

# 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

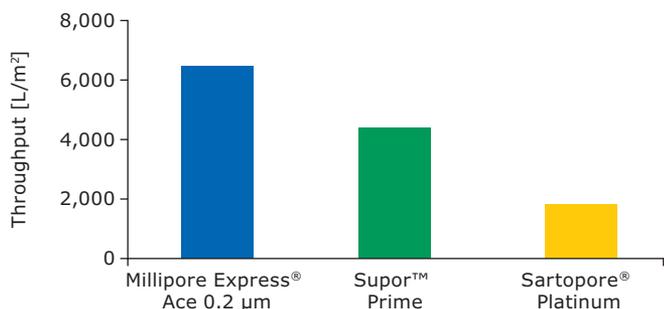
- OptiScale® 25 capsule
- Opticap® XL 150, 300, 600: sterile or gamma compatible capsules

### 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

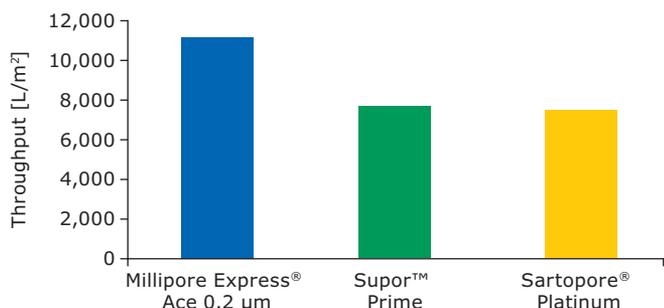
## Higher Throughput Means Fewer Filters

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

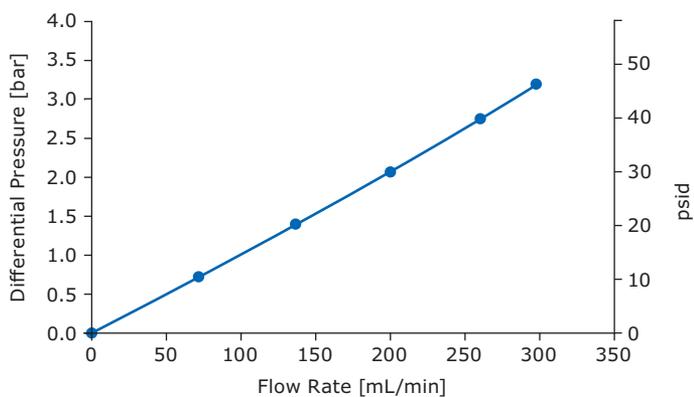
OptiScale® 25 Capsules	
<b>Nominal Dimensions</b>	
Diameter	31 mm (1.21 in.)
Length	39 mm (1.52 in.)
<b>Filtration Area</b>	
	3.5 cm <sup>2</sup>
<b>Materials of Construction</b>	
Filter membrane	Hydrophilic polyethersulfone
Supports	Polypropylene
Structural components	Polypropylene
Vent cap	Polypropylene
<b>Housing Vent</b>	
	Capped vent with female Luer connections on inlet side of device.
<b>Maximum Inlet Pressure</b>	
	4100 mbar (60 psi) at 25 °C
<b>Maximum Differential Pressure</b>	
Forward	4100 mbar (60 psi) at 25 °C
<b>Bacterial Endotoxin</b>	
	Aqueous extraction contains <0.25 EU/mL as determined by the Limulus Ameboyte Lysate (LAL) Test as described in USP <85>.
<b>TOC/Conductivity</b>	
	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.
<b>Sterilization</b>	
	May be autoclaved for 1 cycle at 123 °C for 60 min.
<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® Ace membrane meets the criteria for a “non-fiber releasing” filter as defined in 21 CFR 210.3(b)(6).
<b>Component Material Toxicity</b>	
	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> ).
<b>Indirect Food Additive</b>	
	All component materials meet the FDA Indirect Food Additive requirements cited in 21 CFR 177–182.
<b>Quality Management System</b>	
	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

