Theralite

DESIGNED FOR:
HCO-HD (High Cut Off)

MEMBRANE:
HCO (PAES/PVP, BPA-free)

The **Theralite** dialyser is only intended to be used for blood purification in haemodialysis mode in diseases where removal of plasma components with molecular weights up to 45 kDa is indicated.

SPECIALISED FOR MULTIPLE MYELOMA PATIENTS

The **Theralite*** dialyser, featuring the proprietary High Cut-Off (HCO) membrane, targets the removal of free light chain (FLC) proteins. In patients with mutiple myeloma, these light chains can be overproduced and lead to acute renal failure.[1,2]

FOCUSED ON HIGHER PERMEABILITY

The **Theralite** dialyser is able to effectively remove large toxins including FLCs, which can help provide positive treatment outcomes for patients with Multiple Myeloma disease.[1,3-10]

> Features the unique HCO membrane, which is characterised by its large pore size[1,11]
> Providing still an effective retention of large proteins[7]

WITH BIOCOMPATIBILITY IN MIND

> The 3-layer-membrane structure has been designed to optimise the removal of large proteins, while acting as a safety barrier to endotoxins[12]
> The **Theralite** dialysers are steam sterilised inside-out** to promote biocompatibility, avoiding exposure to chemicals such as ethylene oxide and manufacturing residues[13,1]

* Do not use **Theralite** dialysers in HDF or HF mode
* **Theralite** dialysers must not be used for pediatric dialysis and for regular treatment of chronic renal failure
* CAUTION! **Theralite** dialysers must only be used on the direction of a physician who has evaluated all the pertinent features of this device in relation to the individual patient

The images are for illustration purposes only and may differ from the actual product.

THERALITE Specifications

MATERIALS	THERALITE
Membrane	High Cut Off Polyarylethersulfone and Polyvinylpyrrolidone blend BPA-free
Potting	Polyurethane (PUR)
Housing	Polycarbonate (PC)
Gaskets	Silicone rubber (SIR)
Protection caps	Polypropylene (PP)
Sterilisation	Steam
Sterile barrier	Medical Grade Paper

SPECIFICATIONS	
UF-Coefficient (mL/(h*mmHg))***	52
KoA urea (mL/min)***	1662
Blood Compartment volume (mL)	140
Minimum recommended priming volume (mL)	1000
Maximum TMP (mmHg)	300
Recommended Q_B (mL/min)	200-500
Sterilisation	Steam (inside-out)**
Storage conditions	≤30°C (or ≤86°F)
Units per box	1
Gross/net weight (g)	630/270

MEMBRANE	
Effective Membrane Area (m^2)	2.1
Fiber inner diameter (µm)	215
Fiber wall thickness (µm)	50

SIEVING COEFFICIENTS***	
Vitamin B12 (1,4 kDa)	1.0
Inulin (5,2 kDa)	1.0
β_2-microglobulin (11,8 kDa)	1.0
Myoglobin (17 kDa)	0.95
Albumin (66,4 kDa)	0.2

CLEARANCES IN VITRO (mL/min)***	THERALITE
Urea (60 Da) (Q_B/Q_D, mL/min)	
200/500	199
300/500	286
400/500	349
500/500	390
Creatinine (113 Da)	
200/500	196
300/500	273
400/500	326
500/500	361
Phosphate (142 Da)	
200/500	195
300/500	269
400/500	320
500/500	354
Vitamin B12 (1.4 kDa)	
200/500	175
300/500	221
400/500	252
500/500	274
Inulin (6.2 kDa)	
200/500	157
300/500	191
400/500	214
500/500	230
Myoglobin (17 kDa)	
200/500	126
300/500	146
400/500	160
500/500	170

ALBUMIN LOSS IN-VITRO***	
Average loss per hour of treatment (g/h)	≤7.0

*** According to ISO 8637-1
> UF-Coefficient: measured with bovine blood, Hct 32%, Pct 60g/L, at 37°C
> KoA urea: calculated at Q_B=300 mL/min, Q_D=500mL/min, UF=0 mL/min
> Sieving coefficients: measured with bovine plasma, Q_B=300 mL/min, UF=60 mL/min
> Clearances In-Vitro: measured at UF=0 mL/min, ±10%
> Albumin loss in-vitro (HD): measured with bovine plasma (Pct 60g/L, at 37°C – Albumin level 20–30 g/l.), Q_B=200ml/min, Q_D=500ml/min, UF=0ml/min
** At the end of the manufacturing process, the dialyser is sterilised with steam. Steam enters the closed sterile packaging, reaching the inside and outside of the device.

1. Boschetti-de-Fierro A, et al. *Extended characterization of a new class of membranes for blood purification: the high cut-off membranes.* Int J Artif Organs 2013; 36:455-463.
2. Hutchison CA, et al. *The pathogenesis and diagnosis of acute kidney injury in multiple myeloma.* Nat Rev Nephrol 2012; 8:43-51.
3. Hutchison CA, et al. *Efficient Removal of Immunoglobulin Free Light Chains by Haemodialysis for Multiple Myeloma: In Vitro and In Vivo Studies.* J Am Soc Nephrol 2007; 18:886-895.
4. Hutchison CA, et al. *Treatment of Acute Renal Failure Secondary to Multiple Myeloma with Chemotherapy and Extended High Cut-Off Haemodialysis.* Clin J Am Soc Nephrol 2009; 4:745-754.
5. Bachmann U, et al. *Combination of bortezomib-based chemotherapy and extracorporeal free light chain removal for treating cast nephropathy in multiple myeloma.* NDT plus 2008; 1:106-108.
6. Zannetti BA, et al. *Bortezomib-based therapy combined with high cut-off haemodialysis is highly effective in newly diagnosed multiple myeloma patients with severe renal impairment.* Am J Hematol 2015; 90:647-652.
7. Villa G, et al. *Cytokine removal with high cut-off membrane: review of literature.* Blood Purif 2014; 38:167-173.
8. Cantaluppi V, et al. *HCO Hemodialyzers Efficiently Removed Immunoglobulin Free Light Chains And Reduce Tubular Injury Induced By Plasma Of Patients With Multiple Myeloma.* Nephrol Dial Transplant 2013; 28:i415-i427.
9. Dahal K, et al. *Recovery of kidney function following delayed use of theralite™ dialyser in a patient with myeloma cast nephropathy.* Clin Nephrol 2013; 79:318-322.
10. Li Cavoli G, et al. *High cut-off dialyser haemodialysis in cast nephropathy.* Clin Kidney J 2012; 5: 80.
11. Wańkowicz Z. *The role of technological progress vs. accidental discoveries and clinical experience.* Med Sci Monit. 2013; 19:984-992.
12. Schepers E, et al. *Assessment of the association between increasing membrane pore size and endotoxin permeability using a novel experimental dialysis simulation set-up.* BMC Nephrology 2018; 19:1
13. Golli-Bennour EE, et al. *Cytotoxic effects exerted by polyarylsulfone dialyser membranes depend on different sterilization processes.* Int Urol Nephrol. 2011; 43:483-490.
14. D'Ambrosio FP, et al. *Ethylene oxide allergy in dialysis patients.* Nephrol Dial Transplant. 1997; 12:1461-1463.

The products meet the applicable provisions of Annex I (Essential Requirements) and Annex II (Full quality assurance system of the Council Directive 93/42/EEC of 14 June 1993, amended by Directive 2007/47/EC).
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For safe and proper use of the device, please refer to the Instructions for Use

CE 2797

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