Vantive

HDx THERAPY

Enabled by **THERANOVA** dialyser with **MCO** membrane

Discover how HDx Therapy Expanded Dialysis may make A WORLD OF DIFFERENCE for patients, clinicians & healthcare systems

A WORLD OF DIFFERENCE

ONE CHANGE CAN TRANSFORM HD TREATMENT

Expanded Haemodialysis is a dialysis treatment where diffusion and convection are conveniently combined along a hollow fibre dialyser equipped with a High Retention Onset (HRO) membrane[1] – defined as medium cut-off, with no special requirement of a particular hardware, preparation of replacement fluid, or additional nursing skill, compared to the necessary ones required to perform conventional haemodialysis (HD) in standard mode.[2]

WHAT A DIFFERENCE AN X MAKES

01
POSITIVE OUTCOMES

HDx therapy may reduce the burdens of haemodialysis therapy.[3,4]

Read more

02
REMOVING LARGE-MIDDLE MOLECULES

The efficient removal of large-middle molecules may reduce the risk of inflammation, toxicity, and organ damage.[2]

Read more

03
UNIQUE MEMBRANE

A different membrane design allows for a filtration profile that is close to that of the natural kidney.[1]

Read more

04
PROVEN RESULTS

HDx therapy's large and growing evidence-base.[47]

Read more

HOW CAN HDx THERAPY OPEN UP A WHOLE WORLD IN HD THERAPY?

ANSWERING CRITICAL PATIENT NEEDS

Patient-reported symptom burden has a significant impact on patient quality of life.[7]

PATIENT-REPORTED OUTCOMES

Uraemic PRURITUS

HDx therapy may significantly lower uraemic pruritus, a predictor of poor sleep, in HD patients.[8]

Read more

RESTLESS LEGS SYNDROME

HDx therapy may reduce the occurrence of restless legs syndrome (RLS), common in HD patients.[5,9]

Read more

RECOVERY TIME

HDx therapy may significantly reduce recovery time, positively associated with hospitalisation and mortality, after dialysis treatments.[10,11,12]

Read more

CREATING POSITIVE HEALTHCARE OUTCOMES

HDx therapy can help free resources and relieve the strain on healthcare systems.[3,14,31]

ECONOMIC OUTCOMES

HOSPITALISATION RATES

HDx therapy may reduce hospitalisation rates.[3,31]

Read more

MEDICATION USAGE

HDx therapy has been associated with decreases in medication usage.[15,16,17]

Read more

COST OF CARE

HDx therapy may reduce pressures on healthcare systems and total cost of care.[3,13,14,16,31]

Read more

A BETTER NIGHT'S SLEEP CAN MAKE A WORLD OF DIFFERENCE

URAEMIC PRURITUS

Daily bouts of itching that tend to worsen at night and may prevent sleep.[8]

IMPLICATIONS FOR PATIENTS[18]

>42%

Of HD patient suffer from moderate to severe pruritus

- Poor quality of life scores
- Depression
- Cardiovascular disease
- Impaired sleep
- Higher mortality risk

HDx THERAPY MAY IMPROVE PATIENT-REPORTED PRURITUS

One randomised clinical study found **HDx** therapy to deliver statistically significant improvements in key aspects of patient-reported uraemic pruritus compared to conventional HD.[8]

MOLECULE ASSOCIATION

IL-6 is a pleiotropic cytokine that regulates the immune and inflammatory response and affects hematopoiesis, metabolism and organ development.[19] IL-6 is commonly observed in Chronic Kidney Disease (CKD) patients and markedly increased in HD patients with uraemic pruritus[20], which is caused by increased generation resulting from oxidative stress, chronic inflammation and fluid overload.[19]

INTERLEUKIN-6 (IL-6)

[25 kDa]

THERANOVA dialysers are indicated for treatment of chronic and acute renal failure by Haemodialysis

Do not use in haemodiafiltration or haemofiltration mode or isolated Ultrafiltration

HDx THERAPY CAN GIVE PATIENTS A LEG UP

RESTLESS LEGS SYNDROME (RLS)

A neurological condition characterised by an irresistible urge to move the limbs accompanied by uncomfortable sensations.[23]

IMPLICATIONS FOR PATIENTS

20%

Of patients with ESRD will have RLS[21,22]

- Poor quality of life scores[23]
- Depression[23]
- Evidence of muscle atrophy[23]
- Cardiovascular disease[24]
- Higher mortality risk[23]
- Impaired Sleep[23]

