xevonta

Haemodialysis

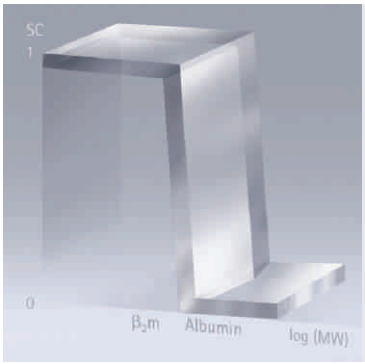
B BRAUN
SHARING EXPERTISE

xevonta – a new dimension of efficiency and effectiveness

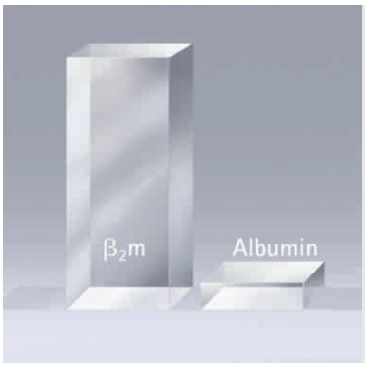
- Outstanding performance profile for an efficient treatment
- Excellent in small molecule clearance
- Optimal selectivity: maximal β_2m-elimination with simultaneous minimal albumin loss
- Excellent biocompatibility
- High endotoxin retention
- Minimum rinse volume
- Complete product range: 6 high flux and 6 low flux variants

Excellent conditions for brilliant performance

Sieving profile
Pioneering high-tech production by B. Braun meets the highest demands on dialysers.
By precisely defining pore diameters and maximising the number of pores, we have created the distinctive sieving profile of the amembris membrane, which ensures an outstanding clearance spectrum.



Selectivity
The excellent shape of the sieving coefficient curve is the impressive result of the precisely defined pore diameters and compelling evidence of the superior selectivity of amembris. The high diffusive elimination, combined with the selective convective elimination of middle molecules, particularly low-molecular proteins, demonstrates the outstanding performance of xevonta.



Optimal ratio β_2m vs. albumin
The excellent selectivity characteristic of amembris produces outstanding results for the elimination of β_2-microglobulin and concomitantly offers an impressive retention of albumin. amembris ensures the best conditions for a highly efficient treatment and for achieving the recommended target ranges of serum albumin[1].

x design
The new x-shaped design of xevonta, with its bundle head expansion and appropriate packing density, provides the consistent homogeneous distribution of dialysis fluid in the dialyser. Each individual fibre is evenly washed around, thus contributing to the optimum clearance performance of xevonta. xevonta also has excellent priming and deaeration characteristics.

amembris –
an innovation in fibre development

Efficiency has a new name

With amembris, B. Braun has made a giant leap in the development of a high-performance, biocompatible, Polysulfone-based synthetic membrane.

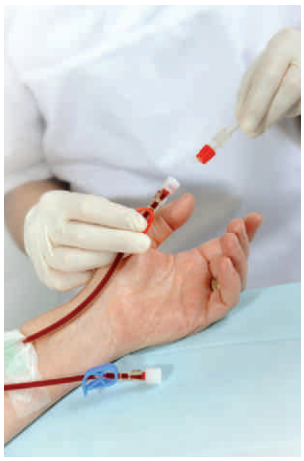
The fibre development for dialysis is characterised by high and unique demands ensuring excellent treatment outcomes.

Key elements of a perfect dialysis membrane are a narrow pore size distribution, a precisely defined maximum pore size, high surface and overall porosity, a thin active separation layer, an optimum wall thickness-diameter ratio of the hollow-fibre membrane and hydrophilic surface characteristics. This ensures high hydraulic and diffusive permeability – the condition for high clearance performance – and achieves a clear separation limit between molecules which have to be eliminated to a maximal extent, e.g. β_2m, and the substances – e.g. albumin – for which maximum possible retention is required.

It is also crucial that the blood-contacting surface is as smooth as possible in order to reduce any interaction with blood components to a bare minimum. The formation of hydrophilic, hydrophobic, negatively and positively charged domains on the blood-contacting membrane surface also considerably contribute to biocompatibility. Furthermore, it must be reliably ensured that there can be no transfer of endotoxins from the dialysate circuit into the blood compartment.

All these complex demands clearly have been realised with amembris. Innovative fibre technology, combined with state-of-the-art housing design and continuous and diligent quality controls in production have created a new generation of high-performance dialysers: xevonta.

