THE ONLY DIALYZER NOT MADE WITH BPA AND DEHP IN NORTH AMERICA

ELISIO™ POLYNEPHRON™: Confidence From The Inside Out

When Nipro set out to reimagine the single-use, high-flux, hollow-fiber dialyzer, our goal was to evolve the new ELISIO™ POLYNEPHRON™ into a product delivering multiple, valuable advantages.

Our design and engineering teams accomplished these objectives, innovating an array of powerful, practical features – including thousands of fibers in each membrane, with each fiber acting as a nephron. By utilizing a membrane that functions more like a human kidney, outstanding biocompatibility, hemocompatibility, and solute-removal performance is achieved, resulting in superior clearances for better patient outcomes.

Evolution of the Dialyzer

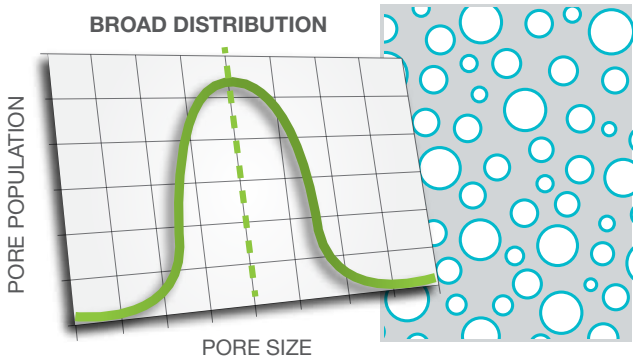
By combining more than 30 years of global experience in design and manufacture of dialyzers with extensive research and engineering innovation, Nipro created the ELISIO™ POLYNEPHRON™ Single Use, Hollow-Fiber Dialyzer. This state-of-the-art product evolves and advances our extensive fiber and dialyzer manufacturing expertise to your benefit. The result: state-of-the-art performance through a synthesis of a remarkable new membrane material and significant design improvements.

Together, the innovations and advantages Nipro has designed into ELISIO™ POLYNEPHRON™ deliver greater confidence to everyone involved in the dialysis process.

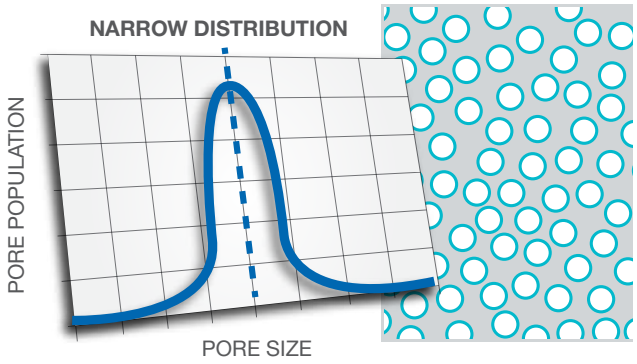
POLYNEPHRON™: State-of-the-Art Membrane

To function more like the human kidney, we built thousands of fibers into each ELISIO™ dialyzer – thus POLYNEPHRON™ – where every fiber acts as a nephron (human kidney element). This unique hollow-fiber formulation, developed by Nipro, features a one-of-a-kind, highly optimized structure to deliver outstanding biocompatibility, hemocompatibility, and solute-removal performance.

- Newly formulated PES (polyethersulfone) composition for more well-balanced membrane properties
- 3D chemical structure modeling with ideal mix of hydrophilic and hydrophobic domains reduces membrane fouling
- Advanced pore-spinning technology creates more homogenous pore sizes to optimize sieving properties
- Uniform pore size results in improved removal of uremic toxins and low-molecular-weight proteins, with limited loss of important proteins such as albumin
- Unique ripple structure inside dialyzer creates less dialysis channeling for more homogenous flow and better diffusive transport and enhanced small molecule clearances
- Improved mechanical fiber strength reduces risk of fiber leakage



