

## 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: D50CDS065S020FLM-PH-ETO**



### **Materials of Construction**

**Filter Membrane:** 0.65 um Pre-filter/0.2 um Final, Pharmaceutical Grade Polyethersulfone (PES) Sterilizing Grade - Hydrophilic

**Supports:** Polypropylene

**Capsule Body:** Polypropylene

### **Filter Dimensions and Specifications**

**Outer Diameter:** 54 mm (2.12")

**Capsule Body Thickness:** 8 mm (0.314")

**Length, Fitting to Fitting:** 32 mm (1.25")

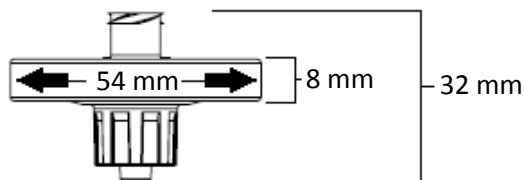
**Filter Area:** 15.9 cm<sup>2</sup> (2.5 in<sup>2</sup>)

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

**Inlet Fitting:** Luer Loc Female

**Outlet Fitting:** Luer Loc Male

**Volume Filtered:** 175 ml to 980 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<br>(ATCC 19146) | 7                             |

### ***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



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