

Pellicon® XL 50 Cassette and Labscale® TFF System

Easy-to-use, high performance, tangential flow filtration cassette and system for process development work at volumes from 50 to 1000 mL

Concentrate, desalt and exchange buffers with the Labscale® TFF system and Pellicon® XL 50 cassette (typical starting volumes: 50 to 1000 mL).

The Pellicon® XL 50 cassette couples our superior ultrafiltration and microfiltration membranes with the first linearly scalable tangential flow filtration (TFF) cassette for processing small volumes. Whether you choose the Biomax® ultrafiltration membrane for its high flux and wide pH compatibility, the unique Ultracel® ultrafiltration membrane for its low protein binding and easy cleaning, or the Durapore® microfiltration membrane for its ultra-low protein binding and excellent retention performance, you are assured of reliable and consistent performance.

For linear scalability to exist within a family of TFF devices, the channel geometry (path length and channel height) must be identical for each filter. The Pellicon® XL 50 cassette is the only TFF product of this size that can make this claim. The feed and permeate flow channels in every Pellicon® XL 50 cassette operate with the same pressure drop, flow velocity and concentration profile as the larger Pellicon® 2 cassettes. Other cassettes change feed or permeate flow channel dimensions or flow directions when scaling from a low-volume to a high-volume device. Pellicon® XL 50 cassettes avoid these changes, providing simple, reliable linear scale-up.

The Labscale® TFF System is easy to use for sample preparation while also providing the necessary controls for process development and scale-up work. The system can be operated in concentration or continuous diafiltration modes. Specifically designed to operate with the Pellicon® XL 50 cassette, the 500 mL system reservoir accepts direct docking of the device, eliminating the need for tubing connections. This feature, in addition to the diaphragm pump assembly, provides a final working volume of <15 mL (depending on starting volume of sample to be concentrated).



Pellicon® XL 50 Cassette

Predictable, Superior Performance

- Robust thermoplastic construction
- Controlled channel height
- Superior membranes
 - Biomax® (polyethersulfone) membrane
 - Ultracel® (composite regenerated cellulose) membrane
 - Durapore® (hydrophilic polyvinylidene fluoride) membrane

Easy to Use

- Self-contained – no holder required
- Integral connections; accessory kit provided
- Can operate with peristaltic pump or the Labscale® TFF system

Speed to Market

- True linear scalability with UF membranes
- Same flow path and channel height as larger Pellicon® 2 cassettes
- Allows process development and scaling studies

Applications

- Concentration, desalting and buffer exchange of proteins, polysaccharides, lipid solutions, viruses, colloids cell suspensions and mammalian cells
- Harvest, washing or clarification of cell cultures, lysates and fermentation broths
- Sample preparation
- Membrane selection studies
- Preparation of material for clinical trials
- Small-volume processing

Consistent High Flux and High Product Recovery

High-quality Ultrafiltration (UF) Membranes

Biomax® polyethersulfone and Ultracel® composite cellulose membranes have a void-free structure that prevents solute leakage through microdefects associated with conventional UF membranes that have voids beneath their thin skins. As a result, we can make these membranes more permeable than conventional UF membranes while maintaining retention—resulting in high-retention, high flux membranes. The high quality of our ultrafiltration membranes is further ensured by our pioneering multiple-solute mixed retention profile test. Our retention profile test, unlike the single solute protein retention 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.

The Premier Microporous (MF) Membrane

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.

Superior Filter Quality

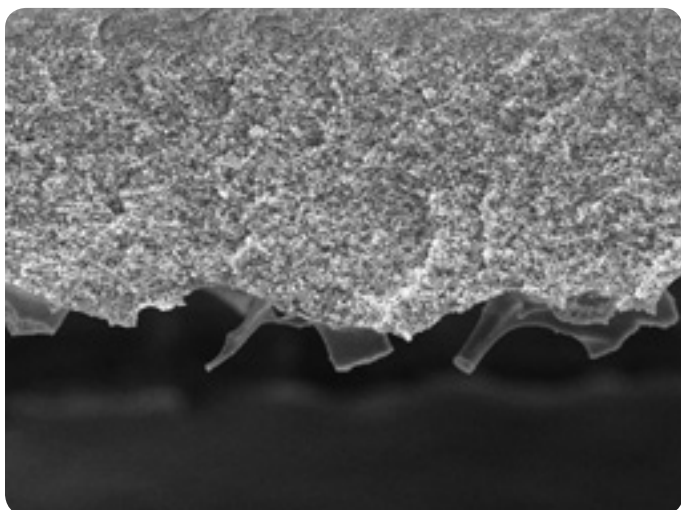
Pellicon® XL 50 cassettes are 100% integrity tested in manufacturing to ensure consistent and reliable performance. The integrity test procedure and specifications are supplied in the Certificate of Quality so users can confirm integrity.

