

Impella CP[®] with SmartAssist[®]

Next Generation Heart Recovery Technology



SmartAssist[®] Platform

The latest innovation on the Impella platform integrates the trusted performance of the Impella CP heart pump with state-of-the-art SmartAssist technology. This next generation heart pump is designed to improve patient outcomes by using real-time intelligence to optimize positioning, managing and weaning of the Impella device for better patient care.



Impella[®] Heart Pump

Greater hemodynamic support and ease of use. New sensor technology allows for repositioning in the ICU without the need for imaging.*



Advanced Pump Metrics

Intelligent pump metrics on the Automated Impella[®] Controller assist in positioning, managing and weaning the Impella device.



Impella Connect[®]

Cloud-based, remote view of the Impella device status for collaborative patient management and better patient outcomes.

* For ventricularized pumps

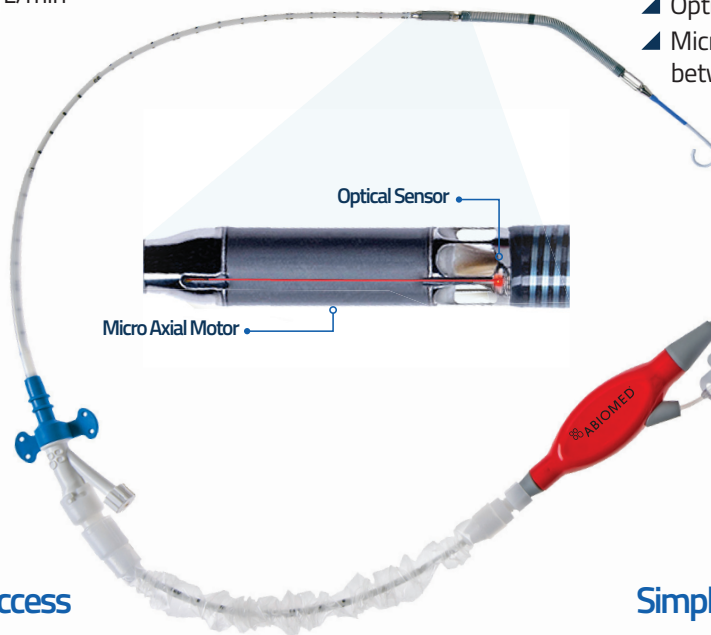
Impella CP with SmartAssist

New Features to Improve Hemodynamic Support and Ease of Use

Greater Hemodynamic Support

Confident positioning allows for sustained higher flows.

- ▲ Peak flows up to 4.3 L/min



Confident Positioning

New hemodynamic sensors assist in managing and positioning Impella CP.

- ▲ Optical sensor senses aortic pressure
- ▲ Micro-axial motor senses pressure difference between aorta and left ventricle

Maintain Arterial Access

Reaccess sheath allows for escalation of care and is designed to improve hemostasis.

- ▲ Allows access to the artery with up to a 0.035" guidewire
- ▲ 4 cm additional length

Simplified Set-up

Improve ease of use and faster set-up time.

- ▲ Reduction in set-up steps with fewer connections
- ▲ Single fluid line management in ICU



Advanced Pump Metrics

Designed to optimize pump management and assist in weaning

- ▲ Left ventricular placement signal
- ▲ Only percutaneous heart pump that displays Cardiac Power Output
- ▲ Displays trends of LVEDP and MAP to assist weaning
- ▲ 50% reduction in timing to resolve suction event²

Cardiac Power Output: #1 Correlation to Mortality in AMI Cardiogenic Shock¹

- ▲ $CPO \text{ (in watts)} = (MAP \times \text{Cardiac Output}) / 451$

Impella CP® Heart Pump Specifications

PART NUMBER	DESCRIPTION
0048-0003	Impella heart pump, 9 Fr catheter, 6 Fr pigtail, 14 Fr micro-axial pump, Percutaneous insertion through the femoral artery
0043-0003	Impella Controller Purge Cassettes, Box of 5
0052-3025	14Fr Combo Introducer Kit containing 13cm and 25cm length sheaths
0052-3005	0.018" x 260 cm PTFE Guidewire for Impella 2.5 and Impella CP

Maximum Flow: 4.3 L/min

Maximum Mean: 3.7 L/min

Speed Range: 0 to 46,000 rpm

Interventional Length: 92-98cm

Learn more visit www.Abiomed.com/SmartAssist

High-Risk PCI

The Impella 2.5®, the Impella CP®, and the Impella CP® with SmartAssist® Systems are temporary (≤ 6 hours) ventricular support devices indicated for use during high-risk percutaneous coronary interventions (PCI) performed in elective or urgent, 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 2.5, the Impella CP, and the Impella CP® with SmartAssist® Systems 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 2.5®, Impella CP®, and the Impella CP® with SmartAssist®, Impella 5.0® and Impella LD® Catheters, in conjunction with the Automated Impella Controller (collectively, "Impella® System Therapy"), are temporary ventricular support devices intended for short term use (≤ 4 days for the Impella 2.5, Impella CP, and the Impella CP with SmartAssist, and ≤ 6 days for the Impella 5.0 and Impella LD) 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). 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 2.5, Impella CP, and the Impella CP with SmartAssist, Impella 5.0 and Impella LD catheters 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 cm² or less); Moderate to severe aortic insufficiency (echocardiographic assessment graded as $\geq +2$); Severe peripheral 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

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

Impella Connect

The Impella Connect® transfers the video image of the screen on the Automated Impella® Controller to an authorized remote user. The transmitted image can be viewed by authorized remote users. The users can include the hospital's clinicians, Abiomed local support staff, and Customer Support Center (CSC) team members.

PRECAUTIONS

- Impella Connect is not intended to provide real-time information for monitoring patient status on the Automated Impella® Controller.
- During use of the Impella Connect, there will be a delay between when an image appears on the controller screen and when it is displayed at a remote viewing location.
- The Impella Connect is not a source of patient alarms, nor is its use intended as a replacement for monitoring the controller's alarms.
- During use of the Impella Connect, receipt of the displayed controller information is not confirmed by the Automated Impella® Controller, nor is the delivery of the displayed controller information to the authorized remote users guaranteed.

The Impella Connect is not designed for use during transport.

Radiated and conducted electromagnetic interference can affect the performance of the Impella Connect, causing a temporary loss of connectivity. To clear interference, either increase the distance between system components and the EMI source or turn off the EMI source. Any electromagnetic interference related to the Impella Connect will have no impact on any of the controller functional specifications. Portable and mobile RF communications equipment can affect medical electrical equipment.

In addition to the information above, learn more about Abiomed and Impella: Visit www.abiomed.com/important-safety-information



24/7 Impella Clinical Support and Technical Expertise 1-800-422-8666 (US)