

# 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>Comprehensive validation</b>	Product has been rigorously validated to product specification and industry standards with comprehensive documentation to support compliance

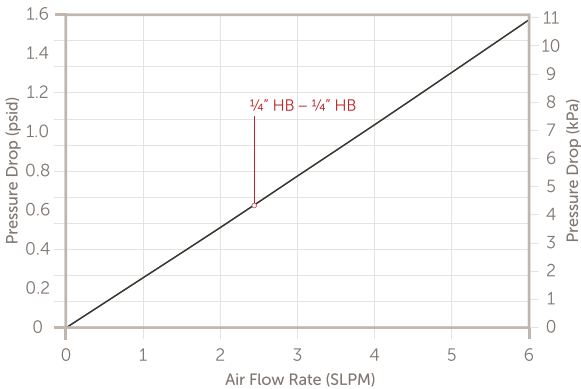
## SPECIFICATIONS

		50mm Disc	3"/5"/10" In-line Capsule	
Materials	Media	UPE	UPE	
	Support	Polyethylene	Polyethylene	
	Core, cage, end caps	Polypropylene	Polypropylene	
	O-ring	N/A	Silicone	
Sealing technology		Thermal and ultrasonic bonding	Thermal bonding without adhesives	
Pore size		0.22 μm	0.22 μm	
Filtration area		19.6 cm²	3":	0.18 m²
			5"	0.33 m²
			10"	0.65 m²
Integrity	Bubble Point	≥1.45 bar (21 psi) 60% IPA with water	≥1.45 bar (21 psi) 60% IPA with water	
Maximum operating conditions	Maximum operating temperature	60°C (140°F)	60°C (140°F)	
	Maximum operating pressure	30 psi (2.1 bar) @ 25°C (77°F)	60 psi (4.1 bar) @ 25°C (77°F)	
		20 psi (1.4 bar) @ 60°C (140°F)	30 psi (2.1 bar) @ 60°C (140°F)	
	Maximum differential pressure	Forward 30 psi (2.1 bar) @ 25°C (77°F)	Forward 60 psi (4.1 bar) @ 25°C (77°F)	
		Reverse 10 psi (0.7 bar) @ 25°C (77°F)	Reverse 30 psi (2.1 bar) @ 25°C (77°F)	
Bacteria Retention*	>10 <sup>7</sup> CFU/cm² B. diminuta per the ASTM F838.			
Gamma stability	Gamma irradiation stable up to 45 kGy			
Endotoxin releasing*	<0.25 EU/mL as determined by the LAL test, meeting the requirements of USP <85>			
Particulates*	Particulate matter release meets the requirement of USP <788>			
Non-fiber releasing	Manufactured with non-fiber release materials and tested according to 21 CFR 210.3 (b) (6)			
Material toxicity*	All components meet the requirements of the USP <87>, Biological Reactivity Test			
Animal free	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			
Extractables*	Non-Volatile Residue (NVR) tested at two successive 24-hour extractions in 50% ethanol with vibration per USP <665>&<1665>			
Quality	100% integrity tested, manufactured in accordance with ISO 9001 and ISO 13485 certified quality management system			

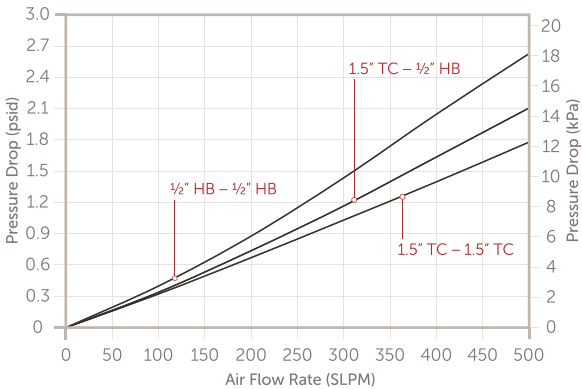
\*Test post-gamma irradiation. Refer to our validation guide for details.

