

# 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 Lifeguard 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.

### Table of Contents

#### OptiScale Capsule Filters

Specifications . . . . .	4
Ordering Information . . . . .	7

#### Opticap XL Capsule Filters

Specifications . . . . .	5
Typical Clean Water Flow Rates . . . . .	6
Ordering Information . . . . .	7

#### Cartridge Filters

Specifications . . . . .	5
Ordering Information . . . . .	7

## Opticap XL Disposable Capsule Filters



*Opticap XL Filters*

Opticap XL disposable capsule filters with Lifeguard 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 Lifeguard 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*

Lifeguard 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
<b>Nominal Dimensions</b> <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)
<b>Filtration Area</b>	13.8 cm <sup>2</sup>
<b>Materials of Construction</b> <i>Filter media:</i> <i>Structural components:</i> <i>Vent cap:</i> <i>Internal seal rings:</i>	Borosilicate glass microfiber Polycarbonate PVDF Viton® fluoroelastomers
<b>Housing Vent</b>	Adjustable vent with male luer and female Luer-Lok™ connections on inlet side of device.
<b>Maximum Inlet Pressure</b>	5.5 bar (80 psi) at 25 °C.
<b>Oxidizable Substances</b>	Capsules meet the requirements of the USP Oxidizable Substance for Sterile Water for Filtration Test after a water flush of ≤ 100 mL.
<b>Sterilization</b>	May be autoclaved for 3 cycles of 60 minutes at 121 °C
<b>Good Manufacturing Practices</b>	These products are manufactured in a Millipore facility which adheres to FDA Good Manufacturing Practices.
<b>Component Material Toxicity</b>	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.
<b>Indirect Food Additive</b>	All component materials meet the FDA Indirect Food Additive requirements cited in 21 CFR 177–182.

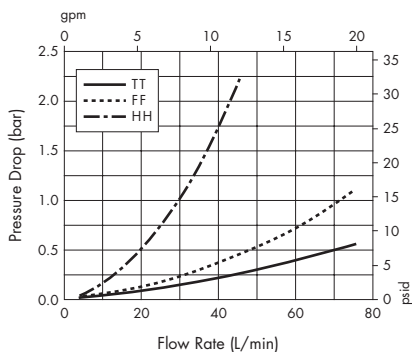
## Specifications

	Opticap XL 5	Opticap XL 10	4-inch Cartridge	Per 10-inch Cartridge
<b>Nominal Dimensions</b>				
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.)
<b>Filtration Area</b>	0.19 m <sup>2</sup> (2.0 ft <sup>2</sup> )	0.46 m <sup>2</sup> (5.0 ft <sup>2</sup> )	0.19 m <sup>2</sup> (2.0 ft <sup>2</sup> )	0.46 m <sup>2</sup> (5.0 ft <sup>2</sup> )
<b>Materials of Construction</b>				
Filter media:	Borosilicate glass microfiber		Borosilicate glass microfiber	
Supports:	Polypropylene		Polypropylene	
Structural components*:	Polypropylene		Rigid polypropylene	
Vent O-rings:	Silicone		—	
O-rings:	—		Silicone	
<b>Vent/Drain</b>	¼ in. hose barb with double O-ring seal		—	
<b>Maximum Inlet Pressure</b>	5.5 bar (80 psi) at 23 °C 2.8 bar (40 psi) at 60 °C 1.0 bar (15 psi) at 80 °C		—	
<b>Maximum Operating Temperature</b>	—		80 °C continuous	
<b>Maximum Differential Pressure</b>				
Forward:	3.4 bar (50 psid) at ambient room temperature		3.4 bar (50 psid) at 25 °C	
<b>NVR Gravimetric Extractables</b>	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		
<b>Bacterial Endotoxin</b>	Aqueous extraction contains < 1.0 EU/mL as determined by the Limulus Amebocyte Lysate (LAL) Test.			
<b>Oxidizable Substances</b>	Capsules meet the requirements of the USP Oxidizable Substances Test after a water flush of: ≤ 2000 mL		—	≤ 5000 mL
		≤ 5000 mL		
<b>Sterilization by Autoclave</b>	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.	
<b>Good Manufacturing Practices</b>	These products are manufactured in a Millipore facility which adheres to FDA Good Manufacturing Practices.			
<b>Component Material Toxicity</b>	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.			
<b>Indirect Food Additive</b>	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.			

