Filtration, Separation & Preparation



# Millipore Express® SHC Hydrophilic Filters

High capacity, sterilizing-grade PES filters

Millipore Express® SHC (Sterile, High Capacity) filters provide superior throughput and capacity in applications where sterilizing-grade performance is needed and premature filter plugging is a concern. These filters are ideal for sterile filtration of cell culture media, protein solutions and other high fouling fluids. Millipore Express® SHC filters contain two polyethersulfone membrane layers,  $0.5~\mu\text{m}/0.2~\mu\text{m}$ , and come in a range of device formats and sizes to suit your application needs.



#### **Filter formats**

Millipore Express® SHC filters are offered in a range of filter formats and capsule sizes, and allow easy scale-up of your small volume filtration steps to larger, full-scale filtration processes.

- OptiScale® small-scale disposable capsule filters
- Opticap® XL 150/300/600 small-scale disposable capsule filters with optional filling bell— gamma compatible or presterilized
- Opticap® XL disposable capsule filters— autoclavable, gamma compatible, or presterilized
- Opticap® XLT disposable capsule filters— autoclavable, gamma compatible, or presterilized. Gamma compatible XLT capsules are also available in high area formats.
- · Standard and high area cartridge filters

#### **Benefits**

- High capacity, high flux hydrophilic PES membranes
- Validated sterilizing-grade performance
- · Easy wetting and integrity testing
- Superior throughput in high fouling streams, including media and protein containing solutions
- Increased capacity for improved process efficiency and economy
- Broad chemical compatibility across a wide pH range (1-14) — caustic compatible

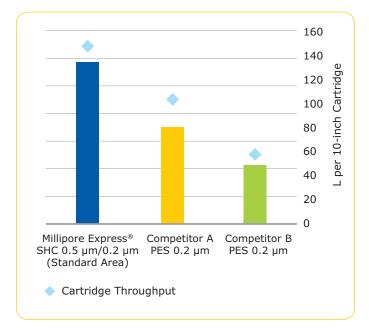
## **Applications**

- Media additives
- Column protection
- Concentrated protein streams
- Cell harvest (post clarification)
- Caustics/pH adjusters
- Buffers
- CIP solutions



## Fewer filter change outs and extended capacity

Millipore Express® SHC filters are designed to maximize the capacity of constrained filtration systems. With its high flux and superior capacity, you can double your output without significant capital expense (see figures 1 and 2).



Millipore Express® Competitor A Competitor B SHC 0.5 μm/0.2 μm PES 0.2 μm (Standard Area)

Cartridge Throughput

Figure 1.
CHO Cell Culture Growth Media: No Prefiltration

**Figure 2.**Protein Concentrate Post Ultrafiltration

## **Mobius® Single-use Solutions**

Millipore Express® SHC hydrophilic filters are part of the Mobius® integrated, disposable bioprocess solution. No matter what your application step, Mobius® solutions 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 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.

## **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 faster and easier to set up than conventional 25 mm and 47 mm discs, and completely disposable. OptiScale® capsule filters offer speed-to-market strategies for efficiently developing compounds and biotherapeutics.



OptiScale® disposable capsule filters

# Opticap® XL and XLT Disposable Capsule Filters

#### **Convenient and easy-to-use**

Opticap® XL and XLT's capsule design allows unparalleled hydraulic stress resistance in a disposable filter and eliminates the time and expense associated with 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 a ribbed housing for easy gripping even with gloved hands. Additionally, the Opticap® XL 150, 300 and 600 devices have the option to add a filling bell to protect an open container from airborne particles.

#### **Opticap® XL Capsule Filters**

Opticap® XL disposable capsule filters have a unique capsule design that minimizes hold-up volume and reduces production losses. Opticap® XL 150, 300, 600, 3, 5 and 10 capsules are available with Millipore Express® SHC membranes in autoclavable, sterile and gamma compatible formats.

## Opticap® XLT 10, 20 and 30 Capsule Filters

Opticap® XLT disposable T-line capsule filters with Millipore Express® SHC membrane 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. 10-, 20- and 30-inch Opticap® XLT gamma compatible capsules are also available, with 2x the membrane area of the standard area capsules for increased capacity.



Opticap® XL 150, 300, and 600 capsules, shown with optional filling bell attachment



Opticap® XLT filters

## **Cartridge Filters**

Millipore Express® SHC 5-, 10-, 20- and 30-inch standard area cartridge filters provide fast flow rates and extended throughput and are designed to withstand multiple steam-in-place cycles. 10-, 20- and 30-inch cartridges are also available in formats with 2x the membrane area of the standard area cartridges. Each cartridge is integrity tested during manufacturing. Code 0 and code 7 O-ring adaptors are available to suit your application and housing needs.



