

# Millipore Express® SHR Hydrophilic Filters

Sterilizing-grade PES membrane for fast, efficient, economical filtration of cell culture media and mycoplasma removal

Devices containing Millipore Express® SHR (Sterile, High-retention) membrane provide sterilizing-grade performance and mycoplasma removal across a range of bioprocess solutions, including: cell culture media, media additives, process intermediates and other biological fluids. These devices provide high sterility assurance, broad chemical compatibility, high flow rates and extended throughput for superior process efficiency and economy. The optional on-board polyethersulfone membrane prefilter protects the high-flux sterilizing-grade 0.1 µm rated membrane from premature plugging, allowing for enhanced throughput in high-fouling streams.



## Benefits

- High-flux and devices with increased area reduce the number of filters required for improved process economy
- Designed and qualified for sterilizing-grade performance and mycoplasma removal
- Available with an on-board PES membrane prefilter for extended throughput in high-fouling media
- Robust construction that will withstand multiple sterilization cycles
- Easy wetting and integrity testing
- Broad chemical compatibility across a wide pH range (pH 1–14)

## Filter Formats

- 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 standard area disposable capsule filters—autoclavable, gamma compatible, or presterilized. Gamma compatible capsules are also available in high area formats.
- Standard and high area cartridge filters

## Filter Applications

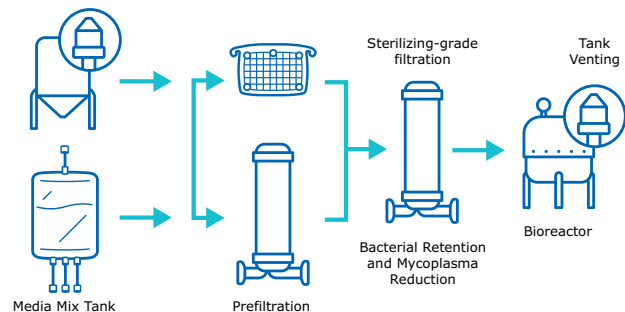
- Mycoplasma protection
- Cell culture media
- Media additives
- Serum
- Process intermediates

## Scalable, Disposable Products for Ease of Use

Sterilizing-grade Millipore Express® SHR 0.1 µm rated membranes are available in the following filter formats and capsule sizes with an optional onboard prefilter:

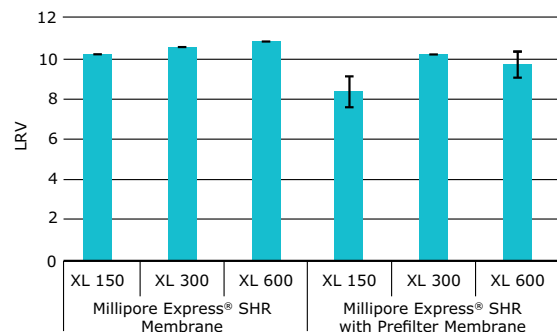
- Membrane discs (25 mm and 47 mm)
- Standard area cartridge filters 5–30 inch available with silicone, EPDM or fluoroelastomer O-rings
- High area cartridge filters 10–30 inch available with silicone, EPDM or fluoroelastomer O-ring
- OptiScale® disposable scaling devices
- Opticap® XL 150, 300, 600, 3, 5 and 10 autoclavable, gamma-compatible or sterile capsules
- Standard area Opticap® XLT 10, 20 and 30 inch autoclavable, gamma compatible or sterile capsules
- High area Opticap® XLT 10, 20 and 30 inch gamma compatible capsules

## Typical Process Flow



**Figure 1.** Sterilizing-grade Millipore Express® SHR Membranes for Bacterial Retention and Mycoplasma Removal

## Microbiological Performance

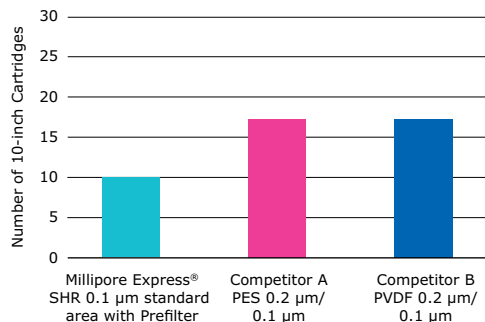


**Figure 2.** Results of *A. laidlawii* challenge at a level of  $10^7$  CFU/cm<sup>2</sup> of filter area (n=3).

## Enhanced Sterility Assurance

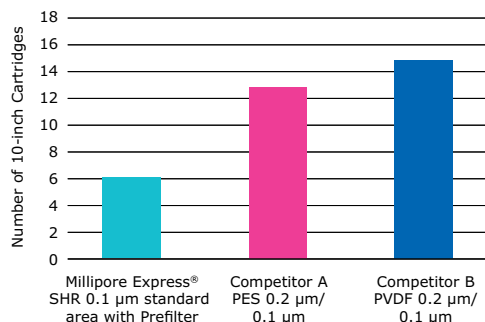
Devices with Millipore Express® SHR sterilizing-grade membranes are designed for the removal of mycoplasma and small microorganisms that could pass through a 0.2 µm rated sterilizing-grade filter. Millipore Express® SHR filters have demonstrated high mycoplasma removal—typical Log Reduction Value (LRV) >7 using *Acholeplasma laidlawii* ATCC® 23206 and our validated test method.

## Extended Filter Capacity



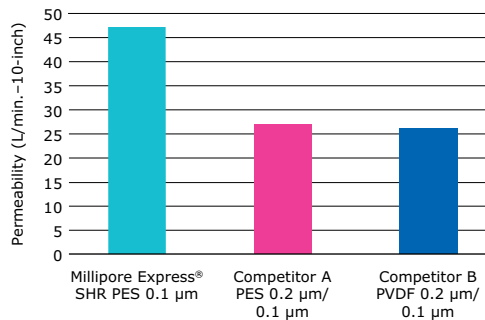
**Figure 3.** Number of 10-inch cartridges needed to filter 10,000 L of NS0 Serum-free, Protein-free, Cell Culture Media over 2 hours at 10 psi (n=2).

## Superior Efficiency and Economy



**Figure 4.** Number of 10-inch cartridges needed to filter 10,000 L of CHO Serum-free Cell Culture Media in 2 hours at 10 psi (n=2).

## Higher Permeability



**Figure 5.** Permeability per 10-inch\* cartridge

\*Tested in duplicate at 10 psi on 47 mm disc and scaled to standard area 10-inch

## Mobius® Single-use Solutions

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

## 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 capsules have the option to add a filling bell to protect an open container from airborne particles.



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

### 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® SHR 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® SHR 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® XLT filters



Opticap® XLT capsule stand

## Cartridge Filters

Millipore Express® SHR 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 high area formats for plugging fluids. These high area filters can reduce the number of filter elements needed. 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® High Area (left) compared to Standard Area (right) cartridge filters



Millipore Express® SHR cartridge filters

## Specifications

### OptiScale® Disposable Capsules

Millipore Express® SHR 0.1 µm and 0.5 µm/0.1 µm with Prefilter Membranes

| Description                          | OptiScale® 25 Capsules  | OptiScale® 47 Capsules   |
|--------------------------------------|---|--|
| <b>Nominal Dimensions</b>            |   |  |
| Diameter                             | 31 mm (1.21 in.)  | 70 mm (2.75 in.)   |
| Length                               | 39 mm (1.52 in.)  | 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 |
| <b>Filtration Area</b>               | 3.5 cm <sup>2</sup>   | 17.7 cm <sup>2</sup>   |
| <b>Materials of construction</b>     |   |  |
| Filter membrane                      | Hydrophilic polyethersulfone  | Hydrophilic polyethersulfone   |
| Supports                             | Polypropylene   | —  |
| Structural components                | Polypropylene   | Polyvinylidene fluoride  |
| Vent cap                             | Polypropylene   | Fluoroelastomer  |
| O-rings                              | —   | Fluoroelastomer  |
| <b>Housing Vent</b>                  | Capped vent with female Luer connections on inlet side of device  | Adjustable vent with male Luer and female Luer-Lok™ connections on inlet side of the device  |
| <b>Maximum Inlet Pressure</b>        | 4100 mbar (60 psi) at 25 °C   | 5500 mbar (80 psi) at 25 °C  |
| <b>Maximum Differential Pressure</b> |   |  |
| Forward                              | 4100 mbar (60 psi) at 25 °C   | 5500 mbar (80 psi) at 25 °C  |
| Reverse                              | 0 mbar (0 psi)  | 690 mbar (10 psi) at 25 °C   |
| <b>Bacterial Endotoxin</b>           | Autoclaved filter effluent meets the WFI specification for USP <643>, Total Organic Carbon, and for USP <645>, Conductivity, after a WFI flush of 15 mL   | —  |
| <b>Oxidizable Substances</b>         | —   | Effluent meets the USP Oxidizable Substance Test requirements for sterile purified water after a water flush of: 100 mL                                  |
| <b>Sterilization</b>                 | May be autoclaved for 1 cycle of 123 °C for 60 min.   | May be autoclaved for 3 cycles of 60 min. at 126 °C  |
| <b>Particle Shedding</b>             | Effluent meets the acceptance criteria set forth in USP <788> for large volume parenterals.   | —  |
| <b>Non-fiber Releasing</b>           | Millipore Express® SHR membranes meet the criteria for a “non-fiber releasing” filter as defined in 21 CFR 210.3(b)(6).   |  |
| <b>Component Material Toxicity</b>   | Component materials were tested and meet the criteria of the USP <88> Reactivity Test for Class VI plastics. Millipore Express® SHR filters meet the requirements of the USP <88> Safety Test, utilizing a 0.9% sodium chloride extraction. |  |
| <b>Indirect Food Additive</b>        | All component materials meet the FDA Indirect Food Additive requirements cited in 21 CFR 177–182.   |  |
| <b>Good Manufacturing Practices</b>  | These products are manufactured in a facility which adheres to FDA Good Manufacturing Practices.  |  |

