

### ZenPure

# PureFlo® PES Capsules (SZL) Pharmaceutical Grade PES Filter

The PureFlo® SZL Series PES filter capsule have been designed for improved wetability in processes which require critical integrity validation testing. The filter capsule in its all-polypropylene construction provides excellent chemical compatibility and superior flow per unit area as compared to other membrane capsules. PureFlo® PES Filter Capsules have been specially designed for sterilizing in biopharmaceutical applications. Its hydrophilic PES membrane does not require pre-wetting agents, thereby eliminating a potential source of contamination. The PES membrane is low protein-binding.

The capsules were specially designed with an easy-to-wet-out structure of PES membrane, PET support and internal Nylon end caps. The capsules were designed for simple and efficient filtration of small volumes used in low-flow application, laboratory, and pilot runs. No adhesives, binders, or surfactants are used in the manufacturing process of these capsules. They are rinsed with pyrogen-free water to reduce extractables and downtime. All filter capsules are 100% integrity-tested to ensure filter performance each and every time out of the package. The capsule can be ordered presterilized.

Applications						
Culture Media	Fermentation Broths					
Serums	SVP (Small volume parenterals)					
Vaccines	Product Sterilization					
Reagents & Buffers	Biologics					
Antibiotics Beverages						
WFI-POU Scale-up	processes					



### **Specifications:**

### **Regulatory Compliance:**

Manufactured from materials that conform to the requirements of 21 CFR Part 177 of the U.S. Code of Federal Regulations and USP Class VI Biological test for Plastics

### **Bacterial Retention:**

Complete retention of  $\geq 10^7$  organisms/cm<sup>2</sup> of *Brevundimonas diminuta* in accordance with the current HIMA challenge methodology (ASTM F838-83). Validation guide available upon request.

### **Autoclavable & Sanitizable:**

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). Capsules must not be in situ steam-sterilized.

### **Water Bubble Point Specification:**

 $0.1 \ \mu m$  : 23 psi (0.16 MPa) in IPA  $0.2 \ \mu m$  : 47 psi (0.32 MPa )

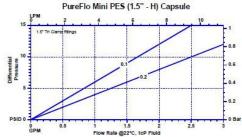
### **Bacterial Endotoxin:**

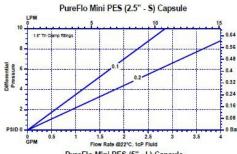
Effluent is non-Pyrogenic per USP Bacterial Endotoxin (0.25 EU/ml), determined using Limulus Amebocyte Lysate (LAL) test.

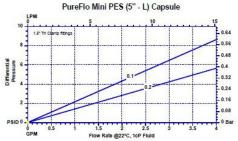
Features	Benefits
■ Hydrophilic PES Membrane	<ul> <li>Inherently hydrophilic for easy wet-ability for integrity testing</li> <li>High flow rate reduces processing time</li> <li>Low protein-binding membrane maximizing yields</li> </ul>
	■ Biologically inert membrane  ■ Bacterially retentive to produce sterile solutions
■ Small, Compact Design	■ Simple, quick, and efficient filtration ■ Low hold-up volume reduces product waste
■ Low Levels of Filter Extractables	<ul> <li>No adhesives, binders, or surfactants are used during manufacturing resulting in superior downstream cleanliness</li> <li>All capsules are rinsed with pyrogen-free water</li> </ul>

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### PureFlo® PES Filter Capsules







Note - Graphs based on Sanitary

### **Materials of Construction**

Membrane: Hydrophilic Polyethersulfone

Membrane Supports: PET

End Caps: Nylon

Cage, Core, Shell: Polypropylene

### **Fitting Connections**

NPT, Sanitary Flange, Hose Barb, Coupling Vent/Drain - Luer Lock, Plug, Bleed Valve

### **Dimensions (Nominal)**

Length: 1.5 in (38 mm) Length: 2.5 in (63.5 mm) Length: 5.0 in (127 mm) Length: 7.5 in (191 mm)

Length: 10 in (254 mm) Diameter: 2.88 in (73 mm)

#### **Effective Filtration Area**

2.5 in - 1.48 ft<sup>2</sup> (1380 cm<sup>2</sup>) 1.5 in - 0.77 ft<sup>2</sup> (720 cm<sup>2</sup>) 5.0 in - 2.8 ft<sup>2</sup> (2600 cm<sup>2</sup>) 7.5 in - 4.3 ft<sup>2</sup> (3990 cm<sup>2</sup>) 10 in - 5.6 ft<sup>2</sup> (5200 cm<sup>2</sup>)

