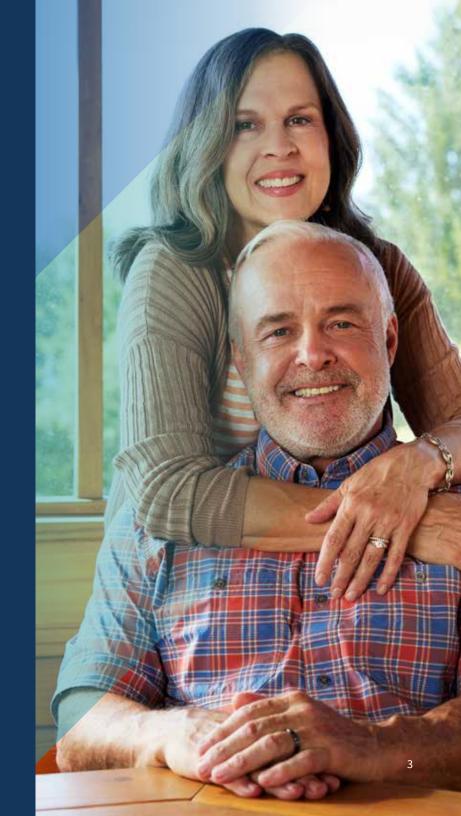




In This Patient Booklet You Will Learn About:

- Heart Disease & Heart Failure
- Coronary Artery Disease
- Treating Heart Failure
- Protected PCI with Impella
- Impella Technology
- Importance of Protected PCI with Impella
- If Protected PCI Right is For You
- Who May Not Benefit from Protected PCI
- Talking With Your Cardiologist



Heart Disease & Heart Failure

Heart disease, also called coronary artery disease, is a chronic condition in which the arteries that supply blood to your heart become narrowed or blocked due to a buildup of fatty material, called plaque. If an artery becomes blocked, it can stop blood flow and cause a heart attack.

Advanced heart failure is a chronic, progressive condition in which the heart is too weak to pump enough oxygen-rich blood throughout the body.

Heart Failure Symptoms

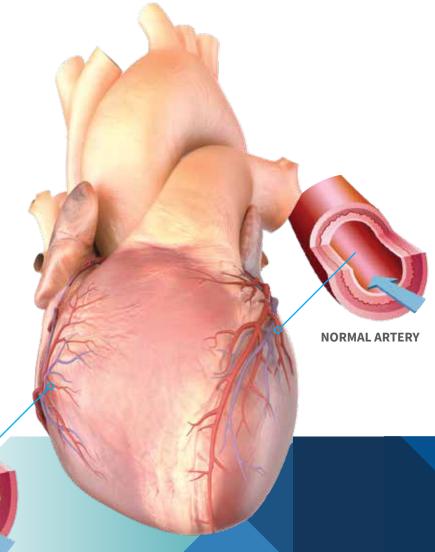
Signs and symptoms may include:

• Angina - chest pain or discomfort during or after physical exertion

• **Fatigue** - exhaustion from doing typical daily activities (i.e. going to mailbox, grocery shopping, etc.)

• Shortness of breath - difficulty breathing





Coronary Artery Disease

Patients with coronary artery disease may undergo a procedure called Percutaneous Coronary Intervention (PCI), commonly known as angioplasty or stenting.

For some patients, angioplasty or stenting might not be an option. These patients will be referred for heart surgery.

Coronary Artery Disease Symptoms

Symptoms can range from mild to severe and may include:

- **Shortness of Breath** trouble catching your breath when doing regular activities or laying down / at rest, often exacerbated / made worse by laying flat
- **Edema** swelling in the legs, ankles, feet, stomach and neck
- **Coughing** a persistent unexplained cough could be a sign that fluid is building up in your lungs
- Fatigue feeling of constant tiredness or weakness
- **Reduced Ejection Fraction** a decrease in the amount of blood your heart pumps with each beat. Normal is 55-70%
- Angina (Chest Pain) you may experience a heaviness, tightness, pressure, aching, burning, numbness, fullness, squeezing or a dull ache. The pain may radiate to the shoulder, arm, neck, back or jaw.



