# SZV Series PES – Dual Layer Filter Capsules

SZV-Series PES capsules are gamma-irradiatable, easy-to-use filtration units, ideally suited for integration into single-use sterile assemblies. The hydrophilic, asymmetric Polyethersulfone (PES) membrane demonstrates exceptional throughput capacity and flow performance in liquid applications. The materials and design were carefully selected to ensure quick and reliable pre- and post-use integrity testing in critical biopharmaceutical applications. The filter capsules are available in a complete spectrum of sizes to simplify scale-up throughout each stage of the drug development process.

# **Application**

- Buffers and Media
- Final Drug Product
- Vaccines
- Scale up processing

- Product Sterilization
- Bio Bags
- Biologics
- Ultra-Pure Water

- Ophthalmic
- Pharmaceuticals
- Antibiotics
- Serums

# Part Number: SZVXS020LTCTC





### **Technical Data Sheet**

#### **Popular Configuration:**

Catalog Number	Micron Rating	Inlet Connection	Outlet Connection	Vent Connection	Gamma Sterilization	
SZVXS020LTCTC	0.65 μm / 0.2 μm (Dual Layer)	1.5" Tri-Clamp	1.5" Tri-Clamp	Bleed Valve with 1/8" Hose Barb	up to 50kGy	
* Find the complete list of evallable standard inlet and evidet fittings in page 5						

Find the complete list of available standard inlet and outlet fittings in page 5.

#### **Micron Rating:**

Final Media: 0.2 µm PES [Sterilizing Grade Membrane]

Pre-Filter: Highly Asymmetric 0.65 µm PES

#### **Effective Filtration Area:**

L-Size;  $2.8 ft^2$  (2,600 $cm^2$ )

#### **Materials of Construction:**

Membrane: Pharmaceutical Grade PES (Polyethersulfone) Sterilizing Grade

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

Media Supports: Polyester (PET)

Shell: Gamma Stable Polypropylene

Cage, Core, End Caps: Nylon

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

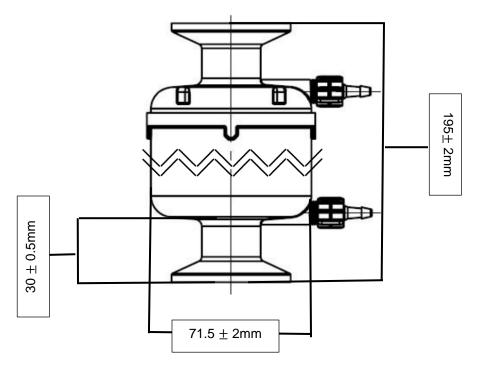
Maximum Operating Temperature: 176°F/80°C





#### **Nominal Dimension:**

Part Number: SZVXS020LTCTC



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

Upstream Volume: 176 ml Downstream Volume: 44 ml

## **Typical Filtered Volume:**

55.0L - 100.0L

#### **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:

Gamma Irradiation: The filters can be Gamma Sterilized up to 50kGy.

Autoclave: The filters can be autoclaved up to 10 cycles at 125°C (257°F) for 30 minutes.

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

#### Shelf Life:

The SZV capsules have a shelf life of 3 years from the date of manufacture.





