

#### **Data Sheet**

# Millipore Express<sup>®</sup> SHF Hydrophilic Filters

Sterilizing-Grade PES membrane for fast, efficient, economical buffer filtration



- High-flux hydrophilic PES sterilizing-grade membrane
- Faster flow, up to 2.5 times faster than most other sterilizing grade membranes
- Increased output without increasing filtration area
- Lower cost from improved process economics
- Optimized for buffer filtration which requires sterility assurance and high flow rates
- Broad chemical compatibility across a wide pH range—NaOH compatible

Millipore Express SHF (Sterile High-Flux) devices are the choice for optimal buffer filtration. A sterilizing grade, 0.2  $\mu$ m hydrophilic polyethersulfone (PES) membrane, Millipore Express SHF filters provide sterility assurance, broad chemical compatibility, and exceptionally high flow rates for buffers at the high and low range of pH, 1–14.

The high flow rate of the Millipore Express SHF membrane cuts your filtration time in half, dramatically improving filtration economics and extending production capacity. The membrane is caustic compatible and offers high-flux performance with a full range of buffer chemistries. Its low extractables and non-fiber releasing properties contribute to clean processes. With Millipore Express SHF filters, you increase productivity, shorten cycle-time and reduce costs.

#### Superior Performance, Speed and Value

For biotech and pharmaceutical customers seeking fast, efficient and economical sterile buffer filtration, no PES membrane delivers more than Millipore Express SHF.

- Fast filtration with sterility assurance
- Broad chemical compatibility even at high pH
- Low filtration costs reduced up-front filter and overall filtration costs.

Membrane Types	Filter Formats
Millipore Express SHF     PES membranes	OptiScale® small-scale disposable capsule filters
	Opticap® XL and XLT disposable capsule filters – autoclavable, sterile and gamma compatible Cartridge filters

#### Developed to Enhance Buffer Filtration

Millipore Express SHF filters use a fast flowing process membrane specifically developed for the filtration of buffers, pH adjusters and other aqueous intermediate pharmaceutical and biotech process solutions. Designed to offer high-flux performance and improved economics, Millipore Express SHF membrane is compatible with a wide range of buffer chemistries, including acids and sodium hydroxide.

#### More than Twice as Fast

Millipore Express SHF filters have flow rates that are up to two to two-and-a-half times faster than other sterilizing grade membranes for lower filtration costs and increased production capacity. You get fast flowing filters with broad chemical compatibility, especially at the high pH of caustic and buffer solutions.

#### **Reduced Surface Area and Lower Costs**

Because Millipore Express SHF filters feature flow rates faster than most other membranes, you can maintain batch volume while reducing filtration surface area. This high-flux benefit has been shown to deliver greater than 50 percent savings in filtration costs, improving your process economics.

# Reduced Process Time and Extended Capacity

Millipore Express SHF filters are ideal for maximizing the capacity of constrained buffer filtration systems. With its superior flux, you can reduce processing time by half, doubling your output without significant capital expense.

#### Reliable Performance

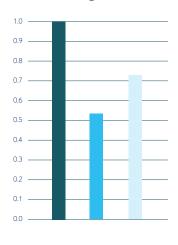
Millipore Express SHF membrane delivers all the benefits you'd expect from a quality Millipore membrane. Reliable sterilizing performance. Multiple steam-in-place or autoclave sterilization cycles. Broad chemical compatibility. Easy integrity testing. And fast flow to help you fill your buffer filtration tank quickly—now with the added benefits of improving efficiency and economics.

#### **Regulatory Compliance**

Millipore Express SHF filters are designed, developed and manufactured in accordance with a Quality Management System approved by an accredited registering body of an ISO® 9000 Quality Systems Standard. Each device is shipped with a Certificate of Quality. All cartridge filters are 100% integrity tested during manufacture and supported by a Validation Guide for compliance with regulatory requirements. For traceability and easy identification, each filter is identified with product name and other characteristics.

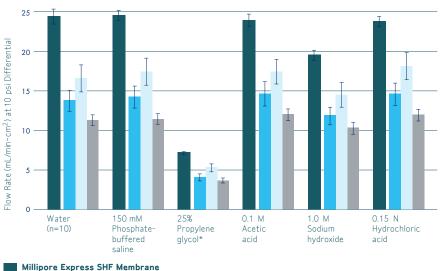
#### SUPERIOR FLUX

Relative Water Permeability of 10-inch Cartridges





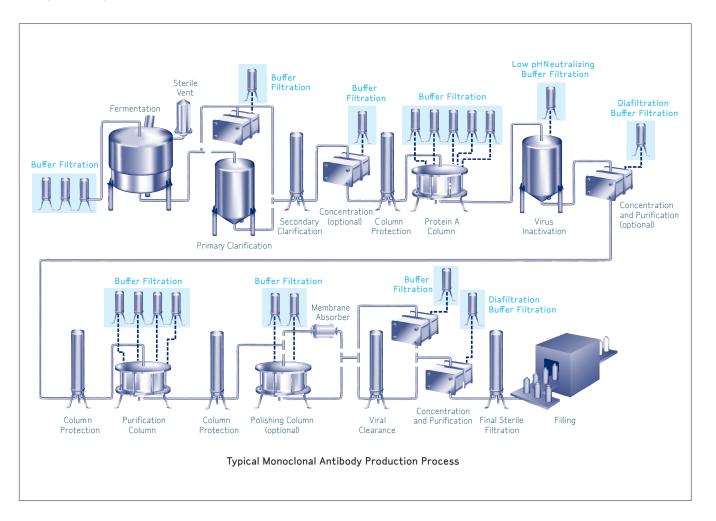
Millipore Express SHF Membrane Flux Relative to Competitors (n=2)

