Baxter
Polyflux 2H/6H
DIALYZER

Polyflux 2H/6H

DESIGNED FOR:	OTHER APPLICABLE THERAPIES:	MEMBRANE:
HFHD (High flux HD)	**CONVECTIVE** (HDF-HF)	**POLYAMIX** (PAES/PVP, PA, **BPA-free**)

소아와 같은 적은 체중의 환자군

저체중 환자를 위해 특화됨

Polyflux 2H/6H 투석기(dialyzer) 시리즈는 저체중 환자, 일반적으로 소아 환자를 대상으로 효과적인 성능의 고유량(high-flux) 혈액투석을 제공합니다.[1,2,3]

혈액 구획 용적의 축소에 집중

- **Polyamix** 막은 해당 특정 환자 집단에게 효과적인 고유량(high-flux) 성능을 지원할 목적으로 보다 소형화한 하우징 설계에 통합되었습니다.[3]
- **Polyflux 2H/6H**의 혈액구획 용적을 각각 17 ml와 52 ml로 감소시켰습니다.
- 투석기 구획이 작아 프라이밍이 간편하고 쉬워졌습니다.

생체 적합성 고려

Polyflux 2H/6H 투석기는 대류 요법(혈액투석여과 또는 혈액여과 모드) 뿐만 아니라 기존의 고유량(high-flux) 혈액투석 요법에도 사용할 수 있습니다.

- 3중 막 구조는 내독소(endotoxin)에 대한 안전 장벽 역할을 하는 동시에,[5] 높은 확산 및 대류 이동율(transport rate)이 최적의 조합을 이루도록 설계되었습니다.[4]
- **Polyflux 2H/6H** 투석기는 에틸렌옥사이드, 제조 잔류물과 같은 화학물질에 노출을 피하고, 생체적합성을 향상시키기 위해 인사이드-아웃(inside-out) 증기 멸균 처리됩니다.[6]

Polyflux 2H/6H Specifications

MATERIALS	POLYFLUX 2H	POLYFLUX 6H
Membrane	**Polyamix** Polyarylethersulfone, Polyvinylpyrrolidone and Polyamide blend BPA-free	
Potting	Polyurethane (PUR)	
Housing	Polycarbonate (PC)	
Gaskets	Silicone rubber (SIR)	
Protection caps	Polypropylene (PP)	
Sterilization	Steam (inside-out)	
Sterile barrier	Medical Grade Paper	

SPECIFICATIONS		
UF-Coefficient (mL/(h*mmHg))*	15	33
KoA urea*	146	461
Blood Compartment volume (mL)	17	52
Minimum recommended priming volume (mL)	500	1000
Maximum TMP (mmHg)	600	
Recommended Q_B (mL/min)	20-100	50-300 (HDF, HF: 50-200)
Storage conditions	<30°C (or <86°F)	
Units per box	24	
Gross/net weight (g)	98/75	152/140

MEMBRANE		
Effective Membrane Area (m²)	0.2	0.6
Fiber inner diameter (µm)	215	
Fiber wall thickness (µm)	50	

SIEVING COEFFICIENTS*	
Vitamin B12 (1,4 kDa)	1.0
Inulin (5,2 kDa)	1.0
β_2-microglobulin (11,8 kDa)	0.82
Myoglobin (17 kDa)**	0.37
Albumin (66,4 kDa)**	0.0022

* According to EN 1283/ISO 8637:
- UF-Coefficient: measured with bovine blood, Hct 32%, Pct 60g/L, 37°C
- KoA for urea: calculated at UF = 0 mL/min, at Q_B = 60 mL/min and Q_D = 300 mL/min for P2H, at Q_B = 200 mL/min and Q_D = 500 mL/min for P6H
- 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%
  HDF/HF mode: measured at UF=20 mL/min (2H) or UF=30 mL/min (6H), ±10%

CLEARANCES IN VITRO (mL/min)*	2H	6H	2H	6H
	HEMODIALYSIS MODE (HD)		HEMODIAFILTRATION MODE (HDF/HF)	
Urea (60 Da) (Q_B-Q_D, mL/min)				
20/30	16			
60/30	24			
100/30	26			
60/300	53			
100/300	72		79	
50/500		50		
100/500	76	97		99
150/500		136		141
200/500		167		174
Creatinine (113 Da)				
20/30	14			
60/30	22			
100/30	24			
60/300	44			
100/300	55		64	
50/500		49		
100/500	59	89		94
150/500		116		125
200/500		136		147
Phosphates (142 Da)				
20/30	15			
60/30	23			
100/30	25			
60/300	48			
100/300	62		70	
50/500		50		
100/500	65	93		96
150/500		124		131
200/500		146		156
Vitamin B12 (1.4 kDa)				
20/30	10			
60/30	15			
100/30	18			
60/300	27			
100/300	32		43	
50/500		45		
100/500	35	68		79
150/500		81		94
200/500		90		104
Inulin (5.2 kDa)				
20/30	7			
60/30	10			
100/30	11			
60/300	19			
100/300	21		33	
100/500	23			65
150/500				74
200/500				79

1. 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.
2. Goldstein SL, et al. *Polyflux® 6H dialyzer: a new option for small children requiring dialysis Int* J Artif Organs 2007; 30:321-324.
3. Cochat P, et al. *Pediatric Dialysis. Chapter 19. Maintenance hemodialysis during infancy*. 2012. Kluwer Academic Publishers, Dordrecht, pp 35-46.
4. Krieter DH, et al. *A new synthetic dialyzer with advanced permselectivity for enhanced low-molecular weight protein removal*. Artif Organs 2008; 32:547-554.
5. Ertl T, et al. *Barrier function of low and high flux synthetic membranes for endotoxins in contaminated dialysis fluid*. Blood Purif 2003; 21:358.
6. D'Ambrosio FP, et al. *Ethylene oxide allergy in dialysis patients*. Nephrol Dial 1997;12:1461-1463.

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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