

Cellgyn® TPE Tubing

SaniSure Cellgyn® TPE tubing is designed specifically for the most demanding bio-pharmaceutical applications. It is ideal for use in single-use assemblies, process filling, and sampling devices and is compatible with all common tube sealers and aseptic tube welders such as Vante, Terumo, BioWelder, GE Sterile Tube Fuser and many more. SaniSure´s Cellgyn® is exceptionally clear and has superior gas barrier properties and pressure performance vs. silicone tubing.

- Standard and custom sizes available
- Manufactured for pharmaceutical and biopharmaceutical applications

Key Features

- Thermoplastic elastomer (SEBS)
- Translucent
- Compatible with common welding/ sealing machines
- Weld compatible with common TPE tubing brands
- Tasteless, odorless
- Contains no phthalate plasticizers or peroxides that can leach out into transported fluid
- Sterilization Methods: autoclave, gamma irradiation, and chemical sterilants
- Hardness: durometer 68 Shore A
- Packaging: Double bagged
- Working Low Temperature Range: *-80°F (-62°C)
- Working High Temperature Range: 275°F (135° C) *Embrittlement Temperature

Compliance

- U.S. Pharmacopeia 43, National Formulary 38 (USP), General Chapter <88> Class VI, Biological Reactivity Tests, In Vivo (2020)
- U.S. Pharmacopeia 43, National Formulary 38 (USP), General Chapter <87> Class VI, Biological Reactivity Tests, In Vitro (2020)
- ISO 10993 (various parts) / Biological Evaluation of Medical Devices
- Comprehensive extractables testing and characterization after gamma irradiation
- RoHS Compliant
- REACH Compliant
- Conflict Minerals
- California Proposition 65
- ICH Q3D Elemental Impurities

Applications

- Single-Use Assemblies
- Sealing
- Welding
- Buffer and media preparation
- Cell media processing
- Transfer sets
- Bag manifolds

Physical	Typical Values
Specific Gravity	0.89
Hardness (Shore A, at 10 Sec.)	68
Tensile Stress	-
100% Strain, 70°F	390 psi
Flow: 100% Strain, 70°F	660 psi
Tensile Strength (Break at 73°F)	870 psi
Tensile Elongation (Break at 73°F)	510 psi
Compression Set %	-
72°F, 22.0 Hours	17%
158°F, 22.0 Hours	58%
212°F, 22.0 Hours	69%

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Regulatory Testing

Biocompatibility USP <87> and USP <88>[2]	Based on the testing performed by SaniSure on representative samples of the above product, this product meets the requirements of the standards listed below: • USP <87> • USP <88>
Biocompatibility (ISO 10993 and USP Class VI)[1]	A Representative sample of the compound used to manufacture this product has been tested according to ISO 10993 and USP Class VI testing requirements. The sample met the requirements of the following tests: • Systemic Injection Test (USP Class VI and ISO 10993) • Intracutaneous Toxicity Test (USP Class VI and ISO 10993) • Intramuscular Implantation Test (USP Class VI and ISO 10993) • Agar Diffusion (ISO 10993-5) • L929 MEM Elution (ISO 10993-5) • Implant Effects (ISO 10993-6) • Sensitization (Kligman Maximization) (ISO 10993-10) • Systemic Toxicity (ISO 10993-11)
Extractables - USP[2]	Based on the testing performed by SaniSure on representative samples of the above product, this product meets the requirements of the standards listed below: • USP <665>
Endotoxin Testing[2]	Based on the testing performed by SaniSure on representative samples of the above product, this product meets the requirements of the standards listed below: • USP <85>
Particulate Testing[2]	Based on the testing performed by SaniSure on representative samples of the above product, this product meets the requirements of the standards listed below: • USP <788>

[1]The biocompatibility information listed in this section is based on information provided by our compound source. Testing is based on single lots, although lot-to-lot variance would not be expected to show different results.

[2]The assessment is available upon request at https://sanisure.com/resources/

Presence of Substance

Based on the information made available to us by our raw material supplier, we have found that the product listed above does not intentionally contain the following substances:

- Bisphenol A (BPA)
- Latex
- Melamine
- Nitrosamines
- Phthalates (plasticizers)
- Polyvinyl Chloride (PVC)
- Slip Agents

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Animal Derivatives (BSE/ TSE)

Based on the information provided to SaniSure by its material suppliers and review of our product formula and our materials handling and processing procedures, we have been able to determine that the product listed above does not contain ingredients derived from animals including animal fats (tallow). Based on this information there would be no known sources of Bovine Spongiform Encephalopathy (BSE) or Transmissible spongiform encephalopathy (TSE).

