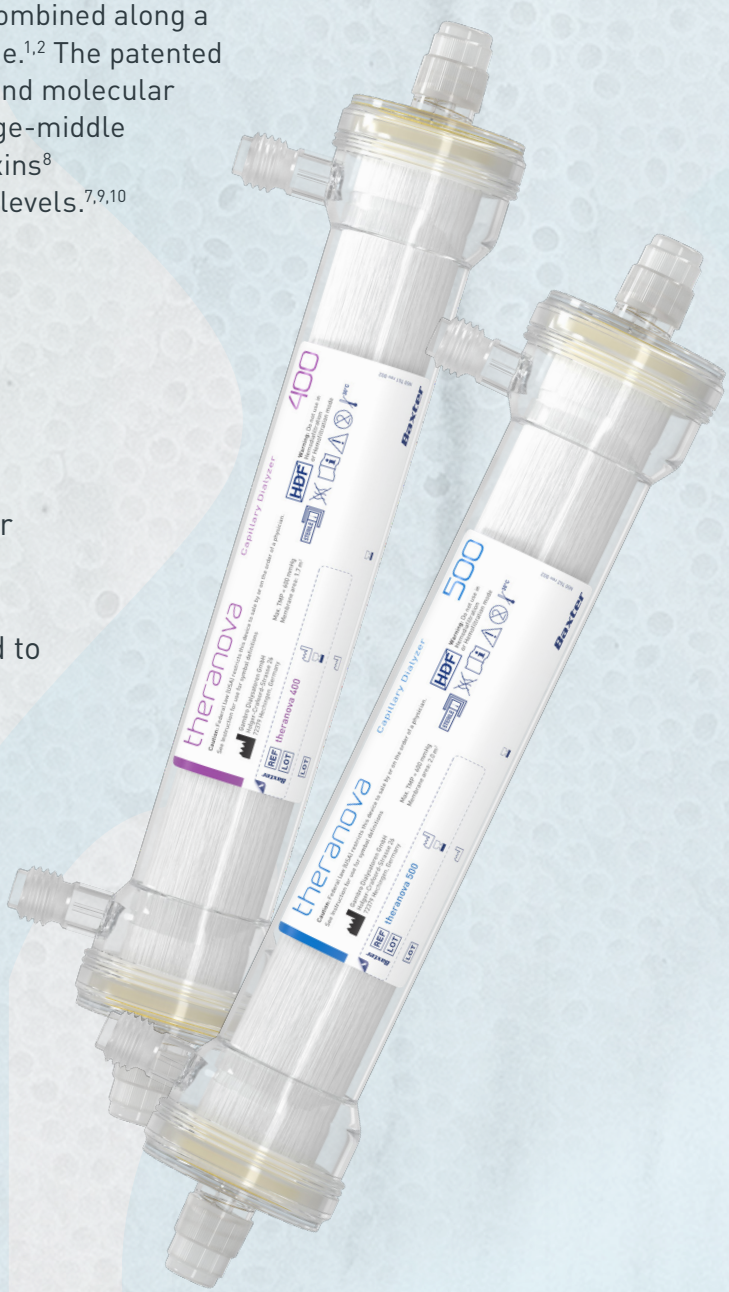
Baxter
Theranova
DIALYZER

BAXTER KIDNEY CARE
PD | HD | HDx | EDUCATION | SUPPORT

THERANOVA 400/500 DIALYZER

HDx THERAPY ENABLED BY THE THERANOVA DIALYZER BRINGS US 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.[1,2] 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)[3-7], while selectively retaining endotoxins[8] and essential proteins and maintaining stable serum albumin levels.[7,9,10]



RETAIN HD SIMPLICITY

- Compatible with existing HD workflows[7]
- Compatible with any HD machine[7]

PROVIDE HDx THERAPY

- Greater clearances and intradialytic reduction ratios for middle molecules, at ordinary blood flow rates, than high-flux HD[4]
- Superior removal of large-middle molecules compared to high-flux HD[3-7]

COMPARED TO HIGH FLUX HD, CHOOSING HDx THERAPY ENABLED BY THE THERANOVA DIALYZER MAY

REDUCE HOSPITALIZATIONS

Up to 45% reduction in all-cause hospitalizations[11]

Randomized controlled trial of US hemodialysis patients

REDUCE 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[12-15]

