

Lifegard™ Filters

Superior filters for the clarification and prefiltration of viscous biological fluids when high contaminant holding capacity is required



- ▶ *Exceptional retention of viscous biologicals*
- ▶ *High contaminant holding capacity and adsorptive removal properties*
- ▶ *A robust membrane with a long service life and excellent wet strength*
- ▶ *Designed for rigorous process conditions*
- ▶ *Ideal for designing scalable solutions from bench top to full-scale manufacturing*

Lifegard glass microfiber medium was designed for removal of deformable and non-deformable particles and microorganisms from liquids. Versatile depth-type products retain contaminants within the matrix of glass microfiber medium. The Lifegard media is used to achieve exceptional retention efficiency. Because of its high holding capacity, adsorptive removal properties and excellent wet strength, it is very well-suited for the clarification and prefiltration of serum, plasma proteins, gene therapy and other viscous biologicals.

The Filter of Choice in Plasma and Protein Serum Applications

Lifegard filters protect downstream sterile filters and chromatography columns while effectively removing contaminants and retaining valuable fractions of interest. These filters will remove colloids, aggregated and non-product proteins, lipids and other particles before downstream purification.

Regulatory Compliance

Filters with Lifegard media 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 for documentation accuracy. Each Opticap XL capsule and cartridge 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

Lifegard media is available in three formats, two pore sizes, and multiple configurations that vary by filtration area and the type of inlet and outlet connection.

Media Types

- Lifegard
- 1.0 µm nominal
 - 2.0 µm nominal

Filter Formats

- OptiScale™ small scale disposable capsule filters
- Opticap™ XL disposable capsule filters
- Cartridge filters

**From process
development
to full-scale
production,
Millipore
has the right
solution for you!**

**OptiScale Process
Development Screening Tool**



OptiScale Filters

OptiScale disposable capsule filters with Lifegard 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.

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Opticap XL Disposable Capsule Filters



Opticap XL Filters

Opticap XL disposable capsule filters with Lifegard media are available in two filtration areas, providing an optimal choice for your application.

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 Lifegard media minimizes hold-up volume and reduces production losses.

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 Size

A wide range of filtration areas is available to fit all of your application needs 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 capsule filters are supplied with a choice of inlet and outlet connections to optimize your filtration process, including sanitary flanges which provide a higher flow rate, fractional sanitary flanges, and hose barbs.

Cartridge Filters



Cartridge Filters

Lifegard cartridge filters are ideally suited for processes that require maximum pressure differentials. Cartridges are robust, strong, resilient and are designed to withstand multiple steam-in-place cycles.

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

Specifications

	OptiScale
Nominal Dimensions <i>Maximum length:</i> <i>Diameter:</i> <i>Weight:</i>	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 69 mm (2.75 in.) 2.3 oz (67 g)
Filtration Area	13.8 cm ²
Materials of Construction <i>Filter media:</i> <i>Structural components:</i> <i>Vent cap:</i> <i>Internal seal rings:</i>	Borosilicate glass microfiber Polycarbonate PVDF 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 Toxicity	Component materials were tested and meet the criteria of the USP <88> Reactivity Tests for Class VI Plastics. Lifeguard 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.

