

# Sterilizing-Grade Aervent<sup>®</sup> Filters

Premium choice for critical sterile gas filtration

Aervent<sup>®</sup> filters contain sterilizing-grade 0.2 µm Aervent<sup>®</sup> polytetrafluoroethane (PTFE) hydrophobic membrane designed to provide efficient gas filtration. It is recommended for critical applications requiring a phobic filter with validated bacterial and viral retention capabilities.

Filters with hydrophobic Aervent<sup>®</sup> membrane are designed, developed, and manufactured in accordance with a Quality Management System approved by an accredited registering body to an ISO 9001 Quality Systems Standard. Each filter is shipped with a Certificate of Quality. Each Opticap<sup>®</sup> XL capsule, cartridge, and Optiseal<sup>®</sup> cartridge filter is integrity tested during manufacturing and is supported with a comprehensive validation package for compliance with regulatory requirements. For traceability and easy identification, each filter is labeled with the product name, lot number and serial number.



## Benefits

- Reliable particulate and microorganism retention
- Unparalleled thermal and hydraulic stress resistance
- Validated to withstand multiple sterilization cycles

## Multiple Formats Available

Hydrophobic Aervent<sup>®</sup> membranes are available in three device formats, different filtration areas, and multiple configurations that offer end users better flexibility.

## Membrane Types

- Aervent<sup>®</sup> 0.2 µm sterilizing-grade PTFE membrane

## Filter Formats

- Opticap<sup>®</sup> XL disposable capsule filters
- Cartridge filters
- Optiseal<sup>®</sup> cartridge filters
- Optiseal<sup>®</sup>-M cartridge filters

## **Opticap® XL and XLT Capsules**

### **For Pilot and Production Scale Processing**

Our Opticap® XL and XLT single-use capsule filters are available in multiple filtration areas, are gamma or autoclave compatible, and offer a range of inlet and outlet connections.

## **Cartridge Filters**

### **For Pilot and Production Scale Processing**

Our hydrophobic Aervent® cartridge filters are designed for use in stainless-steel housings and provide high throughput and minimal differential pressure. These cartridges are robust, strong, and resilient and are designed to withstand multiple steam-in-place cycles.

A full range of filtration areas and connection options are available for maximum flexibility.

## **Optiseal® and Optiseal®-M Cartridges**

Optiseal® cartridge filters with Aervent® membranes feature a robust cartridge-to-housing sealing mechanism and are designed for use in stainless steel housings.

