Millipore®
Preparation, Separation,
Filtration & Monitoring Products

Data Sheet

Pellicon® Capsules with Ultracel® Membrane

Accelerate your therapy using our innovative single-use tangential flow filters with superior flux performance

Ideal for single-use tangential flow filtration (TFF), Pellicon® Capsules provide high flux and linear scalability in a plug ‘n play format for optimum process flexibility and productivity.

Pellicon® Capsules are a true single-use solution for your TFF challenges. Supplied sterilized, they eliminate unproductive steps such as sanitization and cleaning, increasing facility throughput while considerably reducing your total operating time by approximately 60% compared to a multi-use process. The holderless, self-contained design enables easy installation and safe removal, improving your product changeover efficiency and mitigating risks of environmental exposure and product cross-contamination. With optimum feed channel design, these spiral-wound capsules perform with high flux to meet your high concentration targets with speed. Pellicon® Capsules were engineered to provide you with performance consistency and linear scalability within the Pellicon® Capsule family as well as within our standard Pellicon® cassettes for reliable process development and predictable scale-up at any stage of your biologics. To help you meet your processing requirements from development to implementation, our global consultants and field experts are ready to provide you with best-in-class support and services.

Benefits

- Plug ‘n play, holderless design for faster installation and safer removal
- True single-use, presterilized capsule that is ready to use in minutes and enables fast product changeover
- Superior mass transfer and flux with optimum feed channel screen for high concentration and productivity
- Optimum recovery with proven ultra-low binding Ultracel® composite regenerated cellulose membrane
- Pellicon® TFF proven performance and linear scalability for ultimate reliability across all scales
- Access to our experienced engineers to help solve your toughest problems—together

Applications

- Antibody drug conjugates
- Monoclonal and bispecific antibodies
- mRNA and plasmids
- Viral vectors and viral vaccines
- Recombinant and non-recombinant proteins

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Plug 'n Play, Holderless Design

The simplified, innovative, self-contained design of the Pellicon® Capsule significantly reduces installation efforts by eliminating the need for a holder or torquing. The easy installation and connectivity of the Pellicon® Capsule minimizes the time, labor, and expense associated with assembling and disassembling TFF devices.

Sterilized and Preservative-free

For added convenience, Pellicon® Capsules are supplied sterilized by irradiation. This feature eliminates the need for membrane sanitization before product contact. Pellicon® Capsules are also supplied with preservative-free reverse osmosis water, significantly reducing pre-use flushing requirements.

Fast Product Changeover

The holderless, self-contained design of the Pellicon® Capsule is ideal to easily and safely remove the entire single-use TFF flow path immediately after product recovery. This enhances product changeover efficiency and saves time, labor, fluids, and footprint in the manufacturing plant due to no cleaning validation requirements, ultimately increasing plant productivity and process flexibility with reduced cross-contamination risks.

Optimum Product Recovery and High Yields

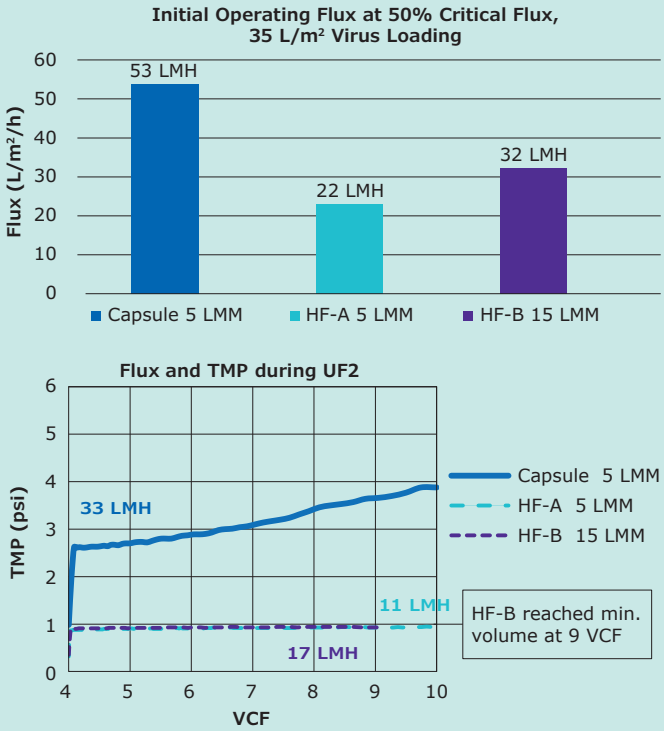
Ultracel® composite membranes offer low fouling and low protein binding capabilities for excellent product retention, recovery, and high yields. Ultracel® membranes are constructed of regenerated cellulose cast on a microporous substrate for defect-free membranes with superior robustness compared to conventional products. The composite technology offers a mechanically robust design able to withstand extreme operating conditions.

