

Biopharmaceutical and Pharmaceutical Filtration



Brevi-Cap

SINGLE-USE, GAMMA STERILIZABLE 1-2 SQ FT FILTER CAPSULES



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 - BREDX (Endo-MAXX charged nylon)



The Strainrite Companies

- Manufacturing and HQ in Auburn, ME USA
- Top-quality liquid filtration products
- Incorporated in 1978
- Clean room manufacturing
- 81,000 sq ft and growing
- 3rd Party GMP Accredited
- ISO9001

Brevi-Cap filter capsules

Uses

- Single use disposable systems
- Scale up/scale down benchtop studies
- OEM Equipment
- Avoidance of CIP and cross contamination
- Reducing operator exposure

Typical fluids filtered

- APIs
- Buffers
- Cell culture media
- Cell suspensions
- Cosmeceuticals
- Final drug product
- Injectables, parenterals
- Lysate suspensions
- Nutraceuticals
- Ophthalmics
- Oral dosage forms
- Ultrapure chemicals/sterile chemicals

Features

- Ultrapure polypropylene capsule ≈1 sq ft and ≈2 sq ft sizes
- Variety of Inlet and outlet connections include sanitary flanges in ³/₄" and 1" hose barbs for 1/8", 3/8" and 1/4" i.d. tubing.
- Gamma irradiatable (with select filter media)
- Autoclavable
- Material compliance
- USP Class VI
- 21 CFR
- BSE/TSE
- ROHS
- REACH
- Easy to scale up
- Low extractables
- Vent and drain are 1/4" hose barb with valve.
- Low fill volumes
- Low hold-up volume

Variety of filtration media available

- Sterilizing grade PES membrane
- Bioburden reduction and prefiltration
- PES membrane
- Charged nylon for endotoxin
- Polypropylene microfiber for prefiltration
- Glass microfiber for pre-filtration
- PTFE vent filter









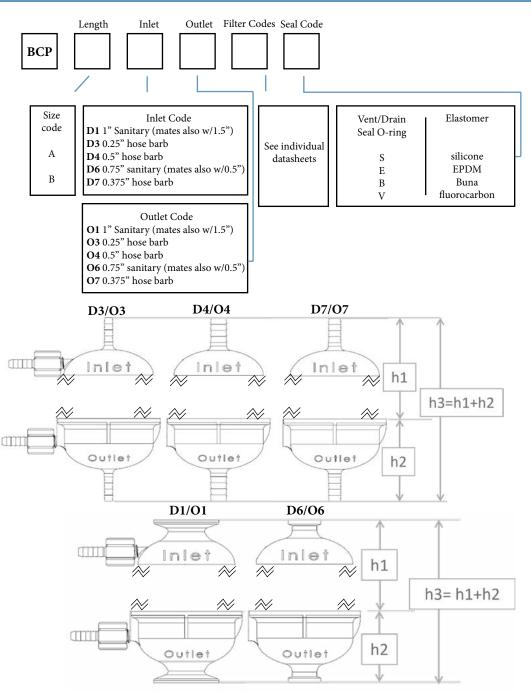


Drawings

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SAMPLE STREET





h1 dimension, Size A & B

	Size A	Size B
Inlet code	inches (mm)	inches (mm)
D1	2.8 (71)	4.4 (112)
D3	3.3 (84)	5.0 (127)
D4	3.3 (84)	5.0 (127)
D6	2.8 (71)	4.4 (112)
D7	3.3 (84)	5.0 (127)

h2 dimension, SizeA & B

Outlet code	inches (mm)
01	2.2 (56)
O3	2.7 (69)
O4	2.7 (69)
O6	2.2 (56)
07	2.7 (69)

h3 dimension, Size A & B

	Size A	Size B
Inlet/Out- let code	inches (mm)	inches (mm)
D1/O1	5.0 (127)	6.6 (168)
D3/O3	6.0 (152)	7.7(196)
D4/O4	6.0 (152)	7.7(196)
D6/O6	5.0 (127)	6.6 (168)
D7/O7	6.0 (152)	7.7(196)

