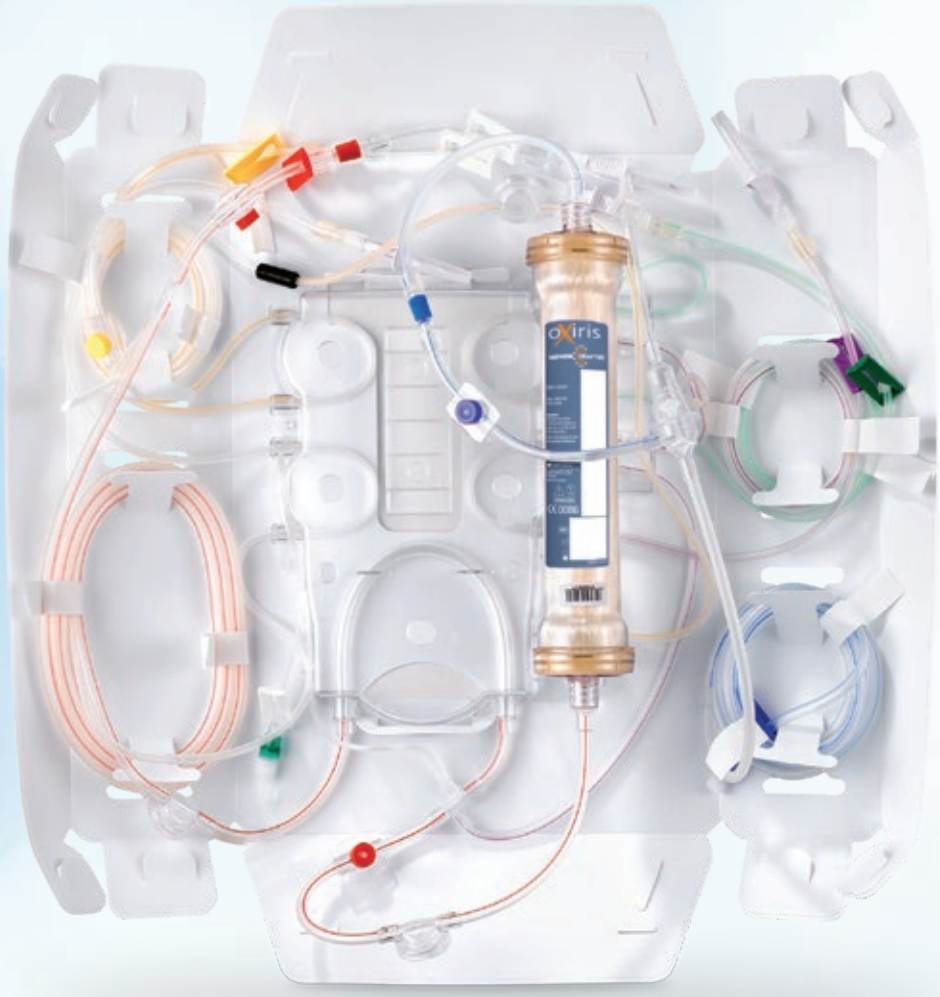
Baxter
Oxiris



OXIRIS Set

The OXIRIS Set has been Authorized by the FDA for the indication to treat patients with COVID-19 infection.

The OXIRIS Set is indicated for use only with the **PRISMAFLEX** control unit or with the **PRISMAX** control unit.

OXIRIS SET

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/m²)

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 m²
Fiber internal diameter (wet)	240 µm
Fiber wall thickness	50 µm

IN VITRO PERFORMANCES

CVVHD clearances

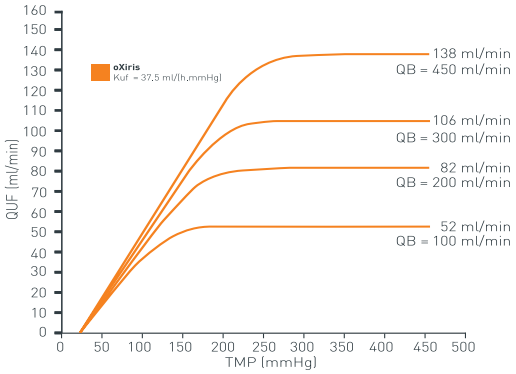
Clearances versus inlet dialysate flow rate
(Continuous veno-venous hemodialysis) (Saline, T = 37°C).

	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	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.

OXIRIS

Emergency Use Authorization for the United States

The OXIRIS Set has been Authorized by the FDA for the indication to treat patients with COVID-19 infection.

The OXIRIS Set has been authorized by FDA under EUA200164.

The OXIRIS Set is Authorized only for the duration of the declaration that circumstances exist justifying the authorization of the emergency use of the OXIRIS set under section 564(b)(1) of the Act, 21 U.S.C. § 360bbb-3(b)(1), unless the authorization is terminated or revoked sooner.

Intended Use for Patients with COVID-19

The OXIRIS Set is indicated for use only with the PRISMAFLEX control unit or with the PRISMAX control unit.

It is intended to treat patients 18 years of age or older with confirmed COVID-19 admitted to the ICU with confirmed or imminent respiratory failure in need of blood purification, including continuous renal replacement therapy, to reduce pro-inflammatory cytokine levels, who have any one of the following conditions:

- Early acute lung injury (ALI)/early acute respiratory distress syndrome (ARDS);
- Severe disease, such as:
  - dyspnea,
  - respiratory frequency ≥ 30/min,
  - blood oxygen saturation ≤ 93%,
  - partial pressure of arterial oxygen to fraction of inspired oxygen ratio < 300, and/or
  - lung infiltrates >50% within 24 to 48 hours; or
- Life-threatening disease, defined as:
  - respiratory failure,
  - septic shock, and/or
  - multiple organ dysfunction or failure

The use of OXIRIS is contraindicated (as mentioned in the IFU) when:

- Patients present a known allergy to heparin or have type II thrombocytopenia caused by heparin (HIT Syndrome type II)
- A drug used simultaneously with OXIRIS is contraindicated per its Instructions for use

Relative contraindications (individual risk/benefit to be determined by treating physician) for the use of OXIRIS include:

- The inability to establish vascular access to safely perform CRRT/ hemoperfusion (SCUF; CVVH; CVVHD; CVVHDF)
- Severe hemodynamic instability
- Known hypersensitivity to any component of the OXIRIS Set

This set is intended for use in the following veno-venous therapies: SCUF; CVVH; CVVHD; CVVHDF.

All treatments administered with the OXIRIS Set must be prescribed by a physician. The size, weight, state of uremia, cardiac status, and general physical condition of the patient must be carefully evaluated by the prescribing physician before each treatment.

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

For more information, please contact your Baxter representative.

www.baxter.com

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USMP/MG146/20-0001 04/20