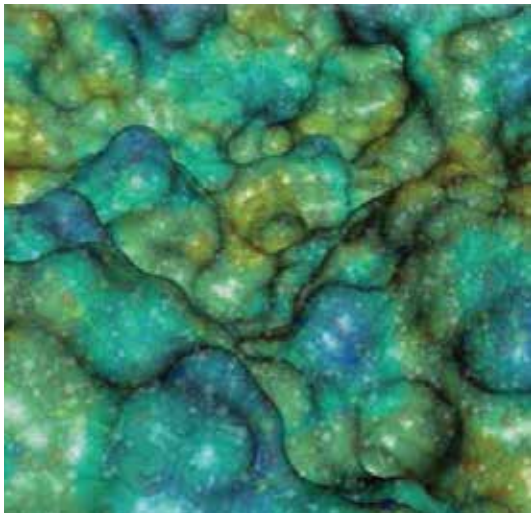
Non-uniform pore size and spacing on membrane surface provides reduced performance.



Optimized, highly uniform ELISIO™ POLYNEPHRON™ pore size and distribution offers far better performance.

Note: Above charts are illustrative representations and are not based on actual data.

Thousands of fibers are built into every dialyzer. The 3D chemical structure modeling affords an ideal mixture of hydrophilic and hydrophobic domains.



Smarter and Safer Design

ELISIO™ advances the dialyzer design in terms of composition, removal performance and results. We start with lighter, polypropylene housing and headers, which do not contain BPA. The inner design – featuring an ultra-smooth polyurethane cut surface and finely finished inner lumen of hollow fibers – ensures smooth blood flow and minimizes potential blood cell damage.

Patient Performance

- Design enhancements optimize blood flow minimizing residual blood in the dialyzer
- Better contact between dialysate and blood compartments provides higher package density for superior performance
- Improved header shape with redesigned caps to optimize blood flow dynamics
- Ultra-smooth polyurethane cut surface on ELISIO™ dialyzer minimizes risk of blood cell damage during hemodialysis

Composition and Safety

- Housing and fibers are not made with BPA or DEHP thereby minimizing risk for endocrine disruption and safeguarding public health
- Header caps are permanently attached, eliminating unexpected removal or reuse
- Caps on blood and dialysate sides maintain aseptic technique during setup
- Packaging for the dialyzer is patented – it is packed in a foil bag that reduces degradation of membrane due to oxidation during gamma sterilization

Improved header shape with redesigned, permanent caps reduces channeling at the blood side while eliminating possibility of unexpected removal or reuse.

Ultra-smooth polyurethane cut surface on ELISIO™ dialyzer minimizes risk of blood cell damage during hemodialysis.

References:

1) Calafat et al 2008. Exposure to bisphenol A and other phenols in neonatal intensive care unit premature infants. Environ Health Perspect; doi:10.1289/ehp.0800265 [Online 10 December 2008]

2) Hugo et al 2008. Bisphenol A at environmentally relevant doses inhibits adiponectin release from human adipose tissue explants and adipocytes. Environ Health Perspect 116:1642-1647.

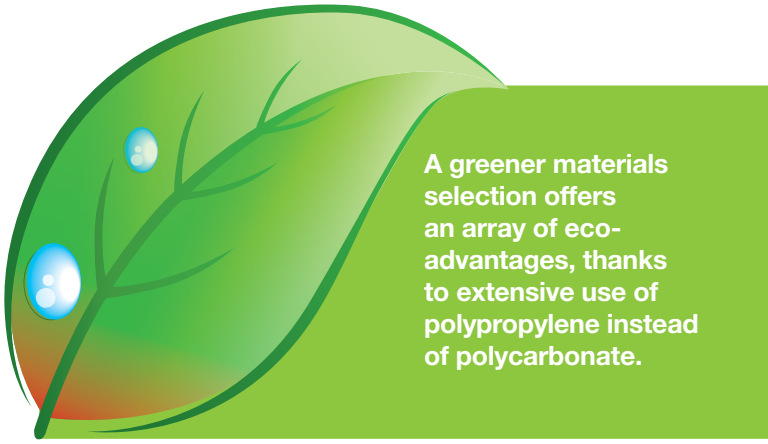
3) Lang et al 2008. Association of urinary bisphenol A concentration with medical disorders and laboratory abnormalities in adults. JAMA 300(11):1303-1310

4) vom Saal et al 2008. Bisphenol A and risk of metabolic disorders. JAMA 300(11):1353-1355 (editorial)

Greener, Easier to Handle, and More Cost Effective

Eco-friendliness

- 10% less CO_2 emission for resin production
- 50% less CO_2 emission when incinerated
- 25% less resin waste and 100˚C lower temperature needed to mold polypropylene parts, compared to typical BPA-derived materials from other manufacturers
- Reduced energy consumption for transportation per product unit, due to lower weights and because about 50% more product can be loaded onto same-size vehicle



A greener materials selection offers an array of eco-advantages, thanks to extensive use of polypropylene instead of polycarbonate.

