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**One-Touch®**

Meissner Filtration Products, Inc. designs, develops, manufactures, and supplies high quality single-use systems. From film to filter, everything necessary to create clean, convenient biocontainer assemblies can be found under one roof.
Meissner’s adaptable, One-Touch® single-use systems are designed specifically for fluid management in the biopharmaceutical industry.

1. Chamber

FluoroFlex® chambers are composed of Meissner’s five layer PVDF-based FluoroFlex® film, which combines inherent purity with high gas barrier properties and industry-leading fluid integrity characteristics. Page 4

2. Tubing

FluoroFlex® 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. Page 20

3. Connectors

Meissner’s FluoroFlex® biocontainers can be ordered with a wide range of connectors or end fittings to address the desired process connectivity. Page 15

4. Filters

Meissner’s full line of single-use capsule filters are available for use with FluoroFlex® biocontainer assemblies. Compact and easy to use, capsule filters are engineered to satisfy the highest standards of filtration reliability and convenience. Capsule filters combine a full range of filter media, pore size ratings and surface areas to satisfy numerous applications. Page 9
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, 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.

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

FluoroFlex® Film

<table>
<thead>
<tr>
<th>Property</th>
<th>Test Protocol</th>
<th>Typical Values</th>
</tr>
</thead>
<tbody>
<tr>
<td>Optical</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Haze</td>
<td>ASTM D1003-07</td>
<td>6.7%</td>
</tr>
<tr>
<td>Clarity</td>
<td>ASTM D1746-09</td>
<td>93%</td>
</tr>
<tr>
<td>Total luminous transmittance</td>
<td>ASTM D1003-07</td>
<td>94%</td>
</tr>
<tr>
<td>Barrier</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Water Vapor Transmission Rate</td>
<td>ASTM F1249-06</td>
<td>1.09 g/m²•24h</td>
</tr>
<tr>
<td>CO₂ Transmission Rate</td>
<td>ASTM F1927-07</td>
<td>0.75 cm³/m²•24h</td>
</tr>
<tr>
<td>CO₂ Transmission Rate</td>
<td>ASTM F2476-05</td>
<td>&lt;1.0 cm³/m²•24h</td>
</tr>
<tr>
<td>Biocompatibility</td>
<td>USP &lt;88&gt;</td>
<td>Pass</td>
</tr>
<tr>
<td>Cytotoxicity</td>
<td>USP &lt;87&gt;</td>
<td>Pass</td>
</tr>
<tr>
<td>Non-volatile Residue</td>
<td>USP &lt;661&gt;</td>
<td>Pass</td>
</tr>
<tr>
<td>Residue on Ignition</td>
<td>USP &lt;661&gt;</td>
<td>Pass</td>
</tr>
<tr>
<td>Heavy Metals</td>
<td>USP &lt;661&gt;</td>
<td>Pass</td>
</tr>
<tr>
<td>Buffering Capacity</td>
<td>USP &lt;661&gt;</td>
<td>Pass</td>
</tr>
</tbody>
</table>

1 Determined on samples gamma irradiated at 29.2 - 36.7 kGy.
2 RH test gas: 100%; RH carrier gas: 0%; 23°C
3 RH test gas: 50%; RH carrier gas: 100%; 23°C
4 RH test gas: 50%; RH carrier gas: 0%; 23°C

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

About FluoroFlex®

Total thickness: 260 μm (10.2 mil)
Meissner’s polyvinylidene fluoride (PVDF) based FluoroFlex® film is a multi-layer coextruded film of an entirely new generation and is optimized to meet requirements within the pharmaceutical industry that are beyond the capabilities of polyolefin-based films. Because PVDF does not require additives, processing aids or stabilizers, it provides FluoroFlex® film its inherent purity and superior leachables and extractables profile. PVDF is also inert, has low adsorption and binding characteristics, and possesses non-stick qualities.

FluoroFlex® film retains the exceptional clarity and high gas barrier properties of Meissner’s TepoFlex® polyolefin-based film. The combined attributes of inherent purity and high gas barrier mitigate the risk of degradation of process solutions and API’s stored and processed in FluoroFlex® biocontainers.

Incorporating elastomeric thermoplastic polyurethane (TPU) strength layers in the patent-pending FluoroFlex® film structure renders it exceptionally strong, yet highly flexible. Our advanced welding technology maximizes the seam strength retention to ensure that FluoroFlex® biocontainers are the industry’s most durable, reducing the risk of costly fluid integrity failures.

FluoroFlex® biocontainers provide superior performance benefits compared to polyolefin-based biocontainers with respect to thermal stability, chemical resistance and robustness. PVDF has an excellent performance history as a filter membrane medium and in pharmaceutical high purity water distribution systems. Extending this proven history of PVDF as a product contact material to FluoroFlex® biocontainers is a logical step in harnessing the highest benefits of single-use processing.

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

FluoroFlex® biocontainers and BioFlex™ fluid path assemblies are supplied gamma-irradiated to ensure an SAL of $10^{-6}$ substantiated according to ISO 11137 methodology. FluoroFlex® 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 package, helping speed your qualification and validation process.

