Millipore®
Expert Pharm/BioPharm
Products & CTDMO Services

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
- Final-filling applications
- Holding/storage bags
- Mixer bags
- Bottle assemblies

Filter Formats

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

- Opticap® XL 50 Capsules, EFA: 19.6 cm^2
- Opticap® XL 300 Capsules, EFA: 480 cm^2
- Opticap® XL 5 Capsules, EFA: 0.39 m^2
- Opticap® XL 10 Capsules, EFA: 0.87 m^2

Features

The polyethersulfone (PES) 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 PES membrane inherently resists wetting and provides superior air flow 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 exhibit superior flow rate under typical operating conditions. See **Figure 2**.

These filters are ideal for venting applications 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 3**). In addition, these devices offer flexibility and and are qualified for sterilization using either gamma irradiation or autoclaving.

Figure 1.

Opticap® XL 50 capsules with Millipore Express® SPG hydrophobic membrane installed on a Mobius® 3 L single-use bioreactor.

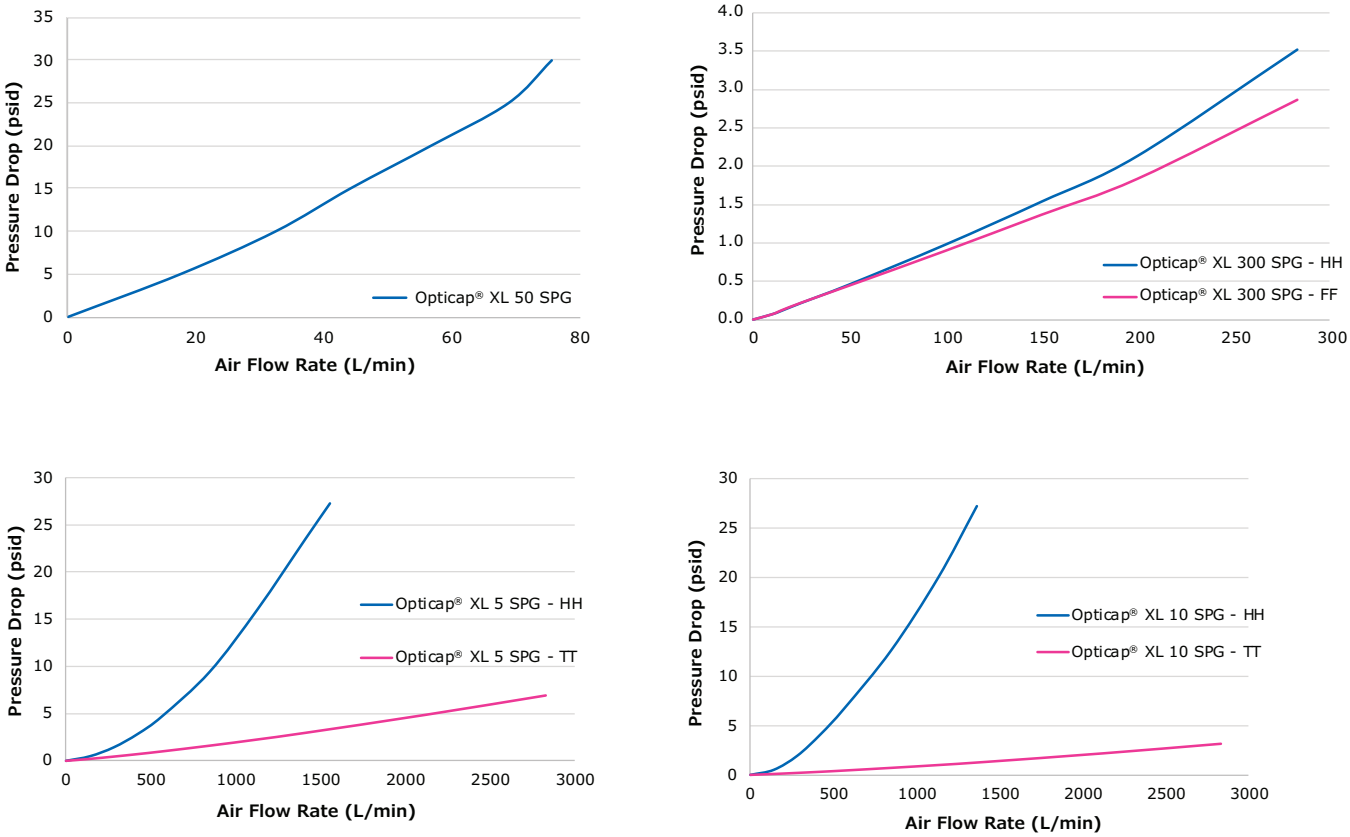


Figure 2.

