

The image is a split-screen advertisement. The left side shows a man with grey hair lying in a hospital bed, looking directly at the camera. He has a medical tube connected to his arm. The right side shows the same man, now outdoors, smiling and holding a young girl with pigtails. The background on the right is a bright, sunny outdoor setting with trees.

Baxter
Theranova
DIALYZER

**CHANGE
ONE THING** **CHANGE
EVERYTHING**

INTRODUCING **THERANOVA** FOR
EXPANDED HEMODIALYSIS [HDx]

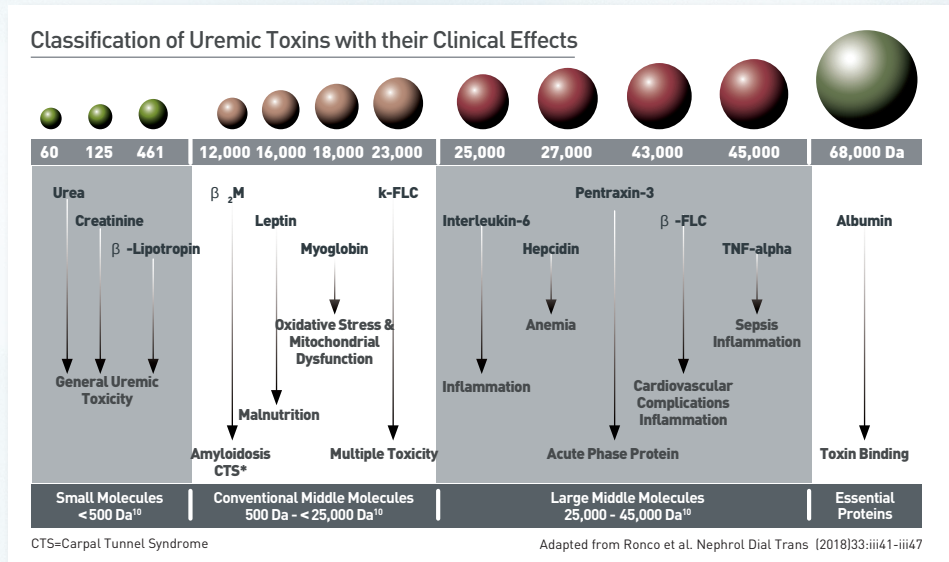
**DE NOVO
GRANTED**
NOW AVAILABLE

THE PROBLEM

Conventional/large middle-molecules are **linked** to **chronic inflammation, cardiovascular disease (CVD)**, secondary immunodeficiency, erythropoietin resistance, **symptom burden** and other dialysis related comorbidities.¹⁻⁴

CONVENTIONAL/LARGE MIDDLE MOLECULAR UREMIC TOXINS **ACCUMULATE** IN KIDNEY FAILURE PATIENTS^{1,2}

Accumulation of these uremic toxins result in **elevated concentrations** in patients with Kidney Failure (KF), and may cause **adverse biologic effects**.¹



~50% of patients with KF die from CVD⁸

Traditional high-flux membranes have **limited ability** to remove conventional and large middle molecular uremic toxins (up to 45,000 Da).^{1,4-6}

ACCUMULATION OF CONVENTIONAL/LARGE MIDDLE MOLECULES MAY CONTRIBUTE TO **DISEASE BURDEN** IN KIDNEY FAILURE PATIENTS^{1,2}

In a National Kidney Foundation (NKF) online survey, majority of patients (n=359) receiving in-center hemodialysis reported experiencing **interdialytic symptoms**.⁹

