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Mini-invasive extracorporeal CO_2 removal system

ProLUNG®

ProLUNG® 3D
for the Aquarius™ System

A LUNG-PROTECTIVE STRATEGY

Distributed by:

NIKKISO

EGTOR

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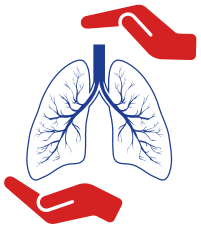
A LUNG-PROTECTIVE STRATEGY

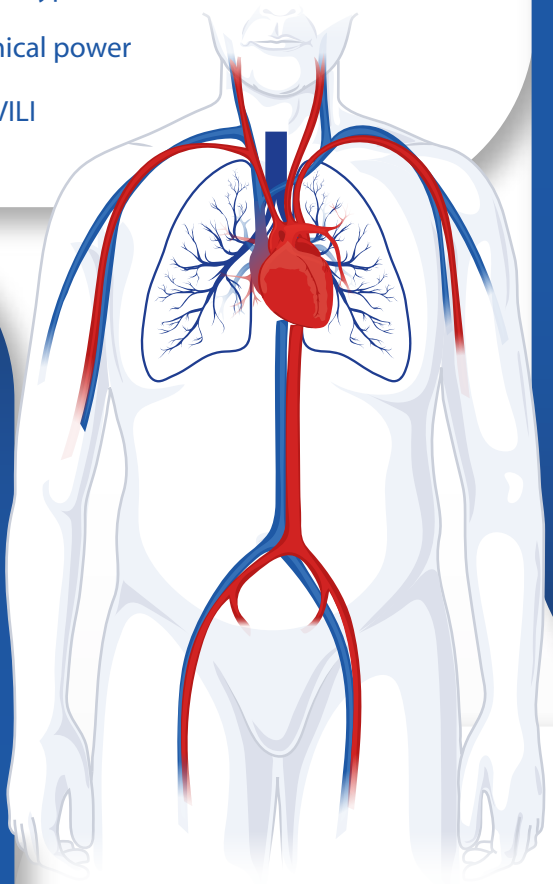
ENABLE PROTECTIVE VENTILATION



- Tidal volume/plateau pressure
- Dynamic hyperinflation
- Mechanical power
- Risk of VILI

PREVENT INTUBATION

- Hypercapnia
- Respiratory acidosis
- Ventilator-associated risks (VILI, VAP)

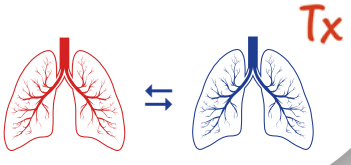


FACILITATE EXTUBATION

- Respiratory acidosis
- Diaphragm work effort
- Inspiratory effort
- Ventilator-associated risks (VILI, VAP)

BRIDGE TO TRANSPLANT[10,11]

- Hypercapnia
- Respiratory acidosis
- Risk of transplantation failure



PROLUNG®
QUALITY AND INNOVATION

ProLUNG® is the reference system for mini-invasive extracorporeal CO_2 removal ($ECCO_2R$). ProLUNG® has all the features necessary to guarantee quality ventilatory support with a clinical rationale: high CO_2 removal capacity (VCO_2 > 100 mL/min), low invasiveness for the patient (13-14 Fr bilumen catheter).

What characteristics should the ideal $ECCO_2R$ system have?

- ☐ High CO_2-removal performance
- ☐ Biocompatibility
- ☐ Reduced priming volume
- ☐ Prolonged kit duration
- ☐ Minimal invasiveness

Why choose ProLUNG®?

ProLUNG® 3D

- ☑ Optimal CO_2-removal capacity (VCO_2 > 100 mL/min at Qb = 400 mL/min)
- ☑ 1.81 m² membrane in polymethylpentene (PMP) covered with phosphorylcholine
- ☑ Priming volume of 125 mL (artificial lung)
- ☑ 3 days therapy (3D)

Double lumen catheter

- ☑ Low invasiveness: double lumen catheter ≥ 13 Fr
- ☑ Femoral, jugular or subclavian vascular access

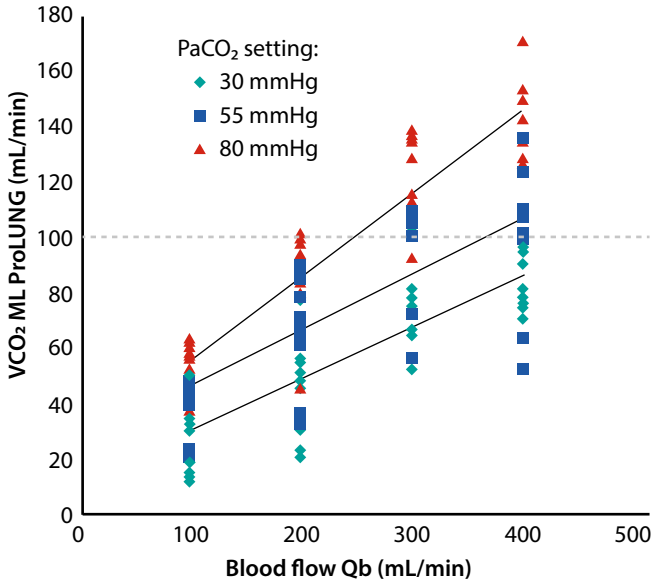
PROLUNG®
FROM THEORY TO PRACTICE

The research group of Gattinoni and Quintel at UMG carried out an animal study in 2018 to evaluate the CO_2-removal capacity of the ProLUNG® system under different conditions [1]. The study included 8 adult pigs with a body weight of 57 kg. The animals were sedated, ventilated and treated with ProLUNG® using a 13 Fr catheter. The CO_2-removal capacity of the VCO_2 ML system (membrane lung) was measured under different conditions of $PaCO_2$, blood flow (Qb) and medical air flow.

