The Impella® RP

A New Way to Treat Right Heart Failure

A Guide for You and Your Family

ABIOMED

About This Booklet

This booklet is for people like you who have failure of the right side of the heart (***right heart failure***) who have not been helped by medication. Your doctor can help you decide if treatment with the Impella® RP is a good option for you.

The booklet explains:

- How the heart works
- What heart failure means
- What the Impella® RP is
- How it is inserted into your heart
- What you can expect before, during and after the procedure
- What are the possible risks and benefits of having this treatment

Please read this booklet carefully and share it with your family and caregivers. For your convenience, a Glossary is provided in the front of the Guide. Terms that are explained in the Glossary are in ***bold italics*** in the text.

If you have questions about the Impella® RP that are not answered in this booklet, please visit our website at www.abiomed.com.

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.

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Glossary

***Catheter*:** a thin, flexible tube used in medical devices and procedures

***Console*:** a special computer used to power and control a medical device

***Defibrillator*:** a small device implanted in your chest that monitors the heart to detect abnormal heartbeats

***Femoral vein*:** a large vein in the groin area

***Heart pump*:** a pump used to support heart function and blood flow in people who have weakened hearts

***Heart transplantation*:** a surgical transplant procedure that takes a working heart from a recently deceased organ donor and implants it into a patient with end-stage heart failure or severe coronary artery disease

Inferior Vena Cava: a large blood vessel in the chest that blood flows through as it travels from the legs back to the heart

***Intensive Care Unit*:** a special department of the hospital that provides intensive care medicine

***Left atrium*:** the heart chamber that receives blood from the lungs and delivers it to the left ventricle

Left heart failure: failure of the left side of the heart to pump enough blood

***Left ventricle*:** the heart chamber that pumps blood through all of the body except for the lungs

***Medical device*:** a machine or instrument used to prevent or treat disease

***Open-heart surgery*:** any surgery in which the chest is opened and surgery is done on the heart muscle, valves, arteries or other parts of the heart

***Pacemaker*:** a small device placed in the chest or abdomen to help control abnormal heart rhythms

***Pulmonary Artery*:** the blood vessel that blood travels through to get from the heart to the lungs

***Right atrium*:** the heart chamber that receives blood from the body and delivers it to the right ventricle

***Right ventricle*:** the heart chamber that pumps blood through the lungs. In the lungs, the blood picks up oxygen from the breath and releases carbon dioxide into the breath

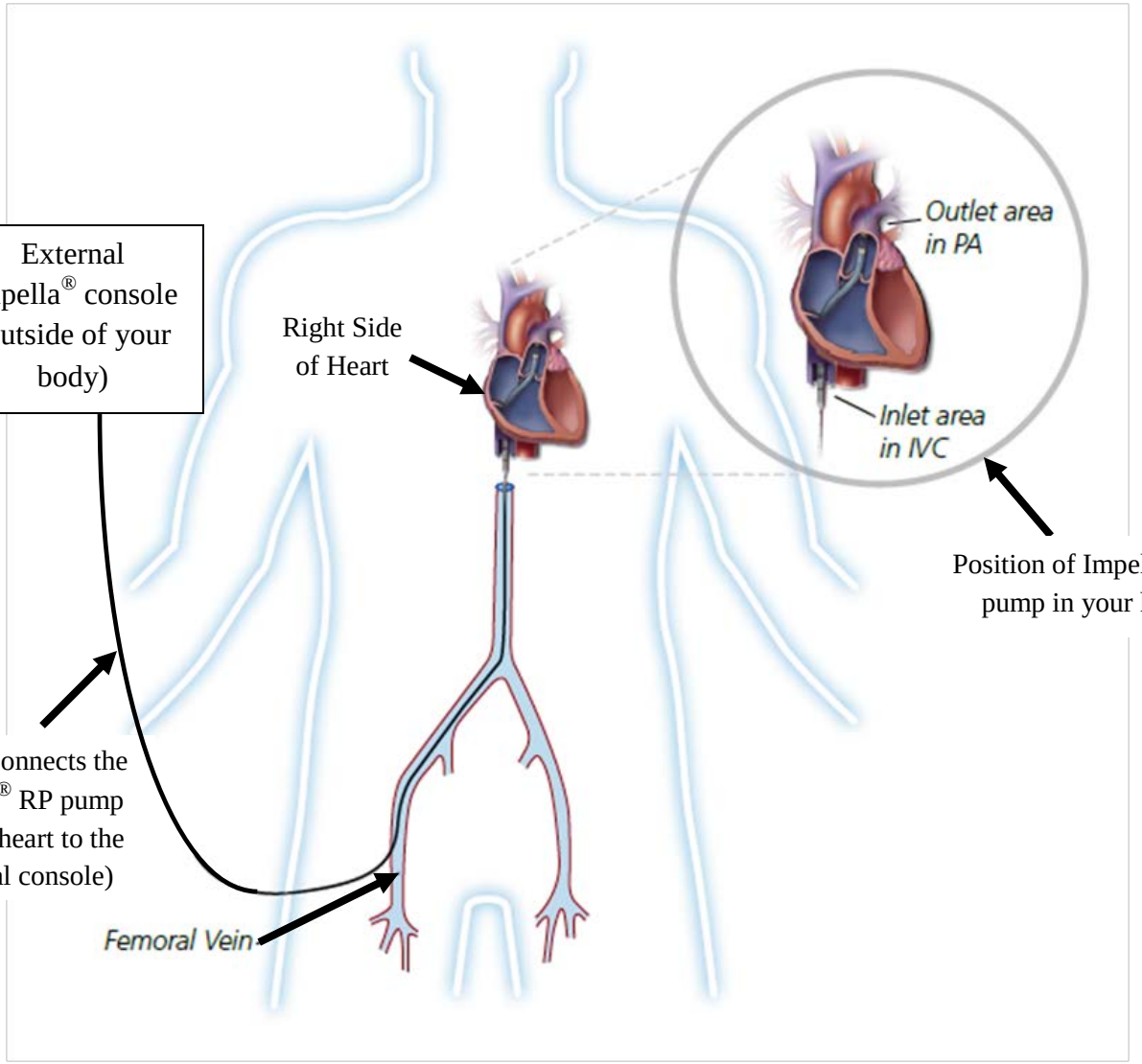
Right heart failure: failure of the right side of the heart to pump enough blood

