



TUFLUX® SIL — 1.8m x 1.5mm

Silicone Tubing

Nicolas Thevenin | Global Product Manager | June, 2011



Table of content

- Press Release
- RAUMEDIC and silicone tubing
- SSB Tubing Strategy
- TuFlux SIL Positioning/Competition
- TuFlux SIL Technical Data
- TuFlux SIL Validation Data
- TuFlux SIL Ordering and Price information



Press Release
May 19, 2011

Press Release

Sartorius Stedim Biotech and RAUMEDIC Sign Partnership Agreement

SSB's product portfolio to be extended by tubing and polymer components

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Goettingen, Germany | Helmbrechts, Germany, May 19, 2011 – Sartorius Stedim Biotech (SSB), an international leading pharma and biotech supplier, and RAUMEDIC, a leading worldwide OEM manufacturer of medical- and pharmaceutical-grade polymer components and systems, announced the signing of a global partnership agreement. This covers arrangements concerning the mutual development of innovative fluid systems and marketing of single-use tubing, which RAUMEDIC produces for and will supply to Sartorius Stedim Biotech on a long-term basis. Sartorius Stedim Biotech will be combining its designing, manufacturing and validation expertise in single-use systems for biopharmaceutical applications with RAUMEDIC proficiency in the development and manufacture of tubing for medical and biopharmaceutical use. The alliance will provide innovative, high-quality and reliable fluid handling systems to biopharmaceutical manufacturers. Through this strategic partnership with RAUMEDIC, Sartorius Stedim Biotech will substantially expand its product and service portfolio in the area of liquid transfer technologies.

Sartorius Stedim Biotech & RAUMEDIC



More than 20 years of excellent relationship as supplier-customer of EVA and PVC tubing.



Today RAUMEDIC is already producing 100% of the EVA tubing assembled on Sartorius Stedim Biotech Flexboy® family.

More than 80% worldwide and 100% in Europe of the PVC tubing of Sartorius Stedim biotech consumption is manufactured by our partner RAUMEDIC.



RAUMEDIC presentation of the company including its product range available on the DDM



RAUMEDIC®
— Lifeline to Health —

in numbers

Turn over 2010 of 65 millions €

450 employees

Tubing

12 000 km of Silicone

1 200 km of EVA

350 000 km of PVC

Injected parts

52 000 000 units

TuFlux SIL

Validation Guide | Technical Specifications & Functional Tests

Dimensions

IDxOD

**Tensile
strenght**

Clamping Test

**Temperature
Resistance**

**Shore
Hardness A**

**Chemical
Compatibility**

**Burst pressure
resistance**

**Water Vapor
Permeability**

**ISO 10993-
5**

**Master
File**

**E.P.
3.1.9**

**Low Extractable
Profile**

Oxygen Permeability

**Pumping Life
Time**

**USP <88>
Class VI**

**USP
<661>**

**USP
<381>
FDA Regulation 21 CFR, part
177.2600**

Flow Rate

**Coils
lenght**

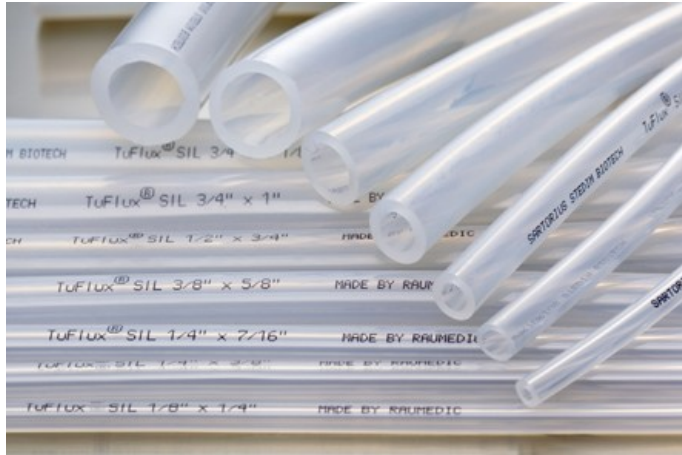
ADCF

REACH

**J.P.
<59>**



TuFlux SIL 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.

