

Data Sheet

Sterilizing-grade Durapore® Multimedia Filters

Superior filters for the sterile filtration of fouling and plugging solutions

Durapore® Multimedia filters combine a 0.22 µm hydrophilic Durapore® membrane with an upstream Milligard® prefilter media, providing sterility assurance, high flow rates and extended throughputs, low extractables, and broad chemical compatibility. The combination of prefiltration media and final sterilizing membrane in one filter results in process compression and improved economics.



Benefits

- Process compression — prefiltration and sterile filtration in one step
- High retention efficiency and throughput
- Optimized for performance and superior economics with sterility assurance
- Ideal for designing scalable solutions from bench top to full-scale manufacturing

Media/Membrane Types

Milligard®/Durapore® (Single Layer Prefilter)	Milligard®/Milligard®/Durapore® (Double Layer Prefilter)
• 0.2 µm/0.22 µm	• 1.2 µm/0.5 µm/0.22 µm
• 0.5 µm/0.22 µm	• 0.5 µm/0.2 µm/0.22 µm
• 1.2 µm/0.22 µm	• 1.2 µm/0.2 µm/0.22 µm

Milligard® pore sizes are nominal

Filter Formats

- OptiScale® small scale, single-use capsule filters
- Opticap® XL disposable capsule filters
- Cartridge filters

Regulatory Compliance

Multimedia filters are designed, developed, and manufactured in accordance with a Quality Management System approved by an accredited registering body to an ISO® 9001 Quality Systems Standard and are shipped with a Certificate of Quality. Each Opticap® XL and cartridge filter is supported by a Validation Guide for compliance with regulatory requirements. For traceability and easy identification, each device is marked with the product name and identifying characteristics.

Multiple Formats Available

Sterilizing-grade Durapore® Multimedia filters are available in three device formats, six media combinations, and multiple configurations that vary by filtration area and type of inlet/outlet connection. We have a format to meet your application needs.



OptiScale® Filters

OptiScale® Process Development Screening Tool

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

OptiScale® capsules are faster and easier to set-up than conventional 25 mm and 47 mm discs.



Cartridge Filters

Cartridge Filters

Multimedia cartridge filters are ideally suited for processes that require maximum pressure differentials. Cartridges are robust, strong, and resilient and are designed to withstand multiple steam-in-place cycles. Each multimedia cartridge filter is integrity tested during the manufacturing process.

A full range of filtration areas is available to suit varying application requirements. A variety of connection options are offered for easy adaptation to existing housings.

Opticap® XL Single-Use Capsule Filters

The patented Opticap® XL capsule design allows unparalleled thermal and hydraulic stress resistance in a disposable filter, resulting in reliability, high confidence in the sterility process and improved cleanliness. The unique capsule design with pleated multimedia minimizes hold-up volume and reduces production losses. Each Opticap® XL capsule is integrity tested during the manufacturing process.

