

Biomax® Membranes

The membrane of choice for fast processing and exceptional chemical resistance

The more open average pore size permitted by the void-free structure of the Biomax® membrane results in higher fluxes with maximum retention.

Conventional UF membranes cast with macrovoids have tighter average pore sizes and must operate with reduced flux to keep retention high.

The high flux and high retention properties of the Biomax® membrane result in faster processing speeds with higher yields, which means shortened processing times and a bioprocessing system that can be smaller and more compact.

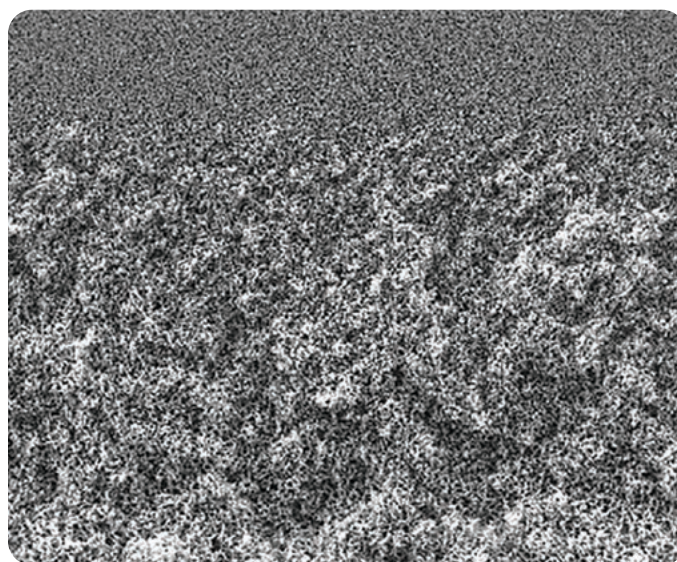
Biomax® membranes are composed of polyethersulfone and are resistant to harsh chemicals used in cleaning, biological decontamination and sanitization. The polyethersulfone Biomax® membrane has been designed to reduce nonspecific protein binding compared to conventional polyethersulfone membranes.

Typical Applications

- Concentration, buffer exchange and depyrogenation of protein solutions containing biomolecules such as albumin, IgG, IgM, monoclonal antibodies, hormones and growth factors
- Harvest, clarification and concentration of vaccines

Advantages of Choosing Biomax® Membranes

- Void-free structure results in high flux, excellent retention and higher yields
- Polyethersulfone membrane provides a stable hydraulic environment, resulting in excellent mechanical strength and integrity
- Biomax® membrane has superior resistance to harsh cleaning chemicals with no degradation of processing performance through multiple cleaning cycles
- Biomax® membranes are available in a wide range of molecular weight cut-offs to meet all of your application needs



Biomax® membrane composite polyethersulfone with void-free structure

Tighter Retention Profile

The retention profile of Biomax® 10 kDa membrane is much sharper than that of a conventional 10 kDa membrane, translating into improved protein retention in your process stream (Figure 1).

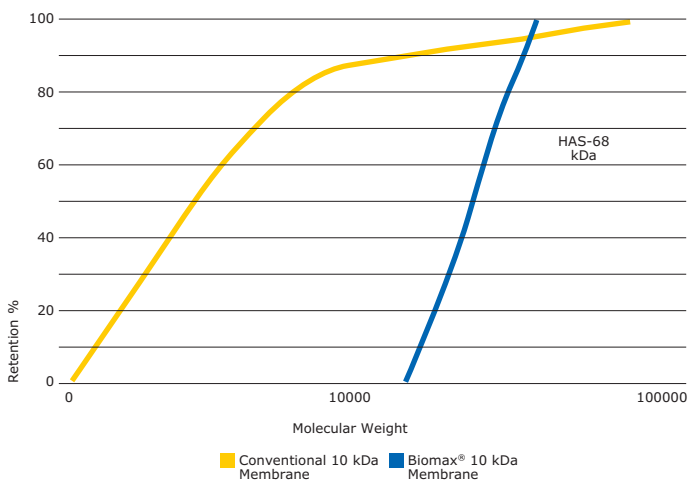


Figure 1.

