

CARDIOPULMONARY



REDUCES THE
INTENSITY AND
DURATION OF
POST-OPERATIVE
SEVERE DELIRIUM

REM2WELL



EUROSETS
EVERY LIFE MATTERS

REMOWELL

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

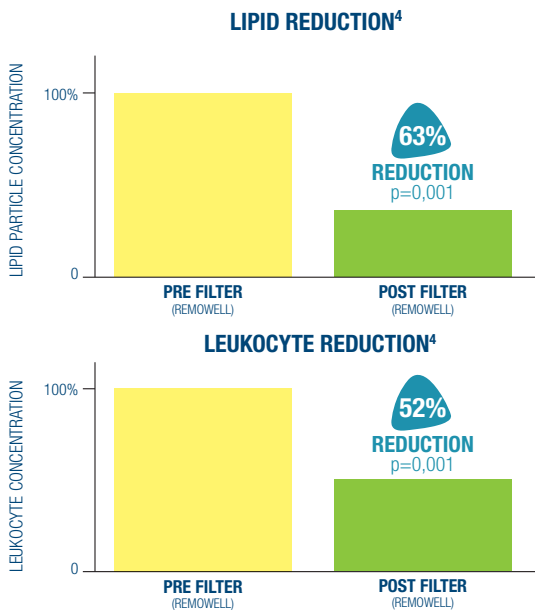
In elderly patients undergoing cardiac surgery, extracorporeal circulation affects the incidence of post-operative delirium and cognitive impairment with an impact on quality of life and mortality. Despite improvements in the biocompatibility of CPB circuits, the activation of inflammatory systemic response 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%.¹

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.

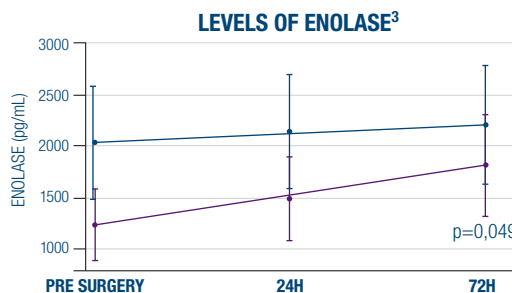
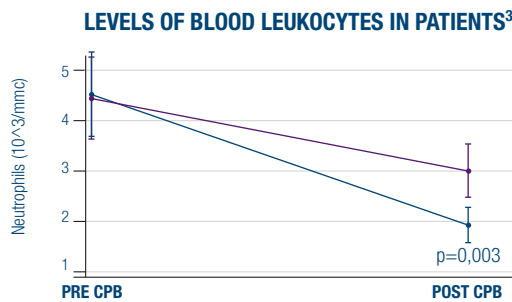
Evidence in the literature² shows that the REMOWELL technology offers efficient LME filtration (Lipid Micro Emboli) in the clinical setting and the subsequent attenuation of NSE release, a known marker of neurological injury. In addition, significantly lower concentration of cystatin C, a known biomarker 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.³

