RENAL CARE

ELISIO™

SYNTHETIC POLYNEPHRON™ HOLLOW-FIBER DIALYZER

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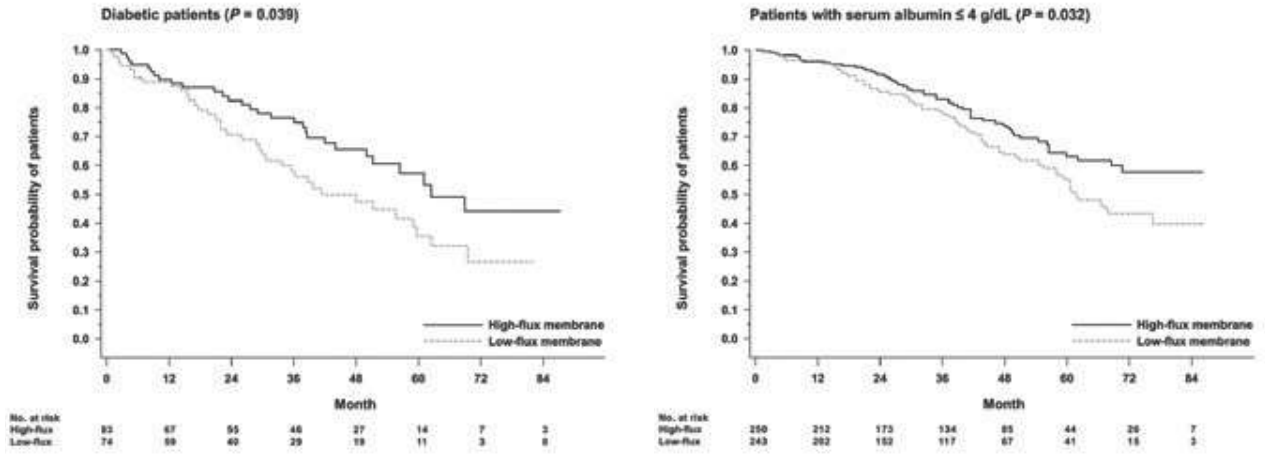
Chronic kidney disease affects more than 10% of the world's population. Patients with end-stage renal disease receiving hemodialysis treatment are often affected by several comorbidities or complications.

One of the most common complications for patients on hemodialysis that accounts for approximately 50% of deaths is cardiovascular diseases. This is caused majorly by the retention of the uremic toxins in the middle and large molecular weight range.[1, 2]

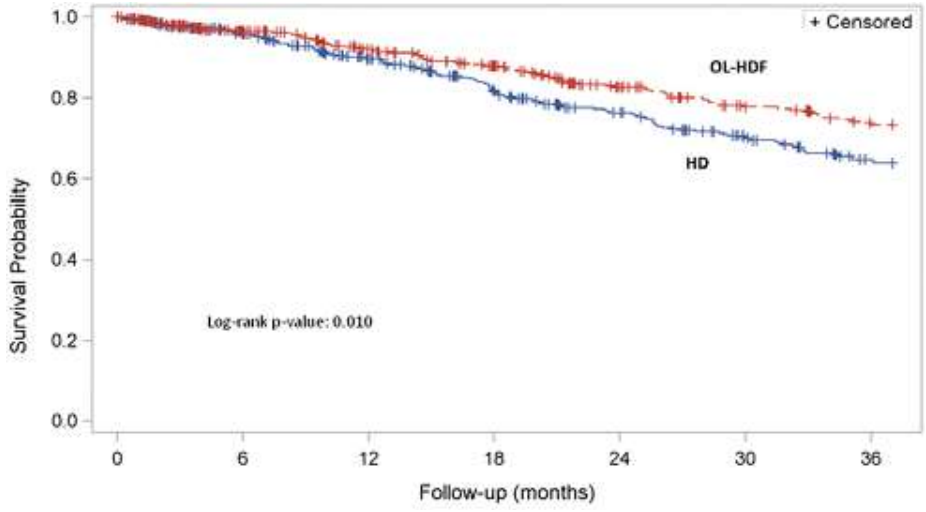
The evolution of membranes has already brought enormous benefits to dialysis patients. Today, high permeability membranes no longer need to demonstrate quality of life and survival benefits, and are currently the standard of care for most dialysis patients. However, the benefits of high flux membranes are more highlighted for specific patient groups such as long-term patients, patients with albumin levels below 4g/l, and diabetic patients.[3]

Dialyzers with high flux synthetic membranes



Thanks to the latest technical advances, high flux membranes and hemodiafiltration (HDF) have improved the clearance of middle to large molecules by combining the techniques of diffusion and convection. Post-dilution online HDF is suggested to be the most efficient mode of HDF.[4]

Innovations in dialysis membranes, machines, and fluids have made post-dilution online HDF a safe and effective technique.[5]

