

Impella® heart pumps

Protected PCI with the Impella® heart pump

Effective hemodynamic support
in elective and urgent high-risk PCI

Johnson & Johnson
MedTech

Heart Recovery



What is Protected PCI?

A Protected PCI (percutaneous coronary intervention) is a minimally invasive cardiac procedure supported with an Impella heart pump.

Impella support helps maintain hemodynamic stability and provides left ventricular unloading during the procedure, which may allow for a more complete revascularization in a single session, reducing long-term incidences of major adverse cardiac and cerebrovascular events (MACCE).

Growing population appropriate for PCI

Protected PCI makes complete revascularization a safe and effective option for your patients who are poor candidates for surgery or conventional PCI.

Which of your patients may benefit from Protected PCI?

Impella heart pumps provide safe and effective hemodynamic support in elective and urgent high-risk PCI for a broad range of patients with complex coronary artery disease, hemodynamic compromise and comorbidities.

Patients benefit from this minimally invasive option that may:

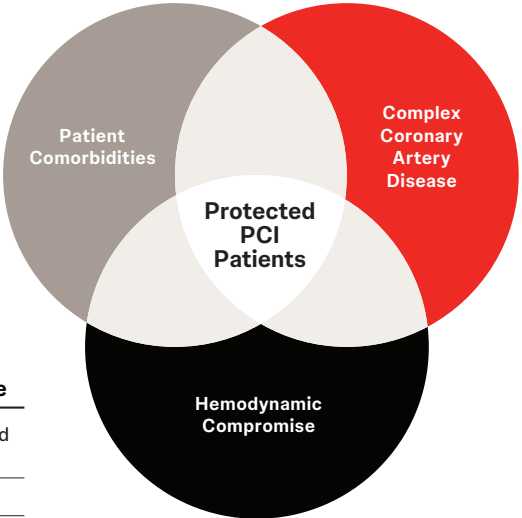
- Reduce symptoms and class of heart failure¹² and improve LVEF¹
- Significantly reduce the overall incidence of post-procedural acute kidney injury (AKI)⁴
- Reduce number of days in the hospital^{2,3}

Patient Comorbidities

- Surgical ineligibility
- Prior cardiac surgery
- Heart failure
- Renal insufficiency
- Diabetes
- Advanced age
- Unstable angina/NSTEMI

Hemodynamic Compromise

- Mild, moderate, severely depressed ejection fraction
- High LVEDP

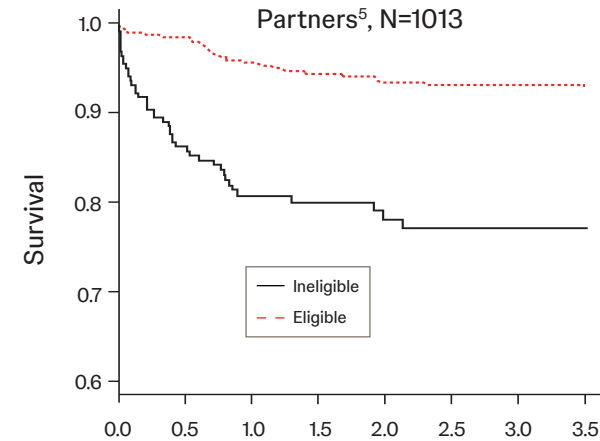


Complex Coronary Artery Disease

- Multi-vessel disease
- Distal left main disease
- Complex lesions (bifurcations, calcification)
- CTO retrograde

Surgical turndown is common and associated with higher mortality

Protected PCI may be an option when surgery is not. Consider Protected PCI for patients who are considered too high-risk and therefore turned down for surgery, and for patients who decline surgical treatment.



Clinical guidelines for Protected PCI with Impella Heart Pumps

The following clinical societies reinforce the benefit of using Impella for appropriate patient populations

2021 ACC/AHA/SCAI guideline for coronary artery revascularization (*J Am Coll Cardiol*)

- In selected high-risk patients, elective insertion of an appropriate hemodynamic support device as an adjunct to PCI may be reasonable to prevent hemodynamic compromise during PCI: Class IIb

2020 SCAI position statement on optimal PCI therapy for complex coronary artery disease (*Catheter Cardiovasc Interv*)

- MCS devices aim to improve the safety and efficacy of PCI in patients at very high risk for revascularization
- Observational studies demonstrate improved procedural cardiovascular hemodynamics and more complete revascularization in the presence of MCS devices despite higher-risk patient profiles

2021 EAPCI/ACVC expert consensus on pVAD (*EuroIntervention*)

- Indication for pVAD-Support in HRPPI: AFP (microaxial flow pump) may be considered in highly selected patients undergoing HRPPI in case of acceptable femoral access (>6mm diameter common femoral artery, no tortuosity);
- IABP and VA ECMO should not be used

