

# FACT SHEET FOR HEALTHCARE PROVIDERS

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

August 3, 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 2.5, Impella CP, Impella CP with SmartAssist, Impella 5.0, and Impella 5.5 with SmartAssist Systems (“Impella Left Ventricular (LV) Support Systems,” in short). The Impella LV Support Systems are authorized for emergency use by healthcare providers (HCP) in the hospital setting for providing temporary ( $\leq 4$  days for Impella 2.5, Impella CP, and Impella CP with SmartAssist; and  $\leq 14$  days for Impella 5.0 and Impella 5.5 with SmartAssist) LV unloading and support to treat critical care patients with confirmed COVID-19 infection who are undergoing extracorporeal membrane oxygenation (ECMO) treatment and who develop pulmonary edema while on veno-arterial (V-A) ECMO support or late cardiac decompensation from myocarditis while on veno-venous (V-V) ECMO support.

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**All patients who are treated with Impella LV Support Systems should receive the Fact Sheet for Patients regarding this device.**

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### What do I need to know about COVID-19 and the need for temporary LV unloading or support during ECMO therapy?

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 at the end of this factsheet.

Critical care COVID-19 patients may require V-A ECMO for circulatory support with oxygenation due to acute cardiopulmonary failure. However, in some patients, V-A ECMO alone does not provide sufficient LV unloading due to retrograde aortic perfusion, which can lead to LV overload and distension, resulting in pulmonary edema. The Impella LV Support Systems may be effective at alleviating this problem by unloading the LV, thereby reducing the LV work, and fully emptying the LV. In addition, COVID-19 patients may require V-V ECMO for

pulmonary failure. Some of these patients suffer from LV decompensation from myocarditis, which may require additional mechanical circulatory support for systemic perfusion. For these patients, the Impella LV Support Systems may be effective at providing the necessary LV support for hemodynamic stability and end-organ perfusion.

### What are the Impella LV Support Systems?

The Impella LV Support Systems are a family of minimally invasive, miniaturized percutaneous circulatory support systems for the left ventricle. Each system consists of the following three components:

- the Impella Catheter: a micro-axial flow pump catheter and its accessories;
- the Automatic Impella Controller (AIC): a reusable external drive console; and
- the Impella Purge Cassette: an infusion pump used to flush the Impella Catheter.

The Impella LV Support Systems are currently FDA-approved for the following indications:

#### High-risk percutaneous coronary intervention (PCI):

The Impella 2.5, Impella CP, and Impella CP with SmartAssist Systems are temporary ( $\leq 6$  hours) ventricular support devices indicated for use during high-risk PCI performed in elective or urgent, hemodynamically stable patients with severe coronary artery disease, when a heart team, including a cardiac surgeon, has determined high-risk PCI is the appropriate therapeutic option. Use of the Impella 2.5 and Impella CP Systems in these patients may prevent hemodynamic instability, which can result from repeat episodes of reversible myocardial ischemia that occur during planned temporary coronary occlusions and may reduce peri- and post-procedural adverse events.

#### Cardiogenic shock:

The Impella 2.5, Impella CP, Impella CP with SmartAssist, Impella 5.0, and Impella 5.5 with SmartAssist Catheters, in conjunction with the

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**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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Automated Impella Controller (collectively, “Impella System Therapy”), are temporary ventricular support devices intended for short term use ( $\leq 4$  days for the Impella 2.5, Impella CP, and Impella CP with SmartAssist; and  $\leq 14$  days for the Impella 5.0 and Impella 5.5 with SmartAssist) and indicated for the treatment of ongoing cardiogenic shock that occurs immediately ( $< 48$  hours) following acute myocardial infarction or open heart surgery or in the setting of cardiomyopathy, including peripartum cardiomyopathy, or myocarditis as a result of isolated left ventricular failure that is not responsive to optimal medical management and conventional treatment measures (including volume loading and use of pressors and inotropes, with or without IABP). The intent of Impella System Therapy is to reduce ventricular work and to provide the circulatory support necessary to allow heart recovery and early assessment of residual myocardial function.

FDA has authorized the emergency use of this product for use by HCP in the hospital setting for providing temporary ( $\leq 4$  days for Impella 2.5, Impella CP, and Impella CP with SmartAssist; and  $\leq 14$  days for Impella 5.0 and Impella 5.5 with SmartAssist) LV unloading and support to treat critical care patients with COVID-19 infection who are undergoing ECMO and who develop pulmonary edema while on V-A ECMO support or late cardiac decompensation from myocarditis while on V-V ECMO support.

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

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

- Improvement in hemodynamics status
- Recovery of left ventricular function
- Improvement in survival

The Impella LV Support Systems have been designed to minimize the risks of complications associated with their uses. However, known and potential risks of the Impella LV Support Systems include:

- Death
- Acute renal dysfunction
- Aortic insufficiency
- Aortic valve injury
- Atrial fibrillation
- Bleeding
- Cardiac tamponade
- Cardiogenic shock
- Cardiopulmonary resuscitation
- Cerebral vascular accident/stroke
- Device malfunction
- Hemolysis
- Hepatic failure
- Insertion site infection
- Limb ischemia
- Myocardial infarction
- Need for cardiac, thoracic or abdominal operation
- Perforation
- Renal failure
- Sepsis
- Severe hypotension
- Thrombocytopenia
- Thrombotic vascular (non-central nervous system) complication
- Transient ischemic attack
- Vascular injury
- Ventricular fibrillation or tachycardia

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

### What are the alternatives to providing temporary LV unloading or support during ECMO therapy?

There are currently no adequate, approved, available alternatives to treat critical care patients with COVID-19 infection who are undergoing ECMO and who develop pulmonary edema while on V-A ECMO support or late cardiac decompensation from myocarditis while on V-V ECMO support.

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### Contraindications of the Impella LV Support Systems

The authorized Impella LV Support Systems are contraindicated for patients with the following conditions:

- Mural thrombus in the left ventricle;
- Presence of a mechanical aortic valve or heart constrictive device;
- Aortic valve stenosis/calcification (equivalent to an orifice area of 0.6 cm<sup>2</sup> or less);
- Moderate to severe aortic insufficiency (echocardiographic assessment graded as  $\geq +2$ );
- Severe arterial disease precluding placement of the Impella catheter;
- Significant right heart failure;
- Presence of an Atrial or Ventricular Septal Defect (including post-infarct VSD);
- Left ventricular rupture; or
- Cardiac tamponade.

### What is an Emergency Use Authorization (EUA)?

The United States FDA has authorized the emergency use of the Impella LV Support Systems System for use by HCP in the hospital setting for providing temporary ( $\leq$  4 days for Impella 2.5, Impella CP, and Impella CP with SmartAssist; and  $\leq$  14 days for Impella 5.0 and Impella 5.5 with SmartAssist) LV unloading and support to treat critical care patients with confirmed COVID-19 infection who are undergoing ECMO treatment and who develop pulmonary edema while on V-A ECMO support or late cardiac decompensation from myocarditis while on V-V ECMO support.

The authorized use of the Impella LV Support Systems 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, available alternatives. In addition, the FDA's determination is based on the totality of scientific evidence available showing that it is reasonable to believe that the Impella LV Support Systems may be effective for the authorized emergency use.

The EUA for the Impella LV Support Systems System 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 for the emergency use).

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### How can I learn more?

#### **CDC websites:**

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

#### **FDA websites:**

**General:** [www.fda.gov/novelcoronavirus](http://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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