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

Best-in-class air flowrate	Optimized membrane structure provides high air flow at lower pressure drop while maintaining high retention level
High hydrophobicity	Low blockage risk under humid process conditions and long lifespan
Sterilizing grade meets Bacterial Challenge Test (ASTM F838)	Challenged in liquid, ensures that microorganisms, such as bacteria, are removed from the fluid stream while not adversely affecting product
Gamma irradiation compatible	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
PFAS Alternative	Alternative to materials regulated by Per and Polyfluoroalkyl Substances (PFAS)
Comprehensive validation	Product has been rigorously validated to product specification and industry standards with comprehensive documentation to support compliance



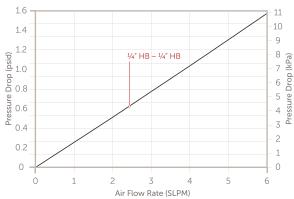
SPECIFICATIONS

		50mm Disc	3"/5"10" In	-line Capsule
Materials	Media	UPE	UPE	
	Support	Polyethylene	Polyethyle	ene
	Core, cage, end caps	Polypropylene	Polypropylene	
	O-ring	Silicone	Silicone	
Sealing technology		Thermal and ultrasonic bonding	Thermal b	onding without
Pore size		0.22 μm	0.22 μm	
Filtration area		19.6 cm ²	3":	0.18 m ²
			5"	0.33 m ²
			10"	0.65 m ²
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°С (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 15 psi (1.0 bar) @ 25°C (77°F)	Reverse 3 (77°F)	0 psi (2.1 bar) @ 25°C
Bacteria Retention*	>10 ⁷ CFU/cm ² 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 Re	activity 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			

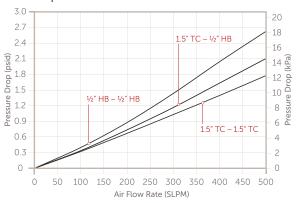
^{*}Test post-gamma irradiation. Refer to our validation guide for details.

PERFORMANCE DATA

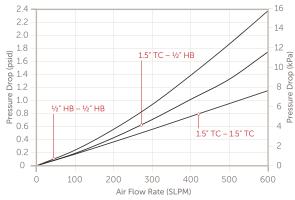
50 mm Disc



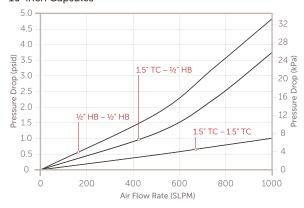
3-inch Capsules



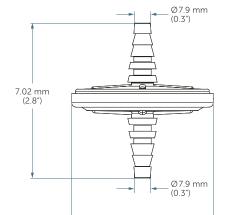
5-inch Capsules



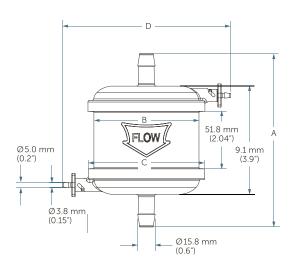
10-inch Capsules



DIMENSIONS

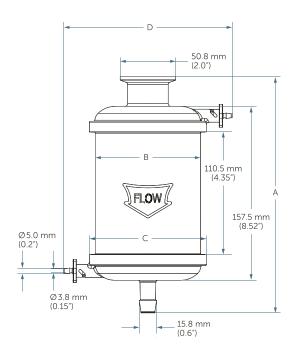


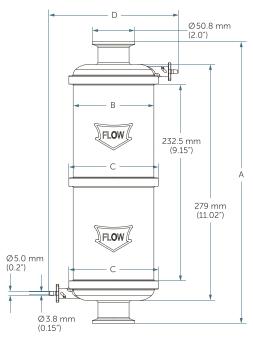
64.6 mm (2.5")



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

PART NUMBER	SIZE	INLET AND OUTLET CONNECTION	PACKAGING CONFIGURATION
PSTSUED022HS032	3" capsule	1/2" hose barb	Two per box
PSTSUED022HS051	5" capsule	1/2" hose barb	One per box
PSTSUED022HS101	10" capsule	1/2" hose barb	One per box
PSTSUED022SH0010	50 mm disc	1/4" stepped hose barb	Ten per box

ORDERING INFORMATION

PART NUMBER	SIZE	INLET AND OUTLET CONNECTION	PACKAGING CONFIGURATION
PSTSUED022TH032	3" capsule	1.5" sanitary TC inlet and 1/2" hose barb outlet	Two per box
PSTSUED022TH051	5" capsule	1.5" sanitary TC inlet and 1/2" hose barb outlet	One per box
PSTSUED022TH101	10" capsule	1.5" sanitary TC inlet and 1/2" hose barb outlet	One per box
PSTSUED022TS032	3" capsule	1.5" sanitary TC	Two per box
PSTSUED022TS051	5" capsule	1.5" sanitary TC	One per box
PSTSUED022TS101	10" capsule	1.5" sanitary TC	One per box

Note: Pre-sterilized capsules by Gamma irradiation available, refer to part number matrix for corresponding part number or check with your Entegris specialist. Entegris and MKS have developed compatible capsule heating jackets, available directly from MKS. Check with you 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 <u>entegris.com</u> and select the <u>Contact Us</u> link to find the customer service center nearest you.

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