Sani-Tech® Ultra

The Next Generation

Sani-Tech® Ultra Tubing and Sani-Link® Ultra Manifolds



SAINT-GOBAIN

Sani-Link® Ultra

Platinum-Cured Manifolds



Sani-Link® Ultra Manifolds

The Sani-Link® Ultra manifold is a true industry first and has been awarded a U.S. Patent (No. 6,290,265) for its unique features. Utilizing SIB® (Smooth Inner Bore) technology, Sani-Link® Ultra minimizes the need for fittings, connections or assembly; all leak points and entrapment areas have been eliminated.

Characteristics

Process engineers and designers can specify custom combinations of Sani-Link® Ultra manifold configurations. Sani-Link® Ultra manifolds are available for use with either Sani-Tech® Ultra 50 or Sani-Tech® Ultra 65 tubing. Ultra-low TOCs ensure that contamination by extractables is kept to an absolute minimum.

Sani-Link® Ultra manifolds can be manufactured as part of complete gamma-irradiated assemblies for easy implementation. Assembly components can include filters, bags, tube clamps (e.g., Pure-Fit® TC) and sterile connectors (e.g., Pure-Fit® SC).

Biocompatibility

Sani-Link® Ultra manifolds are manufactured from the finest grade of silicone materials and are fully characterized, validated and tested to a variety of specifications including USP Class VI criteria, ISO 10993 and European Pharmacopoeia 3.1.9. All detailed testing protocols are available on our product validation guide.

Features/Benefits

- Original patented technology (No. 6,290,265)
- Ultra-pure, Ultra-low TOCs
- Fully characterized and tested to all current standards
- Unsurpassed surface smoothness
- Eliminates entrapment, leak points and pulsation, assembly time and fitting connections
- Ready-to-install system in sizes 1/16" to 1" in customized lengths, available in multiple configurations
- Fully autoclavable and sterilizable
- Biologically safe
- Custom striping and identification capabilities
- Complete custom gamma-irradiated or non-gamma irradiated assemblies available

Typical Applications

- Sterile filling
- Peristaltic pumps
- Filtration and fermentation
- Sampling
- Closed collection systems
- Drug delivery and discovery

Sani-Tech® Ultra

Platinum-Cured Silicone Tubing



The Next Generation in Tubing

Sani-Tech® Ultra represents the next generation in ultra-pure platinum-cured silicone tubing. Quite simply, it's a better product. Features like ultra-low extractables and longer pump life were engineered into Ultra by the experienced materials scientists of Saint-Gobain Performance Plastics to meet the stringent requirements of the biopharmaceutical market.

Characteristics

Fluid integrity is vitally important in many biopharmaceutical applications. Sani-Tech® Ultra formulations are manufactured and packaged in a certified clean room from the finest grade of silicone materials. Ultra-low TOCs ensure that contamination by extractables is kept to an absolute minimum, and the formulation imparts no taste or odors. Saint-Gobain Performance Plastics' silicone tubing is known for its superior pump life — and Sani-Tech® Ultra is no exception.

Biocompatibility

Sani-Tech® Ultra is fully characterized, validated and tested to a variety of specifications including USP Class VI, ISO 10993, and European Pharmacopoeia 3.1.9. All detailed testing protocols are available on our product validation guide. Sani-Tech® Ultra has a Master File with the U.S. Food and Drug Administration.

Features/Benefits

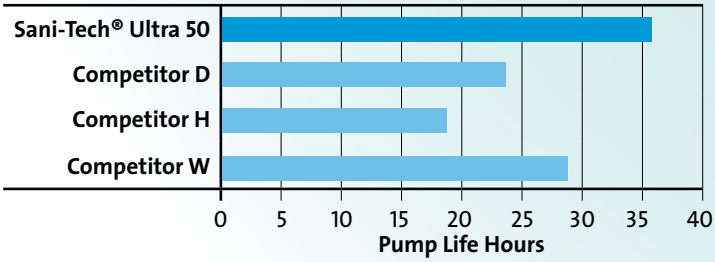
- Biopharmaceutical grade
- Ultra-low extractables
- Excellent flexibility
- Laser etched for lot traceability
- Available in 50 and 65 durometers
- Superior pump life
- Fully autoclavable and sterilizable
- Non-yellowing formulation
- Imparts no taste or odors
- Temperature range from -80°F (-62°C) to 500°F (260°C)
- Meets all USP Class VI, EP 3.1.9, FDA, and ISO criteria

