

Pellicon® 3 Cassettes with Ultracel® Membrane

The optimum tangential flow filtration devices for monoclonal antibodies and other therapeutic proteins.

Pellicon® 3 cassettes with Ultracel® membrane are advanced, high-performance cassettes that are ideal for today's higher titer therapeutic antibodies, as well as for the more demanding filtration processes that require higher operating pressures, temperatures, concentrations 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 cassette design and automated manufacturing process provide unbeatable performance consistency and enhanced linear scalability within the Pellicon® cassette family as well as within Pellicon® capsules. 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 composite 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
- Choice of screens to best optimize your process

Applications

- Monoclonal antibodies
- Recombinant and non-recombinant proteins
- Vaccine

Optimized feed channel design

For optimal performance in a range of applications, choose the Pellicon® 3 device with the Ultracel® membrane feed channel screen that best fits your needs. The C screen option is optimal for processes that require maximum mass transfer and flux. The D screen is optimized for applications that require higher viscosity and concentration.

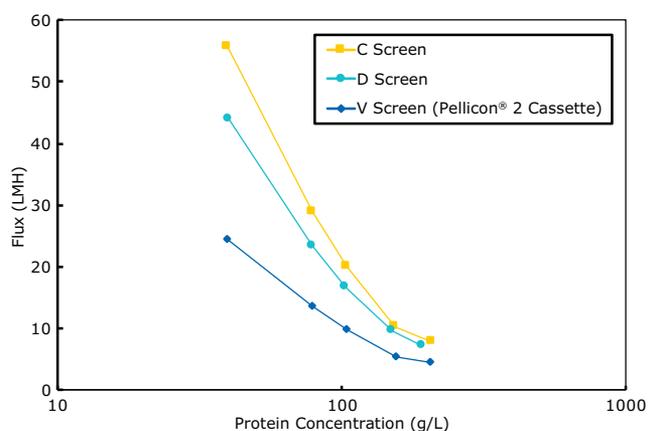
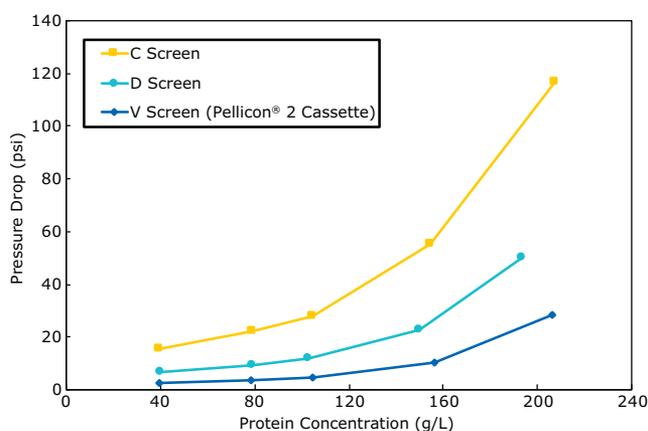
Achieve Higher Target Concentrations

Processing High Viscosity antibody concentrations > 150 g/L

Higher concentration processes have higher viscosities resulting in higher processing pressures. Our Pellicon® 3 Cassettes with Ultracel® 30 kDa membrane and 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 Ultracel® Membrane Screen Comparison



Optimum product recovery and high yields

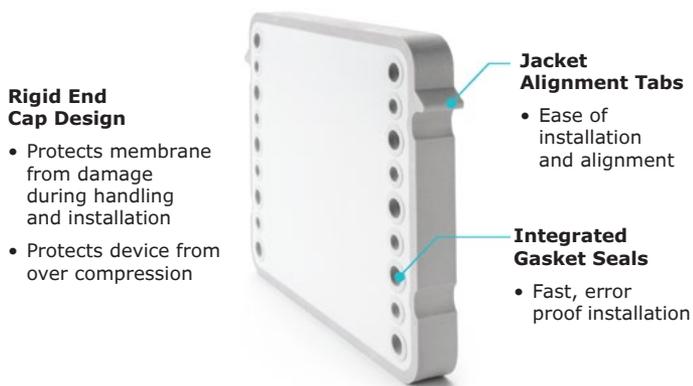
Ultracel® composite membranes offer low fouling and low protein binding for excellent product retention, recovery and higher yields. Ultracel® membranes are constructed of regenerated cellulose membrane cast on a microporous substrate for defect-free membranes with superior robustness compared to conventional membranes. The composite 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.

Extreme temperature and chemical capability

Pellicon® 3 cassettes are manufactured using the most modern polymers and plastics, enabling continuous operation at 50 °C and 0.5 N NaOH up to 50 hours*. These materials of construction ensure low extractables in a wide range of solvents, acids and bases.

*Contact your local representative for additional information.

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.