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

REDUCE COST OF CARE

Up to $4,772 lower cost per-patient, with savings demonstrated in 96% of the 10,000 simulations[11]

Randomized controlled trial of US hemodialysis patients

IMPROVE PATIENT-REPORTED OUTCOMES

RECOVERY TIME

Up to 2.5 hours reduction in patient-reported recovery time[16]

Single center, retrospective analysis

RESTLESS LEGS

Up to 55% reduction in patients meeting diagnostic criteria for Restless Leg Syndrome[17]

Prospective, multicenter, observational study

PRURITUS

Reduction in Patient-Reported Pruritis[18]

Randomized, prospective, controlled, open-label study

THERANOVA SPECIFICATIONS[7]

MATERIALS	THERANOVA 400	THERANOVA 500
Membrane	Medium Cut-Off Polyarylethersulfone (PAES) / Polyvinylpyrrolidone (PVP) blend BPA-free	
Potting	Polyurethane (PUR)	
Housing	Polycarbonate (PC)	
Gaskets	Silicone rubber (SIR)	
Protection caps	Polypropylene (PP)	
Sterilization	Steam	
Sterile barrier	Tyvek	

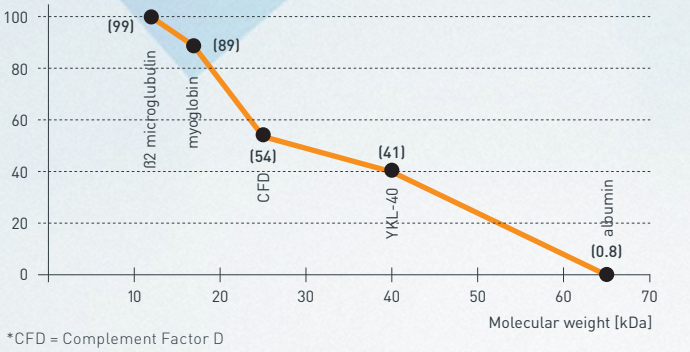
SPECIFICATIONS		
UF-Coefficient (mL/(h-mmHg))*	48	59
KoA urea*	1482	1630
Blood Compartment volume (mL)	91	105
Minimum recommended blood compartment volume (mL)	300	
Maximum TMP (mmHg)	600	
Q_B (mL/min)	200-600	
Dialysate flow rate (mL/min)	300-800	
Storage conditions	≤ 30 °C / 86 °F	
Units per box	24	
Gross/net weight (g)	229/170	246/190

MEMBRANE		
Membrane Area (m²)	1.7	2.0
Fiber inner diameter (µm)	180	
Fiber wall thickness (µm)	35	
Sieving profile – before blood exposure[5]		
MWCO (cut-off) [kDa]	56 ± 3	
MWRO (retention onset) [kDa]	9.4 ± 0.2	

ORDERING		
Product Code	955691	955692

* According to ISO 8637-1:
– UF-Coefficient: measured with bovine blood, Hct 32%, Pct 60g/L, 37°C
– KoA urea: calculated at Q_B=300 mL/min, Q_D=500mL/min, UF=0 mL/min
– Sieving coefficients: measured with human plasma, Q_B=300 mL/min, UF=60 mL/min

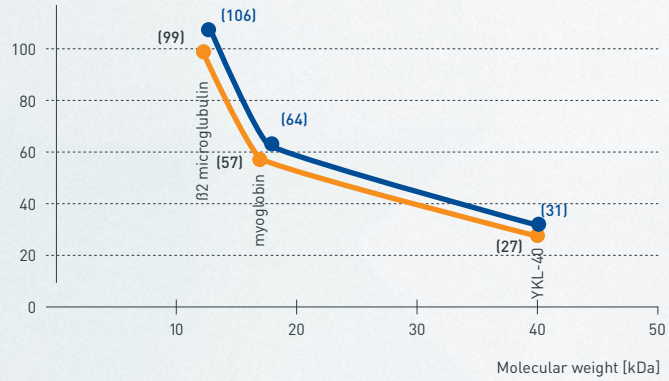
SIEVING COEFFICIENT [%][20]



*CFD = Complement Factor D
YKL-40 = Chitinase-3-Like Protein 1

CLEARANCES IN VITRO

CLEARANCE IN PLASMA [mL/min]*[19]



