



TuFlux[®] TPE

Sartorius Stedim Biotech's new Sealable and Weldable TPE-Tube

Product Information

TuFlux[®] TPE is a translucent thermoplastic elastomer tubing that guarantees an easy identification due to the embedded color stripe aligned with corresponding tube holder for safe welding applications. The cell growth tests performed on the TuFlux[®] TPE tubes are excellent and reproducible and it can be co-welded to established TPE brands in the market with pre-validated welding parameters under sterile conditions.



Description

Sartorius Stedim Biotech's TuFlux[®] TPE is designed to facilitate fluid transfer in the biopharmaceutical manufacturing processes. TuFlux[®] TPE is a highly resistant sealable and weldable tubing manufactured by Raumedic AG. TuFlux[®] TPE 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.

Sartorius Stedim Biotech's TuFlux[®] TPE is available as non-sterile tubing coils and can also be mounted and sterilized on any Sartorius Stedim Biotech single-use assembly

Applications

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

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

Features & Benefits



- **Unique color coding**, aligned with BioWelder[®] TC tube holders, and printing of ID and OD dimensions on the tubing facilitates tubing **identification and ease of use** to mitigate operator errors.



- Antioxidant level in tubing formulation is optimized for **best cell growth results**. No inhibition of cell growth even under worst case surface to volume ratios in small scale applications



- Validated BioWelder[®] TC parameters for **co-welding of TuFlux[®] TPE** to other TPE tubes. Welding parameters have been **validated for all combinations of gamma-irradiated & autoclaved TPE tubes**.

- **Validation- & Extractable Guide** for TuFlux[®] TPE available: Ease the validation of TuFlux[®] TPE in a process.
- **TuFlux[®] TPE is available from stock** as non-sterile tubing coil packaged in a double PE bag.
- **TuFlux[®] TPE is suitable to be used with peristaltic pumps** for liquid transfer applications.

Integration

- All TuFlux® TPE tubing dimensions can be integrated into Sartorius Stedim Biotech assemblies. TuFlux® TPE can be pre-assembled to bags, filters and then Gamma sterilized to offer a ready-to-use solution.
- TuFlux® TPE can also be assembled with filter capsules 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.

Validation

TuFlux® TPE has been extensively qualified in collaboration with Raumedic applying the most stringent tests. Biological, chemical and physical tests combined with extensive extractable testing to provide users of TuFlux® TPE 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.

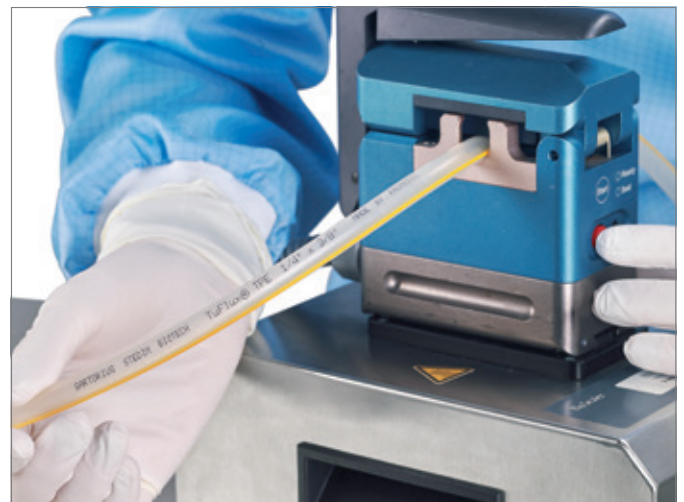
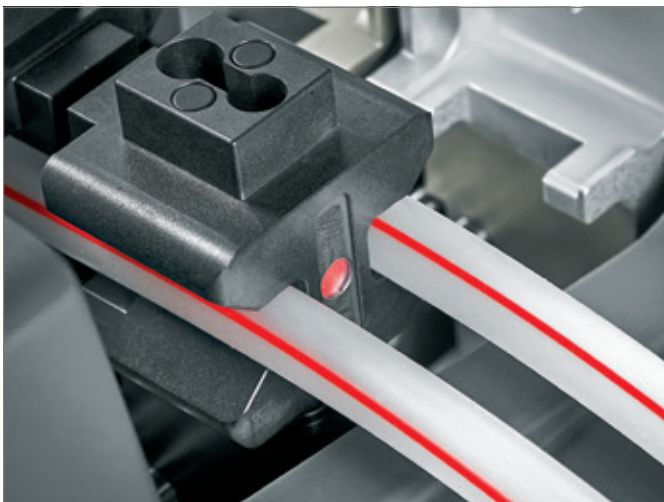
Technical Data

Specifications

Color	Transparent
Material	Synthetic thermoplastic elastomer
Shore A hardness	60 ± 5
Tensile strength at break	≥ 5.0 MPa
Elong. at break	≥ 450%
Operating temp.	-55°C to 135°C
Shelf Life	5 years non sterile 3 years sterile
Compliant to	- USP<87> & USP<88> Class VI - ISO 10993-5 - ADCF - USP<661> - REACH - 2011/65/EC for heavy metals
Sterilization	Gamma irradiation (max 50 kGy) and autoclave 123°, 30 min)

Ordering Information

SSB PN #	Product Description	Coil [m ft]	Diameter [ID × OD]	ID [mm inch]	WT [mm inch]	Color stripe
FSA121869	TUFLUX® TPE 1/8"ID × 1/4"OD YELLOW	200 m 656 ft	1/8" × 1/4"	3.2 0.125	1.6 0.06	Yellow
FSA121870	TUFLUX® TPE 1/4"ID × 3/8"OD ORANGE	125 m 410 ft	1/4" × 3/8"	6.4 0.25	1.6 0.06	Orange
FSA121871	TUFLUX® TPE 1/4"ID × 7/16" OD RED	100 m 328 ft	1/4" × 7/16"	6.4 0.25	2.4 0.09	Red
FSA121872	TUFLUX® TPE 3/8"ID × 5/8"OD WHITE	50 m 164 ft	3/8" × 5/8"	9.5 0.375	3.2 0.125	White
FSA121873	TUFLUX® TPE 1/2"ID × 3/4"OD GREY	30 m 98 ft	1/2" × 3/4"	12.6 0.125	3.2 0.5	Grey
FSA121874	TUFLUX® TPE 3/4"ID × 1"OD BLUE	20 m 66 ft	3/4" × 1"	19.1 0.125	3.2 0.75	Blue
FSA121875	TUFLUX® TPE 3/4"ID × 1"-1/8"OD BLACK	20 m 66 ft	3/4" × 1 1/8"	19.1 0.75	4.8 0.188	Black



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