Outstanding performance profile for an efficient treatment

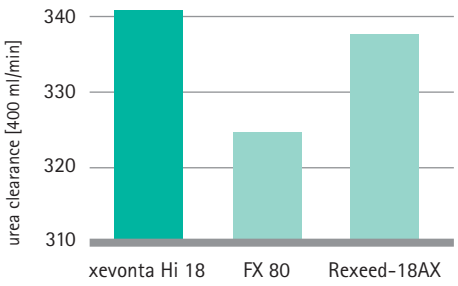


Excellent in small molecule clearance

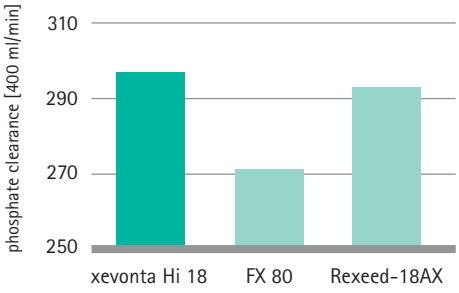
xevonta, with its outstanding clearance data, especially for urea and phosphate, offers optimised preconditions for an optimal dialysis dose and patient outcome.

In direct comparison with the best performing products on the market, xevonta low and high flux dialysers offer exceptionally high values in small molecule clearance.

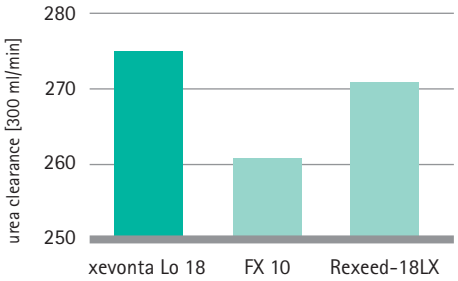
high flux urea clearance



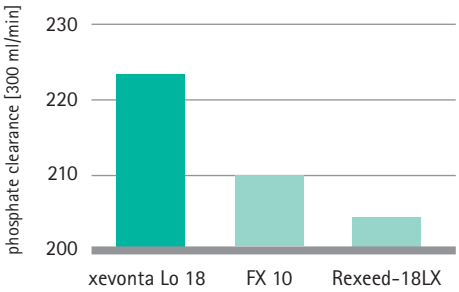
high flux phosphate clearance



low flux urea clearance



low flux phosphate clearance



Q_D = 500 ml/min, Q_F = 0 ml/min

Data from manufacturers' published specification sheets

Technical Data
xevonta high flux dialysers

In vitro performance	Hi 10	Hi 12	Hi 15	Hi 18	Hi 20	Hi 23
Ultrafiltration coefficient (ml/h/mmHg)	58	69	87	99	111	124
Clearances: Q_B = 200 ml/min						
Urea	186	191	197	198	199	199
Creatinine	173	182	190	194	196	197
Phosphate	175	183	191	194	196	198
Vitamin B_{12}	118	129	146	155	161	166
Inulin	73	84	100	110	119	126
Clearances: Q_B = 300 ml/min						
Urea	241	255	272	281	287	290
Creatinine	216	232	252	263	271	276
Phosphate	212	228	251	263	271	277
Vitamin B_{12}	132	148	171	184	195	204
Inulin	78	91	110	122	133	144
Clearances: Q_B = 400 ml/min						
Urea	290	306	329	341	349	354
Creatinine	243	262	289	304	316	324
Phosphate	231	254	282	297	309	320
Vitamin B_{12}	158	174	197	210	220	227
Inulin	89	103	124	138	150	160
Sieving coefficients						
Inulin	1.0					
β_2-microglobulin	> 0.8					
Albumin	< 0.001					
Surface (m^2)	1.0	1.2	1.5	1.8	2.0	2.3
Wall thickness/intern. diameter (µm)	35/195					
Priming volume (ml) bloodside	54	68	90	103	119	135
Membrane material	amembris (PS, PVP)					
Sterilisation	Gamma					
Units per box	20					
Art. No.	720 4622	720 4630	720 4649	720 4657	720 4665	720 4670

In vitro performance and physical data acc to EN 1283
Clearances: Q_D = 500 ml/min, Q_F = 0 ml/min; UF-coefficient: ANSI/AAMI RD 16, human blood, Hct. 32 %, total protein 6 %, T = 37°C; Sieving coefficients: Q_B = 300 ml/min, Q_F = 60 ml/min

Subject to modifications

xevonta low flux dialysers

In vitro performance	Lo 10	Lo 12	Lo 15	Lo 18	Lo 20	Lo 23
Ultrafiltration coefficient (ml/h/mmHg)	8	9	10	12	14	15
Clearances: Q_B = 200 ml/min						
Urea	184	189	194	196	198	199
Creatinine	163	171	182	188	191	192
Phosphate	143	156	170	177	182	187
Vitamin B_{12}	75	86	101	110	118	124
Clearances: Q_B = 300 ml/min						
Urea	236	249	267	276	281	285
Creatinine	201	217	237	248	256	262
Phosphate	168	186	210	223	234	243
Vitamin B_{12}	86	98	116	127	133	143
Clearances: Q_B = 400 ml/min						
Urea	276	291	311	322	329	333
Creatinine	218	238	265	280	292	300
Phosphate	182	205	234	251	265	278
Vitamin B_{12}	89	103	123	135	145	153
Surface (m^2)	1.0	1.2	1.5	1.8	2.0	2.3
Wall thickness/intern. diameter (µm)	35/195					
Priming volume (ml) bloodside	54	68	90	103	119	135
Membrane material	amembris (PS, PVP)					
Sterilisation	Gamma					
Units per box	20					
Art. No.	720 4525	720 4533	720 4541	720 4550	720 4568	720 4570

