Patient Information for the Impella 2.5® and Impella CP® with SmartAssist®

A Guide for You, Your Family and Caregivers

ABIOMED®

Federal Law (USA) restricts this device to sale by or on the order of a physician.

Please address any questions you have about the Impella 2.5 or Impella CP with SmartAssist to your doctor.
Rx only

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About This Booklet

This booklet is for general information only. Your doctor should always be your primary source of information about your heart condition and your general health.

This booklet is for people who are preparing to have, or have already had, a high-risk percutaneous coronary intervention (HRPCI) with Impella 2.5 or Impella CP with SmartAssist, which are collectively referred to as “Impella”. If you have questions about Impella that are not covered in this booklet, please visit our patient website at **www.Impella.com**.

People with severe blockages in their coronary arteries, with or without reduced pumping ability, are often treated with coronary artery bypass surgery, commonly known as open heart surgery. However, your team of physicians, including a cardiac surgeon, has determined that surgery is too risky due to other non-heart-related problems such as advanced age, diabetes, kidney failure, prior heart surgery, etc. and that HRPCI is the appropriate procedure for you. Your PCI is considered high-risk due to the extent or location of your coronary blockages and the impact the procedure may have on your heart, especially if its pumping ability is already compromised. Hemodynamic instability, uncontrolled swings in blood pressure and heart function, may occur during a HRPCI procedure and can increase risk of complications or death and can limit your doctor’s ability to treat all blockages. The Impella heart pump is placed into your heart and provides pumping assistance to ensure blood flow is uninterrupted during your HRPCI procedure to minimize the risks hemodynamic instability.

This booklet explains what the Impella heart pump is, how it is inserted, what it feels like when your heart gets support from Impella, and what you can expect after the Impella device is removed.

To help you better understand some of the terms used in this booklet, a Glossary is included starting on page 4 and can be found online at **www.Impella.com**

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Glossary

Aorta: The large artery that carries blood from the heart to the branch arteries throughout the body. The part of the aorta at the top of the left ventricle is called the ascending aorta.

Atherosclerosis: Thickening of artery walls due to the build-up of plaque and other deposits— causes restriction of blood flow.

Anti-Platelet Medication: Once a stent (see below) is placed in a coronary artery, medication is required to reduce the risk of the stent clotting over time. This medication reduces the blood's ability to clot.

Blood vessels: An extensive network of flexible arteries, veins, and capillaries that carry blood to and from the heart and throughout the body. The blood vessels are the transportation system of the body.

Catheter: Thin, flexible tube that can be inserted into the body to treat conditions or perform procedures.

Caution: A statement describing actions that could result in minor or moderate injury to the patient, device damage, or improper functioning of a device.

Coronary arteries: A network of blood vessels that originate in the aorta and supply the heart muscle with blood.

Coronary artery bypass grafting (CABG): An open heart surgery procedure that treats the symptoms of coronary artery disease. The surgery reroutes (or "bypasses") the blood flow around the blockages in the coronary arteries, restoring blood flow to the heart muscle. Also called coronary artery bypass surgery.

Coronary artery disease (CAD): A disease in which plaque deposits containing cholesterol and fat globules, called atherosclerosis, are deposited within the arteries.

Ejection fraction (EF): A measure of how efficiently the heart is able to pump blood from the left ventricle. Ejection fraction is expressed as the percentage of blood that is ejected when the ventricle contracts. This measure describes how efficiently the left ventricle pumps oxygenated blood to the body.

Heart valves: Flap-like structures that maintain blood flow in one direction through the heart.

Hemodynamic Instability: A state requiring pharmacologic or mechanical support to maintain a normal blood pressure or adequate blood flow.

Glossary

High-Risk Percutaneous Coronary Intervention (HRPCI): You are considered high-risk when the extent or location of your coronary blockages and the temporary effects of PCI treatment on your heart function (especially if your heart function is already compromised) increase your risk for hemodynamic instability (uncontrolled swings in blood pressure and heart failure) during the procedure

Minimally invasive: In minimally invasive surgical procedures, surgeons use small incisions and catheters to minimize tissue injury during the procedure. This can be safer than conventional surgery and lead to faster healing.

Open-heart surgery: A surgical procedure, also known as CABG, where arterial and venous grafts are used to bypass narrowed or blocked coronary arteries. The surgery is typically performed by opening the chest through the sternum (breast bone) to provide access to the heart. The heart itself may not be opened.

