

# One-Touch<sup>®</sup>

Single-Use Systems





*Operational Excellence*

*Quality*

#### **Experience One-Touch® Single-Use Systems**

The One-Touch® single-use systems portfolio is built on a solid foundation of quality, operational excellence and technical expertise, which is unparalleled in the industry. Our commitment to quality is demonstrated by the use of pre-qualified dynamic single-use component libraries and extensive product quality certification.

Combined, they provide an unprecedented level of quality documentation and traceability for each fluid contact component. We operate in a paperless, highly automated, manufacturing environment with a very high degree of error proofing, and one of the shortest lead times in the industry. Product quality

certification is fully integrated and the serialization of each and every single-use product manufactured is one of our quality hallmarks. Our single-use systems design engineers are recognized for their design and scale-up expertise, process flow recommendations and validation support.

The profound polymer expertise and the in-house manufacture of many of the underlying components that go into single-use assemblies allows us to elevate our value proposition. Meissner guarantees sterility validation is ensured and maintained according to ISO 11137 methodology.

*Technical Expertise*

## TepoFlex® Biocontainers

Meissner's polyethylene-based TepoFlex® biocontainers are optimized for single-use system requirements within the biopharmaceutical industry. Manufactured without slip agents, the resulting TepoFlex® film is exceptionally clear and clean. The film's low leachables / extractables profile reduces the potential for product interference. By employing the industry's highest combined gas, water vapor and oxygen barrier, the risk of degradation of culture media, buffers, intermediate and bulk drug products stored in TepoFlex® biocontainers is minimized. TepoFlex® biocontainers retain at least 95% of the film strength in the seams, mitigating the risk of loss of fluid integrity.

TepoFlex® film is certified animal component free (ACF), and is extruded, manufactured into biocontainers and packaged in ISO Class 7 cleanrooms.







### BioFlex® Tubing Assemblies

Meissner's BioFlex® tubing assemblies are designed for secure fluid transfer in unit processing applications and optimized for intra or inter unit functionality. The assemblies reduce process risk, provide for rapid set-up and change over, and maximize process flexibility in the deployment of both single-use and hybrid systems.

Customizable to process requirements, the assemblies are available with a range of

connectivity, tubing and accessory component options, for both low and high pressure applications, to achieve the functionality necessary for your process. BioFlex® tubing assemblies can be integrated with filter capsules in a variety of surface areas and filter media for application requirements ranging from process stream sterilization through clarification. Provisions can be made for pre and post-use filter integrity testing procedures.

*FluoroFlex® biocontainers represent an entirely new generation of process solutions for pharma's most demanding requirements.*

### **FluoroFlex® Biocontainers**

FluoroFlex® biocontainers represent an entirely new generation of process solutions for pharma's most demanding requirements. At its core is a breakthrough multilayer, coextruded PVDF product contact film with an established gas barrier. FluoroFlex® film is free of additives, inherently pure, and provides a very low leachables and extractables profile. This new material also offers thermal stability, chemical resistance and strength far beyond what can be achieved with traditional polyolefin-based materials. This creates new opportunities for the implementation of single-use systems.

FluoroFlex® film is certified animal component free (ACF), and is extruded, manufactured into biocontainers and packaged in ISO Class 7 cleanrooms.





*Liquid ma*

*management solutions ideally suited to address intra-facility transfers and inter-facility transport*

### Product Portfolio Standards Guides

Meissner has compiled biocontainer assembly Standards Guides for our TepoFlex® PE and FluoroFlex® PVDF portfolios. Each guide features best practice designs for the most common liquid management applications. The highlighted products are available for immediate order and new designs are incorporated on a regular basis. Both Standards Guides are available for download at [www.meissner.com](http://www.meissner.com).



### Product Qualification Guides

Meissner maintains comprehensive Qualification Guides in support of our One-Touch® biocontainer product portfolios. This level of integrated quality documentation is unmatched in industry, and is intended to fast track process qualification and validation efforts. Meissner offers customers these comprehensive Qualification Guides once a non-disclosure agreement is in place.