High CO_2-removal capacity VCO_2 > 100 mL/min

The measured VCO_2 reached a maximum value of 171 mL/min.

Typically, a removal of VCO_2 > 100 mL/min can be obtained with $PaCO_2$ settings between 55 and 80 mmHg, an extracorporeal blood flow (Qb) of 400 mL/min and a gas flow greater than 6 L/min.

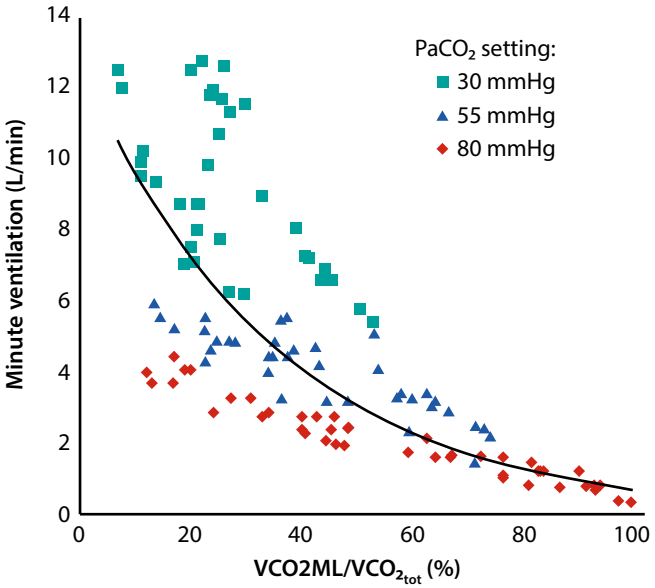


VCO_2 (ML) as a function of blood flow (Qb) and three different settings of $PaCO_2$: 30, 55 e 80 mmHg.

Reduction of ventilatory burden

Minute ventilation is reduced proportionally to the quantity of CO_2 removed by ProLUNG® (VCO_2 (ML)/$VCO_{2_{tot}}$).

With a $PaCO_2$ of 74 mmHg and pH 7.3, it was possible to remove up to 138.8 mL/min of CO_2 allowing a reduction of ventilation from 7.4 to 1.9 L/min with no complications. This corresponds to a reduction in mechanical power from 9.3 to 2.6 J/min.



Minute veintilation at 3 different settings of $PaCO_2$ plotted as a function of VCO_2(ML)/$VCO_{2_{tot}}$.

"Minimally invasive extracorporeal CO_2 removal removes a relevant amount of CO_2 thus allowing mechanical ventilation to be significantly reduced depending on extracorporeal blood flow and inflow PCO_2. Extracorporeal CO_2 removal may provide the physiologic prerequisites for controlling ventilator-induced lung injury.

The main result of this study was that a considerable amount of CO_2 was removed by the Estor ProLUNG system using only a minimally invasive cannulation and a blood flow rate similar to that used in renal dialysis".

Duscio et al. Crit Care Med. 2019, 47(1):33-40

PROLUNG®
CLINICAL APPLICATIONS

$ECCO_2R$ is a minimally invasive extracorporeal support for the management of ventilatory insufficiency[2]. $ECCO_2R$ can facilitate protective ventilation at low tidal volumes or low plateau pressures in patients in mechanical ventilation, as well as facilitating rapid extubation[3]. In patients undergoing non-invasive ventilation (NIV) at risk of failure, $ECCO_2R$ can prevent the invasiveness and complications of intubation [3-5].

COPD [6-9]

In COPD patients with exacerbations initially managed in NIV and at risk of failure, ProLUNG® reduces the risk of intubation, thus avoiding the associated comorbidities and the prolonged hospitalization associated with invasive mechanical ventilation. In COPD patients already in invasive mechanical ventilation, ProLUNG® contributes to protective ventilation with the aim of facilitating weaning from the ventilator.

ARDS [6,7]

In patients with moderate ARDS where it is not possible to pursue protective ventilation because of hypercapnic respiratory acidosis, ProLUNG® allows the setting of adequate tidal volumes and plateau pressures, thus avoiding the onset of volutrauma and barotrauma.

TRANSPLANTATION [10,11]

In all phases of lung transplantation (pre-intra-post), the use of ProLUNG® protects the lung, avoiding excessive ventilator load and allowing a better management of the transplantation procedure, thus avoiding the risk of having to resort to ECMO in an emergency.

TISSUE LESIONS [12]

In the presence of tissue lesions of the respiratory system (broncho-pleural fistulas, ruptures of the trachea or diaphragmatic lesions), the use of ProLUNG® facilitates protective ventilation.

REFRACTORY ASTHMA – EXACERBATION OF BRONCHIECTASIS [2,13]

In patients with refractory asthma or with exacerbation of bronchiectasis, ProLUNG® facilitates protective ventilation by reducing the load induced by invasive mechanical ventilation and normalizing blood pH values.

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A LUNG-PROTECTIVE STRATEGY

ProLUNG® PLAQUA3D	
Treatment modality	Hemoperfusion
Blood flow	Qb ≤ 450 mL/min (Aquarius™ system)
Membrane type	Polymethylpentene covered with phosphorylcholine
Membrane surface	1,81 m²
Priming volume	Around 250 mL (artificial lung (125 mL) + blood lines)
Sterilization	Ethylene oxide
Duration of single circuit	3 days
Rinsing and priming	2 L physiological solution with 10,000 IU of heparin
Vascular access	≥ 13 Fr double lumen central venous catheter

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For contraindications, warnings and precautions, please refer to Instruction For Use (IFU).