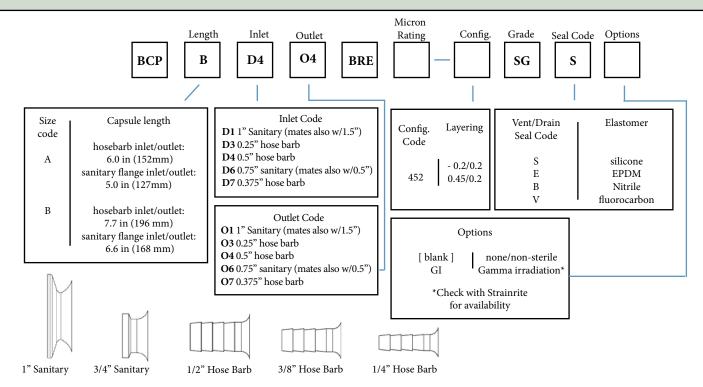


Pur-MAXX E SG Sterilizing Grade PES Membrane Filters

Designed for:	Sterilizing-filtration of SVPs, biopharmaceuticals, ophthlamics, APIs, biologicals, therapeutics. For ultra-pure chemicals, buffers, water, nutraceuticals, media. Upstream & downstream processing.
Membrane:	Two layers polyethersulfone membrane
Support Layers:	Polypropylene
Filter Hardware:	Polypropylene
Toxicity / Material Compliance:	USP Class VI
	21 CFR
	REACH, ROHS, BSE/TSE
Validation:	Retains 1x10 ⁷ / cm ² cfu of Brevundimonas diminuta
Quality:	100% of filter units DI flushed
	100% of filter units integrity tested
	Certificate of Quality
Sterilization:	Autoclavable, Gamma Irradiatable
Surface Area:	$A = 1.02 \text{ ft}^2(948 \text{ cm}^2)$ B = 1.86 ft ² (1,728 cm ²)



ORDER GUIDE: Brevi-Cap Capsule Filters with Sterilizing Grade Double-Layer PES 0.2 μ m Membrane



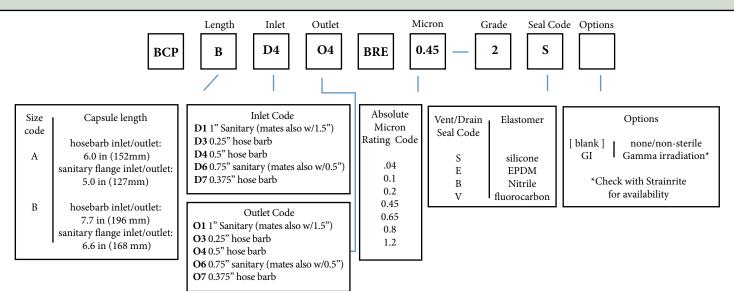
INTEGRITY TESTING						
Size	Wetting Fluid	Diffusive Flow Integrity Test			Bubble Point	
		Test Pressure (psig)	Air Flow Limit (ml/min)		(psig)	
А	Water	40	0.2/0.2 0.45/0.45	≤2.8 ≤4.6	≥ 49	
В	Water	40	0.2/0.2 0.45/0.45	≤5.0 ≤6.9	≥ 49	

Pur-MAXX E PES Membrane Pre - Filters and Bioburden Reduction Filters



Designed for:	Prefiltration and bioburden reduction of LVPs, SVPs, biopharmaceuticals, ophthlamics, APIs, biologicals, therapeutics, ultra-pure chemicals, buffers, water, nutraceuticals. Upstream and downstream processing. Protection of final filters to improve economics.
Membrane:	Polyethersulfone membrane
Support Layers:	Polypropylene
Filter Hardware:	Polypropylene
Toxicity / Material Compliance:	USP Class VI
	21 CFR
	REACH, ROHS, BSE/TSE
Quality:	100% of filter units DI flushed and integrity tested
	Certificate of Quality
Sterilization:	Autoclavable, Gamma Irradiatable
Surface Area:	$A = 1.28 \text{ ft}^2 (1,189 \text{ cm}^2)$ B = 2.32 ft ² (2,155 cm ²)

