

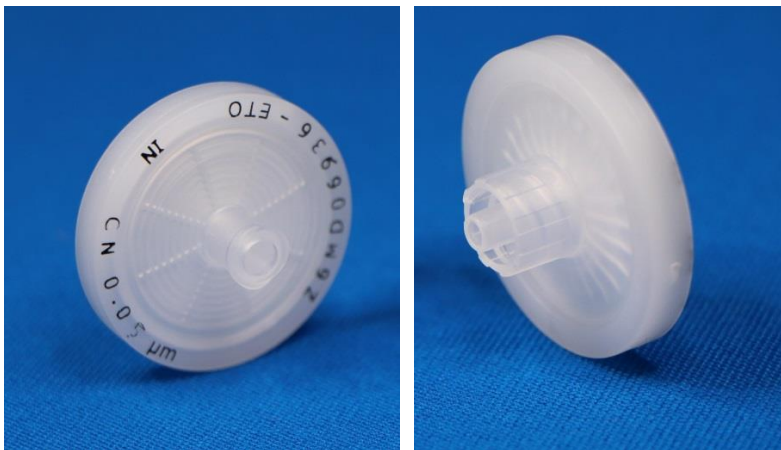


STERILE SYRINGE FILTER

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: D25CDS065S020FLM-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: 33 mm (1.30")

Capsule Body Thickness: 5.1 mm (0.200")

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

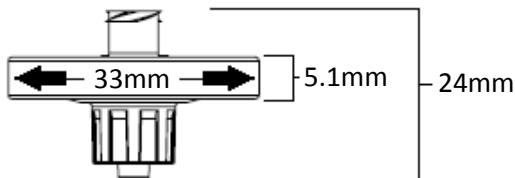
Filter Area: 4.6 cm² (0.7 in²); competitive standard contains 3.5 cm²

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

Inlet Fitting: Luer Loc Female

Outlet Fitting: Luer Loc Male

Volume Filtered: 85 ml to 280 ml



Integrity Data

Pore Size	Min, Bubble Point, 25°C	Challenge Microorganisms	CFU per cm²
0.20 µm	≥3.5 bar (50 psi)	Brevundimonas Diminuta (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