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Durapore® 0.45 µm Hydrophilic Filters

The superior solution for extending the life of downstream sterilizing filters by removing colloidal and particulate contaminants

Hydrophilic 0.45 µm Durapore® polyvinylidene fluoride (PVDF) membrane provides low protein binding, high flow rates and high throughputs. Durapore® 0.45 µm membrane contributes to clean processes due to low extractables, broad chemical compatibility, and its non-fiber releasing properties.

Durapore® 0.45 µm hydrophilic filters remove particles and microorganisms from aqueous liquid streams. These filters are ideally suited for large volume parenteral or ophthalmics manufacturing, where prefiltration is either unnecessary or already present at an earlier point in the process, or where protein binding must be minimized.

Membrane Types

Durapore® hydrophilic

- 0.45 µm with prefilter
- 0.45 µm without prefilter

Filter Formats

- OptiScale® small scale disposable capsule filters
- Millipak® low-volume capsule filters
- Opticap® XL disposable capsule filters
- Cartridge filters

Benefits

- Low protein binding membrane yields high protein recovery with minimal loss of valuable product
- Superior membrane for filtration processes requiring high flow rates and throughputs
- Ideal for bioburden reduction before final sterilization
- Ideal for designing scalable solutions from bench top to full-scale manufacturing

Multiple Formats Available

Hydrophilic Durapore® membranes are available in four formats and multiple configurations that vary by filtration area and type of inlet/outlet connection. We have a format to meet your application needs.

Regulatory Compliance

Filters with hydrophilic Durapore® 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 and are shipped with a Certificate of Quality. Each Millipak®, Opticap® XL and cartridge filter is integrity tested during manufacturing and is supported by a Validation Guide for compliance with regulatory requirements. For traceability and easy identification, each device is marked with the product name and identifying characteristics.

OptiScale® Filters

OptiScale® Process Development Screening Tool

OptiScale® disposable capsule filters provide a convenient small-volume option for process screening and scaling. These "drop in" filters are ideal for evaluating biopharmaceuticals. OptiScale® capsule filters offer speed-to-market strategies for efficiently developing compounds and biotherapeutics.

The OptiScale® disposable capsule is ideally suited for process development and screening. OptiScale® capsules are faster and easier to set-up than conventional 25 mm and 47 mm discs.

Millipak® Filters

Millipak® Low-Volume Capsule Filters

Millipak® filters with 0.45 µm hydrophilic Durapore® membranes are uniquely designed for the removal of particles and microorganisms. The stacked disc design allows minimal hold-up volume and no particle shedding, making Millipak® units ideally suited for high value added applications. Each Millipak® filter is integrity tested during the manufacturing process.

Millipak® filters are available in two different stack sizes. Adjustable, easy-to-turn, upstream vents and drain valves with hose barb connections allow for easy process control.

Opticap® XL Disposable Capsule Filters

Opticap® XL 2, 4, 5 and 10" disposable capsule filters with 0.45 µm hydrophilic Durapore® membrane are available in multiple filtration areas, providing an optimal choice for every application. Each Opticap® XL capsule is integrity tested during the manufacturing process.

The patented Opticap® XL capsule design allows unparalleled thermal and hydraulic stress resistance in a disposable filter, resulting in reliability, high confidence in the sterilization process and improved cleanliness. The unique capsule design with pleated Durapore® membrane minimizes hold-up volume and reduces production losses.

Opticap® XL Filters

Convenient and Easy to Use

Opticap® XL capsule filters eliminate the time and the expense associated with assembling, cleaning, and validating stainless steel housings. Adjustable, easy-to-turn upstream vents and drain valves with O-ring seals and hose barb connections allow for easy process control. Other ease-of-use features include flow directional arrows and ribbed edges for easy gripping even with gloved hands.

The Right Size

A wide range of filtration areas is available to fit all of your application needs,
and allow easy scale-up of your small volume filtration steps to larger, full-scale filtration processes.

The Right Connections

Self-contained and disposable, Opticap® XL capsule filters are supplied with a choice of inlet and outlet connections to optimize your filtration process, including sanitary flanges that provide a higher flow rate, fractional sanitary flanges, and hose barbs.

Cartridge Filters

Cartridge Filters

Hydrophilic Durapore® cartridge filters provide high throughput with minimal differential pressure. Cartridges are robust, strong, resilient and are designed to withstand multiple steam-in-place cycles. Each Durapore® cartridge filter is integrity tested during the manufacturing process.