## Specifications

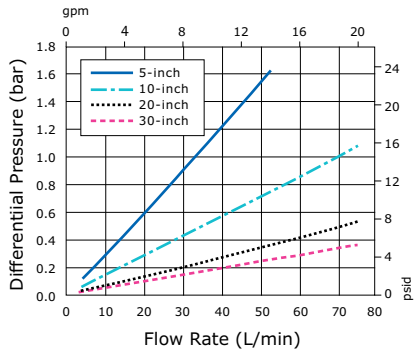
### Cartridge Filters

Millipore Express® SHR 0.1 µm and 0.5 µm/0.1 µm with Prefilter Membranes

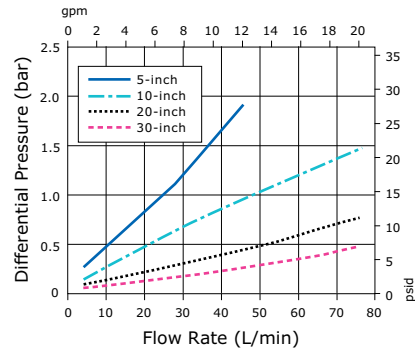
|  | 5-inch Cartridge  | Per Standard Area<br>10-inch Cartridge     | Per High Area<br>10-inch Cartridge  |
|--|---|--|---|
| <b>Nominal Dimensions</b>              |   |  |   |
| Diameter                               | 6.9 cm (2.7 in.)  | 6.9 cm (2.7 in.)                           | 6.9 cm (2.7 in.)  |
| Length                                 | 12.7 cm (5 in.)   | 25.4 cm (10 in.)                           | 25.4 cm (10 in.)  |
| <b>Filtration Area</b>                 |   |  |   |
| Millipore Express® SHR                 | 0.29 m <sup>2</sup> (3.1 ft <sup>2</sup> )  | 0.60 m <sup>2</sup> (6.5 ft <sup>2</sup> ) | —   |
| Millipore Express® SHR w/ Prefilter    | 0.23 m <sup>2</sup> (2.5 ft <sup>2</sup> )  | 0.49 m <sup>2</sup> (5.3 ft <sup>2</sup> ) | 1.0 m <sup>2</sup> (10.8 ft <sup>2</sup> )  |
| <b>Materials of Construction</b>       |   |  |   |
| Filter membrane                        | Hydrophilic polyethersulfone  |  | Hydrophilic polyethersulfone  |
| Film edge                              | Polypropylene   |  | Polypropylene   |
| Supports                               | Polypropylene   |  | Polypropylene   |
| Cage and end caps                      | Polypropylene   |  | Polypropylene   |
| Core                                   | Polysulfone   |  | Polyethersulfone  |
| O-rings                                | Silicone, EPDM or Fluoroelastomer   |  | Silicone, EPDM or Fluoroelastomer   |
| <b>Maximum Differential Pressure</b>   |   |  |   |
| Millipore Express® SHR                 |   |  |   |
| Forward                                | 6900 mbar (100 psi) at 25 °C<br>1700 mbar (25 psi) at 80 °C<br>1000 mbar (15 psi) at 135 °C   |  | —   |
| Reverse                                | 2100 mbar (30 psi) at 25 °C<br>69 mbar (1 psi) at 135 °C  |  | —   |
| Millipore Express® SHR w/Prefilter     |   |  |   |
| 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>300 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  |
| <b>70/30 IPA Bubble Point at 23 °C</b> |   |  |   |
|  | ≥2590 mbar (37.5 psi) with nitrogen   |  |   |
| <b>Air Diffusion at 23 °C</b>          |   |  |   |
| Millipore Express® SHR                 | ≤15.9 cc/min.   | ≤33.3 cc/min.                              | —   |
| Millipore Express® SHR w/Prefilter     | ≤12.8 cc/min.   | ≤27.1 cc/min.                              | ≤54.2 cc/min.   |
| <b>Bacterial Retention</b>             |   |  |   |
|  | Quantitative retention of 10 <sup>7</sup> CFU/cm <sup>2</sup> <i>Brevundimonas diminuta</i> ATCC® 19146 per ASTM® methodology   |  |   |
| <b>Mycoplasma Removal</b>              |   |  |   |
|  | Typical Log Reduction Value (LRV) >7 using <i>A. laidlawii</i> ATCC® 23206 and our validated test method  |  |   |
| <b>Bacterial Endotoxin</b>             |   |  |   |
|  | Aqueous extraction contains <0.25 EU/mL as determined using the Limulus Amebocyte Lysate (LAL) test.  |  |   |
| <b>TOC/Conductivity at 25 °C</b>       |   |  |   |
|  | Autoclaved filter effluent meets the WFI specification for USP <643>, Total Organic Carbon, and for USP <645>, Conductivity, after a WFI flush of:  |  |   |
| Millipore Express® SHR                 | 5.5 L   | 10 L                                       | —   |
| Millipore Express® SHR w/Prefilter     | 9.5 L   | 20 L                                       | 20 L  |
| <b>Oxidizable Substances</b>           |   |  |   |
|  | Effluent meets the USP Oxidizable Substance Test requirements for sterile purified water after a water flush of:  |  |   |
| Millipore Express® SHR                 | 1000 mL   |  | —   |
| Millipore Express® SHR w/ Prefilter    | 2000 mL   |  | 2000 mL   |
| <b>Sterilization</b>                   |   |  |   |
| Millipore Express® SHR                 | Autoclave: 25x, 60 min. cycles at 126 °C<br>In-line steam: 25 forward cycles, 30 min., 135 °C at ≤300 mbar (5 psi)<br>or, 22 forward cycles, 30 min., 135 °C at ≤300 mbar (5 psi) and 3<br>reverse cycles, 30 min., 135 °C at <69 mbar (1 psi)  |  | —   |
| Millipore Express® SHR w/Prefilter     | Autoclave: 25x, 60 min. cycles at 126 °C<br>In-line steam: 25x forward cycles, 30 min., 135 °C at ≤300 mbar (5<br>psi) or, 22 forward cycles, 30 min., 135 °C at ≤300 mbar (5 psi) and<br>3 reverse cycles, 30 min., 135 °C at <69 mbar (1 psi) or, 3 forward<br>cycles, 30 min., 135 °C at ≤1000 mbar (15 psi) |  | Autoclave: 5X, 60 min. cycles at<br>126 °C<br>In-line steam: 5X forward cycles,<br>30 min., ≤135 °C at ≤300 mbar<br>(5 psi) |
| <b>Cytotoxicity</b>                    |   |  |   |
|  | Non-toxic per MEM elution ISO® 10993-5  |  |   |
| <b>Particle Shedding</b>               |   |  |   |
|  | Effluent meets the acceptance criteria set forth in USP <788> for large volume parenterals.   |  |   |
| <b>Non-fiber Releasing</b>             |   |  |   |
|  | Millipore Express® SHR membranes meet the criteria for a “non-fiber releasing” filter as defined in 21 CFR 210.3(b)(6).   |  |   |
| <b>Component Material Toxicity</b>     |   |  |   |
|  | Component materials were tested and meet the criteria of the USP <88> Reactivity Test for Class VI plastics. Millipore Express® SHR filters meet the requirements of the USP <88> Safety Test, utilizing a 0.9% sodium chloride extraction.   |  |   |
| <b>Indirect Food Additive</b>          |   |  |   |
|  | All component materials meet the FDA Indirect Food Additive requirements cited in 21 CFR 177–182.   |  |   |
| <b>Good Manufacturing Practices</b>    |   |  |   |
|  | These products are manufactured in a facility which adheres to FDA Good Manufacturing Practices.  |  |   |

# Typical Clean Water Flow Rates

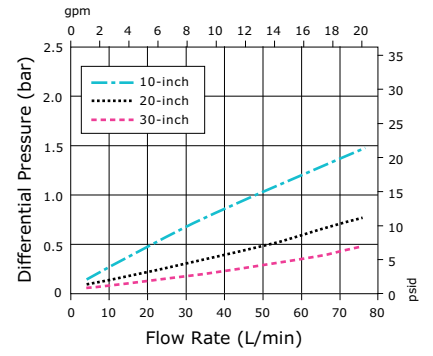
**Standard Area Cartridge Filters with Millipore Express® SHR 0.1 µm Membrane**



**Standard Area Cartridge Filters with Millipore Express® SHR 0.5/0.1 µm Membrane with prefilter**



**High Area Cartridge Filters with Millipore Express® SHR 0.5/0.1 µm Membrane with prefilter**



## Specifications

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

Millipore Express® SHR 0.1 µm Membrane

|  | Opticap® XL<br>3 Capsules  | Opticap® XL<br>5 Capsules                  | Opticap® XL<br>10 Capsules                 | Opticap® XLT<br>10 Capsules                | Opticap® XLT<br>20 Capsules                 | Opticap® XLT<br>30 Capsules                 |
|--|--|--|--|--|---|---|
| <b>Nominal Dimensions</b>              |  |  |  |  |   |   |
| Maximum length                         | 17.3 cm (6.8 in.)  | 21.6 cm (8.5 in.)                          | 33.5 cm (13.2 in.)                         | 38.1 cm (15.0 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.)                          | 10.7 cm (4.2 in.)                          | 10.7 cm (4.2 in.)                           | 10.7 cm (4.2 in.)                           |
| <b>Fitting to Fitting</b>              |  |  |  |  |   |   |
| Sanitary flange to sanitary flange     | —  |  |  | 15.2 cm (6.0 in.)                          |   |   |
| Sanitary flange to hose barb           | —  |  |  | 17.5 cm (6.9 in.)                          |   |   |
| Hose barb to hose barb                 | —  |  |  | 19.8 cm (7.8 in.)                          |   |   |
| <b>Filtration Area</b>                 | 0.16 m <sup>2</sup> (1.7 ft <sup>2</sup> )   | 0.29 m <sup>2</sup> (3.1 ft <sup>2</sup> ) | 0.60 m <sup>2</sup> (6.5 ft <sup>2</sup> ) | 0.60 m <sup>2</sup> (6.5 ft <sup>2</sup> ) | 1.21 m <sup>2</sup> (13.0 ft <sup>2</sup> ) | 1.81 m <sup>2</sup> (19.5 ft <sup>2</sup> ) |
| <b>Materials of Construction</b>       |  |  |  |  |   |   |
| Filter membrane                        | Hydrophilic polyethersulfone   |  |  |  |   |   |
| Film edge                              | Polypropylene  |  |  |  |   |   |
| Supports                               | Polypropylene  |  |  |  |   |   |
| Core                                   | Polysulfone  |  |  |  |   |   |
| Structural components*                 | Polypropylene  |  |  |  |   |   |
| Vent O-rings                           | Silicone   |  |  |  |   |   |
| Vent/Drain                             | 6 mm (¼ in.) hose barb with double O-ring seal   |  |  |  |   |   |
| <b>Maximum Inlet Pressure</b>          | 6900 mbar (100 psi) intermittent at 23 °C<br>5500 mbar (80 psi) at 23 °C<br>2800 mbar (40 psi) at 60 °C<br>1000 mbar (15 psi) at 80 °C   |  |  |  |   |   |
| <b>Maximum Differential Pressure</b>   |  |  |  |  |   |   |
| 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   |  |  |  |   |   |
| <b>70/30 IPA Bubble Point at 23 °C</b> | ≥2590 mbar (37.5 psi) with nitrogen  |  |  |  |   |   |
| <b>Air Diffusion at 23 °C</b>          | Through a water wet membrane at 3.4 bar (50 psi):<br>≤8.7 cc/min.    ≤15.9 cc/min.    ≤33.3 cc/min.    ≤33.3 cc/min.    ≤66.6 cc/min.    ≤99.9 cc/min.   |  |  |  |   |   |
| <b>Bacterial Retention</b>             | Quantitative retention of 10 <sup>7</sup> CFU/cm <sup>2</sup> <i>Brevundimonas diminuta</i> ATCC® 19146 per ASTM® methodology  |  |  |  |   |   |
| <b>Mycoplasma Removal</b>              | Typical Log Reduction Value (LRV) >7 using <i>A. laidlawii</i> ATCC® 23206 and our validated test method   |  |  |  |   |   |
| <b>Bacterial Endotoxin</b>             | Aqueous extraction contains <0.25 EU/mL as determined by the Limulus Amebocyte Lysate (LAL) Test.  |  |  |  |   |   |
| <b>TOC/Conductivity at 25 °C</b>       | Autoclaved filter effluent meets the WFI requirements of USP <643> for Total Organic Carbon and USP <645> for Water Conductivity after a WFI water flush of:<br>3.0 L                      5.5 L                      10 L                      10 L                      20 L                      30 L |  |  |  |   |   |
| <b>Oxidizable Substances</b>           | Meets the USP Oxidizable Substances Test requirements for sterile purified water after a water flush of:<br>1000 mL                      1000 mL                      1000 mL                      1000 mL                      2000 mL                      3000 mL                                     |  |  |  |   |   |
| <b>Sterilization</b>                   | May be autoclaved for 3 cycles of 60 minutes at 126 °C (Cannot be steam sterilized in-line)  |  |  |  |   |   |
| <b>Cytotoxicity</b>                    | Non-toxic per MEM elution ISO® 10993-5   |  |  |  |   |   |
| <b>Particle Shedding</b>               | Effluent meets the acceptance criteria set forth in USP <788> for large volume parenterals.  |  |  |  |   |   |
| <b>Non-fiber Releasing</b>             | Millipore Express® SHR membranes meet the criteria for a “non-fiber releasing” filter as defined in 21 CFR 210.3(b)(6).  |  |  |  |   |   |
| <b>Component Material Toxicity</b>     | Component materials were tested and meet the criteria of the USP <88> Reactivity Test for Class VI plastics. Millipore Express® SHR filters meet the requirements of the USP <88> Safety Test, utilizing a 0.9% sodium chloride extraction.  |  |  |  |   |   |
| <b>Indirect Food Additive</b>          | All component materials meet the FDA Indirect Food Additive requirements cited in 21 CFR 177–182.  |  |  |  |   |   |
| <b>Good Manufacturing Practices</b>    | These products are manufactured in a facility which adheres to FDA Good Manufacturing Practices.   |  |  |  |   |   |