TuFlux SIL can be purchased as silicone tubing coil (non sterile) or assembled and sterilized on Sartorius Stedim Biotech single use products.

TuFlux SIL Application




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

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

Several dimensions and different wall thickness are available to match the process requirements in term of flow rate and to be perfectly adapted to a peristaltic pump for maximum pumping efficiency.

TuFlux SIL Features & Benefits



TUFLUX® SIL

- 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.

TuFlux SIL 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: 25

TuFlux SIL Tubing coils



TuFlux SIL is available as non sterile tubing coil packaged in a double PE bag.

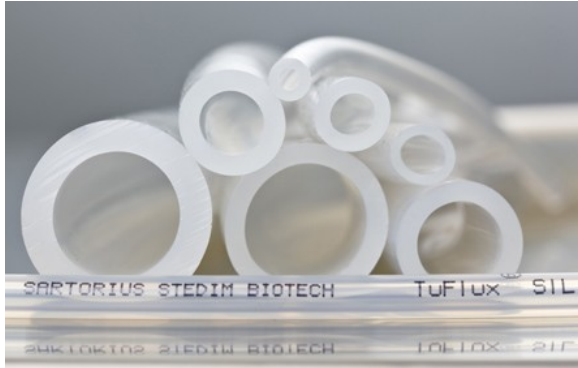
The length of a roll is depending on the tubing dimensions and varies between 100 m to 15 m.

The minimum order quantity is 1 roll.

Available from stock

TuFlux SIL coils are available from stock.

TuFlux SIL Integration

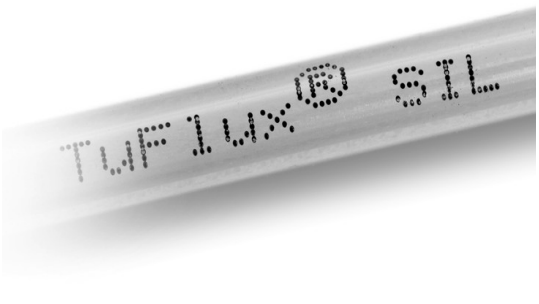


All TuFlux SIL tubing dimensions can be integrated into any Sartorius Stedim Biotech assembly.

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.

TuFlux SIL Security of Supply | Quality Assurance

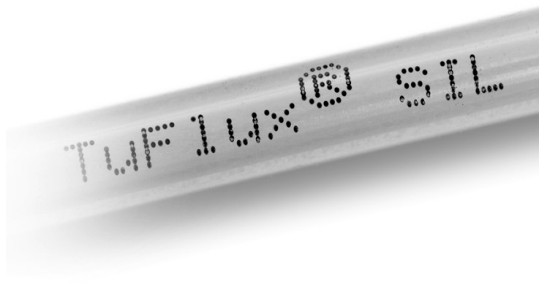


TuFlux[®] SIL

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.

Sartorius Stedim Biotech Quality Systems for Single-Use Products follow applicable ISO and FDA regulations. Design, Manufacture and Sterilization processes are conducted under conditions that mirror biopharmaceutical operations and meet cGMP requirements.

TuFlux SIL Validation



TuFLux SIL has been extensively qualified in collaboration with Raumedic applying the most stringent tests to provide users of TuFlux SIL a silicone tubing with data representing a wide range of process conditions covering many applications. TuFLux SIL is tested for compliance to:

E.P. 3.1.9

USP <88> Class VI, systemic toxicity and intracutaneous tests

Cytotoxicity according to ISO 10993-5

Haemolysis test according to ISO 10993-4

USP <381> : Test for elastomeric closures for injections

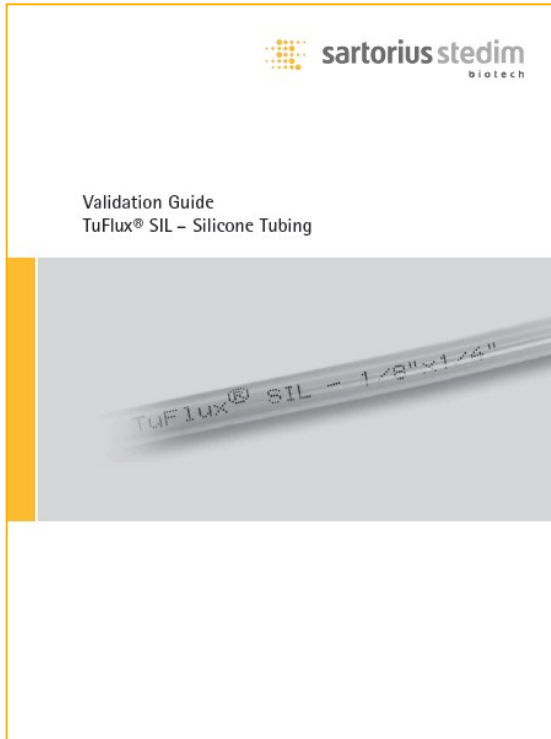
USP <661> : Tests for plastic

FDA 21 CFR 177.2600

Animal Derived Component Free

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

TuFlux SIL Validation Guide



1. **INTRODUCTION**
 - 1.1. Security of Supply
 - 1.2. cGMP Quality Assurance from Sartorius Stedim Biotech
 - 1.3. Quality Assurance
 - 1.4. Complete Traceability
 - 1.5. Quality Management System
 - 1.6. Human Resources
 - 1.7. Infrastructure
 - 1.8. Purchasing
2. **TECHNICAL SPECIFICATIONS**
 - 2.1. Tubing Manufacturing
 - 2.2. Tubing Dimensions
 - 2.3. Type and Part Numbers Overview
 - 2.4. Material of Construction
 - 2.5. Physical Properties
 - 2.6. Physico Chemical Test
 - 2.7. Chemical Compatibility
 - 2.8. Biocompatibility
 - 2.9. Tubing Printing
 - 2.10. Extractable profile
 - 2.11. FT-IR and DSC profiles
 - 2.12. Sterilization Compatibility
 - 2.13. Shelf Life and Recommended Storage Conditions
3. **FUNCTIONAL QUALIFICATION TESTS**
 - 3.1. Burst Pressure test
 - 3.2. Pumping Life Time
 - 3.3. Clamping Test
 - 3.4. Clamping Force
 - 3.5. Barrier Properties to Water Vapor
 - 3.6. Oxygen Permeability
 - 3.7. Flow Rate Data

TuFlux SIL

Validation Guide I Tubing dimensions

Part Number	Description	ID x OD Dimensions (mm)	Wall Thickness (mm)	Tubing coil Length (m)	Minimum Order Quantity
FSA117425	TuFlux SIL 1/8" x 1/4"	3.2 x 6.4	1.6	100	1 coil
FSA117426	TuFlux SIL 1/4" x 3/8"	6.4 x 9.5	1.6	50	1 coil
FSA117427	TuFlux SIL 1/4" x 7/16"	6.4 x 11.1	2.4	50	1 coil
FSA117428	TuFlux SIL 3/8" x 5/8"	9.5 x 15.9	3.2	25	1 coil
Part Number	Description	ID x OD Dimensions (inch)	Wall Thickness (inch)	Tubing coil Length (ft)	Minimum Order Quantity
FSA117429	TuFlux SIL 1/2" x 3/4"	12.7 x 19.1	2.5	25	1 coil
FSA117430	TuFlux SIL 1/2" x 3/4"	19.1 x 25.4	3.2	15	1 coil
FSA117425	TuFlux SIL 3/4" x 1 1/4"	19.1 x 25.4	0.06	328	1 coil
FSA117426	TuFlux SIL 3/4" x 1 1/8"	19.1 x 28.6	4.8	15	1 coil
FSA117426	TuFlux SIL 1/4" x 3/8"	19.1 x 28.6	0.06	164	1 coil
FSA117427	TuFlux SIL 1/4" x 7/16"	19.1 x 28.6	0.09	164	1 coil
FSA117428	TuFlux SIL 3/8" x 5/8"	19.1 x 28.6	0.13	82	1 coil
FSA117429	TuFlux SIL 1/2" x 3/4"	19.1 x 28.6	0.13	82	1 coil

TuFlux SIL

Validation Guide | Material of Construction & Tubing Printing



Source: www.raumedic.com

Silicone rubber, grade TuFlux SIL, addition cross-linked hot vulcanisate based on vinyl methyl dimethyl polysiloxane using silicic acid fillers and platinum catalyst.

