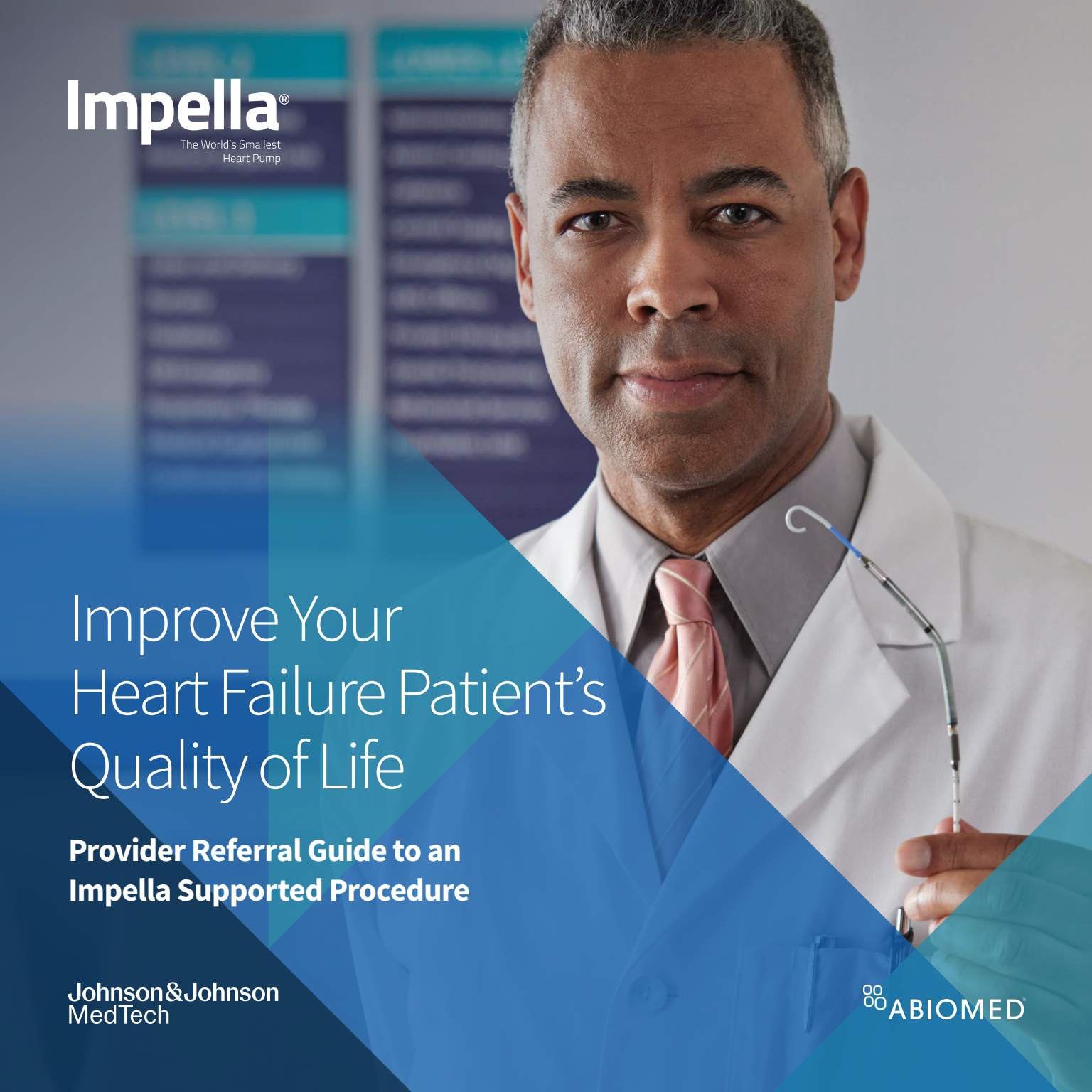
Impella®
The World's Smallest Heart Pump



Improve Your Heart Failure Patient's Quality of Life

Provider Referral Guide to an Impella Supported Procedure

Johnson&Johnson MedTech

ABIOMED

CONTENTS

*As referenced in SCAI Statement

Could an Impella Supported Procedure Be Right for Your Patient?

