

# Patient Information for the Impella® 2.5

A Guide for You, Your Family and Caregivers



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 to your doctor.

Rx only

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## About This Booklet

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 2.5 that are not covered in this booklet, please contact Abiomed or visit our website at [www.abiomed.com](http://www.abiomed.com).

This booklet is for people who are about to have or already have had a high-risk percutaneous coronary intervention (HRPCI) with Impella 2.5, which is called the Impella 2.5 in this booklet. People with your type of heart disease (depressed heart function plus severe coronary artery blockages) are normally treated with coronary artery bypass surgery. You are having this procedure instead of bypass surgery because your team of heart physicians, including a cardiac surgeon, have evaluated your condition and determined that surgery is too risky because of other additional non-heart health problems you have (co-morbidities such as advanced age, diabetes, kidney failure, prior heart surgery, etc.) and that “high risk” PCI is the appropriate procedure for you. Your PCI is considered “high risk” because although your condition is stable now, the extent or location of your coronary blockages and the temporary effects of PCI treatment on your already decreased heart function increase your risk for hemodynamic instability (uncontrolled swings in blood pressure and heart failure) during the procedure. Hemodynamic instability that occurs during a PCI procedure may increase your risk of death or other serious complications and can limit your doctor’s ability to treat all of your blockages completely. The Impella 2.5 device is a blood pump that is placed into your heart through a peripheral artery that will support your circulatory system during your elective or urgent high risk PCI (HRPCI) procedure to minimize the risks of unstable blood pressure.

This booklet explains what the Impella 2.5 is, how it is inserted, what it feels like when your heart gets support from the Impella 2.5, and what you can expect after the Impella 2.5 is removed. It’s a good idea to encourage your family and caregivers to review this booklet.

To help you better understand some of the terms used in this booklet, a Glossary is included starting on page 4.

## Table of Contents

Glossary.....	4
About the Heart .....	6
How the Heart Works .....	6
The Right and Left Sides of the Heart .....	6
The Coronary Arteries.....	7
Coronary Artery Disease .....	7
Treating Your Coronary Artery Disease .....	8
Treating the Heart with the Impella 2.5 .....	9
About the Impella 2.5 .....	9
Who Should Be Treated with the Impella 2.5?.....	11
The Impella 2.5 is Not Right for Everyone .....	11
Who Should NOT Be Treated with the Impella 2.5?.....	11
What Has Been the Experience with the Impella 2.5? .....	12
Risks You Should Know About .....	12
Risks Studied Previously.....	12
Other Potential Risks .....	13
Benefits You Should Know About .....	14
How the Impella 2.5 Can Help You .....	14
What to Expect During Your Treatment .....	14
Before the Procedure.....	14
During the Procedure.....	15
After the Procedure .....	15
Impella 2.5 Clinical Study Experience .....	16
Summary of Clinical Trial Data.....	16

## Glossary

**Aorta:** The large artery that carries blood from the heart to be distributed by 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, chronic medication to reduce the risk of the stent clotting over time is required. This medication is targeted to reduce the blood's ability to clot.

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

**Catheter:** Thin 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):** A 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 **atherosclerosis** and fat globules are deposited within the arteries.

**Ejection fraction (EF):** A measure of how efficiently the heart is able to eject blood from the ventricles. **Ejection fraction** is expressed as the percentage of blood contained in the ventricle that is ejected when the ventricle contracts. This measure is applied to both the right and left ventricles to describe how efficiently the right ventricle pumps oxygen-poor blood to the lungs and 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.

**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

already decreased heart function 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 specialized tools to injure as little tissue as possible. This can be safer than conventional surgery and lead to faster healing.

**Open-heart surgery:** A surgical procedure 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 the narrowed *coronary arteries* of the heart found in coronary heart disease by inserting a *catheter* with a balloon on the end and inflating the balloon to open up the vessel. During the procedure, coronary stents) are usually placed to hold the artery open. Also commonly referred to as *percutaneous transluminal coronary angioplasty (PTCA)*.