2014 AHA/ACC guideline for the management of patients with Non-ST-Elevation acute coronary syndromes (*Circulation*)

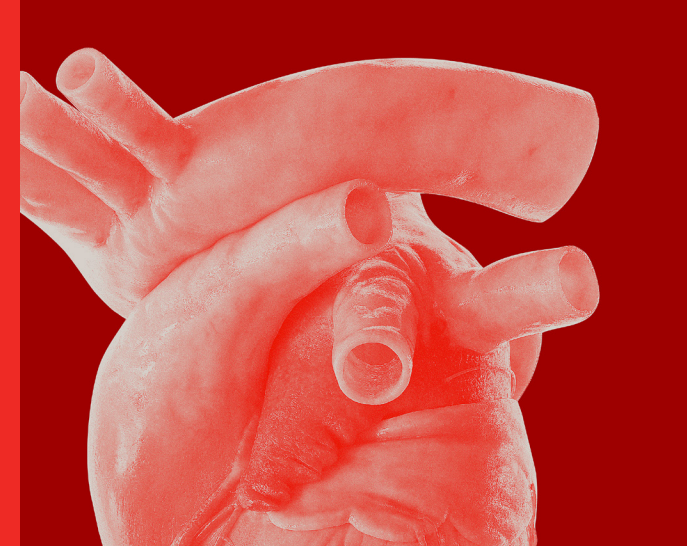
- Revascularization in Heart Failure: Class I
- pVADs: Large amount of ischemic territory/poor LV function

Categories referencing Impella Devices include Percutaneous LVAD, pVAD, Non-durable MCS, TCS, and Percutaneous MCS

Safety and Efficacy

Impella is the only FDA-approved, non-surgical heart pump that has been determined to be safe and effective to assist the pumping function of the heart during stent placement and ensure blood flow is maintained to critical organs.

During a Protected PCI or protected stenting procedure, the Impella heart pump is placed temporarily in the heart to assist the pumping function while the physician performs the necessary treatment (angioplasty, stent placement, etc.).



Clinical evidence

- Extensive data, including randomized controlled trial data and FDA-reviewed studies, support Impella® safety and efficacy^{10,11,12}
- Impella 2.5® and Impella CP® maintain patient hemodynamics which may allow for more complete revascularization and reduction in major adverse coronary and cerebrovascular events (MACCE)⁸
- Impella heart pumps are associated with reduction of kidney injury during high-risk PCI⁴
- PROTECT III, the most contemporary data, continues to show a reduction in MACCE with Impella¹¹

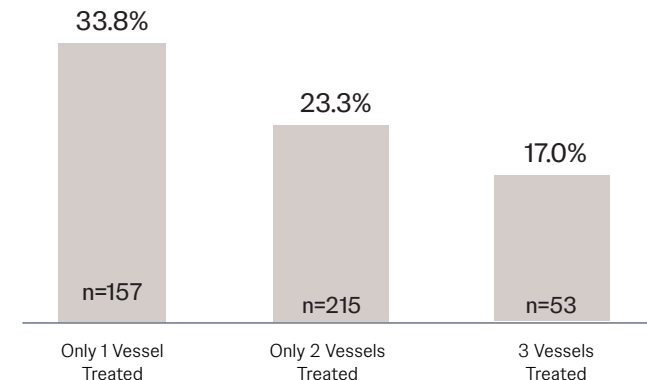


MACCE at 90 Days¹⁸

PROTECT II, all patients

Inclusion Criteria = 3VD or LM

p=0.019



FDA Approved Randomized Controlled Trials PROTECT II

Benefits of Impella

Complete revascularization associated with improved outcomes

Benefits in high-risk acute coronary syndrome (ACS) patients at 1 year⁶

71% risk reduction in all-cause death **27%** risk reduction in major adverse cardiovascular events (MACE) **41%** risk reduction in myocardial infarction (MI)

Benefits in high-risk STEMI patients at 3 years⁷

26% risk reduction in cardiovascular (CV) Death/MI **47%** risk reduction in CV Death/MI/Revascularization

Meta-analysis of benefits in 11 high-risk STEMI studies⁹

29% risk reduction in CV Death/MI



Resources

For a detailed list of resources on the Impella heart pumps, please scan the QR code or visit the link below.



Fewer days in the hospital

after the procedure compared to traditional therapy such as the intra-aortic balloon pump^{2,3}



Fewer post-hospitalization adverse events

within 90 days after your PCI procedure including death, heart attack and stroke compared to other support methods⁸



Fewer repeat visits

to the hospital for heart-related issues than traditional therapy such as the intra-aortic balloon pump²

Improve your patient outcomes

Physicians who implement best practices and protocols find significantly improved in-hospital safety in high-risk PCI patients with fewer complications when using the Impella heart pump.

