Millipore®
Preparation, Separation,
Filtration & Monitoring Products

Data Sheet

Viresolve® Barrier Filters

A powerful upstream viral safety solution designed to prevent bioreactor contamination

Multiple potential sources of adventitious virus exist within a manufacturing environment, putting your upstream process at risk for contamination. Bioreactor contaminations are highly disruptive and costly events, but the risk of contamination can be minimized with a holistic upstream viral safety strategy.

Viresolve® Barrier filters provide robust, effective bioreactor protection. They are designed to efficiently process chemically defined cell culture media without impacting media composition, performance, or resulting protein quality. Viresolve® Barrier filters retain high levels of virus, mycoplasma, and bacteria, including spirochetes, while providing high flow and capacity.

Available in a range of sizes, Viresolve® Barrier single-use capsule filters provide scalable performance from process development to large-scale manufacturing. These filters can replace sterile filters and can be used in front of bioreactors or media storage containers. The gamma-compatible filter capsules are offered as standalone units or as ready-to-use, presterilized, standard Mobius® single-use assemblies.

Benefits

Robust protection from adventitious agents

- ≥3.0 log removal of parvovirus
- ≥4.0 log removal of bacteriophage PhiX-174 (φX-174)
- ≥6.0 log removal of mycoplasma
- Sterilizing-grade protection from bacteria
- 100% integrity tested in manufacturing, ensuring quality and consistency

Efficient virus filtration of cell culture media

- No impact to cell culture media performance
- High-flux virus filtration
- Easy to implement, install, and integrity test

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Expand your Upstream Risk Mitigation Strategy

Until recently, upstream viral contamination risk mitigation relied on careful sourcing of raw materials, testing of cell banks, and control of facilities and workflow. Despite these precautions, viral contaminations occurred.

Filtration of cell culture media with Viresolve® Barrier filters enables you to focus on processing, by minimizing the likelihood of bioreactor contamination and potential disruption of production timelines.

Options for Preventing Upstream Viral Contamination

Cell Culture Media Treatment Requirements	Viresolve® Barrier Filter	High temperature short time (HTST)	UV-C inactivation	Gamma irradiation
Robust parvovirus clearance	✓	Virus and system dependant	Virus and system dependant	Virus and system dependant
Point of use implementation	✓	✓	✓	
Easy to scale	✓			
Small footprint	✓			
Easy to implement and use	✓		✓	✓

Viresolve® Barrier Filters

Viresolve® Barrier filters contain a polyethersulfone (PES) membrane that efficiently removes viruses from cell culture media. An integrated 0.1 µm PES membrane layer provides sterilizing-grade performance enabling removal of bacteria, mycoplasma and virus in a single filtration device. These capsule filters mitigate the risk of bioreactor contamination while maintaining cell culture performance.

Viresolve® Barrier filters are supported by the Emprove® Program which provides comprehensive product-specific information to simplify your compliance needs.

Micro Filters for Process Development

- Small-volume filters for process development, optimization, and sizing studies
- Process development (PD) kit contains nine presterilized devices made from one membrane lot

Capsule Filters

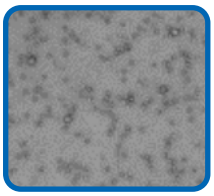
- Pilot, medium, and large-volume processing
- Gamma-compatible
- 100% integrity tested in manufacturing
- Available in presterilized Mobius® single-use assemblies

Robust Clearance

Viresolve® Barrier filters were challenged with a panel of microorganisms. The figure below summarizes the results of challenge studies and highlights the robust retention performance of Viresolve® Barrier filters.

Challenge studies with bacteriophage φX-174, a model for parvovirus contaminants, are performed on each lot of Viresolve® Barrier membrane and devices. All samples must demonstrate ≥4.0 logs φX-174 retention.