Protein retention of Biomax® membrane versus conventional polyethersulfone UF membrane.

Superior Flux

At working concentrations of protein, Biomax® membranes have higher flux for a given protein retention than conventional polyethersulfone UF membranes. In this example, Biomax® 10 kDa membrane demonstrates a 40% improvement in process flux over a conventional 10 kDa polyethersulfone membrane using 10% BSA (Figure 3).

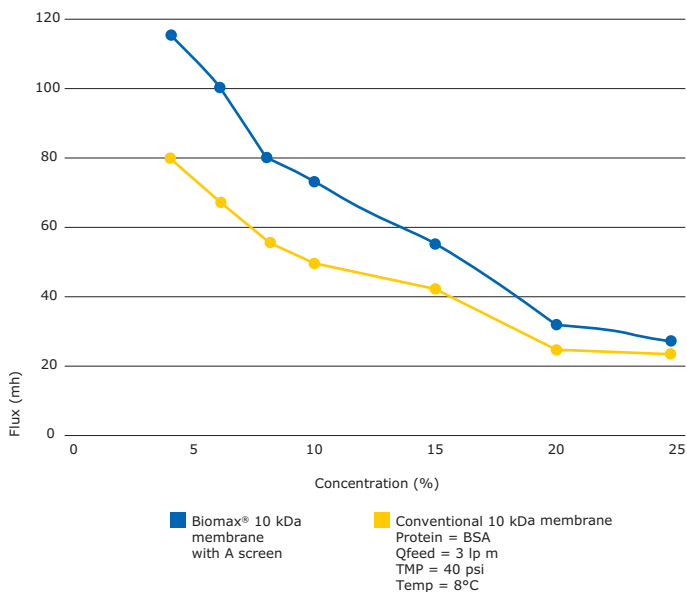


Figure 3.

High flux of Biomax® membrane versus conventional polyethersulfone UF membrane.

Improved Integrity

The void-free structure of the Biomax® membrane significantly reduces the incidence of microdefects, resulting in improved membrane integrity (Figure 2).

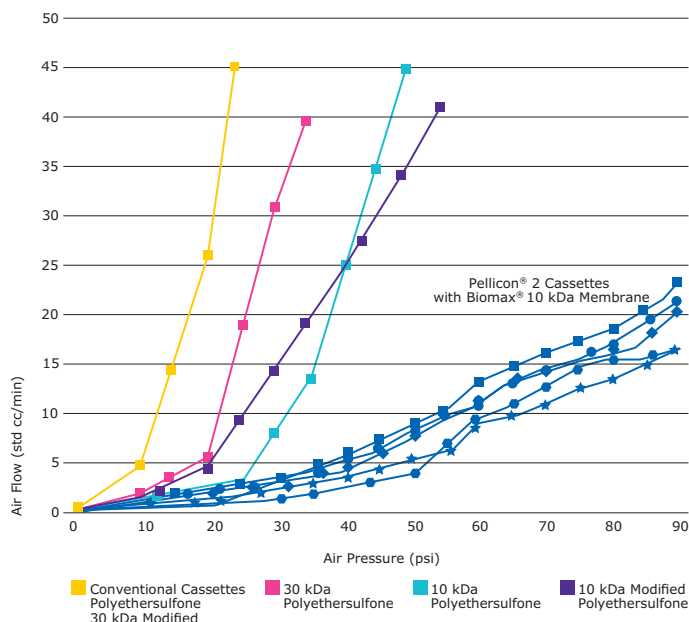


Figure 2.

Integrity testing of Biomax® membranes versus conventional polyethersulfone UF membranes.

Improved Process Yields

You can decrease the size of the system and improve your yield, thereby reducing your overall processing costs (Table 1).

Parameter	Biomax® 10 kDa Membrane	Conventional Polyethersulfone (10 kDa) Membrane
Retention (%)	99.95	99.9
Flux (lmh)	118.0	80.0
Recirculation rate (lpm)	4.0	6.0
Pipe diameter (inches)	1.5	2.5
Hold-up volume (liters)	8.4	20.8
Yield improvement (%)	2 – 3	—

Table 1.

