

RENAL  
CARE



# ELISIO™

SYNTHETIC POLYNEPHRON™  
HOLLOW-FIBER DIALYZER



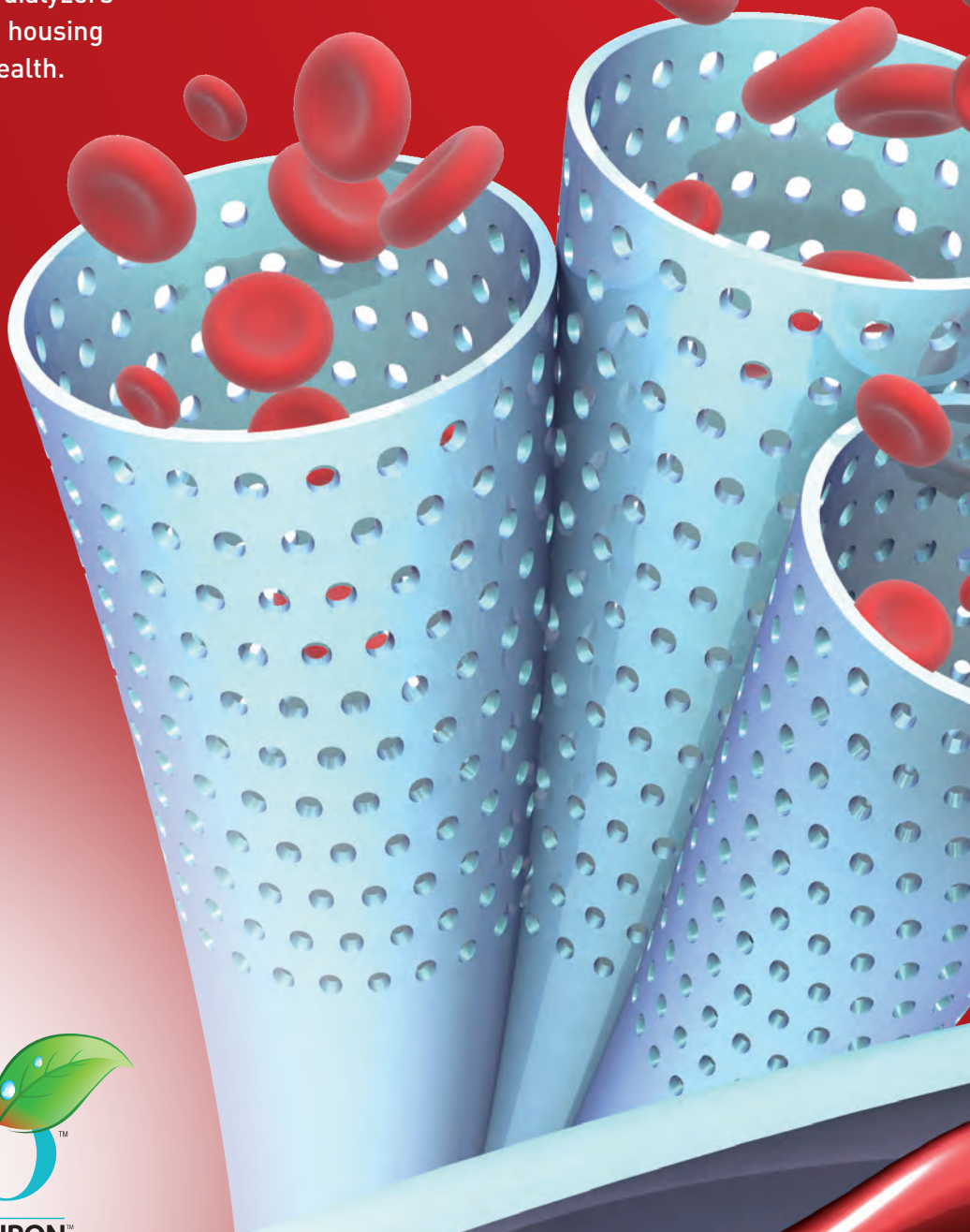
# Evolution of the dialyzer

By combining more than 40 years of global experience in design and manufacture of dialyzers, with extensive research and engineering innovation, Nipro created the ELISIO synthetic hollow-fiber dialyzer, with a unique POLYNEPHRON™ membrane delivering outstanding performance, excellent biocompatibility and low thrombogenicity.

