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https://millipore.nt-rt.ru || mailto:mer@nt-rt.ru

Polysep™ II Filters

Superior filters provide multiple filtration stages in a single compact configuration for critical prefiltration applications

Polysep II filters are ideal for a broad range of aqueous-based applications. The Polysep II media consists of a borosilicate glass layer and a layer of mixed esters of cellulose membrane. The depth of the microfiber filter layer provides high particle loading capacity, and retention of large particulates while maintaining high flow rates. The mixed cellulose ester membrane layers provide the high retention needed during critical prefiltration steps while protecting more expensive downstream filtration devices and equipment.

Benefits

- Combines the dirt-holding capacity of a depth filter with the retention efficiency of a membrane filter
- Provides outstanding protection of more expensive downstream filters
- Exceptional retention efficiency for critical prefiltration processes
- Perfect choice when high flow rate and high throughput are required
- Ideal for designing scalable solutions from bench top to full-scale manufacturing

Media Types	Filter Formats
Polysep II 1.0 µm/0.2 µm/0.1 µm 1.0 µm/0.2 µm 1.0 µm/0.5 µm 1.0 µm/1.2 µm 2.0 µm/1.2 µm Pore sizes are nominal	○ OptiScale® small scale disposable capsule filters ○ Opticap® XL 2 disposable capsule filters

APPLICATIONS

Cell Culture Media

Polysep II prefilters effectively remove particles including lipids, and colloidal contaminants without obstructing the flow of vital media constituents.

Ophthalmics

Polysep II prefilters reduce particle and bioburden before sterilizing filtration and will withstand process variability.

Serum

Polysep II prefilters remove lipids, colloids, and particles from serum before final sterilizing filtration without obstructing the passage of serum proteins.

Large Volume Parenterals (LVP)

Extend the service life of downstream sterilizing filters by removing colloidal and particulate contaminants. The robust design withstands high differential and operating pressures, high flow rates and multiple steam-in-place or hot water sanitization cycles.

Buffer Preparation

Reduce particulate contamination and bioburden before final sterilizing filtration and provide excellent protection for sterilizing grade membrane filters in applications requiring more extensive buffer prefiltration.

REGULATORY COMPLIANCE

Polysep II filters 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 and are shipped with a Certificate of Quality. Each Opticap XL 2 capsule filter is supported by a Validation Guide for compliance with regulatory requirements.

For traceability and easy identification, each filter is marked with identifying characteristics.

OPTISCALE PROCESS DEVELOPMENT SCREENING TOOL

OptiScale disposable capsule filters with Polysep II media 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.

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

The Right Connections

Self-contained and disposable, Opticap XL 2 capsule filter is 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.

Robust Construction

Opticap XL 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.

SPECIFICATIONS (OptiScale Capsule Filters)

Nominal Dimensions	
Maximum length:	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
Diameter:	69 mm (2.75 in.)
Weight:	2.3 oz (67 g)
Filtration Area (see legend below)	
W1, W3, W6, W2, W9:	13.8 cm^2
Materials of Construction	
Filter media:	Borosilicate glass microfiber and mixed esters of cellulose
Structural components:	Polycarbonate
Vent cap:	PVDF
Internal seal rings:	Viton® fluoroelastomers
Housing Vent	Adjustable vent with male luer and female Luer-Lok™ connections on inlet side of device.
Maximum Inlet Pressure	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 3 cycles of 60 minutes at 121 °C
Good Manufacturing Practices	These products are manufactured in a Millipore facility which adheres to FDA Good Manfacturing Practices.
Non-Fiber Releasing	Polysep II media 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. Polysep II Filters meet the requirements of the current USP <88> Safety Test.
Indirect Food Additive	All component materials meet the FDA Indirect Food Additive requirements cited in 21 CFR 177–182.

Legend for Filtration Area

Nominal pore size of media
W1 = 1.0 µm/0.2 µm/0.1 µm
W3 = 1.0 µm/0.2 µm
W6 = 1.0 µm/0.5 µm
W2 = 1.0 µm/1.2 µm
W9 = 2.0 µm/1.2 µm

SPECIFICATIONS (Opticap XL 2 Capsule Filters)