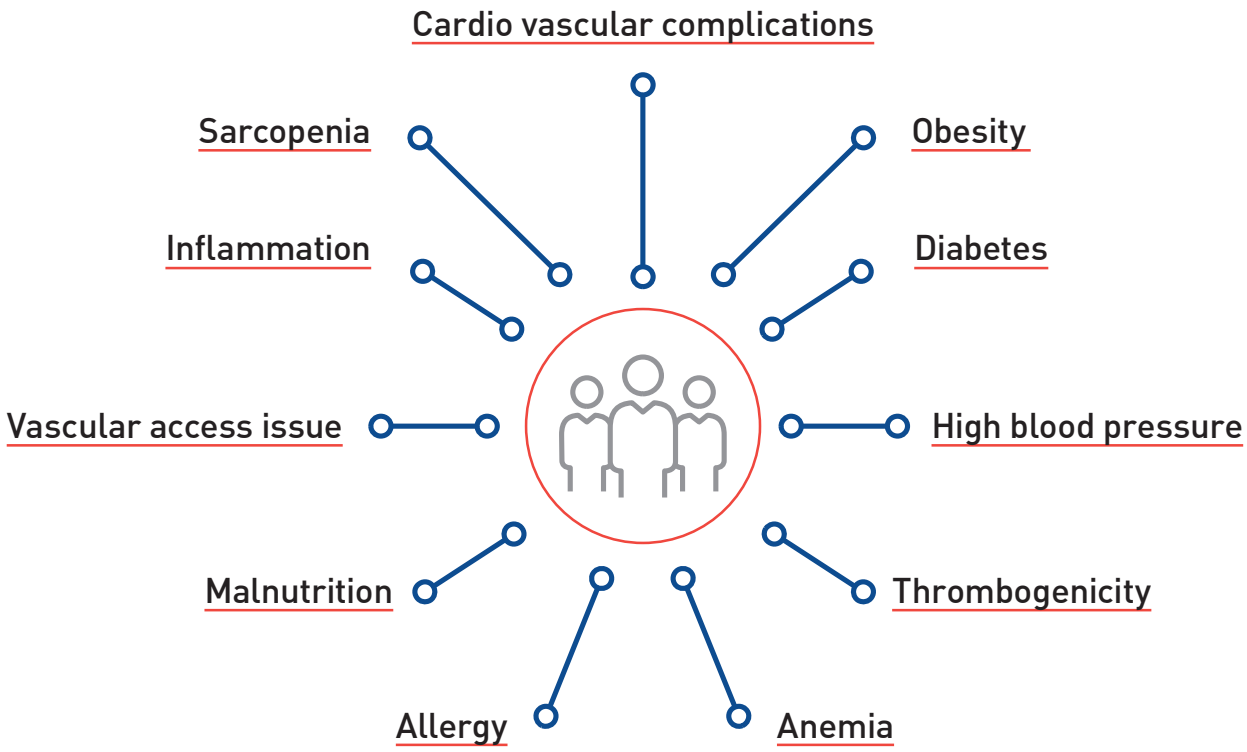


New combination dialysis machines that conveniently carry out HD and HDF

High permeability membranes have proven to be beneficial for the majority of patients. Combined with high volume hemodiafiltration, the majority of dialysis patients have their needs covered.

Dialysis patient has several comorbidities

Despite the evidence demonstrating the benefits of these treatments, a patient undergoing dialysis remains a complex patient with one or more complications.



An individualized approach remains ideal to cover the individual needs of each patient, as well as to ensure that the patient is treated in the best possible way.

Are all membranes equal?

Survival rates

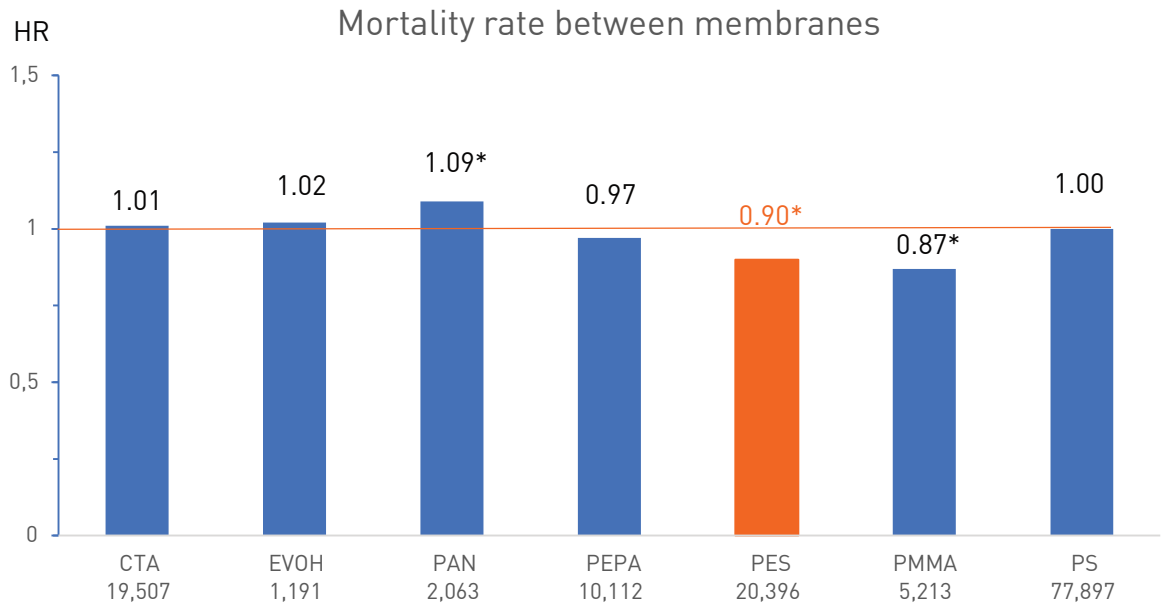
Different membranes such as polysulfone, polyethersulfone, cellulose triacetate or acrylonitrile membranes, among others, are often compared in terms of performance or biocompatibility.

Some membranes created without endocrine disruptors reduce the inflammatory responses. Asymmetric membranes have better HDF performance compared to symmetric membranes. Some have the ability to retain albumin while maintaining excellent clearance of medium-sized uremic toxins and will be advantageous to anemic patients.

With the shift from the evidence-based medicine to patient-centric medicine in recent years, it is becoming increasingly important to identify the benefits of different membranes for patients. What is the **impact on patient survival** when it comes to membrane selection?