Treating the Heart with the Impella® RP

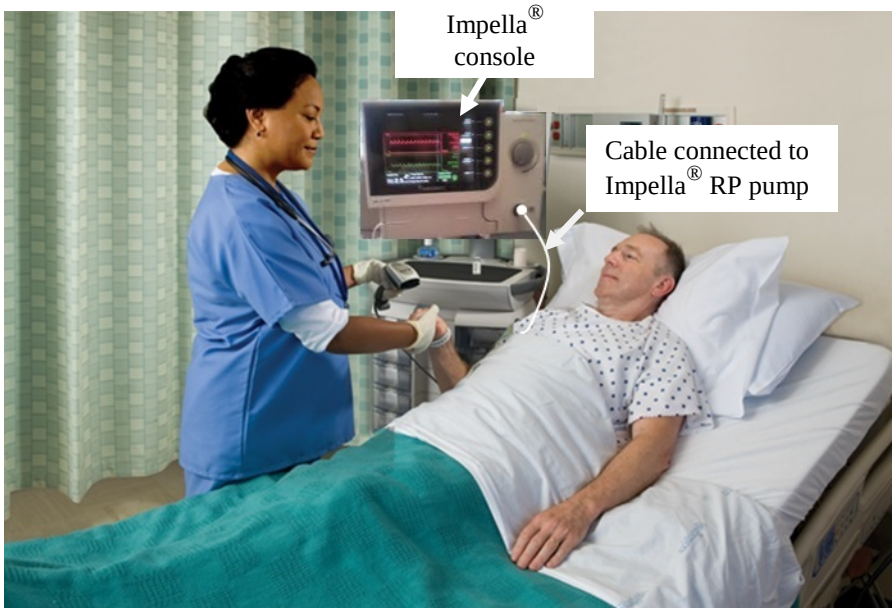
The Impella® RP

The Impella® RP is a small heart pump at the end of a thin, flexible tube (***catheter***). It is implanted through a vein in a patient's leg (***femoral vein***). Once implanted, it pumps blood for the right side of the heart. It does this by pumping blood from outside the heart, from a vessel called the ***inferior vena cava*** (labeled IVC in the picture below), through the heart into a vessel leading to the lungs, called the ***pulmonary artery*** (labeled PA in the picture below).

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



During your therapy, the Impella® RP pump will be permanently connected to the console, which will be monitored by your caregivers. Both the Impella® RP pump and its console are only approved for use in the hospital, so you cannot be discharged home from the hospital while the Impella® RP is in place.



Who Should Use the Impella® RP

The Impella® RP may help patients who need emergency support of the right heart. Typical patients who may use the Impella® RP include:

- Patients whose right heart fails after receiving a heart pump to support the left side of the heart
- Patients whose right heart fails because of a heart attack
- Patients whose right heart fails after a heart transplant
- Patients whose right heart fails after heart surgery

The Impella® RP must be used in a hospital. Patients who receive an Impella® RP must stay in the hospital until it is removed.