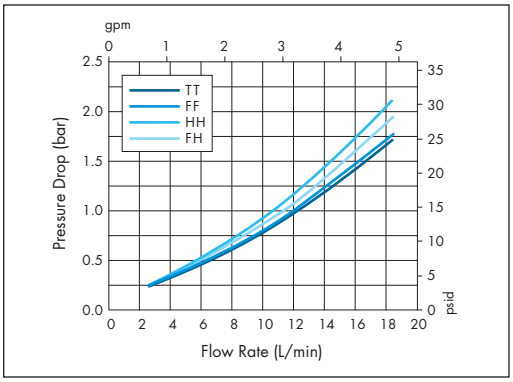
Nominal Dimensions	
Maximum length:	14.2 cm (5.6 in.)
Body Diameter	8.4 cm (3.3 in.)
Filtration Area (see legend below)	
W2, W3, W6, W9:	0.06 m^2 (0.6 ft^2)
W1:	N/A
Materials of Construction	
Filter media:	Borosilicate glass microfiber and mixed esters of cellulose
Structural components*:	Polypropylene
Supports:	Polypropylene
Vent cap:	Polypropylene
Vent O-ring:	Silicone
Filter support material:	Polypropylene
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:	3.5 bar (50 psid) at 25 °C.
NVR Gravimetric Extractables	After autoclaving and a 24 hour soak in ASTM® Type 1reagent grade water at controlled room temperature ≤ 45 mg after a 600 mL flush
USP Bacterial Endotoxin	Aqueous extraction contains < 0.5 EU/mL as determined by the Limulus Amebocyte Lysate (LAL) Test.
Oxidizable Substances	Capsules meet the requirements of the USP Oxidizable Substances Test after a water flush of ≤ 1000 mL
Sterilization	May be autoclaved for 3 cycles of 30 minutes at 121 °C. (Cannot be steam sterilized in-line.)
Good Manufacturing Practices	These products are manufactured in a Millipore facility which adheres to FDA Good Manfacturing Practices.
Non-Fiber Releasing	Polysep II media meets the criteria for a "non-fiber releasing" filter as defined in 21 CFR 210.3 (b) (6).
Component Material Toxicity	Component materials meet the requirements of the USP <88> Reactivity Tests for Class VI Plastics. This product meets the requirements of the USP <88> Safety Test utilizing a 0.9% sodium chloride extraction.
Indirect Food Additive	All component materials meet the FDA Indirect Food Additive requirements cited in 21 CFR 177–182.

*Cage, core, end caps and capsule housing

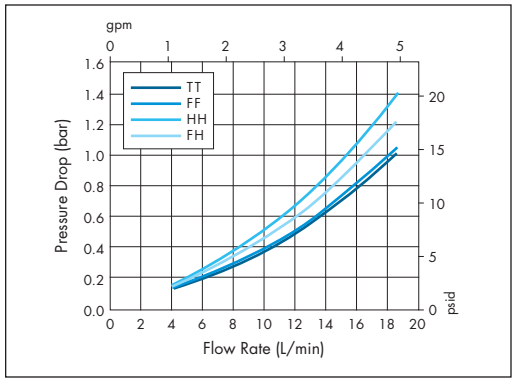
Legend for Filtration Area
Nominal pore size of media
W1 = 1.0 µm/0.2 µm/0.1 µm
W3 = 1.0 µm/0.2 µm
W6 = 1.0 µm/0.5 µm
W2 = 1.0 µm/1.2 µm
W9 = 2.0 µm/1.2 µm

TYPICAL CLEAN WATER FLOW RATES

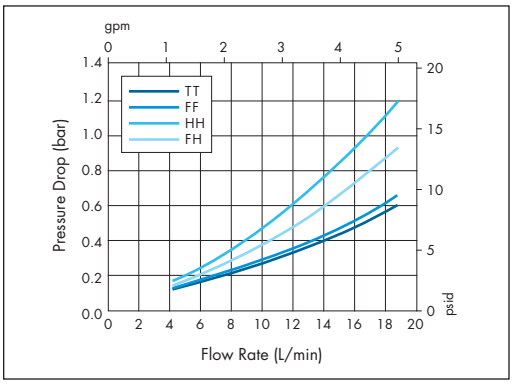
Opticap XL 2 Capsule with Polysep II Media — 1.0/0.2 µm Nominal (W3)



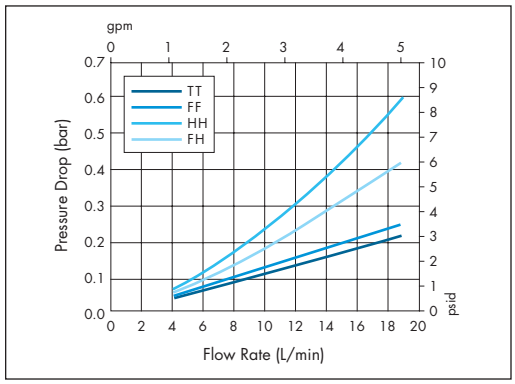
Opticap XL 2 Capsule with Polysep II Media — 1.0/0.5 µm Nominal (W6)



Opticap XL 2 Capsule with Polysep II Media — 1.0/1.2 µm Nominal (W2)



Opticap XL 2 Capsule with Polysep II Media — 2.0/1.2 µm Nominal (W9)

