Baxter
Theranova
DIALYZER

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 (LMM)[1], many of which have been linked to the development of inflammation, cardiovascular disease, and other comorbidities in dialysis patients.[2,3] With HDx therapy, **Theranova** provides superior removal of large-middle molecules compared with standard HD and HDF modalities and it does so using regular HD workflow and infrastructure.[4]

HDx therapy is enabled by the **Theranova** dialyzer series, which combines diffusion and convection along the hollow fiber.[2] It features an innovative Medium Cut-Off (MCO) membrane that combines a higher permeability for large-middle molecules than that of high-flux dialyzers, used in both conventional HD and HDF therapies, while maintaining stable albumin levels.[5,6]

PROVIDE EXPANDED HD, RETAIN HD SIMPLICITY

- Markedly greater clearances and intradialytic reduction ratios for middle molecules than regular HD – at ordinary blood flow rates[4]
- Superior removal of large-middle molecules compared to HD and HDF modalities[4]
- Limited albumin removal of between 1 and 4 grams per session, with demonstrated stable albumin levels over 6 months.[5,6] Same result in albumin removal rate was observed in vitro in treatments up to 8 hours[19]
- Compatible with any HD monitor[7,8]

WITH BAXTER'S LATEST DIALYZER INNOVATION, COMING CLOSER TO THE NATURAL KIDNEY[9,10]

- High permeability to large-middle molecules
- Effective selectivity by size exclusion
- Enhanced convective transport through augmented internal filtration
- Effective retention of endotoxins equivalent to other dialysis membranes[11]

CLINICAL AND PATIENT-REPORTED OUTCOMES

- While HDx therapy may offer the potential to improve access to care and to help improve the effectiveness and quality of care, it may simultaneously offer dialysis service providers and healthcare systems alike the opportunity to reduce the total cost of care, primarily driven by potential reduction of cardiovascular events, infections, medication usage, all-cause hospitalizations, hospitalization rate and length of stay[6,12,13,14,15]
- HDx therapy may improve patient-reported outcomes including symptom burden, restless leg syndrome (CRLS) criteria, pruritus, and dialysis recovery time[14,16,17,18]

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

THERANOVA SPECIFICATIONS

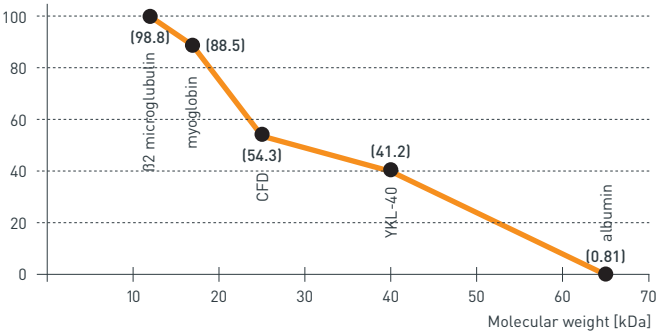
MATERIALS	**THERANOVA** 400	**THERANOVA** 500
Membrane	Medium Cut Off Polyarylethersulfone and Polyvinylpyrrolidone blend BPA-free	
Potting	Polyurethane (PUR)	
Housing	Polycarbonate (PC)	
Gaskets	Silicone rubber (SIR)	
Protection caps	Polypropylene (PP)	
Sterilization	Steam	
Sterile barrier	Tyvek	

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 (or <86°F)	
Units per box	24	
Gross/net weight (g)	229/170	246/190

MEMBRANE		
Effective Membrane Area (m^2)	1.7	2.0
Fiber inner diameter (µm)	180	
Fiber wall thickness (µm)	35	
Sieving profile – before blood exposure[9]		
MWCO (cut-off) [kDa]	56 +/-3	
MWRO (retention onset) [kDa]	9.4 +/- 0.2	

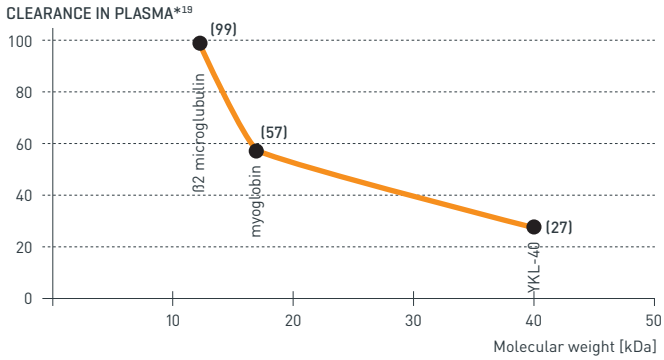
* According to EN 1283/ISO 8637-1:
– UF-Coefficient: measured with bovine blood, Hct 32%, Pct 60g/L, 37°C
– KoA urea: calculated at Q_B=300 mL/min, Q_D=500mL/min, UF=0 mL/min
– Sieving coefficients: measured with human plasma, Q_B=300 mL/min, UF=60 mL/min
– Clearances Aqueous: measured at UF=0 mL/min, ±10% (±20% Cyt. C, ±30% Myo.)