HDx THERAPY MAY PREVENT DISCOMFORT

A large observational study in prevalent HD patients found an approximate 55% reduction in the number of patients meeting RLS criteria after 12 months on **HDx** therapy.[9]

MOLECULE ASSOCIATION

A1M is a microglobulin, belonging to a protein family. It is described as a circulating "waste bin" which continuously removes free radicals and oxidising agents, particularly heme, from the tissues. It is subsequently transported to the kidneys, where it is broken down. A1M's urinary excretion is associated with faster Chronic Kidney Disease (CKD) progression and high mortality as well as restless syndrome.[25]

a1-MICROGLOBULIN (A1M)

[33 kDa]

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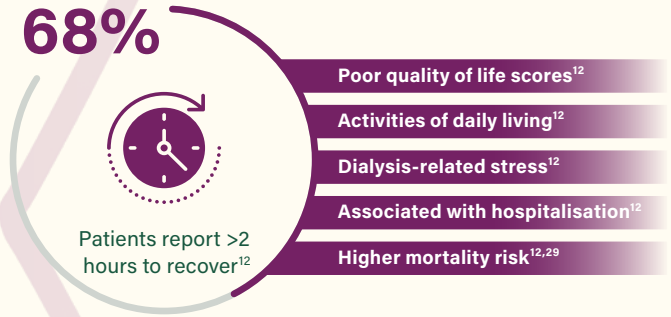
HDX THERAPY CAN HELP PATIENTS ENJOY MORE OF LIFE

RECOVERY TIME

The time in minutes that it takes a patient to recover after a haemodialysis session.[28]

IMPLICATIONS FOR PATIENTS

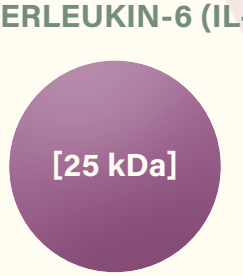


FASTER RECOVERY WITH HDx THERAPY

HDx therapy may significantly reduce dialysis recovery time and improve perceived fatigue level.[11]

MOLECULE ASSOCIATION

IL-6 is a pleiotropic cytokine that regulates the immune and inflammatory response and affects hematopoiesis, metabolism and organ development.[10] In people on chronic HD, fatigue appears associated with the serum level of interleukin, supporting that inflammation plays a role.[30]



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HELP PATIENTS SPEND LESS TIME IN YOUR WORLD

HOSPITALISATION RATES

Research reveals that **HDx** therapy is likely to significantly lower hospitalisation rates.[3,31]

REDUCTION IN HOSPITALISATION EVENTS

A randomised controlled trial of 171 prevalent HD patients showed a **45%** lower all-cause hospitalisation rate over 12 months with **HDx** therapy compared to the control high-flux HD arm.[31]

Health resource utilisation	THERANOVA dialyser (*n* = 86)	high-flux HD (*n* = 85)[a]	*p*-value
Hospitalisation events	**18**	**31**	**-**
Total hospital days	**74**	**139**	**-**
Total patient-years	**32.4**	**30.5**	**-**
Hospitalisation rate per PY (SE)	**0.56 (0.13)**	**1.02 (0.12)**	**0.042**
Hospital length of stay (mean days [SE])	**4.11 (0.57)**	**4.63 (0.58)**	**0.406**

a One high-flux HD randomised participant did not complete baseline.

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WHERE LESS CAN BE MORE

FEWER MEDICATIONS

HDx therapy has the potential to reduce the need for medication for conditions related to uraemic toxins such as anaemia and inflammation.[16]

LOWER DOSES

Research has shown that patients under **HDx** therapy may have a decreased Erythropoietin Resistance Index (ERI). Also, these patients may need a lower ESA dose over time without a concomitant reduction in haemoglobin level, when compared with patients under High-Flux HD and HDF therapies.[14,15,16,17]

MEDICATION UTILISATION PER PATIENT YEAR

ESA - INTERNATIONAL UNITS[a]

HD HF mean (95% CI) N = 81	**HDx** therapy mean (95% CI) N = 81	Percent change **HDx** therapy vs HD HF
181318	**168124[a]**	**-7%**

IRON - MILIGRAMS

HD HF mean (95% CI) N = 81	**HDx** therapy mean (95% CI) N = 81	Percent change **HDx** therapy vs HD HF
959	**759[a]**	**-21%**