## Specifications

Capsule Filters	Opticap® XL 2 Capsule	Opticap® XL 4 Capsule	Opticap® XL 5 Capsule	Opticap® XL 10 Capsule
<b>Nominal Dimensions</b>				
<b>Maximum length:</b>	14.3 cm (5.6 in.)	19.6 cm (7.7 in.)	21.6 cm (8.5 in.)	33.5 cm (13.2 in.)
<b>Body diameter:</b>	8.4 cm (3.3 in.)	8.4 cm (3.3 in.)	10.7 cm (4.2 in.)	10.7 cm (4.2 in.)
<b>Vent to vent diameter:</b>	12.5 cm (4.9 in.)	12.5 cm (4.9 in.)	14.5 cm (5.7 in.)	14.5 cm (5.7 in.)
<b>Filtration Area</b>	0.10 m <sup>2</sup> (1.1 ft <sup>2</sup> )	0.21 m <sup>2</sup> (2.3 ft <sup>2</sup> )	0.32 m <sup>2</sup> (3.5 ft <sup>2</sup> )	0.65 m <sup>2</sup> (7.0 ft <sup>2</sup> )
<b>Materials of Construction</b>				
<b>Filter media:</b>	Hydrophobic PTFE			
<b>Supports:</b>	Polypropylene			
<b>Structural components:</b>	Polypropylene			
<b>Vent O-rings:</b>	Silicone			
<b>Vent/Drain</b>	1/4 in. hose barb with double O-ring seal			
<b>Maximum Inlet Pressure</b>	5.5 bar (80 psi) at 23 °C 2.8 bar (40 psi) at 60 °C 1.0 bar (15 psi) at 80 °C			
<b>Maximum Differential Pressure</b>				
<b>Forward</b>	5.5 bar (80 psid) at ambient temperature, 1.0 bar (15 psid) at 80 °C			
<b>Reverse</b>	4.1 bar (60 psid) intermittent			
<b>Bubble Point at 23 °C</b>	≥ 1100 mbar (16 psig) in 70/30 IPA/water			
<b>Air Diffusion</b>	Through 70/30% IPA/water wet membrane at ambient room temperature and 970 mbar (14 psig) nitrogen:  -                   ≤ 9 cc/min                   ≤ 12 cc/min                   ≤ 24 cc/min			
<b>HydroCorr™ Test</b>	At 2620 mbar (38 psig) ≤ 0.12 mL/min                   ≤ 0.25 mL/min                   ≤ 0.38 mL/min                   ≤ 0.75 mL/min			
<b>Gravimetric Extractables</b>	After autoclaving and 24 hr soak in 70/30% IPA/water at controlled room temperature: ≤ 15 mg                   ≤ 15 mg                   ≤ 28 mg                   ≤ 45 mg			
<b>Bacterial Endotoxin</b>	Aqueous extraction contains < 0.25 EU/mL as determined by the Limulus Amebocyte Lysate (LAL) Test.			
<b>Bacterial Retention</b>	Quantitative retention of 10 <sup>7</sup> CFU/cm <sup>2</sup> <i>Brevundimonas diminuta</i> ATCC® 19146 per ASTM® F838 methodology			
<b>Sterilization</b>	May be autoclaved for 30 cycles of 30 minutes at 135 °C.			
<b>Non-Fiber Releasing</b>	Aervent® membrane meets the criteria for a "non-fiber releasing" filter as defined in 21 CFR 210.3 (b) (6).			
<b>Component Material Toxicity</b>	Component materials meet the criteria for Class VI testing based on USP <88> Biological Reactivity Tests, <i>in vivo</i> and the specifications of ISO 10993-5 Tests for <i>in vitro</i> cytotoxicity and USP <87> Biological Reactivity Tests, <i>in vitro</i> .			
<b>European Pressure Equipment Directive</b>	We certify that the Opticap® XL10 capsule filter complies with the European Pressure Equipment Directive, 2014/68/EU of 15 May 2014. The Opticap® XL10 capsule filter has been classified under Article 4 § 3 of the Directive 2014/68/EU. It has been designed and manufactured in accordance with Article 4 § 3 of the Directive 2014/68/EU, the Opticap® XL10 capsule filter does not bear the CE mark.			
<b>Viral Aerosol Retention</b>	Rated for aerosol retention of a total challenge of 10 <sup>8</sup> –10 <sup>10</sup> plaque forming units of φX-174 virus particles at 50 SCFM per 10-inch cartridge.			
<b>Bacterial Aerosol Growth</b>	Retains <i>B. diminuta</i> liquid aerosol for 21 days at a minimum challenge of 10 <sup>7</sup> CFU/cm <sup>2</sup> .			

