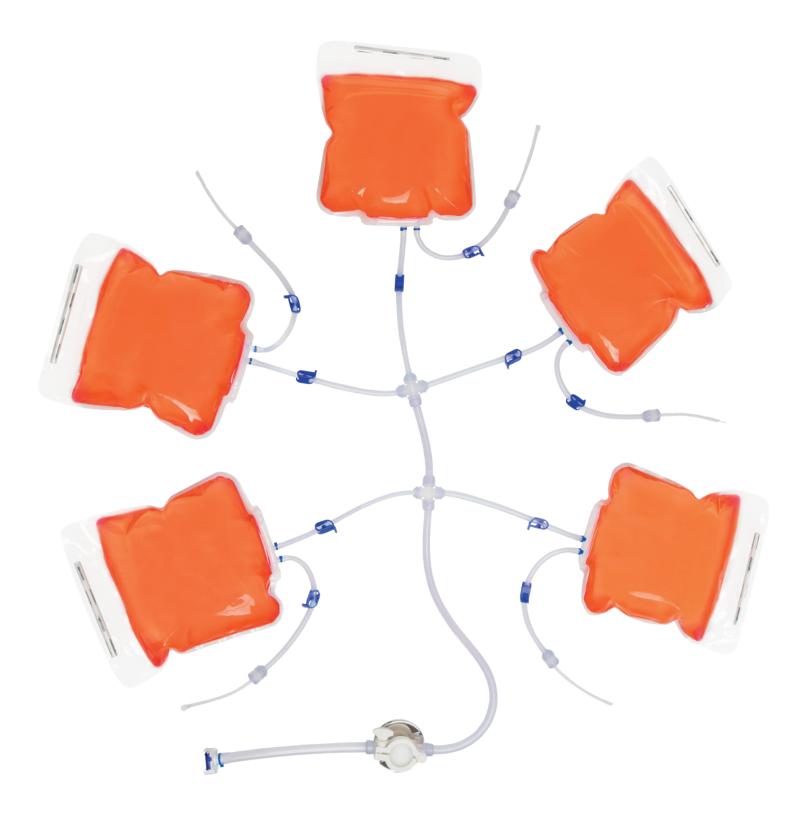


Modular Overmolding





BioLink® Modular Overmolding

BioLink[®] modular overmolding technology incorporates and expands the best attributes of conventional overmolding. It also combines the adaptability and relative processing speed associated with traditional mechanical connections.

BioLink[®] modular overmolded junctions are constructed from Meissner's ultra clean pharmaceutical-grade M-Flex[™] TPE tubing and Meissner's own injection molded polypropylene modules. Lengths of M-Flex[™] TPE tubing with unitized overmolded end fittings can be welded to filters, specialized gauges, or additional tubing lengths of various diameters to create one continuous assembly with virtually limitless design configurations. Fully automated welding processes create permanent bonds between tubing sections and BioLink[®] fluid path components for superior system robustness and security. This patented technology delivers permanently bonded BioLink[®] junctions that feature a smooth inner bore to minimize flow disturbances in critical applications.

Optimized for single-use applications, BioLink[®] assemblies allow Meissner's Applications Engineering Team to create assemblies tailored to your specific requirements that result in reduced process risk. BioLink[®] modular overmolding delivers maximum flexibility to design assemblies by providing a robust way to join a variety of tubing sizes and allowing for connections to filters or single-use gauge tees (SGTs). Union modules, T-fittings (single bifurcation modules), X-fittings (dual bifurcation modules) and connectivity modules to attach filters and SGTs are standard.

Benefits of BioLink®

Expanded Design Space -

- Delivers endless connection opportunities without the need for manual processing after overmolding, resulting in flexible and adaptable assembly designs
- · Facilitates direct connection to filters and SGTs

Increased Assembly Robustness, Reduced Process Risk -

- Automated welding processes create permanent bonded connections
- Eliminates operator interaction with critical process steps that are present in traditional overmolding and typical mechanical connections

Reduced Fluid Contact Materials -

- BioLink[®] junctions feature only two materials of construction: M-Flex[™] thermoplastic elastomer (TPE) and polypropylene
- The polypropylene resin is the same material used in Meissner's filter components, further eliminating extraneous fluid contact materials

Assembly Simplification -

 Standardized connection geometry allows for streamlined and simplified assembly designs

Speed -

 BioLink[®] assemblies are manufactured from stocked standard components resulting in reduced lead times

Product Specifications

Materials of Construction

Tubing: M-Flex[™] thermoplastic elastomer (TPE) Modules: Polypropylene (PP)

Meissner's M-Flex[™] TPE tubing and PP modules are certified animal component free (ACF) and gamma stable. BioLink[®] has been tested extensively in accordance with numerous 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 the testing regimen these materials have been subjected to is provided below.

Biocompatibility Testing

Property	Test Method	Result	
USP Class VI	USP <88>	Pass	
Outotovicity	USP <87>	Pass	
Cytotoxicity	ISO 10993-5	Pass	
Buffering Capacity	USP <661>	< 1 mL	
Nonvolatile Residue	USP <661>	USP <661> < 1 mg	
Residue on Ignition	USP <661>	< 1 mg	
Heavy Metals	USP <661>	< 1 ppm	

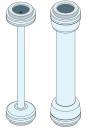
BioLink® Fundamentals

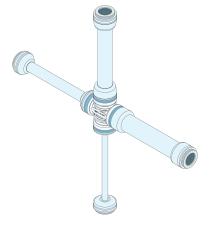
Meissner stocks standard lengths of M-Flex[™] TPE tubing with unitized overmolded ends applied:

- The same unitized overmolded end-fitting is used on tubing diameters from 1/8" to 1/2" ID
- Overmolded ends are manufactured using the same TPE material as the M-Flex[™] tubing
- Tapered design provides smooth inner bore and clean transitions

Three standard fluid path connection modules form the basis for BioLink[®] tubing to tubing connections:

- All modules feature the same joint design which interfaces with the unitized overmolded end fitting on stocked tubing sections
- Connections to Meissner filters and SGT products are also available
- Meissner's automated welding equipment permanently bonds tubing sections to the associated module based on assembly design requirements. This results in a singleuse assembly manufacturing process that is as adaptable as those based on typical mechanical connections





Options

BioLink[®] modular overmolding assemblies are available with a variety of tubing sizes and connectivity options, as indicated below. Please note that any size tubing can be permanently bonded to any module, filter or SGT (single-use gauge tee).

Tubing Sizes

1/8" ID x 1/4" OD	1/4" ID x 7/16" OD	3%" ID x 5%" OD	1/2" ID x 3/4" OD
(3.2 mm ID x 6.4 mm OD)	(6.4 mm ID x 11.1 mm OD)	(9.5 mm ID x 15.9 mm OD)	(12.7 mm ID x 19.1 mm OD)

Connection Types

Union	T-fitting (Single Bifurcation Module)	X-fitting (Dual Bifurcation Module)	Filters & SGT



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