ORDER GUIDE: Brevi-Cap Capsule Filter with Pharmaceutical-Grade Bio-Reduction PES Membrane



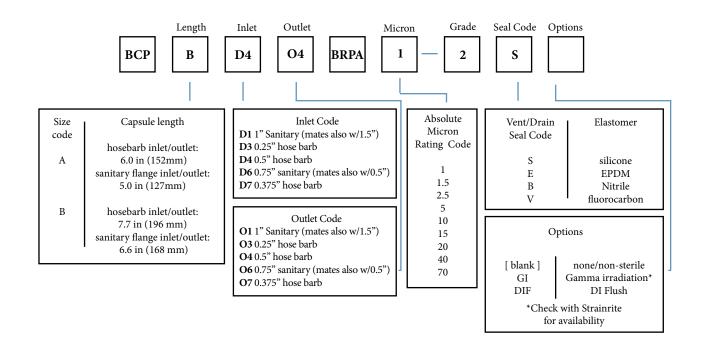
	INTEGRITY TESTING							
Micron Rating		0.04	0.1	0.2	0.45	0.65	0.8	1.2
	Wetting Fluid	IPA	IPA	Water	Water	Water	Water	Water
	Diffusive Flow Test Pressure	36 PSIG	24 PSIG	39.2 PSIG	30 PSIG	21 PSIG	12 PSIG	6 PSIG
Size A	AIR Diffusive Flow Limit	≤18 (ml/min)						
	Bubble Point	≥45 PSIG	≥30 PSIG	≥49 PSIG	≥38 PSIG	≥27 PSIG	≥16 PSIG	≥8 PSIG
	Diffusive Flow Test Pressure	36 PSIG	24 PSIG	39.2 PSIG	30 PSIG	21 PSIG	12 PSIG	6 PSIG
Size B	AIR Diffusive Flow Limit (ml/min)	≤33 (ml/min)						
	Bubble Point	≥45 PSIG	≥30 PSIG	≥49 PSIG	≥38 PSIG	≥27 PSIG	≥16 PSIG	≥8 PSIG



Poly-MAXX Polypropylene Microfiber

Designed for:	Prefiltration and bioburden reduction of parenterals, biopharmaceu- ticals, ophthlamics, APIs, biologicals, therapeutics, ultra-pure chem- icals, buffers, water, nutraceuticals. For upstream and downstream processing. Protection of downstream filters. Removal of gels.	
Filter Medium:	Melt blown polypropylene microfiber – absolute rated	
Support Layers:	Polypropylene	
Filter Hardware:	Polypropylene	
Toxicity / Material Compliance:	USP Class VI	
	21 CFR	
	REACH, ROHS, BSE/TSE	
Quality:	DI flush - optional	
	Certificate of Quality	
Sterilization:	Autoclavable, Gamma Irradiatable	
Surface Area:	$ \begin{aligned} A &= 1.05 \ \text{ft}^2 \ (975 \ \text{cm}^2) \\ B &= 1.91 \ \text{ft}^2 \ (1,774 \ \text{cm}^2) \end{aligned} $	

ORDER GUIDE: Brevi-Cap Capsule Filters with Pharmaceutical-Grade Polypropylene Microfiber Media









