Millipore®
Preparation, Separation,
Filtration & Monitoring Products

Data Sheet

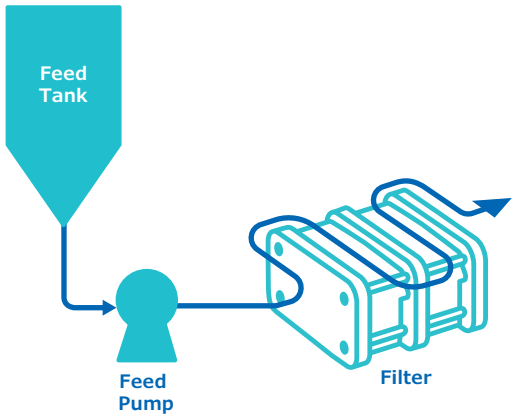
BioContinuum™ Ultrafiltration Platform

Pellicon® Single-Pass Tangential Flow Filtration

Versatile ultrafiltration technology for biopharmaceutical processes requiring flexibility, capacity, and efficiency.

Pellicon® single-pass tangential flow filtration (single-pass TFF) is a versatile technology for more productive, high capacity and cost effective downstream processes that allows facilities to meet the demands of higher titer and connected or continuous processes. Its small footprint makes single-pass TFF convenient to implement anywhere in a process where volume reduction is needed to eliminate tank bottlenecks, reduce column sizes, and/or increase the performance of chromatography and filtration steps.

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 higher 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.



Benefits

- Versatile applicability for process intensification
- Reliable performance with proven Pellicon® cassettes and capsules
- Easy installation and operation
- Fast, reliable scale-up/down from lab to production
- Comprehensive choice of membrane sizes, types, and cut-offs to best match your process requirements

Applications

- Monoclonal antibodies (mAbs)
- Recombinant and non-recombinant proteins
- Plasma
- Vaccines

Ideal for...

- Achieving high concentrations and high yields
- In-process volume concentration for improved facility fit
- Intensified performance for chromatography and filtrations steps
- Connected and continuous processes

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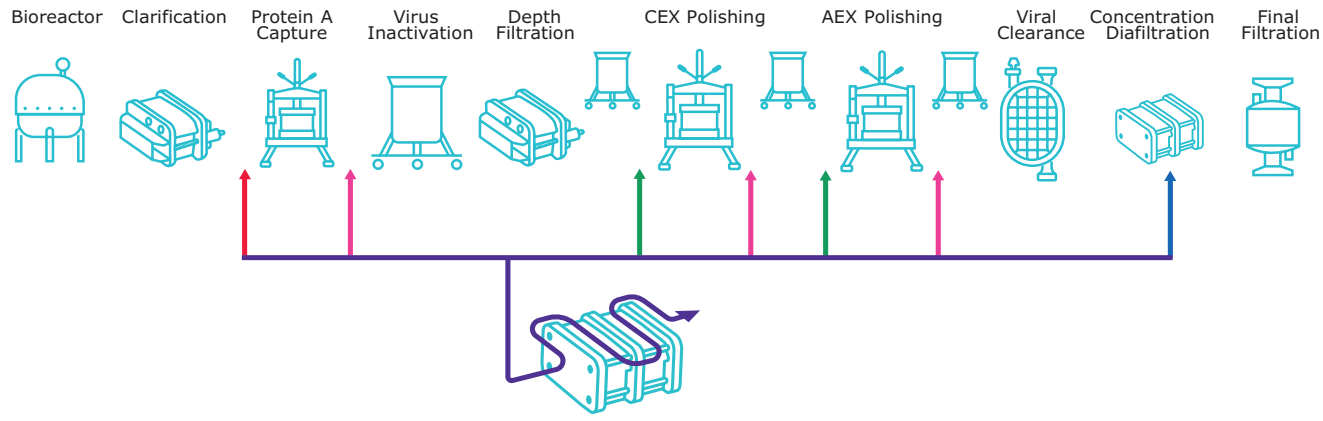
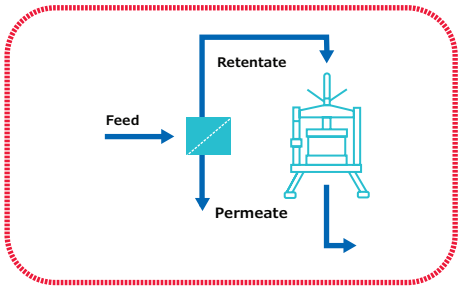
Versatile applicability for process intensification

Pellicon® single-pass TFF is a convenient way to reduce volumes to eliminate tank bottlenecks, reduce the size of subsequent steps, concentrate with inline buffer addition for desalting, and facilitate high final product concentration with greatly improved recovery.

