ABOUT THIS BROCHURE

THIS BOOKLET IS INTENDED FOR GENERAL INFORMATION ONLY. YOUR DOCTOR SHOULD ALWAYS BE YOUR PRIMARY SOURCE OF INFORMATION ABOUT YOUR HEART CONDITION AND YOUR GENERAL HEALTH.

If you have questions about the Impella heart pump that are not covered in this booklet, please visit our patient and caregiver website at www.Impella.com

Glossary

For a detailed list of words contained in this brochure and their meanings, please scan the QR code or visit the link below.

www.Impella.com/glossary
In This Patient Brochure You Will Learn About:

— Heart Disease & Heart Failure
— Coronary Artery Disease
— Treating Heart Failure
— What is Protected PCI with Impella
— What is Impella?
— Why is Protected PCI with Impella Important
— Is Protected PCI Right For Me?
— Who Should NOT be Treated with 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** - shortness of breath
- **Reduced Ejection Fraction** - a decrease in the amount of blood your heart pumps with each beat. Normal is 55-70%

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

About 18.2 million adults age 20 and older have Coronary Artery Disease.²

Coronary heart disease is the most common type of heart disease, killing 365,914 people in 2017³

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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
What is 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.

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 protects the kidneys from acute injury.

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).

Learn more about Protected PCI visit www.Impella.com
What is Impella®

Impella, the world’s smallest heart pump is a support system of percutaneous catheter-based devices offering hemodynamic support to the heart.

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 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.).

Watch the Animation
See how the device is inserted and how it works.
www.Impella.com/animation
What are the benefits of Impella?

- Impella allows your heart to rest and recover by temporarily assisting the pumping function
- The Impella is a heart pump intended for temporary (≤ 6 hours) use by patients having PCI due to severe disease of the blood vessels supplying the heart and reduced heart function
- The Impella 2.5® and the Impella CP® with SmartAssist® devices are smaller than the width of a pencil and can be inserted using a non-surgical technique
- 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 quality of life and has the ability to save cost for the healthcare system\textsuperscript{1,2,3}

\*IQ Database and last taken from November 2020

Why is Protected PCI with Impella Important?

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, decreasing the likelihood of repeat procedures and multiple hospital stays.

What are the benefits of Protected PCI with Impella?

- **Reduces Heart Failure Symptoms** (fatigue, shortness of breath, swelling, coughing)\(^1\)\(^,\)\(^7\) such that 8-in-10 patients experience improved quality of life\(^6\)\(^,\)\(^7\)
- **Fewer Days in The Hospital** after your procedure compared to traditional therapy such as the intra-aortic balloon pump\(^2\)\(^,\)\(^3\)\(^,\)\(^8\)\(^,\)\(^9\)\(^,\)\(^10\)\(^,\)\(^11\)
- **Fewer Post-Hospitalization Adverse Events** in 90 days after your PCI procedure including death, heart attack and stroke compared to other support methods\(^5\)
- **Fewer Repeat Visits** to the hospital for heart-related issues than traditional therapy such as the intra-aortic balloon pump\(^4\)

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6. After a Protected PCI with Impella. Protect II. Data on file at Abiomed.
The use of the Impella may allow you to have a high-risk PCI procedure (HRPCI) that you could not have without support from the device. 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 HRPCI procedure, so it is better able to handle the process of repairing any blockages in the coronary arteries
- Maintains adequate blood flow and blood pressure during the HRPCI procedure
- Allows for a more complete revascularization (unblocking of arteries) without significantly increasing the safety risks
- Improves quality of life after the procedure
Is Protected PCI Right for Me?

You might be a candidate for Protected PCI, if you have severe coronary artery disease and:

- Your cardiologist has told you that a PCI (angioplasty) or stent placement is risky
- Your surgeon has told you that you are not a candidate for surgery due to your risk factors
- You have other health concerns like diabetes, kidney disease, or obesity

You might be a candidate for Protected PCI, if you also have additional risk factors, such as:

- Advanced age diabetes
- History of chest pain
- Other diseases of the blood vessels in the body
- Chronic heart failure
Following the Protected PCI procedure, I felt better than I had in a long time. Today, I am back to enjoying life with my wife and family and I am beyond grateful.

Mongin Smyly
Impella Heart Pump Patient

Who Should NOT have a Protected PCI

IMPELLA IS NOT RIGHT FOR EVERYONE.

If you have any of the conditions listed below, you may not be able to be treated with Protected PCI. Your doctor will determine whether you have any of the following conditions:

- Defects in your arteries and veins which 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 using this to 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?

Download the discussion guide from www.impella.com
Indications for Use

How is the Impella 2.5® and Impella CP® with SmartAssist® Device Used

The Impella 2.5 and Impella CP with SmartAssist, the World’s Smallest Heart Pumps, are intended for temporary (less than or equal to six hours) use to maintain stable heart function. The Impella 2.5 and 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.

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/my-hospital