

PALL BY AND AND

Life Sciences

Centramate[™], Centrasette[™], Maximate[™] and Maxisette[™] Cassettes

For Development, Pilot-Scale and Production in Ultrafiltration and Microfiltration Processes

Filtration. Separation. Solution.sm

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Ultrafiltration and Microfiltration TFF - Cassette Membranes

Pall offers a comprehensive selection of tangential flow filtration (TFF) products to meet the increasing diversity of biological and biopharmaceutical processes and applications. Pall[®] membrane cassettes and their associated hardware and systems are the preferred choice in applications that require gentle processing and characteristics tailored to the application.

Membranes for UF and MF TFF

Pall Omega[™] ultrafiltration (UF) membranes have been developed and manufactured to give consistent performance. Products are available for laboratory, development, pilot, and production-scale TFF applications.

Pall Supor[®] TFF microfiltration (MF) membranes are optimized for product clarification and recovery in biotechnology and pharmaceutical applications.

Pall membranes provide superior performance and stability to meet the challenges of each unique TFF application. Each membrane is available in a broad range of cassette types and configurations.

Omega Membrane

Omega polyethersulfone (PES) membranes have been specifically modified to minimize protein binding to the surface and interstitial structure of the membrane. This polymeric membrane is stable against biological and physical degradation due to the unique chemical properties of PES.

Omega membranes are cast on a highly porous, non-woven polyolefin support. They have an anisotropic structure, a thin skinlike top layer with a highly porous underlying support. The structure of the skin determines the porosity and permeability characteristics of the membrane. Anisotropic membranes have higher water permeability and can typically be cleaned quicker and easier than membranes with a uniform, sub-micron depth structure.

Damage to the skin of anisotropic membranes is easily detected with an integrity test. This may not be the case for membranes with sub-micron porous underlayers.

Supor TFF Membrane

Supor TFF membrane is a modified polyethersulfone membrane with a uniform depth structure. The membrane porosity is optimized for microfiltration TFF applications including harvest, concentration and clarification of cell cultures and fermentation broths. Use **Supor** TFF membranes to harvest bacterial, mammalian, and insect cells; separate red blood cells from hemoglobin; and clarify yeast broth and bacterial lysates.

Characteristics of Omega and Supor TFF membranes

- Low affinity and adsorption characteristics resulting in higher product recovery
- Available in a wide variety of cassette configurations, for easy and direct scale-up/scale-down
- Greatest selection of ultrafiltration membrane rating available:
 650 Da – 1000 kDa to fit specific application needs
- Wide range of membrane pore sizes to optimize the process
- Compatible with acids, bases and a variety of other cleaning agents to optimize cleaning procedures.





Top: Maxisette Membrane Cassettes Bottom: Centrasette Membrane Cassettes

Tangential Flow Filtration Membrane Cassettes Centramate™, Centrasette™, Maximate™, and Maxisette™ Cassettes





Top: Centramate Membrane Cassettes Bottom: Centrasette Cassette

Centramate Cassettes

Centramate cassettes are perfect for laboratory scale and development applications in TFF. Small area formats with 0.009 m² and 0.018 m² may be used with the **Centramate** LV holder for process volumes of a few liters down to a few milliliters. The 0.09 m² format is used with the **Centramate** Stainless Steel or **Centramate** PE holders. **Centramate** cassettes are available in a range of channel formats and membranes to meet every application requirement. The cassettes are supplied with the same membrane and construction materials as used in the **Centrasette** Membrane cassettes.

Applications developed on a **Centramate** cassette can be easily scaled up by adding cassettes to a **Centramate** holder or by switching to the **Centrasette** cassette format with identical path length and channel format.



Centrasette and Centrasette II Feed Port Comparison

Centrasette and Centrasette II Cassettes

Centrasette cassettes, available in the same range of membrane and screen formats as the **Centramate** cassettes, have been widely used for years in various process applications including concentration and diafiltration by the biopharmaceutical industry. **Centrasette** cassettes are available with membrane areas of 0.46, 1.9, and 2.3 m² (5, 20, and 25 ft²). Larger cassette areas simplify installation in large TFF systems, reducing the number of gaskets required and minimizing risk of leakage.

Pall continues to improve membrane cassettes to meet the more rigid requirements of today's applications.

The **Centrasette** II membrane cassette uses the same components as in the original **Centrasette** cassette. Therefore revalidation may not be necessary.

Feed ports in the **Centrasette** II have been enlarged to twice the size of the **Centrasette** cassette and membrane area has been increased by about 10%. The larger fluid port design will enhance the membrane's performance by:

- Improving fluid flow distribution between and through cassettes
- Allowing more efficient cleaning
- Reducing the pressure profile across the feed/retentate channels

Both types of **Centrasette** cassettes are available with 3 different membrane area options to meet small scale and larger process volume requirements. The **Centrasette** cassettes fit in a variety of **Centrasette** holders as well as similar holders from other manufacturers.

