

# 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.

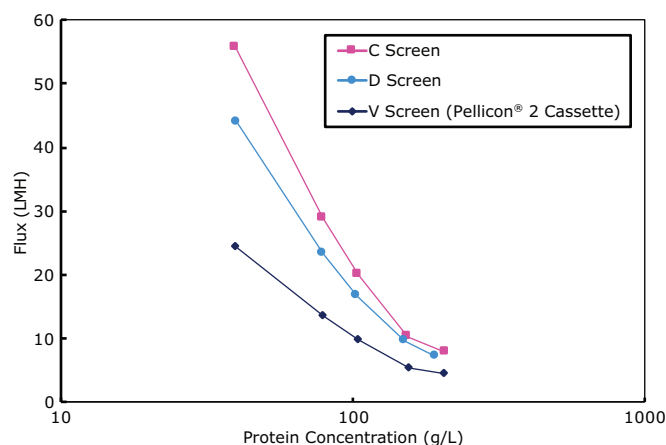
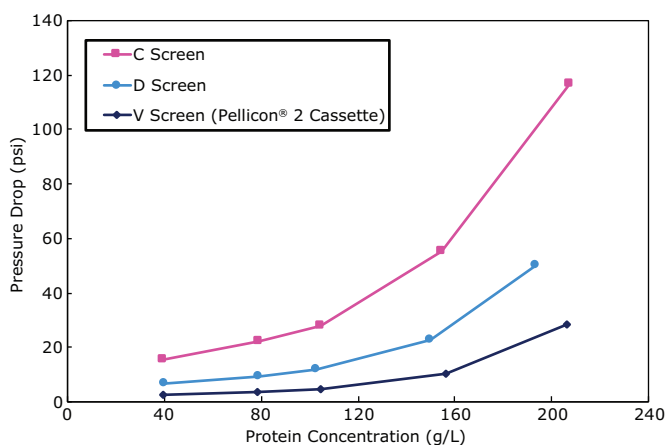
### Achieve Higher Target Concentrations

#### 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<sup>2</sup>, 0.11 m<sup>2</sup>, 0.57 m<sup>2</sup> and 1.14 m<sup>2</sup>, 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.

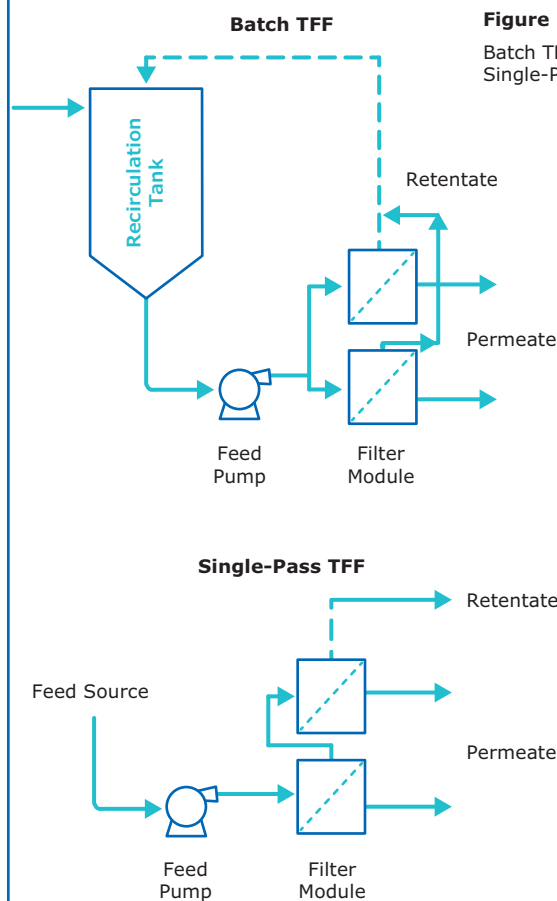
Each cassette is identified with a unique serial number and shipped with an individual Certificate of Quality.

## 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

## 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

### 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 3.**  
Mobius® FlexReady Solution with Flexware® Assemblies.



**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 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 cm<sup>2</sup>)**



**Pellicon® 3 Cassette (0.11 m<sup>2</sup>)**



**Pellicon® 3 Cassette (0.57 m<sup>2</sup>)**



**Pellicon® 3 Cassette (1.14 m<sup>2</sup>)**

## Specifications

### Materials and Assembly

<b>Materials of Construction</b>	<ul style="list-style-type: none"> <li>• Polypropylene</li> <li>• Polyethylene</li> <li>• Composite regenerated cellulose</li> <li>• Thermoplastic elastomer</li> <li>• Stainless steel (0.57 m<sup>2</sup> and 1.14 m<sup>2</sup> cassettes only)</li> </ul>
<b>Storage Solution</b>	3-4% benzyl alcohol, 20% glycerin and water
<b>Membrane</b>	Ultracel® membrane – Composite regenerated cellulose (regenerated cellulose membrane cast on a microporous polyethylene membrane)
<b>Assembly Design</b>	Automated assembly and testing of heat-sealed packets bound together by an injection-molded polypropylene jacket