Superior Chemical Resistance Results in Excellent Cleanability

A simple caustic cleaning regimen restores normalized water permeability (NWP) to near initial levels following sequential process runs (Figure 5).

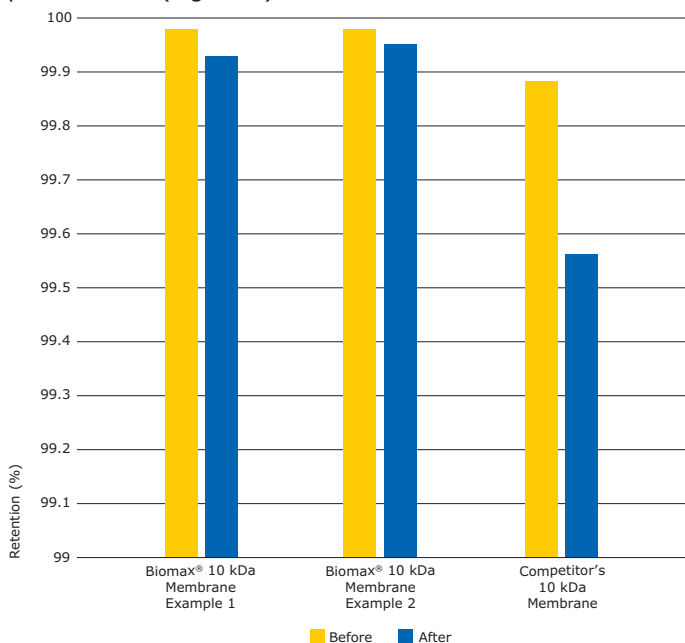


Figure 4.

Caustic resistance of Biomax® membrane versus conventional Polyethersulfone UF membrane.

Results

After 100 hours in 600 ppm chlorine, the Biomax® 10 kDa membrane showed no appreciable change in air integrity or BSA retention (Table 2).

	Sample A	Sample B
Air integrity (sccm) prior to exposure	7	8
BSA retention % prior to exposure	99.97	99.97
Air integrity (sccm) after exposure	3	10
BSA retention % after exposure	99.97	99.97

Table 2.

Biomax® Membrane Mixed Dextran Test

The need for more rejection information and for better membrane manufacturing consistency and control led us to develop the Mixed Dextran Rejection Test for ultrafiltration (UF) membranes.

A large number of marker solutes has been used in the past to characterize the retention properties of UF membranes. Traditionally, solutions of single proteins were used and a ranking system of Nominal Molecular Weight limits (NMWL) was adopted by the UF user community. For each membrane, the NMWL value gives an estimate of the molar mass of the smallest protein that is retained at an arbitrarily selected minimum level (usually 90%). This system of ranking has proved to be very useful and is still used to classify UF membranes. The NMWL method, however, offers very limited information about the properties of UF membranes (approximate rejection value for only one solute size) and therefore is no longer sufficient for the sophisticated user of state-of-the-art separation processes. Although protein processing represents the most important type of applications for UF membranes, using proteins as markers has many disadvantages,

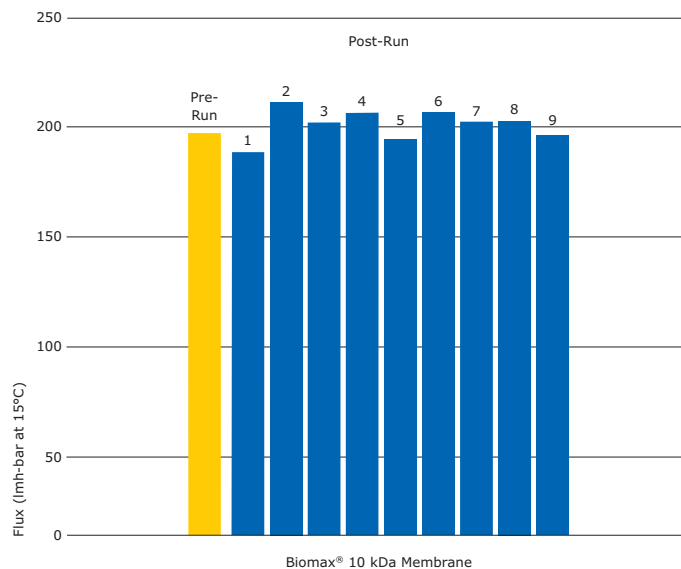


Figure 5.

