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REMOWELL2 AF PLUS

Oxygenating device for extracorporeal circulation in cardio surgery

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Certified Quality System

PRODUCT TECHNICAL DATA SHEET

Description

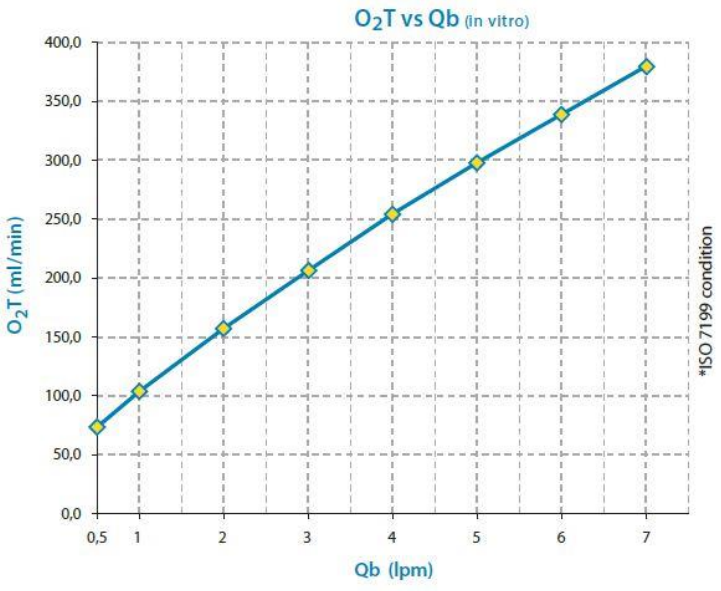
REMOWELL2 AF PLUS is a microporous hollow-fibre membrane oxygenator consisting of a gas exchange module with an integrated heat exchanger and an integrated 38µm arterial filter that ensures arterial blood filtration with removal of microaggregates and microemboli.
REMOWELL2 AF PLUS also has a hard-shell cardiotomy/venous reservoir integrated with two cardiotomy filters, designed to allow venous drainage of the patient's blood, both through the hydrostatic load (height difference between the patient and the reservoir) and the vacuum-assisted venous drainage (VAVD) technique.
The distinctive characteristic of REMOWELL2 CVR is the reduction of lipidic particles and leukocytes in the portion of extracavitary blood, coming from the surgical field and gradually collected in the pericardial sac.
Reduction of lipidic particles and leukocytes in extracavitary blood is achieved through:
* Retention by cascade filtration process: sequential filtering media layers enable to partially hold back leukocytes and lipidic particles,
* Decantation and separation of the surnatant: thanks to the sedimentation of the blood collected in the extracavitary cardiotomy reservoir and to a special skimming system, further lipidic particles collecting in the surnatant can be removed.
REMOWELL2 AF PLUS hard-shell cardiotomy/venous reservoir is fitted with a pressure relief valve.
REMOWELL2 AF PLUS inner contact surfaces are coated with A.G.I.L.E. (Advanced Generation Inert Layer E.C.C.) system, based on Phosphoriylcoline (PC), improving the device blood compatibility by reducing platelet adhesion on the coated surface.
The device is single use, non-pyrogenic, supplied STERILE and individually packed. Sterilised by ethylene oxide.

