

FACT SHEET FOR PATIENTS

Coronavirus Disease 2019 (COVID-19)

Emergency Use of the oXiris Set device for COVID-19

April 22, 2020

This Fact Sheet contains information to help you understand the benefits and risks of using the oXiris Set device 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 treat your COVID-19 using the oXiris Set device to try to remove some substances that are causing your body's defense (immune) system to not function properly.

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.).

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 do I need to know about the emergency use of the oXiris Set device?

The oXiris Set device 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 you are likely to get more ill within the next 1-24 hours. This device has 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 oXiris Set device?

Potential benefits of the oXiris Set device includes:

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

Potential risks of the oXiris Set device includes:

- Very low blood pressure and reduced delivery of blood to vital organs
- Abnormal heart rhythm
- Bleeding
- Clotting
- Stroke from air entering the bloodstream
- Stroke or organ injury from device particles entering the bloodstream
- Infection
- Damage to blood cells
- Abnormalities of blood electrolytes (e.g., low blood potassium)
- Reduction in blood cells (platelets and white blood cells)
- Allergic reaction to device

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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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- 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)

What is an EUA?

The United States FDA authorized use of the oXiris Set device, to remove substances that are disturbing the balance and normal function of your immune system, 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.

The oXiris Set device 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, 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 treatment of patients during the COVID-19.

The EUA for the oXiris Set device is in effect for 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).

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