



International Filter Products

Revolutionary systems for your industry

PureFlo® MKL Series PES 1.2µm – Single Layer Filter Capsules

PureFlo® MKL Filter Capsules are designed for applications where sterility of the affluent is mandatory (Sterile Compounding and Pharmaceutical use). The product contains a PES 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.

PureFlo® MKL Filter Capsules



LFLM Connections

Inlet:

Luer Lock Female

Outlet:

Luer Lock Male



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www.internationalfilterproducts.com

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Application

- Buffers and Media
- SVP (Small Volume Parenteral)
- Vaccines
- Scale up processing
- Bio Bags Compatible
- Biologics
- Ultrapure Water
- Fermentation Broths
- Pharmaceuticals Pre-Filtration
- Antibiotics
- Serums

Technical Data Sheet

Micron Rating:

Final Membrane: 1.2 μm PES

Effective Filtration Area:

Mini Capsule: 77.5 in^2 (500 cm^2)

Materials of Construction:

Membrane: PES (Polyethersulfone)

Membrane Feature: Hydrophilic, Low Protein Binding, High Flow Rate

Shell, Cage, Core, End Caps: Polypropylene

Sealing: Thermally Bonded

Operating Conditions:

Maximum Operating Pressure:

Liquid: 5.5 bar (80psi) at 72°F/22°C

Gas: 4.1 bar (60psi) at 72°F/22°C

Minimum Burst Pressure: 8.3 bar (120psi) at 72°F/22°C

Maximum Forward Differential Pressure: 5.0 bar (72psi) at 72°F/22°C

Maximum Reverse Differential Pressure: 2.1 bar (30psi) at 72°F/22°C

Maximum Operating Temperature: 176°F/80°C

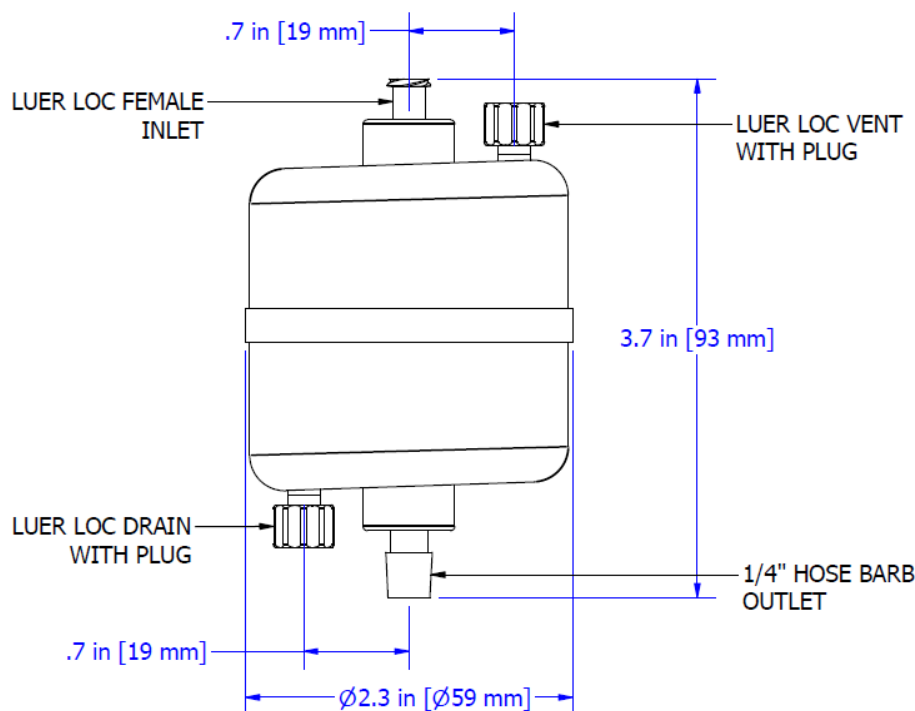




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Nominal Dimension:



Typical Filtered Volume:

15.8L – 85.8L

[Aqueous and alcohol base solutions]

*Volume Filtered is an estimated range for Sterile Compounding, Pharmaceutical & Biological applications. The Filtration Volume is significantly influenced by your solution's viscosity, active ingredients, etc., properties. The best way to determine the exact filtration volume per filter is to try it with your solution.

Hold-Up Volume (Approx.):

Upstream Volume: 36 ml

Downstream Volume: 13 ml

Filter Integrity:

The finished product was sampled and shown to exhibit a minimum bubble point of ≥ 11.6 psi (0.8 bar) in 60%IPA / 40% water.





