

СТЕРИЛИЗУЮЩИЕ ФИЛЬТРЫ AERVENT



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Sterilizing-Grade Aervent® Filters

Premium choice for critical sterile gas filtration

Aervent® filters contain sterilizing-grade 0.2 µm Aervent® 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® 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® XL capsule, cartridge, and Optiseal® 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® membranes are available in three device formats, different filtration areas, and multiple configurations that offer end users better flexibility.

Membrane Types

- Aervent® 0.2 µm sterilizing-grade PTFE membrane

Filter Formats

- Opticap® XL disposable capsule filters
- Cartridge filters
- Optiseal® cartridge filters
- Optiseal®-M cartridge filters

Specifications

Capsule Filters	Opticap® XL 2 Capsule	Opticap® XL 4 Capsule	Opticap® XL 5 Capsule	Opticap® XL 10 Capsule
Nominal Dimensions				
Maximum length:	14.3 cm (5.6 in.)	19.6 cm (7.7 in.)	21.6 cm (8.5 in.)	33.5 cm (13.2 in.)
Body diameter:	8.4 cm (3.3 in.)	8.4 cm (3.3 in.)	10.7 cm (4.2 in.)	10.7 cm (4.2 in.)
Vent to vent diameter:	12.5 cm (4.9 in.)	12.5 cm (4.9 in.)	14.5 cm (5.7 in.)	14.5 cm (5.7 in.)
Filtration Area	0.10 m² (1.1 ft²)	0.21 m² (2.3 ft²)	0.32 m² (3.5 ft²)	0.65 m² (7.0 ft²)
Materials of Construction				
Filter media:	Hydrophobic PTFE			
Supports:	Polypropylene			
Structural components:	Polypropylene			
Vent O-rings:	Silicone			
Vent/Drain	¼ in. hose barb with double O-ring seal			
Maximum Inlet Pressure	5.5 bar (80 psi) at 23 °C			
	2.8 bar (40 psi) at 60 °C			
	1.0 bar (15 psi) at 80 °C			
Maximum Differential Pressure				
Forward	5.5 bar (80 psid) at ambient temperature, 1.0 bar (15 psid) at 80 °C			
Reverse	4.1 bar (60 psid) intermittent			
Bubble Point at 23 °C	≥ 1100 mbar (16 psig) in 70/30 IPA/water			
Air Diffusion	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
HydroCorr™ Test	At 2620 mbar (38 psig)			
	≤ 0.12 mL/min	≤ 0.25 mL/min	≤ 0.38 mL/min	≤ 0.75 mL/min
Gravimetric Extractables	After autoclaving and 24 hr soak in 70/30% IPA/water at controlled room temperature:			
	≤ 15 mg	≤ 15 mg	≤ 28 mg	≤ 45 mg
Bacterial Endotoxin	Aqueous extraction contains < 0.25 EU/mL as determined by the Limulus Amebocyte Lysate (LAL) Test.			
Bacterial Retention	Quantitative retention of 10 ⁷ CFU/cm² <i>Brevundimonas diminuta</i> ATCC® 19146 per ASTM® F838 methodology			
Sterilization	May be autoclaved for 30 cycles of 30 minutes at 135 °C.			
Non-Fiber Releasing	Aervent® membrane meets the criteria for a “non-fiber releasing” filter as defined in 21 CFR 210.3 (b) (6).			
Component Material Toxicity	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 in vitro cytotoxicity and USP <87> Biological Reactivity Tests, <i>in vitro</i> .			
European Pressure Equipment Directive				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 sound engineering practice to ensure safe use. In compliance with Article 4 § 3 of the Directive 2014/68/EU, the Opticap® XL10 capsule filter does not bear the CE mark.
Viral Aerosol Retention	Rated for aerosol retention of a total challenge of 10 ⁸ –10 ¹⁰ plaque forming units of φX-174 virus particles at 50 SCFM per 10-inch cartridge.			
Bacterial Aerosol Growth	Retains <i>B. diminuta</i> liquid aerosol for 21 days at a minimum challenge of 10 ⁷ CFU/cm².			

