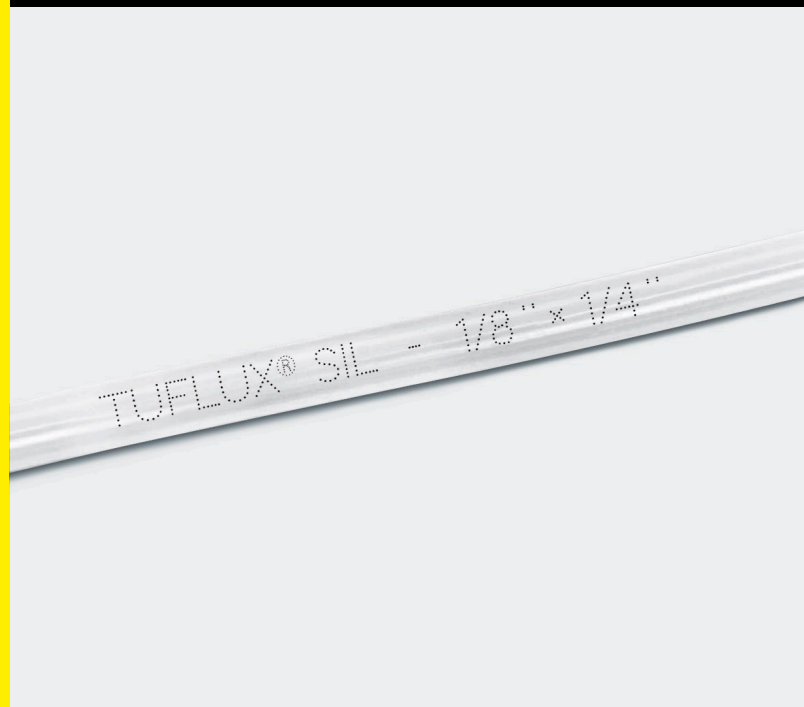


# Tuflux<sup>®</sup> SIL

## Sartorius Silicone Tubing



### Product Information

Sartorius Tuflux<sup>®</sup> SIL is designed to facilitate fluid transfer in the biopharmaceutical manufacturing processes. Tuflux<sup>®</sup> SIL is a highly resistant platinum cured silicone tubing manufactured by Raumedic. Tuflux<sup>®</sup> 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<sup>®</sup> 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	Translucent
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<sup>-6</sup> 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 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	20	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	66	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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