Data from PROTECT III Study demonstrates that evolution and adoption of best practices leads to reduced rates of death, stroke, myocardial infarction and repeat procedures (MACCE) when Impella is used to support high-risk PCI patients.



Enhance quality of life

Statistics show that

45% of PCI patients have incomplete revascularization¹³⁻¹⁶

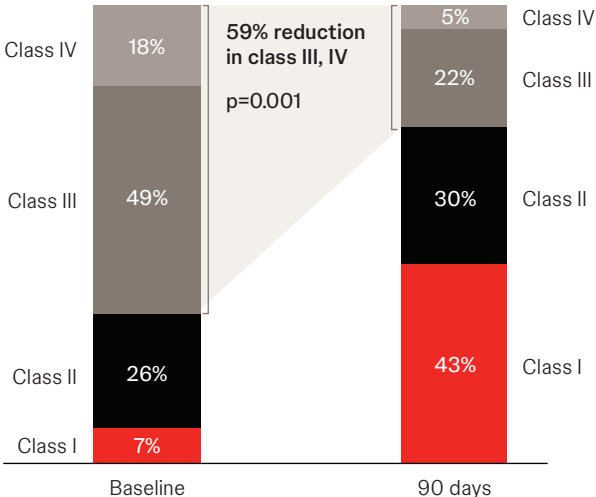
14% of PCI patients are “staged” and not all staged patients return for a second procedure, leading to an incomplete revascularization¹⁷



8 out of 10 patients

experienced improved ejection fraction¹² or NYHA heart failure class¹² after a Protected PCI procedure with the Impella Heart Pump.

NYHA class improvement post-procedure¹²



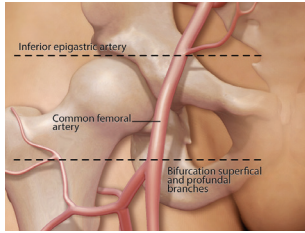
How protected PCI with Impella works

The Impella device is inserted through a small incision and advanced through the arteries and into the heart. Once in place, the Impella heart pump is turned on, pulling blood from the left ventricle and releasing it into the aorta. This active 'unloading' of the left ventricle increases blood flow to the brain and other vital organs and may protect the kidneys from acute injury.

When the heart is strong enough to pump on its own and the Impella heart pump is no longer needed, the device will be removed (before the patient goes home from the hospital).

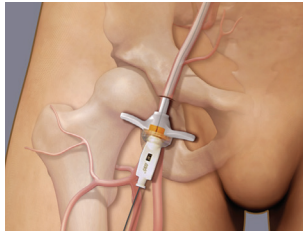
The insertion procedure

Step 1



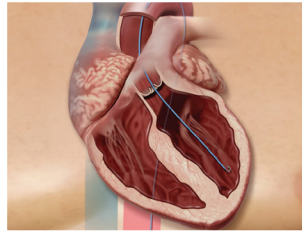
Access common femoral artery

Step 2



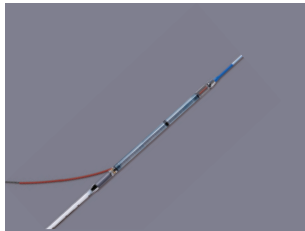
Pre-dilate, insert a 14 Fr sheath into the common femoral artery

Step 3



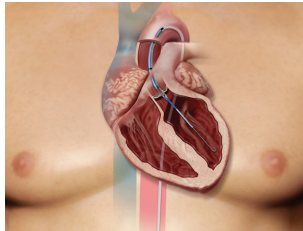
Advance a guidewire with a diagnostic catheter into the left ventricle

Step 4



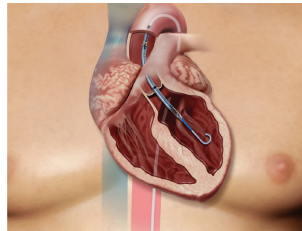
Prepare the Impella pump to guide it along the wire

