Steridyne®

0.2 µm VTV-grade Large Capsule Filter (UltraCap® H.D. Model)

Description

This Steridyne® VTV0.2 capsule filter is a hydrophobic PVDF membrane filter optimized for critical air and gas applications. This sterilizing grade filter is virus retentive and ideal for pharmaceutical gases, bioreactor air and sterile venting. Encapsulated Steridyne® filters withstand gamma irradiation and are applicable for integration into single-use systems needing aeration or gas exhaust. The filter is 100% integrity tested during manufacture and has the added benefit of quality certification that meets the critical demands of the pharmaceutical, biotechnology, and related industries.

Materials of Construction

All components of the filter are either animal free or in compliance with EMA/410/01 Rev. 3 (EDQM 5.2.8 07/2011:50208), and US Code of Federal Regulations 9 CFR 94.18 and 21 CFR 189.5. These materials are listed for food contact use in the Code of Federal Regulations (CFR), Title 21, as below:

Membrane:	Polyvinylidene flouride (PVDF)	CFR Title 21, 177.2510
Upstream support:	Polypropylene	CFR Title 21, 177.1520
Downstream support:	Polypropylene	CFR Title 21, 177.1520
Outer guard:	Polypropylene	CFR Title 21, 177.1520
Core:	Polypropylene	CFR Title 21, 177.1520
End caps:	Polypropylene	CFR Title 21, 177.1520
Capsule shell:	Polypropylene	CFR Title 21, 177.1520
Sealing method:	Thermal bonding	

Pore Size	0.2 µm
Effective Filtration Area	7.9 ft^2 (0.73 m^2) per 10”
Typical Air Flow Rate	21.3 scfm/psid (26.24 Nm^3h^{-1} at Δp 50 mbar), inline with 1" inlet/outlets *Capsule configuration and I/O selection may affect pressure drop and flow rate*
Minimum Bubble Point	18 psi (1.2 bar), 60% IPA/40% water
Maximum Diffusion Rate	15 mL/min @ 15 psig (1.03 bar), 60% IPA, per 10" (25 cm)
Maximum WIT Rate	0.4 mL/min water at 20 psi per 10" (0.4 mL/min water at 1.38 bar per 25 cm) *Specification can vary by instrumentation; consult Meissner.*
Bacterial Retention	>10^7 per cm^2 removal of *Brevundimonas diminuta* per ASTM F838

Operating Characteristics

Opertating temperature range:	32 °F to 100 °F (0 °C to 38 °C)
Maximum Temperature rating:	140 °F @ 55 psig (60 °C @ 3.8 bar) liquid, @ 35 psig (2.4 bar) gas
Maximum Operating pressure:	90 psig @ 100 °F (6.2 bar @ 38 °C), liquid service
Maximum Operating pressure:	60 psig @ 100 °F (4.1 bar @ 38 °C), gas service
Maximum reverse pressure:	15 psig @ 100 °F (1.0 bar @ 38 °C)

Sterilization

Autoclave: 121 to 135 °C (15 to 30 psi, 1 to 2 bar), 30 to 60 min, ≥ 3 cycles.
Irradiation: 25 to 40 kGy once. Do not autoclave irradiated capsules.
Capsules must not be in-line steam sterilized.

Biological Safety

Steridyne® filters meet the requirements as specified in the current USP <88> Class VI plastics, <87> cytotoxicity, physicochemical, and USP 43 oxidizable substances tests. No binders, adhesives, or surfactants are used in its construction. Filters comply with Commission Regulation (EU) No. 10/2011.

Quality Assurance

Each Steridyne® VTV0.2 is supplied with a Certificate of Quality verifying the high standards and superior performance of the product. Steridyne® filters comply with the Food and Drug Administration Code of Federal Regulations, Title 21, Parts 210 and 211. Product is manufactured and packaged in a cleanroom facility that, through voluntary compliance, meets or exceeds FDA Good Manufacturing Practice Standards. To ensure product reliability, Meissner’s Quality Assurance staff continually audits the manufacturing process for conformance to its Quality Management System. Each Steridyne® filter is integrity tested during manufacture and is clearly marked with filter type, lot number, and serial number.