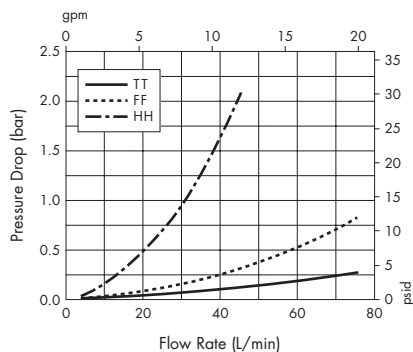
\*Cage, core, end caps, capsule housing (Opticap XL), outer sleeve (cartridges)

## Typical Clean Water Flow Rates

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



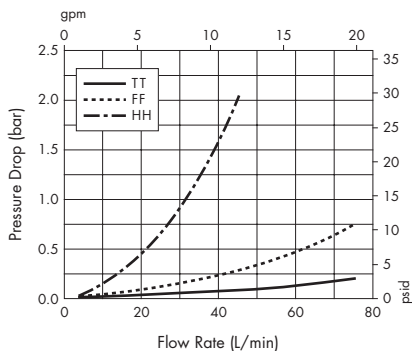
Opticap XL 5 Capsule with Lifegard Media — 2.0 µm Nominal (KP20)



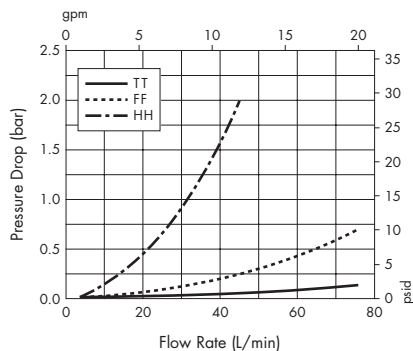
### Opticap XL Capsule Legends Refer to Connection Type

- 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

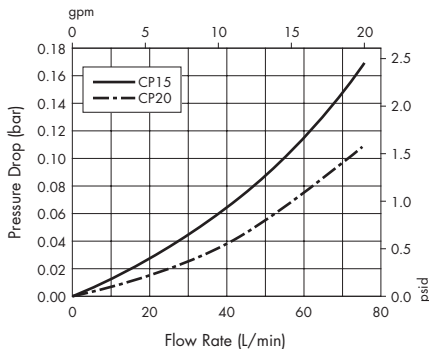
Opticap XL 10 Capsule with Lifegard Media — 1.0 µm Nominal (KP15)