Low Working Volume

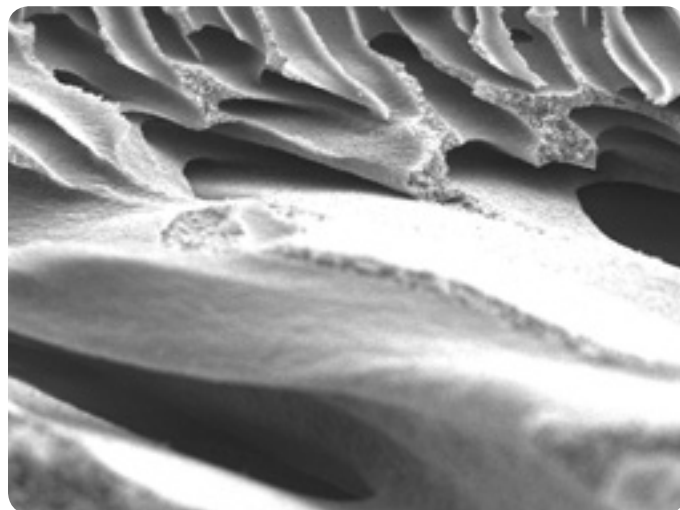
The Pellicon® XL 50 cassette's low holdup (3.2 mL) and working volumes (as low as 15 mL) permit high concentration factors to be reached and maximize recovery of small sample volumes.

The Labscale® TFF System

The Labscale® TFF System is sold as a complete, ready-to-use system, or you can design your own custom small-volume TFF system by selecting only the components you need. The Labscale® TFF System has a graduated 500 mL acrylic reservoir with retentate backpressure valve, feed and retentate pressure indicators, a stirrer assembly and diaphragm pump assembly. All wetted parts meet the requirements of USP <88>, Class VI and 21 CFR 211.72.



New void-free Biomax®-10 modified polyethersulfone membrane.



Conventional 10 kD polyethersulfone membrane with subsurface voids.

Figure 1.

Comparison of new void-free UF membranes with conventional UF membranes containing subsurface voids.

Specifications

Pellicon® XL 50 Cassette	
Materials of Construction	
Membranes	Polyethersulfone (Biomax®) Composite regenerated cellulose (Ultracel®) Hydrophilic polyvinylidene fluoride (Durapore®)
Screens	Polypropylene
Exterior Housing	Polypropylene
Fittings/connectors	Polypropylene
Luer Caps	Polypropylene
Specifications	
Fittings	Female Luer
Filtration Area	50 cm ² (0.05 ft ²)
Device Width	3.0 cm (1.2 in.)
Device Length	18.8 cm (7.4 in.)
Holdup Volume (typical)	3.2 mL
Maximum Operating Pressure	5.6 bar (80 psig)
Maximum Operating Pressure for Scale-Up to Pellicon®-2 (feed to permeate)	2.7 bar (40 psig) up to 45°C
Optimum Tangential Flow Rate for Polarized Solutions	30–50 mL/min
Membrane pH Compatibility	Biomax® membranes: 1–14 Ultracel® membranes: 2–12 (continuous) Ultracel® membranes: 2–13 (cleaning) Durapore® membranes: 1.5–9 (continuous) 1–11 (cleaning)
Biocompatibility/Toxicity	All wetted parts have been tested and meet the requirements of USP <88>, Class VI Biological Test for Plastics.
Extractables	Gravimetric extractables level < 7.5 mg/device after RO water flush. USP oxidizables test negative after RO water flush.
Prefiltration Requirements	Prefiltration of sample using 100 µm nominal pore size filter is recommended.
LabScale® TFF System	
Footprint	21.6 x 27.9 cm (8.5 x 11 in.)
Height	45.7 cm (18 in.)
Weight	5.9 kg (13 lb.)
Maximum Inlet Pressure	4.2 bar (60 psig)
Operating Temperature Range	4–45°C
Feed Flow Rate	10–100 mL/min at 60 psi
Minimum Recirculation Volume	20 mL
Power	115V, 60 Hz or 230V, 50 Hz, CE mark
Materials of Construction	
500 mL Reservoir	Acrylic
Reservoir Cover	Polypropylene
Reservoir Gasket	EPDM
Retentate Valve Diaphragm	EPDM and polypropylene
Luer Fittings	316 stainless steel/polypropylene
Tubing	Dow Corning® Pharma Advanced Pump Tubing
Diaphragm Pump Housing	Glass-filled polypropylene
Diaphragm Pump Diaphragm	PTFE coated
Diaphragm Pump Check Valve	Polypropylene and Simriz® perfluoroelastomer
Housing/Enclosure	Polyurethane

