Evodial

DESIGNED FOR:
HFHD (High flux)

OTHER APPLICABLE THERAPIES:
CONVECTIVE (HDF-HF)

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

SPECIALIZED FOR HIGH BLEEDING RISK PATIENTS

The **Evodial*** dialyser 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 dialyser design, which can accomodate standard haemodialysis, but also convective therapies (haemodiafiltration and haemofiltration)

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

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

EVODIAL Specifications

PRODUCT CODE	**EVODIAL** 1.6 110652A	**EVODIAL** 2.2 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	Multi-layer-aluminium bag	
SPECIFICATIONS		
UF-Coefficient (mL/(h·mmHg))*	45	56
KoA urea (mL/min)*	691	780
Blood compartment volume (mL)	101	130
Minimum recommended priming volume (mL)	1000	
Maximum TMP (mmHg)	450	
Recommended QB (mL/min)	200-500	200-500
Units per box	24 units per box	
Net weight (g)	229	269
Sterilization	Gamma irradiation	
Storage conditions	+4°C to +30°C	
Shelf life	2 years	
MEMBRANE		
Effective Membrane Area (m^2)	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** 1.6 110652A	**EVODIAL** 2.2 110651A
Urea (60 Da) (Q_B/Q_D, mL/min)		
200/500	183	187
300/500	237	246
400/500	272	285
500/500	297	312
Creatinine (113 Da)		
200/500	168	174
300/500	209	220
400/500	236	249
500/500	255	271
Phosphate (142 Da)		
200/500	149	156
300/500	179	190
400/500	198	212
500/500	212	228
Vitamin B12 (1.4 kDa)		
200/500	98	106
300/500	110	120
400/500	118	130
500/500	125	137

INTENDED PURPOSE[9]

Evodial dialysers are intended to purify blood in haemodialysis, haemodiafiltration and haemofiltration.

INDICATION[9]

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

CONTRAINDICATIONS[9]

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

NOTE[9]

Evodial dialysers are for use in adult patients.

* According to ISO 8637-1
> UF-Coefficient: measured with bovine blood, Hct 32%, Pct 60g/L, 37°C, Q_B=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, Q_B=300 mL/min, UF=60mL/min; Myoglobin, Albumin measured with **Evodial** 2.2 in anticoagulated human plasma, Q_B=300 mL/min, UF=60mL/min

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. Vantive. 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).

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

CE 0123

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

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