### FluoroFlex® Film Attributes and Single-Use Processing Benefits

<table>
<thead>
<tr>
<th>FluoroFlex® Film Attributes</th>
<th>Single-Use Processing Benefits</th>
</tr>
</thead>
<tbody>
<tr>
<td>Inherent purity of product contact layer</td>
<td>Very low leachables and extractables profile</td>
</tr>
<tr>
<td>Non adsorbing product contact layer</td>
<td>Low protein and lipid binding levels</td>
</tr>
<tr>
<td>Exceptional clarity</td>
<td>Opportunities for process monitoring</td>
</tr>
<tr>
<td>High gas barrier</td>
<td>Increased stability and shelf life for process solutions, intermediates and API</td>
</tr>
<tr>
<td>Exceptional strength and toughness</td>
<td>Increased biocontainer robustness and fluid integrity due to the film’s high tensile and applied welding technology</td>
</tr>
<tr>
<td>Thermal stability</td>
<td>Compatible with hot PW or WFI for storage and formulation applications</td>
</tr>
<tr>
<td>Wide range of chemical resistance</td>
<td>Well suited to aggressive chemical solvents</td>
</tr>
<tr>
<td>Process streamlining</td>
<td>Opportunity to streamline product contact materials across the entire process</td>
</tr>
</tbody>
</table>
Bill of Materials

<table>
<thead>
<tr>
<th>Item</th>
<th>Description</th>
<th>Material</th>
<th>Qty</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>500 mL End-Ported Biocontainer</td>
<td>FluoroFlex®</td>
<td>1</td>
</tr>
<tr>
<td>2</td>
<td>Ratcheting Pinch Clamp, Medium</td>
<td>Polypropylene</td>
<td>2</td>
</tr>
<tr>
<td>3</td>
<td>¼” x ⅜” Tubing, 6” Length 6.4 mm x 9.5 mm Tubing, 15.2 cm Length</td>
<td>TPE or Plt. Silicone</td>
<td>2</td>
</tr>
<tr>
<td>4</td>
<td>¼” Hosebarb x Female Luer Adapter 6.4 mm Hosebarb x Female Luer Adapter</td>
<td>Polypropylene</td>
<td>1</td>
</tr>
<tr>
<td>5</td>
<td>Male Luer Plug</td>
<td>Polypropylene</td>
<td>1</td>
</tr>
<tr>
<td>6</td>
<td>½” Hosebarb x Male Luer Adapter 6.4 mm Hosebarb x Male Luer Adapter</td>
<td>Polypropylene</td>
<td>1</td>
</tr>
<tr>
<td>7</td>
<td>Female Luer Plug</td>
<td>Polypropylene</td>
<td>1</td>
</tr>
<tr>
<td>8</td>
<td>Protective Cover, Small</td>
<td>Vinyl</td>
<td>2</td>
</tr>
</tbody>
</table>

Standards

<table>
<thead>
<tr>
<th>Part Number</th>
<th>Biocontainer</th>
<th>Tubing</th>
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<tbody>
<tr>
<td></td>
<td>Volume</td>
<td>Dimensions</td>
</tr>
<tr>
<td>DUF2191F-N00B01-00</td>
<td>50 mL</td>
<td>5.3” x 5.4” 13.3 cm x 13.7 cm</td>
</tr>
<tr>
<td>DUF2194F-N00B01-00</td>
<td>250 mL</td>
<td>6.0” x 7.9” 15.2 cm x 20.1 cm</td>
</tr>
<tr>
<td>DUF2195F-N00B01-00</td>
<td>500 mL</td>
<td>7.0” x 10.4” 17.8 cm x 26.4 cm</td>
</tr>
<tr>
<td>DUF2101F-N00B01-00</td>
<td>1 L</td>
<td>7.8” x 12.1” 19.8 cm x 30.7 cm</td>
</tr>
<tr>
<td>DUF2102F-N00B01-00</td>
<td>2 L</td>
<td>9.5” x 13.4” 24.1 cm x 34.0 cm</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Biocontainer</td>
</tr>
<tr>
<td></td>
<td>Volume</td>
<td>Dimensions</td>
</tr>
<tr>
<td>DUF2191F-N00B11-00</td>
<td>50 mL</td>
<td>5.3” x 5.4” 13.3 cm x 13.7 cm</td>
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<tr>
<td>DUF2194F-N00B11-00</td>
<td>250 mL</td>
<td>6.0” x 7.9” 15.2 cm x 20.1 cm</td>
</tr>
<tr>
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<td>500 mL</td>
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<tr>
<td>DUF2101F-N00B11-00</td>
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</tr>
<tr>
<td>DUF2102F-N00B11-00</td>
<td>2 L</td>
<td>9.5” x 13.4” 24.1 cm x 34.0 cm</td>
</tr>
</tbody>
</table>