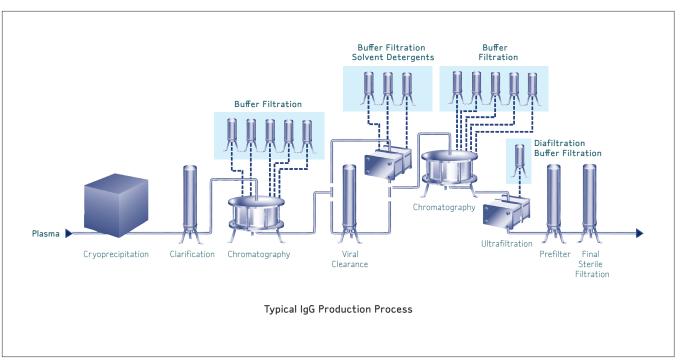


Millipore Expres
Competitor A
Competitor B1
Competitor B2

\*Includes 0.2 M Arginine-HCI, 0.5 M Sodium Phosphate

#### Millipore Express SHF Filters for All Your Buffer Filtration Needs





From process development to full-scale production, Millipore has the right solution for all of your process needs.





OptiScale Filters

# OptiScale Process Development Screening Tool

OptiScale disposable capsule filters 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 capsule is ideally suited for process development and screening. OptiScale capsules are faster and easier to set-up than conventional 47 mm discs, and completely disposable.

Cartridge Filters

### **Cartridge Filters**

Millipore Express SHF 5- 10-, 20-, and 30-inch cartridge filters provide very high flow rates. Cartridges are robust, strong, resilient and designed to withstand multiple steam-in-place cycles. Each cartridge is integrity tested during manufacturing.

Code O and code 7 O-ring adaptors are available to suit your application and housing needs.

### Opticap XL and XLT Disposable Capsule Filters





# Convenient and Easy to Use

Opticap XL and XLT 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.



Opticap XLT Filters

## The Right Size

Opticap XLT 10, 20 and 30 capsules are available 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

Designed to optimize your filtration process, Opticap XL and XLT disposable capsule filters are available with a choice of inlet and outlet connections, including sanitary flanges, fractional sanitary flanges as well as hose barbs.

# **Proven Integrity**

Each capsule is integrity tested during the manufacturing process to ensure reliable performance in your process.

#### **Robust Construction**

Opticap XL and XLT's capsule design allows unparalleled hydraulic stress resistance in a disposable filter.

# Opticap XL 3, 5 and 10 Capsule Filters

Opticap XL disposable capsule filters have a unique design to minimize hold-up volume and reduce production losses.

# Opticap XLT 10, 20 and 30 Capsule Filters

Opticap XLT disposable T-line capsule filters are available with or without a pressure gauge port for ease in monitoring process conditions. The T-line design accommodates series or parallel filtration to match your application needs, and a specially-designed stand enables quick and easy integration into your existing process.



Opticap XLT Capsule Stand

# Cartridge Filters and OptiScale Disposable Capsules

	OptiScale Capsules	Cartridge Filters 5-inch	Per 10-inch Filter			
Nominal Dimensions Diameter: Length:  Weight	69 mm (2.75 in.) 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 67 g (2.3 oz)	6.9 cm (2.7 in.) 12.5 cm (5 in.)	6.9 cm (2.7 in.) 25.4 cm (10 in.)			
Filtration Area	17.7 cm <sup>2</sup>	0.29 m <sup>2</sup> (3.1 ft <sup>2</sup> )	0.54 m <sup>2</sup> (5.8 ft <sup>2</sup> )			
Materials of Construction Filter membrane: Film edge: Supports: Cage and end caps: Core: Structural components: Vent cap: O-rings:	Hydrophilic polyethersulfone — Polypropylene Polycarbonate Polycarbonate Polycarbonate Polyvinylidene fluoride (PVDF) Fluorocarbon rubber	Hydrophilic polyethersulfone Polypropylene Polypropylene Polypropylene Polysulfone — — Silicone, EPDM or fluorocarbon rubber				
Housing Vent	Adjustable vent with male luer and female Luer-Lok® connections on inlet side of the device	_				
Maximum Inlet Pressure	5516 mbar (80 psi) at 25 ℃	_				
Maximum Differential Pressure Forward:  Reverse:	_ _	6895 mbar (100 psi) at 25 °C 1700 mbar (25 psi) at 80 °C 340 mbar (5 psi) at 135 °C 2068 mbar (30 psi) at 25 °C 69 mbar (1 psi) at 135 °C				
Bubble Point at 23 °C						
Air Diffusion at 23 °C  Through a water wet membrane at 2758 mbar (40 psi):	_	≥ 4000 mbar (58 psi) air with water  ≤16.4 cc/min.   ≤30 cc/min.				
Bacterial Retention	_	Quantitative retention of 10 <sup>7</sup> CFU/cm <sup>2</sup> Brevundimonas diminuta ATCC® 19146 per ASTM® methodology				
Bacterial Endotoxin	_	Aqueous extraction contains <0.25 EU/mL as determined using the Limulus Amebocyte Lysat (LAL) test.				
TOC/Conductivity		Carbon and USP <6	SP <643> for Total Organic			
Oxidizable Substances	Effluent meets the USP Oxidizable Substance Test requirements for sterile purified water after a water flush of ≤100 mL.	Effluent meets the USP Oxidizable Substance Test requirements for sterile purified water after a water flush of: 1000 mL.				
Sterilization	May be autoclaved for 3 cycles of 60 min at 126 °C.	Autoclave: May be autoclaved 25x, 60 min cycles at 126 °C In-line Steam: 25x (forward), 30 min cycles at 135 °C, or 22x (forward) and 3x (reverse), 30 min cycle: at 135 °C				
USP Toxicity	_	Non-toxic per MEM	elution ISO® 10993-5.			
Particle Shedding	_	Passes USP test for injectables.	or particulates in			
Non-fiber Releasing	Millipore Express SHF membrane meets criteria for a "r 210.3 (b)(6).	non fiber releasing" fi	lter as defined in 21 CFR			
Component Material Toxicity	Component materials were tested and meet the criteria of the USP <88> Reactivity Test for Class VI plastics. Millipore Express SHF 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.					
Good Manufacturing Practice These products are manufactured in a facility which adheres to FDA Good Manufacturing Pr						