An Impella supported procedure, or a Protected-PCI (percutaneous coronary intervention), refers to a minimally invasive stenting procedure that utilizes the Impella heart pump for hemodynamic support in high-risk patients.

In a randomized controlled trial, 8-in-10 patients treated with Impella heart pumps experienced reduction in heart failure symptoms or improvement in heart function.[1,7] Their native heart function recovered, and heart failure symptoms, such as fatigue, shortness of breath, swelling, and coughing,[1,6] diminished just 90 days after a Protected PCI procedure, as compared to alternative treatment options.[1]

Patients experiencing ONE OR MORE of the following may benefit from a referral for an Impella® supported procedure:

1. Reduced/Low Ejection Fraction (EF)

☐ Preserved ☐ Borderline ☐ Reduced

2. HIGH-RISK:

☐ **H**ospital Admission(s) for Heart Failure
☐ **I**neligible for Cardiac Surgery
☐ **G**raft Failure (Prior Coronary Artery Bypass Graft)
☐ **H**eart Failure - Chronic

☐ **R**efractory or Chronic Unstable Angina
☐ **I**ncreasing SOB due to CAD/Worsening Edema
☐ **S**evere Coronary Artery Disease
☐ **K**idney Disease - Chronic

3. Additional Risk Factors:

☐ History of Myocardial Infarction (MI)
☐ Diabetes
☐ Hypertension
☐ Uncontrolled Dyslipidemia (with elevated LDL)
☐ Inability to Tolerate Optimal Medical Therapy
  ☐ Anti-Anginal ☐ Heart Failure
☐ Decreased Ability to Perform ADLs
☐ Smoking and/or COPD

Complex Anatomy Considerations

☐ Multi-Vessel Disease
☐ Unprotected Left Main
☐ Last Remaining Conduit
☐ Complex Lesion
  ☐ Bifurcation ☐ Calcification
☐ CTO Retrograde
☐ Large Area of Myocardium at Risk

Patients who have had an Impella supported procedure experience:

Fewer days in the hospital after your procedure compared to traditional therapy such as theintra-aortic balloon pump[2,7]

Fewer post-hospitalization adverse events in 90 days after your PCI procedure including death, heart attack and stroke compared to other support methods[6]

Fewer repeat visits to the hospital for heart-related issues than traditional therapy such as theintra-aortic balloon pump[7]

Surgical Turndown is Common and Associated with Higher Mortality

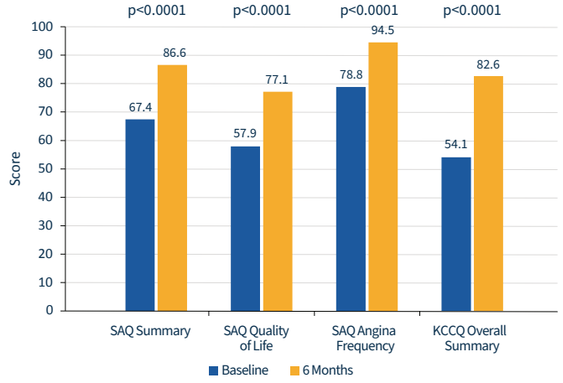
Consider a Protected PCI with Impella for your high-risk patients who are turned down for or decline surgical treatment.