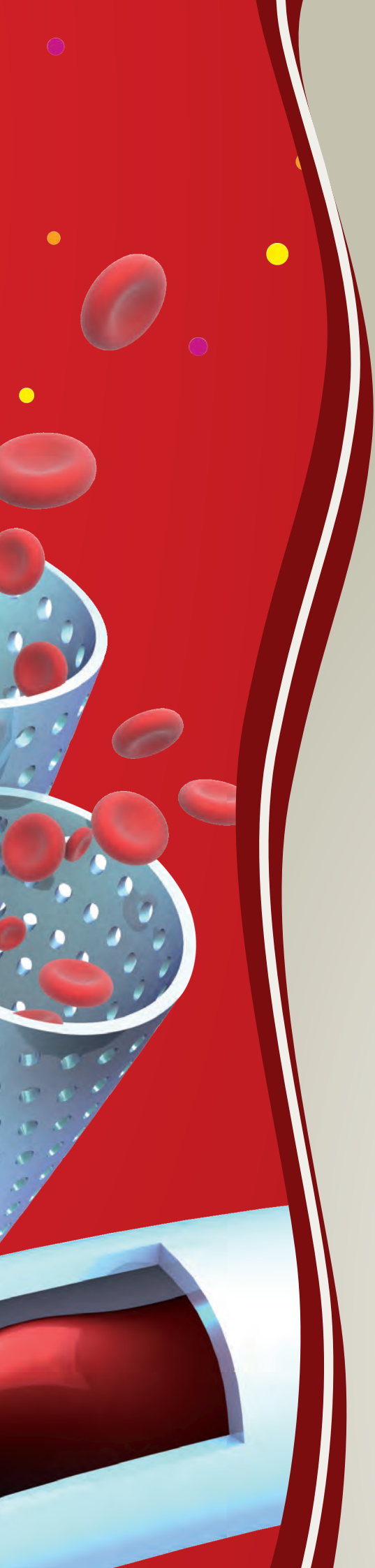
ELISIO is one of the first synthetic dialyzers totally BPA-free (membrane fiber, housing and potting) improving patients' health.

By using the ELISIO dialyzers with the unique dry gamma sterilization method of Nipro, you can minimize your patients' exposure to chemical agents and the risk of contamination.

**eli:io**  
POLYNEPHRON™







## ELISIO™ unique features

- POLYNEPHRON™ membrane
- BPA-free membrane fiber, housing and potting
- Low radiation dose of  $\pm 15$  kGy and dry oxygen-free gamma sterilization
- Transparency of the dialyzer's headers allowing visual control of air bubbles

# The most versatile choice for the medical staff...

ELISIO dialyzer family has the right options to meet your patients' individual needs and facilitate your product handling and storage.

- Available in a broad range of surface areas
- Suitable for a full range of applications: HD, HF and HDF
- Optimizing the ease of use and operational efficiency



## ELISIO portfolio

Flux	Surface							
	0.9 m <sup>2</sup>	1.1 m <sup>2</sup>	1.3 m <sup>2</sup>	1.5 m <sup>2</sup>	1.7 m <sup>2</sup>	1.9 m <sup>2</sup>	2.1 m <sup>2</sup>	2.5 m <sup>2</sup>
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 m<sup>2</sup> up to 2.5 m<sup>2</sup>.

### 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<sup>(1)</sup> 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.

<sup>(1)</sup> *In vivo* external study in 2014 conducted by BioArt Products, Rostock, Germany.  
Qb: 350 ml/min, Qd: 700 ml/min, Qs: 0 ml/min in HD and 90 ml/min in HDF, n=6



# ... and an optimal solution for the patients

With the ELISIO dialyzers, your patients are in safe hands. The totally BPA-free dialyzer with the unique POLYNEPHRON™ membrane enables you to optimize treatment outcome and improve patients' health and safety.