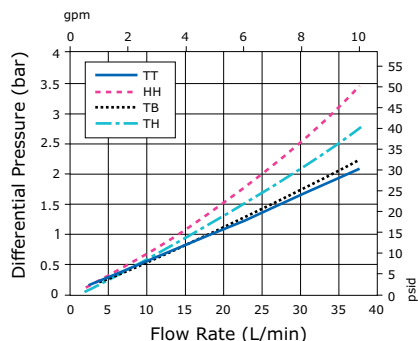
\* Cage, end caps and capsule housing

## Typical Clean Water Flow Rates

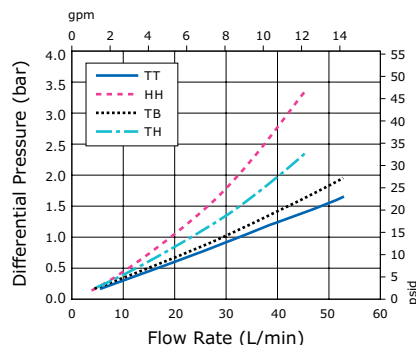
### Opticap® XL and XLT Disposable Capsules (Autoclavable Only)

Millipore Express® SHR 0.1 µm Membrane

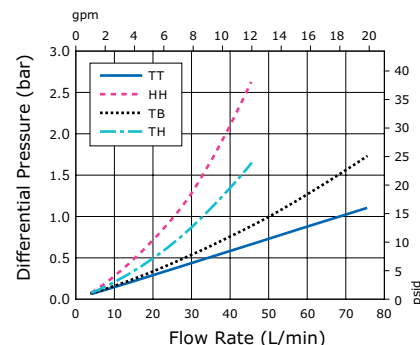
**Opticap® XL 3 Capsule Filters with 0.1 µm Millipore Express® SHR Membrane**



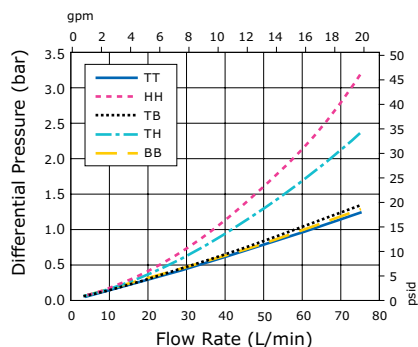
**Opticap® XL 5 Capsule Filters with 0.1 µm Millipore Express® SHR Membrane**



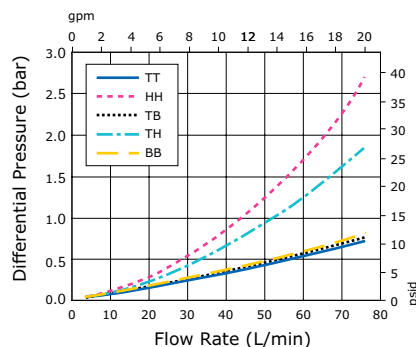
**Opticap® XL 10 Capsule Filters with 0.1 µm Millipore Express® SHR Membrane**



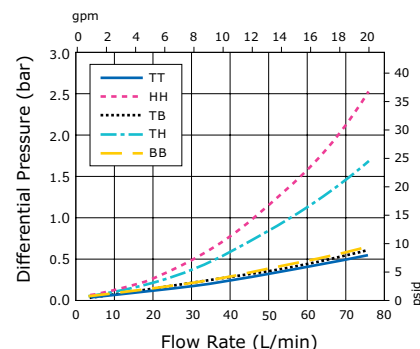
**Opticap® XLT 10 Capsule Filters with 0.1 µm Millipore Express® SHR Membrane**



**Opticap® XLT 20 Capsule Filters with 0.1 µm Millipore Express® SHR Membrane**



**Opticap® XLT 30 Capsule Filters with 0.1 µm Millipore Express® SHR Membrane**



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

- TT = 38 mm (1½ in.) sanitary flange inlet and outlet
- HH = 14 mm (½ in.) hose barb inlet and outlet
- TH = 38 mm (1½ in.) sanitary flange inlet and 14 mm (½ in.) hose barb outlet
- TB = 38 mm (1½ in.) sanitary flange inlet and 25 mm (1 in.) hose barb outlet

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

- TT = 38 mm (1½ in.) sanitary flange inlet and outlet
- TH = 38 mm (1½ in.) sanitary flange Inlet and 16 mm (⅝ in.) hose barb outlet
- HH = 16 mm (⅝ in.) hose barb inlet and outlet
- TB = 38 mm (1½ in.) sanitary flange inlet and 25 mm (1 in.) hose barb outlet
- BB = 25 mm (1 in.) hose barb inlet and outlet



## Specifications

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

Millipore Express® SHR 0.5/0.1 µm Membrane with Prefilter

|  | Opticap® XL<br>3 Capsules   | Opticap® XL<br>5 Capsules                  | Opticap® XL<br>10 Capsules                 | Opticap® XLT<br>10 Capsules                | Opticap® XLT<br>20 Capsules                 | Opticap® XLT<br>30 Capsules                 |
|--|---|--|--|--|---|---|
| <b>Nominal Dimensions</b>              |   |  |  |  |   |   |
| Maximum length                         | 17.3 cm (6.8 in.)   | 21.6 cm (8.5 in.)                          | 33.5 cm (13.2 in.)                         | 38.1 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.)                          | 10.7 cm (4.2 in.)                          | 10.7 cm (4.2 in.)                           | 10.7 cm (4.2 in.)                           |
| <b>Fitting to Fitting</b>              |   |  |  |  |   |   |
| Sanitary flange to sanitary flange     | —   |  |  | 15.2 cm (6.0 in.)                          |   |   |
| Sanitary flange to hose barb           | —   |  |  | 17.5 cm (6.9 in.)                          |   |   |
| Hose barb to hose barb                 | —   |  |  | 19.8 cm (7.8 in.)                          |   |   |
| <b>Filtration Area</b>                 |   |  |  |  |   |   |
|  | 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> (10.6 ft <sup>2</sup> ) | 1.48 m <sup>2</sup> (15.9 ft <sup>2</sup> ) |
| <b>Materials of Construction</b>       |   |  |  |  |   |   |
| Filter membrane                        | Hydrophilic polyethersulfone  |  |  |  |   |   |
| Film edge                              | Polypropylene   |  |  |  |   |   |
| Supports                               | Polypropylene   |  |  |  |   |   |
| Core                                   | Polysulfone   |  |  |  |   |   |
| Structural components*                 | Polypropylene   |  |  |  |   |   |
| Vent O-rings                           | Silicone  |  |  |  |   |   |
| <b>Vent/Drain</b>                      |   |  |  |  |   |   |
|  | 6 mm (¼ in.) hose barb with double O-ring seal  |  |  |  |   |   |
| <b>Maximum Inlet Pressure</b>          |   |  |  |  |   |   |
|  | 6900 mbar (100 psi) intermittent at 23 °C   |  |  |  |   |   |
|  | 5500 mbar (80 psi) at 23 °C   |  |  |  |   |   |
|  | 2800 mbar (40 psi) at 60 °C   |  |  |  |   |   |
|  | 1000 mbar (15 psi) at 80 °C   |  |  |  |   |   |
| <b>Maximum Differential Pressure</b>   |   |  |  |  |   |   |
| Forward                                | 6900 mbar (100 psi) intermittent at 25 °C   |  |  |  |   |   |
|  | 5500 mbar (80 psi) at 25 °C   |  |  |  |   |   |
|  | 1000 mbar (15 psi) at 80 °C   |  |  |  |   |   |
| Reverse                                | 2100 mbar (30 psi) intermittent at 25 °C  |  |  |  |   |   |
| <b>70/30 IPA Bubble Point at 23 °C</b> |   |  |  |  |   |   |
|  | ≥2590 mbar (37.5 psi) with nitrogen   |  |  |  |   |   |
| <b>Air Diffusion at 23 °C</b>          |   |  |  |  |   |   |
|  | Through a water wet membrane at 3.4 bar (50 psi):   |  |  |  |   |   |
|  | ≤7.2 cc/min.  | ≤12.8 cc/min.                              | ≤27.1 cc/min.                              | ≤27.1 cc/min.                              | ≤54.2 cc/min.                               | ≤81.3 cc/min.                               |
| <b>Bacterial Retention</b>             |   |  |  |  |   |   |
|  | Quantitative retention of 10 <sup>7</sup> CFU/cm <sup>2</sup> <i>Brevundimonas diminuta</i> ATCC® 19146 per ASTM® methodology   |  |  |  |   |   |
| <b>Mycoplasma Removal</b>              |   |  |  |  |   |   |
|  | Typical Log Reduction Value (LRV) >7 using <i>A. laidlawii</i> ATCC® 23206 and our validated test method  |  |  |  |   |   |
| <b>Bacterial Endotoxin</b>             |   |  |  |  |   |   |
|  | Aqueous extraction contains <0.25 EU/mL as determined by the Limulus Amebocyte Lysate (LAL) Test.   |  |  |  |   |   |
| <b>TOC/Conductivity at 25 °C</b>       |   |  |  |  |   |   |
|  | Autoclaved filter effluent meets the WFI requirements of USP <643> for Total Organic Carbon and USP <645> for Water Conductivity after a WFI water flush of:  |  |  |  |   |   |
|  | 5.5 L   | 9.5 L                                      | 20 L                                       | 20 L                                       | 40 L  | 60 L  |
| <b>Oxidizable Substances</b>           |   |  |  |  |   |   |
|  | Meets the USP Oxidizable Substances Test requirements for sterile purified water after a water flush of:  |  |  |  |   |   |
|  | 2 L   | 2 L  | 2 L  | 2 L  | 4 L   | 6 L   |
| <b>Sterilization</b>                   |   |  |  |  |   |   |
|  | May be autoclaved for 3 cycles of 60 minutes at 126 °C (Cannot be steam sterilized in-line)   |  |  |  |   |   |
| <b>Cytotoxicity</b>                    |   |  |  |  |   |   |
|  | Non-toxic per MEM elution ISO® 10993-5  |  |  |  |   |   |
| <b>Particle Shedding</b>               |   |  |  |  |   |   |
|  | Effluent meets the acceptance criteria set forth in USP <788> for large volume parenterals.   |  |  |  |   |   |
| <b>Non-fiber Releasing</b>             |   |  |  |  |   |   |
|  | Millipore Express® SHR membranes meet the criteria for a “non-fiber releasing” filter as defined in 21 CFR 210.3(b)(6).   |  |  |  |   |   |
| <b>Component Material Toxicity</b>     |   |  |  |  |   |   |
|  | Component materials were tested and meet the criteria of the USP <88> Reactivity Test for Class VI plastics. Millipore Express® SHR filters meet the requirements of the USP <88> Safety Test, utilizing a 0.9% sodium chloride extraction. |  |  |  |   |   |
| <b>Indirect Food Additive</b>          |   |  |  |  |   |   |
|  | All component materials meet the FDA Indirect Food Additive requirements cited in 21 CFR 177–182.   |  |  |  |   |   |
| <b>Good Manufacturing Practices</b>    |   |  |  |  |   |   |
|  | These products are manufactured in a facility which adheres to FDA Good Manufacturing Practices.  |  |  |  |   |   |