• 500 mL biocontainer shown
• Packaged in quantities of 5
End-Ported Biocontainer Assemblies - Small Volume Plus

Bill of Materials

<table>
<thead>
<tr>
<th>Item</th>
<th>Description</th>
<th>Material</th>
<th>Qty</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>500 mL End-Ported Biocontainer</td>
<td>FluoroFlex®</td>
<td>1</td>
</tr>
<tr>
<td>2</td>
<td>¼” x ⅜” Tubing, 3” Length 6.4 mm x 9.5 mm Tubing, 7.8 cm Length</td>
<td>TPE</td>
<td>2</td>
</tr>
<tr>
<td>3</td>
<td>¼” Hosebarb x Female Luer Adapter 6.4 mm Hosebarb x Female Luer Adapter</td>
<td>Polypropylene</td>
<td>1</td>
</tr>
<tr>
<td>4</td>
<td>Swabable Valve / Needleless Injection Site</td>
<td>Polycarbonate / Silicone</td>
<td>1</td>
</tr>
<tr>
<td>5</td>
<td>Male Luer Cap</td>
<td>Polypropylene</td>
<td>1</td>
</tr>
<tr>
<td>6</td>
<td>½” x ¼” Tubing, 24” Length 3.2 mm x 6.4 mm Tubing, 61.0 cm Length</td>
<td>TPE</td>
<td>1</td>
</tr>
<tr>
<td>7</td>
<td>⅛” (3.2 mm) Hosebarb Plug</td>
<td>Polypropylene</td>
<td>1</td>
</tr>
<tr>
<td>8</td>
<td>½” x ¼” Hosebarb Reduction Fitting 6.4 mm x 3.2 mm Hosebarb Reduction Fitting</td>
<td>Polypropylene</td>
<td>1</td>
</tr>
<tr>
<td>9</td>
<td>Ratcheting Pinch Clamp, Small</td>
<td>Polypropylene</td>
<td>1</td>
</tr>
<tr>
<td>10</td>
<td>Ratcheting Pinch Clamp, Medium</td>
<td>Polypropylene</td>
<td>1</td>
</tr>
<tr>
<td>11</td>
<td>¼” x ⅜” Tubing, 6” Length 6.4 mm x 9.5 mm Tubing, 15.2 cm Length</td>
<td>TPE</td>
<td>1</td>
</tr>
<tr>
<td>12</td>
<td>½” Hosebarb x Male Luer Adapter 6.4 mm Hosebarb x Male Luer Adapter</td>
<td>Polypropylene</td>
<td>1</td>
</tr>
<tr>
<td>13</td>
<td>Female Luer Plug</td>
<td>Polypropylene</td>
<td>1</td>
</tr>
<tr>
<td>14</td>
<td>Protective Cover, Small</td>
<td>Vinyl</td>
<td>1</td>
</tr>
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Standards

<table>
<thead>
<tr>
<th>Part Number</th>
<th>Biocontainer</th>
<th>Tubing</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Volume</td>
<td>Dimensions</td>
</tr>
<tr>
<td>DUF3191F-N00B01-00</td>
<td>50 mL</td>
<td>5.3&quot; x 5.4&quot;</td>
</tr>
<tr>
<td></td>
<td></td>
<td>13.3 cm x 13.7 cm</td>
</tr>
<tr>
<td>DUF3194F-N00B01-00</td>
<td>250 mL</td>
<td>6.0&quot; x 7.9&quot;</td>
</tr>
<tr>
<td></td>
<td></td>
<td>15.2 cm x 20.1 cm</td>
</tr>
<tr>
<td>DUF3195F-N00B01-00</td>
<td>500 mL</td>
<td>7.0&quot; x 10.4&quot;</td>
</tr>
<tr>
<td></td>
<td></td>
<td>17.8 cm x 26.4 cm</td>
</tr>
<tr>
<td>DUF3101F-N00B01-00</td>
<td>1 L</td>
<td>7.8&quot; x 12.1&quot;</td>
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<tr>
<td></td>
<td></td>
<td>19.8 cm x 30.7 cm</td>
</tr>
<tr>
<td>DUF3102F-N00B01-00</td>
<td>2 L</td>
<td>9.5&quot; x 13.4&quot;</td>
</tr>
<tr>
<td></td>
<td></td>
<td>24.1 cm x 34.0 cm</td>
</tr>
</tbody>
</table>