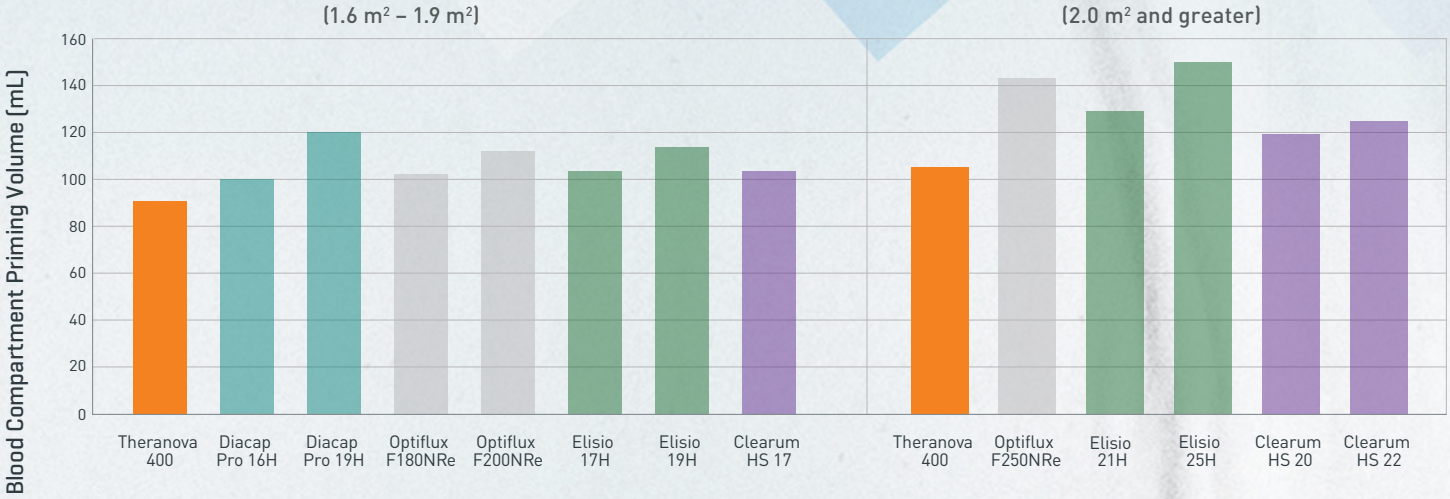
*In Vitro **Theranova 400** and **Theranova 500** analysis performed at:
Q_B = 300 mL/min, Q_D = 500 mL/min, UF =10mL/min

CLEARANCES IN AQUEOUS SOLUTION [mL/min]*

		Q_D = 300 mL/min					Q_D = 500 mL/min					Q_D = 800 mL/min				
UF = 0 mL/min	**Q_B (mL/min)**	**200**	**300**	**400**	**500**	**600**	**200**	**300**	**400**	**500**	**600**	**200**	**300**	**400**	**500**	**600**
Urea (60 Da)	Theranova 400	191	246	272	285	291	198	282	344	388	418	199	293	376	445	502
	Theranova 500	192	250	276	288	294	199	285	351	397	428	200	295	381	454	515
Phosphate (95 Da)	Theranova 400	179	225	250	266	276	192	261	311	348	376	196	279	345	400	446
	Theranova 500	182	230	256	271	281	194	267	320	358	388	197	283	354	413	462
Creatinine (113 Da)	Theranova 400	184	232	258	273	282	194	269	323	362	391	198	285	357	416	465
	Theranova 500	186	237	263	278	286	196	274	331	372	402	199	288	365	428	481
Vitamin B12 (1.4 kDa)	Theranova 400	148	178	199	214	226	164	207	239	264	285	174	227	267	301	329
	Theranova 500	152	185	206	222	235	169	215	249	277	299	178	236	280	317	348
Inulin (5.2 kDa)	Theranova 400	119	140	156	169	180	133	161	183	200	216	144	178	204	225	245
	Theranova 500	124	147	164	178	189	139	170	193	213	230	150	188	216	241	262
Cytochrome C (12 kDa)	Theranova 400	109	128	142	153	164	122	146	165	180	194	133	161	183	202	219
	Theranova 500	114	134	150	162	173	128	155	175	192	208	139	171	196	217	236
Myoglobin (17 kDa)	Theranova 400	93	108	119	129	138	104	123	137	150	161	114	135	152	166	180
	Theranova 500	98	114	127	138	148	110	130	147	161	173	120	144	163	180	195

*±10 %, Cytochrome C ±20 %, Myoglobin ±30 %

SEE HOW THERANOVA DIALYZERS WITH MCO MEMBRANE HAVE SMALLER BLOOD COMPARTMENT VOLUMES THAN SIMILAR SIZED DIALYZERS WITH HIGH-FLUX MEMBRANES.