Typical Applications

- Sterile fill and transfers
- Drug delivery
- Cell harvest
- Media processing
- Sanitary peristaltic pump tubing
- Production filtration and fermentation
- Bioreactor process lines

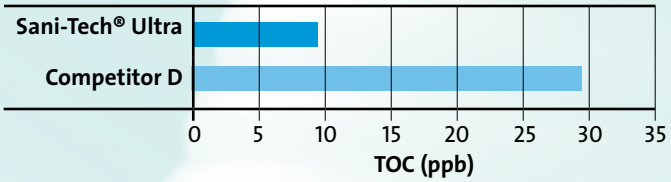
Comparative Peristaltic Pump Tubing Life

The table below depicts hours until failure of 1/4" ID x 3/8" OD tubing. In each case, a 3-roller pump head was utilized operating at 600 RPM at room temperature (73°F).



Comparative Extractables Concentrations

The table below illustrates the TOC concentrations of post autoclaved tubing samples. In each case the samples were subjected to a DI water flush and the effluent was analyzed.



Sani-Tech® Ultra Tubing Available Sizes

Part Number	ID Inches (mm)	OD Inches (mm)	Wall Inches
ULTRA-C-012-0	.012 (.30)	.024 (.61)	.006
ULTRA-C-020-0	.020 (.51)	.036 (.91)	.008
ULTRA-C-025-0	.025 (.64)	.047 (1.2)	.011
ULTRA-C-030-0	.030 (.76)	.066 (1.7)	.018
ULTRA-C-030-2	.030 (.76)	.155 (3.9)	.062
ULTRA-C-040-0	.040 (1.0)	.086 (2.2)	.023
ULTRA-C-058-0	.058 (1.5)	.076 (1.9)	.009
ULTRA-C-062-1	1/16 (1.6)	1/8 (3.2)	1/32
ULTRA-C-062-2	1/16 (1.6)	3/16 (4.7)	1/16
ULTRA-C-062-3	1/16 (1.6)	1/4 (6.4)	3/32
ULTRA-C-062-4	1/16 (1.6)	5/16 (7.9)	1/8
ULTRA-C-062-5	1/16 (1.6)	7/16 (11.1)	3/16
ULTRA-C-062-6*	1/16 (1.6)	9/16 (14.2)	1/4
ULTRA-C-078-1	5/64 (2.0)	9/64 (3.6)	1/32
ULTRA-C-078-2	5/64 (2.0)	13/64 (5.2)	1/16
ULTRA-C-078-3	5/64 (2.0)	17/64 (6.7)	3/32
ULTRA-C-078-4*	5/64 (2.0)	21/64 (8.3)	1/8
ULTRA-C-078-5	5/64 (2.0)	29/64 (11.5)	3/16
ULTRA-C-078-6	5/64 (2.0)	37/64 (14.7)	1/4
ULTRA-C-093-1	3/32 (2.4)	5/32 (4.0)	1/32
ULTRA-C-093-2	3/32 (2.4)	7/32 (5.5)	1/16
ULTRA-C-093-3	3/32 (2.4)	9/32 (7.1)	3/32
ULTRA-C-093-4	3/32 (2.4)	11/32 (8.7)	1/8
ULTRA-C-093-5*	3/32 (2.4)	15/32 (11.9)	3/16
ULTRA-C-093-6*	3/32 (2.4)	19/32 (15.1)	1/4
ULTRA-C-125-1	1/8 (3.2)	3/16 (4.7)	1/32
ULTRA-C-125-2	1/8 (3.2)	1/4 (6.4)	1/16
ULTRA-C-125-3	1/8 (3.2)	5/16 (7.9)	3/32
ULTRA-C-125-4	1/8 (3.2)	3/8 (9.5)	1/8
ULTRA-C-125-5	1/8 (3.2)	1/2 (12.7)	3/16
ULTRA-C-125-6	1/8 (3.2)	5/8 (15.8)	1/4
ULTRA-C-156-1	5/32 (4.0)	7/32 (.5.5)	1/32
ULTRA-C-156-2	5/32 (4.0)	9/32 (7.1)	1/16
ULTRA-C-156-3	5/32 (4.0)	11/32 (8.7)	3/32
ULTRA-C-156-4	5/32 (4.0)	13/32 (10.3)	1/8
ULTRA-C-156-5*	5/32 (4.0)	17/32 (13.5)	3/16