Millipore Express® SHC cartridge filters



Millipore Express® High Area (left) compared to Standard Area (right) Cartridge Filters

## **OptiScale® Disposable Capsules**

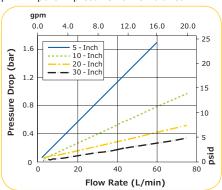
|   | OptiScale® 25 Capsules  | OptiScale® 47 Capsules   |  |
|---|---|--|--|
| Nominal Dimensions                                  |   |  |  |
| Diameter<br>Length                                  | 31 mm (1.21 in.)<br>39 mm (1.52 in.)  | 70 mm (2.75 in.)<br>82 mm (3.24 in.) w/flange inlet/hose barb outlet<br>74 mm (2.91 in.) w/flange inlet/flange outlet<br>94 mm (3.70 in.) w/hose barb inlet/hose barb outlet |  |
| Filtration Area                                     |   |  |  |
|   | 3.5 cm <sup>2</sup>   | 17.7 cm <sup>2</sup>   |  |
| Materials of Construction                           |   |  |  |
| Filter membrane<br>Film edge<br>Vent cap<br>O-rings | Hydrophilic polyethersulfone<br>Polypropylene<br>Polypropylene<br>Polypropylene   | Hydrophilic polyethersulfone<br>Polycarbonate<br>Polyvinylidene fluoride<br>Fluoroelastomer  |  |
| Housing Vent  |   |  |  |
|   | Capped vent with female Luer connections on inlet side of device  | Adjustable vent with male Luer and female<br>Luer-Lok™ connections on inlet side of the device   |  |
| Maximum Inlet Pressure                              |   |  |  |
|   | 4100 mbar (60 psi) at 25 °C   | 5100 mbar (80 psi) at 25 °C  |  |
| Maximum Differential Pressure                       |   |  |  |
| Forward<br>Reverse                                  | 4100 mbar (60 psi) at 25 °C<br>0 mbar (0 psi)   | 5100 mbar (80 psi) at 25 °C<br>690 mbar (10 psi) at 25 °C  |  |
| Bacterial Endotoxin                                 |   |  |  |
|   | Aqueous extraction contains <0.25 EU/mL as determined by Limulus Amebocyte Lysate (LAL).  | _  |  |
| TOC/Conductivity at 25 °C                           |   |  |  |
|   | Autoclaved filter effluent meets the WFI specification for USP <643>, Total Organic Carbon, and for USP <645>, Conductivity, after a WFI water flush of 15 mL.  | _  |  |
| Oxidizable Substances                               |   |  |  |
|   | _   | Effluent meets the USP Oxidizable Substance Test requirements for sterile purified water after a water flush of 100 mL.  |  |
| Sterilization                                       |   |  |  |
|   | May be autoclaved for 1 cycle at 123 °C for 60 min.   | May be autoclaved for 3 cycles at 126 °C for 60 min  |  |
| Particle Shedding                                   |   |  |  |
|   | Effluent meets the acceptance criteria set forth in USP <788> for large volume parenterals.   |  |  |
| Non-fiber Releasing                                 |   |  |  |
|   | Millipore Express $^{\circ}$ SHC membranes meet the criteria 210.3(b)(6).   | for a "non-fiber releasing" filter 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® SHC 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 Practices                        | Those products are manufactured in a facility which   | adheres to EDA Cood Manufacturing Practices  |  |
|   | These products are manufactured in a facility which   | auneres to FDA Good Manufacturing Practices.   |  |

