PureFlo® MKP Series PES 0.2µm – Single Layer Filter Capsules

MKP pharma-grade capsules were designed for small-scale filtration, clarification, and filling applications in the pharmaceutical and biotechnology industries worldwide. This family of products is particularly suitable for scale-up testing where a full-size capsule or cartridge would be excessive. The all-polypropylene construction provides excellent compatibility with a wide range of chemicals. The capsules are thermally sealed, and 100% integrity tested. The filters are manufactured in accordance with GMP and comply with <USP 797> guidelines. The filters are flushed with pharmaceutical-grade purified pyrogens-free water, and 100% integrity tested prior to dispatch. Our filters and free from animal-derived components raw materials can be traced by Lot Number and are strictly regulated maintaining ISO 13485 & ISO 14001 quality standards.

PureFlo® MKP Filter Capsules with various Inlet/Outlet Connections

3H3H Connections

Inlet:
3/8” Hose Barb

Outlet:
3/8” Hose Barb

2H2H Connections

Inlet:
1/4” Hose Barb

Outlet:
1/4” Hose Barb

LFLM Connections

Inlet:
Luer Lock Female

Outlet:
Luer Lock Male

www.internationalfilterproducts.com
7914 Ajay Drive,
Sun Valley, California, 91352
Phone: 818-504-8115
Email: sales@internationalfilterproducts.com

Application

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

Technical Data Sheet

Micron Rating:

Final Membrane: 0.2 µm PES [Sterilizing Grade Membrane]

Effective Filtration Area:

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

Materials of Construction:

Membrane: Pharmaceutical Grade PES (Polyethersulfone) Sterilizing Grade

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 bar (72 psi) 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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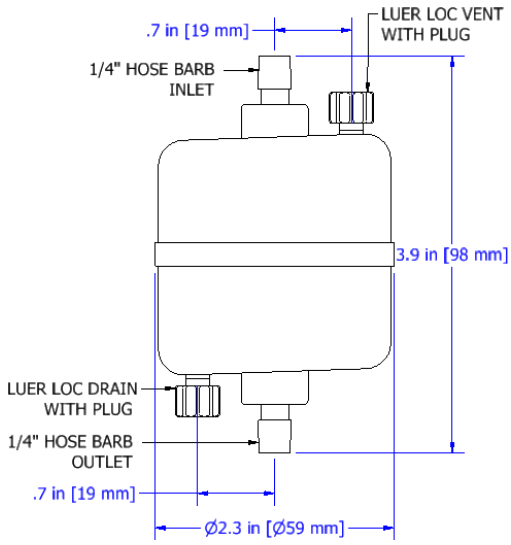
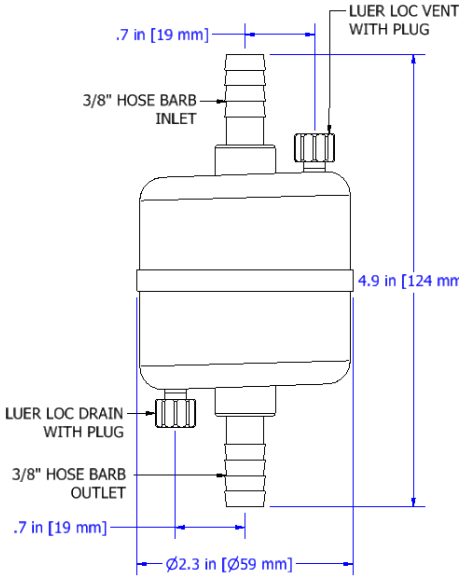
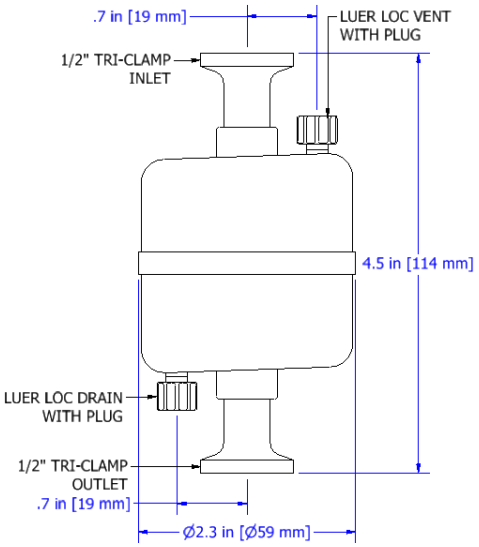
Nominal Dimension:



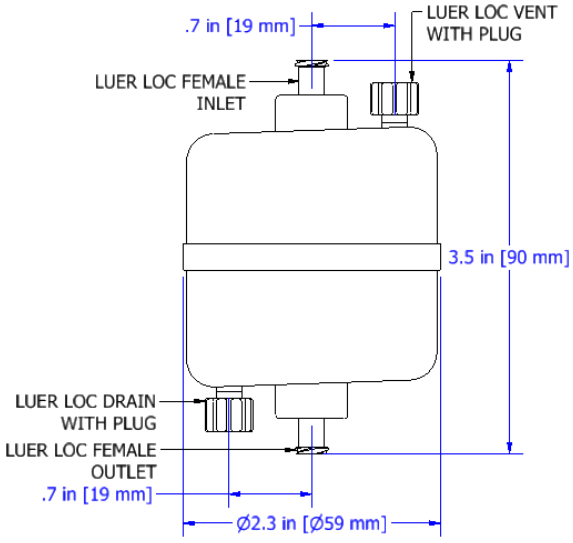
2H2H Connections



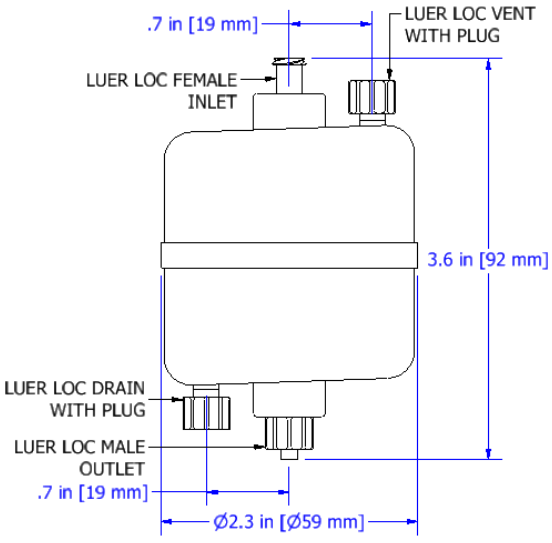
3H3H CONNECTIONS



MTMT Connections



LFLF Connections



LFLM Connections

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Typical Filtered Volume:

4.5L - 24.5L

[Aqueous and alcohol base solution]

*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.

Filter Integrity:

The finished product was sampled and shown to exhibit a minimum bubble point of ≥18 psi (1.2 bar) in 60%IPA / 40% water, ≥17.5 psi (1.2 bar) in 70%IPA / 30% water, and ≥ 50 psi (3.5 bar) in DI Water (at 22℃).

Bacterial Retention ASTM F838-05:

The filters are quantitatively retentive towards *Brevundimonas diminuta* (ATCC #19146) at a minimum challenge level of 10^7 CFU per cm^2 of filtration area, consistent with ASTM F838-05

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.

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Regulatory Information

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 MKP 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.

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MKP- Series PES Mini Capsules (Pharmaceutical Grade)

Ordering Guide

M	K	P	[1]	[2]	[3]	[4]	[5]

[1]	[2]	[3] Inlet and [4] Outlet	[5]
Micron Rating (Pre-Filter/Final Filter)	Filter Size Code [Filtration Area]	Inlet and Outlet Connection	Sterilization
• S020 : 0.2 µm Note: All final membranes are sterilizing grade.	• B [Filtration Area: 360 cm^2] • C [Filtration Area: 420 cm^2] • D [Filtration Area: 500 cm^2]	• 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 • LM : Luer Lock Male • MT : 1/2" Tri-Clamp	-ETO Ethylene Oxide Sterilization

Example:

Part Number	Description
MKPS020DLFLM-ETO	PureFlo® MKP Series Capsule, 0.2 um PES Sterilizing Grade Hydrophilic Membrane, Effective Filtration Area 500 cm^2, Luer Lock Female Inlet, Luer Lock Male Outlet, Factory sterilized by ETO

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Special Configuration:

Layer Option:

- Single 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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