Virus

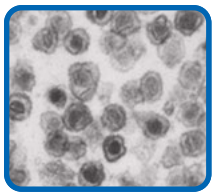


Minute virus of Mice (MVM)

Relevant parvovirus contaminant

Target organism

Typical LRV above 4



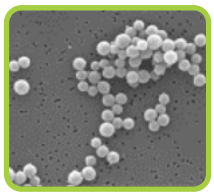
Murine leukemia virus (x-MuLV)

Model large virus

Similar size to endogenous virus particles

LRV >6

Mycoplasma

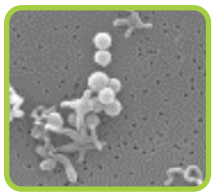


A. laidlawii

Standard model mycoplasma

Model organism for 0.1 µm filters

LRV >8



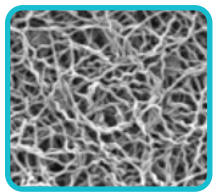
M. orale

Relevant contaminant

Can penetrate 0.1 µm filters

LRV >8

Spirochete



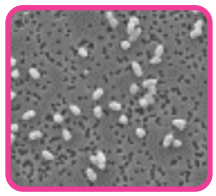
L. illini

Model spirochete bacteria

Can penetrate 0.1 µm filters

LRV >8

Bacteria



B. diminuta

Standard model bacteria

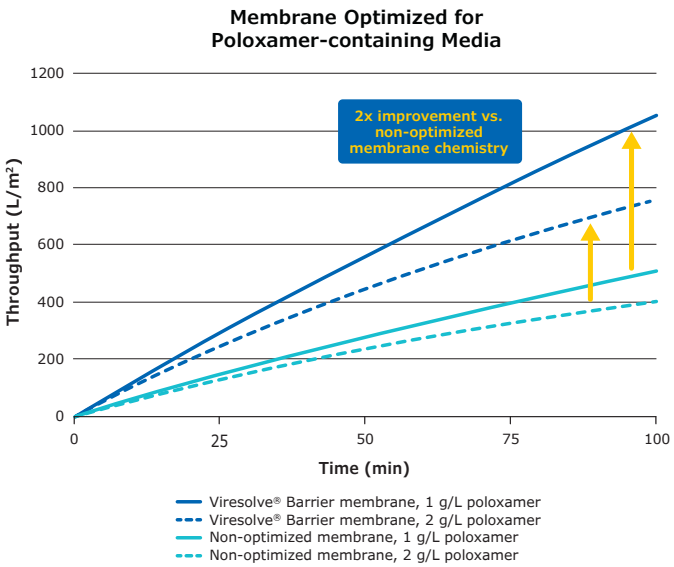
Tested by ASTM® F838-05

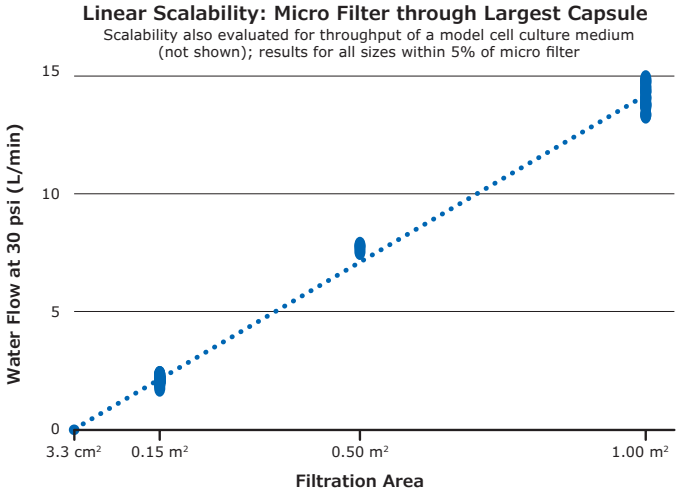
LRV >8

Fast, Efficient Processing

Viresolve® Barrier filters provide high flux virus filtration of chemically defined media containing poloxamer or hydrolysates.

The filter capsules show linear scalability from lab through pilot and production scale devices.

