# **Steridyne®**

# 0.2 µm VTV-grade Standard Capsule Filter — CJ2 Model

#### Description

The Steridyne® VTV0.2 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 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 animal component free (ACF). These materials are listed for food contact use in the Code of Federal Regulations (CFR), Title 21, as below:

Membrane: Polyvinylidene fluoride (PVDF) CFR Title 21, 177.2510 Polypropylene CFR Title 21, 177.1520 Upstream support: Downstream support: Polypropylene CFR Title 21, 177,1520 Polypropylene Outer guard: CFR Title 21, 177.1520 Polypropylene Core: CFR Title 21, 177.1520 Polypropylene End caps: CFR Title 21, 177.1520 Capsule shell: 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 9.8 mL/min @ 15 psi (1.03 bar) 60% IPA/40% water

Maximum Water Intrusion Rate 0.3 mL/min water @ 20 psig (1.38 bar)

Specification can vary by instrumentation; consult factory.

Typical Air Flow Rate 9.50 scfm @ 1 psid (11.70 Nm³/hr @ ∆P 50 mbar)

Bacterial Retention >10<sup>7</sup> per cm<sup>2</sup> 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 (71 °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.

Irradiation: 25 to 40 kGy once. Do not autoclave irradiated capsules. Capsules must not be in-line steam sterilized.

# **Biological Safety**

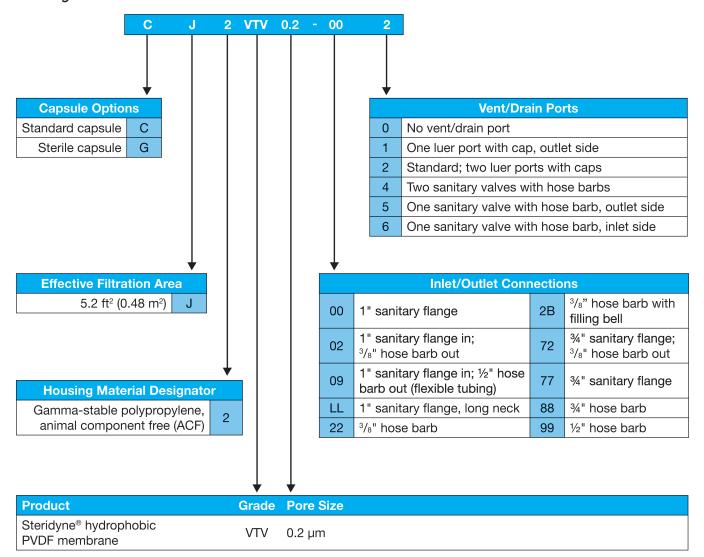
Steridyne® filters meet the requirements as specified in the current USP <88> Class VI plastics, <87> cytotoxicity and pyrogenicity tests. No binders, adhesives, or surfactants are used in its construction. Filters comply with Commission Regulation (EU) No 10/2011.

# **Quality Assurance**

Each Steridyne® VTV0.2 filter 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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