Baxter

Evodial
DIALYZER

# 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.[1,2] It has been designed with the **HeprAN** heparin-grafted membrane,[3,4] and provides a convenient solution for patients requiring reduced or even heparin-free dialysis.[1,5]

## 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[1]
- May allow reduced systemic heparin dosing, without compromising the dialysis sessions[4,6,7]
- Study data indicate that no significant amount of heparin is released from the membrane during a dialysis session[8]

## WITH ENHANCED CONVENIENCE[1,5]

- 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 accomodate 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 | **HeprAN** (heparin-grafted **AN69 ST**) : Acrylonitrile and Sodium methallyl sulfonate copolymer + polyethyleneimine surface treatment + heparin grafted BPA-free | | | |
| Potting | Polyurethane (PUR) | | | |
| Housing | Polycarbonate (PC) | | | |
| Protection caps | Polyethylene (PE): 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 volume (mL) | 69 | 83 | 101 | 130 |
| Minimum recommended priming volume (mL) | 1000 | | | |
| Maximum TMP (mmHg) | 450 | | | |
| Recommended $Q_B$ (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 (17 kDa)* | 0.63 | | | |
| Albumin (66,4 kDa)* | 0.003 | | | |

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

## INTENDED PURPOSE[9]

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

## INDICATION[9]

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

## CONTRAINDICATIONS[9]

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[9]

Evodial dialyzers are for use in adult patients.

* 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 $Q_B$=300 mL/min, $Q_D$=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 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. Frascá 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).

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




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GBU-RC20-220002 (v2.0) 03/2023



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