## **Cartridge Filters**

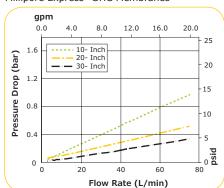
|  | 5-inch Cartridge  | Per Standard Area 10-inch Cartridge   | Per High Area 10-inch Cartridge   |
|--|---|---|---|
| Nominal Dimensions   |   |   |   |
| Diameter   | 6.9 cm (2.7 in.)  | 6.9 cm (2.7 in.)  |   |
| Length   | 12.7 cm (5 in.)   | 25.4 cm (10 in.)  |   |
| Filtration Area  |   |   |   |
|  | 0.23 m <sup>2</sup> (2.5 ft <sup>2</sup> )  | 0.49 m² (5.3 ft²)   | 1.0 m² (10.8 ft²)   |
| Materials of Constructi  | on  |   |   |
| Filter membrane<br>Film edge<br>Cage and end caps<br>Core<br>O-rings | Hydrophilic polyethersulfone<br>Polypropylene<br>Polypropylene<br>Polysulfone<br>Silicone, EPDM or Fluoroelastomer  |   | Hydrophilic polyethersulfone Polypropylene Polypropylene Polyethersulfone Silicone, EPDM or Fluoroelastomer |
| Maximum Differential   | Pressure  |   |   |
| Forward  | 6900 mbar (100 psi) at 25 °C<br>1700 mbar (25 psi) at 80 °C<br>1000 mbar (15 psi) at 135 °C   |   | 6900 mbar (100 psi) at 25 °C<br>1700 mbar (25 psi) at 80 °C<br>340 mbar (5 psi) at 135 °C                   |
| Reverse  | 2100 mbar (30 psi) at 25 °C<br>69 mbar (1 psi) at 135 °C  |   | 2100 mbar (30 psi) at 25 °C<br>69 mbar (1 psi) at 135 °C  |
| Bubble Point at 23 °C  |   |   |   |
|  | ≥4000 mbar (58 psi) air with water  |   |   |
| Air Diffusion at 25 °C   | ( F- /  |   |   |
|  | Through a water wet membrane at 2.8   | bar (40 psi):   |   |
|  | ≤13.3 cc/min.   | ≤28.2 cc/min.   | ≤56.4 cc/min.   |
| Bacterial Retention  | \$15.5 CC/IIIII.  | 520.2 CC/IIIII.   | 230.4 (с/11111.   |
| вастена кетептон   | Quantitative retention of 10 <sup>7</sup> CFU/cm <sup>2</sup> E   | Brevundimonas diminuta ATCC® 19146 pe   | er ASTM® methodology  |
| Bacterial Endotoxin  |   |   | · · · · · · · · · · · · · · · · · · ·   |
|  | Aqueous extraction contains <0.25 FU/   | mL as determined using the Limulus Ame  | ehocyte Lysate (LAL) test.  |
| TOC/Conductivity at 2  |   |   |   |
| Toc/conductivity at 2.   |   | I specification for USP <643>, Total Orga   | nic Carbon, and for USP <645>,  |
|  | 9.5 L   | 20 L  | 20 L  |
| Oxidizable Substances  |   |   |   |
|  |   | tance Test requirements for sterile purified  | water after a water flush of 2000 ml  |
| Sterilization  | Emache meets the ost oxidizable subst   | tance rest requirements for sterile parimet   | a water area a water mash of 2000 me.   |
| Autoclave  | 25x, 60 min. cycles at 126 °C   |   | 5x, 60 min. cycles at 126 °C  |
|  | •   | . 240 (5)   | •   |
| In-line steam  | 25x forward cycles, 30 min., 135 °C at 22x forward cycles, 30 min., 135 °C at $\leq$ 30 min., 135 °C at $<$ 69 mbar (1 psi) or 135 °C at 1000 mbar (15 psi) | 340 mbar (5 psi) and 3x reverse cycles,   | 5x forward cycles, 30 min., 135 °C at ≤ 340 mbar (5 psi)  |
| USP Cytotoxicity   |   |   |   |
|  | Non-toxic per MEM elution ISO® 10993-   | -5  |   |
| Particle Shedding  |   |   |   |
| -  | Effluent meets the acceptance criteria s  | set forth in USP <788> for large volume   | parenterals.  |
| Non-fiber Releasing  | and the same and a same and a steel as a  |   | r <del></del>   |
| index releasing  | Millinora Evnrace® SHC membrance me   | et the criteria for a "non-fiber releasing"   | filter as defined in 21 CED 210 3/h)/6)   |
| Component Meterial =   | · · ·   | et the criteria for a mon-moer releasing  |   |
| Component Material To  | Component materials were tested and i   | meet the criteria of the USP <88> Reacti<br>ents of the USP <88> Safety Test, utilizi |   |
|  |   |   |   |
| Indirect Food Additive   |   |   |   |
| Indirect Food Additive   | All component materials meet the FDA  | Indirect Food Additive requirements cited   | l in 21 CFR 177-182.  |
|  | •   | Indirect Food Additive requirements cited   | l in 21 CFR 177–182.  |
| Indirect Food Additive  Good Manufacturing Pi                        | ractices  | Indirect Food Additive requirements cited facility which adheres to FDA Good Manuf    |   |

## **Typical Clean Water Flow Rates**

Standard Area Cartridge Filters with 0.5/0.2 µm Millipore Express® SHC Membranes

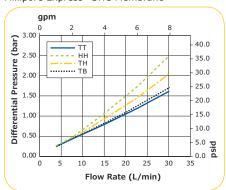


High Area Cartridge Filters with 0.5/0.2  $\mu m$  Millipore Express® SHC Membranes

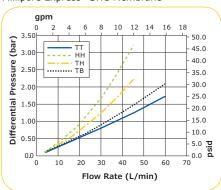


## Opticap® XL and XLT Disposable Capsules (Autoclavable Only)

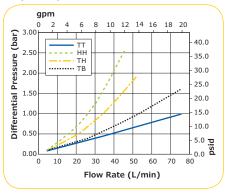
Opticap® XL 3 Capsules with 0.5/0.2  $\mu m$  Millipore Express® SHC Membrane



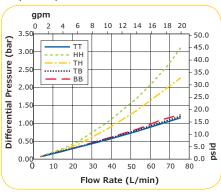
Opticap® XL 5 Capsules with 0.5/0.2 µm Millipore Express® SHC Membrane



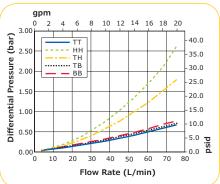
Opticap® XL 10 Capsules with 0.5/0.2  $\mu m$  Millipore Express® SHC Membrane



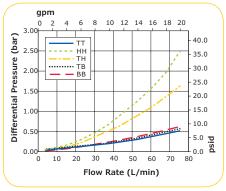
Opticap® XLT 10 Capsules with 0.5/0.2  $\mu m$  Millipore Express® SHC Membrane



Opticap® XLT 20 Capsules with 0.5/0.2  $\mu m$  Millipore Express® SHC Membrane



Opticap® XLT 30 Capsules with 0.5/0.2  $\mu m$  Millipore Express® SHC Membrane



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

TT = 38 mm (1 $\frac{1}{2}$  in.) sanitary flange inlet and outlet

HH = 14 mm (9/16 in.) 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 $\frac{1}{2}$  in.) sanitary flange inlet and 25 mm (1 in.) hose barb outlet

