (at break)	D412-98	3,595(41.4)
Ultimate Elongation, %	D412-98	553
Tear Resistance, lb-f/inch (kN/m)	D624-91, Die C	509 (83.1)
Compression Set, Constant Deflection % @ 158°F (70°C) for 22 hours	D395-02 Method B	29
Brittle Temperature, °F (°C)	D746-98	< -112 (-80)
Specific Gravity	D792-02	1.11
Water Absorption, % 24 hours at 73°F (23°C)	D570-98	1.13
Maximum Recommended Operating Temperature °F (°C)	n/a	180 (82)
Tensile Modulus, @ 100% Elongation, psi (MPa)	D412-98	1,546
Color	n/a	Transparent Natural

* 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® MPF-300+ Product Characteristics

ISO 10993 - Cytotoxicity	Non-cytotoxic
ISO 10993 - Hemocompatibility	Non-hemolytic
ISO 10993 - Pyrogens	Non-pyrogenic
USP <88>, Plastic Class VI	Meets criteria

TYGON® MPF-300+ Sterilization Methods

Autoclavable	Yes
Gas	Yes
Radiation	Yes (2.5 MRad)



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TYGON® is a registered trademark.

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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