Membrane Selection Guide and Pellicon® XL 50 Cassette Ordering Information

Biomax® membranes – polyethersulfone

- Suitable for storage in alkaline and acidic solutions
- pH range 1 – 14
- Hydrophilic and low protein binding
- Void-free for higher yield and reliability

Ultracel® membranes – composite regenerated cellulose

- The most hydrophilic and lowest protein binding

- Stable, reproducible flux and resistance to fouling by proteins, lipids and antifoams
- Easiest UF membranes to clean

Durapore® membranes

- Hydrophilic and ultra-low protein binding
- High flux
- Excellent retention performance
- High mechanical and chemical resistance

Membrane	NMWC0 kDa or microns	Approximate molecular weight range of solutes retained >99%, kD	Catalogue No.
Polyethersulfone			
Biomax®-5	5	5 – 12 (growth factors, hormones)	PXB0 05A 50
Biomax®-8	8	25 – 50 (growth factors, hormones)	PXB0 08A 50
Biomax®-10	10	50 – 100 (growth factors, hormones)	PXB0 10A 50
Biomax®-30	30	100 – 140 (enzymes)	PXB0 30A 50
Biomax®-50	50	140 – 300 (IgGs)	PXB0 50A 50
Biomax®-100	100	300 – 500 (small viruses and antigens)	PXB1 00C 50
Biomax®-300	300	>500 (IgMs, large viruses)	PXB3 00C 50
Biomax®-500	500	>.03 µm (colloids, particulates)	PXB5 00C 50
Biomax®-1000	1,000	>.03 µm (colloids, particulates)	PXB0 1MC 50
Composite Regenerated Cellulose			
Ultracel®-5	5	8 – 18 (proinsulin, hematopoietic factors)	PXC0 05C 50
Ultracel®-10	10	18 – 60 (hemoglobin, enzymes)	PXC0 10C 50
Ultracel®-30	30	60 – 200 (monoclonal IgGs)	PXC0 30C 50
Ultracel®-100	100	200 – 500 (small viruses and antigens)	PXC1 00C 50
Ultracel®-300	300	>500 (large viruses, IgMs)	PXC3 00C 50
Ultracel®-1000	1,000	>.03 µm (colloids, particulates)	PXC0 1MC 50
Hydrophilic PVDF			
Durapore®	0.10 µm	clarify cell lysates and protein solutions, clarify viral cultures	PXVV PPC 50
Durapore®	0.22 µm	harvest and wash colloidal suspensions, bacterial cells, clarify protein solutions and viral cultures	PXGV PPC 50
Durapore®	0.45 µm	harvest and wash colloidal suspensions, cell and viral cultures, clarify protein solutions and viral cultures	PXHV MPC 50
Durapore®	0.65 µm	harvest cell cultures or colloidal suspensions	PXDV PPC 50

