Durapore® Family Guide

MilliporeSigma is the U.S. and Canada Life Science business of Merck KGaA, Darmstadt, Germany.

Millipore®

Expert Pharm/BioPharm Products & CTDMO Services

overview

Choosing the right membrane filter is critical to the success of your process. A trusted name in the industry, Durapore® polyvinylidene fluoride (PVDF) membranes are available in multiple pore sizes and formats to meet the needs of different operations in bioprocessing including liquid sterile filtration, sterile tank and gas venting, pre-use in-line integrity testing and final sterilizing filtration.

Filters containing Durapore® membranes are low protein binding and non-fiber releasing with broad chemical compatibility and low extractables. They can be used in a wide range of applications including filtration of cell culture media and feeds, monoclonal antibodies (mAbs), vaccine, plasma and viral vector intermediates, and for different operations in ophthalmics and large and small volume parenteral production. All Durapore® sterilizing filters are 100% integrity tested during manufacturing.

Our Durapore® Membrane Family

Durapore® 0.1 µm and 0.22 µm Membrane
Sterilizing-grade membranes for cell culture media, buffers, intermediate and final filtration.

Multimedia Durapore® Membrane
Sterilizing-grade membrane with integrated Milligard® prefilter media for difficult-to-filter streams.

Durapore® CBR 0.1 µm and 0.2 µm Membrane
Bioburden reduction membranes for non-critical applications.

Durapore® 0.45 µm Membrane
Bioburden reduction and particulate removal filters. Durapore® 0.45 µm membranes are available with or without an integrated 0.5 µm Milligard® prefilter.

Charged Durapore® 0.22 µm Membrane
Charged sterilizing-grade membranes for endotoxin removal and low preservative adsorption.

Hydrophobic Durapore® 0.22 µm Membrane
Sterilizing-grade membranes for sterile tank and gas venting.

Durapore® 5.0 µm Membrane
Membranes for aggregate and particulate removal in sterile bulk applications.

Multilayer Durapore® Membrane
Sterilizing-grade double layer membranes (0.45/0.22 µm) for difficult-to-filter streams.

Hydrophobic-hydrophilic Durapore® 0.22 µm Membrane
Barrier membranes containing both hydrophobic and hydrophilic membrane for pre-use integrity testing of sterile filtration systems.

selection & applications guide

We offer a full portfolio of membrane filters to meet the needs of different bioprocess applications. The table below provides a high-level overview of key applications and our preferred filtration solutions as a starting point for development or optimization.

	mAb Process Intermediates	Plasma	Vaccines & Viral Vectors	Ophthalmics	SVPs	LVPs	Cell Culture Media/Serum	Buffers	Final Filtration	Gas	Colloids	Lipid Removal
Particle Removal and Sterile Filter Protection												
Milligard® PES Filters	●	●	●	●	●	●	●	●			●	
Milligard® Filters	●	●	●		●		●				●	
Polysep™ II Filters	●	●	●				●				●	●
Lifegard™ Filters		●					●				●	●
Bioburden Reduction												
Milligard® PES Filters	●	●	●		●	●		●				
Durapore® 0.45 Filters		●	●		●	●						
Sterile Filtration												
Millipore Express® SHC Filters	●	●	●		●	●	●				●	●
Millipore Express® SHF Filters			●	●	●	●		●	●			
Millipore Express® PHF Filters	●	●				●		●				
Durapore® 0.22 µm Filters		●	●	●	●	●			●			
Durapore® Multilayer Filters			●								●	●
Aervent® Filters										●		
Aerex® Filters										●		
Millipore Express® SPG Filters										●		
Mycoplasma Removal and Sterile Filtration												
Millipore Express® SHR Filters							●					

The Emprove® Program

Your fast track through regulatory challenges

Complementing our product portfolio, the Emprove® Program provides three types of dossiers to support different stages of development and manufacturing operations such as qualification, risk assessment and process optimization. The dossiers consolidate comprehensive product-specific testing data, quality statements and regulatory information in a readily-available format to simplify your compliance needs.

For more information, please visit:

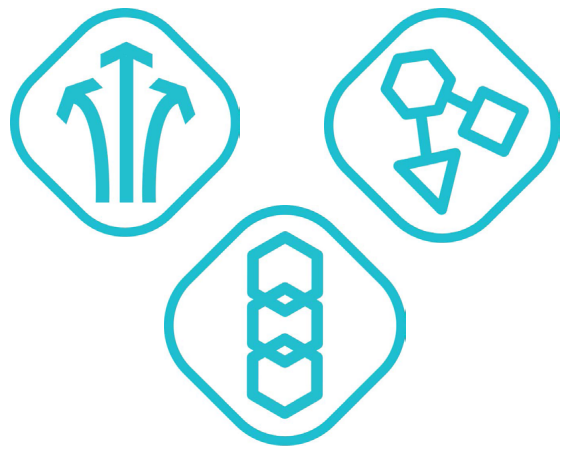
EMDMillipore.com/Emprove

or SigmaAldrich.com/Emprove

Mobius® Single-Use Solutions

Durapore® filters are part of the Mobius® component library.

Whether you are looking to introduce single-use manufacturing components into your current process or investigating how you can implement a single-use process train, Mobius® products and solutions help meet your evolving process needs.



For more information, please visit:

EMDMillipore.com/singleuse-myway

formats

Multiple formats offer flexibility and scalable solutions for both single-use and stainless steel operations.

	Format Size	Durapore® 0.1 µm & 0.22 µm	Charged Durapore® 0.22 µm	Durapore® Multilayer 0.45/0.22 µm	Durapore® Multimedia	Durapore® 0.45 µm	Durapore® CBR 0.1 µm/ 0.22 µm	Durapore® 5.0 µm	Hydrophobic Durapore® 0.22 µm	Hydrophobic Hydrophilic Durapore® 0.22 µm
Single-use Capsule Filters (small to large scale)										
OptiScale® Capsules	25, 47	A		A	A	A				
Opticap® XL Capsules	2	A				A				
	4	G, S, A				A				
	5	A				A			A	
	10	G, S, A		G, S, A	A	G, S, A			A	
Opticap® XLT Capsules	10, 20, 30	G, S, A		G, S, A		G, S				
Cartridge Filters for Stainless Steel Operations (small to large scale)										
Millidisk® Cartridges	10, 20, 30, 40	A				A		A		
Optiseal® Cartridges	4	A	A							
Cartridges	5	A				A				
	10, 20, 30	A*	A	A	A	A	A			A
	40	A								
Filters for Final Filtration										
Millipak® Barrier Capsules	200									G
Millidisk® Barrier Cartridges	40									A
Millipak® Final Fill Capsules	20	G, S				G, S			G, S	
	40	G, S				G, S				
	60	G, S				G, S		G, S	G, S	
	100	G ,S				G, S				
	200	G, S				G, S		G, S	G, S	

G = GAMMA-COMPATIBLE (CAPSULES): Product is gamma-compatible and can be autoclaved
A = AUTOCLAVABLE: Product can be autoclaved
S = STERILE (CAPSULES): Product has been pre-sterilized by gamma irradiation
* 10 inch cartridges also available in high area formats.

Quality Documentation

Filters with Durapore® membranes 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 Durapore® filter is supplied with a Certificate of Quality.

Each cartridge filter, Millipak® Final Fill, Opticap® XL and Opticap® XLT capsule filter is integrity tested during manufacturing and is supported with an Emprove® Material Qualification Dossier or Validation Guide. For traceability and easy identification, each device is marked with the product name and identifying characteristics.

Emprove® Program

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OptiScale® Capsules

For Screening and Scaling

Our OptiScale® disposable capsule filters provide a convenient small-volume option for process development screening and scaling. They are ideal for quickly evaluating performance of different filters with various process streams.

OptiScale® Capsules

Cartridge Filters

For Pilot and Production Scale Processing

Cartridge Filters

Our cartridge filters are designed for pilot and production scale processing in stainless steel housings. These filters provide minimal differential pressure with high flow rates and throughput and are designed to withstand multiple steam-in-place cycles. A full range of filtration areas and connection options are available for maximum flexibility.

Cartridge Filters

Durapore 0.1 µm or 0.22 µm high area cartridge filters contain more membrane compared to standard cartridge filters. These filters are designed to maximize filtration area while minimizing filter footprint.

Optiseal™ Cartridge Filters

Optiseal® cartridge filters are designed for small-volume processing and feature a robust cartridge-to-housing sealing mechanism for use in stainless steel housings under rigorous processing conditions. The cartridges contain membrane in a pleated configuration, resulting in efficient and economical particle removal while providing high flow rates and throughput.

Optiseal® Cartridge Filters

Millidisk® Cartridge Filters

Millidisk® Cartridge filters are designed for small-volume processing in stainless steel housings. These filters contain Durapore® membrane in a stacked disc format to minimize hold-up volume.

Millidisk® Cartridge Filters

Capsule Filters

For Pilot and Production Scale Processing

Opticap® XL and XLT Capsules

Opticap® XL single-use capsule filters are designed for pilot and production scale processing, are available with a range of inlet/outlet connections and are offered in autoclavable, sterile and gamma-compatible formats.

These capsules minimize cleaning, assembly and validation requirements which translates to increased flexibility, more rapid turnaround and less downtime than maintaining stainless steel operations.

Opticap® XLT single-use capsule filters are available with or without a pressure gauge port. The T-line design accommodates series or parallel filtration, and a specially-designed stand enables quick and easy integration into your existing operations.

Opticap® XL Capsules

Opticap® XLT Capsules

Filters for Final Filtration

Millipak® Final Fill Capsules

For Maximum Product Yield in High Value, Small-Volume Processing

Millipak® Final Fill capsule filters are designed for reliable filtration of small-volume, high value solutions. In final filling, it is critical to maximize product recovery and maintain sterility. The filter's stacked disc design minimizes hold-up volume over standard pleated devices, increasing product recovery.

These user-friendly filters feature a multi-purpose port that simplifies venting, integrity testing and sampling, and is validated to maintain an aseptic flow path even after multiple actuations.

Millipak® Final Fill filters contain the proven and trusted Durapore® membrane in multiple pore sizes offering flexibility for your specific process needs.

Benefits

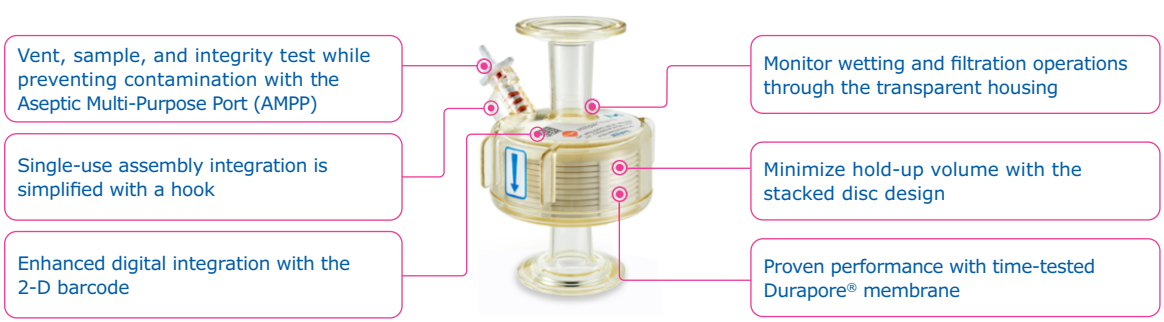
- Maximizes product recovery in final and high value filtration
- Simplifies operation and reduces risk of microbial and particulate contamination
- Contains Durapore® membrane for high flow rates, low binding and extractables, and broad chemical compatibility
- Improves integration into single-use assemblies

Membrane Pore Sizes

Available with particulate removal, bioburden reduction and sterilizing-grade Durapore® polyvinylidene fluoride (PVDF) membranes for both liquid and solvent applications.

- Hydrophilic Durapore® membrane: 0.1 µm, 0.22 µm, 0.45 µm, 5.0 µm
- Hydrophobic Durapore® membrane: 0.22 µm

Millipak® Final Fill Filters Design Features



Millipak® Final Fill Capsules

Maximize Product Recovery

In applications like final filtration where maximizing product recovery is critical, the low hold-up volume of Millipak® Final Fill filters translates to more vials filled, as compared to traditional pleated filters. Millipak® Final Fill filters incorporate Durapore® membrane bonded to solid discs instead of the support material in pleated filters, resulting in lower hold-up volume and reduced risk of particulates, Figure 1. Consistent, high product recoveries are achieved across filtration areas from 100-1000 cm^2. Millipak® Final Fill filters maximize your product recovery, increasing the efficiency of this critical process step, Figure 2.

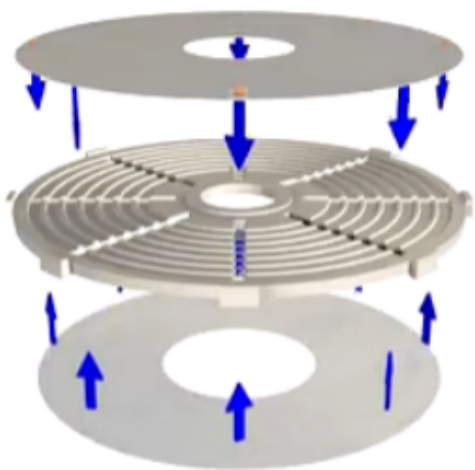


Figure 1

Membrane is bonded to solid discs instead of support material used in pleated filters, resulting in lower hold-up volume and reduced risk of particulates.

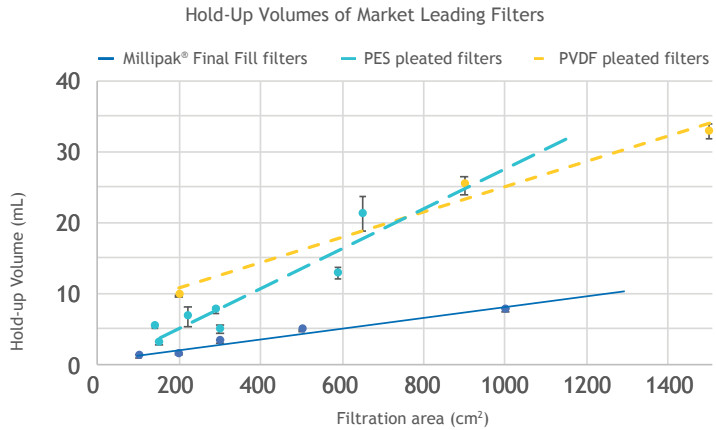


Figure 2

Hold-up volume of Millipak® Final Fill filters as compared to pleated polyethersulfone (PES) or polyvinylidene fluoride (PVDF) filters of different areas. Values represent the mean and standard deviation from replicate tests.

Millipak® Final Fill Capsules

Robust Protection Combined with Ease of Use

The Aseptic Multi-Purpose Port (AMPP) has been designed for ergonomic use with gloves, and visible 'open' and 'closed' locking positions, Figure 3. It contains three O-rings – the lower O-ring seals the flow path when the AMPP is closed, and two upper O-rings maintain an aseptic area that prevents cross-contamination between the environment and flow path. This sterile boundary is maintained after heavy microbial challenge and multiple actuations keeping your process safe from contaminant exposure. This is critical in final fill, and also for sterility assurance in redundant filtration trains where the flow path downstream of the redundant filter must not be compromised.

Filter venting, integrity testing and sampling can all be performed through the single AMPP, lowering the risks associated with multiple filter connection points and streamlining process design.

Scalable

Multiple filter sizes enable easy scale up and sizing. All Millipak® Final Fill filter capsules are available as non-sterilized (gamma irradiation and autoclave compatible) or sterilized by gamma irradiation.

Size Format / Durapore® Membrane	20 (100 cm²)	40 (200 cm²)	60 (300 cm²)	100 (500 cm²)	200 (1000 cm²)
0.1 µm	√	√	√	√	√
0.22 µm	√	√	√	√	√
0.45 µm	√	√	√	√	√
5.0 µm			√		√
0.22 µm phobic	√		√		√

Figure 3

Aseptic Multi-Purpose Port (AMPP).

Mobius® Single-use Solutions

Millipak® Final Fill filters are part of the Mobius® library. This provides you with the flexibility to design single-use assemblies that meet your specific processing requirements.

For more information, please visit: EMDMillipore.com/Singleuse-MyWay

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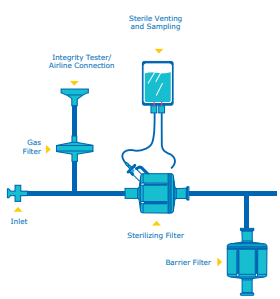
Filters for Final Filtration

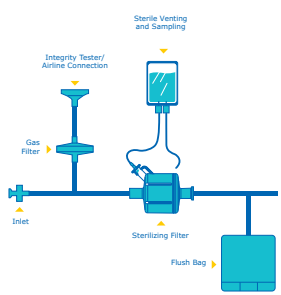
Millidisk® Barrier Cartridge and Millipak® Barrier Capsule Filters

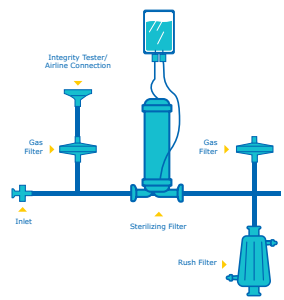
For Pre-Use Post-Sterilization Integrity Testing

Milllipak® Barrier capsules and Millidisk® Barrier cartridge filters simplify in-line pre-use, post-sterilization integrity testing (PUPSIT) of single or redundant liquid filtration systems.

The filters contain separate layers of hydrophobic and hydrophilic 0.22 µm Durapore® sterilizing-grade membranes in a stacked disk design allowing the sterile flow of liquid and gas. These permeable sterile barrier filters simplify wetting, flushing and integrity testing of upstream sterile filters in filtration assemblies while maintaining the system sterility and removing the constraint of a flush bag or can.







	Barrier Filter	Flush Bag	Downstream Filter
Ability to Retest	✔	✘	✔
Ability to Dry the Product Filter	✔	✘	✔
Simple Design	✔	✔	✘

Filters Containing Durapore® 0.1 µm and 0.22 µm Membrane

For sterile filtration of liquids

Filters containing hydrophilic, Durapore® polyvinylidene fluoride (PVDF) membranes can be used for applications requiring the highest degree of sterility assurance. Durapore® 0.1 µm membrane filters can be used for filtration of cell culture media and feeds.

Filters containing Durapore® 0.22 µm membrane are suitable for sterile filtration of liquids.

Benefits

- Protects processes from microbial contamination
- Low protein binding membrane yields high protein recovery with minimal product loss
- Broad chemical compatibility, low extractables
- For filtration processes requiring high flow rates and throughputs

Filter Formats

- OptiScale® capsules
- Cartridge filters: standard and high area formats
- Optiseal® cartridges
- Millidisk® cartridges
- Opticap® XL and XLT capsules
- Millipak® Final Fill capsules

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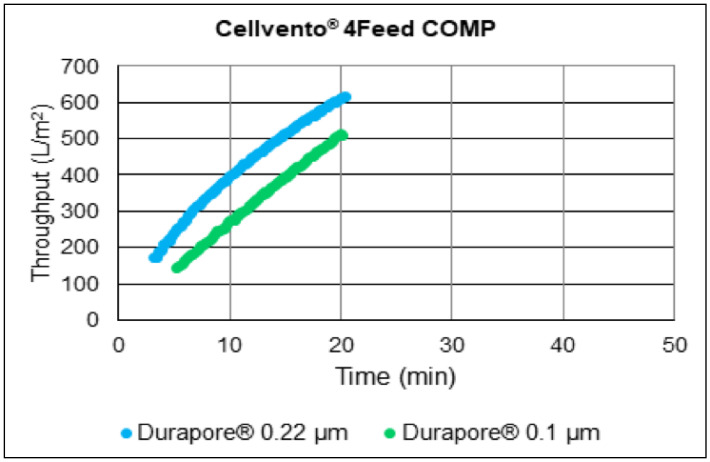
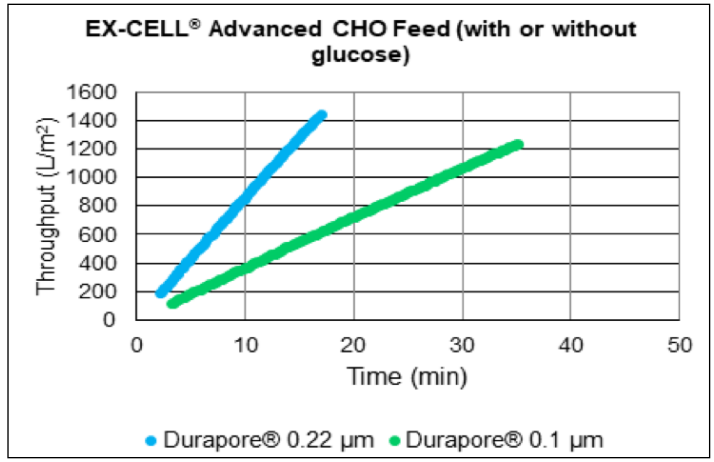
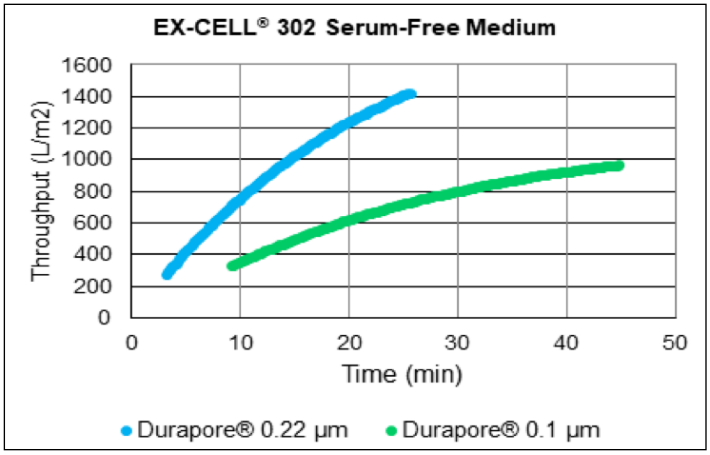
Filters Containing Durapore® 0.1 µm and 0.22 µm Membrane

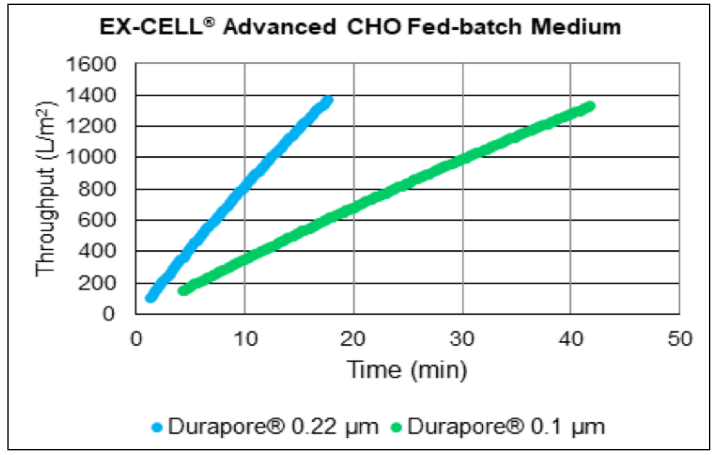
Performance of filters containing Durapore® 0.1 µm and 0.22 µm sterilizing-grade membrane with a panel of cell culture media: figures show throughput over time for the panel of media.

The filters have different microbial retention characteristics determined by membrane pore size. Filter selection is generally guided by retention requirements for the process step, throughput performance in the process fluid, and compatibility of the process fluid with the filter.









Filters Containing Durapore® 0.1 µm and 0.22 µm Membrane

OptiScale® Capsule Filter Specifications

Description	OptiScale® 25	OptiScale® 47
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
Body Diameter:	31 mm (1.21 in.)	70 mm (2.75 in.)
Weight:	0.19 oz (5.5 g)	2.4 oz (69 g)
Filtration Area	3.5 cm^2	17.7 cm^2
Materials of Construction		
Filter membrane:	Hydrophilic PVDF	Hydrophilic PVDF
Structural components:	Polypropylene	Polycarbonate
Supports:	Polypropylene	Polypropylene
Vent cap:	Polypropylene	PVDF
Internal seal rings:	—	Fluoroelastomers
Housing Vent	Capped vent with female Luer connections on inlet side of device.	Adjustable vent with male luer 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
Maximum Differential Pressure		
Forward:	4.1 bar (60 psi) at 25 °C	5.6 bar (80 psi) at 25 °C
Reverse:	0 psi at 25 °C	0.7 psi at 25 °C
Oxidizable Substances	—	Meets the USP Oxidizable Substances Test requirements for sterile purified water after a water flush of 100 mL
Bacterial Endotoxin	Aqueous extraction contains <0.25 EU/mL as determined by the Limulus Amebocyte Lysate (LAL) Test. This meets the requirements of USP <85>.	—
Total Organic Carbon (TOC) / Conductivity	Filter effluent meets the WFI requirement of USP <643>, for Total Organic Carbon and USP <645> for Water Conductivity at 25 ºC after a WFI flush of 15 mL.	—
Sterilization	May be autoclaved for 1 cycle of 60 minutes at 123 °C.	May be autoclaved for 3 cycles of 60 minutes at 126 °C.
Non-Fiber Releasing	Durapore® membrane meets the criteria for a “non-fiber releasing” filter; defined in 21 CFR 210.3 (b) (6).	
Toxicity	Component materials meet the criteria of the USP <88> Biological Reactivity Test for Class VI Plastics.	
Indirect Food Additive	All component materials meet the FDA Indirect Food Additive requirements cited in 21 CFR 177-182 based on information provided by raw material suppliers.	