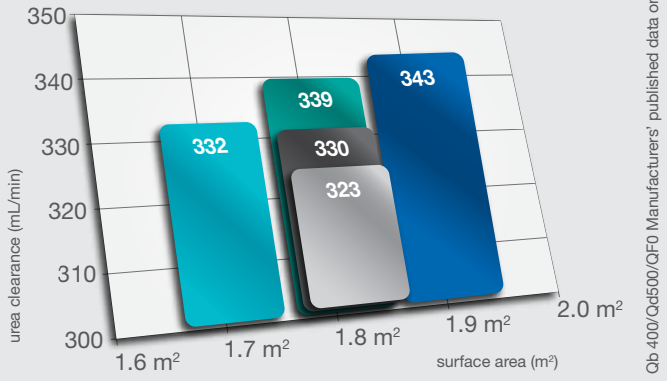
Handling and Savings

- 25% lighter than some competitors, making it easier to transport and handle safely
- Significant disposal cost savings

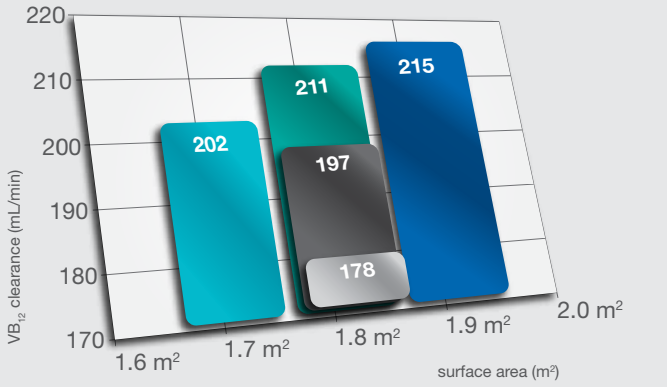
The ELISIO™-H Dialyzer Delivers Excellent Clearances

Superior In-Vitro Clearances

Testing demonstrates that the ELISIO™ POLYNEPHRON™ dialyzer provides higher clearances of small molecules.



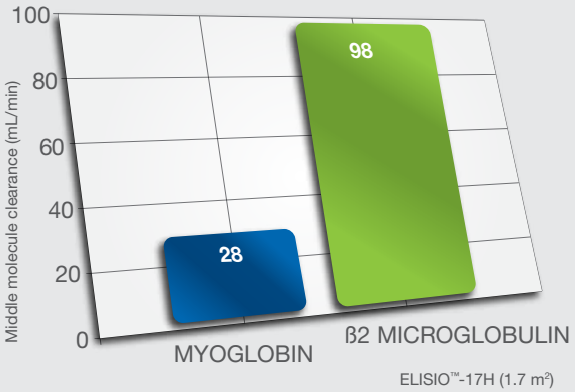
Qb 400/Qd500/QF0 Manufacturers' published data on file.