Percutaneous coronary intervention (PCI): PCI is a non-surgical procedure used to treat coronary artery disease by inserting a catheter with a balloon on the end and inflating the balloon to open up the vessel. It is also commonly referred to as percutaneous transluminal coronary angioplasty (PTCA). During the procedure, coronary stents are often placed to hold the artery open. This procedure is called stenting.

Primary endpoint: An important pre-agreed upon result in a clinical trial.

Revascularization: The restoration of blood flow to parts of the body that have suffered lack of blood flow.

Stent: A wire mesh tube inserted into a blood vessel and expanded to keep the vessel open. Coronary stents may be bare metal or drug eluting and require antiplatelet medication.

Warning: A statement describing an action or situation that could seriously harm the patient

About the Heart

This section is intended for general information only. Your doctor should always be your primary source of information about your heart, its current condition and the best treatment options.

How the Heart Works

The heart is a muscle that pumps blood through the body. The heart pumps blood by expanding and contracting (beating) about 100,000 times each day.

Blood pumped by the heart brings oxygen to the body. It also removes carbon dioxide and other waste produced by the body. A healthy body depends on the heart pumping enough blood to deliver oxygen and food and to remove waste.

The Right and Left Sides of the Heart

The heart is divided into two sides, the right side and the left side. The right side of the heart pumps blood through the lungs. The left side of the heart pumps blood through the rest of the body. ***Heart valves*** keep the blood moving in the right direction through the heart.

Each side of the heart has two chambers, an atrium and a ventricle (Figure 1).

- The ***right atrium*** (labeled RA) receives deoxygenated blood from the body and delivers it to the right ventricle.
- The ***right ventricle*** (labeled RV) pumps blood through the lungs. In the lungs, the blood picks up oxygen.
- The ***left atrium*** (labeled LA) receives oxygenated blood from the lungs and delivers it to the left ventricle.
- The ***left ventricle*** (labeled LV) pumps oxygenated blood through the rest of the body.

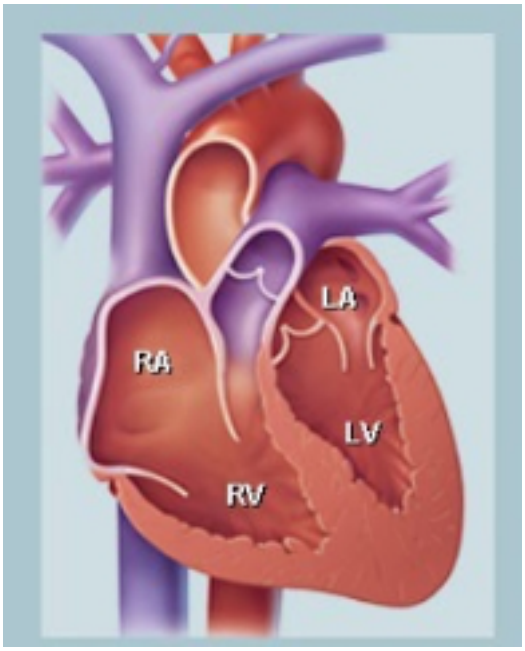


Figure 1. The chambers of the heart

The Coronary Arteries

Like all organs, your heart requires oxygen to stay healthy and functional. Although filled with blood, the heart does not get oxygen from the blood in its chambers. The heart gets oxygen from a network of ***blood vessels*** called the ***coronary arteries*** (Figure 2)

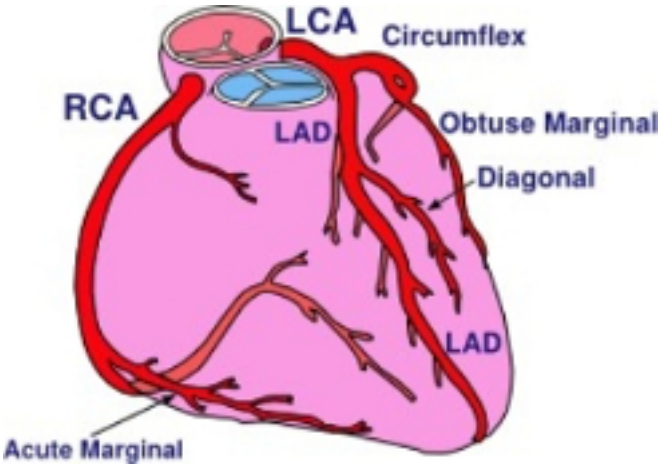


Figure 2. The ***coronary arteries*** run along the outside of the heart. The right coronary artery (RCA) supplies the right side of the heart with blood. The left coronary artery (LCA) supplies the left side. Both of these major arteries divide into smaller blood vessels, as shown.