Each year 655,000 Americans die from heart disease — that's 1 in every 4 deaths.¹



About 20.1 million adults age 20 and older have coronary artery disease.²



Coronary heart disease is the most common type of heart disease, killing 382,820 people in 2020.²

Treating Heart Disease

Based on your test results, your doctor and the heart team (a group of doctors with various specialties) may determine that you are not a candidate for heart surgery due to higher-than-normal risk.

Your heart team may recommend a PCI for you. This minimally invasive heart procedure uses a small catheter to take pictures and deliver tools that are used to open or unblock arteries narrowed by plaque.

The most common type of PCI is angioplasty, during which a tiny balloon is inflated to compress the plaque against the sides of the artery to help blood flow better. After angioplasty, a stent may be placed to keep the artery open.

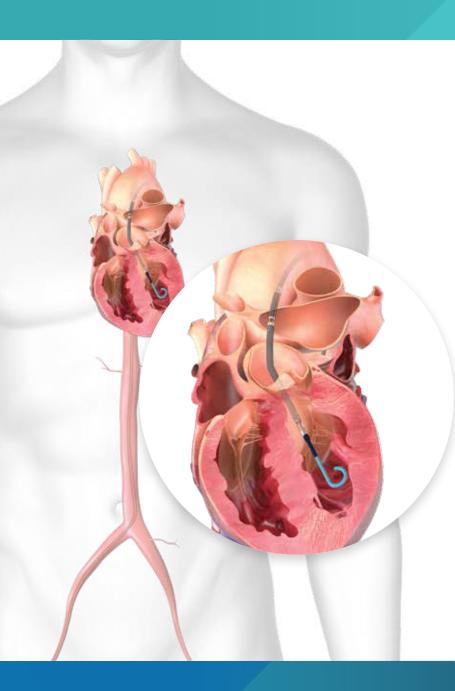
If you have health risks such as diabetes, kidney disease, or anatomic issues with your heart, you may not qualify for a conventional PCI. However, a procedure called Protected PCI with Impella may be an option for some patients with these additional health risks.

Other possible treatment options include:

- **Medicine** non-invasive treatment, but if symptoms persist, or if your coronary artery disease worsens, you may need a heart procedure
- **Percutaneous Coronary Intervention** (PCI) minimally invasive treatment
- Open-Heart Surgery invasive treatment

All heart procedures have risks:

- An allergic reaction to the medication used in conjunction with the procedure
- Clots that can travel through your blood vessels and block the blood flow to other organs, including your lungs, making breathing difficult, or increasing risk of stroke
- An infection, which could be localized or spread throughout your body
- Injury or irritation to your heart tissue, valves and blood vessels. The injury or irritation may cause your heart to beat irregularly or result in life-threatening conditions
- Bleeding, low blood pressure, low platelet count and/or damage to red blood cells. These conditions can be life-threatening
- Your liver, kidneys, or other parts of the body may not receive enough blood to function efficiently and may not work normally
- Your heart may not get better, or your heart failure condition may worsen
- The Impella may have an unexpected problem requiring it to be removed, which would result in your heart support being stopped
- An infection at the incision site. If you are obese, have diabetes, or if you've previously had CABG, the risk of infection is greater
- Memory loss and/or loss of mental clarity



Protected PCI with Impella

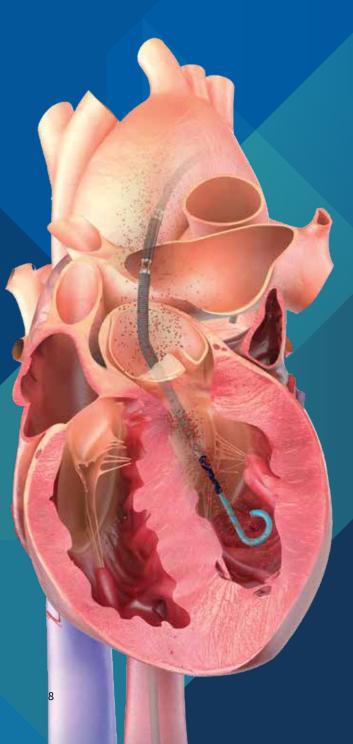
Protected PCI is a stenting procedure to treat complex coronary artery disease. It includes the use of the Impella heart pump.

The use of the Impella heart pump during a PCI allows your blood pressure and blood flow to be maintained during the procedure, which may allow your doctor to perform a more complete and optimized procedure.

Impella is temporarily 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.

When your heart is strong enough to pump on its own and the Impella heart pump is no longer needed, your cardiologist will remove it before you go home from the hospital.