### Maximum Operating Conditions

<b>Recommended Feed Flow Rate</b>	4–8 L/m <sup>2</sup> /min
<b>Inlet Pressure</b>	100 psi
<b>Forward Transmembrane Pressure</b>	80 psi (5.5 bar) at 4–40°C, 200 hours continuous 40 psi (2.7 bar) at 4–50°C, 50 hours continuous
<b>Reverse Transmembrane Pressure</b>	30 psi (2.1 bar) at 25°C, 3 min intervals, 10 cycles
<b>Maximum Caustic Exposure (One Time)</b>	0.5N NaOH at 50°C up to 50 hours
<b>Operating pH Range</b>	2–13

### Regulatory Information

<b>Component Material Toxicity</b>	Component materials were tested and meet the criteria of the USP <88> Biological Reactivity Tests for Class VI Plastics.
<b>Good Manufacturing Practices</b>	These products are manufactured in a facility that adheres to current Good Manufacturing Practices.
<b>ISO® 9001 Quality Standard</b>	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.
<b>100% Integrity Tested in Manufacturing</b>	Each unit must pass our integrity test based on air flow through the fully wetted membranes of the filter.
<b>Validated Production Process</b>	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.)
<b>C-Screen</b>			
88 cm <sup>2</sup>	206 (8.1)	56 (2.2)	8.3 (0.33)
0.11 m <sup>2</sup>	206 (8.1)	56 (2.2)	24 (0.93)
0.57 m <sup>2</sup>	206 (8.1)	178 (7.0)	26 (1.03)
1.14 m <sup>2</sup>	206 (8.1)	178 (7.0)	42 (1.66)
<b>D-Screen</b>			
88 cm <sup>2</sup>	206 (8.1)	56 (2.2)	8.3 (0.33)
0.11 m <sup>2</sup>	206 (8.1)	56 (2.2)	25 (0.98)
0.57 m <sup>2</sup>	206 (8.1)	178 (7.0)	29 (1.13)
1.14 m <sup>2</sup>	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 cm <sup>2</sup>	1.5	2.4	3.6	2.0
0.11 m <sup>2</sup>	18	15	23	17
0.57 m <sup>2</sup>	85	68	118	75
1.14 m <sup>2</sup>	170	127	227	138

## Ordering Information

### Pellicon® 3 Cassettes with Ultracel® Membrane

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

### Accessories

Holder Type	Cassette Size	Area Range	Cat. No.
<b>Pellicon® 3 Cassette Holders</b>			
Stainless Steel Mini-Holder	88 cm <sup>2</sup> and 0.11 m <sup>2</sup>	88 cm <sup>2</sup> to 0.55 m <sup>2</sup>	XX42PMINI
Acrylic Cassette Holder Low Retentate Volume	0.57 m <sup>2</sup> and 1.14 m <sup>2</sup>	0.57 m <sup>2</sup> to 5.7 m <sup>2</sup>	XX42PRV60
Stainless Steel Holder	0.57 m <sup>2</sup> and 1.14 m <sup>2</sup>	0.57 m <sup>2</sup> to 5.7 m <sup>2</sup>	XX42P0080
Stainless Steel Cassette Holder and Assembly	0.57 m <sup>2</sup> and 1.14 m <sup>2</sup>	0.57 m <sup>2</sup> to 5.7 m <sup>2</sup>	XX42P0K80
Manifold Support Plate	0.57 m <sup>2</sup> and 1.14 m <sup>2</sup>	NA	XXPEL3MAP
Process Scale Holder	0.57 m <sup>2</sup> and 1.14 m <sup>2</sup>	1.14 m <sup>2</sup> and up	Contact Local Representative
Hydraulic Process Scale Holder	0.57 m <sup>2</sup> and 1.14 m <sup>2</sup>	1.14 m <sup>2</sup> 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 cm <sup>2</sup> cassette	XXSPTFF01
Diverter plate for 0.57 m <sup>2</sup> and 1.14 m <sup>2</sup> cassettes	XXSPTFF02
Retentate collection plate for 0.57 m <sup>2</sup> and 1.14 m <sup>2</sup> cassettes	XXSPTFF03

## To Place an Order or Receive Technical Assistance

Please visit  
[MerckMillipore.com/contactPS](https://www.MerckMillipore.com/contactPS)

For additional information, please visit  
[MerckMillipore.com](https://www.MerckMillipore.com)

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