In vitro performance and physical data acc to EN 1283
Clearances: Q_D = 500 ml/min, Q_F = 0 ml/min; UF-coefficient: ANSI/AAMI RD 16, human blood, Hct. 32 %, total protein 6 %, T = 37°C

Subject to modifications

Optimal selectivity: maximal β_2m-elimination with simultaneous minimal albumin loss

The innovative fibre technology, implemented in the amembris membrane, results in a precisely adjustable pore size distribution, thus enabling an extremely clear separation limit between the substances to be eliminated and those to be retained.

This ensures excellent retention of albumin, in spite of a high sieving coefficient for β_2-microglobulin.

β_2-microglobulin is a low molecular weight protein (11,800 Da) that accumulates in the plasma of ESRD patients.

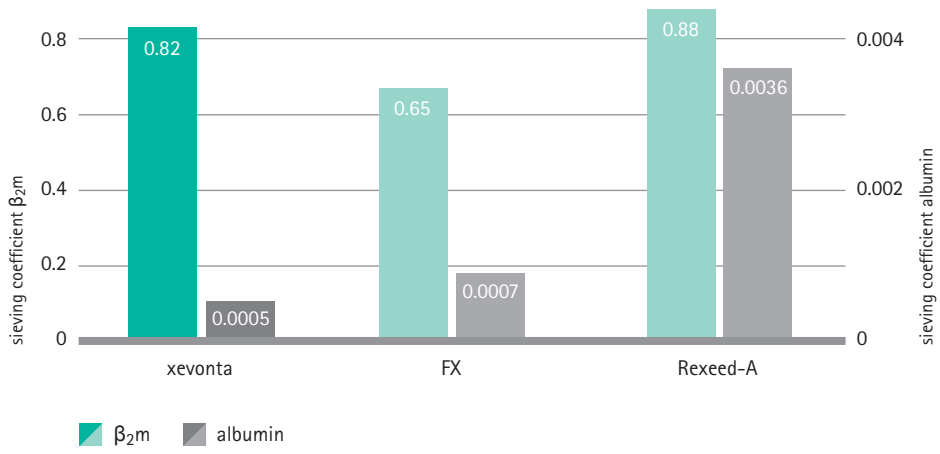
In addition, the kinetics of β_2-microglobulin removal are thought to be generalisable and representative of the kinetic behaviour of other middle molecules[2]. In the European Best Practice Guidelines[3], β_2-microglobulin has been proposed as a general marker for middle molecules.

β_2-microglobulin is widely recognised as a key component in the genesis and development of dialysis-associated amyloidosis, a syndrome that is clinically expressed in terms of destructive arthropathies and carpal tunnel syndrome[4].

A low serum albumin concentration has been well documented to be a predictor of mortality in haemodialysis patients[5,6]. The European Best Practice Guidelines recommend a serum albumin level above 40g/L[1].

With its outstanding selectivity, xevonta allows for an efficient elimination of middle molecules and concurrently shows an impressively good retention for albumin. In particular, elderly, malnourished or multimorbid ESRD patients may benefit from these performance characteristics of xevonta.

high flux sieving coefficients



unpublished data, EXCorLab, 2009, measurement conditions acc to EN 1283

1 European Best Practice Guidelines for Haemodialysis (Part 2): EBPG guideline on nutrition, NDT 22: ii45-ii87 (2007)

2 Leypoldt J: Kinetics of β_2-Microglobulin and Phosphate during Hemodialysis: Effects of Treatment Frequency and Duration, Semin Dial 18: 401-408 (2005)

3 European Best Practice Guidelines for Haemodialysis: Haemodialysis dose quantification: middle molecules, NDT 17: 21-23 (2002)

4 Drueke TB: β_2-microglobulin and amyloidosis, NDT 15: 17-24 (2000)

5 Owen WF et al.: The urea reduction ratio and serum albumin concentration as predictors of mortality in patients undergoing hemodialysis, N Engl J Med 329: 1001-1006 (1993)

6 Foley RN et al.: Hypoalbuminemia, cardiac morbidity, and mortality in end-stage renal disease, J Am Soc Nephrol 7: 728-736 (1996)

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