Data Sheet
Impella RP® with SmartAssist®

The only percutaneous pump approved for right heart support with single vascular access, designed for intelligent patient management.

- The pump is inserted with single venous access and advanced over a wire into the pulmonary artery using standard catheterization techniques.
- 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.

New Features

Real-time guidance to help with pump management and weaning
- PA and CV placement waveforms assist in confirming positioning and identifying issues

Improved ease of use
- Easy Guide Lumen for quicker insertion
- Reduction in set-up steps with fewer connections

Trend Screen and calculated PAPi assist with pump weaning

Specifications

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 pump operation

Optical Sensor:
Measures the central venous placement signal during pump operation

Catheter Shaft:
Braided catheter for differential sensor, optical sensor, motor cable and purge lumen

Blue Impella Plug:
Connections - 1 luer connection for purge fluid, 1 electrical connection to patient cable
Electronics - Differential pressure sensor and optical 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

Overview

1. Pigtail
2. Outlet
3. Cannula
4. Inlet
5. EasyGuide Lumen
6. Repositioning Unit
7. Catheter Shaft
8. Blue Impella Plug
9. Side arm
10. Patient cable

For additional information about flow rates see the Instructions For Use manual.
Impella RP® with SmartAssist®

**Impella RP with SmartAssist Heart Pump Kit**
Part number: 0046-0035
- Impella RP with SmartAssist Catheter
- Purge Cassette (1000185)
- Introducer Kit (0052-3021)
- 0.027”, 260 cm Placement Guidewire (0052-3018)
- Reimbursement Sheet (0046-9063)

**Automated Impella Controller™**
Part number: 0042-0040-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

**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, shapeable tip used for placement of Impella catheter into pulmonary artery via the femoral vein.

**Purge Cassette**
5 Package: 1000200
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.

**RIGHT-SIDE SUPPORT**
The Impella RP® with SmartAssist® 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 for less than 48 hours following left ventricular assist device implantation, myocardial infarction, heart transplant, or open-heart surgery, without the presence of profound shock, end organ failure, or acute neurologic injury.

**Important Risk Information for Impella devices**

**CONTRAINDICATIONS**
The Impella RP with SmartAssist 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 with SmartAssist 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, Thromboembolism, 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 with SmartAssist.

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