Step 5

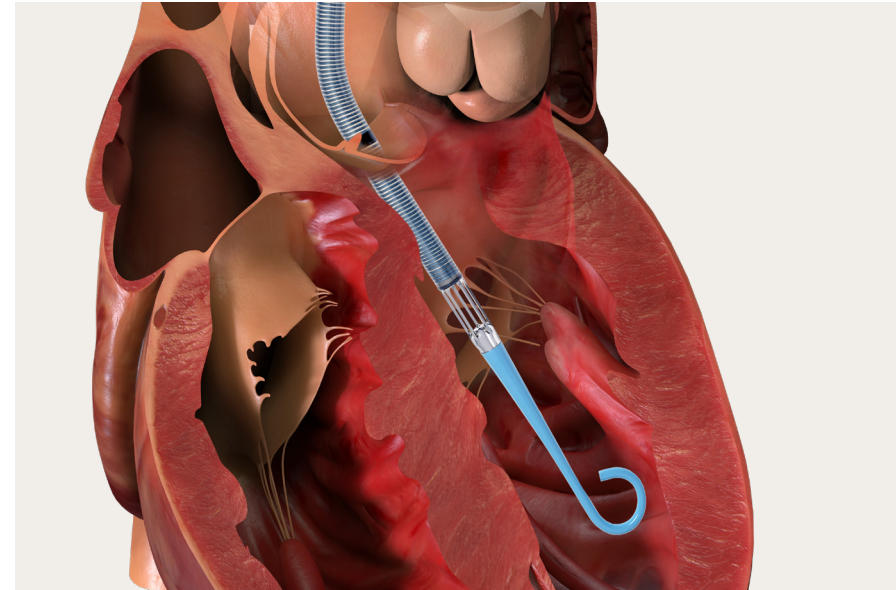


Insert and place across the aortic valve and confirm position placement

Step 6



Remove the guidewire and start the Impella device to start pulling blood from the left ventricle into the aorta



Protected PCI with Impella | Advancing the way heart failure is treated

References

1. Burzotta, F., et al. (2019). J Interv Cardiol, 2019(5), 1-10. **2.** Gregory, D., et al. (2013). Am Health Drug Benefits, 6(2), 88-99. **3.** Maini, B., et al. (2014). Expert Rev Pharmacoecon Outcomes Res, 14(3), 403-416. **4.** Flaherty, M.P., et al. (2017). Circ Res, 120(4), 692-700. **5.** Waldo, S.W., et al. (2014). Circulation, 130 (25), 2295-2301. **6.** G  n  reux, P., et al. (2012). J Am Coll Cardiol, 59(24). **7.** Mehta, S.R., et al. (2019). N Engl J Med, 381(15), 1411-1421. **8.** Dangas, G.D., et al. (2014). Am J Cardiol, 113(2), 222-228. **9.** Baine, K.R., et al. (2020). JAMA Cardiol, 10, Dixon, S.R., et al. (2009). JACC Cardiovasc Interv, 2(2), 91-96. **11.** O'Neill, W., et al. (2022). American Heart Journal, 248,139-149. **12.** Analysis from O'Neill, W.W., et al. (2012). Circulation, 126(14), 1717-1727. **13.** Farooq, V., et al. (2013). Circulation,128(2), 141-151. **14.** Hannan E.L., et al. (2006). Circulation, 113(20):2406-2412. **15.** Sarno, G., et al. (2010). Am J Cardiol, 106(10), 1369-75. **16.** Jim  nez-Navarro, M.F., et al. (2015). Heart, 101(15), 1233-1239. **17.** Watkins, S., et al. (2015). EuroIntervention, 10(12), 1402-1408. **18.** O'Neill, W. (2013, Oct 31). A Prospective, Randomized Clinical Trial of Hemodynamic Support With Impella 2.5 Versus Intra-Aortic Balloon Pump in Patients Undergoing High-Risk Percutaneous Coronary Intervention. TCT 2013, San Francisco, CA.

INDICATIONS FOR USE

High-Risk PCI

The Impella 2.5  , Impella CP   and Impella CP   with SmartAssist   Systems are temporary ($\leq$ 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, Impella CP, and 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  , Impella CP   with SmartAssist  , Impella 5.0  , Impella 5.5   with SmartAssist   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 ($\leq$ 4 days for the Impella 2.5, Impella CP, and the Impella CP with SmartAssist, and $\leq$ 14 days for the Impella 5.0, Impella 5.5 with SmartAssist 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)

in adult patients, and in pediatric patients weighing $\geq$ 52 kg for Impella CP with SmartAssist and $\geq$ 30 kg for Impella 5.5 with SmartAssist. 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.

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 $\geq$ +2); Severe arterial disease precluding placement of the Impella System; Presence of an Atrial or Ventricular Septal Defect (including post-infarct VSD); Significant right heart failure*; Left ventricular rupture*; Cardiac tamponade*; Combined cardiorespiratory failure*.

Those with an asterisks (*) apply to the cardiogenic shock indication.

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 Cardiac or Vascular injury (including ventricular perforation).

In addition to the risks above, there are other **WARNINGS** and **PRECAUTIONS** associated with Impella devices.

Visit <http://www.abiomed.com/important-safety-information> to learn more.

To learn more about Protected PCI and how Impella may be an option for your patients visit: www.HeartRecovery.com