



Data Sheet

Milligard® Filters

Superior filters for critical prefiltration applications

Milligard filters provide the finest prefiltration available. Milligard filters are constructed of homogeneous polymers of cellulose esters on a polyester web resulting in a versatile filter with high reproducibility and efficacy due to the highly retentive, non-fiber releasing membrane. The homogenous cellulose ester membrane provides the high retention needed during critical prefiltration steps while protecting more expensive downstream filtration devices from premature plugging.

Milligard filters are available in single and double layer formats.

Benefits

- Effectively protect expensive downstream filters from premature plugging
- High dirt holding capacity combined with high retention efficiency
- Unparalleled thermal and hydraulic stress resistance
- Validated to withstand multiple sterilization cycles
- Ideal for designing scalable solutions from bench top to full-scale manufacturing



| Media Types | Filter Formats |
|--|--|
| Milligard 0.2 µm 0.5 µm 1.2 µm 0.5/0.2 µm 1.2/0.5 µm Milligard pore sizes are nominal | <ul style="list-style-type: none">○ OptiScale® small scale disposable capsule filters○ Opticap® XL 2 disposable capsule filters |

APPLICATIONS

Cell Culture Media

Effectively remove particles and colloidal contaminants without obstructing the flow of vital media constituents. Milligard prefilters provide the high flow rates and consistently high throughput required to accomplish the separation in a timely and cost-effective manner.

Final Aseptic Fill of Small Volume Parenterals (SVP)

Extend the service life of downstream sterilizing filters by removing colloidal and particulate contaminants.

Large Volume Parenterals (LVP)

Extend the service life of downstream sterilizing filters by removing colloidal and particulate contaminants. Extremely robust and able to withstand high operating pressures, Milligard filters offer dependable retention and high flow rates needed for high volume manufacturing.

Plasma Proteins—Human Albumin

Remove colloids, aggregated and non-product proteins, lipids and particles prior to downstream purification without retaining the fractions of interest. Milligard filters provide superior protection of downstream sterile filters and/or chromatography columns.

Serum

Effectively remove lipids, colloids, and particles from serum before the final sterilizing filtration without obstructing the passage of serum proteins. Milligard filters provide high flow rates and consistently high throughput.

REGULATORY COMPLIANCE

Milligard 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.

MULTIPLE FORMATS AVAILABLE

Milligard filters are available in single or double layer, three formats, many pore sizes, and multiple configurations that vary by filtration area and the type of inlet/outlet connection.

OPTISCALE PROCESS DEVELOPMENT SCREENING TOOL

OptiScale disposable capsule filters with Milligard 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 filter eliminates 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 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.

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.

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 | 13.8 cm ² |
| Materials of Construction | |
| Filter media: | 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 Manufacturing Practices. |
| Component Material | Component materials meet the requirements of the USP <88> Reactivity Tests for Class VI Plastics. |
| Toxicity | This product is non-toxic per the USP <88> Safety Test. |
| Indirect Food Additive | All components meet the FDA Indirect Food Additive requirements cited in 21 CFR 177-182. |

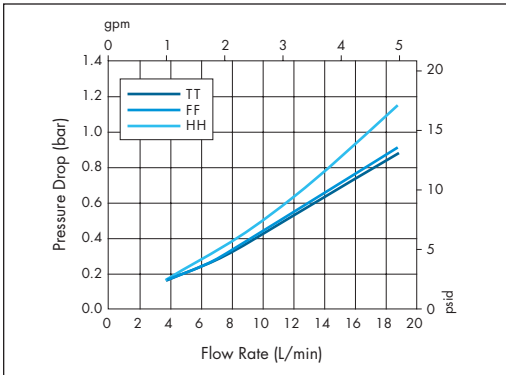
SPECIFICATIONS (Opticap XL 2 Capsule Filters)