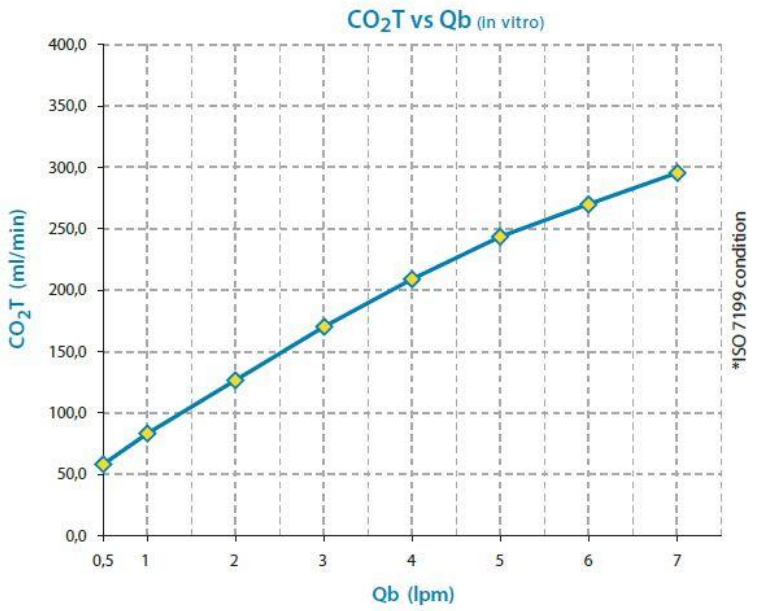
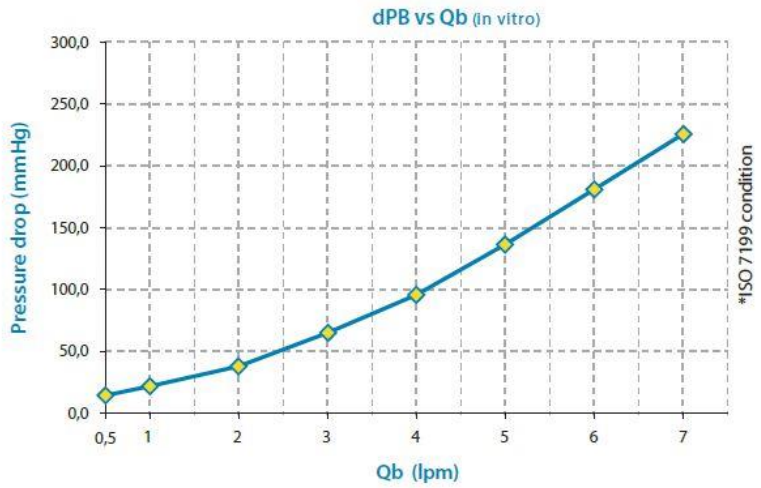
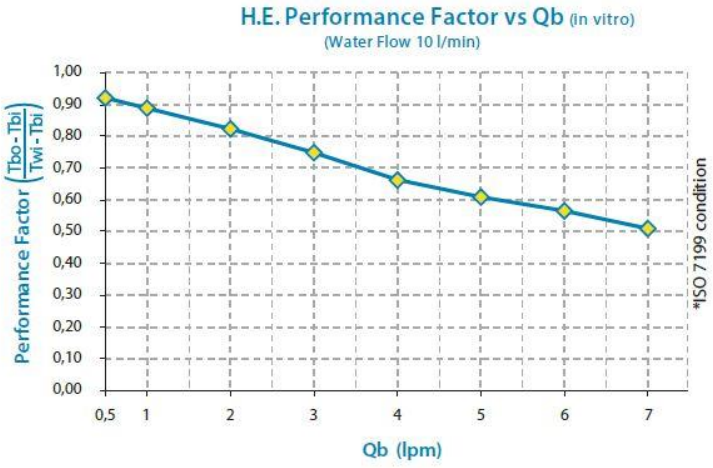
Intended use and indications for use

REMOWELL2 AF PLUS is intended for use in extracorporeal perfusion circuit during cardiopulmonary bypass in cardiac surgery to oxygenate and remove carbon dioxide from the blood and regulate the blood temperature.
REMOWELL2 AF PLUS, being integrated with arterial filter, enables filtration of arterial blood with removal of microemboli and microaggregates larger than 38 µm.
REMOWELL2 AF PLUS is equipped of a hard-shell cardiotomy/venous reservoir intended to collect, store and filter venous and cardiotomy suctioned blood during cardiopulmonary bypass procedure up to 6 hours in surgery.
The hard-shell cardiotomy/venous reservoir is also intended for use during vacuum-assisted venous drainage (VAVD) procedures.

