International Filter Products

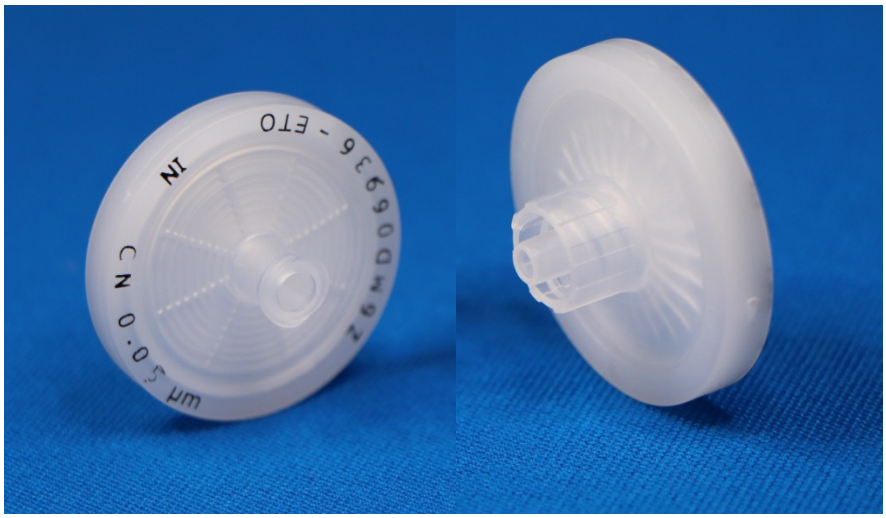
Revolutionary systems for your industry

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: **D25CS020LFLM-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: 33 mm (1.30")

Capsule Body Thickness: 5.1 mm (0.200")

Length, Fitting to Fitting: 24 mm (0.945")

Filter Area: 4.6 cm^2 (0.7 in^2); competitive standard contains 3.5 cm^2

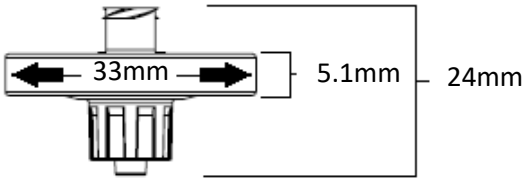
Sterilization: The filter is factory sterilized with Ethylene Oxide Gas (ETO)

Inlet Fitting: Luer Loc Female

Outlet Fitting: Luer Loc Male

Volume Filtered: 60 ml to 200 ml

Allowable Flowrate: 8 ml per min to 15 ml per min



Integrity Data

Pore Size	Min, Bubble Point, 25°C	Challenge Microorganisms	CFU per cm^2
0.20 µm	≥3.5 bar (50 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
- Factory Sterilized: Ethylene Oxide Gas (ETO)
- Product was 100% Integrity Tested and flushed with filtered water @ 0.05 um

Regulatory

- Complies with the guideline in USP 797
- 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 requirements 21 CFR part 600 and 21 CFR part 680 are used in the aseptic processing.