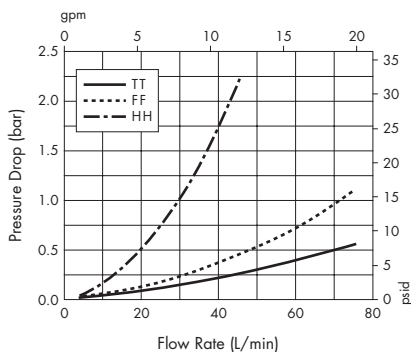
Specifications

	Opticap XL 5	Opticap XL 10	4-inch Cartridge	Per 10-inch Cartridge
Nominal Dimensions				
Maximum length:	21.6 cm (8.5 in.)	33.5 cm (13.2 in.)	—	—
Body diameter:	10.7 cm (4.2 in.)	10.7 cm (4.2 in.)	—	—
Vent to vent diameter:	14.5 cm (5.7 in.)	14.5 cm (5.7 in.)	—	—
Outside diameter:	—	—	6.9 cm (2.7 in.)	6.9 cm (2.7 in.)
Filtration Area	0.19 m ² (2.0 ft ²)	0.46 m ² (5.0 ft ²)	0.19 m ² (2.0 ft ²)	0.46 m ² (5.0 ft ²)
Materials of Construction				
Filter media:	Borosilicate glass microfiber		Borosilicate glass microfiber	
Supports:	Polypropylene		Polypropylene	
Structural components *:	Polypropylene		Rigid polypropylene	
Vent O-rings:	Silicone		—	
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 Operating Temperature	—		80 °C continuous	
Maximum Differential Pressure				
Forward:	3.4 bar (50 psid) at ambient room temperature		3.4 bar (50 psid) at 25 °C	
NVR Gravimetric Extractables	After autoclaving and a 24 hour soak in ASTM® Type 1 reagent grade water at controlled room temperature:			
1.0 µm:	≤ 105 mg	≤ 255 mg	—	≤ 250 mg
2.0 µm:	≤ 93 mg	≤ 225 mg		after a 5 L flush
	after a 2 L flush	after a 5 L flush		
Bacterial Endotoxin	Aqueous extraction contains < 1.0 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:			
	≤ 2000 mL	≤ 5000 mL	—	≤ 5000 mL
Sterilization by Autoclave	May be autoclaved for 3 cycles of 30 minutes at 121 °C. (Cannot be steam sterilized in-line.)		May be autoclaved for 10 cycles of 30 minutes at 121 °C; or steam sterilized for 10 cycles of 30 minutes at 121 °C at 1 bar; or hot water sanitized at 80 °C for 30 minutes.	
Good Manufacturing Practices	These products are manufactured in a Millipore facility which adheres to FDA Good Manufacturing Practices.			
Component Material Toxicity	Component materials were tested and meet the criteria of the USP <88> Reactivity Test for Class VI Plastics. Lifeguard filters meet the requirements of the USP <88> Safety Test utilizing a 0.9% sodium chloride extraction.			
Indirect Food Additive	The Lifeguard media 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.			

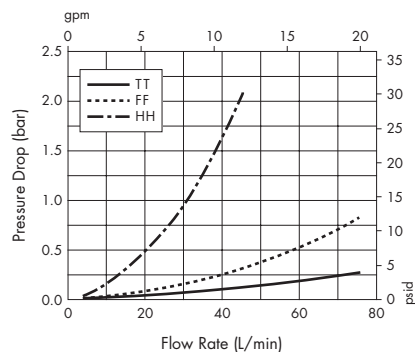
*Cage, core, end caps, capsule housing (Opticap XL), outer sleeve (cartridges)

Typical Clean Water Flow Rates

Opticap XL 5 Capsule with Lifegard Media — 1.0 μm Nominal (KP15)



Opticap XL 5 Capsule with Lifegard Media — 2.0 μm Nominal (KP20)



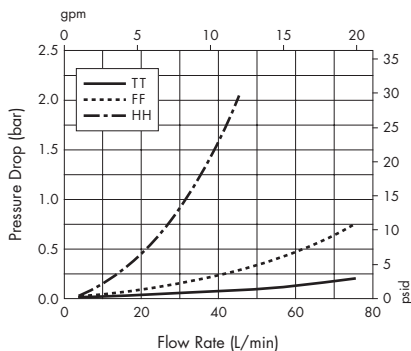
Opticap XL Capsule Legends Refer to Connection Type

TT = 38 mm (1½ in.) Sanitary Flange Inlet and Outlet

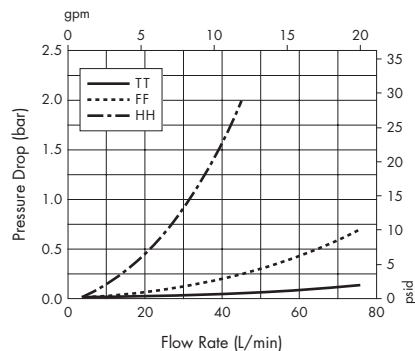
FF = 19 mm (¾ in.) Sanitary Flange Inlet and Outlet

