pure confidence

Scale-up quickly and reliably with Pellicon® Tangential Flow Filtration Cassettes
Pellicon TFF cassettes set the standard in scalable, reliable performance.

Tangential flow filtration (TFF) is a separation process that uses membranes to separate components in a liquid solution or suspension on the basis of size or molecular weight differences. Pellicon cassettes combine the advantages of efficient, gentle processing and linear scalability for effective, predictable scale-up from laboratory to process applications. Whether you are clarifying, concentrating or purifying milliliters or thousands of liters of solution, you can have confidence in the Pellicon product family of TFF cassettes to take you from bench top to process volumes with predictable, scalable results. The rugged design and chemical compatibility of Pellicon cassettes makes it the most reliable and best performing ultrafiltration system available.

Starting with the first cassette in 1973, the Pellicon product family of TFF products has continued to expand and improve over the years, with our product development team continuously working to extend the technology to new applications. Millipore has most recently introduced the Pellicon XL, the next generation of Pellicon cassettes that sets a new standard in performance with a choice of premier membranes, thermoplastic design to minimize extractables, and ease-of-use features.

Millipore is dedicated to providing the highest quality and most innovative products, based on membrane and chromatography technologies, to our pharmaceutical and biotechnology customers. Our Applications Specialists and Systems Engineers can offer the technical and business advantage to solve our customers’ development and manufacturing challenges. With Millipore’s Pellicon cassettes, you can have confidence that your process will reliably scale-up and yield high purity product.
Because of their reputation for performance and reliability, Pellicon cassettes with Millipore’s membranes have been employed in virtually every plasma, vaccine and biotech protein production process in the world.

Starting with the Pellicon XL and Pellicon 2 Mini cassettes for laboratory and process development and moving up to higher volumes with the Pellicon 2 Cassette or Pellicon 2 Maxi cassette, Millipore incorporates the same membrane and channel geometry throughout the entire Pellicon family of products. All flow paths are identical in length, width, height, spacer, and are fed in parallel. Therefore, every Pellicon cassette operates with the same pressure drop, flow velocity, and concentration profile and has been demonstrated to be accurate in 1:10,000 fold scale-up. Not all cassettes on the market can provide linearity because they change feed or permeate flow channel dimensions or flow directions. This creates different pressure, flow and concentration gradients in each device and necessitates repetitive scaling tests. Pellicon cassettes offer true linearity because Millipore understands that the speed of scale-up and the reduction in the number of scaling tests means increased productivity by getting your product ready for market faster, easier and safer.

Increase your speed to market by reducing scale-up testing.

Pellicon cassettes’ true linear scalability allows for faster but gentler processing of proteins. This results in higher product yields and a more cost-effective solution for your purification and separation needs.
Pellicon cassettes are available in a range of membranes, feed channels, and surface areas to meet your application needs.

Millipore’s 45 years of leadership in membrane technology has resulted in innovative processes for the biopharmaceutical industry. Our Applications Specialists and System Engineers understand the needs of bioprocessing engineers and scientists and can optimize the Pellicon cassettes by helping you to select the right membrane, channel configuration, and surface area for each application. The result is a Pellicon TFF cassette that has you up and running quickly and effectively.

**HIGH PURITY, HIGH YIELD, FAST PROCESSING WITH VOID-FREE UF MEMBRANES**

Millipore membranes are constructed of robust materials that minimize extractables and assure the highest purity and cleanliness, and come in a range of chemical types and molecular weight cut-offs. The unique void-free structure provides consistent integrity and retention performance, stable hydraulic performance, and improved yield and capacity. Our membranes are subjected to our advanced multiple-solute retention profile tests to measure and ensure reproducible performance.

