CLR 2.0

DONOR BLOOD PURIFICATION

The CLR 2.0 blood filter addresses the shortage of viable transplant organs from brain-dead donors (DBD) by enabling precise fluid balance control and removal of circulating cytokines from the vascular space, while conserving the beneficial cellular elements and proteins in the circulating blood.

SIMPLE TO USE

- Designed to work seamlessly with the NxStage System One blood therapy pump
- Glycerin-free fibers do not require rinsing
- No anticoagulation required with pre-dilution replacement therapy

HIGHLY BIOCOMPATIBLE

- Polysulfone membrane offers excellent blood compatibility
- Meets the requirements of ISO 10993-4 selection of tests for interactions with blood

SAFE

- When used with the NxStage System One, the CLR 2.0 filter does not increase risk of disease transmission per PHS guidelines[1]
- The CLR is High Cutoff (HCO), the safest and most effective at removing proinflammatory cytokines in humans[2]
- Hollow fibers used in the CLR 2.0 are proven to remove TNFα, IL-1β, IL-6 and IL-8 which are significantly upregulated in DBD organ donors[3]
- Allows precise control of donor fluid balance without significantly lowering blood chemistry results (Na, BUN, Creat., AST, ALT, etc.)

[1]Aligning OPTN Policies with the 2013 PHS Guideline for Reducing Transmission of HIV, HBV, and HCV Through Solid Organ Transplantation https://optn.transplant.hrsa.gov/media/1162/phs_webinar_qa.pdf

[2]Atan R *et al.* Techniques of extracorporeal cytokine removal: a systematic review of human studies (2013) *Renal Failure* 35:8,1061-1070.

[3]Schwarz P *et al.* Brain Death-Induced Inflammatory Activity is Similar to Sepsis-Induced Cytokine Release (2018) *Cell Transplant* 27(10) 1417-1424.

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CLR 2.0 Specifications and Indications

SPECIFICATIONS

PHYSICAL SPECIFICATIONS

Filter Length: 25.3cm
Fiber internal diameter: 200µm
Membrane surface area: 2.0m²
Priming volume: 132mL
Pressure drop: 74mmHg (*bovine blood, Q_b 100, TMP 100)
Maximum Transmembrane pressure: 500mmHg

DBD DONOR THERAPY MODE

NxStage System One: CVVH, PRE-DILUTION

SIEVING COEFFICIENTS

In Vitro Tested in Aqueous Solution Q_b 200 mL/min; TMP 50		
Solute	(m.w.) Daltons	Sieving Coefficient
Urea	60	1.0
Creatinine	113	1.0
Vitamin B12	1355	.984
In Vitro Tested in Bovine Blood (Q_b 400, TMP 400) Hct 25%, Temp 37°C, Protein 6gm/dL		
Myoglobin	17,000	0.170
Albumin	65,000	0.014
In Vivo Tested in 10 human subjects undergoing CBP[1]		
IL-6	26,000	1.246

CLINICAL EXPERIENCE– DBD DONORS

Based on OPO experience[2] filtering DBD donors with the CLR 2.0 filter, there is no indication that filtration artificially lowers blood chemistries. Average ranges for treatment times between 6-9 hours with the CLR 2.0:

Analyte	Pre-Filter Rx	Post-Filter Rx	Pre-Rx Range	Post-Rx Range
Na	141	140	139-152	134-144
BUN	19	21	9-39	9-33
Creat	1.4	1.3	0.7-2.69	0.96–2.04
AST	62	57	34-117	35-84
ALT	77	77	30-132	29-138
Albumin	2.5	3.0	2.1-2.7	2.2-3.9
P:F Ratio	342	464	57-552	100-571

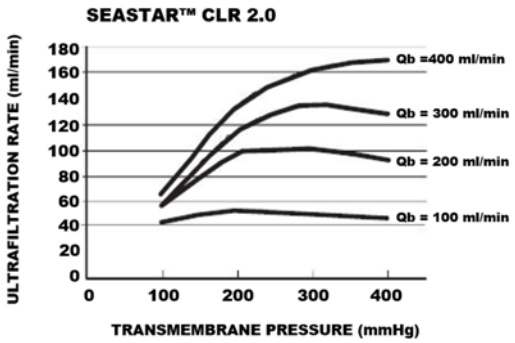
[1]Clar A *et al.* Derivation of Sieving Coefficients to Determine the Efficacy of the Hemoconentrator In Removal of Four Inflammatory Mediators Produced During Cardiopulmonary Bypass (1997) *ASAIO J* 43:163-170.
[2]Our Legacy (Orlando, FL), actual experience with the CLR 2.0 filter to date.

DONOR MANAGEMENT GOALS

It's been shown that achieving more Donor Management Goals results in more organs transplanted per donor. The CLR 2.0 will help achieve more goals faster:

End Point	DMG	CLR Effect[2]
MAP, Vasopressors	60-100 mmHg	BP increases, vasopressors weaned within first 2 hours
CVP	4-10mmHg	Fluid balance achieved
Ejection fraction	>50%	Removes fluid overload, clears congestive heart failure
ABG pH	7.3– 7.45	Replacement therapy fluid controls pH/ acidosis
PaO_2: FiO_2	>300 on	Clearing pulmonary edema
Serum Sodium Blood glucose	135-160 mEq/L <150 mg/dL	Replacement therapy fluid controls Na, K, glucose, etc.
Hemoglobin	> 10 mg/dL	Removes fluid overload
Urine output	1-3 mL/kg/h	Reverses anuria

ULTRAFILTRATION RATES



FDA CLEARED INDICATIONS FOR USE

The SeaStar CLR 2.0 hemofilter is indicated for use in patients with fluid overload, uremia and/or electrolyte disturbances associated with oligoanuria acute renal failure. It may also be used when removal of excess fluid is indicated, such as patients in pulmonary edema or congestive heart failure refractory to diuretic therapy.

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