Superior Flux with Optimum Feed Channel Design

Pellicon® Capsules with Ultracel® membrane contain the C feed channel screen. The C screen is the ideal feed channel turbulence promoter for optimal flux performance for the concentration of therapeutic biologics and applications that require high productivity. At feed flow rates of 4-8 L/min/m^2 (LMM), capsules have superior flux performance for faster processing and use smaller systems to achieve high final concentrations.

Speed Up Your Gene Therapy with Superior Flux Performance

Flux evaluations with a virus model feed for AAV demonstrated Pellicon® Capsules have superior performance compared to hollow fiber modules operating at the same crossflow rate (5 LMM) or even at triple the crossflow rate of capsules (15 LMM). A UF1/DF/UF2 process simulation showed how higher flux at low crossflow rates makes for a more productive TFF process, in which concentration targets are succesfully achieved in less time.



The study was performed using 300 kDa membrane (cellulose for Pellicon® Capsule; PES for hollow fibers HF-A: 60 cm and HF-B: 20 cm). Model feed consisted of a lysed, clarified, bacteriophage-spiked, non-transduced HEK293 stream at 35 L/m^2 loading. Process simulation was performed with a permeate-controlled (2-pump) system for a UF1[4×], DF[5DV], UF2[2.5×] process. Initial operating flux (top) and transmembrane pressure (TMP) vs volumetric concentration factor (VCF) for the UF2 step (10X overall concentration target; bottom) are shown.

Due to larger system hold-up volume required to attain a 3× crossflow rate of 15 LMM, hollow fiber HF-B could not reach 10× concentration. Although a crossflow rate of 5 LMM allowed for reduced system hold-up volume and achievable VCF target for HF-A, a tradeoff of lower flux resulted in 3.2× longer processing times for the hollow fiber compared to Pellicon® Capsule (354 vs 112 min). The longer required run time for hollow fibers is consistent with their lower starting flux. Virus yield was >98% for all filters.

Reliable Performance and Linear Scalability

All Pellicon® Capsules are manufactured with the same materials of construction and utilize the same flow channel length and height, turbulence promoter, and flow direction, ensuring consistent performance at every scale. Furthermore, Pellicon® Capsules provide the same high performance as Pellicon® cassettes and are linearly scalable, making it easy to transition to and from cassettes.

Manufacturing Consistency and Reproducibility

Our controlled, automated manufacturing process provides the highest level of capsule performance consistency. The high level of process control ensures consistent, reproducible performance in terms of scale up and scale down, from run to run, and campaign to campaign, ensuring process consistency. All Pellicon® Capsules are manufactured in accordance with an ISO 9001 Quality Management System.

Quality Assurance

All Pellicon® Capsules are manufactured using the same equipment, process, and quality assurance. Each Pellicon® Capsule lot is 100% integrity tested during manufacturing to ensure that every filter is integral, robust, and within specification. Additionally, Pellicon® Capsules are subjected to a complete array of quality control release tests. Each capsule is identified with a unique serial number and lots can be traced to an individual Certificate of Quality.