In a cohort group, more than 136.000 patients were followed over 2 years. Patients were studied based on the membrane they had received. The final outcome was the association between types of dialyzer membranes and all-causes mortality. The polysulfone membrane group was defined as the reference group. The study showed a reduction of mortality rate by **more than 10%** for the group who received Polyethersulfone (PES) and Polymethylmetacrylate (PMMA) membranes.

It was suggested that the chemical structure of the membrane can influence the survival of patients.[6]



Hazard Ratio of all-cause mortality among 7 types of dialyzer membranes in 136.676 patients undergoing maintenance hemodialysis using standard Cox proportional hazards regression.

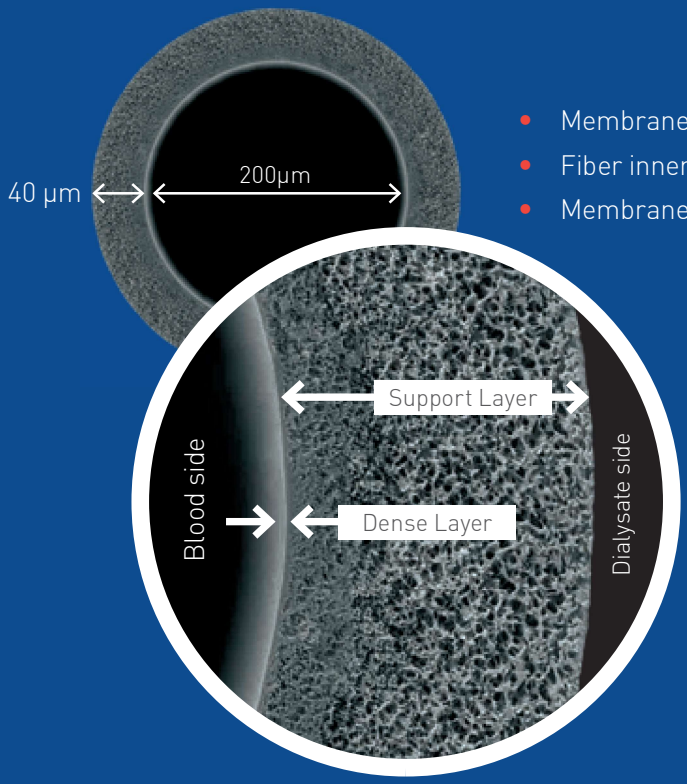
As shown here, the quality of a polyethersulfone membrane or a polymethylmetacrylate membrane has a significant impact on the survival of dialysis patients.

ELISIO-H

a polynephron™ membrane made with polyethersulfone (PES) covers most of the challenges your dialysis patient may present:

- **Clearances of middle molecular weight (MW) molecules**
- **Retention of albumin**
- **Biocompatibility**
- **Not made with BPA**
- **Low inflammation**
- **Good endotoxin retention**
- **Low thrombogenicity**
- **Reduced platelet loss**
- **Environmentally-friendly**

Oustanding performances



- Membrane fiber with an asymmetric structure
- Fiber inner diameter of 200 µm
- Membrane fiber wall of 40 µm

- Dense layer improves the diffusion efficiency
- Larger support layer enhances the echanical strength of the fibers

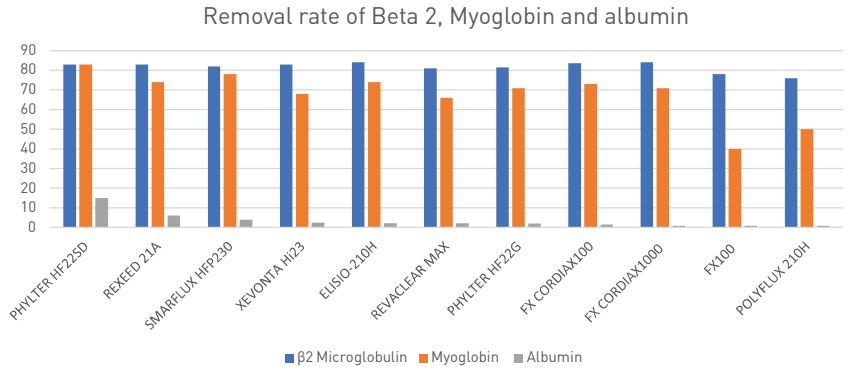
ELISIO-H allows excellent clearances for β2-microglobulin and myoglobin.

Compared to the most common synthetic membranes on the market, ELISIO-H can be used in HD, HF, and HDF (pre- and post-dilution) with minimal loss of albumin in HDF.

Removal of Middle Size Molecules

Beta-2 microglobulin (β2M) is a surrogate marker of middle-sized uremic toxins and is a key component of dialysis-associated amyloidosis.

Blood levels of β2M are predictive of all-cause mortality in hemodialysis patients regardless of the duration of dialysis, diabetes, or the patient's level of nutrition. It is therefore important to choose a membrane that reduces blood β2M levels while preserving essential elements such as albumin. A comparative study of the most widely used membranes has shown that Elisio H performs well in terms of both β2M and myoglobin reduction while maintaining ideal albumin levels.[7]



Qb: 350 ml/min, Qd: 600ml/min and QV: 23l.