## Specifications

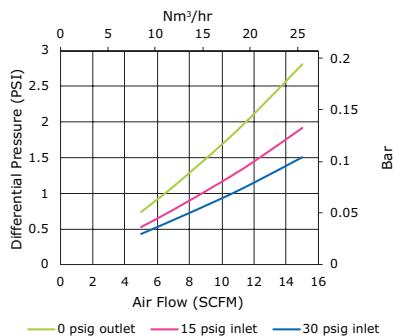
Cartridge Filters	5-inch Cartridge	10-inch Cartridge
<b>Nominal Dimensions</b>		
<b>Maximum length:</b>	12.5 cm (5 in.)	25 cm (10 in.)
<b>Vent to vent diameter:</b>	6.9 cm (2.7 in.)	6.9 cm (2.7 in.)
<b>Filtration Area</b>	0.32 m <sup>2</sup> (3.5 ft <sup>2</sup> )	0.65 m <sup>2</sup> (7.0 ft <sup>2</sup> )
<b>Materials of Construction</b>		
<b>Filter media:</b>	Hydrophobic PTFE	
<b>Supports:</b>	Polypropylene	
<b>Structural components:</b>	Polypropylene	
<b>O-rings:</b>	Silicone	
<b>Vent O-rings:</b>	Stainless Steel	
<b>Maximum Differential Pressure</b>		
<b>Forward</b>	5.5 bar (80 psid) at ambient temperature, 1.8 bar (25 psid) at 80 °C	
<b>Reverse</b>	4.1 bar (60 psid) intermittent	
<b>Bubble Point at 23 °C</b>	≥ 1100 mbar (16 psig) in 70/30 IPA/water	
<b>Air Diffusion</b>	Through 70/30% IPA/water wet membrane at ambient room temperature and 970 mbar (14 psig) nitrogen:	
	≤ 12 cc/min	≤ 24 cc/min
<b>HydroCorr™ Test</b>	At 2620 mbar (38 psig) ≤ 0.38 mL/min	≤ 0.75 mL/min
<b>Gravimetric Extractables</b>	After autoclaving and 24 hr soak in 70/30% IPA/water at controlled room temperature: ≤ 18 mg	≤ 35 mg
<b>Bacterial Endotoxin</b>	Aqueous extraction contains < 0.25 EU/mL as determined by the Limulus Amebocyte Lysate (LAL) Test.	
<b>Bacterial Retention</b>	Quantitative retention of 10 <sup>7</sup> CFU/cm <sup>2</sup> <i>Brevundimonas diminuta</i> ATCC® 19146 per ASTM® F838 methodology	
<b>Sterilization</b>	May be steam sterilized 100 times (forward) and 50 times (reverse) for 30 minutes at 145 °C.	
<b>Non-Fiber Releasing</b>	Aervent® membrane meets the criteria for a "non-fiber releasing" filter as defined in 21 CFR 210.3 (b) (6).	
<b>Component Material Toxicity</b>	Component materials meet the criteria of the USP <88> Biological Reactivity <i>in vivo</i> test for Class VI Plastics. This product is non-cytotoxic per ISO 10993-5 and USP <87> Biological reactivity <i>in vitro</i> tests.	
<b>Viral Aerosol Retention</b>	Rated for aerosol retention of a total challenge of 10 <sup>8</sup> –10 <sup>10</sup> plaque forming units of φX-174 virus particles at 50 SCFM per 10-inch cartridge.	
<b>Bacterial Aerosol Growth</b>	Retains <i>B. diminuta</i> liquid aerosol for 21 days at a minimum challenge of 10 <sup>7</sup> CFU/cm <sup>2</sup> .	

