Steridyne®

VMV0.2 Medium Capsule Filter (CF Model)

Description

Steridyne® 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.

Materials of Construction

All components of the Steridyne® filter capsule are either animal free or in compliance with EMEA/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 Fluoride	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 housing:	Polypropylene	CFR Title 21, 177.1520
Sealing method:	Thermal bonding	

Pore Size 0.2 µm

Typical Air Flow Rate 0.78 scfm @ 1 psid (1.0 Nm^3/hr @ Δp 50 mbar)

Minimum Bubble Point 18 psi (1.24 bar), 60% IPA/40% Water
17 psi (1.17 bar), 70% IPA/30% Water

Bacterial Retention >10^7 per cm^2 removal of *Brevundimonas diminuta* per ASTM F838

Operating Characteristics

Operating temperature range: 32 ºF to 100 ºF (0 °C to 38 °C)
Maximum temperature rating: 160 ºF @ 35 psig (72 °C @ 2,4 bar)
Maximum operating pressure (liquid service): 75 psig @ 100 ºF (5.2 bar @ 38 ºC)
Maximum operating pressure (gas service): 50 psig @ 100 ºF (3.4 bar @ 38 ºC)

Sterilization

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

Biological Safety

Steridyne® filters meet the requirements as specified in the USP <88> Class VI plastics, physicochemical, oxidizable substances, and USP <87> cytotoxicity tests. Bacterial endotoxin levels in aqueous extracts of Steridyne® filters are less than 0.5 EU/mL, as determined using the *Limulus* amebocyte lysate (LAL), test USP <85>. No binders, adhesives or surfactants are used in the construction of Steridyne® filters. Filters comply with Commission Regulation (EU) No 10/2011.

Quality Assurance

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.

MEISSNER FILTRATION PRODUCTS

Ordering Guide

Capsule Options	
Standard capsule	C
Sterile capsule	G

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

Vent / Drain Ports	
0	No vent / drain port
1	One luer port with cap, outlet side
2	Two luer ports with caps
4	Two sanitary valves with hose barbs
5	One sanitary valve with hose barb, outlet side
6	One sanitary valve, inlet side

Effective Filtration Area	
B	0.73 ft² (680 cm²)

Inlet / Outlet Connections			
33	Hose barb (1/4" - 3/8")	44	1/4" MNPT
3B	Hose barb (1/4" - 3/8") with filling bell	77	3/4" sanitary (TC) flange
41	1/4" MNPT inlet, 1/4" hose barb outlet		

Product	Filter Grade	Retention Rating
Steridyne® PVDF membrane (hydrophobic)	VMV	0.2

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

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