Specifications

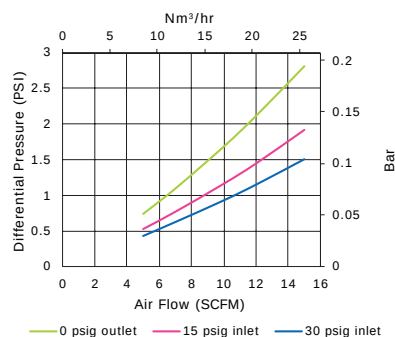
Cartridge Filters	5-inch Cartridge	10-inch Cartridge
Nominal Dimensions		
Maximum length:	12.5 cm (5 in.)	25 cm (10 in.)
Vent to vent diameter:	6.9 cm (2.7 in.)	6.9 cm (2.7 in.)
Filtration Area	0.32 m² (3.5 ft²)	0.65 m² (7.0 ft²)
Materials of Construction		
Filter media:	Hydrophobic PTFE	
Supports:	Polypropylene	
Structural components:	Polypropylene	
O-rings:	Silicone	
Vent O-rings:	Stainless Steel	
Maximum Differential Pressure		
Forward	5.5 bar (80 psid) at ambient temperature, 1.8 bar (25 psid) at 80 °C	
Reverse	4.1 bar (60 psid) intermittent	
Bubble Point at 23 °C	≥ 1100 mbar (16 psig) in 70/30 IPA/water	
Air Diffusion	Through 70/30% IPA/water wet membrane at ambient room temperature and 970 mbar (14 psig) nitrogen:	
	≤ 12 cc/min	≤ 24 cc/min
HydroCorr™ Test	At 2620 mbar (38 psig)	
	≤ 0.38 mL/min	≤ 0.75 mL/min
Gravimetric Extractables	After autoclaving and 24 hr soak in 70/30% IPA/water at controlled room temperature:	
	≤ 18 mg	≤ 35 mg
Bacterial Endotoxin	Aqueous extraction contains < 0.25 EU/mL as determined by the Limulus Amebocyte Lysate (LAL) Test.	
Bacterial Retention	Quantitative retention of 10 ⁷ CFU/cm² <i>Brevundimonas diminuta</i> ATCC® 19146 per ASTM® F838 methodology	
Sterilization	May be steam sterilized 100 times (forward) and 50 times (reverse) for 30 minutes at 145 °C.	
Non-Fiber Releasing	Aervent® membrane meets the criteria for a “non-fiber releasing” filter as defined in 21 CFR 210.3 (b) (6).	
Component Material Toxicity	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.	
Viral Aerosol Retention	Rated for aerosol retention of a total challenge of 10 ⁸ –10 ¹⁰ plaque forming units of φX–174 virus particles at 50 SCFM per 10-inch cartridge.	
Bacterial Aerosol Growth	Retains <i>B. diminuta</i> liquid aerosol for 21 days at a minimum challenge of 10 ⁷ CFU/cm².	

Specifications

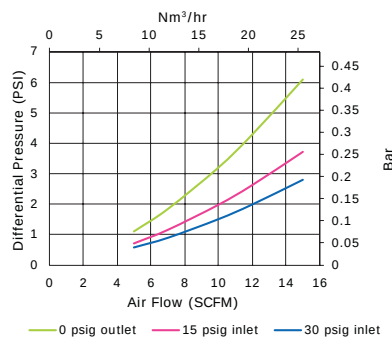
Optiseal® Cartridge Filters	Optiseal® Cartridge	Optiseal®-M Cartridge
Filtration Area	0.18 m ² (1.9 ft ²)	0.05 m ² (0.54 ft ²)
Materials of Construction		
Filter media:	PTFE membrane	
Outer sleeve, core, end caps, pleat supports:	Polypropylene	
O-rings:	Silicone	
Maximum Differential Pressure		
Forward	5.5 bar (80 psid) at ambient temperature 1.75 bar (25 psid) at 80 °C 0.35 bar (5 psid) at 135 °C	
Reverse	4.1 bar (60 psid) intermittent	
Bubble Point at 23 °C	≥ 1100 mbar (16 psig) in 70/30 IPA/water	
Air Diffusion	Through 70/30% IPA/water wet membrane at ambient room temperature and 970 mbar (14 psig) nitrogen: ≤ 6 cc/min	-
HydroCorr™ Test	At 2.6 bar (38 psig) ≤ 0.2 mL/min	≤ 0.06 mL/min
Gravimetric Extractables	After autoclaving and 24 hr soak in 70/30% IPA/water at controlled room temperature: ≤ 10 mg	≤ 10 mg
Sterilization	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
Bacterial Endotoxin	Aqueous extraction contains < 0.25 EU/mL as determined by the Limulus Amebocyte Lysate (LAL) Test.	
Bacterial Retention	Quantitative retention of 10 ⁷ CFU/cm ² <i>Brevundimonas diminuta</i> ATCC® 19146 per ASTM® F838 methodology	
Component Material Toxicity	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.	
Non-Fiber Releasing	Aervent® membrane meets the criteria for a “non-fiber releasing” filter as defined in 21 CFR 210.3 (b) (6).	
Bacterial Aerosol Growth	Retains <i>B. diminuta</i> liquid aerosol for 21 days at a minimum challenge of 10 ⁷ CFU/cm ² .	
Viral Aerosol Retention	Rated for aerosol retention of a total challenge of 10 ⁸ –10 ¹⁰ 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