Tangential Flow Filtration Membrane Cassettes Centramate™, Centrasette™, Maximate™, and Maxisette™ Cassettes

Maximate Cassettes

The **Maximate** membrane cassette offers the opportunity to simulate the performance of the larger **Maxisette** membrane cassette on a smaller scale. The path length in **Maximate** membrane cassettes is identical to that used in the **Maxisette** format but the membrane surface area and hold up volume are proportionately lower, meaning that processing and optimization studies may be performed on smaller batches.

Maxisette Cassettes

The **Maxisette** format has some distinct benefits that make it advantageous for large volume processes. Most important is that the volumetric flow rate required is 40 % lower compared to cassette formats like the **Centrasette**. This translates to a smaller pump and piping diameter being required for the same membrane area with a corresponding reduction in energy cost. The larger porting in the **Maxisette** (almost 50% larger feed and retentate ports than the **Centrasette** II Cassette) provides lower resistance to high feed flow rates which results in lower pressure drops and easier cleaning.

Membrane Cassette General Information

There are four cassette formats for UF and MF applications – Centramate, Centrasette, Maximate and Maxisette.

Pall TFF membrane cassettes are available in a range of molecular weight cut-offs from 650 Da to 1000 kDa and pore sizes from 0.1 μ m to 0.65 μ m to meet every application requirement. Featured membrane types include:

- Omega
- Supor TFF

Materials of Construction

Membrane Omega Supor TFF	Modified polyethersulfone				
Encapsulant	Polyurethane				
Screens	Polyester				
Spacers Omega Supor TFF	Polyolefin/PES Polyolefin				

Cassettes pass current USP biological safety tests for Class VI plastics at 70 °C (158 °F).

Operating Specifications

Cassette Format	Maximum Operating Temperature	Maximum Recommended Operating Pressure			
Centramate	50 °C (122 °F)	5 bar (75 psi)			
Centrasette	50 °C (122 °F)	5 bar (75 psi)			
Maximate	50 °C (122 °F)	5 bar (75 psi)			
Maxisette	50 °C (122 °F)	5 bar (75 psi)			

* Do not exceed maximum pressure rating of any component in the system.

Cassette Channel Configurations

Cassettes are available in fine, medium and suspended screen channel formats to best meet the specific requirements of each application.

Select a cassette channel configuration based on the following criteria:

Selection Criteria					
Clarified, dilute solutions Final concentration below 2% (20 mg/mL) MWCO below 300K					
Clarified solutions; low – medium viscosity Final concentration < 30% (300 mg/mL)					
Particles/cells/cell debris in solution High viscosity					

Storage Agents

Omega, and **Supor** TFF cassettes are shipped wet, in liquid containing a humectant and bactericidal storage solution. This solution consists of 15 - 20% glycerin and 0.05 - 0.1% sodium azide.

The storage solution must be removed and the cassette flushed well with water prior to use to prevent product contamination.

Cassettes are also available with circa 0.3N sodium hydroxide as the storage agent.

Traceability

Each membrane cassette has a unique serial number for full traceability. Each cassette is supplied with:

- · Certificate of Test
- Membrane Cassette Care and Use Procedures
- Material Safety Data Sheet (MSDS) for cassette preservative
- · Two platinum cured silicone gaskets

Tangential Flow Filtration Membrane Cassettes Ordering Information

How to Order Membrane Cassettes

1. Choose a membrane type from Table 1 (e.g. OS, or PS).

- 2. Choose a MWCO from Table 2 or a μm rating code from Table 3, as appropriate (e.g. 010 = 10 kD, M20 = 0.2 $\mu m).$
- 3. Choose a format code from Table 4 (e.g. C10, C11, or C12).

Table 1 – Membrane Type

Code	Membrane	Comments			
OS	Omega modified polyethesulfone	Low protein-binding			
PS	Supor TFF polyethersulfone	Microfiltration-optimized			

Table 2 – Available MWCOs for Omega Ultrafiltration Membranes

Code	D65	001	003	005	010	030	050	070	100	200	300	500	990
MWC)												
(kD)	0.65	1	3	5	10	30	50	70	100	200	300	500	1000

Table 3 – Available Micron Ratings for Supor Microfiltration Membranes

Code (µm)	M10	M20	M45	M65			
Pore Size	0.1	0.2	0.45	0.65			
(µm)							

Typical Examples:

0	S	0	1	0	F	0	6	А	F		Ρ	S	М	2	0	G	0	2	
Me	mb	rane)			0	me	ga			M	emk	oran	е			s	Sup	or
M٧	VCC)/Ra	ting	J	10 kD						MWCO/Rating					0	.2 μ	um	
Fo	rma	t			Centrasette II					Fc	Format				Ma	xin	nate		
Fe	ed C	Char	nnel		Medium Screen					Fe	Feed Channel				Sus	spe	nde		
Are	Area				0.5 m ² (5.4 ft ²)											S	cre	en	
Sp	Special Format			0.3N NaOH						Area			().18	m²	(2 1			
Sto	orag	e Aç	gent	t i						Special Format				1	Nor	ne			