Studies have shown that this minimally invasive procedure can:

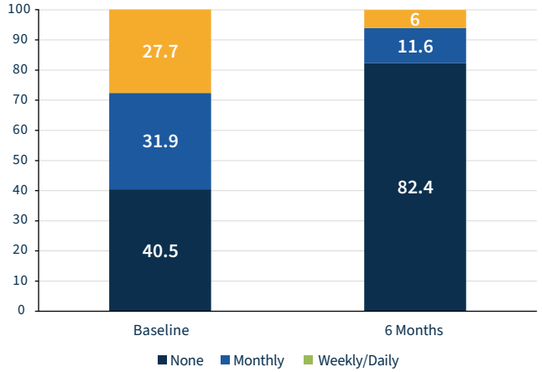
- Reduce symptoms and class of heart failure[1]
- Improve left ventricular ejection fraction[8]
- Reduce the number of days in the hospital[7,9]
- Reduce readmissions due to fewer repeat procedures[7,9]
- Enable more complete revascularization[1]

OPTIMUM
Patient-reported Health Status

Baseline and 6-Month Health Status



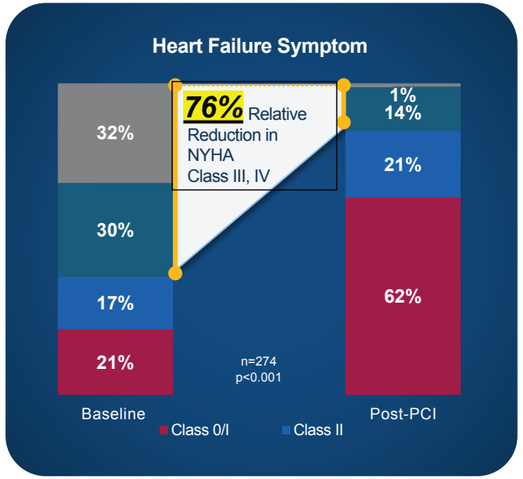
Baseline and 6-Month SAQ Angina Frequency

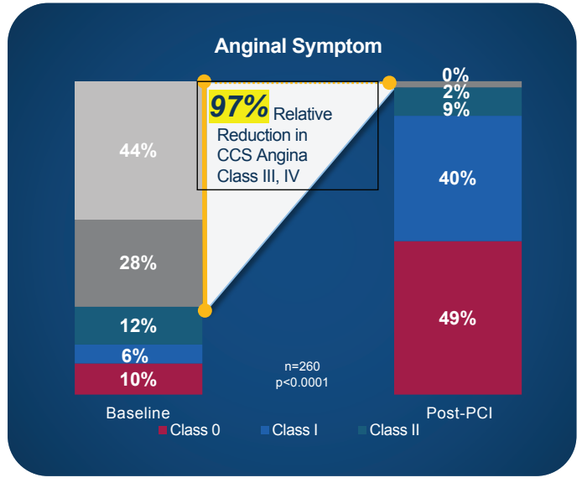


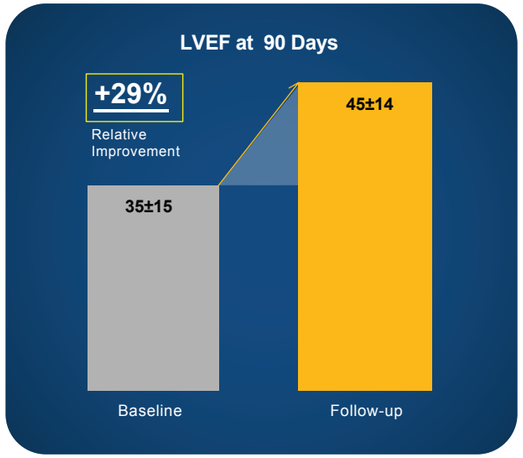
PCI in surgically-ineligible patients is associated with significant, meaningful improvements in symptom burden, physical function and quality of life

LVEF, HF Symptom, and Anginal Symptom Improvements Demonstrated in Impella® Supported HRPCI Patients

RestoreEF STUDY







"SCAI recommends the use of PCI for symptom relief in appropriate patients" SCAI President George D. Dangas, MD, PhD said in the statement, "ORBITA-2 confirms the benefit of PCI in helping stable ischemic heart disease patients, consistent with other prior trials."[17]

More than 1 million Americans diagnosed with HF annually, with mortality exceeding 20% in the first year[15]

CAD is a major contributor to the heart failure burden 60-70% of patients.[14, 16]

