

# TepoFlex<sup>®</sup>

Biocontainer Assemblies



**One-Touch<sup>®</sup>**  
single-use processing solution

**DSR3101B-V02-B9000-01**  
1 L TepoFlex<sup>®</sup> Biocontainer and Filter Assembly

Lot No: J264998101  
Expiration Date October 2011

Track No: A264998101

Serial No: F555555



Irradiation Dot



**MEISSNER**  
FILTRATION PRODUCTS, INC.

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# 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 is one of 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, is Meissner's differentiating hallmark. 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.

- Value Engineered Designs
- Validation Support Services
- Fast Turnaround on Custom Products



### TepoFlex® Film

- Polyethylene Outer Layer
- EVOH Gas Barrier Layer
- ULDPE Fluid Contact Layer

Total thickness:  
320 µm (12.7 mil)

# 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<sup>-6</sup> 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 together all relevant quality documentation and certification in one document, helping to speed your qualification and validation process.

TepoFlex® film is manufactured without the use of slip agents to reduce potential product interference and lower the film's overall extractables/leachables profile.

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
10% DMSO	≤ 1 ppm

**\* Extractables:**

Typical values represent the upper boundary set by the highest value obtained in the extractables study for TepoFlex® biocontainers – surface-to-liquid ratio of 2 cm<sup>2</sup>/mL, 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.

**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.



## TepoFlex® Standards Guide

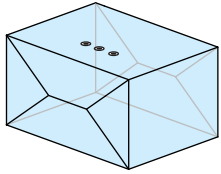
Meissner's *TepoFlex® Standards Guide* features hundreds of standard biocontainer configurations designed to cater to common liquid handling applications in volumes ranging from 50 mL to 1,000 L. Complementary products, such as BioFlex™ fluid path assemblies for secure fluid transfer and FlexStation™ rigid outer shipping and storage containers in standard sizes of 100, 200, 500 and 1,000 liters, can also be found in the Standards Guide.

• Download the [Standards Guide](http://www.meissner.com) at [www.meissner.com](http://www.meissner.com)

200 L TepoFlex® Biocontainer Assembly with FlexStation™ and accessory cart

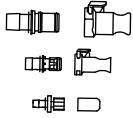
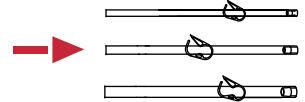
# Options

Maximize Flexibility With Your TepoFlex® Biocontainer



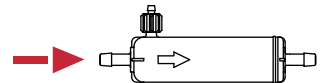
From chambers to tubing to filters, Meissner guarantees the forward and backward traceability of every component in your biocontainer assembly. Our single-use systems are manufactured and packaged in ISO Class 7 cleanrooms, where every component is monitored by our integrated MRP / MES system.

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.



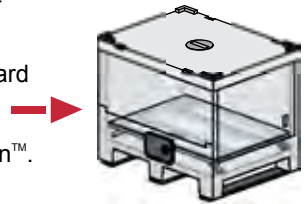
Meissner's TepoFlex® biocontainers can be ordered with a wide range of connectors or end fittings to address the desired process connectivity.

Meissner's full line of capsule filters is available for use with TepoFlex® biocontainer assemblies. 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 satisfy numerous applications.

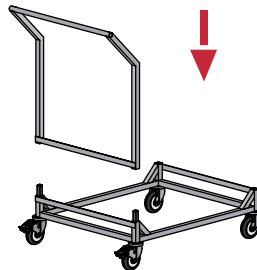


Meissner's BioFlex™ fluid path assemblies provide secure fluid transfer in biopharmaceutical processing applications. The assemblies provide an enhanced level of convenience that maximizes flexibility in the deployment of single-use systems, as well as conventional systems.

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



Other accessories are also available, including a rolling dolly for FlexStation™. Please consult the factory for details.



## Shapes & Sizes

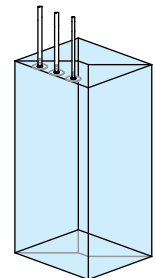
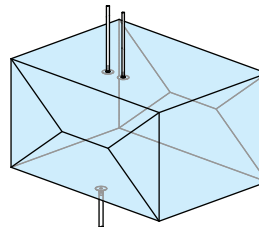
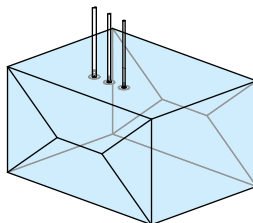
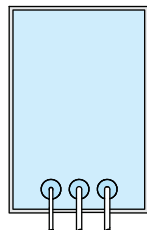
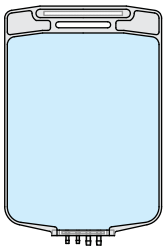
① 2D End-Ported  
50 mL - 20 L

② 2D Face-Ported  
5 L - 200 L

③ 3D Top-Ported  
100 L - 1,000 L

④ 3D Top & Bottom-Ported  
100 L - 1,000 L

⑤ 3D for Drums  
50 L - 200 L



For more information, please consult the  
**TepoFlex® Standards Guide**,  
available for download at [www.meissner.com](http://www.meissner.com)

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