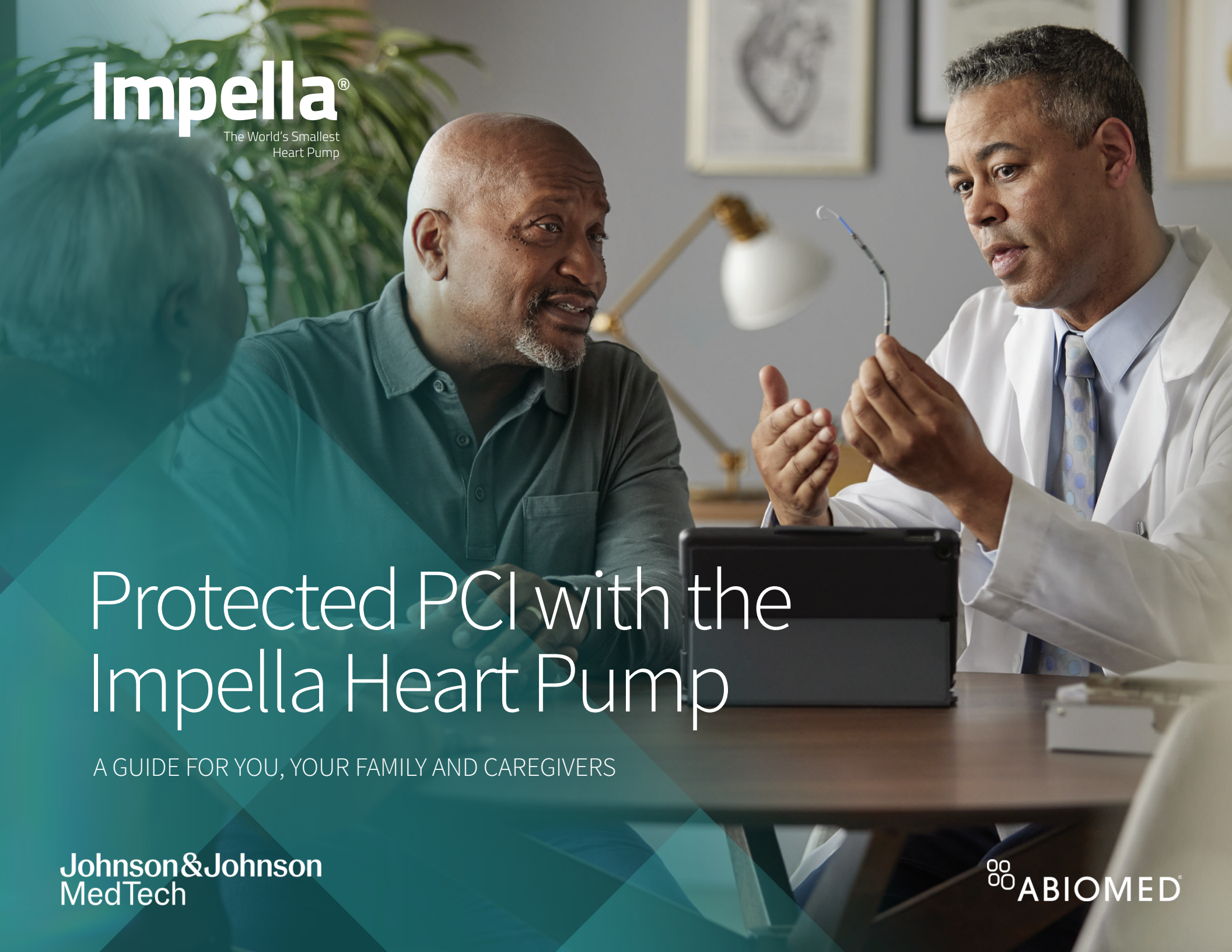




Impella®
The World's Smallest
Heart Pump

Protected PCI with the Impella Heart Pump

A GUIDE FOR YOU, YOUR FAMILY AND CAREGIVERS

Johnson & Johnson
MedTech

 **ABIOMED®**

A smiling woman with long dark hair, wearing a dark red floral dress, holds a large red heart-shaped pillow. The word "Impella" with a registered trademark symbol is printed in white on the heart. The background is a solid teal color.

