

Millipore Express® Ace 0.2 µm Filters

Advanced Sterilizing-Grade Solution for Exceptional Filtration Capacity and Flux

Millipore Express® Ace 0.2 µm filters are the most recent addition to our Millipore Express® membrane family and deliver exceptional sterile filtration performance for a wide range of applications in any bioprocessing modality. These filters contain a cutting edge, single-layer, hydrophilic polyethersulfone (PES) sterilizing-grade membrane that delivers unmatched flux and throughput.

This innovative membrane design enables more membrane area within a standard filter format, leading to superior filter capacity with minimal footprint.

Millipore Express® Ace 0.2 µm membrane filters can deliver optimal performance with high throughput and excellent retention in a wide range of sterile filtration steps including filtration of cell culture media and process intermediates. And, with surface chemistry designed to minimize protein binding, these filters offer a more sustainable, non-per- and polyfluoroalkyl substances (PFAS), alternative to polyvinylidene fluoride (PVDF) filters for final filtration applications.

Benefits

- Reduced membrane area requirements due to high-capacity single layer membrane.
- Ideal for media filtration by enabling optimal cell culture performance.
- Easily wets to facilitate integrity testing.
- High yields achieved due to low protein binding surface chemistry.
- Contains no intentionally added PFAS for enhanced sustainability.
- Broad chemical compatibility making it suitable for ADC production.



Filter formats

- OptiScale® 25 capsule
- Opticap® XL 150, 300, 600: sterile or gamma compatible capsules

Applications

- Drug substance, drug product filtration
- Growth media and bioreactor additives
- Cell harvest (post clarification) and intermediates
- Column protection
- Concentrated and high viscosity protein streams
- mAb and ADC streams
- Viral vector streams
- mRNA streams
- Vaccine streams
- GLP-1 streams

Higher Throughput Means Fewer Filters

Millipore Express® Ace 0.2 µm filters provide unmatched flux and exceptional filters capacity with minimal footprint enabling you to maximize your output without increasing footprint or capital expense (Figures 1 and 2).

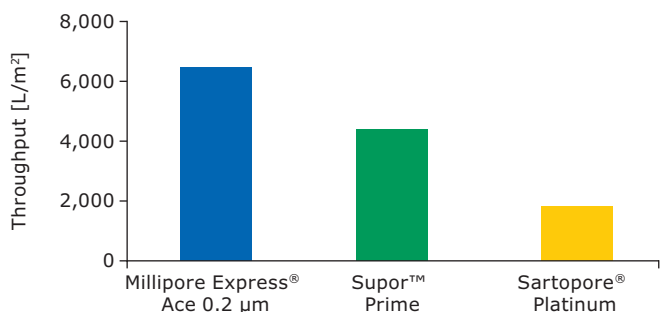


Figure 1.

Predicted throughput for 2-hour filtration run with EX-CELL® Advanced Perfusion Medium and OptiScale® 25 devices containing Millipore Express® Ace 0.2 µm and other sterilizing-grade membranes.

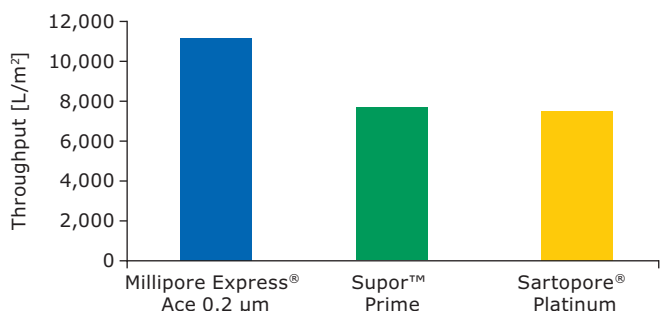


Figure 2.

Predicted throughput for 2-hour filtration run with a mAb process intermediate and OptiScale® 25 devices containing Millipore Express® Ace 0.2 µm and other sterilizing-grade membranes.

OptiScale® Process Development Screening Tool

OptiScale® 25 capsule filters provide a convenient small volume option for process screening and scaling. These disposable “drop in” filters are ideal for quickly evaluating performance of different filters with various process streams. The small filtration area and low hold up volume means your limited volume of process fluid goes further.