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

TT = 38 mm ( $1\frac{1}{2}$  in.) sanitary flange inlet and outlet

TH = 38 mm (1% in.) sanitary flange Inlet and 16 mm (5/8 in.) hose barb outlet

HH = 16 mm (5/8 in.) hose barb inlet and outlet

TB = 38 mm (1 $\frac{1}{2}$  in.) sanitary flange inlet and 25 mm (1 in.) hose barb outlet

BB = 25 mm (1 in.) hose barb inlet and outlet

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

|  |   | (   |  |   |   |   |  |
|--|---|---|--|---|---|---|--|
|  | Opticap® XL 3<br>Capsules   | Opticap® XL 5<br>Capsules                         | Opticap® XL 10<br>Capsules                 | Opticap® XLT 10<br>Capsules                                 | Opticap® XLT 20<br>Capsules                 | Opticap® XLT 30<br>Capsules                 |  |
| Nominal Dimensions   |   |   |  |   |   |   |  |
| Maximum length<br>Body diameter  | 17.3 cm (6.8 in.)<br>10.7 cm (4.2 in.)  | 21.6 cm (8.5 in.)<br>10.7 cm (4.2 in.)            | 33.5 cm (13.2 in.)<br>10.7 cm (4.2 in.)    | 38.1 cm (15.0 in.)<br>10.7 cm (4.2 in.)                     | 62.5 cm (24.6 in.)<br>10.7 cm (4.2 in.)     | 87.1 cm (34.3 in.)<br>10.7 cm (4.2 in.)     |  |
| Fitting to Fitting   |   |   |  |   |   |   |  |
| Sanitary flange to sanitary flange<br>Sanitary flange to hose barb<br>Hose barb to hose barb | _<br>_<br>_   |   |  | 15.2 cm (6.0 in.)<br>17.5 cm (6.9 in.)<br>19.8 cm (7.8 in.) |   |   |  |
| Filtration Area  |   |   |  |   |   |   |  |
|  | 0.13 m <sup>2</sup> (1.4 ft <sup>2</sup> )  | 0.23 m <sup>2</sup> (2.5 ft <sup>2</sup> )        | 0.49 m <sup>2</sup> (5.3 ft <sup>2</sup> ) | 0.49 m <sup>2</sup> (5.3 ft <sup>2</sup> )                  | 0.98 m <sup>2</sup> (10.5 ft <sup>2</sup> ) | 1.47 m <sup>2</sup> (15.8 ft <sup>2</sup> ) |  |
| Materials of Construction  |   |   |  |   |   |   |  |
| Filter membrane<br>Film edge<br>Supports<br>Core<br>Structural components*<br>Vent O-rings   | Hydrophilic polyethersulfone Polypropylene Polypropylene Polysulfone Polypropylene Silicone                                     |   |  |   |   |   |  |
| Vent/Drain   |   |   |  |   |   |   |  |
|  | 6 mm (¼ in.) hose   | barb with double O-rin                            | g seal                                     |   |   |   |  |
| Maximum Inlet Pressure   | 6900 mbar (100 psi<br>5500 mbar (80 psi)<br>2750 mbar (40 psi)<br>1000 mbar (15 psi)  | at 60 °C  |  |   |   |   |  |
| Maximum Differential Pressure  |   |   |  |   |   |   |  |
| Forward  | 6900 mbar (100 psi) intermittent at 25 °C<br>5500 mbar (80 psi) at 25 °C<br>1000 mbar (15 psi) at 80 °C                         |   |  |   |   |   |  |
| Reverse  | 2100 mbar (30 psi)  | intermittent at 25 °C                             | _  |   |   |   |  |
| Bubble Point at 23 °C  | > 1000 mhar (F0 na  |   |  |   |   |   |  |
| Air Diffusion at 23 °C   | ≥4000 mbar (58 ps   | i) air with water                                 |  |   |   |   |  |
| All Diffusion at 23 C  | Through a water we  | Through a water wet membrane at 2.8 bar (40 psi): |  |   |   |   |  |
|  | ≤7.3 cc/min.  | ≤13.3 cc/min.                                     | ≤28.2 cc/min.                              | ≤28.2 cc/min.   | ≤56.3 cc/min.                               | ≤84.5 cc/min.                               |  |
| Bacterial Retention  |   |   |  |   |   |   |  |
|  | Quantitative retenti  | on of 10 <sup>7</sup> CFU/cm <sup>2</sup> Bre     | vundimonas diminuta i                      | ATCC® 19146 per ASTN  | 1® methodology                              |   |  |
| Bacterial Endotoxin  | Quantitative retention of 10 <sup>7</sup> CFU/cm <sup>2</sup> Brevundimonas diminuta ATCC® 19146 per ASTM® methodology          |   |  |   |   |   |  |
|  | Aqueous extraction contains <0.25 EU/mL as determined by the Limulus Amebocyte Lysate (LAL) Test.                               |   |  |   |   |   |  |
| TOC/Conductivity at 25 °C  | Autoclaved filter effluent meets the WFI requirements of USP <643> for Total Organic Carbon and USP <645> for Water             |   |  |   |   |   |  |
|  | Conductivity after a<br>5.5 L   | 9.5 L   | 20 L                                       | 20 L  | 40 L  | 60 L  |  |
| Oxidizable Substances  |   | J.J L   |  |   | 10 L  |   |  |
|  | Meets the USP Oxid  | izable Substances Test                            | requirements for steri                     | le purified water after                                     | a water flush of:                           |   |  |
|  | 2 L   | 2 L   | 2 L  | 2 L   | 4 L   | 6 L   |  |
| Sterilization  | May be autoclaved t   | or 3 cycles of 60 minu                            | tes at 126 °C (cannot                      | be steam sterilized in-                                     | line).                                      |   |  |
| USP Cytotoxicity   | Non-toxic per MEM   | elution ISO® 10993-5                              |  |   |   |   |  |
| Particle Shedding  | Effluent meets the acceptance criteria set forth in USP <788> for large volume parenterals.                                     |   |  |   |   |   |  |
| Non-fiber Releasing  | Millipore Express® SHC membranes meet 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. Millipore Express® |   |  |   |   |   |  |
| Indirect Food Additive   | SHC filters meet the requirements of the USP <88> Safety Test, utilizing a 0.9% sodium chloride extraction.                     |   |  |   |   |   |  |
| Good Manufacturing Practices   | All component materials meet the FDA Indirect Food Additive requirements cited in 21 CFR 177–182.                               |   |  |   |   |   |  |
| Good Flandracturing Fractices  |   | manufactured in a faci                            |  |   | D 1:  |   |  |

