

# Pharmsteri™ II GSV UPE Vent Capsule Filter

*Delivers superior airflow at low pressure drop with lower blockage risk in moist air sterile filtration*

Sterile venting and gas filtration are critical for various process steps in pharmaceutical and biopharmaceutical manufacturing, to maintain a sterile barrier or ensure process gases or wastes are properly filtered. Entegris is a leading expert in controlling particles and impurities and we are leveraging our expertise and experience in material science and filter manufacturing for strict semiconductor applications into the life sciences market.

Pharmsteri™ II GSV (gamma, sterile venting) UPE Vent capsule filters are made of dual-layer hydrophobic ultra-high molecular weight polyethylene (UPE) membrane with nominal pore rating at 0.22 µm, and a high-grade, gamma-stable polypropylene (PP) shell.

The capsule filters are validated with liquid bacterial challenge test ensuring retention even in humid process conditions. UPE membrane provides high hydrophobicity which contributes to reduced blockage risk under moist air and less airflow drop at longer service time.

## APPLICATIONS

- Single use bioreactor vessels or bags
- Mixer vessels or bags
- Storage or holding vessels or bags
- Filling tube sets or bag assemblies
- Carboys or Bottles assemblies
- Filtration or transfer assemblies
- Integrity test manifolds
- Single use cell therapy devices or assemblies



*Provides high air flow at lower pressure drop*

## FEATURES & BENEFITS

<b>Best-in-class air flowrate</b>	Optimized membrane structure provides high air flow at lower pressure drop while maintaining high retention level
<b>High hydrophobicity</b>	Low blockage risk under humid process conditions and long lifespan
<b>Sterilizing grade meets Bacterial Challenge Test (ASTM F838)</b>	Challenged in liquid, ensures that microorganisms, such as bacteria, are removed from the fluid stream while not adversely affecting product
<b>Gamma irradiation compatible</b>	Gamma capability ensures that integrators can connect these filters into any customer-specific, single-use assembly and provide it as a sterile final assembled product
<b>PFAS Alternative</b>	No Per and Polyfluoroalkyl Substances (PFAS) used in the material of construction
<b>Comprehensive validation</b>	Product has been rigorously validated to product specification and industry standards with comprehensive documentation to support compliance

## SPECIFICATIONS

		50mm Disc	1"/3"/5"/10" In-line Capsule	
<b>Materials</b>	Media	Polyethylene	Polyethylene	
	Support	Polyethylene	Polyethylene	
	Core, cage, end caps	Polypropylene	Polypropylene	
	O-ring	NA	Silicone	
<b>Sealing technology</b>		Thermal and ultrasonic bonding	Thermal bonding without adhesives	
<b>Pore size</b>		0.22 µm	0.22 µm	
<b>Filtration area</b>			1"	500 cm <sup>2</sup>
			3"	0.18 m <sup>2</sup>
			5"	0.33 m <sup>2</sup>
			10"	0.65 m <sup>2</sup>
<b>Integrity</b>	Bubble point	≥1.45 bar (21 psi) 60% IPA with water	≥1.45 bar (21 psi) 60% IPA with water	
	Diffusion flow	NA	1"	≤1.35 mL/min @1.10 bar, 60% IPA with water
			3"/5"/10"	NA
	Water intrusion	NA	1"	NA
			3"	≤0.25 mL/min @2.62 bar
			5"	≤0.43 mL/min @2.62 bar
			10"	≤0.55 mL/min @2.62 bar
<b>Maximum operating conditions</b>	Maximum operating temperature	60°C (140°F)	60°C (140°F)	
	Maximum operating pressure	30 psi (2.1 bar) @ 25°C (77°F)	1"	80 psi (5.5 bar) @ 25°C (77°F)
			3"/5"/10"	60 psi (4.1 bar) @ 25°C (77°F)
	Maximum forward differential pressure	20 psi (1.4 bar) @ 60°C (140°F)	1"	30 psi (2.1 bar) @ 60°C (140°F)
			3"/5"/10"	30 psi (2.1 bar) @ 60°C (140°F)
	Maximum reverse differential pressure	30 psi (2.1 bar) @ 25°C (77°F)	1"	30 psi (2.1 bar) @ 25°C (77°F)
3"/5"/10"			60 psi (4.1 bar) @ 25°C (77°F)	
Maximum reverse differential pressure	15 psi (1.0 bar) @ 25°C (77°F)	1"	15 psi (1.0 bar) @ 25°C (77°F)	
		3"/5"/10"	30 psi (2.1 bar) @ 25°C (77°F)	
<b>Bacteria Retention*</b>	>10 <sup>7</sup> CFU/cm <sup>2</sup> B. diminuta per the ASTM F838.			
<b>Gamma stability</b>	Gamma irradiation stable up to 45 kGy			
<b>Endotoxin releasing*</b>	<0.25 EU/mL as determined by the LAL test, meeting the requirements of USP <85>			