## Specifications

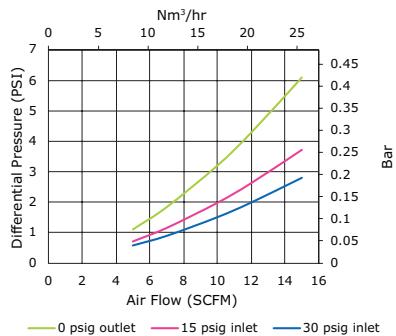
Optiseal® Cartridge Filters	Optiseal® Cartridge	Optiseal®-M Cartridge
<b>Filtration Area</b>	0.18 m <sup>2</sup> (1.9 ft <sup>2</sup> )	0.05 m <sup>2</sup> (0.54 ft <sup>2</sup> )
<b>Materials of Construction</b>		
<b>Filter media:</b>	PTFE membrane	
<b>Outer sleeve, core, end caps, pleat supports:</b>	Polypropylene	
<b>O-rings:</b>	Silicone	
<b>Maximum Differential Pressure</b>		
<b>Forward</b>	5.5 bar (80 psid) at ambient temperature 1.75 bar (25 psid) at 80 °C 0.35 bar (5 psid) at 135 °C	
<b>Reverse</b>	4.1 bar (60 psid) intermittent	
<b>Bubble Point at 23 °C</b>	≥ 1100 mbar (16 psig) in 70/30 IPA/water	
<b>Air Diffusion</b>	Through 70/30% IPA/water wet membrane at ambient room temperature and 970 mbar (14 psig) nitrogen: ≤ 6 cc/min	-
<b>HydroCorr™ Test</b>	At 2.6 bar (38 psig) ≤ 0.2 mL/min	≤ 0.06 mL/min
<b>Gravimetric Extractables</b>	After autoclaving and 24 hr soak in 70/30% IPA/water at controlled room temperature: ≤ 10 mg	≤ 10 mg
<b>Sterilization</b>	May be sterilized 40 times forward and 40 times reverse for 30 minutes at 135 °C	Maintained integrity after 80 steam cycles of 30 minutes at 135 °C
<b>Bacterial Endotoxin</b>	Aqueous extraction contains < 0.25 EU/mL as determined by the Limulus Amebocyte Lysate (LAL) Test.	
<b>Bacterial Retention</b>	Quantitative retention of 10 <sup>7</sup> CFU/cm <sup>2</sup> <i>Brevundimonas diminuta</i> ATCC® 19146 per ASTM® F838 methodology	
<b>Component Material Toxicity</b>	Component materials meet the criteria of the USP <88> Biological Reactivity <i>in vivo</i> test for Class VI Plastics. This product is non-cytotoxic per ISO 10993-5 and USP <87> Biological reactivity <i>in vitro</i> tests.	
<b>Non-Fiber Releasing</b>	Aervent® membrane meets the criteria for a "non-fiber releasing" filter as defined in 21 CFR 210.3 (b) (6).	
<b>Bacterial Aerosol Growth</b>	Retains <i>B. diminuta</i> liquid aerosol for 21 days at a minimum challenge of 10 <sup>7</sup> CFU/cm <sup>2</sup> .	
<b>Viral Aerosol Retention</b>	Rated for aerosol retention of a total challenge of 10 <sup>8</sup> –10 <sup>10</sup> plaque forming units of φX-174 virus particles at 50 SCFM per 10-inch cartridge.	

## Air Flow Rate and Pressure Drop – Opticap® XL Capsule Filters

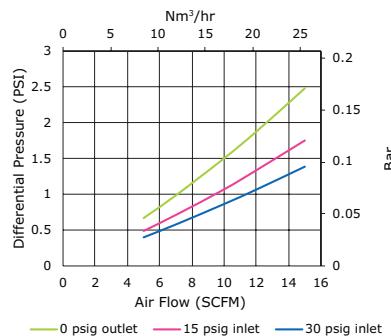
**Opticap® XL 2 Capsule with 0.2 µm Aervent® Membrane – FF Fitting**



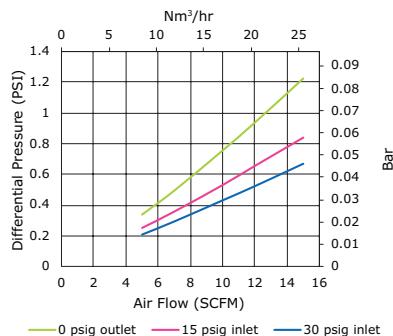
**Opticap® XL 2 Capsule with 0.2 µm Aervent® Membrane – HH Fitting**



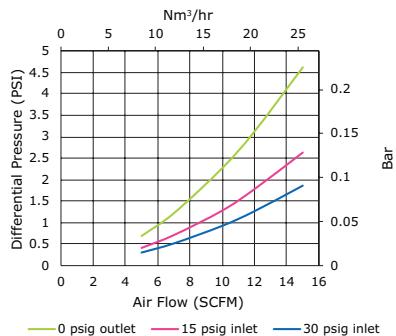
**Opticap® XL 2 Capsule with 0.2 µm Aervent® Membrane – TT Fitting**