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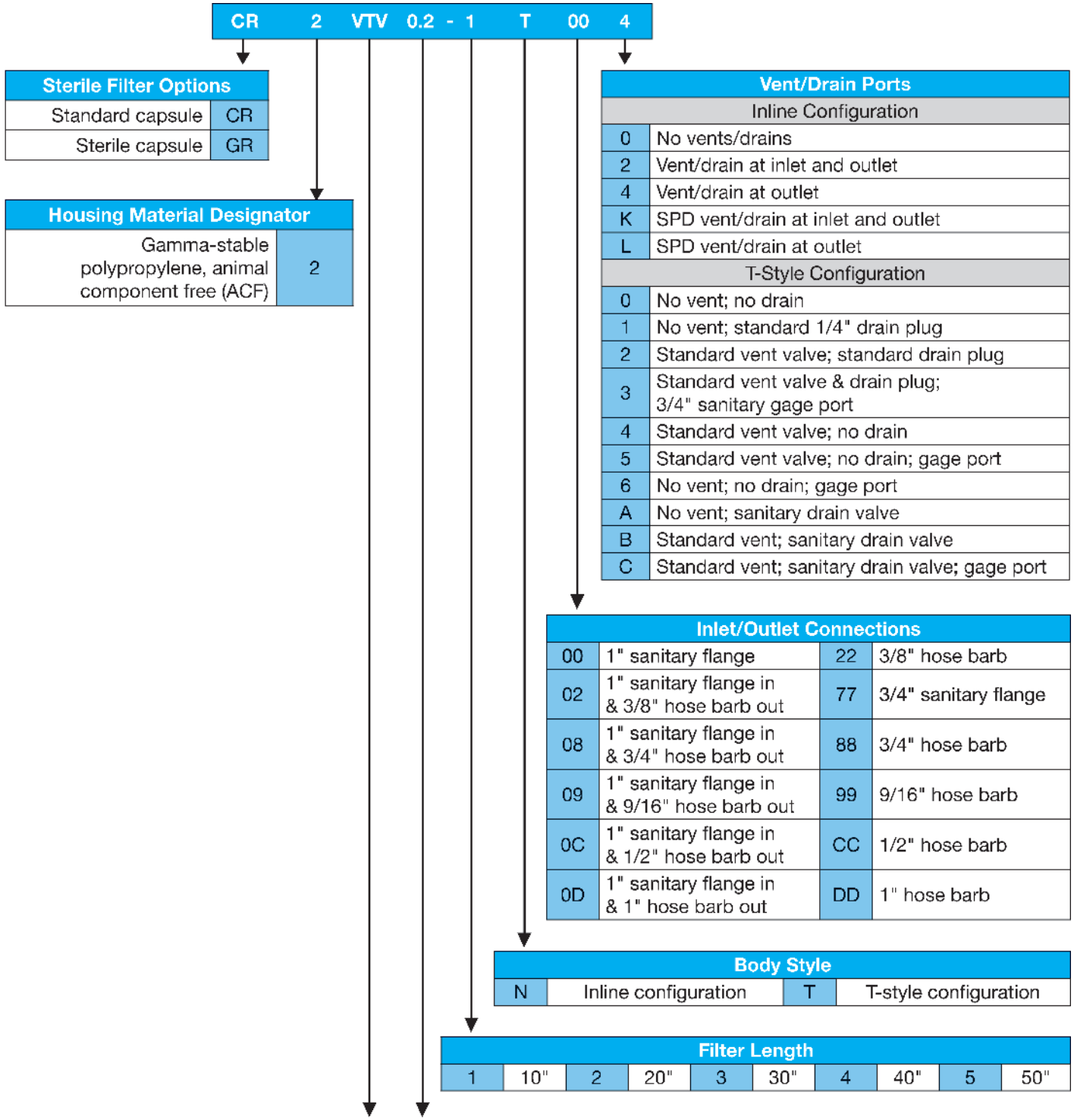
Ordering Guide



Sterile Filter Options	
Standard capsule	CR
Sterile capsule	GR

Housing Material Designator	
Gamma-stable polypropylene, animal component free (ACF)	2

Vent/Drain Ports	
Inline Configuration	
0	No vents/drains
2	Vent/drain at inlet and outlet
4	Vent/drain at outlet
K	SPD vent/drain at inlet and outlet
L	SPD vent/drain at outlet
T-Style Configuration	
0	No vent; no drain
1	No vent; standard 1/4" drain plug
2	Standard vent valve; standard drain plug
3	Standard vent valve & drain plug; 3/4" sanitary gage port
4	Standard vent valve; no drain
5	Standard vent valve; no drain; gage port
6	No vent; no drain; gage port
A	No vent; sanitary drain valve
B	Standard vent; sanitary drain valve
C	Standard vent; sanitary drain valve; gage port

Inlet/Outlet Connections			
00	1" sanitary flange	22	3/8" hose barb
02	1" sanitary flange in & 3/8" hose barb out	77	3/4" sanitary flange
08	1" sanitary flange in & 3/4" hose barb out	88	3/4" hose barb
09	1" sanitary flange in & 9/16" hose barb out	99	9/16" hose barb
0C	1" sanitary flange in & 1/2" hose barb out	CC	1/2" hose barb
0D	1" sanitary flange in & 1" hose barb out	DD	1" hose barb

Body Style			
N	Inline configuration	T	T-style configuration

Filter Length									
1	10"	2	20"	3	30"	4	40"	5	50"

Product	Grade	Pore Size
Steridyne® hydrophobic PVDF membrane	VTV	0.2 µm

Additional information about this filter product is available in the SteriLUX® Green Docs document at www.meissner.com/green-docs.

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