62% of patients feel fatigued/washed out

40% of patients report 4+ hours of recovery time

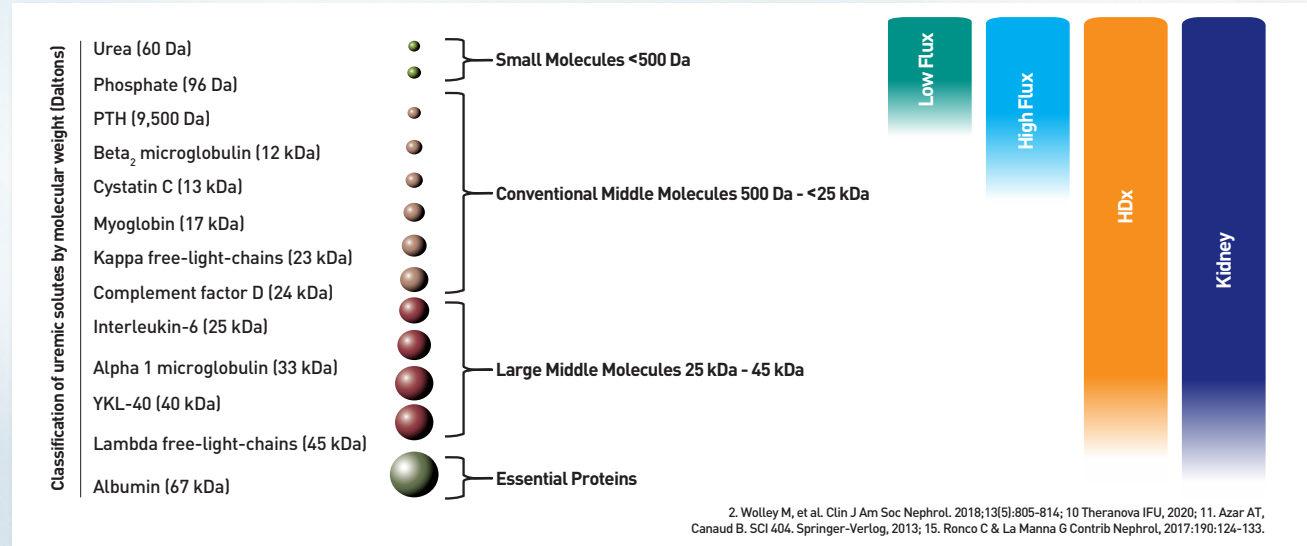
6% of patients skipped a dialysis session

These QoL symptoms were severe and correlated with longer recovery time following hemodialysis, as well as shortened and skipped hemodialysis sessions.⁹

THE SOLUTION

The **Theranova** MCO membrane's unique design includes a tight pore size distribution, with increased nominal pore size and pore density that delivers a **steep sieving curve** resulting in **higher permeability** for uremic toxins (up to 45,000 Da), while **selectively retaining** endotoxins/essential proteins and maintaining **stable albumin** levels.^{1,4-6,10}

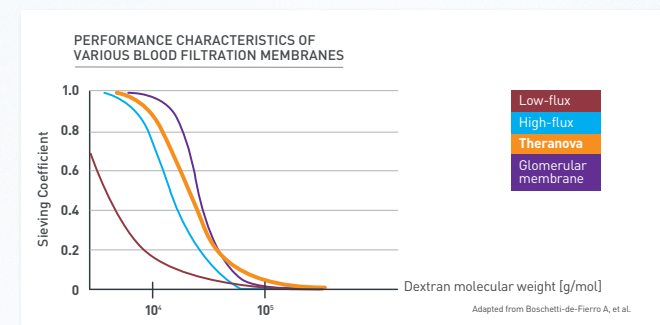
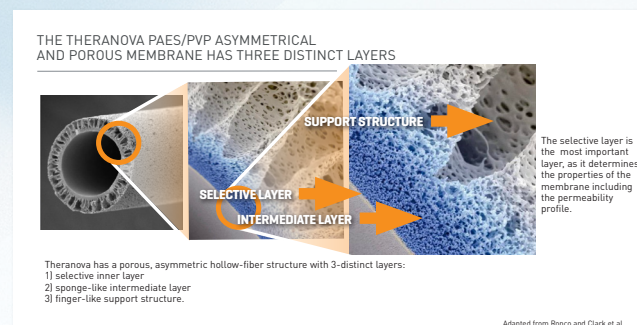
HDx ENABLED BY THERANOVA: ONE STEP CLOSER TO THE NATURAL KIDNEY