<table>
<thead>
<tr>
<th>PROPERTY</th>
<th>BIO MAX MEMBRANES</th>
<th>ULTRACL PLC MEMBRANES</th>
</tr>
</thead>
<tbody>
<tr>
<td>MEMBRANE</td>
<td>Polyethersulfone with void-free structure</td>
<td>Composite regenerated cellulose with void-free structure</td>
</tr>
<tr>
<td>MOLECULAR WEIGHT CUT-OFF</td>
<td>5 kD-1,000 kD</td>
<td>5 kD-1,000 kD</td>
</tr>
<tr>
<td>RELATIVE PROTEIN BINDING</td>
<td>Low to medium – use with &gt; 0.1 mg/mL solutions</td>
<td>Ultra low – far superior for use with dilute protein solutions</td>
</tr>
<tr>
<td>pH RANGE</td>
<td>1-14</td>
<td>2-13</td>
</tr>
<tr>
<td>KEY BENEFIT</td>
<td>• Highest flux</td>
<td>• Ultra low protein binding</td>
</tr>
<tr>
<td></td>
<td>• Chemical compatibility</td>
<td>• Solvent resistant</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Easy to clean</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Use with defoamers</td>
</tr>
</tbody>
</table>
Pellicon cassettes incorporate screened feed channels for high flux at low cross flow and low working volumes. This results in more economical system sizes and faster filtration with higher concentration factors. The lower membrane area minimizes product hold up and adsorption, which in turn increases yields.

The Pellicon cassette technology is available in a range of surface areas, for process development to purifying large volumes in pilot or manufacturing scale. The membranes and feed channels stay the same, ensuring an easy-to-use, scale-up or scale-down transition from one surface area to the next.

**FEED CHANNELS FOR VISCOSITY AND VOLUMETRIC CONCENTRATION**

<table>
<thead>
<tr>
<th>CHANNEL TYPE</th>
<th>High Pressure Drop</th>
<th>Low Pressure Drop</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>A Screen (fine screen)</td>
<td>C Screen (coarse screen)</td>
</tr>
<tr>
<td></td>
<td>V Screen (suspended screen)</td>
<td></td>
</tr>
<tr>
<td>SOLUTION TYPE</td>
<td>Dilute protein solution or low viscosities (Monoclonal antibodies)</td>
<td>Concentrated protein solutions or high viscosities (IgG, biopolymers)</td>
</tr>
</tbody>
</table>

**FROM PROCESS DEVELOPMENT TO LARGE-SCALE ULTRAFILTRATION**

The Pellicon cassette technology is available in a range of surface areas, for process development to purifying large volumes in pilot or manufacturing scale. The membranes and feed channels stay the same, ensuring an easy-to-use, scale-up or scale-down transition from one surface area to the next.

<table>
<thead>
<tr>
<th>CASSETTE</th>
<th>Pellicon XL 50 cassettes</th>
<th>Pellicon 2 Mini cassettes</th>
<th>Pellicon 2 Cassettes</th>
<th>Pellicon 2 Maxi cassettes</th>
</tr>
</thead>
<tbody>
<tr>
<td>SURFACE AREA</td>
<td>50 cm²</td>
<td>0.1 m²</td>
<td>0.5 m²</td>
<td>2.5 m² *</td>
</tr>
<tr>
<td>APPLICATIONS</td>
<td>process development</td>
<td>laboratory ultrafiltration</td>
<td>process development, pilot or small manufacturing</td>
<td>large pilot or manufacturing</td>
</tr>
<tr>
<td>VOLUMES</td>
<td>15 to 1000 mL</td>
<td>80 mL to 10 liter</td>
<td>2 L or more</td>
<td>250 L or more</td>
</tr>
</tbody>
</table>

* 2.0 m² with V-screen
In order to help you to achieve regulatory compliance, Millipore offers a number of validation services to ensure that all your process filtration is in compliance. Millipore can provide this service on site, a unique advantage, in order to field test, qualify and certify the equipment under actual operating conditions. By using Access™ Pharmaceutical Filtration Services, you enjoy the advantage of a supplier with experience in dealing with the FDA, EMEA, TGA, the MCA, Koseisho, and other biopharmaceutical regulatory agencies. Our services can help you speed your time to market and keep your process optimized and in control.

Pellicon cassettes are manufactured in a cGMP compliant facility and are 100% integrity tested in manufacturing to ensure rugged and reliable performance. All Quality Control test procedures and specifications are supplied in the Certificate of Quality and Validation Guides. In addition, Pellicon cassettes are subjected to a complete array of quality control release tests. All wetted parts meet the requirements of USP Class VI testing and CFR 21 regulations. Pellicon cassettes are designed, developed and manufactured in accordance with a Quality Management System approved by an accredited registering body to an ISO 9000 Quality Systems Standard.

