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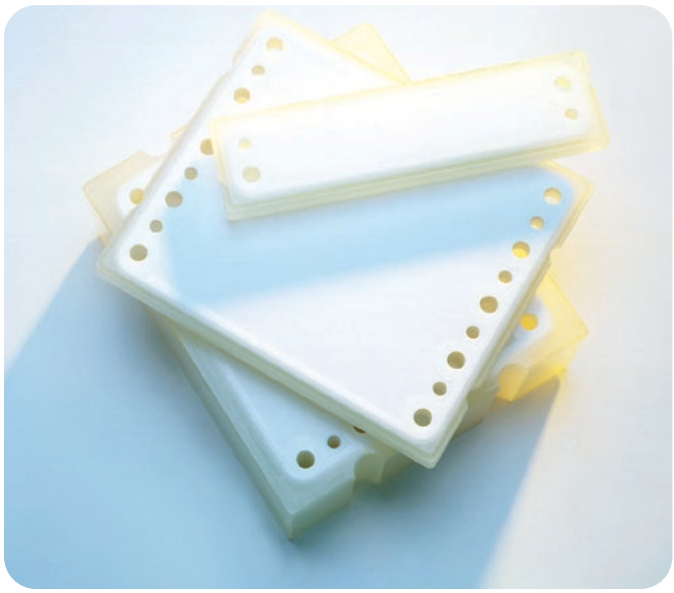
Pellicon® 2 Filters and Holders

High performance tangential flow filters for biopharmaceutical process development, scale-up and scale-down, concentration, purification, and cell harvesting applications.

- Void-free membranes to match virtually any separation challenge
- Short flow path for higher flux and higher resolution separation capability
- Choice of flow channel configuration providing process optimization capability
- Predictable, fast, scale-up
- True linear scalability from laboratory size modules to industrial assemblies for processing thousands of liters



Typical Applications

Concentration, desalting or buffer exchange of:

- Protein solutions
- Polysaccharide solutions
- Virus suspensions

Harvest, washing or clarification of:

- Cell cultures and lysates
- Colloidal suspensions
- Viral cultures

Consistent High Flux and High Product Recovery

Our Biomax® polyethersulfone and Ultracel® composite regenerated cellulose membranes have void-free structures that guard against leakage of solutes through microdefects normally associated with voids beneath the thin skins of conventional UF membranes (Figures 1 and 2).

These void-free membranes are more permeable, resulting in high-flux with equivalent or superior product retention (Figure 3). These void-free membranes provide the advantages of fast, high yield processing, and smaller systems.

The long established Durapore® hydrophilic PVDF microfiltration membrane is well known for its exceptional combination of high flux, low protein binding, and high product recoveries.

Easy, Reliable Linear Scale-Up from the Lab to the Production Plant

Pellicon® 2 Mini filters scale-up easily and reliably from the laboratory to the production plant (Figures 4 and 5). By ensuring every flow channel has the same length, height and turbulence promoter as well as flow direction and materials of construction, we maintain the same ultrafilter/microfilter performance at all scales. Thus, rapid and reliable translation of processes from lab to manufacturing scale is easily achieved.

Linear Scale-Up

Mini filters (0.1 m^2/1.1 ft^2) and holders are designed for laboratory ultrafiltration/microfiltration of 100 mL to 10 L volumes, yet scale up linearly to Pellicon® 2 Cassette (0.5 m^2/5.4 ft^2) and Maxi (2.5 m^2/26.9 ft^2, 2.0 m^2/21.5 ft^2) filters used in the pilot or manufacturing plant to process volumes from one liter to thousands of liters.

Whether you operate 0.1 m^2 or 100 m^2 of installed area, every Pellicon® 2 filter operates with the same pressure drop, flow velocity and concentration profile for true, rapid and simple linear scale-up.

*Pelllicon® 2 filters with screens A and C come in 0.1, 0.5 and 2.5 m2. Pellicon® 2 filters with V screen come in 0.1, 0.5, and 2.0 m^2.

Greater Process Reliability and Reproducibility

The combination of defect-free membranes with our highly reliable manufacturing processes, offers greater consistency of process parameters.

The high quality of our ultrafiltration membranes is further ensured by our pioneering multiple solute mixed-dextran retention profile test. Unlike the single solute protein retention test, our retention profile test measures and ensures reproducible retention performance of our UF membranes over the entire range of molecular weights retained by the membrane, not just at one or two molecular weights.