Importance of Protected PCI with Impella

During a PCI, interruptions of coronary blood flow can cause problems, especially for patients with severe heart disease. Protected PCI with Impella ensures blood flow is maintained to critical organs, enabling your physician to perform a complete and optimized procedure, which decreases the likelihood of repeat procedures and multiple hospital stays.

What are the benefits of Protected PCI with Impella?



Reduced Heart Failure Symptoms

(fatigue, shortness of breath, swelling, coughing)^{1,2} such that 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^{2,8}



Fewer Days in The Hospital

after your procedure compared to traditional therapy such as the intra-aortic balloon pump³⁻⁷



Fewer Repeat Visits

to the hospital for heart-related issues than traditional therapy such as the intra-aortic balloon pump³



Fewer Post-Hospitalization Adverse Events

in 90 days following your PCI procedure including death, heart attack and stroke compared to other support methods¹



Reduced angina (chest pain)

is also a common benefit of Protected PCI.

- 1. Dangas, G.D., et al. (2014). Am J Cardiol, 113(2), 222-228. 2. O'Neill, W.W., et al. (2012). Circulation, 126(14), 1717-1727. 3. Gregory, D., et al. (2013). Am Health Drug Benefits, 6(2), 88-99.
- 4. Maini, B., et al. (2014). Catheter Cardiovasc Interv, 83(6), E183-E192. 5. Gregory, D., et al. (2013). J Manag Care Med, 16(1), 61-69. 6. O'Neill, W.W., et al. (2014). J Interv Cardiol, 27(1), 1-11.

7. Roos, J.B., et al. (2013). J Med Econ, 16(3), 3381-390. 8. PROTECT II Data on File

The use of Impella may allow you to have a PCI procedure that you could not have without support from Impella technology. While your cardiologist will discuss treatment options with you, a heart team will evaluate you to recommend the option that's right for you.

Benefits of a Protected PCI may include:

- Reduces the amount of work your heart has to do during the procedure
- Maintains adequate blood flow and blood pressure during the procedure
- Allows for a more complete revascularization (unblocking of arteries) without significantly increasing the safety risks
- Improves quality of life after the procedure



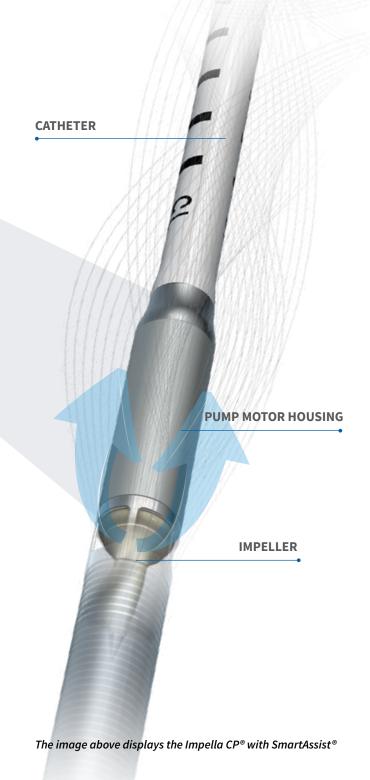
BLOOD OUTLET

Impella Technology

Impella, the world's smallest heart pump, is the only FDA-approved, non-surgical heart pump proven 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 your heart to assist the pumping function while your physician performs the necessary treatment (angioplasty, stent placement, etc.).

BLOOD INLET

FLEXIBLE PIGTAIL



What are the benefits of Impella?

- Impella allows your heart to rest and recover by temporarily assisting the pumping function
- Impella allows for more complete revascularization
- Impella reduces the patient's length of stay in the hospital^{3, 6-9}
- Impella heart pumps have the unique ability to enable heart recovery, allowing patients to return home with their native heart. Heart recovery is the ideal option for optimal quality of life and has the ability to reduce costs for the healthcare system¹⁻³



Non-Surgical

A treatment option for qualified patients with severe heart disease, including patients who are too high-risk for surgery



Improved Quality of Life

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^{5,6}



Safe and Effective

Proven safe & effective with more than 250,000* patients treated and has a lower complication rate than other options⁴