**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.

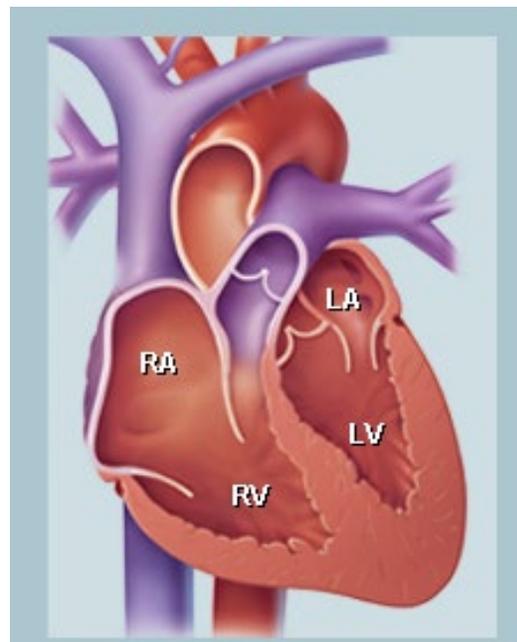
Blood pumped by the heart brings oxygen and food to every part of the body. It also removes carbon dioxide and other waste produced by the body. A healthy body depends on the heart pumping enough blood to deliver oxygen and food and to remove waste.

### 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. In a healthy heart, both sides of the heart work fine.

Each side of the heart has two chambers, an atrium and a ventricle.

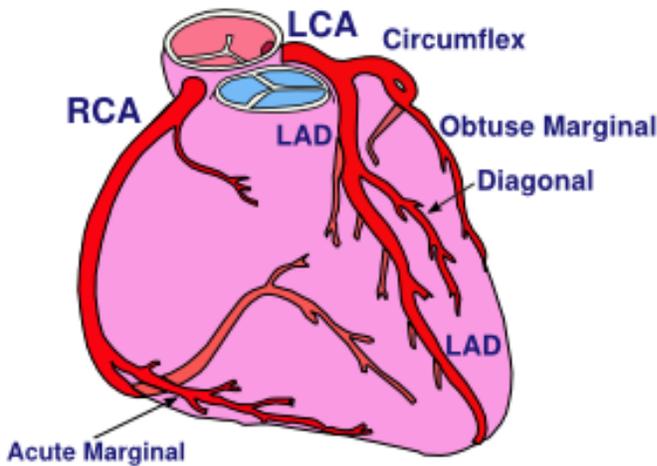
- The **right atrium** (labeled RA) receives blood from the body and delivers it to the right ventricle.
- The **right ventricle** (labeled RV) pumps blood through the lungs. In the lungs, the blood picks up oxygen from the breath and releases carbon dioxide into the breath.
- The **left atrium** (labeled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



**Figure 2.** The chambers of the heart.

## The Coronary Arteries

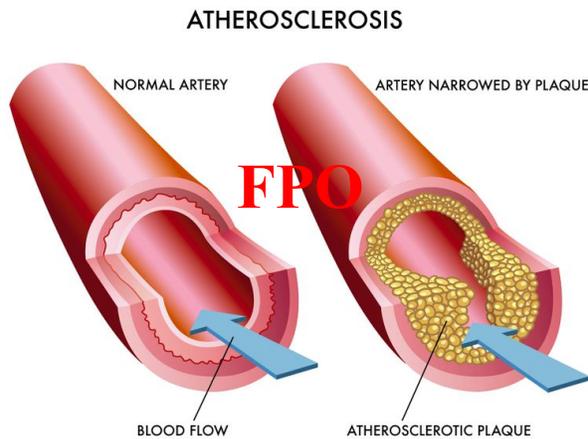
Like all organs, your heart is made of tissue that requires oxygen and other nutrients to stay healthy and functional. Even though the heart is always filled with blood, it does not get oxygen or nutrients from the blood that is in its chambers. It gets all of its oxygen and nutrients from its own blood supply, a network of **blood vessels** called the **coronary arteries**.



**Figure 3.** 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 off into variously named smaller blood vessels, as shown.

## Coronary Artery Disease

When plaque builds up in your arteries, the condition is called **atherosclerosis**. **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 muscle may not get enough of the oxygen and nutrients it needs to pump properly. If not corrected, this restricted blood flow can lead to symptoms such as angina (chest pain) or significant heart muscle damage (heart attack and/or heart failure).