- 500 mL biocontainer shown
- Packaged in quantities of 5

FluoroFlex® → Small Volume Plus → Without Filter
### Bill of Materials

<table>
<thead>
<tr>
<th>Item</th>
<th>Description</th>
<th>Material</th>
<th>Qty</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>10 L End-Ported Biocontainer</td>
<td>FluoroFlex®</td>
<td>1</td>
</tr>
<tr>
<td>2</td>
<td>Ratchet Pinch Clamp, Large</td>
<td>PBT</td>
<td>2</td>
</tr>
<tr>
<td>3</td>
<td>½” x ¾” Tubing, 12” Length 9.5 mm x 14.3 mm Tubing, 30.5 cm Length</td>
<td>TPE or Plt. Silicone</td>
<td>2</td>
</tr>
<tr>
<td>4</td>
<td>Coupling Body, ¾” Hosebarb, MPC Coupling Body, 9.5 mm Hosebarb, MPC</td>
<td>Polycarbonate</td>
<td>1</td>
</tr>
<tr>
<td>5</td>
<td>Sealing Plug, MPC</td>
<td>Polycarbonate</td>
<td>1</td>
</tr>
<tr>
<td>6</td>
<td>Coupling Insert, ¾” Hosebarb, MPC Coupling Insert, 9.5 mm Hosebarb, MPC</td>
<td>Polycarbonate</td>
<td>1</td>
</tr>
<tr>
<td>7</td>
<td>Sealing Cap, MPC</td>
<td>Polycarbonate</td>
<td>1</td>
</tr>
<tr>
<td>8</td>
<td>Ratchet Pinch Clamp, Medium</td>
<td>Polypropylene</td>
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</tr>
<tr>
<td>9</td>
<td>½” x ¾” Tubing, 12” Length 6.4 mm x 9.5 mm Tubing, 30.5 cm Length</td>
<td>TPE or Plt. Silicone</td>
<td>1</td>
</tr>
<tr>
<td>10</td>
<td>⅜” Hosebarb x Female Luer Adapter 6.4 mm Hosebarb x Female Luer Adapter</td>
<td>Polypropylene</td>
<td>1</td>
</tr>
<tr>
<td>11</td>
<td>Male Luer Plug</td>
<td>Polypropylene</td>
<td>1</td>
</tr>
<tr>
<td>12</td>
<td>Protective Cover, Small</td>
<td>Vinyl</td>
<td>1</td>
</tr>
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</table>

* 10 L biocontainer shown

### Standards

<table>
<thead>
<tr>
<th>Part Number</th>
<th>Biocontainer Volume</th>
<th>Biocontainer Dimensions</th>
<th>Tubing</th>
</tr>
</thead>
<tbody>
<tr>
<td>DUF3104F-N00B01-00</td>
<td>5 L</td>
<td>13.0” x 15.5” 33.0 cm x 39.4 cm</td>
<td>TPE</td>
</tr>
<tr>
<td>DUF3105F-N00B01-00</td>
<td>10 L</td>
<td>15.0” x 22.0” 38.1 cm x 55.9 cm</td>
<td>TPE</td>
</tr>
<tr>
<td>DUF3106F-N00B01-00</td>
<td>20 L</td>
<td>17.3” x 27.0” 43.9 cm x 68.6 cm</td>
<td>TPE</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Part Number</th>
<th>Biocontainer Volume</th>
<th>Biocontainer Dimensions</th>
<th>Tubing</th>
</tr>
</thead>
<tbody>
<tr>
<td>DUF3104F-N00B11-00</td>
<td>5 L</td>
<td>13.0” x 15.5” 33.0 cm x 39.4 cm</td>
<td>Platinum-Cured Silicone</td>
</tr>
<tr>
<td>DUF3105F-N00B11-00</td>
<td>10 L</td>
<td>15.0” x 22.0” 38.1 cm x 55.9 cm</td>
<td>Platinum-Cured Silicone</td>
</tr>
<tr>
<td>DUF3106F-N00B11-00</td>
<td>20 L</td>
<td>17.3” x 27.0” 43.9 cm x 68.6 cm</td>
<td>Platinum-Cured Silicone</td>
</tr>
</tbody>
</table>
**SteriLUX® PVDF**

SteriLUX® disposable capsule filters are absolute-rated PVDF membrane filters optimized for sterile filtration, prefiltration and clarification of pharmaceutical and biological solutions. The surface-modified SteriLUX® membrane filter is manufactured by Meissner’s proprietary process to provide immediate water-wettability, unmatched flow, high mechanical strength, thermal and chemical stability, and ultra-low binding characteristics.

**Advantages**
- Available in 0.1 µm and 0.2 µm ratings with standard biocontainer assemblies
- Qualifies as a sterilizing grade filter per ASTM F838-05 liquid bacterial challenge
- High flow rates at low pressure drops
- Ultracean – no additives or surfactants
- 100% integrity tested
- Hydrophilic PVDF membrane
- Fully integrity testable in water
- High thermal and hydrolytic stability

**Applications**
SteriLUX® capsule filters can be used to filter microbiological growth media, cell and tissue culture media and additives, bulk pharmaceutical chemicals, acids, bases, organic solvents, pharmaceutical preparations and active ingredients, parenterals, biopharmaceuticals, vaccines, serum, blood products, ophthalmic solutions, reagents, water for injection (WFI), and compressed gases.