| | |
|--------------------------------------|---|
| Nominal Dimensions | |
| Maximum length: | 14.2 cm (5.6 in.) |
| Nominal Diameters | |
| Body diameter: | 8.4 cm (3.3 in.) |
| Vent to vent diameter: | 12.5 cm (4.9 in.) |
| Filtration Area | |
| Single layer: | 0.10 m ² (1.1 ft ²) |
| Double layer: | 0.07 m ² (0.8 ft ²) |
| Materials of Construction | |
| Milligard Media: | Mixed esters of cellulose |
| Supports: | Polyester |
| 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: | 3.4 bar (50 psid) at ambient room temperature. |
| NVR Gravimetric Extractables | After autoclaving and a 24 hour soak in ASTM® Type 1 reagent grade water at controlled room temperature: |
| Milligard Media: | ≤ 15 mg |
| After a flush of: | 1000 mL |
| Oxidizable Substances | Meets the requirements of the USP Oxidizable Substances Test after a water flush of ≤ 1000 mL |
| Bacterial Endotoxin | Aqueous extraction contains < 0.5 EU/mL as determined by the Limulus Amebocyte Lysate (LAL) Test. |
| 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 Manufacturing Practices. |
| Non-Fiber Releasing | Milligard 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. Milligard filters meet 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. |

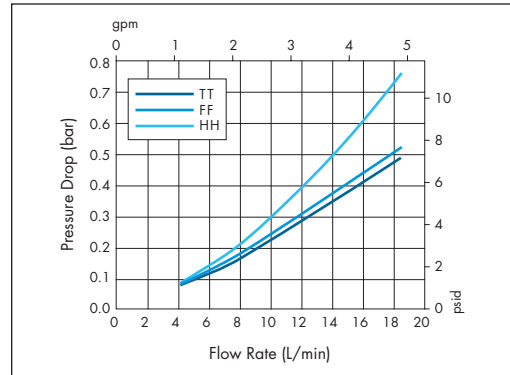
*Cage, core, end caps and capsule housing

TYPICAL CLEAN WATER FLOW RATES

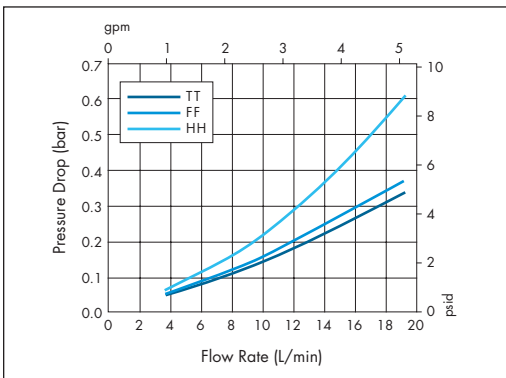
Opticap XL 2 Capsule with Milligard Media 0.2 µm Nominal (KW03)



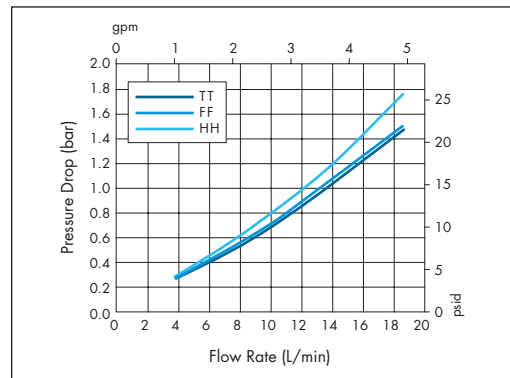
Opticap XL 2 Capsule with Milligard Media 0.5 µm Nominal (KW06)



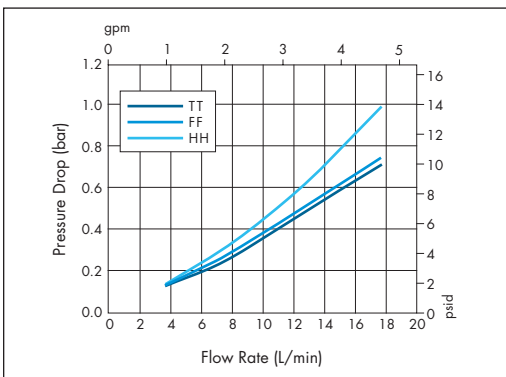
Opticap XL 2 Capsule with Milligard Media 1.2 µm Nominal (KW19)