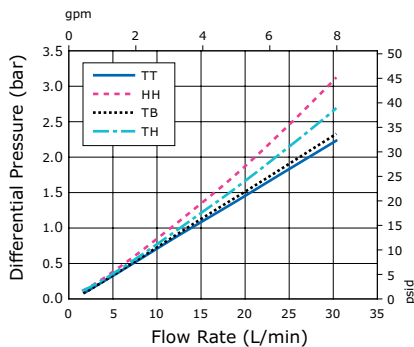
\* Cage, end caps and capsule housing

## Typical Clean Water Flow Rates

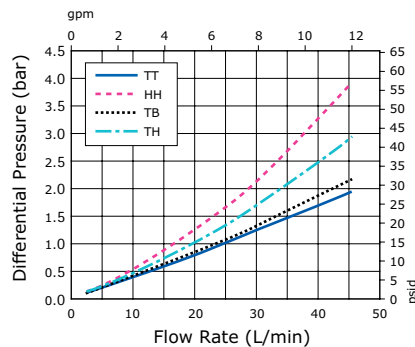
### Opticap® XL and XLT Disposable Capsules (Autoclavable Only)

Millipore Express® SHR 0.5/0.1 µm Membrane with Prefilter

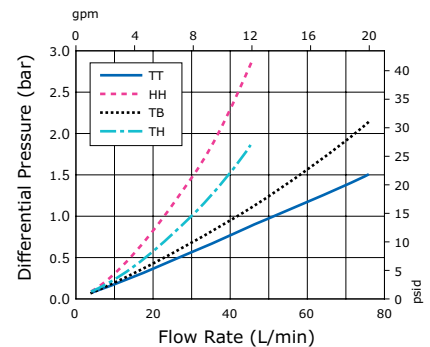
**Opticap® XL 3 Capsule Filters with 0.5/0.1 µm Millipore Express® SHR Membrane with prefilter**



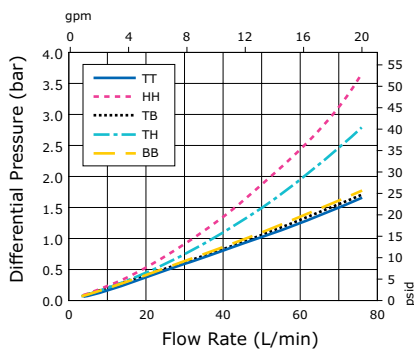
**Opticap® XL 5 Capsule Filters with 0.5/0.1 µm Millipore Express® SHR Membrane with prefilter**



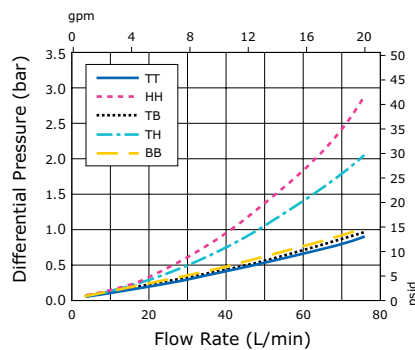
**Opticap® XL 10 Capsule Filters with 0.5/0.1 µm Millipore Express® SHR Membrane with prefilter**



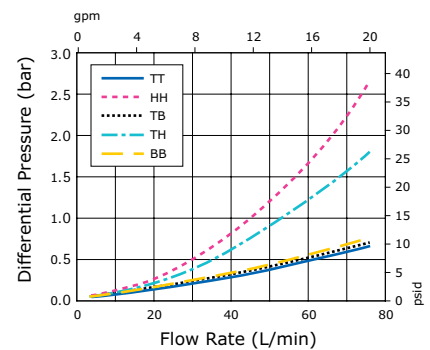
**Opticap® XLT 10 Capsule Filters with 0.5/0.1 µm Millipore Express® SHR Membrane with prefilter**



**Opticap® XLT 20 Capsule Filters with 0.5/0.1 µm Millipore Express® SHR Membrane with prefilter**



**Opticap® XLT 30 Capsule Filters with 0.5/0.1 µm Millipore Express® SHR Membrane with prefilter**



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

- TT = 38 mm (1½ in.) sanitary flange inlet and outlet
- HH = 14 mm (9/16 in.) hose barb inlet and outlet
- TH = 38 mm (1½ in.) sanitary flange inlet and 14 mm (9/16 in.) hose barb outlet
- TB = 38 mm (1½ in.) sanitary flange inlet and 25 mm (1 in.) hose barb outlet

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

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

## Specifications

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

Millipore Express® SHR 0.1 μm Membrane

|  | Opticap® XL 150 Capsules  | Opticap® XL 300 Capsules                      | Opticap® XL 600 Capsules                      |
|--|---|---|---|
| <b>Nominal Dimensions</b>              |   |   |   |
| Maximum length                         | 9.7 cm (3.8 in.)  | 11.9 cm (4.7 in.)                             | 16.5 cm (6.5 in.)                             |
| Maximum length with bell               | 11.4 cm (4.5 in.)   | 13.7 cm (5.4 in.)                             | 18.3 cm (7.2 in.)                             |
| Body diameter                          | 5.6 cm (2.2 in.)  | 5.6 cm (2.2 in.)                              | 5.6 cm (2.2 in.)                              |
| <b>Filtration Area</b>                 | 0.025 m <sup>2</sup> (0.268 ft <sup>2</sup> )   | 0.048 m <sup>2</sup> (0.517 ft <sup>2</sup> ) | 0.101 m <sup>2</sup> (1.090 ft <sup>2</sup> ) |
| <b>Materials of Construction</b>       |   |   |   |
| Filter membrane                        | Hydrophilic polyethersulfone  |   |   |
| Supports                               | Polyethylene  |   |   |
| Core                                   | Polysulfone   |   |   |
| Structural components*                 | Gamma stable polypropylene  |   |   |
| Vent O-rings                           | Silicone  |   |   |
| Bell                                   | Polycarbonate   |   |   |
| <b>Vent/Drain</b>                      | 6 mm (¼ in.) hose barb with double O-ring seal  |   |   |
| <b>Maximum Inlet Pressure</b>          | 6900 mbar (100 psi) intermittent at 23 °C<br>5500 mbar (80 psi) at 23 °C<br>2800 mbar (40 psi) at 60 °C<br>1000 mbar (15 psi) at 80 °C  |   |   |
| <b>Maximum Differential Pressure</b>   |   |   |   |
| 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  |   |   |
| <b>70/30 IPA Bubble Point at 23 °C</b> | ≥2590 mbar (37.5 psi) with nitrogen   |   |   |
| <b>Air Diffusion at 23 °C</b>          | Through a water wet membrane at 3.4 bar (50 psi):<br>≤1.4 cc/min.   | ≤2.8 cc/min.                                  | ≤5.8 cc/min.                                  |
| <b>Bacterial Retention</b>             | Quantitative retention of 10 <sup>7</sup> CFU/cm <sup>2</sup> <i>Brevundimonas diminuta</i> ATCC® 19146 per ASTM® methodology   |   |   |
| <b>Mycoplasma Removal</b>              | Typical Log Reduction Value (LRV) >7 using <i>A. laidlawii</i> ATCC® 23206 and our validated test method  |   |   |
| <b>Bacterial Endotoxin</b>             | Aqueous extraction contains <0.25 EU/mL as determined by the Limulus Amebocyte Lysate (LAL) Test.   |   |   |
| <b>TOC/Conductivity at 25 °C</b>       | Gamma sterilized filter effluent meets the WFI requirements of USP <643> for Total Organic Carbon and USP <645> for Water Conductivity after a WFI flush of:<br>2.0 L   | 2.5 L   | 3.0 L   |
| <b>Oxidizable Substances</b>           | Meets the USP Oxidizable Substances Test requirements for sterile purified water after a WFI flush of 1 L.  |   |   |
| <b>Sterilization</b>                   |   |   |   |
| Gamma-compatible capsules              | Gamma compatible to 45 kGy, may be autoclaved for 3 cycles of 60 minutes at 123 °C (Cannot be steam sterilized in-line)   |   |   |
| Sterile capsules                       | May be autoclaved for 3 cycles of 60 minutes at 123 °C (Cannot be steam sterilized in-line)   |   |   |
| <b>Sterility</b>                       |   |   |   |
| Sterile capsules                       | These capsules meet current USP and AAMI guidelines for sterility utilizing a validated sterilization cycle.  |   |   |
| <b>Cytotoxicity</b>                    | Non-toxic per MEM elution ISO® 10993-5  |   |   |
| <b>Particle Shedding</b>               | Effluent meets the acceptance criteria set forth in USP <788> for large volume parenterals.   |   |   |
| <b>Non-fiber Releasing</b>             | Millipore Express® SHR membranes meet the criteria for a “non-fiber releasing” filter as defined in 21 CFR 210.3(b)(6).   |   |   |
| <b>Component Material Toxicity</b>     | Component materials were tested and meet the criteria of the USP <88> Reactivity Test for Class VI plastics. Millipore Express® SHR filters meet the requirements of the USP <88> Safety Test, utilizing a 0.9% sodium chloride extraction. |   |   |
| <b>Indirect Food Additive</b>          | All component materials meet the FDA Indirect Food Additive requirements cited in 21 CFR 177-182.   |   |   |
| <b>Good Manufacturing Practices</b>    | These products are manufactured in a facility which adheres to FDA Good Manufacturing Practices.  |   |   |

\* Cage, end caps and capsule housing

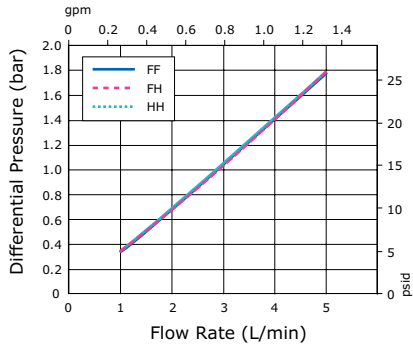
## Typical Clean Water Flow Rates

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

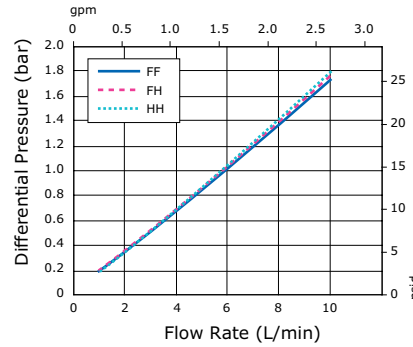
#### Millipore Express® SHR 0.1 µm Membrane

Filters tested post gamma radiation at 25–45 kGy and autoclaved at 123 °C for 60 minutes.

