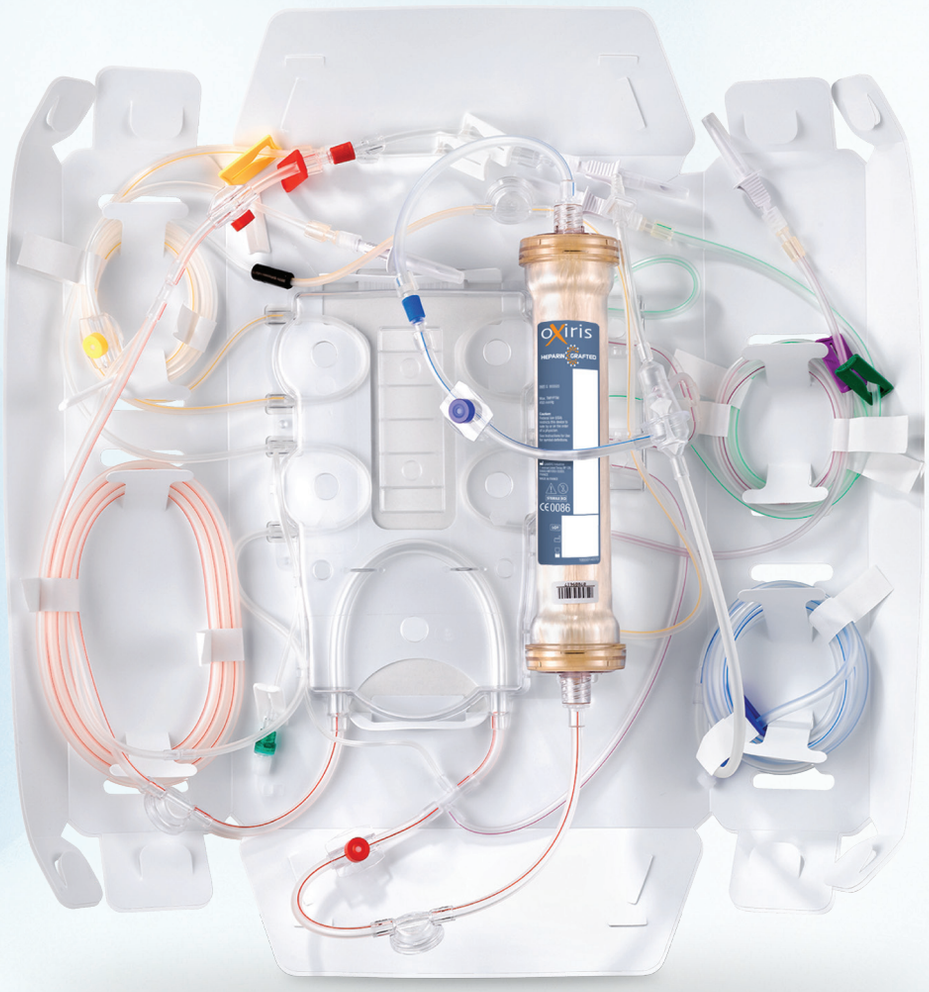
Baxter

Oxiris

CYTOKINE - ENDOTOXIN AND CRRT HEMOFILTER



Oxiris Set

3-IN-1 CRRT-SEPSIS MANAGEMENT

Blood purification beyond CRRT
by targeting cytokine and endotoxin removal Powered By

PrisMax and **Prismaflex**

OXIRIS SET

The **Oxiris** set is indicated for use only with the **Prismaflex** control unit or with **PrisMax** control unit (in countries where **PrisMax** is cleared or registered). It is intended for patients in need of blood purification, including continuous renal replacement therapy, and in conditions where excessive endotoxin and inflammatory mediator levels exist.

