Millipore®
Preparation, Separation,
Filtration & Monitoring Products

Data Sheet

Pellicon® 3 Cassettes with Biomax® Membrane

The device of choice for applications requiring higher yield, fast processing, and exceptional chemical resistance

Pellicon® 3 cassettes with Biomax® membrane are the optimum tangential flow filtration (TFF) devices for the filtration of solutions containing therapeutical proteins, albumin, hormones, vaccines and growth factors. These advanced, high-performance cassettes are ideal for today's higher titer therapeutic antibodies, higher viscosity feed formulations as well as the more demanding filtration processes that require higher operating pressures, temperatures and caustic cleaning regimes.

From small-scale to full-scale production, Pellicon® 3 cassettes are designed for use in research, process scale-up/scale-down, applications development and full-scale manufacturing. The Pellicon® 3 design and automated manufacturing process provide unbeatable performance consistency between cassette sizes. Pellicon® 3 devices also offer greater cassette size selection for improved scale-up and scale-down process development. The streamlined design allows operators to quickly and easily handle, install, and remove Pellicon® 3 cassettes. The materials of construction are compatible with a broad range of chemical cleaning agents that many TFF systems require to ensure proper sanitization.

Benefits

- Robust, void-free membrane provides optimum product retention and performance consistency
- Unique feed screen design enables high mass transfer, flux for higher final concentration
- Fast, reliable scale up/down from lab to production scale
- Rugged, reliable design ideally suited to filtration processes with higher operating pressures, temperatures and caustic cleaning regimes
- Automated manufacturing delivers unbeatable performance consistency and reliability
- Easy to install and clean
- Extreme temperature and chemical compatibility

MilliporeSigma is the U.S. and Canada Life Science business of Merck KGaA, Darmstadt, Germany.

MilliporeSigma

Applications

- Monoclonal antibodies
- Albumin
- Hormones
- Vaccines
- Growth Factors
- Recombinant protein

Optimum Product Recovery and High Yields

High flux and retention properties of the Biomax® membrane result in faster processing speeds with higher yields, which means shortened processing times and a bioprocessing system that can be smaller and more compact.

Fast Processing and Exceptional Chemical Resistance

Superior Flux

At working concentrations of protein, Biomax® membranes have higher flux for a given protein retention than conventional polyethersulfone ultrafiltration (UF) membranes. In this example, Biomax® 10 kDa membrane demonstrates a 40% improvement in process flux over a conventional 10 kDa polyethersulfone membrane using 10% BSA **(Figure 1)**.

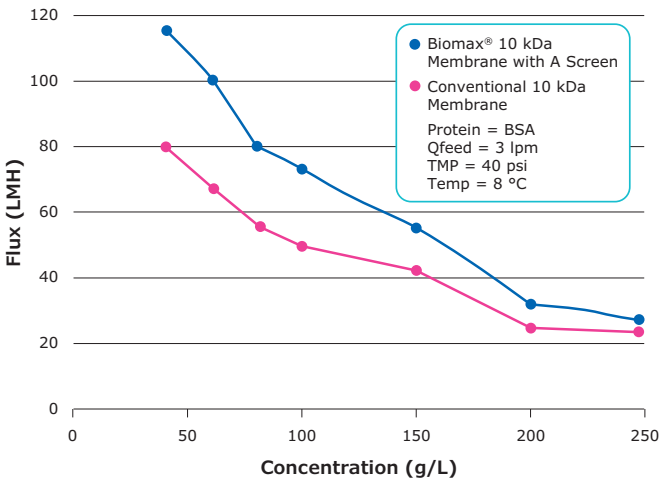


Figure 1. High flux of Biomax® membrane versus conventional polyethersulfone UF membrane.