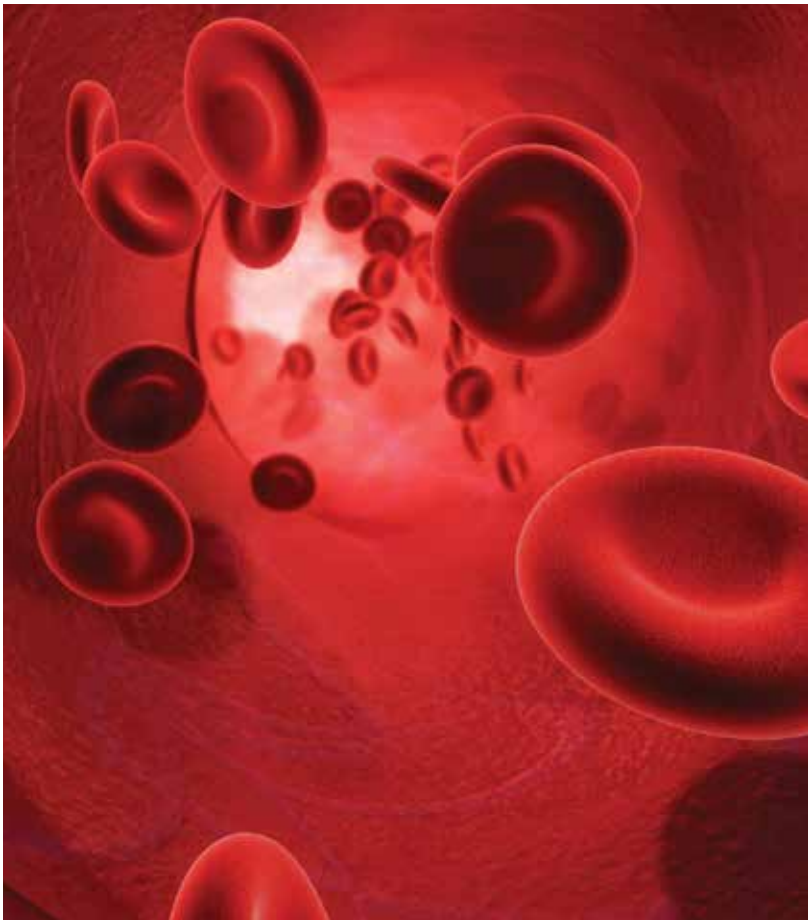
ELISIO™-17H
Company G
Company A
Company F
ELISIO™-19H

Excellent In-Vivo Clearances

For middle molecule clearances, the ELISIO™-17H dialyzer demonstrated excellent performance with regard to ß2 microglobulin and myoglobin.

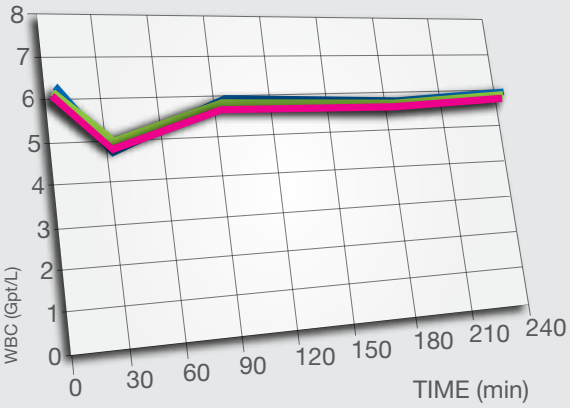


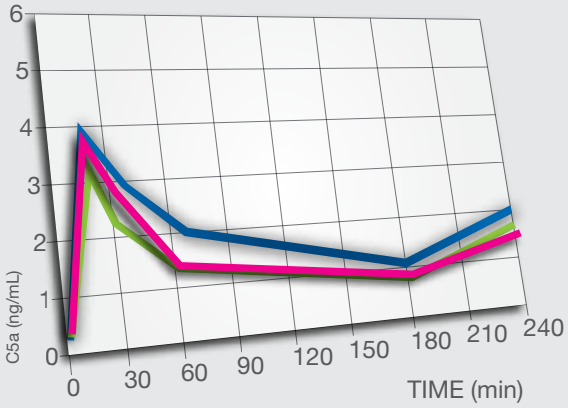
Testing Conditions: Qb 300 mL/min; Qd 500 mL/min; 8 patients
Clinical data obtained in Germany, 8 patients, Feb-Mar 2010



Exceptional Biocompatibility

The ELISIO™ POLYNEPHRON™ synthetic membrane exhibited excellent biocompatibility on WBC and C5a.





