Baxter

Nephral ST
DIALYZER

# Nephral ST

DESIGNED FOR:
**HFHD** (High flux)

OTHER APPLICABLE THERAPIES:
**CONVECTIVE** (HDF-HF, **AFB.K**)

MEMBRANE:
**AN 69** 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.[1,2] The membrane is designed to provide effective removal of uremic toxins and inflammatory mediators by adsorption.[3]

## FOCUSED ON PATIENT BIOCOMPATIBILITY

- Different biocompatibility profile, compared to other fully synthetic membranes[3,4]
- **Nephral** ST is a dialyzer for Acetate-Free-Biofiltration,[5] which is a therapy that carries a lower long-term intradialytic hypotension rate and reduces systolic blood pressure by comparison with bicarbonate dialysis[6]
- May be an alternative for patients who have experienced hypersensitivity reactions to conventional membrane types[7]

## WITH A UNIQUE ADSORPTION PROFILE

- The unique adsorptive capabilities of the surface treated **AN 69** ST membrane of the **Nephral** ST dialyzers may improve toxin removal efficiency[3]
- In addition to conventional middle molecule markers such as $\beta_2$m, the **Nephral** ST dialyzers may also help enhance removal of cytokines such as TNF-α, IL-6 and IL-8[3,8]
- The membrane is also able to bind heparin during priming with a pre-heparinized saline solution,[1,3] and may be used to minimize the risk associated with systemic heparinization[1,9]


The images are for illustration purposes only and may differ from the actual product.

# **Nephral** ST Dialyzer Specifications

| | NEPHRAL ST 200 | NEPHRAL ST 300 | NEPHRAL ST 400 | NEPHRAL ST 500 |
|---|---|---|---|---|
| PRODUCT CODE | 101939A | 101940A | 101941A | 101942A |
| **MATERIALS** | | | | |
| Membrane | **AN 69** ST Acrylonitrile and Sodium methallyl sulfonate blend BPA-free | | | |
| Potting | Polyurethane (PUR) | | | |
| Housing | Polycarbonate (PC) | | | |
| Surface treatment agent | Polyethyleneimine (PEI) | | | |
| Protective end caps | Polyethylene (PE): Blood caps (HDPE)/Dialysate caps (LDPE) | | | |
| Sterile barrier | PET/Aluminium/PE | | | |
| **SPECIFICATIONS** | | | | |
| UF-Coefficient (mL/(h*mmHg))* | 35 | 40 | 52 | 64 |
| KoA urea* | 453 | 529 | 663 | 786 |
| Blood Compartment volume (mL) | 69 | 83 | 101 | 130 |
| Minimum recommended priming volume (mL) | 2000 Heparinized solution: 5000 IU/L | | | |
| Maximum TMP (mmHg) | 450 | | | |
| Recommended $Q_B$ (mL/min) | 150-400 | 200-400 | 200-500 | 200-500 |
| Sterilization | Gamma irradiation | | | |
| Storage conditions | +4°C to +30°C | | | |
| Shelf life | 2 years | | | |
| Units per box | 24 | | | |
| **MEMBRANE** | | | | |
| Membrane Area (m²) | 1.05 | 1.30 | 1.65 | 2.15 |
| Fiber inner diameter (µm) | 210 | | | |
| Fiber wall thickness (µm) | 45.5 | | | |
| **SIEVING COEFFICIENTS*** | | | | |
| Creatinine (113 Da) | 1 | | | |
| Inulin (5.2 kDa) | 1 | | | |
| Myoglobin (17 kDa) | 0.60 | | | |
| Albumin (66.4 kDa) | 0.002 | | | |

