Millipore®
Filtration, Separation
& Preparation

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 provides 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
- Automated manufacturing delivers unbeatable performance consistency and reliability
- Easy to install and clean
- Extreme temperature and chemical compatibility

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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 UF membranes. In this example, Biomax® 10 membrane demonstrates a 40% improvement in process flux over a conventional 10 kDa polyethersulfone membrane using 10% BSA (**Figure 1**).

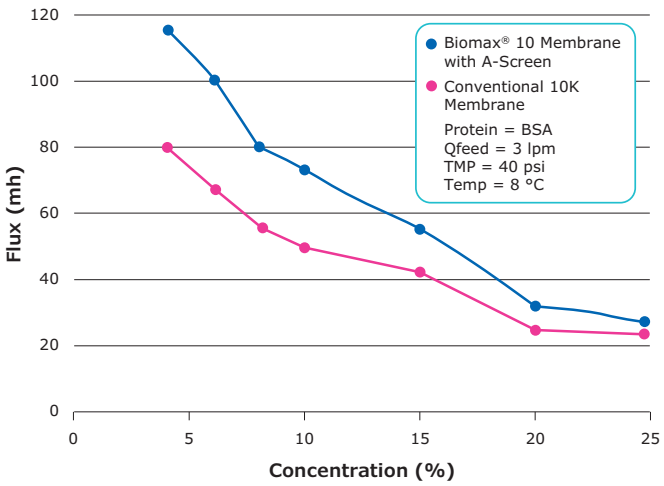


Figure 1. High flux of Biomax® membrane versus conventional polyethersulfone UF membrane.

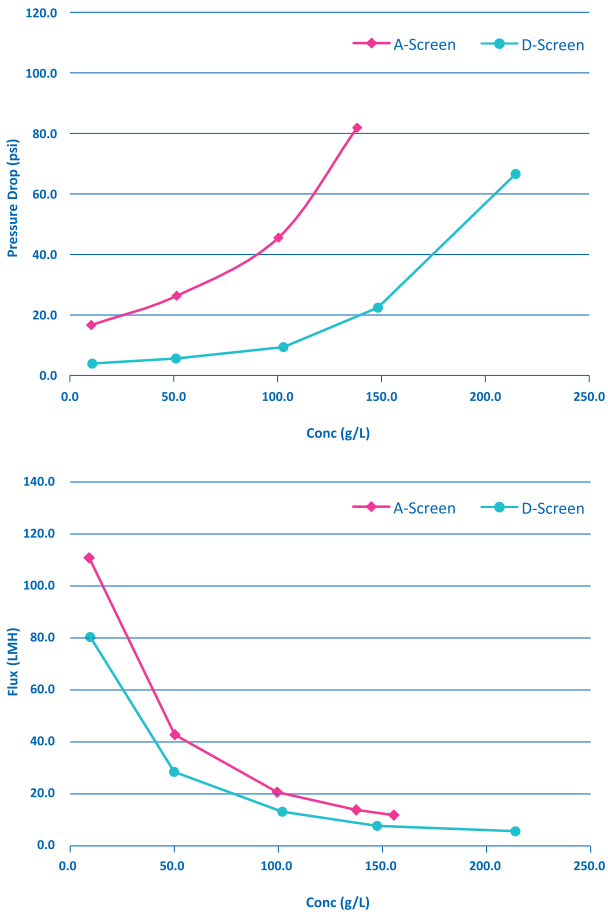
Achieve Higher Target Concentrations

Processing High Viscosity antibody concentrations > 150 g/L

Higher concentration processes have higher viscosities resulting in higher processing pressures. Our Pellicon® 3 Cassette with Ultracel® and Biomax® 30 kD membrane with D-Screen are 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 Cassette 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 (**Figure 2**).