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

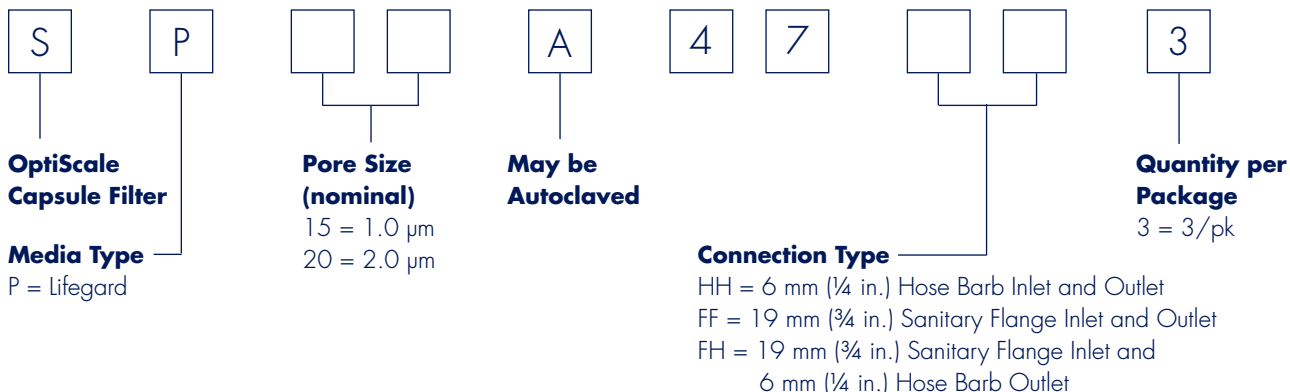


### Cartridge Legend Refers to Pore Size

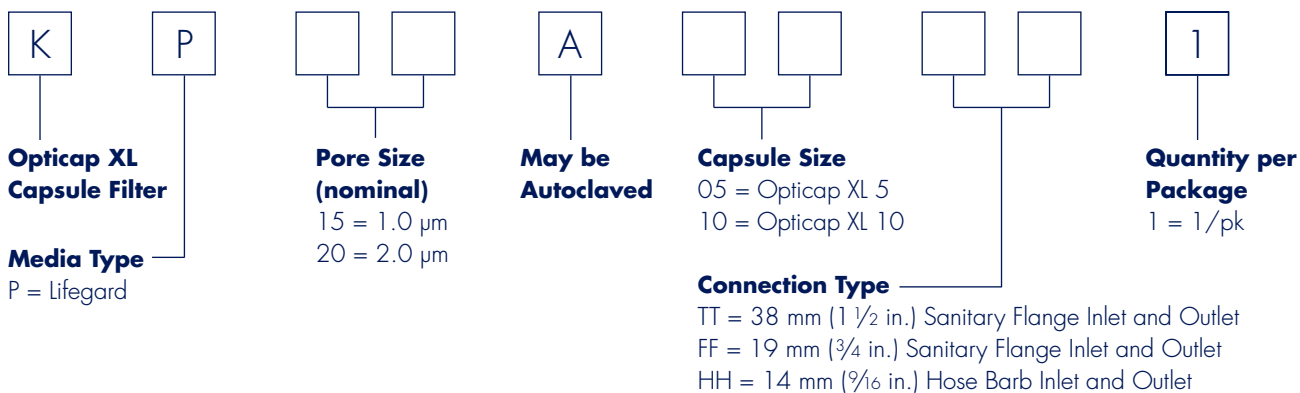
- CP15 = 1.0 µm
- CP20 = 2.0 µm

## Ordering Information

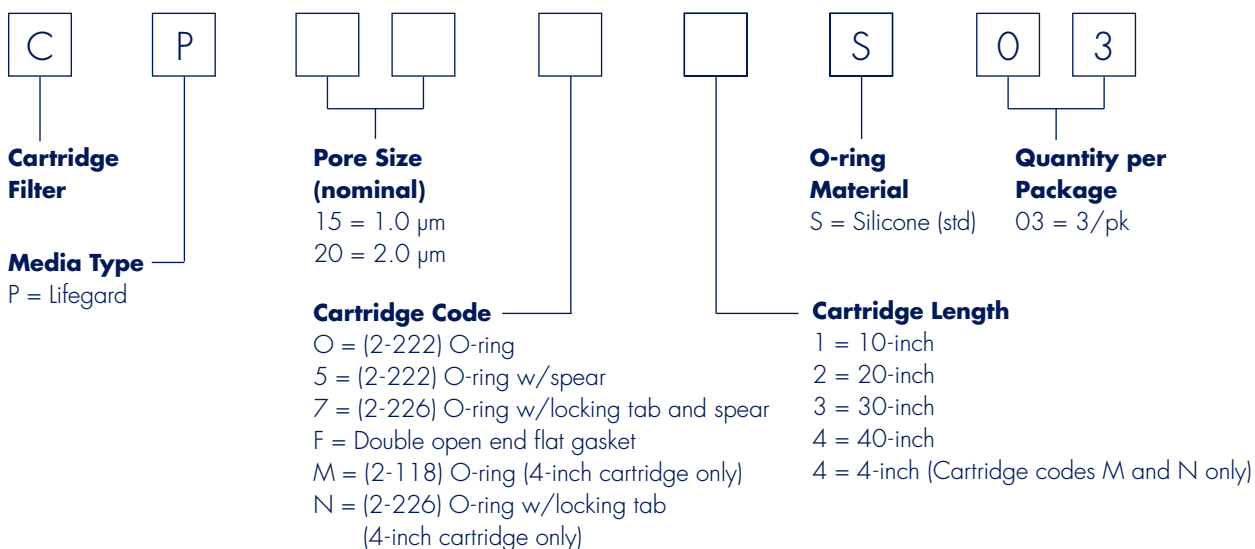
### OptiScale Capsule Filters



### Opticap XL Capsule Filters



### Cartridge Filters



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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  
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CP20MS03  
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