Coronary Artery Disease

When plaque builds up in your arteries, the condition is called ***atherosclerosis*** (Figure 3)***. Coronary artery disease*** is caused by ***atherosclerosis*** in your ***coronary arteries***, leading to blockages in these vessels. Depending on the site and severity of the blockage, certain areas of the heart may not get enough oxygen to pump properly. If not corrected, this restricted blood flow can lead to symptoms such as angina (chest pain) or significant heart damage (heart attack and/or heart failure).

Treating Your Coronary Artery Disease

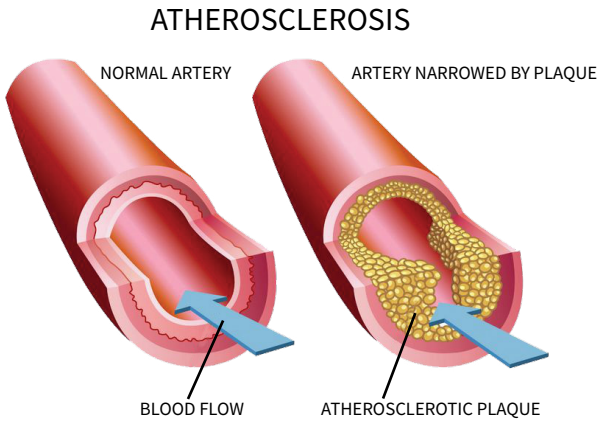


Figure 3**.** The buildup of plaque in an artery is called ***atherosclerosis***

Treatment for ***coronary artery disease*** usually means making lifestyle changes, taking medications, seeing your cardiologist for regular checkups, and possibly undergoing surgical or other procedures.

Your cardiologist will look at many factors and will probably suggest a number of tests and procedures. Factors your cardiologist will consider are:

- Your medical history
- Family history of ***coronary artery disease***
- Your risk factors for ***coronary artery disease***, including:
  - High blood pressure
  - High levels of "bad" cholesterol with low levels of "good" cholesterol
  - Diabetes
  - Obesity
- The results of diagnostic tests
- Physical exam

To provide you with the best choice of treatments for your heart disease, your doctor has referred you to a ***heart team***. A heart team includes a cardiologist, a cardiac surgeon, and other healthcare professionals who work with your doctor. They have determined that the severity of your heart disease, and the symptoms it is causing, is unlikely to respond to medicine alone and that revascularization, a procedure to re-establish blood flow to your heart, is required. Based on your test results, your doctor and the heart team have determined that you are not a suitable candidate for cardiac surgery (CABG) due to higher than normal risks caused by your medical condition and that PCI is the appropriate therapeutic option for you. Your doctor and the heart team have also determined that your condition, which includes severe blockages and possibly prior heart muscle damage, means that your PCI is high-risk (HRPCI) and will have a higher than normal risk of hemodynamic instability that may benefit from the use of the Impella to help maintain heart function during the HRPCI procedure.

Treating the Heart with the Impella Heart Pump

The Impella 2.5 and the Impella CP with SmartAssist (collectively referred to as "Impella") are similar heart pumps that provide different amounts of blood flow. Your doctor will decide which Impella heart pump is right for you.

Impella is a small heart pump at the end of a thin, flexible tube ***(catheter)***. It is placed through an artery in the leg (femoral artery) and advanced into the left ventricle. Once placed, it pumps blood from the left ventricle through the heart into the ascending ***aorta*** (Figure 3).

The end of the ***catheter*** coming from the artery is connected outside of your body to an external console, a special computer that powers and controls the Impella.

