ВЫСОКОЭФФЕКТИВНЫЕ ФИЛЬТРЫ PELLICON 3

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Россия +7(495)268-04-70
Казахстан +7(7172)727-132
Киргизия +996(312)96-26-47

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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 provides unbeatable performance consistency and enhanced linear scalability between cassette sizes. Pellicon® 3 cassettes 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 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 applications.

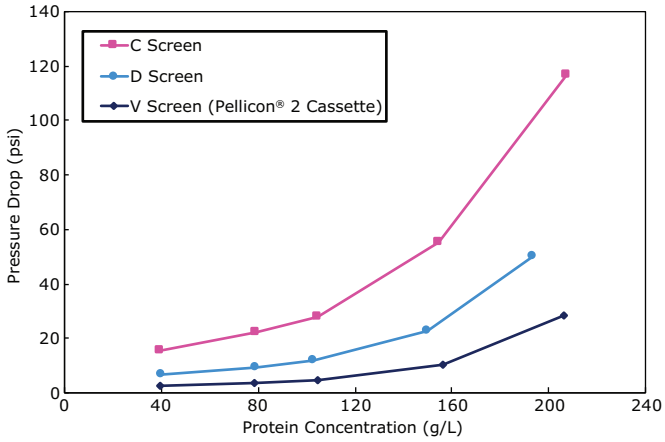
Achieve Higher Target Concentrations

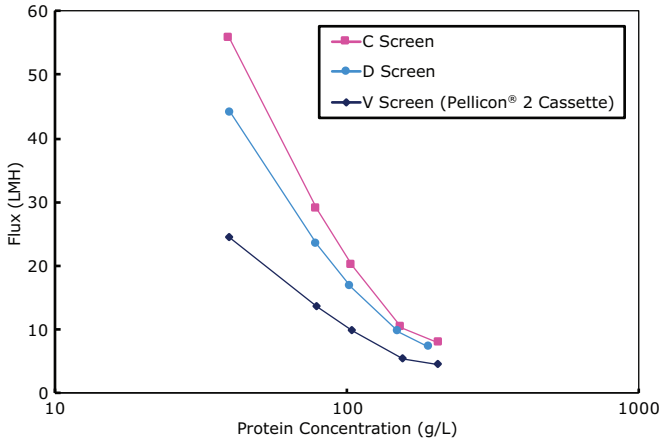
Processing High Viscosity antibody concentrations > 150 g/L

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 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

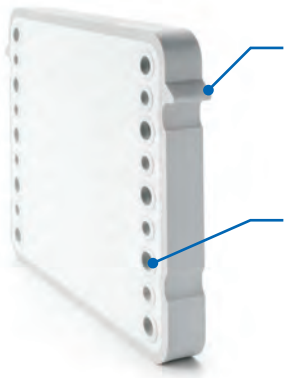
Offered in four sizes, 88 cm^2, 0.11 m^2, 0.57 m^2 and 1.14 m^2, all Pellicon® 3 cassettes are constructed of identical materials and have the same flow channel length, height, turbulence promoter and flow direction. This ensures that every Pellicon® 3 cassette maintains the same performance profile 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.

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

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 0.5N 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 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

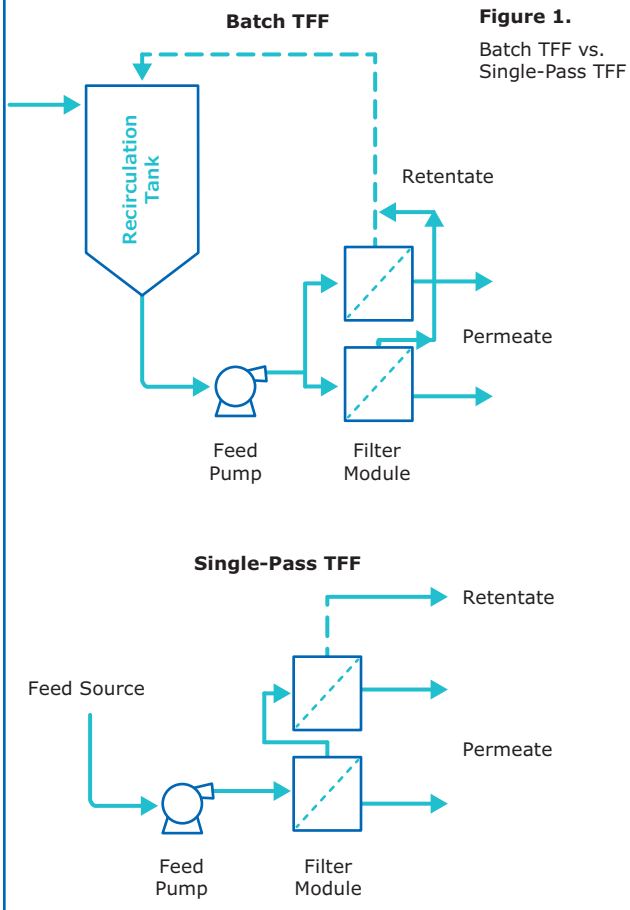


Figure 1.
Batch TFF vs. Single-Pass TFF

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 Donnan 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 BioReliance® Services team offers a range of validation services to help you meet your process and regulatory requirements.