Figure 3.

OptiScale® 25 capsule filter.

Opticap® XL Capsule Filters

Convenient and easy-to-use

Opticap® XL 150, XL 300 and XL 600 capsules are ideal for smaller processes or pilot-scale manufacturing and offer flexibility, rapid turnaround, less manufacturing downtime and minimize the cleaning, assembly and validation associated with stainless steel operations.

These versatile capsule filters can be easily integrated into Mobius® single-use assemblies, for a ready-to-use single-use system.



Figure 4.

Opticap® XL 150, 300, and 600 capsules.

Filter Validation Services

Our comprehensive Validation Services help you meet global regulatory requirements. From extractables and leachables testing to bacterial retention and chemical compatibility studies, our experts provide data-driven support to confirm process safety and performance. With harmonized global labs and deep experience in filter validation, we make compliance straightforward and reliable.

For more information, please visit:

[SigmaAldrich.com/validation-services](https://www.sigmaaldrich.com/validation-services)

The Emprove® Program – The Smart Way to Master Compliance and Control

Millipore Express® Ace 0.2 µm filters are supported by the Emprove® Program which complements our product portfolio and provides convenient access to reliable technical, regulatory and supply information in Emprove® Dossiers to support your risk assessment continuum. A subscription to our Emprove® Suite can help you stay current: In addition to accessing the Emprove® Dossiers, you can also receive notification updates to document changes, as well as generate metrics and reports.

For more information, please visit:

[SigmaAldrich.com/emprove](https://www.sigmaaldrich.com/emprove)

Specifications

OptiScale® Capsules

OptiScale® 25 Capsules	
Nominal Dimensions	
Diameter	31 mm (1.21 in.)
Length	39 mm (1.52 in.)
Filtration Area	
	3.5 cm ²
Materials of Construction	
Filter membrane	Hydrophilic polyethersulfone
Supports	Polypropylene
Structural components	Polypropylene
Vent cap	Polypropylene
Housing Vent	
	Capped vent with female Luer connections on inlet side of device.
Maximum Inlet Pressure	
	4100 mbar (60 psi) at 25 °C
Maximum Differential Pressure	
Forward	4100 mbar (60 psi) at 25 °C
Bacterial Endotoxin	
	Aqueous extraction contains <0.25 EU/mL as determined by the Limulus Ameboyte Lysate (LAL) Test as described in USP <85>.
TOC/Conductivity	
	Autoclaved filter effluent meets the WFI specification for USP <643>, Total Organic Carbon, and for USP <645>, Conductivity, after a WFI water flush of 15 mL.
Sterilization	
	May be autoclaved for 1 cycle at 123 °C for 60 min.
Particle Shedding	
	Effluent meets the acceptance criteria set forth in USP <788> for large volume parenterals.
Non-fiber Releasing	
	Millipore Express® Ace membrane meets the criteria for a “non-fiber releasing” filter as defined in 21 CFR 210.3(b)(6).
Component Material Toxicity	
	Component materials meets the criteria for Biological Reactivity Testing. These tests can be any one or a combination of the following test methods USP<88> Class VI (<i>in vivo</i>), USP <87> (<i>in vitro</i>), ISO 10993-5 (<i>in vitro</i>).
Indirect Food Additive	
	All component materials meet the FDA Indirect Food Additive requirements cited in 21 CFR 177–182.
Quality Management System	
	This product was manufactured in a facility whose Quality Management System is approved by an accredited registering body to the appropriate ISO 9001 Quality Management Systems Standard.