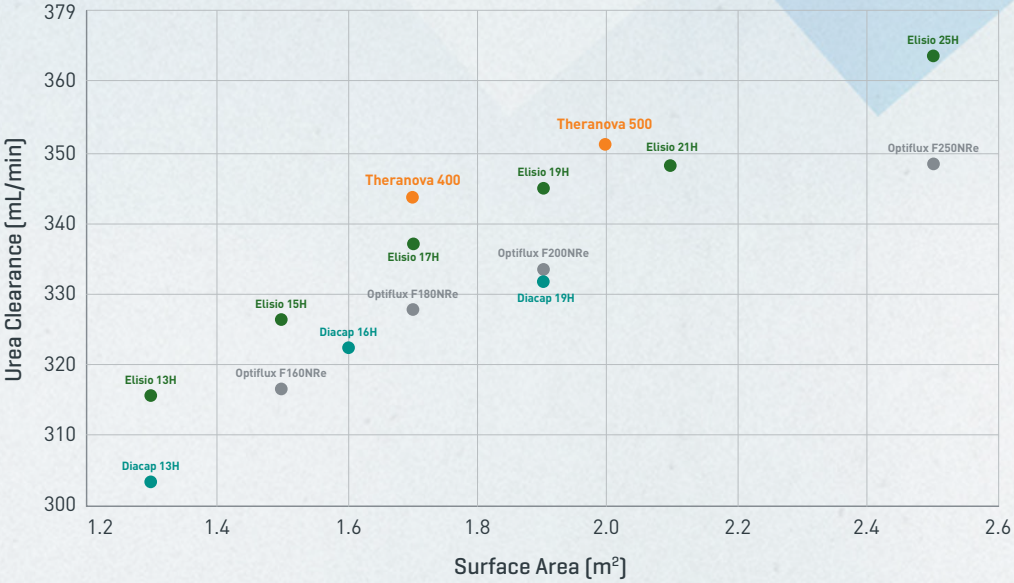


CROSS REFERENCE: SPECIFICATIONS*

	Manufacturer	Dialyzer (2.0 m² and greater)	Surface Area (m²)	Blood Compartment Priming Volume (mL)	Ultrafiltration Coefficient (mL/(h*mmHg))	Membrane	Sterilization Method
Surface area (1.6 m2 – 1.9 m2)	**Baxter**	**THERANOVA 400**	**1.7**	**91**	**48**	**Polyarylethersulfone / Polyvinylpyrrolidone**	**Steam**
	Fresenius Medical Care	**Optiflux F180NRe**	1.7	102	76	Polysulfone	Electron Beam
		Optiflux F180NR	1.7	105	58	Polysulfone	EtO
		Optiflux F200NRe	1.9	113	74	Polysulfone	Electron Beam
	Nipro	**ELISIO-17H**	1.7	105	74	Polyethersulfone	Dry Gamma
		ELISIO-19H	1.9	115	76	Polyethersulfone	Dry Gamma
	B. Braun	**Diacap Pro 16H**	1.6	100	85	Polysulfone	Oxygen-free Gamma
		Diacap Pro 19H	1.9	120	97	Polysulfone	Oxygen-free Gamma
	Medtronic	**Clearum HS 17**	1.7	105	55	Polyethersulfone / Polyvinylpyrrolidone	Moist heat with saturated steam
Surface Area (2.0 m2 and greater)	**Baxter**	**THERANOVA 500**	**2.0**	**105**	**59**	**Polyarylethersulfone / Polyvinylpyrrolidone**	**Steam**
	Fresenius Medical Care	**Optiflux F250NRe**	2.5	142	111	Polysulfone	Electron Beam
	Nipro	**ELISIO-21H**	2.1	130	82	Polyethersulfone	Dry Gamma
		ELISIO-25H	2.5	149	93	Polyethersulfone	Dry Gamma
	Medtronic	**Clearum HS 20**	2.0	120	64	Polyethersulfone / Polyvinylpyrrolidone	Moist heat with saturated steam
		Clearum HS 22	2.2	126	70	Polyethersulfone / Polyvinylpyrrolidone	Moist heat with saturated steam

*Competitor's specifications are subject to change without notice. Competitor specification content is extracted from promotional materials. Always refer to manufacturers' Instructions For Use for further information and operating instructions.