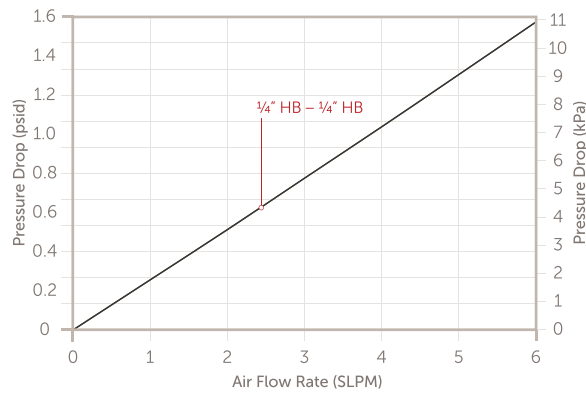
## SPECIFICATIONS

<b>Particulates*</b>	Particulate matter release meets the requirement of USP <788>
<b>Non-fiber releasing</b>	Manufactured with non-fiber release materials and tested according to 21 CFR 210.3 (b) (6)
<b>Material toxicity*</b>	All components meet the requirements of the USP <87>, Biological Reactivity Test
<b>Animal free</b>	Raw materials used to manufacture this product are not animal derived, meeting the EU directive for animal free CPMP EMA/410/01 and 21 CFR parts 189.5
<b>Extractables*</b>	Non-Volatile Residue (NVR) tested at two successive 24-hour extractions in 50% ethanol with vibration per USP <665> & <1665>
<b>Quality</b>	100% integrity tested, manufactured in accordance with ISO 9001 and ISO 13485 certified quality management system

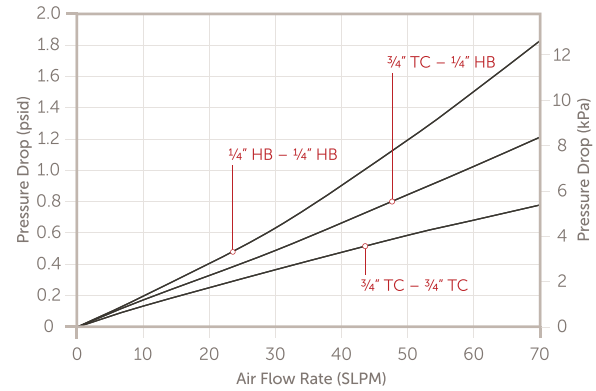
\*Test post-gamma irradiation. Refer to our validation guide for details.