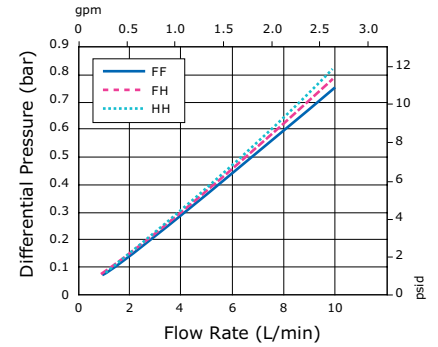
#### Opticap® XL 150 with 0.1 µm Millipore Express® SHR Membrane



#### Opticap® XL 300 with 0.1 µm Millipore Express® SHR Membrane



#### Opticap® XL 600 with 0.1 µm Millipore Express® SHR Membrane



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

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

FH = 19 mm (¾ in.) sanitary flange inlet and 14 mm (9/16 in.) hose barb outlet

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

## Specifications

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

Millipore Express® SHR 0.1 µm Membrane

|  | Opticap® XL<br>3 Capsules   | Opticap® XL<br>5 Capsules                  | Opticap® XL<br>10 Capsules                 | Opticap® XLT<br>10 Capsules                | Opticap® XLT<br>20 Capsules                 | Opticap® XLT<br>30 Capsules                 |
|--|---|--|--|--|---|---|
| <b>Nominal Dimensions</b>              |   |  |  |  |   |   |
| Maximum length                         | 17.3 cm (6.8 in.)   | 21.6 cm (8.5 in.)                          | 33.5 cm (13.2 in.)                         | 38.1 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.)                          | 10.7 cm (4.2 in.)                          | 10.7 cm (4.2 in.)                           | 10.7 cm (4.2 in.)                           |
| <b>Fitting to Fitting</b>              |   |  |  |  |   |   |
| Sanitary flange to sanitary flange     | —   |  |  | 15.2 cm (6.0 in.)                          |   |   |
| Sanitary flange to hose barb           | —   |  |  | 17.5 cm (6.9 in.)                          |   |   |
| Hose barb to hose barb                 | —   |  |  | 19.8 cm (7.8 in.)                          |   |   |
| <b>Filtration Area</b>                 |   |  |  |  |   |   |
|  | 0.17 m <sup>2</sup> (1.8 ft <sup>2</sup> )  | 0.31 m <sup>2</sup> (3.3 ft <sup>2</sup> ) | 0.69 m <sup>2</sup> (7.4 ft <sup>2</sup> ) | 0.69 m <sup>2</sup> (7.4 ft <sup>2</sup> ) | 1.38 m <sup>2</sup> (14.8 ft <sup>2</sup> ) | 2.06 m <sup>2</sup> (22.2 ft <sup>2</sup> ) |
| <b>Materials of Construction</b>       |   |  |  |  |   |   |
| Filter membrane                        | Hydrophilic polyethersulfone  |  |  |  |   |   |
| Film edge                              | Polypropylene   |  |  |  |   |   |
| Supports                               | Polypropylene   |  |  |  |   |   |
| Core                                   | Polysulfone   |  |  |  |   |   |
| Structural components*                 | Polypropylene   |  |  |  |   |   |
| Vent O-rings                           | Silicone  |  |  |  |   |   |
| <b>Vent/Drain</b>                      |   |  |  |  |   |   |
|  | 6 mm (¼ in.) hose barb with double O-ring seal  |  |  |  |   |   |
| <b>Maximum Inlet Pressure</b>          |   |  |  |  |   |   |
|  | 6900 mbar (100 psi) intermittent at 23 °C   |  |  |  |   |   |
|  | 5500 mbar (80 psi) at 23 °C   |  |  |  |   |   |
|  | 2800 mbar (40 psi) at 60 °C   |  |  |  |   |   |
|  | 1000 mbar (15 psi) at 80 °C   |  |  |  |   |   |
| <b>Maximum Differential Pressure</b>   |   |  |  |  |   |   |
| Forward                                | 6900 mbar (100 psi) intermittent at 25 °C   |  |  |  |   |   |
|  | 5500 mbar (80 psi) at 25 °C   |  |  |  |   |   |
|  | 1000 mbar (15 psi) at 80 °C   |  |  |  |   |   |
| Reverse                                | 2100 mbar (30 psi) intermittent at 25 °C  |  |  |  |   |   |
| <b>70/30 IPA Bubble Point at 23 °C</b> |   |  |  |  |   |   |
|  | ≥2590 mbar (37.5 psi) with nitrogen   |  |  |  |   |   |
| <b>Air Diffusion at 23 °C</b>          |   |  |  |  |   |   |
|  | Through a water wet membrane at 3.4 bar (50 psi):   |  |  |  |   |   |
|  | ≤9.4 cc/min.  | ≤17.3 cc/min.                              | ≤38.8 cc/min.                              | ≤38.8 cc/min.                              | ≤77.6 cc/min.                               | ≤116.4 cc/min.                              |
| <b>Bacterial Retention</b>             |   |  |  |  |   |   |
|  | Quantitative retention of 10 <sup>7</sup> CFU/cm <sup>2</sup> <i>Brevundimonas diminuta</i> ATCC® 19146 per ASTM® methodology   |  |  |  |   |   |
| <b>Mycoplasma Removal</b>              |   |  |  |  |   |   |
|  | Typical Log Reduction Value (LRV) >7 using <i>A. laidlawii</i> ATCC® 23206 and our validated test method  |  |  |  |   |   |
| <b>Bacterial Endotoxin</b>             |   |  |  |  |   |   |
|  | Aqueous extraction contains <0.25 EU/mL as determined by the Limulus Amebocyte Lysate (LAL) Test.   |  |  |  |   |   |
| <b>TOC/Conductivity at 25 °C</b>       |   |  |  |  |   |   |
|  | Gamma sterilized filter effluent meets the WFI requirements of USP <643> for Total Organic Carbon and USP <645> for Water Conductivity after a WFI flush of:  |  |  |  |   |   |
|  | 3.5 L   | 6.0 L                                      | 11 L                                       | 11 L                                       | 22 L  | 33 L  |
| <b>Oxidizable Substances</b>           |   |  |  |  |   |   |
|  | Meets the USP Oxidizable Substances Test requirements for sterile purified water after a water flush of:  |  |  |  |   |   |
|  | 1.0 L   | 1.0 L                                      | 1.5 L                                      | 1.5 L                                      | 3.0 L                                       | 4.5 L                                       |
| <b>Sterilization</b>                   |   |  |  |  |   |   |
| Gamma-compatible capsules              | Gamma compatible to 45 kGy, may be autoclaved for 3 cycles of 60 minutes at 123 °C (Cannot be steam sterilized in-line)   |  |  |  |   |   |
| Sterile capsules                       | May be autoclaved for 3 cycles of 60 minutes at 123 °C (Cannot be steam sterilized in-line)   |  |  |  |   |   |
| <b>Sterility</b>                       |   |  |  |  |   |   |
| Sterile capsules                       | These capsules meet current USP and AAMI guidelines for sterility utilizing a validated sterilization cycle.  |  |  |  |   |   |
| <b>Cytotoxicity</b>                    |   |  |  |  |   |   |
|  | Non-toxic per MEM elution ISO® 10993-5  |  |  |  |   |   |
| <b>Particle Shedding</b>               |   |  |  |  |   |   |
|  | Effluent meets the acceptance criteria set forth in USP <788> for large volume parenterals.   |  |  |  |   |   |
| <b>Non-fiber Releasing</b>             |   |  |  |  |   |   |
|  | Millipore Express® SHR membranes meet the criteria for a “non-fiber releasing” filter as defined in 21 CFR 210.3(b)(6).   |  |  |  |   |   |
| <b>Component Material Toxicity</b>     |   |  |  |  |   |   |
|  | Component materials were tested and meet the criteria of the USP <88> Reactivity Test for Class VI plastics. Millipore Express® SHR filters meet the requirements of the USP <88> Safety Test, utilizing a 0.9% sodium chloride extraction. |  |  |  |   |   |
| <b>Indirect Food Additive</b>          |   |  |  |  |   |   |
|  | All component materials meet the FDA Indirect Food Additive requirements cited in 21 CFR 177–182.   |  |  |  |   |   |
| <b>Good Manufacturing Practices</b>    |   |  |  |  |   |   |
|  | These products are manufactured in a facility which adheres to FDA Good Manufacturing Practices.  |  |  |  |   |   |

\* Cage, end caps and capsule housing

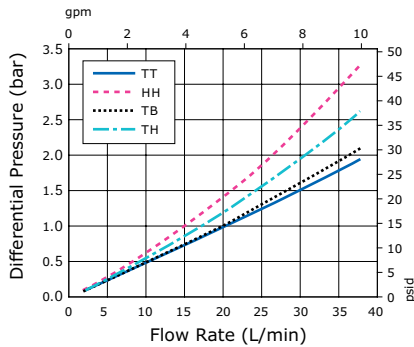
## Typical Clean Water Flow Rates

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

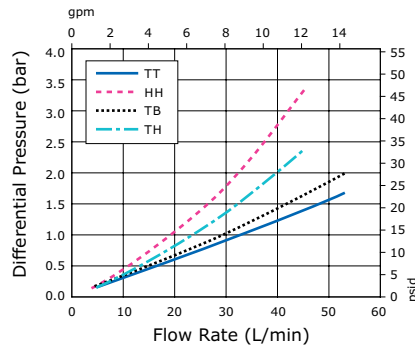
#### Millipore Express® SHR 0.1 µm Membrane

Filters tested post gamma radiation at 25–45 kGy and autoclaved at 123 °C for 60 minutes.