### FlexStation® Rigid Outer Containers

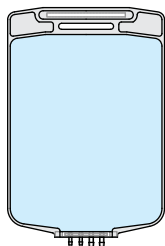
FlexStation® rigid transport and shipping containers are available to create versatile integrated single-use process solutions for robust liquid management. These durable plastic outer containers are reusable and collapsible for storage and handling when not in use. They are ideally suited to address intra-facility transfers and inter-facility transport of buffers, culture media, and bulk product. FlexStation® rigid outer containers represent a cost-effective alternative to stationary stainless steel storage and transport bins and are suitable for cold chain distribution.

TepoFlex® biocontainers deployed in FlexStation® rigid outer containers have been qualified for liquid transport in accordance with International Safe Transit Association (ISTA) Series 3 testing.

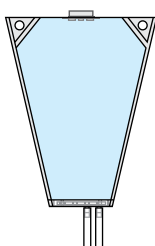


## TepoFlex® & FluoroFlex®

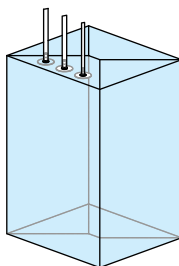
1 2D End-Ported  
50 mL - 20 L



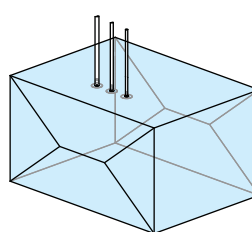
2 FlexFill™  
500 mL - 6 L



3 3D Top-Ported  
for QuaDrums™  
50 L - 200 L

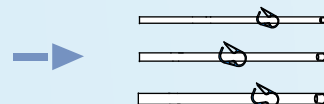


4 3D Top-Ported  
for FlexStation®  
100 L - 1,000 L

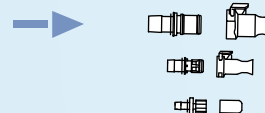


Meissner's biocontainer assemblies come in a variety of shapes and sizes. Please refer to the TepoFlex® and FluoroFlex® Standards Guides for a complete listing of biocontainer assemblies. For custom configurations, please contact the factory.

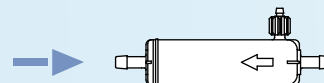
Biocontainer assemblies come standard with either TPE or Platinum-cured Silicone tubing. Tubing is available in a variety of lengths and diameters to suit customer-specific needs.



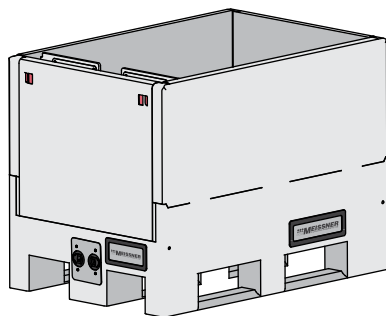
Meissner's biocontainers can be ordered with a wide range of connectors or end fittings to address the desired process connectivity.



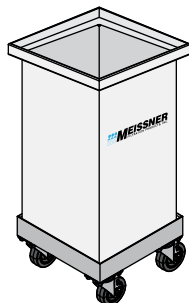
Meissner's full line of capsule filters is available for use with our biocontainer assemblies. Compact and easy to use, capsule filters are engineered to satisfy the highest standards of filtration reliability and convenience. Capsule filters are available with a variety of pore sizes and surface areas to accommodate numerous applications.



## FlexStation® & QuaDrum™



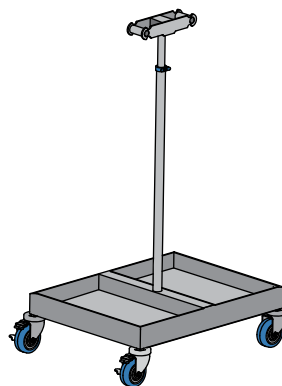
100 L, 200 L, 500 L, 1,000 L



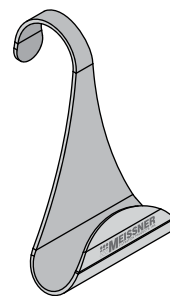
50 L, 100 L, 200 L

Lids are available with all FlexStation® and QuaDrum™ containers.

## FlexCessories™



Adjustable biocontainer hanging stand



Biocontainer hanger