Albumin loss

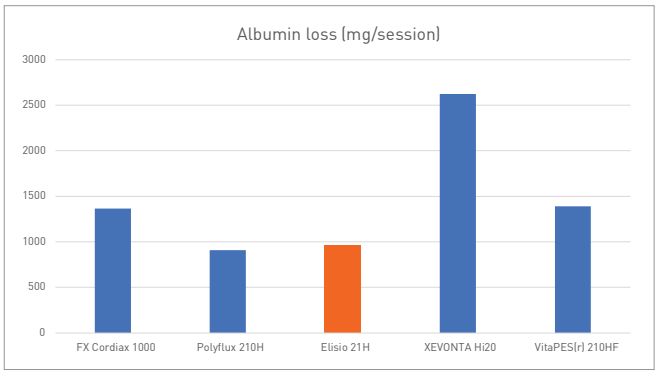
Serum albumin is a well-known marker to assess the quality of care in dialysis patients and is an indicator of the nutritional state of the patients.[9]

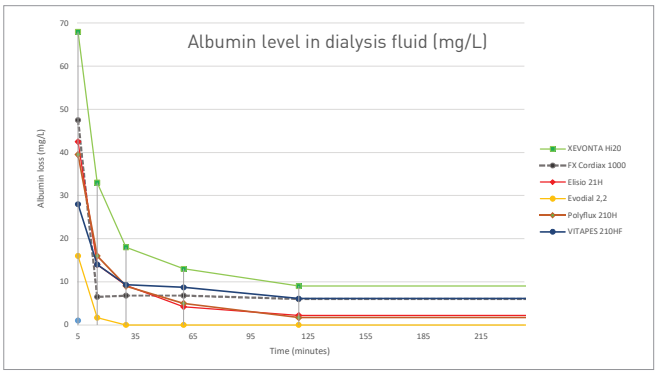
Hypoalbuminemia is common among the dialysis patient population and is associated with all-cause, cardiovascular, and infection-related mortality.[10, 11] Next to malnutrition, chronic inflammation also contributes to hypoalbuminemia in dialysis patients.[12]

In dialysis patients, concurrent metabolic acidosis and chronic inflammation negatively impact albumin synthesis.[9] Therefore, it is essential that patients do not lose albumin through the membrane.

The choice of the dialyzer used may affect the amount of albumin lost during a hemodialysis session.

Elisio presents a high clearance of middle molecular weight molecules while keeping the albumin loss at a low level.





In 6 different patients with a similar dialysis prescription: duration 4 hours, blood flow 400ml/min, infusion flow 100 ml/min, dialysate flow 700 ml/min, dialysate temperature 35.5°C, and constant ultrafiltration rate.[13]

ELISIO™ is not made with BPA

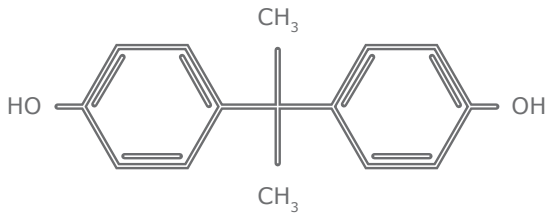
Improved patients' health by using BPA-free materials for the membrane fiber, housing and potting.

BPA (Bisphenol A) is an organic synthetic compound, used in the manufacturing of certain plastics and epoxy resins.

BPA is known as:[2]

- Endocrine (hormone) disruptor
- A potential cause for adverse effects on glucose balance, cardiovascular- and immune system

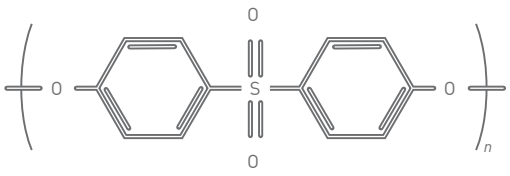
BPA is associated with increased loss of residual kidney function, diabetes and cardiovascular disease.



BPA

Membrane fiber:

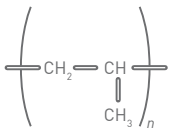
Polynephron™ = polyethersulfone (PES) is BPA-free



PES

Housing:

ELISIO polypropylene (PP) Housing is BPA-free



PP

SCENIHR recommendation:[2]

In February 2015, the Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR), an entity advising the European Commission, recommended the use of medical devices without BPA if possible. This applies especially for medical devices that directly come into contact with patient's blood.

2. The safety of the use of bisphenol A in medical devices; Scientific Committee on Emerging and Newly-Identified Health Risks (SCENIHR); published 18 Feb 2015

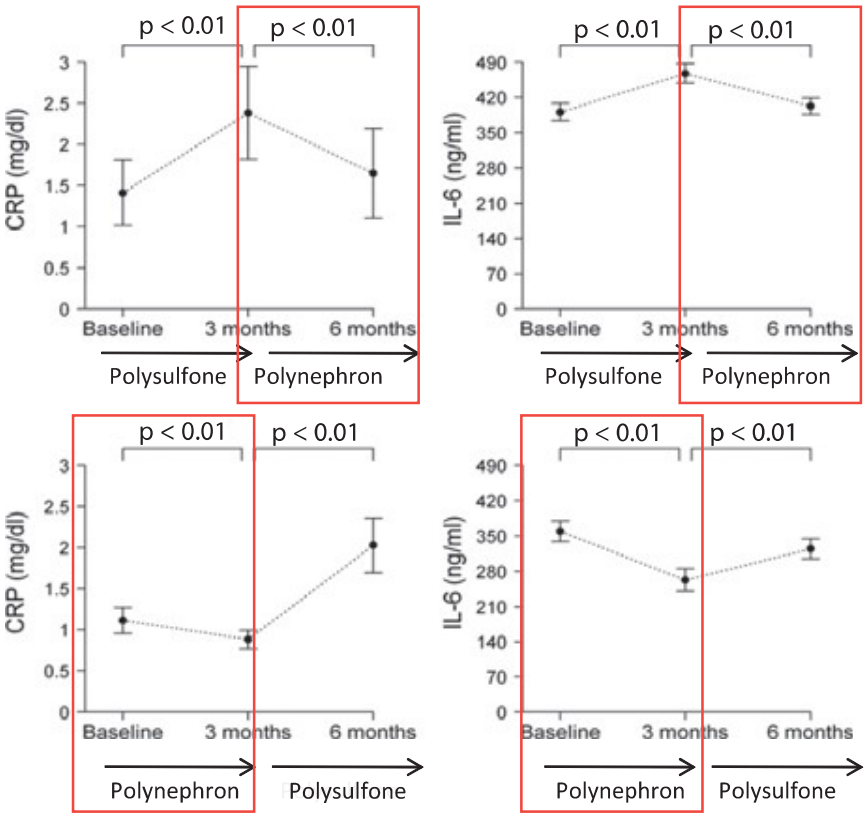
Inflammation

Inflammation in dialysis patients is associated with 30-50% higher mortality risk, and is specifically associated with cardiovascular mortality.[14,15]