INSULIN - INTERNATIONAL UNITS

HD HF mean (95% CI) N = 81	**HDx** therapy mean (95% CI) N = 81	Percent change **HDx** therapy vs HD HF
5383	**3434[a]**	**-36%**

HYPERTENSION MEDICATIONS - TABLETS

HD HF mean (95% CI) N = 81	**HDx** therapy mean (95% CI) N = 81	Percent change **HDx** therapy vs HD HF
1183	**731[a]**	**-38%**

a Statistically significant difference found in corresponding univariate GLM analysis of outcome on **HDx** therapy. All had a P-value <0.01.

Adapted after Ariza: An initial evaluation of **HDx** therapy on hospitalisations, drug utilisation, costs, and patient utility in Colombia.[16]

LOWER USE

Patients receiving **HDx** therapy may have a decreased use of supportive medications such as iron, insulin and antihypertensive medications vs those treated with conventional high-flux HD.[16]

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BETTER CARE CAN LOWER EXPENSES

FREEING UP RESOURCES

Recently published research has shown promising signs that **HDx** therapy has the potential to positively impact the burden on healthcare systems.[14,16,31]

REDUCING THE COST OF CARE

HDx therapy may offer health care systems the opportunity to reduce the total cost of care, primarily driven by potential reduction of cardiovascular events, infections, medication usage, all-cause hospitalisations, hospitalisation rate and length of stay.[3,13,14,16,17,31]

ECONOMIC OUTCOMES

HOSPITALISATION EVENTS[31]

Probabilistic analysis determined that **THERANOVA** dialyser was associated with lower costs in **96%** of the 10,000 simulations.

Item	Unit cost (USD)	Per-patient cost		
		THERANOVA	high-flux HD	Difference
All-cause Hospitalisation[a]	$2518 per day	$5756	$11,853	-$6097
Dialyser cost[b]	$15.00 ea/ $6.50 ea	$2340	$1014	$1326
Cumulative		$8096	$12,867	-$4771

a All-cause hospitalisation was defined as any serious adverse event that resulted in hospitalisation

b **THERANOVA** dialyser was priced at $15 in the United States and high-flux dialyser was assumed to cost $6.50

Adapted after Blackowicz: Economic evaluation of expanded haemodialysis with the **THERANOVA** 400 dialyser: A post hoc evaluation of a randomised clinical trial in the United States.[31]

MEDICATION UTILISATION[16]

Percentage change in average annual cost analysis HDx vs HD-HF			
ESA*	IRON	INSULIN	ANTIHYPERTENSIVES
-7.27%	-20.83%	-32.64%	-30.16%

*Erythropoietin stimulating agents

Adapted after Ariza: An initial evaluation of HDx therapy on hospitalisations, drug utilisation, costs, and patient utility in Colombia.[16]

CARDIOVASCULAR EVENTS

A retrospective, observational study found that HDx therapy compared to HD-HF is likely to significantly lower nonfatal cardiovascular events by **35%**.[3]