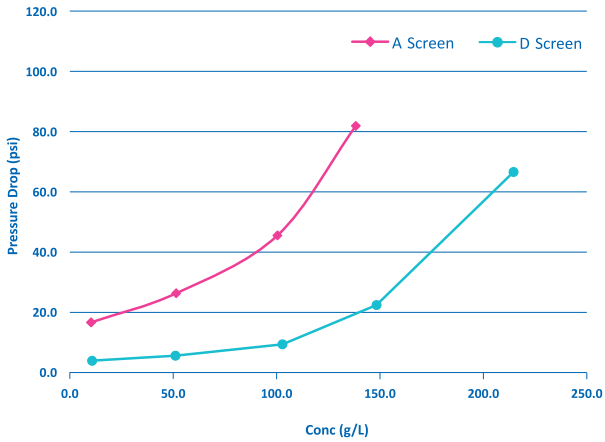
Achieve Higher Target Concentrations

Processing high viscosity antibody concentrations > 150 g/L

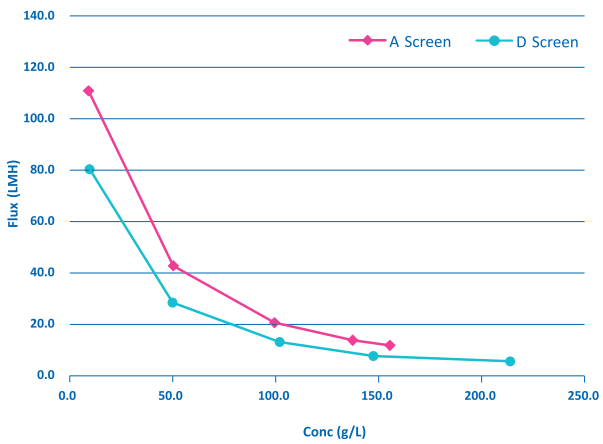
Higher concentration processes have higher viscosities resulting in higher processing pressures. Our Pellicon® 3 Cassette with Biomax® 30 kDa membrane and D Screen is designed to reduce pressure drop while maintaining high mass transfers and process fluxes. As a result, users can process higher concentration formulations under similar processing limits and conditions.

- Pressure drop within operating specifications
- Higher flux than more open channels: reduces process time
- Higher concentration target achievable

Pellicon® 3 Cassettes with Biomax® Membrane Screen Comparison



Pellicon® 3 Cassettes with Biomax® Membrane Screen Comparison



Excellent Cleanability

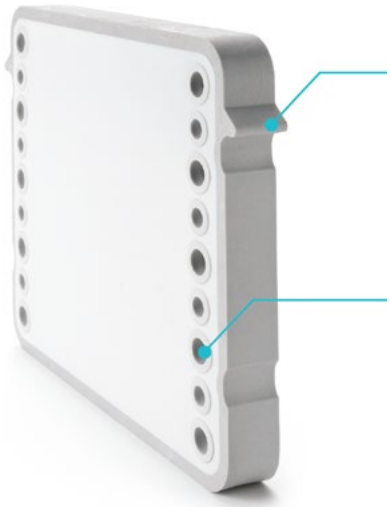
Biomax® membranes are composed of polyethersulfone and are resistant to harsh chemicals used in cleaning, biological decontamination, and sanitization. The polyethersulfone Biomax® membrane has been modified to reduce non-specific protein binding compared to conventional polyethersulfone membranes. The technology offers a mechanically robust design able to withstand process upsets and extreme operating conditions.

Streamlined installation and rugged design

Pellicon® 3 cassettes incorporate a hard polypropylene jacket and end cap design that protects the membrane surface from impacts and potential damage. The end cap includes integral seals, which simplify the installation by eliminating the need for external gaskets between each device.

Rigid End Cap Design

- Protects membrane from damage during handling and installation
- Protects device from over compression



Jacket Alignment Tabs

- Ease of installation and alignment

Integrated Gasket Seals

- Fast, error proof installation

Fast, Reliable Linear Scale-Up from the Lab to the Production Plant

All Pellicon® 3 cassettes are constructed of identical materials and have the same flow channel length, height, turbulence promoter, and flow direction. This ensures that every Pellicon® 3 cassette maintains the same performance profile at every scale, from 250 milliliters to thousands of liters.

Reliable Product Performance Delivering Exceptional Consistency and Reproducibility

Our controlled, automated manufacturing process provides the highest level of cassette performance consistency. The high level of process control ensures consistent, repeat performance in terms of scale up to scale down, from run to run and campaign to campaign.

