Impella RP® Heart Pump Patient Selection Criteria Checklist

Treatment with the Impella RP System is appropriate for patients with a body surface area >1.5 m^2, who develop signs of acute right ventricular failure:

1. Within 48 hours post-implantation of an FDA approved surgical LVAD; or
2. Within 48 hours post-heart surgery, post-heart transplant or post-myocardial infarction

The checklists below are based on the exclusion criteria for the Impella RP pre-market clinical study. These checklists are provided to help you determine if Impella RP support is an appropriate treatment for your patient, and if your patient is likely to benefit from Impella RP support.

Has your patient received a surgical LVAD within 48 hrs and has any of the following?	Has your patient had cardiac surgery, heart transplant or AMI within 48 hrs and has any of the following?
☐ INTERMACS I patients (crash and burn with worsening lactate levels or acidosis)	☐ Patients in profound cardiogenic shock, i.e., SBP < 75mmHg and CI < 1.3 l/min/m^2 despite two or more high dose inotropes, PH<7.1 not corrected by 100 Ml NaHCO3, DIC, anoxic brain Injury or CGS >24 hrs
☐ Evidence of end-organ failure (bilirubin >5 or creatinine >4 within 24 hrs of implant)	☐ Ami with acute mechanical complication (VSD, ventricular rupture or pap rupture)
☐ Evidence of acute neurologic injury	☐ Unsuccessful revascularization of RCA
☐ Active infection defined as two of the following (WBC >12,5000 or positive blood culture or fever)	☐ Active infection defined as two of the following (WBC >12,5000 or positive blood culture or fever)
☐ RA, RV or PA thrombus	☐ RA, RV or PA thrombus
☐ Prosthetic valves In the right heart	☐ Prosthetic valves in the right heart
☐ Structural tricuspid disease	☐ Structural tricuspid disease
☐ ASD or PFO (unrepaired)	☐ ASD or PFO (unrepaired)
☐ Pulmonary valve stenosis or insufficiency	☐ Pulmonary valve stenosis or insufficiency
☐ Severe pulmonary hypertension (PAS>60mmHg)	☐ Severe pulmonary hypertension (PAS>60mmHg)
☐ Documented DVT and/or presence of IVC filter	☐ Documented DVT and/or presence of IVC filter
☐ Anatomic abnormalities precluding insertion	☐ Anatomic abnormalities precluding insertion
☐ PA conduit	☐ PA conduit
☐ Patients on right-sided support or ECMO	☐ Patients on right-sided support or ECMO
☐ Current Pulmonary Embolism	☐ Current Pulmonary Embolism
☐ Aortic Dissection or Marfan Syndrome	☐ Aortic Dissection or Marfan Syndrome
☐ Allergy or intolerance to contrast	☐ Allergy or intolerance to contrast
☐ HIT or sickle cell disease	☐ HIT or sickle cell disease
	☐ Existing congenital heart disease that would preclude placement
If your patient received a surgical LVAD >48 hrs ago, or you checked any of the above boxes, your patient is not a candidate	**If your patient had cardiac surgery, heart transplantation, or AMI > 48 hrs ago, or you checked any of the above boxes, your patient is not a candidate**

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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Right-Side Support
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 m2, who develop acute right heart failure or decompensation following left ventricular assist device implantation, myocardial infarction, heart transplant, or open-heart surgery.

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. Learn more visit:
www.abiomed.com/important-safety-infomation

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