



# International Filter Products

*Revolutionary systems for your industry*

## SKL Series Dual Layer PES Filter Capsules

SKL Series Dual Layer PES filter capsule with all polypropylene construction provides excellent chemical compatibility and superior flow per unit area as compared to other membrane capsules. The PES filter capsules have been specially designed for sterilizing in biopharmaceutical applications. The filters come with pre layer configuration, which increases the filtration volume significantly (up to 35%). The hydrophilic PES membrane does not require pre-wetting agents, thereby eliminating a potential source of contamination. The PES membrane is a low protein binding media. The capsules were designed with built-in luer loc caps for simple and efficient evacuation of air and liquid. The units are used for filtration of small to medium volumes used in production, laboratory, and pilot runs. No adhesives, binders, or surfactants are used in the manufacturing process of these capsules. All filter capsules are 100% integrity tested to ensure filter performance. All filters are USP <797> compliant, manufactured in a Class 7 Cleanroom, following ISO 13485 standards and include a **Complete Certificate of Conformance**.

### Application

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

**Part Number: SKLS080020S2HS2HS-PH-ETO**



SKL Series Capsule with 1/4"-3/8" Tapered Hose Barb Inlet and Outlet Connection



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## Technical Data Sheet

### Popular Configuration:

Catalog Number	Micron Rating	Inlet Connection	Outlet Connection	Vent Connection	Sterilization
SKLS080020S2HS2HS-PH-ETO	0.8 µm / 0.2 µm (Dual Layer)	1/4"-3/8" Tapered Hose Barb	1/4"-3/8" Tapered Hose Barb	Luer Loc Cap	ETO Sterilized
❖ Find the complete list of available standard inlet and outlet fittings in page 5.					

### Micron Rating:

**Final Media:** 0.2 µm PES [Sterilizing Grade]

**Pre-Filter:** 0.8 µm PES

### Effective Filtration Area:

S-Size; 1.3 ft<sup>2</sup> (1,250 cm<sup>2</sup>)

### Materials of Construction:

Membrane: Pharmaceutical Grade PES (Polyethersulfone) Sterilizing Grade

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

Media Supports: Polypropylene

Shell, Cage, Core, End Caps: Polypropylene

Valve O-Rings: Silicon (Standard)