IN ALL BUT ONE COMPARISON, THE THERANOVA DIALYZER SHOWS GREATER UREA CLEARANCE WITH A SIMILAR OR SMALLER SURFACE AREA.



CROSS REFERENCE: SMALL MOLECULE IN-VITRO CLEARANCE SPECIFICATIONS*

(QB=400 mL/min; QD=500 mL/min)

	Manufacturer	Dialyzer	Surface Area (m^2)	Urea (mL/min)	Creatinine (mL/min)	Phosphate (mL/min)	Vitamin B12 (mL/min)
Surface Area (1.6 m2 – 1.9 m2)	Baxter	THERANOVA 400**	1.7	344	323	311	239
	Fresenius Medical Care	Optiflux F180NRe	1.7	328	290	297	181
		Optiflux F180NR	1.7	323	285	289	178
		Optiflux F200NRe	1.9	333	298	298	189
	Nipro	ELISIO-17H	1.7	337	306	292	211
		ELISIO-19H	1.9	345	314	305	222
	B. Braun	Diacap Pro 16H	1.6	322	284	261	183
		Diacap Pro 19H	1.9	332	305	278	202
	Medtronic	Clearum HS 17	Not Listed				
Surface Area (2.0 m^2 and greater)	Baxter	THERANOVA 500**	2.0	351	331	320	249
	Fresenius Medical Care	Optiflux F250NRe	2.5	349	321	328	226
	Nipro	ELISIO-21H	2.1	348	326	314	228
		ELISIO-25H	2.5	363	342	329	247
	Medtronic	Clearum HS 20	Not Listed				
		Clearum HS 22	Not Listed				

*Competitor's specifications are subject to change without notice. Competitor specification content is extracted from promotional materials. Always refer to manufacturers' Instructions For Use for further information and operating instructions.

**+/- 10% clearance

CROSS REFERENCE: MIDDLE AND LARGE-MIDDLE MOLECULE CLEARANCE SPECIFICATIONS

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

The **Theranova** dialyzer with **MCO** membrane provides increased removal of various conventional middle molecules (500 Da to <25 kDa) and large-middle molecules (25 kDa to 45 kDa) compared to high-flux membranes.

Mean Overall Clearance (mL/min)

Manufacturer		Dialyzer	Surface Area (m^2)	Blood Compartment Volume	β2-microglobulin [β2m] (12 kDa)	Myoglobin (17 kDa)	Kappa free light chains [κ-FLC] (23 kDa)	Complement Factor D [CFD] (24 kDa)	α1-microglobulin [α1m] (33 kDa)	Chitinase-3-like protein 1 [YKL-40] (40 kDa)	Lambda free light chains [λ-FLC] (45 kDa)
Surface Area (1.6m^2 - 1.9m^2) Q_B=300/Q_D=500	**Baxter**	**THERANOVA 400***	**1.7**	**91**	**67.9**	**52**	**26.2**	**26.5**	**3.8**	**Only RR available**	**8.5**
	Fresenius Medical Care	**Optiflux F180NRe**	1.7	105	NOT LISTED						
		Optiflux F180NR	1.7	102	NOT LISTED						
		Optiflux F200NRe	1.9	113	NOT LISTED						
	Nipro	**ELISIO-17H**	1.7	105	NOT LISTED						
		ELISIO-19H	1.9	115	NOT LISTED						
	B. Braun	**Diacap Pro 16H**	1.6	100	NOT LISTED						
		Diacap Pro 19H	1.9	120	NOT LISTED						
	Medtronic	**Clearum HS 17**	1.7	105	NOT LISTED						