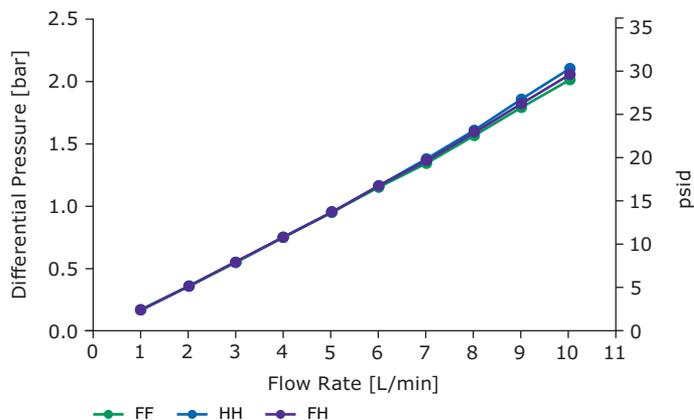
### Opticap® XL Capsules (Sterile and Gamma Compatible)

	Opticap® XL 150 Capsules	Opticap® XL 300 Capsules	Opticap® XL 600 Capsules
<b>Nominal Dimensions</b>			
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.)
<b>Filtration Area</b>			
	0.025 m <sup>2</sup> (0.269 ft <sup>2</sup> )	0.050 m <sup>2</sup> (0.538 ft <sup>2</sup> )	0.10 m <sup>2</sup> (1.076 ft <sup>2</sup> )
<b>Materials of Construction</b>			
Filter membrane	Hydrophilic polyethersulfone		
Supports	Polyethylene		
Core	Polysulfone		
Structural components	Irradiation compatible 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 4 & 25 °C 5500 mbar (80 psi) at 4 & 25 °C 1724 mbar (25 psi) at 80 °C		
<b>Maximum Differential Pressure</b>			
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		
<b>Bubble Point</b>			
	≥4140 mbar (60 psi) air with water ≥1320 mbar (19.1 psi) nitrogen with 70/30% IPA/water mixture		
<b>Air Diffusion</b>			
	Through a water wet membrane at 2.8 bar (40 psi): ≤2.6 cc/min.   ≤4.2 cc/min.   ≤6.4 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® F838 Methodology.		
<b>Bacterial Endotoxin</b>			
	Aqueous extraction contains <0.25 EU/mL as determined by the Limulus Ameboocyte Lysate (LAL) Test as described in USP <85>.		
<b>TOC/Conductivity</b>			
	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		
<b>Sterilization</b>			
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).		
<b>Sterility</b>			
Sterile capsules	These capsules meet current USP and AAMI guidelines for sterility utilizing a validated sterilization cycle.		
<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® Ace 0.2 µm membrane meets the criteria for a “non-fiber releasing” filter as defined in 21 CFR 210.3(b)(6).		
<b>Component Material Toxicity</b>			
	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> ).		
<b>Indirect Food Additive</b>			
	All component materials meet the FDA Indirect Food Additive requirements cited in 21 CFR 177-182.		
<b>Quality Management System</b>			
	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.		

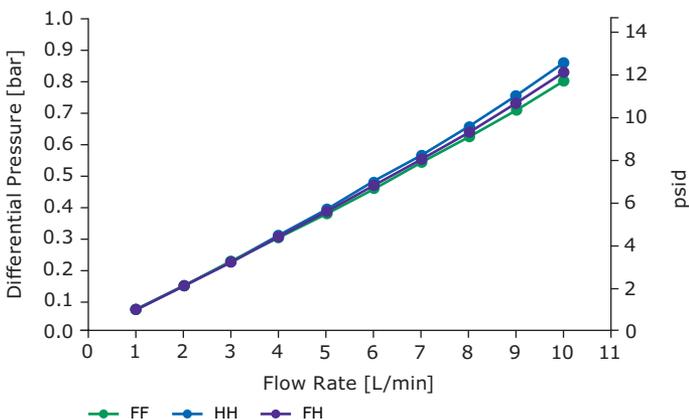
## Typical Clean Water Flow Rates



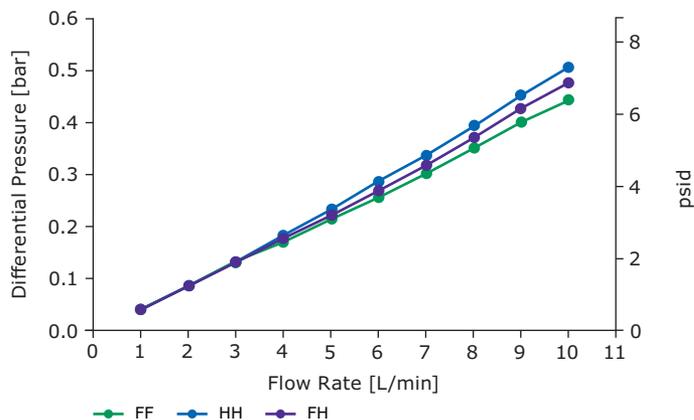
**Figure 5.**  
Water Flow Rate vs Differential Pressure at 23 °C for Optiscale® 25 with Millipore Express® Ace 0.2 µm Membrane.