Low Product Loss

Pellicon® 2 filters have a low minimum working volume—as low as 175 mL of retentate volume per square meter of membrane area. This low retentate volume permits high concentration factors to be reached with low starting volumes and maximizes the recovery of small sample volumes.

To prevent product loss, Pellicon® 2 filters are 100% tested in manufacturing to ensure that every filter is integral.

In addition, Biomax® and Ultracel® membranes are exposed to a highly sensitive, high-pressure integrity test. The integrity test procedure and specifications are supplied so you can confirm integrity at high pressure when the filter is installed (Figure 6).

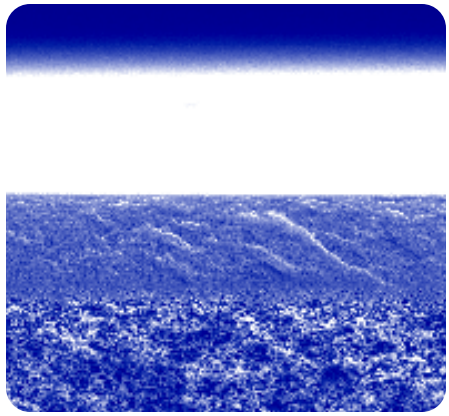


Figure 1. Void-free Biomax® 10 modified polyethersulfone membrane

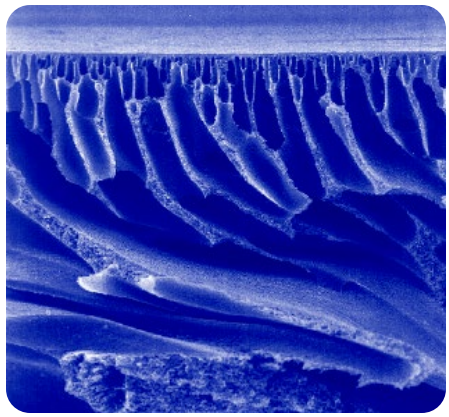


Figure 2. Conventional 10 kD polyethersulfone membrane with sub-surface voids

Pellicon® 2 Filters Proof of Performance

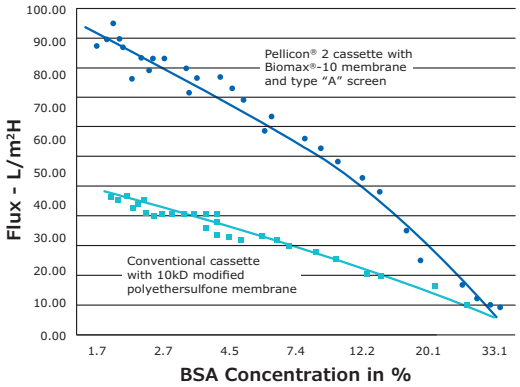


Figure 3. Flux versus BSA concentration

Feed pressure: 5.6 bar/80 psi
Retentate pressure: 2.1 bar/30 psi
Temperature: 10–13.5 °C
Initial volume 28 L
Final volume: 2 L

Conclusion

Pellicon® 2 filters with Biomax® membranes provide up to two-times the process flux of conventional cassettes resulting in faster processing and smaller systems.

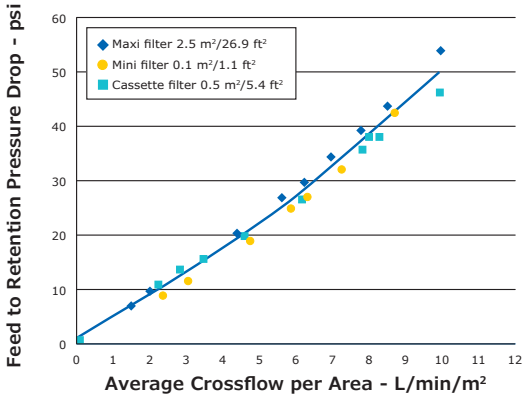


Figure 4. Feed to retentate pressure drop versus average crossflow on a 10% BSA solution

Temperature: 8 °C

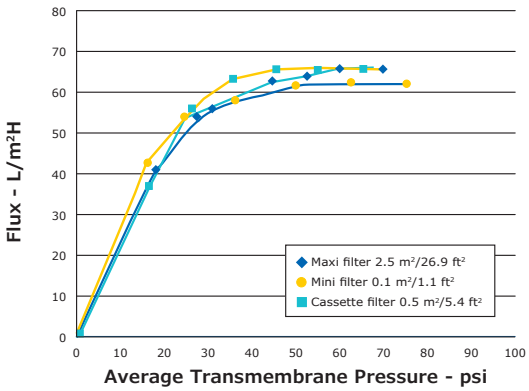


Figure 5. Flux versus average transmembrane pressure on a 10% BSA solution.

