



Data Sheet

Durapore® 0.1 µm and 0.22 µm Hydrophilic Filters

Superior filters for the sterile filtration of biopharmaceutical liquids

A trusted name in the industry for over 25 years, Durapore sterilizing-grade 0.1 µm and 0.22 µm hydrophilic polyvinylidene fluoride (PVDF) membranes are low protein binding and provide sterility assurance, high flow rates and throughputs. The Durapore membrane contributes to clean processes due to low extractables, broad chemical compatibility, and its non-fiber releasing properties.

Benefits

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



Membrane Types	Filter Formats
Durapore 0.1 µm hydrophilic 0.22 µm hydrophilic	<ul style="list-style-type: none">◦ OptiScale® small scale disposable capsule filters◦ Millipak® low-volume capsule filters◦ Opticap® XL 2 disposable capsule filters

OPTISCALE PROCESS DEVELOPMENT SCREENING TOOL

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

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



MILLIPAK LOW-VOLUME CAPSULE FILTERS

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

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



OPTICAP XL 2 DISPOSABLE CAPSULE FILTERS

Convenient and Easy to Use

Opticap XL 2 capsule filters eliminate the time and 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 direction arrows and ribbed housing for easy gripping even with gloved hands.

The Right Size

The Opticap capsule product family provides a wide range of sizes for easy scale-up of your small volume filtration steps to larger, full-scale filtration processes.



The Right Connections

Self-contained and disposable, Opticap XL 2 capsule filters are supplied with a choice of inlet and outlet connections to optimize your filtration process, including sanitary flanges which provide a high flow rate, fractional sanitary flanges and hose barbs.

Proven Integrity

Each capsule is integrity tested during the manufacturing process to ensure reliable performance in your process.

Robust Construction

Opticap XL 2 capsule's design allows unparalleled thermal and hydraulic stress resistance in a disposable filter, resulting in reliability, high confidence in the sterility process, and improved cleanliness.

REGULATORY COMPLIANCE

Filters with hydrophilic Durapore membrane are designed, developed, and manufactured in accordance with a Quality Management System approved by an accredited registering body to an ISO® 9000 Quality Systems Standard. Each Durapore filter is shipped with a Certificate of Quality. Each Millipak® and Opticap® XL 2 capsule filter is integrity tested during manufacturing and is supported with 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 hydrophilic Durapore membranes are available in three formats, two pore sizes, and multiple configurations that vary by filtration area and type of inlet/outlet connection. We have a format to meet your application needs.

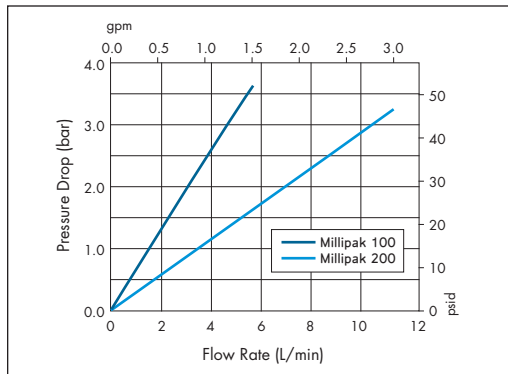
SPECIFICATIONS (Opticap XL 2 Capsule Filters – Autoclavable)

Nominal Dimensions	
Maximum length:	14.2 cm (5.6 in.)
Body diameter:	8.4 cm (3.3 in.)
Filtration Area	0.09 m ² (0.93 ft ²)
Materials of Construction	
Filter membrane:	Hydrophilic PVDF
Film edge:	Polypropylene
Supports:	Polypropylene
Structural components*:	Polypropylene
Vent O-rings:	Silicone
Vent/Drain	¼ in. hose barb with double O-ring seal
Maximum Inlet Pressure	5.5 bar (80 psi) at 23 °C 2.8 bar (40 psi) at 60 °C 1.0 bar (15 psi) at 80 °C
Maximum Differential Pressure	
Forward:	5.5 bar (80 psid) at 25 °C, 1.0 bar (15 psid) at 80 °C
Reverse:	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
0.22 µm:	≥ 3450 mbar (50.0 psig) air with water
NVR Gravimetric Extractables	After autoclaving and a 24 hour soak in ASTM® Type 1 reagent grade water at controlled room temperature: ≤ 10 mg
Oxidizable Substances	Meets the requirements of the USP Oxidizable Substances Test after a water flush of: 500 mL
Bacterial Endotoxin	Aqueous extraction contains < 0.5 EU/mL as determined by the Limulus Amebocyte Lysate (LAL) Test.
Bacterial Retention	Quantitative retention of 10 ⁷ CFU/cm ² <i>Brevundimonas diminuta</i> ATCC® 19146 per ASTM® methodology.
Sterilization	May be autoclaved for 3 cycles of 60 minutes at 126 °C. (Cannot be steam sterilized in-line)
Good Manufacturing Practices	These products are manufactured in a Millipore facility which adheres to FDA Good Manufacturing Practices.
Non-Fiber Releasing	Durapore membrane meets the criteria for a “non-fiber releasing” filter as defined in 21 CFR 210.3 (b) (6).
Component Material Toxicity	Component materials were tested and meet the criteria of the USP <88> Reactivity Test for Class VI Plastics. Sterilizing-grade Durapore Filters meet the requirements of the current 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 component materials also meet the FDA Indirect Food Additive requirements cited in 21 CFR 177–182.

