

PureFlo® JKP Series PTFE 0.2µm – Single Layer Filter Capsules

JKP Capsule filter assemblies are ready-to-use filters that offer high flows, increased throughputs, and high strength, all with the convenience and cleanliness of a disposable and easy-to-install filter assembly in a small package. These capsules are designed for small pre-filtration, clarification, and final filtration, in pharmaceutical, and biotechnological applications. The filtration shell is an all-polypropylene construction that provides excellent chemical compatibility, truly flexible, clean, and optimal. 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® JKP Filter Capsules with various Inlet/Outlet Connections





Inlet: 3/8" Hose Barb

Outlet: 3/8" Hose Barb



LFLM Connections

<u>Inlet:</u> Luer Lock Female

Outlet: Luer Lock Male (Cas Pressure: 0.55 Mpa / 0.41Mpa R 20

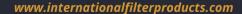
2H2H Connections

Inlet: 1/4" Hose Barb

Outlet: 1/4" Hose Barb









Application

Oil Base Solution

> Testosterone

DMSO

Low Flow Filtration

Hormones

Alcohol Base Solution

Bio Bags Compatible

Pharmaceuticals

Biologics

Ketones

Product Sterilization

Organic Solvent

Technical Data Sheet

Micron Rating:

Final Membrane: 0.2 µm PTFE [Sterilizing Grade Membrane]

Effective Filtration Area:

Junior Capsule: $43.5 in^2 (280 cm^2)$

Materials of Construction:

Membrane: Pharmaceutical Grade PTFE (Polytetrafluoroethylene) Sterilizing Grade

Membrane Feature: Hydrophobic, Chemically Inert, High Temperature Resistance

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







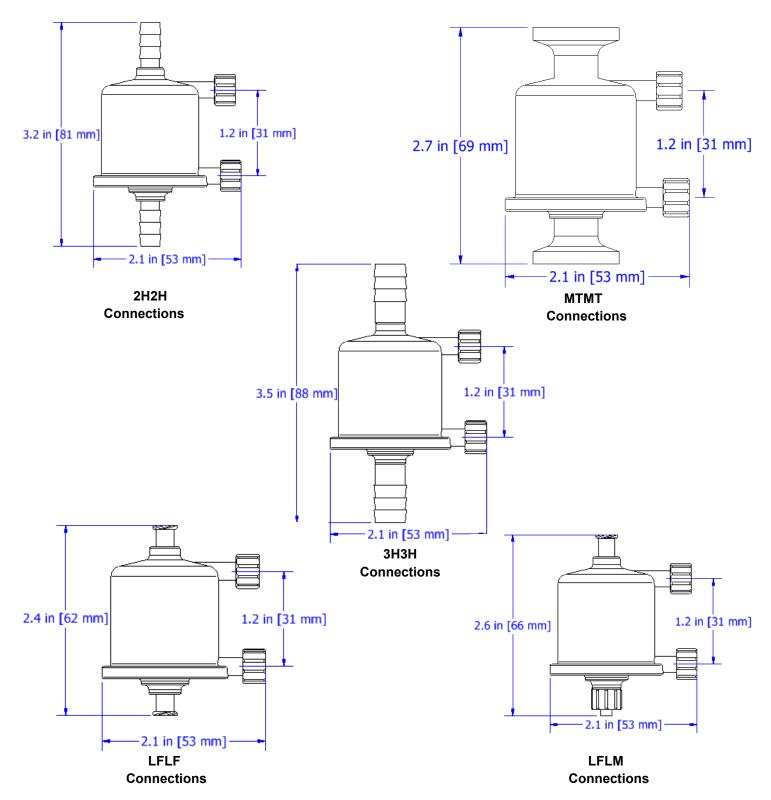




International Filter Products

Revolutionary systems for your industry

Nominal Dimension:











Typical Filtered Volume:

1.8L - 8.0L [Oil base solutions]

3.5L - 14.0L [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.

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, and ≥17.5 psi (1.2 bar) in 70%IPA / 30% water.

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.









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 JKP 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.





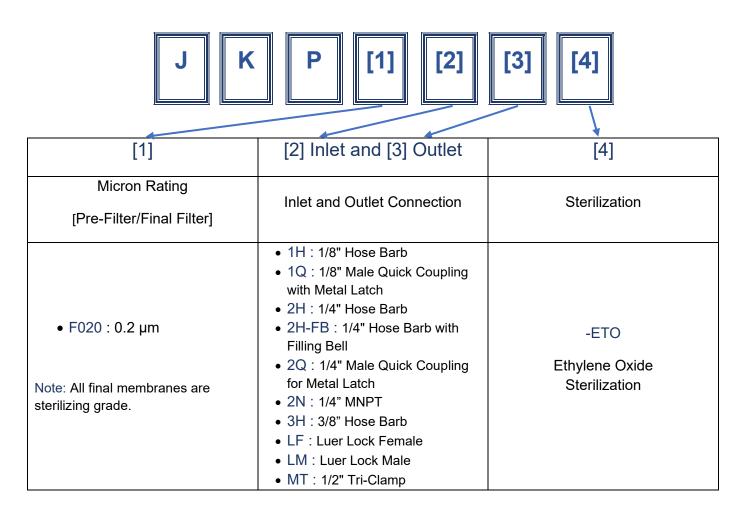






JKP- Series PTFE Junior Capsules (Pharmaceutical Grade)

Ordering Guide



Example:

JKPF020LFLM-ETO

PureFlo® JKP Series Capsule, 0.2 um PTFE Sterilizing Grade Hydrophobic Membrane, Effective Filtration Area 280 cm², Luer Lock Female Inlet, Luer Lock Male Outlet, Factory sterilized by ETO

Part Number Description









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: ¼" 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