*IQ Database and last taken from March 2023

1. Maini, B., et al. (2014). Expert Rev Pharmacoecon Outcomes Res, 14(3), 403-416. 2. Cheung, A., Danter, M., & Gregory, D. (2012). TCT-385 Comparative Economic Outcomes in Cardiogenic Shock Patients Managed with the Minimally Invasive Impella or Extracorporeal Life Support. Journal Of The American College Of Cardiology, 60(17), B110. 3. Gregory, D., et al. (2013). Am Health Drug Benefic, 6(2), 88-99. 4. Dangas, G.D., et al. (2014). Am J Cardiol, 113(2), 222-228. 5. O'Neill, WW., et al. (2012). Circulation, 126(14), 1717-1727. 6. Maini, B., et al. (2014). Catheter Cardiovasc Interv, 83(6), E183-E192. 7. Gregory, D., et al. (2013). J Manag Care Med, 16(1), 61-69. 8. O'Neill, W.W., et al. (2014). Interv Cardiol, 27(1), 1-11. 9. Roos, J.B., et al. (2013). J Med Econ, 16(3), 3381-390



Who may not benefit from Protected PCI

IMPELLA IS NOT RIGHT FOR EVERYONE.

If you have any of the conditions listed below, you may not derive benefit from Protected PCI. Your doctor will determine whether you have any of the following conditions:

- Defects in your arteries and veins that could limit the opening for the pump to pass including:
 - Calcium deposits or hardening of the blood vessel walls
 - A replacement heart valve or other heart device
 - Severe narrowing of one of your heart valves
- Presence of loosely attached clot(s) inside your blood vessels or heart, which may break off while the pump is in use and result in harm to you
- A problem with your aortic valve that allows blood to leak back into the left ventricle from the aortic artery—this can cause your heart to work harder and, over time, may decrease the ability of your heart to supply enough fresh blood to your body

Talking With Your Cardiologist

Discussion Guide

If you or a loved one has been turned down for heart surgery, talk to your doctor to learn if Protected PCI with Impella could be an option. Consider asking these questions as you review your treatment options for severe coronary artery disease and/or advanced heart failure with your cardiologist:

- Am I considered high-risk for PCI?
- What's my Ejection Fraction (EF)?
- If I am considered high-risk, is Protected PCI with the Impella heart pump an option for me?
- Does my hospital or center offer Protected PCI with the Impella heart pump?
- What does a Protected PCI procedure involve?
- What are the benefits of a Protected PCI for me?
- How long does it take to recover after a Protected PCI?

Notes

Download the discussion guide from **www.Impella.com**

Indications for Use

How is the Impella 2.5° and Impella CP° with SmartAssist° Device Used?

Impella CP with SmartAssist, the world's smallest heart pump, is intended for temporary (less than or equal to six hours) use to maintain stable heart function. Impella CP with SmartAssist can potentially lower certain risks in patients with severe coronary artery disease who otherwise have stable heart function and are undergoing percutaneous coronary intervention (PCI) such as an angioplasty or stenting, when a team of doctors that includes a heart surgeon has determined that a PCI with Impella is appropriate for this patient. 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.

Important Risk Information for the Impella 2.5 and Impella CP with SmartAssist Devices

Protected PCI is not right for everyone.

You should **NOT** be treated with the Impella 2.5 or Impella CP with SmartAssist if your doctor determines you have certain pre-existing conditions, such as: severe narrowing of your heart valves; clots in your blood vessels; replacement heart valve; or certain deficiencies in your heart valve.

Many of the risks related to the Impella 2.5 and Impella CP with SmartAssist devices are the same as those with the PCI being completed and the placement of any pump used to help the heart. Risks related to the use of the Impella 2.5 and Impella CP with SmartAssist can include certain allergic reactions to medications, infections, blood clots, injury to heart tissue, valves or blood vessels, bleeding, low blood pressure, low platelet count and/or damage to red blood cells. Some of these conditions could be life threatening.

To learn more about **additional risk information** associated with the use of the Impella 2.5 and Impella CP with SmartAssist, speak with your doctor and visit **www.abiomed.com/important-safety-information**

Protected PCI is Possible at a Hospital Near You

Improve Your Quality of Life

To learn more about a hospital or heart center near you with an established Impella heart pump program visit:

www.Impella.com/find-a-hospital



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www.abiomed.com

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FEDERAL LAW RESTRICTS THIS DEVICE FOR SALE BY OR ON THE ORDER OF A PHYSICIAN.