Baxter
Theranova
DIALYZER

Theranova 500

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).[1] Indeed, many of them are linked to the development of inflammation, cardiovascular disease, and other co-morbidities in dialysis patients.[2] 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.[3]

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.[4,5]

PROVIDE EXPANDED HD, RETAIN HD SIMPLICITY

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

WITH BAXTER'S LATEST DIALYZER INNOVATION, COMING CLOSER TO THE NATURAL KIDNEY[4,5]

- 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[8]

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.[9,‡]
- Restless Leg Syndrome criteria are reduced approximately 50% after 6 months for prevalent HD patients in a large observational study by Baxter.[11,‡] A smaller before-after study found no difference in patient-reported symptom burden.[10,‡‡]

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

‡ Based on data presented in a congress abstract – see reference for details.
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THERANOVA 500 SPECIFICATIONS

MATERIALS	**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))*	59
KoA urea*	1630
Blood Compartment volume (mL)	105
Minimum recommended priming volume (mL)	300
Maximum TMP (mmHg)	600
Recommended Q_B (mL/min)	200-600
Storage conditions	<30°C (or <86°F)
Units per box	24
Gross/net weight (g)	246/190

MEMBRANE	
Effective Membrane Area (m^2)	2.0
Fiber inner diameter (µm)	180
Fiber wall thickness (µm)	35
Sieving profile – before blood exposure[4]	
MWCO (cut-off) [kDa]	56 +/-3
MWRO (rentation onset) [kDa]	9.4 +/- 0.2

SIEVING COEFFICIENTS*	
Vitamin B12 (1,4 kDa)	1.0
Inulin (5,2 kDa)	1.0
$ß_2$-microglobulin (11,8 kDa)	1.0
Myoglobin (17 kDa)	0.9
Albumin (66,4 kDa)	0.008

CLEARANCES IN VITRO (mL/min)*	**THERANOVA** 500
Urea (60 Da) (Q_B-Q_D, mL/min)	
200/500	199
300/500	285
400/500	351
400/800	381
500/800	454
Phosphate (95 Da)	
200/500	194
300/500	267
400/500	320
400/800	354
500/800	413
Creatinine (113 Da)	
200/500	196
300/500	274
400/500	331
400/800	365
500/800	428
Vitamin B12 (1.4 kDa)	
200/500	169
300/500	215
400/500	249
400/800	280
500/800	317
Inulin (5.2 kDa)	
200/500	139
300/500	170
400/500	193
400/800	216
500/800	241
Cytochrome C (12 kDa)	
200/500	128
300/500	155
400/500	175
400/800	196
500/800	217
Myoglobin (17 kDa)	
200/500	110
300/500	130
400/500	147
400/800	163
500/800	180

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

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

1. Ronco C, et al. *The rise of Expanded Hemodialysis*. Blood Purif 2017; 44:I-VIII.
2. Hutchison CA, et al. *The Rationale for Expanded Hemodialysis Therapy (HDx)*. Contrib Nephrol 2017; 191:142-52.
3. Kirsch AH, et al. *Performance of hemodialysis with novel medium cut-off dialyzers*. Nephrol Dial Transpl 2017; 32(1):165-72.
4. Boschetti-de-Fierro A, et al. *MCO membranes: Enhanced Selectivity in High-Flux Class*. Scientific Reports 2015; 5:18448.
5. Zweigart C, et al. *Medium cut-off membranes – closer to the natural kidney removal function*. Int J Artif Organs 2017; 40(7):328-334.
6. Baxter. Data on file. *Theranova Limited Controlled Distribution Report*. 2016.
7. Baxter. *Theranova 400/500 Instructions For Use. N50 648 rev 003*, 2017-05-29.
8. 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.
9. 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-PO357.
10. 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-PO353.
11. 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-PO296.

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)

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