A variety of connections are offered to meet your application and housing requirements.

Specifications

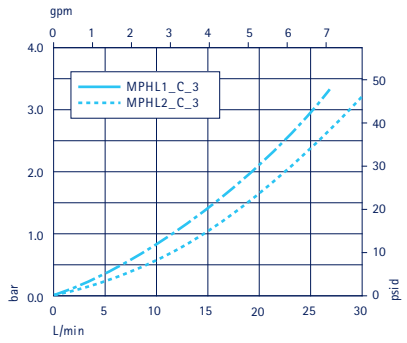
	OptiScale® 25 Capsules	OptiScale® 47 Capsules	Millipak® 100	Millipak® 200
Nominal Dimensions				
Maximum length:	39 mm (1.52 in.) with female Luer-Lok™ inlet/male luer slip outlet	82 mm (3.24 in.) with flange inlet/ hose barb outlet; 74 mm (2.91 in.) with flange inlet/ flange outlet; 94 mm (3.70 in.) with hose barb inlet/hose barb outlet	13 cm (5.1 in.)	15.5 cm (6.1 in.)
Body diameter:	31 mm (1.21 in.)	69 mm (2.75 in.)	7.6 cm (3.0 in.)	7.6 cm (3.0 in.)
Weight:	0.19 oz (5.5 g)	2.3 oz (67 g)	–	–
Filtration Area	3.5 cm^2	17.7 cm^2	500 cm^2 (0.54 ft^2)	1000 cm^2 (1.08 ft^2)
Materials of Construction				
Filter membrane:	Hydrophilic PVDF	Hydrophilic PVDF	Hydrophilic polyvinylidene fluoride (PVDF)	
Structural components:	Polycarbonate	Polycarbonate	Polycarbonate	
Supports:	Polypropylene	Polypropylene	Polycarbonate	
Vent caps:	Polypropylene	Polyvinylidene fluoride (PVDF)	Polyvinylidene fluoride (PVDF)	
Internal seal rings:	Fluoroelastomers	Fluoroelastomers	–	
Housing Vent	Capped vent with female Luer connections on inlet side of device.	Adjustable vent with male Luer slip and female Luer-Lok connections on inlet side of device.		
Maximum Inlet Pressure	4.1 bar (60 psi) at 25 °C	5.5 bar (80 psi) at 25 °C	5.2 bar (75 psi) at 25 °C	
Maximum Differential Pressure				
Forward:	4.1 bar (60 psi) at 25 °C	5.5 bar (80 psig) at 25 °C	4.1 bar (60 psid) at 25 °C,	
		–	1.7 bar (25 psid) at 80 °C,	
		–	345 mbar (5 psid) at 123 °C	
Reverse:	0 bar (0 psi)	0.7 bar (10 psig) at 25 °C	690 mbar (10 psid) at 25 °C	
Bubble Point at 23 °C			≥ 1790 mbar (26 psig) air with water	
Gravimetric Extractables	–	–	After autoclaving and a 24 hour soak in ASTM® Type 1 reagent grade water at controlled room temperature:	
			≤ 2.5 mg	≤ 5.0 mg
Oxidizable Substances	–	Meets the requirements of the USP Oxidizable Substance for Sterile Water for Filtration Test after a water flush of:		
		100 mL	200 mL	200 mL
Bacterial Endotoxin	Aqueous extraction contains <0.25 EU/mL as determined by the Limulus Amebocyte Lysate (LAL) Test after a WFI flush of 10 mL.	–	Aqueous extraction contains < 0.5 EU/mL as determined by the Limulus Amebocyte Lysate (LAL) Test.	
Sterilization	May be autoclaved for 1 cycle of 60 minutes at 123 °C	May be autoclaved for 3 cycles of 60 minutes at 123 °C.	May be autoclaved for 3 cycles of 90 minutes at 123 °C. Capable of 45 kilogray (4.5 Megarad) gamma exposure. (Cannot be steam sterilized in-line.)	
Good Manufacturing Practices	These products are manufactured in a facility which adheres to Good Manfacturing Practices.			
Non-Fiber Releasing	Durapore® membrane meets the criteria for a "non-fiber releasing" filter; defined in 21 CFR 210.3 (b) (6).			
Component Material Toxicity	Component materials were tested and meet the criteria of the USP <88> Reactivity Test for Class VI Plastics. Sterilizing-grade Durapore® Filters meet the requirements of the current USP <88> Safety Test.			
Indirect Food Additive	Durapore® membrane meets the FDA Indirect Food Additive requirements cited in 21 CFR 177.2910. All other component materials also meet the FDA Indirect Food Additive requirements cited in 21 CFR 177-182.			

