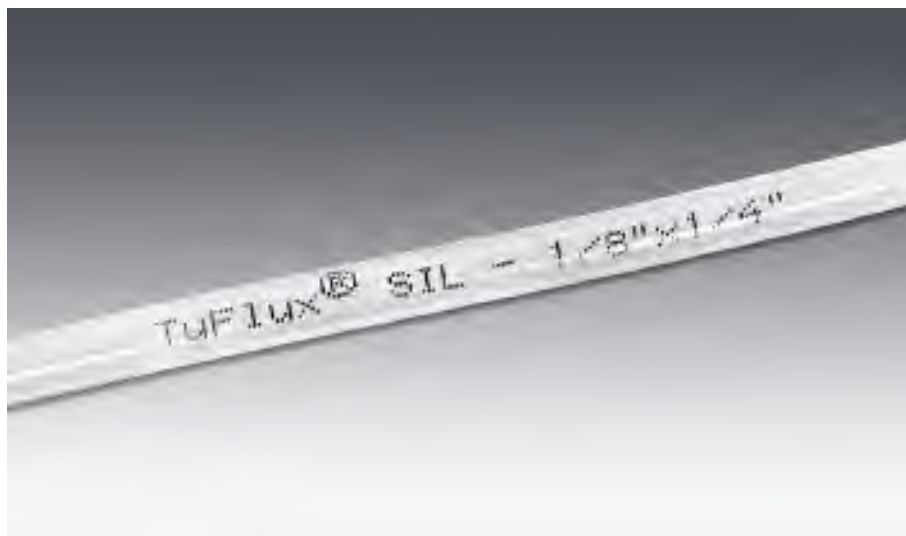




TuFlux[®] SIL

Sartorius Stedim Biotech Silicone Tubing



Specifications

Colour	Transparent
Material	Platinum cured silicone suitable for pumping application
Shore hardness A	60 ± 5
Temperature range	from -60°C to +200°C (-76°F to +392°F)
Tear strength	> 8.0 MPa
Elongation at break	> 500%
Compliant	E.P. 3.1.9, USP <88> Class VI, ADCF
Printing	Physiologically inert ink showing tubing dimensions
Sterilization	Gamma irradiation and autoclave
Tubing coils packaging	Primary and secondary PE packaging

Description

Sartorius Stedim Biotech TuFlux[®] SIL is designed to facilitate fluid transfer in the biopharmaceutical manufacturing processes. TuFlux[®] SIL is a highly resistant platinum cured silicone tubing manufactured by Raumedic. TuFlux[®] SIL is available in 7 different dimensions from 1/8" (3.2 mm) to 3/4" (19.1 mm) for the internal dimensions and a wall thickness from 1.6 to 4.8 mm.

Applications

TuFlux[®] SIL is designed to be used in many pharmaceutical and biopharmaceutical applications such as:

- Media and Buffer processing
- Filtration
- Fermentation
- Cell harvest

Flexibility

Sartorius Stedim Biotech silicone tubing TuFlux[®] SIL is available as non sterile tubing coils and can also be mounted and sterilized on any Sartorius Stedim Biotech single-use assembly. Several dimensions are available to match the process requirements in term of flow rate and to be perfectly adapted to the peristaltic pump for maximum pumping efficiency.

Features & Benefits

- Low extractable profile and unique Validation Guide for TuFlux[®] SIL available: Ease the validation of TuFlux[®] SIL in a process.
- Shore hardness A 60: Very good rupture strength in peristaltic pumps and reduced kink effect.
- Platinum Cured Silicone: Resistant against weak acids and bases and extraordinary heat and cold resistance.
- Translucent: Visual contact with the fluid.
- Printing of ID and OD dimensions on the tubing: Facilitates tubing identification.
- Coils wrapped in double PE-bags: Tubing protected and easy to introduce in clean room.
- "Low-Tack" significantly reduced surface friction: Easier handling with gloves.
- Certificate of Release: Delivered with each order for traceability

Tubing coil

TuFlux[®] SIL is available from stock as non sterile tubing coil packaged in a double PE bag. The length of a coil is depending on the tubing dimensions and varies between 100 m to 15 m.