3/8" Hose Barb





1" Sanitary

3/4" Sanitary

1/2" Hose Barb

1/4" Hose Barb

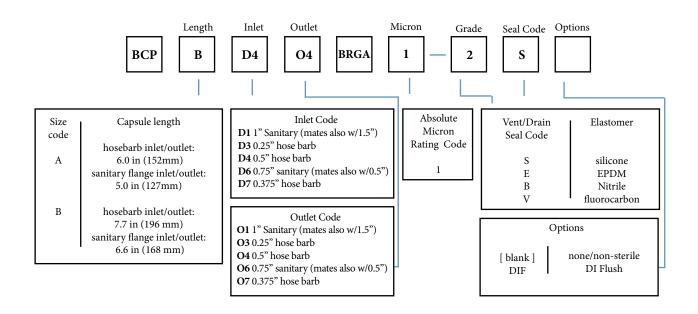


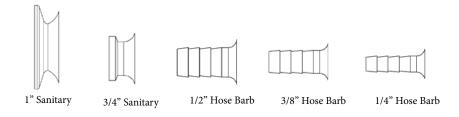
Fiber-MAXX Glass Microfiber Pre-Filters

Designed for:	Prefiltration and bioburden reduction, biopharmaceuticals, ophthlamics, APIs, biologicals, therapeutics, ultra-pure chemicals, buffers, water, nutraceuticals, upstream and downstream processing. Protection of downstream filters. Removal of gels.
Filter Medium:	Absolute rated microglass depth media
Support Layers:	Polypropylene and Polyester
Filter Hardware:	Polypropylene
Toxicity / Material Compliance:	USP Class VI
	21 CFR
	REACH, ROHS, BSE/TSE
Quality:	DI flush - optional
	Certificate of Quality
Sterilization:	Autoclavable
Surface Area	A = $0.78 \text{ ft}^2 (725 \text{ cm}^2)$ B = $1.42 \text{ ft}^2 (1,319 \text{ cm}^2)$



ORDER GUIDE: Brevi-Cap Capsule Filters with Pharmaceutical-Grade Glass Microfiber Media





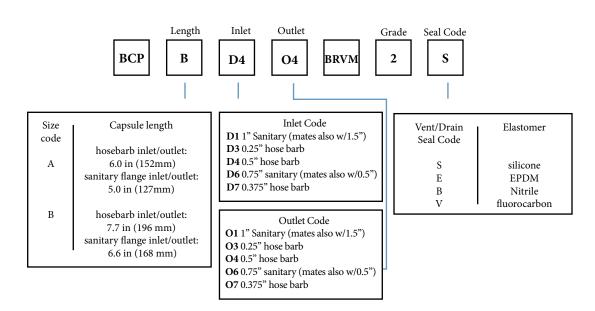
Vent-MAXX PTFE Membrane Sterile Air Filters



Designed for:	Critical sterilizing air and gas filtration for: bioreactor sterile inlet air, bio-reactor exhaust gas, sterile holding tanks, sterile blanketing. Common gasses sterile-filtered are air, nitrogen, and CO2.
Membrane:	Two layers 0.2 µm PTFE membrane
Support Layers:	Polypropylene
Filter Hardware:	Polypropylene
Toxicity / Material Compliance:	USP Class VI
	21 CFR
	REACH, ROHS, BSE/TSE
Validation:	<i>Brevundimonas diminuta</i> retention: 10 ⁷ cfu /cm ² in liquid and aerosol challenges
Quality:	100% of filter units DI flushed
	100% of filter units integrity tested
	Certificate of Quality
Sterilization:	Autoclavable
Surface Area:	A = 1.28 ft ² (1,189 cm ²) B = 2.32 ft ² (2,155 cm ²)



ORDER GUIDE: Brevi-Cap Capsule Filters with Sterilizing Grade Vent-MAXX Double-Layer PTFE Membrane



	INTEGRITY TESTING				
ſ	Size	Wenting Fluid		Diffusive Flow Integrity Test	
			Test Pressure (psig)	Air Flow Limit (ml/min)	
	А	IPA	14	4.6	
	В	IPA	14	8.3	

