

Polyflux L

DESIGNED FOR:

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, 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 BIOCOMPATIBILITY²

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

- Since 1988, over 300 million Polyflux dialyzers have been used globally³
- The Polyflux L dialyzers are designed to prevent endotoxins from crossing the dialyzer membrane^{1,2}
- The Polyflux L dialyzers are steam sterilized inside-out, to promote biocompatibility, avoiding exposure to chemicals such as ethylene oxide and manufacturing residues^{4,5}

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 phosphates⁶
- A clinical case series study suggests the Polyflux L dialyzers may reduce the signs and symptoms of hemodialysis-associated eosinophilia⁷



Polyflux L Specifications

| MATERIALS | POLYFLUX 14 L | POLYFLUX 17 L | POLYFLUX 21 L | |
|---|--|---------------|---------------|--|
| 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))* | 10 | 12.5 | 15 | |
| KoA urea* | 851 | 1026 | 1268 | |
| Blood Compartment volume (mL) | 81 | 104 | 123 | |
| Minimum recommended priming volume (mL) | 500 | | | |
| Maximum TMP (mmHg) | 600 | | | |
| Recommended Q _B (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 | | | |
| Fiber wall thickness (µm) | 50 | | | |

^{*} According to EN 1283/ISO 8637:

| CLEARANCES IN VITRO (mL/min)* | POLYFLUX 14 L | POLYFLUX 17 L | POLYFLUX 21 L |
|--|---------------|---------------|---------------|
| Urea (60 Da) (Q _B -Q _D , 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 | 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 |
| Phosphates (142 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 |
| 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 |

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 **C**€ 0086

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[–] UF-Coefficient: measured with bovine blood, Hct 32%, Pct 60g/L, 37°C

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

[–] Clearances In-Vitro: measured at UF=0 mL/min, $\pm 10\,\%$

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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.