Pellicon® Capsules 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:

https://sigmaaldrich.com/emprove.

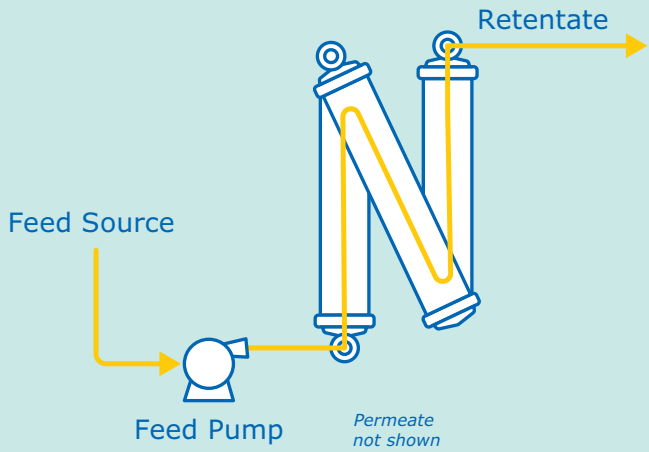
Services and Support

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.

Pellicon® Capsules 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.

Pellicon® Capsules are ideally suited for single-pass TFF. 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.



Applications

- In-process volume reduction
- In-line dilution/de-salting
- Intensified capture or polishing
- Final formulation/concentration

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 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.

Process-Scale Single-Use TFF Systems

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 m^2, 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 from pre-clinical to manufacturing scale. Closed mode of operation is possible with specifically designed flow path and equipment, allowing to reduce contamination risk and protect operators while increasing flexibility and efficiency.

Assembling Large Areas

Pellicon® Capsule manifold formats E and L are individual assemblies of either 3 or 4.5 m^2 of membrane area. The E format is an extender assembly that enables increased membrane area installations when aseptically connected to an L assembly.

Desired Area (m^2)	Cat. No. Required	
	E Manifold	L Manifold
6	PCC----30E	PCC----30L
7.5	PCC----30E	PCC----45L
9	PCC----45E	PCC----45L

E and L manifolds must be ordered separately.

Specifications

Materials of Construction

Pellicon® Capsule Filter

Membrane: Composite Regenerated Cellulose (Ultracel®)
Screens: Polypropylene, Polyester
Internal Seals: EPDM, Thermoplastic Elastomer
Housing/Core/Port-Caps: PPO/PS Blend
Potting Material: BPA-free epoxy, Polyurethane

Assembly Components

Connectors, AseptiQuik® G/L: Polycarbonate
Sanitary Gaskets/Tubing: Silicone
Clamps: Glass-reinforced Nylon
Hose Fittings/Clamp Tamper-evident Covers: Polypropylene
Hose Clamps: Stainless Steel

Accessory Components

Base for 1.5 m^2 Device: PPO/PS Blend and Cold-rolled Steel with Powder Coat
Base for 3 & 4.5 m^2 Manifolds: Cold-rolled Steel with Powder Coat
Manifolds Center Unification Bracket: Polycarbonate

Pellicon® Capsule Stand

Base: Stainless Steel
Clips: Carbon Fiber Reinforced Nylon

Sterility

This product is sterilized by irradiation. The sterilization has been validated according to ANSI/AAMI/ISO 11137.

