

ПРЕДВАРИТЕЛЬНЫЕ ФИЛЬТРЫ MILLIGARD PES



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Milligard® PES Filters

Process Efficiency Made Easy

Milligard® PES filters are designed for effective bioburden control and reliable removal of particles from a broad range of fluid streams. These membrane based filters can provide validated bioburden reduction in applications where sterilizing filtration is not required. They can be used at different stages in a bioprocess production train enabling more efficient performance of sterile filters and protection of other unit operations.



Benefits

- Fast flow and high throughput
- Validated bioburden reduction (1.2/0.2 µm nominal and 1.2/0.45 µm pore sizes only)
- Predictable scalability from small-scale to production scale devices
- High thermal stability; compatible with steam-in-place and autoclave sterilization methods
- Caustic stable
- Single-use, gamma ready formats

Available Pore Sizes for Bioburden and Particulate Reduction

- 1.2/0.2 µm nominal
- 1.2/0.45 µm

Available Pore Sizes for Particulate Reduction

- 1.2/0.8 µm

Filter Formats

Milligard® PES filters are offered in a range of filter formats and capsule sizes, and allow easy scale-up from small to larger, full-scale filtration processes.

- OptiScale® 25 capsules
- Opticap® XL capsules
- Cartridges

Quality Management System

Milligard® PES 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 cartridge filter is supported by documentation to meet appropriate regulatory requirements. For traceability and easy identification, each filter is marked with identifying characteristics.

OptiScale® 25 Capsules

Single-use, Small-Scale Tool for Process Screening and Scaling

Our OptiScale® 25 single-use capsule filters are ideal for evaluating performance of different filters with various process streams.

Opticap® XL Capsules

For Bench to Production Scale Processing

Opticap® XL single-use capsule filters eliminate the time and expense associated with assembling, cleaning, and validating stainless steel housings. Capsules may be sterilized by autoclaving or gamma irradiation. Capsules are available with a variety of inlet and outlet connections.

Cartridge Filters

For Pilot and Production Scale Processing

Our cartridge filters are designed for use in stainless steel housings and provide high throughput and minimal differential pressure. A full range of filtration areas and connection options are available for maximum flexibility.

Specifications

OptiScale® 25 Capsules, Opticap® XL Capsules and Cartridge Filters

Description	OptiScale® 25 Capsules	per 10-inch Cartridge	Opticap® XL 5 Capsules	Opticap® XL 10 Capsules
Nominal Dimensions				
Diameter:	3.1 cm (1.21 in.)	6.9 cm (2.7 in.)	10.7 cm (4.2 in.)	10.7 cm (4.2 in.)
Length:	3.9 cm (1.52 in.)	31.8 cm (12.5 in.)	21.6 cm (8.5 in.)	33.5 cm (13.2 in.)
Approximate Filtration Area	3.5 cm ²			
1.2/0.2 µm nominal (m ² /ft ²)	—	0.60 m ² (6.4 ft ²)	0.30 m ² (3.2 ft ²)	0.60 m ² (6.4 ft ²)
1.2/0.45 µm (m ² /ft ²)	—	0.60 m ² (6.4 ft ²)	0.30 m ² (3.2 ft ²)	0.60 m ² (6.4 ft ²)
1.2/0.8 µm (m ² /ft ²)	—	0.53 m ² (5.7 ft ²)	0.29 m ² (3.1 ft ²)	0.57 m ² (6.1 ft ²)
Materials of Construction				
Upstream Membrane:	Hydrophilic polyethersulfone			
Downstream Membrane:	Hydrophilic polyethersulfone			
Filter Supports:	Polypropylene			
Core:	—	Polypropylene	Polyester	
Cage:	—	Polypropylene	Gamma stable polypropylene	
Endcaps:	—	Polypropylene	Gamma stable polypropylene	
Capsule Housing:	—	—	Gamma stable polypropylene	
O-ring:	—	Silicone	—	
Vent Cap:	Polypropylene		—	
Vent O-ring:	—	—	Silicone	
Housing Vent	Capped vent with female Luer connection 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 psi) at 4-25 °C 1.7 bar (25 psi) at 80 °C 0.3 bar (4 psi) at 135 °C	5.5 bar (80 psi) at 4-25 °C 1.7 bar (25 psi) at 80 °C —	5.5 bar (80 psi) at 4-25 °C 1.7 bar (25 psi) at 80 °C —
Reverse:	0 bar	1.4 bar (20 psi) at 4-25 °C 0.07 bar (1 psi) at 135 °C	1.4 bar (20 psi) at 4-25 °C —	1.4 bar (20 psi) at 4-25 °C —
Bubble Point at 25 °C				
1.2/0.2 µm nominal:	—	≥ 2700 mbar (39.2 psi) air with water		
1.2/0.45 µm:	—	≥ 2290 mbar (33.3 psi) air with water		
1.2/0.8 µm:	—	≥ 990 mbar (14.3 psi) air with water		
Bioburden Reduction	—	The 1.2/0.2 µm nominal filter typically provides ≥6 log removal of <i>Brevundimonas diminuta</i> based on ASTM® F838 methodology. The 1.2/0.45 µm filter typically provides ≥6 log removal of <i>Serratia marcescens</i> based on ASTM® D3863 and F838 methodology.		

