

TepoFlex®

Biocontainer Assemblies



One-Touch® Single-Use Systems

The One-Touch® single-use systems portfolio is built on a solid foundation of quality, technical capability and operational excellence, which is unparalleled in the industry. Our unique manufacturing approach employs pre-qualified dynamic single-use component libraries, and product quality certification is included for each assembly. Combined, these provide unprecedented levels of quality documentation and traceability for each fluid contact component. Comprehensive product quality certificates and serialization of each and every single-use product manufactured are our quality trademarks.

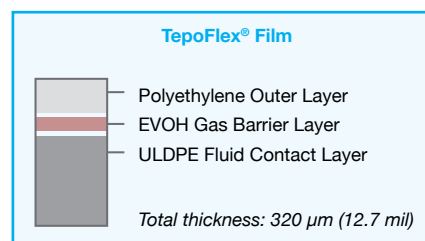
[Comprehensive Certificate of Quality](#) | [Serialization of Every Single-Use Product](#) | [Full Traceability](#)

Technical Expertise

Meissner's single-use systems are designed by engineers proficient in liquid management applications, from development scale through production. Our polymer expertise, and the manufacture of many of the underlying components that go into our single-use assemblies, are Meissner's differentiating hallmarks. Our expanding repository of component and design knowledge allows us to value engineer the next generation of single-use assemblies to cater to your specific process needs. Meissner's comprehensive standards portfolio incorporates best practice designs with commonly requested functionalities. Our application engineering team is recognized for their design and scale-up expertise, process flow recommendations and validation support. Coupling this expertise with our streamlined manufacturing operations and support services allows Meissner to provide one of the shortest lead times in the industry for custom products.

TepoFlex® Standards Guide

Meissner's TepoFlex® Standards Guide features hundreds of standard biocontainer configurations designed to cater to common liquid handling applications in volumes ranging from 50 mL to 1,000 L. Complementary products, such as BioFlex® tubing assemblies, QuaDrum® storage containers and FlexStation® rigid outer shipping and storage containers, can also be found in the Standards Guide. Download the guide at www.meissner.com/tepoFlex.



100 L TepoFlex® biocontainer assembly
deployed in a QuaDrum® storage container

TepoFlex® Biocontainers

Meissner's polyolefin-based TepoFlex® film is optimized for single-use system requirements within the biopharmaceutical industry. The film's exceptional clarity is a testament to its cleanliness. Free of slip agents, TepoFlex® film couples a low extractables and leachables profile with the industry's highest combined gas and water vapor barrier properties. This feature mitigates the risk of degradation of culture media, buffers, intermediate and bulk drug products stored in TepoFlex® biocontainers. Both impact and tear resistant, TepoFlex® biocontainers are durable and retain >95% of the film strength in the seams. This quality attribute mitigates the risk of loss of fluid integrity.

TepoFlex® film is certified animal component free (ACF). The film is extruded, manufactured into biocontainers and packaged in ISO Class 7 cleanrooms. TepoFlex® biocontainers and all BioFlex® fluid path assemblies are supplied gamma irradiated to ensure an SAL of 10⁻⁶ substantiated according to ISO 11137 methodology.

TepoFlex® film, biocontainers and all components of single-use assemblies are supported by a comprehensive Qualification Guide. This guide brings all relevant quality documentation and certification together in one document, helping to speed your qualification and validation process.

Slip agent free | **Low extractables/leachables profile**

Film Properties

Property ¹	Test Protocol	Typical Values	
Optical			
Haze	ASTM D1003-07	5%	
Clarity	ASTM D1746-03	93%	
Total luminous transmittance	ASTM D1003-07	92%	
Barrier			
Water Vapor Transmission Rate ²	ASTM F1249-06	0.42 g/m ² • 24h	0.027 g/100 in ² • 24h
O ₂ Transmission Rate ³	ASTM F1927-07	0.06 cm ³ /m ² • 24h	0.004 cm ³ /100 in ² • 24h
CO ₂ Transmission Rate ⁴	ASTM F2476-05	<1.0 cm ³ /m ² • 24h	<0.06 cm ³ /100 in ² • 24h
Fluid Integrity			
Film strength retained in seam	ASTM D882-02	>95%	

TepoFlex® film passes biocompatibility according to USP <87>, USP <88>, USP <661>, ISO 10993 parts 5, 6, 10 and 11, as well as EP 3.1.5.

¹ Determined on samples gamma irradiated at 29.2 - 36.6 kGy.

² RH test gas: 100%; RH carrier gas: 0%

³ RH test gas: 50%; RH carrier gas: 100%

⁴ RH test gas: 50%; RH carrier gas: 0%

This technical information consists of typical product data and should not be used as a specification.

What are slip agents and what is the benefit of removing them?