Prospective multicenter study assessing 90-day LVEF, HF and anginal symptom improvements
Wollmuth, J., Patel, M. et al. (2022). JSCAI, 100350. https://doi.org/10.1016/j.jscai.2022.100350

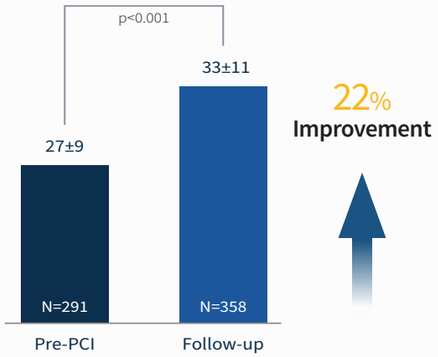
Protected PCI with Impella Clinical Evidence

The clinical data supporting the safety and effectiveness of Impella supported procedures includes prospective, randomized and nonrandomized clinical trial data, including registry data, and a published literature review with a total of 3,301 patients, presented to the FDA in support of the high-risk PCI indication. Published clinical data has also shown that the use of the Impella heart pump is associated with a reduction of kidney injury during high-risk PCI procedures.

Protected PCI Improves Quality of Life

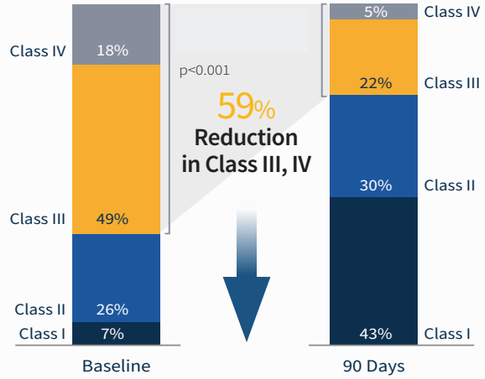
Clinical data demonstrates that Protected PCI improves quality of life by increasing ejection fraction, reducing NYHA class, reducing adverse events, and reducing acute kidney injury requiring dialysis.[1, 6, 10]

LVEF Improvement Post-Protected PCI



N=156
Patients from Impella arm of PROTECT II Trial with LVEF measurements available at baseline and 90 days

NYHA Class Improvement Post-Procedure



N=124
Patients from Impella arm of PROTECT II Trial with NYHA measurements available at baseline and 90 days

Analysis from O'Neill WW et al. Circulation. 2012 Oct 2:126(14):1717-27
PROTECT II Data on File

FDA Approved Randomized Controlled Trial PROTECT II

Complete Revascularization is Associated with Improved Outcomes*

Benefits in high-risk acute coronary syndrome (ACS) patients at **1 year**[11]

71% Risk reduction in all-cause death

27% Risk reduction in major adverse cardiovascular events (MACE)

41% Risk reduction in **myocardial infarction (MI)**

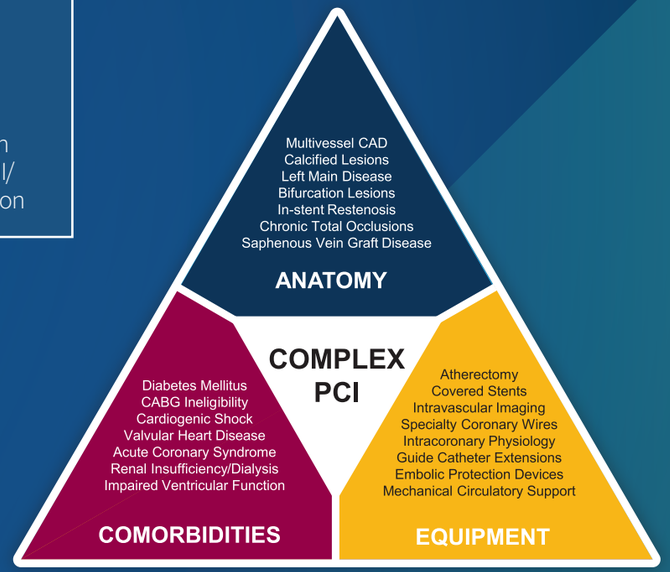
Benefits in high-risk STEMI patients at **3 years**[12]