**Specifications**
- **Filter Media:** Polyvinylidene Fluoride (PVDF) Membrane
- **Bacterial Retention:** ASTM F838-05 Challenge
  - 0.1 µm, 0.2 µm > 10^7 LRV/cm²
- **Brevundimonas diminuta**
  - 0.1 µm and 0.2 µm meet the FDA definition of a sterilizing grade filter

---

**STyLUX® PES**

STyLUX® disposable capsule filters are absolute-rated, polyethersulfone membrane filters designed to provide greater bacteria and particle removal at high flow rates and extremely low pressure drops. STyLUX® capsules contain an asymmetric membrane which offers the greatest assurance of filtration performance, stability and service life for controlling contaminants in demanding environments. The highly porous polyethersulfone membrane is permanently hydrophilic, has exceptional flow rates, and provides excellent compatibility and extremely low extractables in a wide range of fluids and applications.

**Advantages**
- Available in 0.1 µm and 0.2 µm ratings with standard biocontainers
- Qualifies as a sterilizing grade filter per ASTM F838-05 liquid bacterial challenge
- Extremely high flow rates at low pressure drops
- Ultracean – no additives, surfactants, or post treatments
- 100% integrity tested during manufacture

**Applications**
STyLUX® capsule filters offer the greatest security for high quality filtration in a wide variety of applications. STyLUX® capsules are designed for removal of particulates, colloids and microorganisms from a broad range of pharmaceutical and biological liquids. Typical liquids include pharmaceutical preparations, antibiotics, vaccines, protein solutions, immunologicals, virus suspensions, radiodiagnostics, enzymes, ophthalmic solutions, reagents, salt solutions, nutrients, tissue culture media, serum and blood-based products, biologicals and many more.

**Specifications**
- **Filter Media:** Polyethersulfone (PES) Membrane
- **Bacterial Retention:** ASTM F838-05 Challenge
  - 0.1 µm, 0.2 µm > 10^7 LRV/cm²
- **Brevundimonas diminuta**
  - 0.1 µm and 0.2 µm meet the FDA definition of a sterilizing grade filter
EverLUX® PES

The EverLUX® polyethersulfone (PES) capsule filter is designed for very high contaminant capacity, extended service life and high flow with low pressure drop in a wide range of biological fluids. Optimized for sterile filtration, prefiltration and clarification applications, the permanently hydrophilic EverLUX® membrane offers up to 2.5 times higher flow rates than other PES membranes. Its asymmetric structure extends the membrane’s capacity and service life by withstanding higher particle loads and protein concentrations. Increased membrane thickness allows the EverLUX® to retain its sterilizing properties, while its tapered pore structure allows more contaminant capacity than even conventional PES membranes. The fast-flowing, high-throughput, low-binding and bacteria-retentive properties of the EverLUX® PES membrane make it a very reliable, cost-effective and time-saving filter.

Advantages

- Available in 0.2 µm ratings for standard biocontainers
- Pharmaceutical validated, sterilizing grade
- Unique, patented PES membrane with very high flow rates and exceptional service life
- Minimum pressure drop
- Chemical compatibility across pH 1-14
- Low adsorption, high transmission of proteins, active ingredients, and preservatives
- Superior throughput in high contaminant fluids, including growth media, serum and protein-containing solutions.
- Lower filtration costs through increased service life and contaminant-holding capacity
- Fully integrity testable in water
- 100% integrity tested during manufacture
- Cleanroom manufactured

Applications

EverLUX® capsules are frequently used for buffers, blood products, complex biologicals, serum, cell and tissue culture media, process intermediates, supernatants, vaccines and ophthalmic solutions.

Specifications

Filter Membrane: Polyethersulfone (PES)

EverLUX® capsules are made with filter media which meets the criteria for a non-fiber releasing filter as defined in 21 CFR 210.3 (b)(6). EverLUX® capsule components are biosafe in compliance with USP Class VI Plastics biologicals reactivity tests. All materials of construction are FDA approved for food contact use per CFR Title 21,177.

Bacterial Retention:

ASTM F838-05 Challenge:
STW 0.2 µm > 10⁷ cfu/cm²
Brevundimonas diminuta
STW 0.2 µm meets the FDA definition of a sterilizing grade filter.

* The filter media listed are available with standard bicontainer assemblies, but for custom assemblies other filters may be ordered.
* To view Meissner’s full range of filter media, please visit www.meissner.com.
End-Ported Biocontainer Assemblies - Small Volume with Filter

Bill of Materials

<table>
<thead>
<tr>
<th>Item</th>
<th>Description</th>
<th>Material</th>
<th>Qty</th>
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</thead>
<tbody>
<tr>
<td>1</td>
<td>1 L End-Ported Biocontainer</td>
<td>FluoroFlex®</td>
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<tr>
<td>2</td>
<td>Ratchet Pinch Clamp, Medium</td>
<td>Polypropylene</td>
<td>2</td>
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<tr>
<td>3</td>
<td>¼&quot; x ⅜&quot; Tubing, 12&quot; Length 6.4 mm x 9.5 mm Tubing, 30.5 cm Length</td>
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<tr>
<td>4</td>
<td>Coupling Insert, ¼&quot; Hosebarb, MPC Coupling Insert, 6.4 mm Hosebarb, MPC</td>
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<td>5</td>
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<td>6</td>
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<td>8</td>
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<td>13</td>
<td>Meissner Capsule Filter</td>
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<td>Protective Cover, ¼&quot; (6.4 mm) Hosebarb</td>
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*1 L biocontainer shown