Slip agents are polymer additives, commonly referred to as internal lubricants such as oleamide, erucamide and stearamide. When added to the polymer matrix, slip agents migrate to the film's outer layers. This results in a waxy surface coating which imparts scratch resistance and surface lubricity, allowing the film to slide easily over itself. However, slip agents reduce film clarity and may interfere with the seal integrity of biocontainers. Most importantly, slip agents are a significant source of leachable compounds, have been shown to interfere with bioassays, and may affect product stability and shelf life. TepoFlex® film does not contain slip agents.

Model Solvents	Typical Values*
WFI	< 2 ppm
PBS pH 3	< 2 ppm
PBS pH 11	< 1 ppm
3M NaCl	≤ 1 ppm
96% EtOH	≤ 5 ppm
1% Tween 80	< 5 ppm

* Extractables:

Typical values represent the upper boundary set by the highest value obtained in the extractables study for TepoFlex® biocontainers, tested for 3 months at 40°C and 75% RH, from any of the target compounds identified by a comprehensive analytical screen consisting of TOC, IEC, ICP-OES, ICP-AES, GC/MS and LC/MS.



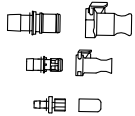
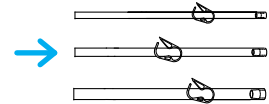
500 L TepoFlex® biocontainer assembly deployed in the FlexStation® 500

Options

Maximize Flexibility With Your TepoFlex® Biocontainer

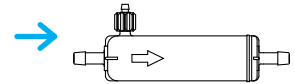
From chambers to tubing to filters, Meissner guarantees the forward and backward traceability of every component in your biocontainer assembly. Our single-use systems are manufactured and packaged in ISO Class 7 cleanrooms, where every component is monitored by our integrated MRP/MES system.

TepoFlex® 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.



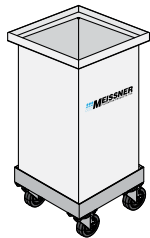
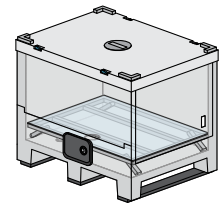
Meissner's TepoFlex® biocontainers can be ordered with a wide range of **connectors or end fittings** to address the desired process connectivity.

Meissner's full line of capsule filters is available for use with TepoFlex® biocontainer assemblies. **Capsule filters** are available with a variety of retention ratings and surface areas to satisfy numerous applications.



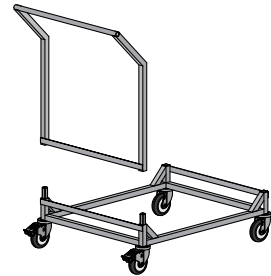
Meissner's **BioFlex®** tubing assemblies provide secure fluid transfer in biopharmaceutical processing applications. These assemblies provide an enhanced level of convenience that maximizes flexibility in the deployment of single-use systems, as well as conventional systems.

FlexStation® rigid transport and shipping containers are available in standard sizes of 100 L, 200 L, 500 L and 1,000 L to fit standard 3D biocontainers.



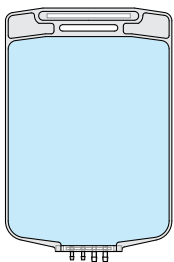
QuaDrum® storage containers are available in standard sizes of 50 L, 100 L and 200 L to fit standard 3D biocontainer assemblies.

Other **accessories** are available, including carts and dollies for QuaDrum® and FlexStation® rigid outer containers. Visit www.meissner.com for details.

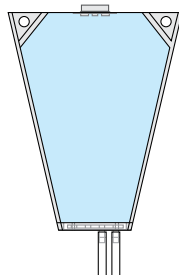


Shapes & Sizes

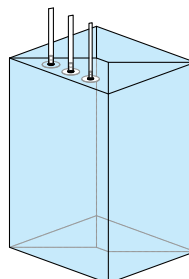
① 2D End-ported
50 mL - 20 L



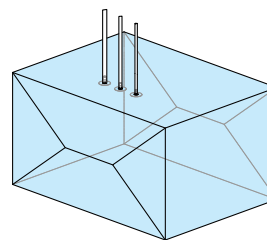
② FlexFill®
500 mL - 6 L+



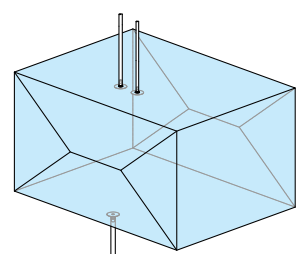
③ 3D Top-ported
for QuaDrum®
50 L - 200 L



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



⑤ 3D Top & Bottom-Ported
for FlexStation®
100 L - 1,000 L



Download the TepoFlex® Standards Guide at www.meissner.com/tepoflex

MEISSNER
FILTRATION PRODUCTS