Filters Containing Durapore® 0.1 µm and 0.22 µm Membrane

Cartridge Filter Specifications

Description	5-inch cartridge	Per standard 10-inch cartridge	Per high area 10-inch cartridge
Nominal Dimensions			
Outer diameter	6.9 cm (2.7 in.)	6.9 cm (2.7 in.)	6.9 cm (2.7 in.)
Filtration area	0.35 m2 (3.7 ft²)	0.69 m2 (7.4 ft²)	1.1 m² (11.5 ft²)
Materials of Construction			
Filter membrane:	Hydrophilic polyvinylidene fluoride (PVDF)		
Film edge:	Polypropylene		
Supports:	Polypropylene		
Structural components:	Polypropylene		
O-rings:	Silicone		
Maximum Differential Pressure			
Forward:	5.5 bar (80 psid) at 25 °C		5.5 bar (80 psid) at 25 °C
	1.7 bar (25 psid) at 80 °C		1.7 bar (25 psid) at 80 °C
	0.35 bar (5 psid) at 135 °C		0.35 bar (5 psid) at 135 °C
Reverse:	3.4 bar (50 psid) at 25 °C, intermittent		3.4 bar (50 psid) at 25 °C, intermittent
Bubble Point at 23° C			
0.1 µm:	≥ 4830 mbar (70.0 psig) air with water		≥ 4830 mbar (70.0 psig) air with water
0.22 µm:	≥ 3450 mbar (50.0 psig) air with water		≥ 3450 mbar (50.0 psig) air with water
Air Diffusion	Through a water wet membrane at ambient temperature:		
0.1 µm at 3.9 bar (56 psig):	≤ 10.0 cc/min	≤ 20.0 cc/min	≤ 31.0 cc/min
0.22 µm of 2.8 bar (40 psig):	≤ 6.6 cc/min	≤ 13.3 cc/min	≤ 20.6 cc/min
Bacterial Endotoxins	Aqueous extraction contains < 0.5 EU/mL as determined by the Limulus Amebocyte Lysate (LAL) Test. This meets the requirements of USP <85>.		
Bacterial Retention	Quantitative retention of 10^7 CFU/cm² *Brevundimonas diminuta* ATCC® 19146 per ASTM® methodology.		
Sterilization			
Autoclave:	126 °C, 60 minutes up to 30 times		126 °C, 60 minutes up to 30 times
Steam-in-place:	135 °C, 30 minutes, up to 30 times		135 °C, 30 minutes, up to 30 times
Toxicity	Component materials meet the requirements of the current USP <88> Biological Reactivity Tests for Class VI Plastics.		
Oxidizable Substances	-	-	Meets the requirements of the USP Oxidizable Substances Test after a water flush of 1500 mL.
NVR Gravimetric Extractables	-	-	≤ 30 mg
Total Organic Carbon (TOC)	Autoclaved filter effluent meets the WFI requirement of USP <643>, for Total Organic Carbon and USP <645> for Water Conductivity at 25 °C after a WFI flush of:		-
0.1 µm	3.5 L per 10-inch cartridge		-
0.22 µm	5.5 L per 10-inch cartridge		-
Non-Fiber Releasing	Durapore® membrane meets the criteria for a “non-fiber releasing” filter as defined in 21 CFR 210.3 (b) (6).		
Indirect Food Additive	All component materials meet the FDA Indirect Food Additive Requirements cited in 21 CFR 177-182 based on information provided by raw material suppliers.		

Filters Containing Durapore® 0.1 µm and 0.22 µm Membrane

Optiseal® Cartridge Filter Specifications

Description	Optiseal®
Materials of Construction	
Filter membrane:	Hydrophilic PVDF
Structural components:	Polypropylene
O-rings:	Silicone
Connections	Optiseal® cartridges incorporate a unique double 2-123 (silicone) O-ring seal and are used with Optiseal® stainless steel housings.
Pore Sizes	0.1 µm or 0.22 µm
Filtration Area	0.18 m^2 (1.9 ft^2)
Maximum Differential Pressure	
Forward:	5.5 bar (80 psid) at 25 °C, 3.5 bar (50 psid) at 80 °C, 0.35 bar (5 psid) at 135 °C
Reverse:	3.5 bar (50 psid) at 25 °C
Gravimetric Extractables	The extractables level was equal to or less than 10 mg per cartridge after 24 hours in ASTM® Type 1 reagent-grade water at controlled room temperature
Oxidizable Substances	Meets the USP Oxidizable Substances Test requirements for sterile purified water after a water flush of 500 mL.
Bacterial Endotoxin	The cartridge meets the definition of a sterilizing-grade filter as described in the FDA "Guideline of Sterile Drug Products Produced by Aseptic Processing" (June 1987).
Bacterial Retention	Quantitative retention of 10^7 CFU/cm^2 *Brevundimonas diminuta* ATCC® 19146 per ASTM© F838 methodology.
Toxicity	Component materials meet the requirements of the USP <88> Biological Reactivity tests for Class VI plastics.
Integrity Test	
0.1 µm	Bubble point: > 4830 mbar (70.0 psi) at 25 ºC. Air Diffusion: < 7 cc/min per cartridge at 3.9 bar (56.0 psi) through a 25 °C water wet membrane.
0.22 µm	Bubble point: > 3450 mbar (50.0 psi) at 25 ºC. Air Diffusion: < 5 cc/min per cartridge at 2.8 bar (40.0 psi) through a 25 °C water wet membrane.
Multiple Steaming	Cartridges maintain integrity (per bacterial retention testing) after 30 steam cycles of 30 minutes at 135 °C.
Continuous Steaming	Cartridges maintain integrity after 100 hours of continuous steaming at 135 °C.

Filters Containing Durapore® 0.1 µm and 0.22 µm Membrane

Millidisk® Cartridge Filter Specifications

Description	Millidisk® 10	Millidisk® 20	Millidisk® 30	Millidisk® 40
Filtration Area	500 cm^2 (0.54 ft^2)	1000 cm^2 (1.08 ft^2)	1500 cm^2 (1.61 ft^2)	2000 cm^2 (2.15 ft^2)
Materials of Construction				
Filter membrane:	Hydrophilic PVDF			
Structural components:	Polysulfone			
O-rings:	Silicone			
Maximum Differential Pressure				
Forward:	4.1 bar (60 psid) at 25 °C, 1.7 bar (25 psid) at 80 °C, 345 mbar (5 psid) at 123 °C			
Reverse:	690 mbar (10 psid) at 25 °C			
Bubble Point at 23 °C				
0.1 µm:	≥ 4830 mbar (70.0 psig) in water*			
0.22 µm:	≥ 3450 mbar (50.0 psig) in water			
Connections	Millidisk® filters incorporate a double 2-118 (silicone) O-ring seal and are used with Millidisk® or Millidisk®/ Milligard® stainless steel housings.			
Gravimetric Extractables	Maximum values post autoclaving and a 24 hour soak in ASTM® Type 1 reagent grade water for hydrophilic units and in 70/30 IPA/Water solution for hydrophobic units:			
	2.5 mg/unit	5 mg/unit	7.5 mg/unit	10 mg/unit
Oxidizable Substances	Meets the USP Oxidizable Substances Test requirements for sterile purified water after steaming and a water flush of 200 mL.			
Bacterial Endotoxin	Aqueous extraction contains < 0.5 EU/mL per 10-inch filter as determined by the Limulus Amebocyte Lysate (LAL) test. This meets the requirements of USP <85>.			
Bacterial Retention	Quantitative retention of 10^7 CFU/cm^2 *Brevundimonas diminuta* ATCC® 19146 per ASTM© F838 methodology.			
Sterilization	Autoclave: 126 °C, 60 minutes, up to 5 times Steam-in-place: 135 °C, 60 minutes, up to 5 times			
Toxicity	Component materials meet the requirements of USP <88> Biological Reactivity Tests for Class VI Plastics.			

*Transient pressure excursion above the maximum differential and inlet pressures of the unit for integrity testing is acceptable.

Filters Containing Durapore® 0.1 µm and 0.22 µm Membrane

Opticap® XL and XLT Autoclavable Capsule Filter Specifications

Description	Opticap® XL 2	Opticap® XL 4	Opticap® XL 5	Opticap® XL 10	Opticap® XLT 10	Opticap® XLT 20	Opticap® XLT 30
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.)	37.6 cm (14.8 in.)	62.5 cm (24.6 in.)	87.1 cm (34.3 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.)	—	—	—
Fitting to Fitting							
Sanitary flange to sanitary flange:	—	—	—	—	15.2 cm (6.0 in.)	15.2 cm (6.0 in.)	15.2 cm (6.0 in.)
Sanitary flange to hose barb:	—	—	—	—	17.5 cm (6.9 in.)	17.5 cm (6.9 in.)	17.5 cm (6.9 in.)
Hose barb to hose barb:	—	—	—	—	19.8 cm (7.8 in.)	19.8 cm (7.8 in.)	19.8 cm (7.8 in.)
Filtration Area	0.09 m² (0.93 ft²)	0.19 m² (2.09 ft²)	0.35 m² (3.7 ft²)	0.69 m² (7.4 ft²)	0.69 m² (7.4 ft²)	1.4 m² (14.8 ft²)	2.1 m² (22.2 ft²)
Materials of Construction							
Filter membrane:	Hydrophilic PVDF						
Film edge:	Polypropylene						
Supports:	Polypropylene						
Structural components*:	Polypropylene						
Vent O-rings:	Silicone						
Vent/Drain	1/4 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, 1.0 bar (15 psid) at 80 °C				5.5 bar (80 psid) at 25 °C, 1.7 bar (25 psid) at 80 °C		
Reverse:	3.4 bar (50 psid) at 25 °C, intermittent				3.4 bar (50 psid) at 25 °C		
Bubble Point at 23 °C							
0.1 µm:	≥ 4830 mbar (70.0 psig) air with water						
0.22 µm:	≥ 3450 mbar (50.0 psig) air with water						
Air Diffusion	Through a water wet membrane at ambient temperature:						
0.1 µm at 3.9 bar (56 psig):	—	≤ 7.5 cc/min	≤ 10.0 cc/min	≤ 20.0 cc/min	≤ 20.0 cc/min	≤ 40.0 cc/min	≤ 60.0 cc/min
0.22 µm at 2.8 bar (40 psig):	—	≤ 5.5 cc/min	≤ 6.6 cc/min	≤ 13.3 cc/min	≤ 13.3 cc/min	≤ 26.6 cc/min	≤ 39.9 cc/min
NVR Gravimetric Extractables	After autoclaving and a 24-hour soak in ASTM® Type 1 reagent grade water at controlled room temperature:						
	≤ 10 mg	≤ 10 mg	≤ 15 mg	≤ 25 mg	≤ 25 mg	≤ 50 mg	≤ 75 mg
Oxidizable Substances	Meets the requirements of the USP Oxidizable Substances Test requirements for sterile purified water after a water flush of:						
	500 mL	500 mL	500 mL	1000 mL	1000 mL	2000 mL	3000 mL
Bacterial Endotoxin	Aqueous extraction contains < 0.5 EU/mL as determined by the Limulus Amebocyte Lysate (LAL) Test. This meets the requirements of USP <85>.						
Bacterial Retention	Quantitative retention of 10^7 CFU/cm² *Brevundimonas diminuta* ATCC® 19146 per ASTM® F838 methodology.						
Sterilization	May be autoclaved for 3 cycles of 60 minutes at 126 °C. Cannot be steam sterilized in-line.						

Filters Containing Durapore® 0.1 µm and 0.22 µm Membrane

Opticap® XL and XLT Autoclavable Capsule Filter Specifications

Description	Opticap® XL 2	Opticap® XL 4	Opticap® XL 5	Opticap® XL 10	Opticap® XLT 10	Opticap® XLT 20	Opticap® XLT 30
Non-Fiber Releasing	Meets the criteria for a "non-fiber releasing" filter as defined in 21 CFR 210.3 (b) (6).						
Toxicity	Component materials meet the criteria of the USP <88> Biological Reactivity Test for Class VI Plastics.						
Indirect Food Additive	All component materials meet the FDA Indirect Food Additive requirements cited in 21 CFR 177-182 based on information provided by raw material suppliers.						

*Cage, core, end caps, and capsule housing

Opticap® XL and XLT Sterile and Gamma-Compatible Capsule Filter Specifications

Description	Opticap® XL 4	Opticap® XL 10	Opticap® XLT 10	Opticap® XLT 20	Opticap® XLT 30
Nominal Dimensions					
Maximum length:	19.6 cm (7.7 in.)	33.5 cm (13.2 in.)	38.1 cm (15 in.)	62.5 cm (24.6 in.)	87.1 cm (34.3 in.)
Body diameter:	8.4 cm (3.3 in.)	—	—	—	—
Fitting to Fitting					
Sanitary flange to sanitary flange:	—	—	15.2 cm (6.0 in.)	15.2 cm (6.0 in.)	15.2 cm (6.0 in.)
Sanitary flange to hose barb:	—	—	17.5 cm (6.9 in.)	17.5 cm (6.9 in.)	17.5 cm (6.9 in.)
Hose barb to hose barb:	—	—	19.8 cm (7.8 in.)	19.8 cm (7.8 in.)	19.8 cm (7.8 in.)
Filtration Area	0.18 m^2 (1.9 ft^2)	0.73 m^2 (7.8 ft^2)	0.73 m^2 (7.8 ft^2)	1.45 m^2 (15.6 ft^2)	2.17 m^2 (23.4 ft^2)
Materials of Construction					
Filter membrane:	Hydrophilic PVDF				
Film edge:	Polyethylene				
Supports:	Polyester/polyethylene				
Structural components*:	Gamma-stable polypropylene				
Vent O-rings:	One inner silicone-coated ethylene propylene diene monomer (EPDM) O-ring. One outer silicone O-ring.				
Vent/Drain	$^1/_4$ 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 1.0 bar (15 psid) at 80 °C		5.5 bar (80 psid) at 25 °C 1.7 bar (25 psid) at 80 °C		
Reverse:	3.5 bar (50 psid) at 25 °C		3.5 bar (50 psid) at 25 °C		
Bubble Point at 23 °C					
0.1 µm:	≥ 4830 mbar (70.0 psig) air with water				
0.22 µm:	≥ 3450 mbar (50.0 psig) air with water				
Air Diffusion	**Through a water wet membrane at ambient temperature:**				
0.1 µm at 3.9 bar (56 psig):	≤ 5.7 cc/min	≤ 21.1 cc/min	≤ 21.1 cc/min	≤ 42.2 cc/min	≤ 63.3 cc/min
0.22 µm at 2.8 bar (40 psig):	≤ 4.6 cc/min	≤ 14.0 cc/min	≤ 14.0 cc/min	≤ 28.0 cc/min	≤ 42.0 cc/min
Oxidizable Substances	Meets the requirements of the USP Oxidizable Substances Test after a water flush of:				
	1000 mL	1000 mL	1000 mL	2000 mL	3000 mL

Filters Containing Durapore® 0.1 µm and 0.22 µm Membrane

Opticap® XL and XLT Sterile and Gamma-Compatible Capsule Filter Specifications

Description	Opticap® XL 4	Opticap® XL 10	Opticap® XLT 10	Opticap® XLT 20	Opticap® XLT 30
NVR Gravimetric Extractables	—	≤ 25 mg	≤ 25 mg	≤ 50 mg	≤ 75 mg
Bacterial Endotoxin	Aqueous extraction contains < 0.25 EU/mL as determined by the Limulus Amebocyte Lysate (LAL) Test. This meets the requirements of USP <85>.		Aqueous extraction contains < 0.5 EU/mL as determined by the Limulus Amebocyte Lysate (LAL) Test. This meets the requirements of USP <85>.		
Bacterial Retention	Quantitative retention of 10^7 CFU/cm² *Brevundimonas diminuta* ATCC® 19146 per ASTM® F838 methodology.				
Sterilization					
Gamma-compatible:	Gamma-compatible to 45 kGy. May be autoclaved for 3 cycles of 60 minutes at 123 °C. (Cannot be steam sterilized in-line.)				
Sterile:	May be autoclaved for 3 cycles of 60 minutes at 123 °C. (Cannot be steam sterilized in-line.)				
Non-Fiber Releasing	Meets the criteria for a “non-fiber releasing” filter as defined in 21 CFR 210.3 (b) (6).				
Total Organic Carbon (TOC) / Conductivity	Gamma sterilized filter effluent meets the WFI requirement of USP <643>, for Total Organic Carbon and USP <645> for Water Conductivity at 25 °C after a WFI flush of 26 L.	—	—	—	—
Toxicity	Component materials meet the criteria of the USP <88> Biological Reactivity Test for Class VI Plastics.				
Indirect Food Additive	All component materials meet the FDA Indirect Food Additive requirements cited in 21 CFR 177-182 based on information provided by raw material suppliers.				

*Cage, core, end caps, and capsule housing

Filters Containing Durapore® 0.1 µm and 0.22 µm Membrane

Millipak® Final Fill Capsule Filter Specifications

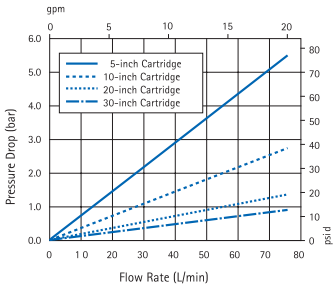
Description	Millipak® Final Fill 20	Millipak® Final Fill 40	Millipak® Final Fill 60	Millipak® Final Fill 100	Millipak® Final Fill 200
Nominal Dimensions					
Maximum length	8.1 cm (3.2 in.)	8.6 cm (3.4 in.)	10.9 cm (4.3 in.)	11.9 cm (4.7 in.)	14.5 cm (5.7 in.)
Body diameter	7.6 cm (3.0 in.)	7.6 cm (3.0 in.)	7.6 cm (3.0 in.)	7.6 cm (3.0 in.)	7.6 cm (3.0 in.)
Body diameter w/ anti-roll edges	–	–	–	8.1 cm (3.2 in.)	8.1 cm (3.2 in.)
Filtration area	100 cm^2 (0.11 ft^2)	200 cm^2 (0.22 ft^2)	300 cm^2 (0.32 ft^2)	500 cm^2 (0.54 ft^2)	1000 cm^2 (1.08 ft^2)
Aseptic Multi-Purpose Port (AMPP)	3.2 mm (1/8 in.) hose barb				
Materials of Construction					
Filter membrane:	Hydrophilic PVDF				
Support discs:	Polysulfone				
Filter capsule:	Polysulfone				
Aseptic Multi-Purpose Port (AMPP)	Polyethersulfone				
AMPP O-rings:	Silicone				
Hold-up Volume	20 psi above the Bubble Point Specification for 1 minute				
	1.1 mL	1.5 mL	3.2 mL	4.8 mL	7.2 mL
Maximum Inlet Pressure	60 psi (4.1 bar) at 25 °C	80 psi (5.5 bar) at 25 °C			
Maximum Differential Pressure					
Forward:	60 psi (4.1 bar) at 25 °C	80 psi (5.5 bar) at 25 °C			
	25 psi (1.7 bar) at 80 °C				
Reverse:	10 psi (0.7 bar) at 25 °C				
Bubble Point at 23 °C					
0.1 µm:	≥ 70 psi (4830 mbar) air with water*				
0.22 µm:	≥ 50 psi (3450 mbar) air with water				
Bacterial Retention for 0.1 µm and 0.22 µm	Quantitative retention of 10^7 CFU/cm^2 *Brevundimonas diminuta* ATCC® 19146 per ASTM® F838 methodology.				
Microbial Challenge Testing	Vents were tested utilizing a bacterial challenge method with 10^7 *B. Diminuta* assuring a sterile fluid path during actuation.				
Bacterial Endotoxin	Aqueous extraction contains < 0.25 EU/mL per device as determined using the Limulus Amebocyte Lysate (LAL) test, meeting requirements of USP <85>, EP 2.6.14 and JP 4.01.				
Total Organic Carbon (TOC) / Conductivity	Samples exhibited < 500 ppb TOC per USP <643> and < 1.3 µS/cm conductivity per USP <645> at 25 °C after sterilization and a water flush of:				
	1.0 L	2.0 L	2.0 L	3.0 L	5.0 L
Sterilization	Device integrity and retention was maintained after 3 autoclave cycles of 90 minutes at 126 °C. Devices can withstand a dose ≤ 40 kGy gamma exposure.				
Toxicity	Component materials meet the criteria for Class VI testing based on USP <88> Biological Reactivity, *in vivo*, USP <87> Biological Reactivity, *in vitro*, and ISO 10993-5 Tests for *in vitro* Cytotoxicity. This product also meets physicochemical specifications, as described in USP <661> Containers-Plastics.				
Particle Shredding	Effluent meets the acceptance criteria set forth in USP <788> for large volume parenterals.				
Non-Fiber Releasing	This product was manufactured with a Durapore® membrane which meets the criteria for a "non-fiber releasing" filter as defined in 21 CFR 210.3 (b)(6), validated based on large volume parenteral specifications as detailed in USP <788> Particulate Matter in Injections.				
Indirect Food Additive	All component materials meet the FDA Indirect Food Additive requirements cited in 21 CFR 177–182, based on information provided by raw material suppliers.				
Quality Management System	These products are manufactured in a facility which is certified to ISO 9001:2015 Quality Management Systems.				

*Transient pressure excursion above the maximum differential and inlet pressures of the unit for integrity testing and capsule blow-down is acceptable.