Genetically Modified Organisms (GMO's)
GMO's may be present in the product listed above as a result of specific characteristics of the raw materials utilized by SaniSure's supplier and/or of their manufacturing process(es).

Manufacturing Standard

The above material is manufactured in an ISO 9001:2015 accredited facility. This product is manufactured in an unclassified, controlled environment.

Dimensional Tolerances

Inside and outside diameter tolerances are maintained to RMA E1 tolerances.

Sterilization

The recommended maximum dosage for gamma irradiation of the above product is 50 kGy. When required of SaniSure, the standard range for gamma irradiation of products is between 27.5 and 40 kGy.

Shelf Life and Storage Conditions

If stored according to the following recommendations, SaniSure recommends that customers dispose of this product after five (5) years from the date of manufacturing. Store this product in an ambient temperature and humidity environment. The product should be free from exposure to direct outside weather influences and stored in a dark space out of direct contact with light. The area should be free from volatile solvents, corrosive gases, or other potentially harmful vapors. Stack the product flat in an opaque container during storage. The container should be kept off the floor (e.g., on shelving or skids) and remain closed and sealed while in storage. The product should be free of kinking and not be subjected to crushing forces from the weight of the product above it.

SaniSure makes no representations or warranties as to the accuracy of the information contained or referenced herein. Most results mentioned above are based on single lots of material. Although a lot-to-lot variance would not be expected to show different results, this data should not be construed as a warranty of fitness for use. Prior to use for any application, the user has the sole responsibility for determining the suitability of these products in any application. Based on the information made available to us by our material suppliers, Perfluoroalkoxy (PFA) in the form of finished articles is not expected to emit or release chemicals under normal circumstances and is therefore exempt from REACH registration.



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Sizing Chart Standard Offerings

Part Number	ID		OD		Wall		Working Pressure (psi)	Burst Pressure (psi)	Vacuum Rating (hg)	Bend Radius(in)
	(inch)	(mm)	(inch)	(mm)	(inch)	(mm)				
CGN-125X250-50	0.125	3.2	0.250	6.4	0.062	1.6	37	111		
CGN-187X312-50	0.187	4.8	0.312	8.0	0.062	1.6	27.8	83.4	29.5	1.25
CGN-187X375-50	0.187	4.8	0.375	9.5	0.094	2.4	37.1	111.4	29.5	1
CGN-250X375-50	0.250	6.4	0.375	9.5	0.062	1.6	22.2	66.6	29.5	1
CGN-250X437-50	0.250	6.4	0.437	11.1	0.094	2.4	30.2	90.7	29.5	2.25
CGN-250X500-50	0.250	6.4	0.500	12.7	0.125	3.2	37	111	29.5	1.25
CGN-312X437-50	0.312	8.0	0.437	11.1	0.062	1.6	18.5	55.6	10	2.5
CGN-312X500-50	0.312	8.0	0.500	12.7	0.094	2.4	25.7	77.1	29.5	1.75
CGN-375X500-50	0.375	9.5	0.500	12.7	0.062	1.6	15.9	47.6	29.5	3
CGN-375X562-50	0.375	9.5	0.562	14.3	0.094	2.4	22.2	66.5	29.5	2.25
CGN-375X625-50	0.375	9.5	0.625	15.9	0.125	3.2	27.8	83.3	10	3.25
CGN-500X750-50	0.500	12.7	0.750	19.1	0.125	3.2	22.2	66.6	15	3.5
CGN-625X875-50	0.625	15.9	0.875	22.2	0.062	1.6	18.5	55.5	0	5.5
CGN-750X1000-50	0.750	19.1	1.000	25.4	0.125	3.2	15.9	47.6	0	6.25
CGN-750X1125-50	0.750	19.1	1.125	28.6	0.187	4.8	22.2	66.6	10	6.25
CGN-1000x1375-20	1.000	25.4	1.375	34.9	0.187	4.8	17.5	52.6	0	8.75
CGN-3MMx7MM-50		3		7		2				
CGN-6MMx12MM-50		6		12		3				
CGN-8MMx16MM-50		8		16		4				
CGN-10MMx17MM-50		10		17		3.5				

NOTE: Standard coil length is 50 feet. Other length and spools available, consult factory.

Custom sizes available

Vacuum Rating
Note: Testing conducted on tubing maintained in a straight configuration (no bends) at a standard laboratory temperature of 23°C in accordance with ISO 7233 Method A

Bend Radius:
Note: Testing conducted at standard laboratory temperature of 23°C, in accordance with ISO 10619-1 Method A1.

Burst
Note: Tested at 23°C Temp

Tubing has printing
Also available with no print upon request

Please contact our quality department for the most up-to-date regulatory information. Specifications in this document are subject to change without notice.

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