Specifications (continued)

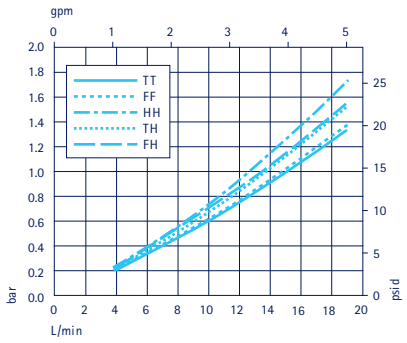
	Opticap® XL 2	Opticap® XL 4	Opticap® XL 5	Opticap® XL 10	Cartridge (per 10-inch element)
Nominal Dimensions					
Maximum length:	14.2 cm (5.6 in.)	19.6 cm (7.7 in.)	21.6 cm (8.5 in.)	33.5 cm (13.2 in.)	–
Body diameter:	8.4 cm (3.3 in.)	8.4 cm (3.3 in.)	10.7 cm (4.2 in.)	10.7 cm (4.2 in.)	6.9 cm (2.7 in.)
Filtration Area	0.09 m^2 (0.93 ft^2)	0.19 m^2 (2.09 ft^2)	0.35 m^2 (3.7 ft^2)	0.69 m^2 (7.4 ft^2)	0.69 m^2 (7.4 ft^2)
Materials of Construction					
Filter membrane:	Hydrophilic PVDF				Hydrophilic PVDF
Prefilter Media	Mixed esters of cellulose				Mixed esters of cellulose
Film edge:	–				Polypropylene
Supports:	Polypropylene				Polypropylene
Structural components:	Polypropylene				Polypropylene
Vent O-rings:	Silicone				–
O-rings:	Silicone				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 25 °C (with prefilter)				5.5 bar (80 psid) at 25 °C
	1.0 bar (15 psid) at 80 °C (with prefilter)				1.8 bar (25 psid) at 80 °C
	3.4 bar (50 psid) at 25 °C (without prefilter)				345 mbar (5 psid) at 135 °C
Reverse:	3.4 bar (50 psid) at 25 °C, intermittent				3.5 bar (50 psid) at 25 °C, intermittent
Bubble Point at 23 °C	≥ 1930 mbar (28 psig) air with water				
Air Diffusion	Through a water wet membrane at ambient temperature:				Through a water wet membrane at 23 °C at 1.5 bar (22 psi): ≤ 15 cc/mm
	–	≤ 4.5 cc/min	≤ 7.5 cc/min	≤ 15 cc/min	
Gravimetric Extractables	After autoclaving and a 24 hour soak in ASTM® Type 1 reagent grade water at controlled room temperature:				
With prefilter	–	–	–	≤ 50 mg	≤ 45 mg
Without prefilter	≤ 10 mg	≤ 10 mg	≤ 15 mg	≤ 25 mg	≤ 20 mg
Oxidizable Substances	After autoclaving and a 24 hour soak in ASTM® Type 1 reagent grade water at controlled room temperature:				
	500 mL	500 mL	500 mL	1000 mL	1000 mL
Bacterial Endotoxin	Aqueous extraction contains < 0.5 EU/mL as determined by the Limulus Amebocyte Lysate (LAL) Test.				
Sterilization					
With prefilter	May be autoclaved for 3 cycles of 60 minutes at 121 ° C. Cannot be steam sterilized in-line.				May be autoclaved for 10 cycles of 60 minutes at 121 ° C; steam sterilized for 10 cycles of 30 minutes at 121 ° C; or hot water sanitized for 30 cycles of 30 minutes at 80 °C.
Without prefilter	May be autoclaved for 3 cycles of 60 minutes at 126 ° C. Cannot be steam sterilized in-line.				May be autoclaved for 30 cycles of 60 minutes at 126 ° C; steam sterilized for 30 cycles of 30 minutes at 135 °C; or hot water sanitized for 30 cycles of 30 minutes at 80 °C.
Good Manufacturing Practices	These products are manufactured in a facility which adheres to FDA Good Manufacturing Practices.				
Non-Fiber Releasing	Durapore® membrane meets the criteria for a "non-fiber releasing" filter as defined in 21 CFR 210.3 (b) (6).				
Component Material Toxicity	Component materials were tested and meet the criteria of the USP <88> Reactivity Test for Class VI Plastics. Sterilizing-grade Durapore® Filters are non-toxic per the current USP <88> Safety Test.				
Indirect Food Additive	Durapore® membrane meets the FDA Indirect Food Additive requirements cited in 21 CFR 177.2910. All other component materials also meet the FDA Indirect Food Additive requirements cited in 21 CFR 177–182. All component materials meet the requirements of the EU framework regulation [1935/2004/EC] regarding materials and articles intended to contact food.				
European Pressure Equipment Directive	We certify certifies that this product complies with the European Pressure Equipment Directive, 97/23/EC of 29 May 1977. This product has been classified under Article 3 § 3 of the Pressure Vessel Directive. It has been designed and manufactured in accordance with sound engineering practice to ensure safe use. In compliance with Article 3 § 3 of this Pressure Equipment Directive, this product does not bear the CE mark.				