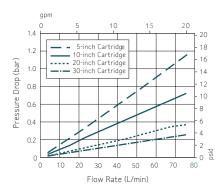
# Opticap XL and XLT Disposable Capsules (Autoclavable)

	Opticap XL 3	Opticap XL 5	Opticap XL 10	Opticap XLT 10	Opticap XLT 20	Opticap XLT 30	
Nominal Dimensions							
Maximum length:	17.3 cm (6.8 in.)	21.6 cm (8.5 in.)	33.5 cm (13.2 in.)	37.6 cm (14.8 in.)	62.5 cm (24.6 in.)	87.1 cm (34.3 in.)	
Body diameter:	10.7 cm (4.2 in.)	10.7 cm (4.2 in.)	10.7 cm (4.2 in.)	_	_	_	
Fitting to Fitting							
Sanitary flange to							
sanitary flange:	— 15.2 cm (6.0 in.) 15.2 cm (6.0 in.) 15.2 cm (6.0 in.)					15.2 cm (6.0 in.)	
Sanitary flange to							
hose barb:	<del>-</del> 17.5			17.5 cm (6.9 in.)	17.5 cm (6.9 in.)	17.5 cm (6.9 in.)	
Hose barb to hose barb:	: —			19.8 cm (7.8 in.)	19.8 cm (7.8 in.)	19.8 cm (7.8 in.)	
Filtration Area	0.16 m <sup>2</sup> (1.7 ft <sup>2</sup> )	0.29 m <sup>2</sup> (3.1 ft <sup>2</sup> )	0.54 m <sup>2</sup> (5.8 ft <sup>2</sup> )	0.54 m <sup>2</sup> (5.8 ft <sup>2</sup> )	1.08 m <sup>2</sup> (11.6 ft <sup>2</sup> )	1.62 m <sup>2</sup> (17.4 ft <sup>2</sup> )	
Materials of Construction							
Filter membrane:	Hydrophilic polye	thersulfone					
Film edge:	Polypropylene						
Supports:	Polypropylene						
Structural components <sup>1</sup> :							
Core:	Polysulfone						
Vent O-rings	Silicone						
Vent/Drain	¼ in. hose barb w	ith double O-ring s	seal				
Maximum Differential							
Pressure	FF47 1 (00	.) 1.25.00					
Forward:	5516 mbar (80 p		1.05.00				
		psi) intermittent a	t 25 °C				
Reverse:	1034 mbar (15 psi) at 80 °C						
Bubble Point at 23 °C	2068 mbar (30 psi) intermittent at 25 °C						
Air Diffusion at 23 °C	≥4000 mbar (58 psi) air with water  Though a water water manhana at 2750 mbar (40 psi):						
All Diffusion at 25 C		Through a water wet membrane at 2758 mbar (40 psi):					
Bacterial Retention	$\leq$ 9.1 cc/min.   $\leq$ 16.4 cc/min.   $\leq$ 30 cc/min.   $\leq$ 30 cc/min.   $\leq$ 60 cc/min.   $\leq$ 90 cc/min.   Quantitative retention of 10 <sup>7</sup> CFU/cm <sup>2</sup> Brevundimonas diminuta ATCC® 19146 per ASTM® methodology						
Bacterial Endotoxin	Aqueous extraction contains <0.25 EU/mL as determined by the Limulus Amebocyte Lysate (LAL) Test (per 10-inch						
Dacterial Endotoxiii	filter).						
TOC/Conductivity	Autoclaved filter meets the WFI requirements of USP <643> for Total Organic Carbon and USP <645> for						
,	Water Conductivity after a WFI water flush of 10L at 25 °C (per 10-inch filter)						
Oxidizable Substances				ts for sterile purified		er flush of:	
	≤1000 mL	≤1000 mL	≤1000 mL	≤1000 mL	≤2000 mL	≤3000 mL	
Sterilization	May be autoclaved for 3 cycles of 60 minutes at 126 °C. (Cannot be steam sterilized in-line).						
Non-Fiber Releasing	Component materials meet criteria for a "non fiber releasing" filter as defined in 21 CFR 210.3 (b)(6).						
Component Material	Component materials were tested and meet the criteria of the USP <88> Reactivity Test for Class VI plastics.						
Toxicity	Millipore Express SHF filters meet the requirements of the USP <88> Safety Test, utilizing a 0.9% sodium chloride						
	extraction.						
USP Toxicity	Non-toxic per MEM Elution ISO 10993-5						
Good Manufacturing Practices	These products are manufactured in a facility which adheres to FDA Good Manufacturing Practices.						
Indirect Food Additive	All component materials meet the FDA Indirect Food Additive requirements cited in 21 CFR 177-182.						

