Vantive

OXIRIS

Pre-connected Set for Removal
of inflammatory mediators,
endotoxin, fluid, and uremic toxins.

Powered by **PrisMax** and **Prismaflex**

Oxiris Set

INDICATION:

The **Oxiris** set is indicated for use in critically ill patients with a body weight equal or greater than 30 kg (66 lb) for hemoperfusion and/or renal replacement modalities such as:

- > Slow Continuous UltraFiltration (SCUF)
- > Continuous Veno-Venous HemoDialysis (CVVHD)
- > Continuous Veno-Venous Hemofiltration (CVVH)
- > Continuous Veno-Venous HemoDiaFiltration (CVVHDF)

When used for hemoperfusion only, the SCUF mode shall be used with no fluid removal prescription, as the indication is to reduce elevated levels of inflammatory mediators, such as cytokines, and to reduce endotoxins. If patients suffer from acute kidney injury and/or volume overload, the **Oxiris** set is indicated for continuous renal replacement therapies (CRRT), to perform fluid management and removal of uremic toxins. The removal of inflammatory mediators and endotoxins is performed simultaneously when indicated for CRRT.

INTENDED PURPOSE:

The **Oxiris** set is a single use device that provides blood purification via diffusion, convection and adsorption through a semipermeable membrane. The **Oxiris** set is for use only in conjunction with the **Prismaflex** control unit or with the **PrisMax** control unit.

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 set hollow fiber: Acrylonitrile and sodium methallyl sulfonate copolymer + Polyethyleneimine (surface treatment agent) + heparin grafted (4500+/-1500 IU/m²)

Filter housing and headers: Polycarbonate

Filter potting compound: Polyurethane

Tubing material: Plasticized polyvinyl chloride (PVC)

Cartridge: Polyethyleneterephtalate Glycol (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 m²
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	41	64	116
Creatine (± 10%)	17	41	61	107
Phosphate (± 20%)	16	39	57	96
Vitamin B_{12} (± 20%)	16	35	46	67
Inulin (± 20%)	15	28	35	46

*Transmembrane pressure.
**Access blood flow rate.
***(1)Ultrafiltration flow rate.

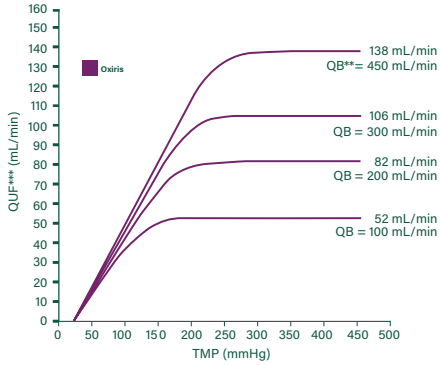
(1) The ultrafiltration flow rate is the "patient fluid removal flow rate + replacement flow rate + pre-blood-pump flow rate".

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 **PrisMax** or **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) Q_B = 100 mL/min, Q_{UF} = 20 mL/min	
Myoglobin	0.70
Albumin	< 0.0045

Cytokine adsorption

(2)Cytokine adsorption removal rate (%)
(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

(3)Lipopolysaccharide adsorption removal rate (%)
(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:

Product Description	Code N°	N° units/box
Oxiris set	973003	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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