**Impella RP® System**

The Impella RP pumps blood from the inferior vena cava to the pulmonary artery. The pump is inserted with single venous access and advanced over a wire into the pulmonary artery using standard catheterization techniques.

- The only FDA approved percutaneous heart pump indicated for right heart failure.
- Inserted percutaneously through the femoral vein and into the pulmonary artery.
- Provides circulatory assistance for up to 14 days in certain patients with a body surface area ≥ 1.5 m² (refer to Indications on the back of this document).
- Delivers flow of greater than 4.0+L/min of blood from the inlet area, which sits in the inferior vena cava, through the cannula, to the outlet opening in the pulmonary artery.

**4.0+ L/minute Maximum Flow Rate**

- 6 Fr pigtail
- Outlet area
- Cannula Length 17 cm
- 11 Fr delivery catheter
- 22 Fr pump motor

**Impella RP® Heart Pump Specifications**

**Flow Rate:** >4.0+L/min  
**Speed Range:** 0 to 33,000 rpm

**Cannula:**  
22 Fr Polyurethane coated nitinol designed for right-heart anatomy

**Pressure Sensor:**  
Measures the pressure difference between the inside and outside of the cannula to monitor flow during catheter operation.

**Catheter Shaft:**  
Braided catheter with triple internal lumens for differential pressure, purge and electrical signal

**Blue Impella Plug:**
- **Connections** - 1 luer connections for purge fluid, 1 electrical connection to patient cable
- **Electronics** - Differential pressure sensor to measure pressure signal, electronic memory for retention of operating parameters

**Repositioning Unit:**  
Graduated shaft from 11 Fr to 15 Fr with yellow anchor ring, anticontamination sleeve, and hemostatic valve for repositioning of the catheter.

**Photo of medical device**

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**Clinical Support**
24 hours per day, 7 days a week:  
1-800-422-8666 (US)

**ABIOMED, Inc.**
Voice: 978-646-1400  
Facsimile: 978-777-8411  
Email: marketing@abiomed.com
Automated Impella Controller
Part number: 0042-0000-US
The controller provides an interface for monitoring and controlling the function of all Impella catheters.
- 10.4” color display for easy viewing
- Mounts to Controller Cart (not shown) for transport within hospital
- 60 minutes of battery back up power for mobile transport

Purge Cassette
Single Package: 0043-0002
5 Package: 0043-3003
The purge cassette delivers rinsing fluid to the Impella catheter. The purge fluid (5% dextrose solution) flows from the purge cassette through the catheter to the microaxial blood pump to prevent blood from entering the motor.

Introducer kit
Part number: 0052-3021
Vascular access kit used for percutaneous insertion of the Impella catheter.
- 23 Fr x 30 cm Peel-away introducer with hemostatic valve
- 8, 12, 16, 20, 23 Fr Dilators
- 0.035” x 150 cm Guidewire

0.027”, 260cm Placement Guidewire
Part number: 0052-3018
Guidewire with a radiopaque, shapable tip used for placement of Impella catheter into pulmonary artery via the femoral vein.

Purge Cassette
Single Package: 0043-0002
5 Package: 0043-3003
The purge cassette delivers rinsing fluid to the Impella catheter. The purge fluid (5% dextrose solution) flows from the purge cassette through the catheter to the microaxial blood pump to prevent blood from entering the motor.

INDICATIONS FOR USE
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. Visit www.abiomed.com/important-safety-information to learn more.