$ECCO_2R$ in ARF

Disclaimer on use of $ECCO_2R$ in COVID-19*

- A public health emergency has been declared by the Secretary of Health and Human Services (HHS) on February 4, 2020. The FDA has issued and Emergency Use Authorization for the Hemolung RAS to treat lung failure caused by Coronavirus Disease 2019 (COVID-19). Per the EUA, the FDA believes that the Hemolung RAS has the potential to treat lung failure as an adjunct to noninvasive or invasive mechanical ventilation, to reduce hypercapnia and hypercapnic acidosis due to COVID-19 and/or to maintain normalized levels of partial pressure of carbon dioxide (PCO_2) and pH in patients suffering from acute, reversible respiratory failure due to COVID-19 for whom ventilation of CO_2 cannot be adequately, safely, or tolerably achieved and, in turn, may provide clinical benefit.

***The Hemolung RAS an investigational medical device with an FDA-approved Investigational Device Exemption (IDE) for use in an ongoing clinical trial for patients with COPD who are experiencing acute hypercapnic respiratory failure. The Hemolung RAS has not been FDA cleared or approved.**

The Hemolung RAS has been authorized for the above emergency use by FDA under an EUA;

This device is authorized only for the duration of the declaration that circumstances exist justifying the authorization of the emergency use of the Hemolung RAS under Section 564(b)(1) of the Act, 21 U.S.C. § 360bbb- 3(b)(1), unless the authorization is terminated or revoked sooner.

Remember, $ECCO_2R$ is not ECMO!

ECMO

Indicated for treating refractory hypoxemia in the most severe cases of ARDS.

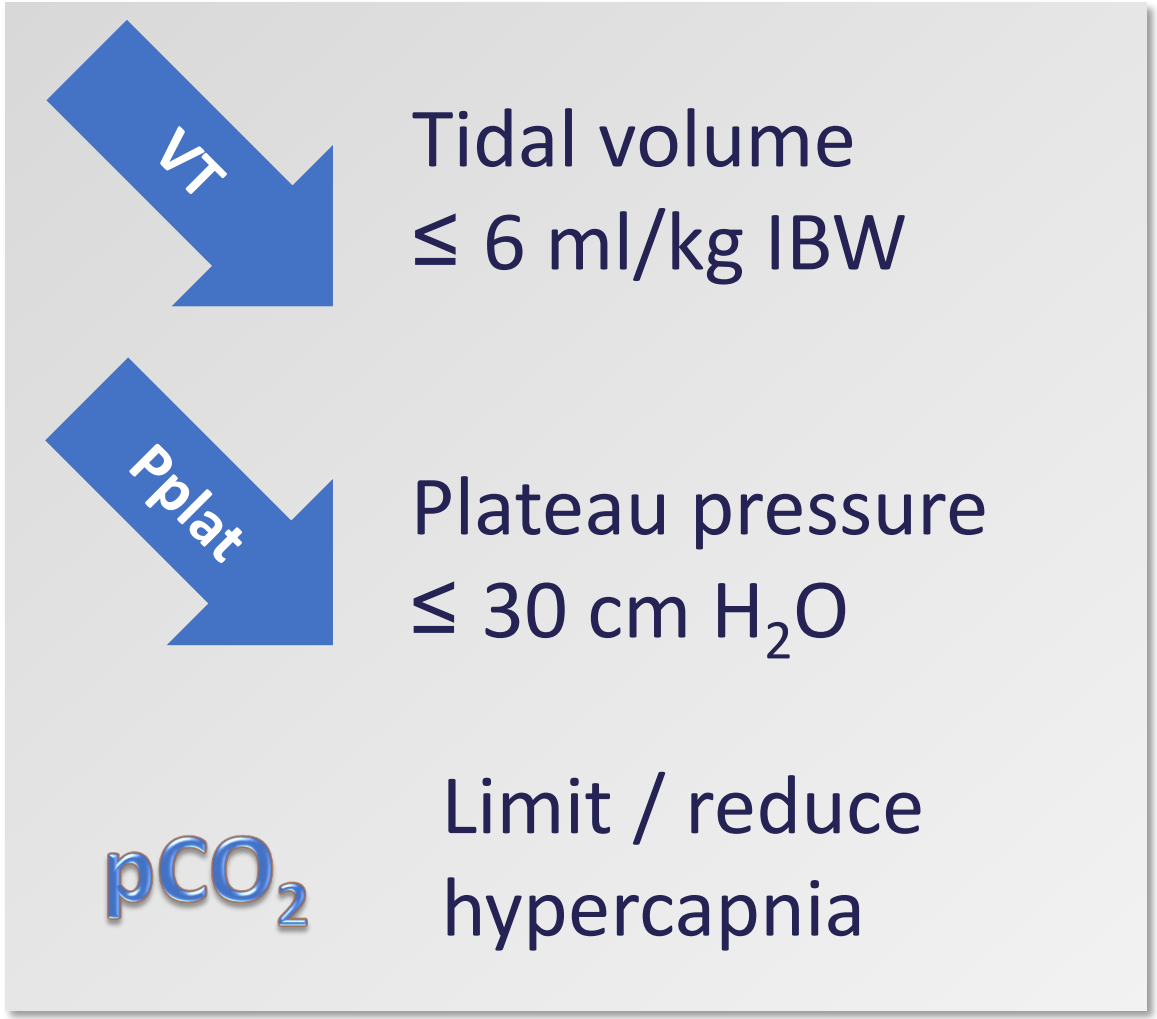
$ECCO_2R$

Indicated for facilitating lung protective ventilation in ALL stages of ARDS.

Early Intervention is Key

$ECCO_2R$ Facilitates Lung Protection

- ***Enables prevention or reduction of VILI***
  - Low-flow $ECCO_2R$ enables statistically significant reductions in tidal volume below 6 mL/kg (IBW) to **3-4 mL/kg** as well as reduction in minute ventilation, driving pressure, and peak airway pressures, while maintaining $PaCO_2$ and arterial pH to within 10% of normal range.



$ECCO_2R$ in Acute, Reversible, Respiratory Distress

Improves ventilator-free days

- In a randomized controlled study conducted by Bein et al. (2013) in 79 patients with moderate and to severe Acute Respiratory Distress Syndrome (ARDS), an ad hoc analysis of the subset of patients with severe ARDS found a statistically significant improvement in 60-day ventilator-free days (VFD) using low-flow, partial $ECCO_2R$ to enable ultra-low tidal volume ventilation compared to a standard-of-care control group treated with conventional ARDSNet low tidal volume ventilation alone.

For the SARS-CoV-2 epidemic and patients who develop acute, reversible respiratory distress associated with COVID-19, and in the spirit of Emergency Use, the Hemolung can be an important front-line tool in reducing time that patients spend on a ventilator to free ventilator availability for new patients.