OXIRIS SET GENERAL DATA	
Weight	890 g
Overall Dimensions	27 x 22 x 9 cm
Blood volume in set ± 10 %	193 ml
Minimal patient weight	30 kg

Materials
Oxiris hollow fiber: Acrylonitrile and sodium methallyl sulfonate copolymer + Polyethyleneimine (surface treatment agent) + heparin grafted (4500+/-1500 IU/m^2)
Filter housing and headers: Polycarbonate
Filter potting compound: Polyurethane
Tubing material: Plasticized polyvinyl chloride (PVC)
Cartridge: PETG
Sterilization mode: EtO (ethylene oxide)

Filter operating specifications	
Maximum TMP* (mmHg/kPa)	450/60
Maximum blood pressure (mmHg/kPa)	500/66.6
Range of blood flow rate	100-450 ml/min

Filter data	
Nominal physical characteristics:	
Effective surface area	1.5 m^2
Fiber internal diameter (wet)	240 µm
Fiber wall thickness	50 µm

IN VITRO PERFORMANCES

CVVHD clearances

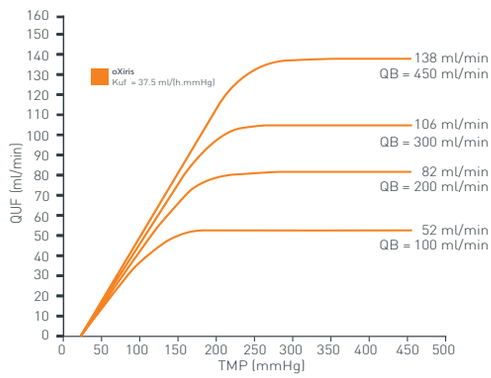
Clearances versus inlet dialysate flow rate
(Continuous veno-venous hemodialysis) (Saline, T = 37°C).

	Oxiris set Q_B** = 200 ml/min Q_{UF}**** = 0 ml/min			
QD l/h ml/min	1 17	2.5 42	4 67	8 133
Urea (±10%)	17	42	66	117
Vitamin B_{12} (±20%)	17	38	51	68
Inulin (±20%)	16	33	40	49

*Transmembrane pressure.
**Access blood flow rate.
***Protein concentration.
****Ultrafiltration flow rate [1].
[1] The ultrafiltration flow rate is the "patient fluid removal flow rate + replacement flow rate + pre-blood-pump flow rate".

CVVH performances[1]

"In vitro" ultrafiltration with blood (values ±15%)
(Continuous veno-venous hemofiltration)
(Bovine blood at 37°C, Hematocrit 32%, Cp*** 60 g/l).
Ultrafiltration is controlled by the **Prismaflex** system and is independent of the ultrafiltration coefficient (KUF)



Sieving coefficient	
(Bovine plasma, Cp 60 g/l, T = 37°C) Q_B =100 ml/min, Q_{UF} = 20 ml/min	
Urea	1
Vitamin B_{12}	1
Inulin	0.96
(Human plasma, Cp 60 g/l, T=37°C)	
Myoglobin	0.70
Albumin	<0.0045

Cytokine adsorption

Cytokine adsorption removal rate (%) [2]
(human plasma, Cp 60 g/l, 37°C)
Q_B = 150 ml/min, Q_{UF} = 0 ml/min

IL-10 (± 10%)	96
IL-6 (± 10%)	84
HMGB-1 (± 10%)	94
TNF-α (± 30%)	82

[2]Removal Rate expressed at t=120 min with a theoretical initial IL-10, IL-6, HMGB-1 and TNF-α respective concentration of 500 pg/ml, 1500 pg/ml, 30 ng/ml and 250 pg/ml.

Endotoxin adsorption

Lipopolysaccharide adsorption removal rate (%)[3]
(human plasma, Cp 60 g/l, 37°C)
Q_B = 150 ml/min, Q_{UF} = 0 ml/min

LPS (± 20%)	75

[3]Removal Rate expressed at t=120 min with an initial LPS concentration after stabilization of 50±10 EU/ml
Cp: Protein concentration
RR: removal rate
IL-10: Interleukin-10
IL-6: Interleukin-6
HMGB-1: High-mobility group box 1
TNF-α: Tumor necrosis factor – α
LPS: Lipopolysaccharide

ORDERING INFORMATION

	Code N°	N° units/box
Oxiris S set	955503	4

1. Typical mean values obtained from laboratory testing of post-sterilization sample lots. Results may vary depending on patient and clinical conditions. Adsorption removal rate obtained in vitro are likely to differ from in vivo results. Adsorption characteristics change with the duration of observation.

For safe and proper use of the devices mentioned herein, please refer to the Instructions for Use.

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