



elio  
POLYNEPHRON

Confidence From  
The Inside Out

# 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.

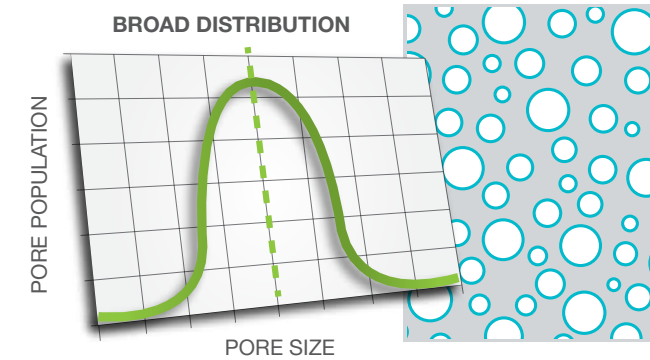
Together, the innovations and advantages Nipro has designed into ELISIO™ POLYNEPHRON™ deliver greater confidence to everyone involved in the dialysis process.



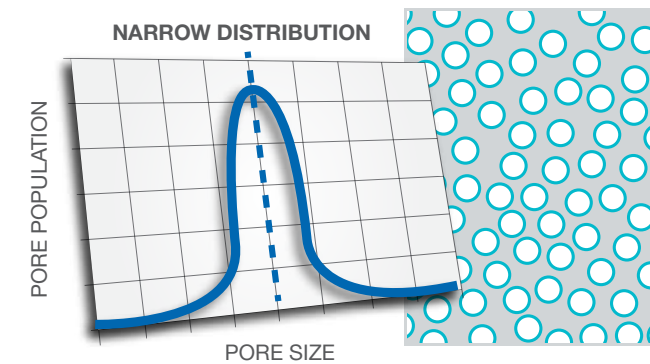
# POLYNEPHRON™: State-of-the-Art Membrane

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



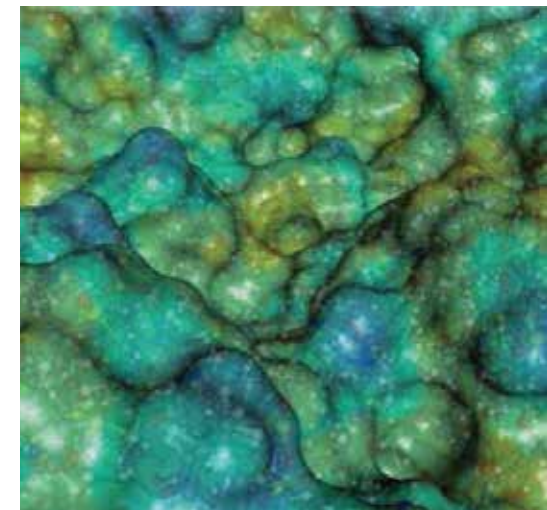
Non-uniform pore size and spacing on membrane surface provides reduced performance.



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)



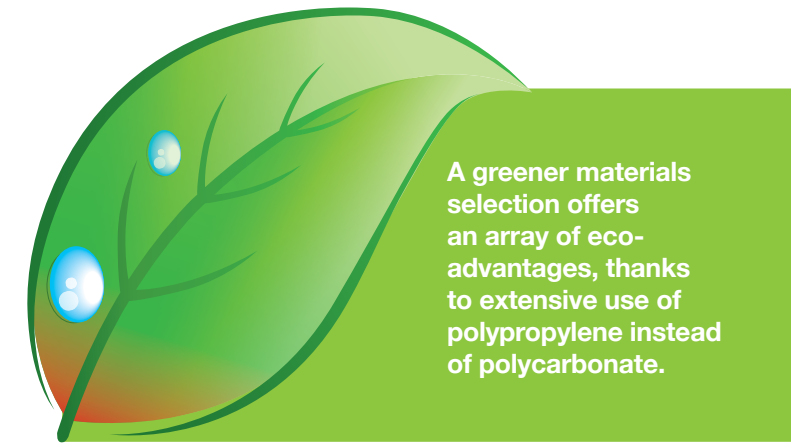
# Greener, Easier to Handle, and More Cost Effective

## Eco-friendliness

- 10% less CO<sub>2</sub> emission for resin production
- 50% less CO<sub>2</sub> 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