Extreme Temperature and Chemical Capability

Pellicon® 3 cassettes are manufactured using the most modern polymers and plastics enabling continuous operation at 50 °C and 1.0 N NaOH up to 200 hours. These materials of construction ensure low extractables in a wide range of solvents, acids and bases.

Quality Assurance

All Pellicon® 3 cassettes are manufactured using the same equipment, process, and quality assurance. Each Pellicon® 3 cassette manufacturing lot is 100% integrity tested during manufacturing to ensure that every filter is integral, robust, and within specification. Additionally, Pellicon® 3 cassettes are subjected to a complete array of quality control release tests.

Each cassette is identified with a unique serial number and laser engraved with a 2D bar code linking to a unique Certificate of Quality.

Pellicon® 3 Cassettes are Supported by the Emprove® Program – The Smart Way to Master Compliance and Control

Complementing our product portfolio, the Emprove® Program 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:

https://sigmaaldrich.com/emprove

Services and Support

Our technical experts offer best-in-class field support from process development to implementation, helping you overcome barriers and achieve your goals faster. To accelerate and simplify your path to market, our Validation Services team can help you select, test, and validate the filters, assemblies and systems you need and assist with meeting your process and regulatory requirements.

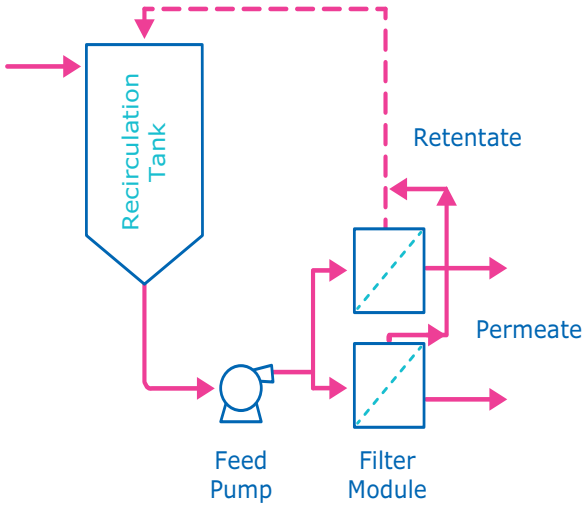
Single-Pass TFF

As part of the BioContinuum™ Ultrafiltration Platform, Pellicon® Single-Pass TFF is a powerful purification tool that runs at constant operating conditions to concentrate product pools without recirculation, allowing for higher final concentrations and improved product recovery compared to traditional batch processes. It can easily run connected with other steps to reduce in-process volumes and intensify operations in the purification of therapeutic proteins.

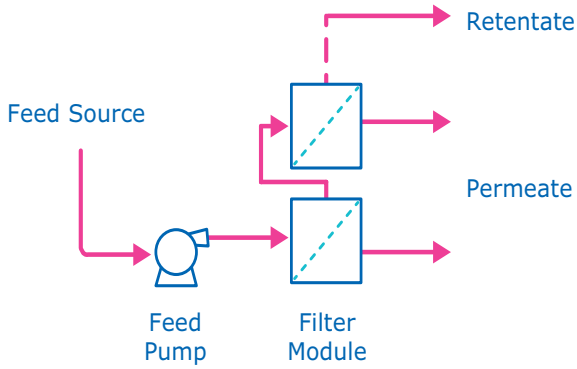
Applications

- In-process volume reduction
- In-line dilution/de-salting
- Intensified capture or polishing
- Final formulation/concentration

Batch TFF



Single-Pass TFF



TFF Systems

Cogent® Lab Systems

When developing a TFF step at small scale, using a model that is representative of large-scale performance is essential. It not only allows for the successful transfer from laboratory scale to larger volumes but also maintains consistent process parameters. Our family of Cogent® Lab systems uses a similar design, sensing technologies, and accessories as our manufacturing-scale equipment. With a homogeneous design and flow range from 20 to 6000 mL/min, our Cogent® Lab systems have been specifically created to simplify process development. These systems offer linear performance and a uniform and intuitive software experience, reducing training requirements and ensuring smooth scale-up and scale-down.

