



DESIGNED TO REDUCE THE INTENSITY AND DURATION OF POST-OPERATIVE SEVERE DELIRIUM IN PATIENTS UNDERGOING CARDIAC SURGERY.

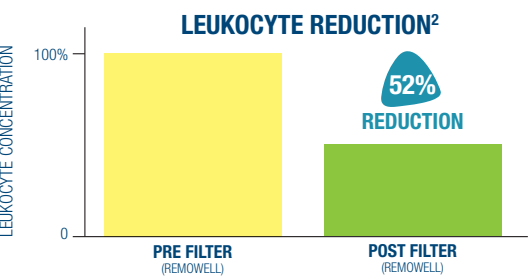
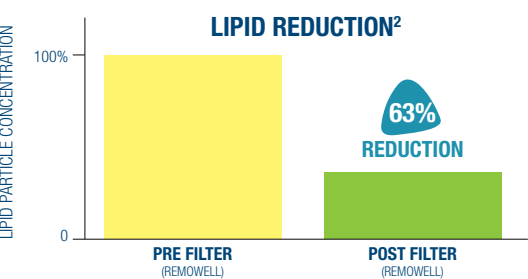
In elderly patients undergoing cardiac surgery, extracorporeal circulation affects the incidence of post-operative delirium and cognitive impairment with an impact on quality of life and mortality. Despite improvements in the biocompatibility of CPB circuits, the activation of inflammatory systemic response may result in clinically relevant organ dysfunction. Concerning brain, prolonged hypoperfusion and microembolization during conventional CPB have been related to postoperative neurologic impairment with an incidence varying from 30% to 60%.

REMOWELL2 is designed to reduce the intensity and duration of post-operative severe delirium in patients undergoing cardiac surgery, thanks to its unique and patented cardiotomy features that can reduce lipids and leukocytes coming from pericardial suction blood.

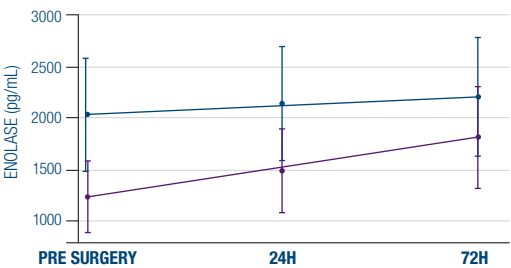
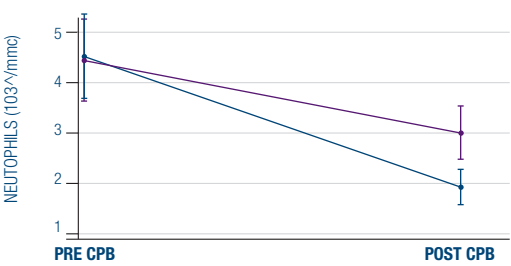
Evidence in the literature shows that the REMOWELL technology offers efficacious LME filtration (Lipid Micro Emboli) in the clinical setting and the subsequent attenuation of NSE release, a known marker of neurologic injury. In addition, significantly lower concentration of cystatin C, a known biomarker of kidney function, was found in the postoperative period, suggesting a renoprotective role for LME filtration.

The Remowell filtration technology effectively contributes to reduce the intensity and duration of post-operative delirium with a reduced need for active involvement of intensive care personnel with the patient.¹

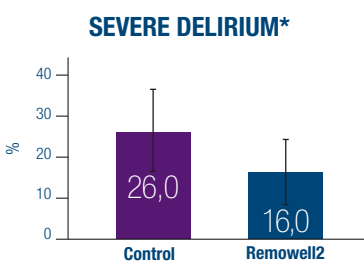
DEVICE PERFORMANCE



DEVICE CLINICAL PERFORMANCE¹



DEVICE CLINICAL CLAIM¹



***Severe delirium:**

- ≥ 4 positive CAM (> 24h)
- Delirium therapy in hospital
- Delirium therapy at discharge

● Control ● Remowell2

ORDERING GUIDE

RESERVOIR	OXYGENATOR MODULE	
	A.L.ONE AF Plus (1.65 m²) code AG5204 (4 pcs/pack)	AMG (1.81 m²) code AG5012 (4 pcs/pack)
 REMOWELL2 CVR code AG5074 (1 pc/pack)	REMOWELL2 AF Plus (1.65 m²) code AG5301 (1 pc/pack)	REMOWELL2 AMG (1.81 m²) code AG5103 (1 pc/pack)
	INTEGRATED A.L.ONE AF Plus MODULE and REMOWELL2 CVR	INTEGRATED AMG MODULE and REMOWELL2 CVR

CODE	DESCRIPTION	NO./PACK
EU2331	Adult/paediatric Oxygenator Holder	1
EU2489	Holder for Oxygenator adult light	1
EU2490	Adjustable holder for adult Oxygenator	1
EU2147/P	REMOWELL2 CVR holder	1
EU2257	Holder for A.L.ONE Oxygenator	1