| CLEARANCES IN VITRO (mL/min)* | NEPHRAL ST 200 | NEPHRAL ST 300 | NEPHRAL ST 400 | NEPHRAL ST 500 |
|---|---|---|---|---|
| **Urea (60 Da)** (QB/QD, mL/min) | | | | |
| 200/500 | 162 | 170 | 180 | 186 |
| 300/500 | 202 | 216 | 234 | 247 |
| 400/500 | 231 | 249 | 273 | 290 |
| 500/500 | | | 302 | 323 |
| **Creatinine (113 Da)** | | | | |
| 200/500 | 144 | 153 | 166 | 174 |
| 300/500 | 175 | 189 | 209 | 223 |
| 400/500 | 198 | 215 | 240 | 259 |
| 500/500 | | | 265 | 287 |
| **Phosphate (142 Da)** | | | | |
| 200/500 | 126 | 135 | 149 | 159 |
| 300/500 | 149 | 163 | 184 | 199 |
| 400/500 | 167 | 184 | 209 | 228 |
| 500/500 | | | 229 | 252 |
| **Vitamin B12 (1.4 kDa)** | | | | |
| 200/500 | 75 | 84 | 97 | 107 |
| 300/500 | 85 | 96 | 113 | 126 |
| 400/500 | 93 | 105 | 125 | 141 |
| 500/500 | | | 135 | 154 |

## INTENDED PURPOSE[10]

**Nephral** ST dialyzers are intended to purify blood in hemodialysis, hemodiafiltration and hemofiltration.

## INDICATION[10]

**Nephral** ST dialyzers are indicated for the treatment of chronic renal failure.

## CONTRAINDICATIONS[10]

It is strictly contra-indicated to rinse the extracorporeal circuit with a solution containing heparin for patients presenting a known allergy to heparin or having type II thrombocytopenia caused by heparin (HIT Syndrome type II).

## NOTE[10]

**Nephral** ST dialyzers are for use in adult patients with chronic renal failure who require dialysis.

* 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 for Creatinine and Inulin measured with bovine plasma, QB=300 mL/min, UF=60 ml/min
- Sieving coefficients for Myoglobin and Albumin measured with human plasma, QB=300 mL/min, UF=60 mL/min
- Clearances In-Vitro: measured at UF=0 mL/min, ±10% (excepted for vit.B12 ±20%)

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


1. Chanard J, et al. The clinical evaluation of low-dose heparin in haemodialysis: a prospective study using the heparin-coated AN 69 ST membrane. Nephrol Dial Transplant 2008; 23:2003-9.
2. Lavaud S, et al. Assessment of the heparin-binding AN 69 ST hemodialysis membrane: II. Clinical studies without heparin administration. ASAIO J. 2005; 51:348-51.
3. Thomas M, et al. AN 69: Evolution of the world's first high permeability membrane. Contrib Nephrol 2011; 173:119-129.
4. Randoux C, et al. Filtration of native and glycated B2-microglobulin by charged and neutral dialysis membranes. Kidney Int 2001; 60,1571-1577.
5. Santoro A, et al. Potassium Profiling in Acetate-free Biofiltration. Contrib to Nephrol 2002; 137(137):260-7.
6. Tessitore N, et al. Acetate-free biofiltration reduces intradialytic hypotension: a European multicenter randomized controlled trial. Blood Purif 2012; 34:354-363.
7. Coentrao L, et al. Treatment of severe dialysis reactions with the AN 69-ST membrane: biocompatibility does matter. Nephrol Dial Transplant 2010; 10.1093.
8. Bouman C, et al. Cytokine filtration and adsorption during pre-and postdilution hemofiltration in four different membranes. Blood Purif 1998; 16, 261-268.
9. Kessler M, et al. Anticoagulation in chronic hemodialysis: progress toward an optimal approach. Semin Dial 2015; 28:474-489.
10. Nephral ST instructions for use.


The products comply with relevant General Safety and Performance Requirements (GSPRs) of ANNEX I of Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 (Medical Device Regulation, MDR).

CE 0123
Notified body: TÜV SÜD Product Service GmbH, Germany
Medical device of class IIb.


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