The etiology of inflammation is multifactorial originating both in patients' comorbidities as well as dialysis-related factors (such as membrane incompatibility).[15]

In general, the vascular access type, malnutrition, oxidative stress, and hypoalbuminemia can influence the inflammatory state of patients.[16]

The concentration of BPA in urine, the measure of BPA exposure in the general population, is linked to oxidative stress and inflammation.[17]



Elisio

Circulating inflammatory biomarkers in patients dialyzed with polysulfone or polynephron dialyzers for 3 months.

Similarly in dialysis context, BPA exposure has been associated with inflammation and cardiovascular disorders in cultured cells, rodents and humans, through the induction of the oxidative stress[18-20].

Most dialysis patients have a higher inflammatory status which can be aggravated by an incompatible membrane. Therefore, the goal of dialysis therapy is to reduce the inflammatory mediators as much as possible and to increase compatibility profile of the membranes.

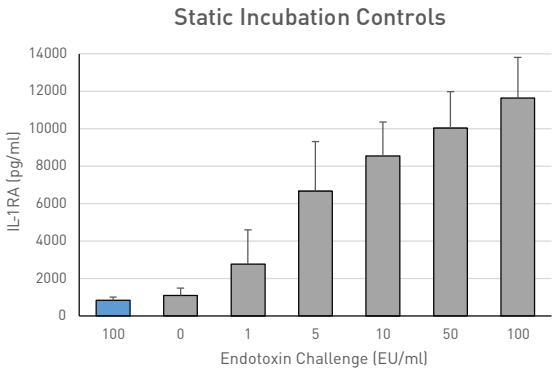
Pro-inflammatory markers such as C-reactive protein (CRP) or Interleukin 6 (IL-6) are typically indicative of elevated inflammation.[14] From the graphs we can deduce that the concentrations of these inflammatory molecules have a very different trend, depending on the dialyzer that is used.

This study, which compared the effect of 3-month treatment with the polyethersulfone Elisio dialyzer versus 3 months with a polysulfone (PS) dialyzer, clearly demonstrates a significant decrease of the inflammatory markers IL-6 and CRP with Elisio highlighting its superior biocompatibility.[21]

Endotoxin retention

EXCELLENT RETENTION OF ENDOTOXINS

Due to the highly porous nature of high flux membranes, there is a risk of contaminants passing through the membrane from the dialysate side. The chemical characteristics and asymmetric structure of the ELISIO-H membrane minimizes the potential risk of contaminating the blood side. In one in vitro study, interleukin 1 receptor antagonist (IL-1RA) production in blood cells was measured after spiking the dialysis fluid with 100 EU/ Lipopolysaccharide (LPS).*



*(Qb 250 ml/min, Qd 500 ml/min, keeping the blood and dialysis fluid heated and recirculated for 3 h, n=5).

Compared to blood that was stimulated with different quantities of the same LPS, the study concludes that blood leaving from the ELISIO-H dialyzer did not induce any IL-1RA production even though the dialysis fluid was heavily contaminated with LPS. This thereby indicates that, with ELISIO-H, no LPS passed through the membrane from the contaminated dialysate side. Based on these results and the good pressure resistance, ELISIO-H can be considered a safe and reliable dialyzer for high volume HDF.

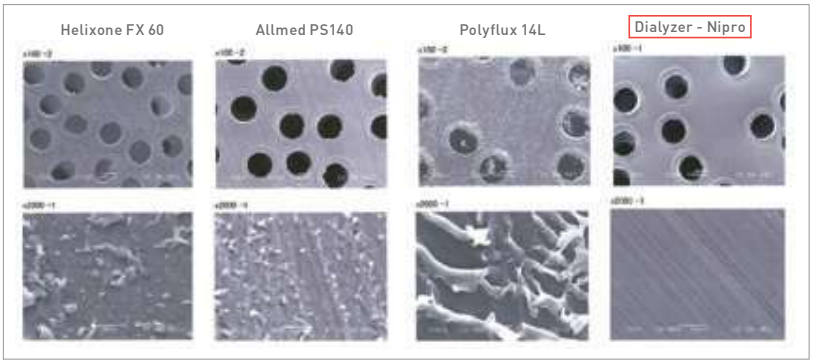
*Pyrogen Retention of the ELISIO-H Dialyzer *in vitro*, internal study, 2008.

Thrombogenicity and platelet activation

When it comes to thrombogenicity, it is important to look at all the contact points between the blood and the dialyzer. The potting is the first point of contact between the blood and the dialyzer.

A smooth surface of the potting is important to prevent hemolysis and the activation of platelets, and thus the coagulation cascade.