- Reduces the potential risk for increased loss of residual kidney function, diabetes and cardiovascular disease
- Optimal balance between clearances of middle molecular weight (MW) molecules (like  $\beta$ 2-microglobulin and myoglobin) and retention of albumin
- Excellent biocompatibility and low thrombogenicity
- Sterilization method minimizes patients' exposure to chemical agents and risk of contamination



# ELISIO™ is BPA-free

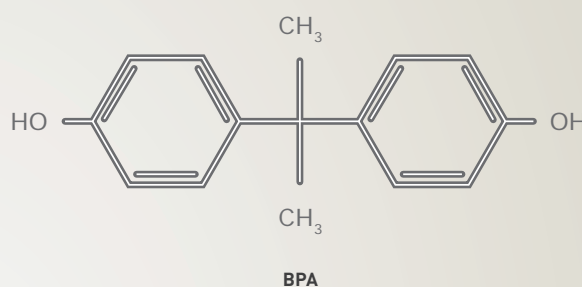
Improved patients' health by using BPA-free materials for the membrane fiber, housing and potting.

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

## BPA is known as:<sup>[2]</sup>

- 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.**

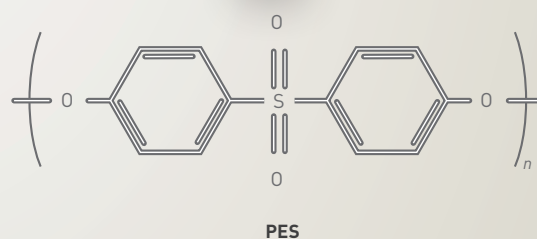


## ELISIO is totally BPA-free



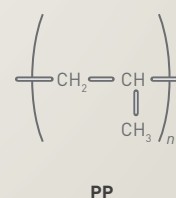
**Membrane fiber:**

Polynephron™ = polyethersulfone (PES) is BPA-free



