



## Tygon® ND 100-80 Medical Tubing for Medical Device Manufacturers

TYGON® ND 100-80, one of the medical industry's leading Non-DEHP tubing offerings, has been specifically formulated in a higher durometer that makes it possible to produce smaller diameter tubings with a high resistance to kinking and collapse.

### Characteristics

TYGON® ND 100-80 is available exclusively to medical device manufacturers in five extremely small sizes for use in their medical devices used in intravenous or intra-arterial infusion, and other surgical and hospital applications. It is rigid enough for easy handling, yet soft enough to reduce problems with puncturing.

Since TYGON® ND 100-80 is thermoplastic in nature, it can be fabricated into cannulas or protective sheath products using thermoforming and flaring techniques.

Based upon a unique chemistry developed by Saint-Gobain, TYGON® ND Series tubing was formulated to meet the requirements of Regulation (EC) 1907/2006 on the Registration, Evaluation, Authorization and Restriction of Chemicals (REACH) and Regulation (EU) 2017/745 on medical devices (EU MDR) of not containing any reportable substances or chemicals of concern. Every individual compound lot is tested to ensure DEHP levels are <1000 ppm. 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, ND 100-80 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.

### Biocompatibility

TYGON® ND 100-80 is made from a biocompatible, non-DEHP polymer material developed specifically for medical device needs. The product meets the requirement of the USP <88>, Plastic Class VI criteria. It has extremely good blood interaction characteristics, very low extractable in soapy water and refluxed water. This is rare for a plasticized PVC as usually there will be an increase in extraction in one of those mediums. It is animal derivative free and also lead stabilizer free.

### *From the Experts:*

The most trusted Non-DEHP tubing  
in the Medical Device Industry

### Features/Benefits

- High rigidity for kink resistance
- Compatible with blood
- Clear, with a glass-smooth inner bore
- Reduced flexibility for suction applications
- Meets USP <88>, Plastic Class VI Criteria
- No reportable substances or chemicals of concern for REACH and EU MDR

### Typical Applications

- Intravenous or intra-arterial infusion

### Plasticizer

- TOTM

**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](http://www.medical.saint-gobain.com/resources/regulatory-and-quality/medical-product-disclaimer). **Caution:** For manufacturing, processing or repacking"

## TYGON® ND 100-80 Inventoried Sizes

Part Number	Inside Diameter		Outside Diameter		Wall Thickness		Coil Length	French Sizes	Needle Gauge
	Inches	mm	Inches	mm	Inches	mm			
AAD04091	.010	.25	.030	.76	.010	.25	500	3	30
AAD04103	.020	.51	.060	1.52	.020	.51	500	5	23
AAD04119	.030	.76	.090	2.29	.030	.76	500	7	20 – 21
AAD04127	.040	1.02	.070	1.78	.015	.38	500	6	18 – 20
AAD04133	.050	1.27	.090	2.29	.020	.51	500	7	17 – 18

### TYGON® ND 100-80 Typical Physical Properties

Property	ASTM Method	Value or Rating
Durometer Hardness, Shore A, 15 sec.	D2240	80
Color	—	Clear
Tensile Strength, psi (MPa)	D412	2,625 (18.1)
Ultimate Elongation, %	D412	350
Tear Resistance, lb-f/inch (kN/m)	D1004	275 (48.2)
Specific Gravity	D792	1.22
Water Absorption, % 24 hrs. @ 73°F (23°C)	D570	0.10
Compression Set, Constant Deflection, % @ 158°F (70°C) for 22 hrs.	D395 Method B	59
Maximum Recommended Operating Temp., °F (°C)	—	185 (85)
Brittleness by Impact Temp., °F (°C)	D746	-31 (-35)
Tensile Modulus, @ 100% Elongation, psi (MPa)	D412	1,450 (10.0)

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® ND 100-80 Characteristics

The biocompatibility of TYGON® ND 100-80 has been tested and found to be non-toxic in the following test protocols:

Opacity	Transparent
FDA Approved for Food Contact	No
NSF 51 Standard	No
USP <88>, Plastic Class VI	Meets criteria

### Sterilization Methods

Autoclavable	Yes
Gas	Yes
Radiation	Yes

Saint-Gobain Non-DEHP tubing contains DEHP levels of <1000 ppm.

TYGON® is a registered trademark.



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**IMPORTANT:** It is the user's responsibility to ensure the suitability and safety of Saint-Gobain 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 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, TYGON® is a registered trademark. 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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