

TYGON®

ND 100-65 Medical Tubing

Medical Products

From the ND Experts:
The next generation in non-DEHP tubing

Features/Benefits

- Crystal clear for easy visualization of fluid flow
- Ideal for contact with bodily fluids
- Non-wetting surface permits complete drainage
- Meets USP Class VI criteria
- REACH compliant
- Withstands EtO, gas and gamma sterilization

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 Tubing

TYGON® ND 100-65, one of the medical industry's first non-DEHP tubing offerings, has been formulated specifically to meet the demanding challenges of applications such as dialysis, chemotherapy drug delivery and minimally invasive surgeries.

Characteristics

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 Registration, Evaluation, Authorization and restriction of Chemical substances (REACH) compliant for DEHP. To ensure compliance, 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 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 developed specifically for blood contact medical device needs. It meets USP Class VI, ISO 10993, European Pharmacopoeia 3.1.1.2 and European REACH requirements. It is also non-hemolytic and non-pyrogenic.

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.

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	2,075 (14.3)
Ultimate Elongation, %	D412	415
Tear Resistance, lb-f/inch (kN/m)	D1004	185 (32.4)
Specific Gravity	D792	1.19
Water Absorption, % 24 hrs. @ 23°C	D570	0.12
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	817 (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	Pass
ISO 10993 – Genotoxicity	Pass
ISO 10993 – In Vitro Platelet Aggregation	Pass
ISO 10993 – Irritation/Sensitization	Pass
ISO 10993 – Unactivated Partial Thromboplastin Time Assay	Pass
USP Class VI	Pass
USP Physicochemical Testing/Plastics	Pass
USP Pyrogens	Pass
USP – Chromogenic Testing	Pass
USP – Chromogenic Validation	Pass
USP Physicochemical Testing/Elastomeric Closures	Pass
C3a Complement Activation Assay	Pass
Hemocompatibility	Pass
European Pharmacopoeia 3.1.1.2	Pass

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.

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

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 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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