**Figure 4.** The buildup of plaque in an artery is called ***atherosclerosis***.

## Treating Your Coronary Artery Disease

Treatment for ***coronary artery disease*** usually means making lifestyle changes, taking medications, seeing your cardiologist for regular checkups, and possibly undergoing surgical or other invasive 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 the most optimal 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 your severity of heart disease and the symptoms it is causing are unlikely to respond to medicine alone and that revascularization (a new source of blood flow) of your heart muscle 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 (coronary artery bypass grafting or CABG) due to higher than normal risks caused by your overall medical condition and that PCI is the appropriate

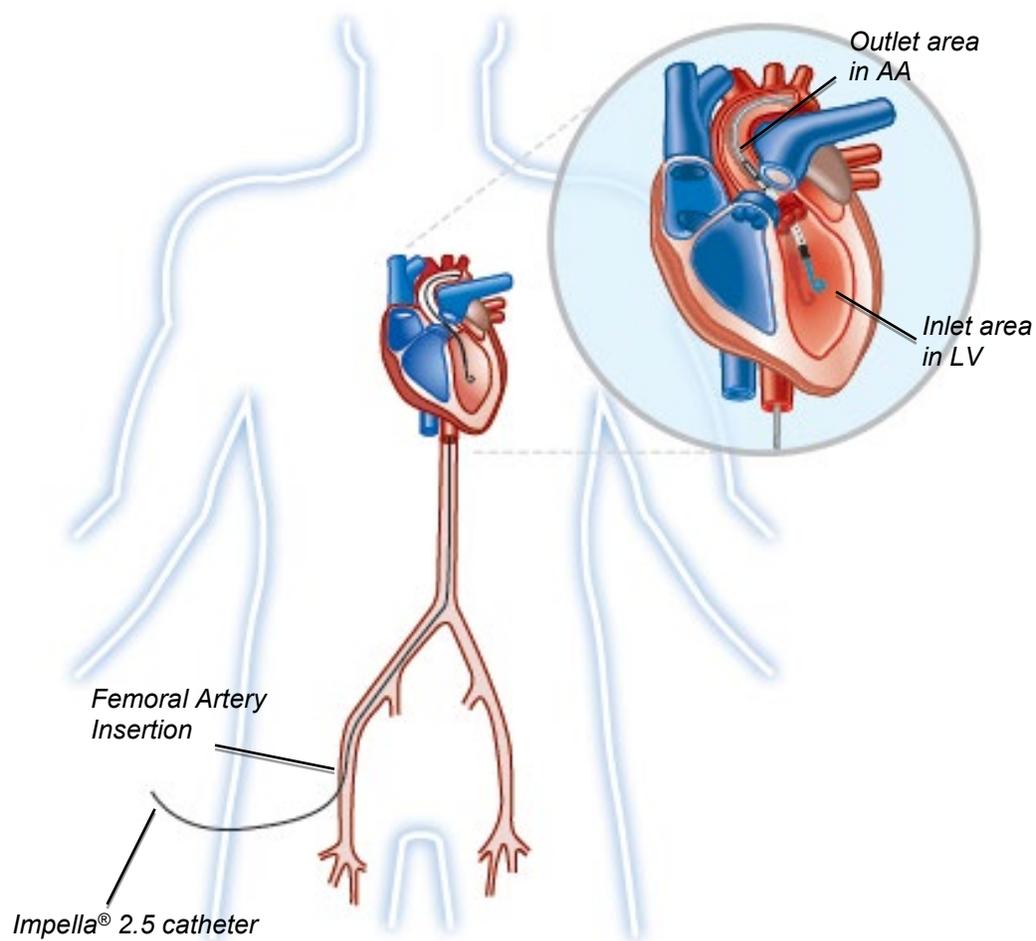
therapeutic option for you. In addition, it has also been determined that your condition, which results from a combination of severe blockages and prior heart muscle damage, means that your PCI (called high risk PCI or HRPCI) will have a higher than normal risk of hemodynamic instability and that you may benefit from the use of the Impella 2.5 System to help maintain heart function during the HRPCI procedure.

## Treating the Heart with the Impella 2.5

### About the Impella 2.5

The Impella 2.5 is a small pump at the end of a thin, flexible tube (***catheter***). It is implanted through an artery in a patient's leg (femoral artery). Once implanted, it pumps blood for the left side of the heart. It does this by pumping blood from the left ventricle (labeled LV in the picture below) through the heart into a vessel called the *ascending aorta* (labeled AA in the picture below).