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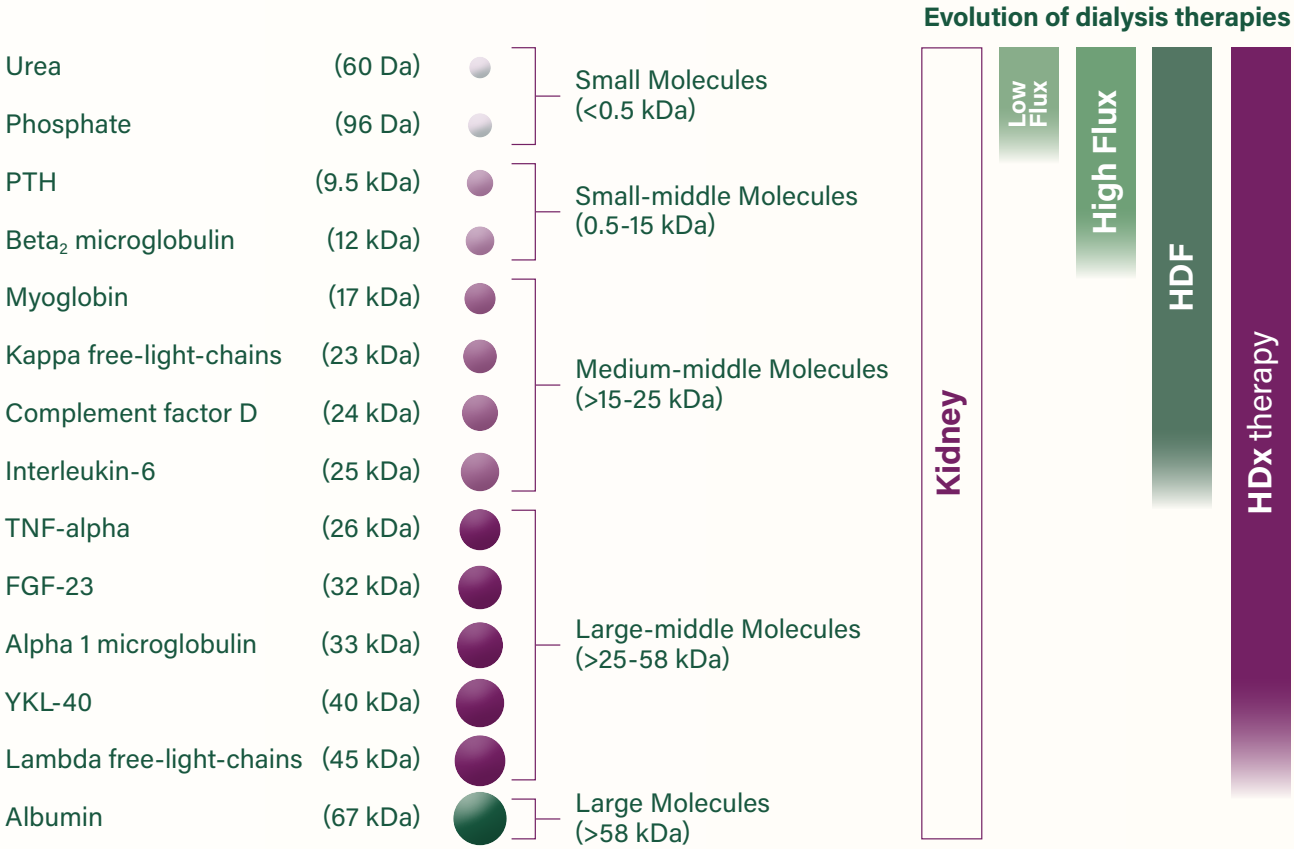
IS IT POSSIBLE TO GET CLOSER TO THE NATURAL KIDNEY?

USING A MEMBRANE WITH EXPANDED PERMEABILITY AND SELECTIVITY[1]

Until now, current dialytic therapies have had limited capability in removing large-middle molecule uraemic toxins.[32,48] Large-middle molecules can contribute to inflammation, cardiovascular events and other dialysis-related co-morbidities.[48]

Uraemic Toxin Classes by molecular weight (Daltons)[32,50]



Adapted after Rosner M, et al. Classification of Uraemic Toxins and Their Role in Kidney Failure. *Clin J Am Soc Nephrol*. 2021;16(12):1918-1928[32]
EUTOX Uraemic Solutes Database. June 2022. Uraemic-toxins.org[50]