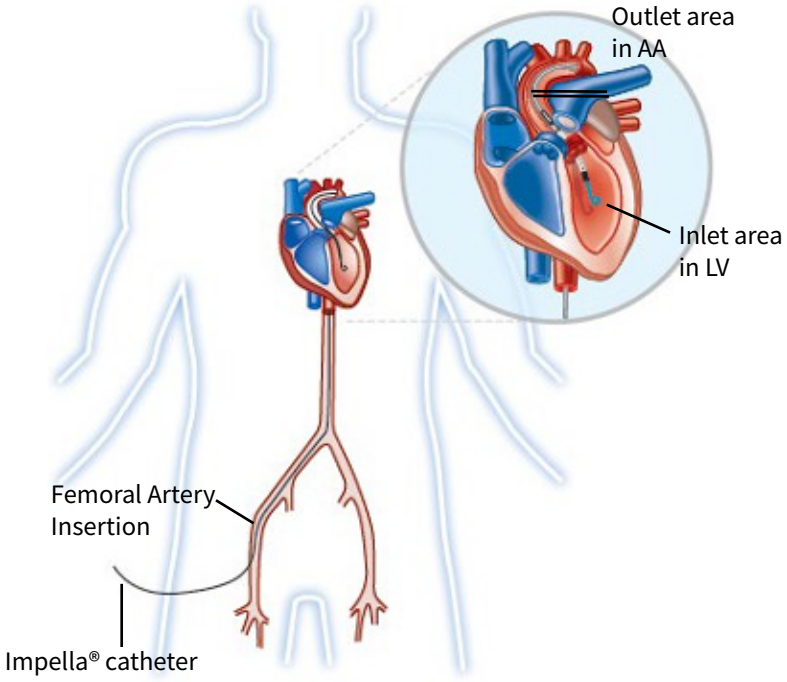


Figure 3. The Impella is placed in the body to support your heart

Impella assists the pumping function of your heart during your HRPCI procedure to ensure blood flow and blood pressure are maintained as your coronary artery blockages are repaired.

Visit https://www.impella.com/about-impella to see a video showing insertion of the Impella.

During your procedure, Impella will be connected to the console, which will be monitored by your caregivers.

Who is a Candidate for the Impella Heart Pump?

PCI procedures performed with one or more of the following risk factors are often referred to as high-risk PCI or HRPCI procedures. The Impella® heart pump is used during HRPCI to potentially reduce the risk of complications during and after the procedure. The risk factors include:

- Advanced age
- Diabetes
- History of chest pain
- Other diseases of the ***blood vessels*** in the body
- Chronic heart failure

The Impella heart pump may be used during HRPCI under the following conditions:

- Support should be temporary, lasting no more than 6 hours
- Adequate blood supply to the organs with no signs of other circulatory problems
- Severe ***coronary artery disease*** and with or without reduced left ventricular ***ejection fraction***
- A team of heart specialists, including a cardiac surgeon, has determined that HRPCI is the right therapeutic option

Using the Impella 2.5 may prevent interruption of blood flow during your HRPCI procedure and may also help to reduce complications (additional medical problems) during and after your procedure.

The Impella is Not Right for Everyone

If you have any of the conditions listed below, Impella may not be right for you. Your doctor will determine whether you have any of these conditions:

- Defects in your veins and arteries, including calcium deposits or hardening of the vessel walls, which could block the open area available for the pump to pass
- A replacement heart valve or other heart device, which could block the open area available for the pump to pass
- Severe narrowing of one of your ***heart valves***, which could block the open area available for the pump to pass
- 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.

What Has Been the Experience with the Impella?

Abiomed received approval from the U.S. Food and Drug Administration (FDA) to begin a HRPCI pivotal clinical trial, known as the Protect II study, for the Impella 2.5. This pivotal study was a study to determine if the safety and effectiveness of the Impella 2.5 was better than medical management with another hemodynamic support device called the intra-aortic balloon pump, or IABP, during HRPCI procedures. The FDA used the Protect II results as an important data set for its review and approval of the Impella 2.5 use during HRPCI. Your physician will have more details on the outcome of this study and the risks and benefits of using Impella in this setting.

Risks You Should Know About

All procedures have risks. Many of the risks related to having HRPCI with support from the Impella heart pump are the same as those related to having PCI without support from a heart pump, and those related to the placement of any pump used to help the heart.