Figure 2. Cogent® Lab Systems

Cogent® Process-Scale TFF System

The fully automated Cogent® TFF system is designed to separate and purify monoclonal antibodies, vaccines, plasma, and therapeutic proteins. It is ideally suited for both pilot and production scale applications, thereby supporting rapid scale up from small to large scale operations. This system has a very low hold-up volume for maximum volume concentration and optimal product recovery, thus enhancing process performance.

Figure 3. Cogent® Process-Scale System

Process Scale Single Use TFF Systems

Our process-scale single-use TFF systems provide a combination of single-use Flexware® assemblies and hardware specifically designed for efficient concentration and diafiltration of proteins. With an installable filter area ranging from 0.5 to 20 m^2, flow range from 2 to 80 L/min and tank size from 50 to 500 L, our range of single-use TFF systems can adapt to your process needs. The closed flow path minimizes the risk of contamination while protecting operators and increasing process flexibility and efficiency.

Figure 4. Mobius® TFF 80 System

Process & Formulation Materials backed by Emprove® Program

The integration of chemical raw materials as required by process and formulation design may present challenges to the TFF process from a process and quality perspective. Our portfolio of standard and customized raw materials including excipients is backed up by deep regulatory expertise and our Emprove® qualification to support your risk assessment and help streamline the approval process, including regulatory compliance and a dedicated portfolio with specified low levels of bioburden and endotoxins.

Our application experts can also support direct integration of excipients and process chemicals by aiding in the development of your process with a comprehensive understanding of potential challenges such as non-specific product and excipient adsorption, high viscosity, and mitigation strategies, including excipient-driven viscosity reduction to achieve high concentrations in TFF. In addition, we support integration of both your device and excipients, as well as help troubleshoot Donnan effects that may occur during processing of high-concentration formulas.

SAFC®

Pharma &
Biopharma Raw
Material Solutions

Pellicon® 3 Cassette (88 cm^2)

Pellicon® 3 Cassette (0.11 m^2)

Pellicon® 3 Cassette (0.57 m^2)

Pellicon® 3 Cassette (1.14 m^2)

Figure 5. Pellicon® 3 Cassette Sizes

Specifications

Maximum Operating Conditions

Materials of Construction:	Polypropylene, Polyethylene, Polyethersulfone, Thermoplastic elastomer, Stainless steel (0.57 m^2 and 1.14 m^2 cassettes only)
Storage solution:	1.1% acetic acid, 1.6% sodium phosphate, 24.8% glycerin and water
Membrane:	Biomax® PES – Polyethersulfone
Assembly Design:	Automated assembly and testing of heat sealed packets bound together by an injection-molded polypropylene jacket

Maximum Operating Conditions

Recommended Feed Flow Rate:	4–6 L/m^2/min
Maximum Inlet Pressure:	100 psi
Forward Transmembrane Pressure:	80 psi (5.5 bar) at 4–40 °C, 200 hours continuous (4 hours continuous, 88 cm^2 format only) 40 psi (2.7 bar) at 4–50 °C, 50 hours continuous
Reverse Transmembrane Pressure:	30 psi (2.1 bar) at 25 °C, 3 min intervals, 10 cycles (5 cycles, micro format only)
Maximum Caustic Exposure:	1.0 N NaOH at 50 °C (up to 2 hours, 88 cm^2 format only), (Contact us for exposure parameters.)
Operating pH Range:	1 – 14

Nominal Dimensions

Filtration Area (nominal)	Length mm (in.)	Width mm (in.)	Thickness mm (in.)
A Screen			
88 cm^2	206 (8.1)	56 (2.2)	8 (0.3)
0.11 m^2	206 (8.1)	56 (2.2)	22 (0.9)
0.57 m^2	206 (8.1)	178 (7.0)	25 (1.0)
1.14 m^2	206 (8.1)	178 (7.0)	39 (1.5)
D Screen			
88 cm^2	206 (8.1)	56 (2.2)	9 (0.4)
0.11 m^2	206 (8.1)	56 (2.2)	23 (0.9)
0.57 m^2	206 (8.1)	178 (7.0)	27 (1.1)
1.14 m^2	206 (8.1)	178 (7.0)	42 (1.7)

Quality Information

Component Material Toxicity:	Component materials were tested and meet the criteria of the USP <88> Biological Reactivity Tests for Class VI Plastics.
ISO 9001 Quality Standard:	This product was manufactured in a facility whose Quality Management System is approved by an accredited registering body to the appropriate ISO 9001 Quality Systems Standard.
100% Integrity Tested in Manufacturing:	Each unit must pass our integrity test based on air flow through the fully-wetted membranes of the filter.
Validated Production Process:	This product was fabricated using a validated manufacturing process.