Achieve regulatory compliance

In order to help you to achieve regulatory compliance, Millipore offers a number of validation services to ensure that all your process filtration is in compliance. Millipore can provide this service on site, a unique advantage, in order to field test, qualify and certify the equipment under actual operating conditions. By using Access™ Pharmaceutical Filtration Services, you enjoy the advantage of a supplier with experience in dealing with the FDA, EMEA, TGA, the MCA, Koseisho, and other biopharmaceutical regulatory agencies. Our services can help you speed your time to market and keep your process optimized and in control.

Validation and pharmaceutical services include:
- Extractables Analysis for custom compatibility testing and recommendations.
- Automatic Integrity Testing Validation to support IQ/OQ for tangential flow as well as cartridge filters.
- Filtration Process Review for on-site analysis of filter performance.

In addition, Millipore can also assist your validation efforts through:
- Applications engineering capabilities from biopharmaceutical specialists to help integrate and optimize the use of TFF technology in your facility.
- Design and fabrication of standard and custom turnkey TFF systems for drug manufacturing facilities using Millipore’s own specialized equipment manufacturing facilities registered to an ISO 9000 Quality Systems Standard.
- Installation and operational qualification services with complete documentation and testing packages.
- Training on TFF process scale-up, optimization, validation and development.
Applications

- Concentration, clarification, and desalting of proteins and other biomolecules such as nucleotides, antigens, and monoclonal antibodies
- Buffer exchange
- Process development - scale-up and scale-down studies
- Membrane selection studies
- Pre-chromatographic clarification to remove colloidal particles
- Depyrogenation of small molecules such as dextrose and antibiotics
- Harvest, washing, or clarification of cell cultures, lysates, colloidal suspensions, and viral cultures
- Sample preparation
**Labscale™ TFF System**
A complete ready-to-use system that concentrates, desalts, and exchanges buffers using a Pellicon XL cassette for starting volumes from 1.5 to 1000 mL.
- The 500 mL reservoir accepts direct docking of the Pellicon XL cassette for quick and easy assembly.
- Multimanifold option combines up to three Pellicon XL cassettes for faster processing of increased volumes or simultaneous testing of up to 3 different membranes.

**Pellicon Holders**
Pellicon cassette holders come in various sizes and choices of materials.
- Pellicon 2 Mini Holder in stainless steel for sanitary applications operates one to three Mini cassettes for process development and small volume manufacturing.
- Acrylic Pellicon Holder for non-sanitary applications allowing for up to 5 m² of filter area.
- Stainless Steel Pellicon System Holder connects to existing sanitary pump and piping for up to 5 m² of filter area.
- Process Scale Pellicon System Holder is vertically mounted for a compact footprint and easy to change cassettes, expands for a total membrane area of 80 m² per holder.

**ProFlux® Systems**
From bench-top to large floor models, ProFlux systems offer a series of highly flexible filtration systems. Each system uses a common user interface, which facilitates training and product development as well as maintains consistency in the facility.
- The sanitary bench-top ProFlux M12 system processes up to 100 liters for R&D, pilot studies and small-scale production. The compact system is simple to operate, easy to clean, and includes time-saving automation.
- The sanitary ProFlux A30 and A60 Systems (with automated control) and M30 and M60 Systems (for manual operation) are ideal for concentration, clarification or purification of up to 500 liters of solution in development or production applications. The systems feature low hold-up volumes to allow high concentration factors.
- Larger ProFlux systems are available for processing thousands of liters.

**Custom Engineered Systems**
Millipore’s Custom Engineered TFF Systems offer high yields and optimum operating efficiency while simultaneously being designed for sanitary, validatable operation. These systems feature time-saving options such as automated diafiltration, product recovery, clean-in-place, steam-in-place and integrity testing. Millipore can supply custom systems in any size range and with any degree of automation.

*Up to 4 m² for Pellicon 2 Cassettes with V screen

Please refer to the enclosed data sheets for each product's specifications and ordering information.

For further information about Pellicon TFF products, contact the Millipore subsidiary nearest you or call us at 781-533-6000. In the U.S. and Canada call 1-800-MILLIPORE. Or visit our web site at www.millipore.com/bioprocess or email us at tech_service@millipore.com

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