

FACT SHEET FOR HEALTHCARE PROVIDERS

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

May 29, 2020

Coronavirus
Disease 2019
(COVID-19)

This Fact Sheet informs you of the significant known and potential risks and benefits of the emergency use of the Impella RP System ("Impella RP," in short). The Impella RP is authorized for emergency use in the hospital setting to provide temporary right ventricular support for up to 14 days in critical care patients with a body surface area $\geq 1.5 \text{ m}^2$, who develop acute right heart failure or decompensation due to COVID-19 related complications, including pulmonary embolism (PE).

The Impella RP is not intended to be the primary treatment modality for PE. Other adjunctive measures, including thrombolytic therapy and open or percutaneous thrombus extraction, may be carried out separately or simultaneously.

All patients who are treated with Impella RP should receive the Fact Sheet for Patients: Emergency Use of Impella RP System During the COVID-19 Outbreak

What do I need to know about COVID-19 and related acute right heart failure or decompensation?

Current information on COVID-19 infection for healthcare providers, including case definitions and information about clinical signs and symptoms and/or epidemiological criteria, is available on the CDC website listed below.

COVID-19 could cause complications such as PE that could further lead to acute right ventricular failure or decompensation. Patients with such complications may be initially treated with thrombolytic therapy. If acute right ventricular failure persists due to pressure overload, the Impella RP can then be used to provide support to the right ventricle.

What is the Impella RP?

Impella RP is a minimally invasive, miniaturized percutaneous circulatory support system for the right ventricle. It is comprised of the following three components:

- the Impella RP Catheter: a 23 Fr micro-axial flow pump catheter and its accessories

- the Automatic Impella Controller (AIC): a reusable external drive console
- the Impella Purge Cassette: an infusion pump used to flush the Impella RP Catheter

The Impella RP received FDA premarket approval (PMA) in 2017 for use in providing temporary right ventricular support for up to 14 days in patients with a body surface area $\geq 1.5 \text{ m}^2$, who develop acute right heart failure or decompensation following left ventricular assist device implantation, myocardial infarction, heart transplant, or open-heart surgery. This emergency use authorization is for temporary right ventricular support in critical care patients who develop acute right heart failure or decompensation due to COVID-19 related complications, including PE (an indication for which the Impella RP has neither been FDA-cleared or -approved).

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

Known and potential benefits of the Impella RP include:

- Improvement in hemodynamics status
- Recovery of native right ventricular function
- Improvement in survival

The Impella RP has been designed to minimize the risks of complications associated with its use. However, known and potential risks of the Impella RP include:

- Death
- Arrhythmia
- Atrial fibrillation
- Bleeding
- Cardiac tamponade
- Cardiogenic shock
- Device malfunction
- Hemolysis
- Hepatic failure
- Insertion site infection
- Perforation
- Phlegmasia cerulea dolens (a severe form of deep venous thrombosis)
- Pulmonary valve insufficiency
- Respiratory dysfunction
- Sepsis
- Thrombocytopenia

Report Adverse events, including problems with test 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**

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- Thrombotic vascular (non-central nervous system) complication
- Tricuspid valve injury
- Vascular injury
- Venous thrombosis
- Ventricular fibrillation and/or tachycardia

When used in appropriately selected patients in accordance with the Instructions for Use, the known and potential benefits of the Impella RP outweigh the known and potential risks.

What are the alternatives to treat acute right heart failure or decompensation associated with COVID-19 complications?

There are currently no adequate, approved, available alternatives to treat acute right heart failure or decompensation due to COVID-19 related complications, including PE.

Contraindication of the Impella RP

Impella RP is contraindicated for patients with the following conditions:

- Disorders of the pulmonary artery wall that would preclude placement or correct positioning of the Impella RP device
- Mechanical valves, severe valvular stenosis or valvular regurgitation of the tricuspid or pulmonary valve
- Mural thrombus of the right atrium or vena cava
- Anatomic conditions precluding insertion of the pump
- Presence of a vena cava filter or caval interruption device, unless there is clear access from the femoral vein to the right atrium that is large enough to accommodate a 22 Fr catheter

What is an Emergency Use Authorization (EUA)?

The United States (U.S.) FDA has issued an Emergency Use Authorization (EUA) for the Impella RP System for temporary right ventricular support in critical care patients who develop acute right heart failure or decompensation due to COVID-19 related complications, including PE. 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, including alternative devices used as medical devices, during the COVID-19 outbreak.

The use of the Impella RP under this EUA has not undergone the same type of review as an FDA-approved or cleared device. However, FDA may issue an EUA when certain criteria are met, which includes that there are no adequate, approved, 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 Impella RP System may be effective for use in temporary right ventricular support in critical care patients who develop acute right heart failure or decompensation due to COVID-19 related complications, including PE.

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?

CDC websites:

General: <https://www.cdc.gov/COVID19>

FDA websites:

General: www.fda.gov/novelcoronavirus

EUAs: <https://www.fda.gov/medical-devices/emergency-situations-medical-devices/emergency-use-authorizations>

Manufacturer: Abiomed, Inc.

22 Cherry Hill Drive
Danvers, MA 01923

For Technical Assistance:

Phone: 1-800-422-8666 (24/7)

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