ULTRA-C-156-6	5/32 (4.0)	21/32 (16.7)	1/4
ULTRA-C-187-1	3/16 (4.7)	1/4 (6.4)	1/32
ULTRA-C-187-2	3/16 (4.7)	5/16 (7.9)	1/16
ULTRA-C-187-3	3/16 (4.7)	3/8 (9.5)	3/32
ULTRA-C-187-4	3/16 (4.7)	7/16 (11.1)	1/8
ULTRA-C-187-5	3/16 (4.7)	9/16 (14.2)	3/16
ULTRA-C-187-6	3/16 (4.7)	11/16 (17.4)	1/4
ULTRA-C-250-1	1/4 (6.4)	5/16 (7.9)	1/32
ULTRA-C-250-2	1/4 (6.4)	3/8 (9.5)	1/16
ULTRA-C-250-3	1/4 (6.4)	7/16 (11.1)	3/32
ULTRA-C-250-4	1/4 (6.4)	1/2 (12.7)	1/8
ULTRA-C-250-5*	1/4 (6.4)	5/8 (15.8)	3/16
ULTRA-C-250-6*	1/4 (6.4)	3/4 (19.0)	1/4
ULTRA-C-312-1	5/16 (7.9)	3/8 (9.5)	1/32
ULTRA-C-312-2	5/16 (7.9)	7/16 (11.1)	1/16
ULTRA-C-312-3	5/16 (7.9)	1/2 (12.7)	3/32
ULTRA-C-312-4	5/16 (7.9)	9/16 (14.3)	1/8
ULTRA-C-312-5	5/16 (7.9)	11/16 (17.4)	3/16
ULTRA-C-312-6*	5/16 (7.9)	13/16 (20.6)	1/4
ULTRA-C-375-1*	3/8 (9.5)	7/16 (11.1)	1/32
ULTRA-C-375-2	3/8 (9.5)	1/2 (12.7)	1/16
ULTRA-C-375-3	3/8 (9.5)	9/16 (14.3)	3/32
ULTRA-C-375-4	3/8 (9.5)	5/8 (15.9)	1/8
ULTRA-C-375-5	3/8 (9.5)	3/4 (19.0)	3/16
ULTRA-C-375-6*	3/8 (9.5)	7/8 (22.2)	1/4
ULTRA-C-500-1*	1/2 (12.7)	9/16 (14.3)	1/32
ULTRA-C-500-2	1/2 (12.7)	5/8 (15.9)	1/16
ULTRA-C-500-3	1/2 (12.7)	11/16 (17.4)	3/32
ULTRA-C-500-4	1/2 (12.7)	3/4 (19.1)	1/8
ULTRA-C-500-5	1/2 (12.7)	7/8 (22.2)	3/16
ULTRA-C-500-6*	1/2 (12.7)	1 (25.4)	1/4
ULTRA-C-625-1*	5/8 (15.9)	11/16 (17.4)	1/32
ULTRA-C-625-2	5/8 (15.9)	3/4 (19.1)	1/16
ULTRA-C-625-3*	5/8 (15.9)	13/16 (22.2)	3/32
ULTRA-C-625-4	5/8 (15.9)	7/8 (22.2)	1/8
ULTRA-C-625-5	5/8 (15.9)	1 (25.4)	3/16
ULTRA-C-625-6*	5/8 (15.9)	1-1/8 (28.5)	1/4
ULTRA-C-750-1*	3/4 (19.1)	13/16 (20.6)	1/32
ULTRA-C-750-2*	3/4 (19.1)	7/8 (22.2)	1/16
ULTRA-C-750-3*	3/4 (19.1)	15/16 (23.8)	3/32
ULTRA-C-750-4	3/4 (19.1)	1 (25.4)	1/8
ULTRA-C-750-5	3/4 (19.1)	1-1/8 (28.5)	3/16
ULTRA-C-750-6	3/4 (19.1)	1-1/4 (31.7)	1/4
ULTRA-C-875-1*	7/8 (22.2)	15/16 (23.8)	1/32
ULTRA-C-875-2	7/8 (22.2)	1 (25.4)	1/16
ULTRA-C-875-3*	7/8 (22.2)	1-1/16 (26.9)	3/32
ULTRA-C-875-4	7/8 (22.2)	1-1/8 (28.5)	1/8
ULTRA-C-875-5	7/8 (22.2)	1-1/4 (31.7)	3/16
ULTRA-C-875-6	7/8 (22.2)	1-3/8 (34.9)	1/4
ULTRA-C-1000-1*	1 (25.4)	1-1/16 (26.9)	1/32
ULTRA-C-1000-2*	1 (25.4)	1-1/8 (28.5)	1/16
ULTRA-C-1000-3*	1 (25.4)	1-3/16 (30.1)	3/32
ULTRA-C-1000-4	1 (25.4)	1-1/4 (31.7)	1/8
ULTRA-C-1000-5	1 (25.4)	1-3/8 (34.9)	3/16
ULTRA-C-1000-6	1 (25.4)	1-1/2 (38.1)	1/4