Milligard® PES filters are supported by 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.

Mobius® Single-use Solutions

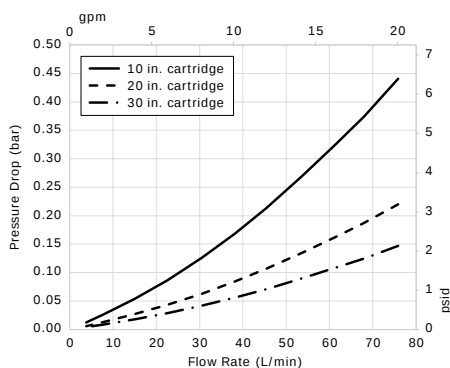
Milligard® PES filters are part of the Mobius® library. This provides you with the flexibility to design single-use assemblies that meet your specific processing requirements.

OptiScale® 25 Capsules, Opticap® XL Capsules, and Cartridge Filters (continued)

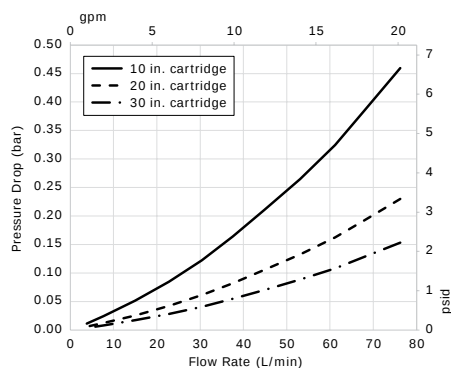
Description	OptiScale® 25 Capsules	per 10-inch Cartridge	Opticap® XL 5 Capsules	Opticap® XL 10 Capsules
Bacterial Endotoxin	Aqueous extraction contains <0.25 EU/mL per device as determined using the Limulus Amebocyte Lysate (LAL) test, meeting requirements of USP <85>, EP 2.6.14 and JP 4.01.			
TOC/Conductivity at 25 °C	This product exhibits less than 500 ppb TOC per USP <643> and less than 1.3 µS/cm at 25 °C per USP <645> after autoclaving and purified water flush of 15 mL.	After sterilization and a controlled water flush of 20 L per 10-inch device, sample exhibited ≤500 ppb TOC per USP <643> and ≤1.3 µS/cm per USP <645> at 25 °C.		
Sterilization	May be autoclaved for 1 cycle at 123 °C for 60 min.	Device integrity was maintained after 25 autoclave cycles of 60 minutes at 128 °C. Device integrity was maintained after in-line steam of 10 forward and 5 reverse cycles of 30 minutes at 135 °C.	Device integrity was maintained after gamma irradiation up to 40 kGy and 3 wet autoclave cycles of 60 minutes at 123 °C.	
Non-Fiber Releasing	Devices tested and meet requirements of USP <788> for large volume parenterals.			
Component Material Toxicity	Component Materials meet the criteria of the USP <88> Reactivity Test for Class VI Plastics. This product is non-cytotoxic per USP <87> Cytotoxicity MEM Elution Test.		Component materials meet the criteria for Class VI testing based on USP <88> Biological Reactivity, <i>in vivo</i> . This product meets the specifications of ISO 10993-5 Tests for in vitro cytotoxicity and USP <87> Biological Reactivity, <i>in vitro</i> . This product also meets physicochemical specifications, as described in USP <661> Containers-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.			
Quality Management System	This product was manufactured in a facility whose Quality Management System is approved by an accredited registering body to the appropriate ISO® 9001 Quality Management Systems Standard.			

