

Data Sheet

Optiseal[®] Cartridge Filters with Aervent[®] Membrane

For sterile filtration of gases

Optiseal[®] filters with Aervent[®] membrane are 0.2 µm hydrophobic cartridges. They are designed for sterilizing applications, removing particles and microorganisms from gases and solvents. They are made with PTFE membrane and polypropylene components for broad application compatibility.

Optiseal[®] filters with Aervent[®] membrane are designed to be used with Optiseal[®] housings. For traceability and easy identification, each Optiseal[®] cartridge is labeled with its lot number, serial number, pore size and an abbreviated catalogue number.

Optiseal[®] filters with Aervent[®] membrane are designed, developed and manufactured in accordance with a Quality Management System approved by an accredited registered body to an ISO[®] 9001 Quality Systems Standard. Each unit is integrity tested during manufacturing to guarantee integrity. For documentation accuracy each cartridge includes a Certificate of Quality, summarizing lot release and audit testing data.



Typical Applications

Optiseal[®] cartridges with Aervent[®] membrane will sterilize air or gas streams in:

- Sterile tank venting
- Fermentation air applications
- Bioreactor inlet and outlet gas filtration
- Lyophilizers
- Autoclaves
- Sterile process gases

Optiseal[®] filters with Aervent[®] membrane can also be used to sterilize alcohol streams. Compatibility is assured for a wide range of solvents.

Double O-ring Seal

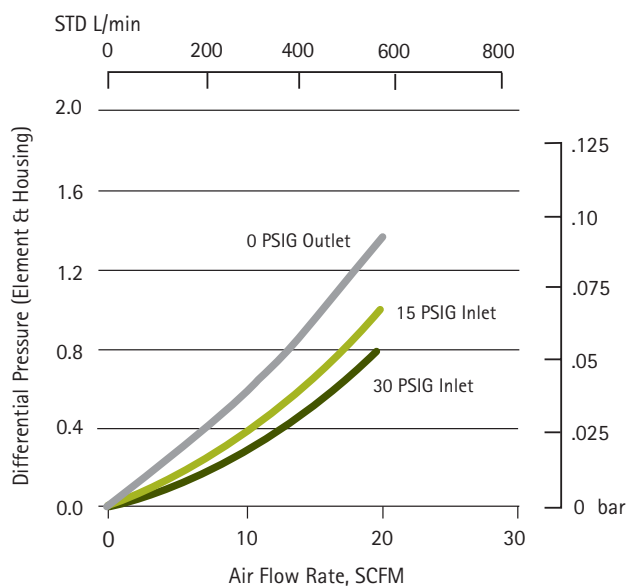
The standard double O-ring seal has been improved by the inclusion of a steaming support ring in the housing base. The ring provides extra support during continuous steaming or multiple steam cycles.

Clean Construction

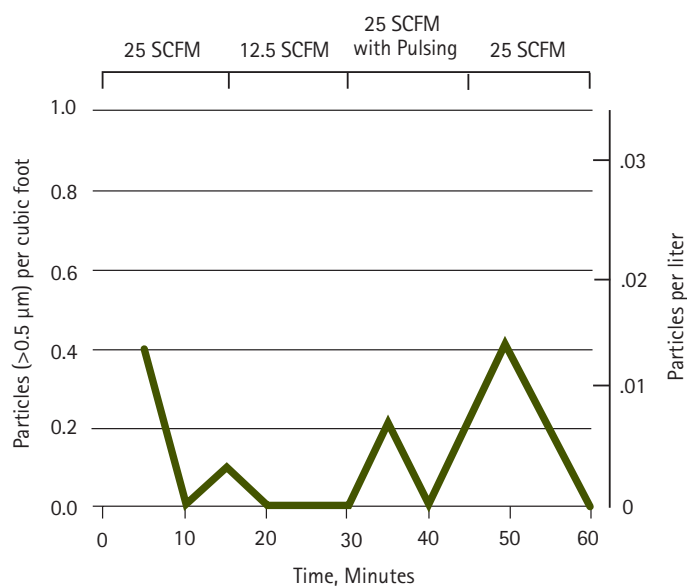
No surfactants or adhesives are used in construction. Each cartridge is double bagged.

Specifications

Materials of Construction	PTFE membrane Polypropylene upstream and downstream supports, core, cage and endcaps. Silicone O-rings (2-123)
Connections	Optiseal® cartridges incorporate a unique double 2-123 (silicone) O-ring seal and are used with Optiseal® stainless steel housings.
Pore Size	0.2 µm hydrophobic
Effective Filtration Area	0.18 m ² (1.9 ft ²)
Maximum Differential Pressure, bar (psid)	Forward: 5.5 bar (80 psid) @ 25 °C, 1.75 bar (25 psid) @ 80 °C, 0.35 bar (5 psid) @ 135 °C; Reverse Pressure: 4.1 bar (60 psid)
Sterilizability	Cartridges can be steamed at least 40 times in the forward direction and 40 times in the reverse direction at 135 °C for 30 min.
Integrity Testing	Diffusion of nitrogen at 23 °C: <6 mL/min per cartridge at 965 mbar (14 psid) in 70% IPA. Bubble point at 23 °C: >1100 mbar (16 psid) in 70% IPA. HydroCorr™ Water Flow Integrity Test: <0.2 mL/min pure water flow at 2.6 bar (38 psid) per cartridge.
Bacterial Retention	Quantitative retention of 10 ⁷ CFU/cm ² <i>Brevundimonas diminuta</i> (ATCC® 19146) per ASTM® F838-83 methodology. The filters meet the definition of sterilizing-grade filters as described in the FDA "Guideline on Sterile Drug Products Produced by Aseptic Processing" (1987).
Bacterial Endotoxin	Aqueous extraction contains ≤0.5 EU/mL as determined by the Limulus Amebocyte Lysate (LAL) Test
Gravimetric Extractables	Maximum in 70/30 IPA at ambient temperature after autoclaving: 10 mg/cartridge.
Component Material Toxicity	Component materials meet the criteria of the USP <88> Reactivity Test for Class VI Plastics. These products meet the requirements of the USP <88> Safety Test, utilizing a 0.9% sodium chloride extraction.
Good Manufacturing Practices	These products are manufactured in a facility which adheres to FDA Device Good Manufacturing Practices.
Non-Fiber Releasing	Component materials meet the "non-fiber releasing" criteria as defined in 21 CFR 210.3 (b) (6).