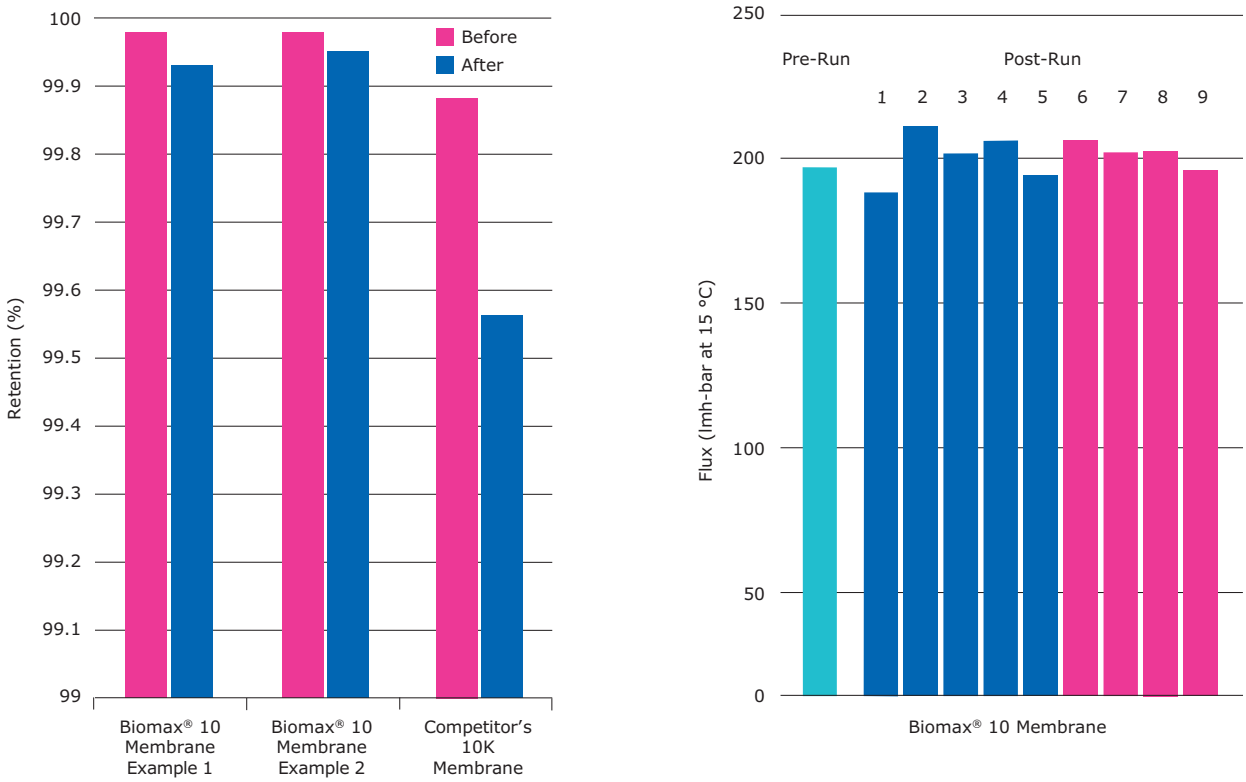
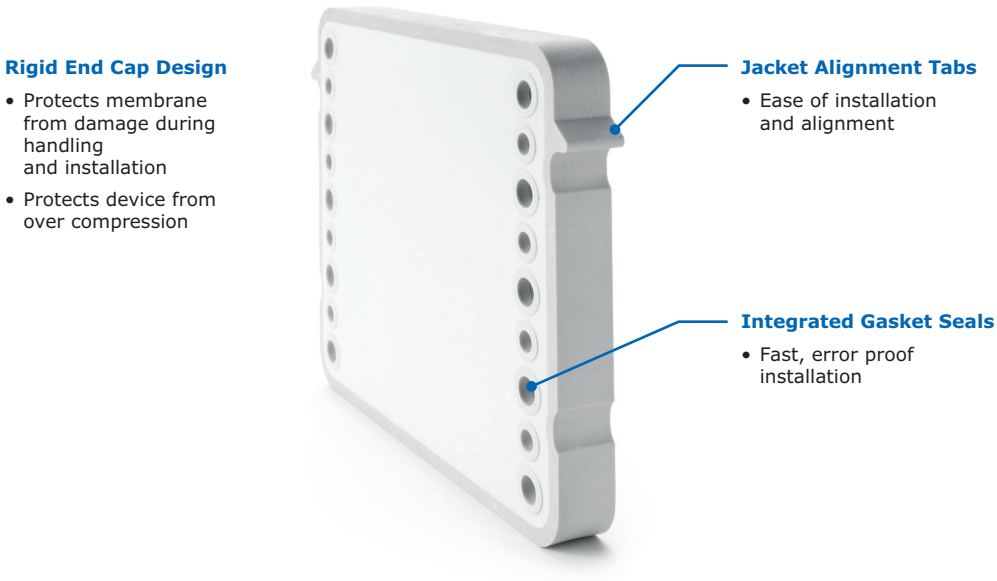