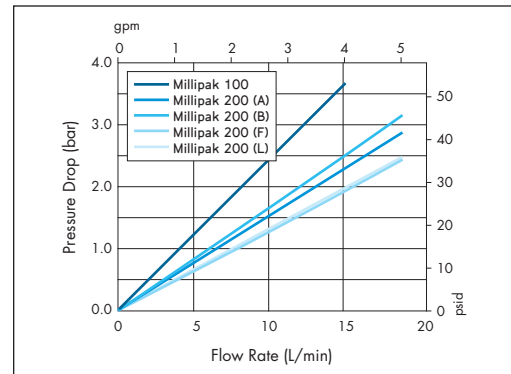
*Cage, core, end caps and capsule housing

TYPICAL CLEAN WATER FLOW RATES

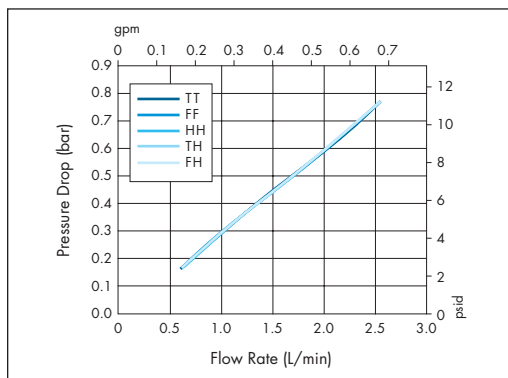
Millipak 100/200 Capsule Filter —
0.1 μm Hydrophilic Durapore Membrane



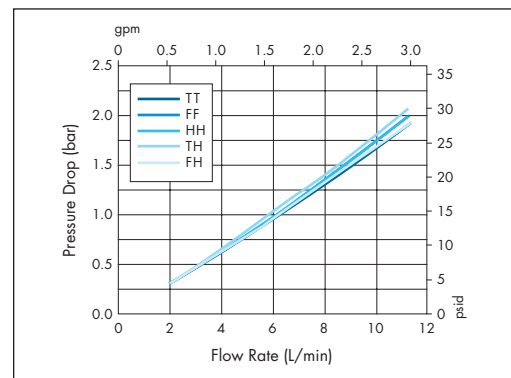
Millipak 100/200 Capsule Filter —
0.22 μm Hydrophilic Durapore Membrane



Opticap XL 2 Capsule Filters —
0.1 μm Hydrophilic Durapore Membrane



Opticap XL 2 Capsule Filters —
0.22 μm Hydrophilic Durapore Membrane



Millipak Capsule Legend Refers to Connection Type

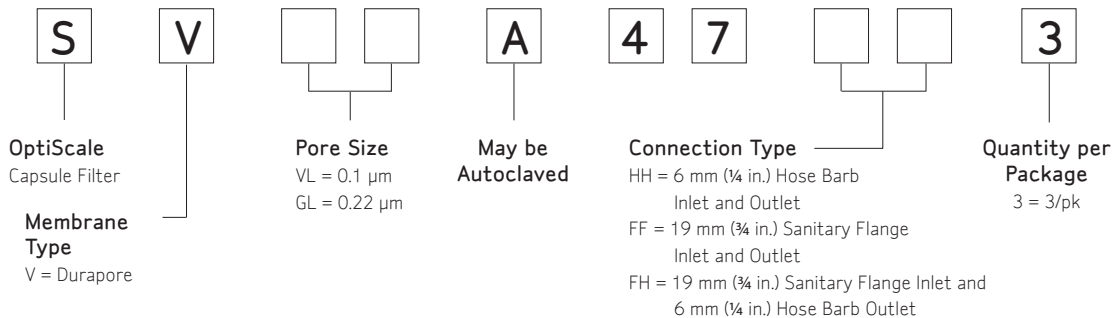
- A = 14 mm ($\frac{9}{16}$ in.) Hose Barb Inlet and Outlet
- B = 6 mm ($\frac{1}{4}$ in.) NPTM Inlet and Outlet
- F = 19 mm ($\frac{3}{4}$ in.) Sanitary Flange Inlet and Outlet
- L = 38 mm ($1\frac{1}{2}$ in.) Sanitary Flange Inlet and Outlet