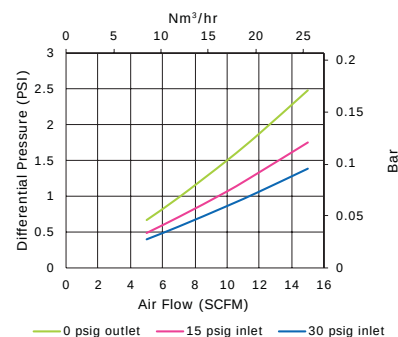
Opticap® XL 2 Capsule with 0.2 µm Aervent® Membrane – FF Fitting



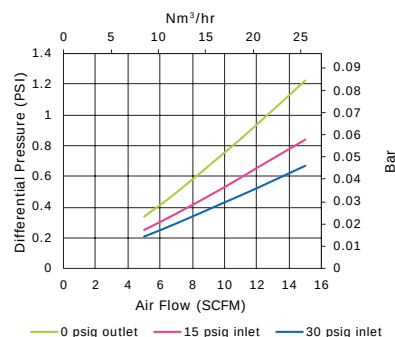
Opticap® XL 2 Capsule with 0.2 µm Aervent® Membrane – HH Fitting



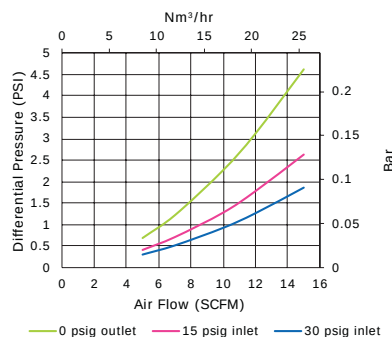
Opticap® XL 2 Capsule with 0.2 µm Aervent® Membrane – TT Fitting



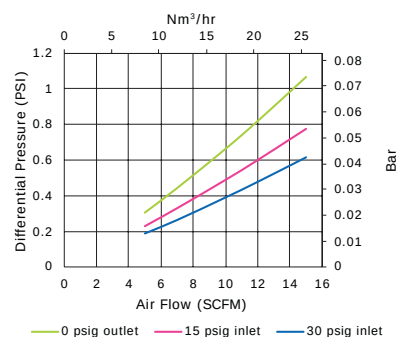
Opticap® XL 4 Capsule with 0.2 µm Aervent® Membrane – FF Fitting



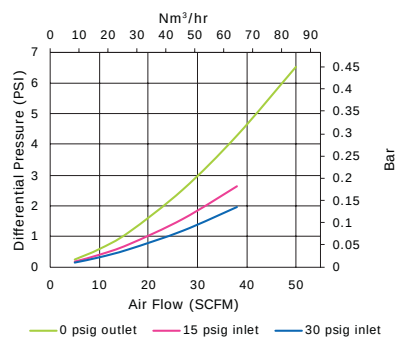
Opticap® XL 4 Capsule with 0.2 µm Aervent® Membrane – HH Fitting



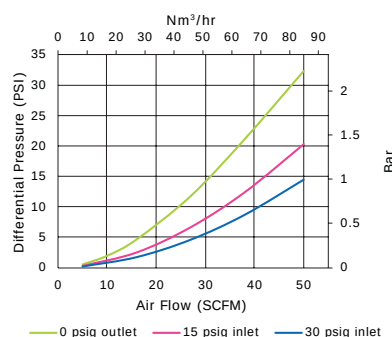
Opticap® XL 4 Capsule with 0.2 µm Aervent® Membrane – TT Fitting



