Theralite™

High Cut-off technology

A new technology for efficient and direct removal of free light chain (FLC) proteins*

Theralite™ utilizes a unique membrane technology with the ability to target serum free light chains and other plasma components with a molecular weight up to 45 kDa.

The elimination properties of synthetic membranes are primarily determined by pore size and structure. Theralite™ High Cut-off technology is characterized by its large pore size. The Theralite High Cut-off membrane was developed to achieve high permeability for substances in the molecular weight range of 15–45 kDa.

With Theralite technology, the membrane's structure and pore-size distribution also ensure effective retention of larger proteins with molecular weights greater than 60 kDa such as clotting factors and immunoglobulins.

Theralite technology is a key component in Myeloma Kidney Therapy. For more information please visit www.gambro.com/myeloma-kidney-therapy

*Hutchinson, C. A., et al, *Efficient removal of immunoglobulin free light chains by hemodialysis for multiple myeloma: in vitro and in vivo studies.* J Am Soc Nephrol, 2007 Mar, 18(3):886-95.

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Specifications	
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

Performance				
Hemodialysis (HD) QD = 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
Serum free light chains, clearance in vitro (± 20%) Q_B = 250 ml/min, QD = 500 ml/min, UF = 0 ml/min Bovine plasma, protein level 60 g/l, 37°C Plasma level: human κ = 500 mg/l, human λ = 250 mg/l				
Clearance κ-FLC [ml/min]				38
Clearance λ-FLC [ml/min]				33
Albumin loss (HD) in vitro Q_B = 200 ml/min, QD = 500 ml/min, UF = 0 ml/min Bovine plasma, protein level 60 g/l, 37°C, Albumin level 20–30 g/l				
First 4 hours of treatment [g]				<= 28.0
After 4 hours of treatment [g/h] ± 20%				7.0

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