

TYGON®

MEDICAL/SURGICAL TUBING FORMULATION S-50-HL

FEATURES/BENEFITS:

- Crystal Clear for Easy Visualization of Fluid Flow
- Ideal for Contact with Blood
- Flexible and Resilient with Established Performance in Peristaltic Pump Applications
- Non-Wetting Surface Permits Complete Drainage
- Documented Biocompatibility to the ISO 10993 Standard
- Meets USP Class VI Criteria

TYPICAL APPLICATIONS INCLUDE:

- Minimally Invasive Devices
- Medical Laboratories
- Blood and I.V. Solutions
- Dialysis Equipment
- Wound Drainage
- Inhalation Equipment
- Chemotherapy Drug Delivery
- Pharmaceutical Handling

Sets the standard for performance and durability in the extracorporeal circuit and other blood contact applications



Tygon's unparalleled reputation for consistent performance is the result of controlling each formulation ingredient.

TYGON ESTABLISHES THE STANDARD

Since the first open-heart surgery in the 1960s, doctors, surgeons and other healthcare professionals have come to recognize Tygon as the definitive tubing to use with blood in peristaltic pump applications. Today, Tygon S-50-HL continues to be the tubing of choice for bypass procedures as well as for use in numerous clinical, biological and pharmaceutical applications.

With the increasingly complex nature of medical devices used in applications such as chemotherapy, dialysis and minimally invasive surgery, highly specialized modifications of Tygon healthcare tubings have been developed to meet specific demands. While these new challenges have broadened the Tygon family of products, one thing has never changed: the high quality and consistent performance of Tygon tubing.

QUALITY-VALIDATED CONSISTENCY WITH EACH PRODUCTION RUN

Norton compounds its own materials to specific formulation requirements using select ingredients that have been carefully qualified and specified. To ensure formulation integrity, full characterization of chemical make-up and physical property and biological safety testing are performed on each lot of material before it is released to production for extrusion.

Once the compound has been approved, in-process inspection protocols specify exact processing parameters so that tubing clarity and appearance are optimized. Dimensional control starts with custom tooling and is assured through use of continuous in-line laser micrometers and off-line verification with computerized imaging

equipment. Final product inspection can include flow rate testing, burst testing and measurement of other key performance characteristics in Norton's own testing laboratory.

DOCUMENTED BIOCOMPATIBILITY

Demonstrating consistency in material from lot to lot once a medical device or drug is marketed is increasingly important. That is why Norton is the first to fully characterize its medical tubing to the latest ISO 10993 standards and FDA guidelines for biocompatibility. (Refer to the Norton Medical/Healthcare brochure for additional details). Additionally, Tygon S-50-HL tubing fully complies with the requirements of USP XXIII Class VI Criteria and is non-toxic, non-hemolytic and non-pyrogenic.

READILY BONDED TO SIMPLIFY ATTACHMENT

A major factor when selecting a tubing material is the type of component parts to be bonded to the tubing. Effective bonding of Tygon S-50-HL is easily accomplished using a variety of methods including heat, electronic (RF)/ultrasonic, solvent and adhesive. Factors to be considered in 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.

