FACT SHEET FOR PATIENTS

Emergency Use of Impella RP System During the COVID-19 Outbreak

May 29, 2020

Coronavirus Disease 2019 (COVID-19)

You are being given this Fact Sheet because your healthcare provider needs to use the Impella RP System ("Impella RP," in short) to treat your acute right heart failure or decompensation caused by COVID-19 complications, including pulmonary embolism (blood clot lodged in the lungs). Acute right heart failure or decompensation means your right heart is not pumping enough blood through your lungs.

This Fact Sheet contains information to help you understand the risks and benefits of using the Impella RP to treat your acute right heart failure or decompensation caused by COVID-19 complications. 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 caused by the SARS-CoV-2 virus. The virus can cause mild to severe respiratory illness and has 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 is the Impella RP?

The Impella RP System is a temporary right heart pump system 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 RP be used on me?

You are experiencing acute right heart failure or decompensation caused by COVID-19 related complications. This means your right heart has weakened and is not pumping enough blood through your lungs.

The Impella RP helps reduce the amount of work your own right ventricle must do. While the Impella RP is working, your right heart has time to rest and recover its ability to pump blood. Once the right side of your heart is working on its own again, the Impella RP will be removed.

What are the known and potential risks and benefits of the Impella RP?

Known and potential benefits of the Impella RP include:

- Improvement in blood circulation
- Recovery of native right ventricular function
- Improvement in survival

Known and potential risks of the Impella RP include:

- Death
- Major bleeding
- Damage to red blood cells caused by the pump
- Stroke
- Blood clot lodged in the lungs
- Poorly functioning heart valves in your right heart
- Allergic reaction to the medication, for instance a blood thinner called heparin, which is used in conjunction with the Impella RP blood pump
- Clots developed in your blood vessels
- Infection
- Injuries to your heart tissue and blood vessels by the device
- Irritation to your heart tissue by the device, which may cause your heart to beat irregularly
- Poor blood flow to your liver, causing it to not function normally
- Worsening of your heart failure condition
- Device not functioning properly

Your doctor will determine if you are an appropriate patient for Impella RP. FDA has concluded that the known and potential benefits from the use of the Impella RP outweigh its potential risks for the emergency use during the COVID-19 outbreak.

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How is the Impella RP device used?

The Impella RP heart pump helps pump blood from a blood vessel outside the heart (inferior vena cava), bypassing the right heart (right atrium and right ventricle), into a blood vessel leading to the lungs (pulmonary artery). It is implanted into the right side of your heart through a small incision in the major vein in the leg (femoral vein).

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.

When should the Impella RP device NOT be used?

The Impella RP should not be used in patients with the following conditions. Please talk to your doctor about whether any of these conditions apply to you:

- Defects in the veins and arteries, including calcium deposits or hardening of the vessel walls, which could block the open area available for the pump to pass;
- A rigid replacement heart valve, or a leaky or severely narrowed tricuspid or pulmonary valve;
- Loosely attached clot(s) in the blood vessels or heart, which may break off while the pump is in use and result in harm to the patient;
- Anatomic conditions that do not allow the blood pump to be inserted; and/or
- A blood filter in one of the large veins which may block the open area available for the pump to pass.

Is the Impella RP FDA-approved or cleared for treating my condition?

No. The Impella RP is not approved or cleared by the FDA for treating your specific condition, that is, acute right heart failure or decompensation caused by COVID-19 complications. However, the Impella RP is approved for treating acute right heart failure or decompensation caused by other conditions, including left ventricular assist device (a permanent mechanical heart pump) implantation, myocardial infarction (heart attack), heart transplant, or open-heart surgery. FDA has authorized the use of the Impella RP for acute right heart failure or decompensation caused by COVID-19 complications, including pulmonary embolism 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 devices used as medical devices, during the COVID-19 outbreak. The Impella RP available under this EUA 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 demonstrating that it is reasonable to believe that the Impella RP may be effective for treating acute right heart failure or decompensation caused by COVID-19 complications, including pulmonary embolism.

The EUA for the Impella RP 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).

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.