REMOWELL2 AF PLUS is furthermore intended to reduce the content of lipidic particles and leukocytes in the portion of extracavitary blood coming from the surgical field and gradually collected in the pericardial sac.
The blood to be treated should contain anticoagulant.
REMOWELL2 AF PLUS is indicated for use on adult patients undergoing extracorporeal circulation during cardiopulmonary bypass procedures.
REMOWELL2 AF PLUS has a maximum blood flow rate of 7 l/min.
REMOWELL2 AF PLUS should not be used for more than 6 hours. Contact with blood for longer periods is not advised.

Technical features and materials

OXYGENATOR MODULE		
Recommended blood flow range	0.5 -7 l/min	
Recommended gas flow range	0.25 - 14 l/min	
Max blood pressure	750 mmHg (100 kPa)	
Max water pressure	1500 mmHg (200 kPa)	
Membrane type	Microporous polypropylene	
Membrane surface area	1.65 m^2	
Heat exchanger surface area	0.08 m^2	
Arterial filter pore size Arterial filter surface area	80 µm 200 cm^2	38 µm 230 cm^2
Air-handling capability	≥ 98%	
Static priming volume (oxygenator module + heat exchanger)	225 ml	
Residual blood volume	126 ml	
Ports		
Oxygenator venous inlet	3/8” (9.53 mm)	
Oxygenator arterial outlet	3/8” (9.53 mm)	
Oxygenator gas inlet	1/4" (6.35 mm)	
Oxygenator gas outlet	3/8” (9.53 mm)	
Water ports	1/2" Hansen coupling	
Arterial temperature probe port	YSI Series 400 fitting	
Arterial sampling port	female luer lock with one-way valve	
Cardioplegia line port	1/4" (6.35 mm)	
Air-purge line port	1/4" (6.35 mm)	
Performance Data		
Oxygen transfer rate		

Carbon dioxide transfer rate	
Blood side pressure drop	
Heat exchanger performance factor R	

*** ISO 7199 condition**

Bovine blood	PVCO2 = 45 ± 5 mmHg	Qb/Qg = 1
Hb = 12 ± 1g/dL	B.E. = 0 ± 5 mEq/L	FiO2 = 100%
SVO2 = 65 ± 5%	Temp = 37 ± 1°C	

Materials	
Housing	Polycarbonate (PC)
Microporous hollow fiber membrane	Polypropylene (PP)
Filtering media	Polyester (PET)
Potting	Polyurethane (PU)
Heat exchanger	Stainless steel
Seals	Thermoplastic Elastomer - Stirene-Butilene-Etilene-Stirene (SEBS)
Caps and adapters	Polypropylene (PP), Thermoplastic Elastomer - Stirene-Butilene-Etilene-Stirene (SEBS)
Biocompatible coating	Phosphorylcholine (PC)
Materials in contact with blood	DEHP free Latex free