Typical Clean Water Flow Rates

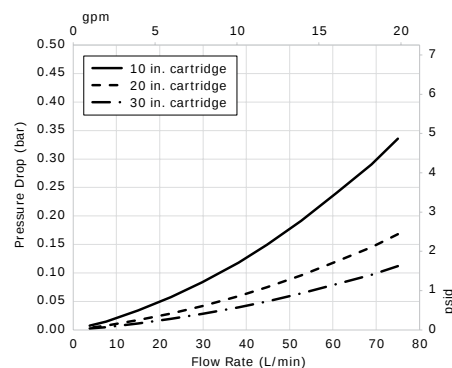
Milligard® PES Membrane in a Cartridge Filter – 1.2/0.2 µm Nominal



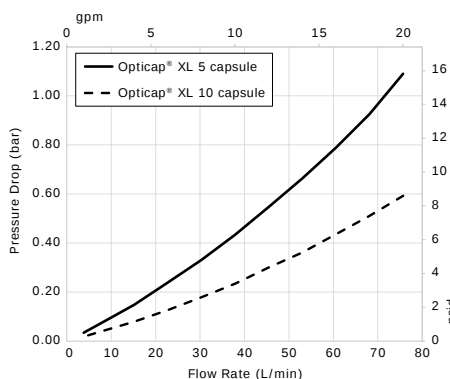
Milligard® PES Membrane in a Cartridge Filter – 1.2/0.45 µm



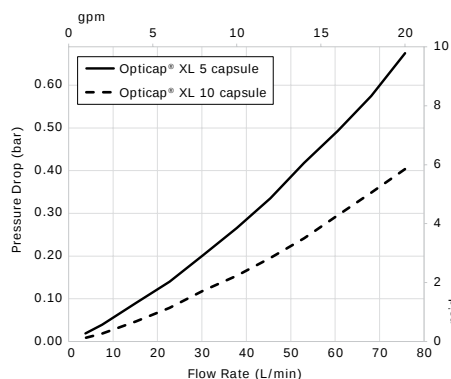
Milligard® PES Membrane in a Cartridge Filter – 1.2/0.8 µm



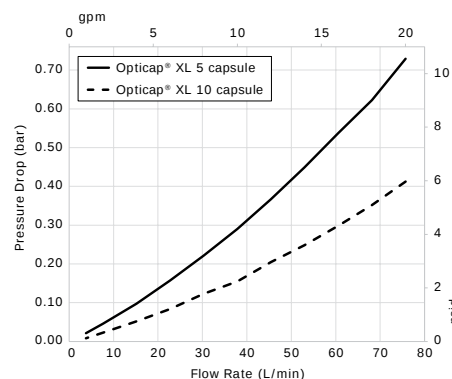
Milligard® PES Membrane in an Opticap® XL Capsule Filter – 1.2/0.2 µm Nominal