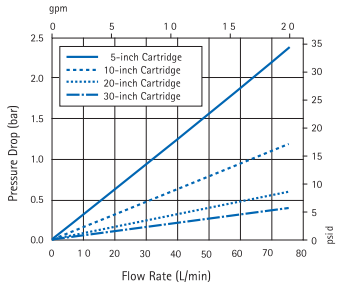
Filters Containing Durapore® 0.1 µm and 0.22 µm Membrane

Typical Clean Water Flow Rates – Cartridge Filters

Cartridge Filters — 0.1 µm Durapore® Membrane

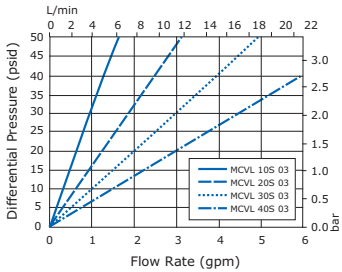


Cartridge Filters — 0.22 µm Hydrophilic Durapore® Membrane

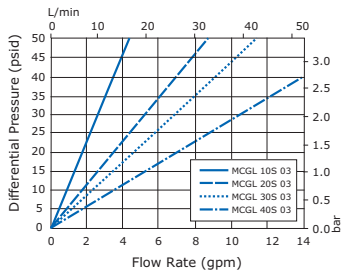


Typical Clean Water Flow Rates – Millidisk® Cartridge Filters

Millidisk® Cartridge Filters — 0.1 µm Durapore® Membrane



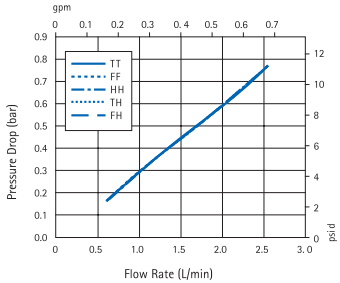
Millidisk® Cartridge Filters — 0.22 µm Hydrophilic Durapore® Membrane



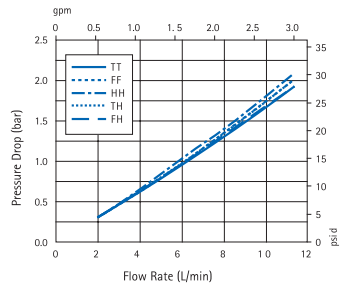
Filters Containing Durapore® 0.1 µm and 0.22 µm Membrane

Typical Clean Water Flow Rates – Opticap® XL Autoclavable Capsules

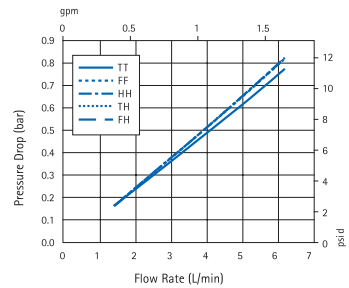
Opticap® XL 2 Capsules — 0.1 µm Durapore® Membrane



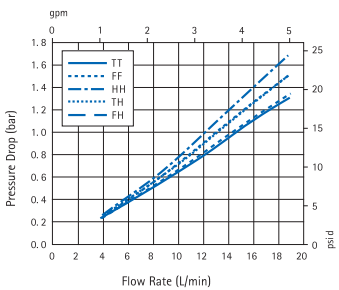
Opticap® XL 2 Capsules — 0.22 µm Hydrophilic Durapore® Membrane



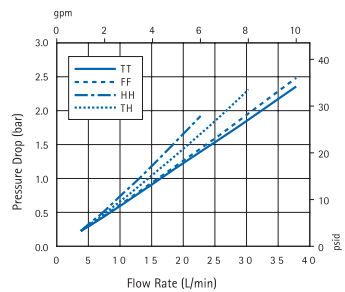
Opticap® XL 4 Capsules — 0.1 µm Durapore® Membrane



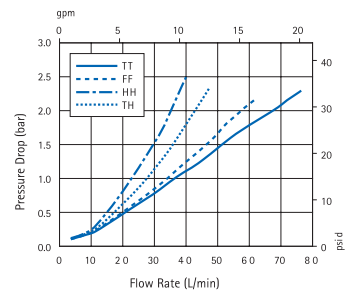
Opticap® XL 4 Capsules — 0.22 µm Hydrophilic Durapore® Membrane



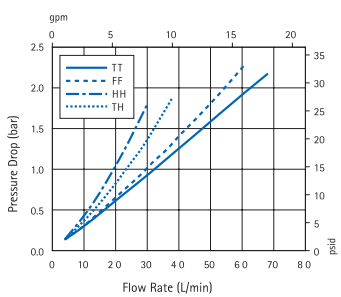
Opticap® XL 5 Capsules — 0.1 µm Durapore® Membrane



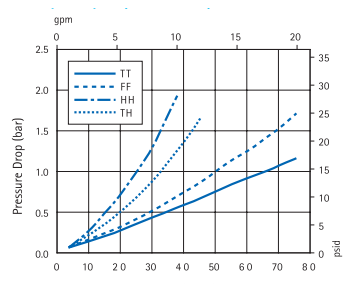
Opticap® XL 5 Capsules — 0.22 µm Hydrophilic Durapore® Membrane



Opticap® XL 10 Capsules — 0.1 µm Durapore® Membrane



Opticap® XL 10 Capsules — 0.22 µm Hydrophilic Durapore® Membrane



Opticap® XL Capsule Legends Refer to 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

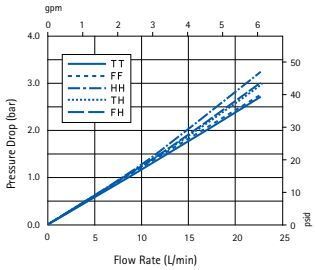
TH = 38 mm (1½ in.) Sanitary Flange Inlet and 14 mm (9/16 in.) Hose Barb Outlet

FH = 19 mm (¾ in.) Sanitary Flange Inlet and 14 mm (9/16 in.) Hose Barb Outlet (XL 2 and 4 only)

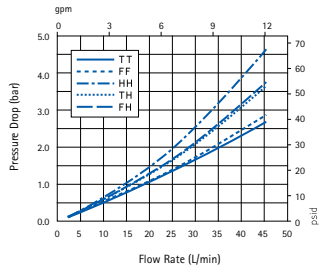
Filters Containing Durapore® 0.1 µm and 0.22 µm Membrane

Typical Clean Water Flow Rates - Opticap® XL Sterile and Gamma-Compatible Capsules

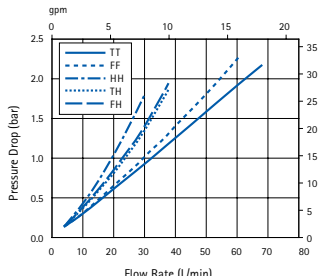
Opticap® XL 4 Capsules — 0.1 µm Durapore® Membrane



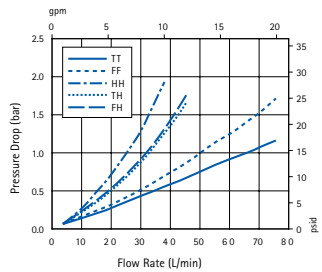
Opticap® XL 4 Capsules — 0.22 µm Hydrophilic Durapore® Membrane



Opticap® XL 10 Capsules — 0.1 µm Durapore® Membrane



Opticap® XL 10 Capsules — 0.22 µm Hydrophilic Durapore® Membrane



Opticap® XL Capsule Legends Refer to 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

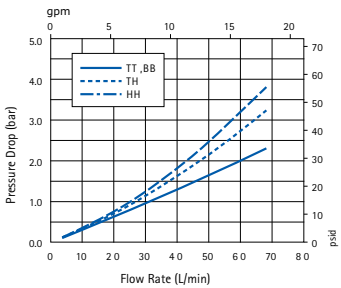
TH = 38 mm (1½ in.) Sanitary Flange Inlet and 14 mm (9/16 in.) Hose Barb Outlet

FH = 19 mm (¾ in.) Sanitary Flange Inlet and 14 mm (9/16 in.) Hose Barb Outlet (XL 2 and 4 only)

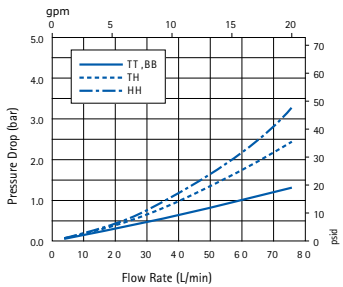
Filters Containing Durapore® 0.1 µm and 0.22 µm Membrane

Typical Clean Water Flow Rates - Opticap® XLT Autoclavable Capsules

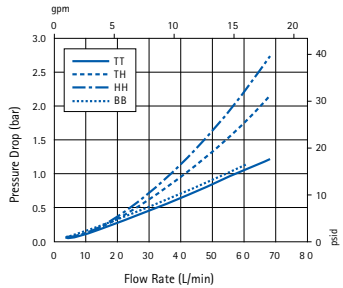
Opticap® XLT 10 Capsules — 0.1 µm Durapore® Membrane



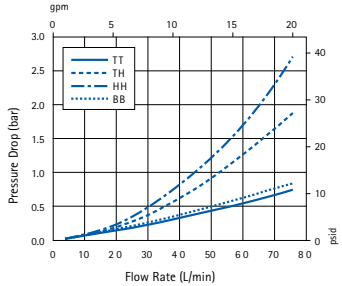
Opticap® XLT 10 Capsules — 0.22 µm Hydrophilic Durapore® Membrane



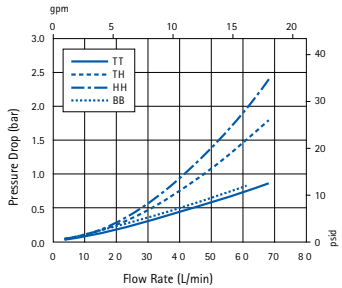
Opticap® XLT 20 Capsules — 0.1 µm Durapore® Membrane



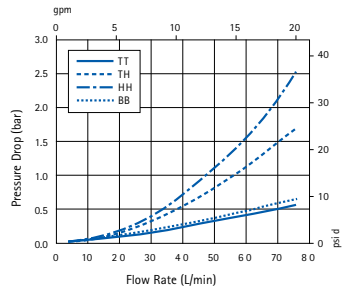
Opticap® XLT 20 Capsules — 0.22 µm Hydrophilic Durapore® Membrane



Opticap® XLT 30 Capsules — 0.1 µm Durapore® Membrane



Opticap® XLT 30 Capsules — 0.22 µm Hydrophilic Durapore® Membrane



Opticap® XLT Capsule Legends Refer to Connection Type

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

TH = 38 mm (1½ in.) Sanitary Flange Inlet and 16 mm (⅝ in.) Hose Barb Outlet

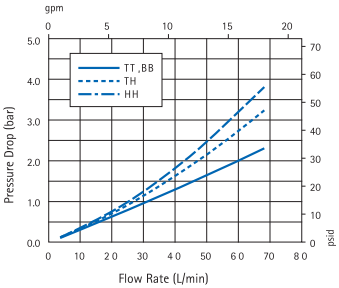
HH = 16 mm (⅝ in.) Hose Barb Inlet and Outlet

BB = 25 mm (1 in.) Hose Barb Inlet and Outlet

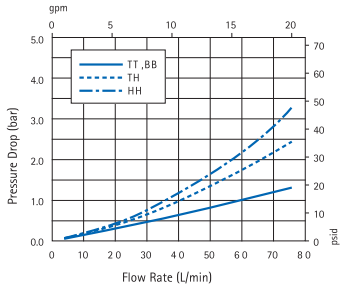
Filters Containing Durapore® 0.1 µm and 0.22 µm Membrane

Typical Clean Water Flow Rates - Opticap® XLT Sterile and Gamma-Compatible Capsules

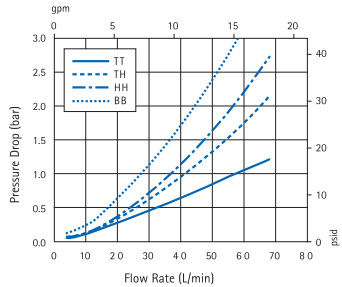
Opticap® XLT 10 Capsules — 0.1 µm Durapore® Membrane



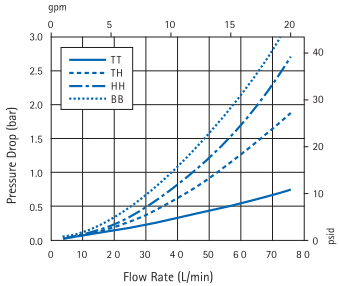
Opticap® XLT 10 Capsules — 0.22 µm Hydrophilic Durapore® Membrane



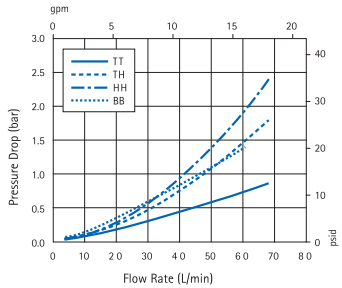
Opticap® XLT 20 Capsules — 0.1 µm Durapore® Membrane



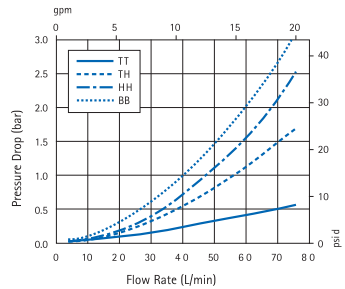
Opticap® XLT 20 Capsules — 0.22 µm Hydrophilic Durapore® Membrane



Opticap® XLT 30 Capsules — 0.1 µm Durapore® Membrane



Opticap® XLT 30 Capsules — 0.22 µm Hydrophilic Durapore® Membrane



Opticap® XLT Capsule Legends Refer to Connection Type

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

TH = 38 mm (1½ in.) Sanitary Flange Inlet and 16 mm (⅝ in.) Hose Barb Outlet

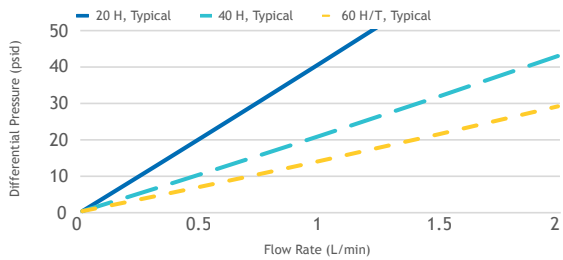
HH = 16 mm (⅝ in.) Hose Barb Inlet and Outlet

BB = 25 mm (1 in.) Hose Barb Inlet and Outlet

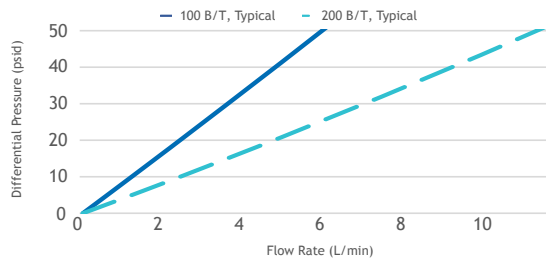
Filters Containing Durapore® 0.1 µm and 0.22 µm Membrane

Typical Clean Water Flow Rates – Millipak® Final Fill Capsule Filters

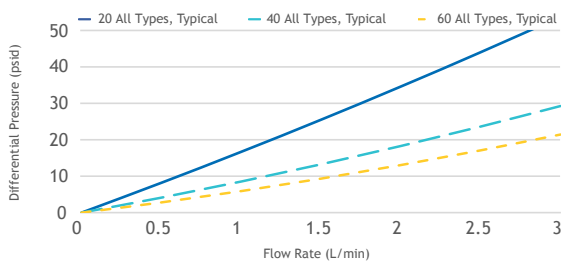
Millipak® Final Fill 20/40/60 Capsule Filters — 0.1 µm Durapore® Membrane



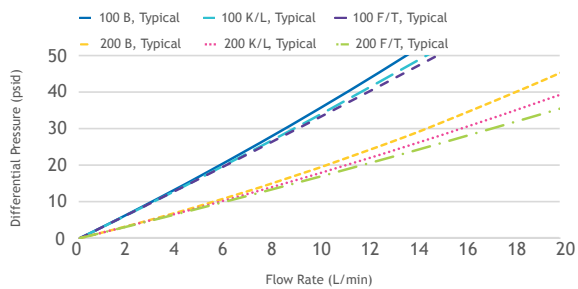
Millipak® Final Fill 100/200 Capsule Filters — 0.1 µm Durapore® Membrane



Millipak® Final Fill 20/40/60 Capsule Filters — 0.22 µm Durapore® Membrane



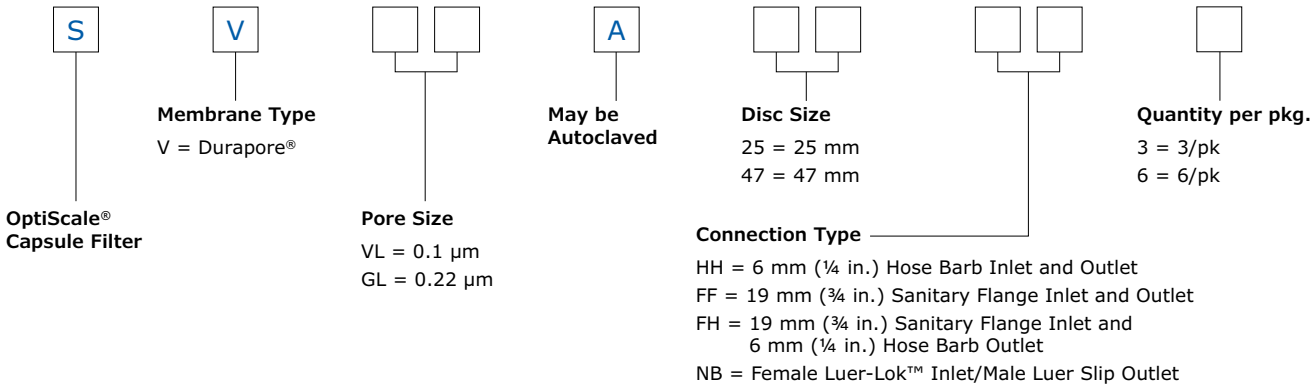
Millipak® Final Fill 100/200 Capsule Filters — 0.22 µm Durapore® Membrane



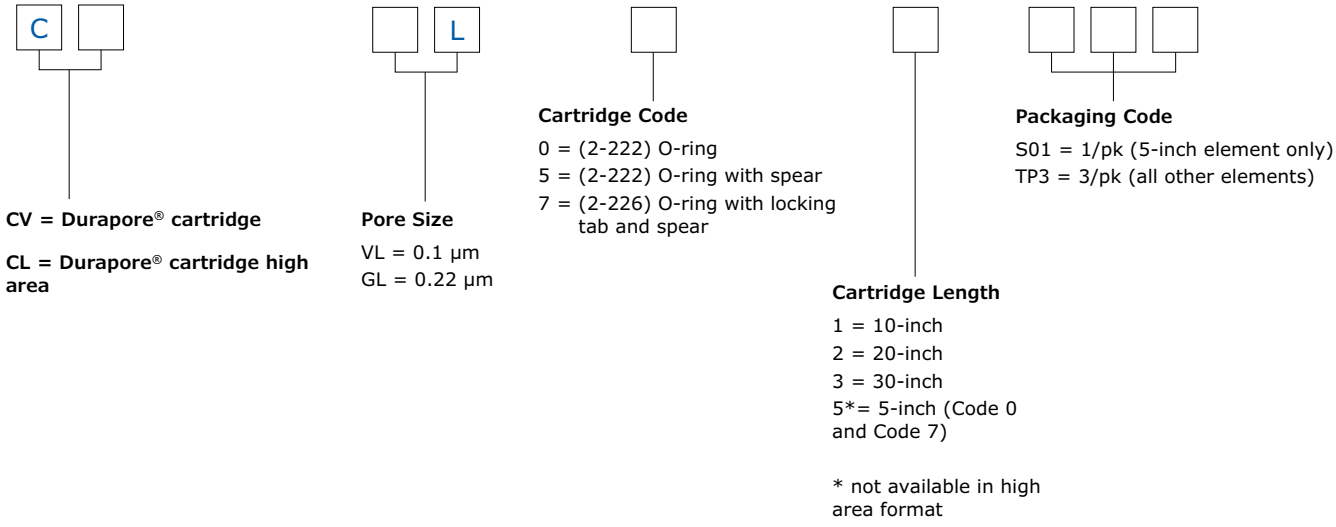
Filters Containing Durapore® 0.1 µm and 0.22 µm Membrane

Ordering Information

OptiScale® Capsules



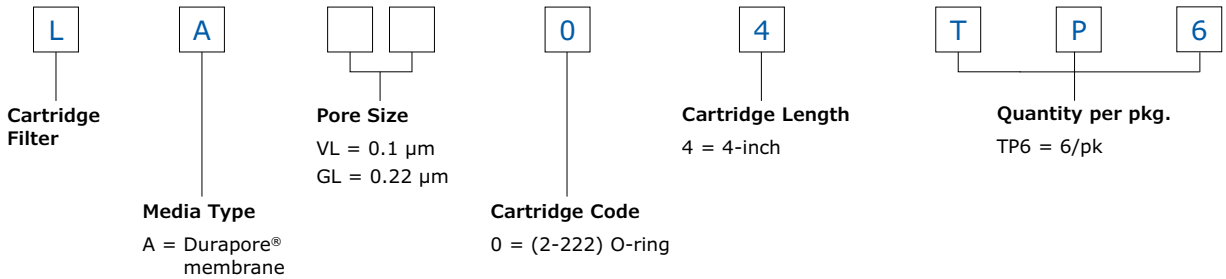
Cartridge Filters



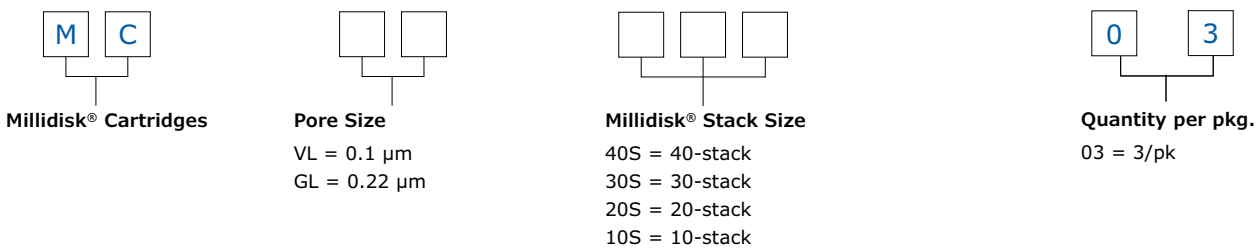
Filters Containing Durapore® 0.1 µm and 0.22 µm Membrane

Ordering Information

Optiseal® Cartridges



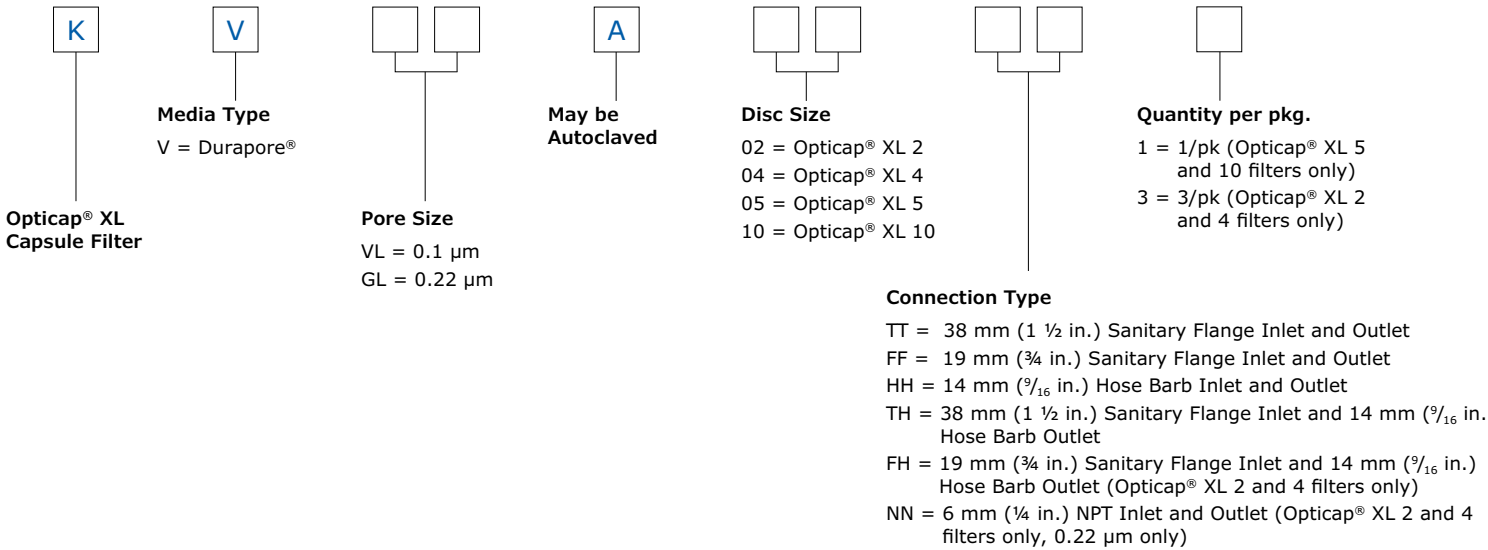
Millidisk® Cartridges



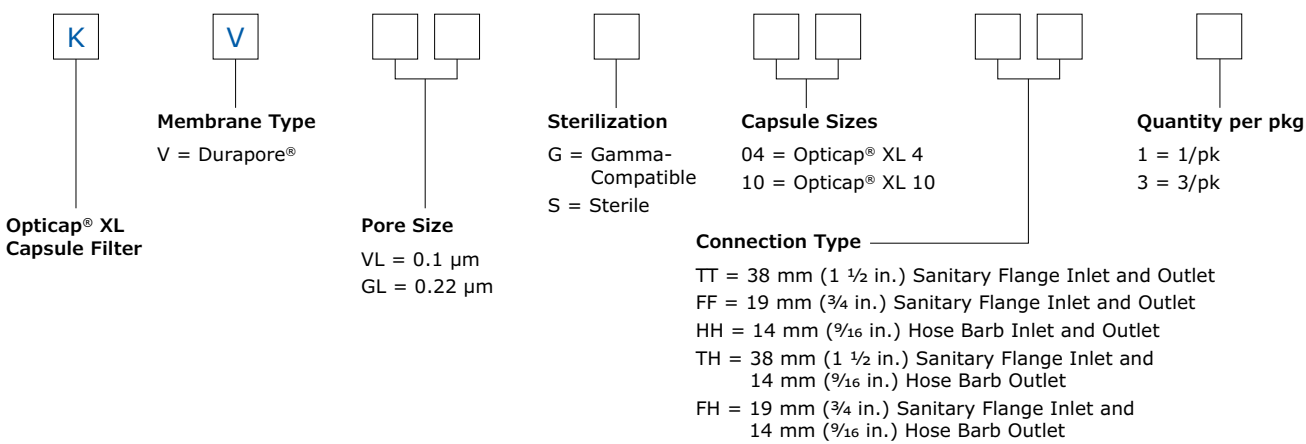
Filters Containing Durapore® 0.1 µm and 0.22 µm Membrane

Ordering Information

Opticap® XL Autoclavable Capsule Filters



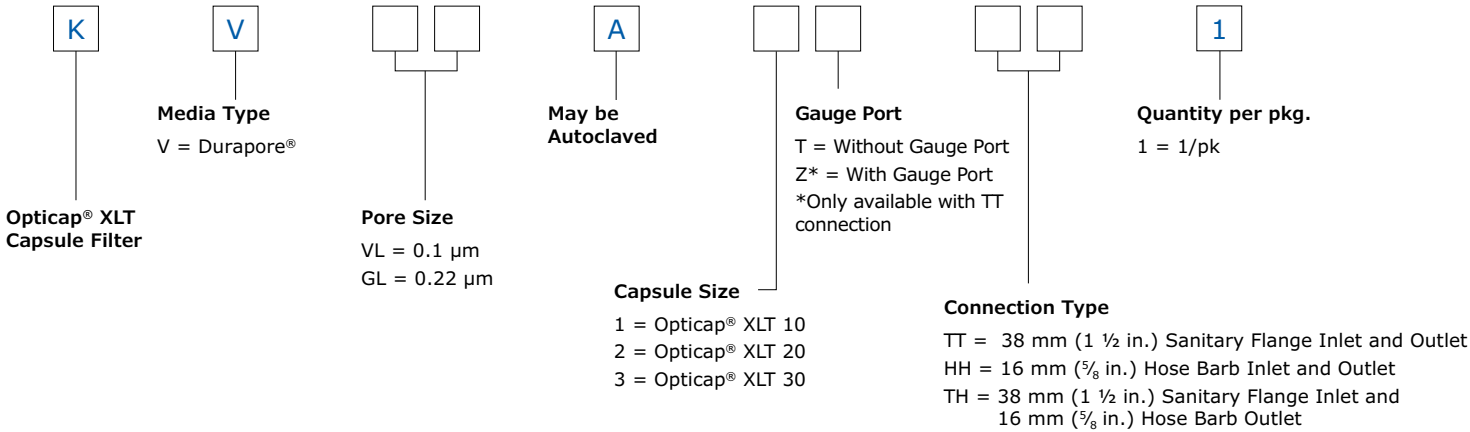
Opticap® XL Sterile and Gamma-Compatible Capsule Filters