Figure 2. Caustic resistance of Biomax® membrane versus conventional Polyethersulfone UF membrane



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. All cassettes are manufactured in accordance with GMP.

Extreme Temperature and Chemical Capability

Pellicon® 3 cassettes are manufactured using the most modern polymers and plastics enabling continuous operation at 50 °C and 1.0N 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.

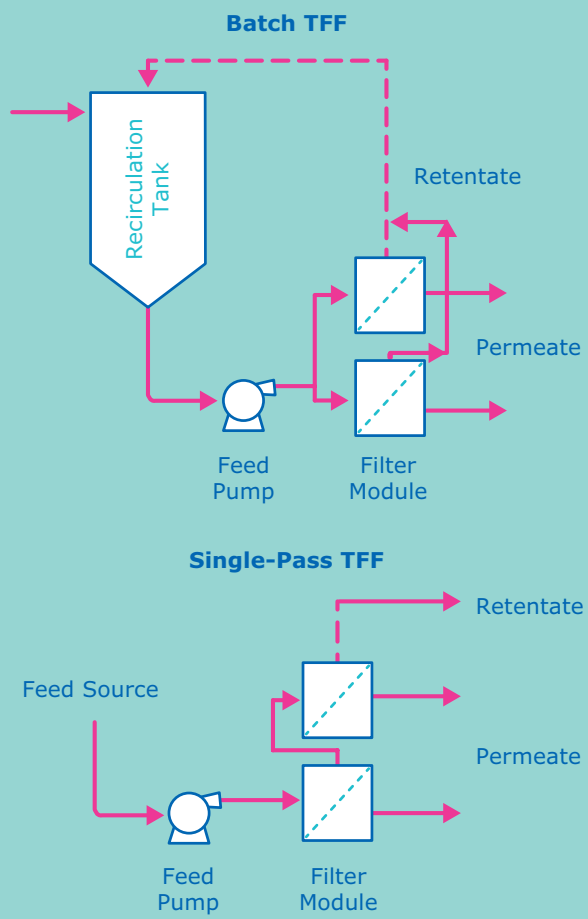
Each cassette is identified with a unique serial number and shipped with an individual Certificate of Quality.

Single Pass TFF

Pellicon® 3 cassettes run in single-pass TFF mode is a simple and efficient way to increase production capacity by reducing process volumes and tank requirements. Single-Pass TFF systems can concentrate process streams without the recirculation required in traditional TFF steps and require a smaller pump and less piping resulting in a more compact footprint and lower cost. For concentrated final formulations, Single-Pass TFF can increase recovery due to lower hold-up volume. Single-Pass TFF also enables continuous processing where in-line concentration is coupled to other process steps.

Applications

- Product concentration/volume reduction
- In-line delution/de-salting
- Final formulation/concentration



TFF Systems

Mobius® FlexReady Solution with Flexware® Assemblies for TFF

The Mobius® FlexReady Solution with Flexware® Assemblies for TFF is a fully automated system designed to achieve optimum performance during the purification of MAbs, vaccines, plasma and therapeutic proteins.

- Standard hardware platform supports multi-unit operation, multi-product and multiscale production maximizing the flexibility of high-value investments
- Flexware® single-use assemblies provide ease-of-use, robust reproducibility, elimination of carryover from previous batches
- Full process automation enables you to easily and reproducibly produce clinical and preclinical scale quantities of high-value drug products
- Comprehensive services ensure rapid implementation and optimized performance

Figure 3. Mobius® FlexReady Solution with Flexware® Assemblies

Cogent® TFF Systems Family

The fully automated Cogent® Process Scale 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.