<sup>&</sup>lt;sup>1</sup> Cage, end caps and capsule housing

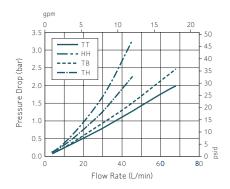
#### TYPICAL CLEAN WATER FLOW RATES

### Cartridge Filters with Millipore Express SHF Hydrophilic Membrane

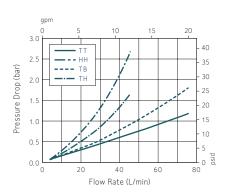


#### Opticap XL and XLT Disposable Capsules (Autoclavable)

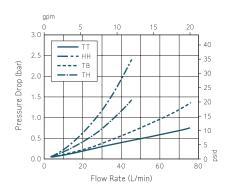
Opticap XL 3 Capsule Filters with 0.2 µm Millipore Express SHF Membrane



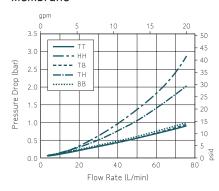
Opticap XL 5 Capsule Filters with 0.2 µm Millipore Express SHF Membrane



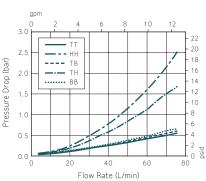
Opticap XL 10 Capsule Filters with 0.2 µm Millipore Express SHF Membrane



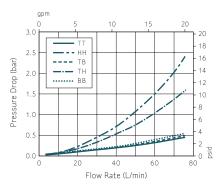
Opticap XLT 10 Capsule Filters with 0.2 µm Millipore Express SHF Membrane



Opticap XLT 20 Capsule Filters with 0.2 µm Millipore Express SHF Membrane



Opticap XLT 30 Capsule Filters with 0.2 µm Millipore Express SHF Membrane



#### Opticap XL Capsule Legends Refer to Connection Type

TT = 38 mm (1 ½ in.) Sanitary Flange Inlet and Outlet

 $HH = 14 \text{ mm} (9/_{16} \text{ in.}) \text{ Hose Barb Inlet and Outlet}$ 

TH = 38 mm (1  $\frac{1}{2}$  in.) Sanitary Flange Inlet and

14 mm (9/16 in.) Hose Barb Outlet

TB = 38 mm (1 ½ in.) Sanitary Flange Inlet and 25 mm (1 in.) Hose Barb Outlet

#### Opticap XLT Capsule Legends Refer to Connection Type

TT = 38 mm (1 ½ in.) Sanitary Flange Inlet and Outlet

TH = 38 mm (1 ½ in.) Sanitary Flange Inlet and

16 mm (  $^{5}\!/_{8}$  in.) Hose Barb Outlet

 $HH = 16 \text{ mm} (\frac{5}{8} \text{ in.}) \text{ Hose Barb Inlet and Outlet}$ 