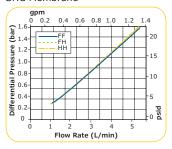
<sup>\*</sup>Cage, end caps and capsule housing

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

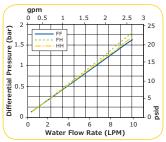
| - F F 1   | ( )   |  |  |
|---|---|--|--|
|   | Opticap® XL 150 Capsules  | Opticap® XL 300 Capsules   | Opticap® XL 600 Capsules   |
| Nominal Dimensions  |   |  |  |
| Maximum length<br>Maximum length with bell<br>Body diameter   | 9.7 cm (3.8 in.)<br>11.4 cm (4.5 in.)<br>5.6 cm (2.2)   | 11.9 cm (4.7 in.)<br>13.7 cm (5.4 in.)<br>5.6 cm (2.2 in.)           | 16.5 cm (6.5 in.)<br>18.3 cm (7.2 in.)<br>5.6 cm (2.2 in.)   |
| Filtration Area   | 0.014 m² (0.155 ft²)  | 0.029 m² (0.316 ft²)   | 0.059 m² (0.631 ft²)   |
| Materials of Constructio                                      |   | (0.020.0)  |  |
| Filter membrane<br>Supports<br>Core<br>Structural components* | Hydrophilic polyethersulfone<br>Polyethylene<br>Polysulfone<br>Gamma stable polypropylene                                   |  |  |
| Vent O-rings<br>Bell  | Silicone<br>Polycarbonate   |  |  |
| Vent/Drain  | 6 mm (¼ in.) hose barb with do  | ouble O-ring seal  |  |
| Maximum Inlet Pressure  | <u> </u>  | -  |  |
|   | 6900 mbar (100 psi) intermitte<br>5500 mbar (80 psi) at 23 °C<br>2750 mbar (40 psi) at 60 °C<br>1000 mbar (15 psi) at 80 °C | nt at 23 °C  |  |
| Maximum Differential P  | ressure   |  |  |
| Forward   | 6900 mbar (100 psi) intermitte<br>5500 mbar (80 psi) at 25 °C<br>1000 mbar (15 psi) at 80 °C                                |  |  |
| Reverse  Bubble Point at 23 °C                                | 2100 mbar (30 psi) intermitten  | 1 at 23 °C   |  |
|   | ≥4000 mbar (58 psi) air with w  | vater  |  |
| Air Diffusion at 23 °C  |   |  |  |
|   | Through a water wet membran   | e at 2.8 bar (40 psi):   |  |
|   | ≤1.0 cc/min.  | ≤1.9 cc/min.   | ≤3.7 cc/min.   |
| Bacterial Retention   | Ouantitative retention of 10 <sup>7</sup> CFU   | /cm² <i>Brevundimonas diminuta</i> ATC                               | C® 19146 per ASTM® methodology   |
| Bacterial Endotoxin   | Aqueous extraction contains < 0.  | 25 EU/mL as determined by the Li                                     | mulus Amebocyte Lysate (LAL) Test.   |
| TOC/Conductivity at 25  | Gamma sterilized filter effluent  | meets the WFI requirements of ter Conductivity after a water flu     |  |
|   | 1 L   | 2 L  | 3 L  |
| Oxidizable Substances   |   |  |  |
|   | Meets the USP Oxidizable Substitush of 1.0 L  | tances Test requirements for ster                                    | ile purified water after a water   |
| Sterilization   |   |  |  |
| Gamma-compatible capsules Sterile capsules                    | steam sterilized in-line).  | may be autoclaved for 3 cycles of aved for 3 cycles of 60 minutes at | 60 minutes at 123 °C (cannot be t 123 °C (cannot be steam  |
| Sterility Sterile capacites                                   | These consider west   | Dand AAMI auddelines C. 1 200  | Williams a validate distance of the state of |
| Sterile capsules  Cytotoxicity                                | mese capsules meet current USF  | and AAMI guidelines for sterility t                                  | itilizing a validated sterilization cycle  |
| Cytotoxicity  | Non-toxic per MEM elution ISO   | ® 10993-5  |  |
| Particle Shedding   | tome per rier cludon 150  |  |  |
|   | Effluent meets the acceptance   | criteria set forth in USP <788> fo                                   | or large volume parenterals.   |
| Non-fiber Releasing   |   |  | υ . μ  |
| <b>9</b>  | Millipore Express® SHC membra<br>21 CFR 210.3(b)(6).  | anes meet the criteria for a "non-                                   | fiber releasing" filter as defined in  |
| Component Material Tox  | Component materials were test   | SHC filters meet the requirements                                    | SP <88> Reactivity Test for Class<br>s of the USP <88> Safety Test,  |
| Indirect Food Additive  | All component materials meet t  | the FDA Indirect Food Additive re                                    | quirements cited in 21 CFR   |
| Good Manufacturing Pra  | 177-182.  |  |  |
|   |   | ed in a facility which adheres to                                    | FDA Good Manufacturing Practices   |
| Cago, and cans and cans                                       | · · · · · · · · · · · · · · · · · · ·   | a a racincy winds duricles to  | 2 500a Hanaractaring Fractices   |