Temperature: 8 °C
Feed to retentate pressure drop: 2.8 bar/40 psi

Conclusion

(Figures 4 and 5) Pellicon® 2 family of cassette filters scale linearly from 0.1 to 0.5 to 2.5 m² (1.1 to 5.4 to 26.9 ft²) sizes for rapid, accurate and safe process scale-up and transfer

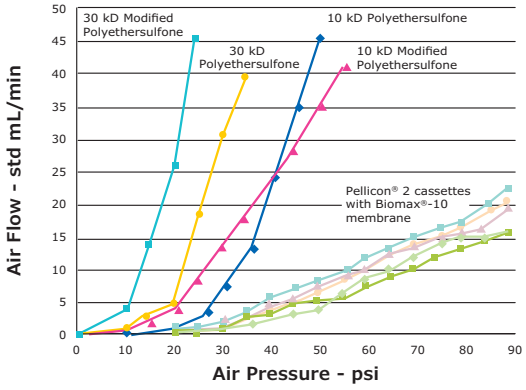


Figure 6. Integrity test comparison-air flow through wetted cassettes

Conclusion

The void-free structure of Biomax® membranes is demonstrated by low, linear air diffusion values. This performance ensures better process reliability and safety and better product retention for higher yields.

Biocompatibility

All wetted parts have been tested and meet the requirements of the USP<88> Class VI biological reactivity test.

Validation Support

Since 1973, Pellicon® filters and systems have been successfully used for development and scale-up of processes for manufacturing injectable protein and polysaccharide drugs, in the serum fractionation, biotechnology, vaccine and pharmaceutical industries.

Pellicon® 2 filters are supported by Validation Support Data Package proving performance claims and demonstrating the suitability of these filters for drug manufacturing in validated processes. This package is available upon request.

A Choice of Feed Channel Screens

Pellicon® 2 filters incorporate three types of feed-channel screens:

- ***Type A screen*** is optimized to operate Biomax® membranes with maximum flux with low-viscosity solutions.
- ***Type C screen*** is optimized to operate Ultracel® membranes with maximum flux. The Type C screen is also available with Biomax®-50,100, 300, 500 and Biomax® 1000 membranes for concentration and diafiltration of viscous solutions.
- ***Type V screen*** is optimized for very viscous solutions or solutions with higher levels of suspended solids.

Normalized Recirculation Rates

Filter Type	Feed Screen	Feed Flow
Pellicon® 2 Cassettes	A	4.0–6.0 lpm/m²
	C	4.0–7.0 lpm/m²
	V	4.0–8.0 lpm/m²

Screen Selection Guidelines

Solution Type	Screen Type
Dilute protein solution or low viscosity solutions (MAbs, interferons)	A screen
Concentrated protein solutions or high viscosity solutions (IgG, biopolymers)	C screen
High viscosity solutions (polysaccharides, certain microfiltration or clarification applications)	V screen

Specifications

Temperature Range

Device Size (m²)	Biomax®	Ultracel®
0.1	4 to 50 °C	4 to 30 °C
0.5	4 to 50 °C	4 to 30 °C
2.0/2.5	4 to 50 °C	4 to 30 °C

Maximum Forward Transmembrane Pressure

Device Size (m²)	Biomax®	Ultracel®
0.1	6.8 bar (100 psi) Max	6.8 bar (100 psi) Max
0.5	6.8 bar (100 psi) at 30 °C	3.4 bar (50 psi) at 30 °C
2.0/2.5	6.8 bar (100 psi) at 30 °C	3.4 bar (50 psi) at 30 °C

Maximum Reverse Transmembrane Pressure

Device Size (m²)	Biomax®	Ultracel®
0.1	0.33 bar (5 psi)	0.33 bar (5 psi)
0.5	0.33 bar (5 psi)	0.33 bar (5 psi)
2.0/2.5	0.33 bar (5 psi)	0.33 bar (5 psi)