Convenient and Easy to Use

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

The Right Connections

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



Opticap® XL Filter



Specifications

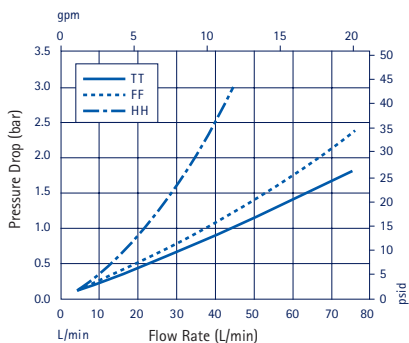
	OptiScale® 25	OptiScale® 47
Single and Double Layer Prefilters		
Nominal Dimensions		
Filtration Area	3.5 cm ²	13.8 cm ²
Body diameter:	39 mm (1.52 in.) with female Luer-Lok™ inlet/male luer slip outlet	82 mm (3.24 in.) with flange inlet/hose barb outlet 74 mm (2.91 in.) with flange inlet/flange outlet 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)
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 caps:	Polypropylene	PVDF
Internal seal rings:		Fluoroelastomers
Housing Vent	Capped vent with female Luer connections on inlet side of device.	Adjustable vent with male Luer slip and female Luer-Lok™ connections on inlet side of device.
Bubble Point at 23 °C	≥ 3450 mbar (50.0 psi) air with water	
Maximum Inlet Pressure	4.1 bar (60 psi) at 25 °C	5.5 bar (80 psi) at 25 °C
Oxidizable Substances	–	Capsules meet the requirements of the USP Oxidizable Substance for Sterile Water for Filtration Test after a water flush of ≤ 100 mL.
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.
Good Manufacturing Practices	These products are manufactured in a facility which adheres to Good Manufacturing Practices.	
Component Material Toxicity	Component materials meet the requirements of USP <88> Reactivity Tests for Class VI Plastics. This product is non-toxic per the USP <88> Safety Test.	
Indirect Food Additive	The Durapore® membrane used in these products meets the FDA Indirect Food Additive requirements cited in 21 CFR 177.2910. All other components meet the FDA Indirect Food Additive requirements cited in 21 CFR 177-182	

Specifications

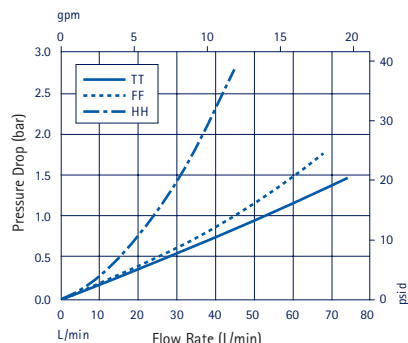
	Opticap® XL 10		Cartridge Filters per 10-inch Element	
	Single Layer Prefilter	Double Layer Prefilter	Single Layer Prefilter	Double Layer Prefilter
Nominal Dimensions				
Maximum length:	33.5 cm (13.2 in.)	33.5 cm (13.2 in.)	–	–
Body diameter:	10.7 cm (4.2 in.)	10.7 cm (4.2 in.)	6.9 cm (2.7 in.)	6.9 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-ring:	Silicone		–	
O-ring:	–		Silicone	
Housing Vent	1/4 in. hose barb with double O-ring seal		–	
Nominal Vent to Vent Diameter	14.5 cm (5.7 in.)		–	
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		≥ 3450 mbar (50 psig) air with water	
Air Diffusion	Through a water wet membrane at 23 °C at 2.8 bar (40 psi): ≤ 13.3 cc/min		Through a water wet membrane at 23 °C at 2.8 bar (40 psi): ≤ 13.3 cc/min	
		≤ 10.8 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.			
Oxidizable Substances	Meets the requirements of the USP Oxidizable Substances Test 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 methodology.			
Sterilization	May be autoclaved for 3 cycles of 60 minutes at 123 °C. (Cannot be steam sterilized in-line).		May be autoclaved for 6 cycles of 30 minutes at 123 °C or steam sterilized for 6 cycles of 30 minutes at 123 °C.	
Good Manufacturing Practices	These products are manufactured in a facility which adheres to Good Manufacturing Practices.			
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).			
Component Material Toxicity	Component materials meet the requirements of USP <88> Reactivity Tests for Class VI Plastics. This product is non-toxic per the USP <88> Safety Test.			
Indirect Food Additive	The Durapore® membrane used in these products meets the FDA Indirect Food Additive requirements cited in 21 CFR 177.2910. All other components meet the FDA Indirect Food Additive requirements cited in 21 CFR 177-182			
European Pressure Equipment Directive	We certify that this product complies with the European Pressure Equipment Directive, 97/23/EC of 29 May 1997. This product has been classified under Article 3 § 3 of the Pressure Vessel Directive. It has been designed and manufactured in accordance with sound engineering practice to ensure safe use. In compliance with Article 3 § 3 of this Pressure Equipment Directive, this product does not bear the CE mark.		–	