BB = 25 mm (1 in.) Hose Barb Inlet and Outlet

TB = 38 mm (1 ½ in.) Sanitary Flange Inlet

25 mm (1 in.) Hose Barb Outlet

# Opticap XL 150, 300 and 600 Disposable Capsules (Sterile and Gamma Compatible)

	Opticap XL 150	Opticap XL 300	Opticap XL 600			
Nominal Dimensions	• •		· ·			
Maximum length: Body diameter:	9.7 cm (3.8 in.) 5.6 cm (2.2 in.)	11.9 cm (4.7 in.) 5.6 cm (2.2 in.)	16.5 cm (6.5 in.) 5.6 cm (2.2 in.)			
Fitting to Fitting Sanitary flange to						
Sanitary flange:						
Sanitary flange to						
hose barb: Hose barb to hose barb:	_	_	_			
Filtration Area	0.022 m <sup>2</sup> (0.240 ft <sup>2</sup> )	0.048 m <sup>2</sup> (0.514 ft <sup>2</sup> )	0.097 m <sup>2</sup> (1.046 ft <sup>2</sup> )			
Materials of Construction Filter membrane: Film edge: Supports: Structural components <sup>1</sup> :	Hydrophilic polyethersulfone  Polyethylene Gamma stable polypropylene					
Core: Vent O-rings <sup>2</sup> :	Polysulfone Silicone					
Vent/Drain	¼ in. hose barb with d	louble O-ring seal				
Maximum Inlet Pressure	6895 mbar (100 psi) intermittent at 23 °C 5515 mbar (80 psi) at 23 °C 2758 mbar (40 psi) at 60 °C 1035 mbar (15 psi) at 80 °C					
Maximum Differential						
<b>Pressure</b> Forward:	6895 mbar (100 psi) intermittent at 25 °C 5515 mbar (80 psi) at 25 °C 1035 mbar (15 psi) at 80 °C					
Reverse:	2068 mbar (30 psi) in					
Bubble Point at 23 °C	≥4000 mbar (58 psi) air with water					
Air Diffusion at 23 °C	Through a water wet membrane at 2758 mbar (40 psi): ≤ 1.4 cc/min.   ≤ 2.8 cc/min.   ≤ 5.8 cc/min.					
Bacterial Retention				9146 per ASTM® methodology		
	Aqueous extraction contains < 0.25 EU/mL as determined by the Limulus Amebocyte Lysate (LAL) Test					
Bacterial Endotoxin			<u> </u>			
Bacterial Endotoxin TOC/Conductivity at 25 °C	Gamma Sterilized filte		nts of USP <643> for T	otal Organic Carbon and USP <645>		
	Gamma Sterilized filte for Water Conductivit 2 L	er meets the WFI requireme by after a WFI water flush o 2.5 L	nts of USP <643> for T f: 3 L			
TOC/Conductivity at 25 °C  Oxidizable Substances  Sterilization Gamma compatible:	Gamma Sterilized filte for Water Conductivit 2 L   Meets the USP Oxidiz ≤ 1000 mL   Gamma compatible to sterilized in-line).	er meets the WFI requirements and the state of the state	nts of USP <643> for T f: 3 L rements for sterile puri ≤ 1000 mL for 3 cycles of 60 minut	fied water after a water flush of:  des at 123 °C. (Cannot be steam		
TOC/Conductivity at 25 °C  Oxidizable Substances  Sterilization	Gamma Sterilized filter for Water Conductivit 2 L  Meets the USP Oxidizes ≤ 1000 mL  Gamma compatible to sterilized in-line).  May be autoclaved for	er meets the WFI requirements after a WFI water flush of 2.5 L able Substances Test requires ≤ 1000 mL	nts of USP <643> for T f: 3 L rements for sterile puri ≤1000 mL for 3 cycles of 60 minut 123 °C. (Cannot be ster	fied water after a water flush of:  es at 123 °C. (Cannot be steam  am sterilized in-line.)		
TOC/Conductivity at 25 °C  Oxidizable Substances  Sterilization Gamma compatible:  Sterile capsules:  Sterility	Gamma Sterilized filter for Water Conductivit 2 L  Meets the USP Oxidizes ≤ 1000 mL  Gamma compatible to sterilized in-line).  May be autoclaved for	er meets the WFI requirements and a compared to the west of the we	nts of USP <643> for T f: 3 L rements for sterile puri ≤1000 mL for 3 cycles of 60 minut 123 °C. (Cannot be ster	fied water after a water flush of:  es at 123 °C. (Cannot be steam  am sterilized in-line.)		
TOC/Conductivity at 25 °C  Oxidizable Substances  Sterilization Gamma compatible:  Sterile capsules:  Sterility Sterile capsules:	Gamma Sterilized filter for Water Conductivit 2 L  Meets the USP Oxidized ≤ 1000 mL  Gamma compatible to sterilized in-line). May be autoclaved for Meets current USP ar	er meets the WFI requiremently after a WFI water flush or 2.5 L able Substances Test required 1000 mL  45 kGy. May be autoclaved the acceptance of 60 minutes at and AAMI guidelines for steril aution ISO 10993-5.	nts of USP <643> for T f: 3 L rements for sterile puri ≤1000 mL for 3 cycles of 60 minut 123 °C. (Cannot be ster	fied water after a water flush of:  es at 123 °C. (Cannot be steam  am sterilized in-line.)		
TOC/Conductivity at 25 °C  Oxidizable Substances  Sterilization Gamma compatible: Sterile capsules: Sterility Sterile capsules: USP Toxicity	Gamma Sterilized filte for Water Conductivit 2 L  Meets the USP Oxidize ≤ 1000 mL  Gamma compatible to sterilized in-line). May be autoclaved fo  Meets current USP ar Non-toxic per MEM eli Passes USP test for part	er meets the WFI requiremently after a WFI water flush or 2.5 L able Substances Test required 1000 mL 45 kGy. May be autoclaved for 3 cycles of 60 minutes at and AAMI guidelines for sterilution ISO 10993-5. iculates in injectables.	nts of USP <643> for T f: 3 L rements for sterile puri ≤1000 mL for 3 cycles of 60 minut 123 °C. (Cannot be steatility utilizing a validated	fied water after a water flush of:  es at 123 °C. (Cannot be steam  am sterilized in-line.)		
TOC/Conductivity at 25 °C  Oxidizable Substances  Sterilization Gamma compatible: Sterile capsules: Sterility Sterile capsules: USP Toxicity Particle Shedding	Gamma Sterilized filte for Water Conductivit 2 L  Meets the USP Oxidize ≤ 1000 mL  Gamma compatible to sterilized in-line). May be autoclaved fo  Meets current USP ar Non-toxic per MEM eli Passes USP test for part Millipore Express SHF 210.3(b)(6).  Component materials	er meets the WFI requirements after a WFI water flush or 2.5 L able Substances Test required at 1000 mL.  45 kGy. May be autoclaved to 3 cycles of 60 minutes at 1000 mL at 1000 mL at 1000 mL.  45 kGy. May be autoclaved to 3 cycles of 60 minutes at 1000 mL at 1000 mL at 1000 mL.  45 kGy. May be autoclaved to 3 cycles of 60 minutes at 1000 mL at 1000 mL.	nts of USP <643> for T f:  3 L rements for sterile puri ≤1000 mL  for 3 cycles of 60 minut 123 °C. (Cannot be steadity utilizing a validated ria for a "non-fiber rele criteria of the USP <88	fied water after a water flush of:  es at 123 °C. (Cannot be steam am sterilized in-line.)  sterilization cycle.		
TOC/Conductivity at 25 °C  Oxidizable Substances  Sterilization Gamma compatible: Sterile capsules: Sterility Sterile capsules: USP Toxicity Particle Shedding Non-Fiber Releasing  Component Material	Gamma Sterilized filter for Water Conductivity 2 L  Meets the USP Oxidized ≤ 1000 mL  Gamma compatible to sterilized in-line). May be autoclaved for Meets current USP ar Non-toxic per MEM ell Passes USP test for part Millipore Express SHF 210.3(b)(6). Component materials Millipore Express SHF chloride extraction.	er meets the WFI requirements after a WFI water flush or 2.5 L able Substances Test required 1000 mL  45 kGy. May be autoclaved the AAMI guidelines for steril aution ISO 10993-5. iculates in injectables.  The membrane meets the criterian were tested and meet the filters meet the requirements.	nts of USP <643> for T f: 3 L rements for sterile puri ≤1000 mL for 3 cycles of 60 minut 123 °C. (Cannot be steadity utilizing a validated ria for a "non-fiber rele criteria of the USP <88 nts of the USP <88> Sa	fied water after a water flush of:  les at 123 °C. (Cannot be steam am sterilized in-line.)  sterilization cycle.  Assing filter as defined in 21 CFR  > Reactivity Test for Class VI plastics.		
TOC/Conductivity at 25 °C  Oxidizable Substances  Sterilization Gamma compatible: Sterile capsules: Sterility Sterile capsules: USP Toxicity Particle Shedding Non-Fiber Releasing  Component Material Toxicity	Gamma Sterilized filte for Water Conductivit 2 L  Meets the USP Oxidized 1000 mL  Gamma compatible to sterilized in-line). May be autoclaved for Meets current USP and Non-toxic per MEM ell Passes USP test for part Millipore Express SHF 210.3(b)(6).  Component materials Millipore Express SHF chloride extraction.  All component material	er meets the WFI requirements after a WFI water flush or 2.5 L able Substances Test requirements at 1000 mL.  45 kGy. May be autoclaved to 3 cycles of 60 minutes at 1000 mL at	nts of USP <643> for T f:  3 L rements for sterile puri ≤1000 mL  for 3 cycles of 60 minut 123 °C. (Cannot be steadity utilizing a validated ria for a "non-fiber rele criteria of the USP <88> Sa cood Additive requirement	fied water after a water flush of:  ses at 123 °C. (Cannot be steam am sterilized in-line.)  sterilization cycle.  asing" filter as defined in 21 CFR  > Reactivity Test for Class VI plastics. fety Test, utilizing a 0.9% sodium		

