

# Evodial

DESIGNED FOR:

**HFHD** (High flux)

OTHER APPLICABLE THERAPIES:

**CONVECTIVE** (HDF-HF, AFB-K)

MEMBRANE:

**HEPRAN** (heparin-grafted **AN69** ST, BPA-free)

## SPECIALIZED FOR HIGH BLEEDING RISK PATIENTS

The **Evodial**\* dialyzer series is specialized for patients with a high risk of bleeding<sup>1,2</sup>. It has been designed with the **HeprAN** heparin-grafted membrane<sup>3,4</sup> and provides a convenient solution for patients requiring reduced or even heparin-free dialysis<sup>1,5</sup>.

## FOCUSED ON HEPARIN-FREE DIALYSIS

- May increase the rate of successful heparin-free HD therapy sessions, compared to the current standard of care for high bleeding risk patients<sup>1</sup>
- May allow reduced systemic heparin dosing, without compromising the dialysis sessions<sup>4,6,7</sup>
- Study data indicate that no significant amount of heparin is released from the membrane during a dialysis session<sup>8</sup>

## WITH ENHANCED CONVENIENCE<sup>1,5</sup>

- May reduce nurse workload and disposable consumption
- This could result in a lower use of healthcare resources, compared to standard heparin-free dialysis
- Polyvalent dialyzer design, which can accommodate standard hemodialysis, but also convective therapies (hemodiafiltration and hemofiltration), as well as acetate-free-biofiltration (AFB-K, with potassium profile)



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

\* Do not use **Evodial** in patients with a known allergy to heparin or type II thrombocytopenia caused by heparin (HIT syndrome type II)

# Evodial Specifications

|  | EVODIAL 1.0   | EVODIAL 1.3 | EVODIAL 1.6 | EVODIAL 2.2 |
|--|---|-------------|-------------|-------------|
| PRODUCT CODE                               | 110654A   | 110653A     | 110652A     | 110651A     |
|  |   |             |             |             |
| MATERIALS                                  |   |             |             |             |
| Membrane                                   | <b>HeprAN</b> (heparin-grafted <b>AN69 ST</b> ) :<br>Acrylonitrile and Sodium methallyl sulfonate<br>copolymer + polyethyleneimine surface treatment<br>+ heparin grafted<br>BPA-free |             |             |             |
| Potting                                    | Polyurethane (PUR)  |             |             |             |
| Housing                                    | Polycarbonate (PC)  |             |             |             |
| Protection caps                            | Polyethylene (PE):<br>Blood caps (HDPE)/Dialysate caps (LDPE)   |             |             |             |
| Sterile barrier                            | PET/Aluminium/PE  |             |             |             |
|  |   |             |             |             |
| SPECIFICATIONS                             |   |             |             |             |
| UF-Coefficient (mL/(h•mmHg))*              | 29  | 37          | 45          | 56          |
| KoA urea*                                  | 494   | 611         | 691         | 780         |
| Blood compartment<br>volume (mL)           | 69  | 83          | 101         | 130         |
| Minimum recommended<br>priming volume (mL) | 1000  |             |             |             |
| Maximum TMP (mmHg)                         | 450   |             |             |             |
| Recommended Q <sub>B</sub> (mL/min)        | 150-400   | 200-400     | 200-500     | 200-500     |
| Units per box                              | 24 units per box  |             |             |             |
| Net weight (g)                             | 168   | 191         | 229         | 269         |
| Sterilization                              | Gamma irradiation   |             |             |             |
| Storage conditions                         | +4°C to +30°C   |             |             |             |
| Shelf life                                 | 2 years   |             |             |             |
|  |   |             |             |             |
| 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                       |   |             |             |             |
| Creatinine (113 Da)                        | 1   |             |             |             |
| Inulin (5,2 kDa)                           | 1   |             |             |             |
| Myoglobin (117 kDa)*                       | 0.63  |             |             |             |
| Albumin (66,4 kDa)*                        | 0.003   |             |             |             |

\* According to ISO 8637-1  
- UF-Coefficient: measured with bovine blood, Hct 32%, Pct 60g/L, 37°C, QB=300 mL/min, TMP=100 mmHg  
- KoA urea: calculated at Q<sub>B</sub>=300 mL/min, Q<sub>D</sub>=500mL/min, UF=0 mL/min  
- Clearances In-Vitro: measured at UF=0 mL/min, 37±1°C  
- Sieving coefficients: Creatinine, Inulin measured with Evodial 2.2 in anticoagulated bovine plasma, QB=300 mL/min, UF=60mL/min;  
Myoglobin, Albumin measured with Evodial 2.2 in anticoagulated human plasma, QB=300 mL/min, UF=60mL/min

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

1.

