

Vantive

Theranova
DIALYZER

ONE EFFORTLESS DIALYZER SWITCH

CAN MAKE A WORLD OF DIFFERENCE



VANTIVE KIDNEY CARE

PD | HD | HDx | CRRT | EDUCATION | SUPPORT

HDx THERAPY ENABLED BY
THERANOVA DIALYZERS
MAY LEAD TO:

LESS HOSPITALIZATIONS^{1,2}

LESS MEDICATION USAGE³⁻⁶

LESS PATIENT-REPORTED
RECOVERY TIME⁷

LESS PATIENT-REPORTED
SYMPTOM BURDEN^{8,9}

THE PROBLEM

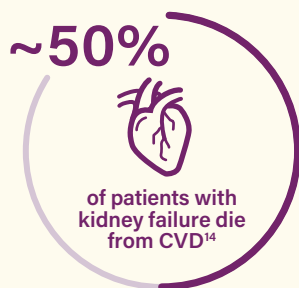
ACCUMULATION OF LARGE MIDDLE MOLECULAR UREMIC TOXINS

CONTRIBUTES TO DISEASE BURDEN IN KIDNEY FAILURE PATIENTS^{9,10}

In a National Kidney Foundation (NKF) online survey, **87% of patients** (n=359) receiving in-center hemodialysis reported experiencing **interdialytic symptoms**:¹¹



Large middle-molecules are linked to **chronic inflammation, cardiovascular disease (CVD), secondary immunodeficiency, erythropoietin resistance, symptom burden** and other dialysis-related comorbidities.^{9,10,12,13}



Traditional high-flux membranes have **limited ability** to remove large middle molecular uremic toxins (up to 45 kDa).^{13,15,16}

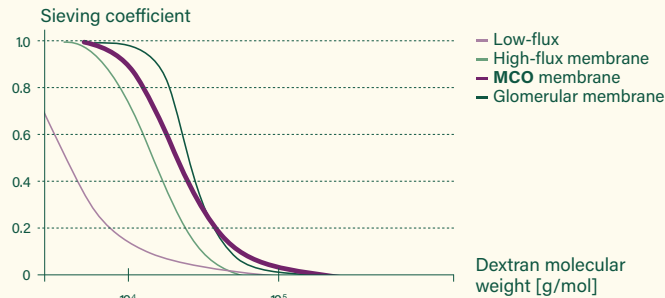
Classification of Molecules ¹⁷	Representative Molecules ¹⁷⁻¹⁹	Relevant Clinical Effects	Dialytic Clearance ¹⁷
Small Molecules <0.5 kDa	Urea (60 Da)	General Uremic Toxicity ^{20,21}	Removed by Low-Flux HD
	Phosphate (95 Da)	Vascular Calcification ²² Chronic Kidney Disease-Mineral and Bone Disorder ²³	
Small-middle Molecules 0.5-15 kDa	PTH (9.2 kDa)	Chronic Kidney Disease-Mineral and Bone Disorder ²³	Removed by High-Flux HD
	Beta 2 microglobulin (12 kDa)	Amyloidosis/Carpal Tunnel Syndrome (CTS) ^{20,21}	
Medium-middle Molecules >15-25 kDa	Myoglobin (17 kDa)	Oxidative Stress & Mitochondrial Dysfunction ²¹	Removed by HDF
	Kappa free-light-chains (23 kDa)	Multiple Toxicity ^{21,24}	
	Complement factor D (24 kDa)	Contributor to Proinflammatory Status of Uremia ¹⁸	
	Interleukin-6 (25 kDa)	Pruritus ²⁵ , Recovery Time ²⁶ , Chronic Inflammation ¹⁰ , CV Disease ¹⁰ , Protein-Energy Wasting in CKD ¹⁰	
Large-middle Molecules >25-45 kDa	TNF-alpha (26 kDa)	Sepsis ²¹ , Chronic Inflammation ¹⁰ , CV Disease ¹⁰ , Protein-Energy Wasting in CKD ¹⁰	Removed by HDx therapy
	FGF-23 (32 kDa)	Secondary immunodeficiency, CV Disease ¹⁰	
	Alpha 1 microglobulin (33 kDa)	Restless Legs Syndrome (RLS) ^{22,27}	
	YKL-40 (40 kDa)	Inflammation ²⁸	
	Lambda free-light-chains (45 kDa)	Chronic Inflammation, Secondary Immunodeficiency ¹⁰	
Large Molecules >58 kDa	Albumin (68 kDa)	Toxin Binding ²¹	Kidney

