SARTORIUS

Product Datasheet

Braided Tuflux® SIL

Sartorius Pressure Resistant Silicone Tubing

Product Information

Braided Sartorius Tuflux® SIL is designed to facilitate fluid transfer in the biopharmaceutical manufacturing processes with elevated pressure requirements. Braided Tuflux® SIL is a highly resistant platinum cured silicone tubing braided with a medical grade PET mesh material manufactured by Raumedic. Tuflux® SIL is available in six different dimensions from ⅛" (3.2 mm) to 1" (25.4 mm) for the internal dimensions and a wall thickness from 2.9 to 4.8 mm.

Applications

Braided 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.

Features and Benefits

- Pressure resistance up to 60 bar dependent on the tube dimension
- Validation Guide for Braided Tuflux® SIL available: Ease the validation of Braided Tuflux® SIL in a process.
- Shore hardness A 60: Robust combination of strength and Flexibility.
- 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 braided with medical grade PET mesh material
Shore hardness A	60 ± 5
Temperature range	-20 °C to + 135 °C (-4 °F to + 275 °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 10 m to 25 m.

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

Integration

- All Braided Tuflux® SIL tubing dimensions can be integrated into any Sartorius assembly.
- Braided Tuflux® SIL could be pre-assembled to bags, filters and then gamma sterilized to offer a ready-to-use solution.
- Braided 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

Braided Tuflux® SIL coils are available from stock.

Validation

Braided 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 Braided 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
- USP<85>: Bacterial endotoxines
- USP<77>: Biological reactivity in vitro or ISO 10993-5
- Haemolysis test according to ISO 10993-4
- USP <661>: Tests for plastic
- Animal Derived Component Free
- REACH compliant

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

Pressure Resitance Data

Part Number	ID × OD Dimensions [inch]	Water Burst Pressure [bar]	Maximum Recommended Working Pressure For Single Tube [bar]
FSA309865	⅛" × 0.355"	≥ 60	24
FSA309864	¼" × ½"	≥ 43	17
FSA309862	⅜" × ⅝"	≥ 39	15
FSA309862	½" × ⅞"	≥ 29	11
FSA309861	¾" × 1 – ⅛"	≥ 18	7
FSA309860	1" × 1 – ⅜"	≥ 11	4

Order Information

Part Number	Description	ID × OD Dimensions [mm]	Wall Thickness [mm]	Tubing Coil Length [m]	Minimum Order Quantity
FSA309865	Tuflux® SIL ⅛" × 0.355"	3.2 × 9.0	2.9	25	1 coil
FSA309864	Tuflux® SIL ¼" × ½"	6.4 × 12.7	3.2	15	1 coil
FSA309862	Tuflux® SIL ⅜" × ⅝"	9.5 × 15.9	3.2	15	1 coil
FSA309862	Tuflux® SIL ½" × ⅞"	12.7 × 19.1	4.8	15	1 coil
FSA309861	Tuflux® SIL ¾" × 1 – ⅛"	19.1 × 28.6	4.8	10	1 coil
FSA309860	Tuflux® SIL 1" × 1 – ⅜"	25.4 × 34.9	4.8	10	1 coil

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Status: 11 | 2022