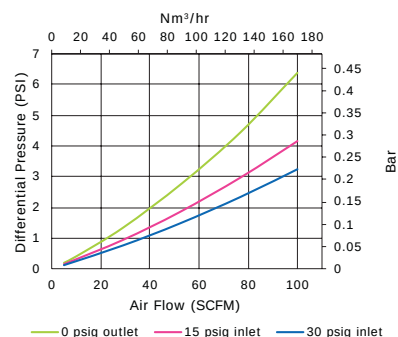
Opticap® XL 5 Capsule with 0.2 µm Aervent® Membrane – FF Fitting



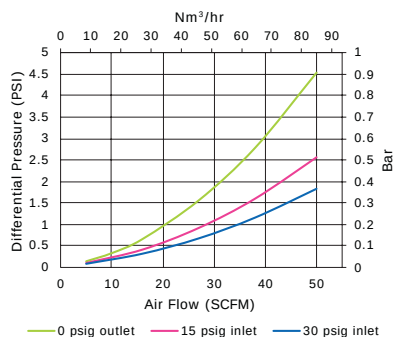
Opticap® XL 5 Capsule with 0.2 µm Aervent® Membrane – HH Fitting



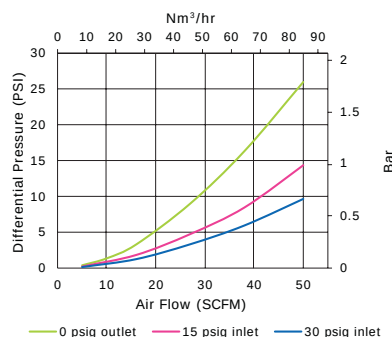
Opticap® XL 5 Capsule with 0.2 µm Aervent® Membrane – TT Fitting



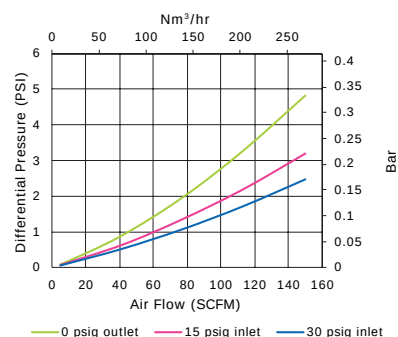
Opticap® XL 10 Capsule with 0.2 µm Aervent® Membrane – FF Fitting



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

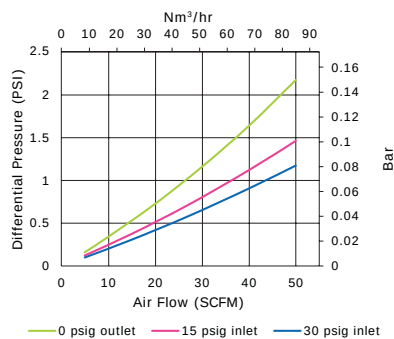


Opticap® XL 10 Capsule with 0.2 µm Aervent® Membrane – TT Fitting

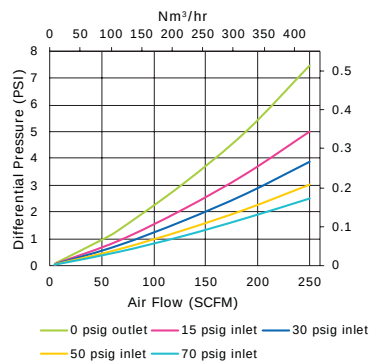


Air Flow Rate and Pressure Drop – Cartridge Filters

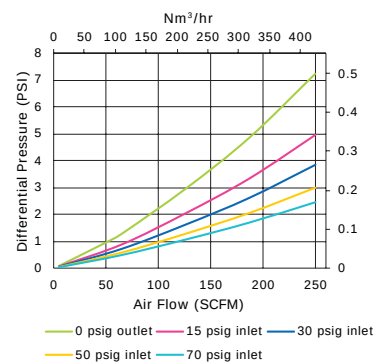
5-inch Cartridge with 0.2 μ m Aervent® Membrane – Code 7



