

Evodial

DESIGNED FOR:

HFHD (High flux)

OTHER APPLICABLE THERAPIES:

CONVECTIVE (HDF-HF, AFB-K)

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 patients¹
- 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 session⁷

WITH ENHANCED CONVENIENCE¹

- 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)



* 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			

* 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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MANUFACTURER
Gambro Industries
7, Avenue Lionel Terray
69883 Meyzieu Cedex
France

Baxter Healthcare Corporation
One Baxter Parkway
Deerfield, IL 60015
USA
1-800-422-9837