

TYGON®

Saint-Gobain
Life Sciences – Medical



Tygon® ND 100-65 Tubing for Medical Device Manufacturers

TYGON® ND 100-65, is the medical industry's leading Non-DEHP tubing offering. Our tubing is formulated specifically to meet the demanding challenges of applications such as dialysis, chemotherapy, drug delivery and minimally invasive surgeries.

Characteristics

Typical applications from open heart surgery to dialysis, ND 100-65 tubing has been specially formulated for medical device manufacturers that require a Non-DEHP plasticized material. ND 100-65 sets the new standard for performance and durability in blood contact applications.

Based upon a unique chemistry developed by Saint-Gobain, TYGON® ND Series tubing was formulated to be 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-100-65 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 100-65 is made from a biocompatible non-DEHP polymer material. It meets the requirement of the USP <88>, Plastic Class VI and ISO 10993. It is also non-hemolytic and non-pyrogenic. 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.

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"

From the Experts:

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

Features/Benefits

- Crystal clear for easy visualization of fluid flow
- Ideal for contact with body fluids
- Non-wetting surface permits complete drainage
- Meets USP <88>, Plastic Class VI Criteria
- No reportable substances or chemicals of concern for REACH and EU MDR

Typical Applications

- Minimally invasive devices
- Blood and IV solutions
- Dialysis equipment
- Inhalation equipment
- Chemotherapy drug delivery
- Kidney dialysis pumps
- Peristaltic pumps

Plasticizer

- TOTM



TYGON® ND 100-65 Manufactured Sizes and Pressures

Part Number	I.D. (inches)	O.D. (inches)	Wall Thickness (inches)	Length (feet)	Minimum Bend Radius (inches)	Max. Suggested Working Pressure at 73°F (psi)*	Vacuum Rating In. of Mercury at 73°F
ADF00001	1/32	3/32	1/32	50	1/8	100	29.9
ADF00002	1/16	1/8	1/32	50	1/4	55	29.9
ADF00003	1/16	3/16	1/16	50	1/8	100	29.9
ADF00004	3/32	5/32	1/32	50	3/8	40	29.9
ADF00005	3/32	7/32	1/16	50	1/4	70	29.9
ADF00006	1/8	3/16	1/32	50	1/2	30	25
ADF00007	1/8	1/4	1/16	50	3/8	55	29.9
ADF00009	5/32	7/32	1/32	50	3/4	25	15
ADF00010	5/32	9/32	1/16	50	1/2	45	29.9
ADF00011	3/16	1/4	1/32	50	1	20	10
ADF00012	3/16	5/16	1/16	50	5/8	40	29.9
ADF00013	3/16	3/8	3/32	50	1/8	55	29.9
ADF00014	3/16	7/16	1/8	50	3/8	70	29.9
ADF00016	1/4	5/16	1/32	50	1-5/8	18	5
ADF00017	1/4	3/8	1/16	50	1	30	25
ADF00018	1/4	7/16	3/32	50	3/4	45	29.9
ADF00019	1/4	1/2	1/8	50	5/8	55	29.9
ADF00022	5/16	7/16	1/16	50	1-3/8	25	15
ADF00023	5/16	1/2	3/32	50	1	35	29.9
ADF00024	5/16	9/16	1/8	50	7/8	45	29.9
ADF00027	3/8	1/2	1/16	50	1-3/4	20	10
ADF00028	3/8	9/16	3/32	50	1-3/8	30	25
ADF00029	3/8	5/8	1/8	50	1-1/8	40	29.9
ADF00032	7/16	9/16	1/16	50	2-1/4	20	8
ADF00033	7/16	5/8	3/32	50	1-3/4	25	18
ADF00034	7/16	11/16	1/8	50	1-3/8	35	29.9
ADF00036	1/2	5/8	1/16	50	2-7/8	18	6
ADF00037	1/2	11/16	3/32	50	2-1/8	25	15
ADF00038	1/2	3/4	1/8	50	1-3/4	30	25
ADF00041	9/16	3/4	3/32	50	2-1/2	20	10
ADF00045	5/8	13/16	3/32	50	3	20	9
ADF00046	5/8	7/8	1/8	50	2-3/8	25	15
ADF00047	5/8	15/16	5/32	50	2	30	25
ADF00053	3/4	1	1/8	50	3-1/4	20	10
ADF00059	7/8	1-1/8	1/8	50	4-1/8	20	8
ADF00062	1	1-1/4	1/8	50	5-1/8	18	5
ADF02002	1/16	1/8	1/32	100	1/4	55	29.9
ADF02003	1/16	3/16	1/16	100	1/8	100	29.9
ADF02004	3/32	5/32	1/32	100	3/8	40	29.9
ADF02006	1/8	3/16	1/32	100	1/2	30	25
ADF02007	1/8	1/4	1/16	100	3/8	55	29.9
ADF02011	3/16	1/4	1/32	100	1	20	10
ADF02012	3/16	5/16	1/16	100	5/8	40	29.9
ADF02017	1/4	3/8	1/16	100	1	30	25
ADF02018	1/4	7/16	3/32	100	3/4	45	29.9
ADF02022	5/16	7/16	1/16	100	1-3/8	25	15
ADF02027	3/8	1/2	1/16	100	1-3/4	20	10
ADF02028	3/8	9/16	3/32	100	1-3/8	30	25
ADF02029	3/8	5/8	1/8	100	1-1/8	40	29.9
ADF02037	1/2	11/16	3/32	100	2-1/8	25	15
ADF02038	1/2	3/4	1/8	100	1-3/4	30	25