** Please consult factory for availability*

Typical Physical Properties

Property	ASTM Method	Ultra 50 Value or Rating (metric)	Ultra 65 Value or Rating (metric)
Durometer Hardness Shore A, 15 Sec	D2240	50	65
Tensile Strength psi (MPa)	D412	1293 (8.91 MPa)	1373 (9.47 MPa)
Ultimate Elongation, 100%	D412	719	608
Tear Resistance ppi (kN/m)	D624	185 (32.4 Kn/M)	179 (31.3 Kn/M)
Specific Gravity	D792	1.14	1.17
Tensile Modulus, at 200% elongation psi (MPa)	D412	200 (1.38 MPa)	302 (2.08 MPa)

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.

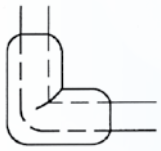
Sani-Tech® Ultra Options

- Custom laylines
- Gamma irradiated
- Bulk spool packaging
- Custom sizes available
- Available in custom lengths and durometers

Sterilization Methods

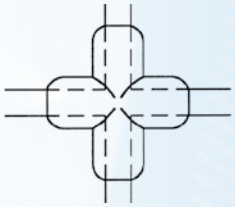
- Autoclavable
- Radiation – up to 5.0 Mrad (50 Kilogray)
- Gas – ethylene oxide

Sani-Link® Ultra Manifolds *(consult factory for additional sizes)*



Sani-Link® Ultra Elbow

Available Sizes
1/8" x 1/4" O.D.
1/8" x 5/8" O.D.
1/4" x 7/16" O.D.
1/4" x 1/2" O.D.
1/4" x 5/8" O.D.
3/8" x 7/16" O.D.
3/8" x 5/8" O.D.
3/8" x 7/8" O.D.
1/2" x 5/8" O.D.
1/2" x 7/8" O.D.



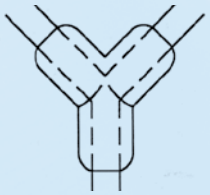
Sani-Link® Ultra Cross

Available Sizes
1/4" x 7/16" O.D.
3/8" x 7/16" O.D.
3/8" x 5/8" O.D.



Sani-Link® Ultra Tee*

Available Sizes
1/8" x 1/4" O.D.
1/8" x 5/8" O.D.
1/4" x 7/16" O.D.
1/4" x 1/2" O.D.
1/4" x 5/8" O.D.
3/8" x 7/16" O.D.
3/8" x 5/8" O.D.
3/8" x 7/8" O.D.
1/2" x 5/8" O.D.
1/2" x 7/8" O.D.
1-3/8" x 3/16" O.D.



Sani-Link® Ultra Wye

Available Sizes
1/8” x 3/16” O.D.
1/8” x 1/4” O.D.
1/8” x 5/8” O.D.
3/16” x 1/4” O.D.
3/16” x 7/16” O.D.
1/4” x 7/16” O.D.
1/4” x 5/8” O.D.
1/4” x 3/4” O.D.
3/8” x 7/16” O.D.
3/8” x 5/8” O.D.
3/8” x 3/4” O.D.
1/2” x 5/8” O.D.
1/2” x 3/4” O.D.
3/4” x 1-1/4” O.D.

Sani-Link® Ultra Double Wye

Sani-Link® Ultra Double “Y” is designed for use in double-headed peristaltic pump applications. This revolutionary new product is one complete unit manufactured from our silicone resin to extend pump life and ensure continuous product flow. Since this closed system utilizes the SIB® technology, there is no longer a need for clamps in your product application, providing you with a leak-free connection.

Characterization

The bio-compatibility of Sani-Tech® Ultra platinum-cured silicone tubing, manufactured with Sani-Tech® silicone, has been tested and complies with the parameters set forth in the following test protocols:

- USP Class VI (88) biological reactivity, in vivo
  – Intracutaneous test, Systemic injection test, Implantation test
- USP 87 biological reactivity, in vitro
  – L929 MEM elution, AGAR diffusion
- USP 381 elastomeric closure for injection
- USP 661 containers
- USP 151 pyrogen test
- European Pharmacopoeia 3.1.9
- USP limits for total organic carbons
- Gamma irradiation
- Infrared analysis
- Test of leachables
- Heavy metals
- ISO 10993

Sterilization Methods

- Autoclavable
- Radiation – up to 5.0 Mrad (50 Kilogray)
- Gas – ethylene oxide

NOTE: Sani-Tech® Ultra tubing will not deteriorate with repeated autoclaving. This method of sterilization is strongly recommended. Sani-Tech® Ultra silicones should not be considered for consistent steam applications.

