

# FACT SHEET FOR HEALTHCARE PROVIDERS

Emergency Use of CAPIOX Emergency Bypass System During the COVID-19 Pandemic  
November 21, 2020

Coronavirus  
Disease 2019  
(COVID-19)

This Fact Sheet informs you of the significant known and potential risks and benefits of the emergency use of the Terumo CAPIOX Emergency Bypass System (or "CAPIOX EBS") for use by healthcare providers in the hospital setting for providing long-term (> 6 hours) respiratory or cardiopulmonary support to treat patients 18 years or older with Coronavirus Disease 2019 (COVID-19) who have acute respiratory failure or acute cardiopulmonary failure, where other available treatment options have failed, and continued clinical deterioration is expected or the risk of death is imminent.

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**All patients who are treated with this device during the COVID-19 pandemic will receive the Fact Sheet for Patients: Emergency Use of CAPIOX Emergency Bypass System During the COVID-19 Pandemic.**

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## What do I need to know about COVID-19 and associated complications, specifically acute respiratory failure or acute cardiopulmonary failure?

Current information on COVID-19 infection, including case definitions and information about clinical signs and symptoms and/or epidemiological criteria, is available on the CDC website listed at the end of this fact sheet.

COVID-19 can cause severe acute respiratory syndrome (SARS), which in turn can trigger acute respiratory and/or acute cardiopulmonary failure in patients. Extracorporeal membrane oxygenation (ECMO) is a treatment that uses a pump to circulate blood through an artificial lung back into the bloodstream of a patient. ECMO is considered a treatment option for these critically ill patients, when other available treatment options have failed, and continued clinical deterioration is expected or the risk of death is imminent.

## What is the CAPIOX EBS?

The CAPIOX EBS is an extracorporeal life support system comprised of the following components:

- The CAPIOX EBS Circuit is a kit consisting of a membrane oxygenator with microporous polymethylpentene (PMP) hollow fibers, a centrifugal pump, and blood tubing. The blood contacting surfaces are coated with proprietary X coating.
- The CAPIOX Centrifugal Pump Controller controls and drives the disposable centrifugal pump in the CAPIOX EBS Circuit.
- The CAPIOX EBS Cannula Kit consists of cannulas used to connect the blood vessels to the circuit and supporting tools for catheterization. The kit includes one cannula, one dilator, one entry needle, one guide wire, pre-dilators, one syringe, and one scalpel. The blood contacting surface of the cannula is coated with X coating.

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

Known and potential benefit of the CAPIOX EBS includes:

- Maintaining an adequate amount of gas exchange or perfusion to sustain life

The CAPIOX EBS has been designed to minimize the risks of complications associated with its use. However, known and potential risks of the CAPIOX EBS include:

- Complications associated with percutaneous catheterization
- Complications associated with exposure of blood to a pump-driven extracorporeal system (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 due to exposure to foreign materials (e.g., bleeding, intracranial)

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**Report Adverse events**, including problems with test performance or results, 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**

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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 of the CAPIOX EBS

CAPIOX EBS is contraindicated for patients with the following conditions:

- Known heparin sensitivity
- Placement of an inferior vena cava filter

## What are the alternatives to treat acute respiratory failure or acute cardiopulmonary failure associated with COVID-19 complications?

FDA has determined that 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 under K191407 and there is one oxygenator module for use as a component in an ECMO system that is FDA-cleared under K191935. However, based on disease projection models driving increased demand, these cleared alternatives are not sufficiently available during the COVID-19 pandemic.

## What is an Emergency Use Authorization (EUA)?

The United States Food and Drug Administration (FDA) has authorized the emergency use of the CAPIOX EBS for use by healthcare providers in the hospital setting for providing long-term (> 6 hours) respiratory or cardiopulmonary support to treat patients 18 years or older with COVID-19 who have acute respiratory failure or acute cardiopulmonary failure where other available treatment options have failed, and continued clinical deterioration is expected or the risk of death is imminent. 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, including alternative devices used as medical devices, due to shortages, during the COVID-19 outbreak.

The authorized use of the CAPIOX EBS 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, 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 CAPIOX EBS may be effective for the authorized emergency use.

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 for the emergency use).

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## How can I learn more?

### **CDC websites:**

**General:** <https://www.cdc.gov/COVID19>

**Healthcare Professionals:**

<https://www.cdc.gov/coronavirus/2019-nCoV/guidance-hcp.html>

### **FDA websites:**

**General:** [www.fda.gov/novelcoronavirus](http://www.fda.gov/novelcoronavirus)

**EUAs:** <https://www.fda.gov/medical-devices/emergency-situations-medical-devices/emergency-use-authorizations>

**Manufacturer:** Terumo Cardiovascular

6200 Jackson Road

Ann Arbor, MI 48103

**For Technical Assistance:**

Phone: (800) 441-3220 (24/7)

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