Steridyne®

Hydrophobic PVDF Membrane Filter

MEISSNER FILTRATION PRODUCTS

Steridyne® Filter Cartridge

Steridyne® filter cartridges are hydrophobic, pleated, 0.2 µm absolute-rated PVDF membrane filters. In air and gas streams, they are virus retentive and will remove contaminants to 0.01 µm. Offering high flow rates and broad chemical compatibility, the Steridyne® filter is ideal for the removal of particles and microorganisms from gases in the pharmaceutical, biologicals, chemical, and food and beverage industries. It is optimized for sterile tank venting, fermentation air and compressed air and gas filtration applications.

The Steridyne® filter can also be used to filter many low surface tension chemicals and solvents. It is a sterilizing grade filter, based on ASTM F838-05 liquid bacterial challenge testing.

The Steridyne® PVDF filter membrane is manufactured by Meissner's state-of-the-art process. All filter support components are polypropylene. Through a unique process, the membrane and polypropylene support components are thermally bonded to the cartridge end caps. This produces an integral filter cartridge with excellent mechanical strength, wide chemical compatibility and minimal extractables.

The Steridyne® filter's PVDF membrane is made without wetting agents, post treatments or other added materials. Steridyne® filters are certified as non-fiber-releasing. Each Steridyne® filter cartridge is 100% integrity tested during manufacture. Each lot is tested for bacterial retention, according to ASTM methodology.

Features and Benefits

- Inert, rugged PVDF membrane and polypropylene components offer wide chemical compatibility and thermal strength in a broad range of fluids and applications
- Absolute 0.2 µm rated filter meets sterilizing grade filter criteria per ASTM F838-05 methodology and is virus retentive in air and gas applications
- Contains no binders or adhesives for wide solvent compatibility with extremely low extractables
- 100% integrity tested during manufacture to ensure product integrity, consistency and reliability
- Integrity testable for assured product integrity and effectiveness in operation
- Biologically inert and non-toxic, the filter meets FDA requirements for food contact use and passes USP Class VI Plastics biological reactivity tests
- Filters comply with European Commission Directive 2002/72/EC and subsequent amendments up to 2008/39/EC

Typical Applications

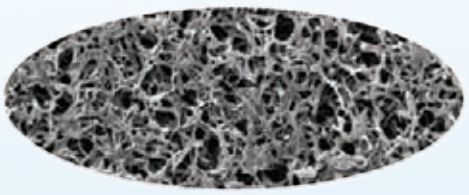
Steridyne® meets the need for critical contamination control in the pharmaceutical, biologicals, biopharmaceutical, bioprocessing, microelectronics, chemical, food and beverage and other process industries. It will remove particles and microorganisms from a wide range of process fluids. Typical air and gas applications include:

- Sterile tank venting
- Process gases
- Compressed air
- Fermentor inlet air and off-gases
- Nitrogen and other inert gases
- Bioreactor inlet and outlet air

Steridyne® wets immediately in compatible non-aqueous liquids. In aqueous liquids, the Steridyne® filter must be pre-wet by immersion in a low surface tension liquid (<35 dynes/cm). Typical liquid applications include:*

- Acids
- Alcohols
- Antibiotic and solvent mixtures
- Solvents
- Weak bases

* Not recommended for concentrated chlorinated hydrocarbon and ketone solutions. Consult Meissner for chemical compatibility.



Steridyne® SEM

Materials of Construction

Filter Membrane: Polyvinylidene Fluoride (PVDF)

Upstream Support: Polypropylene

Downstream Support: Polypropylene

Core/Outer Guard: Polypropylene

End Caps: Polypropylene

Sealing Method: Thermal Bonding

O-ring/Gasket Seal: Buna, EPR, polyethylene, silicone, Teflon® over silicone, Teflon® over Viton®

All materials of construction listed above are FDA approved for food contact use per 21 CFR 177. Filters comply with European Commission Directive 2002/72/EC and subsequent amendments up to 2008/39/EC.

Steridyne® filters are manufactured in conformance to cGMP. Steridyne® filters meet the requirements as specified in the current USP Class VI plastics, physicochemical, oxidizable substances, and 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. No binders, adhesives or surfactants are used in the construction of Steridyne® filters. Steridyne® filters are non-fiber-releasing as defined in 21 CFR 210.3(b)(6) and 211.72.

Filtration Rating (Absolute)

0.2 µm

Integrity Testing

Minimum Bubble Point, 60% IPA
18 psi (1,2 bar)

Cartridge Dimensions (nominal)

Diameter: 2.75" (7 cm)
Lengths: 10", 20", 30", 40"
(25 cm, 50 cm, 75 cm, 100 cm)

Bacterial Retention

Steridyne® retains >10^7 cfu/cm^2 *Brevundimonas diminuta*, qualifying it as a sterilizing grade filter, per ASTM F838-05 liquid challenge methodology.

Sterilization

Steam-in-place (SIP):
saturated steam @ 121-135 °C, 30-60 minutes
[15 psi (1 bar) to 30 psi (2 bar), 30-60 minutes]

Autoclave: 121-135 °C, 30-60 minutes

Steridyne® cartridges are capable of repeated sterilization cycles without loss of integrity. For applications requiring autoclave/SIP, a stainless steel reinforcement ring must be ordered. See "Reinforcement Ring Option" in Ordering Information.