Our experienced BioReliance® 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 cm²)

Pellicon® 3 Cassette (0.11 m²)

Pellicon® 3 Cassette (0.57 m²)

Pellicon® 3 Cassette (1.14 m²)

Specifications

Materials and Assembly

Materials of Construction	• Polypropylene • Polyethylene • Composite regenerated cellulose • Thermoplastic elastomer • Stainless steel (0.57 m^2 and 1.14 m^2 cassettes only)
Storage Solution	3-4% benzyl alcohol, 20% glycerin and water
Membrane	Ultracel® 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	4–8 $L/m^2/min$
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)	0.5N NaOH at 50°C up to 50 hours
Operating pH Range	2–13

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 that adheres to current 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 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. 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.

Nominal Dimensions

Filtration Area	Length mm (in.)	Width mm (in.)	Thickness mm (in.)
C-Screen			
88 cm^2	206 (8.1)	56 (2.2)	8.3 (0.33)
0.11 m^2	206 (8.1)	56 (2.2)	24 (0.93)
0.57 m^2	206 (8.1)	178 (7.0)	26 (1.03)
1.14 m^2	206 (8.1)	178 (7.0)	42 (1.66)
D-Screen			
88 cm^2	206 (8.1)	56 (2.2)	8.3 (0.33)
0.11 m^2	206 (8.1)	56 (2.2)	25 (0.98)
0.57 m^2	206 (8.1)	178 (7.0)	29 (1.13)
1.14 m^2	206 (8.1)	178 (7.0)	45 (1.78)

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 cm²	1.5	2.4	3.6	2.0
0.11 m²	18	15	23	17
0.57 m²	85	68	118	75
1.14 m²	170	127	227	138

Ordering Information

Pellicon® 3 Cassettes with Ultracel® Membrane

Description	Cat. No.
3kD NMWL with C-Screen	
88 cm²	**P3C003C00**
0.11 m²	**P3C003C01**
0.57 m²	**P3C003C05**
1.14 m²	**P3C003C10**
5kD NMWL with C-Screen	
88 cm²	**P3C005C00**
0.11 m²	**P3C005C01**
0.57 m²	**P3C005C05**
1.14 m²	**P3C005C10**
10kD NMWL with C-Screen	
88 cm²	**P3C010C00**
0.11 m²	**P3C010C01**
0.57 m²	**P3C010C05**
1.14 m²	**P3C010C10**
30kD NMWL with C-Screen	
88 cm²	**P3C030C00**
0.11 m²	**P3C030C01**
0.57 m²	**P3C030C05**
1.14 m²	**P3C030C10**
30kD NMWL with D-Screen	
88 cm²	**P3C030D00**
0.11 m²	**P3C030D01**
0.57 m²	**P3C030D05**
1.14 m²	**P3C030D10**

Accessories

Holder Type	Cassette Size	Area Range	Cat. No.
Pellicon® 3 Cassette Holders			
Stainless Steel Mini-Holder	88 cm² and 0.11 m²	88 cm² to 0.55 m²	**XX42PMINI**
Acrylic Cassette Holder Low Retentate Volume	0.57 m² and 1.14 m²	0.57 m² to 5.7 m²	**XX42PRV60**
Stainless Steel Holder	0.57 m² and 1.14 m²	0.57 m² to 5.7 m²	**XX42P0080**
Stainless Steel Cassette Holder and Assembly	0.57 m² and 1.14 m²	0.57 m² to 5.7 m²	**XX42P0K80**
Manifold Support Plate	0.57 m² and 1.14 m²	NA	**XXPEL3MAP**
Process Scale Holder	0.57 m² and 1.14 m²	1.14 m² and up	**Contact Local Representative**
Hydraulic Process Scale Holder	0.57 m² and 1.14 m²	1.14 m² and up	**Contact Local Representative**

Cleaning

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**

Single-Pass TFF Accessories

Description	Cat. No.
Diverter plate and silicone gasket kit for 88 cm² cassette	**XXSPTFF01**
Diverter plate for 0.57 m² and 1.14 m² cassettes	**XXSPTFF02**
Retentate collection plate for 0.57 m² and 1.14 m² cassettes	**XXSPTFF03**

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