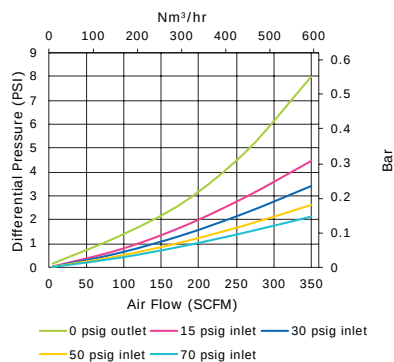
10-inch Cartridge with 0.2 μ m Aervent® Membrane – Code 0



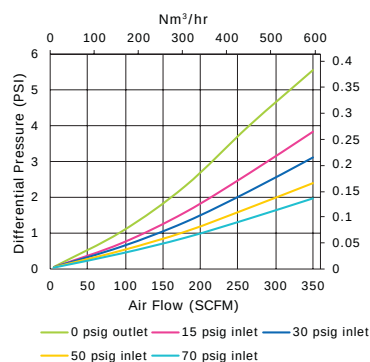
10-inch Cartridge with 0.2 μ m Aervent® Membrane – Code 7



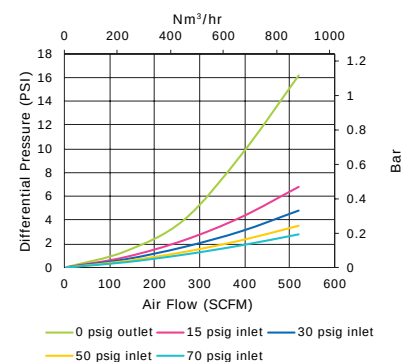
20-inch Cartridge with 0.2 μ m Aervent® Membrane – Code 0



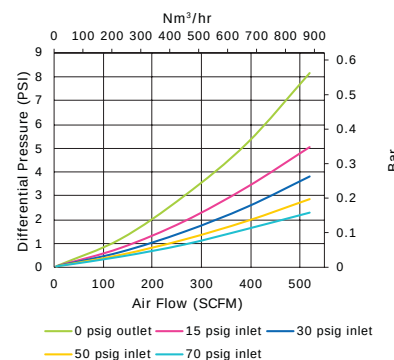
20-inch Cartridge with 0.2 μ m Aervent® Membrane – Code 7



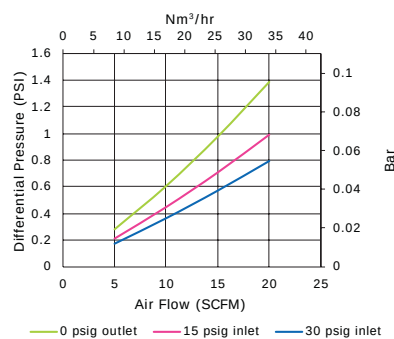
30-inch Cartridge with 0.2 μ m Aervent® Membrane – Code 0