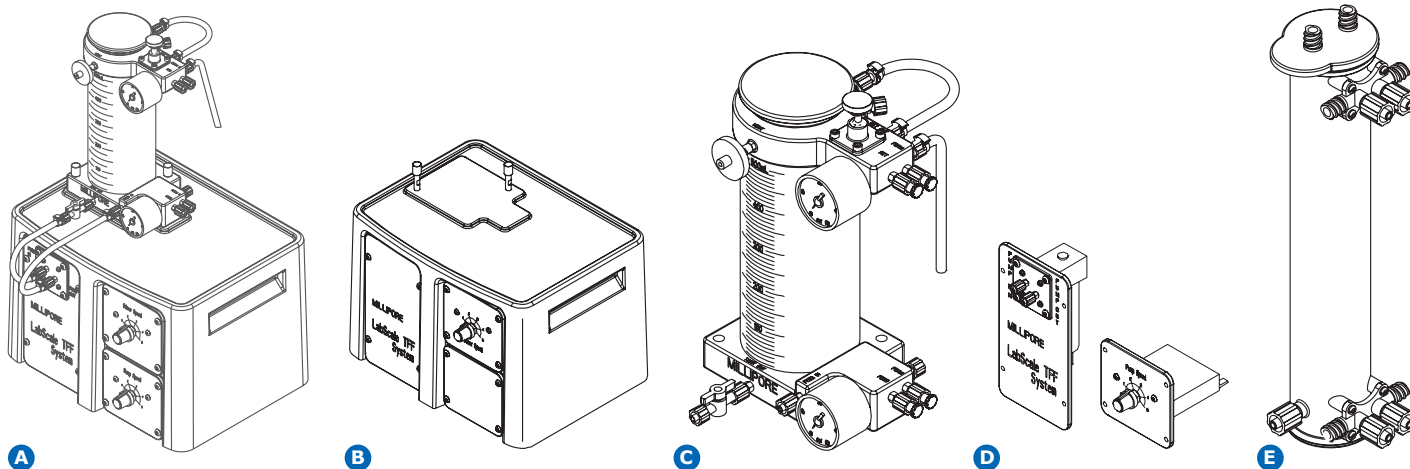
Each Pellicon® XL 50 cassette is packaged one per box and includes Operating Instructions, an Accessory Kit and a Certificate of Quality.

Accessories

- The 100 mL Reservoir can be used with the Pellicon® XL 50 cassette for simple separations of small volumes.
- The Multimanifold mounts directly onto the Labscale® System reservoir and allows up to three Pellicon® XL 50 cassettes to be used for either faster processing or simultaneous testing of three different membranes.
- The Analog Pressure (0 – 60 psi) Gauge Kit can be used with the Pellicon® XL 50 Cassette for accurate scaling studies.

Ordering Information

Description	Voltage	Catalogue No.
Labscale® TFF System		
A. Labscale® Systems include a stirbase module, a 500 mL reservoir with gauges and a diaphragm pump module	115V (US)	XX42 LSS 11
	230V (EU, Asia)	XX42 LSS 12
	230V (UK)	XX42 LSS 13
	100V (Japan)	XX42 LSS 14
B. Labscale® System stirbase	115V (US)	XX42 STR 11
	230V (EU, Asia)	XX42 STR 12
	230V (UK)	XX42 STR 13
	100V (Japan)	XX42 STR 14
C. Labscale® System 500 mL reservoir		XX42 RES 01
D. Labscale® System pump module (requires a Labscale® stirbase)		XX42 PMP 01
Accessories		
Pellicon® XL 50 Cassette accessory kit 4 Luer barb fittings, 4 tubing clamps, 1 retentate clamp, Dow Corning® Pharma Advanced Pump Tubing, 1.2 m (4 ft)		XXPX LFT KT
Pellicon® XL 50 Cassette stand		XXPX LST ND
Gauge kit 1 pressure gauge, 0–60 psi, and connection fittings		XXPX LGA GE
Multimanifold		XXMU LTI MN
100 mL Reservoir (see illustration E)		XX42 RES 05
Stand for mounting 100 mL reservoir on the Labscale® System		XXRE S05 ST



Pellicon® 2 Cassettes and Holders

Reliable Linear Scale-up from the Lab to the Production Plant

For processing volumes from 100 mL to 1000 L, we offer Pellicon® 2 cassettes and holders. These high performance TFF filters are used for biopharmaceutical process development, scale-up/scale-down, concentration, purification and cell harvesting applications. The same ultrafiltration and microfiltration membranes incorporated in Pellicon® XL 50 cassettes are found in the Pellicon® 2 cassettes and can easily and reliably scale up for use in pilot or manufacturing plants.

For more information and specifications, ask for the Pellicon® 2 data sheet.



To Place an Order or Receive Technical Assistance

For additional information, please visit www.merckmillipore.com.

To place an order or receive technical assistance, please visit www.merckmillipore.com/contactPS.

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