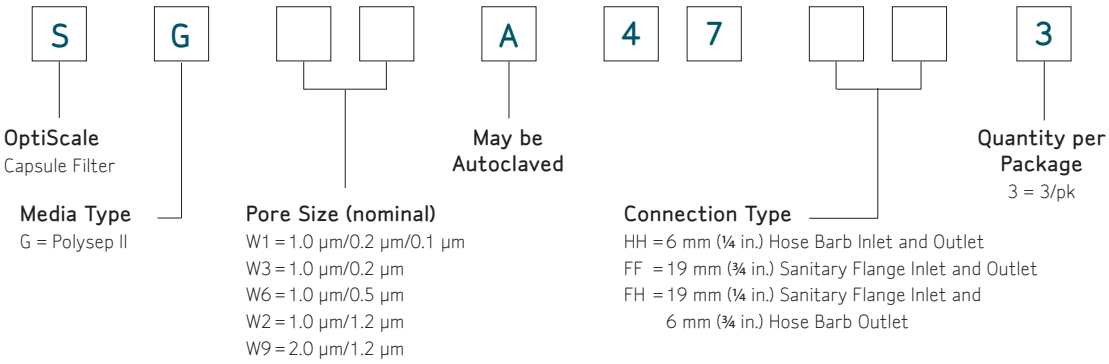


Opticap XL Capsule Legends
Refer to Connection Type

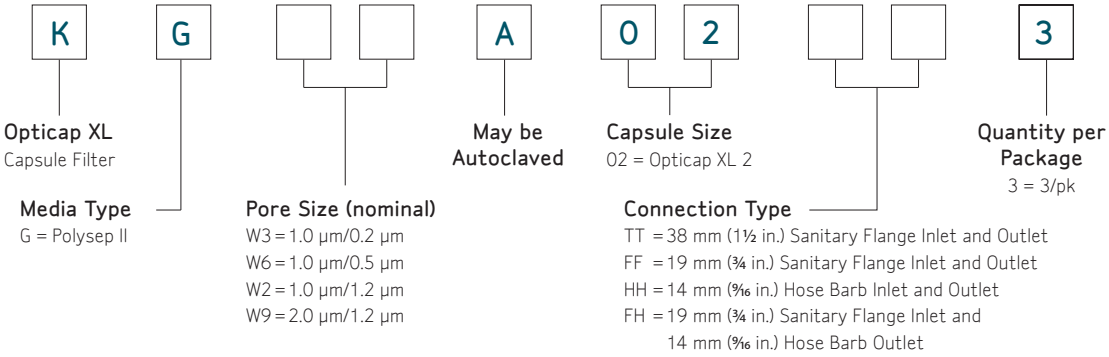
TT = 38 mm (1½ in.) Sanitary Flange Inlet and Outlet
FF = 19 mm (¾ in.) Sanitary Flange Inlet and Outlet
HH = 14 mm (⁹⁄₁₆ in.) Hose Barb Inlet and Outlet
FH = 19 mm (¾ in.) Sanitary Flange Inlet and 14 mm (9/16 in.) Hose Barb Outlet (2 and 4 only)

ORDERING INFORMATION

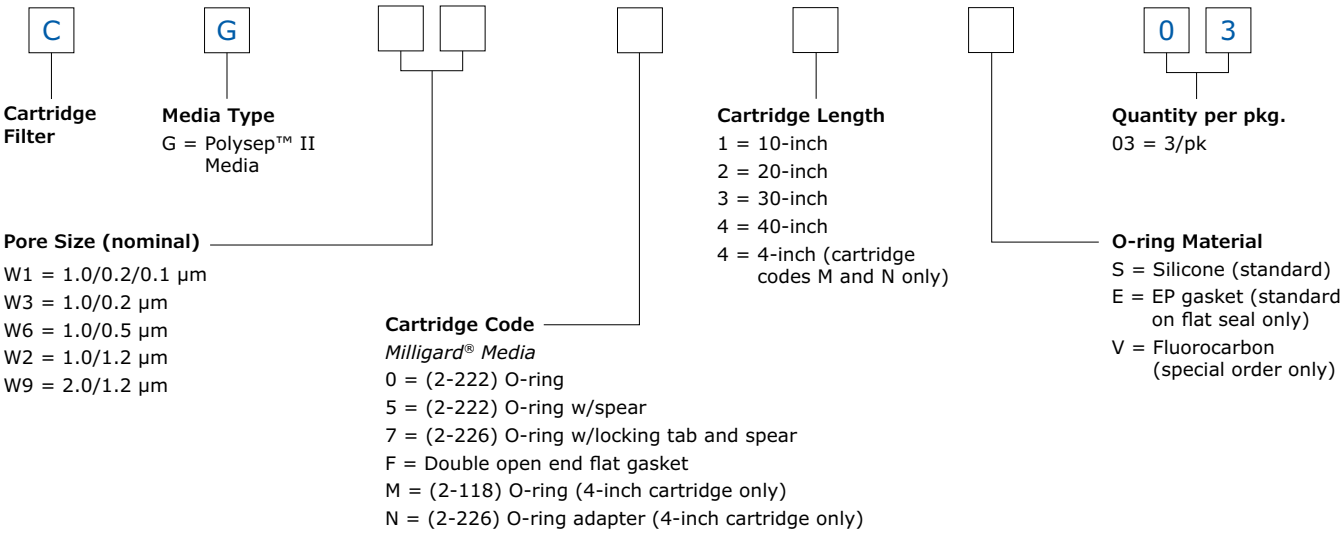
OptiScale Capsule Filters



Opticap XL 2 Capsule Filters



Cartridge Filters



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