Milligard® PES Membrane in an Opticap® XL Capsule Filter – 1.2/0.45 µm

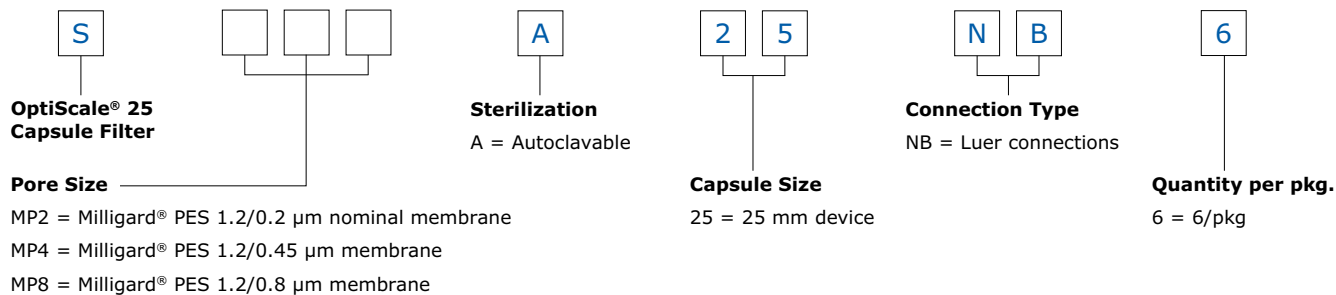


Milligard® PES Membrane in an Opticap® XL Capsule Filter – 1.2/0.8 µm

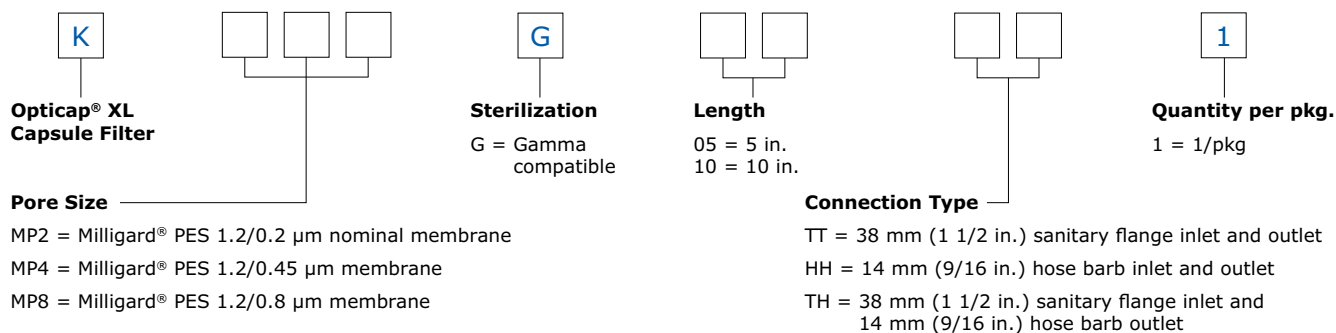


Ordering Information

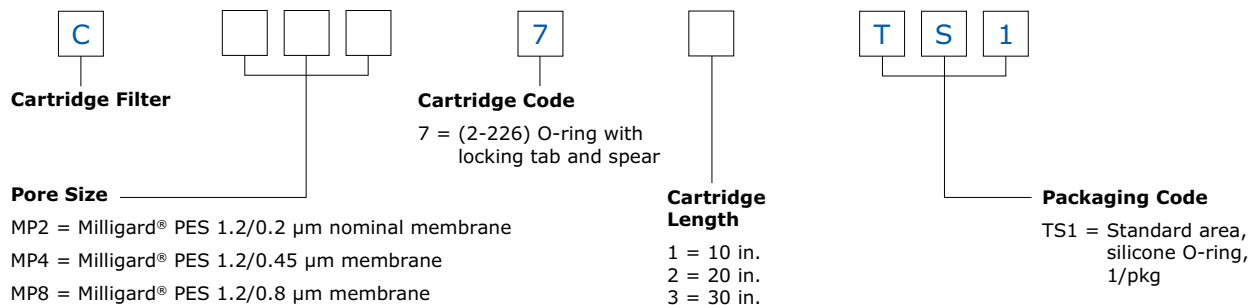
Milligard® PES Membrane in OptiScale® 25 Capsule Filters



Milligard® PES Membrane in Opticap® XL Capsule Filters



Milligard® PES Membrane in Cartridge Filters



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