Prefiltration Required

Mini, Cassette and Maxi:	100 µm

Dimensions

Device	Width	Length	Thickness
Mini	5.6 cm	21 cm	1.5 cm (V screen-2.16 cm)
Cassette	17.8 cm	21 cm	1.5 cm (V screen-2.16 cm)
Maxi	17.8 cm	21 cm	7.6 cm (V screen-9.0 cm)

Membrane Selection Guideline

Membrane Type	Materials	Benefits
Biomax®	Modified polyethersulfone	Highest flux ultrafiltration membrane Excellent chemical resistance Void-free structure for higher yield and reliability
Ultracel®	Regenerated cellulose (ideal for protein solutions < 20 g/L) Composite membranes cast on a microporous substrate for defect-free membranes with superior adhesion. Brings higher resolution, improved yields and superior back-pressure resistance	Extremely low protein binding hydrophilic membrane Highest product recovery and improved performance with difficult to process streams (antifoams, lipids, protein transmission applications)
Durapore®	Hydrophilic PVDF	Very hydrophilic microporous membrane for cell harvest or clarification applications

Pellicon 2 Membrane Selection Chart

Approximate Molecular Weight (range of solutes retained >99%, kD)		Membrane	NMWL (kD) or Microns	Membrane Material	pH Range
High Flux Biomax® Membranes—Void-free for Higher Yield and Reliability					
12–25	(growth factors, hormones)	Biomax®-5	5	modified polyethersulfone	1–14
25–50	(growth factors, hormones)	Biomax®-8	8	modified polyethersulfone	1–14
50 –100	(albumin, hemoglobin)	Biomax®-10	10	modified polyethersulfone	1–14
100 –140	(enzymes)	Biomax®-30	30	modified polyethersulfone	1–14
140–300	(IgG's)	Biomax®-50	50	modified polyethersulfone	1–14
300–500	(small viruses and antigens)	Biomax®-100	100	modified polyethersulfone	1–14
>500	(IgM's, large viruses)	Biomax®-300	300	modified polyethersulfone	1–14
>0.03 µm	(large viruses, colloids, particulates)	Biomax®-500	500	modified polyethersulfone	1–14
>0.03 µm	(large viruses, cells, colloids, particulates)	Biomax®-1000	1000	modified polyethersulfone	1–14
Ultracel® Membranes—for High Recoveries					
8–18	(proinsulin, hematopoetic factors)	PLCCC	5	regenerated cellulose	2–13
18–60	(hemoglobin, enzymes)	PLCGC	10	regenerated cellulose	2–13
60–200	(monoclonal IgG's)	PLCTK	30	regenerated cellulose	2–13
200–500	(small viruses, viral antigens)	PLCHK	100	regenerated cellulose	2–13
>500	(large viruses, IgM's)	PLCMK	300	regenerated cellulose	2–13
>0.03 µm	(large viruses, cells, colloids, particulates)	PLCXK	1000	regenerated cellulose	2–13
Durapore® Membranes—for Microporous Applications					
Clarify cell lysates and protein solutions, clarify viral cultures		VVPP	0.1 µm	hydrophilic PVDF	2–11
Harvest & wash colloidal suspensions, bacterial cells; clarify protein solutions and viral cultures		GVPP	0.22 µm	hydrophilic PVDF	2–11
Harvest & wash colloidal suspensions, cell & viral cultures, clarify protein solutions & viral cultures		HVMP	0.45 µm	hydrophilic PVDF	2–11
Harvest cell cultures or colloidal suspensions		DVPP	0.65 µm	hydrophilic PVDF	2–11