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**

Laura Hernandez
Impella Heart Pump Patient

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

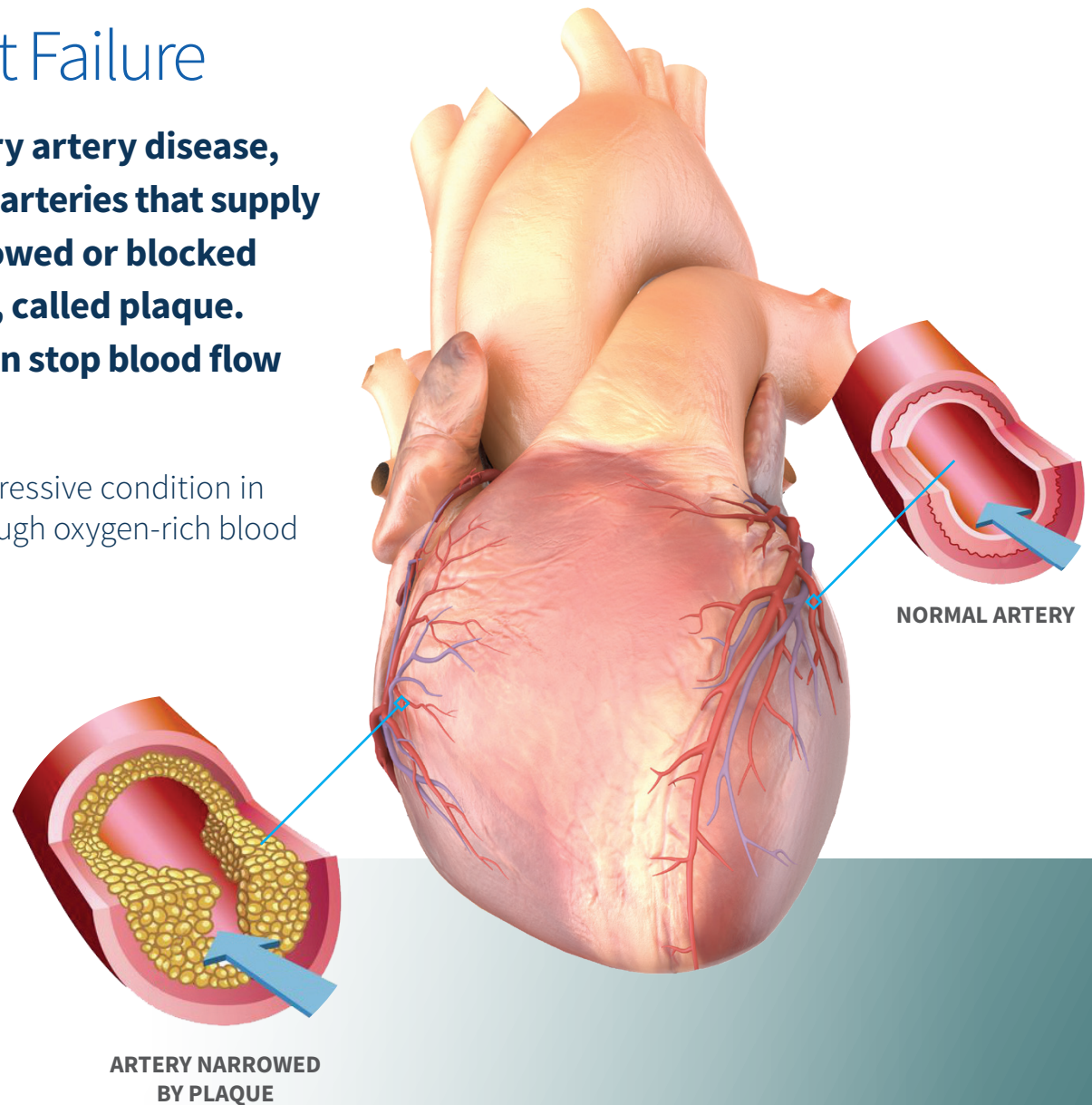
Heart disease, also called coronary artery disease, is a chronic condition in which the arteries that supply blood to your heart become narrowed or blocked due to a buildup of fatty material, called plaque. If an artery becomes blocked, it can stop blood flow and cause a heart attack.

