Baxter
Evodial
DIALYZER

# Evodial

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

OTHER APPLICABLE THERAPIES:
**CONVECTIVE** (HDF-HF)

MEMBRANE:
**HEPRAN** (heparin-grafted AN 69 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]

## 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[4,5,6]
- Study data indicate that no significant amount of heparin is released from the membrane during a dialysis session[7]

## WITH ENHANCED CONVENIENCE[1]

- 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).


*** 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

| MATERIALS | EVODIAL 1.0 | EVODIAL 1.3 | EVODIAL 1.6 | EVODIAL 2.2 |
|---|---|---|---|---|
| Membrane | **HeprAN** (heparin-grafted AN 69 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))* | 30 | 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) | | | |
| 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)** | 0.7 | | | |
| Albumin (66,4 kDa)** | <0.0065 | | | |

| 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 | 173 | 181 | 189 | 195 |
| 300/500 | 216 | 231 | 250 | 265 |
| 400/500 | 241 | 261 | 311 | 338 |
| **Phosphate (95 Da)** | | | | |
| 200/500 | 135 | 146 | 156 | 168 |
| 300/500 | 156 | 172 | 187 | 207 |
| 400/500 | 168 | 187 | 205 | 230 |
| **Creatinine (113 Da)** | | | | |
| 200/500 | 156 | 166 | 176 | 184 |
| 300/500 | 187 | 204 | 220 | 237 |
| 400/500 | 205 | 226 | 246 | 269 |
| **Vitamin B12 (1.4 kDa)** | | | | |
| 200/500 | 85 | 96 | 111 | 126 |
| 300/500 | 92 | 106 | 124 | 143 |
| 400/500 | 96 | 111 | 131 | 153 |

* According to 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 (or human**) 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%)


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. 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.
6. Frascá GM, et al. *Post-Dilution Hemodiafiltration With a Heparin-Grafted Polyacrylonitrile Membrane*. Ther Apher Dial 2015; 19:154-161.
7. Baxter. Data on File. *Evodial Heparin leaching data*. Study report BM10-008.


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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