FluoroFlex® → Small Volume → Filter Included
## Standards

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<td>EverLUX™ 0.2 μm</td>
<td>CMSTW0.2-115</td>
<td>TPE</td>
<td>1 L</td>
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**Bill of Materials**

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<tr>
<th>Item</th>
<th>Description</th>
<th>Material</th>
<th>Qty</th>
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<tbody>
<tr>
<td>1</td>
<td>5 L End-Ported Biocontainer</td>
<td>FluoroFlex®</td>
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<td>Ratchet Pinch Clamp, Large</td>
<td>PBT</td>
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<td>4</td>
<td>Meissner Capsule Filter</td>
<td>See options on p. 14</td>
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<tr>
<td>5</td>
<td>Protective Cover, Small</td>
<td>Vinyl</td>
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<tr>
<td>6</td>
<td>½&quot; x ¾&quot; Tubing, 12&quot; Length 9.5 mm x 14.3 mm Tubing, 30.5 cm Length</td>
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<td>Coupling Insert. ½&quot; Hosebarb, MPC Coupling Insert. 9.5 mm Hosebarb, MPC</td>
<td>Polycarbonate</td>
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<td>8</td>
<td>Sealing Cap, MPC</td>
<td>Polycarbonate</td>
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<td>Ratchet Pinch Clamp, Medium</td>
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<tr>
<td>10</td>
<td>¼&quot; x ⅜&quot; Tubing, 12&quot; Length 6.4 mm x 9.5 mm Tubing, 30.5 cm Length</td>
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<td>¼&quot; Hosebarb x Female Luer Adapter 6.4 mm Hosebarb x Female Luer Adapter</td>
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<tr>
<td>12</td>
<td>Male Luer Plug</td>
<td>Polypropylene</td>
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• 5 L biocontainer shown

**FluoroFlex® ➔ Process Volume ➔ Filter Included**
### Standards

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<tr>
<th>Part Number</th>
<th>Filter</th>
<th>Filter Part Number</th>
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<th>Biocontainer</th>
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<th>Biocontainer</th>
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<th>Biocontainer</th>
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<td>Volume</td>
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<td>17.3&quot; x 27.0&quot;</td>
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FluoroFlex® → Process Volume → Filter Included

(continued)
PC Quick Disconnect Couplings (QDC) - MPC Series

Materials
- Polycarbonate (PC)
- Animal Component Free (ACF)

Common Vernacular
- Coupling Body
  - Female QDC or MPC body
- Sealing Plug
  - Male / QDC / MPC Plug
- Coupling Insert
  - Male QDC or MPC Insert
- Sealing Cap
  - Female QDC or MPC Cap

Typical Usage and Applications
- Industry standard quick connect
- Buffer and culture media transfer lines
- Filter and tubing sets
- More economical than polysulfone series

Connectivity
- Coupling Body
  - ¼” (6.4 mm) or ⅜” (9.5 mm) HB
  - Female quick connect interface
- Sealing Plug
  - Male quick connect interface
- Coupling Insert
  - ¼” (6.4 mm) or ⅜” (9.5 mm) HB
  - Male quick connect interface
- Sealing Cap
  - Female quick connect interface

Gamma Irradiation
- Blue in color pre-gamma irradiation
- Grey to clear post-gamma
- Up to 50 kGy

PC Large Bore Quick Disconnect Couplings - MPX Series

Materials
- Polycarbonate (PC)
- Animal Component Free (ACF)

Common Vernacular
- Coupling Body
  - Female QDC or MPX Body
- Sealing Plug
  - Male / QDC / MPX Plug
- Coupling Insert
  - Male QDC or MPX Insert
- Sealing Cap
  - Female / QDC / MPX Cap

Typical Usage and Applications
- Industry standard large bore quick connect
- Buffer and culture media transfer lines
- Filter and tubing sets
- More economical than polysulfone series

Connectivity
- Coupling Body
  - ½” (12.7 mm) HB
  - Female large bore quick connect interface
- Sealing Plug
  - Male large bore quick connect interface
- Coupling Insert
  - ⅜” (9.5 mm) or ½” (12.7 mm) HB
  - Male large bore quick connect interface
- Sealing Cap
  - Female large bore quick connect interface

Gamma Irradiation
- Blue in color pre-gamma irradiation
- Grey to clear post-gamma
- Up to 50 kGy
Luer Fittings

Materials
- Polypropylene (PP)
- Animal Component Free (ACF)

Common Vernacular
- Luer-Lok™

Typical Usage and Applications
- Sampling operations
  - Small volume sample chambers
  - Syringe sampling
- Industry standard small flow connectivity