Typical Clean Water Flow Rates

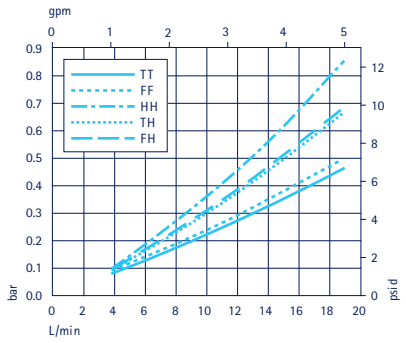
Millipak® 100/200 Filter with 0.45 µm Durapore® Membrane (MPHL)



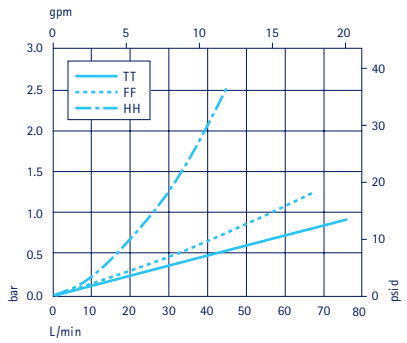
Opticap® XL 2 Capsule Filters 0.45 µm Durapore® Membrane without prefilter (KPHL)



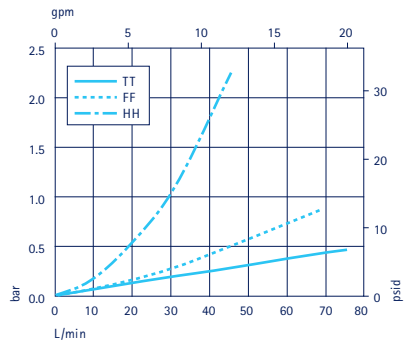
Opticap® XL 4 Capsule Filters 0.45 µm Durapore® Membrane without prefilter (KPHL)



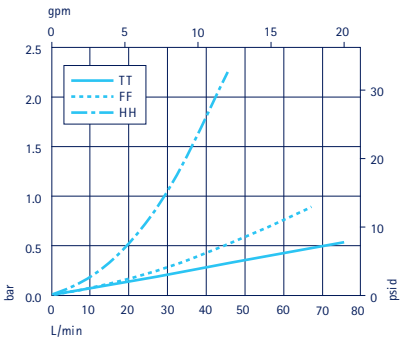
Opticap® XL 5 Capsule Filters 0.45 µm Durapore® Membrane without prefilter (KPHL)



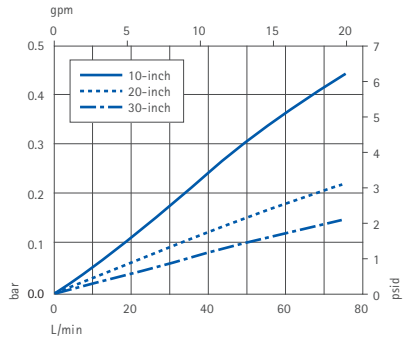
Opticap® XL 10 Capsule Filters 0.45 µm Durapore® Membrane without prefilter (KPHL)