**Housing :**

ELISIO polypropylene (PP) Housing is BPA-free

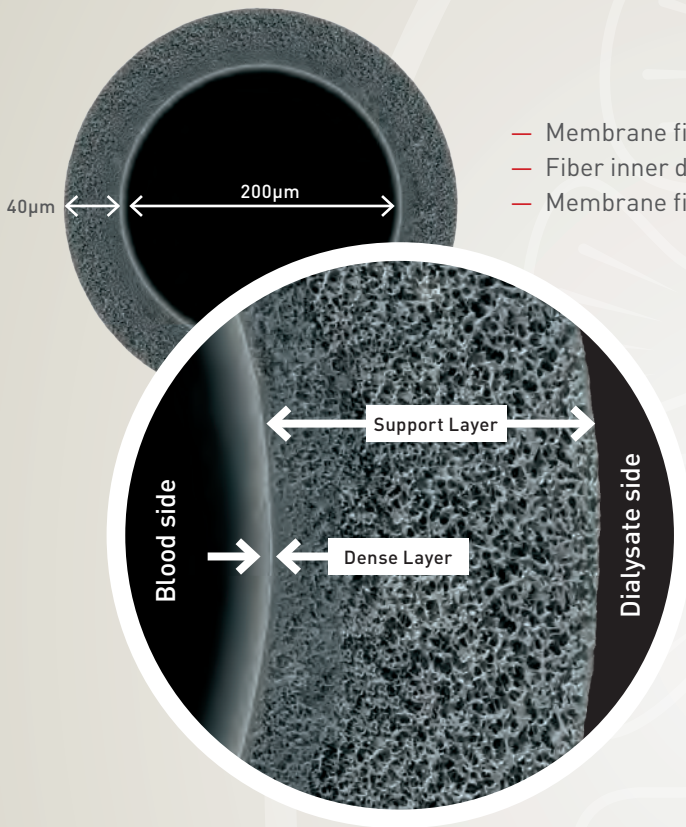


## SCENIHR recommendation:<sup>[2]</sup>

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

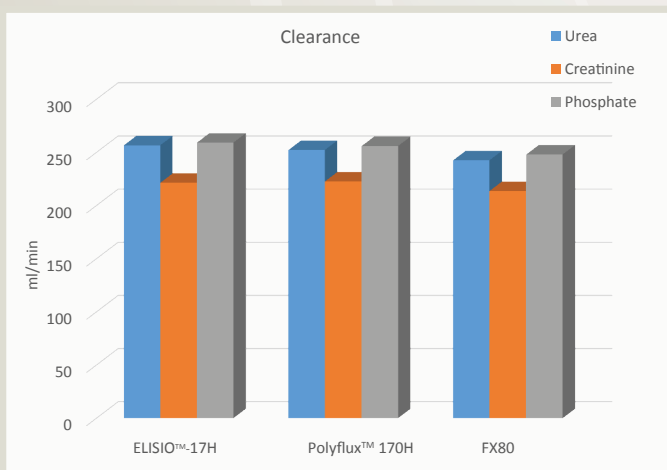
# ELISIO™ grants outstanding performances



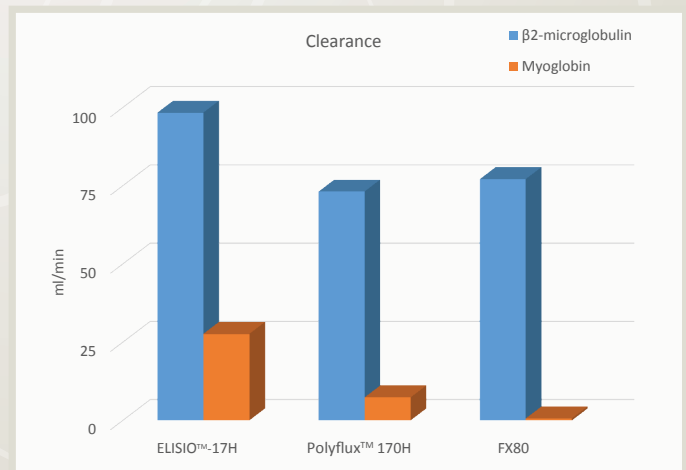
- Membrane fiber with an asymmetric structure
- Fiber inner diameter of 200 μm
- Membrane fiber wall of 40 μm

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

## ELISIO™-H delivers outstanding clearances for low and middle MW molecules<sup>[3]</sup>



ELISIO has excellent clearances for low molecular weight substances



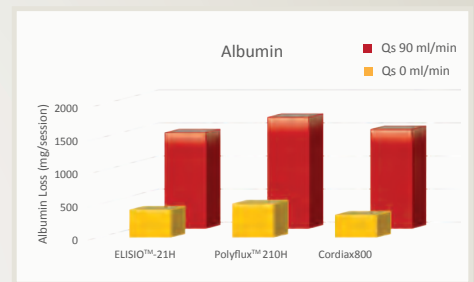
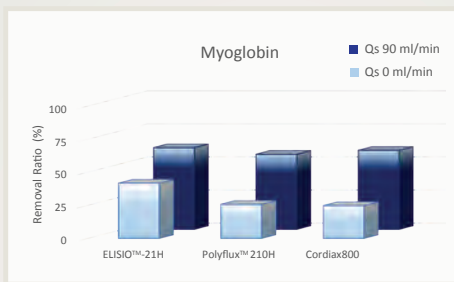
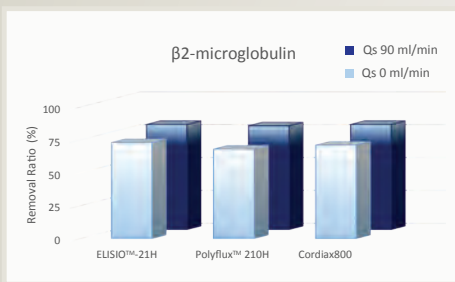
ELISIO demonstrates better clearances of β2-microglobulin and myoglobin than the reference dialyzers