# **Typical Clean Water Flow Rates**

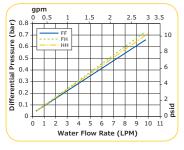
Opticap® XL 150 Capsules with 0.5/0.2 µm Millipore Express® SHC Membrane



Opticap® XL 300 Capsules with 0.5/0.2 µm Millipore Express® SHC Membrane



Opticap® XL 600 Capsules with 0.5/0.2 µm Millipore Express® SHC Membrane



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

FF: 19 mm (3/4 in.) sanitary flange inlet and outlet

FH: 19 mm (3/4 in.) sanitary flange inlet and 14 mm (9/16 in.) hose barb outlet

**HH:** 14 mm (9/16 in.) hose barb inlet and outlet

<sup>\*</sup>Cage, end caps and capsule housing

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

|  | Opticap® XL 3<br>Capsules  | Opticap® XL 5<br>Capsules   | Opticap® XL 10<br>Capsules              | Per 10" Standard Area<br>Opticap® XLT Capsule                     | Per 10" High Area Opticap <sup>®</sup><br>XLT Capsule**  |  |
|--|--|---|---|---|--|--|
| Nominal Dimensions   |  |   |   |   |  |  |
| Maximum length<br>Body diameter  | 17.3 cm (6.8 in.)<br>10.7 cm (4.2 in.)   | 21.6 cm (8.5 in.)<br>10.7 cm (4.2 in.)  | 33.5 cm (13.2 in.)<br>10.7 cm (4.2 in.) | 25.4 cm (10 in.)<br>6.9 cm (2.7 in.)                              | 25.4 cm (10 in.)<br>6.9 cm (2.7 in.)   |  |
| Fitting to Fitting   |  |   |   |   |  |  |
| Sanitary flange to sanitary flange<br>Sanitary flange to hose barb<br>Hose barb to hose barb |  |   |   | 15.2 cm (6.0 in.)<br>17.5 cm (6.9 in.)<br>19.8 cm (7.8 in.)       |  |  |
| Filtration Area  | 0.13 m <sup>2</sup> (1.4 ft <sup>2</sup> )   | 0.24 m² (2.6 ft²)   | 0.54 m² (5.8 ft²)                       | 0.49 m² (5.3 ft²)   | 1.0 m² (10.8 ft²)  |  |
| Materials of Construction  |  |   |   |   |  |  |
| Filter membrane<br>Film edge<br>Supports<br>Core<br>Structural components*<br>Vent O-rings   | Hydrophilic polyethe<br>Polyethylene<br>Polyester<br>Polysulfone<br>Gamma stable polyp<br>Silicone |   |   |   | Hydrophillic polyethersulfon<br>Polyethylene<br>Polyester<br>Polyethersulfone<br>Gamma stable Polypropylen<br>Silicone |  |
| Vent/Drain   | 6 mm (¼ in.) hose l  | barb with double O-ring   | seal                                    |   |  |  |
| Maximum Inlet Pressure   |  |   |   |   |  |  |
|  | 6900 mbar (100 psi<br>5500 mbar (80 psi)<br>2700 mbar (40 psi)<br>1000 mbar (15 psi)               | at 60 °C  |   |   |  |  |
| Maximum Differential Pressure  |  |   |   |   |  |  |
| Forward  |  | 6900 mbar (100 psi) intermittent at 25 °C 5500 mbar (80 psi) at 25 °C 1000 mbar (15 psi) at 90 °C |   |   |  |  |
| Reverse  |  | intermittent at 25 °C   |   |   |  |  |
| 70/30 IPA Bubble point at 23 °C  | ≥4000 mbar (58 ps  | i) air with water   |   |   |  |  |
| Air Diffusion at 23 °C   |  |   |   |   |  |  |
|  | Through a water we   | t membrane at 2.8 bar (   | (40 psi):                               |   |  |  |
|  | ≤7.6 cc/min.   | ≤14.0 cc/min.   | ≤31.2 cc/min.                           | ≤31.2 cc/min.   | ≤56.4 cc/min.  |  |
| Bacterial Retention  | Quantitative retention   | on of 10 <sup>7</sup> CFU/cm² <i>Brevu</i>  | ındimonas diminuta ATCC                 | C® 19146 per ASTM® methodol                                       | ogy  |  |
| Bacterial Endotoxin  | Aqueous extraction   | contains <0.25 EU/mL a  | s determined using the L                | imulus Amebocyte Lysate (LAI                                      | _) test.   |  |
| TOC/Conductivity at 25 °C  | Gamma sterilized fil<br>after a WFI flush of:  |   | rements of USP <643> fo                 | or Total Organic Carbon and U                                     | SP <645> for Water Conductivity  |  |
|  | 5.0 L  | 9.5 L   | 21 L                                    |   |  |  |
| Oxidizable Substances  |  |   |   |   |  |  |
| n  | Effluent meets the U   | JSP Oxidizable Substanc   | e Test requirements for s               | sterile purified water after a wa                                 | iter flush of 2 L  |  |
| Sterilization<br>Gamma-compatible capsules<br>Sterile capsules                               |  |   |   | minutes at 123 °C (cannot be s                                    |  |  |
| Sterility  |  |   |   |   |  |  |
| Sterile capsules   | These capsules mee   | t current USP and AAMI  | guidelines for sterility ut             | ilizing a validated sterilization                                 | cycle.   |  |
| Cytotoxicity   | Non-toxic per MEM (  | elution ISO® 10993-5  |   |   |  |  |
| Particle Shedding  | Effluent meets the 3   | occentance criteria set fo  | orth in USP <788> for lan               | go volumo narontorals   |  |  |
| Non-fiber Releasing  | Emacin meets tile a  | iccoptance criteria set 10  | III OOF \/002 IUI Idf                   | ge volume parements.  |  |  |
|  | Millipore Express® S   | HC membranes meet the   | e criteria for a "non-fiber             | releasing" filter as defined in                                   | 21 CFR 210.3(b)(6).  |  |
| Component Material Toxicity  |  |   |   | :88> Reactivity Test for Class \<br>a 0.9% sodium chloride extrac | /I plastics. Millipore Express® SHr<br>tion.   |  |
| Indirect Food Additive   |  |   |   |   |  |  |
|  | All component mate   | rials meet the FDA Indir  | ect Food Additive require               | ments cited in 21 CFR 177-18                                      | 2.   |  |

