

FACT SHEET FOR PATIENTS

Emergency Use of Impella Left Ventricular Support Systems During the COVID-19 Outbreak

August 3, 2020

Coronavirus
Disease 2019
(COVID-19)

You are being given this Fact Sheet because your healthcare provider has determined it is appropriate to use the Impella 2.5, Impella CP, Impella CP with SmartAssist, Impella 5.0, or Impella 5.5 with SmartAssist System ("Impella Left Ventricular (LV) Support Systems," in short) to provide temporary LV support to treat your COVID-19 infection by treating your pulmonary edema (too much fluid in the lungs) or your late cardiac decompensation from myocarditis (weakened left heart caused by inflammation of the heart muscle), while you are undergoing the extracorporeal membrane oxygenation (ECMO) therapy.

This Fact Sheet contains information to help you understand the risks and benefits of using the Impella LV Support Systems for such emergency use. After reading this Fact Sheet, if you have questions or would like to discuss the information provided further, 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. 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 are the Impella LV Support Systems?

The Impella LV Support Systems are a temporary left heart pump intended to help you maintain stable heart function without open chest surgery. It includes a mini

heart pump mounted at the end of a thin, flexible tube (catheter), a console that drives the pump, and an infusion system that flushes the pump.

Why will the Impella LV Support System be used on me?

Your doctor may decide to use this device during the ECMO treatment of your COVID-19 infection if you have too much fluid in your lungs or your left heart has been weakened by inflammation of the heart muscle and is not pumping enough blood to meet your body's needs.

The emergency use of the Impella LV Support System may provide temporary support to your left heart and may help reduce the amount of work your own left heart must do. While the Impella LV Support System is working, the amount of fluid in your lungs should begin to decrease giving your left heart time to rest and recover its ability to pump blood. Once your symptoms have improved enough, the Impella LV Support System will be removed.

What are the known and potential risks and benefits of the Impella LV Support Systems?

The known and potential benefits of the Impella LV Support Systems include:

- Improvement in blood circulation
- Recovery of left heart function
- Improvement in survival

The known and potential risks of the Impella LV Support Systems include:

- Death
- Acute kidney failure
- Leaky or damaged aortic valve (the heart valve between the left ventricle and the aorta)
- Irritation to your heart tissue by the device, which may cause your heart to beat irregularly
- Bleeding
- Injuries to your heart tissue and blood vessels by the device

How can I learn more? 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.

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- Heart attack or cardiac arrest
- Damage to red blood cells caused by the pump
- Low blood platelet count
- Stroke
- Device not functioning properly
- Poor blood flow to your liver, causing it to not function normally
- Infection
- Severe low blood pressure
- Reduced blood flow to the extremities (hands, feet, and legs)

Your doctor will determine if you are an appropriate patient for the Impella LV Support Systems. If you are, the potential benefits from the use of the Impella LV Support Systems are expected to outweigh the potential risks when used to treat COVID-19 infection.

You have the option to refuse this product. If you choose to decline use of this device, you should discuss any alternative options with your healthcare provider.

How are the Impella LV Support Systems used?

The Impella LV catheter is implanted into the left side of your heart through a small incision in the femoral artery (major artery in the groin) or through a small incision in a subclavian artery (an artery in the chest). It helps pump blood by drawing blood out of the heart and pumping it into the aorta (the main artery that carries blood away from your heart to the rest of your body). By doing so, it helps reduce the work your left heart has to do or helps you maintain stable left heart function.

When should the Impella LV Support Systems NOT be used?

The Impella LV Support Systems should not be used in patients with the following conditions. Please talk to your

doctor about whether any of these conditions apply to you:

- Blood clot in the left ventricle;
- Presence of a mechanical aortic valve or heart constrictive device;
- Narrowed/calcified aortic valve;
- Moderate to severe leaky aortic valve;
- Severe arterial disease that prevents placement of the Impella catheter;
- Significant right heart failure;
- Hole between left and right sides of the heart;
- Left ventricular rupture; or
- Blood or fluid build-up in the space between the heart muscle and the outer covering sac of the heart.

Are the Impella LV Support Systems FDA-approved or cleared for treating my condition?

No. The Impella LV Support Systems are not approved or cleared by the FDA for treating your specific condition, that is, to treat your COVID-19 infection by providing temporary LV unloading and support to relieve pulmonary edema or reverse late cardiac decompensation from myocarditis during ECMO therapy. However, the Impella LV Support Systems are approved for providing temporary LV unloading and support during high-risk percutaneous coronary intervention (a procedure used to open clogged heart arteries) and during cardiogenic shock (a condition in which the heart suddenly cannot pump enough blood to meet the body's needs). FDA has authorized the use of the Impella LV Support Systems through an emergency access mechanism called an Emergency Use Authorization (EUA).

What is an EUA?

This 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, including alternative products used as medical devices, during the COVID-19 outbreak. The Impella LV Support Systems made available under this EUA has not

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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 demonstrating that it is reasonable to believe that the Impella LV Support Systems may be effective at treating your COVID-19 infection by relieving your pulmonary edema or for reversing your late cardiac decompensation from myocarditis, while you are undergoing the ECMO therapy.

The EUA for the Impella LV Support Systems is in effect for the duration of the COVID-19 declaration justifying emergency use of the product, unless terminated or revoked (after which the product may no longer be used for the emergency use).

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