Typical Clean Water Flow Rates

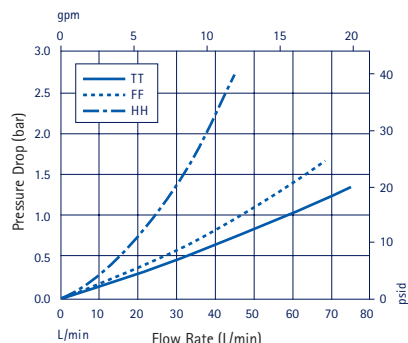
Opticap XL 10 Capsule with Multimedia Durapore® – 0.2/0.22 µm (KV03)



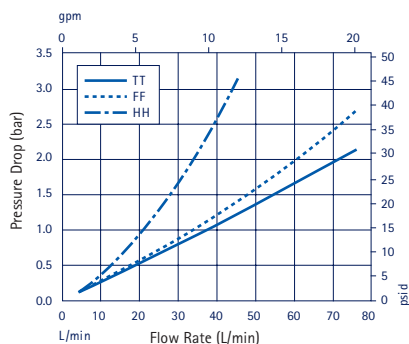
Opticap XL 10 Capsule with Multimedia Durapore® – 0.5/0.22 µm (KV06)



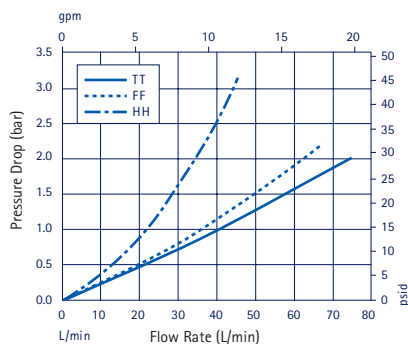
Opticap XL 10 Capsule with Multimedia Durapore® – 1.2/0.22 µm (KV19)



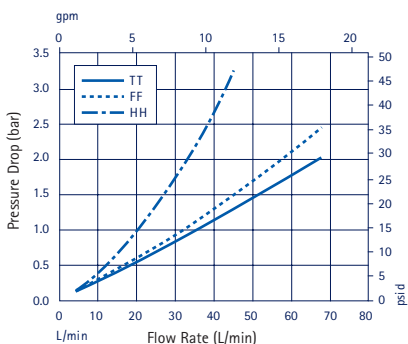
Opticap XL 10 Capsule with Multimedia Durapore® – 1.2/0.5/0.22 µm (KVSC)



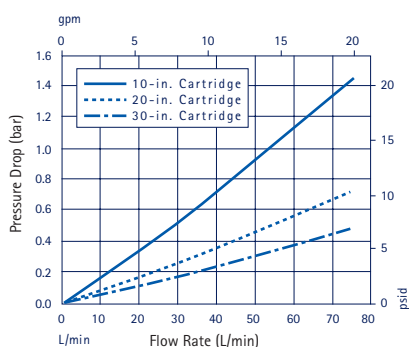
Opticap XL 10 Capsule with Multimedia Durapore® – 0.5/0.2/0.22 µm (KVSS)



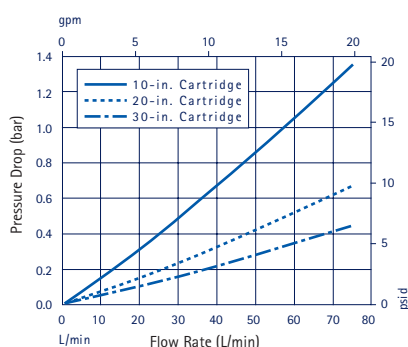
Opticap XL 10 Capsule with Multimedia Durapore® – 1.2/0.2/0.22 µm (KV SX)