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 studies**[13]

29% Risk reduction in CV Death/MI



Riley, R. et al. (2020). SCAI Position Statement, Catheter Cardiovasc Interv, doi: 10.1002/ccd.28994

The cost-effectiveness of the Impella platform has been demonstrated through a randomized controlled trial, all-payer population-based studies, and a systemic review of reduced length of stay. Study observations include fewer readmissions, fewer days in the hospital, and a better quality of life through reduced heart failure symptoms, after an Impella-supported procedure.

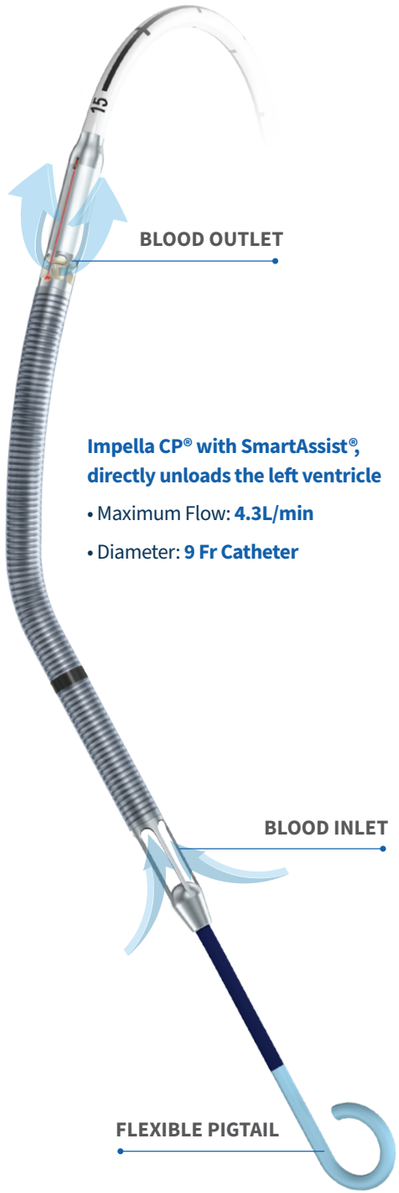
**As referenced in SCAI Statement*

How an Impella Supported Procedure Works

Impella is the only FDA-approved, non-surgical heart pump proven safe and effective to assist the pumping function of the heart during stent placement. Impella ensures blood flow is maintained to critical organs which may allow the physician to perform a more complete and optimized procedure.

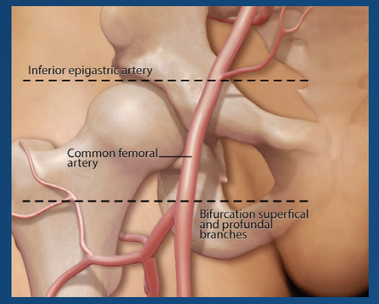
The Impella device is inserted through a small incision and advanced through the arteries and into the heart. Once in place, the Impella heart pump is turned on, pulling blood from the left ventricle and releasing it into the aorta. This active 'unloading' of the left ventricle increases blood flow to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

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



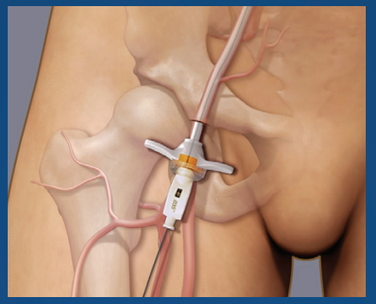
The Insertion Procedure

STEP 1



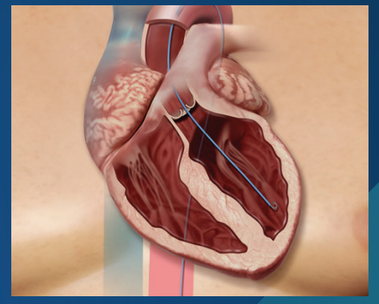
Access common femoral artery.