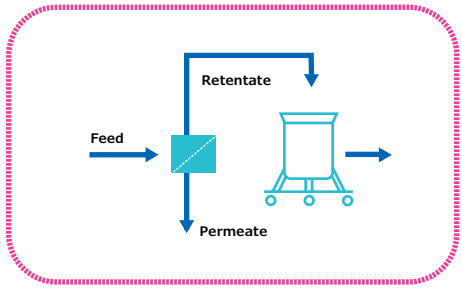
The small footprint of single-pass TFF facilitates the integration of inline concentration steps anywhere within a biomanufacturing process where volume reduction is needed, including before or after column chromatography or at final concentration and formulation.





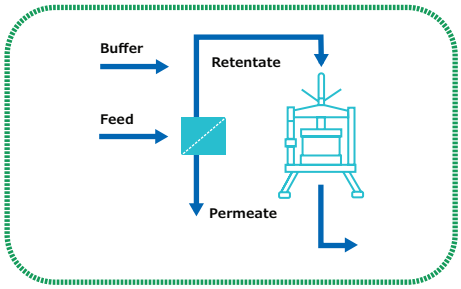
Intensified Capture

- Reduce low titer/high volume product pools
- Faster loading



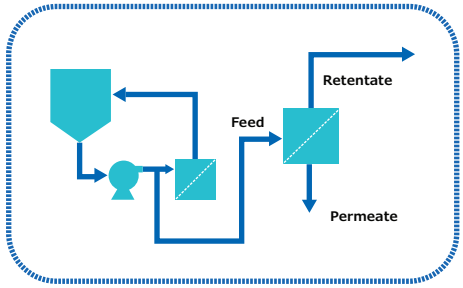
In-process Pool Concentration

- Reduce volumes expanded beyond tank capacity
- Eliminate tank requirements



Intensified Polishing

- Reduce column size, buffer volume, and time
- Higher column productivity



Final Ultrafiltration

- Higher final concentration
- Simplified and higher product recovery

Reliable performance

Integration of single-pass TFF into a biomanufacturing process is easy with existing, proven Pellicon® cassettes and capsules.

Pellicon® Cassettes

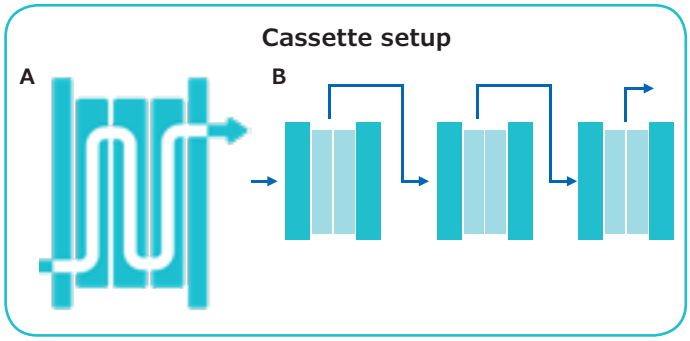
Our high performance Pellicon® 2 and 3 cassettes deliver high protein yield and consistent product purity and quality from run to run at every scale and for a variety of drug products. Pellicon® cassettes are designed for use in research, process scale-up/down, applications development, and commercial manufacturing. The materials of construction are compatible with a broad range of cleaning agents required for proper membrane regeneration with no product carryover after multiple cycles of reuse.

Pellicon® Capsules

Pellicon® Capsules are the ideal TFF devices for the filtration of solutions that require single-use capabilities, providing enhanced ease-of-use, process flexibility, rapid batch turnaround, and reduced risks. Our innovative capsules have a holderless design and are provided gamma sterilized and wetted with purified water for easy installation and reduced pre-use steps. The self-contained format of capsules makes it easier and safer to remove the entire flow path to reduce risks of operator exposure and product cross-contamination.

Easy installation and operation

Pellicon® single-pass TFF operates at constant feed flow rates and retentate pressures for simpler operation and smaller pump requirements compared to batch TFF. The straight-through flow path lowers working volumes that limit concentration factors and reduces footprint for improved facility fit. Existing Pellicon® filters and accessories are easily installed for single-pass operation. Pellicon® cassettes can be configured in single-pass mode by use of same-sized diverter plates (A) or connecting standard holders in series (B). Pellicon® Capsules are easily connected from port to port, simplifying installation even further.