REFERENCES

- Mantovani et al. **Post-operative delirium and cognitive dysfunction in aged patients undergoing cardiac surgery: a randomized comparison between two blood oxygenators.** (Bioengineering 2023,10,1429)
- A.dell'Amore et al. **Efficacy of a New Oxygenator-Integrated Fat and Leukocyte Removal Device.** Asian Cardiovasc Thorac Ann 2010;0:1–5

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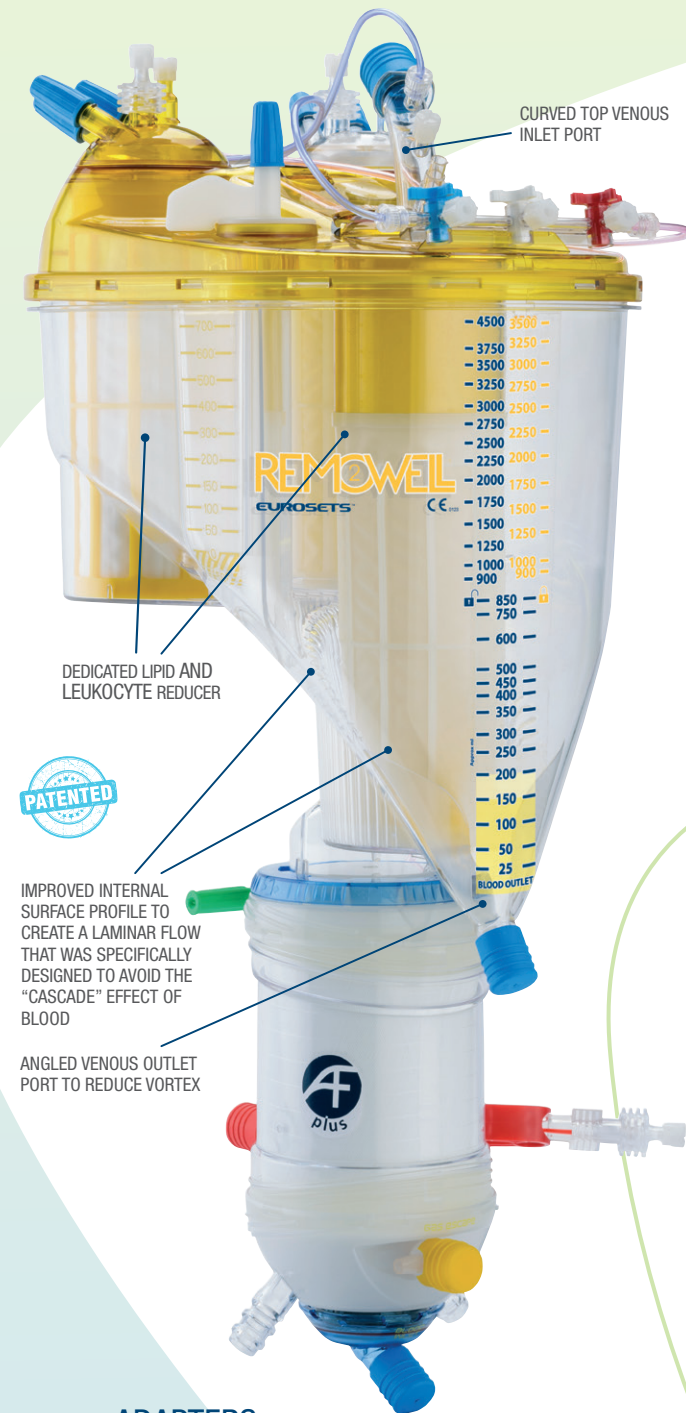