STEP 2



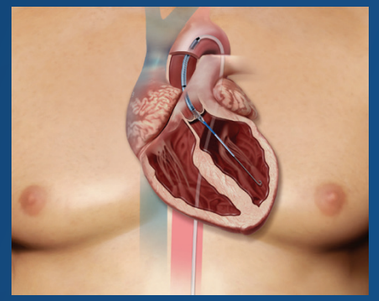
Pre-dilate, insert a 14 Fr sheath into the common femoral artery.

STEP 3



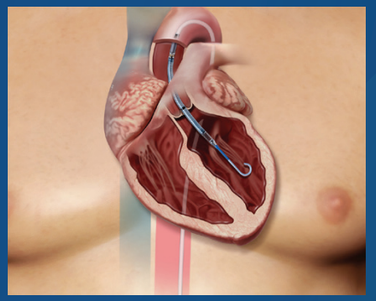
Advance a guidewire with a diagnostic catheter across the aortic valve.

STEP 4



Inset Impella and place across the aortic valve and confirm position placement.

STEP 5



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

More than 300,000 Patients Supported with the Impella Heart Pump*

Examples of Real-Life Protected PCI Patients

ROGELIO LANDIN, 63 LEG PAIN WITH PRIOR ISCHEMIC ATTACKS

Three coronary arteries were almost completely blocked

Since Rogelio had already been on the maximum medical therapy to improve his blood flow, more powerful drugs were not the answer. Due to his condition Rogelio was a prime candidate for a Protected PCI with Impella. Once the blockages were all removed, stent placed, and his heart was pumping well on its own, the pump was removed.

Now Rogelio likes to include physical activity whenever he can.

CARLOS MERCADO, 54 HEART ATTACK AFTER A HISTORY OF HEART DISEASE

Multi-vessel disease and reduced ejection fraction

Twelve years after a prior CABG, Carlos suffered a mild heart attack and he was diagnosed with complex multi-vessel disease with a reduced ejection fraction. Carlos' physicians determined he was an appropriate candidate for Protected PCI. Two days after his procedure he returned home to his family.

Carlos is back to volunteering in his community and working at his family's flower shop.

MARY HANEL, 80 DETERIORATING QUALITY OF LIFE

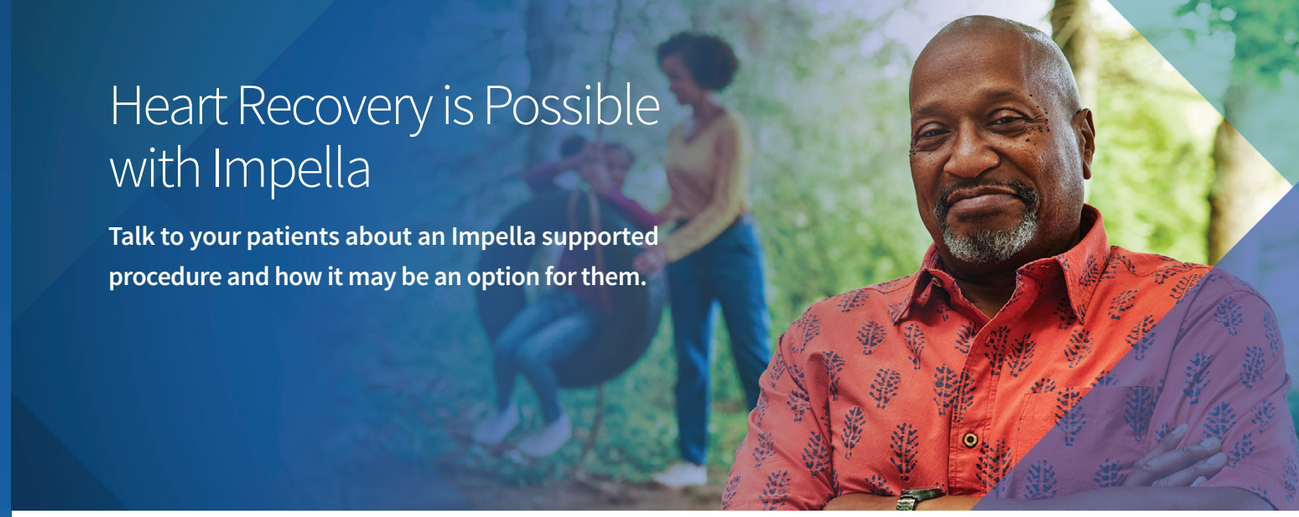
Severe blockages in her heart and chest pain

