

BAXTER KIDNEY CARE PD | HD | HDx | EDUCATION | SUPPORT

THERANOVA 400/500 DIALYZER

HDx THERAPY ENABLED BY THE THERANOVA DIALYZER BRINGS US ONE STEP CLOSER TO THE NATURAL KIDNEY¹

The **Theranova** dialyzer features an **MCO** membrane which enables Expanded Hemodialysis therapy. It delivers superior removal of conventional/large middle molecules (up to 45 kDa) compared to high flux membranes, while retaining stable serum albumin levels.²

PROVIDE EXPANDED HD, RETAIN HD SIMPLICITY

- Compatible with existing HD workflows²
- Compatible with any HD monitor²

CHOOSING THE THERANOVA DIALYZER MAY REDUCE HOSPITALIZATIONS BY 45%

An analysis of a randomized controlled trial of US hemodialysis patients showed that all-cause hospitalizations were 45% lower in patients treated with the **Theranova** dialyzer compared to patients treated with high flux HD (p = 0.042).³

THE THERANOVA DIALYZER MAY IMPROVE PATIENT-REPORTED OUTCOMES COMPARED TO HIGH FLUX

- Up to 2 hours reduction in patient-reported recovery time⁴
 - Single center, retrospective analysis
- Up to 55% reduction in patients meeting diagnostic criteria for Restless Leg Syndrome⁵
 - Prospective, multicenter, observational study
- May reduce patient-reported pruritis⁶
 - Kidney Disease QoL Short form-36 assessment completed at baseline and at study completion at 12 weeks

THERANOVA SPECIFICATIONS

MATERIALS	THERANOVA 400	THERANOVA 500	
Membrane	Medium Cut-Off Polyarylethersulfone (PAES) / Polyvinylpyrrolidone (PVP) bler BPA-free		
Potting	Polyurethane (PUR)		
Housing	Polycarbonate (PC)		
Gaskets	Silicone rubber (SIR)		
Protection caps	Polypropylene (PP)		
Sterilization	Steam		
Sterile barrier	Tyvek		
SPECIFICATIONS			
UF-Coefficient (mL/(h*mmHg))*	48	59	
KoA urea*	1482	1630	
Blood Compartment volume (mL)	91	105	
Minimum recommended priming volume (mL)	300		
Maximum TMP (mmHg)	600		
Q _B (mL/min)	200-600	200-600	
Storage conditions	≼ 30 °C / 86 °F		
Units per box	24		
Gross/net weight (g)	229/170	246/190	
MEMBRANE			
Membrane Area (m²)	1.7	2.0	
Fiber inner diameter (µm)	180		
Fiber wall thickness (µm)	35		
Sieving profile – before blood exposure ⁷			
MWCO (cut-off) [kDa]	56 +/-3		
MWRO (retention onset) [kDa]	9.4 +/- 0.2		
ORDERING			
	055/01	955692	





YKL-40 = Chitnase-3-Like Protein 1

The **Theranova** Dialyzer is indicated for patients with chronic kidney failure who are prescribed intermittent hemodialysis. It provides an expanded solute removal profile with increased removal of various middle molecules (up to 45 kDa) that may play a pathologic role in the uremic clinical syndrome. The **Theranova** Dialyzer is not intended for hemofiltration or hemodiafiltration therapy. The total extracorporeal blood volume for the **Theranova** Dialyzer and the set should represent less than 10% of the patient's blood volume.

For single use only.

Rx Only. For the safe and proper use of this device, refer to the Instructions for Use.

1. Zweigart C, Boschetti-de-Fierro A, Hulko M, et al. Medium cut-off membranes - closer to the natural kidney removal function. Int J Artif Organs. 2017; 40[7]:328–334. 2. Theranova IFU, 2021. 3. Blackowicz, MJ, et al. Economic evaluation of expanded hemodialysis with the Theranova 400 dialyzer: A post hoc evaluation of a randomized clinical trial in the United States. Hemodialysis International. 2022; 26: 449–455. 4. Bolton S, Gair R, Nilsson LG, Matthews M, Stewart L, McCullagh N. Clinical Assessment of Dialyzers on patient-reported outcomes IRPROSI: COREXH Registry. Blood Purofit. 6. Lim JH, Park Y, Yook JM, et al. Randomized controlled trial of medium cut-off versus high-flux dialyzers on quality of life outcomes in maintenance hemodialysis patients. 2020; 10:7780. 7. Boschetti-de-Fierro A, Voigt M, Storr M, et al. MCO Membranes: Enhanced Selectivity in High-Flux Class. Sci Rep. 2015; 51]:18448. 8. Baxter Data on File. Theranova Performance Evaluation: Clearance (Human Plasma). 2022. 9. Baxter Data on File. Theranova Performance Evaluation: Sieving coefficients: measured with human plasma. 2021.

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*In Vitro $Theranova~400^{**}$ analysis performed at: $\rm Q_{g}$ = 300 mL/min, $\rm Q_{g}$ = 500, UF =10mL/min ** YKL-40 is referenced for both Theranova 400 and 500

CLEARANCES IN AQUEOUS SOLUTION (mL/min)*	THERANOVA 400	THERANOVA 500
Urea (60 Da) (Q _B -Q _D , mL/min)		
200/500	198	199
300/500	282	285
400/500	344	351
400/800	376	381
500/800	440	404
Phosphate (95 Da)	100	10/
200/500	192	194
400/500	201	207
400/800	2/5	25/
500/800	400	413
Creatinine (113 Da)		
200/500	194	196
300/500	269	274
400/500	323	331
400/800	357	365
500/800	416	428
Vitamin B12 (1.4 kDa)		
200/500	164	169
300/500	207	215
400/500	239	249
400/800	267	280
500/800	301	317
Inulin (5.2 kDa)	100	100
200/500	133	139
400/500	183	193
400/800	204	216
500/800	204	241
Cytochrome C (12 kDa)		
200/500	122	128
300/500	146	155
400/500	165	175
400/800	183	196
500/800	202	217
Myoglobin (17 kDa)		
200/500	104	110
300/500	123	130
400/500	137	147
400/800	152	163
200/800	00	180