

HelixFlex™ TPE Tubing

Sterilizable, weldable and sealable
for biopharma & CGT applications

Freudenberg Medical manufactures TPE tubing to suit a wide range of high-performance fluid transfer requirements for the pharmaceutical and biotech industry. HelixFlex™ tubing is heat sealable, weldable, pumpable, sterilizable, and produced in a Class 8 cleanroom within an FDA-registered site.

The HelixFlex™ Advantage

- Excellent heat seal and sterile weldability
- Sterilizable by four different methods
- Peristaltic pump ready at 68 Shore A
- Cleanroom manufactured in FDA site
- Safe material solution for bioprocessing
- Clear, not cloudy, for optimal flow visibility

PART NUMBER	ID x OD (mm)	ID x OD (in)	ID x OD (in)	WALL (mm)	WALL (in)	LENGTH (m/ft)
HF125-2A	3.2 x 6.4	1/8 x 1/4	0.126 x 0.252	1.60	0.06	15/50
HF187-2A	4.8 x 8.0	3/16 x 5/16	0.189 x 0.315	1.60	0.06	15/50
HF187-3A	4.8 x 9.5	3/16 x 3/8	0.189 x 0.374	2.35	0.09	15/50
HF250-2A	6.4 x 9.5	1/4 x 3/8	0.252 x 0.374	1.55	0.06	15/50
HF250-3A	6.4 x 11.2	1/4 x 7/16	0.252 x 0.441	2.40	0.09	15/50
HF250-4A	6.4 x 12.7	1/4 x 1/2	0.252 x 0.500	3.15	0.12	15/50
HF312-3A	7.9 x 12.7	5/16 x 1/2	0.311 x 0.500	2.40	0.09	15/50
HF375-2A	9.6 x 12.7	3/8 x 1/2	0.378 x 0.500	1.55	0.06	15/50
HF375-3A	9.6 x 14.3	3/8 x 9/16	0.378 x 0.563	2.35	0.09	15/50

*Material certification and lot traceability included in every shipment

Compliance & Biocompatibility

- USP <85> Bacterial endotoxins
- USP <87> Biological reactivity, In-Vitro
- USP <88> Biological reactivity, In-Vivo
- USP <151> Pyrogen Test
- USP <661> Plastic Packaging Systems
- USP <788> Particulate Matter in Injections
- USP <665> Extractables Study - Polymeric Components/Systems & Toxicological Evaluation

European Pharmacopeia 3.1.6.

FDA 21 CFR 177.2600

ISO 10993-5 Cytotoxicity

ASTM F 756-17/ISO 10993-4 Haemolysis

*Documentation available upon request

TYPICAL APPLICATIONS

- Demanding fluid transfer processes
- Bioprocess lines
- Filling and sampling
- Peristaltic pumping
- Cell harvesting & fermentation
- Bioreactor processes
- Vaccine manufacturing

PHYSICAL PROPERTIES

TEST TYPE	VALUE	UNIT
Burst pressure <i>DIN EN ISO 1402</i>		
– standard tubing	7.34	Bar
– sealed ends	7.54	Bar
– welded ends	7.74	Bar
Elongation at break <i>ISO 37</i>	650	%
Modulus at elongation <i>ISO 37</i>		
– 50%	1.9	MPa
– 100%	2.2	MPa
– 200%	2.6	MPa
– 300%	3.1	MPa
Tensile strength at break <i>ISO 37</i>	6.8	MPa
Shore Hardness <i>DIN ISO 48-4</i>	68	Shore A
Density <i>DIN EN ISO 1183-1</i>	0.893	g/cm ³
Water vapor transmission rate <i>DIN 53122-1</i> (23°C, 85% RH duration)		
– 10 day duration	0.006	g/m ² *d
– 28 day duration	0.3	g/m ² *d
Water absorption (24h, 23°C water)	<1	%

*All above tests performed with HF 375-3A

Sterilization

Sterilizable by autoclave, gamma irradiation, x-ray, and e-beam according to material supplier. Freudenberg testing complete for gamma irradiation with a maximum dose of 45 kGy.

Shelf Life

Shelf life is 2 years if sterilized.

Weld and Seal Conditions

Parts welded using Vante 3960 Sterile Tube Welder.

Welding blade heated to 250 +/- 10 °C. Total cycle time 130 seconds.

EXTENDED PHYSICAL PROPERTIES

Part Number	ID x OD (mm)	ID x OD (in)	Avg. Burst (bar)	Avg. Burst (psi)	Working DIN EN ISO 7751 (bar)	Working DIN EN ISO 7751 (psi)
HF125-2A	3.20 x 6.40	1/8 x 1/4	19.70	285.72	4.93	71.43
HF187-2A	4.80 x 8.00	3/16 x 5/16	9.50	137.79	2.38	34.45
HF187-3A	4.80 x 9.50	3/16 x 3/8	TBD	TBD	TBD	TBD
HF250-2A	6.40 x 9.50	1/4 x 3/8	6.20	89.92	1.55	22.48
HF250-3A	6.40 x 11.20	1/4 x 7/16	6.80	98.63	1.70	24.66
HF250-4A	6.40 x 12.70	1/4 x 1/2	10.60	153.74	2.65	38.44
HF312-3A	7.90 x 12.70	5/16 x 1/2	7.70	111.68	1.93	27.92
HF375-2A	9.60 x 12.70	3/8 x 1/2	TBD	TBD	TBD	TBD
HF375-3A	9.60 x 14.30	3/8 x 9/16	6.00	87.02	1.50	21.76

PUMP PERFORMANCE

Pump Capacity	0-600 rpm
Recommended Continuous Use	Up to 60 hours at 160 rpm
Flow Rate Stability @ 200 rpm	≥ 93 % for 48 hours
Flow Rate Stability @ 600 rpm	≥ 87 % for 7 hours
Tube Size	3/8" x 9/16" (9.5 mm x 14.3 mm)
Tube Condition for Testing	Gamma irradiated max 45 kGy

* Pump tested using Kroslo Research II Pump



www.freudenbergmedical.com/biopharma

Disclaimer: It is the user's responsibility to ensure the suitability and safety of HelixFlex™ tubing for all intended uses and that the materials to be used comply with all applicable medical and biopharmaceutical regulatory requirements. Freudenberg Medical assumes no responsibility for product failures that occur due to misuse of the materials it provides arising out of the design, fabrication or application of the products into which the materials are incorporated.

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