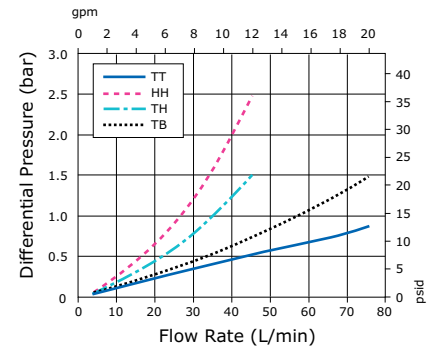
**Gamma Compatible Opticap® XL 3 with 0.1 µm Millipore Express® SHR Membrane**



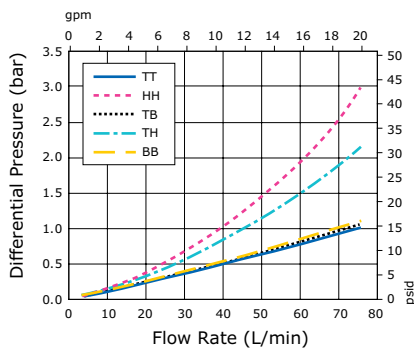
**Gamma Compatible Opticap® XL 5 with 0.1 µm Millipore Express® SHR Membrane**



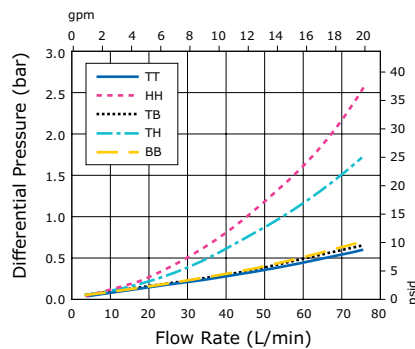
**Gamma Compatible Opticap® XL 10 with 0.1 µm Millipore Express® SHR Membrane**



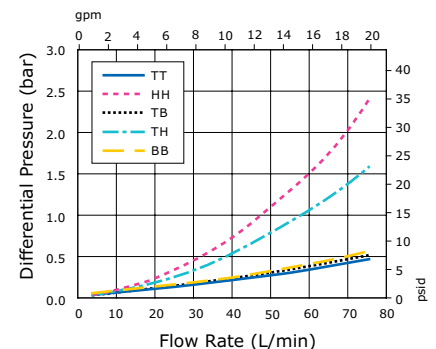
**Gamma Compatible Opticap® XLT 10 with 0.1 µm Millipore Express® SHR Membrane**



**Gamma Compatible Opticap® XLT 20 with 0.1 µm Millipore Express® SHR Membrane**



**Gamma Compatible Opticap® XLT 30 with 0.1 µm Millipore Express® SHR Membrane**



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

- TT = 38 mm (1½ in.) sanitary flange inlet and outlet
- HH = 14 mm (9/16 in.) hose barb inlet and outlet
- TH = 38 mm (1½ in.) sanitary flange inlet and 14 mm (9/16 in.) hose barb outlet
- TB = 38 mm (1½ in.) sanitary flange inlet and 25 mm (1 in.) hose barb outlet

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

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

## Specifications

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

Millipore Express® SHR 0.5/0.1 µm Membrane with Prefilter

|  | Opticap® XL 150 Capsules  | Opticap® XL 300 Capsules                      | Opticap® XL 600 Capsules                      |
|--|---|---|---|
| <b>Nominal Dimensions</b>              |   |   |   |
| Maximum length                         | 9.7 cm (3.8 in.)  | 11.9 cm (4.7 in.)                             | 16.5 cm (6.5 in.)                             |
| Maximum length with bell               | 11.4 cm (4.5 in.)   | 13.7 cm (5.4 in.)                             | 18.3 cm (7.2 in.)                             |
| Body diameter                          | 5.6 cm (2.2 in.)  | 5.6 cm (2.2 in.)                              | 5.6 cm (2.2 in.)                              |
| <b>Filtration Area</b>                 |   |   |   |
|  | 0.015 m <sup>2</sup> (0.163 ft <sup>2</sup> )   | 0.028 m <sup>2</sup> (0.308 ft <sup>2</sup> ) | 0.062 m <sup>2</sup> (0.664 ft <sup>2</sup> ) |
| <b>Materials of Construction</b>       |   |   |   |
| Filter membrane                        | Hydrophilic polyethersulfone  |   |   |
| Supports                               | Polyethylene  |   |   |
| Core                                   | Polysulfone   |   |   |
| Structural components*                 | Gamma stable polypropylene  |   |   |
| Vent O-rings                           | Silicone  |   |   |
| Bell                                   | Polycarbonate   |   |   |
| <b>Vent/Drain</b>                      |   |   |   |
|  | 6 mm (¼ in.) hose barb with double O-ring seal  |   |   |
| <b>Maximum Inlet Pressure</b>          |   |   |   |
|  | 6900 mbar (100 psi) intermittent at 23 °C   |   |   |
|  | 5500 mbar (80 psi) at 23 °C   |   |   |
|  | 2800 mbar (40 psi) at 60 °C   |   |   |
|  | 1000 mbar (15 psi) at 80 °C   |   |   |
| <b>Maximum Differential Pressure</b>   |   |   |   |
| Forward                                | 6900 mbar (100 psi) intermittent at 25 °C   |   |   |
|  | 5500 mbar (80 psi) at 25 °C   |   |   |
|  | 1000 mbar (15 psi) at 80 °C   |   |   |
| Reverse                                | 2100 mbar (30 psi) intermittent at 25 °C  |   |   |
| <b>70/30 IPA Bubble Point at 23 °C</b> |   |   |   |
|  | ≥2590 mbar (37.5 psi) with nitrogen   |   |   |
| <b>Air Diffusion at 23 °C</b>          |   |   |   |
|  | Through a water wet membrane at 3.4 bar (50 psi):   |   |   |
|  | ≤1.0 cc/min.  | ≤1.9 cc/min.                                  | ≤3.7 cc/min.                                  |
| <b>Bacterial Retention</b>             |   |   |   |
|  | Quantitative retention of 10 <sup>7</sup> CFU/cm <sup>2</sup> <i>Brevundimonas diminuta</i> ATCC® 19146 per ASTM® methodology   |   |   |
| <b>Mycoplasma Removal</b>              |   |   |   |
|  | Typical Log Reduction Value (LRV) >7 using <i>A. laidlawii</i> ATCC® 23206 and our validated test method  |   |   |
| <b>Bacterial Endotoxin</b>             |   |   |   |
|  | Aqueous extraction contains <0.25 EU/mL as determined by the Limulus Amebocyte Lysate (LAL) Test.   |   |   |
| <b>TOC/Conductivity at 25 °C</b>       |   |   |   |
|  | Gamma sterilized filter effluent meets the WFI requirements of USP <643> for Total Organic Carbon and USP <645> for Water Conductivity after a WFI flush of:  |   |   |
|  | 1 L   | 2 L   | 3 L   |
| <b>Oxidizable Substances</b>           |   |   |   |
|  | Meets the USP Oxidizable Substances Test requirements for sterile purified water after a WFI flush of 1 L.  |   |   |
| <b>Sterilization</b>                   |   |   |   |
| Gamma-compatible capsules              | Gamma compatible to 45 kGy, may be autoclaved for 3 cycles of 60 minutes at 123 °C (Cannot be steam sterilized in-line)   |   |   |
| Sterile capsules                       | May be autoclaved for 3 cycles of 60 minutes at 123 °C (Cannot be steam sterilized in-line)   |   |   |
| <b>Sterility</b>                       |   |   |   |
| Sterile capsules                       | These capsules meet current USP and AAMI guidelines for sterility utilizing a validated sterilization cycle.  |   |   |
| <b>Cytotoxicity</b>                    |   |   |   |
|  | Non-toxic per MEM elution ISO® 10993-5  |   |   |
| <b>Particle Shedding</b>               |   |   |   |
|  | Effluent meets the acceptance criteria set forth in USP <788> for large volume parenterals.   |   |   |
| <b>Non-fiber Releasing</b>             |   |   |   |
|  | Millipore Express® SHR membranes meet the criteria for a “non-fiber releasing” filter as defined in 21 CFR 210.3(b)(6).   |   |   |
| <b>Component Material Toxicity</b>     |   |   |   |
|  | Component materials were tested and meet the criteria of the USP <88> Reactivity Test for Class VI plastics. Millipore Express® SHR filters meet the requirements of the USP <88> Safety Test, utilizing a 0.9% sodium chloride extraction. |   |   |
| <b>Indirect Food Additive</b>          |   |   |   |
|  | All component materials meet the FDA Indirect Food Additive requirements cited in 21 CFR 177-182.   |   |   |
| <b>Good Manufacturing Practices</b>    |   |   |   |
|  | These products are manufactured in a facility which adheres to FDA Good Manufacturing Practices.  |   |   |

\* Cage, end caps and capsule housing

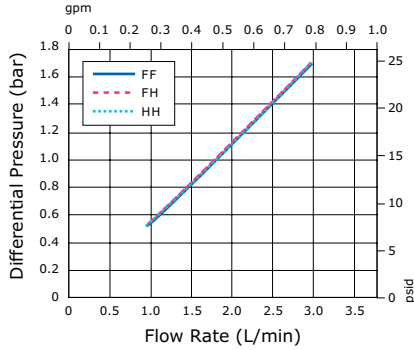
## Typical Clean Water Flow Rates

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

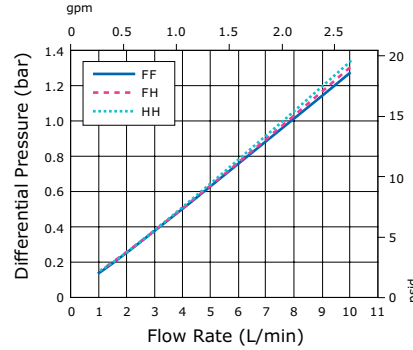
Millipore Express® SHR 0.5/0.1 µm Membrane with Prefilter

Filters tested post gamma radiation at 45–65 kGy and autoclaved at 123 °C for 60 minutes.