Sealing: Thermally Bonded

### Operating Conditions:

Maximum Forward Differential Pressure: **Liquid:** 5.5 bar (80psi) at 77°F/25°C

**Gas:** 4.1 bar (60psi) at 77°F/25°C

Minimum Burst Pressure: 8.3 bar (120psi) at 77°F/25°C

Maximum Reverse Differential Pressure: 3.0 bar (44psi) at 68°F/20°C

Maximum Operating Temperature: 176°F/80°C

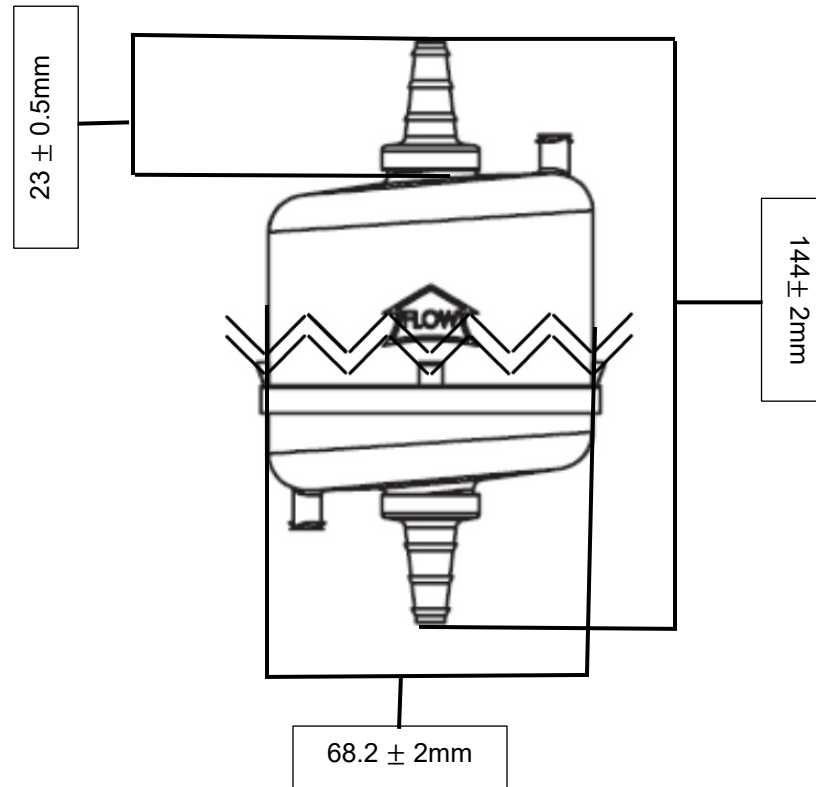


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**Nominal Dimension:**

**Part Number:** SKLS080020S2HS2HS-PH-ETO



**Hold-Up Volume (Approx.):**

Upstream Volume: 103 ml

Downstream Volume: 12 ml

**Typical Filtered Volume:**

28.0L – 55.0L

**Filter Integrity:**

The finished product was sampled and shown to exhibit a minimum bubble point of  $\geq 18$  psi (1.2 bar) in 60%IPA / 40% water and  $\geq 50$  psi (3.5 bar) in DI Water ( at 22°C ).

**Sterilization:**

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).

*Warning:* The filters cannot be sterilized by steam-in-place (SIP)



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## **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.

## **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

## **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 requirement 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 SKL capsules have a shelf life of 3 years from the date of sterilization.





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## SKL - Series PES Mid-Size Capsules

(Pharmaceutical Grade)

### 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"> <li>• S020 : 0.2 μm</li> <li>• DS065S020 : Highly Asymmetric 0.65/0.2 μm</li> <li>• DS045S020 : Highly Asymmetric 0.45/0.2 μm</li> <li>• S080020 : 0.8/0.2 μm</li> </ul> <p>Note: All final membranes are sterilizing grade.</p>	<ul style="list-style-type: none"> <li>• H [Filtration Area: 720 cm<sup>2</sup>]</li> <li>• S [Filtration Area: 1380 cm<sup>2</sup>]</li> <li>• L [Filtration Area: 2600 cm<sup>2</sup>]</li> <li>• E [Filtration Area: 3980 cm<sup>2</sup>]</li> <li>• K [Filtration Area: 5200 cm<sup>2</sup>]</li> </ul>	<ul style="list-style-type: none"> <li>• 1H : 1/8" Hose Barb</li> <li>• 2H : 1/4"-1/2" Tapered Hose Barb</li> <li>• 3H : 3/8" Hose Barb</li> <li>• 4H : 1/2" Hose Barb</li> <li>• 5H : 9/16" Hose Barb</li> <li>• MT : 1/2" Tri-Clamp</li> <li>• TC : 1 1/2" Tri-Clamp</li> </ul>	<p>-ETO</p> <p>Ethylene Oxide Sterilization</p>

#### Example:

**SKLS080020S2HS2HS-PH-ETO**

PureFlo SKL Series Capsule, Dual Layer PES 0.8μm / 0.2μm PES membrane (Sterilizing Grade), Internal Filter Length 2.5", S-Size, Filtration Area 1,250 cm<sup>2</sup>, 1/4"-3/8" Tapered Hose Barb (Inlet/Outlet), ETO Sterilized (Factory Sterilized)

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"-1/2" Tapered Hose Barb
- 2HS = 1/4" to 3/8 " Hose Barb
- 2Q = 1/4" Male Quick Coupling for Metal Latch
- 3H = 3/8" Hose Barb
- 4H = 1/2" Hose Barb
- 4Q = 1/2" Male Quick Coupling for Plastic latch
- 5H = 5/8" Hose Barb
- MT = 1/2" Tri clamps
- TC = 1-1/2" Tri clamp

### Outlet Fitting Option:

- 1H = 1/8" Hose Barb
- 1Q = 1/8" Male Quick Coupling with Metal Latch
- 2H = 1/4"-1/2" Tapered Hose Barb
- 2HS = 1/4" to 3/8 " Hose Barb
- 2Q = 1/4" Male Quick Coupling for Metal Latch
- 3H = 3/8" Hose Barb
- 4H = 1/2" Hose Barb
- 4Q = 1/2" Male Quick Coupling for Plastic latch
- 5H = 5/8" Hose Barb
- MT = 1/2" Tri clamps
- TC = 1-1/2" Tri clamp

