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]

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), 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

MATERIALS	**EVODIAL** 1.0	**EVODIAL** 1.3	**EVODIAL** 1.6	**EVODIAL** 2.2
Membrane	**HeprAN** (heparin-grafted **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))*	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	287	310
500/500			311	338
Creatinine (113 Da)				
200/500	156	166	176	184
300/500	187	204	220	237
400/500	205	226	246	269
500/500			263	290
Phosphate (142 Da)				
200/500	135	146	156	168
300/500	156	172	187	207
400/500	168	187	205	230
500/500			216	244
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

* 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: 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 hemodialyzer/filter is intended for use in hemodialysis, hemodiafiltration and hemofiltration for the treatment of chronic or acute renal failure.
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 2797

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