GOING BEYOND UREA AND BETA$_2$ MICROGLOBULIN

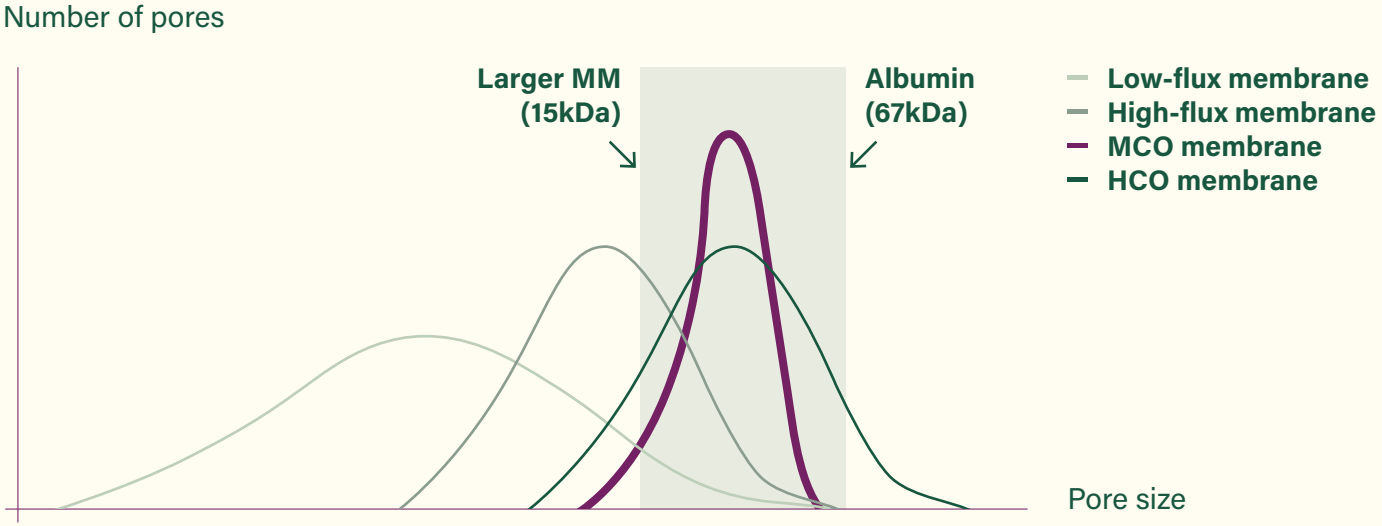
The clinical symptoms and conditions associated with uraemic toxins differ according to their molecular weight, with the large-middle molecules being linked to several clinical effects.[32]

Large-middle molecule linkage with clinical symptoms and outcomes

Large-middle molecules		Relevant clinical effects
TNF-alpha	(26 kDa)	▪ Sepsis[33] ▪ Chronic Inflammation[33] ▪ Cardiovascular Disease[34] ▪ Protein-energy wasting in CKD[34]
FGF-23[50]	(32 kDa)	▪ Secondary Immunodeficiency ▪ Cardiovascular Disease[34]
Alpha 1 microglobulin	(33 kDa)	▪ Restless Legs Syndrome (RLS)[35,36]
YKL-40	(40 kDa)	▪ Inflammation[37]
Lambda free-light-chains	(45 kDa)	▪ Chronic Inflammation ▪ Secondary Immunodeficiency[34]

EXPERTISE IN MEMBRANE MANUFACTURING: MCO MEMBRANE TO PERFORM HDx THERAPY

Membrane formation technologies have enabled precise control of pore size distribution which results in a narrow pore size distribution with a significant number of pores that are large enough for middle molecules to penetrate, but small enough for albumin to not pass through.[38,39]