The minimized diameter (180 microns) of the **Theranova** membrane **enhances internal filtration** expanding solute removal, creating a stable separation profile and **selectivity** throughout treatment.¹⁰

THERANOVA 4 KEY DIFFERENTIATORS

- Higher Permeability
- Selectivity
- Retention
- Enhanced Internal Filtration



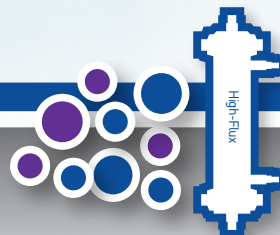
HDx ENABLED BY THERANOVA: NOW IS THE TIME TO CHANGE EVERYTHING



Conventional/large middle molecular (500-45,000 Da) uremic toxins have been linked to the development of inflammation, cardiovascular disease (CVD) and other dialysis related comorbidities²⁴



CVD is associated with inflammation, atherosclerosis and calcification. ~ **50%** of patients with kidney failure (KF) die from CVD¹²⁻¹⁴



Traditional high-flux membranes, have limited capability to remove conventional and large middle molecular uremic toxins (up to 45,000 Da)¹⁵

Theranova, the next evolution in hemodialysis (HD) brings us a **step closer to the natural kidney** by expanding clearance of conventional/large middle molecules (up to 45,000 Da) linked to inflammation and CVD, compared to traditional HD.^{1,4-6,10}

CHANGE ONE THING.

In a post-hoc analysis of a RCT*, HDx therapy showed a **significant reduction of 45% (p=0.049)** in all-cause hospitalizations²³, along with an **annual per patient cost reduction of ~\$4,324**.²⁴

* Weiner DE et al. Efficacy and safety of expanded hemodialysis with the Theranova 400 dialyzer: A randomized controlled trial. CJASN 2020.doi:10.2215/CJN.01210120.



The unique design of the Theranova membrane delivers superior removal of conventional/ large middle molecules (up to 45,000 Da),^{1,3,4} compared to high-flux membranes, while selectively retaining essential proteins and maintaining stable albumin levels^{5,16,17}



HDx therapy showed a significant reduction in hospital days and in-center medication usage, in a retrospective analysis (n=81)¹⁸. A Randomized Control Trial (n=171) showed a significant reduction of 45% in all-cause hospitalizations²³. Improvement in certain inflammatory markers were observed in select patients (n=41)¹⁹.



HDx therapy may improve patient reported kidney disease Quality of Life (QoL) outcomes including symptom burden, restless leg syndrome (RLS) criteria uremic pruritus and dialysis recovery time.^{15,20,21}

CHANGE EVERYTHING.

Simply change the dialyzer membrane to expand clearance and CHANGE EVERYTHING for your patients⁶.

FOR MORE DETAILS CONTACT YOUR **BAXTER REPRESENTATIVE** OR VISIT [HTTPS://HEMODIALYSIS.BAXTER.COM/HDx](https://hemodialysis.baxter.com/HDx)





REFERENCES:

1. 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. *Nature/Sci Rep.* 2020; 10:7780.
2. Wolley M, Jardin M, Hutchison CA, Exploring the Clinical Relevance of Providing Increased Removal of Large Middle Molecules. *Clin J Am Soc Nephrol* 2018;13:805-814.
3. Hutchison CA, Wolley M. The Rationale for Expanded Hemodialysis Therapy (HDx). *Contrib Nephrol.* 2017;191:142-152. Doi:10.1159/000479262.
4. Zweigart C, Boschetti-de-Fierro A, Hulko M, et al. Medium cut-off membranes - closer to the natural kidney removal function. *Int J Artif Organs.* 2017; 40(7):328-334. doi:10.5301/ijao.500060.
5. Kirsch AH, et al. Performance of hemodialysis with novel medium cut-off dialyzers. *Nephrol Dial Transpl* 2017; 32(1):165-72.
6. Boschetti-de-Fierro A, Voigt M, Storr M. et al. MCO Membranes: Enhanced Selectivity in High-Flux Class. *Sci Rep* 5, 18448 (2015). <https://doi.org/10.1038/srep18448>.
7. Ronco C, et al. Expanded haemodialysis: from operational mechanism to clinical results. *Nephrol Dial Trans.* 2018; 33: iii41-iii47.
8. Aoki J, Ikari Y, Cardiovascular Disease in Patients with End-Stage Renal Disease on Hemodialysis, *Ann Vasc Dis Vol* 10, No 4; 2017; 327-337.
9. Alvarez L, et al. Intradialytic Symptoms and Recovery Time in Patients on Thrice-Weekly In-Center Hemodialysis: A Cross-sectional Online Survey, *Kidney Med.* 2020;2(2)125-130.
10. Theranova Instructions for Use, 2020.
11. Azar AT, Canaud B. Chapter 8: Hemodialysis System. In: Azar T, ed. *Modelling and Control of Dialysis Systems.* SCI 404. Springer-Verlog, 2013.
12. Foley RN et al. Clinical epidemiology of cardiovascular disease in chronic renal disease *Am J Kidney Dis.* 1998;32 [Suppl 3]:112-9.
13. Cobo G et al. C-reactive Protein: Repeated Measurements will Improve Dialysis Patient Care. *Sem Dialysis* 2016;29:7-14.
14. Yeun JY, et al. C-Reactive Protein Predicts All-Cause and Cardiovascular Mortality. *Am J Kidney Dis* 2000;35:469-476.
15. Ronco C & La Manna G *Contrib Nephrol*, 2017;190:124-133).
16. 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.*
17. Bunch A, et al. Long Term Effects of Expanded Hemodialysis (HDx) on Clinical and Laboratory Parameters in a Large Cohort of Dialysis Patients. *ASN 2018 Kidney Week Abstract FR-P0766.*
18. Ariza JG et al. Measuring the association of switching patients from hemodialysis to expanded hemodialysis, with hospitalizations, medication use, costs and patient utility. *Virtual International ISPOR 2020.* Poster PUK15.
19. Cantaluppi V et al. Removal of large-middle molecules, inhibition of neutrophil activation and modulation of inflammation-related endothelial dysfunction during expanded hemodialysis (HDx). *Nephrol Dial Transplant* 2019. Abstract F0048.
20. Alarcon JC et al. Impact of medium cut-off dialyzers on patient-reported outcomes (PROs): COREXH Registry. *Blood Purif.* 2020 doi: 10.1159/000508803.
21. Kharbada K et al. A randomised study investigating the effect of medium cut-off haemodialysis on markers of vascular health compared with on-line haemodiafiltration (MoDal study). *Manchester University NHS Foundation Trust.* [Poster clinicaltrials.gov \(NCT03510520\).](https://clinicaltrials.gov/ct2/show/study/NCT03510520)
22. Baxter data on file, 2020.
23. Tran H et al. Reduction in All-Cause Hospitalization Events Seen in a Randomized Controlled Trial Comparing Expanded Hemodialysis vs. High-Flux Dialysis. *ADC Conference 2021 Poster #1070.*
24. Blackowicz M et al. Health Economic Evaluation of the Theranova 400 Dialyzer Among Hemodialysis Patients in the United States: Results from a Randomized-Controlled Trial. *ASN 2020 Kidney Week abstract.*

The **Theranova** Dialyzer is indicated for patients with chronic kidney failure who are prescribed intermittent hemodialysis. It provides an expanded solute removal profile with increased removal of various middle and large molecules (up to 45 kDa) that may play a pathologic role in the uremic clinical syndrome. The **Theranova** Dialyzer is not intended for hemofiltration or hemodiafiltration therapy. The total extracorporeal blood volume for the **Theranova** Dialyzer and the set should represent less than 10% of the patient's blood volume.

For Single Use Only

Rx Only. For safe and proper use of this device refer to the Instructions for Use.

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