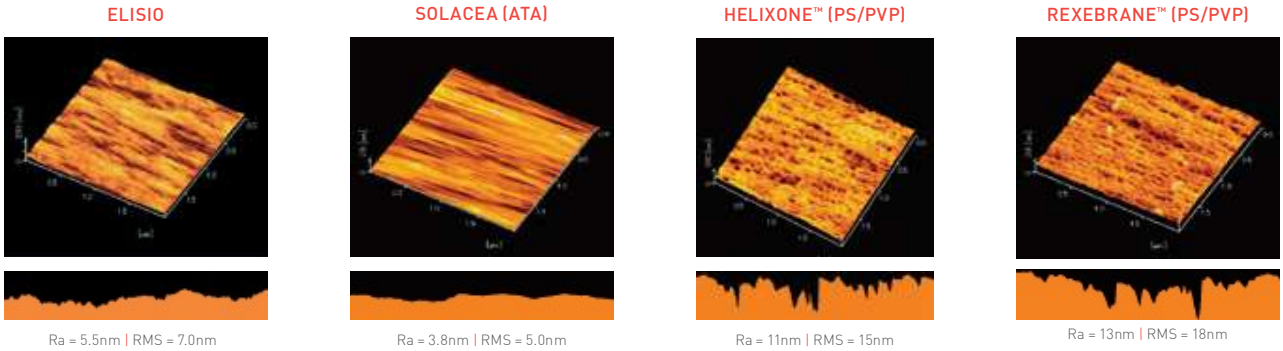
As you can see, the potting of Elisio dialyzer is very smooth compared to other dialyzers. This precision in cut is similar for all Nipro dialyzers.



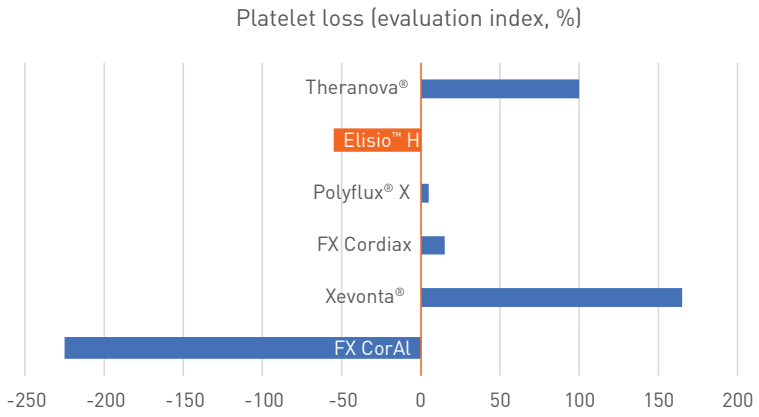
The surface of the fibers is the second contact point between blood and the membrane. It is the active part of the membrane, where the exchange of molecules takes place.

The spinning process during the production of the fiber determines its characteristics.

A minimal roughness of the inner surface prevents hemolysis and reduces the formation of a protein cake.



Platelet loss during hemodialysis is one of the markers of platelet activation and increased risk of thrombocytopenia. Most studies have demonstrated substantial decrease of platelets in the first 15-30 min of dialysis which returns to baseline values at the end of the treatment.[22]
Nevertheless, synthetic membranes have demonstrated variable platelet activation profiles depending on the manufacturer and the type of membrane.



In this study, Elisio-H demonstrates a superior profile in platelet loss compared to other synthetic membranes (the negative values indicate less platelet loss compared to the reference membrane).[23]

Environment-friendly

Green management at Nipro is defined by resource management aimed at protecting environmental conservation standards and preventing the degradation of environmental quality.
Since 2010, Elisio was designed with a polypropylene housing to improve the biocompatibility of the dialyzer. In contrast with the previous polycarbonate housing that contains BPA in its polymer structure, the absence of BPA in Elisio's polypropylene housing limits the exposure of patients' to BPA. Moreover, this change in manufacturing has resulted in a positive impact of energy footprint by more than 30%. The weight of the dialyzer was reduced by 32% reducing the emission of CO_2 during transport. Polypropylene reduces the carbon footprint by more than 60% compared to polycarbonate.*
Gamma Dry Sterilization of Elisio H is an environment-friendly and residue-free method that enables the use of the products immediately after approval.

ELISIO portfolio

Surface

Flux	0.9 m²	1.1 m²	1.3 m²	1.5 m²	1.7 m²	1.9 m²	2.1 m²	2.5 m²
ELISIO-L (Low Flux)		✓	✓	✓	✓	✓	✓	
ELISIO-M (Medium Flux)		✓	✓	✓	✓	✓	✓	
ELISIO-H (High Flux)	✓	✓	✓	✓	✓	✓	✓	✓

Treat your patients' individual needs

The ELISIO portfolio provides you a great flexibility to meet your patients' individual needs, with a wide range of surface areas varying from 0.9 m² up to 2.5 m².

Perfect for different therapies

The same ELISIO-H dialyzers can be used for HD, HDF or HF treatments. In any type of applications, they always perform efficiently, with a minimum albumin loss even in HDF[1] avoiding any restrictions in your therapy demands.

Easy handling

ELISIO dialyzers are easy to use. A balanced combination of 20 different models allows you to minimize the number of different dialyzers needed in your center, keeping the confidence of a great flexibility in therapies, with excellent performances.

As a result, ELISIO helps you to increase your operational efficiency, minimizes your storage volumes and reduces the number of dialyzers' brands to be handled by the staff.

Elisio™-H covers the multiple and distinct needs of your dialysis patients for hemodialysis or high volume hemodiafiltration.