[3] In vivo Clinical study by BioArt Products, Rostock, Germany, Feb. to Mar. 2010. Qb: 300 ml/min, Qd: 500 ml/min and Qs:0 ml/min, n=8

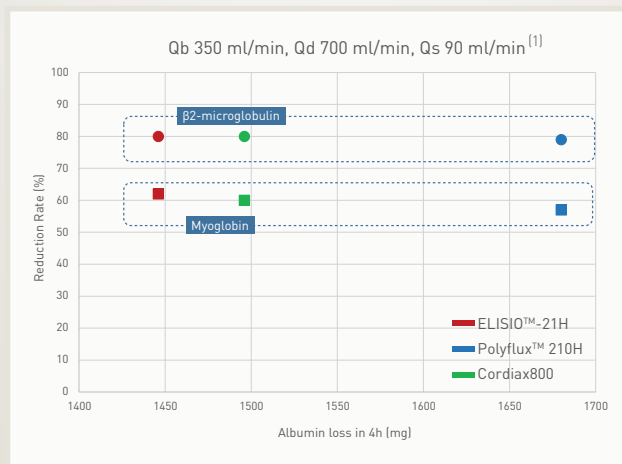


Optimized treatment outcomes and improved patients' life expectancy associated with high volume HDF, thanks to the combination of asymmetric structure and increased inner diameter and fiber wall thickness.

ELISIO™-H offers an optimal balance between clearances of middle MW molecules and albumin retention.



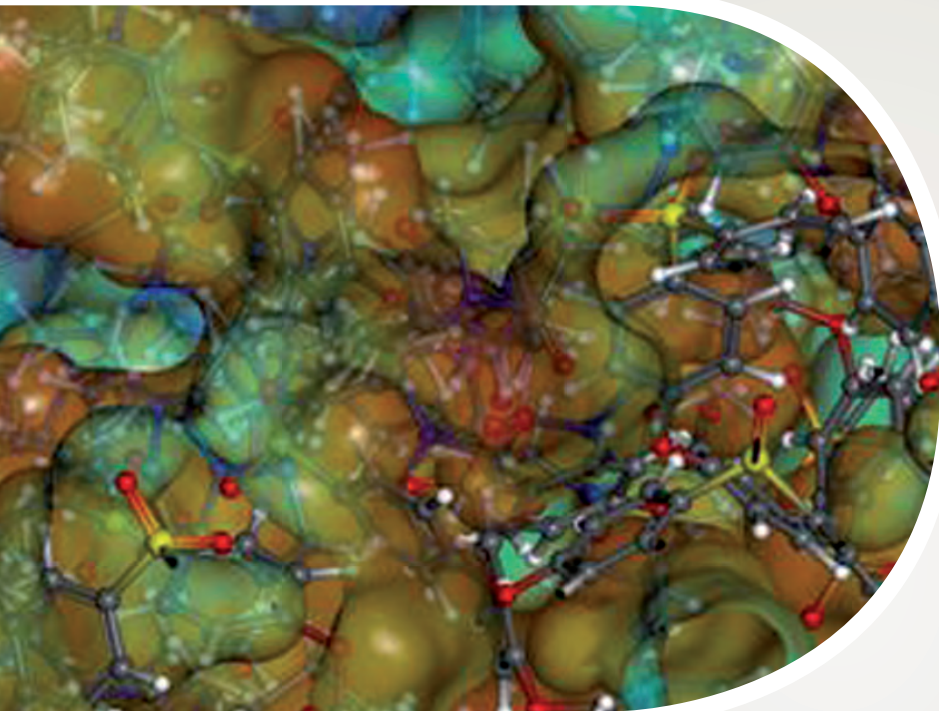
ELISIO allows excellent clearances for β2-microglobulin and myoglobin, and can be used in HD, HF and HDF (pre-and post-dilution) with minimal loss of albumin in HDF<sup>(1)</sup>, compared to the most common synthetic membranes on the market.



