

FACT SHEET FOR HEALTHCARE PROVIDERS

Emergency Use of the Prismaflex HF20 Set during the COVID-19 Pandemic

August 10, 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 Prismaflex HF20 Set to provide continuous renal replacement therapy (CRRT) to treat low weight (8-20 kg) and low blood volume patients who have acute renal failure, fluid overload, or both, and who cannot tolerate a larger extracorporeal circuit volume in an acute care environment during the COVID-19 pandemic.

All patients who are treated with the Prismaflex HF20 Sets during the COVID-19 pandemic will receive the Fact Sheet for Patients: Emergency Use of Prismaflex HF 20 Set during the COVID-19 Pandemic

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). The current information available to characterize the spectrum of clinical illness associated with COVID-19 suggests that symptoms include cough, shortness of breath or dyspnea, fever, chills, myalgias, headache, sore throat or new loss of taste smell. 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 is the Prismaflex HF20 Set?

The Prismaflex HF20 Set is a disposable, extracorporeal circuit that is used with a control unit to provide CRRT to treat patients of low weight (8-20 kg) and low blood volume or who cannot tolerate a larger extracorporeal circuit volume. The Prismaflex HF20 Set should only be used with the Prismaflex control unit or the PrisMax control unit.

What do I need to know about the emergency use of the Prismaflex HF20 Set?

- Healthcare providers should review the instructions for use and insert accompanying the Prismaflex HF20 Set, entitled "Prismaflex HF20 Set."

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 alternatives to the Prismaflex HF20 Set for providing CRRT during the COVID-19 pandemic?

There are no FDA-approved or -cleared alternatives to the Prismaflex HF20 Set to provide CRRT to treat patients of low weight (8-20 kg) and low blood volume or who cannot tolerate a larger extracorporeal circuit volume.

What are the known and potential benefits and risks of using the Prismaflex HF20 Set for CRRT?

Potential benefits of CRRT, including the use of the **Prismaflex HF20 Set** include:

- Correction of acid-base abnormalities
- Correction of electrolyte abnormalities
- Correction of volume overload
- Removal of "uremic" and other toxins

Potential risks of CRRT, including the use of the **Prismaflex HF20 Set** include:

- Hemodynamic compromise (e.g., hypotension, increased vasopressor requirement, reduced cardiac perfusion)
- Arrhythmia
- Blood loss
- Thrombosis
- Air embolism
- Particle embolism
- Infection or pyrogen reaction
- Hemolysis
- Hypothermia
- Thrombocytopenia
- Allergic reaction to device materials or sterilant residuals

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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- Electrolyte or glucose abnormalities (e.g., hypokalemia, hypophosphatemia, hypomagnesemia, hypocalcemia, hypernatremia)
- Acid-base abnormalities (e.g., metabolic acidosis/alkalosis)
- Unintended removal of other blood substances (e.g., vitamins, proteins, trace minerals, 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)

Relative contraindications (individual risk/benefit to be determined by treating physician) for use of the Prismaflex HF20 Set include:

- The inability to establish vascular access
- Severe hemodynamic instability
- Known hypersensitivity to any component of the Prismaflex HF20 Set

Is the Prismaflex HF20 Set FDA-approved or cleared?

No. The Prismaflex HF20 Set is not FDA-approved or cleared. The FDA has authorized this use of the Prismaflex HF20 Set through an emergency access mechanism called an Emergency Use Authorization (EUA).

What is an EUA?

The United States (U.S.) FDA has issued an Emergency Use Authorization (EUA) for the Prismaflex HF20 Set available to provide CRRT to treat patients in an acute care environment during the COVID-19 outbreak. The EUA is supported by the Secretary of Health and Human Service (HHS) 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 Prismaflex HF20 Set 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 it is reasonable to believe that the Prismaflex HF20 Set has met certain

criteria for safety, performance, and labeling and may be effective in providing continuous renal replacement therapy to treat patients in an acute care environment during the COVID-19 outbreak.

The EUA for the Prismaflex HF20 Set is in effect for the duration of the COVID-19 declaration justifying emergency use of these products, 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>

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