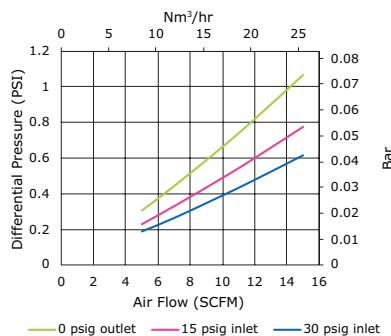
**Opticap® XL 4 Capsule with 0.2 µm Aervent® Membrane – FF Fitting**



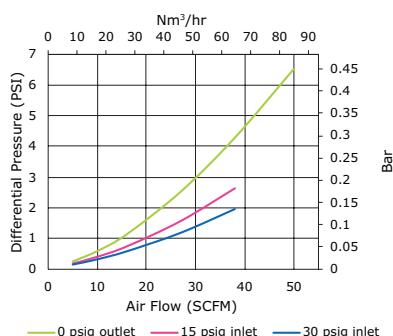
**Opticap® XL 4 Capsule with 0.2 µm Aervent® Membrane – HH Fitting**



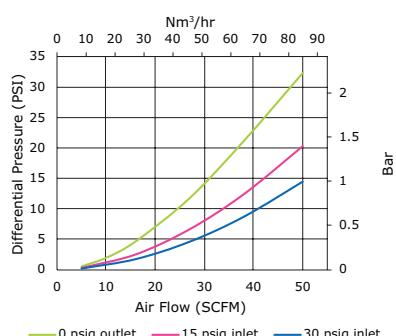
**Opticap® XL 4 Capsule with 0.2 µm Aervent® Membrane – TT Fitting**



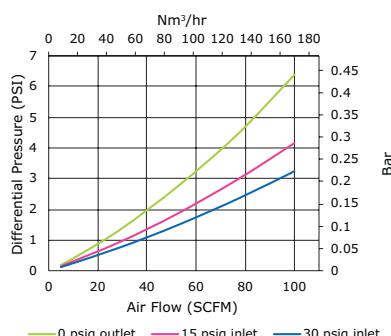
**Opticap® XL 5 Capsule with 0.2 µm Aervent® Membrane – FF Fitting**



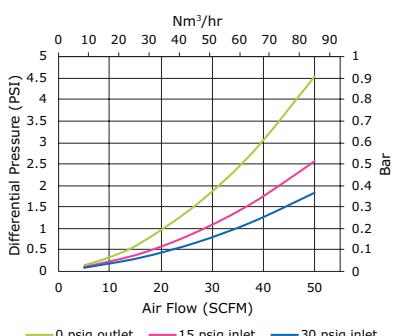
**Opticap® XL 5 Capsule with 0.2 µm Aervent® Membrane – HH Fitting**



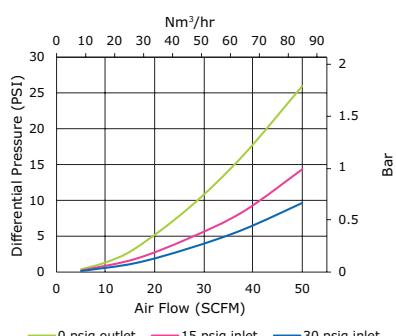
**Opticap® XL 5 Capsule with 0.2 µm Aervent® Membrane – TT Fitting**



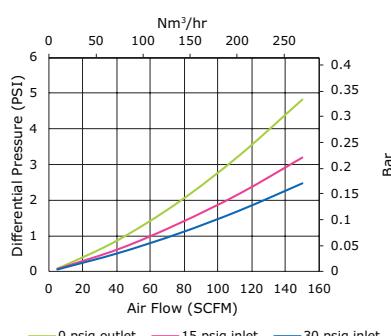
**Opticap® XL 10 Capsule with 0.2 µm Aervent® Membrane – FF Fitting**



