

DESIGNED FOR:

Baxter

Polyflux L DIALYZER

> MEMBRANE: **LFHD** (Low flux) **POLYAMIX** (PAES/PVP/PA, BPA-free)

### THE PROVEN BALANCE OF QUALITY AND PERFORMANCE IN LOW-FLUX

The **Polyflux** L dialyzer series is specialized for low-flux hemodialysis treatments, featuring a distinctive membrane acting as an effective barrier to potential fluid contaminants,<sup>1</sup> while still delivering high performance? Polyflux L dialyzers are a good choice for proven biocompatible yet effective low-flux therapies, designed with safety in mind.

## DESIGNED TO PROMOTE BIOCOMPATIBILITY<sup>2</sup>

The Polyflux L dialyzers are designed to deliver high-quality low-flux hemodialysis treatments.

- Since 1988, over 300 million Polyflux dialyzers have been used globally<sup>3</sup>
- The Polyflux L dialyzers are designed to prevent endotoxins from crossing the dialyzer membrane<sup>1,2</sup>
- The Polyflux L dialyzers are steam sterilized inside-out, to promote biocompatibility, avoiding exposure to chemicals such as ethylene oxide and manufacturing residues<sup>4,5</sup>

# WITH HIGH PERFORMANCE IN MIND

The **Polyflux** L dialyzers feature an exclusive 3-layered membrane structure, designed to support a stable high performance over time.

- Effective clearance of standard dialysis markers, such as urea or phosphates<sup>6</sup>
- A clinical case series study suggests the Polyflux L dialyzers may reduce the signs and symptoms of hemodialysis-associated eosinophilia<sup>7</sup>

# Polyflux L Specifications

MATERIALS	POLYFLUX 14 L	POLYFLUX 17 L	POLYFLUX 21 L	
Membrane	Polyamix			
	Polyarylethersulfone, Polyvinylpyrrolidone			
	and Polyamide blend			
D. ut	BPA-tree			
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))*	10	12.5	15	
KoA urea*	851	1026	1268	
Blood Compartment	0.1	10/	100	
volume (mL)	81	104	123	
Minimum recommended	500			
priming volume (mL)				
Maximum TMP (mmHg)	600			
Recommended Q <sub>B</sub> (mL/min)	200-400	200-500	300-500	
Storage conditions	<30°C (or <86°F)			
Units per box	24			
Gross/net weight (g)	254/225	274/245	294/265	
MEMBRANE				
Effective Membrane Area (m²)	1.4	1.7	2.1	
Fiber inner diameter (µm)		215		

CLEARANCES IN VITRO (mL/min)*	POLYFLUX 14 L	POLYFLUX 17 L	POLYFLUX 21 L
<b>Urea (60 Da)</b> (Q <sub>B</sub> -Q <sub>D</sub> , mL/min)			
200/500	190	194	
300/500	252	264	275
400/500	293	310	328
500/500		342	364
200/700	194	197	
300/700	267	276	285
400/700	319	336	353
500/700		380	403
Creatinine (113 Da)			
200/500	171	179	
300/500	214	230	246
400/500	241	262	283
500/500		284	310
200/700	178	185	
300/700	229	244	258
400/700	264	284	306
500/700		313	341
Phosphate (142 Da)			
200/500	152	163	
300/500	183	200	218
400/500	203	224	247
500/500		240	267
200/700	160	170	
300/700	197	213	231
400/700	221	242	266
500/700		264	292
Vitamin B12 (1.4 kDa)			
200/500	90	101	
300/500	100	114	131
400/500	106	122	142
500/500		128	149
200/700	96	107	
300/700	107	121	138
400/700	114	130	150
500/700		137	159

\* According to ISO 8637-1 - UF-Coefficient: measured with bovine blood, Hct 32%, Pct 60g/L, 37°C

Fiber wall thickness (µm)

– KoA urea: calculated at  $\rm Q_B=300~mL/min, \, Q_D=500mL/min, \, UF=0~mL/min$ 

- Clearances In-Vitro: measured at UF=0 mL/min, ±10%

Schepers E, Glorieux G, Eloot S, et al. Assessment of the association between increasing membrane pore size and endotoxin permeability using a novel experimental dialysis simulation set up. 1. BMC Nephrology. 2018; 19:1.

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.

3. Baxter. Data on file. Dialyzers Sales Report. 2018.

4 Golli-Bennour EE, et al. Cytotoxic effects exerted by polyarylsulfone dialyser membranes depend on different sterilization processes. Int Urol Nephrol. 2011; 43:483-490.

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D'Ambrosio FP, et al. *Ethylene oxide allergy in dialysis patients*. Nephrol Dial 1997;12:1461-1463. Krause B, et al. *Polymeric Membranes for Medical Applications*. Chemie Ingenieur Technik. 2003; 75:1725-1732. 6.

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7. Tielemans C, et al. Clinical assessment of Performance and Blood Compatibility Profile of a New Synthetic Low Flux Hemodialyzer. Blood Purif. 2002; 20:214-215.

The capillary dialyzer/filter is intended for use in hemodialysis 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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