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



The image above displays the buildup of plaque in an artery, which is called atherosclerosis.

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 50-70%³
- **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.



About 695,000 people in the United States died from heart disease in 2021—that's 1 in every 5 deaths.^{1,2}



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



Coronary artery disease is the most common type of heart disease, killing 375,476 people in 2021.²

1. National Center for Health Statistics. Multiple Cause of Death 2018–2021 on CDC WONDER Database. Accessed February 2, 2023. 2. Tsao CW, Aday AW, Almarazgo ZI, Beaton AZ, Bittencourt MS, Boehme AK, et al. Heart Disease and Stroke Statistics—2023 Update: A Report From the American Heart Association. Circulation. 2023;147:e93–e621. 3. American Heart Association. (2023, June 14). Ejection fraction heart failure measurement. [www.heart.org; American Heart Association. https://www.heart.org/en/health-topics/heart-failure/diagnosing-heart-failure/ejection-fraction-heart-failure-measurement](https://www.heart.org/en/health-topics/heart-failure/diagnosing-heart-failure/ejection-fraction-heart-failure-measurement)

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 anatomical 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

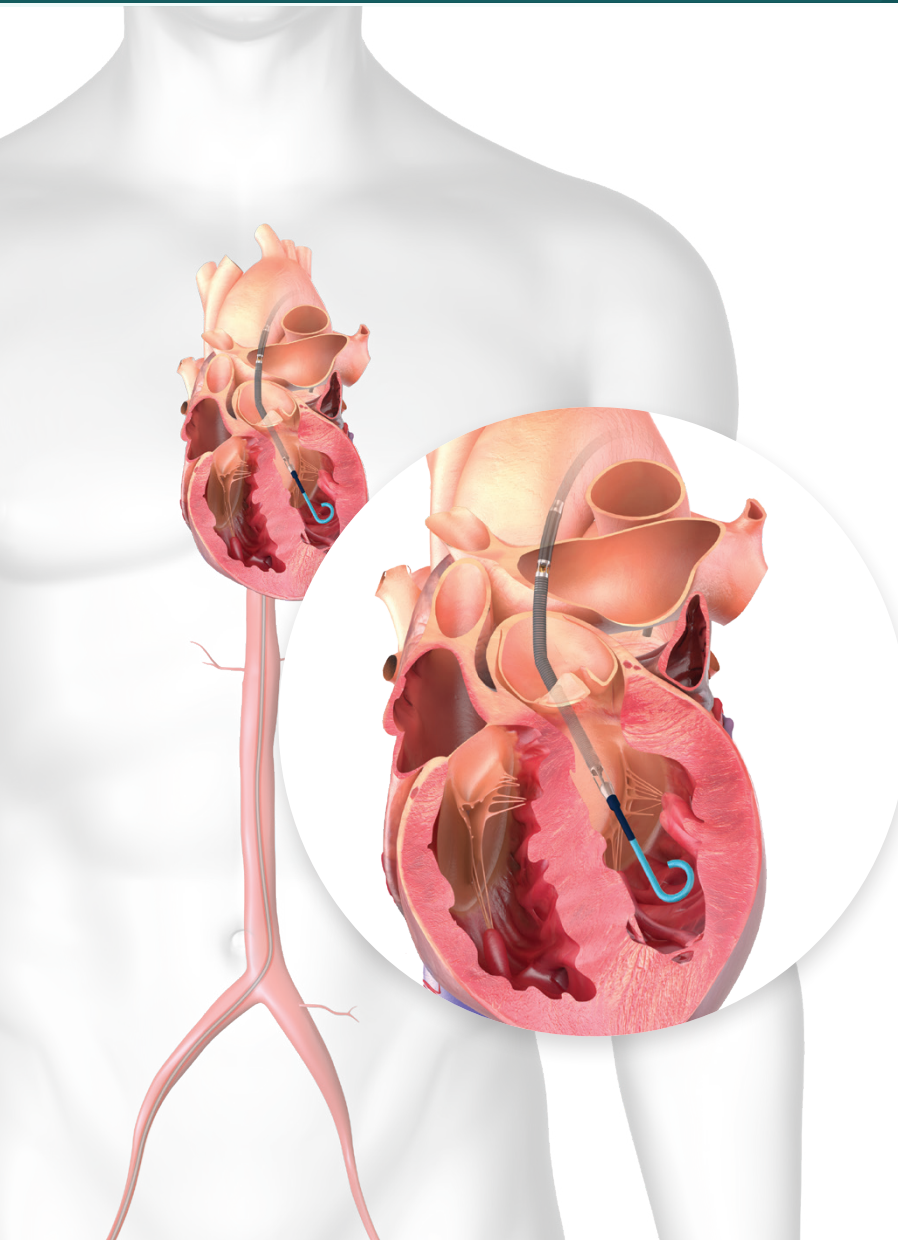
Protected PCI with Impella

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.



