

BioFlex™



BioFlex™ Fluid Path Assemblies

Meissner's BioFlex™ single-use tubing and filter with tubing assemblies provide a secure fluid path in critical biopharmaceutical processing applications. The assemblies reduce process risk while providing an enhanced level of convenience that maximizes flexibility in the deployment of single-use systems, as well as conventional stainless steel or hybrid systems.

Customizable to process requirements, the assemblies are available with a range of connectivity, tubing and accessory component options to provide the functionality necessary for your process. The secure fluid path assemblies can be integrated with filter capsules in a selection of surface areas and media to cater to applications ranging from process stream sterilization and clarification to sterile venting applications. Meissner has extensive experience in single-use system design and implementation and can deliver customized designs using pre-qualified components in some of the industries shortest lead times.



Meissner's BioFlex™ tubing and filter with tubing assemblies are supplied with comprehensive documentation and traceability. Each assembly is serialized, reducing batch record requirements, in some cases. When the tubing assembly includes a filter, the filter serial number is linked to the assembly's serial number. Meissner provides a single cohesive certification package for the complete assembly, which includes component specific lot number information, TSE risk and qualification status as well as applicable filter certification material and specific gamma irradiation dosage information.

Design Benefits

- Increased operational flexibility
- Customizable to specific process requirements
- Seamless integration with Meissner's single-use capsule filters
- Each assembly is serialized for 100% traceability
- Cohesive certification ties in all components of the assembly
- Extensive pre-qualified component library
- Delivered pre-sterilized
- Short lead times

Assembly Design, Components and Filters

Fluid path assemblies have unlimited permutations. The process configurations pictured on the back page illustrate a variety of common applications. Assemblies are configured from our comprehensive library of pre-qualified components.

For applications which require filtration, Meissner offers capsule filters for processing volumes from 10 mL to over 10,000 L. Capsule filters can be specified in sterilizing grades of SteriLUX® PVDF, STyLUX® PES, or EverLUX® PES membranes. Additional filter media is available for selection depending upon customer-specific requirements.