TuFlux[®] Sil is compatible with Gamma Sterilization and autoclave. The Shelf life is 5 years.

Integration

- All TuFlux[®] SIL tubing dimensions can be integrated into any Sartorius Stedim Biotech assembly.
- TuFlux[®] SIL could be pre-assembled to bags, filters and then Gamma sterilized to offer a ready-to-use solution.
- TuFlux[®] SIL can also be assembled on tubing and filtration sets without Gamma sterilization to offer ready-to-autoclave solutions to end users when autoclaving is required in the process.

Security of Supply

Sartorius Stedim Biotech has established multiple manufacturing sites with consistent industrial processes for its fully integrated disposable assemblies. The expertise of designing Single-Use solutions based on collaborative supplier management and customer demand planning assures a state of the art and robust supply chain that can cope with strong market growth.

Quality Assurance

Sartorius Stedim Biotech Quality Systems for Single-Use Products is compliant with ISO 9001 :2008. Design, Manufacture and Sterilization processes are conducted under conditions that mirror biopharmaceutical operations and meet cGMP requirements.

Available from stock

TuFlux® SIL coils are available from stock.

Validation

TuFlux® SIL has been extensively qualified in collaboration with Raumedic applying the most stringent tests. Biological, chemical and physical tests combined with extensive extractable testing provide users of TuFlux® SIL a silicone tubing with data representing a variety of processing conditions covering a lot of applications.

When tubing is mounted on a product, a full compliance with ISO11137 allows for a validated claim of sterility by Gamma irradiation on all Sartorius Stedim Biotech single-use products with a sterility assurance level of 10^{-6} over the shelf life.

TuFlux® SIL is tested for compliance to:

- E.P. 3.1.9
- USP <88>: Class VI Implant test, systemic toxicity tests and intracutaneous tests
- Cytotoxicity according to ISO 10993-5
- Haemolysis test according to ISO 10993-4
- USP <381>: Test for elastomeric closures for injections
- USP <661>: Tests for plastic
- FDA 21 CFR 177.2600
- Animal Derived Component Free
- REACH

Details on methodologies and equipment used as well as further tests performed are detailed in the Validation Guide.



Ordering information

Part Number	Description	ID × OD Dimensions (mm)	Wall thickness (mm)	Tubing coil length (m)	Minimum Order Quantity
FSA117425	TuFlux® SIL 1/8" × 1/4"	3.2 × 6.4	1.6	100	1 coil
FSA117426	TuFlux® SIL 1/4" × 3/8"	6.4 × 9.5	1.6	50	1 coil
FSA117427	TuFlux® SIL 1/4" × 7/16"	6.4 × 11.1	2.4	50	1 coil
FSA117428	TuFlux® SIL 3/8" × 5/8"	9.5 × 15.9	3.2	25	1 coil
FSA117429	TuFlux® SIL 1/2" × 3/4"	12.7 × 19.1	3.2	25	1 coil
FSA117430	TuFlux® SIL 3/4" × 1"	19.1 × 25.4	3.2	15	1 coil
FSA117431	TuFlux® SIL 3/4" × 1 1/8"	19.1 × 28.6	4.8	15	1 coil

Part Number	Description	ID × OD Dimensions (inch)	Wall thickness (inch)	Tubing coil length (ft)	Minimum Order Quantity
FSA117425	TuFlux® SIL 1/8" × 1/4"	1/8" × 1/4"	0.06	328	1 coil
FSA117426	TuFlux® SIL 1/4" × 3/8"	1/4" × 3/8"	0.06	164	1 coil
FSA117427	TuFlux® SIL 1/4" × 7/16"	1/4" × 7/16"	0.09	164	1 coil
FSA117428	TuFlux® SIL 3/8" × 5/8"	3/8" × 5/8"	0.13	82	1 coil
FSA117429	TuFlux® SIL 1/2" × 3/4"	1/2" × 3/4"	0.13	82	1 coil
FSA117430	TuFlux® SIL 3/4" × 1"	3/4" × 1"	0.13	49	1 coil
FSA117431	TuFlux® SIL 3/4" × 1 1/8"	3/4" × 1 1/8"	0.19	49	1 coil

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