

Nephral ST

DESIGNED FOR:

HFHD [High flux]

OTHER APPLICABLE THERAPIES:

CONVECTIVE [HDF-HF, AFB-K]

MEMBRANE:

AN69 ST [BPA-free]

SPECIALIZED FOR HIGH BIOCOMPATIBILITY AND ADSORPTION

The **Nephral ST** dialyzer series features a heparin adsorptive hydrogel membrane, for a reduced use of heparin during dialysis. The membrane is designed to provide effective removal of uremic toxins and inflammatory mediators by adsorption.¹

FOCUSED ON PATIENT BIOCOMPATIBILITY

- Different biocompatibility profile, compared to other fully synthetic membranes^{1,2}
- **Nephral ST** is a dialyzer for Acetate-Free-Biofiltration,³ which is a therapy that carries a lower long-term intradialytic hypotension rate and reduces systolic blood pressure by comparison with bicarbonate dialysis⁴
- May be an alternative for patients who have experienced hypersensitivity reactions to conventional membrane types⁵

WITH A UNIQUE ADSORPTION PROFILE

- The unique adsorptive capabilities of the surface treated **AN69** ST membrane of the **Nephral ST** dialyzers may improve toxin removal efficiency¹
- In addition to conventional middle molecule markers such as β_2m , the **Nephral ST** dialyzers may also help enhance removal of cytokines such as TNF- α , IL-6 and IL-8^{1,6}
- The membrane is also able to bind heparin during priming with a pre-heparinized saline solution^{1,7} and may be used to minimize the risk associated with systemic heparinization^{7,8}



Nephral ST Specifications

MATERIALS	NEPHRAL ST			
	200	300	400	500
Membrane	AN69 ST Acrylonitrile and Sodium methallyl sulfonate blend BPA-free			
Potting	Polyurethane (PUR)			
Housing	Polycarbonate (PC)			
Surface treatment agent	Polyethyleneimine (PEI)			
Protection caps	Polyethylene (PE): Blood caps (HDPE)/Dialysate caps (LDPE)			
Sterilization	Gamma ray [wet]			
Sterile barrier	PET/Aluminium/LDPE			
SPECIFICATIONS				
UF-Coefficient (mL/h*mmHg)*	33	40	50	65
KoA urea*	530	637	824	1045
Blood Compartment volume (mL)	66	83	100	129
Minimum recommended priming volume (mL)	1000 (at UFR = 2000 mL/h) Heparinized solution: 5000 IU/L			
Maximum TMP (mmHg)	450			
Recommended Q _B (mL/min)	150-400	200-400	200-500	200-500
Storage conditions	≥4°C (or ≥39°F) and ≤30°C (or ≤86°F)			
Units per box	24			
Gross/net weight (g)	216/188	233/205	284/251	327/295

MEMBRANE

Effective Membrane Area (m ²)	1.05	1.30	1.65	2.15
Fiber inner diameter (µm)	210			
Fiber wall thickness (µm)	45.5			

SIEVING COEFFICIENTS*

Vitamin B12 (1,4 kDa)	1.0			
Inulin (5,2 kDa)	0,96			
Myoglobin (17 kDa)	0,55			
Albumin (66,4 kDa)	<0,01			

* According to ISO 8637-1

- UF-Coefficient: measured with bovine blood, Hct 32%, Pct 60g/L, at 37°C

- KoA urea: calculated at Q_B=300 mL/min, Q_D=500mL/min, UF=0 mL/min

- Sieving coefficients: measured with bovine plasma, Q_B=300 mL/min, UF=60 mL/min

- Clearances In-Vitro: measured at UF=0 mL/min, ±10% [excepted for vit.B12 ±20%]

CLEARANCES IN VITRO (mL/min)*	NEPHRAL ST			
	200	300	400	500
Urea (60 Da) (Q _B -Q _D , mL/min)				
200/500	173	181	189	195
300/500	216	231	250	265
400/500	241	261	287	310
500/500			311	338
Creatinine (113 Da)				
200/500	156	166	176	184
300/500	187	204	220	237
400/500	205	226	246	269
500/500			263	290
Phosphate (142 Da)				
200/500	135	146	156	168
300/500	156	172	187	207
400/500	168	187	205	230
500/500			216	244
Vitamin B12 (1.4 kDa)				
200/500	85	96	111	126
300/500	92	106	124	143
400/500	96	111	131	153
500/500			136	159

1. Thomas M, et al. AN69: Evolution of the world's first high permeability membrane AN69: Evolution of the world's first high permeability membrane. *Contrib Nephrol* 2011; 173:119-129.
2. Randoux C, et al. New insights in dialysis membrane biocompatibility. *Kidney Int* 2001; 60:1571-1577.
3. Santoro A, et al. Potassium Profiling in Acetate-free Biofiltration. *Contrib Nephrol* 2002; 137(137):260-7.
4. Tessitore N, et al. Acetate-free biofiltration reduces intradialytic hypotension: a European multicenter randomized controlled trial. *Blood Purif* 2012; 34:354-363.
5. Coentrao L, et al. Treatment of severe dialysis reactions with the AN69-ST membrane: biocompatibility does matter. *Nephrol Dial Transplant* 2010; 10.1093.
6. Malard B, et al. Adsorption as a Contributor for Inflammatory Mediators Removal. *Artif Organ* 2017; 41:545-555.
7. Chanard J, et al. The clinical evaluation of low-dose heparin in haemodialysis: a prospective study using the heparin-coated AN69 ST membrane. *Nephrol Dial Transplant* 2008; 23:2003-2009
8. Kessler M, et al. Anticoagulation in chronic hemodialysis: progress toward an optimal approach. *Semin Dial* 2015; 28:474-489.

The hemodialyzer/filter is intended for use in hemodialysis, hemodiafiltration and hemofiltration for the treatment of chronic or acute renal failure.

The products meet the applicable provisions of Annex I (Essential Requirements) and Annex II (Full quality assurance system of the Council Directive 93/42/EEC of 14 June 1993, amended by Directive 2007/47/EC)

For safe and proper use of the device, please refer to the Instructions for Use



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