The surface is coated in a plasma process. This coating provides a less sticky surface of these silicone tubing (Low Tack) in comparison with common non-coated silicone products.

TuFlux tubing is colourless transparent or translucent.

TuFlux SIL is delivered printed with the following printing: “Sartorius Stedim Biotech – TuFlux SIL ID” x OD” – made by Raumedic” ,.

The innocuity of the ink is proven by the tests performed according to ISO 10993-5.

TuFlux SIL

Validation Guide I Physical Properties

Material Hardness

Properties	Standards	Units	Value
Material Hardness	ISO 868	Shore A	60 ± 5

Tensile Properties

Properties	Standards	Units	Value
Ultimate Tensile Strength	ISO 527	MPa	≥ 8.0

Resistance to Tearing

Properties	Standards	Units	Value
Initial Tear Resistance	ASTM D624B	N/mm ²	≥ 35

The material can be used continuously in a temperature range from –60°C (-76°F) to +200°C (+392°F) without losing its integrity or deterioration of its chemical / physiological properties.

TuFlux SIL

Validation Guide I Physicochemical Test, Chemical and Biocompatibility

Physico Chemical Test

European Pharmacopoeia: 3.1.9 & FDA regulation 21CFR, § 177.2600.

USP <661> - Containers, Physicochemical Tests – Plastic

USP <381> - Elastomeric Closures for Injections

Japanese Pharmacopoeia <59>

Chemical Compatibility

A chemical resistance study is conducted to assess the resistance of TuFlux SIL to a variety of 67 chemical solutions.

Biocompatibility

USP <88> Class VI :

ISO 10993-5

ADCF certified

LAL Endotoxin test

TuFlux SIL

Validation Guide | Extractable Profile

Purpose

The goal of this extractable profile test is to supply worse case extractable data to support process developers and toxicologists in their validation studies.

Method

A 2g of sample of TuFlux SIL was immersed for 90days at 40°C in 200mL of the test solutions:

Deionised water

Buffer solution pH 2, 3, 7 & 10

1M Sodium hydroxide

1M Hydrochloric acid

20% Ethyl alcohol

After the incubation period, a portion of the test solution is extracted with 3% dichloromethane. The dried organic phase is analyzed by gas chromatograph with mass selective detector in the scan mode.

Test results

In the migrates of the sample of tubing no foreign substances could be proven with a detection limit at 0.3 mg/L. The detection limit was 0.6 mg/L for the siloxane.

TuFlux SIL

Validation Guide I Burst pressure & Flow Rate

Burst Pressure

Dimensions in mm (ID x OD)	Dimensions in inch (ID x OD)	TuFlux SIL typical value of burst pressure (bar)
3.2 x 6.4	1/8" x 1/4"	4.5
6.4 x 9.5	1/4" x 3/8"	3.1
6.4 x 11.1	1/4" x 7/16"	3.4
9.5 x 15.9	3/8" x 5/8"	3.8
12.7 x 19.1	1/2" x 3/4"	4.6
19.1 x 25.4	3/4" x 1"	3.0
19.1 x 28.6	3/4" x 1 1/8"	4.6

Flow Rate

TuFlux SIL Dimensions (inch)	Flow rate (L/min)
1/4" x 7/16"	> 1,2
3/8" x 5/8"	> 6.0
1/2" x 3/4"	> 8.9
3/4" x 1"	>16.5
3/4" x 1 1/8"	>20.0

TuFlux SIL Ordering Information



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FSA11743		19.1 x 25.4	3.2	15	1 coil
FSA117425	TuFlux SIL 3/4" x 1"	19.1 x 25.4	0.06	328	1 coil
	TuFlux SIL 1/8" x 1/4"	19.1 x 6.4	4.8	15	1 coil
FSA117426	TuFlux SIL 1/4" x 1/8"	6.4 x 3.2	0.06	164	1 coil
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