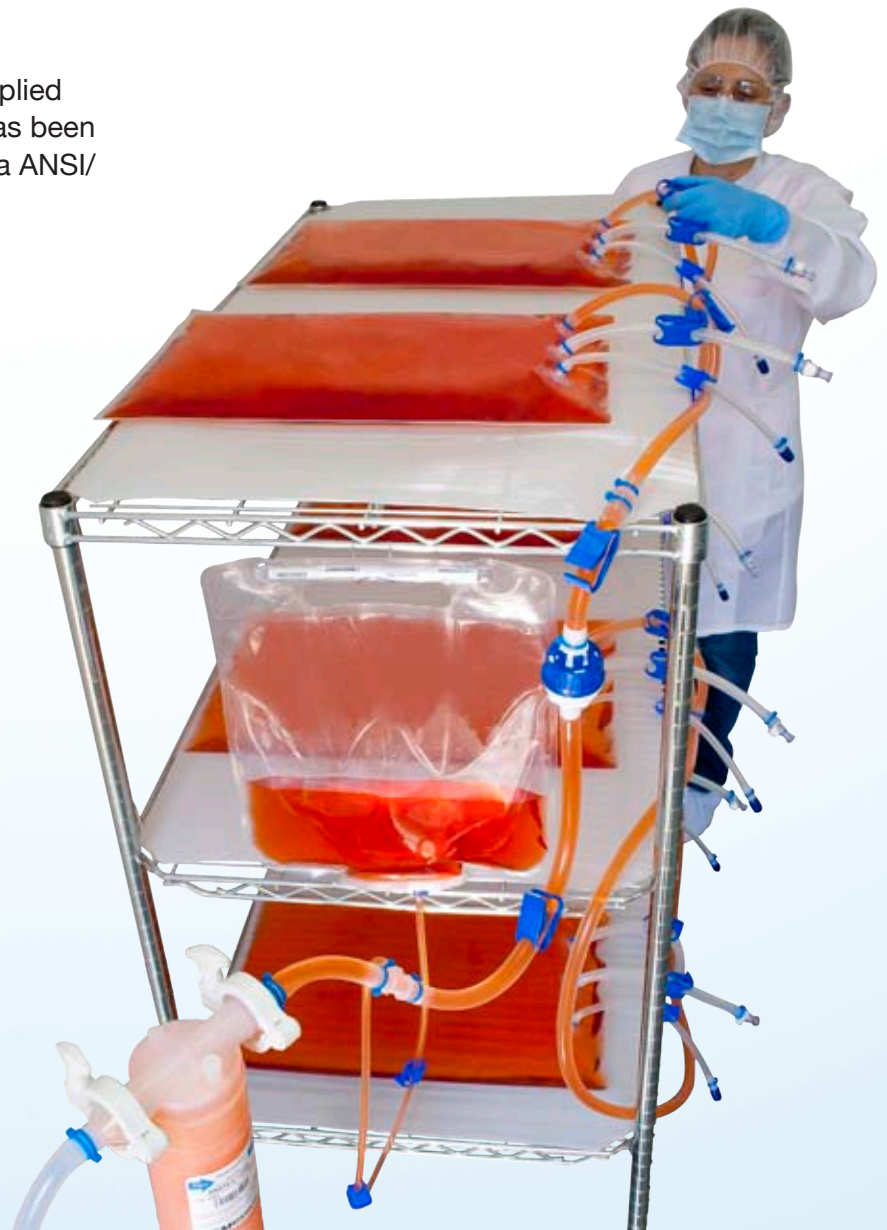
Sterilization

Meissner fluid path assemblies are supplied gamma irradiated at a dosage which has been substantiated as a sterilizing dosage via ANSI/AAMI/ISO 11137-2:2006 methodology.

Additional Information

BioFlex™ fluid path assemblies are part of Meissner's One-Touch® single-use systems portfolio. The One-Touch® portfolio provides seamless integration of biocontainers, rigid outer containers and tubing assemblies with or without filters to provide secure, robust liquid management solutions.

Please visit www.meissner.com for more information on filter options and componentry, or consult Meissner for application assistance.



Process Configurations

Connecting Stainless Steel Process Equipment to Stainless Steel Process Equipment



CRSTW0.2-1N0C2 →
Steam-Thru® Connector

Steam-Thru® Connector →
Steam-Thru® Connector

Connecting a Single-Use System to Stainless Steel Process Equipment



Quick Connect → CSST0.2-224
→ Steam-Thru® Connector

Aseptic Connector →
Steam-Thru® Connector

Connecting a Single-Use System to a Single-Use System



Quick Connect → CFST0.1-33B4
→ TPE Tubing & Plug

Quick Connect →
Quick Connect

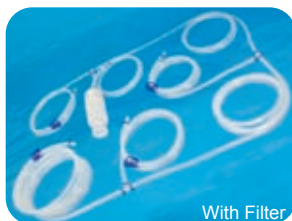
Connecting Stainless Steel Process Equipment to a Single-Use System



Sanitary Flange Fitting →
CLVTH0.2-224 → Quick Connect

Steam-Thru® Connector
→ Aseptic Connector

Filling Assemblies and Manifolds



CLVTH0.2-024 → Four Line
Manifold Terminating in Luers

Luer Fitting → Pump-Y
→ Filling Needle

Fluid Transfer with Sampling and/or Flushing Functionality



CRST0.2-2T0C4 → T to Flush
Biocontainer → MPX

Quick Connect → T to Sampling
Line → Quick Connect

Notes:

- → Arrows indicate flow direction
- Steam-Thru® Connectors provide aseptic connectivity between SUS and stainless steel process equipment
- TPE (Thermo Plastic Elastomer) Tubing + Plug is for use in conjunction with tubing welders
- Aseptic Connectors are designed to allow sterile connections to be made outside of controlled environments
- Quick Connects can be manipulated aseptically under a laminar flow hood
- Reference the TepoFlex® or FluoroFlex® Biocontainer Standards Guide for further component information