D50C Series Sterile Syringe Filter

PureFlo D50C series 50mm disc capsule filters have been specially designed for simple, quick, and efficient filtration of fluids and gases used in laboratory, pilot, and small-scale applications. These filters are appropriate for applications where sterility of the affluent is mandatory (Sterile Compounding and Pharmaceutical use). The small compact design of the filter capsule reduces hold-up volume and exposure to hazardous chemicals. 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: D50CF100020LFLM-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: 54 mm (2.12")

Capsule Body Thickness: 8 mm (0.314") Length, Fitting to Fitting: 32 mm (1.25")

Filter Area: 15.9 cm² (2.5 in²)

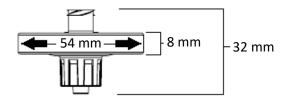
Sterilization: The filter is factory sterilized by Ethylene Oxide Gas (ETO)

Inlet Fitting: Luer Loc Female **Outlet Fitting:** Luer Loc Male

Volume Filtered: 120 ml to 600 ml (30% - 50% less for Oils)







Integrity Data

Pore Size	Min, Bubble Point, 25°C	Challenge Microorganisms	CFU per cm ²
	(60% IPA)		
0.20 μm	≥1.2 bar (18 psi)	Brevundimonas Diminuta (ATCC 19146)	107

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 @ $0.05\,\mathrm{um}$

Regulatory

- Complies with USP 797 Guidelines
- o ASTM F838-05 Bacterial Retention
- o FDA 21 CFR 177.1655
- o USP Class VI Biological Reactivity
- o ISO 10993-Part 1.5 Cytotoxicity
- o ISO 14001; ISO 13485; OHSMS 18001 Certified.
- o 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.