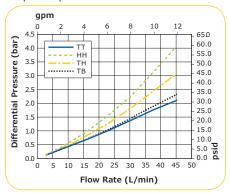
<sup>\*</sup>Cage, end caps and capsule housing

<sup>\*\*</sup>Only available in gamma compatible capsules

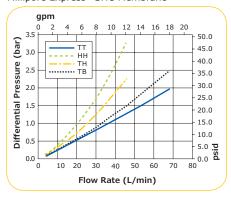
## **Typical Clean Water Flow Rates**

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

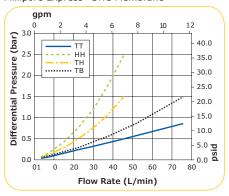
Opticap® XL 3 Capsules with 0.5/0.2  $\mu m$  Millipore Express® SHC Membrane



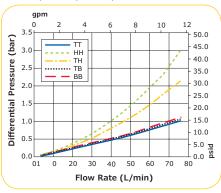
Opticap® XL 5 Capsules with 0.5/0.2 µm Millipore Express® SHC Membrane



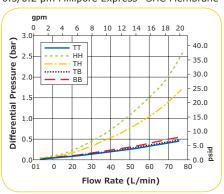
Opticap® XL 10 Capsules with 0.5/0.2  $\mu m$  Millipore Express® SHC Membrane



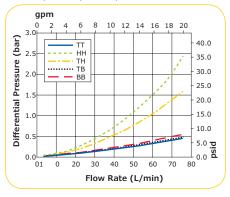
Standard Area Opticap® XLT 10 Capsules with 0.5/0.2  $\mu m$  Millipore Express® SHC Membrane



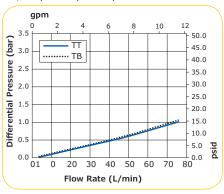
Standard Area Opticap® XLT 20 Capsules with 0.5/0.2 µm Millipore Express® SHC Membrane



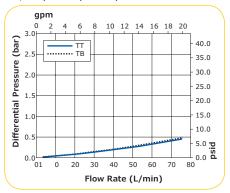
Standard Area Opticap® XLT 30 Capsules with 0.5/0.2 µm Millipore Express® SHC Membrane



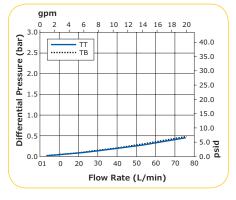
High Area Opticap® XLT 10 Capsules with 0.5/0.2 µm Millipore Express® SHC Membrane



High Area Opticap® XLT 20 Capsules with 0.5/0.2 µm Millipore Express® SHC Membrane



High Area Opticap® XLT 30 Capsules with 0.5/0.2 µm Millipore Express® SHC Membrane