Fast, reliable scale-up/down from lab to production

Pellicon® 2 and 3 cassettes, available in several sizes, are designed to offer consistent performance at every scale for predictable and reliable scale-up. Furthermore, Pellicon® Capsules provide the same high performance and linear scalability of Pellicon® cassettes, making it easy to transition between either filter format. Small-scale experiments are simple to execute and analyze. With one simple trial, fast evaluation of optimum feed flow rate and number of sections over a wide range of conversion targets is possible. To scale-up single-pass TFF, the feed flow rate and number of sections in series are simply maintained at values determined at bench scale.

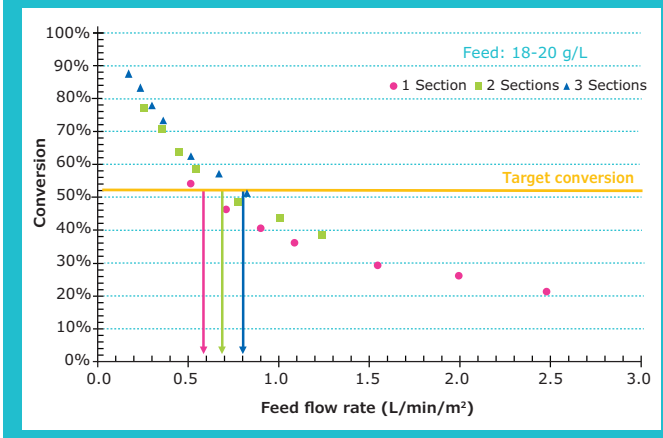
Small-scale evaluation and sizing

Small-scale experiments for single-pass TFF are performed with three identical Pellicon® 3 cassettes assembled in a Pellicon® mini holder with mini diverter plates (Pellicon® single-pass TFF mini kit).

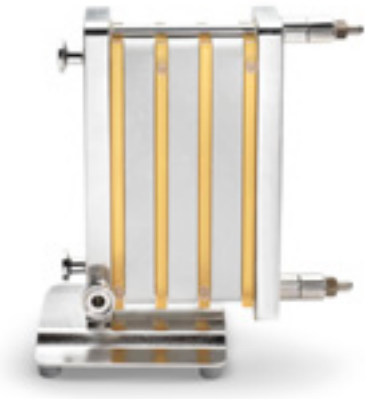
The specially designed diverter plates are used to allow the retentate of one cassette to serve as the feed for the next, generating a serial feed flow path through the filter assembly. This assembly allows the operator to simultaneously evaluate the conversion performance of one-, two-, and three-section processes in 4-6 hours of run time using 1-2 liters of feed material.

One user-configurable assembly for any conversion target

- Fast evaluation of optimum feed flow rate
- Precise selection of number of sections
- Easy scale-up, from lab to production



The required feed flow rate for a conversion target of 52% (—) is 0.6 L/min/m² for a one-section assembly (●), 0.7 L/min/m² for a two-section assembly (■), and 0.8 L/min/m² for a three-section assembly (▲).



Cassette lab-scale single-pass TFF setup

Cassette pilot-scale single-pass TFF setup

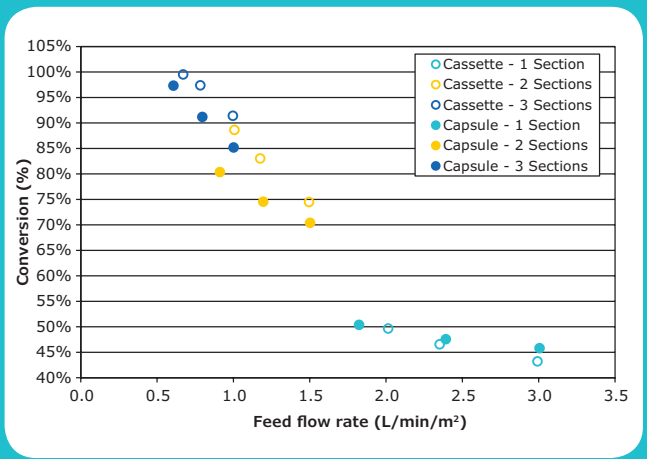
Using single-use technology for single-pass TFF

As more bioprocess operations move toward a single-use approach, there is a growing need for more options to streamline single-use unit operations via technologies such as single-pass TFF.