HARD-SHELL CARDIOTOMY/VENOUS RESERVOIR		
Max. Blood Volume Capacity Venous Reservoir		4500 ml
Max. Blood Volume Capacity Extracavitary Cardiotomy		800 ml
Max Operating Volume		4500 ml
Min. Operating Volume		150 ml up to 5 l/min 200 ml from 5 to 8 l/min
Blood Flow Range		Venous Flow: 0.5-8 l/min Cardiotomies: max. 2.5 l/min (each) Combined Venous and Cardiotomies flow: max. 8 l/min
Dynamic Priming (Hold up) Volume		
Venous Filter		250 ml @ 8 l/min
Volume scales tolerance		± 10%
Filtration		
Venous	Pore size	80 µm
	Efficiency	≥90% at 80 µm
Cardiotomies	Pore size	40 µm
	Efficiency	≥90% at 40 µm
Lipidic Particles Filtration Extracavitary Cardiotomy Reservoir		
Reduction Efficiency @ 60 min.[1]		Average 61% Min. 40% Max. 82%
Leukocytes Filtration Extracavitary Cardiotomy Reservoir		
Reduction Efficiency @ 60 min.[1]		Average 36% Min. 18% Max. 54%
Pressure relief valve		
	Positive pressure	5.3 mmHg
	Negative pressure	-75.2 mmHg
Max negative reservoir pressure		
	Negative pressure	-75.2 mmHg
Ports and lines		
Venous blood inlet port		1/2" (12.7mm) – 360° rotatable
Luer lock at venous inlet		2 x female luer lock
Venous temperature probe port at venous inlet		YSI Series 400 fitting
Intracavitary cardiotomy turret (360° rotatable) ports (mainly blood with limited amount of air)		2 x 1/4" (6.35 mm) 1 x 3/8" (9.53 mm) 1 x female luer lock 1 x female POS lock (ISO 8838) reducible to female luer lock
Extracavitary cardiotomy turret (360° rotatable) ports (mainly air with limited amount of blood)		2 x 1/4" (6.35 mm) 1 x 3/8" (9.53 mm) 1 x female luer lock 1 x female POS lock (ISO 8838) reducible to female luer lock
Cell saver port		1 x 1/4" (6.35 mm)
VENT/VACUUM port		1 x 1/4" (6.35 mm)
Unfiltered luer lock		1 x female luer lock
Sampling manifold		Arterial blood sampling line (red handle stopcock) Venous blood sampling line (blue handle stopcock) Additional sampling/injection port (white handle stopcock)
Venous blood outlet port		3/8" (9.53 mm)
Purge/recirculation line		
Drawing line for blood cardioplegia		

1 Data obtained in in-vitro testing.

Materials	
Housing parts (reservoir and lid)	Polycarbonate (PC)
Filtering media (venous and cardiotomies)	Polyester (PET), Polypropylene (PP)
Defoamer (venous and cardiotomies)	Silicone treated Polyurethane (PU)
Seals	Thermoplastic Elastomer - Stirene-Butilene-Etilene-Stirene (SEBS)
Caps, adapters, selector	Polycarbonate (PC), Polypropylene (PP), Thermoplastic Elastomer - Stirene-Butilene-Etilene-Stirene (SEBS), Polyoxymethylene (POM)
Biocompatible coating	Phosphorylcholine (PC)
Materials in contact with blood	DEHP free Latex free

Adapters	
Venous blood inlet port adapter	1 x 1/2" (12.7mm) / 3/8" (9.53 mm)
Cardioplegia adapter	1 x POS lock male (ISO 8837) with 1/4" (6.35 mm) connector
Other adapters	1 x 3/8" (9.53 mm) / 1/4" (6.35 mm) 1 x 1/4" (6.35 mm) / female luer lock 1 x 3/8" (9.53 mm) / female luer lock

Sterilization and other technical characteristics

REMOWELL2 AF PLUS is sterilized by ethylene oxide (EtO).
The sterility is guaranteed if the package is intact.
The disposable components cannot be resterilized.
The devices must be stored in a dry place with temperature between 0 and 40°C away from heat sources and bright light.
To be used by the expiry date indicated on the label.

The holder is supplied not sterile and sterilization is not required for its use; periodic cleaning with normal aqueous disinfectants is recommended.

CE marking

REMOWELL2 AF PLUS single use medical device is Class IIb in accordance with Appendix IX of Leg. Decree 46 of 24.02.97 (implementation of EC Directive MDD 93/42/EEC regarding medical devices).

This medical device has the CE 0123 marking in accordance with Appendix II excluding (4) of Leg. Decree 46 of 24.02.97 (implementation of EC Directive MDD 93/42/EEC regarding medical devices.

Packaging

Code	Description	Pcs/package
AG 5301	REMOWELL2 AF PLUS	1
EU 2331	REMOWELL2 AF PLUS Holder	1
EU2489	HOLDER OXY ADULT LIGHT	1
EU2490	HOLDER OXY ADULT ADJUSTABLE	1