The reduction rate of β2-microglobulin and myoglobin of ELISIO-H series is equal or better than the main competitors in post-dilution online-HDF condition with lowest albumin loss<sup>(1)</sup>.

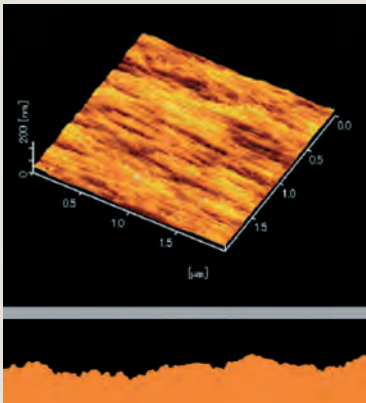
(1) *In vivo* external study in 2014 conducted by BioArt Products, Rostock, Germany. Qb: 350 ml/min, Qd: 700 ml/min, Qs: 0 ml/min in HD and 90 ml/min in HDF, n=6

# ELISIO™ shows excellent biocompatibility



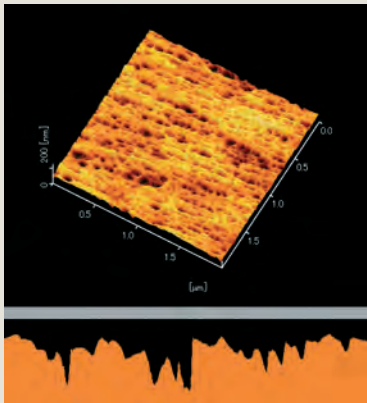
Ideal ratio of hydrophobic (reddish) and hydrophilic (bluish) microdomains.

Polynephron™



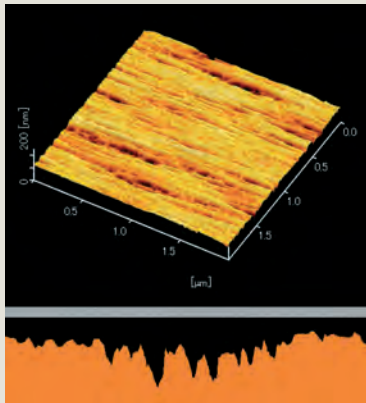
Ra = 5,5 nm | RMS = 7,0 nm

Helixone™



Ra = 11 nm | RMS = 15 nm

Polyamix™



Ra = 7,5 nm | RMS = 11 nm

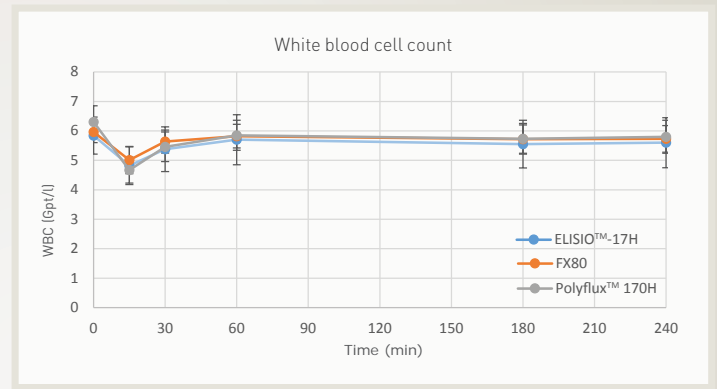
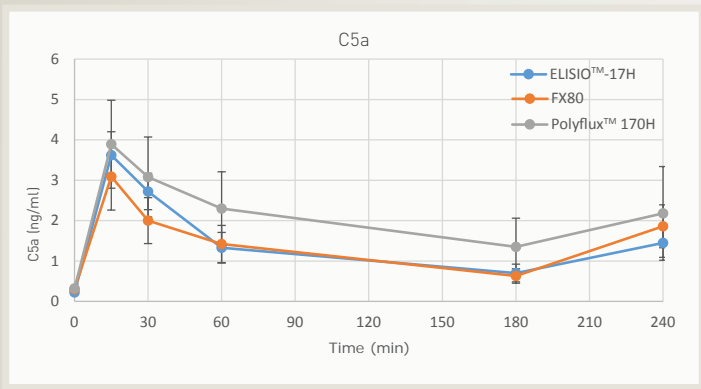
Atomic force microscopic (AFM) image. Ra: average roughness; RMS: square-mean roughness

ELISIO Polynephron has a smooth membrane surface, reducing membrane fouling, optimizing the performances.