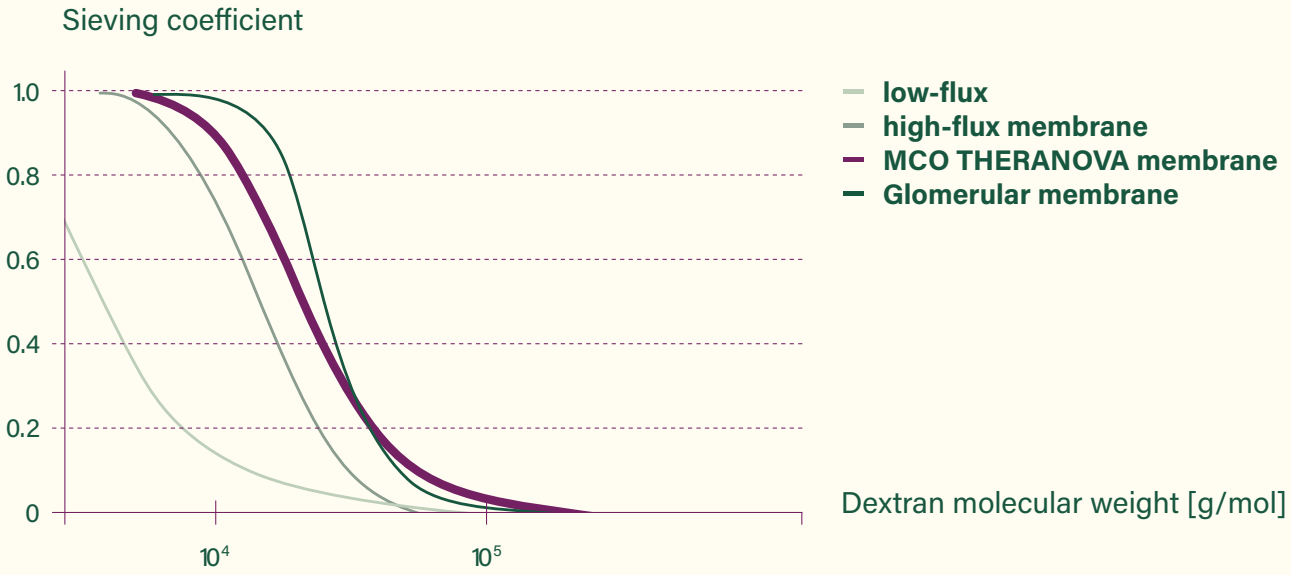


Adapted after Wolley: Exploring the Clinical Relevance of Providing Increased Removal of Large Middle Molecules.[49]

HDx THERAPY: DIFFUSION AND CONVECTION COMBINED INSIDE A DIALYSER

A HAEMODIALYSER WITH AN EXPANDED SOLUTE REMOVAL PROFILE

HDx therapy is a dialysis treatment where diffusion and convection are conveniently combined inside a hollow fiber dialyser.[1] **MCO THERANOVA** membrane provides the patented Molecular Weight Retention Onset (MWRO) and Molecular Weigh Cut-Off (MWCO) range to target the efficient removal of large-middle molecules.[5,6,38] This results in a sieving curve closer to the natural kidney.[1,38]



Adapted after Boschetti-de-Fierro: MCO Membranes: Enhanced Selectivity in High-Flux Class.[38]

A NEW CLASS OF DIALYSERS

THERANOVA dialyser is the only device falling in the classification of Haemodialysers with an expanded solute removal profile, as defined by the US Food and Drug Administration (FDA).[40] **THERANOVA** dialyser also falls into the new class of medium cut-off dialysers, based on the in vitro and clinical use methodology published by the Chinese Nephrology & Blood Purification Innovation Alliance.[45]

FOUR THERAPEUTIC PRINCIPLES THAT MAKE HDx THERAPY POSSIBLE

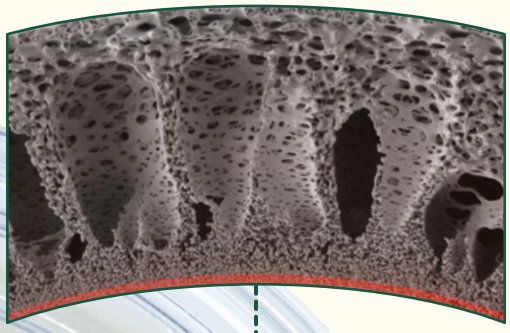
The clearance profile provided by **HDx** therapy enabled by **MCO THERANOVA** dialyser is made possible using regular HD workflow and infrastructure[6] thanks to the combination of 4 principles in a single dialyser device design.

The membrane structure is asymmetric and can be seen in cross section as **three distinct layers**[43]

A finger-like macro-porous outer layer

A sponge-like intermediate layer

A very thin inner layer (skin)



1 HIGH PERMEABILITY TO LARGE-MIDDLE MOLECULES

Membrane with increased nominal pore size that provides significantly higher permeability for large-middle molecules when compared to high-flux membranes used for conventional HD and HDF.[1,2,38]

2 EFFECTIVE SELECTIVITY BY SIZE EXCLUSION

A unique asymmetric 3-layer structure controls the distribution of pore sizes for a stable separation profile.[38]

3 AUGMENTED INTERNAL FILTRATION

A reduced inner diameter increases the convective transport along the membrane, within the same hollow fiber dialyser performing diffusion.[1,2,38]

4 RETENTION OF ENDOTOXINS

The adsorptive properties of the **MCO** membrane make it a safe and effective barrier against potential dialysis fluid contaminants despite the higher permeability.[2,38,42]

Internal filtration IF at 500mL/min Qd	THERANOVA 400 dialyser		THERANOVA 500 dialyser	
Blood flow (QB), mL/min	**300**	**400**	**300**	**400**
IF mL/min	**29.7**	**41.6**	**31.6**	**53.1**

Adapted after Lorenzin: Classification of haemodialyser clinical performance.[44]