Storage Conditions

Temperature: 15–30 °C
Storage Solution: Reverse osmosis water

Operating Conditions

NMWL*	30 kDa	100, 300 kDa
Recommended Feed Flow Rate (L/min/m^2)	4—8	4—6
Maximum Forward TMP	50 psi (3.5 bar) at 4-30 °C	45 psi (3.1 bar)‡ at 4-30 °C
Reverse Pressure Exposure	10 pulse cycles of 30 psi (2.1 bar) reverse pressure at 25 °C	
pH Range	2-13	
Maximum Inlet Pressure		
Filter Only	80 psi (5.5 bar) at 4-30 °C	
Filter with Connectors or 1 m^2 Manifold	75 psi (5.1 bar) at 4-30 °C	
3 & 4.5 m^2 Manifolds	60 psi (4.1 bar) at 4-30 °C	

*Nominal Molecular Weight Limit; ‡With 5 psi permeate pressure (0.3 bar)

Manufacturing Release Criteria

100% Integrity Tested
Each unit must pass our integrity test based on air flow through the fully wetted membrane of the filter, and a housing leak integrity test.

Flow Rate and Pressure Drop
Each unit must pass our pressure drop test with water at 25 °C and average cross flow rate of 6 L/min per m^2.

Regulatory Information

Component Material Toxicity
All materials in the fluid path meet the criteria of the ISO 10993-5 Cytotoxicity MEM Elution Test.

Particulates/Non-Fiber Releasing
The product meets the requirements for a non-fiber releasing filter as defined in 21 CFR 210.3 (b)(6) after a water flush of 20 L/m^2 and confirmed using USP <788> test method and specification.

Bacterial Endotoxins (non-toxic)
A sample aqueous extract contains <0.25 EU/mL as determined by the Limulus Amebocyte Lysate (LAL) test according to USP <85>, Ph. Eur. 2.6.14, and JP 4.01.

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 System Standard.

Ultracel® Membrane Single-use Applications

NMWL (kDa)	Typical Application
30	Antibodies, recombinant proteins, lipid nanoparticles, mRNA, plasmids, viral vectors (small capsid)
100	Small viruses, lipid nanoparticles, mRNA, plasmids, viral vectors (small & large capsid)
300	Large viruses, lipid nanoparticles, plasmids, viral vectors (large capsid)

Connection, Nominal Dimensions, and Hold-up Volume

Area	Connection	Length, in. (cm)	Diameter, in. (cm)	Wet Weight, lbs. (kg)	Feed Channel* mL	Permeate Channel* mL
Pellicon® Capsule Devices						
0.1 m^2	3/4 in. Sanitary Flange	13.9 (35.3)	1.5 (3.8)	0.9 (0.4)	26	62
	AseptiQuik® G Connectors	16.2 (41.1)	1.5 (3.8)	0.9 (0.4)	38	68
0.5 m^2	3/4 in. Sanitary Flange	13.9 (35.3)	2.3 (5.7)	1.7 (0.8)	107	143
	AseptiQuik® G Connectors	16.2 (41.1)	2.3 (5.7)	1.7 (0.8)	119	149
1.5 m^2	AseptiQuik® G Connectors	17.2 (43.7)	4.1 (10.3)	6.6 (3.0)	455	719

Area	Assembly Type	Connection	Length, in. (cm)	Height, in. (cm)	Width, in. (cm)	Tubing ID, in.	Wet Weight lbs. (kg)	Feed Channel* mL	Permeate Channel* mL
Pellicon® Capsule Manifolds									
1 m^2	G	AseptiQuik® G Connectors	7.7 (19.6)	15.9 (40.5)	13.5 (34.4)	3/8	11 (5)	254	306
3 m^2	G	AseptiQuik® G Connectors	15.9 (40.4)	17.4 (44.2)	17.9 (45.4)	3/4	22 (10)	1108	1537
	L	AseptiQuik® L Connectors	16.5 (42.0)	18.5 (46.9)	19.0 (48.2)	3/4		1128	1547
	E	AseptiQuik® L Connectors	18.1 (45.9)	18.5 (46.9)	19.0 (48.2)	1		1288	1627
4.5 m^2	G	AseptiQuik® G Connectors	21.5 (54.6)	17.4 (44.2)	17.9 (45.4)	3/4	31 (14)	1665	2307
	L	AseptiQuik® L Connectors	22.1 (56.2)	18.5 (46.9)	19.0 (48.2)	3/4		1683	2316
	E	AseptiQuik® L Connectors	23.7 (60.2)	18.5 (46.9)	19.0 (48.2)	1		1857	2403

*hold up volumes are general estimates. Please see our performance guides for more details.