Table 4 – Cassette and Screen Formats

Cassette Format	Nominal Area	Fine Screen Code ¹	Medium Screen Code	Suspended Screen Code
Centramate	0.01 m² (0.1 ft²)	-	C12P1	-
	0.02 m² (0.2 ft²)	-	C12P2	C11P2
	0.1 m ² (1.0 ft ²)	C10	C12	C11
Centrasette	0.46 m² (5.0 ft²)	C05	C06	C07
	1.86 m² (20 ft²)	C20	C21	C22
	2.32 m² (25 ft²)	C25	C26	C27
Centrasette II	0.5 m² (5.4 ft²)	F05	F06	F07
	2.0 m² (22 ft²)	F20	F21	F22
	2.5 m² (27 ft²)	F25	F26	F27
Maximate	0.04 m² (0.4 ft²)	-	G01P2	G02P2
	0.19 m² (2.0 ft²)	G10	G01	G02
Maxisette	2.8 m² (30 ft²)	C50	C51	C52

¹ Fine Screen channel not available in any MWCOs greater than 200 kDa.

Tangential Flow Filtration Membrane Cassette Holders Choosing a Cassette Holder



Centramate LV Holder



Centramate Holder and Fittings Kit



TFF cassette holders for the medium and large-scale production environment have a small footprint, yet still are capable of holding large areas of membrane. All stainless steel holders are engineered to precise specifications with a high standard internal and external surface finish and are available with either manual torque (MT) or auto torque (AT) compression systems for ease of use.



Centrasette LV Holder



Centrasette 5 Holder



Centramate 500 S unit



Centrasette P Holder

Operators must use calibrated torque wrenches (supplied with the holder) to effect required compression of cassettes and gaskets in a manual torque cassette holder. Auto-torque cassette holders automatically compensate for cassette compression and temperature reduction.

They also eliminate variability in technique between operators. Auto-torque cassette holders are recommended for process-scale validated processes.

Sanitary stainless steel holders may be sterilized by steam or autoclaving without cassettes installed.

Complete fittings kits consisting of pressure gauges, valves, filtrate manifold, connectors, gaskets and clamps are available for most cassette holders. Ordering a complete fitting kit with the cassette holder simplifies installation into a system and avoids potential delays in starting your process due to missing parts.

Tangential Flow Filtration Membrane Cassette Holders Choosing a Cassette Holder

Choosing a Cassette Holder

The following table lists cassette holders with relative area capacities (screen channel cassettes) and working volumes¹. The Minimate[™] TFF Capsule is also included to complete the range of lab scale products.

Product	Membrane Area	(Nominal) ¹	Working Volumes ²			
Lab and Development Scale (Scale-up and Scale-down studies)			Starting	Final		
Minimate TFF Capsule	0.005 m ²	0.05 ft ²	25 – 500 mL	15 mL		
Centramate LV	0.01 – 0.04 m ²	0.1 – 0.4 ft ²	25 – 4,000 mL	15 mL		
Centramate PE	0.01 – 0.37 m ²	1 – 4 ft ²	0.5 – 80 L	150 mL		
Centramate	0.01 – 0.46 m ²	1 – 5 ft²	0.5 – 100 L	150 mL		
Maximate	0.19 – 1.11 m ²	2 – 12 ft²	1 – 250 L	350 mL		
Pilot Scale (Process Development) Centrasette LV	0.46 – 2.0 m ²	5 – 22 ft²	2.5 – 500 L	400 mL		
Pilot Scale (Process Development)						
Centrasette P	0.46 – 2.0 m ²	5 – 22 ft ²	2.5 – 500 L	400 mL		
Centrasette 5	0.46 – 4.6 m ²	5 – 50 ft²	2.5 – 1,000 L	1,000 mL		
Process Scale (Production)						
Centrastak 100	0.9 – 20.0 m ²	10 – 215 ft ²	10 - 4,000	4 L		
Centrastak 200	1.85 – 40.0 m ²	20 – 430 ft ²	20 - 8,000	10 L		
Centrastak 300	2.8 – 60.0 m ²	30 – 645 ft ²	30 - 12,000	15 L		

 $3.7 - 80.0 \text{ m}^2$ $40 - 860 \text{ ft}^2$ 201 Centrastak 400 40 - 16.000 2.8 – 27.9 m² 30 - 300 ft² 30 - 6,000 Maxisette 25 15 L Maxisette 50 5.6 - 55.8 m² 60 - 600 ft² 60 - 12,000 30 L 5.6 - 92.9 m² 60 - 1,000 ft² Maxisette 100 60 - 20,000 40 L

¹ Fewer suspended screen cassettes will fit due to increased thickness. Some holders can fit more membrane area than can be operated at required cross flow rates due to high pressure drops. Do not use more than the recommended area in these holders. Manual (MT) and auto-torque (AT) version holders are available for Pilot and Process Scale applications.

² Working Volumes are based on an average filtrate flux rate of about 50 LMH and process time of 5 hours. Starting Range covers minimum to maximum area installed for screen channel cassettes. Final process volume represents final concentration volume or minimum working volume for the system. Actual volumes depend on system hold-up volume and operating parameters. Piping (tubing) lengths and internal diameters significantly affect the final volume.



Centrasette 200 AT Holder



Maxisette 25 AT Holder



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