30-inch Cartridge with 0.2 μ m Aervent® Membrane – Code 7

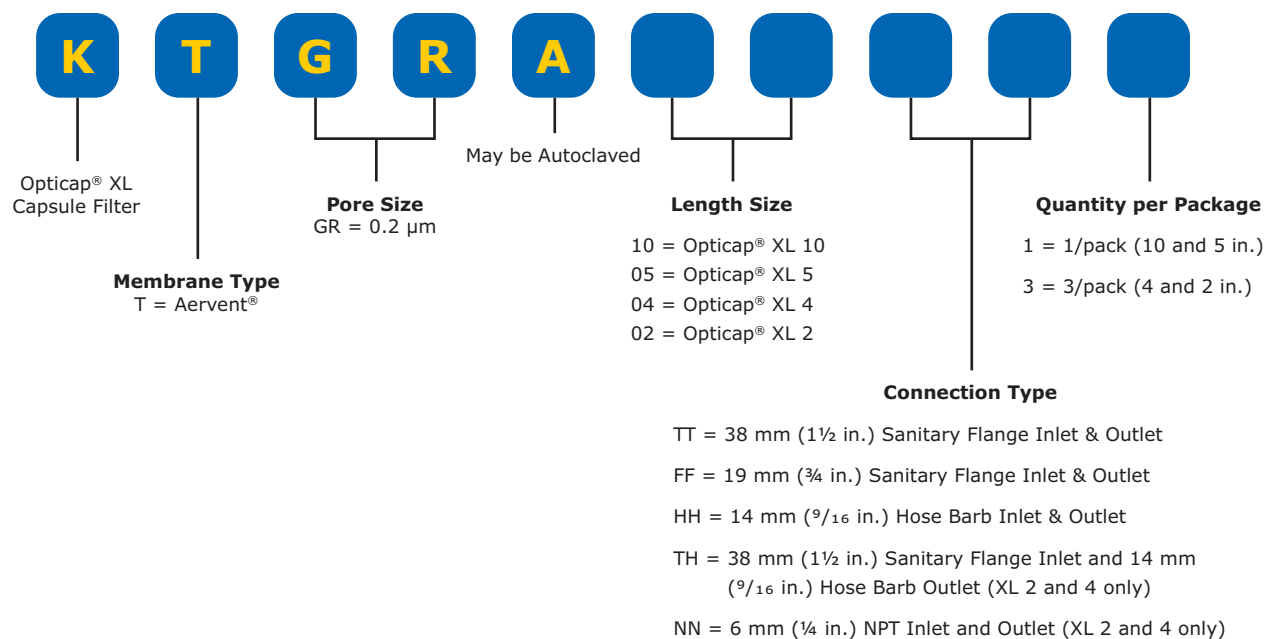


Optiseal® Cartridge with 0.2 μ m Aervent® Membrane

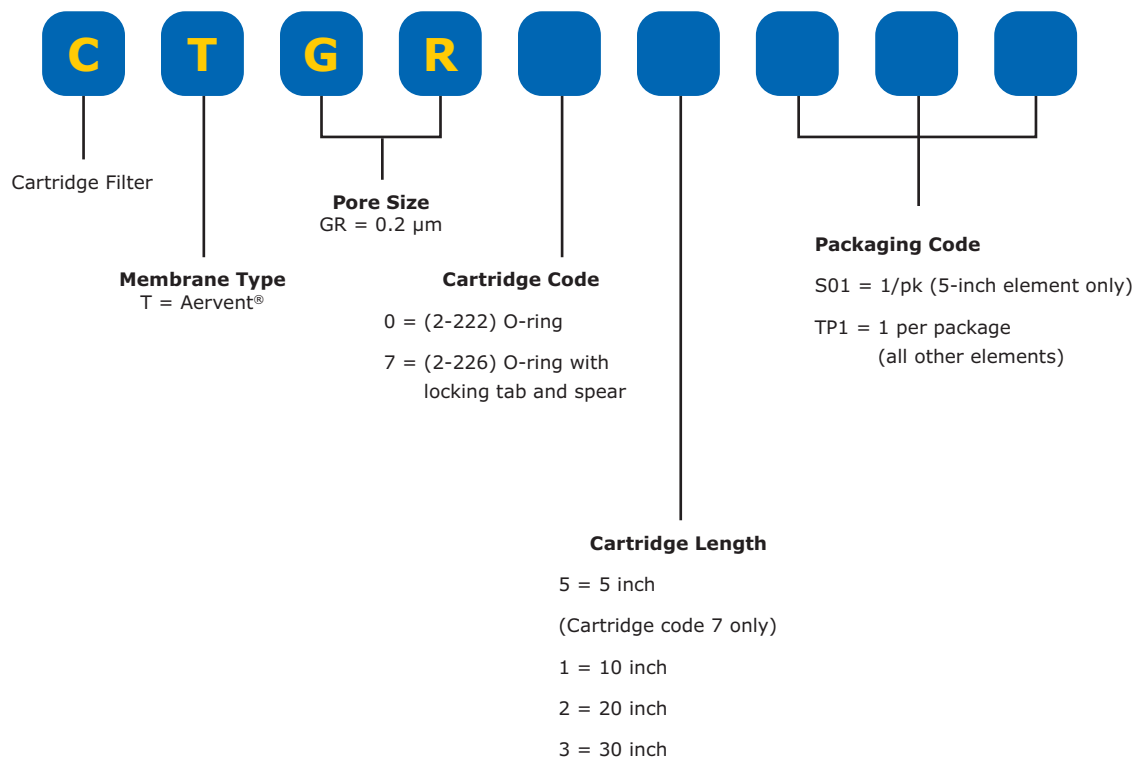


Ordering Information

Opticap® XL Capsule Filters



Cartridge Filters





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