PERFORMANCE DATA

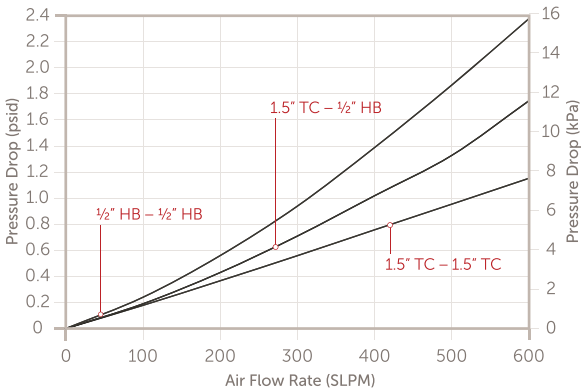
50 mm Disc



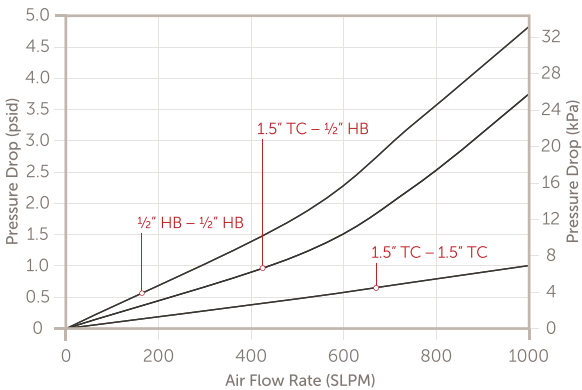
3-inch Capsules



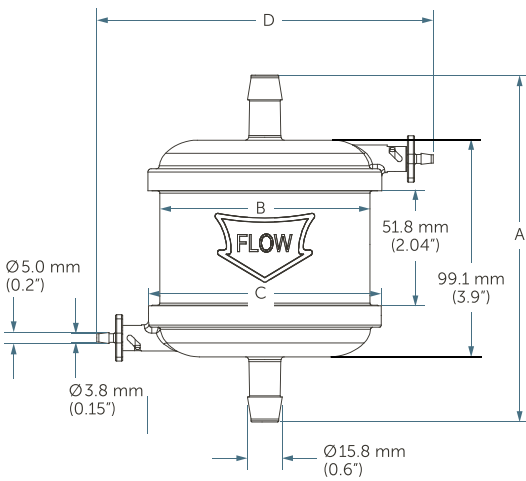
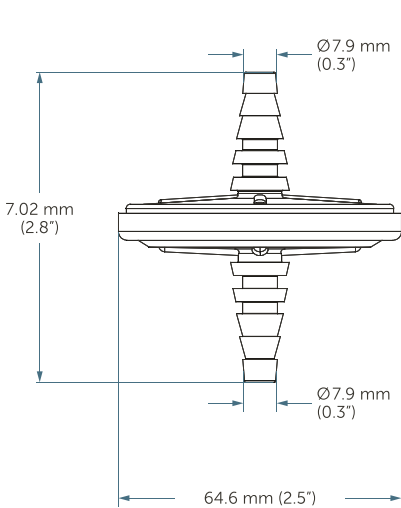
5-inch Capsules



