

Impella CP[®]

Heart Pump



NEXT GENERATION OF HEART RECOVERY

RECOVERING HEARTS. SAVING LIVES.®



Designed for Optimal Positioning in The Left Ventricle

- Cannula shape
- Radiopaque marker
- Flexible catheter
 - Pigtail

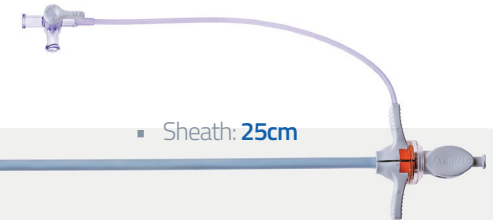


Access Complex Vasculature

- New peelaway 25 cm sheath
- Facilitate insertion in challenging vasculature



▪ Sheath: **13cm**



▪ Sheath: **25cm**

Up to **4.0** L/min
Maximize unloading of
the Heart in the Cath Lab*

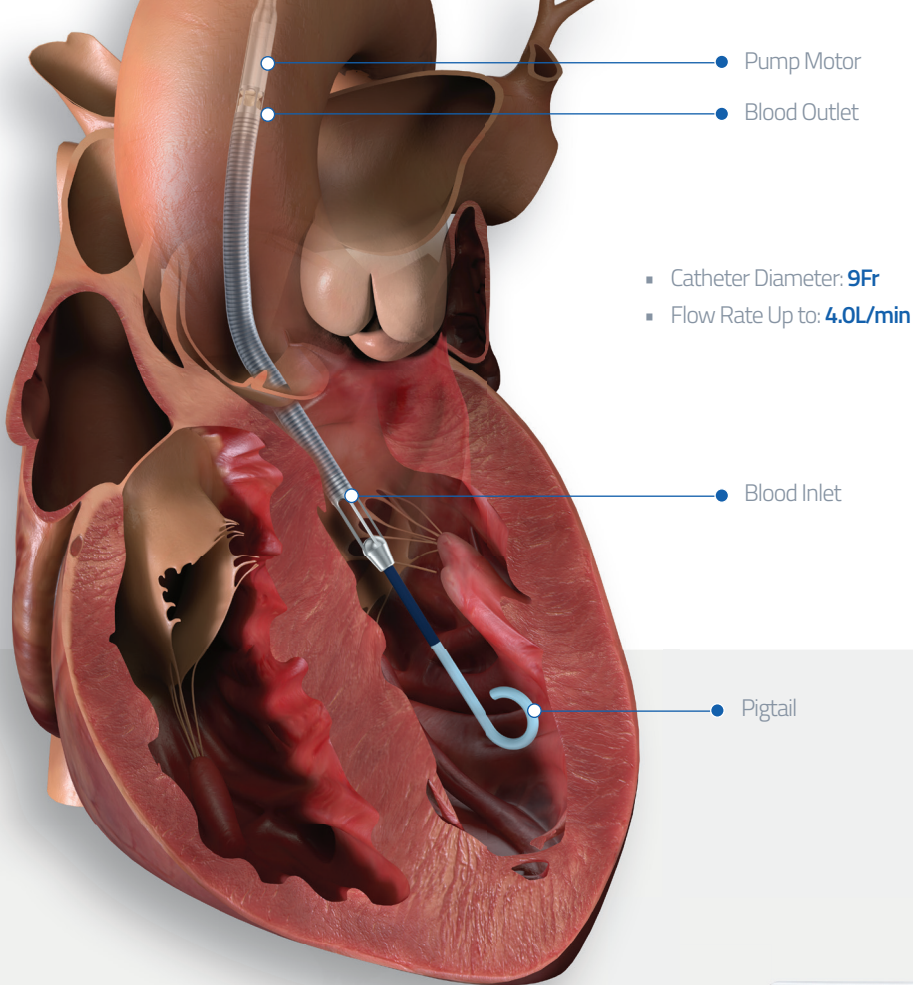
ENHANCED QUALITY OF LIFE

8 out of 10 Patients¹

Experienced Improved Ejection
Fraction² or NYHA Heart Failure Class²
After a Protected PCI procedure with
the Impella heart pump

*For additional information about flow rates see the Instructions For Use manual.
** Based off of Impella 2.5* device data.