Principle Components
- Luer x HB Adapters
- Luer Caps

Connectivity
- \( \frac{1}{8} \)" (3.2 mm) to \( \frac{1}{4} \)" (6.4 mm) HB
- Female and Male Luer Connections

Gamma Irradiation
- Up to 50 kGy

Tubing Clamps

Common Vernacular
- Pinch Clamp
- Ratchet Pinch Clamp

Typical Usage and Applications
- When activated stops or constrains flow on given tubing line

Connectivity
- Large Clamp – Tubing up to \( \frac{3}{4} \)" (19.0 mm) in diameter
- Medium Clamp – Tubing up to \( \frac{7}{16} \)" (11.1 mm) in diameter
- Small Clamp – Tubing up to \( \frac{1}{4} \)" (6.4 mm) in diameter

Materials of Construction
- Large Clamp – PEI
- Medium and Small Clamps - Polypropylene

Protective Covers

Typical Usage and Applications
- For protection of components during shipping and storage, not intended for in process use.

Materials of Construction
- Vinyl
**TC Fittings**

**Materials**
- Polypropylene (PP)
- Platinum-cured silicone (TC Gaskets)
- Animal Component Free (ACF)

**Common Vernacular**
- Sanitary Fittings
- Tri-Clamp® Fittings

**Typical Usage and Applications**
- Single-use / multi-use process equipment connectivity
- Large volume drain / fill lines
- High flow rate applications

**Principal Components**
- TC x Hose Barb Adapters
- TC Gaskets
- TC Blind Caps
- TC Clamps

**Connectivity**
- ¼” (6.4 mm), ⅜” (9.5 mm), ½” (12.7 mm), or ¾” (19.0 mm) HB
- TC Sizes: ¾” (19.0 mm), 1” - 1 ⅜” (25.4 - 38.1 mm)

**Gamma Irradiation**
- Up to 50 kGy

---

**PSU Quick Disconnect Couplings (QDC) - MPC Series**

**Materials**
- Polysulfone (PSU)
- Animal Component Free (ACF)

**Common Vernacular**
- Coupling Body
  - Female QDC or MPC Body
- Sealing Plug
  - Male / QDC / MPC Plug
- Coupling Insert
  - Male QDC or MPC insert
- Sealing Cap
  - Female / QDC / MPC Cap

**Typical Usage and Applications**
- Industry standard quick connect
- Buffer and culture media transfer lines
- Filter and tubing sets
- Higher temperature rating than polycarbonate makes it more suitable to applications where autoclaving may be required

**Connectivity**
- Coupling Body
  - ¼” (6.4 mm) or ⅜” (9.5 mm) HB
- Female quick connect interface
- Sealing Plug
  - Male quick connect interface
- Coupling Insert
  - ¼” (6.4 mm) or ⅜” (9.5 mm) HB
- Male quick connect interface
- Sealing Cap
  - Female quick connect interface

**Gamma Irradiation**
- Up to 50 kGy
- Minimal color shift post-gamma; Yellow in color
PSU Large Bore Quick Disconnect Couplings - MPX Series

Materials
- Polysulfone (PSU)
- Animal Component Free (ACF)

Common Vernacular
- Coupling Body
  - Female QDC or MPX Body
- Sealing Plug
  - Male / QDC / MPX Plug
- Coupling Insert
  - Male QDC or MPX Insert
- Sealing Cap
  - Female / QDC / MPX Cap

Typical Usage and Applications
- Industry standard large bore quick connect
- Buffer solution and cell culture media transfer lines
- Filter and Tubing sets
- Higher temperature rating than polycarbonate makes it more suitable to applications where autoclaving may be required

Connectivity
- Coupling Body
  - ½” (12.7 mm) HB
  - Female large bore quick connect interface
- Sealing Plug
  - Male large bore quick connect interface
- Coupling Insert
  - 9/16” (9.5 mm) or ½” (12.7 mm) HB
  - Male large bore quick connect interface
- Sealing Cap
  - Female large bore quick connect interface

Gamma Irradiation
- Up to 50 kGy
- Minimal color shift post-gamma; Yellow in color

Sampling and Injection Sites

Materials
- Needleless Injection Site
  - Polycarbonate
  - Silicone
- Traditional Injection Site (Latex Free)
  - ABS
  - PVC
  - Polyisoprene

Common Vernacular
- Septum Port
- Swabable Valve
- Sample Port

Typical Usage and Applications
- Sampling operations
  - Small volume sample chambers
  - Syringe sampling
- Industry standard small flow connectivity

Connectivity
- Needleless Sample/Injection Site
  - Connection – Male Luer
  - Sample/Injection Site – Female Luer
- Traditional Sample/Injection Site
  - Connection – Male Luer
  - Sample/Injection Site – Needle
Hose Barb Fittings

Materials
- Polypropylene (PP)
- Animal Component Free (ACF)

Typical Usage and Applications
- Sampling systems
- Tubing manifolds

Connectivity
- 1/8” – 3/4” Hose Barbs (3.2 mm – 19.0 mm)