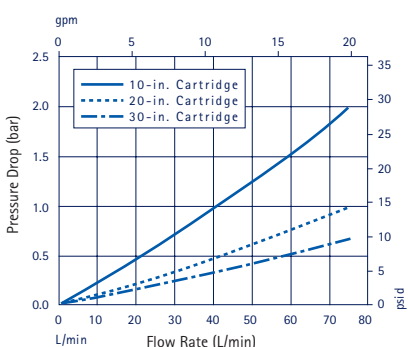
Cartridge Filter with Multimedia Durapore® 0.5/0.22 µm (CV06)



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



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

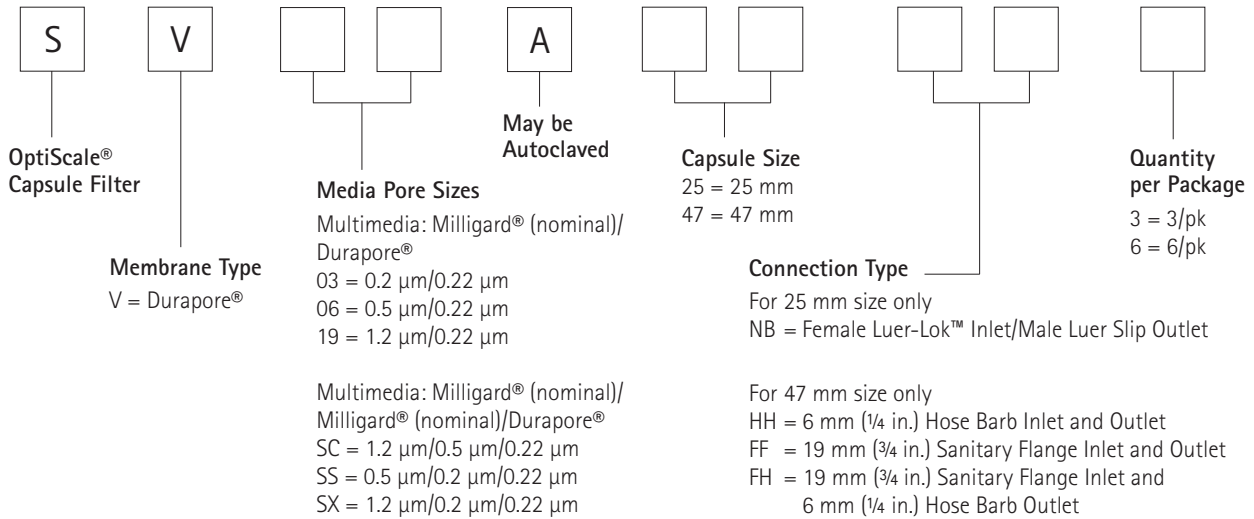


Opticap® XL Legends Refer to Capsule Connection Type

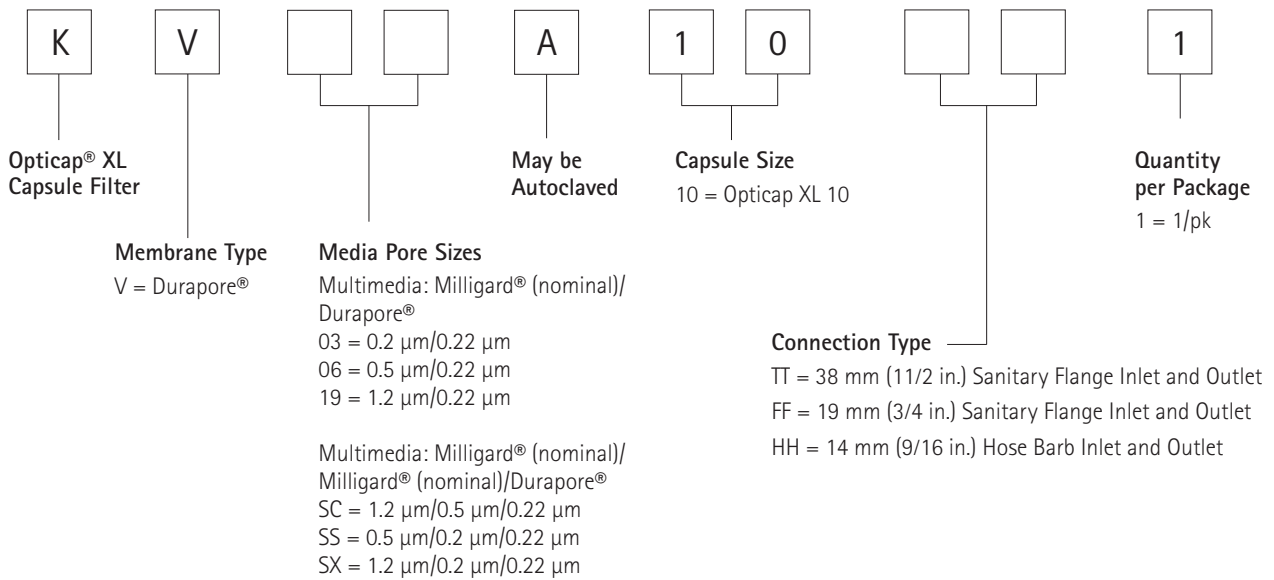
- TT = 38 mm (1 1/2 in.) Sanitary Flange Inlet and Outlet
- FF = 19 mm (3/4 in.) Sanitary Flange Inlet and Outlet
- HH = 14 mm (9/16 in.) Hose Barb Outlet