Laville M, et al. Results of the HepZero study. *Kidney Int* 2014; 86:1260-1267.

2.

Kessler M, et al. Anticoagulation in chronic hemodialysis: progress toward an optimal approach. *Semin Dial* 2015; 28:474-489.

3.

Thomas M, et al. AN69: Evolution of the world’s first high permeability membrane. *Contrib Nephrol* 2011; 173:119-129.

4.

Kessler M, et al. Heparin-grafted dialysis membrane allows minimal systemic anticoagulation in regular hemodialysis patients: A prospective proof-of-concept study. *Hemodial Int* 2013; 17:282-293.

5.

Meijers B , et al. A noninferiority trial comparing a heparin-grafted membrane plus citrate-containing dialysate versus regional citrate anticoagulation: results of the CITED study. *Nephrol Dial Transplant.* 2017; 32(4):707-714.

6.

Morena M, et al. Biocompatibility of heparin-grafted hemodialysis membranes: Impact on monocyte chemoattractant protein-1 circulating level and oxidative status. *Hemodialysis International* 2010; 14:403-410.

7.

Frasca GM, et al. Post-Dilution Hemodiafiltration With a Heparin-Grafted Polyacrylonitrile Membrane. *Ther Apher Dial* 2015; 19:154-161.

8.

Baxter. Data on File. Evodial heparin leaching data. Study report BM10-008.

9.

Evodial instruction 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).



Notified body: TÜV SÜD Product Service GmbH, Germany  
Medical device of class III.

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| CLEARANCES IN VITRO (mL/min)*                                 | EVODIAL 1.0 | EVODIAL 1.3 | EVODIAL 1.6 | EVODIAL 2.2 |
|---|-------------|-------------|-------------|-------------|
| <b>Urea (60 Da)</b> (Q <sub>B</sub> /Q <sub>D</sub> , mL/min) |             |             |             |             |
| 200/500   | 169         | 176         | 183         | 187         |
| 300/500   | 210         | 223         | 237         | 246         |
| 400/500   | 236         | 253         | 272         | 285         |
| 500/500   |             |             | 297         | 312         |
| <b>Creatinine (113 Da)</b>                                    |             |             |             |             |
| 200/500   | 150         | 159         | 168         | 174         |
| 300/500   | 180         | 193         | 209         | 220         |
| 400/500   | 199         | 215         | 236         | 249         |
| 500/500   |             |             | 255         | 271         |
| <b>Phosphate (142 Da)</b>                                     |             |             |             |             |
| 200/500   | 128         | 138         | 149         | 156         |
| 300/500   | 149         | 162         | 179         | 190         |
| 400/500   | 162         | 178         | 198         | 212         |
| 500/500   |             |             | 212         | 228         |
| <b>Vitamin B12 (1.4 kDa)</b>                                  |             |             |             |             |
| 200/500   | 79          | 87          | 98          | 106         |
| 300/500   | 86          | 97          | 110         | 120         |
| 400/500   | 91          | 103         | 118         | 130         |
| 500/500   |             |             | 125         | 137         |

### INTENDED PURPOSE<sup>9</sup>

Evodial dialyzers are intended to purify blood in hemodialysis, hemodiafiltration and hemofiltration.

### INDICATION<sup>9</sup>

Evodial dialyzers are indicated for the treatment of chronic or acute renal failure.

### CONTRAINDICATIONS<sup>9</sup>

It is contra-indicated to use the Evodial dialyzers for patients presenting a known allergy to heparin or having type II thrombocytopenia caused by heparin (HIT Syndrome type II).

### NOTE<sup>9</sup>

Evodial dialyzers are for use in adult patients.



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