

# Theranova 400

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 400 SPECIFICATIONS

| MATERIALS       | THERANOVA 400   |
|-----------------|---|
| Membrane        | Medium Cut Off<br>Polyarylethersulfone and Polyvinylpyrrolidone blend<br>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               |
| KoA urea*                               | 1482             |
| Blood Compartment volume (mL)           | 91               |
| Minimum recommended priming volume (mL) | 300              |
| Maximum TMP (mmHg)                      | 600              |
| Recommended Q <sub>B</sub> (mL/min)     | 200-600          |
| Storage conditions                      | <30°C (or <86°F) |
| Units per box                           | 24               |
| Gross/net weight (g)                    | 229/170          |

| MEMBRANE   |             |
|--|-------------|
| Effective Membrane Area (m <sup>2</sup> )                  | 1.7         |
| 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 |
|---|---------------|
| <b>Urea (60 Da) (Q<sub>B</sub>-Q<sub>D</sub>, mL/min)</b> |               |
| 200/500   | 198           |
| 300/500   | 282           |
| 400/500   | 344           |
| 400/800   | 376           |
| 500/800   | 445           |
| <b>Phosphate (95 Da)</b>                                  |               |
| 200/500   | 192           |
| 300/500   | 261           |
| 400/500   | 311           |
| 400/800   | 345           |
| 500/800   | 400           |
| <b>Creatinine (113 Da)</b>                                |               |
| 200/500   | 194           |
| 300/500   | 269           |
| 400/500   | 323           |
| 400/800   | 357           |
| 500/800   | 416           |
| <b>Vitamin B12 (1.4 kDa)</b>                              |               |
| 200/500   | 164           |
| 300/500   | 207           |
| 400/500   | 239           |
| 400/800   | 267           |
| 500/800   | 301           |
| <b>Inulin (5.2 kDa)</b>                                   |               |
| 200/500   | 133           |
| 300/500   | 161           |
| 400/500   | 183           |
| 400/800   | 204           |
| 500/800   | 225           |
| <b>Cytochrome C (12 kDa)</b>                              |               |
| 200/500   | 122           |
| 300/500   | 146           |
| 400/500   | 165           |
| 400/800   | 183           |
| 500/800   | 202           |
| <b>Myoglobin (17 kDa)</b>                                 |               |
| 200/500   | 104           |
| 300/500   | 123           |
| 400/500   | 137           |
| 400/800   | 152           |
| 500/800   | 166           |

## 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.
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- Kirsch AH, et al. *Performance of hemodialysis with novel medium cut-off dialyzers*. Nephrol Dial Transpl 2017; 32(1):165-72.
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- 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.
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- 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-PO357.
- 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.
- 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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GBU-RC46-210015 v1.0 – June 2021

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