For many years Mary lived with heart failure. She was considered too high-risk for surgery. Mary's heart team implanted the Impella CP® heart pump, cleared blockages, and placed stents. The following day she was discharged.

Today, Mary feels better than she has in years.

To see other patient stories on how a Protected PCI with Impella helped them, visit Impella.com

**IQ Database and last taken from November 2020*



Heart Recovery is Possible with Impella

Talk to your patients about an Impella supported procedure and how it may be an option for them.

Patient Referral & Discussion Questions to Engage Your Patients:

- Does your patient stop to catch their breath from the waiting room to the exam room?
- Has your patient stopped walking their dog around the block?
- Is your patient able to walk out to their mailbox and back without taking a break?
- Does your patient still play with their grandchildren in the backyard or now watch from afar?
- Ask your patient, what did you do a year ago that you no longer do today and wish you could?
- Does your patient feel like they are a burden to their family and unable to contribute?

PROTECTED PCI PATIENT SELECTION TOOL

To determine if a patient may be appropriate to receive a Protected PCI Procedure with Impella, ***visit: heartrecovery.com***

FIND A HOSPITAL NEAR YOU THAT OFFERS PROTECTED PCI WITH IMPELLA

Use this locator to find a hospital in your area that offers Protected PCI with Impella, ***visit: impella.com/find-a-hospital***

References

1. O'Neill, W.W., et al. (2012). Circulation, 126(14), 1717-1727. **2.** Maini B, Gregory D, Scotti DJ, et al. Journal of Catheterization and Cardiovascular Interventions, 2014 May 1;83(6):E183-92. **3.** Gregory D, Scotti DJ. J Manag Care Med. 2013:16(1):61-9. **4.** O'Neill et al, Journal of American College of Cardiology, USPella, 2013. **5.** Rooset et al. Journal of Medical Economics, 2013. **6.** Dangas GD, Kini AS, Sharma SK, et al. Am J Cardiol. 2014;113(2):222-228. **7.** Gregory D, Scotti DJ, de Lissovoy G, et al. Am Health Drug Benefits. 2013 Mar-Apr;6(2):88-99. **8.** Burzotta, F., et al. (2019). J Interv Cardiol, 2019(5):1-10. **9.** Maini, B., et al. (2014). Expert Rev Pharmacoecon Outcomes Res, 14(3),403-416. **10.** Flaherty, M.P., et al. (2017). Circ Res, 120(4), 692-700. **11.** Généreux et al, J Am Coll Cardiol. 2012 Vol. 59, No. 24 **12.** Mehta et al, N Engl J Med. 2019 Oct 10;381(15):1411-1421 **13.** Bainey et al, JAMA Cardiol. Published online May 20, 2020 **14.** Velagaleti R, Vasan R. Cardiol Clin. 2007;25(4):487-95. **15.** Sandhu, A., et al. Circ Heart Failure. 2021; 14:e008538 **16.** Zheng, et al. JACC. 2022; v7.9, No.9; March 8, 2022: 849-860 **17.** Christopher A. Rajkumar, MB, BS et al. NEJM. Nov. 11, 2023.

Indications for Use

High-Risk PCI

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 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

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 (≤ 4 days for Impella CP with SmartAssist, and ≤ 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). 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: Impella CP with SmartAssist, Impella 5.0, Impella 5.5 with SmartAssist 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 cm^2 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 ***http://www.abiomed.com/important-safety-information*** to learn more.

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