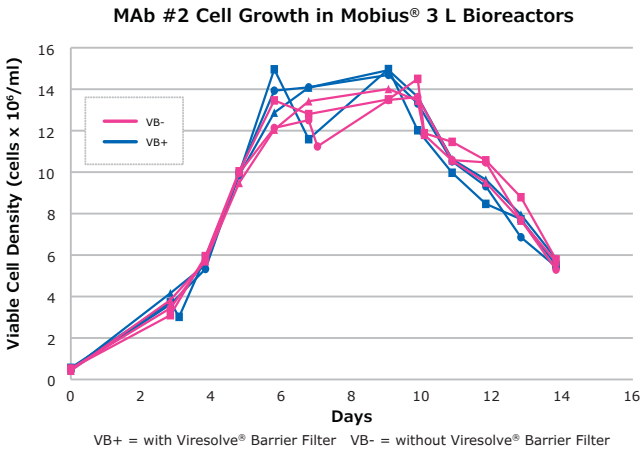


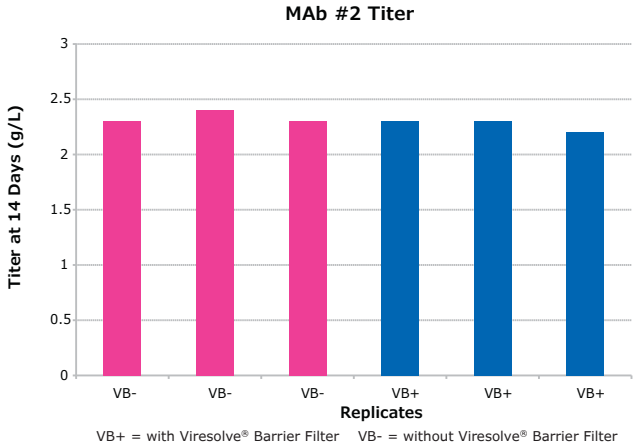


Maintaining Cell Culture Performance

CHO cell culture performance was assessed following media filtration through Viresolve® Barrier filters.

No significant differences in cell growth or mAb titers were observed in cultures grown in media processed through Viresolve® Barrier or sterilizing-grade filters.

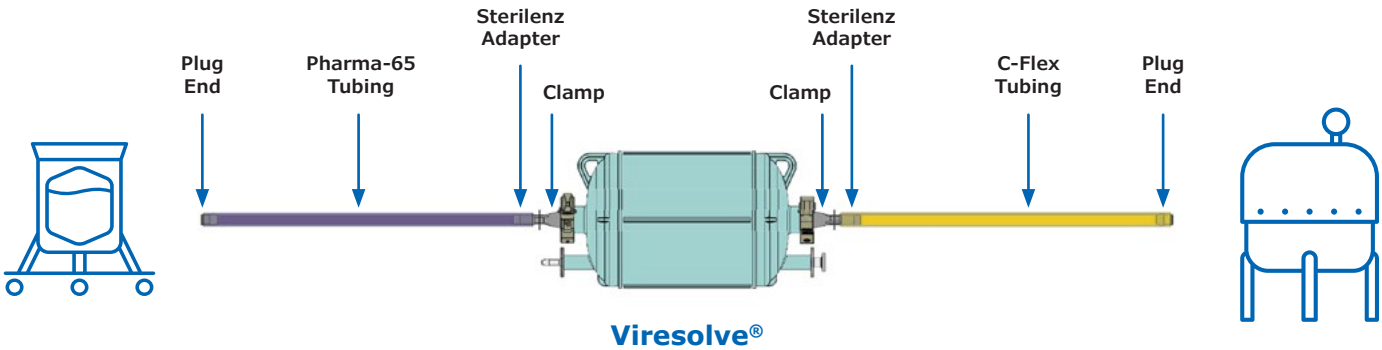




Easy Connectivity in our Mobius® Single-Use Assemblies

Viresolve® Barrier filters are offered presterilized by gamma irradiation and ready to use, in a standard Mobius® assembly. The universal assembly design uses a Triclover (TC) connector and enables sterile connections through tubing welding.

This modular, flexible solution can be easily integrated into your upstream process. All presterilized filter assemblies come with a Mobius® Silver Certificate of Quality.



Viresolve® Barrier filter

Mobius® Single-Use Solutions

Viresolve® Barrier filter capsules are available presterilized and ready-to-use in a standard Mobius® assembly.