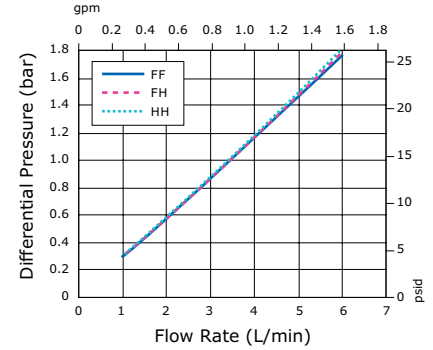
**Gamma Compatible Opticap® XL 150 with 0.5/0.1 µm Millipore Express® SHR Membrane with prefilter**



**Gamma Compatible Opticap® XL 300 with 0.5/0.1 µm Millipore Express® SHR Membrane with prefilter**



**Gamma Compatible Opticap® XL 600 with 0.5/0.1 µm Millipore Express® SHR Membrane with prefilter**



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

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

FH = 19 mm (¾ in.) sanitary flange inlet and 14 mm (⅜ in.) hose barb outlet

HH = 14 mm (⅜ in.) hose barb inlet and outlet



## Specifications

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

Millipore Express® SHR 0.5/0.1 µm Membrane with Prefilter

|  | Opticap® XL<br>3 Capsules  | Opticap® XL<br>5 Capsules                  | Opticap® XL<br>10 Capsules                 | Per Standard Area<br>Opticap® XLT<br>10 Capsules | Per High Area<br>Opticap® XLT<br>10 Capsules** |
|--|--|--|--|--|--|
| <b>Nominal Dimensions</b>              |  |  |  |  |  |
| Maximum length                         | 17.3 cm (6.8 in.)  | 21.6 cm (8.5 in.)                          | 33.5 cm (13.2 in.)                         | 38.1 cm (15.0 in.)                               | 38.1 cm (15.0 in.)                             |
| Body diameter                          | 10.7 cm (4.2 in.)  | 10.7 cm (4.2 in.)                          | 10.7 cm (4.2 in.)                          | 10.7 cm (4.2 in.)                                | 10.7 cm (4.2 in.)                              |
| <b>Fitting to Fitting</b>              |  |  |  |  |  |
| Sanitary flange to sanitary flange     | —  |  |  | 15.2 cm (6.0 in.)                                |  |
| Sanitary flange to hose barb           | —  |  |  | 17.5 cm (6.9 in.)                                |  |
| Hose barb to hose barb                 | —  |  |  | 19.8 cm (7.8 in.)                                |  |
| <b>Filtration Area</b>                 | 0.13 m <sup>2</sup> (1.4 ft <sup>2</sup> )   | 0.24 m <sup>2</sup> (2.6 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> )       | 1.0 m <sup>2</sup> (10.8 ft <sup>2</sup> )     |
| <b>Materials of Construction</b>       |  |  |  |  |  |
| Filter membrane                        | Hydrophilic polyethersulfone   |  |  |  | Hydrophilic polyethersulfone                   |
| Film edge                              | Polypropylene  |  |  |  | Polypropylene                                  |
| Supports                               | Polypropylene  |  |  |  | Polypropylene                                  |
| Core                                   | Polysulfone  |  |  |  | Polyethersulfone                               |
| Structural components*                 | Polypropylene  |  |  |  | Polypropylene                                  |
| Vent O-rings                           | Silicone   |  |  |  | Silicone                                       |
| <b>Vent/Drain</b>                      | 6 mm (¼ in.) hose barb with double O-ring seal   |  |  |  |  |
| <b>Maximum Inlet Pressure</b>          | 6900 mbar (100 psi) intermittent at 23 °C<br>5500 mbar (80 psi) at 23 °C<br>2800 mbar (40 psi) at 60 °C<br>1000 mbar (15 psi) at 80 °C   |  |  |  |  |
| <b>Maximum Differential Pressure</b>   |  |  |  |  |  |
| 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   |  |  |  |  |
| <b>70/30 IPA Bubble Point at 23 °C</b> | ≥2590 mbar (37.5 psi) with nitrogen  |  |  |  |  |
| <b>Air Diffusion at 23 °C</b>          | Through a water wet membrane at 3.4 bar (50 psi):<br>≤7.3 cc/min.      ≤13.6 cc/min.      ≤30.4 cc/min.      ≤30.4 cc/min.      ≤54.2 cc/min.  |  |  |  |  |
| <b>Bacterial Retention</b>             | Quantitative retention of 10 <sup>7</sup> CFU/cm <sup>2</sup> <i>Brevundimonas diminuta</i> ATCC® 19146 per ASTM® methodology  |  |  |  |  |
| <b>Mycoplasma Removal</b>              | Typical Log Reduction Value (LRV) >7 using <i>A. laidlawii</i> ATCC® 23206 and our validated test method   |  |  |  |  |
| <b>Bacterial Endotoxin</b>             | Aqueous extraction contains <0.25 EU/mL as determined by the Limulus Amebocyte Lysate (LAL) Test.  |  |  |  |  |
| <b>TOC/Conductivity at 25 °C</b>       | Gamma sterilized filter effluent meets the WFI requirements of USP <643> for Total Organic Carbon and USP <645> for Water Conductivity after a WFI flush of:<br>5.5 L                      9.5 L                      21 L                      21 L                      21 L |  |  |  |  |
| <b>Oxidizable Substances</b>           | Meets the USP Oxidizable Substances Test requirements for sterile purified water after a water flush of 2 L.   |  |  |  |  |
| <b>Sterilization</b>                   |  |  |  |  |  |
| Gamma-compatible capsules              | Gamma compatible to 45 kGy, may be autoclaved for 3 cycles of 60 minutes at 123 °C (Cannot be steam sterilized in-line)  |  |  |  |  |
| Sterile capsules                       | May be autoclaved for 3 cycles of 60 minutes at 123 °C (Cannot be steam sterilized in-line)  |  |  |  |  |
| <b>Sterility</b>                       |  |  |  |  |  |
| Sterile capsules                       | These capsules meet current USP and AAMI guidelines for sterility utilizing a validated sterilization cycle.   |  |  |  |  |
| <b>Cytotoxicity</b>                    | Non-toxic per MEM elution ISO® 10993-5   |  |  |  |  |
| <b>Particle Shedding</b>               | Effluent meets the acceptance criteria set forth in USP <788> for large volume parenterals.  |  |  |  |  |
| <b>Non-fiber Releasing</b>             | Millipore Express® SHR membranes meet the criteria for a “non-fiber releasing” filter as defined in 21 CFR 210.3(b)(6).  |  |  |  |  |
| <b>Component Material Toxicity</b>     | Component materials were tested and meet the criteria of the USP <88> Reactivity Test for Class VI plastics. Millipore Express® SHR filters meet the requirements of the USP <88> Safety Test, utilizing a 0.9% sodium chloride extraction.                                    |  |  |  |  |
| <b>Indirect Food Additive</b>          | All component materials meet the FDA Indirect Food Additive requirements cited in 21 CFR 177–182.  |  |  |  |  |
| <b>Good Manufacturing Practices</b>    | These products are manufactured in a facility which adheres to FDA Good Manufacturing Practices.   |  |  |  |  |

\* Cage, end caps and capsule housing

\*\*Only available in gamma-compatible formats

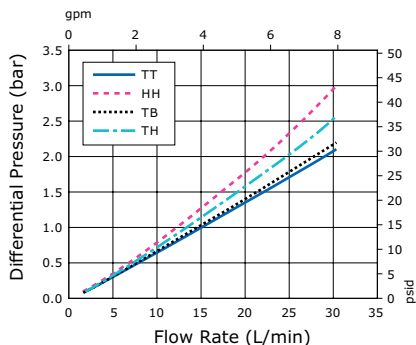
## Typical Clean Water Flow Rates

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

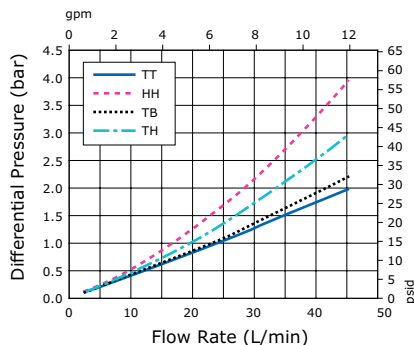
Millipore Express® SHR 0.5/0.1 µm Membrane with Prefilter

Filters tested post gamma radiation at 25–45 kGy and autoclaved at 123 °C for 60 minutes.

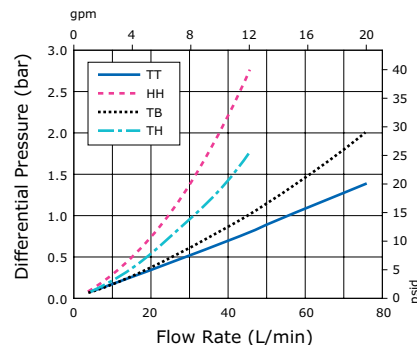
**Gamma Compatible Opticap® XL 3**  
with 0.5/0.1 µm Millipore Express® SHR  
Membrane with prefilter



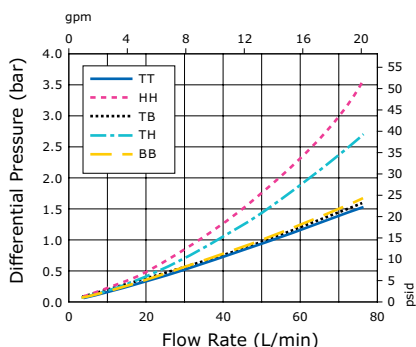
**Gamma Compatible Opticap® XL 5**  
with 0.5/0.1 µm Millipore Express® SHR  
Membrane with prefilter



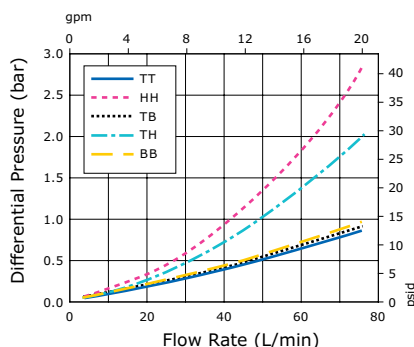
**Gamma Compatible Opticap® XL 10**  
with 0.5/0.1 µm Millipore Express® SHR  
Membrane with prefilter



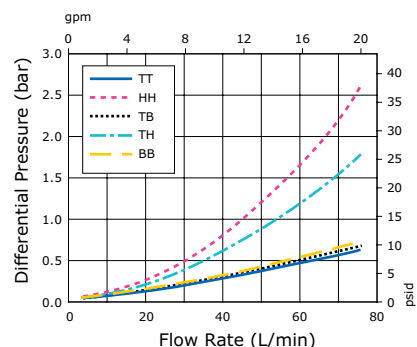
**Gamma Compatible Standard Area**  
**Opticap® XLT 10** with 0.5/0.1 µm Millipore  
Express® SHR Membrane with prefilter



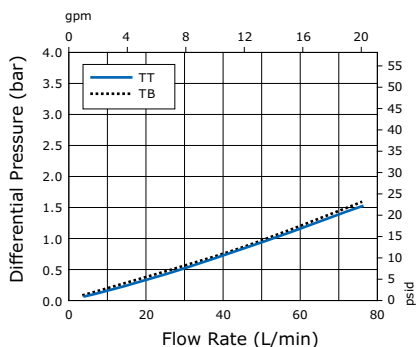
**Gamma Compatible Standard Area**  
**Opticap® XLT 20** with 0.5/0.1 µm Millipore  
Express® SHR Membrane with prefilter



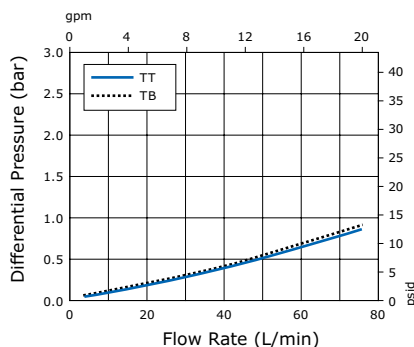
**Gamma Compatible Standard Area**  
**Opticap® XLT 30** with 0.5/0.1 µm Millipore  
Express® SHR Membrane with prefilter



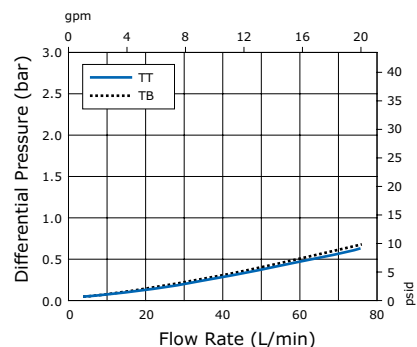
**Gamma Compatible High Area**  
**Opticap® XLT 10** with 0.5/0.1 µm Millipore  
Express® SHR Membrane with prefilter