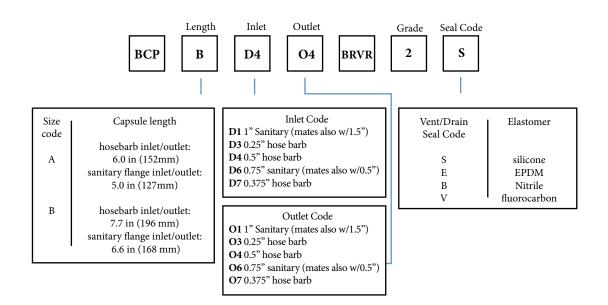
Vent-RITE PTFE Membrane Sterile Air Filters



Designed for:	Sterilizing air and gas filtration for: Sterile air where there is a very low probability of moisture or condensate, and absolute retention in liquids is not required. Common gasses sterile-filtered are air, nitrogen, and CO ₂ .	
Membrane:	0.2 μm PTFE membrane	
Support Layers:	Polypropylene	
Filter Hardware:	Polypropylene	
Toxicity / Material Compliance:	USP Class VI	
	21 CFR	
	REACH, ROHS, BSE/TSE	
Validation:	<i>Brevundimonas diminuta</i> retention: 10 ⁷ cfu /cm ² in aerosol challenges	
Quality:	100% of filter units DI flushed	
	100% of filter units integrity tested	
	Certificate of Quality	
Sterilization:	Autoclavable	
Surface Area:	A = 1.28 ft ² (1,189 cm ²) B = 2.32 ft ² (2,155 cm ²)	



ORDER GUIDE: Brevi-Cap Capsule Filters with Sterilizing Grade Vent-Rite Single-Layer PTFE Membrane



INTEGRITY TESTING						
Size	Wetting Fluid	Diffusive Flow Integrity Test				
		Test Pressure (psig)	Air Flow Limit (ml/min)			
А	IPA	14	≤16.1			
В	IPA	14	≤28.8			

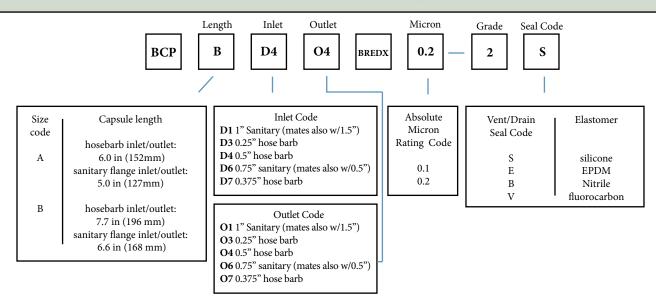


Endo-MAXX CN Filters

Designed for:	Filtration of high purity water where a high degree of endotoxin control is required	
Membrane:	Positive charge nylon 6,6 on polyester substrate	
Support Layers:	Polypropylene	
Filter Hardware:	Polypropylene	
Toxicity / Material Compliance:	USP Class VI	
	21 CFR	
	REACH, ROHS	
	BSE/TSE	
Validation:	Typical endotoxin reduction in water: 2 log	
Quality:	100% of filter units DI flushed	
	100% of filter units integrity tested	
	Certificate of Quality	
Sterilization:	Autoclavable, Gamma Irradiatable	
Surface Area:	$ \begin{array}{l} A = 1.28 \ \text{ft}^2 \ (1,189 \ \text{cm}^2) \\ B = 2.32 \ \text{ft}^2 \ (2,155 \ \text{cm}^2) \end{array} $	



ORDER GUIDE: Brevi-Cap Capsule Filter with Endotoxin Reduction Charged Nylon Membrane



INTEGRITY TESTING						
Micron Rating		0.1	0.2			
Wetting Fluid		Water	Water			
Size A	Diffusive Flow Test Pressure	Consult Strainrite	36 PSIG			
	Air Diffusive Flow Limit	Consult Strainrite	≤18.6 (ml/min)			
	Bubble Point	Consult Strainrite	\geq 46 PSIG			
Size B	Diffusive Flow Test Pressure	Consult Strainrite	36 PSIG			
	Air Diffusive Flow Limit (ml/min)	Consult Strainrite	≤33.4 (ml/min)			
	Bubble Point	Consult Strainrite	≥ 46 PSIG			







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