Manufacturer		Dialyzer	Surface Area (m^2)	Blood Compartment Volume	β2-microglobulin [β2m] (12 kDa)	Myoglobin (17 kDa)	Kappa free light chains [κ-FLC] (23 kDa)	Complement Factor D [CFD] (24 kDa)	α1-microglobulin [α1m] (33 kDa)	Chitinase-3-like protein 1 [YKL-40] (40 kDa)	Lambda free light chains [λ-FLC] (45 kDa)
Surface Area (1.6m^2 - 1.9m^2) Q_B=400/Q_D=600	**Baxter**	**THERANOVA 400***	**1.7**	**91**	**84.7**	**58.7**	**35**	**26.3**	**3.3**	**Only RR available**	**10**
	Fresenius Medical Care	**Optiflux F180NRe**	1.7	105	NOT LISTED						
		Optiflux F180NR	1.7	102	NOT LISTED						
		Optiflux F200NRe	1.9	113	NOT LISTED						
	Nipro	**ELISIO-17H**	1.7	105	NOT LISTED						
		ELISIO-19H	1.9	115	NOT LISTED						
	B. Braun	**Diacap Pro 16H**	1.6	100	NOT LISTED						
		Diacap Pro 19H	1.9	120	NOT LISTED						
	Medtronic	**Clearum HS 17**	1.7	105	NOT LISTED						

*Two prospective, open-label, controlled, randomized crossover pilot studies of HD patients (n=39)
(Kirsch et al. Nephrol Dial Transplant (2017) 32: 165–172)

Mean Reduction Ratio (%)

Manufacturer		Dialyzer	Surface Area (m^2)	Blood Compartment Volume	β2-microglobulin [β2m] (12 kDa)	Myoglobin (17 kDa)	Kappa free light chains [κ-FLC] (23 kDa)	Complement Factor D [CFD] (24 kDa)	α1-microglobulin [α1m] (33 kDa)	Chitinase-3-like protein 1 [YKL-40] (40 kDa)	Lambda free light chains [λ-FLC] (45 kDa)
Surface Area (1.6m^2 - 1.9m^2) Q_B=300/Q_D=500	**Baxter**	**THERANOVA 400***	**1.7**	**91**	**71.5**	**63.1**	**66.3**	**56.9**	**21.7**	**60.5**	**42.5**
	Fresenius Medical Care	**Optiflux F180NRe**	1.7	105	NOT LISTED						
		Optiflux F180NR	1.7	102	NOT LISTED						
		Optiflux F200NRe	1.9	113	NOT LISTED						
	Nipro	**ELISIO-17H**	1.7	105	NOT LISTED						
		ELISIO-19H	1.9	115	NOT LISTED						
	B. Braun	**Diacap Pro 16H**	1.6	100	NOT LISTED						
		Diacap Pro 19H	1.9	120	NOT LISTED						
	Medtronic	**Clearum HS 17**	1.7	105	NOT LISTED						

Manufacturer		Dialyzer	Surface Area (m^2)	Blood Compartment Volume	β2-microglobulin [β2m] (12 kDa)	Myoglobin (17 kDa)	Kappa free light chains [κ-FLC] (23 kDa)	Complement Factor D [CFD] (24 kDa)	α1-microglobulin [α1m] (33 kDa)	Chitinase-3-like protein 1 [YKL-40] (40 kDa)	Lambda free light chains [λ-FLC] (45 kDa)
Surface Area (1.6m^2 - 1.9m^2) Q_B=400/Q_D=600	**Baxter**	**THERANOVA 400***	**1.7**	**91**	**78.5**	**67.9**	**72.9**	**63**	**24.8**	**63.6**	**48.1**
	Fresenius Medical Care	**Optiflux F180NRe**	1.7	105	NOT LISTED						
		Optiflux F180NR	1.7	102	NOT LISTED						
		Optiflux F200NRe	1.9	113	NOT LISTED						
	Nipro	**ELISIO-17H**	1.7	105	NOT LISTED						
		ELISIO-19H	1.9	115	NOT LISTED						
	B. Braun	**Diacap Pro 16H**	1.6	100	NOT LISTED						
		Diacap Pro 19H	1.9	120	NOT LISTED						
	Medtronic	**Clearum HS 17**	1.7	105	NOT LISTED						

*Two prospective, open-label, controlled, randomized crossover pilot studies of HD patients (n=39)
(Kirsch et al. Nephrol Dial Transplant (2017) 32: 165–172)

Theranova 400 Randomized Controlled Trial (RCT)[9]

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	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.[11]

Pre-dialysis serum albumin levels (g/dL)[9]

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	4.0±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 within 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).

