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Revaclear
DIALYZER

Revaclear

DESIGNED FOR:
HFHD (High flux HD)

MEMBRANE:
PORACTON (PAES/PVP, **BPA-free**)

일반적인 혈액투석(HD) 환자군

고유량(high-flux)에서의 성능 최적화

환자의 안전과 생체적합성을 향상시키는 동시에 더 작은 표면적으로 제거율이 최적화되도록 설계된 다양한 고효율 고유량(high-flux) 투석기(dialyzer)입니다.[1]

모든 혈액투석 환자를 위한 성능 최적화[2]

Revaclear 투석기는 고유량 치료의 성능을 최적화하도록 설계되었습니다.

- **Poracton** 투석막은 확산에 대한 저항을 최소화하면서 효과적인 투과성을 제공합니다.[3,4,5]
- 환자 개별적 맞춤 투석을 위해 두 가지의 표면적 옵션을 제공합니다.
- 혈액투석(HD) 연구에 따르면, **Revaclear** 400은 표면적이 22% 더 큰 투석기와 유사한 정도로 작은 용질과 β_2-microglobulin을 제거하는 것으로 나타났습니다.[2]

안전성과 생체 적합성 고려

Revaclear 투석기의 상대적으로 작은 표면적은 일부 환자 위험 관리에 유용할 수 있습니다.

- 혈액 노출이 줄어, 응고 및 미세 염증 발생이 잠재적으로 감소될 수 있습니다.[6]
- 성능이 동일한 투석기와 비교했을 때, 생물학적 유해 폐기물이 덜 생기고, 식염수 필요량을 줄여줍니다.[7,8]

Revaclear Specifications

MATERIALS	REVACLEAR 300	REVACLEAR 400
Membrane	**Poracton** Polyarylethersulfone and Polyvinylpyrrolidone blend BPA-free	
Potting	Polyurethane (PUR)	
Housing	Polycarbonate (PC)	
Gaskets	Silicone rubber (SIR)	
Protection caps	Polypropylene (PP)	
Sterilization	Steam (inside-out)	
Sterile barrier	Tyvek	

SPECIFICATIONS	REVACLEAR 300	REVACLEAR 400
UF-Coefficient (mL/(h*mmHg))*	48	54
KoA urea*	1186	1439
Blood Compartment volume (mL)	74	93
Minimum recommended priming volume (mL)		300
Maximum TMP (mmHg)		600
Recommended Q_B (mL/min)	200-500	200-600
Storage conditions		<30°C (or <86°F)
Units per box		24
Gross/net weight (g)	215/160	225/170

MEMBRANE	REVACLEAR 300	REVACLEAR 400
Effective Membrane Area (m²)	1.4	1.8
Fiber inner diameter (µm)		190
Fiber wall thickness (µm)		35

SIEVING COEFFICIENTS*	REVACLEAR 300	REVACLEAR 400
Vitamin B12 (1,4 kDa)		1.0
Inulin (5,2 kDa)		1.0
β_2-microglobulin (11,8 kDa)		0.95
Myoglobin (17 kDa)		0.68
Albumin (66,4 kDa)		0.0027

* According to EN 1283/ISO 8637:
- UF-Coefficient: measured with bovine blood, Hct 32%, Pct 60g/L, 37°C
- KoA urea: calculated at Q_B=300 mL/min, Q_D=500mL/min, UF=0 mL/min
- Sieving coefficients: measured with human plasma, Q_B=300 mL/min, UF=60 mL/min
- Clearances In-Vitro: measured at UF=0 mL/min, ±10%

CLEARANCES IN VITRO (mL/min)*	REVACLEAR 300	REVACLEAR 400
Urea (60 Da) (Q_B-Q_D, mL/min)		
200-250**/500	196	198
300/500	272	281
400/500	323	338
400/800	355	369
500/800	408	430
Creatinine (113 Da)		
200-250**/500	191	195
300/500	256	267
400/500	298	315
400/800	330	348
500/800	373	398
Phosphates (142 Da)		
200-250**/500	185	191
300/500	242	255
400/500	278	297
400/800	309	330
500/800	345	373
Vitamin B12 (1.4 kDa)		
200-250**/500	146	158
300/500	174	191
400/500	191	213
400/800	212	236
500/800	228	256

** REVACLEAR 500

1. Baxter. *REVACLEAR White Paper*. USMP/MG3/140052, May 2013.
2. Mauric A, et al. *Poster SP401*, presented at 50th ERA-EDTA congress. Istanbul (Turkey), 2013.
3. Ronco C, et al. *Evolution of synthetic membranes for blood purification: the case of the Polyflux family*. Nephrol Dial Transplant 2003;18(Suppl 7):vii10-20.
4. Ward R, et al. *Abstract SA-PO510*, presented at the 40th ASN congress. San Francisco (USA), 2007.
5. Bhimani JP, et al. *Effect of increasing dialysate flow rate on diffusive mass transfer of urea, phosphate and beta2-microglobulin during clinical haemodialysis*. Nephrol Dial Transplant 2010; 25:3990-3995.
6. Yao Q, et al. *Inflammation as a cause of malnutrition, atherosclerotic cardiovascular disease, and poor outcome in hemodialysis patients*. Hemodial Int 2004; 8:118-129.
7. Baxter. Data on file. *Biohazardous waste cost calculation*, 2015.
8. Baxter. *REVACLEAR dialyzer priming guide*. 306150152_C, 2009.

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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