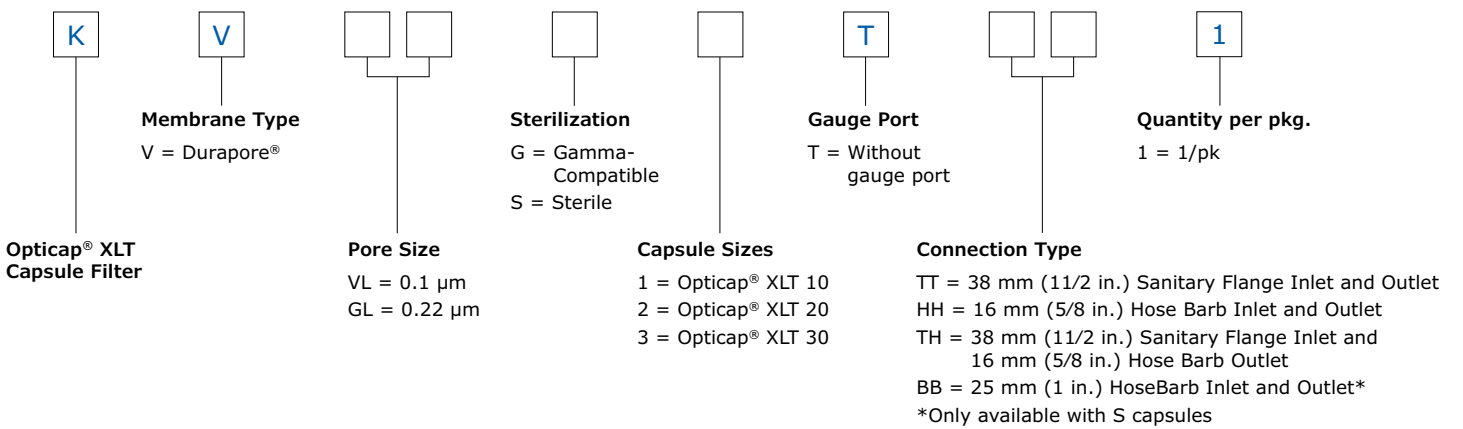
Filters Containing Durapore® 0.1 µm and 0.22 µm Membrane

Ordering Information

Opticap® XLT Autoclavable Capsule Filters



Opticap® XLT Sterile and Gamma-Compatible Capsule Filters



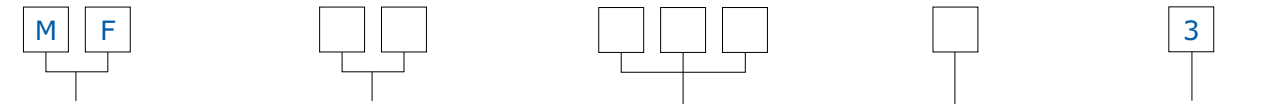
Accessory

Description	Qty/Pk	Cat. No.
Standard Opticap® XLT Capsule Filter Stand	1/pk	**XLTSTAND1**

Filters Containing Durapore® 0.1 µm and 0.22 µm Membrane

Ordering Information

Millipak® Final Fill Capsule Filters



Millipak® Final Fill Filter

Membrane Pore Size

VL = Durapore® 0.1 µm
GL = Durapore® 0.22 µm

Quantity per pkg.

3 = 3/pk

Millipak® Final Fill Filter Series

02G = 20, Non-sterilized
02S = 20, Sterilized by Gamma Radiation
04G = 40, Non-sterilized
04S = 40, Sterilized by Gamma Radiation
06G = 60, Non-sterilized
06S = 60, Sterilized by Gamma Radiation
10G = 100, Non-sterilized
10S = 100, Sterilized by Gamma Radiation
20G = 200, Non-sterilized
20S = 200, Sterilized by Gamma Radiation

Connection Type

Millipak® Final Fill 20, 40, 60

C* = 19 mm (¾ in.) Sanitary Flange Inlet and 6 mm (¼ in.) Hose Barb Outlet
H = 6 mm (¼ in.) Hose Barb Inlet and Outlet

Millipak® Final Fill 60, 100, 200

L* = 38 mm (1½ in.) Sanitary Flange Inlet and 13 mm (½ in.) Hose Barb Outlet
T = 38 mm (1½ in.) Sanitary Flange Inlet and Outlet

Millipak® Final Fill 100, 200

B = 13 mm (½ in.) Hose Barb Inlet and Outlet
K* = 19 mm (¾ in.) Sanitary Flange Inlet and 13 mm (½ in.) Hose Barb Outlet

Millipak® Final Fill 20, 40, 60, 100, 200

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

* available with 0.22 µm Membrane only

Filters Containing Durapore® 0.45 µm Membrane

For bioburden reduction and particulate removal

Filters containing Durapore® 0.45 µm hydrophilic polyvinylidene fluoride (PVDF) membrane can extend the life of sterilizing filters by removing particles and microorganisms from liquid streams. These filters are ideally suited for large volume parenteral or ophthalmics manufacturing where protein binding must be minimized.

Filters containing Durapore® 0.45 µm membrane are available with or without an integrated prefilter, providing opportunities for process efficiency with prefiltration and bioburden reduction in a single filter.

Benefits

- Ideal for bioburden reduction before final sterilization
- Low protein binding membrane yields high protein recovery with minimal product loss
- Broad chemical compatibility, low extractables
- For filtration processes requiring high flow rates and throughputs

Filter Formats

- OptiScale® capsules
- Cartridge filters
- Millidisk® cartridges
- Opticap® XL and XLT capsules
- Millipak® Final Fill capsules

Membrane Types

- 0.45 µm Durapore® membrane with prefilter
- 0.45 µm Durapore® membrane without prefilter

Filters Containing Durapore® 0.45 µm Membrane

OptiScale® Capsule and Cartridge Filter Specifications

Description	OptiScale® 25 Capsule	OptiScale® 47 Capsule	Cartridge (per 10-inch)
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	—
Body diameter:	31 mm (1.21 in.)	69 mm (2.75 in.)	6.9 cm (2.7 in.)
Weight:	0.19 oz (5.5 g)	2.3 oz (67 g)	—
Filtration Area	3.5 cm^2	17.7 cm^2	0.69 m^2 (7.4 ft^2)
Materials of Construction			
Filter membrane:	Hydrophilic PVDF	Hydrophilic PVDF	Hydrophilic PVDF
Prefilter media:	—	—	Mixed esters of cellulose
Film edge:	—	—	Polypropylene
Structural components:	Polypropylene	Polycarbonate	Polypropylene
Supports:	Polypropylene	Polypropylene	Polypropylene
Vent cap:	Polypropylene	Polyvinylidene fluoride (PVDF)	—
Internal seal rings:	—	Fluoroelatomers	Silicone
Housing Vent	Capped vent with female Luer connections on inlet side of device.	Adjustable vent with male luer 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	—
Maximum Differential Pressure			
Forward:	4.1 bar (60 psi) at 25 °C — —	5.5 bar (80 psig) at 25 °C — —	5.5 bar (80 psid) at 25 °C 1.8 bar (25 psid) at 80 °C 345 mbar (5 psid) at 135 °C
Reverse:	0 bar (0 psi)	0.7 bar (10 psig) at 25 °C	3.5 bar (50 psid) at 25 °C, intermittent
Bubble Point at 23 °C	—	—	≥ 1790 mbar (26 psig) air with water
Air Diffusion	—	—	Through a water wet membrane at 23 °C at 1.5 bar (22 psi): ≤ 15 cc/mm
Total Organic Carbon (TOC)/ Conductivity	—	—	Autoclaved filter effluent meets the WFI requirement of USP <643>, for Total Organic Carbon and USP <645> for Water Conductivity at 25 ºC after a WFI flush of 11.5 L
Oxidizable Substances	—	Meets the requirements of the USP Oxidizable Substance Test for sterile purified water after a water flush of: 100 mL	1000 mL
Bacterial Endotoxin	Aqueous extraction contains < 0.25 EU/mL as determined by the Limulus Amebocyte Lysate (LAL) Test. This meets the requirements of USP <85>.	—	Aqueous extraction contains < 0.5 EU/mL as determined by the Limulus Amebocyte Lysate (LAL) Test. This meets the requirements of USP <85>.

Filters Containing Durapore® 0.45 µm Membrane

OptiScale® Capsule and Cartridge Filter Specifications (continued)

Description	OptiScale® 25 Capsule	OptiScale® 47 Capsule	Cartridge (per 10-inch)
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.	**With prefilter:** 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 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.
Non-Fiber Releasing	Meets the criteria for a "non-fiber releasing" filter; defined in 21 CFR 210.3 (b) (6).		
Toxicity	Component materials meet the criteria of the USP <88> Biological Reactivity Test for Class VI Plastics.		
Indirect Food Additive	All component materials meet the FDA Indirect Food Additive requirements cited in 21 CFR 177-182 based on information provided by raw material suppliers.		

Millidisk® Cartridge Filter Specifications

Description	Millidisk® 10	Millidisk® 20	Millidisk® 30	Millidisk® 40
Filtration Area	500 cm^2 (0.54 ft^2)	1000 cm^2 (1.08 ft^2)	1500 cm^2 (1.61 ft^2)	2000 cm^2 (2.15 ft^2)
Materials of Construction				
Filter membrane:	Hydrophilic PVDF			
Structural components:	Polysulfone			
O-rings:	Silicone			
Maximum Differential Pressure				
Forward:	4.1 bar (60 psid) at 25 °C 1.7 bar (25 psid) at 80 °C 345 mbar (5 psid) at 123 °C			
Reverse:	690 mbar (10 psid) at 25 °C			
Bubble Point at 23 °C	≥ 1790 mbar (26.0 psig) in water			
Connections	Millidisk® filters incorporate a double 2–118 (silicone) O-ring seal and are used with Millidisk® or Millidisk®/ Milligard® stainless steel housings.			
Gravimetric Extractables	Through a water wet membrane at an ambient temperature of 1.5 bar (22 psi):			
	2.5 mg/unit	5 mg/unit	7.5 mg/unit	10 mg/unit
Oxidizable Substances	Meets the USP Oxidizable Substances Test requirements for sterile purified water after steaming and water flush of 200 mL.			
Bacterial Endotoxin	An aqueous extraction from a Millidisk® filter contains < 0.5 EU/mL bacterial endotoxin as determined by the Limulus Amebocyte Lysate (LAL) test. This meets the requirements of USP <85>.			

Filters Containing Durapore® 0.45 µm Membrane

Millidisk® Cartridge Capsule Filter Specifications (continued)

Description	Millidisk® 10	Millidisk® 20	Millidisk® 30	Millidisk® 40
Sterilization				
Autoclave:	126 °C, 60 minutes, up to 5 times			
Steam-in-place:	135 °C, 60 minutes, up to 5 times			
Toxicity	Component materials meet the criteria of the USP <88> Biological Reactivity Test for Class VI Plastics.			

Opticap® XL Autoclavable Capsule Filter Specifications

Description	Opticap® XL 2	Opticap® XL 4	Opticap® XL 5	Opticap® XL 10
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.)
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)
Materials of Construction				
Filter membrane:	Hydrophilic PVDF			
Prefilter Media:	Mixed esters of cellulose			
Film edge:	–			
Supports:	Polypropylene			
Structural components*:	Polypropylene			
Vent O-rings:	Silicone			
Vent/Drain	$^1/_4$ 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) 1.0 bar (15 psid) at 80 °C (with prefilter) 3.4 bar (50 psid) at 25 °C (without prefilter)			
Reverse:	3.4 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 an ambient temperature of 1.5 bar (22 psi):			
	–	≤ 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
Without prefilter	≤ 10 mg	≤ 10 mg	≤ 15 mg	≤ 25 mg
Oxidizable Substances	Meets the USP Oxidizable Substances Test requirements for sterile purified water after autoclaving and a water flush of:			
	500 mL	500 mL	500 mL	1000 mL
Bacterial Endotoxin	Aqueous extraction contains < 0.5 EU/mL as determined by the Limulus Amebocyte Lysate (LAL) Test. This meets the requirements of USP <85>.			
Sterilization				
With prefilter	May be autoclaved for 3 cycles of 60 minutes at 121 °C. Cannot be steam sterilized in-line.			
Without prefilter	May be autoclaved for 3 cycles of 60 minutes at 126 °C. Cannot be steam sterilized in-line.			
Non-Fiber Releasing	Meets the criteria for a “non-fiber releasing” filter as defined in 21 CFR 210.3 (b) (6).			

Filters Containing Durapore® 0.45 µm Membrane

Opticap® XL Autoclavable Capsule Filter Specifications (continued)

Description	Opticap® XL 2	Opticap® XL 4	Opticap® XL 5	Opticap® XL 10
Toxicity	Component materials meet the criteria of the USP <88> Biological Reactivity Test for Class VI Plastics.			
Indirect Food Additive	All component materials meet the FDA Indirect Food Additive requirements cited in 21 CFR 177-182 based on information provided by raw material suppliers.			
European Pressure Equipment Directive	This product complies with the European Pressure Equipment Directive, 2014/68/EU of 15 May 2014. This product has been classified under article 4 § 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 4 § 3 of the Directive, 2014/68/EU, this product does not bear the CE mark.			

*Cage, core, end caps, and capsule housing

Opticap® XL and XLT Sterile and Gamma-Compatible Capsule Filter Specifications

Description	Opticap® XL 10	Opticap® XLT 10	Opticap® XLT 20	Opticap® XLT 30
Nominal Dimensions				
Maximum length:	33.5 cm (13.2 in.)	37.6 cm (14.8 in.)	62.5 cm (24.6 in.)	87.1 cm (34.3 in.)
Body diameter:	10.7 cm (4.2 in.)	—	—	—
Fitting to Fitting				
Sanitary flange to sanitary flange:	33.5 cm (13.2 in.)	15.2 cm (6.0 in.)	15.2 cm (6.0 in.)	15.2 cm (6.0 in.)
Sanitary flange to hose barb:	33.2 cm (13.1 in.)	17.5 cm (6.9 in.)	17.5 cm (6.9 in.)	17.5 cm (6.9 in.)
Hose barb to hose barb:	33.2 cm (13.1 in.)	19.8 cm (7.8 in.)	19.8 cm (7.8 in.)	19.8 cm (7.8 in.)
Filtration Area	0.62 m^2 (6.7 ft^2)	0.62 m^2 (6.7 ft^2)	1.24 m^2 (13.3 ft^2)	1.86 m^2 (20.0 ft^2)
Materials of Construction				
Filter membrane:	Hydrophilic PVDF			
Film Edge:	Polyethylene			
Supports:	Polyester/Polyethylene			
Structural components*:	Gamma-stable Polypropylene			
Vent O-rings:	One inner silicone-coated ethylene propylene diene monomer (EPDM) O-ring. One outer silicone O-ring			
Vent/Drain	$^1/_4$ 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:	4.1 bar (60 psid) at 4-40 °C			
Reverse:	2.1 bar (30 psid) at 4-40 °C			
Bubble Point at 23 °C	≥ 1930 mbar (28.0 psig) air with water			
Air Diffusion	Through a water wet membrane at an ambient temperature of 1.5 bar (22 psi):			
	≤ 15 mL/min.	≤ 15 mL/min.	≤ 30 mL/min.	≤ 45 mL/min.
Oxidizable Substances	Meets the requirements of USP Oxidizable Substances Test for sterile purified water after a water flush of:			
	≤ 1500 mL	≤ 1500 mL	≤ 3000 mL	≤ 4500 mL
Bacterial Endotoxin	Aqueous extraction contains < 0.25 EU/mL as determined by the Limulus Amebocyte Lysate (LAL) Test. This meets the requirements of USP <85>.			

Filters Containing Durapore® 0.45 µm Membrane

Opticap® XL and XLT Sterile and Gamma-Compatible Capsule Filter Specifications (continued)

Description	Opticap® XL 10	Opticap® XLT 10	Opticap® XLT 20	Opticap® XLT 30
Sterilization				
Gamma-Compatible:	Gamma-compatible to 40 kGy. May be autoclaved for 3 cycles of 60 minutes at 123 °C. (Cannot be steam sterilized in-line.)			
Sterile Capsules:	May be autoclaved for 3 cycles of 60 minutes at 123 °C. (Cannot be steam sterilized in-line.)			
Non-Fiber Releasing	Meets the criteria for a "non-fiber releasing" filter as defined in 21 CFR 210.3 (b) (6).			
Toxicity	Component materials meet the criteria of the USP <88> Biological Reactivity Test for Class VI Plastics.			
Indirect Food Additive	All component materials meet the FDA Indirect Food Additive requirements cited in 21 CFR 177-182 based on information provided by raw material suppliers.			
Total Organic Carbon (TOC) / Conductivity 25 °C	This product exhibited less than 500 ppb TOC and conductivity less than 1.3 micro Siemens/cm at 25 °C after a water flush of 36 L.			

*Cage, core, end caps, and capsule housing

Millipak® Final Fill Capsule Filter Specifications

Description	Millipak® Final Fill 20	Millipak® Final Fill 40	Millipak® Final Fill 60	Millipak® Final Fill 100	Millipak® Final Fill 200
Nominal Dimensions					
Maximum length	8.1 cm (3.2 in.)	8.6 cm (3.4 in.)	10.9 cm (4.3 in.)	11.9 cm (4.7 in.)	14.5 cm (5.7 in.)
Body diameter	7.6 cm (3.0 in.)	7.6 cm (3.0 in.)	7.6 cm (3.0 in.)	7.6 cm (3.0 in.)	7.6 cm (3.0 in.)
Body diameter w/ anti-roll edges	–	–	–	8.1 cm (3.2 in.)	8.1 cm (3.2 in.)
Filtration Area	100 cm^2 (0.11 ft^2)	200 cm^2 (0.22 ft^2)	300 cm^2 (0.32 ft^2)	500 cm^2 (0.54 ft^2)	1000 cm^2 (1.08 ft^2)
Aseptic Multi-Purpose Port	3.2 mm ($^1/_8$ in.) hose barb				
Materials of Construction					
Filter membrane:	Hydrophilic PVDF				
Support discs	Polysulfone				
Filter capsule	Polysulfone				
Aseptic Multi-Purpose Port (AMPP)	Polyethersulfone				
AMPP O-rings	Silicone				
Hold-up Volume	20 psi above the Bubble Point Specification for 1 minute				
	1.1 mL	1.5 mL	3.2 mL	4.8 mL	7.2 mL
Maximum Inlet Pressure	60 psi (4.1 bar) at 25 °C	80 psi (5.5 bar) at 25 °C			
Maximum Differential Pressure					
Forward:	60 psi (4.1 bar) at 25 °C 25 psi (1.7 bar) at 80 °C	80 psi (5.5 bar) at 25 °C			
Reverse:	10 psi (0.7 bar) at 25 °C				
Bubble Point at 23 °C	≥ 26 psi (1790 mbar) air with water				
Bacterial Endotoxin	Aqueous extraction contains < 0.25 EU/mL per device as determined using the Limulus Amebocyte Lysate (LAL) test, meeting requirements of USP <85>, EP 2.6.14 and JP 4.01.				
Microbial Challenge Testing	Vents were tested utilizing a bacterial challenge method with 10^7 *Brevundimonas diminuta* assuring a sterile fluid path during actuation.				

Filters Containing Durapore® 0.45 µm Membrane

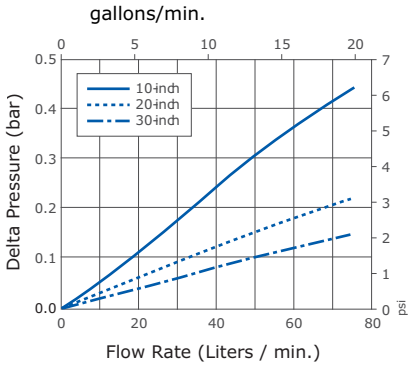
Millipak® Final Fill Capsule Filter Specifications (continued)

Description	Millipak® Final Fill 20	Millipak® Final Fill 40	Millipak® Final Fill 60	Millipak® Final Fill 100	Millipak® Final Fill 200
Total Organic Carbon (TOC) / Conductivity	Samples exhibited < 500 ppb TOC per USP <643> and < 1.3 µS/cm conductivity per USP <645> at 25 °C after sterilization and a water flush of:				
	1.0 L	2.0 L	2.0 L	3.0 L	5.0 L
Sterilization	Device integrity and retention was maintained after 3 autoclave cycles of 90 minutes at 126 °C. Devices can withstand a dose ≤ 40 kGy gamma exposure.				
Toxicity	Component materials meet the criteria for Class VI testing based on USP <88> Biological Reactivity, *in vivo*, USP <87> Biological Reactivity, *in vitro*, and ISO 10993-5 Tests for *in vitro* Cytotoxicity. This product also meets physicochemical specifications, as described in USP <661> Containers-Plastics.				
Particle Shedding	Effluent meets the acceptance criteria set forth in USP <788> for large volume parenterals.				
Non-Fiber Releasing	This product was manufactured with a Durapore® membrane which meets the criteria for a “non-fiber releasing” filter as defined in 21 CFR 210.3 (b)(6), validated based on large volume parenteral specifications as detailed in USP <788> Particulate Matter in Injections.				
Indirect Food Additive	All component materials meet the FDA Indirect Food Additive requirements cited in 21 CFR 177-182 based on information provided by raw material suppliers.				
Quality Management System	These products are manufactured in a facility which is certified to ISO 9001:2015 Quality Management Systems.				

