FACT SHEET FOR HEALTHCARE PROVIDERS

Hemolung RAS **April 23, 2020**

Coronavirus Disease 2019 (COVID-19)

This Fact Sheet informs you of the potential benefits and risks associated with use of a critical care lung support device called the **Hemolung Respiratory Assist System (RAS)**. Hemolung therapy is referred to as extracorporeal carbon dioxide removal (ECCO2R), or respiratory dialysis.

The United States FDA has made Hemolung RAS available under an Emergency Use Authorization (EUA) for treatment of lung failure in Coronavirus Disease 2019 (COVID-19) patients when used an adjunct to noninvasive or invasive mechanical ventilation to reduce hypercapnia and hypercapnic acidosis, and/or (2) to maintain normalized levels of partial pressure of carbon dioxide (PCO2) and pH, in patients suffering from acute, reversible respiratory failure for whom ventilation of CO2 cannot be adequately, safely, or tolerably achieved.

The Hemolung RAS is **NOT** intended to provide extracorporeal membrane oxygenation (ECMO).

All patients and families of patients who will be treated with Hemolung RAS should receive the Fact Sheet for Patients: Hemolung Respiratory Assist System.

What are the symptoms of COVID-19?

Many patients with confirmed COVID-19 have developed fever and/or symptoms of acute respiratory illness (e.g., cough, difficulty breathing). However, limited information is currently available to characterize the full spectrum of clinical illness associated with COVID-19. Based on what is known about the virus that causes COVID-19, signs and symptoms may appear any time from 2 to 14 days after exposure to the virus. Based on preliminary data, the median incubation period is approximately 5 days, but may range 2-14 days.

Public health officials have identified cases of COVID-19 infection throughout the world, including the United States, which may pose risks for public health. Please check the CDC webpage for the most up to date information.

What do I need to know about use of the Hemolung RAS under an EUA?

- Use of the Hemolung RAS is authorized for treatment of lung failure in COVID-19 patients.
- The Hemolung RAS should only be used by specialist intensive care teams trained in its use. Providers should carefully review the Instructions for Use (IFU) to minimize risk of user error.
- "Hemolung CR4 Instructions for Use" should be used with the CR4 version of the Hemolung system and the "Hemolung RAS Instructions for Use" should be used with the CR3 version of the device.
- Use of appropriate personal protective equipment when caring for individuals suspected of having COVID-19 is recommended as outlined in the CDC *Interim Infection Prevention and Control Recommendations for Patients with Confirmed Coronavirus Disease 2019 (COVID-19)* or *Persons Under Investigation for COVID-19 in Healthcare Settings* or on the CDC webpage on *Infection Control*.
- Current information on COVID-19 for healthcare providers is available at CDC's webpage, *Information for Healthcare Professionals* (see links provided in "Where can I go for updates and more information" section below).

What is the Hemolung RAS and how does it function?

Therapy with the Hemolung RAS requires central venous cannulation with a 15.5 French dual lumen catheter and operates with extracorporeal blood flows of 350 - 550 mL/min.

The Hemolung RAS is intended to remove 30% - 50% of basal metabolic CO2 production. The Hemolung RAS is not intended to provide therapeutic levels of oxygenation.

Extracorporeal therapy with the Hemolung requires continuous systemic anticoagulation with unfractionated heparin to prevent clotting of blood in the circuit.

The Hemolung RAS is a fully integrated 3-component system consisting of A) the disposable Hemolung Cartridge with pre-connected circuit, B) the disposable Hemolung Catheter, and C) the Hemolung Controller.

- The Hemolung Cartridge is an integrated centrifugal pump and hollow fiber membrane blood gas exchanger with heparin-coated fibers having a surface area of 0.59 m2.
- The extracorporeal circuit has a priming volume of 260 mL with 6 feet of tubing.
- The Hemolung Catheter is inserted percutaneously using a standard Seldinger technique via either the right internal jugular vein or the femoral vein into the superior or inferior vena cava.
- The rate of CO2 removal provided by the Hemolung is controlled by increasing or decreasing

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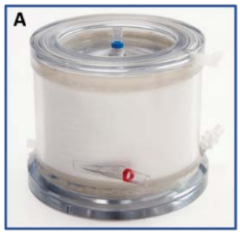
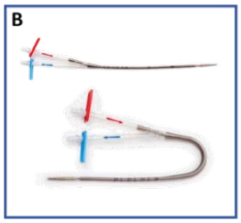
the sweep gas flow through the hollow fiber membranes. Sweep gas is room air that is pulled by negative pressure through the fibers by a vacuum pump in the Controller. No external oxygen or CO2 gas sources are needed.
- The Hemolung has been validated for at least 7 days of continuous use. The Cartridge can be exchanged if necessary.

