Zebragard™

0.2 μm VTZ-grade Standard Capsule Filter (CL2 Model)

Description
The Zebragard™ PVDF membrane barrier filter is a convenient, ready-to-use capsule filter designed to facilitate in-line pre-use, post sterilization integrity testing (PUPSIT) of single or redundant sterile process filter systems. The filter features a uniquely patterned sterilizing grade PVDF membrane having dual hydrophilic and hydrophobic characteristics that enable effective passage of both liquids and gases. This unique feature coupled with pleated membrane technology affords high flow rates and faster air flow recovery at low pressures, broad chemical compatibility, and minimal extractables.

The Zebragard™ filter is 100% integrity tested during manufacture and has the added benefit of quality certification that meets the critical demands of the pharmaceutical, biotechnology and related industries.

Materials of Construction
All components of the Zebragard™ filter capsule are either animal component free (ACF) or in compliance with EMEA/410/01 Rev. 3 (EDQM 5.2.8 07/2011:50208), and US Code of Federal Regulations 9 CFR 94.18 and 21 CFR 189.5. These materials are listed for food contact use in the Code of Federal Regulations (CFR), Title 21, as below:

- **Membrane**: Polyvinylidene fluoride (PVDF) CFR Title 21, 177.2510
- **Upstream support**: Polypropylene CFR Title 21, 177.1520
- **Downstream support**: Polypropylene CFR Title 21, 177.1520
- **Outer guard**: Polypropylene CFR Title 21, 177.1520
- **Core**: Polypropylene CFR Title 21, 177.1520
- **End caps**: Polypropylene CFR Title 21, 177.1520
- **Capsule housing**: Polypropylene CFR Title 21, 177.1520
- **Sealing method**: Thermal bonding

**Pore Size**
0.2 μm

**Minimum Bubble Point**
18 psi (1.24 bar), 60% IPA/40% water
17 psi (1.17 bar), 70% IPA/30% water

**Typical Air Flow Rate**
7.0 scfm at 1 psid (8.62 Nm³/hr at Δp 50 mbar)

**Typical Water Flow Rate**
5.78 psid/GPM (0.095 LPM at Δp 10 mbar)

**Bacterial Retention**
>10⁷ per cm² removal of *Brevundimonas diminuta* per ASTM F838

**Operating Characteristics**
- **Operating temperature range**: 32 °F to 100 °F (0 °C to 38 °C)
- **Maximum operating temperature**: 160 °F @ 35 psig (71 °C @ 2.4 bar)
- **Maximum operating pressure**: 50 psig @ 100 °F (3.4 bar @ 38 °C), gas
- **Maximum operating pressure**: 75 psig @ 100 °F (5.2 bar @ 38 °C), liquid
- **Reverse operating pressure**: 15 psig @ 100 °F (1.0 bar @ 38 °C)

**Sterilization**
- **Autoclave**: 121 °C to 135 °C (15 to 30 psi, 1 to 2 bar), 30 to 60 minutes, ≥ 3 cycles.
- **Irradiation**: 25 to 40 kGy once. Do not autoclave irradiated capsules.
- **Capsules must not be in-line steam sterilized.**

**Biological Safety**
Zebragard™ filters meet the requirements as specified in the current USP <88> Class VI plastics, pyrogenicity and cytotoxicity tests. Bacterial endotoxin levels in aqueous extracts of Zebragard™ filters are less than 0.5 EU/mL, as determined using the *Limulus* amebocyte lysate (LAL) test. No binders, adhesives, or surfactants are used in its construction. Filters comply with Commission Regulation (EU) No 10/2011.

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**MEISSNERS**
Quality Assurance
Each Zebragard™ filter is supplied with a Certificate of Quality verifying the high standards and superior performance of the product. Zebragard™ filters comply with the Food and Drug Administration Code of Federal Regulations, Title 21, Parts 210 and 211. Product is manufactured and packaged in a cleanroom facility that, through voluntary compliance, meets or exceeds FDA Good Manufacturing Practice Standards. To ensure product reliability, Meissner’s Quality Assurance staff continually audits the manufacturing process for conformance to its Quality Management System. Each Zebragard™ filter is integrity tested during manufacture and is clearly marked with filter type, lot number, and serial number.

Ordering Guide

<table>
<thead>
<tr>
<th>Capsule Options</th>
<th>Vent/Drain Ports</th>
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<tbody>
<tr>
<td>Standard capsule</td>
<td>0 No vent/drain port</td>
</tr>
<tr>
<td>Sterile capsule</td>
<td>4 Two sanitary valves with hose barbs</td>
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</tbody>
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<tr>
<th>Effective Filtration Area</th>
<th>Inlet/Outlet Connections</th>
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<tbody>
<tr>
<td>3.3 ft² (0.31 m²)</td>
<td>00 1&quot; sanitary flange</td>
</tr>
<tr>
<td></td>
<td>02 1&quot; sanitary flange in;</td>
</tr>
<tr>
<td></td>
<td>3/8&quot; hose barb out</td>
</tr>
<tr>
<td></td>
<td>09 1&quot; sanitary flange in;</td>
</tr>
<tr>
<td></td>
<td>1/2&quot; hose barb out (flexible tubing)</td>
</tr>
<tr>
<td></td>
<td>CC 1/2&quot; hose barb (rigid tubing)</td>
</tr>
<tr>
<td></td>
<td>LL 1&quot; sanitary flange, long neck</td>
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<tr>
<th>Housing Material Designator</th>
<th>Grade</th>
<th>Pore Size</th>
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<tr>
<td>Gamma-stable polypropylene, animal component free (ACF)</td>
<td>VTZ</td>
<td>0.2 μm</td>
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Additional information about this filter product is available in the Zebragard™ Green Docs document at www.meissner.com/green-docs.

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