Consistent return of water permeability after cleaning.

such as availability in sufficient purity, diversity of protein shape, structure and physical properties and high cost. To satisfy the need for testing a wide variety of UF membranes, one has to select proteins of vastly different sizes. An undesirable consequence of this selection is the potential variation of other properties, such as isoelectric point (resulting in different charge at a given pH), the nature and proportion of hydrophobic and hydrophilic groups on the surface of the molecule (resulting in different adsorption properties), solubility and size-to-molecular weight relationship. All these differences can significantly affect the measured rejection values and therefore make the interpretation more difficult.

Our rejection profile test uses dextrans as test markers. This allows an evaluation of the rejection properties of a UF membrane for a range of solute sizes spanning from solutes that are completely passed through the membrane to solutes that are completely retained, so that one test generates a complete rejection curve.

Low adsorption of dextrans to many UF membranes joins with optimized and controlled boundary conditions in the rejection profile test to assure that the measured rejection profile reflects as closely as possible the steric rejection properties of UF membranes, and therefore offers useful information about the membrane pore size distribution. To take advantage of these characteristics of the rejection profile test, we adopted this test as a standard quality control method for monitoring and controlling the reproducibility of UF membranes. Rejection profile bands were specified for each membrane type. The measured rejection profile of each membrane lot has to fall within these bands. The result has been a significant improvement in lot-to-lot reproducibility of the rejection performance of our UF membranes.

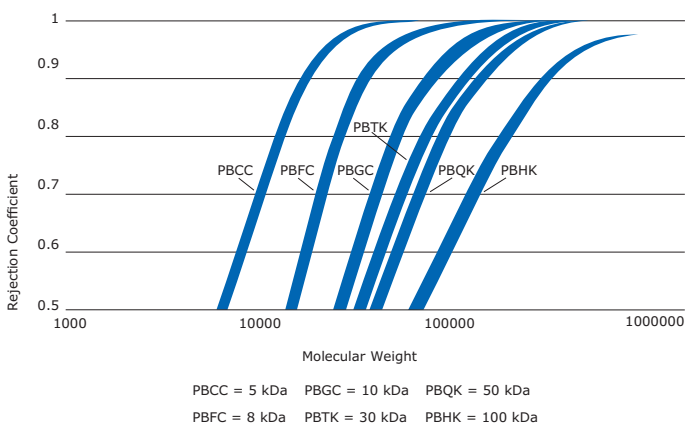


Figure 6.
UF membrane Dextran retention profile.

Device Formats

Biomax® membranes are found in Pellicon® Cassettes



Merck KGaA
Frankfurter Strasse 250
64293 Darmstadt, Germany

Biomax® Membrane Specifications

Materials of Construction	Polyethersulfone with void-free structure pH compatibility - 1–14 Reverse Pressure - \geq 30 psi
Relative Protein Binding	Low to moderate, for use with protein solutions containing more than 0.1 mg/mL of protein

Biomax® Membrane Applications

Biomax® Membrane Code	NMWL* (kDa)	Typical Application
PBCC	5	Growth factors, hormones
PBFC	8	Growth factors, hormones
PBGC	10	Albumin, hemoglobin
PBTK	30	Enzymes
PBQK	50	IgGs
PBHK	100	Small viruses, antigens
PBMK	300	IgMs, large viruses
PBVK	500	Large viruses, colloids, particulates
PBXK	1000	Large viruses, cells, colloids, particulates

*Nominal Molecular Weight Limit

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