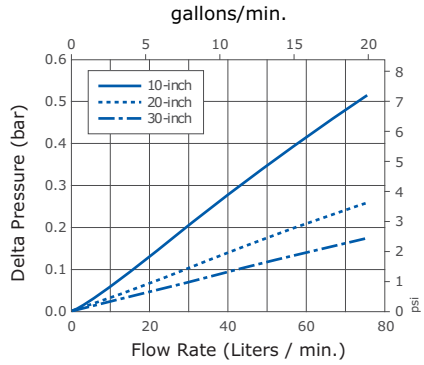
Filters Containing Durapore® 0.45 µm Membrane

Typical Clean Water Flow Rates – Cartridge Filters

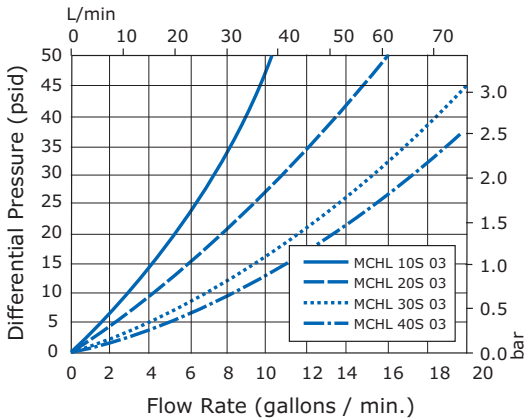
Cartridge Filters - 0.45 µm Durapore® Membrane without Prefilter (CVHL PP)



Cartridge Filters - 0.45 µm Durapore® Membrane with Prefilter (CVHL TP)



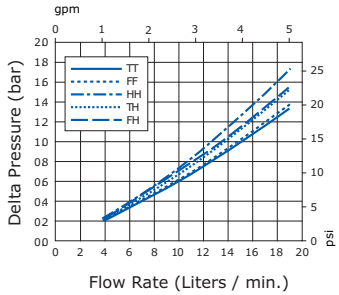
Millidisk® Cartridge Filters – 0.45 µm Hydrophilic Durapore® Membrane



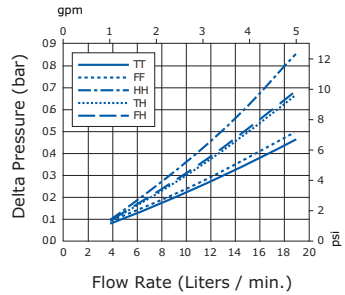
Filters Containing Durapore® 0.45 µm Membrane

Typical Clean Water Flow Rates – Opticap® XL Capsule Filters

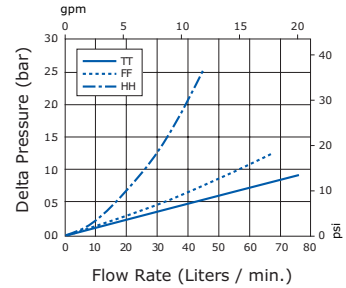
Opticap® XL 2 Capsules – 0.45 µm Durapore® Membrane without prefilter (KPHL)



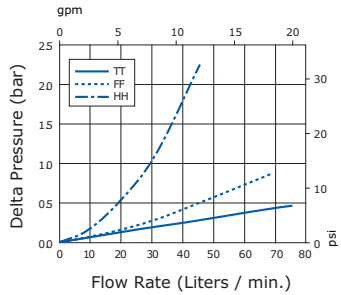
Opticap® XL 4 Capsules – 0.45 µm Durapore® Membrane without prefilter (KPHL)



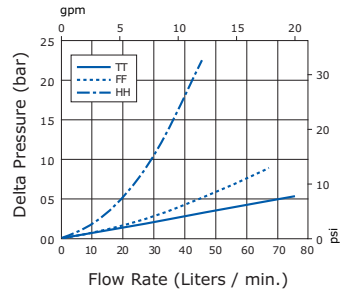
Opticap® XL 5 Capsules – 0.45 µm Durapore® Membrane without prefilter (KPHL)



Opticap® XL 10 Capsules – 0.45 µm Durapore® Membrane without prefilter (KPHL)



Opticap® XL 10 Capsules – 0.45 µm Durapore® Membrane with prefilter (KVHL)



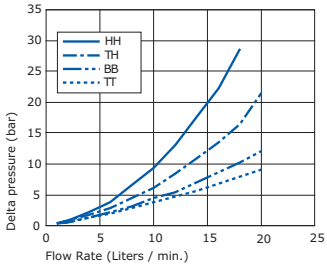
Opticap® XL Capsule Legends Refer to Capsule Connection Type

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

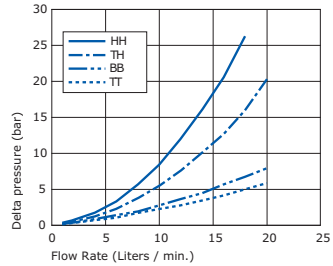
Filters Containing Durapore® 0.45 µm Membrane

Typical Clean Water Flow Rates – Opticap® XLT Capsule Filters

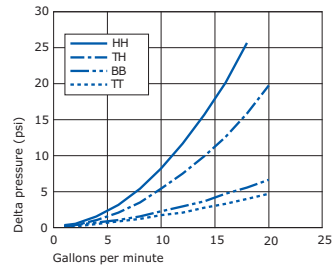
Opticap® XLT 10 Capsules – 0.45 µm Durapore® Membrane without prefilter (KPHL)



Opticap® XLT 20 Capsules – 0.45 µm Durapore® Membrane without prefilter (KPHL)



Opticap® XLT 30 Capsules – 0.45 µm Durapore® Membrane without prefilter (KPHL)

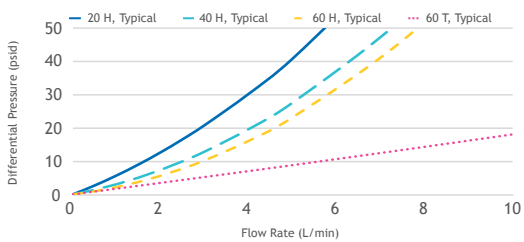


Opticap® XLT Capsule Legends Refer to Capsule Connection Type

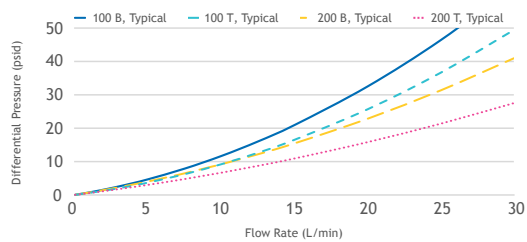
TT = 38 mm (1½ in.) Sanitary Flange Inlet and Outlet
TH = 38 mm (1½ in.) Sanitary Flange Inlet and 16 mm (⅝ in.) Hose Barb Outlet
HH = 16 mm (⅝ in.) Hose Barb Inlet and Outlet
BB = 25 mm (1 in.) Hose Barb Inlet and Outlet

Typical Clean Water Flow Rates – Millipak® Final Fill Capsule Filters

Millipak® Final Fill 20/40/60 Capsules – 0.45 µm Hydrophilic Durapore® Membrane



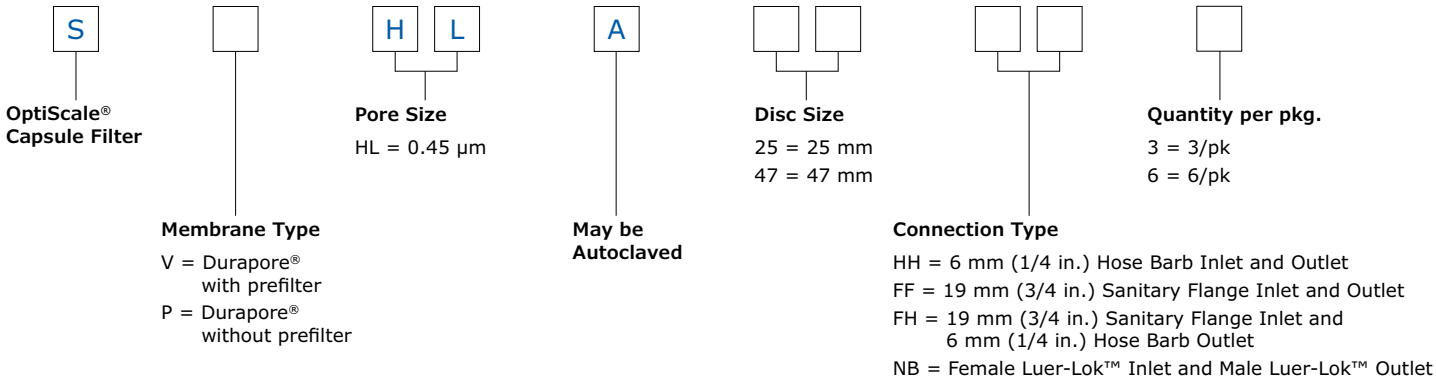
Millipak® Final Fill 100/200 Capsules – 0.45 µm Hydrophilic Durapore® Membrane



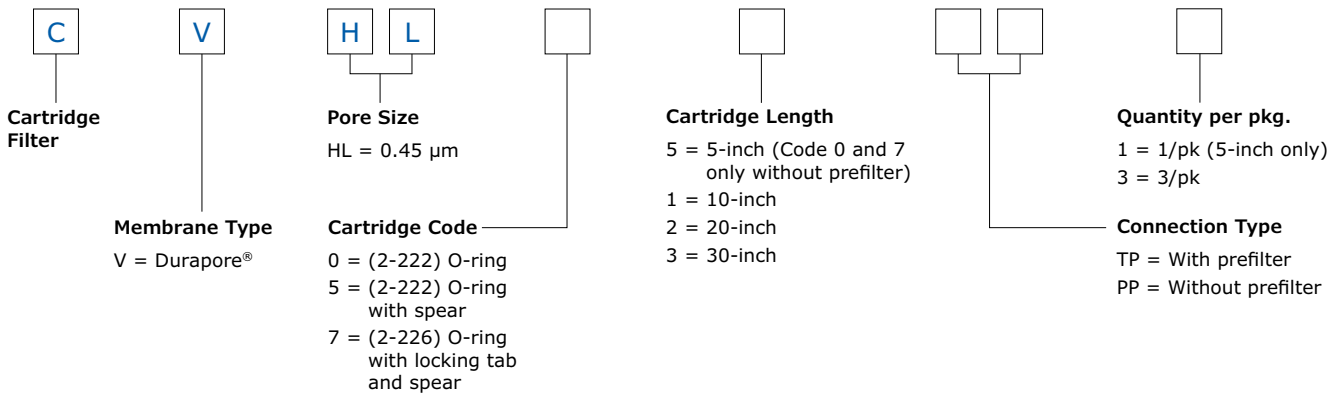
Filters Containing Durapore® 0.45 µm Membrane

Ordering Information

OptiScale® Capsule Filters



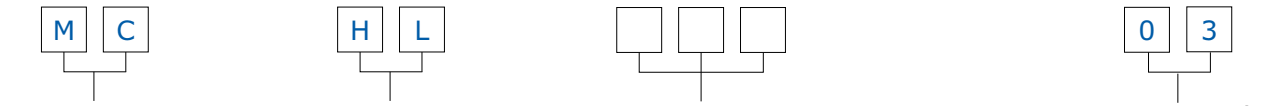
Cartridge Filters



Filters Containing Durapore® 0.45 µm Membrane

Ordering Information

Millidisk® Cartridge Filters



Millidisk® Cartridges

Pore Size

HL = 0.45 µm

Millidisk® Stack Size

40S = 40-stack
30S = 30-stack
20S = 20-stack
10S = 10-stack

Quantity per pkg.

3 = 3/pk

Opticap® XL Capsule Filters

Opticap® XL Capsule Filter

Membrane Type

V = Durapore® with prefilter (Opticap® XL 10 only)
P = Durapore® without prefilter

Pore Size

HL = 0.45 µm

Sterilization

A = Autoclavable
G = Gamma (Opticap® XL 10 only)
S = Sterile (Opticap® XL 10 only)

Capsule Sizes

02 = Opticap® XL 2
04 = Opticap® XL 4
05 = Opticap® XL 5
10 = Opticap® XL 10

Connection Type

TT = 38 mm (1 ½ 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 (1 ½ 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

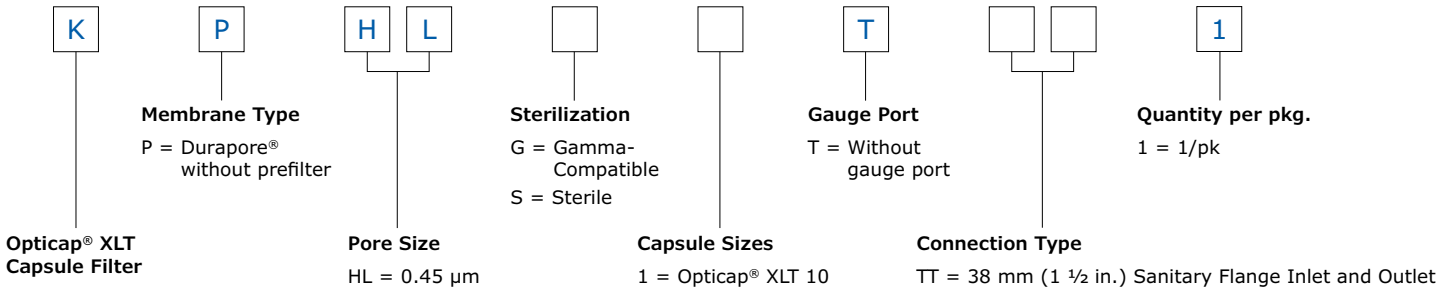
Quantity per pkg.

1 = 1/pk (Opticap® 5 and Opticap® 10 only)
3 = 3/pk (Opticap® XL 2 and Opticap® XL 4 only)

Filters Containing Durapore® 0.45 µm Membrane

Ordering Information

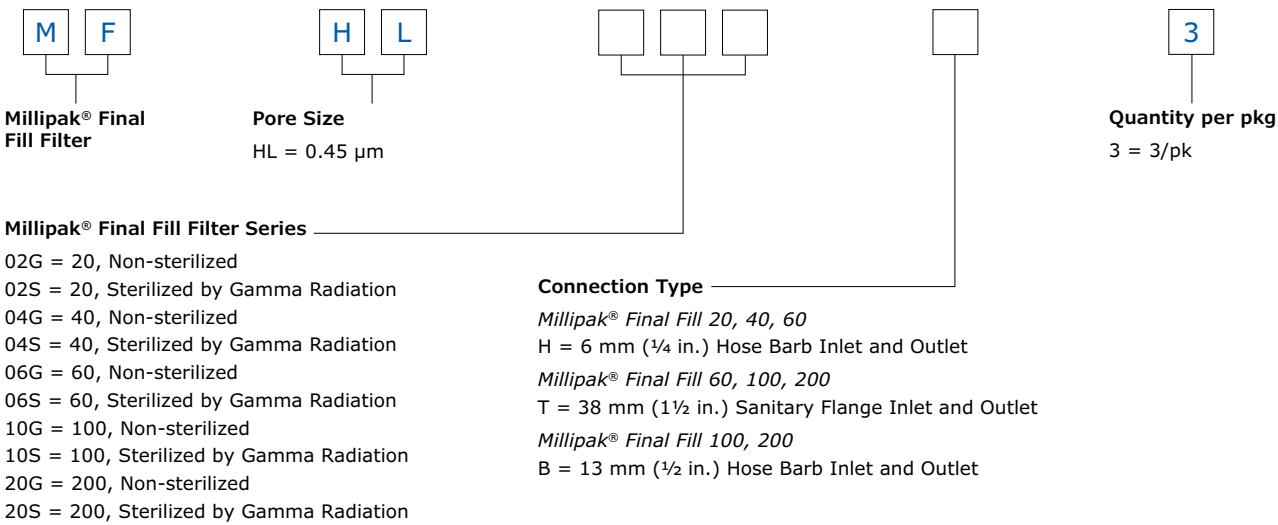
Opticap® XLT Capsule Filters



Accessory

Description	Qty/Pk	Cat. No.
Standard Opticap® XLT Capsule Filter Stand	1/pk	**XLTSTAND1**

Millipak® Final Fill Capsule Filters



Filters Containing Durapore® 5.0 µm Membrane

For particle removal in sterile bulk applications

Filters containing Durapore® 5.0 µm hydrophilic polyvinylidene (PVDF) membrane are ideally suited for removing particles in sterile bulk liquids.

Benefits

- Low protein binding membrane yields high protein recovery with minimal product loss
- Broad chemical compatibility, low extractables
- For filtration processes requiring high flow rates and throughputs

Filter Formats

- Millidisk® cartridges
- Millipak® Final Fill capsules

Filters Containing Durapore® 5.0 µm Membrane

Millidisk® Cartridge Filter Specifications

Description	Millidisk® 10 Filters	Millidisk® 20 Filters	Millidisk® 30 Filters	Millidisk® 40 Filters
Filtration Area	500 cm^2 (0.54 ft^2)	1000 cm^2 (1.08 ft^2)	1500 cm^2 (1.61 ft^2)	2000 cm^2 (2.15 ft^2)
Materials of Construction				
Filter membrane:	Durapore® PVDF membrane			
Structural components:	Polysulfone			
O-rings:	Silicone			
Maximum Differential Pressure				
Forward:	4.1 bar (60 psid) at 25 °C 1.7 bar (25 psid) at 80 °C 345 mbar (5 psid) at 123 °C			
Reverse:	690 mbar (10 psid) at 25 °C			
Connections	Millidisk® filters incorporate a double 2–118 (silicone) O-ring seal and are used with Millidisk® or Millidisk®/ Milligard® stainless steel housings.			
Gravimetric Extractables	Through a water wet membrane at an ambient temperature of 1.5 bar (22 psi):			
	2.5 mg/unit	5 mg/unit	7.5 mg/unit	10 mg/unit
Oxidizable Substances	Meets the USP Oxidizable Substances Test requirements for sterile purified water after steaming and a water flush of 200 mL.			
Bacterial Endotoxin	An aqueous extraction from a Millidisk® filter contains < 0.5 EU/mL bacterial endotoxin as determined by the Limulus Amebocyte Lysate (LAL) test. This meets the requirements of USP <85>.			
Sterilization				
Autoclave:	126 °C, 60 minutes, up to 5 times			
Steam-in-place:	135 °C, 60 minutes, up to 5 times			
Toxicity	Component materials meet the requirements of USP <88> Biological Reactivity Tests for Class VI Plastics.			

Filters Containing Durapore® 5.0 µm Membrane

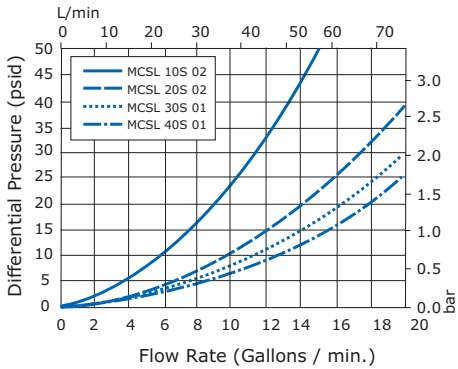
Millipak® Final Fill Capsule Filter Specifications

Description	Millipak® Final Fill 60	Millipak® Final Fill 200
Nominal Dimensions		
Maximum length	10.9 cm (4.3 in.)	14.5 cm (5.7 in.)
Body diameter	7.6 cm (3.0 in.)	7.6 cm (3.0 in.)
Body diameter w/ anti-roll edges	–	8.1 cm (3.2 in.)
Filtration Area	300 cm^2 (0.32 ft^2)	1000 cm^2 (1.08 ft^2)
Materials of Construction		
Filter membrane:	Durapore® PVDF (polyvinylidene fluoride) membrane	
Support discs	Polysulfone	
Filter capsule	Polysulfone	
Aseptic Multi-Purpose Port (AMPP)	Polyethersulfone	
AMPP O-rings	Silicone	
Hold-up Volume	20 psi above the Bubble Point Specification for 1 minute	
	3.2 mL	6.2 mL
Maximum Inlet Pressure	80 psi (5.5 bar) at 25 °C	
Maximum Differential Pressure		
Forward:	50 psi (3.5 bar) at 25 °C 25 psi (1.7 bar) at 80 °C	
Reverse:	10 psi (700 mbar) at 25 °C	
Microbial Challenge Testing	Vents were tested utilizing a bacterial challenge method with 10^7 *Brevundimonas diminuta* assuring a sterile fluid path during actuation.	
Bacterial Endotoxin	Aqueous extraction contains <0.25 EU/mL per device as determined using the Limulus Amebocyte Lysate (LAL) test, meeting requirements of USP <85>, EP 2.6.14 and JP 4.01.	
Total Organic Carbon (TOC) / Conductivity	Samples exhibited < 500 ppb TOC per USP <643> and less than 1.3 µS/cm conductivity per USP <645> at 25 °C after sterilization and a water flush of:	
	2.0 L	5.0 L
Sterilization	Device integrity and retention was maintained after 3 autoclave cycles of 90 minutes at 126 °C. Devices can withstand a dose ≤ 40 kGy gamma exposure.	
Toxicity	Component materials meet the criteria of the USP <88> Biological Reactivity Test for Class VI Plastics.	
Particle Shedding	Effluent meets the acceptance criteria set forth in USP <788> for large volume parenterals.	
Non-Fiber Releasing	This product was manufactured with a Durapore® membrane which meets the criteria for a “non-fiber releasing” filter as defined in 21 CFR 210.3 (b)(6), validated based on large volume parenteral specifications as detailed in USP <788> Particulate Matter in Injections.	
Indirect Food Additive	All component materials meet the FDA Indirect Food Additive requirements cited in 21 CFR 177-182 based on information provided by raw material suppliers.	
Quality Management System	These products are manufactured in a facility which is certified to ISO 9001:2015 Quality Management Systems.	

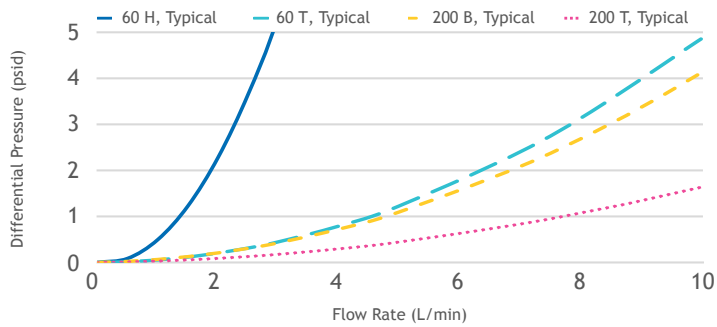
Filters Containing Durapore® 5.0 µm Membrane

Typical Clean Water Flow Rates

Millidisk® Cartridge Filters – 5.0 µm Durapore® Membrane



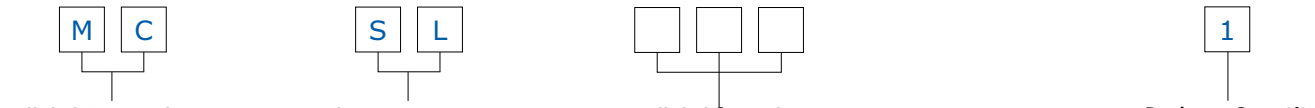
Millipak® Final Fill 60/200 Capsules – 5.0 µm Durapore® Membrane



Filters Containing Durapore® 5.0 µm Membrane

Ordering Information

Millidisk® Cartridge Filters



Millidisk® Cartridges

Membrane Pore Size

SL = Durapore® 5.0 µm

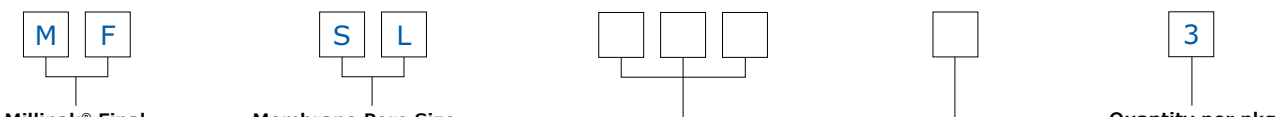
Millidisk® Stack Size

40S = 40-stack
30S = 30-stack
20S = 20-stack
10S = 10-stack

Package Quantity

2 = 2 per package (Millidisk®) 10, 20)
1 = 1 per package (Millidisk®) 30, 40)

Millipak® Final Fill Capsule Filters



Millipak® Final Fill Filter

Membrane Pore Size

SL = Durapore® 5.0 µm

Millipak® Final Fill Filter Series

06G = 60, non-sterilized
06S = 60, sterilized by gamma radiation
20G = 200, non-sterilized
20S = 200, sterilized by gamma radiation

Connection Type

Millipak® Final Fill 60

H = 6 mm (¼ in.) Hose Barb Inlet and Outlet

Millipak® Final Fill 200

B = 13 mm (½ in.) Hose barb inlet and outlet

Millipak® Final Fill 60, 200

T = 38 mm (1½ in.) sanitary flange inlet and outlet

Quantity per pkg.

3 = 3/pk

Durapore® Multimedia Filters

With integrated prefilter for sterile filtration of fouling and plugging solutions

Durapore® Multimedia filters combine a single or double layer of Milligard® prefilter media with a 0.22 µm hydrophilic Durapore® polyvinylidene fluoride (PVDF) membrane in one filter, enabling prefiltration and sterile filtration in a single device.

Benefits

- Process efficiency — prefiltration and sterile filtration in one step
- High retention efficiency and throughput
- Low protein binding membrane yields high protein recovery with minimal product loss
- Broad chemical compatibility, low extractables
- For filtration processes requiring high flow rates and throughputs

Filter Formats

- OptiScale® capsules
- Cartridge filters
- Opticap® XL capsules

Media/Membrane Types

Milligard®/Durapore® Membrane (Single Layer Prefilter)

- 0.2 µm/0.22 µm
- 0.5 µm/0.22 µm
- 1.2 µm/0.22 µm

Milligard® pore sizes are nominal

Milligard®/Durapore® Membrane (Double Layer Prefilter)

- 1.2 µm/0.5 µm/0.22 µm
- 0.5 µm/0.2 µm/0.22 µm
- 1.2 µm/0.2 µm/0.22 µm

Durapore® Multimedia Filters

OptiScale® Capsule Filter Specifications (Single and Double Layer Prefilters)

Description	OptiScale® 25 Capsule	OptiScale® 47 Capsule
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
Body Diameter:	31 mm (1.21 in.)	69 mm (2.75 in.)
Weight:	0.19 oz (5.5 g)	2.3 oz (67 g)
Filtration Area	3.5 cm^2	17.7 cm^2
Materials of Construction		
Filter membrane:	Hydrophilic PVDF	Hydrophilic PVDF
Filter media:	Mixed esters of cellulose	Mixed esters of cellulose
Structural components:	Polypropylene	Polycarbonate
Supports:	Polypropylene	Polypropylene
Vent cap:	Polypropylene	PVDF
Internal seal rings:	—	Fluoroelatomers
Housing Vent	Capped vent with female Luer connections on inlet side of device.	Adjustable vent with male luer 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
Oxidizable Substances	—	Meets the USP Oxidizable Substances Test requirements for sterile purified water after a water flush of ≤ 100 mL.
Sterilization	May be autoclaved for 1 cycle of 60 min at 123 °C.	May be autoclaved for 3 cycles of 60 minutes at 123 °C.
Toxicity	Component materials meet the criteria of the USP <88> Biological Reactivity Test for Class VI Plastics.	
Indirect Food Additive	All component materials meet the FDA Indirect Food Additive requirements cited in 21 CFR 177-182 based on information provided by raw material suppliers.	