Testing Conditions: Qb 300 mL/min; Qd 500 mL/min; 8 patients
Clinical data obtained in Germany, 8 patients, Feb-Mar 2010

■ Polyarylethersulfone ■ POLYNEPHRON™ ■ Polysulfone

Specifications

		ELISIO™-H							
		9H	11H	13H	15H	17H	19H	21H	25H
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
Materials	Membrane	POLYNEPHRON™ (Polyethersulfone)							
	Housing	Polypropylene							
	Header	Polypropylene							
	Potting Compound	Polyurethane							
Sterilization Method		Dry gamma							
Package		24 pcs/case							

ELISIO™ POLYNEPHRON™: Performance Parameters and Specifications

Performance

		ELISIO™-H							
Parameter	Qb/Qd (ml/min)	9H	11H	13H	15H	17H	19H	21H	25H
Effective Surface Area (m^2)		0.9	1.1	1.3	1.5	1.7	1.9	2.1	2.5
KOA Urea (mL/min)*		778	916	1190	1351	1614	1771	1976	2269
Clearances (mL/min)**									
Urea	200/500	190	193	196	198	198	199	200	200
	300/500	246	257	272	278	285	288	291	294
	400/500	278	298	316	326	337	345	348	363
	400/800	307	327	347	359	368	373	378	386
	500/800	339	365	392	408	420	430	437	460
Creatinine	200/500	177	184	191	196	197	198	199	200
	300/500	218	233	250	259	268	273	275	285
	400/500	242	261	280	296	306	314	326	342
	400/800	275	297	318	333	349	358	363	377
	500/800	292	326	353	368	388	409	415	431
Phosphate	200/500	163	171	178	184	188	192	195	196
	300/500	200	213	230	241	254	258	265	276
	400/500	223	246	265	275	292	305	314	329
	400/800	242	263	291	305	322	335	339	352
	500/800	259	293	317	337	357	371	378	405
Vitamin B_{12}	200/500	116	128	140	150	157	164	166	178
	300/500	134	148	165	180	190	200	206	224
	400/500	139	161	181	194	211	222	228	247
	400/800	151	173	197	215	231	245	254	273
	500/800	159	183	209	231	248	263	270	296
Inulin	200/500	81	86	96	102	110	119	124	153
	300/500	89	94	102	112	121	132	145	171
	400/500	92	96	109	118	129	139	151	182
	400/800	97	97	113	125	132	149	159	195
	500/800	101	102	117	131	140	156	166	210
Myoglobin	200/500	58	63	74	84	91	101	104	116
	300/500	61	68	80	90	98	107	111	126
	400/500	63	76	84	94	107	113	122	137
	400/800	68	78	88	99	111	116	125	139
	500/800	70	87	99	110	123	131	138	145
KUF (mL/hr/mmHg)***		53	59	64	67	74	76	82	93
Sieving Coefficient****	Vitamin B_{12}	0.99							
	Inulin	0.93							
	Myoglobin	0.22							
	Albumin	<0.01							

Item Name	Description	Packaging
DD+ELISIO-09H	ELISIO-09H PP (0.9 m^2) Synthetic Hemodialyzer	24/Case
DD+ELISIO-11H	ELISIO-11H PP (1.1 m^2) Synthetic Hemodialyzer	
DD+ELISIO-13H	ELISIO-13H PP (1.3 m^2) Synthetic Hemodialyzer	
DD+ELISIO-15H	ELISIO-15H PP (1.5 m^2) Synthetic Hemodialyzer	
DD+ELISIO-17H	ELISIO-17H PP (1.7 m^2) Synthetic Hemodialyzer	
DD+ELISIO-19H	ELISIO-19H PP (1.9 m^2) Synthetic Hemodialyzer	
DD+ELISIO-21H	ELISIO-21H PP (2.1 m^2) Synthetic Hemodialyzer	
DD+ELISIO-25H	ELISIO-25H PP (2.5 m^2) Synthetic Hemodialyzer	

* Qb 300mL/min, Qd 500mL/min, Qf 10mL/min.
** In Vitro Test Condition (EN1283):Qf 10mL/min.
*** KUF (EN1283):Bovine Blood (Hct 32±2%, Protein 60g/L, 37°C), Qb 300mL/min.
**** SC (EN1283):Qb 300mL/min, Qf 60mL/min.

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