

FACT SHEET FOR PATIENTS

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

August 10, 2020

Coronavirus Disease 2019 (COVID-19)

You, or your child, are being given this Fact Sheet because your healthcare provider believes it is necessary to provide you with continuous renal replacement therapy (CRRT) with the Prismaflex HF20 Set.

This Fact Sheet contains information to help you understand the benefits and risks of using the Prismaflex HF20 Set for your CRRT treatment. After reading this Fact Sheet, if you have questions or would like to discuss the information provided, 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 a disease caused by the SARS-CoV-2 virus. The virus, can cause mild to severe respiratory illness and has spread globally, including the United States. The current information available to characterize the spectrum of clinical illness associated with COVID-19 suggests that symptoms include cough, shortness of breath or difficulty breathing, fever, chills, muscle pain, headache, sore throat or new loss of taste or smell.

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. CRRT is a type of “dialysis” therapy used to filter and

clean your blood when your kidneys are damaged or are not functioning normally.

Why will the Prismaflex HF20 Set be used on me?

A healthcare provider may choose to treat you with the Prismaflex HF20 Set if your kidneys are damaged or not functioning normally and you require CRRT.

What are the known and potential benefits and risks of CRRT, including the use of the Prismaflex HF20 Set?

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

- Correcting the acid-base in your blood
- Correcting electrolyte imbalances in your blood
- Removing excess fluid from your blood
- Removing toxins (other chemicals that can cause harm) from your blood

Potential risks of using the Prismaflex HF20 Set include:

- Very low blood pressure and reduced delivery of blood to vital organs
- Abnormal heart rhythm
- Bleeding
- Clotting
- Stroke from air or particulate matter in the bloodstream
- Infection or fever reaction
- Damage to blood cells
- Reduction of body temperature / chills
- Reduction in blood cells (platelets and white blood cells) that help the blood clot or protect against infection
- Allergic reaction to device
- Abnormalities in your blood substances (e.g., low potassium, low phosphate) or glucose

-
- **Where can I go for updates and more information?** 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.
 - **Have a problem with the product performance or results?** Report adverse events 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.
-

FACT SHEET FOR PATIENTS

Coronavirus Disease 2019 (COVID-19)

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

August 10, 2020

- Abnormalities in your blood acid-base status (e.g., too much acid or base in your blood)
- Removal of other substances from the blood (e.g., vitamins, minerals, proteins, medications)
- Risks related to catheter placement for blood access (e.g., infection, bleeding, clotting, tissue/organ injury)
- Risks related to blood-thinners (e.g., bleeding, allergic reaction)

Relative contraindications that will be determined by your treating physician based on your risk/benefit include:

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

You should discuss any questions or concerns with your health care provider. You have the option to refuse this device. However, your doctor may be recommending this device because an FDA-cleared device may not be available due to shortages caused by COVID-19. If you choose to decline use of this device, you should discuss any alternative options with your healthcare provider.

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). The Prismaflex HF20 is being authorized to address a lack of adequate CRRT treatment for patients of low weight (8-20 kg) and low blood volume or patients who cannot tolerate a larger extracorporeal circuit volume.

What is an EUA?

The United States FDA has made the Prismaflex HF20 Set available under an emergency access mechanism called an EUA. 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 during the COVID-19 pandemic.

The Prismaflex HF20 Set under this EUA has not undergone the same type of review as an FDA-approved or cleared product. 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 product meets certain criteria for safety, performance, and labeling and may be effective in treatment of patients during the COVID-19 pandemic. All of these criteria must be met to allow for the product to be used in the treatment of patients during the COVID-19 pandemic.

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?** 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.
 - **Have a problem with the product performance or results?** Report adverse events 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.
-