

Data Sheet

Pellicon® 3 Cassettes with Biomax® Membrane

The device of choice for applications requiring high flux, low to moderate protein binding, and harsh chemical cleaning and/or sanitization.

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 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

- Optimum product recovery using proven macrovoid-free membrane technology
- 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

Applications

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

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.

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.

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

Offered in four sizes, 88 cm², 0.11 m², 0.57 m² and 1.14 m², 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.

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.

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.

* Contact your local representative for additional information.

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.

Single-Pass TFF has several applications such as:

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

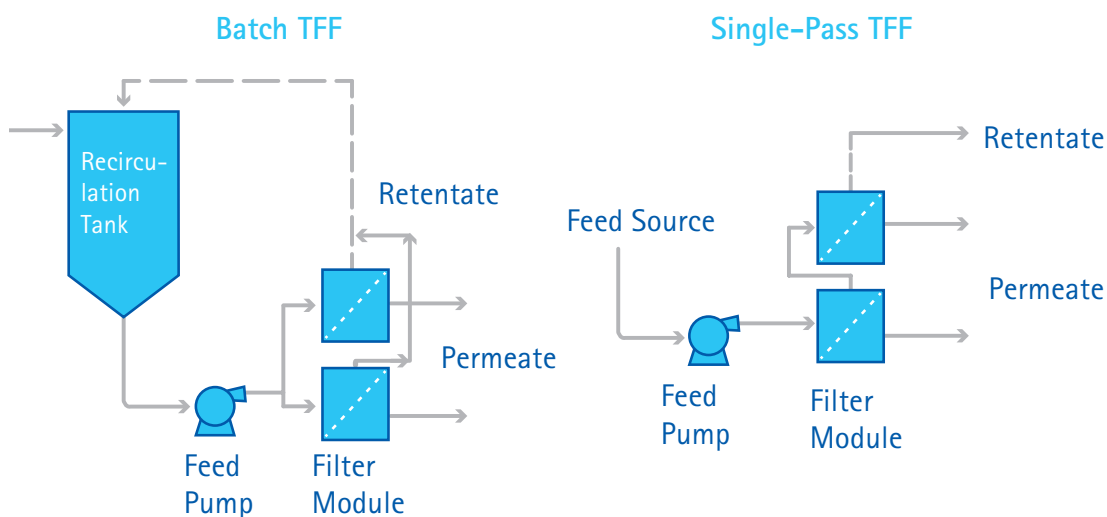


Figure 1.
Batch TFF vs. Single-Pass TFF

Specifications

Materials and Assembly

Materials of Construction:	Polypropylene Polyethylene Polyethersulfone Thermoplastic elastomer Stainless steel (0.57 m ² and 1.14 m ² cassettes only)
Preservative:	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, micro 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 200 hours (Contact Merck Millipore for exposure parameters.)
Operating pH Range:	2 - 14

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 an Merck Millipore facility which adheres to FDA Good Manufacturing Practices.
ISO® 9001 Quality Standard:	This product was manufactured in an Merck Millipore 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 the Merck Millipore 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	Feed Channel (mL)	Permeate Channel (mL)
88 cm ²	1.8	2.8
0.11 m ²	9	7
0.57 m ²	69	39
1.14 m ²	134	88



Pellicon® 3 Cassette (88 cm²)



Pellicon® 3 Cassette (0.11 m²)



Pellicon® 3 Cassette (0.57 m²)



Pellicon® 3 Cassette (1.14 m²)

Ordering Information

Pellicon® 3 Cassettes with Biomax® Membrane			
Description	Catalogue No.		
	10kD NMWL	30kD NMWL	50kD NMWL
88 cm ²	P3B 010 A00	P3B 030 A00	P3B 050 A00
0.11 m ²	P3B 010 A01	P3B 030 A01	P3B 050 A01
0.57 m ²	P3B 010 A05	P3B 030 A05	P3B 050 A05
1.14 m ²	P3B 010 A10	P3B 030 A10	P3B 050 A10

Accessories

Pellicon® 3 Cassette Holders			
Holder Type	Cassette Size	Area Range	Catalogue No.
Stainless Steel Mini-Holder	88 cm ² and 0.11 m ²	88 cm ² to 0.55 m ²	XX42PMINI
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
Manifold Support Plate	0.57 m ²	1.14 m ²	XXPEL3MAP
Process Scale Holder	0.57 m ² and 1.14 m ²	1.14 m ² and up	Contact Local Representative
Hydraulic Process Scale Holder	0.57 m ² and 1.14 m ²	1.14 m ² and up	Contact Local Representative

Cleaning

Description	Catalogue 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

Single-Pass TFF Accessories

Description	Catalogue No.
Diverter plate and silicon gasket kit for 88 cm 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

To Place an Order or Receive Technical Assistance

In the U.S. and Canada,
call toll-free 1-800-645-5476

For other countries across Europe and the world,
please visit: www.emdmillipore.com/offices

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