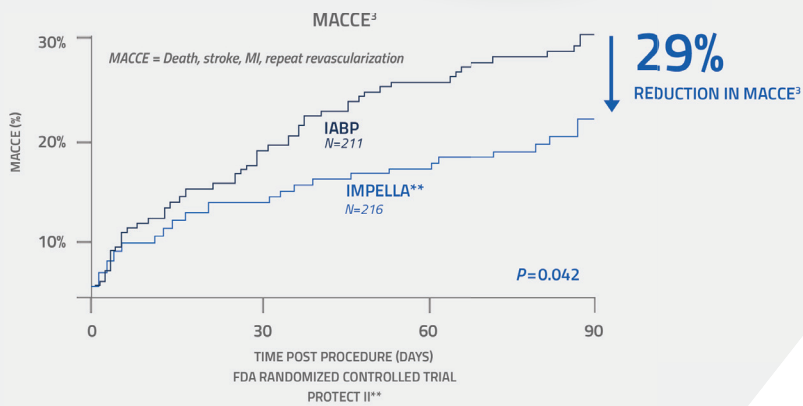
References: 1. Abiomed data on file, PROTECT II. 2. O'Neill W, et al. Circulation. 2012 Oct 2;126(14):1717-27 3. Dangas GD, et al. Am J Cardiol. 2014;113(2):222-228.



Impella CP® Device

ACTIVELY UNLOADS THE LEFT VENTRICLE OFFERING CONTINUOUS HEMODYNAMIC SUPPORT.

The Impella® heart pump pulls blood from the left ventricle through an inlet area near the tip and expels blood from the catheter into the ascending aorta offering hemodynamic support to the heart and organs including the brain and kidneys.



Purge Wizard

Impella® Automated Controller
Step-by-step instructions with
Purge Wizard designed to simplify
patient management in the ICU.

Impella® Heart Pumps

ADVANCING THE FIELD OF HEART RECOVERY.

See how the Impella device provides hemodynamic support for patients considered too high-risk for surgery.

To learn more visit www.abiomed.com

THE IMPELLA® DEVICE IS SUPPORTED BY SEVEN CLINICAL GUIDELINES

Protected PCI

2014 AHA/ACC Guideline for the Management of Patients With Non-ST-Elevation Acute Coronary Syndromes (*Circulation*)

- Revascularization in Heart Failure: **Class I**

- ▲ Revascularization strategy based on degree, severity, and extent of CAD; cardiac lesions; extent of LV dysfunction; prior revascularization
- ▲ PVADs: Large amount of ischemic territory/poor LV function

2011 ACCF/AHA/SCAI Guideline for Percutaneous Coronary Intervention (*J Am Coll Cardiol*)

- High-risk patients: **Class IIb**
- **CLASS III:** HARM without hemodynamic support; for PCI at hospitals without on-site cardiac surgery

Cardiogenic Shock & Other Guidelines

2011 ACCF/AHA/SCAI Guideline for Percutaneous Coronary Intervention (*J Am Coll Cardiol*)

- PCI and Cardiogenic Shock: **Class I**

2012 Use of Mechanical Circulatory Support: American Heart Association (*Circulation*)

- Acutely decompensated heart failure patients: **Class IIa**

2013 International Society for Heart and Lung Transplantation Guidelines for Mechanical Circulatory Support (*J Heart Lung Transplant*)

- Temporary mechanical support for patients with multi-organ failure: **Class I**

2013 ACCF/AHA Guideline for the Management of Heart Failure (*J Am Coll Cardiol*)

- "Bridge to Recovery" or "Bridge to Decision" for patients with acute, profound hemodynamic compromise: **Class IIa**

2013 ACCF/AHA Guideline for the Management of ST-Elevation Myocardial Infarction (*Circulation*)

- STEMI and Cardiogenic Shock: **Class IIb**
- STEMI and Urgent CABG: **Class IIa**

Categories referencing Impella® Devices include Percutaneous LVAD, PVAD, Non-durable MCS, TCS, and Percutaneous MCSD

INDICATIONS FOR USE

Protected PCI

The Impella 2.5® and Impella CP® Systems are a 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 and depressed left ventricular ejection fraction, when a heart team, including a cardiac surgeon, has determined high risk PCI is the appropriate therapeutic option. Use of the Impella 2.5 and Impella CP 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®, 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 and Impella CP, 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 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, Impella 5.0 and Impella LD 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 ≥ +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. Visit www.protectedpci.com/hcp/information/isi and www.cardiogenicshock.com/hcp/information/isi to learn more.



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