Accessory	Height, in. (cm)	Width, in. (cm)	Depth ID, in. (cm)
Pellicon® Capsule Stand			
Stand for sizes 0.1, 0.5 or 1 m^2	10.5 (26.7)	4.5 (11.4)	7.0 (17.8)

Ordering Information

Pellicon® Capsules with Ultracel® Membrane and C Screen

Description	Port Fittings	Cat. No.
30 kDa NMWL Capsules & Manifolds		
0.1 m²	3/4 in. Sanitary Flange	**PCC030C01**
	AseptiQuik® G Connector	**PCC030C01C**
0.5 m²	3/4 in. Sanitary Flange	**PCC030C05**
	AseptiQuik® G Connector	**PCC030C05C**
1 m²	AseptiQuik® G Connector	**PCC030C10G**
1.5 m²	AseptiQuik® G Connector	**PCC030C15C**
3 m²	AseptiQuik® G Connector	**PCC030C30G**
	AseptiQuik® L Connector	**PCC030C30L**
	AseptiQuik® L Connector	**PCC030C30E**
4.5 m²	AseptiQuik® G Connector	**PCC030C45G**
	AseptiQuik® L Connector	**PCC030C45L**
	AseptiQuik® L Connector	**PCC030C45E**
100 kDa NMWL Capsules		
0.1 m²	3/4 in. Sanitary Flange	**PCC100C01**
	AseptiQuik® G Connector	**PCC100C01C**
0.5 m²	3/4 in. Sanitary Flange	**PCC100C05**
	AseptiQuik® G Connector	**PCC100C05C**
300 kDa NMWL Capsules & Manifolds		
0.1 m²	3/4 in. Sanitary Flange	**PCC300C01**
	AseptiQuik® G Connector	**PCC300C01C**
0.5 m²	3/4 in. Sanitary Flange	**PCC300C05**
	AseptiQuik® G Connector	**PCC300C05C**
1 m²	AseptiQuik® G Connector	**PCC300C10G**
1.5 m²	AseptiQuik® G Connector	**PCC300C15C**
3 m²	AseptiQuik® G Connector	**PCC300C30G**
	AseptiQuik® L Connector	**PCC300C30L**
	AseptiQuik® L Connector	**PCC300C30E**
4.5 m²	AseptiQuik® G Connector	**PCC300C45G**
	AseptiQuik® L Connector	**PCC300C45L**
	AseptiQuik® L Connector	**PCC300C45E**

Pellicon® Capsule Stand

Specially designed optional accessory.

Description	Cat. No.
Supports up to two 0.1 m² capsules in parallel or three in series on one side and one 0.5 m² capsule or one 1 m² manifold on the other side.	**PCX001**

Pellicon® XL 50 Cassettes with Ultracel® Membrane and C Screen

Linearly scalable cassette for process development at volumes from 50 to 1000 mL.

Description	Cat. No.
50 cm², 30 kDa NMWL	**PXC030C50**
50 cm², 100 kDa NMWL	**PXC100C50**
50 cm², 300 kDa NMWL	**PXC300C50**

TFF Systems

For process development and purification of clinical and process scale biologics.

Description	Capsule Area Range	Cat. No.
Cogent® Lab Systems	50 cm² (XL cassette) to 1 m²	**Contact Rep.**
Mobius® TF2S System	0.5 to 4.5 m²	**Contact Rep.**
Mobius® TFF 80 System	4.5 to 18 m²	**Contact Rep.**

For more information, go to **SigmaAldrich.com/TFF-systems**

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For additional information, visit
SigmaAldrich.com

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MK_DS1285EN Ver. 7.0
50218
09/2023