REDUCES THE INTENSITY AND DURATION OF POST-OPERATIVE SEVERE DELIRIUM

REM2WELL

CARDIOPULMONARY

EUROSETS
EVERY LIFE MATTERS



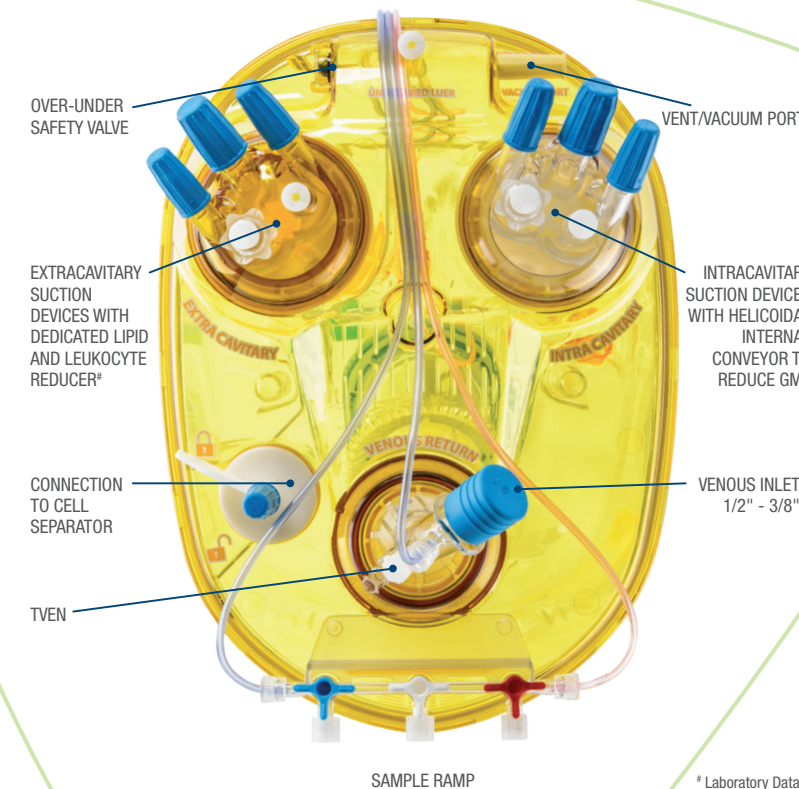
DUAL CHAMBER RESERVOIR WITH LIPID AND LEUKOCYTE REDUCTION

MAIN FEATURES

- 4500 ml total reservoir capacity
- 800 ml cardiotomy capacity
- 3 different filtration systems:
 - Venous inlet (80µm)
 - Intracavitary inlet (40µm)
 - Extracavitary inlet
- Two step lipid-leukocyte depletion:
 - Multilayer cascade filtration (for lipids and leukocytes)
 - Supernatant separator (lipids only)
- Fully PC coated
- Suitable for VAVD

CONNECTIONS

- venous inlet, 360° rotatable 1/2" with 3/8" adapter
- venous reservoir outlet 3/8"
- vent/vacuum port 1/4"
- 4 filtered ports 1/4", 1 of which with 1/4" - Luer lock adapter
- 2 filtered ports 3/8":
 - 1 with 3/8" - 1/4" adapter
 - 1 with 3/8" - Luer lock adapter
- 2 filtered Luer lock ports
- 2 filtered post lock - Luer lock
- 1 unfiltered Luer lock



ADAPTERS



A.L.ONE AF PLUS

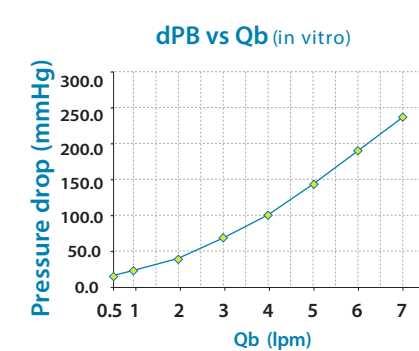
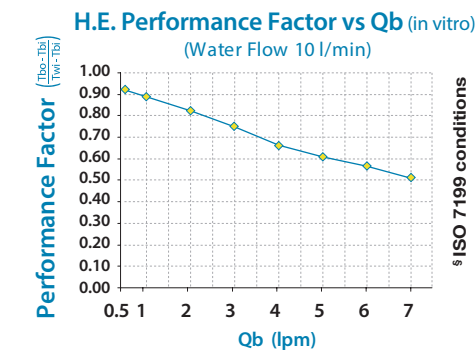
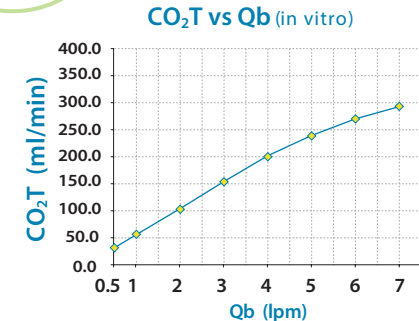
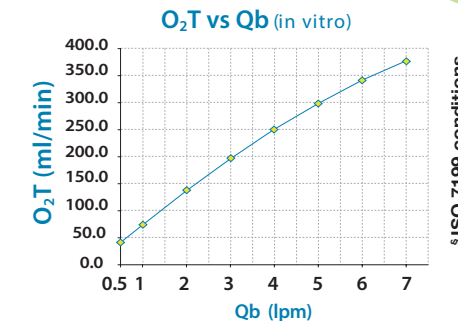
OPTIMIZED PRESSURE RESISTANCE OXYGENATOR MODULE WITH INTEGRATED CASCADE ARTERIAL FILTER