**Gamma Compatible High Area**  
**Opticap® XLT 20** with 0.5/0.1 µm Millipore  
Express® SHR Membrane with prefilter



**Gamma Compatible High Area**  
**Opticap® XLT 30** with 0.5/0.1 µm Millipore  
Express® SHR Membrane with prefilter



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

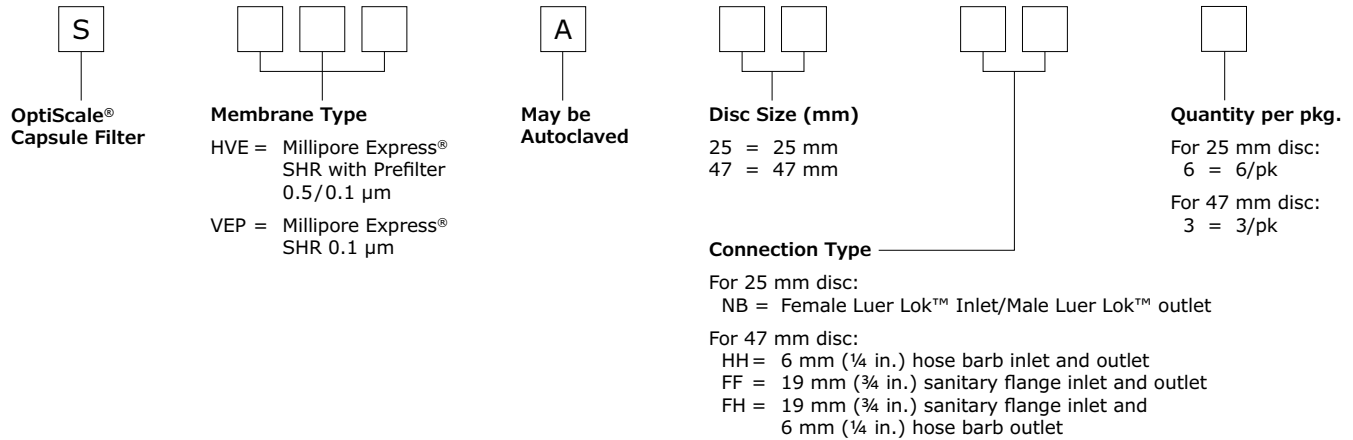
- TT = 38 mm (1½ in.) sanitary flange inlet and outlet
- HH = 14 mm (9/16 in.) hose barb inlet and outlet
- TH = 38 mm (1½ in.) sanitary flange inlet and 14 mm (9/16 in.) hose barb outlet
- TB = 38 mm (1½ in.) sanitary flange inlet and 25 mm (1 in.) hose barb outlet

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

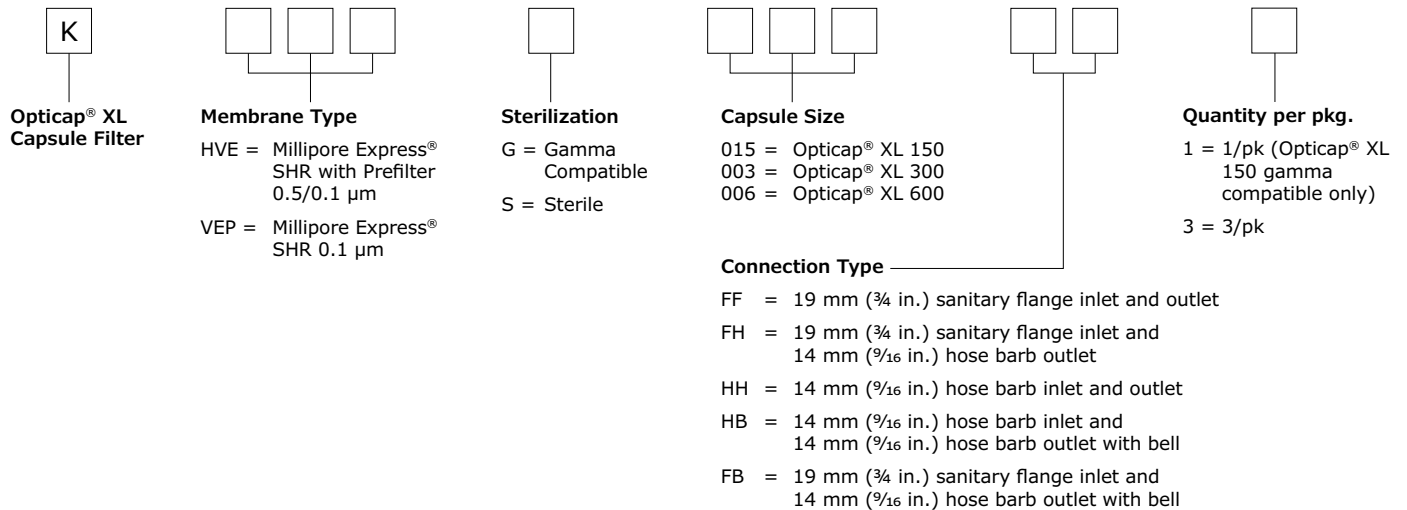
- TT = 38 mm (1½ in.) sanitary flange inlet and outlet
- TH = 38 mm (1½ in.) sanitary flange Inlet and 16 mm (5/8 in.) hose barb outlet
- HH = 16 mm (5/8 in.) hose barb inlet and outlet
- TB = 38 mm (1½ in.) sanitary flange inlet and 25 mm (1 in.) hose barb outlet
- BB = 25 mm (1 in.) hose barb inlet and outlet

## Ordering Information

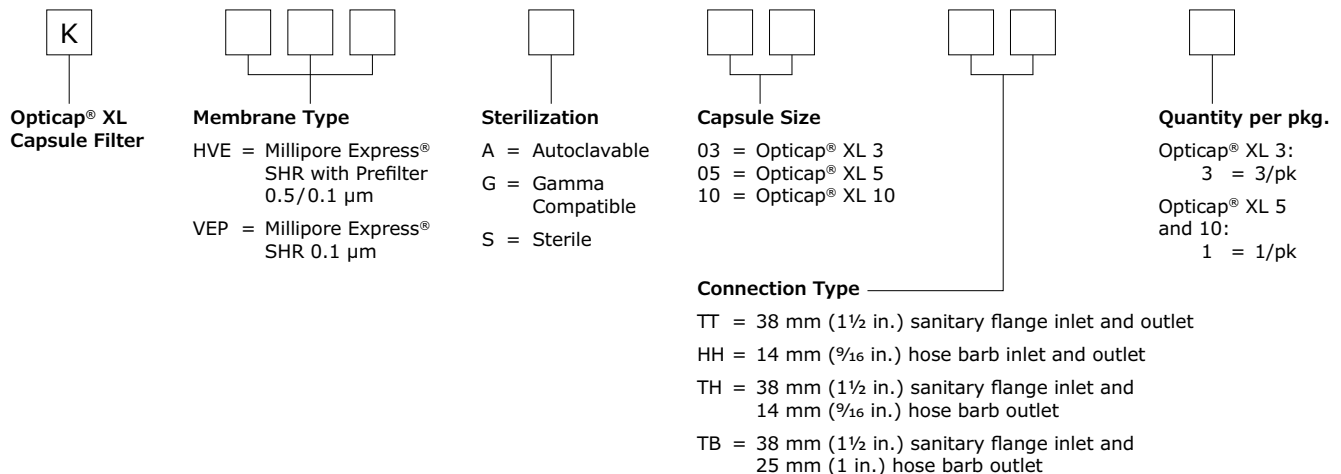
### OptiScale® Capsule Filters



### Opticap® XL 150/300/600 Capsule Filters



### Opticap® XL Capsule Filters



## Ordering Information

### Opticap® XLT Capsule Filters

|  |  |   |   |  |   |
|--|--|---|---|--|---|
| <p><b>K</b></p> <p><b>Opticap® XL Capsule Filter</b></p> | <p><b>Membrane Type</b></p> <p>HVE = Millipore Express® SHR with Prefilter 0.5/0.1 µm</p> <p>VEP = Millipore Express® SHR 0.1 µm</p> | <p><b>Capsule Size</b></p> <p>1 = Opticap® XLT 10<br/>2 = Opticap® XLT 20<br/>3 = Opticap® XLT 30</p> | <p><b>T</b></p> <p><b>T-line Capsule without Gauge Port</b></p>   | <p><b>1</b></p> <p><b>Quantity per pkg.</b></p> <p>1 = 1/pkg</p> | <p><b>Area Type</b></p> <p>H = High Area (10-, 20-, and 30-inch gamma compatible capsules with connections 'TT' and 'TB' only)</p> <p>Leave blank for Standard Area</p> |
|  |  | <p><b>Sterilization</b></p> <p>A = Autoclavable<br/>G = Gamma Compatible<br/>S = Sterile</p>          | <p><b>Connection Type</b></p> <p>TT = 38 mm (1½ in.) sanitary flange inlet and outlet<br/>HH = 16 mm (5/8 in.) hose barb inlet and outlet<br/>TH = 38 mm (1½ in.) sanitary flange inlet and 16 mm (5/8 in.) hose barb outlet<br/>TB = 38 mm (1½ in.) sanitary flange inlet and 25 mm (1 in.) hose barb outlet<br/>BB = 25 mm (1 in.) hose barb inlet and outlet</p> |  |   |

| Description                                | Qty/pk | Cat. No.  |
|--|--------|-----------|
| Standard Opticap® XLT Capsule Filter Stand | 1      | XLTSTAND1 |

### Cartridge Filters

|  |  |  |  |  |
|--|--|--|--|--|
| <p><b>C</b></p> <p><b>Cartridge Filter</b></p> | <p><b>Membrane Type</b></p> <p>HVE = Millipore Express® SHR with Prefilter 0.5/0.1 µm</p> <p>VEP = Millipore Express® SHR 0.1 µm</p> | <p><b>Cartridge Length</b></p> <p>5 = 5-inch (Code 7 only)<br/>1 = 10-inch<br/>2 = 20-inch<br/>3 = 30-inch</p> | <p><b>Area Type</b></p> <p>T = Standard Area<br/>H = High Area (10-, 20-, and 30-inch cartridges with Millipore Express® SHR w/Prefilter 0.5/0.1 µm membrane only)</p> | <p><b>Quantity per pkg.</b></p> <p>1 = 1/pkg (10-inch Code 7 only)<br/>3 = 3/pkg</p> |
|  |  | <p><b>Cartridge Code</b></p> <p>0 = (2-222) O-ring<br/>7 = (2-226) O-ring w/locking tab spear</p>              | <p><b>O-ring Material</b></p> <p>S = Silicone<br/>E = EPDM<br/>F = Fluoroelastomer</p>   |  |

\* Not all product configurations are guaranteed to be available; please contact your EMD Millipore representative to confirm availability.

The user guides for these product – 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.

### To place an order or receive technical assistance

In the U.S. and Canada, call toll-free  
1-800-645-5476

For other countries across Europe  
and the world, please visit:  
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