Opticap® XL Capsule and Cartridge Filter Specifications

Description	Opticap® XL 10 Capsule		Cartridge (per 10-inch)	
	Single Layer Prefilter	**Double Layer Prefilter**	**Single Layer Prefilter**	**Double Layer Prefilter**
Nominal Dimensions				
Maximum length:	33.5 cm (13.2 in.)	33.5 cm (13.2 in.)	—	—
Body diameter:	10.7 cm (4.2 in.)	10.7 cm (4.2 in.)	6.9 cm (2.7 in.)	6.9 cm (2.7 in.)
Filtration Area	0.69 m^2 (7.4 ft^2)	0.56 m^2 (6.0 ft^2)	0.69 m^2 (7.4 ft^2)	0.56 m^2 (6.0 ft^2)
Materials of Construction				
Filter membrane:	Hydrophilic PVDF		Hydrophilic PVDF	
Filter media:	Mixed esters of cellulose		Mixed esters of cellulose	
Film edge:	Polypropylene		Polypropylene	
Structural components:	Polypropylene		Polypropylene	
Supports:	Polypropylene		Polypropylene	
Vent O-rings:	Silicone		—	
O-rings:	—		Silicone	
Housing Vent	$^1/_4$ in. hose barb with double O-ring seal		—	
Nominal Vent to Vent Diameter	14.5 cm (5.7 in.)			

Durapore® Multimedia Filters

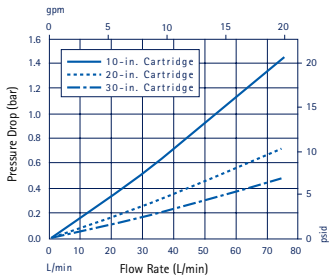
Opticap® XL Capsule and Cartridge Filter Specifications (continued)

Description	Opticap® XL 10 Capsule		Cartridge (per 10-inch)	
	Single Layer Prefilter	**Double Layer Prefilter**	**Single Layer Prefilter**	**Double Layer Prefilter**
Housing Vent	$^1/_4$ in. hose barb with double O-ring seal		—	—
Maximum Inlet Pressure	5.5 bar (80 psi) at 25 °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 1.0 bar (15 psid) at 80 °C		5.5 bar (80 psid) at 25 °C 1.7 bar (25 psid) at 80 °C 345 mbar (5 psid) at 123 °C	
Reverse:	3.4 bar (50 psid) at 25 °C		3.4 bar (50 psid) at 25 °C, intermittent	
Bubble Point at 23 °C	≥ 3450 mbar (50.0 psig) air with water			
Air Diffusion	Through a water wet membrane at 23 °C at 2.8 bar (40 psi): ≤ 13.3 cc/min	≤ 10.8 cc/min	≤ 13.3 cc/min	≤ 10.8 cc/min
Gravimetric Extractables	After autoclaving and a 24-hour soak in ASTM® Type 1 reagent grade water at controlled room temperature: ≤ 50 mg	≤ 75 mg	≤ 45 mg	≤ 70 mg
Bacterial Endotoxin	Aqueous extraction contains < 0.5 EU/mL as determined by the Limulus Amebocyte Lysate (LAL) Test. This meets the requirements of USP <85>.			
Oxidizable Substances	Meets the USP Oxidizable Substances Test requirements for Sterile Purified Water after a water flush of: ≤ 5000 mL		≤ 5000 mL	
Bacterial Retention	Quantitative retention of 10^7 CFU/cm^2 *Brevundimonas diminuta* ATCC® 19146 per ASTM® F838 methodology.			
Sterilization	May be autioclaved for 3 cycles of 60 cycles of 60 min. at 123 °C. (Cannot be steam sterilized in-line).		May be autoclaved for 6 cycles of 30 min. at 123 °C or steam sterilized for 6 cycles of 30 min. at 123 °C.	
Non-Fiber Releasing	Durapore® and Milligard® membranes meet the criteria for a “non-fiber releasing” filter as defined in 21 CFR 210.3 (b) (6).			
Toxicity	Component materials meet the criteria of the USP <88> Biological Reactivity Test for Class VI Plastics.			
Indirect Food Additive	All component materials meet the FDA Indirect Food Additive requirements cited in 21 CFR 177-182 based on information provided by raw material suppliers.			
European Pressure Equipment Directive	This product complies with the European Pressure Equipment Directive, 2014/68/EU of 15 May 2014. This product has been classified under article 4 § 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 4 § 3 of the Directive, 2014/68/EU, this product does not bear the CE mark.		—	

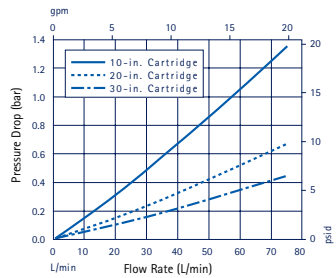
Durapore® Multimedia Filters

Typical Clean Water Flow Rates

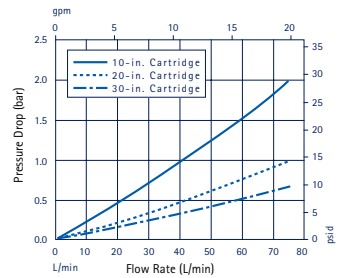
Cartridge Filter – Multimedia Durapore® 0.5/0.22 µm (CV06)



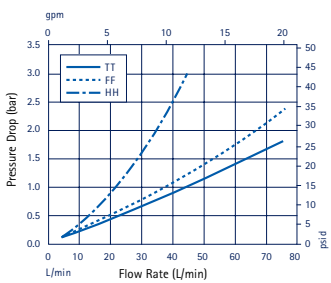
Cartridge Filter – Multimedia Durapore® 1.2/0.22 µm (CV19)



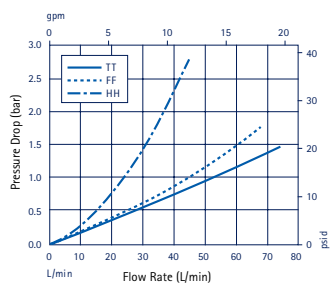
Cartridge Filter – Multimedia Durapore® 0.5/0.2/0.22 µm (CVSS)



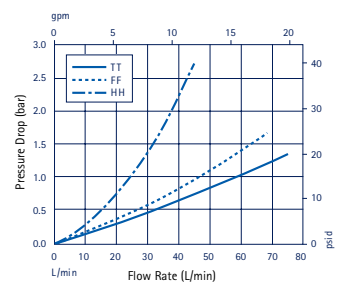
Opticap® XL 10 Capsule — Multimedia Durapore® 0.2/0.22 µm (KV03)



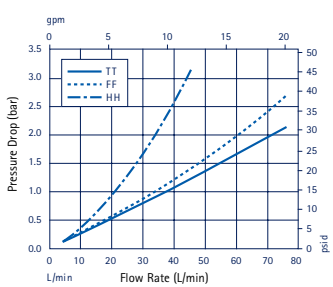
Opticap® XL 10 Capsule — Multimedia Durapore® 0.5/0.22 µm (KV06)



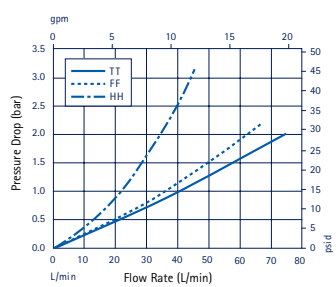
Opticap® XL 10 Capsule — Multimedia Durapore® 1.2/0.22 µm (KV19)



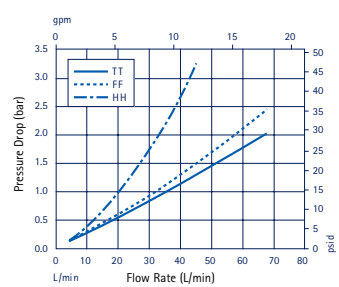
Opticap® XL 10 Capsule — Multimedia Durapore® 1.2/0.5/0.22 µm (KVSC)



Opticap® XL 10 Capsule — Multimedia Durapore® 0.5/0.2/0.22 µm (KVSS)



Opticap® XL 10 Capsule — Multimedia Durapore® 1.2/0.2/0.22 µm (KVSX)



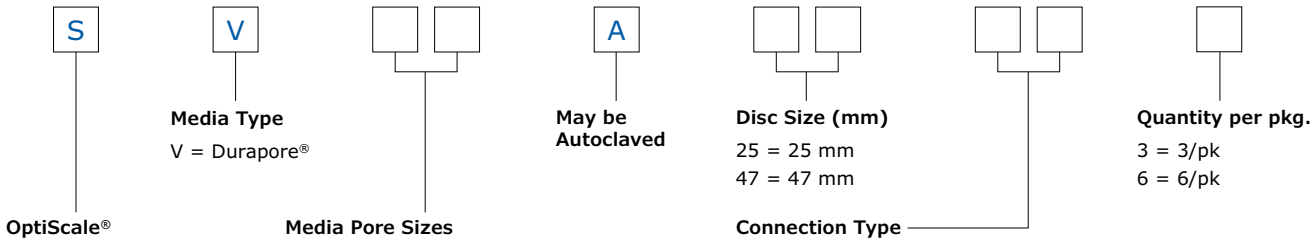
Opticap® XL Legends Refer to Capsule Connection Type

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

Durapore® Multimedia Filters

Ordering Information

OptiScale® Capsule Filters



OptiScale® Capsule Filter

Media Type

V = Durapore®

Media Pore Sizes

Multimedia: Milligard® (nominal)/ Durapore®

03 = 0.2 µm/0.22 µm
06 = 0.5 µm/0.22 µm
19 = 1.2 µm/0.22 µm

Multimedia: Milligard® (nominal)/ Milligard® (nominal)/Durapore®

SC = 1.2 µm/0.5 µm/0.22 µm
SS = 0.5 µm/0.2 µm/0.22 µm
SX = 1.2 µm/0.2 µm/0.22 µm

May be Autoclaved

Disc Size (mm)

25 = 25 mm
47 = 47 mm

Connection Type

For 25 mm size only

NB = Female Luer-Lok™ Inlet/Male Luer Slip Outlet

For 47 mm size only

HH = 6 mm (¼ in.) Hose Barb Inlet and Outlet
FF = 19 mm (¾ in.) Sanitary Flange Inlet and Outlet
FH = 19 mm (¾ in.) Sanitary Flange Inlet and 6 mm (¼ in.) Hose Barb Outlet

Quantity per pkg.

3 = 3/pk
6 = 6/pk

Cartridge Filters

Cartridge Filter

Media Type

V = Durapore®

Media Pore Sizes

Multimedia: Milligard® (nominal)/ Durapore®

03 = 0.2 µm/0.22 µm
06 = 0.5 µm/0.22 µm
19 = 1.2 µm/0.22 µm

Multimedia: Milligard® (nominal)/ Milligard® (nominal)/Durapore®

SC = 1.2 µm/0.5 µm/0.22 µm
SS = 0.5 µm/0.2 µm/0.22 µm
SX = 1.2 µm/0.2 µm/0.22 µm

Cartridge Code

0 = (2-222) O-ring
7 = (2-226) O-ring with locking tab and spear

Cartridge Length

1 = 10-inch
2 = 20-inch
3 = 30-inch

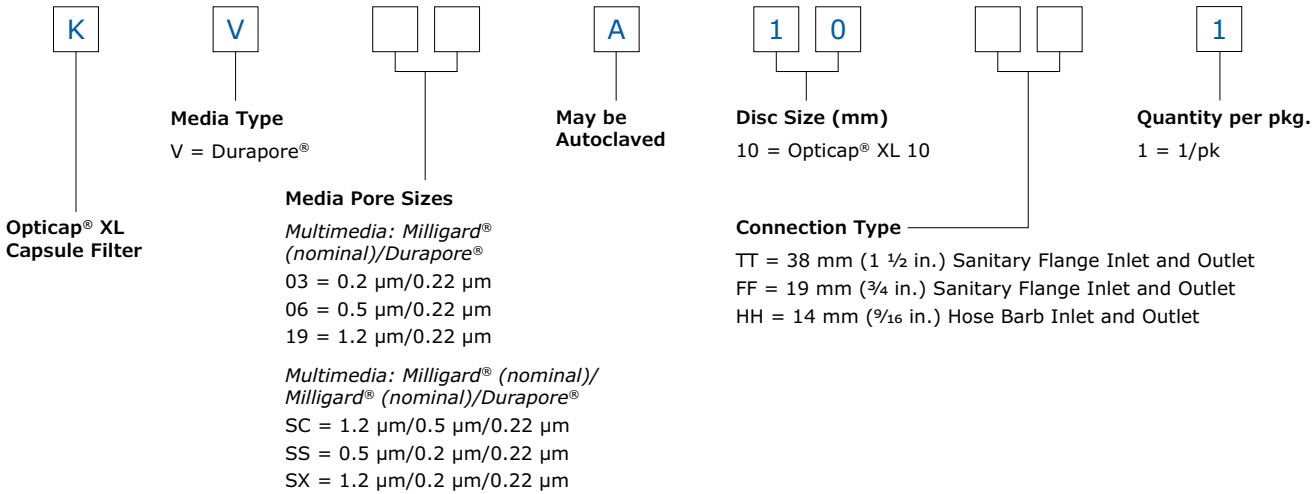
Quantity per pkg.

3 = 3/pk

Durapore® Multimedia Filters

Ordering Information

Opticap® XL Capsule Filters



Filters Containing Charged Durapore® 0.22 µm Membrane

For sterile filtration, endotoxin removal and low preservative adsorption

Filters containing charged Durapore® 0.22 µm membrane are designed for sterile filtration and endotoxin removal from pharmaceutical-grade water systems. These filters are manufactured from 0.22 µm hydrophilic polyvinylidene fluoride (PVDF) membrane modified to have a net positive charge which enables binding of negatively charged endotoxins that would otherwise pass through 0.22 µm sterilizing-grade filters. Charged Durapore® filters reduce adsorptive loss of positively charged preservatives and quartenary amines.

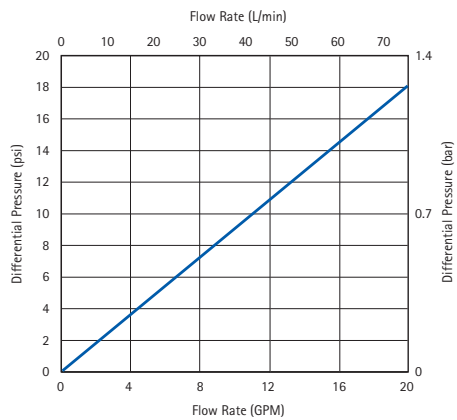
Benefits

- Positively charged membrane that removes negatively charged species such as endotoxins and minimizes adsorption of quaternary amines and other positively charged preservatives
- Low protein binding membrane yields high protein recovery with minimal product loss
- Broad chemical compatibility, low extractables
- For filtration processes requiring high flow rates and throughputs

Filter Formats

- Cartridge filters
- Optiseal® cartridge filters

Typical water flow rate at 23 °C



Filters Containing Charged Durapore® 0.22 µm Membrane

Optiseal® Cartridge and Cartridge Filter Specifications

Description	Optiseal® Cartridge	Cartridge (per 10-inch)
Effective Filtration Area	1.9 ft^2 (0.2 m^2) per 4-inch (10.2 cm) Optiseal® cartridge	7.4 ft^2 (0.7 m^2)
Materials of Construction	Modified polyvinylidene fluoride (PVDF) membrane with a net positive charge. Non-woven polypropylene pleat supports upstream and downstream. Rigid polypropylene outer sleeve, core, end caps and adapter. Silicone O-rings.	
Endotoxin Removal	Charged Durapore® membrane samples exhibit LRV >5 when challenged with 10^6 pg/mL of purified *Escherichia coli* (Type 055:B5 LPS) endotoxins.	
Integrity Test	Each cartridge must pass our integrity test, which is correlated to the *B. diminuta* ASTM® bacterial challenge test.	
Bacterial Retention	Quantitative retention of 10^7 CFU/cm² *Brevundimonas diminuta* ATCC® 19146 per ASTM© F838 methodology.	
Bubble Point at 23 °C	≥ 3100 mbar (45.0 psig) air with water	
Bacterial Endotoxin	Aqueous extraction contains <0.5 EU/mL as determined by the Limulus Amebocyte Lysate (LAL) Test. This meets the requirements of USP <85>.	
Thermal Stress Resistance	135 °C, 30 minutes, up to 10 times, Steam-in-Place	
Hydraulic Stress Resistance	80 psid (5.5 bar) at 25 °C in the forward direction 50 psid (3.4 bar) at 25 °C in the reverse direction	
Toxicity	Component materials meet the criteria of the USP <88> Reactivity Test for Class VI Plastics. This product is non-cytotoxic per ISO 10993-5 and USP <87> Cytotoxicity MEM Elution Test.	
Total Organic Carbon (TOC) / Conductivity	Samples exhibited < 500 ppb TOC per USP <643> after sterilization and a WFI water flush of: 2.0 L at 250 mL/min per 4 in. Optiseal® cartridge	5.5 L at 500 mL/min per 10 in. cartridge
Non-Fiber Releasing	Meets the criteria for a non-fiber releasing filter as defined in the Code of Federal Regulations 21 CFR 210.3 (b) (6).	
Air Diffusion in Water at 23 °C	≤ 4.0 cc/min at 30 psid (2.07 bar) in the forward direction per 4-inch (10.2 cm) Optiseal® cartridge.	≤ 10.0 cc/min at 30 psid (2.07 bar) in the forward direction per 10-inch (25.4 cm) cartridge.
Water Flow Rate/Pressure Drop	≤ 8 psid (0.55 bar) at 2 gpm (7.6 Lpm) per 4-inch (10.2 cm) Optiseal® cartridge at 23 °C.	≤ 3 psid (0.21 bar) at 2 gpm (7.6 Lpm) per 10-inch (25.4 cm) cartridge at 23 °C.

Filters Containing Charged Durapore® 0.22 µm Membrane

Ordering Information

Cartridge Filters

C	C	G L			T P	1
Cartridge Filter	**Media Type** C = Charged Durapore®	**Pore Size** GL = 0.22 µm	**Cartridge Code** 0 = (2-222) O-ring 5 = (2-222) O-ring with spear assembly 7 = (2-226) O-ring with locking outlet and spear assembly 8 = Concentric O-ring with spear assembly	**Cartridge Length** 1 = 10-inch 2 = 20-inch 3 = 30-inch	TP = With prefilter	**Quantity per pkg.** 1 = 1/pk

Optiseal® Cartridge Filters

L	C	G L	0	4	T P	6
Optiseal® Cartridge Filter	**Media Type** C = Charged Durapore®	**Pore Size** GL = 0.22 µm	**Cartridge Code** 0 = (2-123) O-ring	**Cartridge Length** 4 = 4-inch	TP = With prefilter	**Quantity per pkg.** 6 = 6/pk

Filters Containing Multilayer Durapore® 0.45/0.22 µm Membrane

High throughput filters for sterile filtration of challenging streams

Filters containing multilayer Durapore® 0.45/0.22 µm hydrophilic polyvinylidene fluoride (PVDF) membrane provide sterilizing-grade performance for difficult-to-filter streams. These filters improve process efficiency with high product recovery, extended throughput and low pressure drops.

Benefits

- Dual layer filter maximizes product recovery and throughput with low pressure drop
- Low protein binding membrane yields high protein recovery with minimal product loss
- Broad chemical compatibility, low extractables
- For filtration processes requiring high flow rates and throughputs

Filter Formats

- OptiScale® capsules
- Cartridge filters
- Opticap® XL and XLT capsules

Filters Containing Multilayer Durapore® 0.45/0.22 µm Membrane

OptiScale® Capsule and Cartridge Filter Specifications

Description	OptiScale® 25 Capsule	OptiScale® 47 Capsule	Cartridge (per 10-inch)
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	25.4 cm (10 in.)
Body Diameter:	31 mm (1.21 in.)	69 mm (2.75 in.)	6.9 cm (2.7 in.)
Weight:	0.19 oz (5.5 g)	2.3 oz (67 g)	—
Filtration Area	3.5 cm^2	17.7 cm^2	0.55 m^2 (6.0 ft^2)
Materials of Construction			
Filter membrane:	Dual layer hydrophilic PVDF	Dual layer hydrophilic PVDF	Dual layer hydrophilic PVDF
Structural components*:	Polypropylene	Polycarbonate	Polypropylene
Supports:	Polypropylene	Polypropylene	Polypropylene
Vent cap:	Polypropylene	PVDF	—
O-rings:	—	Fluoroelastomers	Silicone
Housing Vent	Capped vent with female Luer connections on inlet side of device.	Adjustable vent with male luer 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	—
Maximum Differential Pressure			
Forward:	4.1 bar (60 psi) at 25 °C	—	5.5 bar (80 psid) at 25 °C
Reverse:	0 bar (0 psi)	—	1.75 bar (25 psid) at 80 °C 345 mbar (5 psid) at 135 °C 3.4 bar (50 psid) at 25 °C, intermittent
Bubble Point at 23 °C	—	≥ 3450 mbar (50.0 psig) air with water	≥ 3450 mbar (50.0 psig) air with water
Air Diffusion	—	—	Through a water wet membrane at 2.8 bar (40 psig) at ambient temperature: ≤ 10.8 cc/min per 10-inch element
Bacterial Retention	—	—	Quantitative retention of 10^7 CFU/ cm^2 *Brevundimonas diminuta* per ASTM® F838 methodology.
Bacterial Endotoxin	Aqueous extraction contains < 0.25 EU/mL as determined by the Limulus Amebocyte Lysate (LAL) Test. Meets the requirements of USP <85>.	—	Aqueous extraction contains < 0.25 EU/mL as determined by the Limulus Amebocyte Lysate (LAL) test. Meets the requirements of USP <85>.
Total Organic Carbon (TOC) / Conductivity	Autoclaved filter effluent meets the WFI requirement of USP <643>, for Total Organic Carbon and USP <645> for Water Conductivity at 25 ºC after a WFI flush of 35 mL.	—	Autoclaved cartridges meet the requirements of USP <643> for Total Organic Compounds and USP <645> for Water Conductivity at 25 ºC after a WFI water flush of 16 liters.

Filters Containing Multilayer Durapore® 0.45/0.22 µm Membrane

OptiScale® Capsule and Cartridge Filter Specifications (continued)

Description	OptiScale® 25 Capsule	OptiScale® 47 Capsule	Cartridge (per 10-inch)
Oxidizable Substances	—	Effluent meets the USP Oxidizable Substance Test requirements for Sterile Purified Water after a water flush of ≤ 100 mL	Effluent meets the USP Oxidizable Substance Test requirements for Sterile Purified Water after a water flush of ≤ 1500 mL per 10-inch element
Sterilization	May be autoclaved for 1 cycle of 60 minutes at 123 °C.	May be autoclaved for 3 cycles of 60 minutes at 126 °C.	May be autoclaved for 30 cycles of 60 minutes at 126 °C or steam sterilized up to 30 times for 30 minutes at 135 °C
Toxicity	Component materials meet the criteria of the USP <88> Biological Reactivity Test for Class VI Plastics.		
Indirect Food Additive	All component materials meet the FDA Indirect Food Additive requirements cited in 21 CFR 177-182 based on information provided by raw material suppliers.		

* Cage, core, end caps and capsule housing

Opticap® XL and XLT Autoclavable Capsule Filter Specifications

Description	Opticap® XL 10	Opticap® XLT 10	Opticap® XLT 20	Opticap® XLT 30
Nominal Dimensions				
Maximum length:	33.5 cm (13.2 in.)	37.6 cm (14.8 in.)	62.5 cm (24.6 in.)	87.1 cm (34.3 in.)
Body diameter:	10.7 cm (4.2 in.)	—	—	—
Fitting to Fitting				
Sanitary flange to sanitary flange:	—	15.2 cm (6.0 in.)	15.2 cm (6.0 in.)	15.2 cm (6.0 in.)
Sanitary flange to hose barb:	—	17.5 cm (6.9 in.)	17.5 cm (6.9 in.)	17.5 cm (6.9 in.)
Hose barb to hose barb:	—	19.8 cm (7.8 in.)	19.8 cm (7.8 in.)	19.8 cm (7.8 in.)
Filtration Area	0.55 m^2 (6.0 ft^2)	0.55 m^2 (6.0 ft^2)	1.1 m^2 (12 ft^2)	1.65 m^2 (18 ft^2)
Materials of Construction				
Filter membrane:	Dual layer hydrophilic PVDF			
Supports:	Polypropylene			
Structural components*:	Polypropylene			
Vent O-rings:	Silicone			
Vent/Drain	$^1/_4$ 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, 1.75 bar (25 psid) at 80 °C			
Reverse:	3.5 bar (50 psid) at 25 °C, intermittent			
Bubble Point at 23 °C	≥ 3450 mbar (50.0 psig) air with water			
Air Diffusion	Through a water wet membrane at 2.8 bar (40 psig) at ambient temperature:			
	≤ 10.8 cc/min	≤ 10.8 cc/min	≤ 21.6 cc/min	≤ 32.4 cc/min

Filters Containing Multilayer Durapore® 0.45/0.22 µm Membrane

Opticap® XL and XLT Autoclavable Capsule Filter Specifications (continued)

Description	Opticap® XL 10	Opticap® XLT 10	Opticap® XLT 20	Opticap® XLT 30
Total Organic Carbon (TOC) / Conductivity	Autoclaved filter effluent meets the WFI requirements of USP <643> for Total Organic Carbon and USP <645> for Water Conductivity at 25 ºC after a WFI water flush of:			
	16 L	16 L	32 L	48 L
Oxidizable Substances	Meets the USP Oxidizable Substances Test requirements for Sterile Purified Water after a water flush of:			
	≤ 1500 mL	≤ 1500 mL	≤ 3000 mL	≤ 4500 mL
Bacterial Endotoxin	Aqueous extraction contains < 0.25 EU/mL as determined by the Limulus Amebocyte Lysate (LAL) Test. This meets the requirements of USP <85>.			
Bacterial Retention	Quantitative retention of 10^7 CFU/cm² *Brevundimonas diminuta* ATCC® 19146 per ASTM® F838 methodology.			
Sterilization	May be autoclaved for 3 cycles of 60 minutes at 126 °C. (Cannot be steam sterilized in-line.)			
Non-Fiber Releasing	Durapore® membrane meets the criteria for a "non-fiber releasing" filter as defined in 21 CFR 210.3 (b) (6).			
Toxicity	Component materials meet the criteria of the USP <88> Biological Reactivity Test for Class VI Plastics.			
Indirect Food Additive	All component materials meet the FDA Indirect Food Additive requirements cited in 21 CFR 177-182 based on information provided by raw material suppliers.			