THE SOLUTION

HDx THERAPY ENABLED BY THERANOVA DIALYZERS:

ONE STEP CLOSER TO THE NATURAL KIDNEY

With **HDx** therapy, diffusion and convection are conveniently combined along a hollow fiber **Theranova** dialyzer equipped with **MCO** membrane.^{13,29} The patented **MCO** membrane's molecular weight retention onset (MWRO) and molecular weight cut-off (MWCO) range delivers superior removal of large-middle molecules (up to 45 kDa)^{12,15-17,34}, while selectively retaining endotoxins⁴³ and essential proteins and maintaining stable serum albumin levels^{30,31}, resulting in a sieving curve closer to that of the natural kidney.^{13,16}

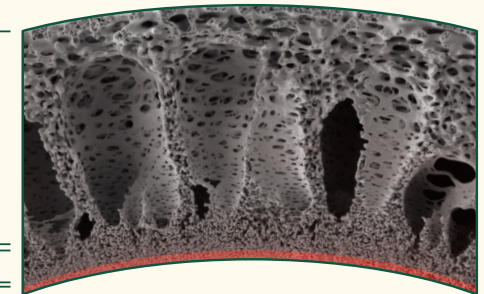


Adapted after Boschetti-de-Fierro: MCO Membranes: Enhanced Selectivity in High-Flux Class.¹⁶

THIS EXPANDED CLEARANCE PROFILE IS MADE POSSIBLE BY FOUR PRINCIPLES OF THE THERANOVA DIALYZER:

- > High permeability to large-middle molecules^{13,16,19}
- > Effective selectivity by size exclusion¹⁶
- > Enhanced internal filtration^{13,16,19}
- > Retention of endotoxins^{16,19}

The membrane structure is asymmetric and can be seen in cross section as **three distinct layers**.⁴⁴



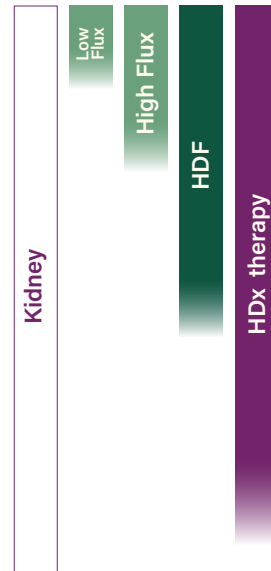
Adapted from Ronco and Clark, et al.⁴⁴

- A finger-like macroporous outer layer
- A sponge-like intermediate layer
- A very thin inner layer (skin)

Classification of uremic solutes by molecular weight (Daltons)¹⁷

Molecular Weight (kDa)	Classification
Urea (60 Da) ¹⁸	Small Molecules <0.5 kDa
Phosphate (95 Da) ¹⁰	
PTH (9,500 Da) ¹⁰	Small-middle Molecules 0.5-15 kDa
Beta ₂ microglobulin (12 kDa) ^{10,18}	
Cystatin C (13 kDa) ¹⁰	
Myoglobin (17 kDa) ¹⁰	Medium-middle Molecules >15-25 kDa
Kappa free-light-chains (23 kDa) ¹⁰	
Complement factor D (24 kDa) ¹⁰	
Interleukin-6 (25 kDa) ¹⁰	
Alpha 1 microglobulin (33 kDa) ¹⁰	Large-middle Molecules >25-45 kDa
YKL-40 (40 kDa) ¹⁰	
Lambda free-light-chains (45 kDa) ¹⁰	
Albumin (68 kDa) ¹⁰	Large Molecules [>58 kDa]

Evolution of dialysis therapies



Adapted after Rosner M, et al. Classification of Uremic Toxins and Their Role in Kidney Failure. *Clin J Am Soc Nephrol.* 2021;16(12):1918-1928¹⁷ and EUTOX Uremic Solutes Database. June 2022. Uremic-toxins.org.¹⁹

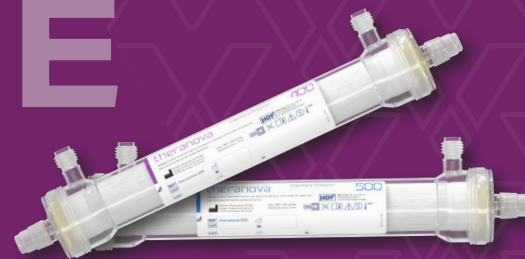
The **Theranova** dialyzer is the only device falling in the classification of hemodialyzers with an expanded solute removal profile, as approved by the US FDA through De Novo pathway, enabling **HDx** therapy - **the next evolution in dialysis**.