## Handling and Savings

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



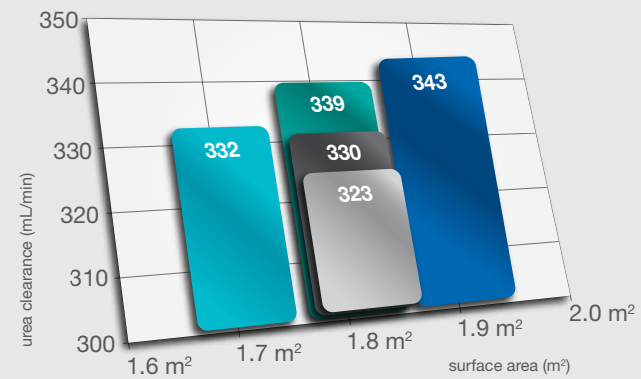
A greener materials selection offers an array of eco-advantages, thanks to extensive use of polypropylene instead of polycarbonate.



# The ELISIO™-H Dialyzer Delivers Excellent Clearances

## Superior In-Vitro Clearances

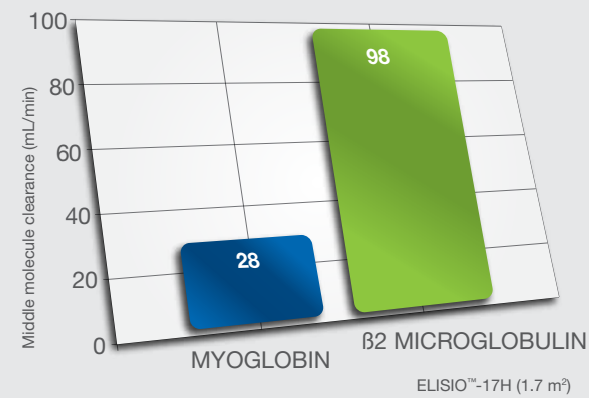
Testing demonstrates that the ELISIO™ POLYNEPHRON™ dialyzer provides higher clearances of small molecules.



Ob 400/Qd500/QfO Manufacturers' published data on file.

## Excellent In-Vivo Clearances

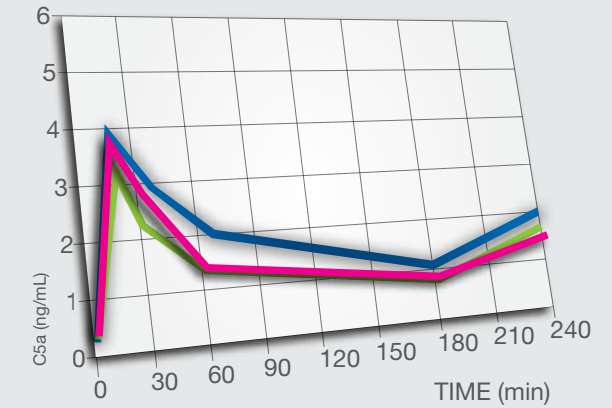
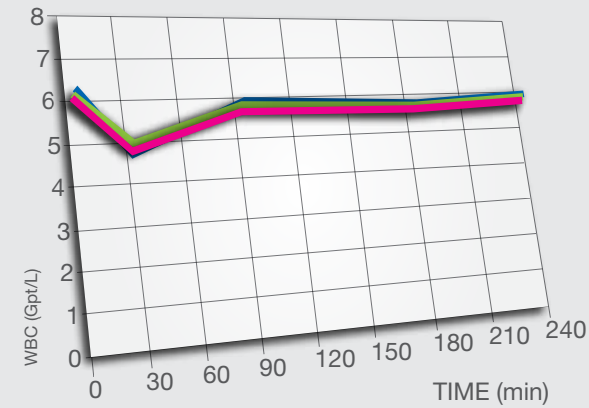
For middle molecule clearances, the ELISIO™-17H dialyzer demonstrated excellent performance with regard to β2 microglobulin and myoglobin.



