Impella RP® Heart Pump Patient Selection Recommendations and Optimal Timing

Treatment with the Impella RP System is appropriate for certain patients with a body surface area ≥1.5 m^2, who develop signs of acute right ventricular failure, including complications for COVID-19 (such as PE). Clinical conditions that were studied in the pre-approval trial were:

1. Post-implantation of an FDA approved surgical LVAD
2. Post-heart surgery, post-heart transplant or post-myocardial infarction

NOTE: THE SINGLE MOST IMPORTANT DETERMINANT OF SURVIVAL AFTER IMPELLA RP IS THE DURATION OF RIGHT HEART DYSFUNCTION. FOR OPTIMAL PATIENT BENEFIT, INSERTION OF THE IMPELLA RP SHOULD OCCUR **WITHIN 48 HOURS** OF THE ONSET OF RIGHT VENTRICULAR DYSFUNCTION.

Clinical conditions in which the Impella RP is NOT recommended
☐ Active infection with positive blood cultures
☐ RA, RV or PA thrombus
☐ Mechanical valves in the right heart*
☐ Unrepaired ASD, PFO, or aortic dissection
☐ PA conduit
☐ Anatomic abnormalities precluding insertion
☐ Moderate to severe pulmonary valve stenosis or insufficiency
☐ Severe pulmonary hypertension (PAS>60mmHg)
☐ Documented DVT and/or presence of IVC filter
☐ Patients on right-sided support or ECMO
☐ Allergy or intolerance to contrast
☐ HIT or sickle cell disease

*__NOTE__: Presence of a tricuspid ring or bio-prosthesis NOT a contra-indication. However, the presence of a tricuspid bio-prosthesis may result in a difficult implantation depending on the valve strut orientation within the RVOT.

Right Ventricular Failure (RVF) is defined as:

- A cardiac index <2.2 l/min/m^2 despite continuous infusion of high dose inotropes

AND ANY OF THE FOLLOWING:

- CVP > 15 mmHg or
- CVP/PCWP or LAP > 0.63 or
- Moderate to severe global RV dysfunction on echocardiography defined as one of the following criteria:
  - Global RV hypokinesis
  - TAPSE score of ≤ 14 mm
  - Right ventricular diameter at basis > 42 mm
  - Right ventricular short axis (or mid-cavity) diameter > 35 mm

High dose inotropes is defined as:

- Dobutamine of ≥ 10 µg/kg/min or equivalent for more than 15 minutes (120 minutes for milrinone) and/or administration of more than one inotrope/vasopressor medication

If you have questions about the appropriate selection of a patient for Impella RP support, or patient management, contact Abiomed's 24 Hour Clinical Support Center at (800-422-8666)

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PMA APPROVED INDICATION
The Impella RP® System is indicated for providing temporary right ventricular support for up to 14 days in patients with a body surface area ≥1.5 m^2, who develop acute right heart failure or decompensation following left ventricular assist device implantation, myocardial infarction, heart transplant, or open-heart surgery.

EMERGENCY USE AUTHORIZATION
The Impella RP System is authorized to be used by healthcare providers (HCP) in the hospital setting for providing temporary right ventricular support for up to 14 days in critical care patients with a body surface area ≥1.5 m^2, for the treatment of acute right heart failure or decompensation caused by complications related to Coronavirus Disease 2019 (COVID-19), including pulmonary embolism (PE). The Impella RP has been authorized only for the duration of the declaration that circumstances exist justifying the authorization of the emergency use of medical devices under section 564(b)(1) of the Act, 21 U.S.C. § 360bbb-3(b)(1), unless the authorization is terminated or revoked sooner.

Important Risk Information for Impella RP System

CONTRAINDICATIONS
The Impella RP System 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.

POTENTIAL ADVERSE EVENTS
The potential adverse effects (eg, complications) associated with the use of the Impella RP System: Arrhythmia, Atrial fibrillation, Bleeding, Cardiac tamponade, Cardiogenic shock, Death, 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, Thrombotic vascular (non-central nervous system) complication, Tricuspid valve injury, Vascular injury, Venous thrombosis, Ventricular fibrillation and/or tachycardia.

In addition to the risks above, there are other **WARNINGS** and **PRECAUTIONS** associated with Impella RP.
Visit www.abiomed.com/important-safety-information to learn more.

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