FACT SHEET FOR PATIENTS

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

Coronavirus Disease 2019 (COVID-19)

WITHDRAWN

You 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 ST Set.

This Fact Sheet contains information to help you understand the benefits and risks of using the Prismaflex ST 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. This new coronavirus was first found in people in December 2019. 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 ST Set?

The Prismaflex ST 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 ST Set be used on me?

The Prismaflex ST Set has been authorized under an Emergency Use Authorization (EUA) for emergency use in the hospital during the COVID-19 pandemic.

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

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:

- Correcting the acid-base balance in your blood
- Correcting electrolyte imbalances in your blood
- Removing excess fluid from your blood
- Removing toxins from your blood

Potential risks of using the Prismaflex ST Set for CRRT 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)
- Allergic reaction to device

- **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.

- Abnormalities in your blood electrolytes (e.g., low potassium, low phosphate) or glucose
- 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)

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 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).

There is a similar product available in the U.S. called the Prismaflex M Set which was cleared by FDA using the 510(k) process. The differences between the Prismaflex M Set and the Prismaflex ST Set are that the Prismaflex ST Set contains a surface treatment on a filter component that is inside the device and this filter component comes in slightly different sizes. It is expected that these differences will not impact the CRRT you will receive and the known potential benefits and risks are anticipated to be the same. As such, this EUA authorizes 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 is an EUA?
The United States FDA has made the Prismaflex ST 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 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 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 ST Set is in effect for the duration of the COVID-19 declaration justifying emergency use of the product, 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.

WITHDRAWN