Opticap XL 2 Capsule Legends Refer to Connection Type

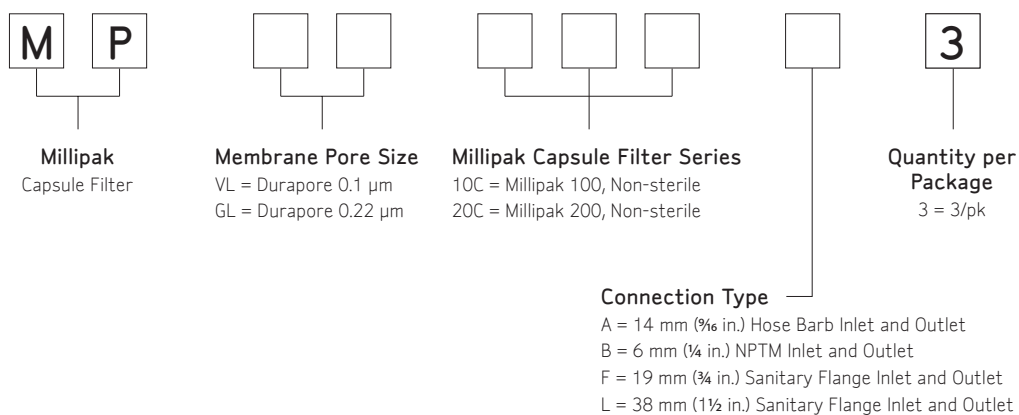
- TT = 38 mm ($1\frac{1}{2}$ in.) Sanitary Flange Inlet and Outlet
- FF = 19 mm ($\frac{3}{4}$ in.) Sanitary Flange Inlet and Outlet
- HH = 14 mm ($\frac{9}{16}$ in.) Hose Barb Inlet and Outlet
- TH = 38 mm ($1\frac{1}{2}$ in.) Sanitary Flange Inlet and 14 mm ($\frac{9}{16}$ in.) Hose Barb Outlet
- FH = 19 mm ($\frac{3}{4}$ in.) Sanitary Flange Inlet and 14 mm ($\frac{9}{16}$ in.) Hose Barb Outlet

ORDERING INFORMATION

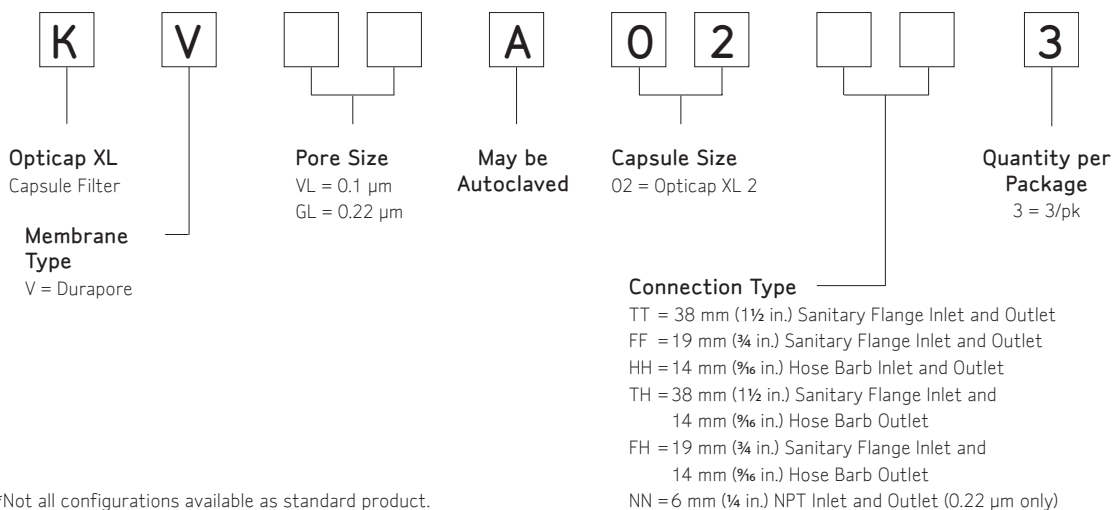
OptiScale Capsule Filters



Millipak Capsule Filters



Opticap XL 2 Capsule Filters*



*Not all configurations available as standard product.



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Lit. No. DS2898EN00 BN0324095 Rev. A 4/09 Printed in U.S.A. DP SBU-09-01721
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