FACT SHEET FOR PATIENTS

Emergency Use of CAPIOX Emergency Bypass System During the COVID-19 Pandemic

November 21, 2020

Coronavirus Disease 2019 (COVID-19)

You are being given this Fact Sheet because your healthcare provider recommends using the CAPIOX Emergency Bypass System (or "CAPIOX EBS") to treat your acute respiratory failure or acute cardiopulmonary failure caused by COVID-19 because other available treatment options have failed and continued clinical deterioration is expected, or your life is in imminent danger. Acute respiratory failure or acute cardiopulmonary failure means you are not getting enough oxygen into your blood or removing enough carbon dioxide out of your body.

This Fact Sheet contains information to help you understand the known and potential risks and benefits of the use of the CAPIOX EBS to treat your acute respiratory failure or acute cardiopulmonary failure caused by COVID-19 complications. After reading this Fact Sheet, if you have questions or would like to discuss the information provided further, 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, which is a new virus in humans causing a contagious respiratory illness. COVID-19 can present with a mild to severe illness, although some people infected with COVID-19 may have no symptoms at all. Older adults and people of any age who have underlying medical conditions have a higher risk of severe illness from COVID-19. Serious outcomes of COVID-19 include hospitalization and death. The SARS-CoV-2 virus can be spread to others not just while one is sick, but even before a person shows signs or symptoms of being sick (e.g., fever, coughing, difficulty breathing, etc.). A full list of symptoms of COVID-19 can be found at the following link: https://www.cdc.gov/coronavirus/2019-ncov/symptoms-testing/symptoms.html.

What is the CAPIOX EBS?

The CAPIOX EBS provides extraocoporeal life support by acting as an artificial heart and lung for a critically ill patient (also known as extracorporeal membrane oxygenation, or ECMO, therapy). It includes a blood loop that contains an artificial lung (oxygenator) and an artificial heart (blood pump), a console that drives the blood pump, and a cannula (plastic tube) kit.

Why will the CAPIOX EBS be used as part of my care?

You are experiencing acute respiratory failure or acute cardiopulmonary failure caused by COVID-19 and other available treatment options have failed. As a result, the oxygen levels in your blood is dangerously low.

The CAPIOX EBS helps remove carbon dioxide from your blood and add oxygen to your blood. While the CAPIOX EBS is working, your lungs and heart have time to rest and heal. After your lungs and heart recover, the CAPIOX EBS will be removed.

What are the known and potential risks and benefits of the CAPIOX EBS?

Known and potential benefits of the CAPIOX EBS include:

- Adding enough oxygen into your blood and removing enough carbon dioxide from your blood or pumping enough blood to your body to keep you alive

Known and potential risks of the CAPIOX EBS include:

- Complications associated with inserting the cannulas into your blood vessels
- Complications associated with exposure of blood to a pump-driven blood loop (for example, blood clots, obstruction of a blood vessel by a blood clot that has become dislodged from the blood loop, low blood platelet count, rupture or destruction of red blood cells, lack of red blood cells, and impaired ability of the blood to form clots)

How can I learn more? The most up-to-date information on COVID-19 is available at the CDC General Webpage: https://www.cdc.gov/COVID19. In addition, please also contact your healthcare provider with any questions/concerns.

- Complications associated with the requirement for using a blood thinner called heparin during therapy to prevent the blood from clotting in the blood loop (for example, bleeding, bleeding inside the skull or brain, low blood platelet count)
- Device malfunctions (for example, blood loop clotting, air in blood loop, blood loop rupture/leak, kinking of tubing)
- Pain or discomfort during or after insertion of the cannulas
- Infection
- Body temperature drops below normal levels
- Minor or severe bleeding, possibly requiring transfusions
- Blood pressure instability, potentially severe
- Irregular heartbeat
- Systemic inflammation
- Kidney or liver failure

Your doctor will determine if you are an appropriate patient for CAPIOX EBS.

You have the option to refuse this product. If you choose to decline use of this device, you should discuss any alternative options with your healthcare provider.

How is the CAPIOX EBS device used?

A healthcare provider will place cannulas in large blood vessels in your legs or neck. Oxygen-poor blood is drawn from your body through one tube and then pumped to an oxygenator that adds oxygen to the blood and removes carbon dioxide from the blood. The oxygen-rich blood is then pumped back into your body through the other tube.

When should the CAPIOX EBS device NOT be used?

The CAPIOX EBS is contraindicated in patients with the following conditions:

- Allergic to heparin
- Blood filter in the inferior vena cava (the large vein that carries the oxygen-poor blood from the lower and middle part of the body into the right upper chamber of the heart)

Please talk to your doctor about whether any of these conditions apply to you.

What are the approved alternatives to treat acute respiratory failure or acute cardiopulmonary failure caused by COVID-19?

There are currently no adequate, approved, and available alternatives to treat acute respiratory failure or acute cardiopulmonary failure associated with COVID-19 when other available treatment options have failed, and continued clinical deterioration is expected or the risk of death is imminent. While FDA-approved or cleared cardiopulmonary bypass devices are being used clinically for ECMO therapy, they are not FDA-approved or cleared for such use. In addition, there is one alternative full ECMO system that is FDA-cleared and there is also one FDA-cleared oxygenator module for use as a component in an ECMO system. However, these cleared alternatives are not sufficiently available during the COVID-19 pandemic due to increased demand.

Is the CAPIOX EBS FDA-approved or cleared for treating my condition?

No. The CAPIOX EBS is not approved or cleared by the United States FDA. Rather, the FDA has made the CAPIOX EBS available under an emergency access mechanism called an Emergency Use Authorization (EUA).

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What is an EUA?

This 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, during the COVID-19 pandemic.

The use of the CAPIOX EBS available under this 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, or available alternatives. In addition, the FDA decision is based on the totality of scientific evidence available demonstrating that it is reasonable to believe that the CAPIOX EBS may be effective for treating COVID-19.

The EUA for the CAPIOX EBS is in effect for the duration of the COVID-19 declaration justifying emergency use of the product, unless terminated or revoked (after which the product may no longer be used).