Typical air pressure drop for Optiseal® cartridges with 0.2 µm Aervent® membrane.



Particle shedding in air after SIP, 30 minutes at 135 °C for Optiseal® cartridges with 0.2 µm Aervent® membrane.

Optiseal® Sanitary Cartridge Housings

The Optiseal® housing is designed for sterile filtration of aqueous solutions and gases using Optiseal® cartridge filters. All wetted surfaces are constructed of 316 L stainless steel and are electropolished, providing excellent durability and maximum corrosion resistance. The housing features easy-to-clean vents, drains, and connections, allowing complete sterilization.

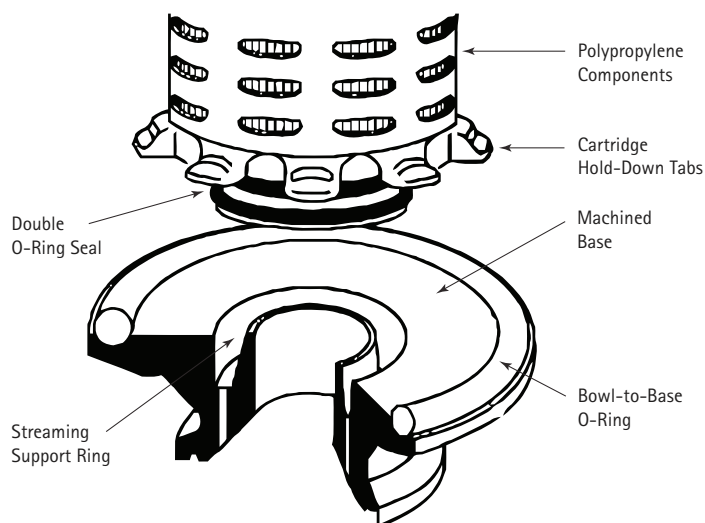
Vent insulating rings are included for added safety. The housing accommodates a double O-ring cartridge configuration, allowing a positive cartridge seal and preventing bacterial and particulate bypass. The Optiseal® housing is designed to engage hold-down tabs on the Optiseal® cartridge, which lock the cartridge in place when the housing is fully assembled.

Specifications

Materials of Construction	Housing: 316 L Stainless Steel Clamp: 304 Stainless Steel Seal Materials: Silicone Vent Insulators: EPDM
Surface Finish	Wetted Surfaces: Polished to a fine sanitary finish, <20 Ra. All welds are ground smooth. Exterior Surfaces: Polished to a fine sanitary finish. The entire housing is electropolished
Connections	Inlet/Outlet: 1 1/2" TC sanitary flange Cartridge: Double O-rings with hold-down tabs Dome to Base: 3" O-rings (2-335)
Dimensions	Inlet to Outlet: 20.2 cm (8")
Shipping Weight	1.3 kg (2.75 lbs)
Operating Conditions	10 bar (145 psi) at 140 °C (284 °F)



Optiseal® housing assembly.



Optiseal® cartridge sealing mechanism.

Ordering Information

Description	Qty/Pk	Catalogue No.
Optiseal® cartridges with 0.2 µm Aervent® membrane	6	LAGR04TP6
Optiseal® housing assembly	1	HP01PPVNO
Other Optiseal® Cartridges		
Optiseal® cartridges with 0.1 µm Durapore® hydrophilic membrane	6	LAVL04TP6
Optiseal® cartridges with 0.22 µm Durapore® hydrophilic membrane	6	LAGL04TP6
Optiseal® cartridges with 0.45 µm Durapore® hydrophilic membrane	6	LAHL04PP6
Optiseal® cartridges with 0.45 µm Durapore® hydrophilic membrane & prefilter layer	6	LAHL04TP6
Optiseal® cartridges with 0.22 µm Durapore® hydrophobic membrane	6	LAGB04TP6
Housing Accessories		
Housing bowl	1	SPPS00001
Housing base	1	HP01PBVNO
1½" TC clamp, (inlet & outlet)	1	YY2004045
1½" TC gasket, silicone, 10 pk	1	YY2004055
Bowl to base clamp	3 piece	SPPS00003
Bowl to base O-ring, silicone	1	SPPS00004
Vent/Drain valve	1	SPPS00005
Vent/Drain valve O-ring, silicone	1	SPPS00006
Vent seal plug, EPR	1	P17023X2
Vent seal plug, Silicone	1	P17023X3
Vent seal plug, fluoroelastomer	1	P17023X1

To Place an Order or Receive Technical Assistance

In Europe, please call Customer Service:

France: 0825 045 645

Germany: 069-86798021

Italy: 848 845 645

Spain: 901 516 645 Option 1

Switzerland: 0848 645 645

United Kingdom: 0870 900 4645

For other countries across Europe,
please call: +44 (0) 115 943 0840

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