Typical Air Flow Rates. Gamma Stable Opticap® XL capsule filters with Millipore Express® SPG (SPG) hydrophobic membrane offer superior performance.

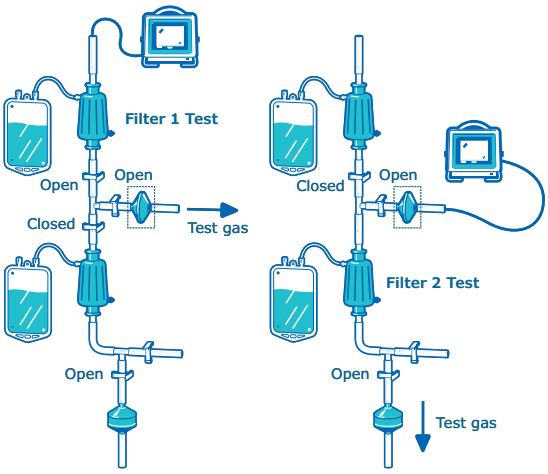


Figure 3.

Single-use redundant filtration assembly with Opticap® XL 50 capsules containing Millipore Express® SPG membrane which maintains the sterile barrier during filter integrity testing.

Opticap® XL capsule filters with Millipore Express® membranes are part of the Mobius® component library. 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

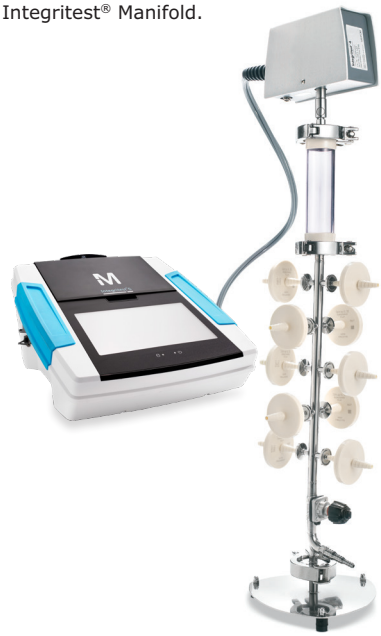
As a complement to the Opticap® XL 50 capsule filters, we also offer the Integritest® Manifold that can be used with up to 10 filters to perform fast, reliable integrity testing in parallel (**Figure 4**). This manifold can be used with Opticap® XL 50 capsule filters to improve your efficiency when performing 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 isopropyl alcohol
- Vertical design with minimal footprint and no moving parts

Figure 4.

Integritest® Manifold.



Specifications

Description	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 Membrane	Hydrophobic Polyethersulfone (PES)	Hydrophobic Polyethersulfone (PES)
Filter Structural Components	Gamma Stable Polybutylene terephthalate based blend	Gamma Stable Polypropylene Polyethylene Support Material Polysulfone Core
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") FF: Sanitary Flange (¾")
Maximum Pressure, bar (psid)	Forward: 4.2 bar (60 psid) at 4-40 °C; Reverse: 2.1 bar (30 psid) at 4-40 °C, intermittent	
HydroCORR™ test*	≤ 0.03 cc/min at 38 psi	≤ 0.16 cc/min at 38 psi
Bacterial Retention	Quantitative retention of 10^7 CFU/cm^2 *Brevundimonas diminuta* (ATCC® 19146) per ASTM F838-05 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; and up to 3 autoclave cycles of 60 min at 126 °C; not in-line steam sterilizable	Gamma compatible up to 45 kGy; and up to 3 autoclave cycles of 60 min at 123 °C; not in-line steam sterilizable
Toxicity	Component materials meet the criteria for USP <88> Biological Reactivity tests, Class VI and USP <87>, Biological Reactivity *in vitro*.	
Quality Management System	These products are manufactured in a facility which is certified to ISO 9001:2015 Quality Management Systems.	
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 local representative for more information.