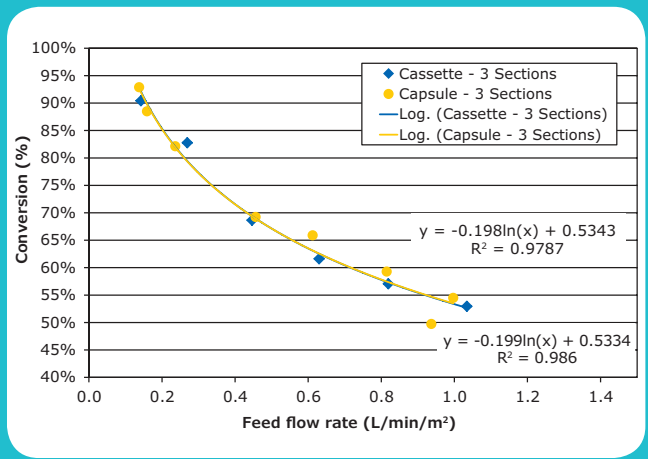
Pellicon® Capsules are ideally suited for single-pass TFF as no holder or diverter plates are required. The single-pass flow path is configured by simply connecting the capsules in series, typically using the “N” configuration where capsules are connected directly from port to port, retentate to feed.

Pellicon® Capsules perform comparably to Pellicon® 3 cassettes, offering high conversions at both low and high feed concentrations.

Comparison of Pellicon® Capsule and Pellicon® 3 Cassette with Ultracel® membrane and C screen



Feed flux excursions, 1 g/L BgG.



Feed flux excursions, 25 g/L BgG (shown for 3 sections).

Comprehensive choice of Pellicon® filters to best match your process requirements

Our Pellicon® family of ultrafiltration products feature devices with Ultracel® or Biomax® membranes in a wide range of surface areas and molecular weight cut-offs, and with several options of feed channel screens for optimal performance to suit different process challenges.

Our broad selection of tangential flow filters enables bench-to-process scale single-pass filtration of mAbs, recombinant proteins, plasma, albumin, hormones, growth factors, vaccines, and viruses.

Biomax® membrane

The high flux and high retention properties of Biomax® membranes result in faster processing with high yields. Composed of modified polyethersulfone (PES), Biomax® membranes are designed to reduce non-specific protein binding compared to conventional PES membranes. They are resistant to harsh chemicals used in cleaning, biological decontamination, and sanitization with no degradation of processing performance over multiple cleaning cycles.

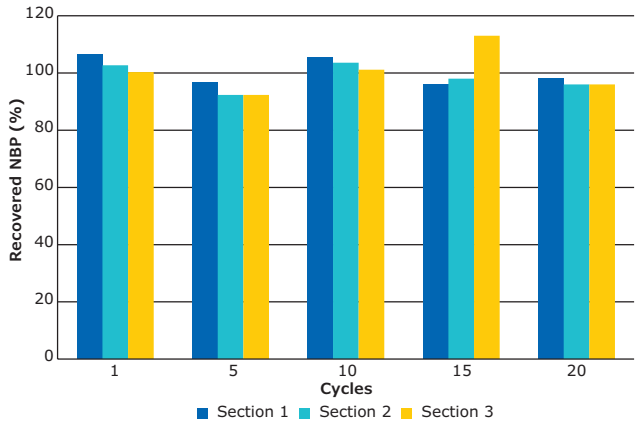
Ultracel® membrane

Ultracel® membranes are constructed of regenerated cellulose cast on a microporous substrate that creates a uniform structure with superior robustness compared to conventional membranes. Ultracel® membranes are used for processes that require low fouling and ultra-low protein binding capabilities and offer resistance to organic solvents together with excellent product retention, recovery, and yields.

Excellent cleanability

Cleaning of single-pass TFF Pellicon® cassettes can be performed without a recirculation loop using typical cleaning agents. Pellicon® cassettes offer excellent cleanability, demonstrated by their consistent cleaning efficiency for each membrane section over multiple process runs and cleaning cycles.

Normalized buffer permeability (NBP) over 20 reuse cycles.



Pellicon® 3 cassette with Ultracel® 30 kDa membrane

Global service and support

Our approach revolves around your specific needs so that we can best address your process requirements. Our skilled and experienced engineers provide comprehensive support to ensure optimized performance and rapid implementation of Pellicon® single-pass TFF anywhere within your process. With careful consideration of your specific process needs, our technical experts help achieve the operational results you need throughout process development, scale-up, and production implementation.