## PERFORMANCE DATA

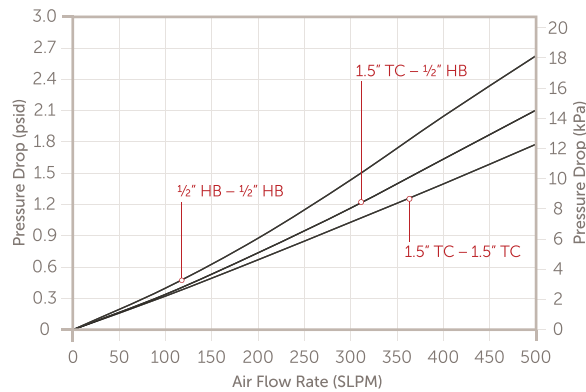
50 mm Disc



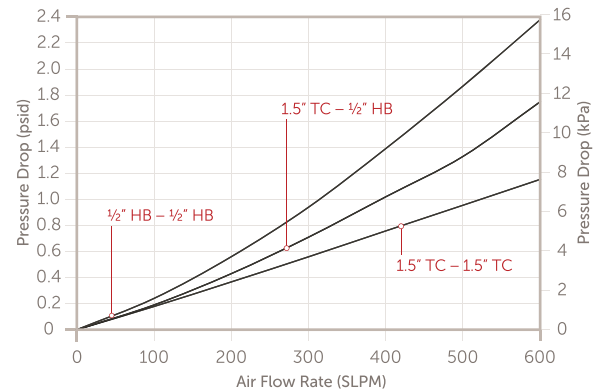
1-inch Capsules



3-inch Capsules

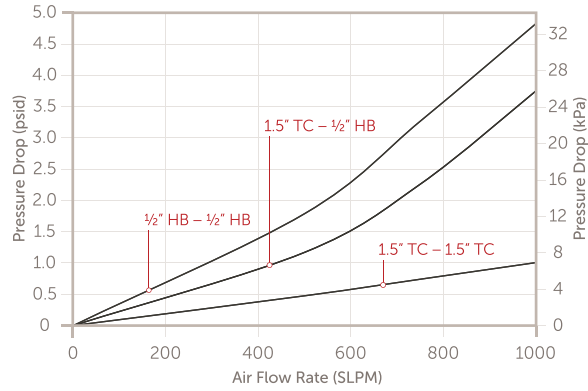


5-inch Capsules

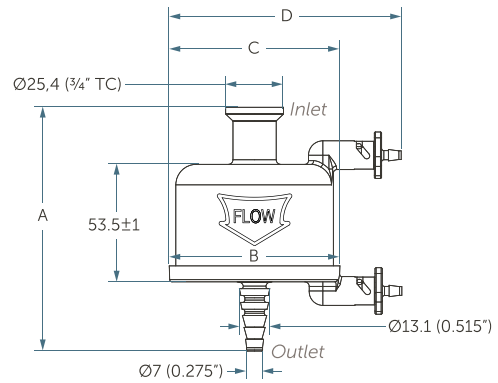
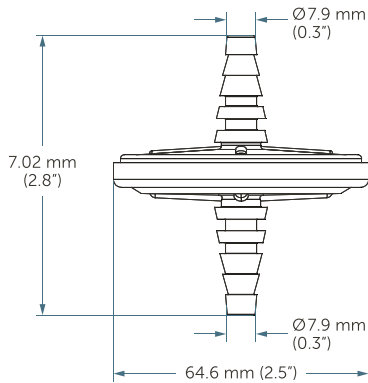


## PERFORMANCE DATA

### 10-inch Capsules

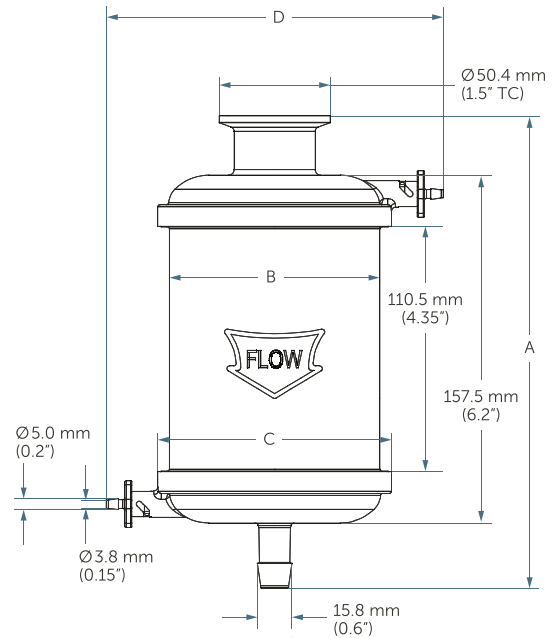
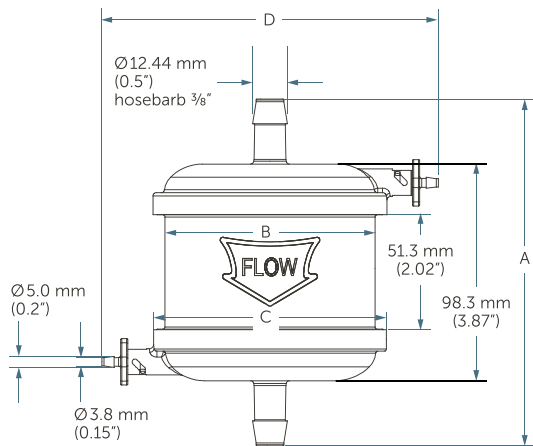


## DIMENSIONS



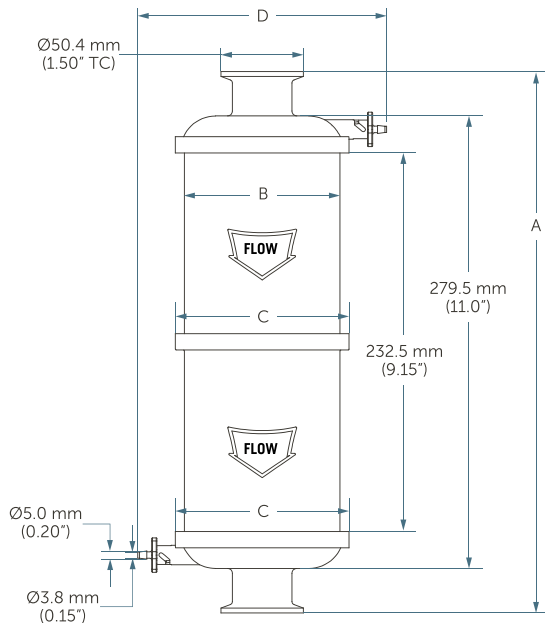
Size - Connections	Total Length - A	Body Diameter - B	Min Width - C	Max Width - D
1-inch 3/4" TC-3/4" TC	102.5 mm (4.04")	69.2 mm (2.72")	75.1 mm (2.96")	101.9 mm (4.01")
1-inch 3/4" TC-1/4" HB	108.0 mm (4.25")	69.2 mm (2.72")	75.1 mm (2.96")	101.9 mm (4.01")
1-inch 1/4" HB-1/4" HB	113.5 mm (4.47")	69.2 mm (2.72")	75.1 mm (2.96")	101.9 mm (4.01")