GO BEYOND UREA

TRY HDx THERAPY ENABLE BY THERANOVA DIALZYERS TODAY

Contact your local **Baxter sales representative** at 1-888-7362543 and visit renalcareus.baxter.com/hdx for more information.

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 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 the safe and proper use of this device, refer to the Instructions for Use.

1. 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. 2. Ronco C. The Rise of Expanded Hemodialysis. Blood Purif. 2017;44(2):I-VIII. 3. Hutchison CA, Wolley M. The Rationale for Expanded Hemodialysis Therapy (HDx). Contrib Nephrol. 2017;191:142 -152. Doi:10.1159/000479262. 4. Kirsch AH, et al. Performance of hemodialysis with novel medium cut-off dialyzers. Nephrol Dial Transpl. 2017; 32(1):165-72. 5. 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. 6. Rosner MH, et al. Classification of Uremic Toxins and Their Role in Kidney Failure. Clin J Am Soc Nephrol. 2021;16(12):1918-1928. 7. Theranova Instructions for Use, 2021. 8. Schepers E, Glorieux G, Eloot S, Hulko M, Boschetti-de-Fierro A, Beck W, Krause, B, Van Biesen W. Assessment of the Association Between Increasing Membrane Pore Size and Endotoxin Permeability Using a Novel Experimental Dialysis Simulation Set-Up. BMC Nephrol. 2018; 19:1 9. Weiner DE, et al. Efficacy and safety of expanded hemodialysis with the Theranova 400 dialyzer: a randomized controlled trial. Clin J Am Soc Nephrol. 2020;15:1310-1319. 10. Molano-Trivino A, et al. Effectiveness of medium cut-off vs high flux dialyzers: a propensity score matching cohort study. In Nephrol Dial Transport. 2021;36:486-U948; i486-i487. 11. Blackowicz MJ, Falzon L, Beck W, Tran H, Weiner DE. Economic evaluation of expanded hemodialysis with the Theranova 400 dialyzer: A post hoc evaluation of a randomized clinical trial in the United States. Hemodial Int. 2022 Jul;26(3):449-455. doi: 10.1111/hdi.13015. Epub 2022 Apr 19. PMID: 35441486; PMCID: PMC9544662. 12. Sanabria RM, Hutchison CA, Vesga, JI, Ariza JG, Sanchez R, Suarez AM. Expanded Hemodialysis and Its Effects on Hospitalizations and Medication Usage: A Cohort Study. Nephron. 2021;145(2):179-187. 13. Lim JH, Jeon Y, Yook JM, et al. Medium cut-off dialyzer improves erythropoiesis stimulating agent resistance in a hepcidin-independent manner in maintenance hemodialysis patients: results from a randomized controlled trial. Sci Rep. 2020;10(1):1-10. 14. Ariza JG, Walton SM, Suarez AM, Sanabria M, Vesga JI. An initial evaluation of expanded hemodialysis on hospitalizations, drug utilization, costs, and patient utility in Colombia. Ther Apher Dial. 2021;25(5):621-627. 15. Hadad-Arrascue F, Nilsson LG, Rivera AS, Bernardo AA, Cabezuelo Romero JB. Expanded hemodialysis as effective alternative to on-line hemodiafiltration: A randomized mid-term clinical trial. Ther Apher Dial. 2022;26(1):37-44. 16. Bolton S, Gair R, Nilsson LG, Matthews M, Stewart L, McCullagh N. Clinical Assessment of Dialysis Recovery Time and Symptom Burden: Impact of Switching Hemodialysis Therapy Mode. Patient Relat Outcome Meas. 2021;12:315-321. 17. Alarcon J.C, Bunch A, Ardila F, et al. Impact of Medium Cut-Off Dialyzers on Patient-Reported Outcomes: COREXH Registry. Blood Purif. 2021;50:110-118. 18. 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. Sci Rep. 2020;10(1):1-11. 19. Baxter Data on File. Theranova Performance Evaluation: Clearance (Human Plasma). 2022. 20. Baxter Data on File. Theranova Performance Evaluation: Sieving coefficients: measured with human plasma. 2021.

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