# TYGON®

#### Saint-Gobain Life Sciences – Medical



# Tygon<sup>®</sup> ND 100-65 Tubing for Medical Device Manufacturers

Tygon® ND 100-65 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 ND 100-65 make it well suited to meet the challenges of applications such as dialysis, drug delivery, and minimally invasive surgery.

#### Characteristics

The unique chemistry developed by Saint-Gobain enables Tygon ND 100-65 to demonstrate very low extractables in both soapy water and refluxed water, which is rare for this type of material. Tygon ND 100-65 also demonstrates excellent blood interaction characteristics.

Tygon ND Series 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.

Tygon ND 100-65 has been tested to various elements of ISO 10993 and USP including cytotoxicity, hemocompatibility, genotoxicity, and <88> Class VI plastic material (refer to the next page for a detailed list of completed tests). Tygon ND 100-65 is not intentionally made or manufactured with animal derived material.

Consistent with many medical tubing market requirements, Tygon ND 100-65 can be effectively bonded/welded using the following methods: heat, electronic (RF)/ ultrasonic, solvent and adhesive. Consider the following factors when selecting a bonding/welding method: 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.

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#### Features/Benefits

- Crystal clear for easy visualization of fluid flow
- Ideal for contact with body fluids
- High surface tension minimizes hold up volume within tubing
- No reportable substances or chemicals of concern for REACH
- Tygon<sup>®</sup> ND 100-65 has met the criteria of various ISO 10993 and USP tests

#### **Typical Applications**

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



#### Tygon<sup>®</sup> ND 100-65 Tubing 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
ADF02012	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

#### Tygon<sup>®</sup> 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)

psi (MPa)

\*\*\*Unless otherwise noted, all tests were conducted at room temperature (73°F). Values shown were determined on 0.075" thick extruded strip s, 0.075" thick molded ASTM plaques or molded ASTM durometer buttons.

## Tygon<sup>®</sup> ND 100-65 Tubing Characteristics

Tygon<sup>®</sup> ND 100-65 has met the following test requirements:

- Genotoxicity, as described in ISO 10993-3 (Ames Assay 2007)\*
- Hemocompatibility, as described in ISO 10993-4 (2008)\*
- In Vitro Platelet Aggregation, as described in ISO 10993-4 (2007)\*
- Unactivated Partial Thromboplastin Time Assay, as described in ISO 10993-4 (2007)\*
- Cytotoxicity, as described in ISO-10993-5 (2009)\*
- Irritation/Sensitization, as described in ISO 10993-10 (2007)\*
- Plastic Class VI, as described in USP <88> (2022)
- Tests for local effects after implantation, as described in ISO 10993-6 (2016)
- Tests for systemic toxicity, as described in ISO 10993-11 (2017)
- Tests for irritation, as described in ISO 10993-23 (2021) \*Fluid path only

## Tygon<sup>®</sup> ND 100-65 Tubing Sterilization Methods

Autoclavable (steam 30 min at 15 psi, 250°F/121°C)	Yes	
EtO (Ethylene Oxide)	Yes	
Radiation (25 kGy/ 2.5 Mrad)	Yes	

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.

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

Custom sizes also available

Saint-Gobain Performance Plastics Corporation's Life Science ("Saint-Gobain") products that are used as components in the manufacture of any Medical Devices (as defined by the FDA) are sold by Saint-Gobain only and exclusively to Medical Device manufacturers for use in the manufacture, assembly or distribution of their medical devices. In addition, Saint-Gobain may at the request of a Medical Device manufacturers to take at o DEM to manufacture a subcontracted finished product for such Medical Device manufacturers as a medical device.

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