

M-Flex[®]

Thermoplastic Elastomer Tubing



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Meissner's M-Flex® thermoplastic elastomer (TPE) tubing provides a robust and secure supply chain paramount for continual single-use adoption in critical biopharmaceutical applications. M-Flex® tubing is translucent and certified animal component free (ACF).

M-Flex® provides a direct replacement option for TPE tubing used in biopharmaceutical applications.

M-Flex® has been tested extensively for biocompatibility in accordance with USP and ISO standards. It meets the requirements as specified in the current USP Class VI plastics tests and is non-cytotoxic. A partial synopsis of biocompatibility testing for M-Flex® is provided below.

M-Flex® is available in a range of standard tubing sizes. Custom sizes can also be extruded.

M-Flex® provides an excellent TPE tubing option with a secure supply chain for reduced risk in your manufacturing process.

Biocompatibility Testing

Property	Test Method	Value
Cytotoxicity, MEM Elution ¹	USP <87>, ISO 10993-5	Pass
Class VI Plastics - 121 °C ¹	USP <88>	Pass
Physicochemical Tests - Plastics ¹	USP <661>	Pass
Bacterial Endotoxin	USP <85>	Pass
Light Obscuration Particle Count	USP <788>	Pass

¹ All test articles gamma irradiated at 26.5 - 34.3 kGy

Substantial Equivalency

An interdisciplinary team of Meissner SME's set out to establish a material and component design space for M-Flex® intended for direct substitution of TPE tubing commonly used in biopharma. Such substantial equivalency fosters standardization and interchangeability of TPE tubing in single-use assemblies catering to a wide spectrum of liquid management applications. Regardless of your application, M-Flex® provides an attractive tubing alternative as welding, sealing, and pumping equivalency demonstrated by testing is documented and detailed in a comprehensive qualification guide.

Platform Versatility

M-Flex® is the TPE of choice in overmolding applications ranging from bottle stoppers to Meissner's modular BioLink® overmolded tubing and filter sets. BioLink® was purposely designed to reduce the number of unique fluid contact materials in a given single-use assembly and eliminate nearly all mechanical connections.

Specifications

M-Flex® tubing performs well over a wide range of temperatures and remains flexible to -60 °C. The tubing can be autoclaved at temperatures as high as 135 °C for up to 60 min. A partial synopsis of the extensive physical and tensile testing conducted on M-Flex® is provided below.

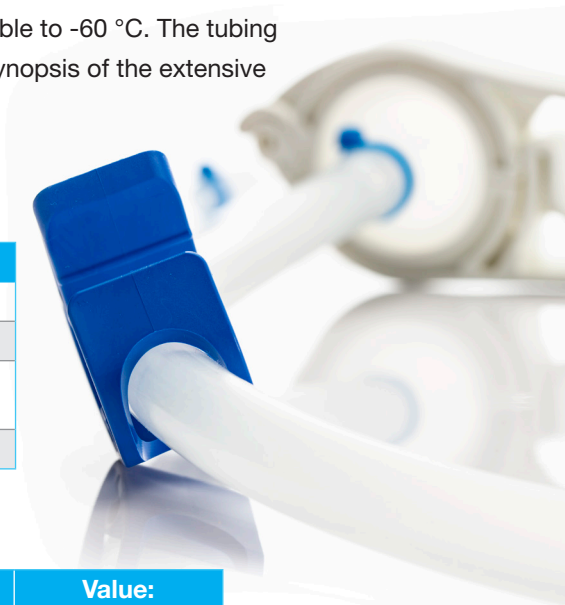
Physical Properties

Property	Test Method	Units	Value:
Durometer Hardness	ASTM D2240	Shore A	67
Specific Gravity	ASTM D792	-	0.901
Density	ASTM D792	g/cm ³	0.899 56.124
Compression Set, 22 hrs @ 22 °C	ASTM D395	lb.ft ³	19