**Operating Conditions** Maximum Operating Pressure:

> Liquid: 5.5 bar (80 psi) at 22 °C Gas: 4.1 bar (59.5 psi) at 22 °C

Minimum Burst Pressure:

8.3 bar (120 psi) at 22 °C

Maximum Forward Differential Pressure:

5 bar (72.5 psi) at 22 °C

Maximum Reverse Differential Pressure:

2.1 bar (30.5 psi) at 22 °C

Maximum Operating Temperature:

PP & Gamma PP: 80 °C

HDPE: 60 °C

### PureFlo PES Capsule (Pharmaceutical grade) Ordering Guide

PureFlo Capsule Filters	Vent & Drain Fitting	ilter Media	Pore size (Micron)	Length	Input Fitting	Output Fitting	Opt	ions
	L = Female Luer Lock		<b>004</b> = 0.04	H = 1.5"	1C 1C	= 1/8" Compression	Grade	O-Ring for Quick
SZ	L = remaie Luer Lock	S = PES	010 = 0.1	<b>S</b> = 2.5"	1H 1H	= 1/8" Hose barbs	-PH = Pharma Grade	-OE = O-ring EPDM
			<b>020</b> = 0.2	L = 5"	1N 1N	= 1/8" MNPT	Shell Material	-ON = O-ring Nitrile
	P = M8 Threaded Plug		<b>045</b> = 0.45	E = 7.5"	1NF	1NF = 1/8" FNPT		-OV = O-ring Viton
PP Shell & Nylon end-	P Shell & Nylon end-		<b>065</b> = 0.65	K = 10"	1Q 1Q	= 1/8" Male Quick Coupling with Metal latch	Blank = Gamma stable	Blank = O-ring Silicon
caps			080 = 0.8		1QF 1Q	= 1/8" Female Quick Coupling with Metal latch	polypropylene	(Standard)
Polyester support			<b>120</b> =1.2		1QFV 10	FV = 1/8" Female Valved Quick Coupling with Metal latch	-NY = Nylon Construction	Prefilters
Polyester support					1QV 1Q	V = 1/8" Male Valved Quick Coupling with Metal latch	-E = Polvethylene shell	-G(pore Size)= Glass
Polypropylene Cage &					2H 2H	= 1/4" to 1/2" Hose barbs	and HDPE media support for	Fiber PreFilter
Core					2HS 2H	S = 1/4" to 3/8" Hose barbs	gamma sterilization	-P(pore Size) = PolyPr
					2LF 2L	= Large Female Luer Lock fitting	Vent & Drain	Media PreFilter
Internal Silicone O-ring					2N 2N	= 1/4" MNPT	-NI = No vent or drain	-S(pore Size) = PES
					2NF 2N	F = 1/4" FNPT	Inlet fitting	PreFilter
70mm Diameter					2P 2P	= 1/4" Push to Connect	-NO = NO vent or drain	
Capsule with Bleed					2PE 2P	E = 1/4" Push to Connect Elbow	Outlet fitting	
Valve					2Q 2Q	= 1/4" Male Quick Coupling for Metal latch	-N = No vent or drain	
					2QF	2QF = 1/4" Female Quick Coupling with Metal latch	fittings	
					2QFP 20	FP = 1/4" Female Quick Coupling with Plastic latch	Sterilizaion	
					2QFV 2	FV = 1/4" Female Valved Quick Coupling with Metal latch	-ETO = Ethylene oxide	
					2QP 2Q	= 1/4" Male Quick Coupling for Plastic latch	sterilization	
					2QV 2Q	V = 1/4" Male Valved Quick Coupling with Metal latch		
					2V 2V	= 1/4" Walther Quick Connect		
					3H	3H = 3/8" Hose Barb		
					3HE	3HE = 3/8" Hose Barb Elbow		
						3H-FB = 3/8" Hose Barb with filling bell or -FC with Cap		
					3NF	3NF = 3/8" FNPT		
					4H 4H	= 1/2" Hose Barb		
					4N 4N	= 1/2" MNPT		
				1	4Q 4Q	= 1/2" Male Quick Coupling for Plastic latch		
					мт мт	= 1/2" Tri clamps		
					тс тс	= 1-1/2" Tri clamp		
						TS = Shower Head		
	•					ent/Drain, 1.5" internal filter, 1/4" MNPT I/O is SZLS020H2N2N		



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