SIEVING COEFFICIENT [%][20]



*CFD = Complement Factor D
YKL-40 = Chitnase-3-Like Protein 1

CLEARANCES IN VITRO



*In Vitro Theranova 400** analysis performed at: QB = 300 mL/min, QD = 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	445	454
Phosphate (95 Da)		
200/500	192	194
300/500	261	267
400/500	311	320
400/800	345	354
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)		
200/500	133	139
300/500	161	170
400/500	183	193
400/800	204	216
500/800	225	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
500/800	166	180

Theranova dialyzers are indicated for treatment of chronic and acute renal failure by Hemodialysis.
For safe and proper use of the device, please refer to the Instructions for Use

1. Rosner M, Reis T, Husain-Syed, et al. Classification of Uremic Toxins and Their Role in Kidney Failure. *Clin J Am Soc Nephrol.* 2021;16(12):1918-1928. **2.** Ronco C, et al. The rise of Expanded Hemodialysis. *Blood Purif.* 2017;44:I–VIII. Doi: 10.1159/000476012. **3.** Hutchison CA, Wolley M. The Rationale for Expanded Hemodialysis Therapy (HDx). *Contrib Nephrol.* 2017; 191:142-52. **4.** Kirsch AH, Lyko R, Nilsson LG, et al. Performance of hemodialysis with novel medium cut-off dialyzers. *Nephrol Dial Transpl.* 2017; 32(1):165-72. **5.** Weiner DE, Falzon L, Skoufos L, et al. Efficacy and safety of expanded hemodialysis with the Theranova 400 dialyzer: a randomized controlled trial. *Clin J Am Soc Nephrol.* 2020;15:1310-1319. **6.** Molano-Trivino A, Sanabria M, Vesga J, Buitrago G, Sanchez R, Rivera A. Effectiveness of medium cut-off vs high flux dialyzers: a propensity score matching cohort study. *In Nephrol Dial Transport.* 2021;36:486-U948; i486-i487. **7.** Baxter Data on File. Theranova Limited Controlled Distribution Report. 2016. **8.** Baxter.Theranova 400/500 Instructions For Use. 2021; N50 648 rev 006. **9.** Boschetti-de-Fierro A, Voigt M, Storr M, et al. MCO Membranes: Enhanced Selectivity in High-Flux Class. *Sci Rep.* 2015;5(1):18448. **10.** Zweigart C, Boschetti-de-Fierro A, Hulko H, et al. Medium cut-off membranes – closer to the natural kidney removal function. *Int J Artif Organs.* 2017; 40(7):328-334. **11.** 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. **12.** Cozzolino M, Magagnoli L, Ciceri P, Conte F, Galassi A. Effects of a medium cut-off (Theranova®) dialyser on haemodialysis patients: a prospective, cross-over study. *Clin. Kidney J.* 2021;14(1):382-389. **13.** Ariza JG, Walton SM, Suarez AM, Sanabria M, Vesga JI. An initial evaluation of expanded hemodialysis on hospitalizations, drug utilization, costs, and patient utility in Colombia. *Ther Apher Dial.* 2021;25(5):621-627. **14.** 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. *Sci Rep.* 2020;10(1):1-11. **15.** Blackowicz MJ, Falzon L, Beck W, Tran H, Weiner DE. 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. https://doi.org/10.1111/hdi.13015. **16.** Penny JD, Jarosz P, Salerno FR, Lemoine S, McIntyre CW. Impact of Expanded Hemodialysis Using Medium Cut-off Dialyzer on Quality of Life: Application of Dynamic Patient-Reported Outcome Measurement Tool. *Kidney Medicine.* 2021;3(6):992-1002. **17.** Alarcon J.C, Bunch A, Ardila F, et al. Impact of Medium Cut-Off Dialyzers on Patient-Reported Outcomes: COREXH Registry. *Blood Purif.* 2021;50:110-118. **18.** Bolton S, Gair R, Nilsson LG, Matthews M, Stewart L, McCullagh N. Clinical Assessment of Dialysis Recovery Time and Symptom Burden: Impact of Switching Hemodialysis Therapy Mode. *Patient Relat Outcome Meas.* 2021;12:315-321. **19.** Baxter Data on File. Theranova Performance Evaluation: Clearance (Human Plasma). 2022. **20.** Baxter Data on File. Theranova Performance Evaluation: Sieving coefficients: measured with human plasma. 2021.

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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