## DIMENSIONS



Size - Connections	Total Length - A	Body Diameter - B	Min Width - C	Max Width - D
3-inch 1.5" TC-1.5" TC	154.5 mm (6.08")	96.0 mm (3.78")	107.0 mm (4.21")	153.0 mm (6.02")
3-inch 1/5" TC-1/2" HB	156.7 mm (6.17")	96.0 mm (3.78")	107.0 mm (4.21")	153.0 mm (6.02")
3-inch 1/2" HB-1/2" HB	159.7 mm (6.29")	96.0 mm (3.78")	107.0 mm (4.21")	153.0 mm (6.02")
3-inch 1.5" TC-3/8" HB	152.5 mm (6.00")	96.0 mm (3.78")	107.0 mm (4.21")	153.0 mm (6.02")
3-inch 3/8" HB-3/8" HB	150.5 mm (5.93")	96.0 mm (3.78")	107.0 mm (4.21")	153.0 mm (6.02")
5-inch 1.5" TC-1.5" TC	213.2 mm (8.39")	96.0 mm (3.78")	107.0 mm (4.21")	153.0 mm (6.02")
5-inch 1.5" TC-1/2" HB	216.5 mm (8.52")	96.0 mm (3.78")	107.0 mm (4.21")	153.0 mm (6.02")
5-inch 1/2" HB-1/2" HB	219.5 mm (8.96")	96.0 mm (3.78")	107.0 mm (4.21")	153.0 mm (6.02")
5-inch 1.5" TC-3/8" HB	211.6 mm (8.33")	96.0 mm (3.78")	107.0 mm (4.21")	153.0 mm (6.02")
5-inch 3/8" HB-3/8" HB	210.0 mm (8.27")	96.0 mm (3.78")	107.0 mm (4.21")	153.0 mm (6.02")

## DIMENSIONS



Size - Connections	Total Length - A	Body Diameter - B	Min Width - C	Max Width - D
10-inch 1.5" TC-1.5" TC	335.5 mm (13.21")	96.0 mm (3.78")	107.0 mm (4.21")	153.0 mm (6.02")
10-inch 1.5" TC-1/2" HB	339.0 mm (13.35")	96.0 mm (3.78")	107.0 mm (4.21")	153.0 mm (6.02")
10-inch 1/2" HB-1/2" HB	342.0 mm (13.46")	96.0 mm (3.78")	107.0 mm (4.21")	153.0 mm (6.02")

## ORDERING INFORMATION

Pharmsteri II GSV UPE: part number

PST ED 022 -

<p><b>Single use</b> SU = single use GS = gamma sterilized</p>	<p><b>Membrane</b> ED = UPE dual-layer</p>	<p><b>Retention rating</b> 022 = 0.22 <math>\mu\text{m}</math></p>	<p><b>Code and O-ring</b> TS = 1.5" TC inlet/outlet, silicone O-ring HS = 1/2" HB inlet/outlet, silicone O-ring TH = 1.5" TC inlet, 1/2" HB outlet RS = 3/8" HB inlet/outlet, silicone O-ring TR = 1.5" TC inlet, 3/8" HB outlet FS = 3/4" TC inlet/outlet, silicone O-ring BS = 1/4" HB inlet/outlet, silicone O-ring FB = 3/4" TC inlet, 1/4" HB outlet SH = 1/4" HB inlet/outlet, disc only</p>	<p><b>Size</b> 00 = 50 mm disc 01 = 1" 03 = 3" 05 = 5" 10 = 10"</p>	<p><b>Pack</b> 1 = 1 ea/box 2 = 2 ea/box 4 = 4 ea/box 10 = 10 ea/box</p>
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## ORDERING INFORMATION

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### Notes:

1. TS/HS/TH/RS/TR code for 3"/5"/10", FS/BS/FB code for 1", SH code for 50mm disc;
2. 5"/10" as 1 ea/box, 3" as 2 ea/box, 1" as 4 ea/box, 50mm disc as 10 ea/box;
3. Entegris and MKS have developed compatible capsule heating jackets, available directly from MKS. Check with your Entegris specialist for more information, or visit the [MKS website for Series 48 Heaters](#).

### FOR MORE INFORMATION

Please call your Regional Customer Service Center today to learn what Entegris can do for you. Visit [entegris.com](https://www.entegris.com) and select the [Contact Us](#) link to find the customer service center nearest you.

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