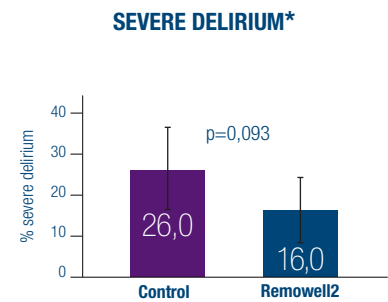
DEVICE PERFORMANCE



DEVICE CLINICAL PERFORMANCE



DEVICE CLINICAL BENEFIT³



***Severe delirium:**

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

● Control ● Remowell2

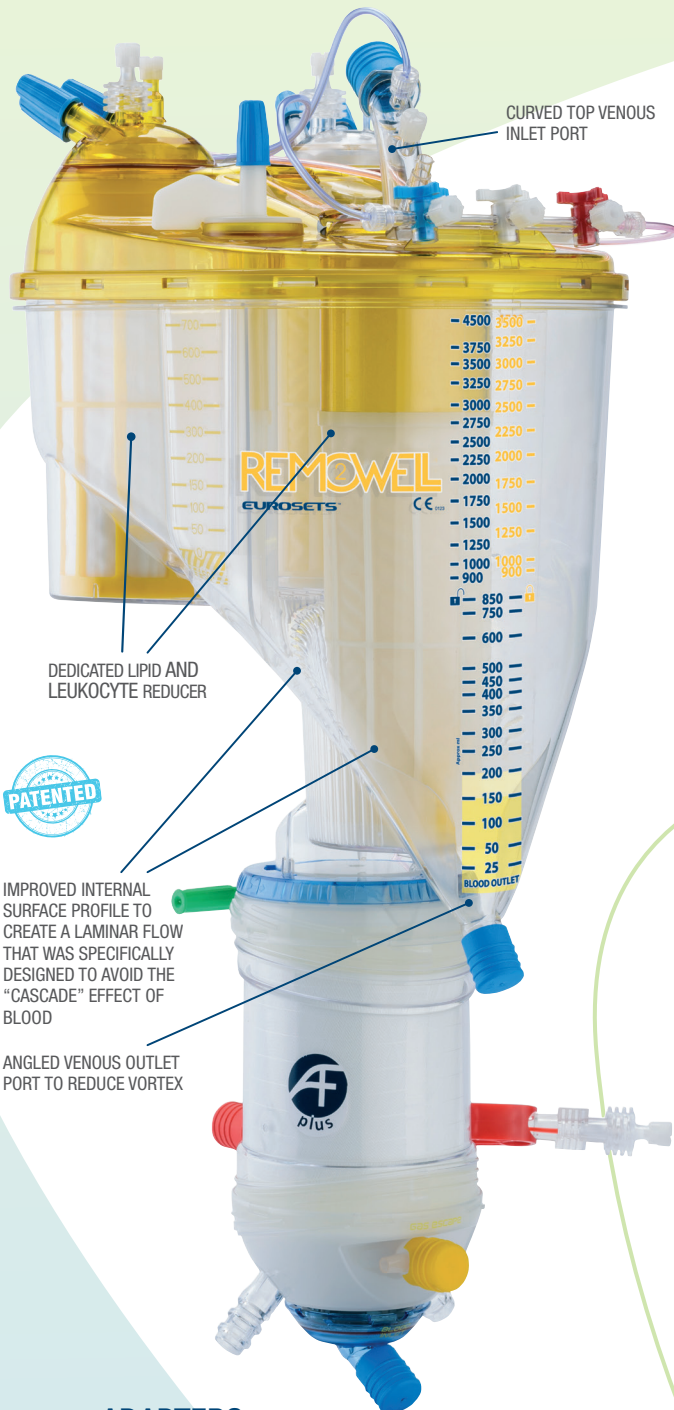
DUAL CHAMBER RESERVOIR WITH LIPID AND LEUKOCYTE REDUCTION

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



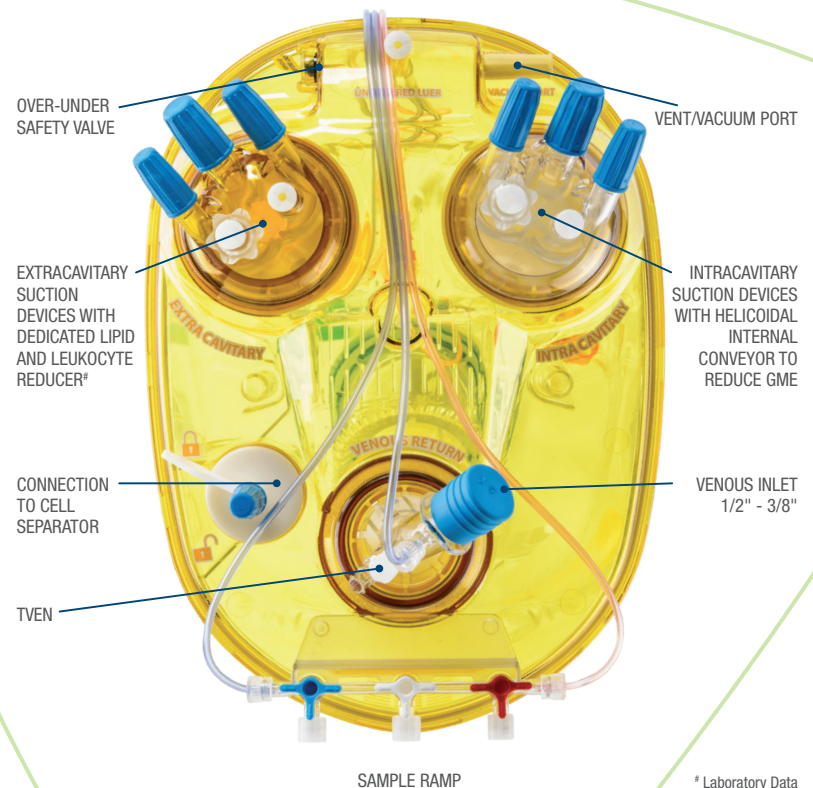
1/4" - Luer (1 pc)
3/8" - Luer (1 pc)