ELISIO™-H Series

HIGH FLUX

PERFORMANCE

Clearance (ml/min)[5]	Qb/ Qd (ml/min)	09H	11H	13H	15H	17H	19H	21H	25H
Urea	200/500	189	192	195	197	198	199	200	200
	300/500	243	253	263	270	275	280	284	293
	400/500	274	291	311	323	332	343	346	361
	400/800	300	325	344	357	362	370	377	385
	500/800	332	363	388	406	417	427	432	457
Creatinine	200/500	175	183	191	194	196	197	198	200
	300/500	213	228	240	252	259	268	269	282
	400/500	237	252	273	288	299	309	319	337
	400/800	265	294	316	331	342	349	355	375
	500/800	282	320	346	363	383	404	410	426
Phosphate	200/500	160	164	170	176	179	183	188	193
	300/500	195	209	224	233	245	251	256	274
	400/500	220	240	255	271	288	296	304	322
	400/800	235	254	280	298	313	325	330	346
	500/800	254	282	315	333	352	368	373	400
Vitamin B12	200/500	114	125	137	148	156	162	165	177
	300/500	128	145	161	173	185	195	198	219
	400/500	132	153	174	188	202	215	219	242
	400/800	141	171	193	209	227	240	250	270
	500/800	151	178	204	223	242	259	264	291
Inulin	200/500	77	82	90	97	105	115	120	149
	300/500	84	86	97	109	117	127	138	166
	400/500	86	90	100	116	126	137	145	176
	400/800	91	92	106	120	128	140	150	185
	500/800	94	97	112	122	135	148	158	203
Myoglobin	200/500	55	61	70	78	88	94	98	112
	300/500	58	64	78	89	96	101	103	123
	400/500	61	70	82	92	104	110	113	132
	400/800	64	71	84	95	106	111	116	137
	500/800	65	81	90	104	110	117	124	141

Ultrafiltration Coefficient

KUF (ml/hr/mmHg)[6]	53	59	64	67	74	76	82	93

Sieving Coefficient[7]

Vitamin B12	0.989[5]
Inulin	0.94
β2-microglobulin	1.02
Myoglobin	0.61
Albumin	0.0017

Specifications

Effective surface area (m^2)		0.9	1.1	1.3	1.5	1.7	1.9	2.1	2.5
Priming volume (ml)		62	70	85	95	105	115	130	149
Effective length (mm)		212	228	245	259	271	281	290	305
Inner Diameter (µm)		200	200	200	200	200	200	200	200
Membrane thickness (µm)		40	40	40	40	40	40	40	40
Maximum TMP (mmHg)		500	500	500	500	500	500	500	500
Material	Membrane	Polynephron™							
	Housing and Header	Polypropylene							
	Potting compound	Polyurethane							
Sterilization method		Dry gamma							
Package		24 pcs/box							

5. *In vitro* test condition (EN1283, ISO 8637: 2010): Qf 0 ml/min.

6. KUF (EN1283, ISO 8637: 2010): Bovine Blood. (Hct 32±2%, Protein 60 g/l, 37°C), Qb 300 ml/min.

7. SC (EN1283, ISO 8637: 2010): Qb 300 ml/min, Qf 60 ml/min.

Clearance data obtained in Japan. Clearance data can vary slightly depending on the test setup, lot nr. and production site.

ELISIO™-M Series

MEDIUM FLUX

PERFORMANCE

Clearance (ml/min)[5]	Qb/ Qd (ml/min)	11M	13M	15M	17M	19M	21M
Urea	200/500	187	190	193	194	195	197
	300/500	240	249	257	265	268	274
	400/500	275	288	300	311	321	331
	400/800	306	320	331	347	352	362
	500/800	331	351	367	383	394	406
Creatinine	200/500	178	184	188	192	193	195
	300/500	221	234	239	248	253	260
	400/500	246	264	272	288	299	305
	400/800	270	290	303	317	328	339
	500/800	300	322	331	349	361	379
Phosphate	200/500	151	159	167	174	177	181
	300/500	173	189	200	213	221	228
	400/500	188	204	217	323	242	252
	400/800	215	232	251	270	284	297
	500/800	227	251	264	286	296	314
Vitamin B12	200/500	95	105	114	124	127	135
	300/500	103	114	126	136	143	156
	400/500	108	122	136	146	157	165
	400/800	112	126	146	157	168	182
	500/800	122	137	155	167	176	191

Ultrafiltration Coefficient

KUF (ml/hr/mmHg)[6]	15	17	20	22	25	27

Sieving Coefficient[7]

Vitamin B12	0.880
Inulin	0.440
Myoglobin	‹ 0.01
Albumin	‹ 0.01

Specifications

Effective surface area (m^2)		1.1	1.3	1.5	1.7	1.9	2.1
Priming volume (ml)		68	80	91	108	115	128
Effective length (mm)		228	245	259	271	281	290
Inner Diameter (µm)		200	200	200	200	200	200
Membrane thickness (µm)		40	40	40	40	40	40
Maximum TMP (mmHg)		500	500	500	500	500	500
Material	Membrane	Polynephron™					
	Housing and Header	Polypropylene					
	Potting compound	Polyurethane					
Sterilization method		Dry gamma					
Package		24 pcs/box					

5. *In vitro* test condition (EN1283, ISO 8637: 2010): Qf 0 ml/min.

6. KUF (EN1283, ISO 8637: 2010): Bovine Blood. (Hct 32±2%, Protein 60 g/l, 37°C), Qb 300 ml/min.

7. SC (EN1283, ISO 8637: 2010): Qb 300 ml/min, Qf 60 ml/min.

Clearance data obtained in Japan. Clearance data can vary slightly depending on the test setup, lot nr. and production site.