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

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

FH = 19 mm (34 in.) sanitary flange inlet and 14 mm (9/16 in.) hose barb outlet

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

HH = 14 mm (9/16 in.) 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 $\frac{1}{2}$  in.) sanitary flange inlet and 25 mm (1 in.) hose barb outlet

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

 $TT = 38 \text{ mm } (1\frac{1}{2} \text{ in.}) \text{ sanitary flange inlet and outlet}$ 

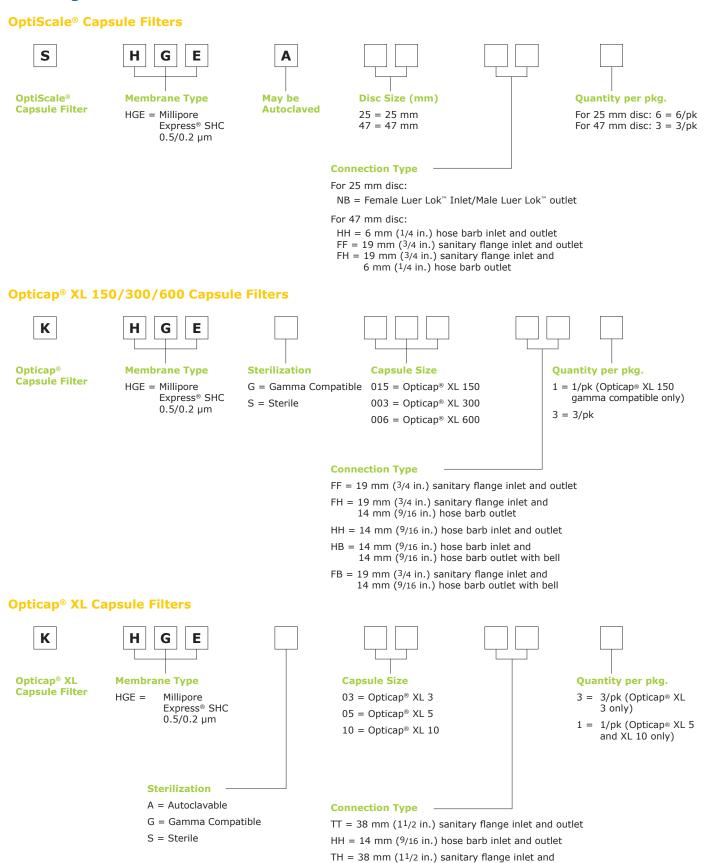
TH = 38 mm (1½ in.) sanitary flange Inlet and 16 mm (5/8 in.) hose barb outlet

HH = 16 mm (5/8 in.) hose barb inlet and outlet

TB = 38 mm (1 $\frac{1}{2}$  in.) sanitary flange inlet and 25 mm (1 in.) hose barb outlet

BB = 25 mm (1 in.) hose barb inlet and outlet

## **Ordering Information**

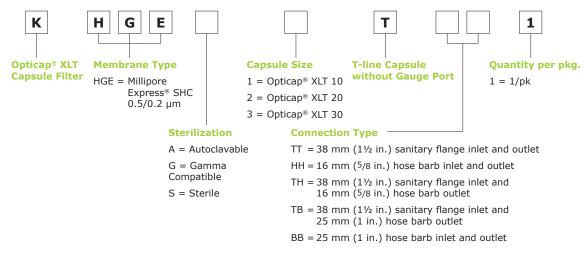


14 mm (9/16 in.) hose barb outlet

TB = 38 mm (11/2 in.) sanitary flange inlet and 25 mm (1 in.) hose barb outlet

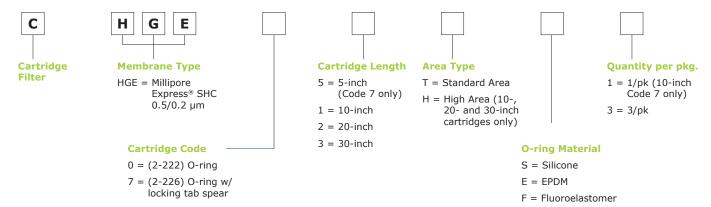
## **Ordering Information**

#### **Opticap® XLT Filters**



| Description                                   | Qty/pk | Catalogue Number |
|---|--------|------------------|
| Standard Opticap® XLT<br>Capsule Filter Stand | 1      | XLTSTAND1        |

### **Cartridge Filters**



## To place an order or receive technical assistance

In Europe, please call Customer Service:

France: 0825 045 645 Germany: 069 86798021 Italy: 848 845 645

Spain: 901 516 645 Option 1 Switzerland: 0848 645 645 United Kingdom: 0870 900 4645 For other countries across Europe,

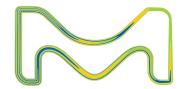
please call: +44 (0) 115 943 0840

Or visit: www.merckmillipore.com/offices

For Technical Service visit:

www.merckmillipore.com/techservice

\*Not all product configurations available; please call your EMD Millipore representative to confirm availability. The user guides for these products – Filters with Millipore Express® Membrane Wetting Instructions, Integrity Testing, Sterilizing and Drying Guidelines - UG4224EN00 and Opticap® XL Capsules and Opticap® XLT Capsules User Guide - UG1011EN00, are available on our website.



**Area Type** 

H= High Area (only

available in gamma

connection types)

compatible Opticap® XLT

capsules with TT and TB