Baxter

Theranova

DIALYZER

# Theranova

DESIGNED FOR:
**HDx**

MEMBRANE:
**MCO** (PAES/PVP, BPA-free)


## HDx THERAPY ENABLED BY MCO THERANOVA DIALYZER

**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** dialyzer 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 has a higher permeability for large-middle molecules than that of high-flux dialyzers (used in conventional HD or 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 conventional blood flow rates[4]
- Superior removal of large-middle molecules compared to both HD with high flux membranes and online HDF with > 23 L target convective volume[4]
- Limited albumin removal of between 1 and 4 grams per session[4], with demonstrated stable albumin levels over 6 months.[5, 6] Same result in albumin removal was observed in vitro in simulated treatments up to 8 hours[19]
- Compatible with existing hemodialysis (HD) monitors, workflow and infrastructure[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

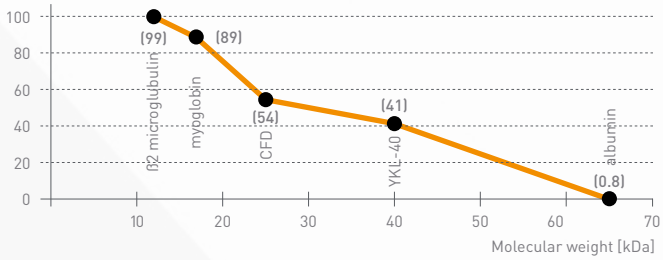
- While **HDx** therapy may offer the potential to improve access to care and to help improve the effectiveness and quality of care, it may simultaneously offer dialysis service providers and healthcare systems alike the opportunity to reduce the total cost of care, primarily driven by potential reduction 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]

# **THERANOVA** DIALYZER 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) | |
| 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 |
| Sterilization | Steam | |
| Storage conditions | ≤ 30 °C / ≤ 86 °F | |
| Units per box | 24 | |
| Gross/net weight (g) | 229/170 | 246/190 |
| **MEMBRANE** | | |
| Effective Membrane Area (m²) | 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 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 = Chitinase-3-Like Protein 1

**INTENDED PURPOSE**[8]

**Theranova** hemodialyzers are intended to purify blood in hemodialysis.

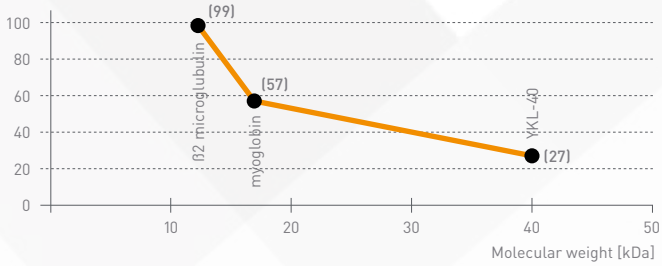
HDF **CAUTION!** Do not use **Theranova** devices for HDF (hemodiafiltration) or HF (hemofiltration) due to higher permeability of larger molecular weight proteins such as albumin.

**INDICATION**[8]

**Theranova** devices are indicated for the treatment of chronic or acute renal failure.

**CLEARANCES IN VITRO**

**CLEARANCE IN PLASMA***[19]




*In Vitro Theranova 400** analysis performed at: $Q_B$ = 300 mL/min, $Q_D$ = 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 |

## For the safe and proper use of the devices referenced within, refer to the complete Instructions for Use.


**1.** Rosner, Mitchell H et al. "Classification of Uremic Toxins and Their Role in Kidney Failure." *Clin J Am Soc Nephrol*, vol. 16,12 (2021): 1918-1928. **2.** Ronco, Claudio. "The Rise of Expanded Hemodialysis." *Blood Purif*, vol. 44,2 (2017): I-VIII. **3.** Hutchison, Colin A, and Martin Wolley. "The Rationale for Expanded Hemodialysis Therapy (HDx)." *Contrib Nephrol*, vol. 191 (2017): 142-152. **4.** Kirsch, Alexander H et al. "Performance of hemodialysis with novel medium cut-off dialyzers." *Nephrol Dial Transplant*, vol. 32,1 (2017): 165-172. **5.** Weiner, Daniel E et al. "Efficacy and Safety of Expanded Hemodialysis with the Theranova 400 Dialyzer: A Randomized Controlled Trial." *Clin J Am Soc Nephrol*, vol. 15,9 (2020): 1310-1319. **6.** Molano, Alejandra P et al. "Medium Cutoff Versus High-Flux Hemodialysis Membranes and Clinical Outcomes: A Cohort Study Using Inverse Probability Treatment Weighting." *Kidney Med*, vol. 4,4 (2022). **7.** Baxter Data on File. Theranova Limited Controlled Distribution Report. 2016. **8.** Theranova 400/500 Instructions for use. 2023; N51031 rev 001. **9.** Boschetti-de-Fierro, Adriana et al. "MCO Membranes: Enhanced Selectivity in High-Flux Class." *Sci Rep*, vol. 5 18448. 16 Dec. 2015. **10.** Zweigart, Carina et al. "Medium cut-off membranes - closer to the natural kidney removal function." *Int J Artif Organs*, vol. 40,7 (2017): 328-334. **11.** Schepers, Eva et al. "Assessment of the association between increasing membrane pore size and endotoxin permeability using a novel experimental dialysis simulation set-up." *BMC Nephrol*, vol. 19,1 (2018). **12.** Cozzolino, Mario et al. "*Effects of a medium cut-off (Theranova®) dialyser on haemodialysis patients: a prospective, cross-over study.*" *Clin Kidney J*, vol. 14,1 (2021): 382–389. **13.** Ariza, Juan G et al. "An initial evaluation of expanded hemodialysis on hospitalizations, drug utilization, costs, and patient utility in Colombia." *Ther Apher Dial*, vol. 25,5 (2021): 621-627 **14.** Lim, Jeong-Hoon et al. "Randomized controlled trial of medium cut-off versus high-flux dialyzers on quality of life outcomes in maintenance hemodialysis patients." *Sci Rep*, vol. 10,1 (2020). **15.** Blackowicz, Michael J 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." *Hemodial Int*, vol. 26,3 (2022): 449-455. **16.** Penny, Jarrin D et al. "Impact of Expanded Hemodialysis Using Medium Cut-off Dialyzer on Quality of Life: Application of Dynamic Patient-Reported Outcome Measurement Tool." *Kidney Med*, vol. 3,6 (2021) 992-1002. **17.** Alarcon, Juan Carlos et al. "Impact of Medium Cut-Off Dialyzers on Patient-Reported Outcomes: COREXH Registry." *Blood Purif*, vol. 50,1 (2021): 110-118. **18.** Bolton, Stephanie et al. "Clinical Assessment of Dialysis Recovery Time and Symptom Burden: Impact of Switching Hemodialysis Therapy Mode." Patient Relat Outcome Meas, vol. 12 (2021): 315-321. **19.** Baxter Data on File. Theranova Performance Evaluation: Clearance (Human Plasma). 2022. BXUH24018F/ 01. **20.** Baxter Data on File. Theranova Performance Evaluation: Sieving coefficients: measured with human plasma. 2021.


The products comply with relevant General Safety and Performance Requirements (GSPRs) of ANNEX I of Regulation [EU] 2017/745 of the European Parliament and of the Council of 5 April 2017 (Medical Device Regulation, MDR).

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Notified body: TÜV SÜD Product Service GmbH, Germany. Medical device of class IIb.


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