HH = 14 mm (⅝ in.) Hose Barb Inlet and Outlet

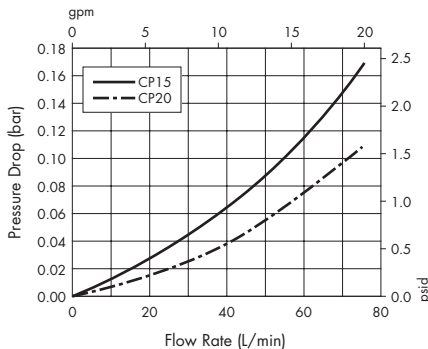
Opticap XL 10 Capsule with Lifegard Media — 1.0 μm Nominal (KP15)



Opticap XL 10 Capsule with Lifegard Media — 2.0 μm Nominal (KP20)



10-inch Cartridge Filters with Lifegard Media — 1.0 and 2.0 μm Nominal



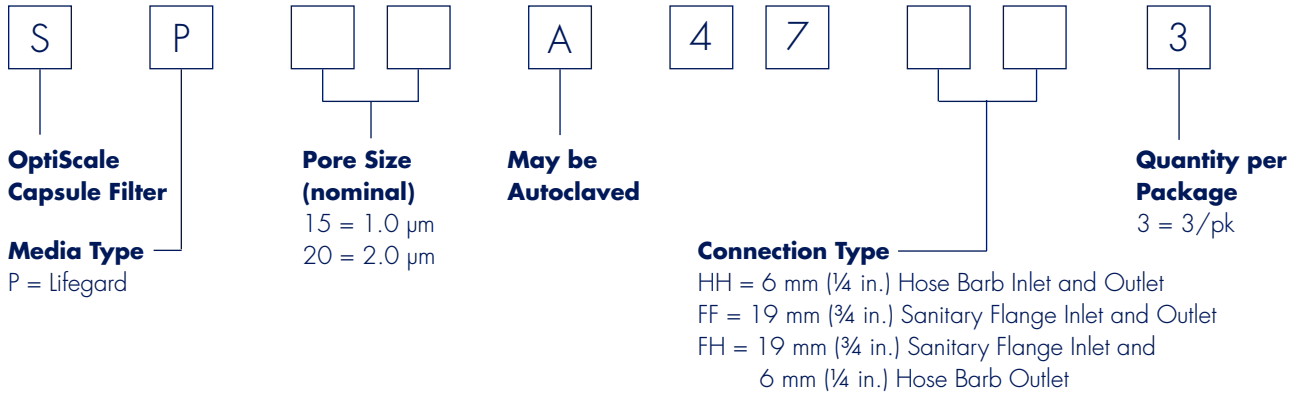
Cartridge Legend Refers to Pore Size

CP15 = 1.0 μm

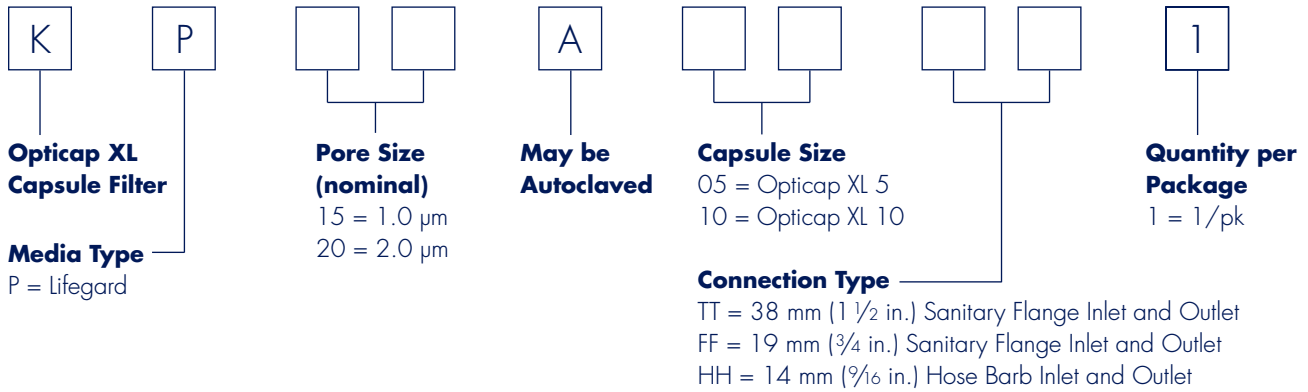
CP20 = 2.0 μm

Ordering Information

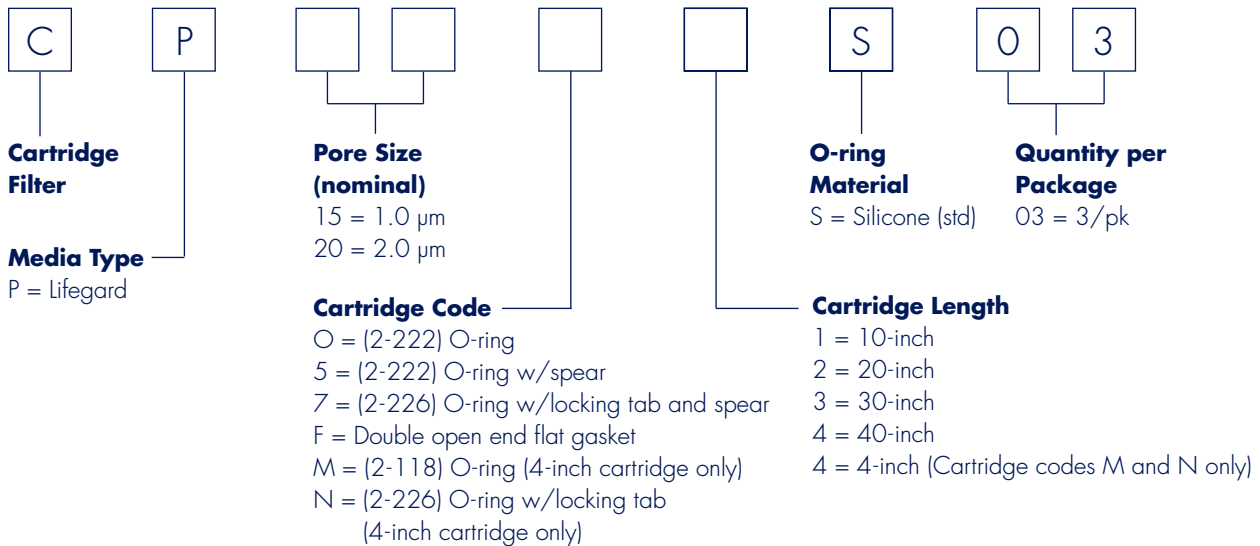
OptiScale Capsule Filters



Opticap XL Capsule Filters



Cartridge Filters



Discover the More in Millipore™

In every application, every step and every scale, count on Millipore to be everywhere for you — from monoclonals to vaccines, from clinical through pilot to full-scale manufacturing. Our technologies are used by most of the world's major biopharmaceutical companies. But we deliver more than advanced separation, purification, sterilization and quality control products. With Millipore, you get services to optimize and validate your processes, comprehensive resources to streamline and enhance your operation, unmatched know how forged from nearly 50 years' experience — and solutions that integrate it all. For higher yields, improved process economics and faster speed to market, discover the more in Millipore.

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MILLIPORE

Lifegard-Cartridge-Filters

KP15A05TT1	CP15OS03
KP15A05FF1	CP15OS03
KP15A05HH1	CP15OS03
KP15A10TT1	CP155S03
KP15A10FF1	CP155S03
KP15A10HH1	CP155S03
KP20A05TT1	CP157S03
KP20A05FF1	CP157S03
KP20A05HH1	CP157S03
KP20A10TT1	CP15FS03
KP20A10FF1	CP15FS03
KP20A10HH1	CP15FS03
	CP15MS03
	CP15NS03
SP15A47HH3	CP20OS03
SP15A47FF3	CP20OS03
SP15A47FH3	CP20OS03
SP20A47HH3	CP205S03
SP20A47FF3	CP205S03
SP20A47FH3	CP205S03
	CP207S03
	CP207S03
	CP207S03
	CP20FS03
	CP20FS03
	CP20FS03
	CP20MS03
	CP20NS03

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