

# Theranova

DESIGNED FOR:

**HDx**

MEMBRANE:

**MCO** [PAES/PVP, BPA-free]

## HDx THERAPY ENABLED BY THERANOVA\*

HDx therapy (expanded HD) is the next evolution in hemodialysis, as it targets the efficient removal of large middle molecules (25 kDa to < 60 kDa)! Indeed, many of them are linked to the development of inflammation, cardiovascular disease, and other co-morbidities in dialysis patients.<sup>2</sup> With HDx therapy, **Theranova** provides superior removal of large middle molecules compared with HD and HDF modalities and it does so using regular HD workflow and infrastructure.<sup>3</sup>

HDx therapy is enabled by the **Theranova** dialyzer series, which features an innovative membrane design that combines a permeability higher than that of regular high-flux dialyzers with effective selectivity for large proteins.<sup>4,5</sup>

## PROVIDE EXPANDED HD, RETAIN HD SIMPLICITY

- Markedly greater clearances and intradialytic reduction ratios for middle molecules than regular HD – at ordinary blood flow rates<sup>3</sup>
- Superior removal of large middle molecules compared to HD and HDF modalities<sup>3</sup>
- Limited albumin removal of between 1 and 4 grams per session<sup>3</sup>
- Compatible with any HD monitor<sup>6,7</sup> and with standard dialysis

## WITH BAXTER'S LATEST DIALYZER INNOVATION, COMING CLOSER TO THE NATURAL KIDNEY<sup>4,5</sup>

- High permeability to large middle molecules
- Effective selectivity by size exclusion
- Augmented internal filtration
- Similar retention of endotoxins to other dialysis membranes of the same material<sup>8</sup>

## CLINICAL EFFICIENCY AND PATIENT-REPORTED OUTCOMES

- Pre-dialysis levels of beta 2 microglobulin and kappa and lambda free light chains were reduced after 3 and 6 months with HDx therapy using the **Theranova** dialyzer in a multi-centric observational study of 41 HD patients?<sup>‡</sup>
- Restless Leg Syndrome criteria are reduced approximately 50% after 6 months for prevalent HD patients in a large observational study by Baxter.<sup>11,‡</sup> A smaller before-after study found no difference in patient-reported symptom burden.<sup>10,‡‡</sup>

### \* Do not use **Theranova** dialyzers in HDF or HF mode

‡ Based on data presented in a congress abstract – see reference for details.

‡‡ Based on data presented in a congress abstract – see reference for details. Restless leg syndrome was only one of several secondary endpoints.



# THERANOVA SPECIFICATIONS

MATERIALS	THERANOVA 400	THERANOVA 500
Membrane	Medium Cut Off 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		
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	
Recommended Q <sub>B</sub> (mL/min)	200-600	250-600
Storage conditions	<30°C (or <86°F)	
Units per box	24	
Gross/net weight (g)	229/170	246/190

MEMBRANE		
Effective Membrane Area (m <sup>2</sup> )	1.7	2.0
Fiber inner diameter (µm)	180	
Fiber wall thickness (µm)	35	
<b>Sieving profile – before blood exposure<sup>4</sup></b>		
MWCO (cut-off) [kDa]	56 +/- 3	
MWRO (retention onset) [kDa]	9,4 +/- 0.2	

SIEVING COEFFICIENTS*		
Vitamin B12 (1,4 kDa)	1.0	
Inulin (5,2 kDa)	1.0	
β <sub>2</sub> -microglobulin (11,8 kDa)	1.0	
Myoglobin (17 kDa)	0.9	
Albumin (66,4 kDa)	0.008	

\* According to EN 1283/ISO 8637:  
 – UF-Coefficient: measured with bovine blood, Hct 32%, Pct 60g/L, 37°C  
 – KoA urea: calculated at Q<sub>B</sub>=300 mL/min, Q<sub>D</sub>=500mL/min, UF=0 mL/min  
 – Sieving coefficients: measured with human plasma, Q<sub>B</sub>=300 mL/min, UF=60 mL/min  
 – Clearances In-Vitro: measured at UF=0 mL/min, ±10% [±20% Cyt. C, ±30% Myo.]

CLEARANCES IN VITRO (mL/min)*	THERANOVA 400	THERANOVA 500
<b>Urea (60 Da) (Q<sub>B</sub>-Q<sub>D</sub>, mL/min)</b>		
200/500	198	199
300/500	282	285
400/500	344	351
400/800	376	381
500/800	445	454
<b>Phosphate (95 Da)</b>		
200/500	192	194
300/500	261	267
400/500	311	320
400/800	345	354
500/800	400	413
<b>Creatinine (113 Da)</b>		
200/500	194	196
300/500	269	274
400/500	323	331
400/800	357	365
500/800	416	428
<b>Vitamin B12 (1.4 kDa)</b>		
200/500	164	169
300/500	207	215
400/500	239	249
400/800	267	280
500/800	301	317
<b>Inulin (5.2 kDa)</b>		
200/500	133	139
300/500	161	170
400/500	183	193
400/800	204	216
500/800	225	241
<b>Cytochrome C (12 kDa)</b>		
200/500	122	128
300/500	146	155
400/500	165	175
400/800	183	196
500/800	202	217
<b>Myoglobin (17 kDa)</b>		
200/500	104	110
300/500	123	130
400/500	137	147
400/800	152	163
500/800	166	180

## For safe and proper use of the device, please refer to the Instructions for Use

- Ronco C, et al. *The rise of Expanded Hemodialysis*. Blood Purif 2017; 44:1-VIII.
- Hutchison CA, et al. *The Rationale for Expanded Hemodialysis Therapy (HDx)*. Contrib Nephrol 2017; 191:142-52.
- Kirsch AH, et al. *Performance of hemodialysis with novel medium cut-off dialyzers*. Nephrol Dial Transpl 2017; 32(1):165-72.
- Boschetti-de-Fierro A, et al. *MCO membranes: Enhanced Selectivity in High-Flux Class*. Scientific Reports 2015; 5:18448.
- Zweigart C, et al. *Medium cut-off membranes – closer to the natural kidney removal function*. Int J Artif Organs 2017; 40(7):328-334.
- Baxter. Data on file. *Theranova Limited Controlled Distribution Report*. 2016.
- Baxter. *Theranova 400/500 Instructions For Use*. N50 648 rev 003, 2017-05-29.
- 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*. BMC Nephrology. 2018; 19:1.
- Cantaluppi V, et al. *Removal of large-middle molecules on expanded hemodialysis (HDx): a multicentric observational study of 6 months follow-up*. ASN 2018 Kidney Week Abstract TH-P0357.
- Krishnasamy R, et al. *Trial evaluating mid cut-off value membrane clearance of albumin and light chains in hemodialysis patients (REMOVAL-HD): a safety and efficacy study*. ASN 2018 Kidney Week Abstract TH-P0353.
- Sanabria M, et al. *Quality of life reported by patients with expanded hemodialysis by the Theranova dialyzer in RTS Colombia*. ASN 2018 Kidney Week Abstract TH-P0296.

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)

