

Tuflux® SIL

Sartorius Silicone Tubing



Product Information

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

Features and 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

Technical Data

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 |

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 depends on the tubing dimensions and varies between 15 m to 100 m.

Tuflux® SIL is compatible with gamma sterilization and autoclave. The shelf life is five years.

Integration

- All Tuflux® SIL tubing dimensions can be integrated into any Sartorius 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 sterilisation to offer ready-to-autoclave solutions to end users when autoclaving is required in the process.

Security of Supply

Sartorius 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 ensures a state-of-the-art and robust supply chain that can cope with strong market growth.

Quality Assurance

Sartorius 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 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.



Order Information

| Part Number | Description | ID × OD Dimensions [mm] | Wall Thickness [mm] | Tubing Coil Length [m] | Minimum Order Quantity |
|-------------|-----------------------|----------------------------|------------------------|---------------------------|---------------------------|
| FSA117425 | Tuflux® SIL ⅛" × ¼" | 3.2 × 6.4 | 1.6 | 100 | 1 coil |
| FSA117426 | Tuflux® SIL ¼" × ⅜" | 6.4 × 9.5 | 1.6 | 50 | 1 coil |
| FSA117427 | Tuflux® SIL ¼" × ⅞" | 6.4 × 11.1 | 2.4 | 50 | 1 coil |
| FSA117428 | Tuflux® SIL ⅜" × ⅝" | 9.5 × 15.9 | 3.2 | 25 | 1 coil |
| FSA117429 | Tuflux® SIL ½" × ¾" | 12.7 × 19.1 | 3.2 | 20 | 1 coil |
| FSA117430 | Tuflux® SIL ¾" × 1" | 19.1 × 25.4 | 3.2 | 15 | 1 coil |
| FSA117431 | Tuflux® SIL ¾" × 1 ⅛" | 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 ⅛" × ¼" | ⅛" × ¼" | 0.06 | 328 | 1 coil |
| FSA117426 | Tuflux® SIL ¼" × ⅜" | ¼" × ⅜" | 0.06 | 164 | 1 coil |
| FSA117427 | Tuflux® SIL ¼" × ⅞" | ¼" × ⅞" | 0.09 | 164 | 1 coil |
| FSA117428 | Tuflux® SIL ⅜" × ⅝" | ⅜" × ⅝" | 0.13 | 82 | 1 coil |
| FSA117429 | Tuflux® SIL ½" × ¾" | ½" × ¾" | 0.13 | 66 | 1 coil |
| FSA117430 | Tuflux® SIL ¾" × 1" | ¾" × 1" | 0.13 | 49 | 1 coil |
| FSA117431 | Tuflux® SIL ¾" × 1 ⅛" | ¾" × 1 ⅛" | 0.19 | 49 | 1 coil |

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Specifications subject to change without notice.

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