What are the potential benefits and risks of Hemolung RAS / $ECCO_2R$?

Potential benefits of Hemolung RAS include:
- Ability to maintain safe pH and CO2 levels in the blood while enabling lung protective ventilation strategies (reduced tidal volumes and/or driving pressures) in patients with moderate to severe respiratory distress.
- Reduced time on mechanical ventilation

Potential risks of Hemolung RAS include:
- Complications associated with percutaneous insertion of a 15.5 French central venous catheter into SVC or IVC.
- Complications associated with exposure of blood to a pump-driven extracorporeal system at flows of 350 – 550 mL/min (e.g., thrombosis, thromboembolism, thrombocytopenia, hemolysis, anemia, coagulopathies).
- Complications associated with the requirement for systemic anticoagulation with unfractionated heparin (UFH) during therapy to prevent the blood from clotting from exposure to foreign materials (e.g., bleeding, intracranial hemorrhage, Heparin Induced Thrombocytopenia).
- Device malfunctions (e.g., circuit clotting, air in circuit, circuit rupture/leak, kinking of tubing)





- Pain or discomfort during or after catheterization
- Infection
- Hypothermia
- Minor or severe bleeding, possibly requiring transfusions
- Blood pressure instability, potentially severe
- Irregular heartbeat
- Systemic inflammation
- Kidney or liver failure

Contraindications:
- Use of Hemolung therapy is contraindicated in patients with known heparin sensitivity.
- Use of the Hemolung 15.5 Fr Femoral Catheter (not the Jugular Catheter) is contraindicated for patients with an inferior vena cava filter.

How should I monitor my patient during Hemolung therapy?

- Blood gases should be monitored regularly to assess Hemolung RAS impact and to prevent overcompensation of ventilatory support (i.e., alkalosis).
- Anticoagulation should be monitored regularly to maintain an aPTT between 1.5 – 2.3 times baseline or ACT between 150 – 180 seconds.
- Blood counts should be monitored daily for signs of anemia or thrombocytopenia.

What are the alternatives to Hemolung RAS / $ECCO_2R$, and the known and potential benefits and risks of such products?

The alternatives to use of Hemolung therapy as an adjunct to mechanical ventilation are:

- Use of mechanical ventilation alone in accordance with current standard practice.
  - The primary risks of standard mechanical ventilation alone are ventilator-induced lung injury, which is known to increase time on mechanical ventilation and mortality, and dangerous levels of PaCO2 and pH.
  - The benefits are lung support without added risks of extracorporeal therapy.
- Use of Extracorporeal Membrane Oxygenation (ECMO) for very severe respiratory distress (when PaO2/FiO2 < 80) with refractory hypoxemia.
  - ECMO is intended to provide full lung support or cardiopulmonary support. The risks of ECMO are similar in nature to low-

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flow ECCO2R, but greater in degree. ECMO requires a much larger catheter or two separate catheters, high blood flows of 5-7 L/min, blood exposure to greater membrane surface area, and more complex device operation.
- The benefit of ECMO is that it provides both oxygenation support and CO2 removal.

What is an EUA?

The EUA is supported by the Secretary of Health and Human Service's (HHS's) declaration that circumstances exist to justify the emergency use of medical devices due to shortages during the COVID-19 pandemic.

The Hemolung RAS, made available under an EUA, has not undergone the same type of review as an FDA-approved or cleared device. FDA may issue an EUA when certain criteria are met, which includes that there are no adequate, approved, available alternatives, and based on the totality of scientific evidence available, it is reasonable to believe that use of Hemolung RAS meets certain criteria for safety, performance, and labeling, and may be effective in treatment of lung failure in COVID-19 patients.

This EUA is in effect for the duration of the COVID-19 declaration justifying emergency use of these devices, unless terminated or revoked (after which the products may no longer be used).

Where can I go for updates and more information?

CDC webpages:
General: https://www.cdc.gov/COVID19
Healthcare Professionals: https://www.cdc.gov/coronavirus/2019-nCoV/guidance-hcp.html
Infection Prevention and Control Recommendations in Healthcare Settings: https://www.cdc.gov/coronavirus/2019-ncov/infection-control/control-recommendations.html
Infection Control: https://www.cdc.gov/coronavirus/2019-ncov/infection-control/index.html
FAQ on Personal Protective Equipment: https://www.cdc.gov/coronavirus/2019-ncov/hcp/respirator-use-faq.html

FDA webpages:
General: www.fda.gov/novelcoronavirus
EUAs: https://www.fda.gov/medical-devices/emergency-situations-medical-devices/emergency-use-authorizations

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