Data Sheet

# Gamma Stable Opticap® XL Capsule Filters with Millipore Express® SPG Hydrophobic Membrane

## Gamma stable sterilizing-grade gas filters with superior flow rates for single-use applications

Gamma Stable Opticap® XL Capsule Filters with Millipore Express® SPG (Sterile Phobic Gamma) hydrophobic membrane are the ultimate choice for optimal gas filtration and venting in single-use applications. The 0.2 µm sterilizing-grade membrane provides sterility assurance and high flow rates. Its ability to maintain flow rates during extended batch durations contributes to higher process confidence.


## Typical Applications

Gamma Stable Opticap® XL Capsule Filters with Millipore Express® SPG Hydrophobic membrane are validated for retention using a liquid bacterial challenge test ensuring retention even in humid process conditions. These filters will sterilize air or gas streams in:

- Single-use bioreactors
- Filtration and bag assemblies
- Carboys
- Filling vessels
- Transfer vessels
- Fill-finish applications
- Holding/storage bags
- Mixer bags
- Bottle assemblies

## Filter Formats

Gamma stable Opticap® XL capsule filters are available in two sizes:

- Opticap® XL 50 Capsules, EFA: 19.6 $cm^2$
- Opticap® XL 300 Capsules, EFA: 480 $cm^2$

## Features

The polyethersulfone membrane based gas filter:

- Can be sterilized by gamma irradiation or autoclaving
- Can be integrity tested using HydroCorr™ Water Flow Integrity Test
- Is validated for liquid bacterial retention
- Maintains superior flow rate over extended process duration

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## Superior Performance, higher process confidence

Gamma stable Opticap® XL Capsule Filters with Millipore Express® SPG Hydrophobic Membrane are sterilizing-grade devices. The hydrophobic membrane inherently resists wetting—providing superior flow rate over extended operating durations. This makes it ideal for single-use applications such as high density cell culture processes using small scale bioreactors, bag assemblies, carboys, and mixers (Figure 1).

Gamma stable Opticap® XL Capsule Filters with Millipore Express® SPG membrane exhibits superior flow rate (up to 3x) when compared to PVDF membrane based vent filters under typical operating conditions. See Figure 3.

These filters are ideal for use in single-use redundant filtration assemblies and standard assemblies with filters, where integrity testing and air blow down of the liquid filter can be performed without breaching sterility (Figure 2). In addition, these devices provide sterilization flexibility and can be sterilized using either gamma irradiation or autoclaving. These devices are qualified for gamma sterilization (up to 45 kGy) and/or 3 autoclave cycles. See the Specification table on the last page for more details.

Figure 1.

Opticap® XL 50 Capsules with Millipore Express® SPG Hydrophobic Membrane installed on a Mobius® CellReady 3L Bioreactor.

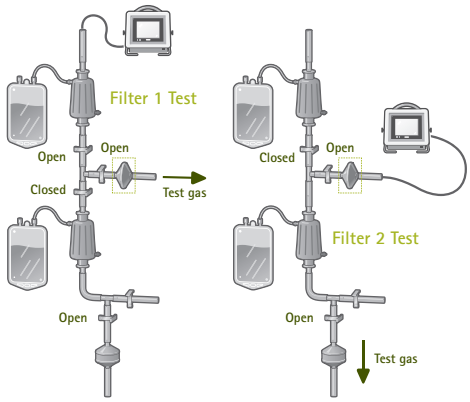


Figure 2.

Single-use redundant filtration assembly with gamma stable Opticap® XL 50 Capsule Filter. Opticap® XL 50 Capsule Filter can be used as shown (in green box above) while integrity testing and drying the assemblies to maintain a sterile barrier.

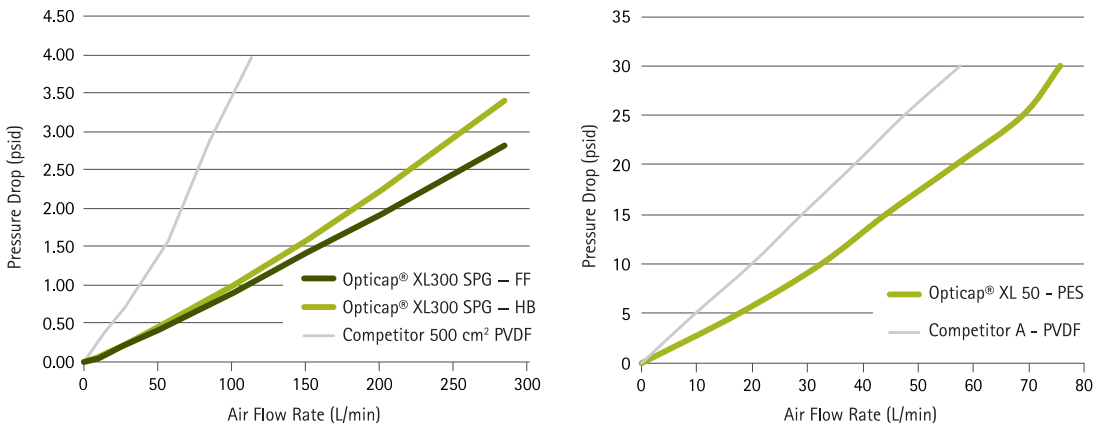


Figure 3.

Typical Air Flow Rates. Gamma Stable Opticap® XL Capsule Filters with Millipore Express® SPG Hydrophobic membrane offer superior performance.