Specifications

Opticap® XL Capsules (Sterile and Gamma Compatible)

	Opticap® XL 150 Capsules	Opticap® XL 300 Capsules	Opticap® XL 600 Capsules
Nominal Dimensions			
Maximum length	9.7 cm (3.8 in.)	11.9 cm (4.7 in.)	16.5 cm (6.5 in.)
Body diameter	5.6 cm (2.2 in.)	5.6 cm (2.2 in.)	5.6 cm (2.2 in.)
Filtration Area			
	0.025 m ² (0.269 ft ²)	0.050 m ² (0.538 ft ²)	0.10 m ² (1.076 ft ²)
Materials of Construction			
Filter membrane	Hydrophilic polyethersulfone		
Supports	Polyethylene		
Core	Polysulfone		
Structural components	Irradiation compatible polypropylene		
Vent O-rings	Silicone		
Vent/Drain			
	6 mm (¼ in.) hose barb with double O-ring seal		
Maximum Inlet Pressure			
	6900 mbar (100 psi) intermittent at 4 & 25 °C 5500 mbar (80 psi) at 4 & 25 °C 1724 mbar (25 psi) at 80 °C		
Maximum Differential Pressure			
Forward	6900 mbar (100 psi) intermittent at 4 & 25 °C 5500 mbar (80 psi) at 4 & 25 °C 1724 mbar (25 psi) at 80 °C		
Reverse	2100 mbar (30 psi) at 25 °C		
Bubble Point			
	≥4140 mbar (60 psi) air with water ≥1320 mbar (19.1 psi) nitrogen with 70/30% IPA/water mixture		
Air Diffusion			
	Through a water wet membrane at 2.8 bar (40 psi): ≤2.6 cc/min. ≤4.2 cc/min. ≤6.4 cc/min.		
Bacterial Retention			
	Quantitative retention of 10 ⁷ CFU/cm ² <i>Brevundimonas diminuta</i> ATCC® 19146 per ASTM® F838 Methodology.		
Bacterial Endotoxin			
	Aqueous extraction contains <0.25 EU/mL as determined by the Limulus Ameboocyte Lysate (LAL) Test as described in USP <85>.		
TOC/Conductivity			
	Irradiated filter effluent meets the WFI requirements of USP <643> for Total Organic Carbon and USP <645> for Water Conductivity at 25 °C after a water flush of: 2 L 2.5 L 3 L		
Sterilization			
Gamma-compatible capsules	Compatible to 45 kGy and may be autoclaved for 3 cycles of 60 minutes at 123 °C (cannot be steam sterilized in-line).		
Sterile capsules	Sterile capsules may be autoclaved for 3 cycles of 60 minutes at 123 °C (cannot be steam sterilized in-line).		
Sterility			
Sterile capsules	These capsules meet current USP and AAMI guidelines for sterility utilizing a validated sterilization cycle.		
Particle Shedding			
	Effluent meets the acceptance criteria set forth in USP <788> for large volume parenterals.		
Non-fiber Releasing			
	Millipore Express® Ace 0.2 µm membrane meets the criteria for a “non-fiber releasing” filter as defined in 21 CFR 210.3(b)(6).		
Component Material Toxicity			
	Component materials meets the criteria for Biological Reactivity Testing. These tests can be any one or a combination of the following test methods USP<88> Class VI (<i>in vivo</i>), USP <87> (<i>in vitro</i>), ISO 10993-5 (<i>in vitro</i>).		
Indirect Food Additive			
	All component materials meet the FDA Indirect Food Additive requirements cited in 21 CFR 177-182.		
Quality Management System			
	This product was manufactured in a facility whose Quality Management System is approved by an accredited registering body to the appropriate ISO 9001 Quality Management Systems Standard.		

Typical Clean Water Flow Rates

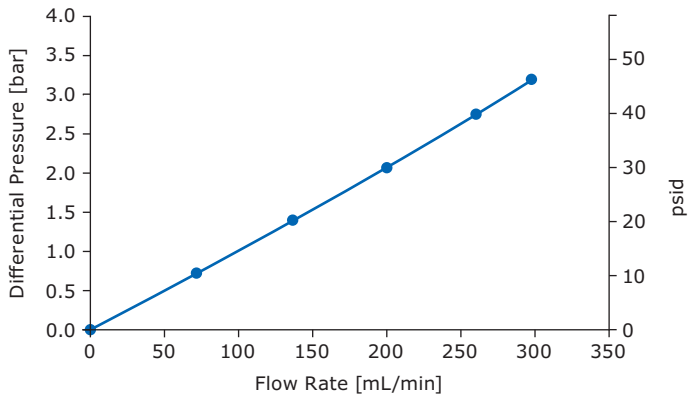


Figure 5.
Water Flow Rate vs Differential Pressure at 23 °C for Optiscale® 25 with Millipore Express® Ace 0.2 µm Membrane.

