## International Filter Products

## 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: D65RF100020LFLM-PH-ETO


## Materials of Construction

Filter Membrane: 1.0 um Pre-filter/0.2 um final, 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: $26 \mathrm{~cm}^{2}\left(4 \mathrm{in}^{2}\right)$
Sterilization: The filter is factory sterilized by Ethylene Oxide Gas (ETO)
Inlet Fitting: Luer Loc Female

Outlet Fitting: Luer Loc Male


## Integrity Data

| Pore Size | Min, Bubble Point, 25${ }^{\circ} \mathbf{C}$ | Challenge Microorganisms | CFU per cm |
| :---: | :---: | :---: | :---: |
| $0.20 \mu \mathrm{~m}$ | $\geq 3.5$ bar (50 psi) | Brevundimonas Diminuta <br> (ATCC 19146) | 7 |

## Operating Parameters

Maximum Working Pressure: 5.5 bar ( 80 Psi ) @ $25^{\circ} \mathrm{C}\left(77{ }^{\circ} \mathrm{F}\right)$
Maximum differential Pressure (forward): 4.1 bar ( 60 Psi @ $25^{\circ} \mathrm{C}\left(77{ }^{\circ} \mathrm{F}\right)$
Maximum differential Pressure (reverse): 2.1 bar ( 30 Psi ) @ $25^{\circ} \mathrm{C}\left(77{ }^{\circ} \mathrm{F}\right)$
Maximum Operating Temperature: $80^{\circ} \mathrm{C}\left(176{ }^{\circ} \mathrm{F}\right)$

Recommended Replacement Pressure: 2.4 bar (35.3 Psi)

## Safety

UPS Bacteria Endotoxins: $\leq 25 \mathrm{EU} / \mathrm{ml}$
Factory Sterilized: Ethylene Oxide Gas (ETO)

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

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