*Safety factor of 5:1 ratio of burst pressure to working pressure.

Custom sizes also available

TYGON® ND 100-65 Typical Physical Properties

Property	ASTM Method	Value or Rating
Durometer Hardness, Shore A, 15 sec.	D2240	65
Color	—	Clear
Tensile Strength, psi (MPa)	D412	1,940 (14.3)
Ultimate Elongation, %	D412	373
Tear Resistance, lb-f/inch (kN/m)	D1004	185 (32.4)
Specific Gravity	D792	1.19
Water Absorption, % 24 hrs. @ 23°C	D570	0.10
Compression Set, Constant Deflection, % @ 158°F (70°C) for 22 hrs.	D395	60
Maximum Recommended Operating Temp., °F (°C)	—	165 (74)
Brittleness by Impact Temp., °F (°C)	D746	-44 (-42)
Tensile Modulus, @ 100% Elongation, psi (MPa)	D412	1,109 (5.6)

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 100-65 Characteristics

The biocompatibility of TYGON® ND 100-65 has been tested and found to be non-toxic in the following test protocols:

ISO 10993 – Cytotoxicity	Non-cytotoxic
ISO 10993 – Genotoxicity	Non-genotoxic
ISO 10993 – In Vitro Platelet Aggregation	Meets criteria
ISO 10993 – Irritation/Sensitization	Non-sensitizer
ISO 10993 – Unactivated Partial Thromboplastin Time Assay	Meets criteria
USP <88>, Plastic Class VI	Meets criteria
USP Physicochemical Testing/Plastics	Meets criteria
USP Pyrogens	Non-pyrogenic
USP – Chromogenic Testing	Meets criteria
USP – Chromogenic Validation	Meets criteria
USP Physicochemical Testing/Elastomeric Closures	Meets criteria
C3a Complement Activation Assay	Meets criteria
Hemocompatibility	Non-hemolytic

Sterilization Methods

Autoclavable	Yes
Gas	Yes
Radiation	Yes (2.5 Mrad)

The values listed for working and burst pressures are derived from tests conducted under controlled laboratory conditions. Many factors will reduce the tubing's ability to withstand pressures, including temperature, chemical attack, stress, pulsation and the attachment to fittings. It is imperative that the user conduct tests simulating the conditions of the application prior to specifying the tubing for use.

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

TYGON® is a registered trademark.



Saint-Gobain
2664 Gilchrist Road
Akron, OH 44305
Tel: 800-798-1554
Tel: (330) 798-9240

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

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.

Saint-Gobain assumes no obligations or liability for any advice furnished by it, or for results obtained with respect to those products. All such advice is given and accepted at the buyer's risk.