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

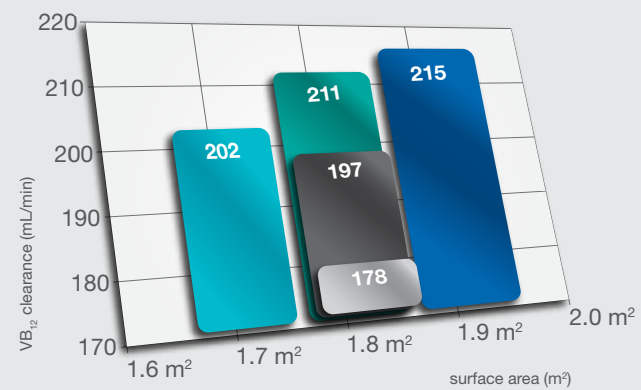
# Exceptional Biocompatibility

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

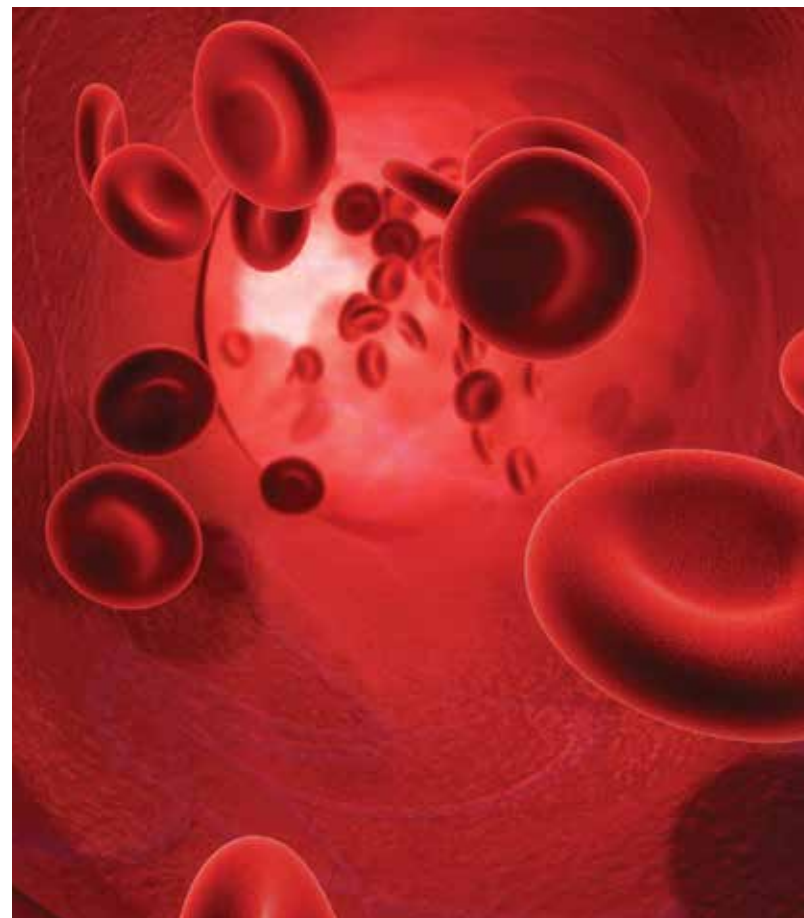


■ Polyarylethersulfone ■ POLYNEPHRON™ ■ Polysulfone

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



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



## Specifications

	ELISIO™-H								ELISIO™-M						
	9H	11H	13H	15H	17H	19H	21H	25H	11M	13M	15M	17M	19M	21M	
Priming Volume (mL)	62	70	85	95	105	115	130	149	68	80	91	108	115	128	
Effective Length (mm)	212	228	245	259	271	281	290	305	228	245	259	271	281	290	
Inner Diameter (µm)	200	200	200	200	200	200	200	200	200	200	200	200	200	200	
Membrane Thickness (µm)	40	40	40	40	40	40	40	40	40	40	40	40	40	40	
Maximum TMP (mmHg)	500	500	500	500	500	500	500	500	500	500	500	500	500	500	
Materials	Membrane	POLYNEPHRON™ (Polyethersulfone)								POLYNEPHRON™ (Polyethersulfone)					
	Housing	Polypropylene								Polypropylene					
	Header	Polypropylene								Polypropylene					
	Potting Compound	Polyurethane								Polyurethane					
Sterilization Method	Dry gamma								Dry gamma						
Package	24 pcs/case								24 pcs/case						