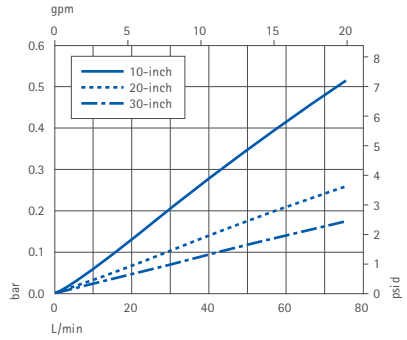
Opticap® XL 10 Capsule Filters 0.45 µm Durapore® Membrane with prefilter (KVHL)



0.45 µm Hydrophilic Durapore® Cartridge without prefilter (CVHL PP)



0.45 µm Hydrophilic Durapore® Cartridge with prefilter (CVHL TP)



Legends Refer to Capsule Connection Type

TT = 38 mm (1½ in.) Sanitary Flange Inlet and Outlet

FF = 19 mm (¾ in.) Sanitary Flange Inlet and Outlet

HH = 14 mm (9/16 in.) Hose Barb Inlet and Outlet

TH = 38 mm (1½ in.) Sanitary Flange Inlet and 14 mm (9/16 in.) Hose Barb Outlet

FH = 19 mm (¾ in.) Sanitary Flange Inlet and 14 mm (9/16 in.) Hose Barb Outlet

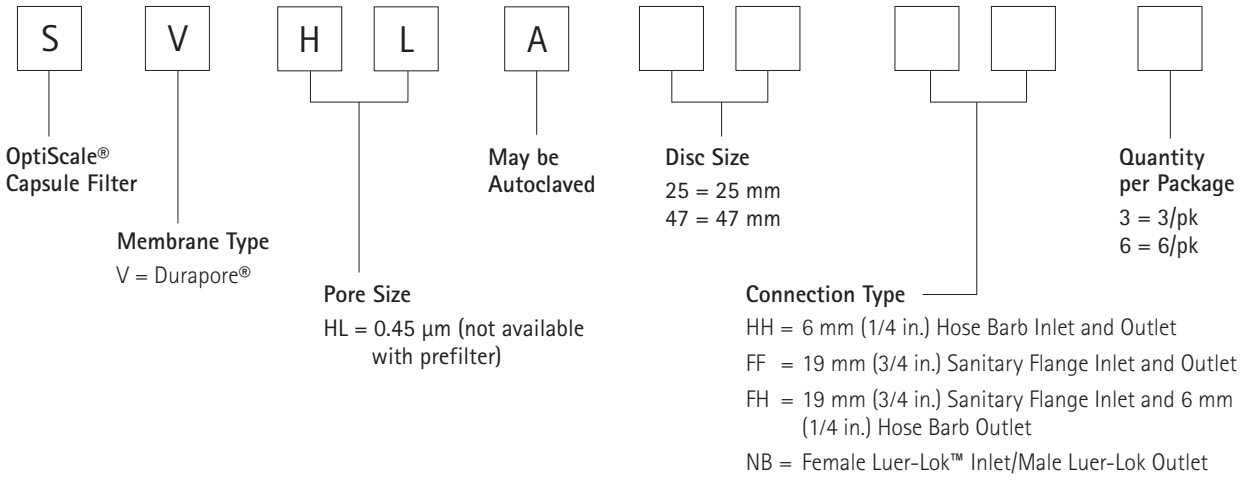
Ordering Information