**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 + 3× 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 + 3× 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 + 3× autoclave.

## Opticap® XL Capsule Legends

### Refer to Connection Type

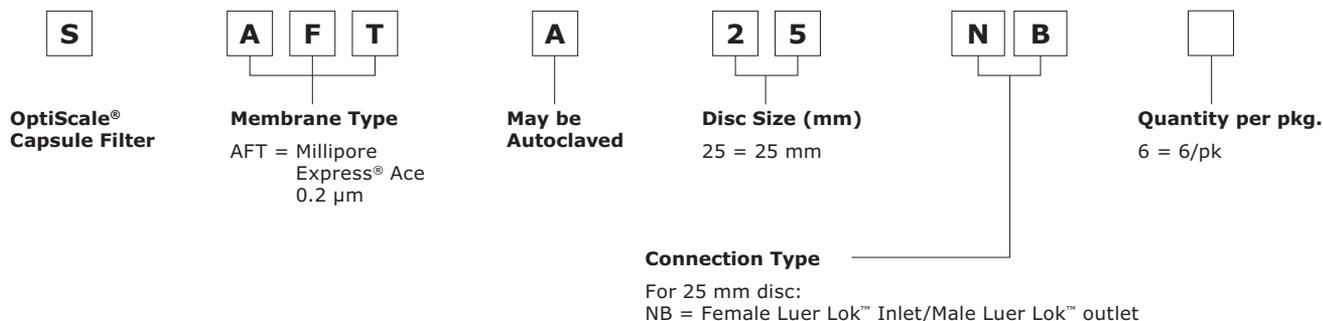
FF = 19 mm (3/4 in.) sanitary flange inlet and outlet

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

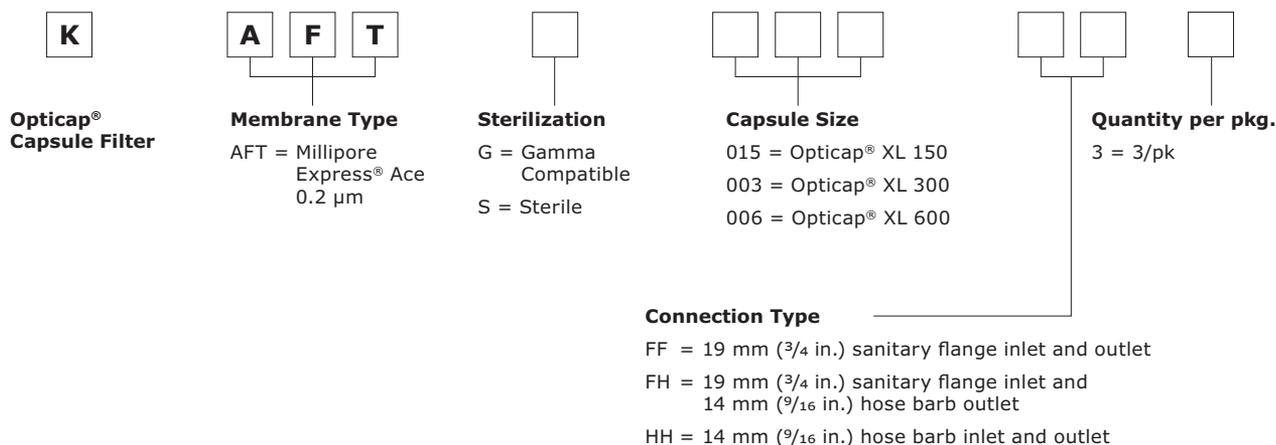
HH = 14 mm (9/16 in.) hose barb inlet and outlet

## Ordering Information

### OptiScale® Capsule Filters



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



Merck KGaA  
Frankfurter Strasse 250  
64293 Darmstadt, Germany

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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