

FACT SHEET FOR PATIENTS

Emergency Use of the multiFiltrate PRO System and multiBic/multiPlus Solutions during the COVID-19 Pandemic

April 30, 2019

Coronavirus
Disease 2019
(COVID-19)

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 multiFiltrate PRO System and multiBic/multiPlus Solutions. CRRT is a type of “dialysis” therapy used to filter and clean your blood when your kidneys are damaged or are not functioning normally.

This Fact Sheet contains information to help you understand the benefits and risks of using the multiFiltrate PRO System and multiBic/multiPlus Solutions 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, which can cause mild to severe respiratory illness, was first identified in Wuhan, China, and has now spread globally, including the United States. There is limited information available about the different types of illness that one may show if infected with the virus. The virus most likely spreads from one person to another at the time when a person shows

signs or symptoms of being sick (e.g., fever, coughing, difficulty breathing, etc.).

What do I need to know about the emergency use of the multiFiltrate PRO System and multiBic/multiPlus Solutions?

The multiFiltrate PRO System and multiBic/multiPlus Solutions have 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 multiFiltrate PRO System and multiBic/multiPlus Solutions if your kidney are damaged or not functioning normally and you require CRRT.

What are the known and potential benefits and risks of CRRT?

Potential benefits of the multiFiltrate PRO System and multiBic/multiPlus Solutions 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 the multiFiltrate PRO System and multiBic/multiPlus Solutions include:

- Very low blood pressure and reduced delivery of blood to vital organs
- Abnormal heart rhythm
- Bleeding
- Clotting
- Stroke from air in the bloodstream
- Infection

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- **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.
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- Damage to blood cells
- Reduction of body temperature / chills
- Reduction in blood cells (platelets and white blood cells)
- Allergic reaction to device
- 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)

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 multiFiltrate PRO System and multiBic/multiPlus Solutions 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).

What is an EUA?

The United States FDA has made the multiFiltrate PRO System and multiBic/multiPlus Solutions available under an emergency access mechanism called an EUA. The EUA is supported by two Secretary of Health and Human Service (HHS) declarations that circumstances exist to justify the emergency use of medical devices, drugs, and biological products during the COVID-19 pandemic.

The multiFiltrate PRO System and multiBic/multiPlus Solutions have 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

REVOKED

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