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 2.5 ***catheter***.



**Figure 1.** The Impella 2.5 is placed in the body to support your heart

The Impella 2.5 is designed to:

- Rest your heart during your high-risk percutaneous coronary intervention (PCI) procedure reducing your heart's workload, and prevent your heart from being overstressed by the procedure as coronary artery blockages are repaired
- Maintain blood flow and blood pressure during the procedure

**Visit <http://www.abiomed.com> to see a video showing insertion of the Impella 2.5 catheter.**

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

## Who Should Be Treated with the Impella 2.5?

**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® 2.5 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 2.5 may be used by patients during HRPCI under the following conditions:

- The support should be temporary, lasting no more than 6 hours
- The patient must be receiving adequate blood supply to the organs with no signs of other circulatory problems
- The patient has severe **coronary artery disease** and depressed left ventricular **ejection fraction** (the amount of blood pumped from the left ventricle is only a small amount of the blood in the chamber)
- A team of heart specialists has determined that HRPCI is the right therapeutic option for the patient

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 2.5 is Not Right for Everyone

### Who Should NOT Be Treated with the Impella 2.5?

If you have any of the conditions listed below, you may not be able to be treated with the Impella 2.5. 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 2.5?

Abiomed received approval from the FDA to begin an HRPPI 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, or IAB, during HRPPI 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 HRPPI. Your physician will have more details available on the outcome of this study and what the risks and the benefits of using the Impella are in this setting.

### Risks You Should Know About

All surgical procedures have risks. Many of the risks related to the Impella 2.5 are the same as those with the procedure being completed and 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 Impella 2.5's approval (see the Section titled "Impella 2.5 Clinical Experience" on page 16 for details). The trial compared the Impella 2.5 with another FDA cleared support device, called an Intra-aortic Balloon Pump.

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%)
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%)

Type of Problem	Number of Patients in the Trial Reporting a Problem at 30 Days (percent occurrence)	
	Impella 2.5	Other Support Device
Having to repeat the procedure to unblock <b>blood vessels</b> 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 <b>blood vessels</b>	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 <b>angiography</b> , 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 2.5.

- You may have an allergic reaction to the medication—for instance, a blood thinner called heparin, which is used in conjunction with the Impella 2.5
- 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 2.5 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 2.5 Can Help You

Your doctor is considering treating you with the Impella 2.5 because the left side of your heart is very weak. Use of the device may allow you to have a high-risk 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 high-risk PCI procedures (see Section titled “Impella 2.5 Clinical Experience” on page 15 for details).

Based on the data from this study, it appears that the benefits of using the Impella 2.5 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

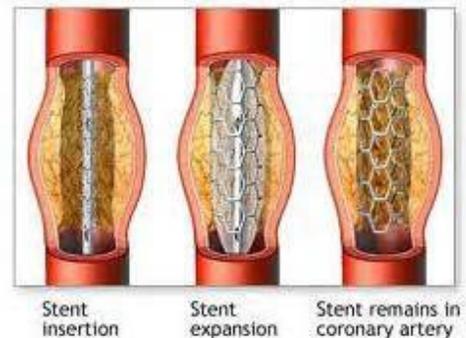
A heart team of doctors, including a cardiac surgeon, has determined that you are not a candidate for cardiac surgery (CABG) due to the risks involved, but that PCI is the appropriate therapeutic option for you. In addition, it has also been determined that your specific condition may benefit from the use of the Impella 2.5 System to help maintain heart function during the HRPCI procedure. Before the Impella 2.5 is inserted into your heart, your doctor will review your medical information with you or a family member to make sure the Impella® 2.5 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 you can use the Impella 2.5 safely.

## During the Procedure

At the beginning of the procedure, your doctor will numb your leg so no pain is felt when the Impella 2.5 **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 2.5 catheter is placed and operating, the HRPPI 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 HRPPI procedure, your doctor will remove the Impella 2.5 **catheter** and you will be moved to a recovery room or coronary care unit (CCU). If your heart continues to need support after the procedure, your doctor may leave the Impella 2.5 **catheter** in place until your condition stabilizes.

When your condition is stabilized, your doctor will remove the Impella 2.5 **catheter** 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®

2.5 **catheter**. 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.

## Impella 2.5 Clinical Study Experience

### 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.