Opticap XL 2 Capsule with Milligard Media 0.5/0.2 µm Nominal (KWSS)



Opticap XL 2 Capsule with Milligard Media 1.2/0.5 µm Nominal (KWSC)



Opticap XL Capsule Legends

Refer to Connection Type

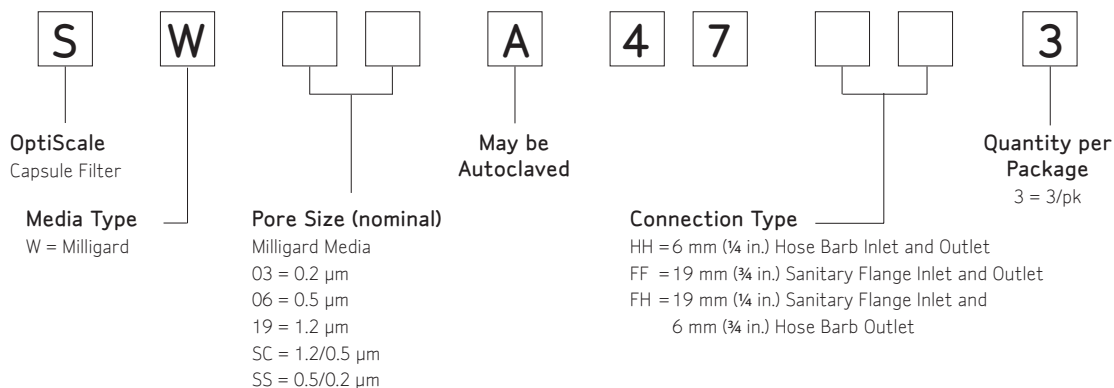
TT = 38 mm (1 1/2 in.) Sanitary Flange Inlet and Outlet

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

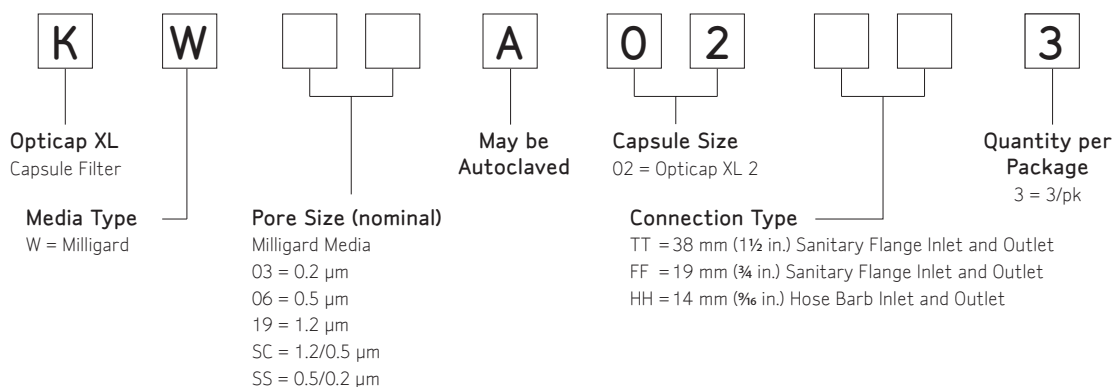
HH = 14 mm (1/2 in.) Hose Barb Inlet and Outlet

ORDERING INFORMATION

OptiScale Capsule Filters



Opticap XL 2 Capsule Filters



For technical assistance, contact Millipore:
1-800-MILLIPORE (1-800-645-5476)
E-mail: tech_service@millipore.com



For customer service, call **1-800-766-7000**.
To fax an order, use **1-800-926-1166**.
To order online: www.fishersci.com

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