

FACT SHEET FOR HEALTHCARE PROVIDERS

**Coronavirus
Disease 2019
(COVID-19)**

Emergency Use of the Prismaflex ST Set during the COVID-19 Pandemic
May 20, 2020

This Fact Sheet informs you of the significant known and potential risks and benefits of the emergency use of the Prismaflex ST Set to provide continuous renal replacement therapy (CRRT) to treat patients in an acute care environment during the COVID-19 pandemic.

All patients who are treated with the Prismaflex ST Sets during the COVID-19 pandemic will receive the Fact Sheet for Patients: Emergency Use of the Prismaflex ST 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 or 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 ST Set?

The Prismaflex ST Set is a disposable, extracorporeal circuit that is used with a control unit to provide CRRT. The Prismaflex ST 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 ST Set?

- The Prismaflex ST Set has been authorized to provide CRRT to treat patients in an acute care environment during the COVID-19 pandemic. The system is intended for patients who have acute renal failure, fluid overload, or both.
- Healthcare providers should review the instructions accompanying the Prismaflex ST Set, entitled “IFU Insert Prismaflex ST Set” and “Prismaflex ST60 Set / ST100 Set / ST150 Set AN69 ST Membrane.”

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 ST Set for providing CRRT during the COVID-19 pandemic?

The only possible alternative to the Prismaflex ST Set is the FDA-cleared version of the product called the Prismaflex M Set, which may not be available due to the shortage. The virus that causes COVID-19, has led to an increased population with critical illness and multiple organ failure, including acute kidney injury, increasing the need for CRRT. The increased number of patients in the hospital and ICU has caused US demand for CRRT filter sets to rapidly increase. As a result, there is a shortage of devices and accessories to provide CRRT in critically ill patients. The manufacturer’s control units available in the US can only be used with the manufacturer’s own extracorporeal circuit sets, Prismaflex ST Set or Prismaflex M Set.

The differences between the Prismaflex M Set and the subject Prismaflex ST Set are that the Prismaflex ST Set contains a polyethyleneimine surface treatment on the membrane (intended to reduce local thrombogenesis) and the ST100 and M100 models have different

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membrane effective surface areas (1m² for the proposed ST100 versus 0.9m² for the FDA-cleared M100). For completeness, the ST60 and M60 models have the same membrane effective surface areas, and the ST150 and the M150 models have the same membrane effective surface area. The differences between the Prismaflex M Set and the Prismaflex ST Set should not impact the overall potential risks or benefits of CRRT. FDA authorized use of the Prismaflex ST Set to be used as an alternative to the FDA-cleared Prismaflex M Set because the Prismaflex M Set may be unavailable due to shortages during the COVID-19 outbreak.

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

Potential benefits of using the Prismaflex ST Set for CRRT include:

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

Potential risks of using the Prismaflex ST Set for CRRT 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
- 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)

Is the Prismaflex ST Set FDA-approved or cleared?

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

What is an EUA?

The United States (U.S.) FDA issued an Emergency Use Authorization (EUA) for the Prismaflex ST Set when used to provide CRRT to treat patients in an acute care environment during the COVID-19 pandemic. The EUA is supported by a 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 ST 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 that it is reasonable to believe that the Prismaflex ST 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 pandemic.

The EUA for the Prismaflex ST 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).

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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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