Procedure
Angioplasty/Stent + Support
Impella = Protected PCI

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, coughing¹



Fewer Days in The Hospital

after your procedure compared to traditional therapy such as the intra-aortic balloon pump²



Fewer Repeat Visits

to the hospital for heart-related issues than traditional therapy such as the intra-aortic balloon pump¹



Fewer Post-Hospitalization Adverse Events

in 90 days following your PCI procedure including death, heart attack and stroke compared to other support methods^{3,4}



Reduced angina (chest pain)

is also a common benefit of Protected PCI.¹

1. Wollmuth, et al. JSCAI, 2022 1(5). <https://doi.org/10.1016/j.jscai.2022.100350> 2. Lansky, et al. The American Journal of Cardiology, 2022. <https://doi.org/10.1016/j.amjcard.2022.08.032>
3. Abu-Much, et al., AHJ, 2024 269:139-148. <https://doi.org/10.1016/j.ahj.2023.12.015> 4. Zeitouni, et al., Circulation: Cardiovascular Interventions, 2023 15(5). <https://doi.org/10.1161/CIRCINTERVENTIONS.121.011534>

Get To Know Them by Heart.

- **General Cardiologist**

Diagnoses, treats, and manages the treatment plans for various heart conditions and cardiovascular disease in patients of all ages.

- **Heart Failure Cardiologist**

Specializes in the diagnoses, treatment, and management of patients with heart failure, focusing on the cause of heart failure to optimize care and improve outcomes for individuals with this condition.