HDx therapy is an effective alternative and has increased clearance of large-middle molecules compared to online HDF⁶ with no special requirement of particular hardware, preparation of replacement fluid, or additional nursing skill compared to that required for conventional HD.²⁹ This is important where online HDF is not available.

THE OUTCOME

ONE EFFORTLESS DIALYZER SWITCH

CAN MAKE A WORLD OF DIFFERENCE



FOR YOUR FACILITY



LESS HOSPITALIZATIONS

Up to 45% reduction in all-cause hospitalizations.¹
Randomized controlled trial of US hemodialysis patients



LESS MEDICATION USAGE

Decreased Erythropoietin Resistance Index (ERI), lower ESA dose over time (without a concomitant reduction in hemoglobin level), and decreased use of supportive medications such as iron, insulin and antihypertensive medications.³⁻⁶

Multicenter, observational study; retrospective analysis; and prospective, randomized, controlled, open-label studies



LESS COST OF CARE

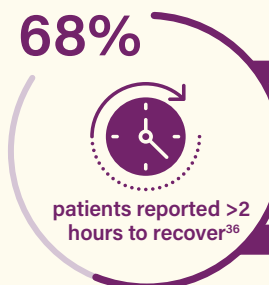
Up to \$4,772 lower cost per-patient, with savings demonstrated in 96% of the 10,000 simulations.¹

Randomized controlled trial of US hemodialysis patients

Lower cost of care with use of the **Theranova** dialyzer was driven by potential reduction of cardiovascular events¹⁹, infections²⁴, medication usage^{4,5}, and all-cause hospitalizations.¹

AND FOR YOUR PATIENTS

68%



patients reported >2 hours to recover³⁶

Poor quality of life scores³⁶

Fewer activities of daily living³⁶

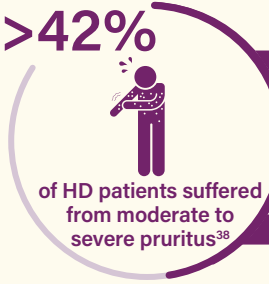
Dialysis-related stress³⁶

Associated with hospitalization³⁶

Higher mortality risk^{26,36}

Prospective cohort study (n=6,040)

>42%



of HD patients suffered from moderate to severe pruritus³⁸

Poor quality of life scores³⁸

Depression³⁸

Cardiovascular disease³⁸

Impaired sleep³⁸

Higher mortality risk³⁸

Dialysis Outcomes and Practice Patterns Study (n=18,801)

20%



of patients with ESRD were diagnosed with RLS^{39,40}

Poor quality of life scores⁴¹

Depression⁴¹

Evidence of muscle atrophy⁴¹

Cardiovascular disease⁴²

Higher mortality risk⁴¹

Impaired Sleep⁴¹

*Single center, observational study (n=137);
Observational, cross-sectional study (n=326)*

LESS PATIENT-REPORTED RECOVERY TIME

Up to 2.5 hours reduction in patient-reported recovery time.⁶

Single center, retrospective analysis

LESS PATIENT-REPORTED PRURITIS

Reduction in patient-reported pruritus.⁹

Randomized, prospective, controlled, open-label study

LESS PATIENT-REPORTED RESTLESS LEG SYNDROME

Up to 55% reduction in patients meeting diagnostic criteria for RLS.⁸

Prospective, multicenter, observational study

GO BEYOND UREA

TRY HDx THERAPY ENABLED BY THERANOVA DIALYZERS TODAY

Contact your local **Vantive sales representative** at 1-888-736-2543 and visit renalcareus.baxter.com/hdx for more information.

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Indications: 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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