Baxter
Theranova
DIALYZER

CHANGE ONE THING CHANGE EVERYTHING

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

Specifications and Comparison Guide

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.

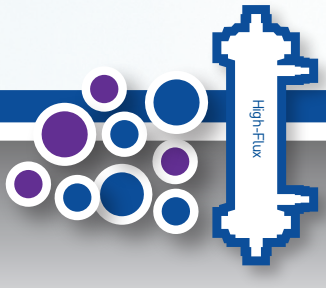
Rx Only. For safe and proper use of this device refer to the Instructions for Use.

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

Theranova, the next evolution in hemodialysis brings us a step closer to the natural kidney by **expanding clearance** of conventional/large middle molecules (500 – 45,000 Da)* compared to traditional high-flux membranes.[1-5]

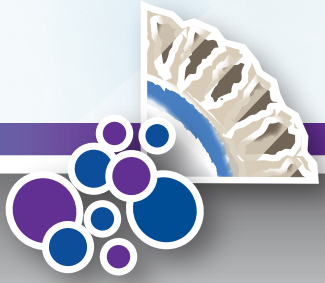
Conventional/large middle molecular (500-45,000 Da) uremic toxins have been linked to the development of inflammation, cardiovascular disease (CVD) and other dialysis related comorbidities[4,6,9]

CVD is associated with inflammation, atherosclerosis and calcification.
~ **50%** of patients with kidney failure (KF) die from CVD[10-12]



Traditional high-flux membranes have limited capability to remove conventional and large middle molecular uremic toxins (up to 45,000 Da)[13]

CHANGE ONE THING.



The unique design of the Theranova membrane delivers superior removal of conventional/ large middle molecules (up to 45,000 Da),[2-5] compared to high-flux membranes, while selectively retaining essential proteins and maintaining stable albumin levels[2,7,8]

HDx therapy showed a significant reduction in hospital days and in-center medication usage, in a retrospective analysis (n=81)[15]. A Randomized Control Trial (n=171) showed a significant reduction of 45% in all-cause hospitalizations[19]. Improvement in certain inflammatory markers were observed in select patients (n=41)[16].

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.[1,2,5,14,17]

CHANGE EVERYTHING.

SIMPLY CHANGE THE DIALYZER MEMBRANE AND EXPAND CLEARANCE FOR HD PATIENTS.[5]

*Conventional middle molecules, 500 Da – <25,000 Da, such as κ-Free Light Chains, large middle molecules 25,000 Da – 45,000 Da such as λ-Free Light Chains[1].

THERANOVA 400

PRODUCT CODE 955691

CLEARANCE/REDUCTION RATIOS

Theranova 400 Dialyzer Clearance (± 10 %, Cytochrome C ± 20 %, Myoglobin ± 30 %)																
UF=0 mL/min	Q_D = 300 mL/min					Q_D = 500 mL/min					Q_D = 800 mL/min					
Q_B (mL/min)	**200**	**300**	**400**	**500**	**600**	**200**	**300**	**400**	**500**	**600**	**200**	**300**	**400**	**500**	**600**	
Urea (60 Da)	191	246	272	285	291	198	282	344	388	418	199	293	376	445	502	
Phosphate (95 Da)	179	225	250	266	276	192	261	311	348	376	196	279	345	400	446	
Creatinine (113 Da)	184	232	258	273	282	194	269	323	362	391	198	285	357	416	465	
Vitamin B_{12} (1.4 kDa)	148	178	199	214	226	164	207	239	264	285	174	227	267	301	329	
Inulin (5.2 kDa)	119	140	156	169	180	133	161	183	200	216	144	178	204	225	245	
Cytochrome C (12 kDa)	109	128	142	153	164	122	146	165	180	194	133	161	183	202	219	
Myoglobin (17 kDa)	93	108	119	129	138	104	123	137	150	161	114	135	152	166	180	

	Mean Reduction Ratio (%)[2]		Mean Overall Clearance (mL/min)[2]	
	300/500	400/600	300/500	400/600
β2-microglobulin [β2m] (12 kDa)	71.5	78.5	67.9	84.7
Myoglobin (17 kDa)	63.1	67.9	52.0	58.7
Kappa free light chains [κ-FLC] (23 kDa)	66.3	72.9	26.2	35.0
Complement Factor D [CFD] (24 kDa)	56.9	63.0	26.5	26.3
α1-microglobulin [α1m] (33 kDa)	21.7	24.8	3.8	3.3
Chitinase-3-like protein 1 [YKL-40] (40 kDa)	60.5	63.6	Only Reduction Ratio available	
Lambda free light chains [λ-FLC] (45 kDa)	42.5	48.1	8.5	10.0