ELISIO™-L Series

LOW FLUX

PERFORMANCE

Clearances (ml/min)[5]	Qb/Qd (ml/min)	11L	13L	15L	17L	19L	21L
Urea	200/500	185	189	192	193	194	196
	300/500	237	248	255	263	267	274
	400/500	271	287	298	310	320	327
	400/800	299	318	330	345	351	362
	500/800	327	348	364	380	391	404
Creatinine	200/500	173	180	186	190	193	195
	300/500	205	221	230	242	249	258
	400/500	229	248	262	274	282	295
	400/800	261	283	295	308	316	327
	500/800	289	311	327	347	361	370
Phosphate	200/500	143	151	158	165	170	174
	300/500	162	179	190	201	210	217
	400/500	180	197	210	225	236	247
	400/800	201	223	240	251	267	276
	500/800	213	237	255	275	289	301
Vitamin B12	200/500	76	87	96	106	110	117
	300/500	86	98	107	119	129	138
	400/500	93	106	119	130	140	148
	400/800	101	114	128	141	149	163
	500/800	107	122	134	149	161	174

Ultrafiltration Coefficient

KUF (mL/hr/mmHg)[6]		11	14	16	18	20	22

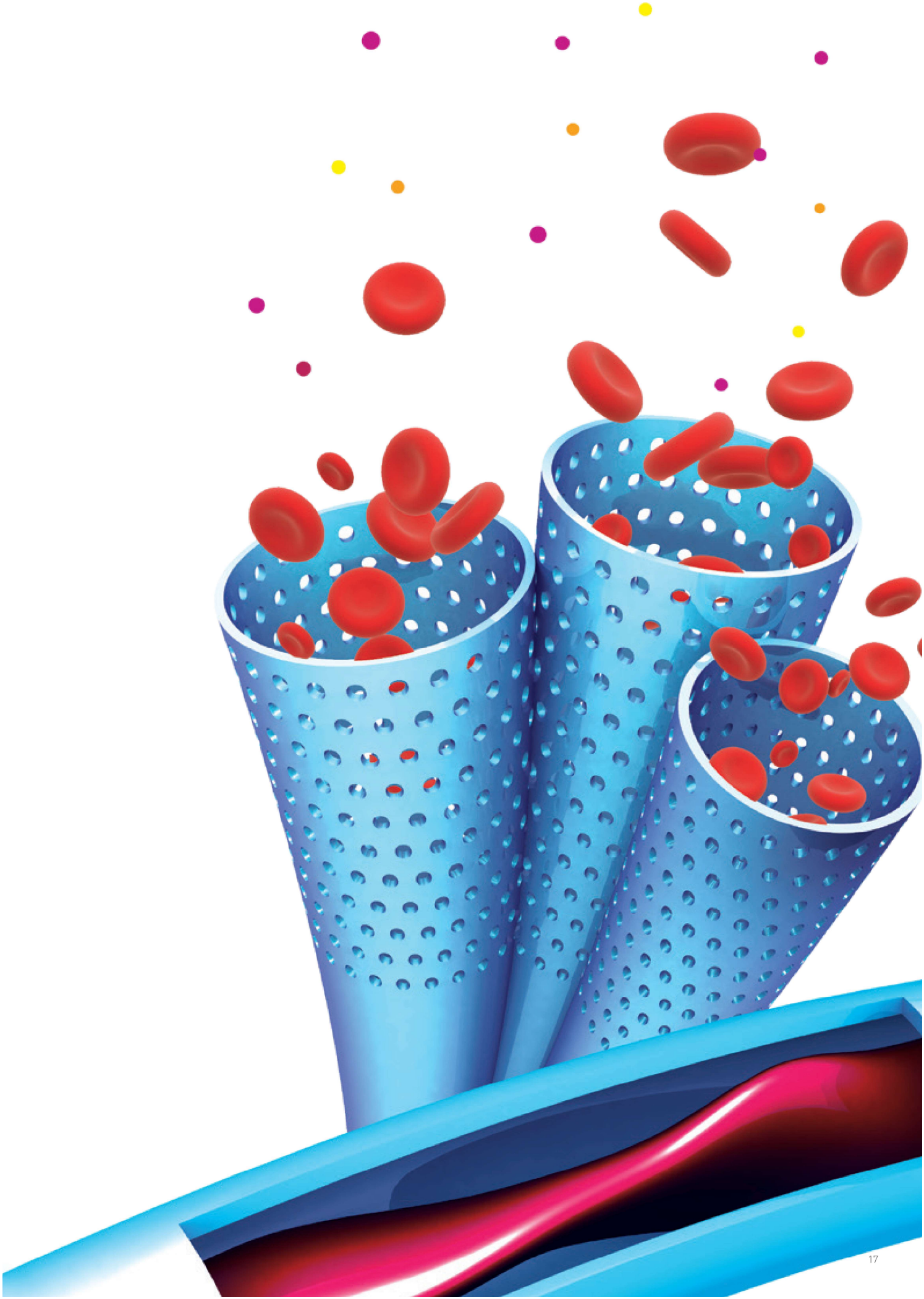
Specifications

Effective Surface Area (m²)		1.1	1.3	1.5	1.7	1.9	2.1
Priming Volume (ml)		69	81	91	104	114	127
Effective Length (mm)		228	245	259	271	281	290
Inner Diameter (µm)		200	200	200	200	200	200
Membrane Thickness (µm)		40	40	40	40	40	40
Maximum TMP (mmHg)		500	500	500	500	500	500
Material	Membrane	Polynephron™					
	Housing and Header	Polypropylene					
	Potting Compound	Polyurethane					
Sterilization Method		Dry Gamma					
Package		24 pcs/box					

5. *In vitro* test condition (EN1283, ISO 8637: 2010): Qf 0 ml/min.

6. KUF (EN1283, ISO 8637: 2010): Bovine Blood. (Hct 32±2%, Protein 60 g/l, 37°C), Qb 300 ml/min.

Clearance data obtained in Japan. Clearance data can vary slightly depending on the test setup, lot nr. and production site.



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