**Opticap® XL 10 Capsule with 0.2 µm Aervent® Membrane – HH Fitting**

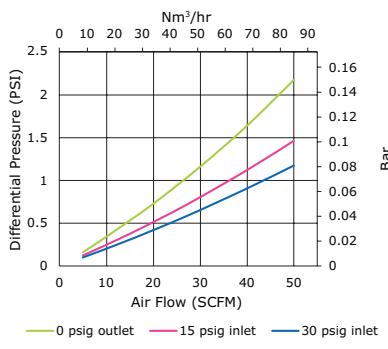


**Opticap® XL 10 Capsule with 0.2 µm Aervent® Membrane – TT Fitting**

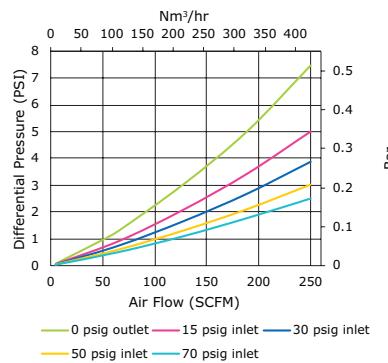


## Air Flow Rate and Pressure Drop – Cartridge Filters

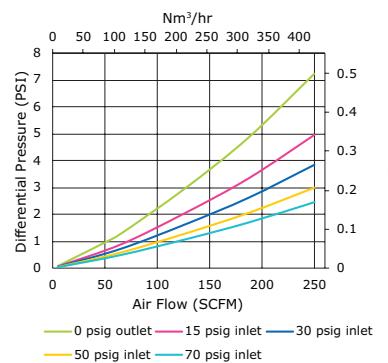
**5-inch Cartridge with 0.2 µm Aervent® Membrane – Code 7**



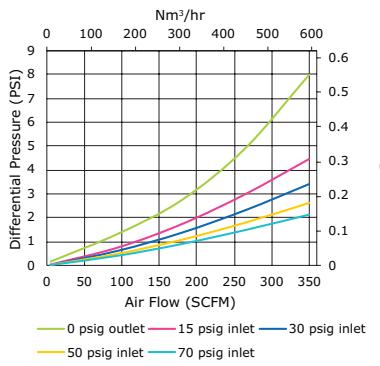
**10-inch Cartridge with 0.2 µm Aervent® Membrane – Code 0**



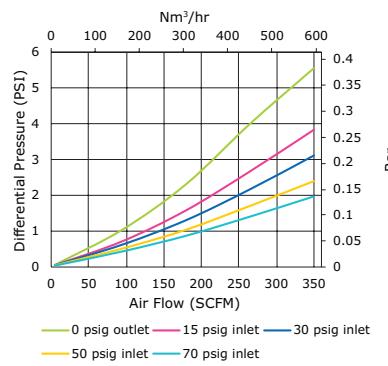
**10-inch Cartridge with 0.2 µm Aervent® Membrane – Code 7**



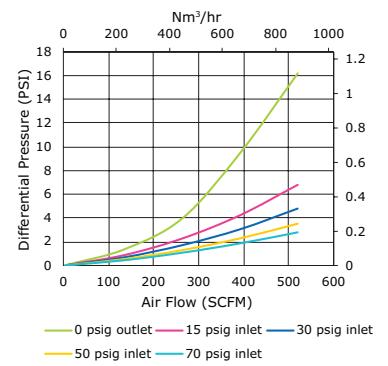
**20-inch Cartridge with 0.2 µm Aervent® Membrane – Code 0**



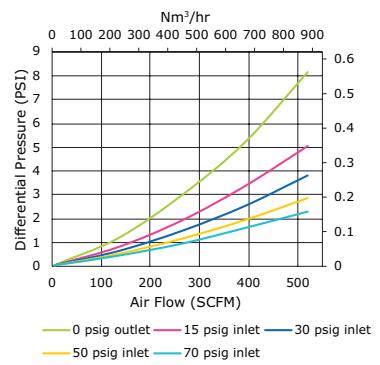
**20-inch Cartridge with 0.2 µm Aervent® Membrane – Code 7**