HOW HDx THERAPY IS CHANGING DIALYSIS ONE STUDY AT A TIME

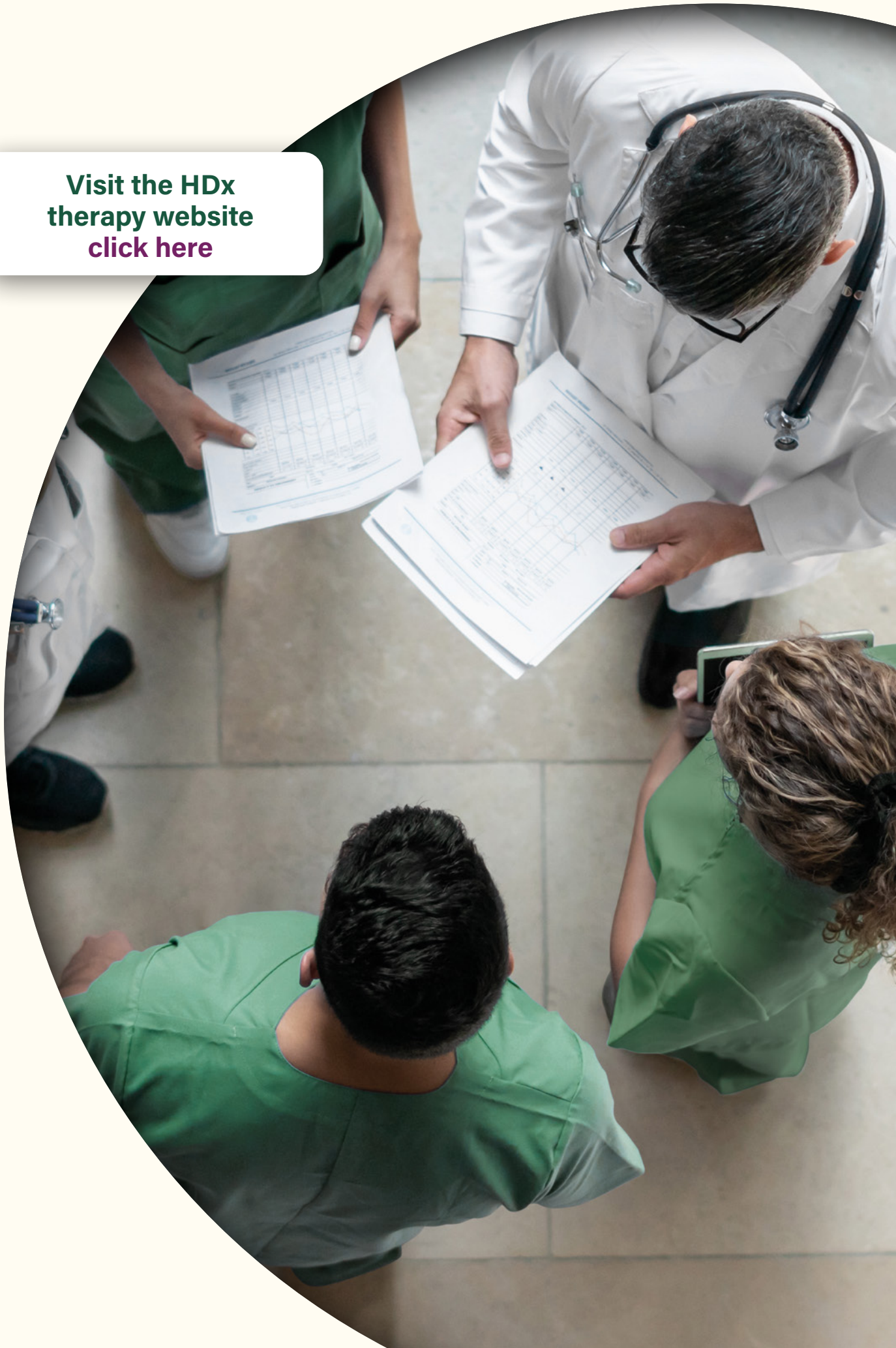
HDx therapy evidence on patient-reported, clinical and economic outcomes continues to grow.[46]

If you want to visit the Compendium of Studies click here

HDx
THERAPY

A WORLD OF DIFFERENCE

Visit the HDx therapy website click here



THERANOVA dialysers are indicated for treatment of chronic and acute renal failure by Haemodialysis.
Do not use in haemodiafiltration or haemofiltration mode or isolated Ultrafiltration
Medical devices of class IIb – Notified body: BSI, NL (CE 2797) – Legal manufacturer: Gambro Dialysatoren GmbH – Hechingen, Germany.[1]
For single use only. For safe and proper use of these devices refer to the Instructions for Use.

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