NORTON

≡ NORTON PERFORMANCE PLASTICS ≡

TYGON S-50-HL TUBING INVENTORIED SIZES

Norton Part Number	I.D. (inches)	O.D. (inches)	Wall Thickness (inches)	Length (feet)	Minimum Bend Radius (inches)	Maximum Working Pressure at 73°F (psi)*	Vacuum Rating In. of Mercury at 73°F
AA00001	1/32	3/32	1/32	50	1/8	100	29.9
AA00002	1/16	1/8	1/32	50	1/4	55	29.9
AA00003	1/16	3/16	1/16	50	1/8	100	29.9
AA00004	3/32	5/32	1/32	50	3/8	40	29.9
AA00005	3/32	7/32	1/16	50	1/4	70	29.9
AA00006	1/8	3/16	1/32	50	1/2	30	25
AA00007	1/8	1/4	1/16	50	3/8	55	29.9
AA00009	5/32	7/32	1/32	50	3/4	25	15
AA00010	5/32	9/32	1/16	50	1/2	45	29.9
AA00011	3/16	1/4	1/32	50	1	20	10
AA00012	3/16	5/16	1/16	50	5/8	40	29.9
AA00013	3/16	3/8	3/32	50	1/2	55	29.9
AA00014	3/16	7/16	1/8	50	3/8	70	29.9
AA00016	1/4	5/16	1/32	50	1-5/8	18	5
AA00017	1/4	3/8	1/16	50	1	30	25
AA00018	1/4	7/16	3/32	50	3/4	45	29.9
AA00019	1/4	1/2	1/8	50	5/8	55	29.9
AA00022	5/16	7/16	1/16	50	1-3/8	25	15
AA00023	5/16	1/2	3/32	50	1	35	29.9
AA00024	5/16	9/16	1/8	50	7/8	45	29.9
AA00027	3/8	1/2	1/16	50	1-3/4	20	10
AA00028	3/8	9/16	3/32	50	1-3/8	30	25
AA00029	3/8	5/8	1/8	50	1-1/8	40	29.9
AA00032	7/16	9/16	1/16	50	2-1/4	20	8
AA00033	7/16	5/8	3/32	50	1-3/4	25	18
AA00034	7/16	11/16	1/8	50	1-3/8	35	29.9
AA00036	1/2	5/8	1/16	50	2-7/8	18	6
AA00037	1/2	11/16	3/32	50	2-1/8	25	15
AA00038	1/2	3/4	1/8	50	1-3/4	30	25
AA00041	9/16	3/4	3/32	50	2-1/2	20	10
AA00045	5/8	13/16	3/32	50	3	20	9
AA00046	5/8	7/8	1/8	50	2-3/8	25	15
AA00047	5/8	15/16	5/32	50	2	30	25
AA00053	3/4	1	1/8	50	3-1/4	20	10
AA00059	7/8	1-1/8	1/8	50	4-1/8	20	8
AA00062	1	1-1/4	1/8	50	5-1/8	18	5
AA02002	1/16	1/8	1/32	100	1/4	55	29.9
AA02003	1/16	3/16	1/16	100	1/8	100	29.9
AA02004	3/32	5/32	1/32	100	3/8	40	29.9
AA02006	1/8	3/16	1/32	100	1/2	30	25
AA02007	1/8	1/4	1/16	100	3/8	55	29.9
AA02011	3/16	1/4	1/32	100	1	20	10
AA02012	3/16	5/16	1/16	100	5/8	40	29.9
AA02017	1/4	3/8	1/16	100	1	30	25
AA02018	1/4	7/16	3/32	100	3/4	45	29.9
AA02022	5/16	7/16	1/16	100	1-3/8	25	15
AA02027	3/8	1/2	1/16	100	1-3/4	20	10
AA02028	3/8	9/16	3/32	100	1-3/8	30	25
AA02029	3/8	5/8	1/8	100	1-1/8	40	29.9
AA02037	1/2	11/16	3/32	100	2-1/8	25	15
AA02038	1/2	3/4	1/8	100	1-3/4	30	25

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

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.



IMPORTANT: It is the user's responsibility to ensure the suitability and safety of Norton 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, Norton 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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TYGON S-50-HL TYPICAL PHYSICAL PROPERTIES

Property	ASTM Method	Value or Rating
Durometer Hardness Shore A, 15 Sec	D2240-91	66
Color	—	Clear
Tensile Strength psi (MPa)	D412-92	2,000 (13.8)
Ultimate Elongation, %	D412-92	350
Tensile Modulus, @ 200% Elongation, psi (MPa)	D412-92	1,100 (7.6)
Tensile Set, %	D412-92	76
Tear Resistance lb-f/inch (kN/m) Die B	D624-91	165 (28.9)
Specific Gravity	D792-91	1.20
Water Absorption, % 24 hrs. @ 23°C	D570-81	0.14
Compression Set Constant Deflection, % @158°F (70°C) for 22 hrs.	D395-89 Method B	53
Brittleness By Impact Temp., °F (°C)	D746-79	-55 (-48)
Maximum Recommended Operating Temp., °F (°C)		-165 (74)
Dielectric Strength v/mil (kV/mm)	D149-93 620	(24.4)

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 S-50-HL TOXICOLOGICAL PROFILE

The biocompatibility of Tygon S-50-HL has been tested and found to be non-toxic in the following test protocols:

- USP Systemic Toxicity and Intracutaneous Reactivity
- USP Intramuscular Implant
- MEM Elution Method
- Hemolysis, ASTM Method
- Mucosal Irritation (Extract – Vaginal)
- Sensitization or Allergenicity, Maximization Method
- Ames Mutagenicity
- USP Physico Chemical Tests
- USP Bacteriostasis / Fungistasis
- Limulus Amebocyte Lysate (LAL) Inhibition Test
- USP Pyrogen Test

Copies of test data are available upon request.

TYGON(S-50-HL STERILIZATION METHODS

- Autoclavable – Steam 30 minutes at 15 psi (250(F).
- Radiation – Radiation up to 2.5 MRad.
- Gas – Ethylene Oxide

TYGON LABORATORY TUBING IS NOT INTENDED FOR USE AS AN IMPLANT MATERIAL

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