Risks Studied Previously

The following table summarizes possible risks 30 days after use of the Impella 2.5 as experienced in the PROTECT II trial, which was reviewed by the FDA prior to the approval of the Impella 2.5 (see the Section titled "Clinical Study Experience with Impella 2.5" on page 15 for details). The trial compared the Impella 2.5 with another FDA-cleared support device, called an intra-aortic Balloon Pump. The Impella CP was studied later using data collected in the Impella Registry, which was reviewed by the FDA prior to approval of the Impella CP. The Impella CP showed similar risk levels to the Impella 2.5.

Type of Problem	**Number of Patients in the Trial Reporting a Problem at 30 Days (percent occurrence)**	
	Impella 2.5	**Other Support Device**
Death	17 of 225 (7.6%)	13 of 222 (5.9%)
Stroke or a temporary blockage to the brain—both are caused by a blood clot that reduces blood flow to the brain; a stroke usually causes permanent brain damage, while a temporary blockage usually resolves after causing moderate symptoms for a short period	1 of 225 (0.4%)	4 of 222 (1.8%)

Type of Problem	Number of Patients in the Trial Reporting a Problem at 30 Days (percent occurrence)	
	Impella 2.5	**Other Support Device**
Heart attack—a heart attack happens when the flow of oxygen- rich blood to part of the heart muscle suddenly becomes blocked and the heart can't get oxygen. If blood flow isn't restored quickly, the section of heart muscle may die and the heart may not pump properly	40 of 225 (17.8%)	27 of 222 (12.2%)
Having to repeat the procedure to unblock ***blood vessels*** in the heart	8 of 225 (3.6%)	13 of 222 (5.9%)
Need for another operation to fix a problem with the heart or ***blood vessels***	4 of 225 (1.8%)	5 of 222 (2.3%)
Sudden kidney failure, where your kidneys lose the ability to remove waste products from your blood	16 of 225 (7.1%)	17 of 222 (7.7%)
Need to pump the patient's chest by hand to re-start breathing or use an electrical shock to restore a normal heartbeat in a heart that is not beating regularly	23 of 225 (10.2%)	16 of 222 (7.2%)
Increase in the amount of blood that leaks back into the left ventricle from the aortic artery because of a problem with the aortic valve	0 of 225 (0%)	0 of 222 (0%)
Severe low blood pressure requiring treatment—low blood pressure may reduce the ability of the brain and other organs to operate normally because of reduced oxygen supply	24 of 225 (10.7%)	26 of 222 (11.7%)
Failure of the procedure as shown by ***angiography***, a technology used to visualize the inside of the heart	8 of 225 (3.6%)	4 of 222 (1.8%)

Other Potential Risks

In addition to the risks identified previously, there may be other potential risks associated with your treatment with the Impella.

- You may have an allergic reaction to the medication—for instance, a blood thinner called heparin, which is used in conjunction with the Impella
- Clots may develop in your ***blood vessels*** that can travel through your ***blood vessels*** and block the blood flow to other organs, including your lungs, making breathing difficult

- You may develop an infection, which could be localized or spread throughout your body
- Your heart tissue, valves, and ***blood vessels*** may be injured by the device as it is placed into your heart or during the time it sits inside your heart. The injury may result in life threatening conditions
- Your heart tissue may be irritated or injured by the device as it is placed into your heart or during the time it sits inside your heart. The irritation or injury may cause your heart to beat irregularly. These conditions can be life threatening
- Insertion of the device may cause 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 left heart support being stopped

Benefits You Should Know About

How the Impella Heart Pump Can Help You

Your doctor is considering using Impella because the left side of your heart is very weak. Use of the device may allow you to have a high-risk PCI procedure (HRPCI) that you could not have without support from the device

In the PROTECT II clinical study, the Impella 2.5 was evaluated in patients undergoing HRPCI procedures (see Section titled “Clinical Study Experience with Impella 2.5” on page 15 for details).

Based on the data from this study, it appears that the benefits of using the Impella during HRPCI may include:

- Reducing 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***
- Maintaining adequate blood flow and blood pressure during the HRPCI procedure

What to Expect During Your Treatment

Before the Procedure

A heart team of doctors, including a cardiac surgeon, has determined that you are not a candidate for cardiac surgery (CABG) due to the risks involved, but that HRPCI is the appropriate therapeutic option for you. In addition, it has also been determined that your specific condition may benefit from the use of the Impella Heart Pump to help maintain heart function during the HRPCI procedure. Before the Impella device is inserted into your heart, your doctor will review your medical information with you or a family member to make sure that HRPCI with the Impella® is right for you.