TECHNICAL CHARACTERISTICS

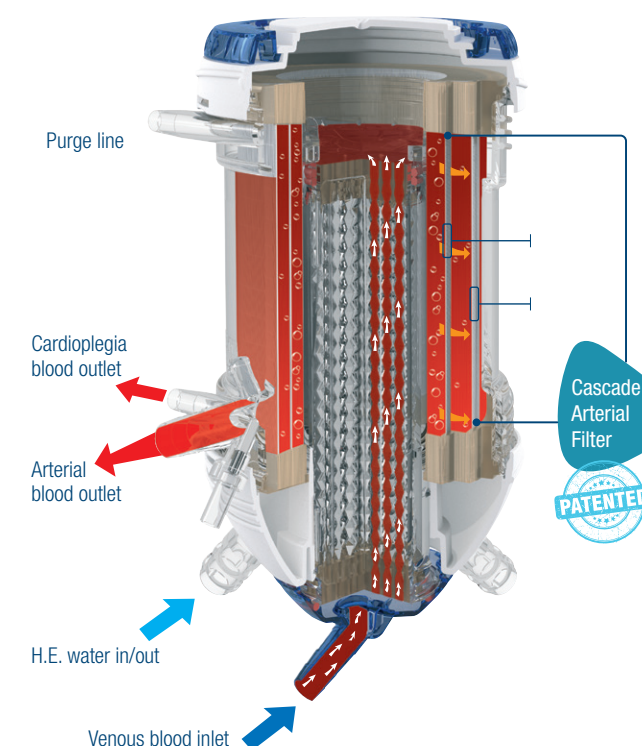
- Priming volume: 225 ml
- Contact surface area: 1.65 m²
- Max. blood flow rate: 7.0 l/min
- Cascade Arterial Filter pore size: 80 µm + 38 µm
- Heat Exchanger surface area: 0.08 m²
- H.E. Performance Factor: $\eta = 0.64$ (at 4 l/min)
- Material: stainless steel
- Coating: Phosphorylcholine (PC)**

CARDIOPLEGIA ADAPTER

Poslock - 1/4" M (1 pc)



ISO 7199 conditions
Bovine blood
Hb = 12 ± 1 g/dL
SVO₂ = 65 ± 5%
PVCO₂ = 45 ± 5 mmHg
B.E. = 0 ± 5 mEq/L
Temp. = 37 ± 1°C
Qb/Qg = 1
FI0₂ = 100%



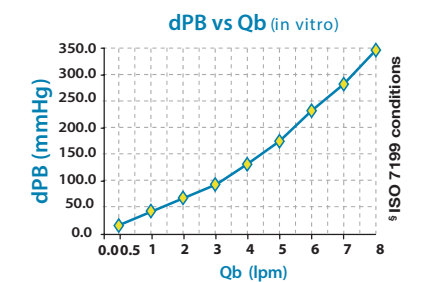
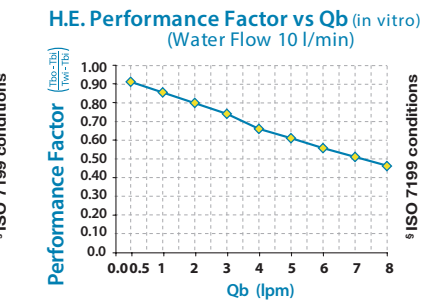
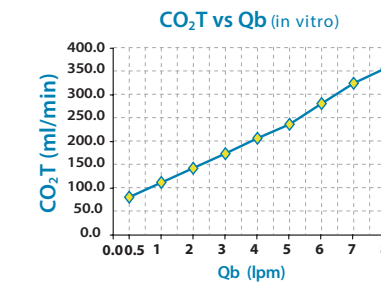
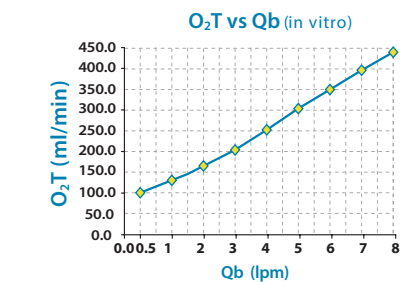
AMG OXYGENATOR MODULE

TECHNICAL CHARACTERISTICS

- Priming volume: 220 ml
- Contact surface area: 1.81 m²
- Max. blood flow rate: 8.0 l/min
- Heat Exchanger surface area: 0.08 m²
- H.E. Performance Factor: $\eta = 0.64$ (at 4 l/min)
- Material: Stainless Steel
- Coating: Phosphorylcholine (PC)**

CARDIOPLEGIA ADAPTER

Poslock - 1/4" M (1 pc)



PHOSPHORYLCHOLINE COATING

Phosphorylcholine or PC is the predominant lipid headgroup found within the outer layer of cell membranes. PC has a natural affinity for water and binds water tightly around itself. As a result, the outer layer of the cell membrane does not promote clot formation (thrombosis).