## Regulatory Compliance

Gamma Stable Opticap® XL Capsule Filters with Millipore Express® SPG membrane are designed, developed and manufactured in accordance with a Quality Management System approved by an accredited registering body to ISO® 9001 and ISO® 14001 Quality Systems Standard. Every Gamma Stable Opticap® XL Capsule Filter with Millipore Express® SPG Hydrophobic Membrane is integrity tested during manufacturing to guarantee sterility assurance and is supported with a comprehensive Validation Guide for compliance with regulatory requirements.

A Certificate of Quality, available for each filter lot, certifies that Gamma Stable Opticap® XL Capsule Filters with Millipore Express® SPG Hydrophobic Membrane meet quality assurance lot release criteria. The bubble point of the membrane is correlated to bacterial retention using the ASTM® F838-05 challenge methodology. Each capsule filter is labeled with its catalogue number, lot number, serial number, and indicator for direction of flow.

Opticap® XL capsule filters with Millipore Express® membranes are part of the Mobius® integrated disposable bioprocess solution. No matter what your application step or scale, 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 capsule filters and connectors, to validated, gamma compatible turnkey assemblies, Mobius® solutions provide faster turnaround time and reliable performance right out of the box.

## Integritest® Manifold: for Parallel Integrity Testing

As a complement to the Opticap® XL 50 capsule filters, we also offer the Integritest® Manifold that can be used with up to 10 filters to perform fast, reliable integrity testing in parallel (Figure 4). This manifold can be used with Opticap® XL 50 and Aervent® 50 capsule filters to improve your efficiency when performing integrity tests such as the HydroCorr™ Water Flow Integrity Test (resistance to water intrusion) and/or bubble point using an automated integrity tester.

The Integritest® Manifold is designed to offer a high degree of integrity test robustness while improving your testing efficiency. This manifold provides flexibility while maintaining ease-of-use with the following features:

- Easy connectivity (TC compatibility and Luer adaptors)
- Hydrocorr™ test friendly; easy to drain, fast setup
- Easy air blow down of filters
- Leak free; easy to clean and sterilize
- Stainless steel welded construction; compatible with IPA
- Vertical design with minimal footprint and no moving parts

**Figure 4.**
Integritest® Manifold.

## Specifications

| | Gamma Stable Opticap® XL 50 Capsule Filters with Millipore Express® SPG Hydrophobic membrane | Gamma Stable Opticap® XL 300 Capsule Filters with Millipore Express® SPG Hydrophobic membrane |
|---|---|---|
| Filtration Area, $m^2$ | 0.00196 (19.6 $cm^2$) | 0.048 (480 $cm^2$) |
| **Materials of Construction** | | |
| Filter Structural Components | Gamma Stable Polypropylene<br>Hydrophobic Polyethersulfone Gamma Stable Polybutylene terephthalate based blend | |
| Inlet/Outlet | Stepped Hosebarb Inlet and Outlet for silicone flexible tubing with 6.5 to 9.5 mm internal diameter; female Luer slip interior | HH: Stepped Hosebarb (9/16")<br>FF: Sanitary Flange (3/4") |
| Maximum Pressure, bar (psid) | Forward: 4.2 bar (60 psid) @ 25 °C; Reverse: 2.1 bar (30 psid) @ 25 °C, intermittent | |
| Hydrocorr™ Test* | ≤0.03 mL/min @ 38 psi | ≤0.16 mL/min @ 38 psi |
| Bacterial Retention | Quantitative retention of $10^7$ CFU/$cm^2$ *Brevundimonas diminuta* (ATCC® 19146) per ASTM® F838-05 (2005) methodology | |
| Bacterial Endotoxin | Aqueous extraction contains ≤0.25 EU/mL as determined by the Limulus Amebocyte Lysate (LAL) Test. | |
| Gamma/Autoclave Stability | Gamma compatible to 45 kGy; OR up to 3 autoclave cycles of 60 min @ 126 °C; not in-line steam sterilizable | Gamma compatible to 45 kGy; and up to 3 autoclave cycles of 60 min @ 123 °C; not in-line steam sterilizable |
| Component Material Toxicity | Component materials meet the criteria of the USP <88> Reactivity Test for Class VI Plastics. | |
| USP Toxicity | Non-toxic per MEM elution ISO® 10993-5 | |
| Good Manufacturing Practices | These products are manufactured in a facility, which adheres to FDA Good Manufacturing Practices. | |
| Non-Fiber Releasing | Component materials meet the "non-fiber releasing" criteria as defined in 21 CFR 210.3 (b) (6). | |

*If you would like to integrity test these filters using alcohol, please contact your EMD Millipore representative for more information.

## Ordering Information

| Description | Qty/Pk | Catalogue No. |
|---|---|---|
| Gamma stable Opticap® XL 50 Capsule Filters with Millipore Express® SPG Hydrophobic membrane. Inlet and outlet: stepped hose barb with female Luer slip interior | 100 | KEGBG050HH00 |
| | 10 | KEGBG050HH10 |
| Gamma stable Opticap® XL 300 Capsule Filters with Millipore Express® SPG 0.2µm membrane, 3pk w/ 9/16" hose barb | 3 | KEGBG003HH3 |
| Gamma stable Opticap® XL 300 Capsule Filters with Millipore Express® SPG 0.2µm membrane, 3pk w/ 3/4" sanitary flange | 3 | KEGBG003FF3 |
| Integritest® Manifold: for Parallel Integrity Testing | 1 | P93795 |


## 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 www.emdmillipore.com/offices

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