Impella CP® with SmartAssist®

Recovering Hearts. Saving Lives.

The Impella® heart pump is an intravascular microaxial blood pump that supports a patient's circulatory system.

Hemodynamic *support*

- Peak flows at systole up to 4.3L/min at P-9
- Sustained higher flows for duration of support

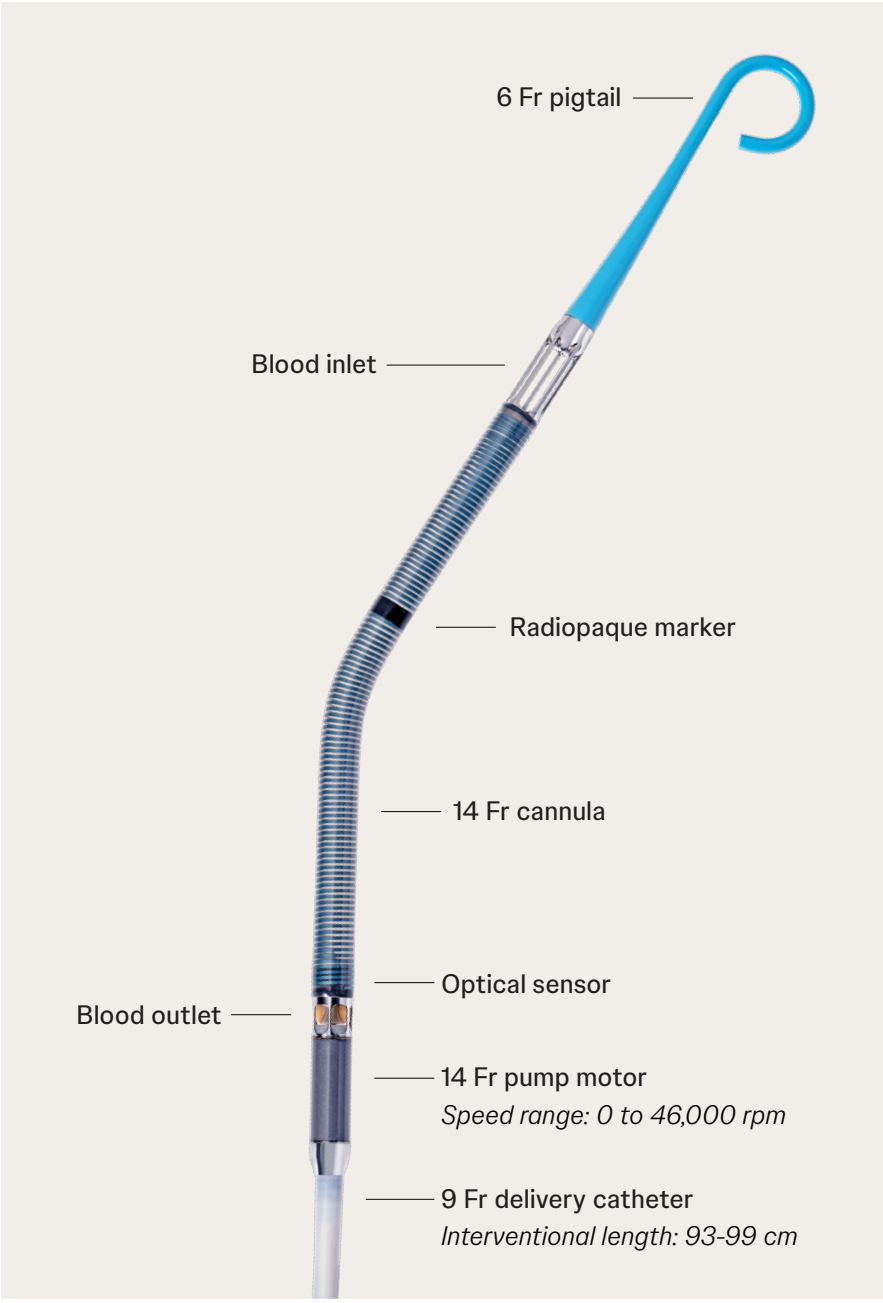
Confident *positioning*

- Enables repositioning without imaging in the ICU*
- Clear, concise alarms for improved troubleshooting

Simplified *set-up*

- Anti-contamination sheath pulled back
- 90 second set-up
- Reduction in set-up steps with fewer connections

*For "Impella Position In Ventricle" alarm only



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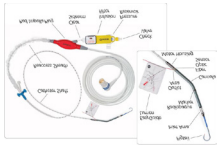
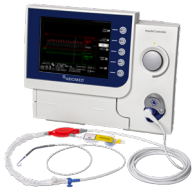


Impella CP with SmartAssist Kit

- Impella Catheter
- Purge Cassette
- Introducer Kit
- 0.018” x 260 cm placement guidewire



Automated Impella Controller

- 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 backup power for mobile transport

Introducer Kit

- Vascular access kit used for percutaneous insertion of the Impella catheter.
- Two 14 Fr (13 cm and 25 cm) peel-away introducers—with hemostatic valve for tight fit around components and single-step “break-away” configuration
- 0.035” x 150 cm Guidewire

0.018” x 260 cm Placement Guidewire

- Guidewire with a radiopaque, shapable tip used for placement of Impella catheter into left ventricle.

Purge Cassette

- The purge cassette delivers rinsing fluid to the Impella catheter. The purge fluid flows from the purge cassette through the catheter to the microaxial blood pump to prevent blood from entering the motor.

High-Risk PCI

The Impella CP® with SmartAssist® Catheter is indicated for providing temporary (≤ 6 hours) ventricular support during elective or urgent high risk percutaneous coronary interventions (PCI) performed in 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 CP® with SmartAssist® System 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 CP with SmartAssist Catheter, in conjunction with the Automated Impella Controller (collectively, “Impella® System Therapy”), are temporary ventricular support devices intended for short term use (≤ 4 days) 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) in adult patients, and in pediatric patients weighing ≥52 kg. 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.

Important Risk Information for Impella devices

Contraindications

The, Impella CP, Impella CP with SmartAssist, Impella 5.5 with SmartAssist and are contraindicated for use with patients experiencing any of 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^2 or less); Moderate to severe aortic insufficiency (echocardiographic assessment graded as ≥ +2); Severe arterial disease precluding placement of the Impella System; Significant right heart failure*; Combined cardiorespiratory failure*; Presence of an Atrial or Ventricular Septal Defect (including post-infarct VSD); Left ventricular rupture*; Cardiac tamponade*

**This condition is a contraindication for the cardiogenic shock indication only.*

Potential adverse events

Acute renal dysfunction, Aortic valve injury, Bleeding, Cardiogenic shock, Cerebral vascular accident/Stroke, Death, Hemolysis, Limb ischemia, Myocardial infarction, Renal failure, Thrombocytopenia and Vascular injury (including ventricular perforation).

In addition to the risks above, there are other **WARNINGS** and **PRECAUTIONS** associated with Impella devices. Learn more visit: **www.abiomed.com/important-safety-information**

Johnson&Johnson MedTech

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