*Cage, core, end caps, and capsule housing

Opticap® XL and XLT Sterile and Gamma-Compatible Capsule Filter Specifications

Description	Opticap® XL 10	Opticap® XLT 10	Opticap® XLT 20	Opticap® XLT 30
Nominal Dimensions				
Maximum length:	33.5 cm (13.2 in.)	37.6 cm (14.8 in.)	62.5 cm (24.6 in.)	87.1 cm (34.3 in.)
Body diameter:	10.7 cm (4.2 in.)	—	—	—
Fitting to Fitting				
Sanitary flange to sanitary flange:	—	15.2 cm (6.0 in.)	15.2 cm (6.0 in.)	15.2 cm (6.0 in.)
Sanitary flange to hose barb:	—	17.5 cm (6.9 in.)	17.5 cm (6.9 in.)	17.5 cm (6.9 in.)
Hose barb to hose barb:	—	19.8 cm (7.8 in.)	19.8 cm (7.8 in.)	19.8 cm (7.8 in.)
Filtration Area	0.60 m² (6.5 ft²)	0.60 m² (6.5 ft²)	1.2 m² (13 ft²)	1.81 m² (19.8 ft²)
Materials of Construction				
Filter membrane:	Dual layer hydrophilic PVDF			
Film Edge:	Polyethylene			
Supports:	Polyester/Polyethylene			
Structural components*:	Gamma-stable polypropylene			
Vent O-rings:	One inner silicone-coated ethylene propylene diene monomoer (EPDM) O-ring. One outer silicone O-ring.			
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, 1.05 bar (15 psid) at 80 °C			
Reverse:	3.5 bar (50 psid) at 25 °C, intermittent			

Filters Containing Multilayer Durapore® 0.45/0.22 µm Membrane

Opticap® XL and XLT Sterile and Gamma-Compatible Capsule Filter Specifications (continued)

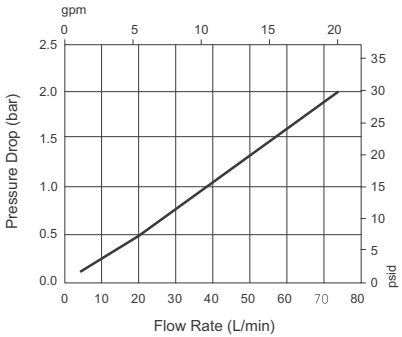
Description	Opticap® XL 10	Opticap® XLT 10	Opticap® XLT 20	Opticap® XLT 30
Bubble Point at 23 °C	≥ 3450 mbar (50.0 psig) air with water			
Air Diffusion	Through a water wet membrane at 2.8 bar (40 psig) at ambient temperature:			
	≤ 15.0 cc/min	≤ 15.0 cc/min	≤ 30.0 cc/min	≤ 45.0 cc/min
Total Organic Carbon (TOC) / Conductivity	Filter effluent meets the WFI requirements of USP <643> for Total Organic Carbon and USP <645> for Water Conductivity at 25 ºC after a WFI water flush of:			
	36 L	36 L	72 L	108 L
Oxidizable Substances	Meets the USP Oxidizable Substances Test requirements for Sterile Purified Water after a water flush of:			
	≤ 1500 mL	≤ 1500 mL	≤ 3000 mL	≤ 4500 mL
Bacterial Endotoxin	Aqueous extraction contains < 0.25 EU/mL as determined by the Limulus Amebocyte Lysate (LAL) Test. This meets the requirements of USP <85>.			
Bacterial Retention	Quantitative retention of 10^7 CFU/cm^2 *Brevundimonas diminuta* ATCC® 19146 per ASTM® F838 methodology.			
Sterilization				
Gamma-compatible:	Gamma-compatible to 45 kGy. May be autoclaved for 3 cycles of 60 minutes at 123 °C. (Cannot be steam sterilized in-line.)			
Sterile capsules:	May be autoclaved for 3 cycles of 60 minutes at 123 °C. (Cannot be steam sterilized in-line.)			
Sterility (Sterile capsules only)	Meets current USP and AAMI guidelines for sterility utilizing a validated sterilization cycle.			
Non-Fiber Releasing	Meets the criteria for a “non-fiber releasing” filter as defined in 21 CFR 210.3 (b) (6).			
Toxicity	Component materials meet the criteria of the USP <88> Biological Reactivity Test for Class VI Plastics.			
Indirect Food Additive	All component materials meet the FDA Indirect Food Additive requirements cited in 21 CFR 177-182 based on information provided by raw material suppliers.			

*Cage, core, end caps, and capsule housing

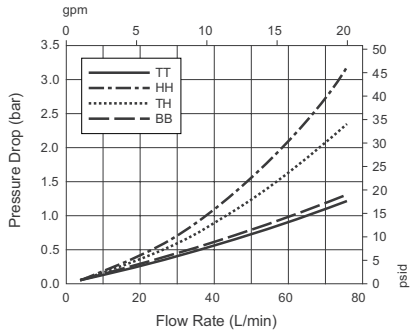
Filters Containing Multilayer Durapore® 0.45/0.22 µm Membrane

Typical Clean Water Flow Rates – Cartridge and Autoclavable Capsule Filters

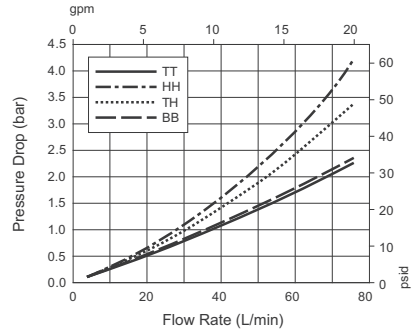
Cartridge Filters — Multilayer Durapore® 0.45/0.22 µm Membrane



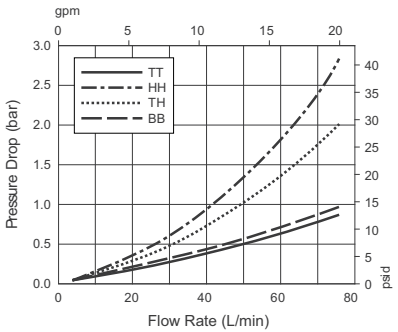
Opticap® XL 10 Capsules — Multilayer Durapore® 0.45/0.22 µm Membrane



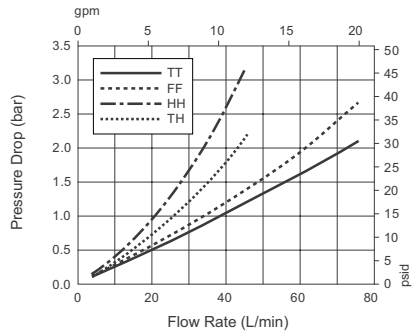
Opticap® XLT 10 Capsules — Multilayer Durapore® 0.45/0.22 µm Membrane



Opticap® XLT 20 Capsules — Multilayer Durapore® 0.45/0.22 µm Membrane



Opticap® XLT 30 Capsules — Multilayer Durapore® 0.45/0.22 µm Membrane



Opticap® XL Capsule Legends Refer to 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

Opticap® XLT Capsule Legends Refer to Connection Type

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

HH = 16 mm (⅝ in.) Hose Barb Inlet and Outlet

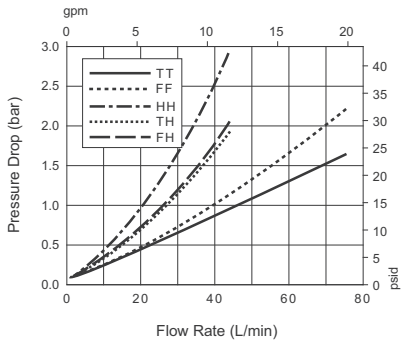
TH = 38 mm (1½ in.) Sanitary Flange Inlet and 16 mm (⅝ in.) Hose Barb Outlet

BB = 25 mm (1 in.) Hose Barb Inlet and Outlet

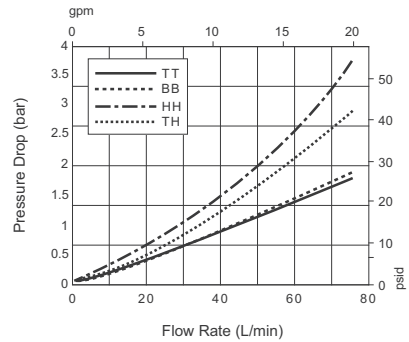
Filters Containing Multilayer Durapore® 0.45/0.22 µm Membrane

Typical Clean Water Flow Rates – Sterile and Gamma-Compatible Capsules

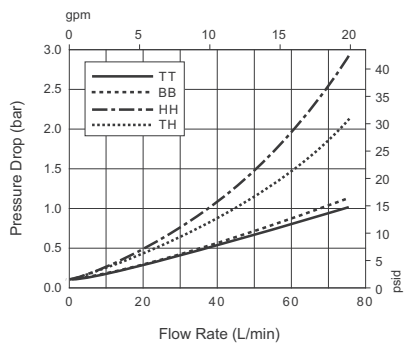
Opticap® XL 10 Capsules — Multilayer Durapore® 0.45/0.22 µm Membrane



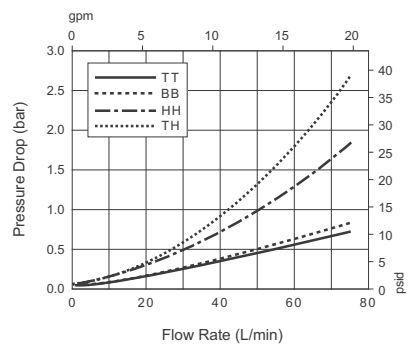
Opticap® XLT 10 Capsules — Multilayer Durapore® 0.45/0.22 µm Membrane



Opticap® XLT 20 Capsules — Multilayer Durapore® 0.45/0.22 µm Membrane



Opticap® XLT 30 Capsules — Multilayer Durapore®0.45/0.22 µm Membrane



Opticap® XL Capsule Legends Refer to 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

Opticap® XLT Capsule Legends Refer to Connection Type

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

HH = 16 mm (⅝ in.) Hose Barb Inlet and Outlet

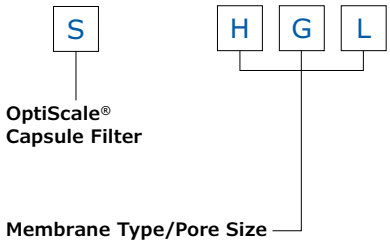
TH = 38 mm (1½ in.) Sanitary Flange Inlet and 16 mm (⅝ in.) Hose Barb Outlet

BB = 25 mm (1 in.) Hose Barb Inlet and Outlet

Filters Containing Multilayer Durapore® 0.45/0.22 µm Membrane

Ordering Information

OptiScale® Capsule Filters



OptiScale® Capsule Filter

Membrane Type/Pore Size

HGL = Hydrophilic Multilayer Durapore® 0.45 µm/0.22 µm

Sterilization

A = Autoclavable

Capsule Size

25 = 25 mm

47 = 47 mm

Connection Type

HH = 6 mm (1/4 in.) Hose Barb Inlet and Outlet

FF = 19 mm (3/4 in.) Sanitary Flange Inlet and Outlet

FH = 19 mm (3/4 in.) Sanitary Flange Inlet and 6 mm (1/4 in.) Hose Barb Outlet

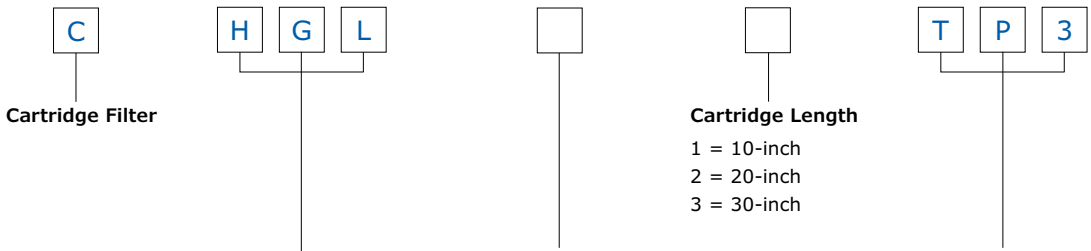
NB = Female Luer-Lok™ Inlet and Male Luer-Lok™ Outlet

Quantity per pkg.

3 = 3/pk

6 = 6/pk

Cartridge Filters



Cartridge Filter

Membrane Type/Pore Size

HGL = Hydrophilic Multilayer Durapore® 0.45 µm/0.22 µm

Cartridge Length

1 = 10-inch

2 = 20-inch

3 = 30-inch

Cartridge Code

0 = (2-222) O-ring

7 = (2-226) O-ring locking adapter and spear

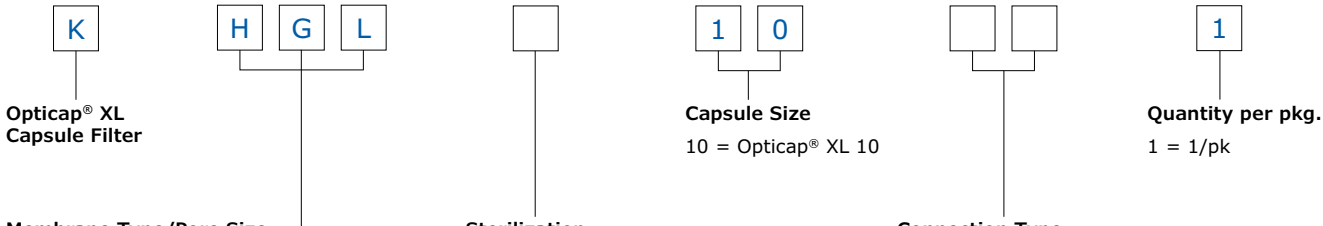
Quantity per pkg.

TP3 = 3/pk

Filters Containing Multilayer Durapore® 0.45/0.22 µm Membrane

Ordering Information

Opticap® XL Capsule Filters



Opticap® XL Capsule Filter

Membrane Type/Pore Size

HGL = Hydrophilic Multilayer Durapore® 0.45 µm/0.22 µm

Sterilization

A = Autoclavable
G = Gamma-Compatible
S = Sterile

Capsule Size

10 = Opticap® XL 10

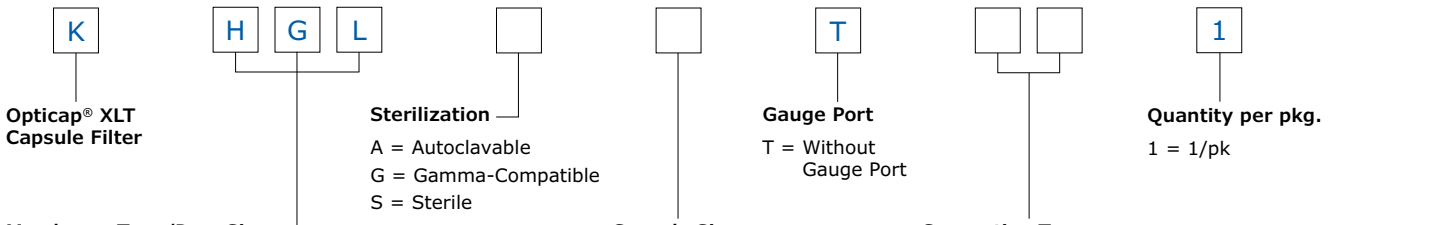
Connection Type

TT = 38 mm (1 ½ 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

Quantity per pkg.

1 = 1/pk

Opticap® XLT Capsule Filters



Opticap® XLT Capsule Filter

Membrane Type/Pore Size

HGL = Hydrophilic Multilayer Durapore® 0.45 µm/0.22 µm

Sterilization

A = Autoclavable
G = Gamma-Compatible
S = Sterile

Capsule Size

1 = Opticap® XLT 10
2 = Opticap® XLT 20
3 = Opticap® XLT 30

Gauge Port

T = Without Gauge Port

Connection Type

TT = 38 mm (1½ in.) Sanitary Flange Inlet and Outlet
HH = 16 mm (⅝ in.) Hose Barb Inlet and Outlet
TH = 38 mm (1 ½ in.) Sanitary Flange Inlet and 16 mm (⅝ in.) Hose Barb Outlet

Quantity per pkg.

1 = 1/pk

Accessory

Description	Qty/Pk	Cat. No.
Standard Opticap® XLT Capsule Filter Stand	1/pk	**XLTSTAND1**

Filters Containing Durapore® CBR 0.1 µm and 0.2 µm Membrane

For bioburden reduction in non-critical applications

Filters containing Durapore® CBR 0.1 µm and 0.2 µm hydrophilic polyvinylidene fluoride (PVDF) membrane are designed for particle removal and bioburden control in non-critical applications, which do not require sterilizing-grade filter performance.

Benefits

- Protects processes from microbial contamination
- Low protein binding membrane yields high protein recovery with minimal product loss
- Broad chemical compatibility, low extractables
- For filtration processes requiring high flow rates and throughput

Filter Formats

- Cartridge filters

Filters Containing Durapore® CBR 0.1 µm and 0.2 µm Membrane

Cartridge Filter Specifications

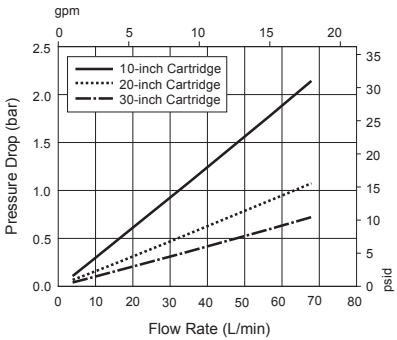
Description	Durapore® CBR 0.1 µm (per 10-inch element)	Durapore® CBR 0.2 µm (per 10-inch element)
Nominal Dimensions		
Outside diameter:	6.9 cm (2.7 in.)	6.9 cm (2.7 in.)
Filtration Area	0.69 m^2 (7.4 ft^2)	0.69 m^2 (7.4 ft^2)
Materials of Construction		
Filter membrane:	Hydrophilic PVDF	Hydrophilic PVDF
Film edge:	Polypropylene	Polypropylene
Supports:	Polypropylene	Polypropylene
Structural components*:	Polypropylene	Polypropylene
O-rings:	Fluorocarbon rubber or silicone	Fluorocarbon rubber or silicone
Maximum Differential Pressure		
Forward:	5.5 bar (80 psid) at 25 °C, 1.75 bar (25 psid) at 80 °C, 345 mbar (5 psid) at 135 °C	
Reverse:	3.4 bar (50 psid) at 25 °C, intermittent	
Bubble Point at 23 °C	≥ 4830 mbar (70.0 psig) air with water	≥ 3100 mbar (45.0 psig) air with water
Air Diffusion	Through a water wet membrane at ambient temperature: ≤ 20 cc/min at 3860 mbar (56 psi) per 10-inch cartridge	≤ 13.3 cc/min at 2.8 bar (40 psig) per 10-inch cartridge
Bacterial Retention	Samples of the Durapore® membrane used in these cartridges meet the criteria for quantitative retention of 10^7 CFU/cm^2 *Brevundimonas diminuta* ATCC® 19146 per ASTM© F838 methodology.	
Total Organic Carbon (TOC) / Conductivity	Autoclaved filter effluent meets the WFI requirement of USP <643>, for Total Organic Carbon and USP <645> for Water Conductivity at 25 °C after a WFI flush of: 3.5 L	5.5 L
Animal Origin Statement	Based on the current information from our suppliers, all component materials used in the manufacture of this device are either animal-free or in compliance with EMA/410/01.	
Non-Fiber Releasing	Meets the criteria for a “non-fiber releasing” filter as defined in 21 CFR 210.3 (b) (6).	
Toxicity	Component materials meet the criteria for the USP <88> Biological Reactivity Tests for Class VI Plastics.	
Indirect Food Additive	All component materials meet the FDA Indirect Food Additive requirements cited in 21 CFR 177-182 based on information provided by raw material suppliers.	

*Outer sleeve, core and end caps

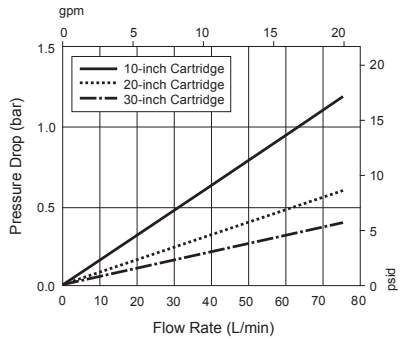
Filters Containing Durapore® CBR 0.1 µm and 0.2 µm Membrane

Typical Clean Water Flow Rates

Cartridge Filters – 0.1 µm Durapore® Membrane (CVVI)



Cartridge Filters – 0.2 µm Durapore® Membrane (CVDI)



Ordering Information

Cartridge Filters

C	V					T	P	

Cartridge Filter

Membrane Type

V = Durapore®

Pore Size

VI = 0.1 µm

DI = 0.2 µm

Cartridge Code

0 = (2-222) O-ring

5 = (2-222) O-ring with spear assembly*

7 = (2-226) O-ring with locking outlet and spear assembly*

Cartridge Length

1 = 10-inch

2 = 20-inch

3 = 30-inch

Packaging Code

TP = 1/pk

O-ring Material

E = Fluorocarbon rubber

S = Silicone

**Durapore® CBR 0.1 only*

Filters Containing Hydrophobic 0.22 µm Durapore® Membrane

For sterile filtration of non-aqueous solutions and gases

Filters containing hydrophobic Durapore® 0.22 µm membrane are recommended for sterile filtration of non-aqueous liquids such as alcohols, solvents, oils and emulsions. Hydrophobic Durapore® filters can also be used for sterile tank and gas venting.

Benefits

- Hydrophobic sterilizing-grade membrane that eliminates particles and microorganisms even at high pH
- Broad chemical compatibility, low extractables
- Offers high flow rates and throughputs for non-aqueous solutions

Filter Formats

- Cartridge filters
- Optiseal® cartridges
- Millidisk® cartridges
- Opticap® XL capsules
- Millipak® Final Fill capsules

Filters Containing Hydrophobic 0.22 µm Durapore® Membrane

Cartridge Filter Specifications

Description	Optiseal® Cartridge	5-inch Cartridge	Per 10-inch Cartridge
Nominal Dimensions			
Maximum length:	12.0 cm (4.7 in.)	12.5 cm (5 in.)	25 cm (10 in.)
Outside diameter:	6.9 cm (2.7 in.)	6.9 cm (2.7 in.)	6.9 cm (2.7 in.)
Filtration Area	0.18 m^2 (1.9 ft^2)	—	0.7 m^2 (7.4 ft^2)
Materials of Construction			
Filter membrane:	Hydrophobic PVDF	Hydrophobic PVDF	
Supports:	Polypropylene	Polypropylene	
O-rings:	Silicone	Silicone	
Connections	Double 2-123 O-ring	Code 7 (2-226) O-ring with locking tab and spear Code 0 (2-222) O-ring	
Maximum Differential Pressure			
Forward:	5.5 bar (80 psid) at 25 °C; 3.5 bar (50 psid) at 80 °C; 0.35 bar (5 psid) at 135 °C		
Reverse:	3.4 bar (50 psid) at 25 °C		
Bubble Point at 23 °C 0.22 µm hydrophobic Durapore® membrane	≥ 2000 mbar (29 psig) in water ≥ 1240 mbar (18 psig) in 60/40 IPA/water ≥ 1170 mbar (17 psig) in 70/30 IPA/water	≥ 2000 mbar (29 psig) in water ≥ 1240 mbar (18 psig) in 60/40 IPA/water ≥ 1170 mbar (17 psig) in 70/30 IPA/water ≥ 1170 mbar (17 psig) in 100 IPA	
Nitrogen Diffusion	At 1.0 bar (15 psig) in 60/40 IPA/water at 23 °C: ≤ 2 cc/min At 1.7 bar (25 psig) in water at 23 °C: ≤ 5.0 cc/min	At 1.7 bar (25 psig) in water at 23 °C: ≤ 5.0 mL/min	≤ 10.0 mL/min
Bacterial Endotoxin	< 0.5 EU/mL as determined by the Limulus Amebocyte Lysate (LAL) Test. This meets the requirements of USP <85>.		
Bacterial Retention	Quantitative retention of 10^7 CFU/cm^2 *Brevundimonas diminuta* ATCC® 19146 per ASTM© F838 methodology.		
Sterilization	30 steam-in-place cycles of 30 min at 135 °C; 10 autoclave cycles of 30 min at 126 °C.	30 steam-in-place cycles at 30 min at 126 °C; 30 autoclave cycles of 60 min at 126 °C.	