3/8" - 1/4" (1 pc)



1/2" - 3/8" (1 pc)



* Laboratory Data

A.L.ONE AF PLUS

OPTIMIZED PRESSURE RESISTANCE OXYGENATOR
MODULE WITH INTEGRATED CASCADE ARTERIAL FILTER

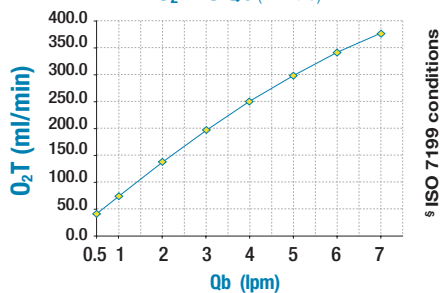
TECHNICAL CHARACTERISTICS

Priming volume:	225 ml
Contact surface area:	1.65 m ²
Max. blood flow rate:	7.0 l/min
Cascade Arterial Filter pore size:	80 μm + 38 μm
Heat Exchanger surface area:	0.08 m ²
H.E. Performance Factor:	$\eta = 0.64$ (at 4 l/min)
Material:	stainless steel
Coating:	Phosphorylcholine (PC)

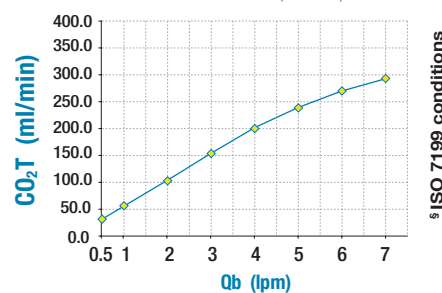
CARDIOPLEGIA ADAPTER

Poslock - 1/4" M (1 pc)

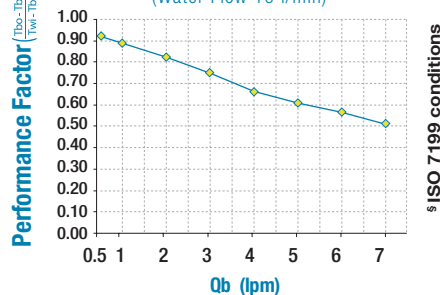
O₂T vs Qb (in vitro)



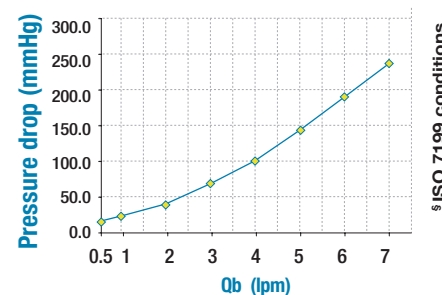
CO₂T vs Qb (in vitro)



H.E. Performance Factor vs Qb (in vitro)
(Water Flow 10 l/min)



dPB vs Qb (in vitro)