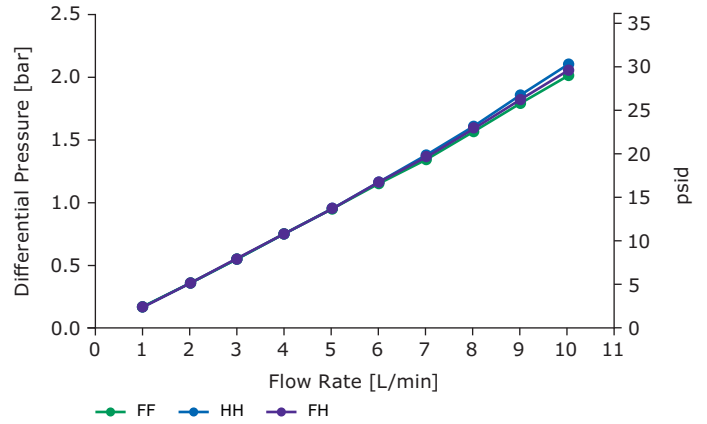


Figure 6.
Water Flow Rate vs Differential Pressure at 23 °C. Gamma Compatible Opticap® XL 150 Capsule with Millipore Express® Ace 0.2 µm Membrane post >45 kGy irradiation + 3x autoclave.

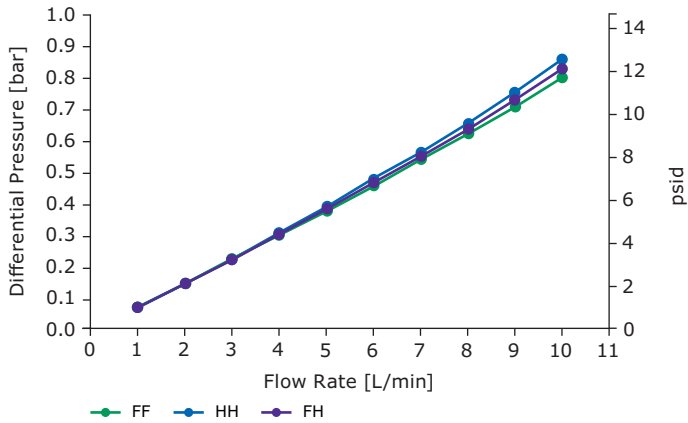


Figure 7.
Water Flow Rate vs Differential Pressure at 23 °C. Gamma Compatible Opticap® XL 300 Capsule with Millipore Express® Ace 0.2 µm Membrane post >45 kGy irradiation + 3x autoclave.

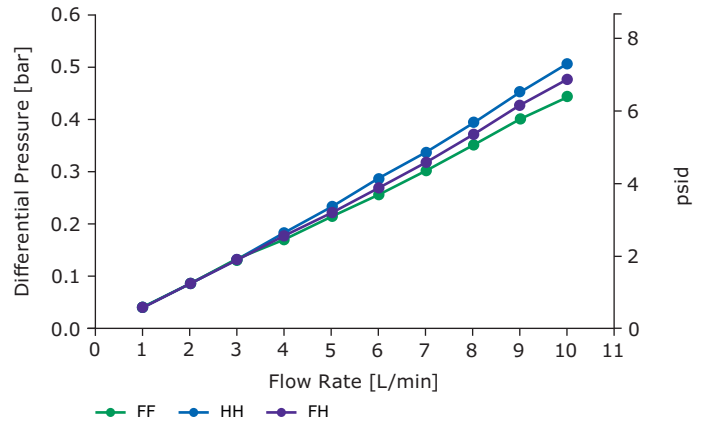


Figure 8.
Water Flow Rate vs Differential Pressure at 23 °C. Gamma Compatible Opticap® XL 600 Capsule with Millipore Express® Ace 0.2 µm Membrane post >45 kGy irradiation + 3x autoclave.