Setup components

To run single-pass TFF, Pellicon® cassettes are installed in existing Pellicon® holders and the serial flow path is typically generated by use of specially designed diverter plates. Standard cassettes are inserted between diverter plates for equal membrane area per section. For most applications, a 3-section (3 cassettes) assembly is sufficient and allows for easy evaluation of a range of concentration targets and quick optimization. The Pellicon® single-pass TFF mini kit is ideally suited for start-up trials with cassettes. Larger diverter plates are available for scale-up. For single-use applications, Pellicon® Capsules are connected from port to port using off-the-shelf components.

Ordering Information

Single-Pass TFF Cassette Accessory	Cassette Size	Cat. No.
Pellicon® Single-Pass TFF Mini Kit (includes 4 diverter plates and 2 gaskets)	Pellicon® 3 88 cm^2 and 0.11 m^2; Pellicon® 2 0.1 m^2	**XXSPTFF01**
Pellicon® Single-Pass TFF Cassette Diverter Plate	Pellicon® 3 0.57 m^2 and 1.14 m^2; Pellicon® 2 0.5 m^2	**XXSPTFF02**
Pellicon® Single-Pass TFF Cassette Retentate Collection Plate	Pellicon® 3 0.57 m^2 and 1.14 m^2; Pellicon® 2 0.5 m^2	**XXSPTFF03**
Note: For large-scale installations, both XXSPTFF02 and XXSPTFF03 are used.		
Cassette Hardware		
Pellicon® MiniX holder	Pellicon® 3 88 cm^2 and 0.11 m^2; Pellicon® 2 0.1 m^2	**XX42PMINIX**
Pellicon® stainless steel holder	Pellicon® 3 0.57 m^2 and 1.14 m^2; Pellicon® 2 0.5 m^2	**XX42P0080**
Pellicon® stainless steel holder and assembly	Pellicon® 3 0.57 m^2 and 1.14 m^2; Pellicon® 2 0.5 m^2	**XX42P0K80**
Pellicon® 3 manifold adapter plate	Pellicon® 3 0.57 m^2 and 1.14 m^2	**XXPEL3MAP**
Process scale holder	Pellicon® 3 0.57 m^2 and 1.14 m^2; Pellicon® 2 0.5 m^2	**On Request**
Hydraulic process scale holder	Pellicon® 3 0.57 m^2 and 1.14 m^2; Pellicon® 2 0.5 m^2	**On Request**
Capsule Accessory	**Capsule Size**	**Cat. No.**
Pellicon® Capsule Stand	Pellicon® Capsule 0.1 m^2 and 0.5 m^2	**PCX001**
Filters		
All Pellicon® tangential flow filters must be purchased separately. See datasheets DS1324EN00, DS1209EN00 (Pellicon® 3), DS1210EN00 (Pellicon® 2), DS1285EN (Pellicon® Capsules) for ordering information.		

Single-Pass TFF Accessories Specifications

Materials			
Accessory	**Single-Pass TFF Mini Kit**	**Cassette Diverter Plate**	**Retentate Collection Plate**
Materials of Construction	Mini diverter plate: Polysulfone	316 L stainless steel	316 L stainless steel
	Gasket: Silicone		
Maximum Operating Conditions			
Maximum Operating Pressure	40 psi (2.7 bar) at 50 °C, 80 psi (5.5 bar) at 40 °C		
Maximum Caustic Exposure	1.0N NaOH up to 50 hours		
Operating pH Range	2-13		
Regulatory Information			
Component Material Toxicity	Mini diverter plate component materials meet the criteria of the USP <88> Biological Reactivity Test, in vivo, for Class VI Plastics.		
FDA 21 CFR	Mini diverter plate component materials meet the criteria for compliance with 21 CFR 177-1655 for plastic components.		

Documentation

Pellicon® Single-Pass TFF Accessories User Guide, 00120342PU

Pellicon® Capsule User Guide, UG1549EN

Pellicon® single-pass TFF mini diverter plate

Pellicon® single-pass TFF cassette diverter plate

Pellicon® single-pass TFF cassette retentate collection plate

BioContinuum™ Platform

Intensify and Evolve. Together.

An expanding offering that empowers biomanufacturers to achieve greater speed, flexibility and reliability through intensified, connected or continuous bioprocessing.

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