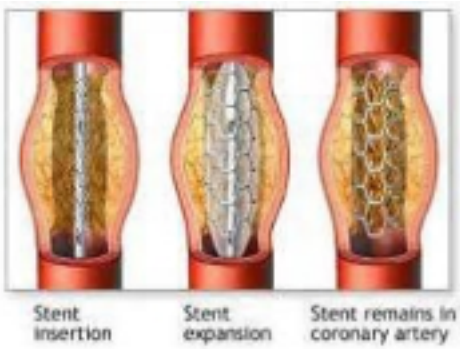
Your doctor may also perform a test using sound waves to look at your heart and ***blood vessels*** —to make sure that Impella can be used safely.

During the Procedure

At the beginning of the procedure, your doctor will numb your leg so no pain is felt when the Impella ***catheter*** is inserted. The ***catheter*** will be inserted into your femoral artery through a small incision in your leg. Then it will be advanced through the artery to your heart. A series of x-rays will be taken to help position the device. The ***catheter*** will be connected to the console and the pump will be turned on.

Once the Impella catheter is placed and operating, the HRPCI procedure continues. You will be sedated but most likely awake during the procedure. You will receive fluids, medications to relax you and blood-thinning medications (anticoagulants). Once the blockages in your ***coronary arteries*** are located, a procedure will be performed to open the blockages. A ***catheter*** is placed at the location of the blockage and a small balloon at the end of the ***catheter*** is inflated, widening the blocked artery. This procedure is called ***balloon angioplasty.*** After the artery is stretched, the balloon is deflated and removed. Your doctor might inflate and deflate the balloon several times before it's removed, stretching the artery a bit more each time. If you have several blockages, the procedure may be repeated at each blockage.

People who have ***balloon angioplasty*** usually also have one or more stents placed in their blocked ***coronary arteries***. The ***stent*** is usually inserted in the artery once it is widened by the inflated balloon. The stent supports the walls of your artery to help prevent it from re-narrowing after the angioplasty procedure. The ***stent*** looks like a tiny coil of wire mesh.



After the Procedure

If the functioning of your heart is stable after the HRPCI procedure, your doctor will remove the Impella heart pump and you will be moved to a recovery room or cardiac care unit (CCU). If your heart continues to need support after the procedure, your doctor may leave the Impella in place until your condition stabilizes.

When your condition has stabilized, your doctor will remove the Impella and the small hole in your femoral artery will be closed and bandaged. You may experience some pain from the surgical incisions that were part of the medical procedure of putting in the Impella® heart pump. Your medical team will give you medication for your heart and pain medication as necessary.

The average hospital stay after an uncomplicated HRPCI procedure is 1 to 2 days. You will probably be able to start walking 12 to 24 hours after surgery. Depending upon the judgment of your doctors, you may be able to resume exercise and driving a few days after you are discharged from the hospital. Due to the stent placement in your coronary arteries, you will be prescribed anti-platelet medication to reduce the risk of the stent clotting over time.

Clinical Study Experience with Impella 2.5

Summary of Clinical Trial Data

An FDA approved clinical trial of the Impella 2.5 was conducted between 2007 and 2010. The study was called the PROTECT II Study. It was designed to find out whether a high-risk percutaneous ***revascularization*** strategy (HRPCI procedure) with the support of the Impella 2.5 device would provide better results than the same procedure with support using another FDA cleared heart pump, called an intra-aortic balloon pump (IABP).

The study included 452 patients who were treated at 112 different hospitals in the United States, Canada, and Europe.

The ***primary endpoint*** (most important measured outcome) of the trial was the number of adverse events that occur within 30 days after the procedure.

Patients were also followed up to 90 days after the procedure and those results were recorded as well.

These are the most important results of the study:

- The Impella 2.5 device may maintain adequate blood flow more consistently than the IABP device
- The number of adverse events (medical complications) at 30 days was about the same for both devices
- There was a trend toward fewer adverse events at 90 days with the Impella 2.5 device compared with the IABP device

After reviewing the overall results of the complete PROTECT II Study, the FDA approved the Impella 2.5 for use in patients undergoing HRPCI procedures.

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.***