Ordering Information

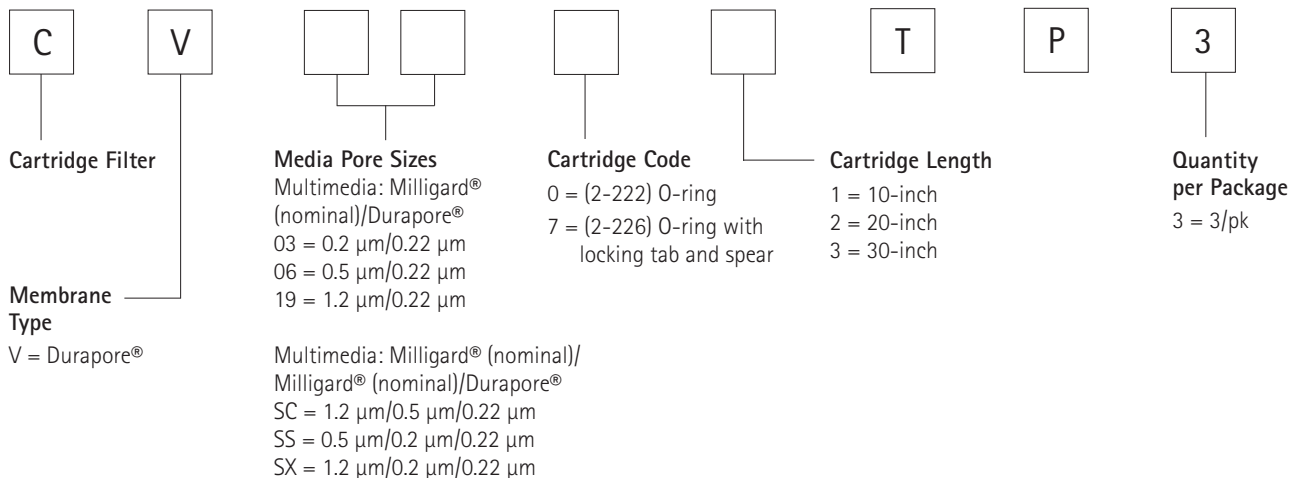
OptiScale® Capsule Filters



Opticap® XL Capsule Filters



Cartridge Filters



To Place an Order or Receive Technical Assistance

In Europe, please call Customer Service:

France: 0825 045 645

Germany: 01805 045 645

Italy: 848 845 645

Spain: 901 516 645 Option 1

Switzerland: 0848 645 645

United Kingdom: 0870 900 4645

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

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