WARNING: Do not use Sani-Tech® Ultra silicone tubing in hot oil or acid applications.

For more than four decades, Saint-Gobain and its family of companies have supplied the world with innovative, high-performance polymer products for the most demanding applications. Our tradition of excellence goes back almost 350 years through our parent company, Compagnie de Saint-Gobain, one of the world's top 100 industrial corporations, with operations in 64 countries. This successful corporation has been built with the single purpose of serving the customer and a commitment to quality and leadership in each of the industries served.

SAINT-GOBAIN

Saint-Gobain Performance Plastics
1234 Street Name
City, State 01234
USA
Tel: +1 (234) 567.8910
Toll Free: +1 (888) 123.4567
Fax: +1 (234) 567.8910
www.website.com

BIOPHARMACEUTICAL PRODUCTS MANUFACTURING FACILITIES

Saint-Gobain Performance Plastics
700 Warner Blvd.
Taunton, MA 02780
Tel: (800) 722-7106
Tel: (508) 823-7701
Fax: (508) 823-1438

Saint-Gobain Performance Plastics
Grindwell Norton Ltd,
Devanahalli Road,
Off Old Madras Road,
Bangalore, 560049, India
Tel: +91 80 28472900
Fax: +91 80 280472616

Saint-Gobain Performance Plastics
3910 Terry-Diane Street
Beaverton, MI 48612
Tel: (888) 387-0067
Tel: (989) 435-9533
Fax: (989) 435-2355

Saint-Gobain Performance Plastics
2664 Gilchrist Road
Akron, OH 44305
Tel: (800) 798-1554
Tel: (330) 798-9240
Fax: (330) 798-6968

Saint-Gobain Performance Plastics
460 Milltown Road
Bridgewater, NJ 08807
Tel: (800) 435-3992
Tel: (908) 218-8888
Fax: (908) 218-9009

Saint-Gobain Performance Plastics
Saint-Gobain KK
10801-5, Haramura,
Suwa-gun
Nagano 391-0106 Japan
Tel: (81) 266-79-6400
Fax: (81) 266-70-1001

Saint-Gobain Performance Plastics
4451 110th Avenue North
Clearwater, FL 33762
Tel: (800) 541-6880
Tel: (727) 531-4191
Fax: (727) 530-5603

Saint-Gobain Performance Plastics
La Mothe-aux-Aulnaies
F-89120 Charny, France
Tel: (33) 3-86-63-78-78
Fax: (33) 3-86-63-77-77

Consult a Saint-Gobain Performance Plastics Sales Representative for the product and material formulation that best suits your specific application needs.

WWW.BIOPHARM.SAINT-GOBAIN.COM

Quality System ISO 9001 Accredited

Sani-Link®, SIB® and Sani-Tech® are registered trademarks.

WARNING: The content of Saint-Gobain tubing materials is not certified by the FDA for implant devices and is neither designed nor intended to be used in medical applications involving permanent implantation in the human body or permanent contact with body fluids or tissues. Failure to comply with this warning may lead to serious bodily injury or death.

IMPORTANT: It is the user's responsibility to ensure the suitability and safety of Saint-Gobain Performance Plastics materials for all intended uses. Laboratory, field or clinical tests must be conducted in accordance with applicable requirements in order to determine the safety and effectiveness for use of materials in any particular application. If intended for medical use, it is the user's responsibility to ensure that the materials to be used comply with all applicable medical regulatory requirements.

Limitation of Liability: Except for products for which Saint-Gobain Performance Plastics (SGPPL) has established a specific written warranty, the products described herein are sold by SGPPL without any guarantee and/or warranty, oral or written. User assumes all risk, if any, including the risk of injury, loss or damage, whether direct, consequential or incidental, arising out of the use, misuse or inability to use these products.

SAINT-GOBAIN PERFORMANCE PLASTICS DISCLAIMS ALL IMPLIED WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE.

NOTE: Saint-Gobain Performance Plastics Corporation does not assume any responsibility or liability for any advice furnished by it, or for the performance or results of any installation or use of the product or of any final product into which the product may be incorporated by the purchaser and/or user.

FLS-5068-0414-SGCS

©2014 Saint-Gobain Performance Plastics