Baxter
Nephral ST
DIALYZER

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 dialysis[4]
- May be an alternative for patients who have experienced hypersensitivity reactions to conventional membrane types[5]

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 efficiency[1]
- 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	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 (m²)	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 EN 1283/ISO 8637:
– 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)*	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	135	146	156	168
300/500	156	172	187	207
400/500	168	187	205	230
500/500			216	244
Phosphates (142 Da)				
200/500	156	166	176	184
300/500	187	204	220	237
400/500	205	226	246	269
500/500			263	290
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 to 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 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

CE 0086

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