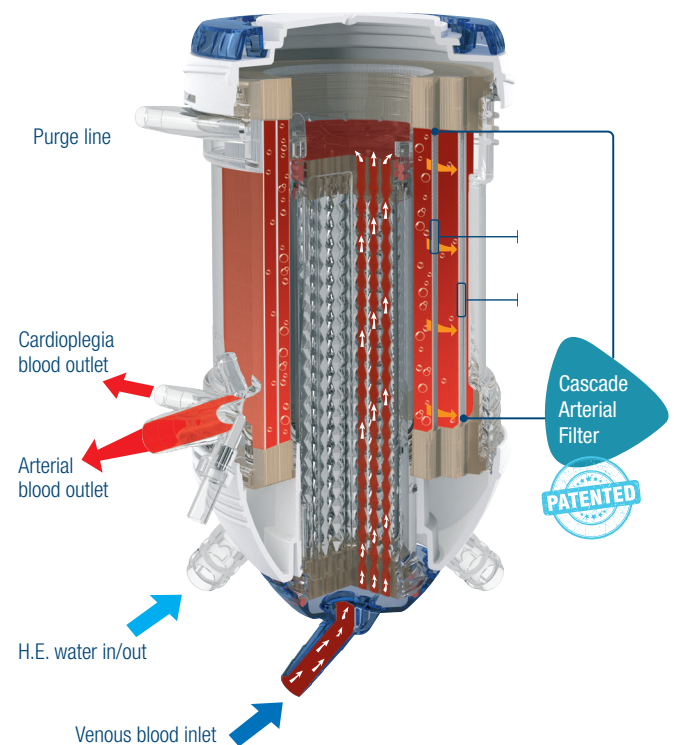
§ ISO 7199 conditions

Bovine blood
Hb = 12 ± 1 g/dL

SVO₂ = 65 ± 5%
PVC_{O2} = 45 ± 5 mmHg

B.E. = 0 ± 5 mEq/L
Temp. = 37 ± 1°C

Qb/Qg = 1
FIO₂ = 100%



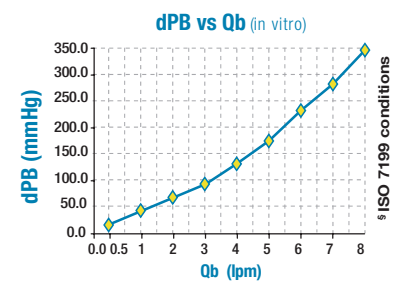
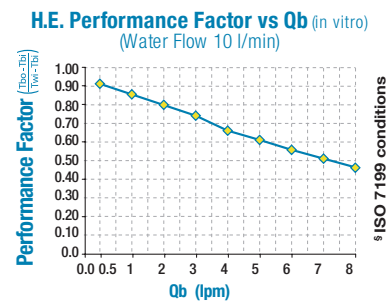
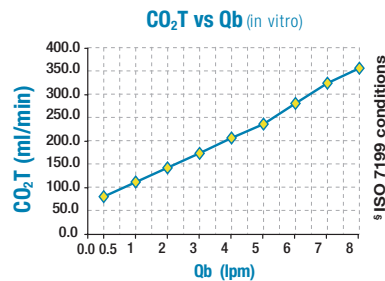
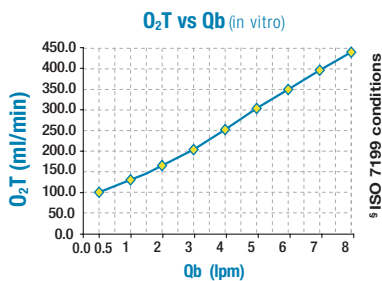
AMG OXYGENATOR MODULE

TECHNICAL CHARACTERISTICS

Priming volume:	220 ml
Contact surface area:	1.81 m ²
Max. blood flow rate:	8.0 l/min
Heat Exchanger surface area:	0.08 m ²
H.E. Performance Factor:	$\eta = 0.64$ (at 4 l/min)
Material:	Stainless Steel
Coating:	Phosphorylcholine (PC)

CARDIOPLEGIA ADAPTER

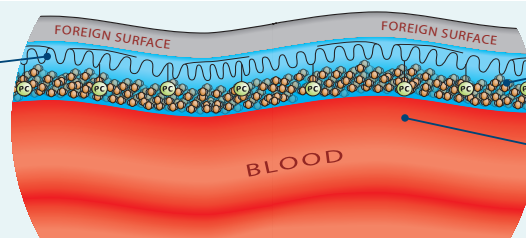
Poslock - 1/4" M (1 pc)



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).

ALKALINE CHAINS SPREAD ACROSS THE SURFACE YIELDING A STABLE COATING THROUGH HYDROPHOBIC INTERACTIONS



HYDRATION LAYER AROUND PC - WITH A COATED SUBSTRATE THE BLOOD THEREFORE "SEES" A LAYER OF WATER

ZWITTERIONIC PC GROUPS EXPRESSED OUTWARDS FROM THE SURFACE

ORDERING GUIDE

RESERVOIR



REMOWELL2 CVR code AG5074 (1 pc/pack)

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 AF Plus (1.65 m²)
code AG5301
(1 pc/pack)

INTEGRATED
A.L.ONE AF Plus MODULE
and REMOWELL2 CVR

REMOWELL2 AMG (1.81 m²)
code AG5103
(1 pc/pack)

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

1. Anastasiadis, K. et al. **Neurocognitive outcome after coronary artery bypass surgery using minimal versus conventional extracorporeal circulation: A randomised controlled pilot study.** Heart 2011, 97, 1082–1088
2. R. Issitt et al. **Quantification of lipid filtration and the effect on cerebral injury during CPB.** Ann Thorac Surgeons 2017;104:884–90
3. 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
4. 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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