

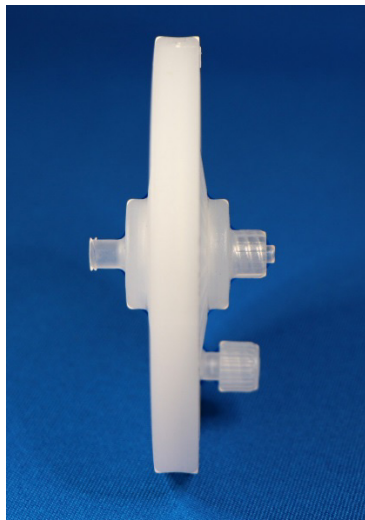


## STERILE SYRINGE FILTER

These filters are designed for applications where sterility of the affluent is mandatory (Sterile Compounding and Pharmaceutical use). The product contains a pharmaceutical grade PES membrane (Sterilizing Grade) and the filters are built in a 10,000-class clean room, flushed, dried and 100% integrity tested prior to packaging. The product is factory sterilized by Ethylene Oxide gas (ETO) ensuring sterility.

## Technical Data Sheet

**Catalog Number: D90RS020FLM-PH-ETO**



### Materials of Construction

**Filter Membrane:** 0.2 um, Pharmaceutical Grade Polyethersulfone (PES) Sterilizing Grade - Hydrophilic

**Supports:** Polypropylene

**Capsule Body:** Polypropylene

### Filter Dimensions and Specifications

**Outer Diameter:** 97 mm (3.82")

**Capsule Body Thickness:** 10.1 mm (0.397")

**Length, Fitting to Fitting:** 41 mm (1.614")

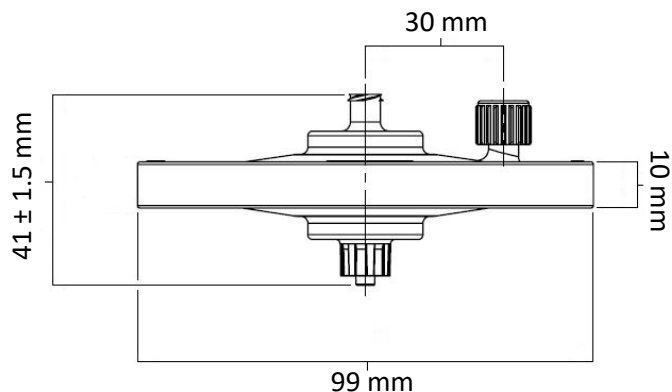
**Filter Area:** 60 cm<sup>2</sup> (9.3 in<sup>2</sup>)

**Sterilization:** The filter is factory sterilized by Ethylene Oxide Gas (ETO)

**Inlet Fitting:** Luer Loc Female

**Outlet Fitting:** Luer Loc Male

**Volume Filtered:** 375 ml to 2,580 ml



### **Integrity Data**

<b>Pore Size</b>	<b>Min, Bubble Point, 25°C</b>	<b>Challenge Microorganisms</b>	<b>CFU per cm<sup>2</sup></b>
0.20 µm	≥3.5 bar (50 psi)	Brevundimonas Diminuta (ATCC 19146)	10 <sup>7</sup>

### **Operating Parameters**

Maximum Working Pressure: 5.5 bar (80 Psi) @ 25 °C (77 °F)

Maximum differential Pressure (forward): 4.1 bar (60 Psi) @ 25 °C (77 °F)

Maximum differential Pressure (reverse): 2.1 bar (30 Psi) @ 25 °C (77 °F)

Maximum Operating Temperature: 80 °C (176 °F)

Recommended Replacement Pressure: 2.4 bar (35.3 Psi)

### **Safety**

UPS Bacteria Endotoxins: ≤25 EU/ml

Factory Sterilized: Ethylene Oxide Gas (ETO)

Product was 100% Integrity Tested and flushed with filtered water @ 0.05 µm

### **Regulatory**

- Complies with USP 797 Guidelines
- ASTM F838-05 - Bacterial Retention
- FDA 21 CFR 177.1655
- USP Class VI - Biological Reactivity
- ISO 10993-Part 1. 5 - Cytotoxicity
- ISO 14001; ISO 13485; OHSMS 18001 Certified.
- ASTM Hemolysis testing
- Human/Veterinarian Use – Applies when the requirements from CGMP CFR part 210 and 211 and additional requirement 21 CFR part 600 and 21 CFR part 680 are used in the aseptic processing.