Opticap® XL Capsule Legends

Refer to Connection Type

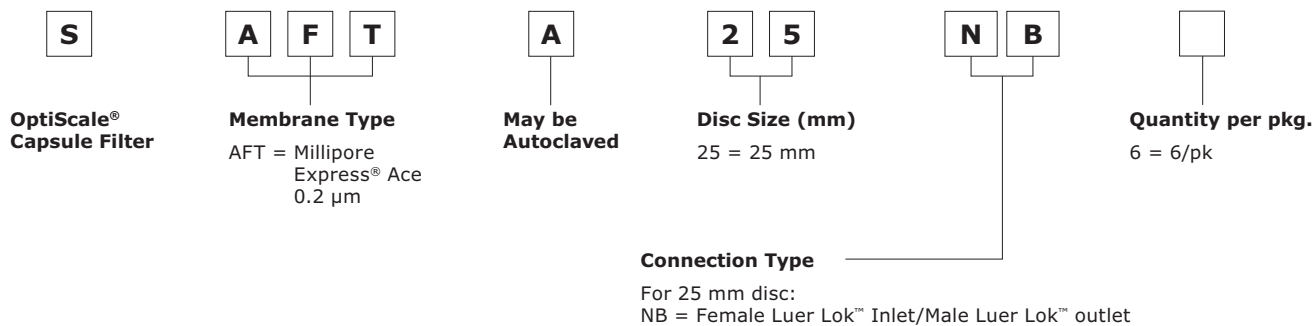
FF = 19 mm (3/4 in.) sanitary flange inlet and outlet

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

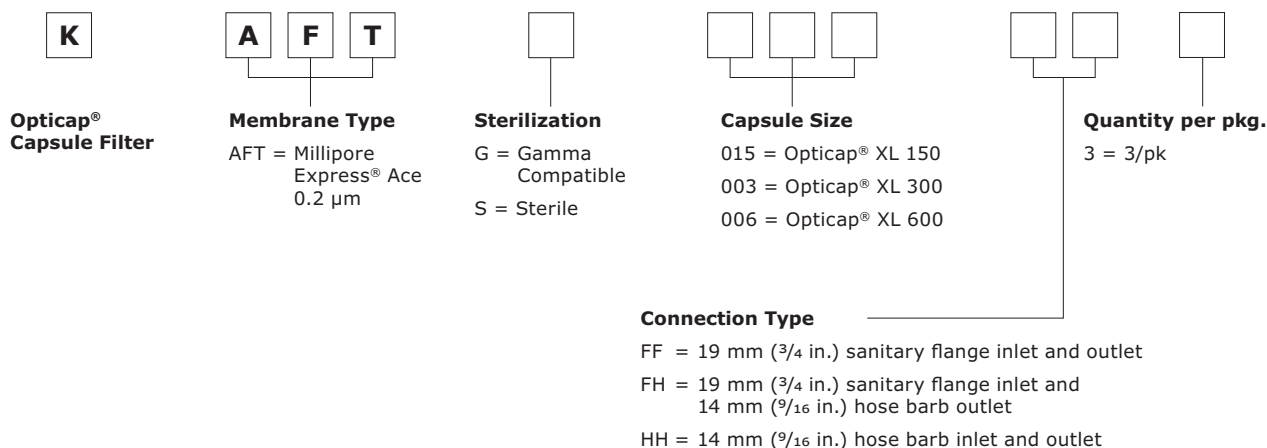
HH = 14 mm (9/16 in.) hose barb inlet and outlet

Ordering Information

OptiScale® Capsule Filters



Opticap® XL 150/300/600 Capsule Filters



MilliporeSigma
400 Summit Drive
Burlington, MA 01803

For additional information, please visit [SigmaAldrich.com](https://www.SigmaAldrich.com)
To place an order or receive technical assistance, please visit
[SigmaAldrich.com/offices](https://www.SigmaAldrich.com/offices)

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unrivalled experience in supporting your scientific advancements.

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