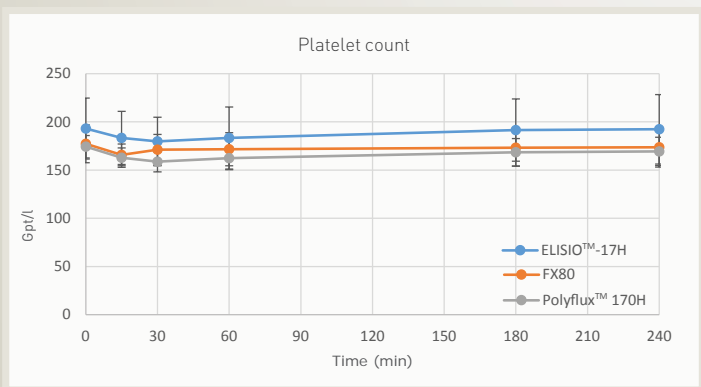
Improved patients' safety thanks to the excellent biocompatibility and low thrombogenicity delivered by the unique POLYNEPHRON™ membrane combined with a smooth membrane surface.

## Excellent biocompatibility (C5a, WBC)



Excellent biocompatibility as depicted by C5a and WBC count<sup>(3)</sup>

## Low thrombogenicity (Platelet)



Low thrombogenicity characteristics as shown by the platelet count<sup>(3)</sup>

[3] *In vivo* Clinical study by BioArt, Rostock, Germany, Feb. to Mar. 2010. Qb: 300 ml/min, Qd: 500 ml/min and Qs:0 ml/min, n=8

# ELISIO™ features a unique sterilization method

Optimized patients' safety by using the unique low radiation dose and dry oxygen-free gamma sterilization method.

- Provides better protection against light due to the aluminum pouch
- Eliminates the use of chemical agents, like EtO, by using gamma sterilization method
- Minimizes the residual radiation with low gamma ray dosage sterilization (around 15 kGy)<sup>(4)</sup>
- Reduces the potential risk of free-radical formation thanks to the use of O<sub>2</sub> scavenger <sup>(4)</sup>
- Minimizes the contamination risk, as gamma sterilization is performed after packaging of product in the final containers

Aluminum pouch



Oxygen scavenger

[4] Sterilization by gamma irradiation; Kátia Aparecida da Silva Aquino; CDN, Intechopen; 21 March. 2012



# ELISIO™ -H Series

## High Flux



Clearance (ml/min) <sup>[5]</sup>	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) <sup>[6]</sup>	53	59	64	67	74	76	82	93
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### SIEVING COEFFICIENT<sup>[7]</sup>

Vitamin B12	0.989
Inulin	0.926
β2-microglobulin	0.803
Myoglobin	0.223
Albumin	0.002

## Specifications

Effective surface area (m <sup>2</sup> )	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, Heater	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



Clearance (ml/min) <sup>[5]</sup>	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) <sup>[6]</sup>	15	17	20	22	25	27

### SIEVING COEFFICIENT<sup>[7]</sup>

Vitamin B12	0.880
Inulin	0.440
Myoglobin	< 0.01
Albumin	< 0.01

## Specifications

Effective surface area (m <sup>2</sup> )	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, Heater	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



Clearances (ml/min) <sup>[5]</sup>	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	270	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) <sup>[6]</sup>	11	14	16	18	20	22
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## Specifications

Effective Surface Area (m <sup>2</sup> )	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, 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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