FACT SHEET FOR HEALTHCARE PROVIDERS

Emergency Use of the oXiris Set Device for COVID-19
April 22, 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 oXiris Set device for the reduction of pro-inflammatory mediators.

The oXiris Set device is authorized for emergency use to treat patients 18 years of age or older with confirmed COVID-19 admitted to the intensive care unit (ICU) with confirmed or imminent respiratory failure in need of blood purification, including use in continuous renal replacement therapy.

All patients who are treated with the oXiris Set device during the COVID-19 pandemic will receive the Fact Sheet for Patients: Emergency Use of the oXiris Set Device to Treat Patients with COVID-19

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 the emergency use of the oXiris Set device?

- The oXiris Set device has been authorized to treat patients 18 years of age or older with confirmed COVID-19 admitted to the ICU with confirmed or imminent respiratory failure in need of blood purification, including use in continuous renal replacement therapy, with any one of the following conditions:
  a) Early acute lung injury (ALI)/early acute respiratory distress syndrome (ARDS); or
  b) Severe disease, defined as:
     1) dyspnea,
     2) respiratory frequency ≥ 30/min,
     3) blood oxygen saturation ≤ 93%,
     4) partial pressure of arterial oxygen to fraction of inspired oxygen ratio < 300, and/or
     5) lung infiltrates > 50% within 24 to 48 hours; or
  c) Life-threatening disease, defined as:
     1) respiratory failure,
     2) septic shock, and/or
     3) multiple organ dysfunction or failure.
- The oXiris Set device is only for use with the Prismaflex control unit or with the PrisMax control unit.
- Healthcare providers should review the instructions accompanying the oXiris Set device, entitled “oXiris Set Instructions for Use.”

Use appropriate personal protective equipment when caring for individuals suspected of having COVID-19 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).

What are the known and potential benefits and risks of the oXiris Set device?

Potential benefits of the oXiris Set device include:

- Reduction of circulating inflammatory mediators

Potential risks of the oXiris Set device include:

- Hemodynamic compromise (e.g., hypotension, increased vasopressor requirement, reduced cardiac perfusion)
- Arrhythmia
- Blood loss
- Thrombosis
- Air embolism
- Infection
- Hemolysis
- Electrolyte imbalance
- Particle embolism
- Thrombocytopenia / leukopenia
- Allergic reaction to device materials
- Unintended removal of other blood substances (e.g., vitamins, proteins, medications)
- Risks related to vascular access placement (e.g., infection, blood loss, thrombosis, tissue/organ injury)
- Risks related to anticoagulation (e.g., blood loss, allergic reaction)

What is an EUA?

The United States FDA has made the oXiris Set device for the reduction of cytokine levels and the associated pro-inflammatory mediators in patients 18 years of age or older with COVID-19 admitted to the ICU with confirmed or imminent respiratory failure in need of blood purification, including use in continuous renal replacement therapy, available under an emergency access mechanism called an Emergency Use Authorization (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, including alternative devices used as medical devices, due to shortages during the COVID-19 pandemic.

The oXiris Set device 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 the oXiris Set device meets certain criteria for safety, performance, and labeling, and that it may be effective in treating patients 18 years of age or older during the COVID-19 pandemic.

The EUA for the oXiris Set device for the reduction of cytokine levels and associated pro-inflammatory mediators to treat patients 18 years of age or older with COVID-19 admitted to the ICU with confirmed or imminent respiratory failure in need of blood purification, including use in continuous renal replacement therapy, is in effect for the duration of the COVID-19 emergency 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

FDA webpages:
General: www.fda.gov/novelcoronavirus
EUAs: (includes links to patient fact sheet and manufacturer's instructions) https://www.fda.gov/medical-devices/emergency-situations-medical-devices/emergency-use-authorizations