International Filter Products
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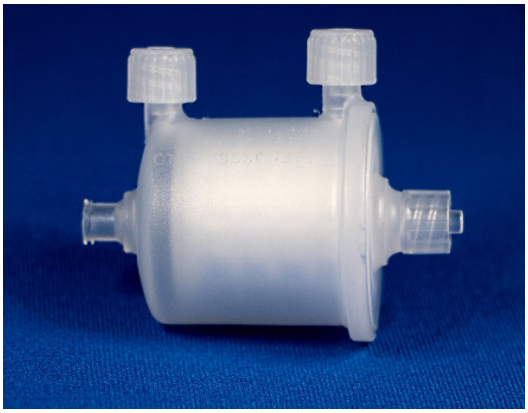
# STERILE SYRINGE FILTER

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:*** **JKPF020LFLM-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:** 54 mm (2.12")

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

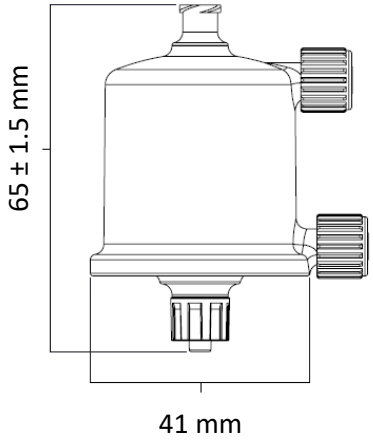
**Filter Area:** 260 $cm^2$ (2.5 $in^2$)

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

**Inlet Fitting:** Luer Loc Female

**Outlet Fitting:** Luer Loc Male

**Volume Filtered:** 1.5 L to 6.8 L




### *Integrity Data*

| Pore Size | Min, Bubble Point, 25°C (60% IPA) | Challenge Microorganisms | CFU per $cm^2$ |
|---|---|---|---|
| 0.20 µm | ≥1.2 bar (18 psi) | Brevundimonas Diminuta (ATCC 19146) | $10^7$ |

### *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
- Product was 100% Integrity Tested and flushed with filtered water @ 0.05 um

### *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.