Tensile Properties

Property	Test Method	Units	Value: Non-Sterile	Value: Post Gamma ²
Tensile Strength at Break	ASTM D412	psi MPA	1510 10.41	1250 8.62
Elongation at Break	ASTM D412	%	870	780
Tensile Strength at 100% Strain	ASTM D412	psi MPA	339 2.34	328 2.26
Tensile Strength at 300% Strain	ASTM D412	psi MPA	603 4.16	589 4.06
Tear Strength	ASTM D624	kN/m lb/in.	39.25 224.1	38.16 217.9

² Gamma irradiated at 26.8 - 34.5 kGy



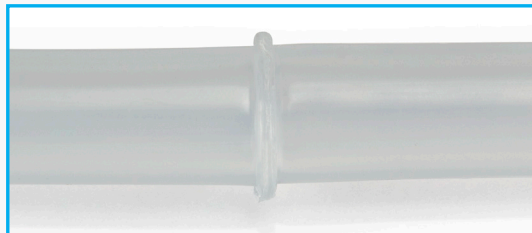
M-Flex® Features

Welding

M-Flex® tubing welds exceptionally well using common industry thermal tubing welders and standard recipes. Meissner's comprehensive welding studies, using a variety of tubing sizes, show high strength quality welds not only for welding of M-Flex® to itself but also when welded to other TPE materials commonly used in biopharmaceutical applications.



C-Flex® welds to M-Flex® using the same settings as required to weld C-Flex® 374.



M-Flex® welds to itself using the same settings as required to weld C-Flex® 374.

Sealing

M-Flex® easily seals using standard TPE Settings on most common thermal sealers. Sealing studies show high strength quality seals.

Pump Performance

M-Flex® performs well in pumping applications. Pump life studies were conducted for a variety of common tubing sizes using peristaltic pumps from different manufacturers. Please contact Meissner for details.

Sterilization

M-Flex® is sterilizable by gamma irradiation or autoclave.

Tubing Sizes

A wide selection of standard M-Flex® tubing sizes are available. Custom sizes can be extruded. Please contact Meissner for details on larger master coils/spools and additional sizes.

Ordering Information

M-Flex® Part Number	Inner Diameter	Outer Diameter	Wall	Coil Length
91T47G11 - C050	1/8" (3.2 mm)	1/4" (6.4 mm)	1/16" (1.6 mm)	50 ft (15 m)
91T47G22 - C050	3/16" (4.8 mm)	5/16" (8.0 mm)	1/16" (1.6 mm)	50 ft (15 m)
91T47G33 - C050	1/4" (6.4 mm)	3/8" (9.5 mm)	1/16" (1.6 mm)	50 ft (15 m)
91T47G34 - C050	1/4" (6.4 mm)	7/16" (11.1 mm)	3/32" (2.4 mm)	50 ft (15 m)
91T47G35 - C050	1/4" (6.4 mm)	1/2" (12.7 mm)	1/8" (3.2 mm)	50 ft (15 m)
91T47G56 - C050	3/8" (9.5 mm)	9/16" (14.3 mm)	3/32" (2.4 mm)	50 ft (15 m)
91T47G57- C050	3/8" (9.5 mm)	5/8" (15.9 mm)	1/8" (3.2 mm)	50 ft (15 m)
91T47G69 - C050	1/2" (12.7 mm)	3/4" (19.0 mm)	1/8" (3.2 mm)	50 ft (15 m)
91T47X22 - C050	3/4" (19.0 mm)	1" (25.4 mm)	1/8" (3.2 mm)	50 ft (15 m)
91T47X23 - C050	3/4" (19.0 mm)	1 1/8" (28.6 mm)	3/16" (4.8 mm)	50 ft (15 m)
91T47X35 - C025	1" (25.4 mm)	1 3/8" (34.9 mm)	3/16" (4.8 mm)	25 ft (7.6 m)