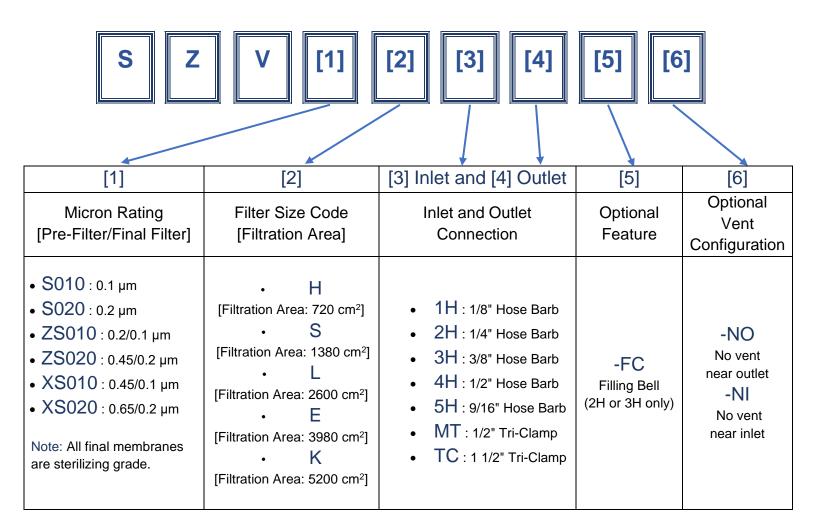
### **Regulatory Compliance:**

Category	Standard or Reference Test		
Physiochemical	<ul> <li>USP Oxidizable Substances</li> <li>USP &lt;645&gt; Conductivity</li> <li>USP &lt;643&gt; Non-Volatile Residue</li> <li>Total Organic Carbon (TOC) Analysis</li> </ul>		
Cleanliness	<ul> <li>USP &lt;85&gt; Bacterial Endotoxin Test</li> <li>USP &lt;788&gt; Particulate Matter</li> <li>21 CFR 210.72 and 2010.3 (b) (6) Fiber Shedding</li> </ul>		
Biocompatibility	<ul> <li>ASTM F756-17 Hemolysis</li> <li>USP &lt;88&gt; (USP Class VI Plastics) Biological Reactivity Tests, In Vivo</li> <li>USP &lt;87&gt; / ISO 10993-5, In Vitro Cytotoxicity</li> <li>21 CFR 177 FDA Indirect Food Additive</li> </ul>		
Bacterial Retention	Quantitative retention of 10 <sup>7</sup> CFU/cm <sup>2</sup> Brevundimonas diminuta per ASTM methodology		
USP Bacterial Endotoxins	A representative sample from the lot is tested to confirm that an aqueous extraction of the product contains <0.25 EU/mL as determined by the Limulus Amebocyte Lysate (LAL) Test.		
Animal-derived Components	No animal-derived material is intentionally added or used during the manufacture of PureFlo Z Series PES Capsules.		
RoHS	Restriction of Hazardous Substances (RoHS 3) Directive 2015/863		
REACH	REACH (Registration, Evaluation, Authorization and Restriction of Chemicals) Article 57, Regulation No. 1907/2006)		
Traceability	<ul> <li>For traceability and easy identification:</li> <li>A Certificate of Conformance is provided with each capsule.</li> <li>Each filter bag and box are labeled with the product part number, lot number, and identifying characteristics.</li> <li>Each capsule is engraved and labeled with the product part number, lot number, and identifying characteristics.</li> </ul>		



# SZV- PureFlo® Z Series PES Mid-Size Capsules

# **Ordering Guide**



## Example:

SZVXS020LTCTC

PureFlo SZV Series Capsule, Highly Asymmetric Dual Layer PES 0.65μm / 0.2μm PES membrane (Sterilizing Grade), 5.0", L-Size, Filtration Area 2,600 cm<sup>2</sup>, 1.5" Tri-Clamps (Inlet/Outlet)

Part Number Description





# **Special Configuration:**

# **Layer Option:**

- Single Layer
- Dual Layer

# Micron Rating Option:

- 0.1 µm
- 0.2 µm
- 0.2/0.1 µm
- 0.45/0.2 µm
- 0.45/0.1 µm
- 0.65/0.2 µm

# Bleed Valve Seal Option:

- Silicone
- EPDM
- Nitrile
- Viton

# **Inlet Fitting Option:**

- 1H = 1/8" Hose Barb
- 2H = 1/4" Hose Barbs
- 3H = 3/8" Hose Barb
- 4H = 1/2" Hose Barb
- 5H = 5/8" Hose Barb
- MT = 1/2" Tri clamps
- TC = 1-1/2" Tri clamp

## **Outlet Fitting Option:**

- 1H = 1/8" Hose Barb
- 2H = 1/4" Hose Barbs
- 3H = 3/8" Hose Barb
- 4H = 1/2" Hose Barb
- 5H = 5/8" Hose Barb
- MT = 1/2" Tri clamps
- TC = 1-1/2" Tri clamp