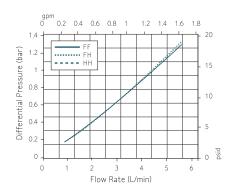
<sup>&</sup>lt;sup>1</sup> Cage, end caps and capsule housing

<sup>&</sup>lt;sup>2</sup> EPDM and fluorocarbon O-rings available by custom order

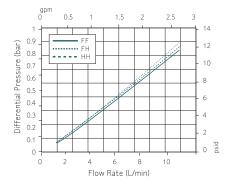
#### TYPICAL CLEAN WATER FLOW RATES

#### Opticap XL and XLT Disposable Capsules (Sterile and Gamma Compatible\*)

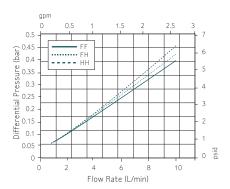
#### Opticap XL 150 with 0.2 µm Millipore Express SHF Membrane



#### Opticap XL 300 with 0.2 µm Millipore Express SHF Membrane



# Opticap XL 600 with 0.2 $\mu m$ Millipore Express SHF Membrane



#### Opticap XL 150, 300 & 600 Capsule Connection Type

FF = 19 mm ( $^{3}/_{4}$  in.) sanitary flange inlet and outlet

FH = 19 mm ( $^{3}$ / $_{4}$  in.) hose barb inlet and 14 mm ( $^{9}$ / $_{16}$  in.) hose barb outlet

 $HH = 14 \text{ mm } (\frac{9}{16} \text{ in.}) \text{ hose barb inlet and outlet}$ 

<sup>\*</sup>Filters were tested post gamma radiation at 45-65kGy and autoclave at 123 °C for 60 minutes.