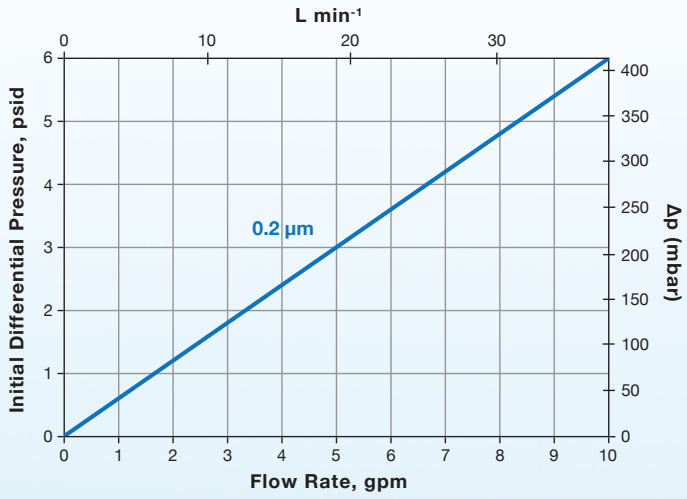
Maximum Operating Temperatures and Pressures

Δp 80 psi @ 32 °F to 100 °F
(Δp 5,5 bar @ 0 °C to 38 °C)

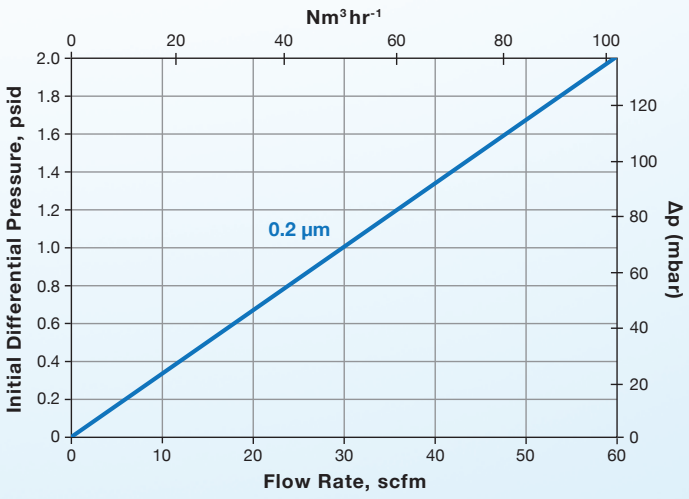
Δp 60 psi @ 150 °F
(Δp 4,1 bar @ 66 °C)

Δp 30 psi @ 180 °F
(Δp 2,1 bar @ 82 °C)

Typical Water Flow Rates per 10" Cartridge



Typical Air Flow Rates per 10" Cartridge



End Cap Configuration

-226 O-ring

External -226 O-rings with locking tabs; open end for C6 and F6 SOE configurations

-222 O-ring

External -222 O-rings; open end for C2 and F2 SOE configurations

-226 nO-Ring

External -226 nO-Ring® with locking tabs; open end for C5 and F5 SOE configurations

-222 nO-Ring

External -222 nO-Ring®, open end for C1 and F1 SOE configurations

Flat Gasket

Flat Gasket; open end for GS and GL DOE configurations

Internal O-ring

Internal O-ring; open end for DN and DA DOE or RN and RA SOE configurations

Button Cap

Button Cap; closed end for C1, C2, C5 and C6 SOE configurations

Alignment Fin

Alignment Fin; closed end for F1, F2, F5 and F6 SOE configurations

Recessed Cap

Recessed Cap; closed end for RN and RA SOE configurations

DOE = Double Open End
SOE = Single Open End

Ordering Information

Filter Grade	Absolute Rating (µm)		Cartridge Length	End Cap Configuration	Reinforcement Ring Option	Seal Material (O-ring or Gasket)
VMV	*0.2*	-	*3*	*F2*	*R*	*S*
VMV	**0.2**		**1** = 10" (25 cm)	**GS** = DOE; flat gaskets (9.75", 19.5", 29.25", 39" length filters)	(Blank) = Standard - no reinforcement ring	O-ring Seal **B** = Buna **E** = EPR **S** = Silicone **T** = Teflon® over silicone **V** = Viton® **X** = Teflon® over Viton®
VTV	**0.2**		**2** = 20" (50 cm)	**GL** = DOE; flat gaskets (20", 30", 40" length filters)	R = Reinforcement ring; required for autoclave/ SIP applications	Gasket Seal **B** = Buna **E** = EPR **P** = Polyethylene **S** = Silicone **T** = Teflon® **V** = Viton®
			3 = 30" (75 cm)	**C1** = SOE; -222 nO-Ring®, button cap end		
			4 = 40" (100 cm)	**C2** = SOE; -222 O-rings, button cap end		
				F1 = SOE; -222 nO-Ring®, fin end		
				F2 = SOE; -222 O-rings, fin end		
				C5 = SOE; -226 nO-Ring®, button cap end		
				C6 = SOE; -226 O-rings, button cap end		
				F5 = SOE; -226 nO-Ring®, fin end		
				F6 = SOE; -226 O-rings, fin end		
				DN = DOE; internal -120 O-rings		
				RN = SOE; internal -120 O-rings, recessed cap end		
				DA = DOE; internal -213 O-rings		
				RA = SOE; internal -213 O-rings, recessed cap end		

Grade Descriptions

VMV = This sterilizing grade filter is absolute, microbially rated and 100% integrity tested during manufacture. It is suited for critical applications when regulatory documentation requirements are minimal. A Certificate of Conformance is available on a lot basis.

VTV = This absolute, microbially rated, sterilizing grade filter meets full traceability requirements for the pharmaceutical industry. It is 100% integrity tested during manufacture. Each VTV grade filter is shipped with a Certificate of Quality stating exact quality control criteria and test performance results. This is a validatable product to meet the stringent requirements of the pharmaceutical industry.

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