- **Interventional Cardiologist**

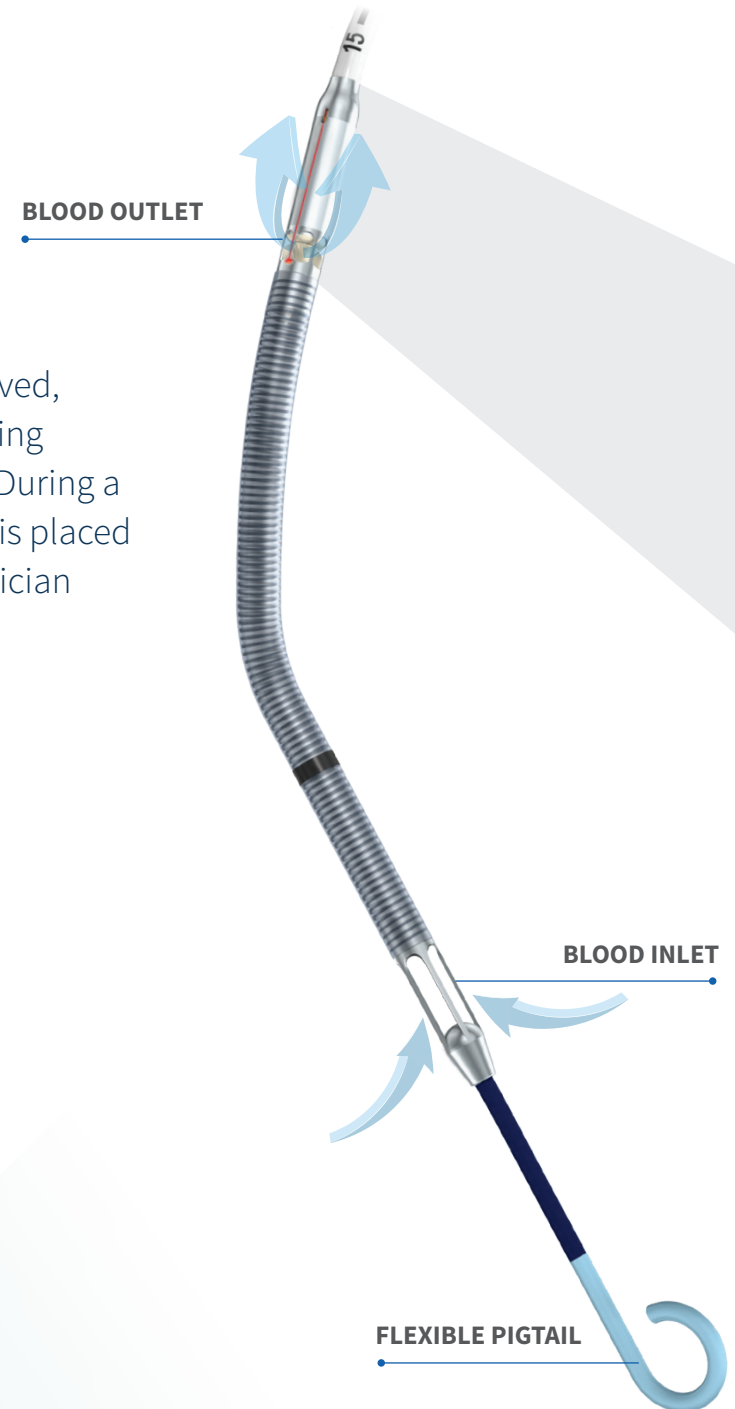
Performs minimally invasive stenting procedures, such as an Impella supported PCI to help reduce CAD-related symptoms and improve patients' quality of life.

Ask your General Cardiologist about Impella and whether seeing an IC could be the right next move for you. Or, contact a Patient Education Specialist to find an IC near you.



Impella Technology

Impella, the world's smallest heart pump, is the only FDA-approved, non-surgical heart pump 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.).



CATHETER

PUMP MOTOR HOUSING

IMPELLER

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^{1,2}
- Impella reduces the patient's length of stay in the hospital³
- 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 system^{1,3}



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

Impella heart pumps can reduce heart failure symptoms and may improve heart function¹



Proven

More than 300,000* patients treated and has a lower complication rate than other options^{4,5}

*IQ Database and last taken from March 2023

1. Wollmuth, et al. JSCAI, 2022 1(5), <https://doi.org/10.1016/j.jscai.2022.100350> 2. O'Neill, et al. AHJ, 2022 248:139-149, <https://doi.org/10.1016/j.ahj.2022.02.006>
3. Lansky, et al. The American Journal of Cardiology, 2022, <https://doi.org/10.1016/j.amjcard.2022.08.032> 4. Abu-Much, et al., AHJ, 2024 269:139-148. <https://doi.org/10.1016/j.ahj.2023.12.015> 5. Zeitouni, et al., Circulation: Cardiovascular Interventions, 2023 15(5), <https://doi.org/10.1161/CIRCINTERVENTIONS.121.011534>

The image above displays the Impella CP® with SmartAssist®

Is Protected PCI Right for You?

You might benefit from 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 such as diabetes, kidney disease or obesity

You might benefit from 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



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

Discussion Guide

- 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?

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Indications for Use

How is the Impella Heart Pump Used?

Impella®, the world's smallest heart pump, is intended for temporary (less than or equal to six hours) use to maintain stable heart function. The Impella heart pump 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 heart pump 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 Heart Pump

Protected PCI is not right for everyone.

You should **NOT** be treated with the Impella heart pump 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 an Impella heart pump supported procedure 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 an Impella heart pump 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

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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