

FACT SHEET FOR PATIENTS

Emergency Use of Spectra Optia Apheresis System with the Depuro D2000 Adsorption Cartridge for COVID-19

April 9, 2020

Coronavirus Disease 2019 (COVID-19)

This Fact Sheet contains information to help you understand the benefits and risks of using the Spectra Optia Apheresis System with the Depuro D2000 Adsorption Cartridge to treat your serious case of COVID-19. After reading this Fact Sheet, if you have questions or would like to discuss the information provided, please talk to your healthcare provider.

You are being given this Fact Sheet because your healthcare provider believes it is necessary to provide you with treatment with a device to try to remove some substances that are causing your body's defense (immune) system to not function properly. The two devices described by your doctor work together to isolate a part of your blood (called plasma) and remove some of these harmful substances from your plasma.

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

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>

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 Terumo and Depuro devices?

The Spectra Optia Apheresis System with the Depuro D2000 Adsorption Cartridge has been authorized under an Emergency Use Authorization (EUA) for emergency use for treatment of patients with confirmed COVID-19 who are showing certain severe symptoms (including high fever, persistent cough, developing more difficulty breathing) indicating that they are likely to get more ill within the next 1-24 hours. These devices have the potential to remove substances in your blood that are not allowing the immune system to function normally.

What are the known and potential benefits and risks of the Terumo and Depuro devices?

Potential benefits of these two devices include:

- Removal of substances from the blood that are causing your immune system to not function properly

Potential risks of these two devices 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
- Damage to blood cells
- Reduction in blood cells (platelets and white blood cells)

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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 device 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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- Imbalance of certain chemicals (e.g., potassium, calcium) and proteins in the blood
- Allergic reaction to device
- Removal of other substances from the blood (e.g., vitamins, 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)

the duration of the COVID-19 declaration justifying emergency use of these devices, unless terminated or revoked (after which the products may no longer be used).

What is an EUA?

The United States FDA authorized use of the Spectra Optia Apheresis System with the Depuro D2000 Adsorption Cartridge to remove substances that are disturbing the balance and normal function of your immune system available under an emergency access mechanism called an EUA. The EUA is supported by the Secretary of Health and Human Service's (HHS's) declaration that circumstances exist to justify the emergency use of medical devices during the COVID-19 pandemic.

These devices have 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, or 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 device meets certain criteria for safety, performance, and labeling conditions, and that it may be effective in treating patients with COVID-19.

The EUA for the Spectra Optia Apheresis System with the Depuro D2000 Adsorption Cartridge is in effect for

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