Specifications

Description	Gamma Stable Opticap® XL 5 Capsule Filters with Millipore Express® SPG Hydrophobic Membrane	Gamma Stable Opticap® XL 10 Capsule Filters with Millipore Express® SPG Hydrophobic Membrane
Filtration Area, m^2	0.39 (3900 cm^2)	0.87 (8700 cm^2)
Materials of Construction		
Filter Membrane	Hydrophobic Polyethersulfone (PES)	
Filter Structural Components	Gamma Stable Polypropylene Gamma Stable Polyester Polysulfone Core	
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") TT: Sanitary Flange (1½")
Maximum Pressure, bar (psid)	Forward: 4.2 bar (60 psid) at 4-50 °C, 1.0 bar (15 psid) at 80 °C; Reverse: 2.1 bar (30 psid) at 4-50 °C,	
Intermittent HydroCORR™ test*	≤0.36 cc/min at 38 psi	≤0.75 cc/min at 38 psi
Bacterial Retention	Quantitative retention of 10^7 CFU/cm^2 *Brevundimonas diminuta* (ATCC® 19146) per ASTM F838-05 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 40 kGy; and up to 1 autoclave cycle of 60 min at 123 °C; not in-line steam sterilizable	
Toxicity	Component materials meet the criteria for Biological Reactivity Testing. These tests can be any one or a combination of the following test methods: USP <88> Class VI (*in vivo*), USP <87> (*in vitro*), ISO 10993-5 Cytotoxicty MEM Elution Test. This product also meets physiochemical specifications, as described in USP <661> Containers-Plastics.	
Quality Management System	These products are manufactured in a facility which is certified to ISO 9001:2015 Quality Management Systems.	
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 local representative for more information.

Ordering Information

Description	Qty/Pk	Cat. No.
Gamma stable Opticap® XL 50 capsule filters with Millipore Express® SPG 0.2 µm 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 0.2 µm hydrophobic membrane, 3 pk w/ 9/16" hose barb	3	**KEGBG003HH3**
Gamma stable Opticap® XL 300 capsule filters with Millipore Express® SPG 0.2 µm hydrophobic membrane, 3 pk w/ ¾" sanitary flange	3	**KEGBG003FF3**
Gamma stable Opticap® XL 5 Capsule Filters with Millipore Express® SPG 0.2 µm hydrophobic membrane, 1 pk w/ 1½" sanitary flange	1	**KEGBG05TT1**
Gamma stable Opticap® XL 5 Capsule Filters with Millipore Express® SPG 0.2 µm hydrophobic membrane, 1 pk w/ 9/16" hose barb	1	**KEGBG05HH1**
Gamma stable Opticap® XL 10 Capsule Filters with Millipore Express® SPG 0.2 µm hydrophobic membrane, 1 pk w/ 1½" sanitary flange	1	**KEGBG10TT1**
Gamma stable Opticap® XL 10 Capsule Filters with Millipore Express® SPG 0.2 µm hydrophobic membrane, 1 pk w/ 9/16" hose barb	1	**KEGBG10HH1**
Integritest® Manifold: for Parallel Integrity Testing	1	**P93795**

User instruction for Millipore Express® SPG membrane in Opticap® XL5 and XL10 capsules

Handling Instructions

Unpacking and Inspection

- Carefully remove the Millipore Express® SPG filters from their packaging.
- Inspect the filter for any visible damage or defects. Do not use if any damage is found.

Installation

- Connect the vent filter to the appropriate system using compatible fittings.
- Ensure all connections are secure to prevent leaks.

Temperature

For optimum performance, use in conjunction with heater jacket to maintain vent filter temperature above the bioreactor set point temperature to avoid condensation.

Pre-Use Integrity Testing

Perform an integrity test according to your standard operating procedures to ensure the filter is functioning correctly.

Sterilization

- To sterilize, the vent filter can be either: Gamma irradiated (up to 40 kGy); or autoclaved for 1 cycle at 123 °C; or gamma irradiated (up to 40 kGy) followed by 1 autoclave cycle at 123 °C.
- Follow the manufacturer's guidelines for sterilization to avoid damaging the filter.

Autoclaving

Sealed devices in autoclave pouches or protect inlet and outlet fittings with sterilization wrap. Capsule inlet and outlets must be unobstructed to allow maximum air displacement and steam flow, but opening should be protected to prevent contamination ingress after sterilization. Failure to select the appropriate pouches or wraps can result in devices damage or ineffective sterilization.

WARNING!

The capsule vents should not be supporting the weight of the capsule during the autoclave cycle.

Post-Use Handling

- After use, perform a post-use integrity test to confirm the filter's performance.
- Dispose of the filter according to your facility's waste disposal protocols.

Storage

- Store unused filters in a clean, dry environment.
- Avoid exposure to direct sunlight and extreme temperatures.

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To place an order or receive technical assistance

Order/Customer Service: **SigmaAldrich.com/order**
Technical Service: **SigmaAldrich.com/techservice**

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