10-inch Capsules

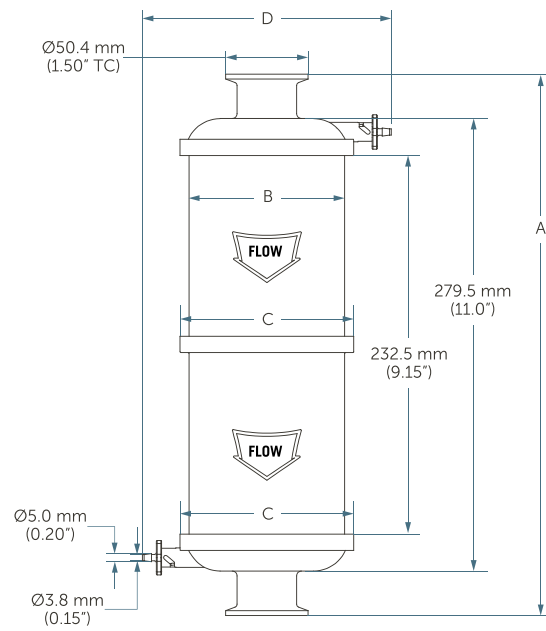
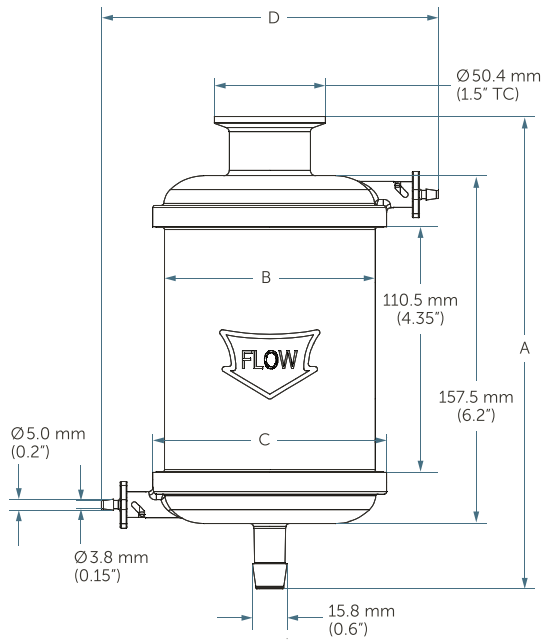


DIMENSIONS



## DIMENSIONS

Size - Connections	Total Length - A	Body Diameter - B	Min Width - C	Max Width - D
3-inch TC-TC	154.5 mm (6.08")	96.0 mm (3.78")	107.0 mm (4.21")	153.0 mm (6.02")
3-inch TC-HB	156.7 mm (6.17")	96.0 mm (3.78")	107.0 mm (4.21")	153.0 mm (6.02")
3-inch HB-HB	159.7 mm (6.29")	96.0 mm (3.78")	107.0 mm (4.21")	153.0 mm (6.02")



Size - Connections	Total Length - A	Body Diameter - B	Min Width - C	Max Width - D
5-inch TC-TC	213.2 mm (8.39")	96.0 mm (3.78")	107.0 mm (4.21")	153.0 mm (6.02")
5-inch TC-HB	216.5 mm (8.52")	96.0 mm (3.78")	107.0 mm (4.21")	153.0 mm (6.02")
5-inch HB-HB	219.5 mm (8.96")	96.0 mm (3.78")	107.0 mm (4.21")	153.0 mm (6.02")
10-inch TC-TC	335.5 mm (13.21")	96.0 mm (3.78")	107.0 mm (4.21")	153.0 mm (6.02")
10-inch TC-HB	339.0 mm (13.35")	96.0 mm (3.78")	107.0 mm (4.21")	153.0 mm (6.02")
10-inch HB-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	-	
				<b>Pack</b>
				1 = box of 1
				2 = box of 2
				4 = box of 4
				10 = box of 10
				<b>Size</b>
				00 = 50 mm disc
				01 = 1"
				03 = 3"
				05 = 5"
				10 = 10"
				<b>Code and O-ring</b>
				TS = 1.5" TC inlet/outlet, silicone O-ring
				HS = ½" HB inlet/outlet, silicone O-ring
				TH = 1.5" TC inlet, ½" HB outlet
				FS = ¾" TC inlet/outlet, silicone O-ring
				BS = ¼" HB inlet/outlet, silicone O-ring
				FB = ¾" TC inlet, ¼" HB outlet
				SH = HB inlet/outlet, disc only
				<b>Retention rating</b>
				022 = 0.22 µm
				<b>Membrane</b>
				ED = UPE dual-layer
				<b>Single use</b>
				SU = single use
				GS = gamma sterilized

### Notes:

1. TS/HS/TH 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. 1" under development, sample available for evaluation
4. 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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