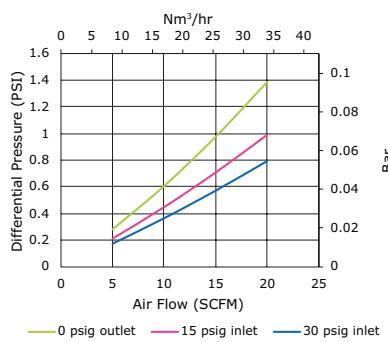
**30-inch Cartridge with 0.2 µm Aervent® Membrane – Code 0**



**30-inch Cartridge with 0.2 µm Aervent® Membrane – Code 7**

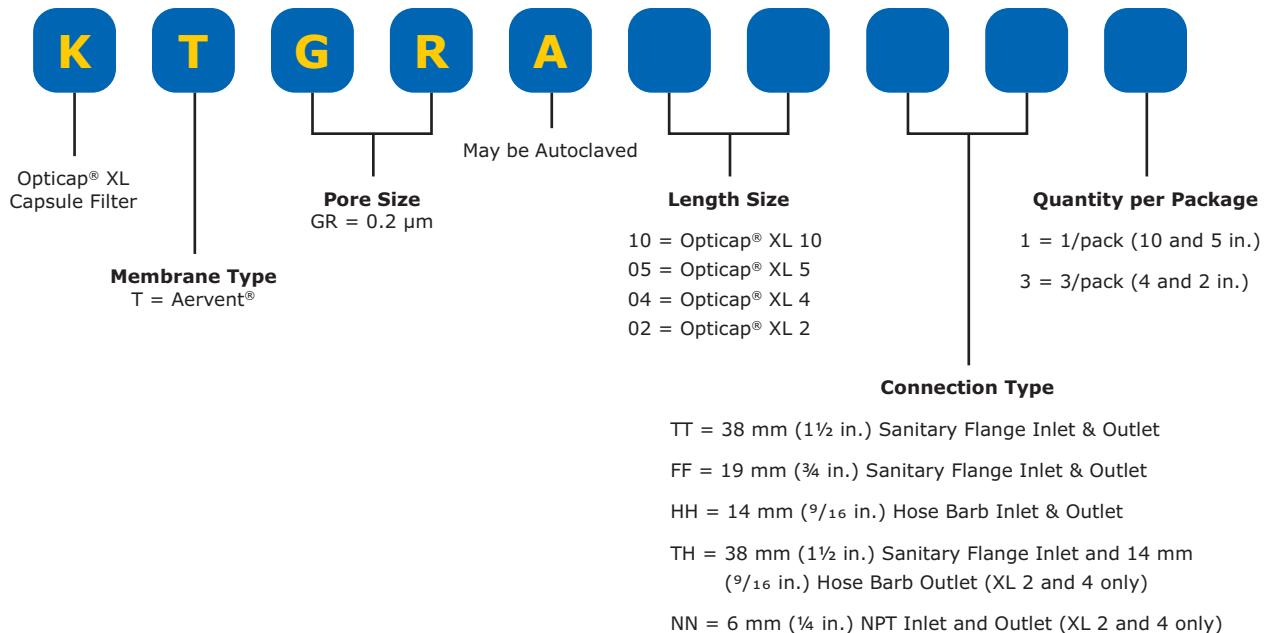


**Optiseal® Cartridge with 0.2 µm Aervent® Membrane**

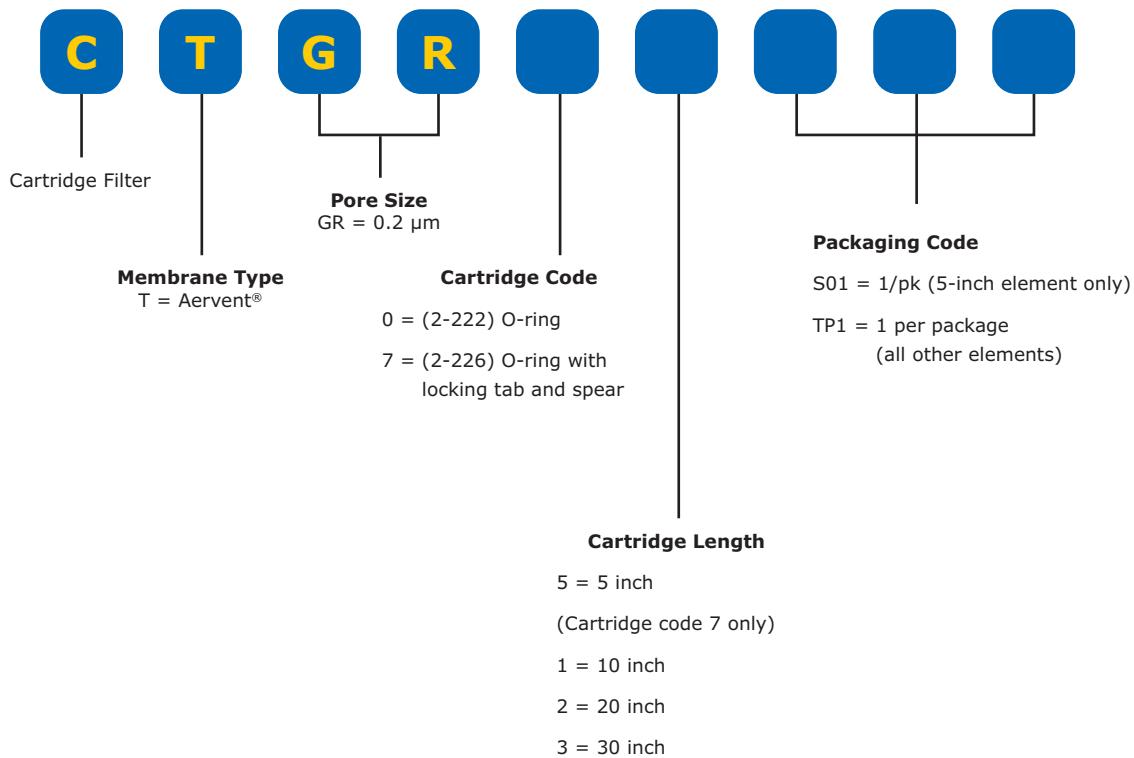


## Ordering Information

### Opticap® XL Capsule Filters



### Cartridge Filters



## Ordering Information

Description	Qty/Pk	Cat. No.
Optiseal® cartridge filter with 0.2 µm Aervent® membrane	1	<b>LAGR04TP1</b>
Optiseal® cartridge filters with 0.2 µm Aervent® membrane	6	<b>LAGR04TP6</b>
Optiseal®-M cartridge filters with 0.2 µm Aervent® membrane	2	<b>LAGRM1S02</b>
Optiseal® housing assembly	1	<b>HP01PPVNO</b>
<b>Housing Accessories</b>		
Housing bowl	1	<b>SPPS00001</b>
Housing base	1	<b>HP01PBVNO</b>
1½ TC clamp, (inlet & outlet)	1	<b>YY2004045</b>
1½ TC gasket, silicone, 10 pk	1	<b>YY2004055</b>
Bowl-to-base clamp	3-piece	<b>SPPS00003</b>
Bowl-to-base O-ring, silicone	1	<b>SPPS00004</b>
Vent/Drain valve	1	<b>SPPS00005</b>
Vent/Drain valve O-ring, silicone	1	<b>SPPS00006</b>
Vent seal plug, EPR	1	<b>P17023X2</b>
Vent seal plug, silicone	1	<b>P17023X3</b>
Vent seal plug, fluoroelastomer	1	<b>P17023X1</b>

## To Place an Order or Receive Technical Assistance

Please visit  
**EMDMillipore.com/contactPS**

For additional information, please visit  
**EMDMillipore.com**

MilliporeSigma  
 400 Summit Drive  
 Burlington, MA 01803