# Opticap XL and XLT Disposable Capsules (Sterile and Gamma Compatible)

	Opticap XL 3	Opticap XL 5	Opticap XL 10	Opticap XLT 10	Opticap XLT 20	Opticap XLT 30	
Nominal Dimensions							
Maximum length:	17.3 cm (6.8 in.)	21.6 cm (8.5 in.)	33.5 cm (13.2 in.)	37.6 cm (14.8 in.)	62.5 cm (24.6 in.)	87.1 cm (34.3 in.)	
Body diameter:	10.7 cm (4.2 in.)	10.7 cm (4.2 in.)	10.7 cm (4.2 in.)	_	_	_	
Fitting to Fitting							
Sanitary flange to							
sanitary flange:	_			15.2 cm (6.0 in.)	15.2 cm (6.0 in.)	15.2 cm (6.0 in.)	
Sanitary flange to							
hose barb:	_			17.5 cm (6.9 in.)	17.5 cm (6.9 in.)	17.5 cm (6.9 in.)	
Hose barb to hose barb:	_			19.8 cm (7.8 in.)	19.8 cm (7.8 in.)	19.8 cm (7.8 in.)	
Filtration Area	0.17 m <sup>2</sup> (1.8 ft <sup>2</sup> )	0.31 m <sup>2</sup> (3.3 ft <sup>2</sup> )	0.57 m <sup>2</sup> (6.1 ft <sup>2</sup> )	0.57 m <sup>2</sup> (6.1 ft <sup>2</sup> )	1.14 m <sup>2</sup> (12.3 ft <sup>2</sup> )	1.71 m <sup>2</sup> (18.4 ft <sup>2</sup> )	
Materials of Construction							
Filter membrane:	Hydrophilic polye	thersulfone					
Film edge:	Polyethylene						
Supports:	Polyester						
Structural components <sup>1</sup> :	Gamma stable po	lypropylene					
Core:	Polysulfone						
Vent O-rings	Silicone						
Vent/Drain	¼ in. hose barb w	ith double 0-ring s	seal				
Maximum Differential							
Pressure							
Forward:	5.5 bar (80 psi) a						
	6.9 bar (100 psi)	intermittent at 25	°C				
	1.0 bar (15 psi) a	t 80 ℃					
Reverse:		ntermittent at 25 °					
Bubble Point at 23 °C		psi) air with water					
Air Diffusion at 23 °C	~		2758 mbar (40 psi):				
						3.2 cc/min.	
Bacterial Retention				diminuta ATCC® 191			
Bacterial Endotoxin				ed by the Limulus A			
TOC/Conductivity	Autoclaved filter meets the WFI requirements of USP <643> for Total Organic Carbon and USP <645> for						
		Water Conductivity after a WFI water flush of 11 L at 25 °C (per 10-inch filter).					
Oxidizable Substances	Meets the USP Oxidizable Substances Test requirements for sterile purified water after a water flush of:						
Charles attack	> 1000 mL	> 1000 mL	≤1500 mL	≤1500 mL	≤3000 mL	≤4500 mL	
Sterilization							
Gamma compatible:	Gamma compatible to 45 kGy. May be autoclaved for 3 cycles of 60 minutes at 123 °C. (Cannot be steam sterilized						
Sterile capsules:	in-line.)  May be autoslayed for 2 sycles of 60 minutes at 122 °C (Cannot be steam starilized in line.)						
·	May be autoclaved for 3 cycles of 60 minutes at 123 °C. (Cannot be steam sterilized in-line.)						
Sterility Storilo conculos:	Monto augment IICD and AAAII guidelines for storility utilizing a conflict of the description and						
Sterile capsules: Non-Fiber Releasing	Meets current USP and AAMI guidelines for sterility utilizing a validated sterilization cycle.						
Component Material	Component materials meet criteria for a "non fiber releasing" filter as defined in 21 CFR 210.3 (b)(6).  Component materials were tested and meet the criteria of the USP <88> Reactivity Test for Class VI plastics.						
Toxicity							
TOXICITY	Millipore Express SHF filters meet the requirements of the USP <88> Safety Test, utilizing a 0.9% sodium chloride						
USP Toxicity	extraction.  Non-toxic per MEM Elution ISO 10993-5						
Good Manufacturing	These products are manufactured in a facility which adheres to FDA Good Manufacturing Practices.						
Practices	These products are manufactured in a racinty which addictes to FDA dood Manufacturing Fractices.						
Indirect Food Additive	All component materials meet the FDA Indirect Food Additive requirements cited in 21 CFR 177–182.						
1 Case and cane and co	The component materials meet the FBN maneet Food Naditive requirements cited in 21 cm (177 Toz.						

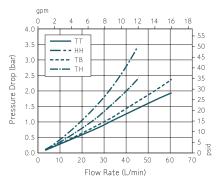
<sup>&</sup>lt;sup>1</sup> Cage, end caps and capsule housing

Filters were tested post gamma radiation at 25-45 kGy  $\,$ 

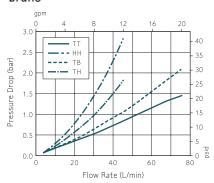
#### TYPICAL CLEAN WATER FLOW RATES

#### Opticap XL and XLT Disposable Capsules (Sterile and Gamma Compatible)

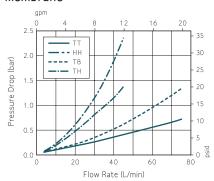
Opticap XL 3 Capsule Filters with 0.2  $\mu m$  Millipore Express SHF Membrane



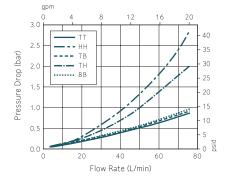
Opticap XL 5 Capsule Filters with 0.2  $\mu m$  Millipore Express SHF Membrane



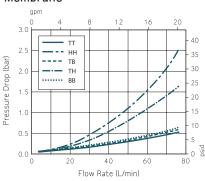
Opticap XL 10 Capsule Filters with 0.2 µm Millipore Express SHF Membrane



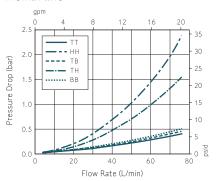
Opticap XLT 10 Capsule Filters with 0.2  $\mu m$  Millipore Express SHF Membrane



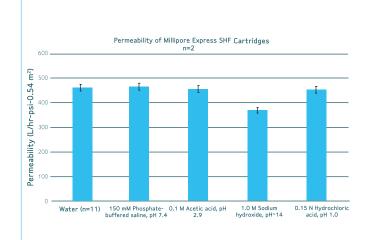
# Opticap XLT 20 Capsule Filters with 0.2 $\mu m$ Millipore Express SHF Membrane

