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	⅛ x ¼	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 ⅜	0.189 x 0.374	2.35	0.09	15/50
HF250-2A	6.4 x 9.5	¼ x ⅜	0.252 x 0.374	1.55	0.06	15/50
HF250-3A	6.4 x 11.2	¼ x 7/16	0.252 x 0.441	2.40	0.09	15/50
HF250-4A	6.4 x 12.7	¼ x ½	0.252 x 0.500	3.15	0.12	15/50
HF312-3A	7.9 x 12.7	5/16 x ½	0.311 x 0.500	2.40	0.09	15/50
HF375-2A	9.6 x 12.7	⅜ x ½	0.378 x 0.500	1.55	0.06	15/50
HF375-3A	9.6 x 14.3	⅜ 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 *DIN EN ISO 1402*		
– standard tubing	7.34	Bar
– sealed ends	7.54	Bar
– welded ends	7.74	Bar
Elongation at break *ISO 37*	650	%
Modulus at elongation *ISO 37*		
– 50%	1.9	MPa
– 100%	2.2	MPa
– 200%	2.6	MPa
– 300%	3.1	MPa
Tensile strength at break *ISO 37*	6.8	MPa
Shore Hardness *DIN ISO 48-4*	68	Shore A
Density *DIN EN ISO 1183-1*	0.893	g/cm^3
Water vapor transmission rate *DIN 53122-1* (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

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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

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