HIGH CUT-OFF MEMBRANE

Baxter

Gambro theralite

SPECIALIZED DIALYZER FOR THE REMOVAL OF FREE LIGHT CHAIN (FLC) PROTEINS

The Gambro THERALITE dialyzer, featuring the proprietary High Cut-Off (HCO) membrane, was developed for the removal of free light chain (FLC) proteins, that are overproduced in patients with Multiple Myeloma and can cause renal failure.[1,2]

EFFECTIVE MEMBRANE DESIGN

- THERALITE dialyzer's HCO membrane is characterized by its large and uniform pore size[1,11]
- High permeability for substances in the molecular weight range of up to 45 kDa[3]
- Effective retention of larger proteins with molecular weights greater than 60 kDa, such as clotting factors[7]
- Manufactured to the same quality standards as the POLYFLUX and REVACLEAR dialzyers
- A key adjunctive treatment in Multiple Myeloma Kidney therapy[1,4,5,9,12]

TYPICAL PATIENT PROFILE: **PATIENTS THAT WOULD BENEFIT FROM FLC REMOVAL, SUCH AS MULTIPLE MYELOMA KIDNEY PATIENTS**

Gambro THERALITE Dialyzer

SPECIFICATIONS	THERALITE
Measured according to EN 1283/ISO 8637	
UF coef. In vitro [ml/(h*mmHg)]	52
Priming volume in vitro [ml]	140
Flow resistance [mmHg] / max. values Q_B = 200-500 ml/min, UF = 0 ml blood compartment	<190
Max. transmembrane pressure [mmHg]	300
Range of blood flow rates [ml/min]	200–500
Range of dialyzate flow rate [ml/min]	300–800
Residual blood volume [ml]	<5 ml
Fluid volumes needed for priming and rinsing [ml]	≥1000

Membrane

Effective membrane area [m²]	2.1
Wall thickness [µm]	50
Inner diameter [µm]:	215

Sterilization agent	Steam
Sterile barrier	Medical grade paper

Components

Membrane	PAES/PVP
Potting material	Polyurethane (PUR)
Housing and caps	Polycarbonate (PC)
O-rings	Silicone rubber (SIR)
Protective caps	Polypropylene (PP)

Dialysis fluid connectors and blood connectors are designed according to EN 1283/ISO 8637

CE 0086

PERFORMANCE	THERALITE			
Hemodialysis (HD) Q_D = 500 ml/min, UF = 0 ml/min Measured acc. to EN 1283 / ISO 8637, clearance in vitro [ml/min] ± 10%				
Q_B [ml/min]	**200**	**300**	**400**	**500**
Urea	199	286	349	390
Phosphate	195	269	320	354
Myoglobin	126	146	160	170

Sieving coefficient in vitro
Measured acc. to EN 1283 / ISO 8637 (± 20%); Bovine plasma, protein level 60g/l, 37°C

Vitamin B12	1.0
Inulin	1.0
Myoglobin	0.95
Albumin	0.2

1. Boschetti-de-Fierro A, *et al. Int J Artif Organs* 2013; 36:455–463.
2. Hutchison CA, *et al. Nat Rev Nephrol* 2012; 8:43–51.
3. Hutchison CA, *et al. J Am Soc Nephrol* 2007; 18:886–895.
4. Hutchison CA, *et al. Clin J Am Soc Nephrol* 2009; 4:745–754.
5. Bachmann U, *et al. NDT plus* 2008; 1:106–108.
6. Zannetti BA, *et al. Am J Hematol* 2015; 90:647–652.
7. Villa G, *et al. Blood Purif* 2014; 38:167–173.
8. Cantaluppi V, *et al. Nephrol Dial Transplant* 2013; 28:i415–i427.
9. Dahal K, *et al. Clin Nephrol* 2013; 79:318–322.
10. Li Cavoli G, *et al. Clin Kidney J* 2012; 5: 80.
11. Wańkowicz Z. *Med Sci Monit.* 2013; 19:984–992.
12. Hutchinson, C; *et al. Neprol Dial Transplant* 2013; 27:3823-3828.

For the safe and proper use of the Theralite (High-Cut Off Dialyzer) refer to contraindications, warnings and precautions, adverse events and the complete directions for use.

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