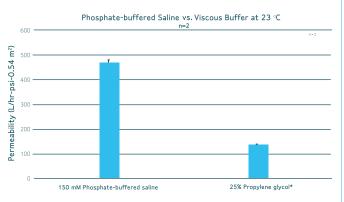


Opticap XLT 30 Capsule Filters with 0.2 µm Millipore Express SHF Membrane



#### Filter Sizing

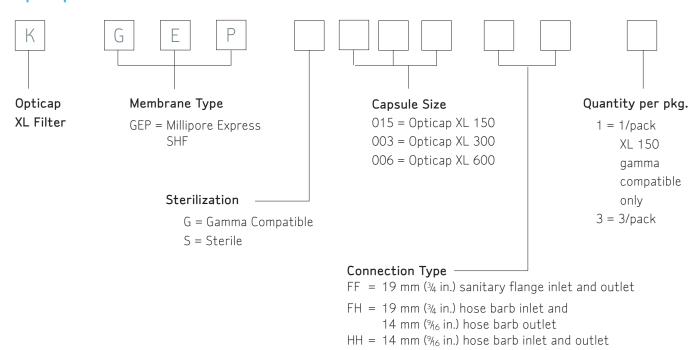




\*Includes 0.2 M Arginine-HCI, 0.5 M Sodium Phosphate

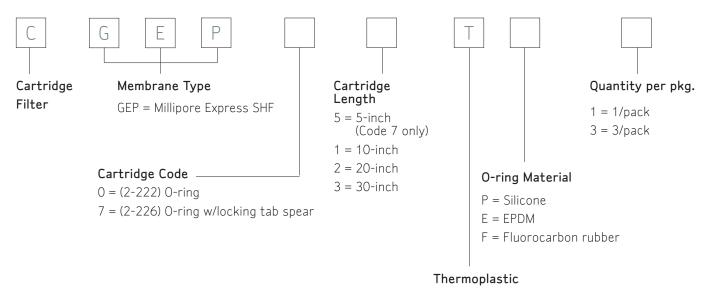
Testing with the Millipore Express SHF filters across a range of commonly used buffers and cleaning solutions (pH = 1 - 14) showed an average permeability of 450 liters per hour per psi per 10-inch cartridge.

## Opticap XL 150/300/600 Filters

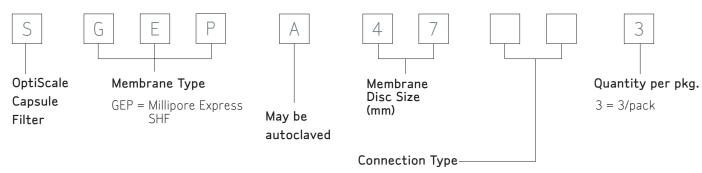


#### ORDERING INFORMATION

#### **Cartridge Filters**



#### OptiScale Filters

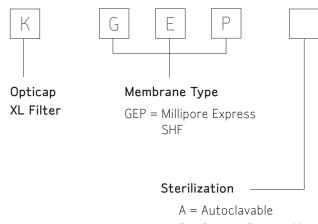


HH = 6 mm (¼ in.) hose barb inlet and outlet

FF = 19 mm (¾ in.) sanitary flange inlet and outlet

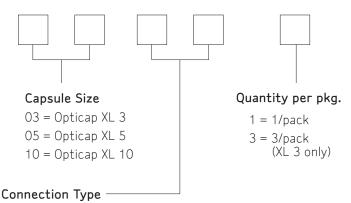
FH = 19 mm (¾ in.) sanitary flange inlet and 6 mm (¼ in.) hose barb outlet

#### **Opticap XL Filters**



G = Gamma Compatible

S = Sterile



TT = 38 mm (1½ in.) sanitary flange inlet and outlet

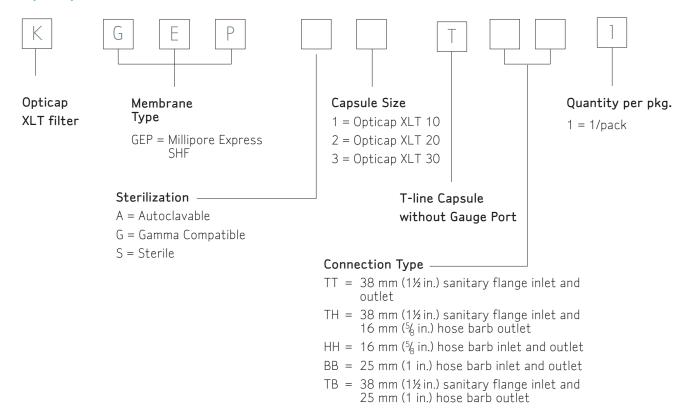
 $HH = 14 \text{ mm} (\%_{16} \text{ in.}) \text{ hose barb inlet and outlet}$ 

TH = 38 mm (1½ in.) sanitary flange inlet and 14 mm ( $\frac{9}{6}$  in.) hose barb outlet

TB = 38 mm (1½ in.) sanitary flange inlet and 25 mm (1 in.) hose barb outlet

#### ORDERING INFORMATION

#### **Opticap XLT Filters**



# TO PLACE AN ORDER OR RECEIVE TECHNICAL ASSISTANCE

For additional information call your nearest Millipore office:

In the U.S. and Canada, call toll-free

1-800-MILLIPORE (1-800-645-5476)

In the U.S., Canada and Puerto Rico, fax orders to 1-800-MILLIFX (1-800-645-5439)

Outside of North America contact your local office.

To find the office nearest you: www.ictsl.net/localizacion

Internet: www.ictsl.net

Technical Service: stecnico@ictsl.net



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#### Go Mobius®

Millipore Express SHF hydrophilic filters are part of the Mobius integrated, disposable bioprocess solution. No matter what your application step or scale, Mobius can help you achieve greater process efficiency and productivity with the right combination of single-use products, application solutions, and expert validation support. From disposable process containers to Millipore patented capsule filters and connectors, to validated, gamma-compatible turnkey assemblies, Mobius solutions provide faster turnaround time and reliable performance, right out of the box.



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