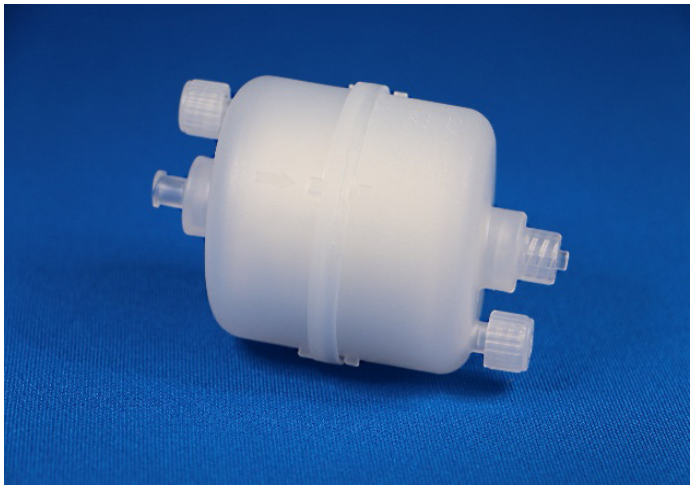
STERILE CAPSULE FILTER

These filters are designed for applications where sterility of the affluent is mandatory (Sterile Compounding and Pharmaceutical use). The product contains a PTFE membrane 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: **MKPF100DLFLM-ETO**



Materials of Construction

Filter Membrane: 1.0 um PTFE membrane - Hydrophobic

Supports: Polypropylene

Core: Polypropylene

Capsule Body: Polypropylene

Filter Dimensions and Specifications

Outer Diameter: 59 mm (2.32")

Length, Fitting to Fitting: 92 mm (3.62")

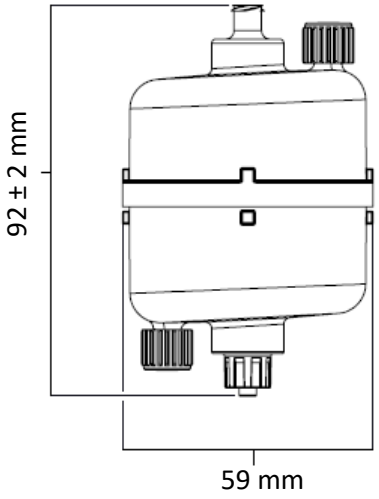
Filter Area: 480 cm^2 (74.4 in^2)

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

Inlet Fitting: Luer Loc Female

Outlet Fitting: Luer Loc Male

Volume Filtered: 12.3 L to 40.3 L



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 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.