Gamma Irradiation
- Up to 50 kGy

Single-Use / Multiple-Use Interface

Materials
- Polysulfone (PSU)
- Seals – Silicone
- Animal Component Free (ACF)

Common Vernacular
- STC Fitting
- Steam-Thru® Connection
- Steam Fitting

Typical Usage and Applications
- Sterile connection of a pre-sterilized single-use system to conventional fixed, e.g., stainless steel equipment
- Harvest from bioreactor to pre-sterilized single-use systems
- Feed from single-use systems to bioreactors

Connectivity
- To single-use system: 3/8” (9.5 mm) or 1/2” (12.7 mm) HB
- To process equipment: 3/4” (19.0 mm) or 1 ½” (38.1 mm) TC Connection
- To steam trap: 3/4” (19.0 mm) TC

Gamma Irradiation
- Up to 50 kGy

Quick Disconnect Couplings with Integrated Valves - HFC Series

Materials
- Polysulfone (PSU)
- Seals – Silicone
- Animal Component Free (ACF)

Common Vernacular
- HFC fitting
- QDC with shut-off valve
- Aseptic Disconnect

Typical Usage and Applications
- Disconnections without the possibility of spilled process fluid
- Disconnections aseptically outside of controlled areas
- Commonly used in lieu of tube sealer or where tubing material, e.g., silicone, cannot be heat sealed

Connectivity
- Coupling Body
  - 1/4” (6.4 mm), 3/8” (9.5 mm), or 1/2” (12.7 mm) HB
  - Female quick connect with integrated valve interface
- Coupling Insert
  - 1/4” (6.4 mm), 3/8” (9.5 mm), or 1/2” (12.7 mm) HB
  - Male quick connect with or without integrated valve interface

Gamma Irradiation
- Up to 50 kGy
For Standard Biocontainer Assemblies

Platinum-Cured Silicone
Meissner uses top quality platinum-cured silicone manufactured specifically for use within the biopharmaceutical and pharmaceutical markets. This ultraclean tubing comes standard in 50A durometer, is certified Animal Component Free (ACF), and is compatible with peristaltic pumping operations.

AdvantaFlex® TPE
This 69A durometer, ACF, TPE tubing is very similar to the 374 C-Flex® with the added advantage of increased compatibility with peristaltic pumping operations and a very low extractables and leachables profile.

Thermoplastic Elastomer Tubing
TPE allows for the integration of thermal welding (aseptic connection) and sealing (aseptic disconnection) connectivity steps into your biopharmaceutical process. Meissner incorporates 374 C-Flex® 62A durometer TPE tubing into many standard product offerings.

PVC
Meissner offers medical grade radiation stable PVC tubing for applications where RF weldability, tubing clarity, and/or process economics are primary drivers.

High Durometer and Extended Life
Higher Durometer and Extended Pump Life Silicone Tubing – Meissner offers silicone tubing in a higher durometer formulation, 65A, for applications where tubing resilience may be required, such as in extended time peristaltic pumping applications (e.g., recirculation mixing, TFF applications, etc.).

Other
Meissner can accommodate custom tubing requirements as necessary, e.g., Sta-Pure®, Tygon®, etc. Please contact Meissner for further details.

Also Available
Meissner’s BioFlex® single-use fluid path assemblies provide secure fluid transfer 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 systems.

Customizable to process requirements, the assemblies are available with a range of connectivity, tubing and accessory component options to achieve the functionality necessary for your process. 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® fluid path assemblies are supplied with comprehensive documentation and traceability. Each assembly is serialized, which may reduce batch record requirements in some cases. When the fluid path 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 fluid path 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.

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.

Assembly Design, Components and Filters
The fluid path assembly configurations on page 22 illustrate a variety of common applications, although they have unlimited permutations. 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 in a wide variety of filtration media.
BioFlex® Fluid Path Assemblies (continued)

Connecting Stainless Steel Process Equipment to Stainless Steel Process Equipment

CRVTH0.1-1T0C4 → Steam Through Connector

Steam Through Connector → Steam Through Connector

Quick Connect → CSST0.2-224 → Steam Through Connector

Aseptic Connector → Steam Through Connector

Connecting a Single-Use System to Stainless Steel Process Equipment

Quick Connect → CSST0.2-224 → Steam Through Connector

Aseptic Connector → Steam Through Connector

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

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

Quick Connect → Quick Connect

Quick Connect → CSST0.2-224 → Quick Connect

Tri-Clamp Fitting → CLVTH0.2-224 → Quick Connect

Steam Through Connector → Aseptic Connector

Connecting Stainless Steel Process Equipment to a Single-Use System

Tri-Clamp Fitting → CLVTH0.2-224 → Quick Connect

Steam Through Connector → Aseptic Connector

Filling Assemblies and Manifolds

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

Luer Fitting → Pump-Y → Filling Needle

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

Quick Connect → T to Sampling Line → Quick Connect

Fluid Transfer with Sampling and/or Flushing Functionality

Notes:
• → Arrows indicate flow direction
• Steam Through 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