

FACT SHEET FOR HEALTHCARE PROVIDERS

Coronavirus
Disease 2019
(COVID-19)

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

April 30, 2020

This Fact Sheet informs you of the significant known and potential risks and benefits of the emergency use of the Fresenius multiFiltrate PRO System and multiBic/multiPlus Solutions to provide continuous renal replacement therapy to treat patients in an acute care environment during the COVID-19 pandemic.

All patients who are treated with the multiFiltrate PRO System and multiBic/multiPlus Solutions during the COVID-19 pandemic will receive the Fact Sheet for Patients: Emergency Use of multiFiltrate PRO System and multiBic/multiPlus Solutions 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). However, limited information is currently available to characterize the full spectrum of clinical illness associated with COVID-19. 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 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 to provide continuous renal replacement therapy to treat patients in an acute care environment during the COVID-19 pandemic.
- Healthcare providers should review the instructions accompanying the multiFiltrate PRO System and

multiBic/multiPlus Solutions, entitled “multiFiltrate PRO System - Instructions for Use,” “Bloodline/Tubing systems for blood purification - Instructions for Use,” “Ultraflux AV400S/600S/1000S – Instructions for Use,” “multiPlus – Instructions for Use,” and “Summary of Product Characteristics” (SmPC) for the multiBic Solutions.

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 known and potential benefits and risks of the multiFiltrate PRO System and multiBic/multiPlus Solutions?

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

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

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

- Hemodynamic compromise (e.g., hypotension, increased vasopressor requirement, reduced cardiac perfusion)
- Arrhythmia
- Blood loss
- Thrombosis
- Air embolism
- Infection
- Hemolysis
- Hypothermia
- Thrombocytopenia
- Allergic reaction to device materials
- Electrolyte or glucose abnormalities (e.g., hypokalemia, hypophosphatemia,

FACT SHEET FOR HEALTHCARE PROVIDERS

Coronavirus
Disease 2019
(COVID-19)

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

April 30, 2020

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)

What is an EUA?

The United States FDA has made the multiFiltrate PRO System and multiBic/multiPlus Solutions available to provide continuous renal replacement therapy to treat patients in an acute care environment during the COVID-19 pandemic under an emergency access mechanism called an Emergency Use Authorization (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, including alternative devices used as medical devices, due to shortages, and drugs and biological products, during the COVID-19 pandemic.

The multiFiltrate PRO System and multiBic/multiPlus Solutions made available under an EUA 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. Based on the totality of scientific evidence available, it is reasonable to believe that the multiFiltrate PRO System and multiBic/multiPlus Solutions have 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 is for the multiFiltrate PRO System and multiBic/multiPlus Solutions to provide continuous renal replacement therapy to treat patients in an acute care environment during the COVID-19 pandemic, and 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>

Report Adverse events: (including problems with product 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**