Hold Up Volume

Area	Biomax® A Screen Feed Channel (mL)	Biomax® D Screen Feed Channel (mL)	Biomax® Approximate Permeate Channel (mL)
88 cm^2	1.8	3	2.8
0.11 m^2	9	23	7
0.57 m^2	69	127	39
1.14 m^2	134	229	88

Ordering Information

Pellicon® 3 Cassettes with Biomax® Membrane

Description	Cat. No.
10 kDa NMWL with A Screen	
88 cm^2	**P3B010A00**
0.11 m^2	**P3B010A01**
0.57 m^2	**P3B010A05**
1.14 m^2	**P3B010A10**
30 kDa NMWL with A Screen	
88 cm^2	**P3B030A00**
0.11 m^2	**P3B030A01**
0.57 m^2	**P3B030A05**
1.14 m^2	**P3B030A10**
50 kDa NMWL with A Screen	
88 cm^2	**P3B050A00**
0.11 m^2	**P3B050A01**
0.57 m^2	**P3B050A05**
1.14 m^2	**P3B050A10**
30 kDa NMWL with D Screen	
88 cm^2	**P3B030D00**
0.11 m^2	**P3B030D01**
0.57 m^2	**P3B030D05**
1.14 m^2	**P3B030D10**

Accessories

Description	Cat. No.
Single-Pass TFF Accessories	
Diverter plate and silicon gasket kit for 88 cm^2 and 0.11 m^2 cassette	**XXSPTFF01**
Diverter plate for 0.57 and 1.14 m^2 cassettes	**XXSPTFF02**
Retentate collection plate for 0.57 and 1.14 m^2 cassettes	**XXSPTFF03**

Hardware*

Holder Type	Cassette Size	Area Range	Cat. No.
Pellicon® 3 Cassette Holders			
Stainless Steel Holder	88 cm^2 and 0.11 m^2	88 cm^2 to 0.55 m^2	**XX42PMINI**
Stainless Steel 88 cm^2 Cassette Holder	88 cm^2	88 cm^2 to 264 cm^2	**XX42PMICR0**
Acrylic Cassette Holder Low Retentate Volume	0.57 m^2 and 1.14 m^2	0.57 m^2 to 5.7 m^2	**XX42PRV60**
Stainless Steel Holder	0.57 m^2 and 1.14 m^2	0.57 m^2 to 5.7 m^2	**XX42P0080**
Stainless Steel Cassette Holder and Assembly	0.57 m^2 and 1.14 m^2	0.57 m^2 to 5.7 m^2	**XX42P0K80**
Process Scale Holder	0.57 m^2 and 1.14 m^2	1.14 m^2 and up	**Contact Local Rep.**
Hydraulic Process Scale Holder	0.57 m^2 and 1.14 m^2	1.14 m^2 and up	**Contact Local Rep.**
Holder Accessories			
Manifold Support Plate	0.57 cm^2 and 1.14 m^2	NA	**XXPEL3MAP**

Cleaning Solutions

Description	Cat. No.
Sodium hydroxide solution, EMPROVE® EXPERT, suitable for cleaning in place, 0.5 mol/L	**137060**
Sodium hydroxide solution 1 mol/L EMPROVE® EXPERT	**137031**
Sodium hydroxide solution 25% low iron EMPROVE® EXPERT	**480659**

*Contact your local field representative for additional information and configurations.

MilliporeSigma
400 Summit Drive
Burlington, MA 01803

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To place an order or receive technical assistance, please visit **SigmaAldrich.com/offices**

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