Ordering Information

Pellicon® 2 Filters

	Filters with A Screens			Filters with Type C Screens		
Membrane	**0.1 m²/1.1 ft²**	**0.5 m²/5.4 ft²**	**2.5 m²/26.9 ft²**	**0.1 m²/1.1 ft²**	**0.5 m²/5.4 ft²**	**2.5 m²/26.9 ft²**
Biomax® Membranes—Modified Polyethersulfone						
Biomax® 5	P2B0 05A 01	P2B0 05A 05	P2B0 05A 25	+	+	+
Biomax® 8	P2B0 08A 01	P2B0 08A 05	P2B0 08A 25	+	+	+
Biomax® 50	P2B0 50A 01	P2B0 50A 05	P2B0 50A 25	P2B0 50C 01	P2B0 50C 05	P2B0 50C 25
Biomax® 100	P2B1 00A 01	P2B1 00A 05	P2B1 00A 25	P2B1 00C 01	P2B1 00C 05	P2B1 00C 25
Biomax® 300	+	+	+	P2B3 00C 01	P2B3 00C 05	P2B3 00C 25
Biomax® 500	+	+	+	P2B5 00C 01	P2B5 00C 05	P2B5 00C 25
Biomax® 1000	+	+	+	P2B0 1MC 01	P2B0 1MC 05	P2B0 1MC 25
Ultracel® Membranes—Regenerated Cellulose, Composite Construction						
5 kD	NA	NA	NA	P2C0 05C 01	P2C0 05C 05	P2C0 05C 25
10 kD	NA	NA	NA	P2C0 10C 01	P2C0 10C 05	P2C0 10C 25
30 kD	NA	NA	NA	P2C0 30C 01	P2C0 30C 05	P2C0 30C 25
100 kD	NA	NA	NA	P2C1 00C 01	P2C1 00C 05	P2C1 00C 25
300 kD	NA	NA	NA	P2C3 00C 01	P2C3 00C 05	P2C3 00C 25
1000 kD	NA	NA	NA	P2C0 1MC 01	P2C0 1MC 05	P2C0 1MC 25
Durapore® Membranes—Hydrophilic PVDF						
0.1 µm	+	+	+	P2VV PPC 01	P2VV PPC 05	P2VV PPC 25
0.22 µm	+	+	+	P2GV PPC 01	P2GV PPC 05	P2GV PPC 25
0.45 µm	+	+	+	P2HV MPC 01	P2HV MPC 05	P2HV MPC 25
0.65 µm	+	+	+	P2DV PPC 01	P2DV PPC 05	P2DV PPC 25

	Filters with V Screens		
Membrane	**0.1 m²/1.1 ft²**	**0.5 m²/5.4 ft²**	**2.0 m²/21.5 ft²**
Biomax® Membranes—Modified Polyethersulfone			
Biomax® 5	P2B0 05V 01	P2B0 05V 05	P2B0 05V 20
Biomax® 8	P2B0 08V 01	P2B0 08V 05	P2B0 08V 20
Biomax® 10	P2B0 10V 01	P2B0 10V 05	P2B0 10V 20
Biomax® 30	P2B0 30V 01	P2B0 30V 05	P2B0 30V 20
Biomax® 50	P2B0 50V 01	P2B0 50V 05	P2B0 50V 20
Biomax® 100	P2B 100V 01	P2B1 00V 05	P2B1 00V 20
Biomax® 300	P2B3 00V 01	P2B3 00V 05	P2B3 00V 20
Biomax® 500	P2B5 00V 01	P2B5 00V 05	P2B5 00V 20
Biomax® 1000	P2B0 1MV 01	P2B0 1MV 05	P2B0 1MV 20
Ultracel® Membranes—Regenerated Cellulose, Composite Construction			
5 kD	P2C0 05V 01	P2C0 05V 05	P2C0 05V 20
10 kD	P2C0 10V 01	P2C0 10V 05	P2C0 10V 20
30 kD	P2C0 30V 01	P2C0 30V 05	P2C0 30V 20
100 kD	P2C1 00V 01	P2C1 00V 05	P2C1 00V 20
300 kD	P2C3 00V 01	P2C3 00V 05	P2C3 00V 20
1000 kD	P2C0 1MV 01	P2C0 1MV 05	P2C01MV 20
Durapore® Membranes—Hydrophilic PVDF			
0.1 µm	P2VV PPV 01	P2VV PPV 05	P2VV PPV 20
0.22 µm	P2GV PPV 01	P2GV PPV 05	P2GV PPV 20
0.45 µm	P2HV MPV 01	P2HV MPV 05	P2HV MPV 20
0.65 µm	P2DV PPV 01	P2DV PPV 05	P2DV PPV 20

Each Pellicon® filter is packed one per box and includes a Certificate of Quality.
Silicone intercassette gaskets are required for use with Pellicon® 2 filters. Two gaskets are packed in the box with every Pellicon® 2 filter.
+ = On request (custom order)
NA = not available

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