EMDMillipore.com/Singleuse-MyWay

The Emprove® Program—your fast track through regulatory challenges.

Complementing our product portfolio, the Emprove® Program supports different stages of development and manufacturing operations. The Emprove® dossiers consolidate comprehensive product-specific testing data, quality statements and regulatory information in a readily-available format to simplify your compliance needs.

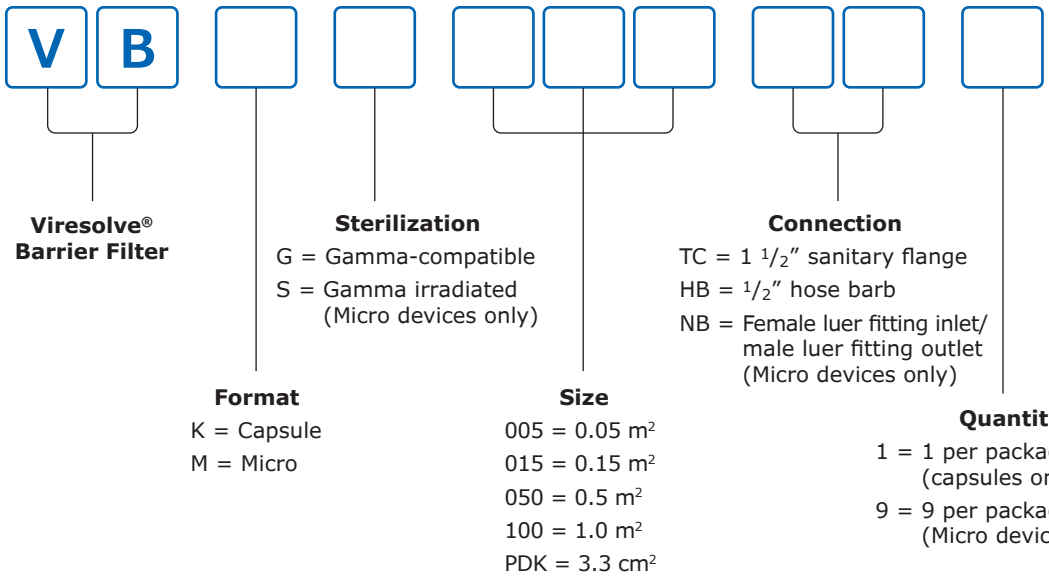
EMDMillipore.com/Emprove or SigmaAldrich.com/Emprove