Filters Containing Hydrophobic 0.22 µm Durapore® Membrane

Millidisk® Cartridge Filter Specifications

Description	Millidisk® 10	Millidisk® 20	Millidisk® 30	Millidisk® 40
Filtration Area	500 cm^2 (0.54 ft^2)	1000 cm^2 (1.08 ft^2)	1500 cm^2 (1.61 ft^2)	2000 cm^2 (2.15 ft^2)
Materials of Construction				
Filter membrane:	Hydrophobic PVDF			
Structural components:	Polysulfone			
O-rings:	Silicone			
Maximum Differential Pressure				
Forward:	4.1 bar (60 psid) at 25 °C 1.7 bar (25 psid) at 80 °C 345 mbar (5 psid) at 123 °C			
Reverse:	690 mbar (10 psid) at 25 °C			
Bubble Point at 23 °C	≥ 1170 mbar (17.0 psig) in 100% IPA using nitrogen as the test gas			
Connections	Millidisk® filters incorporate a double 2-118 (silicone) O-ring seal and are used with Millidisk® or Millidisk®/ Milligard® stainless steel housings.			
Gravimetric Extractables	Maximum values post autoclaving and a 24 hour soak in ASTM® Type 1 reagent grade water for hydrophilic units and in 70/30 IPA/Water solution for hydrophobic units:			
	2.5 mg/unit	5 mg/unit	7.5 mg/unit	10 mg/unit
Oxidizable Substances	Meets the USP Oxidizable Substances Test requirements for sterile purified water after steaming and a water flush of 200 mL.			
Bacterial Endotoxin	An aqueous extraction from a Millidisk® filter contains < 0.5 EU/mL bacterial endotoxin as determined by the LAL test. This meets the requirements of USP <85>.			
Bacterial Retention	Quantitative retention of 10^7 CFU/cm^2 *Brevundimonas diminuta* ATCC® 19146 per ASTM© F838 methodology.			
Sterilization				
Autoclave:	126 °C, 60 minutes, up to 5 times			
Steam-in-place:	135 °C, 60 minutes, up to 5 times			
Toxicity	Component materials meet the criteria of the USP <88> Biological Reactivity Test for Class VI Plastics.			

Filters Containing Hydrophobic 0.22 µm Durapore® Membrane

Opticap® XL Autoclavable Capsule Filter Specifications

Description	Opticap® XL 4	Opticap® XL 5	Opticap® XL 10
Nominal Dimensions			
Maximum length:	14.2 cm (5.6 in.)	21.6 cm (8.5 in.)	33.5 cm (13.2 in.)
Body diameter:	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)	14.5 cm (5.7 in.)	14.5 cm (5.7 in.)
Filtration Area	0.19 m^2 (2.09 ft^2)	0.35 m^2 (3.7 ft^2)	0.69 m^2 (7.4 ft^2)
Materials of Construction			
Filter membrane:	Hydrophobic PVDF	Hydrophobic PVDF	Hydrophobic PVDF
Film edge:	Polypropylene	Polypropylene	Polypropylene
Supports:	Polypropylene	Polypropylene	Polypropylene
Structural components*:	Polypropylene	Polypropylene	Polypropylene
Vent O-rings:	Silicone	Silicone	Silicone
Vent/Drain	¼ in. hose barb with double O-ring seal		
Maximum Inlet Pressure	5.5 bar (80 psi) at 23 °C	5.5 bar (80 psi) at 23 °C	
	2.8 bar (40 psi) at 60 °C	2.8 bar (40 psi) at 60 °C	
	1.0 bar (15 psi) at 80 °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:	3.4 bar (50 psid) at ambient temperature		
Bubble Point at 23 °C	≥ 1170 mbar (17.0 psig) nitrogen with 70/30 IPA/water	≥ 1170 mbar (17.0 psig) nitrogen with 70/30 IPA/water	> 1240 mbar (18.0 psig) nitrogen with 60/40 IPA/water
Air Diffusion	Through a water wet membrane at ambient room temperature		
	≤ 4 cc/min	≤ 5 cc/min	≤ 10 cc/min
Bacterial Endotoxin	Aqueous extraction contains < 0.5 EU/mL as determined by the Limulus Amebocyte Lysate (LAL) Test. This meets the requirements of USP <85>.		
Bacterial Retention	Quantitative retention of 10^7 CFU/cm^2 *Brevundimonas diminuta* ATCC® 19146 per ASTM® F838 methodology.		
Sterilization	May be autoclaved for 20 cycles of 30 minutes at 126 °C.		
Non-Fiber Releasing	Meets the criteria for a “non-fiber releasing” filter as defined in 21 CFR 210.3 (b) (6).		
Toxicity	Component materials meet the criteria of the USP <88> Biological Reactivity Test for Class VI Plastics.		
European Pressure Equipment Directive	This product complies with the European Pressure Equipment Directive, 2014/68/EU of 15 May 2014. This product has been classified under article 4 § 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 4 § 3 of the Directive, 2014/68/EU, this product does not bear the CE mark.		

*Cage, core, end caps, and capsule housing

Filters Containing Hydrophobic 0.22 µm Durapore® Membrane

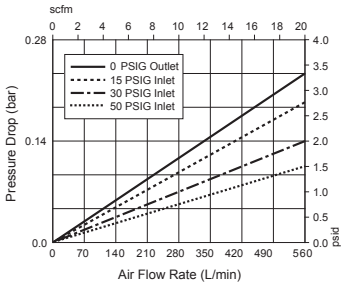
Millipak® Final Fill Capsule Filter Specifications

Description	Millipak® Final Fill 20	Millipak® Final Fill 60	Millipak® Final Fill 200
Nominal Dimensions			
Maximum length	8.1 cm (3.2 in.)	10.9 cm (4.3 in.)	14.5 cm (5.7 in.)
Body diameter	7.6 cm (3.0 in.)	7.6 cm (3.0 in.)	7.6 cm (3.0 in.)
Body diameter w/ anti-roll edges	–	–	8.1 cm (3.2 in.)
Filtration Area	100 cm^2 (0.11 ft^2)	300 cm^2 (0.32 ft^2)	1000 cm^2 (1.08 ft^2)
Aseptic Multi-Purpose Port	3.2 mm ($^1/_8$ in.) hose barb		
Materials of Construction			
Filter membrane:	Hydrophobic PVDF		
Support discs	Polysulfone		
Filter capsule	Polysulfone		
Aseptic Multi-Purpose Port (AMPP)	Polyethersulfone		
AMPP O-rings	Silicone		
Hold-up Volume	20 psi above the Bubble Point Specification for 1 minute		
	1.1 mL	3.2 mL	7.2 mL
Maximum Inlet Pressure	60 psi (4.1 bar) at 25 °C		
Maximum Differential Pressure			
Forward:	60 psi (4.1 bar) at 25 °C 25 psi (1.7 bar) at 80 °C		
Reverse:	10 psi (0.7 bar) at 25 °C		
Bubble Point at 23 °C	≥ 29 psi (2000 mbar) air with water ≥ 18 psi (1240 mbar) in 60/40% IPA water ≥ 17 psi (1170 mbar) in 70/30% IPA water		
Microbial challenge testing	Vents were tested utilizing a bacterial challenge method with 10^7 *Brevundimonas diminuta* assuring a sterile fluid path during actuation.		
Bacterial Endotoxin	Aqueous extraction contains < 0.25 EU/mL per device as determined using the Limulus Amebocyte Lysate (LAL) test, meeting requirements of USP <85>, EP 2.6.14 and JP 4.01.		
Bacterial Retention	Quantitative retention of 10^7 CFU/cm^2 *Brevundimonas diminuta* ATCC® 19146 per ASTM methodology		
Total Organic Carbon (TOC)/ Conductivity	Samples exhibited < 500 ppb TOC per USP <643> and < 1.3 µS/cm conductivity per USP <645> at 25 °C after sterilization and a water flush of:		
	1.0 L	2.0 L	5.0 L
Sterilization	Device integrity and retention was maintained after 3 autoclave cycles of 90 minutes at 126 °C. Devices can withstand a dose ≤ 40 kGy gamma exposure.		
Toxicity	Component materials meet the criteria of the USP <88> Biological Reactivity Test for Class VI Plastics.		
Particle Shedding	Effluent meets the acceptance criteria set forth in USP <788> for large volume parenterals.		
Non-Fiber Releasing	This product was manufactured with a Durapore® membrane which meets the criteria for a "non-fiber releasing" filter as defined in 21 CFR 210.3 (b)(6), validated based on large volume parenteral specifications as detailed in USP <788> Particulate Matter in Injections.		
Indirect Food Additive	All component materials meet the FDA Indirect Food Additive requirements cited in 21 CFR 177-182 based on information provided by raw material suppliers.		
Quality Management System	These products are manufactured in a facility which is certified to ISO 9001:2015 Quality Management Systems.		

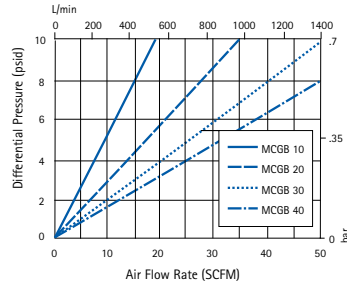
Filters Containing Hydrophobic 0.22 µm Durapore® Membrane

Typical Air Flow Rates and Pressure Drops

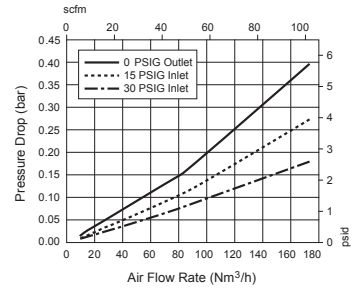
Optiseal® Cartridge – Hydrophobic Durapore® 0.22 µm Membrane



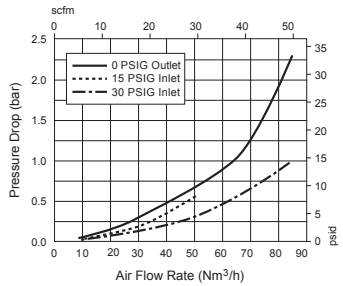
Millidisk® Cartridge – Hydrophobic Durapore® 0.22 µm Membrane



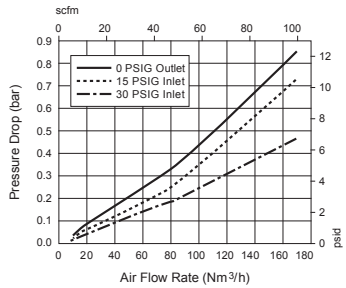
10-inch Cartridge – Hydrophobic Durapore® 0.22 µm Membrane



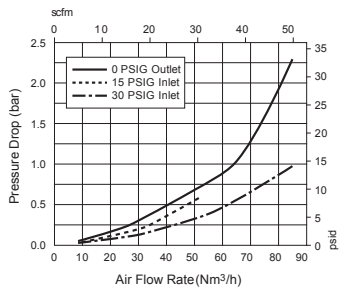
Opticap® XL 5 Capsules – Hydrophobic Durapore® 0.22 µm Membrane, HH Fitting*



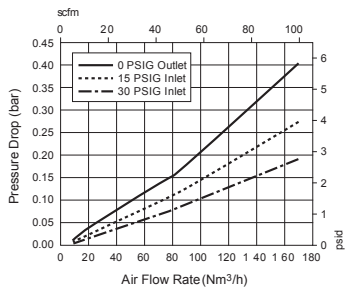
Opticap® XL 5 Capsules – Hydrophobic Durapore® 0.22 µm Membrane, TT Fitting*



Opticap® XL 10 Capsules – Hydrophobic Durapore® 0.22 µm Membrane, HH Fitting*



Opticap® XL 10 Capsules – Hydrophobic Durapore® 0.22 µm Membrane, TT Fitting*



***Opticap® XL Capsule Connection Types**

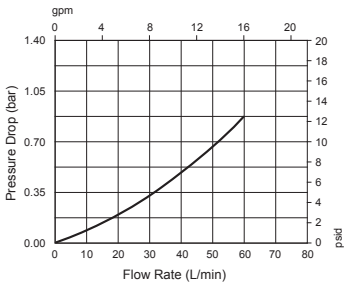
TT = 38 mm (1½ in.) Sanitary Flange Inlet and Outlet

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

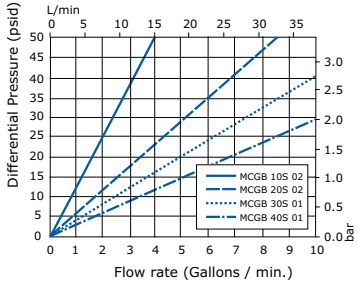
Filters Containing Hydrophobic 0.22 µm Durapore® Membrane

Typical Liquid Flow Rates and Pressure Drops

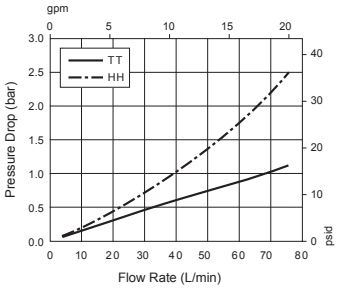
10-inch Cartridge – Hydrophobic Durapore® 0.22 µm Membrane



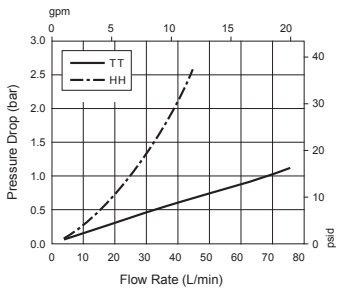
Millidisk® Cartridge – Hydrophobic Durapore® 0.22 µm Membrane



Opticap® XL 5 Capsules – Hydrophobic Durapore® 0.22 µm Membrane



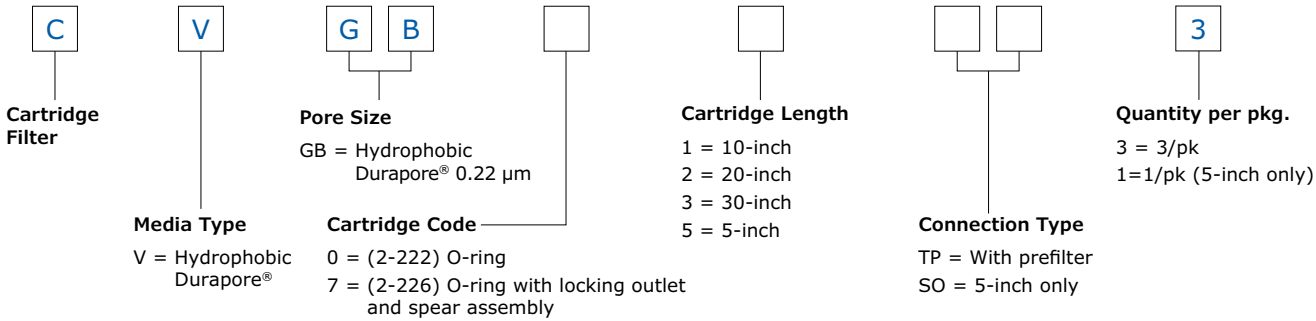
Opticap® XL 10 Capsules – Hydrophobic Durapore® 0.22 µm Membrane



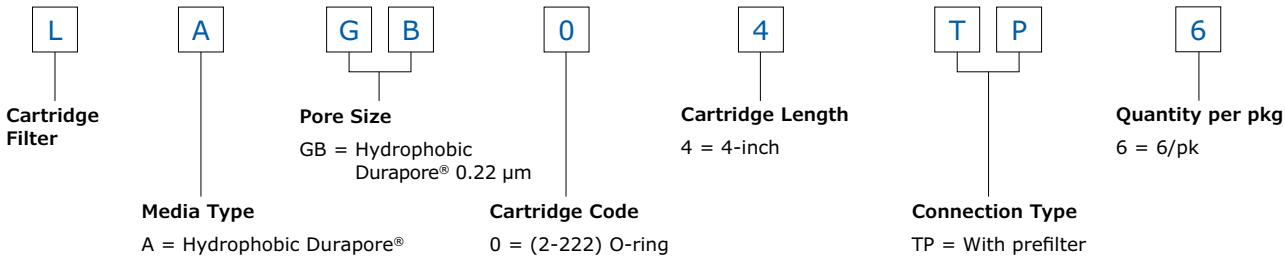
Filters Containing Hydrophobic 0.22 µm Durapore® Membrane

Ordering Information

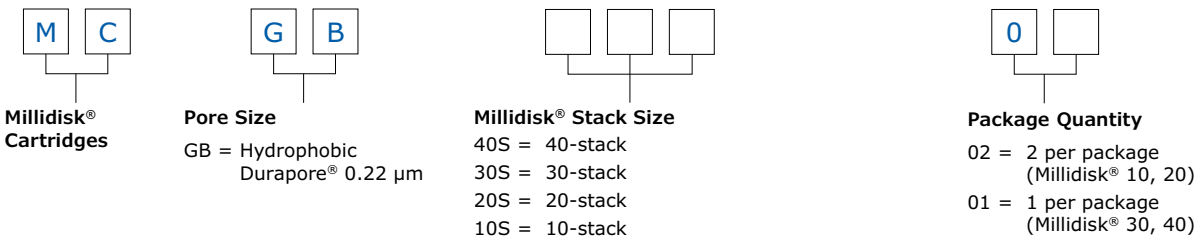
Cartridge Filters



Optiseal® Cartridge Filters



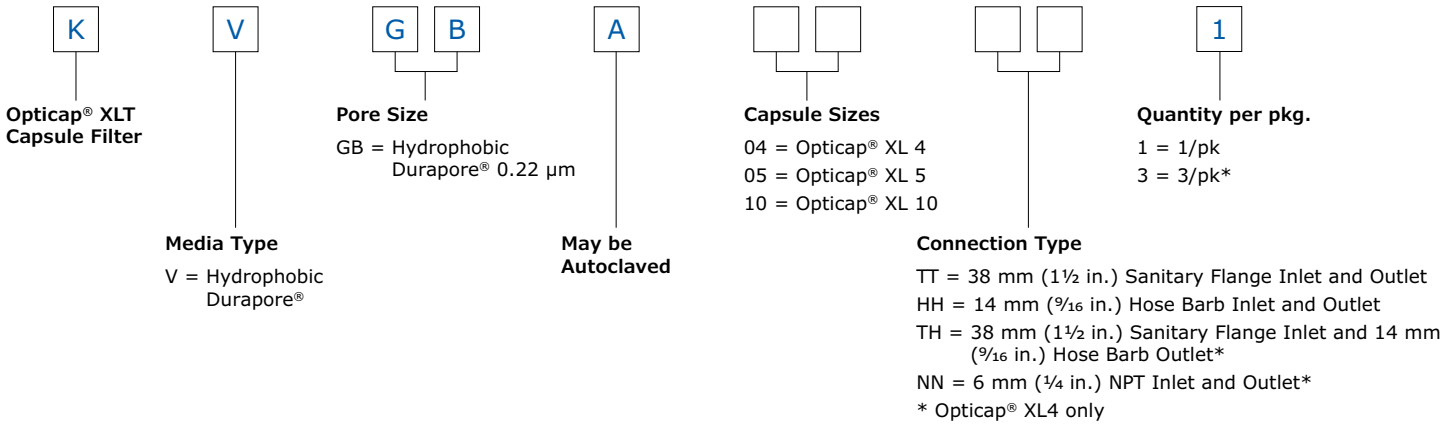
Millidisk® Cartridge Filters



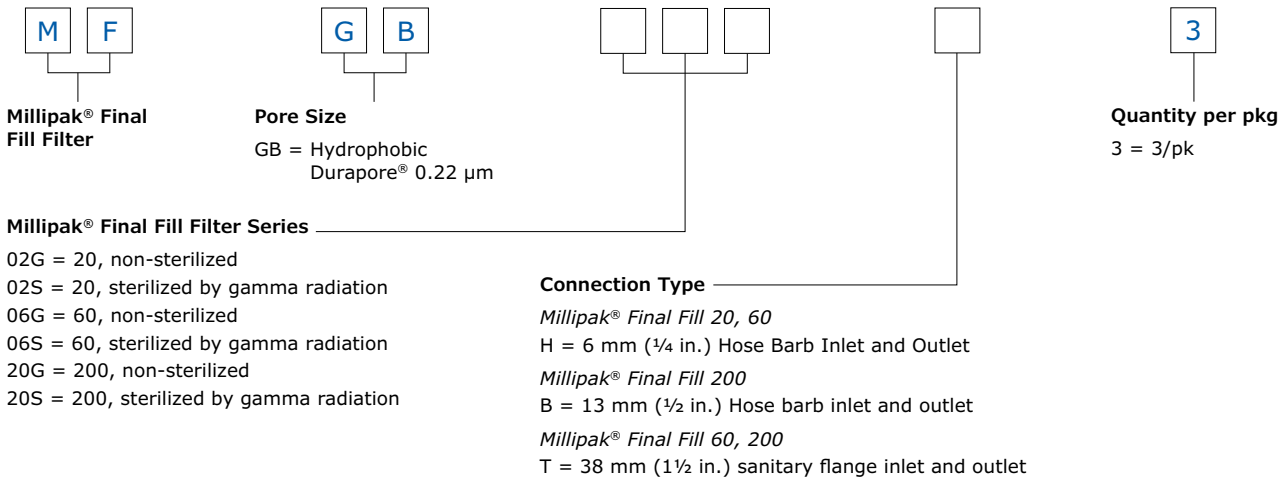
Filters Containing Hydrophobic 0.22 µm Durapore® Membrane

Ordering Information

Opticap® XL Capsule Filters



Millipak® Final Fill Capsule Filters



Barrier Filters Containing Durapore® 0.22 µm Hydrophilic-Hydrophobic Membrane

For pre-use integrity testing of sterile filtration systems

Filters containing these membranes are designed to simplify in-line pre-use integrity testing of sterile filtration systems. The stacked disc design contains layers of sterilizing-grade hydrophilic and hydrophobic Durapore® 0.22 µm membranes creating a permeable barrier which allows sterile flow of liquid and gas.

Benefits

These barrier filters simplify wetting, flushing and integrity testing of upstream sterilizing filters in filtration assemblies while maintaining the system sterility and removing the constraint of a flush bag or can.

Filter Formats

- Millipak® 200 Barrier capsule filter
- Millidisk® 40 Barrier cartridge filter

Barrier Filters containing Hydrophilic-Hydrophobic Durapore® 0.22 µm Membranes

Specifications

Description	Millidisk® 40 Barrier Cartridge	Millipak® 200 Barrier Capsule
Materials of Construction		
Membrane:	Hydrophilic and Hydrophobic Durapore® PVDF membrane	Hydrophilic and Hydrophobic Durapore® PVDF membrane
Structural components/Housing:	Polysulfone	Polycarbonate
O-rings:	Silicone	—
Filtration Area	2000 cm^2 (310 in^2)	1000 cm^2 (1.08 ft^2)
Maximum Differential Pressure		
Forward:	4.1 bar (60 psid) at 25 °C, 1.7 bar (25 psid) at 80 °C	4.1 bar (60 psi) at 25 °C, 1.7 bar (25 psi) at 80 °C
Reverse:	690 mbar (10 psid) at 25 °C	690 mbar (10 psid) at 25 °C
Maximum Recommended Operational Pressure	The maximum forward differential pressure during this operation should not exceed 0.5 bar (7.25 psid) at 25 °C to prevent wetting of hydrophobic membrane.	
Sterilization	May be autoclaved at 135 °C for 60 minutes up to 4 times or steamed-in-place at 135 °C for 60 minutes up to 4 times	May be autoclaved at 123 °C for 90 minutes up to 3 times; not in-line steam sterilizable. Devices can withstand a dose of ≤ 40 kGy gamma exposure.
Bubble Point at 23 °C	≥ 1280 mbar (18.5 psi) in 70/30% IPA/water at 23 °C	
Bacterial Endotoxin	An aqueous extraction contains < 0.5 EU/mL bacterial endotoxin as determined by the LAL test. This meets the requirements of USP <85>.	
Toxicity	Component materials meet the requirements of USP <88> Biological Reactivity Tests for Class VI Plastics.	Component materials meet the requirements of USP <88> Biological Reactivity Tests for Class VI Plastics.
Oxidizable Substances	These filters meet the requirements of the USP WFI Oxidizable Substance requirements after a water flush of 200 mL.	
Bacterial Retention	Quantitative retention of 10^7 CFU/cm^2 *Brevundimonas diminuta* ATCC® 19146 per ASTM® F838 methodology.	

Ordering Information

Description	Qty/Pk	Cat. No.
Millidisk® Barrier Cartridge Filter		
Millidisk® 40 Barrier Filter	3	**MCGBL4S03**
Millipak® Barrier Capsule Filters		
Millipak® 200 Barrier Filter with Hosebarb	3	**MSP010012**
Millipak® 200 Barrier Filter with 1 ½ in. TC	3	**MSP010013**

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