Cartridge Filters

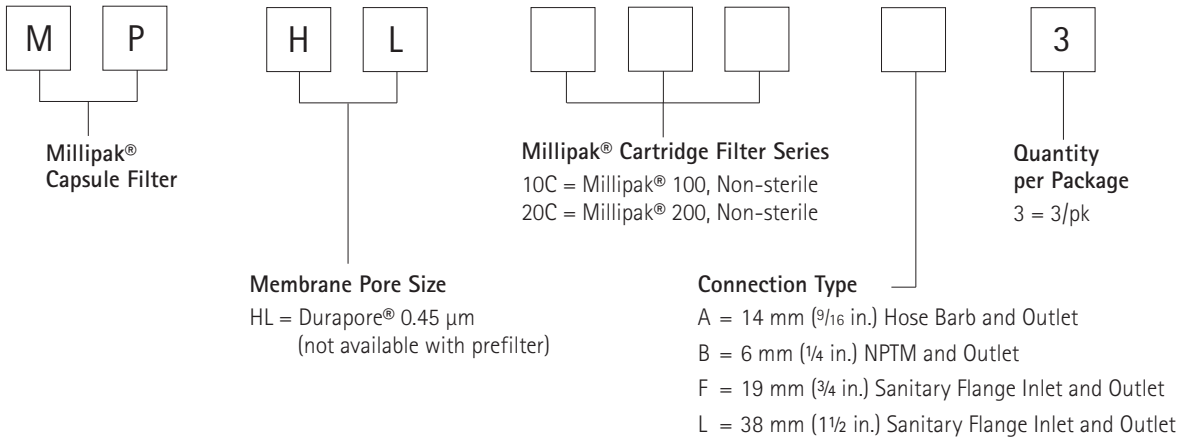
C	V	H L				
Cartridge Filter	**Membrane Type** V = Durapore®	**Pore Size** HL = 0.45 µm	**Cartridge Code** 0 = (2-222) O-ring 5 = (2-222) O-ring with spear 7 = (2-226) O-ring with locking tab and spear	**Cartridge Length** 5 = 5-inch (Code 0 and 7 only without prefilter) 1 = 10-inch 2 = 20-inch 3 = 30-inch 4 = 40-inch (Code 7 only)	TP = With prefilter PP = Without prefilter	**Quantity per Package** 1 = 1/pk (5-inch only) 3 = 3/pk

Ordering Information

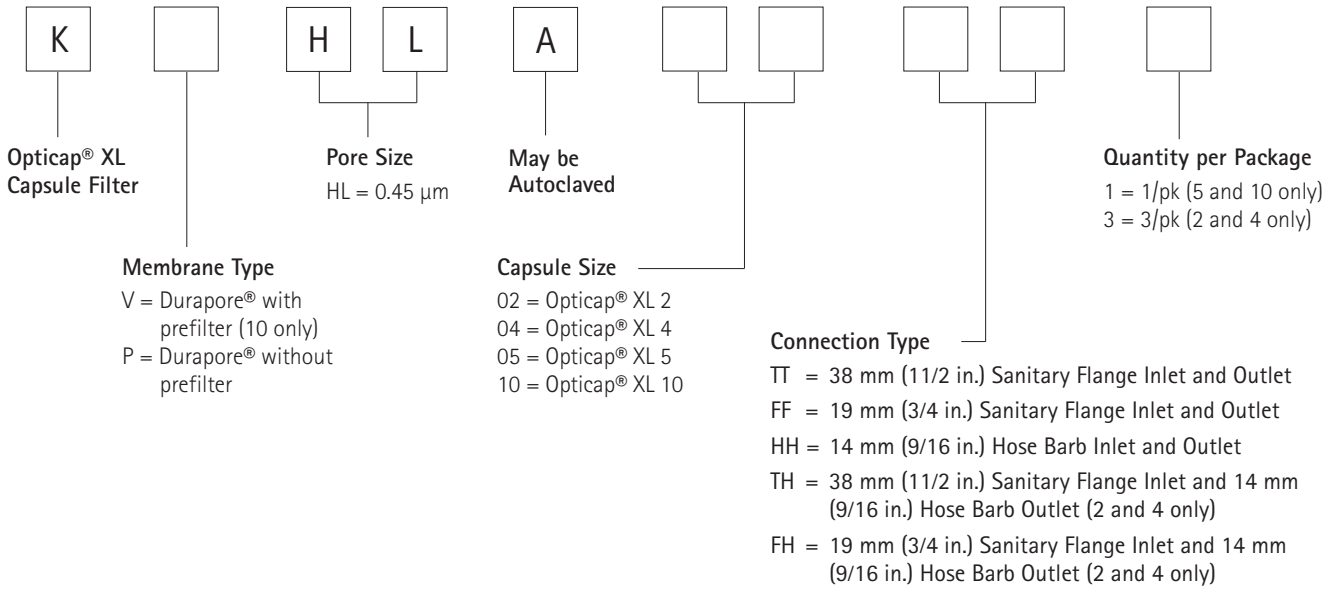
OptiScale® Capsule Filters



Millipak® Capsule Filters



Opticap® XL Capsule Filters



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