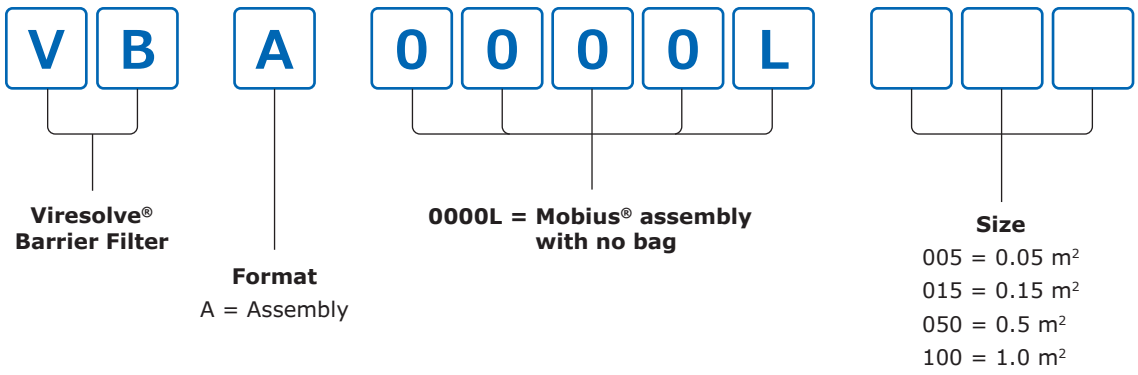
Specifications

Viresolve® Barrier Filters

Membrane Area	3.3 cm^2 Micro Filter	0.05 m^2 Capsule Filter	0.15 m^2 Capsule Filter	0.5 m^2 Capsule Filter	1.0 m^2 Capsule Filter
Nominal Dimensions	Height: 3.8 cm (1.5 in.) Diameter: 3.1 cm (1.2 in.)	Height: 23.6 cm (9.3 in.) Diameter: 19.0 cm (7.5 in.)	Height: 23.6 cm (9.3 in.) Diameter: 19.0 cm (7.5 in.)	Height: 29.7 cm (11.7 in.) Diameter: 19.0 cm (7.5 in.)	Height: 39.6 cm (15.6 in.) Diameter: 19.0 cm (7.5 in.)
Materials of Construction	Membrane: Polyethersulfone (PES) Housing: Gamma-stable polypropylene	Membrane: Polyethersulfone (PES) Support layer: Polyethylene Housing: Gamma-stable polypropylene, polyethersulfone O-rings: Silicone, EPDM			
Standard Connections	Inlet and Vent: Female luer fitting Outlet: Male luer fitting	Inlet and Outlet: $^1/_2$ in. hose barb (HB) or $1^1/_2$ in. sanitary flange (TC) Vents: $^1/_4$ in. hose barb on inlet end of capsule; fractional sanitary flange on outlet end of capsule			
Good Manufacturing Practice	Filters are manufactured in a facility that adheres to Good Manufacturing Practices.				
ISO 9001 Quality Standard	Filters are manufactured in a facility whose Quality Management System is approved by an accredited registering body to the appropriate ISO 9001 Quality Systems Standard.				
Particulate and Bioburden	Filters are manufactured in an ISO Class 8 (per ISO 14644-1) controlled environment for particulate classification only.				
Animal Origin	Component materials are either animal free or in compliance with EMA/410/01 rev.3.				
USP <87> Biological Reactivity Tests	Component materials were tested and meet the criteria for non-cytotoxicity for the USP <87> Cytoxicity MEM Elution Tests.				
USP <88> Biological Reactivity Tests	Component materials were tested and meet the criteria for USP <88> Biological Reactivity Tests for Class VI Plastics.				
Bacterial Endotoxin	An aqueous extract contains less than 0.25 EU/mL, per USP <85>, as determined by the Limulus Amebocyte Lysate (LAL) test.				
Non-particle Releasing	Filters meet the requirements of USP <788>.				
Membrane Bacteriophage Retention	Membrane samples exhibited LRV ≥4 using ΦX-174 bacteriophage at a minimum challenge level of 10^7 pfu/mL in the presence of a chemically defined cell culture medium.				
Device Bacteriophage Retention	Filters are manufactured with retentive membrane, as detailed above.	Filter samples exhibited LRV ≥4.0 using ΦX-174 bacteriophage at a minimum challenge level of 10^7 pfu/mL.			
Mycoplasma Retention	Membrane samples exhibited LRV ≥6.0 using *A. laidlawii* ATCC® 23206 and our validated test method.				
Bacterial Retention	Membrane is validated as sterilizing grade.	Membrane and filters are validated as sterilizing grade—quantitatively retentive of a minimum *B. diminuta* challenge of 10^7 CFU/cm^2 using ASTM F838 methodology.			
Sterilization	Filters were gamma irradiated at 25–40 kGy.	Filter integrity and performance characteristics are maintained after exposure to a maximum gamma radiation dose of 40 kGy.			
Maximum Differential Pressure	Forward: 4.1 bar (60 psi) at 25 °C	Forward: 4.1 bar (60 psi) at 25 °C Reverse: 0.3 bar (5 psi) at 25 °C			
Hydraulic Stress Test		Samples were integral based on an air/water diffusion test, before and after repeated forward stress to 4.1 bar (60 psi) at 25 °C.			
100% Integrity Tested in Manufacturing	Each filter passed an aerosol particle challenge.	Each filter exhibited less than or equal to the following air diffusional flow rates at 3.4 bar (50 psi) in water, at 23 °C: - 0.05 m^2: 2.2 cc/min - 0.15 m^2: 6.6 cc/min - 0.5 m^2: 22 cc/min - 1.0 m^2: 44 cc/min			

Ordering Information





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For additional information,
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