FACT SHEET FOR PATIENTS

Hemolung RAS **April 23, 2020**

Coronavirus Disease 2019 (COVID-19)

You are being given this Fact Sheet because you experienced acute, but reversible, lung failure caused by COVID-19. You required life support with a mechanical ventilator, but even with a ventilator, a dangerous buildup of carbon dioxide in your blood occurred. To maintain life support, a device that provides extracorporeal carbon dioxide removal will be used because your healthcare provider believes your risk of dying from lung failure is increasing.

This Fact Sheet contains information to help you understand the risks and benefits of using this extracorporeal carbon dioxide removal ($ECCO_2R$), or respiratory dialysis, device for the treatment of lung failure caused by COVID-19. After reading this Fact Sheet, if you have questions or would like to further discuss the information provided, please talk to your healthcare provider.

For the most up to date information on COVID-19, please visit the CDC Coronavirus Disease 2019 (COVID-19) webpage: https://www.cdc.gov/COVID19

What is COVID-19?
COVID-19 is caused by the SARS-CoV-2 virus. The virus, which can cause mild to severe respiratory illness, was first identified in Wuhan, China, and has now spread globally, including the United States. There is limited information available about the different types of illness that one may show if infected with the virus. The virus most likely spreads to others when a person shows signs or symptoms of being sick (e.g., fever, coughing, difficulty breathing, etc.).

What is the Hemolung Respiratory Assist System?
The Hemolung Respiratory Assist System, or Hemolung RAS, is designed to remove excess carbon dioxide from the blood to support the lungs. The Hemolung RAS works just like a kidney dialysis machine except it removes carbon dioxide waste molecules to support the lungs instead of the kidneys. Like critical care dialysis, treatment with the Hemolung RAS uses a catheter that is inserted in a vein in the neck or upper leg. Blood is drawn through the catheter and through a cartridge which removes carbon dioxide. Treatment may last between 2 to 7 days, but in severe cases, possibly longer. To receive $ECCO_2R$ therapy with the Hemolung RAS, it is necessary to administer a medicine called heparin to prevent your blood from clotting.

Why will this $ECCO_2R$ device be used on me?
You developed lung complications because you were exposed to the virus that causes COVID-19. The lung complications first caused difficulty breathing that worsened until your lungs became unable to provide your body with enough oxygen or to remove enough of the carbon dioxide waste. You required life support with a mechanical ventilator. Under certain conditions, such as in severe cases of COVID-19, it is hard for a mechanical ventilator to push in enough air into the lungs without causing more lung damage. As the mechanical ventilator ran at the needed level, carbon dioxide was building up in your blood to dangerous levels. Your physician will use the Hemolung RAS to remove the carbon dioxide so the ventilator can help your body get oxygen.

What are the known and potential risks and benefits of the Hemolung RAS?

Known and potential benefits include:

- Enable reductions in mechanical ventilation settings, which may be less traumatic to your lungs, while maintaining safe levels of carbon dioxide in the blood
- May decrease the amount of time on mechanical ventilation

Known and potential risks include:

- Catheter complications
- Pain or discomfort during or after catheterization
- Infection
- Hypothermia
- Minor or severe bleeding, possibly requiring transfusions
- Blood cell damage or other changes to blood chemistry
- Blood clotting
- Blood pressure instability, potentially severe
- Irregular heart beat
- Stroke (from intracranial bleed)

- **Have a problem with the device performance or results?** Report adverse events to MedWatch by submitting the online FDA Form 3500 (https://www.accessdata.fda.gov/scripts/medwatch/index.cfm?action=reporting.home) or by calling 1-800-FDA-1088.
- **How can I learn more?** The most up-to-date information on COVID-19 is available at the CDC webpage: https://www.cdc.gov/COVID19. In addition, please also contact your healthcare provider with any questions/concerns.

- Systemic inflammation
- Kidney or liver failure
- Device failure

Complication risks should be closely monitored by your physician during use. In rare circumstances, some of the above complications can lead to death. Your physician is aware of these risks and has determined that the severity of your condition and the potential benefits of Hemolung RAS therapy outweigh these risks.

Is the Hemolung RAS FDA-approved or cleared?

No. This type of medical device is not yet approved or cleared by the United States (U.S.) FDA. Instead, FDA has made this $ECCO_2R$ device available under an emergency access mechanism called an Emergency Use Authorization (EUA).

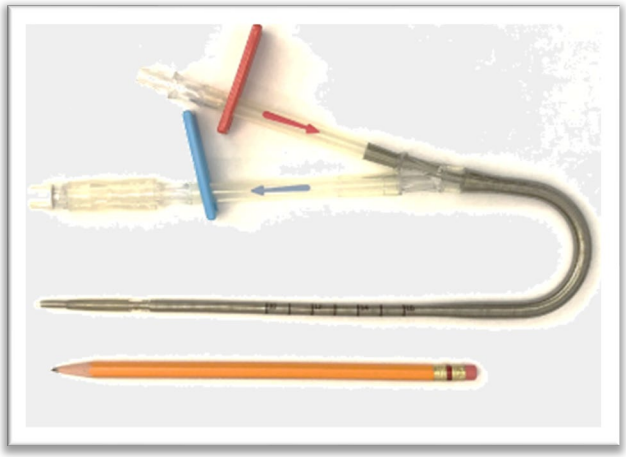
You may discuss any questions or concerns with your health care provider. You have the option at any time to refuse treatment with this device or to stop therapy with this device. If you choose to stop therapy, you will be treated with best practice mechanical ventilation support.

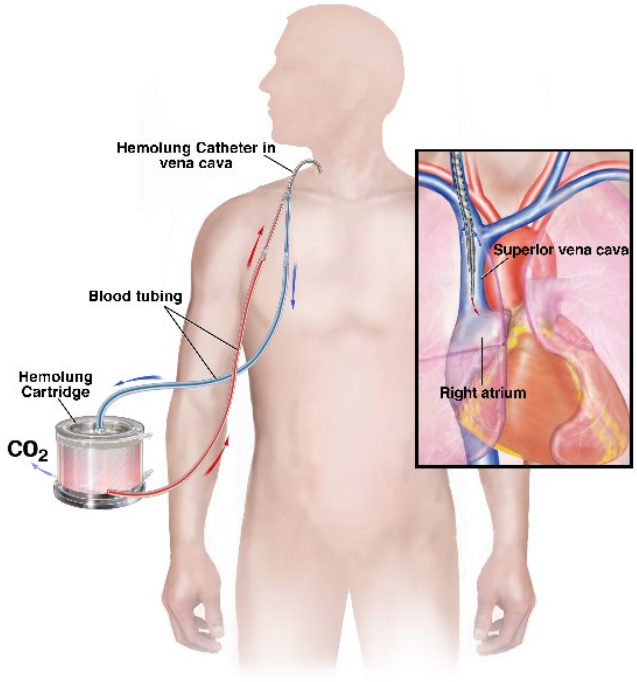
What is an EUA?
The EUA is supported by the Secretary of Health and Human Service's declaration that circumstances exist to justify the emergency use of medical devices during the COVID-19 pandemic.

These devices have 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, or available alternatives. In addition, the FDA decision is based on the totality of scientific evidence available showing that it is reasonable to believe that the device that meets certain criteria for safety, performance, and labeling, and that it may be effective in treating lung failure in patients with COVID-19.

The EUA for the Hemolung RAS device 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).

Illustrations of Hemolung RAS Therapy
The following illustrations show what the Hemolung Catheter looks like, and how the catheter is used so that blood can pass through the Hemolung Cartridge to remove carbon dioxide.





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