

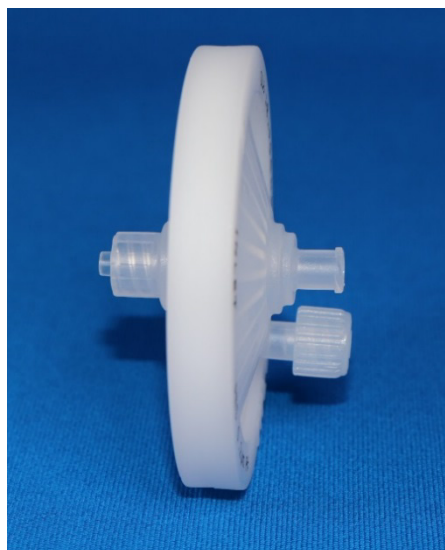


## STERILE SYRINGE FILTER

These filters are designed for applications where sterility of the affluent is mandatory (Sterile Compounding and Pharmaceutical use). The product contains a pharmaceutical grade PTFE 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: D65RF020FLM-PH-ETO**



### **Materials of Construction**

**Filter Membrane:** 0.2 um, Pharmaceutical Grade Teflon (PTFE) Sterilizing Grade - Hydrophobic

**Supports:** Polypropylene

**Capsule Body:** Polypropylene

### **Filter Dimensions and Specifications**

**Outer Diameter:** 73 mm (2.87")

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

**Length, Fitting to Fitting:** 40 mm (1.575")

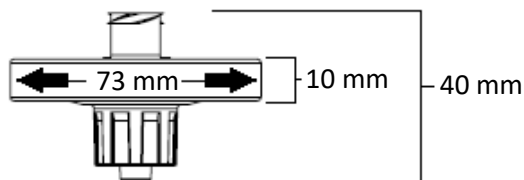
**Filter Area:** 26 cm<sup>2</sup> (4 in<sup>2</sup>)

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

**Inlet Fitting:** Luer Loc Female

**Outlet Fitting:** Luer Loc Male

**Volume Filtered:** 330 ml to 1,340 ml



### ***Integrity Data***

| Pore Size | Min, Bubble Point, 25°C | Challenge Microorganisms               | CFU per cm <sup>2</sup> |
|-----------|-------------------------|--|-------------------------|
| 0.20 µm   | ≥3.5 bar (50 psi)       | Brevundimonas Diminuta<br>(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