

Steridyne®

0.2 µm VTV-grade Medium Capsule Filter (CF Model)

Description

Steridyne® VTV0.2 is a hydrophobic PVDF membrane filter optimized for critical air and gas applications. Designed for bidirectional flow, this sterilizing grade filter is well suited for applications requiring complete removal of bacteria and viruses from air and gas streams, such as fermenter inlet air and exhaust, sterile process air, and sterile venting of carboys, filling vessels, bioreactors and small product or intermediate tanks. Steridyne® capsule filters are manufactured using gamma irradiation tolerant materials and are ideal for integration into single-use systems needing aeration or gas exhaust.

The Steridyne® VTV0.2 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 Steridyne® filter capsule are either animal component 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

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

Maximum Diffusion Rate 1.3 mL/min @ 15 psig (1.03 bar), 60% IPA/40% water

Bacterial Retention >10⁷ per cm² removal of *Brevundimonas diminuta* per ASTM F838

Operating Characteristics

Operating temperature range:	32 °F to 100 °F (0 °C to 38 °C)
Maximum temperature rating:	160 °F @ 35 psig (72 °C @ 2.4 bar)
Maximum operating pressure:	75 psig @ 100 °F (5.2 bar @ 38 °C), liquid service
Maximum operating pressure:	50 psig @ 100 °F (3.4 bar @ 38 °C), gas service
Maximum reverse pressure:	15 psig @ 100 °F (1.0 bar @ 38 °C)

Sterilization

Autoclave: 121 °C to 135 °C (15 to 30 psi, 1 to 2 bar), 30 to 60 minutes, ≥ 3 cycles.

Gamma irradiation: 25 to 40 kGy once. Do not autoclave irradiated capsules.

Capsules must not be in-line steam sterilized.

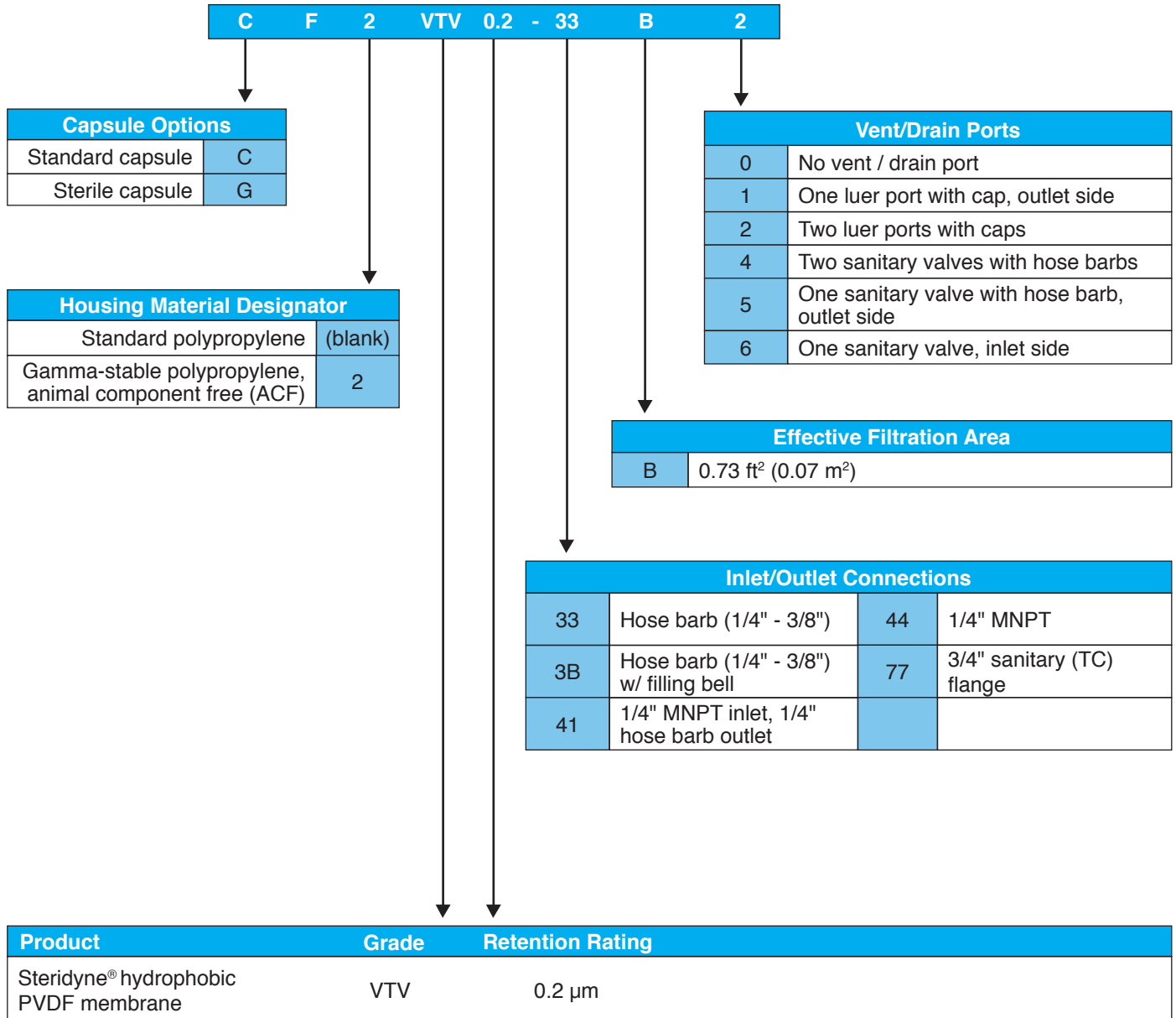
Biological Safety

Steridyne® filters meet the requirements as specified in the current USP <88> Class VI plastics, USP <87> cytotoxicity, and pyrogenicity tests. No binders, adhesives or surfactants are used in the construction of Steridyne® filters. Filters comply with European Commission Regulation 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.

Ordering Guide



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

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