# PureFlo® JKP Series PES 0.80 µm/0.2 µm – Dual Layer Filter Capsule

JKP Capsule filter assemblies are ready-to-use filters that offer high flows, increased throughputs, 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 strictly regulated maintaining ISO 13485 & ISO 14001 quality standards.

## PureFlo® JKP - Series Filter Capsules


## 3H3H Connections

**Inlet:**
3/8" Hose Barb
**Outlet:**
3/8" Hose Barb


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]

**Pre-Filter:** Highly Asymmetric 0.80 µm PES

### Effective Filtration Area:

**Junior Capsule:** 40.3 $in^2$ (260 $cm^2$)

### 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

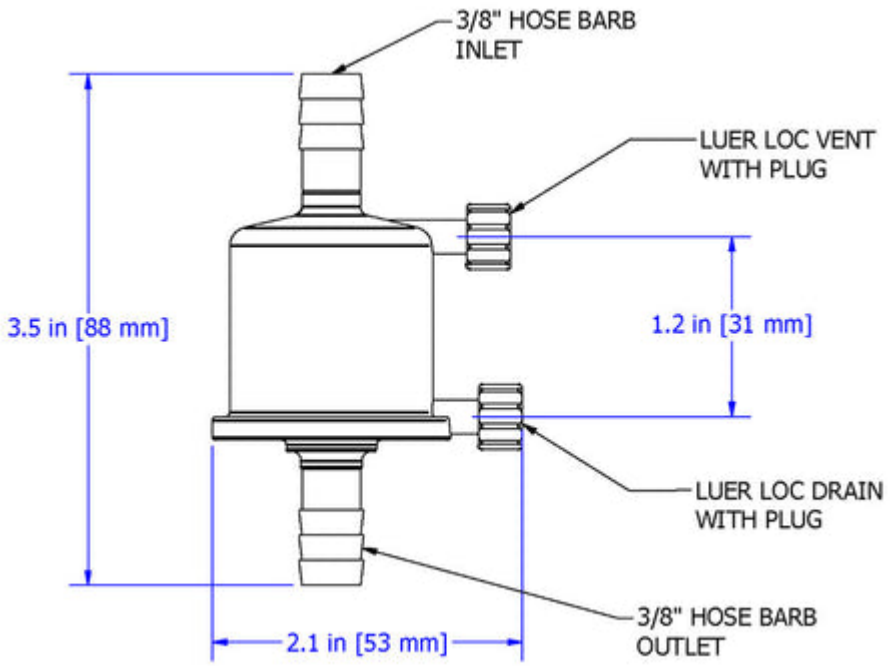
Maximum Forward Differential Pressure: 5 bar (72 psi) at 72°F/22°C

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

Maximum Operating Temperature: 176°F/80°C


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

## Nominal Dimension:




## Typical Filtered Volume:

**3L – 15L**

**[ 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: 9.0 ml

Downstream Volume: 1.5 ml

## 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


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

## 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 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.


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

# JKP- Series PES Junior Capsules (Pharmaceutical Grade)

## Ordering Guide


| [1] | [2] Inlet and [3] Outlet | [4] |
|---|---|---|
| Micron Rating<br><br>[Pre-Filter/Final Filter] | Inlet and Outlet Connection | Sterilization |
| • S080020: 0.8/0.2 µm<br>Note: All final membranes are sterilizing grade. | • 3H : 3/8” Hose Barb | -ETO<br><br>Ethylene Oxide Sterilization |

**Example:**

| Part Number | Description |
|---|---|
| **JKPS0800203H3H-ETO** | PureFlo® JKP Series Capsule, Dual Layer PES 0.8 µm / 0.2 µm PES Sterilizing Grade Hydrophilic Membrane, Effective Filtration Area 260 $cm^2$, 3/8" Hose Barb (Inlet/Outlet), Factory sterilized by ETO |


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

# Special Configuration:

## Layer Option:

- 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 : 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 : ¼” MNPT
- 3H : 3/8” Hose Barb
- LM : Luer Lock Male
- MT : 1/2" Tri-Clamp


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