# ELISIO™ POLYNEPHRON™:

## Performance Parameters and Specifications

Performance		ELISIO™-H									ELISIO™-M					
		9H	11H	13H	15H	17H	19H	21H	25H	11M	13M	15M	17M	19M	21M	
Parameter	Qb/Qd (ml/min)	0.9	1.1	1.3	1.5	1.7	1.9	2.1	2.5	1.1	1.3	1.5	1.7	1.9	2.1	
Effective Surface Area (m <sup>2</sup> )		778	916	1190	1351	1614	1771	1976	2269	801	902	1027	1145	1292	1450	
KOA Urea (mL/min)*																
Clearances (mL/min)**																
Urea	200/500	190	193	196	198	198	199	200	200	190	192	194	196	197	198	
	300/500	246	257	272	278	285	288	291	294	248	256	264	270	276	281	
	400/500	278	298	316	326	337	345	348	363	285	298	309	318	318	334	
	400/800	307	327	347	359	368	373	378	386	311	326	339	350	360	369	
	500/800	339	365	392	408	420	430	437	460	350	368	384	397	409	420	
Creatinine	200/500	177	184	191	196	197	198	199	200	181	185	189	192	195	198	
	300/500	218	233	250	259	268	273	275	285	226	236	244	251	257	263	
	400/500	242	261	280	296	306	314	326	342	251	266	279	290	300	309	
	400/800	275	297	318	333	349	358	363	377	277	295	309	323	334	345	
	500/800	292	326	353	368	388	409	415	431	304	323	340	355	367	379	
Phosphate	200/500	163	171	178	184	188	192	195	196	156	163	170	176	181	186	
	300/500	200	213	230	241	254	258	265	276	183	198	211	221	231	240	
	400/500	223	246	265	275	292	305	314	329	202	219	233	246	257	267	
	400/800	242	263	291	305	322	335	339	352	220	241	258	274	287	300	
	500/800	259	293	317	337	357	371	378	405	236	260	280	298	314	328	
Vitamin B <sub>12</sub>	200/500	116	128	140	150	157	164	166	178	99	109	118	125	132	138	
	300/500	134	148	165	180	190	200	206	224	111	123	134	143	151	158	
	400/500	139	161	181	194	211	222	228	247	113	128	140	151	161	170	
	400/800	151	173	197	215	231	245	254	273	120	138	153	167	179	189	
	500/800	159	183	209	231	248	263	270	296	132	149	163	176	188	198	
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	15	17	20	22	25	27	
Sieving Coefficient****	Vitamin B <sub>12</sub>	0.99														
	Inulin	0.93														
	Myoglobin	0.22														
	Albumin	<0.01														

Item Name	Description
DD+ELISIO-C-09H	ELISIO-09H PP (0.9 m <sup>2</sup> ) Synthetic Hemodialyzer
DD+ELISIO-C-11H	ELISIO-11H PP (1.1 m <sup>2</sup> ) Synthetic Hemodialyzer
DD+ELISIO-C-13H	ELISIO-13H PP (1.3 m <sup>2</sup> ) Synthetic Hemodialyzer
DD+ELISIO-C-15H	ELISIO-15H PP (1.5 m <sup>2</sup> ) Synthetic Hemodialyzer
DD+ELISIO-C-17H	ELISIO-17H PP (1.7 m <sup>2</sup> ) Synthetic Hemodialyzer
DD+ELISIO-C-19H	ELISIO-19H PP (1.9 m <sup>2</sup> ) Synthetic Hemodialyzer
DD+ELISIO-C-21H	ELISIO-21H PP (2.1 m <sup>2</sup> ) Synthetic Hemodialyzer
DD+ELISIO-C-25H	ELISIO-25H PP (2.5 m <sup>2</sup> ) Synthetic Hemodialyzer
DD+ELISIO-C-11M	ELISIO-11M PP (1.1 m <sup>2</sup> ) Synthetic Hemodialyzer
DD+ELISIO-C-13M	ELISIO-13M PP (1.3 m <sup>2</sup> ) Synthetic Hemodialyzer
DD+ELISIO-C-15M	ELISIO-15M PP (1.5 m <sup>2</sup> ) Synthetic Hemodialyzer
DD+ELISIO-C-17M	ELISIO-17M PP (1.7 m <sup>2</sup> ) Synthetic Hemodialyzer
DD+ELISIO-C-19M	ELISIO-19M PP (1.9 m <sup>2</sup> ) Synthetic Hemodialyzer
DD+ELISIO-C-21M	ELISIO-21M PP (2.1 m <sup>2</sup> ) Synthetic Hemodialyzer

\* ELISIO™-H: Qb 300mL/min, Qd 500mL/min, Qf 10mL/min  
 ELISIO™-M: 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.