Benefiting from our leading bioprocess knowledge and engineering expertise, the Cogent® Process Scale System is the culmination of 25 years of custom system design and incorporates many unique, innovative and intelligent design features. This system has a very low hold-up volume for maximum volume concentration and optimal product recovery, thus enhancing process performance.

Figure 4. Cogent® Process Scale System

EMPROVE® Grade Formulation Excipients

The integration of formulation excipients into a TFF process as required by formulation design may present challenges from both a process and regulatory perspective. Our portfolio of high-quality pharmaceutical excipients is backed by our regulatory services and EMPROVE® qualification, to help streamline approval preparation and accelerate processes.

EMPROVE® products for formulation of biologics are designed to support your risk assessment, including multicompendial regulatory compliance and specific qualification with regards to bioburden and endotoxin testing and limitation.

Our formulation 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, viscosity and mitigation strategies. In addition, we support integration of both your device and excipients, as well as help troubleshoot Donnen effects that may occur during processing of high-concentration formulas.

Services and Support

More and more, regulatory inspectors are starting to look closely at downstream process steps like Tangential Flow Filtration. These growing regulatory expectations, together with the quest for high performance and yield, are driving the increasing level of effort that has to be put in Tangential Flow Filtration validation activities. Our Provantage® Services team offers a range of validation services to help you meet your process and regulatory requirements.

Our experienced Provantage® team can save you months of development time by leveraging our proven protocol templates to develop a robust Design of Experiments (DOEs) that is efficient and tailored to meet your processing requirements. Careful consideration of system variables ensures compatibility with your process, accurate scale-up from lab-scale to full-scale manufacturing and optimal lifetime.

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)

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:	1.6% Phosphoric Acid, 1.1% Acetic Acid, 20% 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:	4–8 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:	2 – 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)	8.3 (0.33)
0.11 m^2	206 (8.1)	56 (2.2)	21.6 (0.85)
0.57 m^2	206 (8.1)	178 (7.0)	24.6 (0.97)
1.14 m^2	206 (8.1)	178 (7.0)	39.1 (1.54)
D-Screen			
88 cm^2	206 (8.1)	56 (2.2)	8.9 (0.35)
0.11 m^2	206 (8.1)	178 (2.2)	23 (0.92)
0.57 m^2	206 (8.1)	178 (7.0)	27.2 (1.07)
1.14 m^2	206 (8.1)	178 (7.0)	42.4 (1.67)

Regulatory Information

Component Material Toxicity:	Component materials were tested and meet the criteria of the USP <88> Biological Reactivity Tests for Class VI Plastics.
Good Manufacturing Practices:	These products are manufactured in a facility which adheres to FDA Good Manufacturing Practices.
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 an 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. Principles of statistical process control and determinations of process capability have been applied to critical variables in the device fabrication process. In-process controls are used to assure stability of the 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.
10kD NMWL with A-Screen	
88 cm^2	**P3B010A00**
0.11 m^2	**P3B010A01**
0.57 m^2	**P3B010A05**
1.14 m^2	**P3B010A10**
30kD NMWL with A-Screen	
88 cm^2	**P3B030A00**
0.11 m^2	**P3B030A01**
0.57 m^2	**P3B030A05**
1.14 m^2	**P3B030A10**
50kD NMWL with A-Screen	
88 cm^2	**P3B050A00**
0.11 m^2	**P3B050A01**
0.57 m^2	**P3B050A05**
1.14 m^2	**P3B050A10**
30kD NMWL with D-Screen	
88 cm^2	**P3B030D00**
0.11m^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	**XX42PMICRO**
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 0.5 mol/L suitable for biopharmaceutical production EMPROVE® bio	**137060**
Sodium hydroxide solution 1 mol/L suitable for biopharmaceutical production EMPROVE® bio	**137031**
Sodium hydroxide solution 25% low iron suitable for biopharmaceutical production EMPROVE® bio	**480659**

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

To place an order or receive technical assistance

Visit us at **www.emdmillipore.com**

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