	Albumin Removal (g/treatment)[2]	
Q_B/Q_D (mL/min)	300/500	400/600
Median (range)	2.9 (1.5-3.9)	3.2 (1.9-3.9)

Theranova 400 Randomized Controlled Trial (RCT)[18]

Mean ± STD Reduction Ratio (%)	Theranova 400	ELISIO-17H
Lambda free light chains [λ-FLC] (45 kDa)	33.3±11.0* (p<0.001)	17.2±12.9
Complement Factor D [CFD] (24 kDa)	45.0±10.4* (p<0.001)	23.6±12.1
Kappa free light chains [κ-FLC] (23 kDa)	63.8±11.8* (p<0.001)	50.0±13.2
β2-microglobulin [β2m] (12 kDa)[18]	73.6±10.4* (p<0.001)	65.4±9.4

Open Label, Randomized Controlled Trial evaluating safety and efficacy; 21 US clinics; N=171; 86-Theranova 400; 85-Elisio-17H; 24 week study

*Statistical signficance (< 0.001).

	Theranova (N=86)	High-Flux HD (N=85)	p value
Hospitalization Events	18	31	--
Total Patient-Years	32.4	30.5	--
Hospitalization Rate (per PY)	0.56	1.02	0.0495
Hospital Length of Stay (days)	4.11	4.63	0.4060

A post-hoc analysis of this RCT showed a significant reduction of 45% (p<0.049) in all-cause hospitalizations.[19]

Pre-dialysis serum albumin levels (g/dL)[18]

Group	Baseline	Week 4	Chg vs Baseline Week 4	Week 8	Change vs Baseline Wk 8	Week 24
Control	4.0±0.3	4.0±0.2	0.0±0.2	4.0±0.3	0.0±0.2	4.1±0.4
Theranova	4.0±0.3	4.0±0.3	-0.1±0.2	3.9±0.3	-0.1±0.3	4.0±0.3

- Although small, a statistically-significant reduction in serum albumin noted at Weeks 4 and 8.
- The observed changes at 4 and 8 weeks were well below 5% and the mean levels were still below normal laboratory ranges.
- Changes from baseline were not statistically significant between the two study groups at Week 12 and thereafter.
- The primary safety endpoint of this study was the pre-dialysis serum level of albumin after 24 weeks of treatment.
- The analysis of the endpoint confirmed that Theranova 400 is non-inferior to Elisio-17H in maintaining pre-dialysis serum albumin after 24 weeks of treatment based on a 5% non-inferiority margin (-0.1765 g/dL).

THERANOVA 400

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CHARACTERISTICS/COMPARISON GUIDE*

Characteristics

Theranova 400 Membrane Characteristics			
Surface area (m^2)	1.7	Maximum TMP (mmHg)	600
UF Coefficient in Vitro (mL/h.mmHg)	48	Storage conditions	<30 °C / 86 °F
Residual blood volume (mL)	<1	Blood flow rate Q_B (mL/min)	200 – 600
Priming volume (mL)	≥300	Dialysate flow rate Q_D (mL/min)	300 – 800

Comparison Guide

	Baxter		Fresenius	Asahi KASEI		Nipro		BBraun
(mL/min)	**Theranova 400**	**REVACLEAR 400**	**Optiflux F200NR**	**REXEED-18A**	**REXEED-21A**	**ELISIO-19H**	**ELISIO-21H**	**Diacap Pro 19H**
Urea (60 Da)	344	338	330	330	340	343	346	332
Creatinine (113 Da)	311	315	289	309	317	309	319	305
Phosphate (95 Da)	323	297	290	289	299	296	304	278
Vitamin B12 (1.4 kDa)	239	213	189	197	212	215	219	202
UF Coefficient	48	54	62	71	74	76	82	97
Surface Area (m^2)	1.7	1.8	2.0	1.8	2.1	1.9	2.1	1.9
Membrane	PAES/PVP	PAES/PVP	Polysulfone	Polysulfone	Polysulfone	Polynephron	Polynephron	Polysulfone
Sterilization Method	Steam	Steam	Electron Beam	Gamma-Ray	Gamma-Ray	Dry Gamma	Dry Gamma	Gamma

NOTE: Clearances in Vitro; Q_B=400 mL/min; Q_D=500 mL/min.
Comparison criteria is based on stated clearance values (Vitamin B12, Phosphate, Creatinine, Urea - in order, Q_B=400 mL/min).
This table may not be all-inclusive.

*Recommended cross-reference based on data from manufacturers' published specification sheets.

FOR MORE INFORMATION, CONTACT YOUR BAXTER REPRESENTATIVE, OR VISIT: HTTPS://HEMODIALYSIS.BAXTER.COM/HDx

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