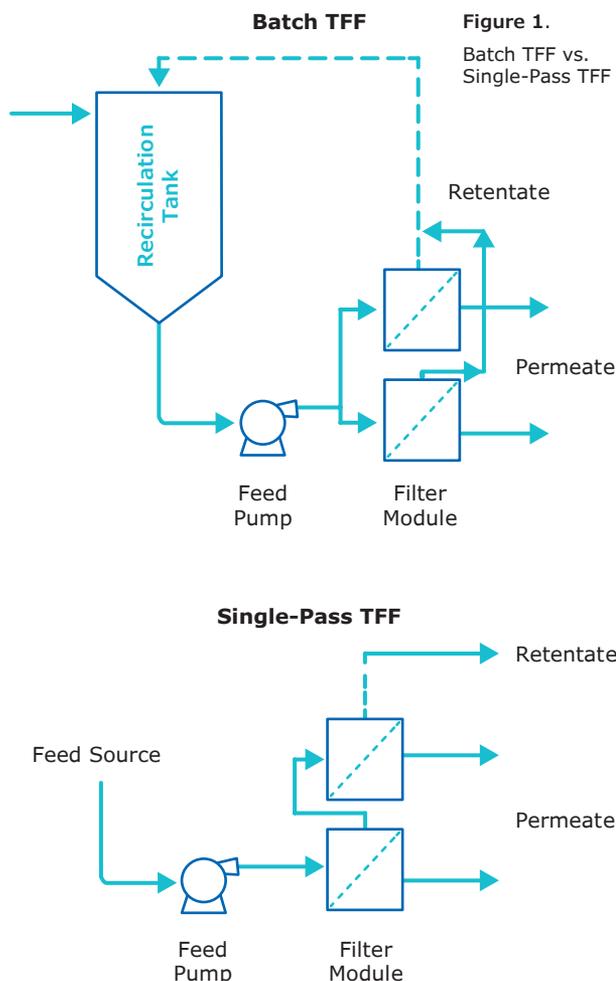
Each cassette is identified with a unique serial number and laser engraved with a 2D bar code linking to a unique Certificate of Quality.

Pellicon® Cassettes for 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



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: 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.

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 cm²)



Pellicon® 3 Cassette (0.11 m²)



Pellicon® 3 Cassette (0.57 m²)



Pellicon® 3 Cassette (1.14 m²)

Figure 4. Pellicon® 3 Cassette Sizes

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® Family

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

Mobius® FlexReady Solution with Flexware® Assemblies for TFF

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 m², 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

Specifications

Materials and Assembly

Materials of Construction	<ul style="list-style-type: none"> • Polypropylene • Polyethylene • Composite regenerated cellulose • Thermoplastic elastomer • Stainless steel (0.57 m² and 1.14 m² cassettes only)
Storage solution	1.1% acetic acid, 1.6% sodium phosphate, 24.8% glycerin and water
Membrane	Ultrace ^l ® membrane – Composite regenerated cellulose (regenerated cellulose membrane cast on a microporous polyethylene membrane)
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
Inlet Pressure	100 psi
Forward Transmembrane Pressure	80 psi (5.5 bar) at 4–40 °C, 200 hours continuous 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
Maximum Caustic Exposure (One Time)	0.5 N NaOH at 50 °C up to 50 hours
Operating pH Range	2–13

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.

Nominal Dimensions

Filtration Area	Length mm (in.)	Width mm (in.)	Thickness mm (in.)
C Screen			
88 cm ²	206 (8.1)	56 (2.2)	8 (0.3)
0.11 m ²	206 (8.1)	56 (2.2)	24 (0.9)
0.57 m ²	206 (8.1)	178 (7.0)	26 (1.0)
1.14 m ²	206 (8.1)	178 (7.0)	42 (1.7)
D Screen			
88 cm ²	206 (8.1)	56 (2.2)	8 (0.3)
0.11 m ²	206 (8.1)	56 (2.2)	25 (1.0)
0.57 m ²	206 (8.1)	178 (7.0)	29 (1.1)
1.14 m ²	206 (8.1)	178 (7.0)	45 (1.8)

Hold-Up Volumes

Membrane Area	Pellicon® 3 Cassettes with Ultracel® membrane with C Screen		Pellicon® 3 Cassettes with Ultracel® membrane with D Screen	
	Feed Channel (mL)	Permeate Channel (mL)	Feed Channel (mL)	Permeate Channel (mL)
88 cm ²	1.5	2.4	3.6	2.0
0.11 m ²	18	15	23	17
0.57 m ²	85	68	118	75
1.14 m ²	170	127	227	138

Ordering Information

Pellicon® 3 Cassettes with Ultracel® Membrane

Description	Cat. No.
3kDa NMWL with C Screen	
88 cm ²	P3C003C00
0.11 m ²	P3C003C01
0.57 m ²	P3C003C05
1.14 m ²	P3C003C10
5kDa NMWL with C Screen	
88 cm ²	P3C005C00
0.11 m ²	P3C005C01
0.57 m ²	P3C005C05
1.14 m ²	P3C005C10
10kDa NMWL with C Screen	
88 cm ²	P3C010C00
0.11 m ²	P3C010C01
0.57 m ²	P3C010C05
1.14 m ²	P3C010C10
30kDa NMWL with C Screen	
88 cm ²	P3C030C00
0.11 m ²	P3C030C01
0.57 m ²	P3C030C05
1.14 m ²	P3C030C10
30kDa NMWL with D Screen	
88 cm ²	P3C030D00
0.11 m ²	P3C030D01
0.57 m ²	P3C030D05
1.14 m ²	P3C030D10

Hardware*

Holder Type	Cassette Size	Area Range	Cat. No.
Pellicon® 3 Cassette Holders			
Stainless Steel Mini-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 Representative
Hydraulic Process Scale Holder	0.57 m ² and 1.14 m ²	1.14 m ² and up	Contact Local Representative
Holder Accessories			
Manifold Support Plate	0.57 cm ² and 1.14 m ²	NA	XXPEL3MAP

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

Cleaning

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.

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