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Sterilization:

International Filter Products typically stocks ETO Sterilized [factory sterilized] filter capsules. Few sterilization methods are mentioned below:

Capsules can be autoclaved 25 times at 125 °C (257°F) for 30 minutes or chemically sanitized in situ using common sanitizing agents or hot water at 90 °C (194°F) for a limited time (dependent on time and temperature).

They can also be ETO sterilized, and the Ethylene Oxide (ETO) Sterilization Process must comply with ISO 10993-7:2008 Biological Evaluation of Medical Devices - Part 7. Each filter is subjected to a validated ETO process. Sterilization of the fluid path must be validated per ANSI/AAMI/ISO 11135 which provides a minimum sterility assurance level (SAL) of 10^{-6} .

Warning: The filters cannot be sterilized by steam-in-place (SIP) and Gamma Irradiation.

Regulatory Compliance 21CFR Part 177 & USP <88>:

The filters are constructed with polypropylene resins and filtration media in compliance with 21CFR Part 177 of the US Code of Federal Regulations and USP Class VI Biological USP <88>Test for Plastic.

USP <85> Bacterial Endotoxins:

The filters were tested to confirm that an aqueous extraction of this product contains <0.25 EU/ml as determined by the Limulus Amebocyte Lysate (LAL) Test

USP <645> Conductivity USP:

Effluent is tested during the manufacturing process and shown to meet the requirements for USP Sterile Water for Injection for conductivity.

USP <87> / ISO 10993-5 Cytotoxicity:

Extract from this product is non-Cytotoxic.

Hemolysis ASTM F756-17:

Extract from this product is non-Hemolytic.

Human and Veterinarian Use:

The product is safe for Human and Veterinarian use. CGMP CFR part 210 & 211, additional requirements of 21 CFR part 600 and 21 CFR part 680 are applicable to the aseptic manufacturing process.

Animal-Derived Components & TSE/BSE Risk:

No animal-derived material is intentionally added or used during the manufacture of this product.

Shelf Life:

The MKL capsules have a shelf life of 3 years from the date of sterilization.

Ethylene Oxide (ETO) Sterilized product packaging provides adequate protection to maintain a sterile barrier throughout the product's distribution, handling, and 3-year shelf life.





MKL- Series PES Mini Capsules

Ordering Guide



[1]	[2]	[3] Inlet and [4] Outlet	[5]
Micron Rating (Pre-Filter/Final Filter)	Filter Size Code [Filtration Area]	Inlet and Outlet Connection	Sterilization
<ul style="list-style-type: none">S120 : 1.2 μm	<ul style="list-style-type: none">D [Filtration Area: 500 cm ²]	<ul style="list-style-type: none">2H : 1/4" Hose BarbLF : Luer Lock Female	-ETO Ethylene Oxide Sterilization

Example:

MKLS120DLF2H-ETO

PureFlo® MKL Series Capsule, 1.2 μ m PES Hydrophilic Membrane, Effective Filtration Area 500 cm², Luer Lock Female Inlet, 1/4" Hose Barb Outlet, Factory sterilized by ETO

Part Number

Description





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Special Configuration:

Layer Option:

- Single Layer
- Dual Layer

Micron Rating Option:

- 0.04 Micron
- 0.1 Micron
- 0.2 Micron
- 0.45 Micron
- 0.65 Micron
- 0.8 Micron
- 1.2 Micron

Inlet Fitting Option:

- 1H : 1/8" Hose Barb
- 1Q : 1/8" Male Quick Coupling with Metal Latch
- 2H : 1/4" Hose Barb
- 2H-FB : 1/4" Hose Barb with Filling Bell
- 2Q : 1/4" Male Quick Coupling for Metal Latch
- 2N : 1/4" MNPT
- 3H : 3/8" Hose Barb
- LF : Luer Lock Female
- MT : 1/2" Tri-Clamp

Outlet Fitting Option:

- 1H : 1/8" Hose Barb
- 1Q : 1/8" Male Quick Coupling with Metal Latch
- 2H : 1/4" Hose Barb
- 2H-FB : 1/4" Hose Barb with Filling Bell
- 2Q : 1/4" Male Quick Coupling for Metal Latch
- 2N : 1/4" MNPT
- 3H : 3/8" Hose Barb
- LM : Luer Lock Male
- MT : 1/2" Tri-Clamp



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