The Impella® RP is Not Right for Everyone

Who Should NOT Be Treated with the Impella® RP

If you have any of the conditions listed below, you may not be able to be treated with the Impella® RP. 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, which could block the open area available for the pump to pass
- A faulty heart valve, which could cause blood flowing in the wrong direction and reducing the pump output
- Severe narrowing of one of your heart valves, which could block the open area available for the pump to pass
- A defect, such as a small channel in your heart, which could shunt the blood flow between its chambers and reduce the pump output
- Loosely attached clot(s) in your blood vessels or heart, which may break off while the pump is in use and result in harm to you
- A filter in one of your large veins, which may block the open area available for the pump to pass

Risks You Should Know About

All surgical procedures have risks. Many of the risks with the Impella® RP are the same as those with the placement of any pump used to help the heart. Other problems that may happen with the Impella® RP are the same as those that occur with any major heart surgery done with general anesthesia (when you are completely unconscious).

Risks

The RECOVER RIGHT trial was set up to determine the likelihood of some of the expected problems that may occur with the Impella® RP. The trial looked at the most serious risks, which are:

- Death: death due to any cause
- Major bleeding: a bleeding event causing abnormal lab values or requiring blood to be put back into the body – during the trial most of the major bleeding was related to the surgery to place the Impella® RP
- Breakdown of red blood cells: damage to red blood cells caused by the pump
- Stroke: a condition when decreased blood flow to the brain causes death of brain cells
- Reduced blood flow to the leg
- Blood clot lodged in the lung
- Poorly functioning right heart valves

The following table summarizes the potential risks 30 days after Impella® RP placement as determined in the RECOVER RIGHT trial.

Event	Number of Patients in Trial Reporting Problem at 30 Days (Total Patients = 30)
Death	8 out of 30
Major Bleeding	18 out of 30
Breakdown of red blood cells	4 out of 30
Stroke	1 out of 30
Reduced blood flow to the leg	1 out of 30
Poorly functioning right heart valves	1 out of 30

Other Potential Risks

In addition to the risks studied in the RECOVER RIGHT trial and provided in the table above, there may be other potential risks associated with your treatment with the Impella® RP. Specifically, while you are being treated:

- You may have an allergic reaction to the medication, for instance a blood thinner called heparin, which is used in conjunction with the Impella® RP device
- Clots may develop in your blood vessels, which 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 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 by the device as it is placed into your heart or during the time it sits inside your heart. The irritation may cause your heart to beat irregularly
- Your liver may not receive enough blood to function efficiently and may not function normally
- Your heart may not get better, or your heart failure condition may worsen
- The Impella® RP device may have a unexpected problem requiring it to be removed, which would result in your right heart support being stopped

What Happens If the Impella® RP Works Poorly or Fails?

Since you will be in the hospital, your doctors and nurses will be able to continuously monitor the performance of the Impella® RP. If the Impella® RP pump begins to work poorly or fails, your doctor will be able to make changes to fix the problem. If the problem cannot be fixed, the Impella® RP will be removed. Your doctor will decide if a new Impella® RP pump should be used.

In addition, your doctor may decide to remove the Impella® RP pump, and place a different type of heart pump, for instance, if your heart needs to be supported for a longer time.

Benefits

How the Impella® RP Can Help You

Your doctor is considering treating you with the Impella® RP because the right side of your heart is very weak. Use of the device for a short time may help your right heart recover.

In a clinical study, the Impella® RP helped many patients improve their heart function with a low rate of problems. However, the device did not help all of the patients.

More studies will be conducted to show the exact effectiveness of the Impella® RP. Based on what we currently know, it appears that the benefits of using the Impella® RP device include:

- Allowing your right ventricle to rest
- Improving or recovering your heart function or allowing you to be a candidate for a permanent heart pump
- Reducing complications related to your surgery to insert your permanent heart pump
- Giving your heart the chance to recover after the Impella® RP is removed
- Reducing the time it takes for your heart to recover
- Avoiding invasive operations like ***open-heart surgery***

Other Right Heart Pumps are Very Invasive

There are other heart pumps that can be used to treat your the right side of your heart. However, to use these other pumps, doctors have to open your chest to allow direct access to your heart. This is called ***open-heart surgery*** and is invasive.

The Impella® RP is Minimally Invasive

With the Impella® RP, doctors do not have to open your chest. The device is inserted into a vein in your leg and moved up the vein until it reaches the heart. Only an incision in your leg is needed.

Because using the Impella® RP procedure is less invasive, you may experience fewer complications during your treatment. You may also recover more quickly.

What to Expect During Your Treatment

Before the Procedure

Before the Impella® RP is inserted, your doctor will review your medical information with you or a family member to make sure the Impella® RP 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® RP safely.

Some patients receive the Impella® RP very soon after heart surgery. It's a good idea to talk to your doctor about the Impella® RP before your surgery, to allow enough time to ask questions and decide whether you want to be treated with the Impella RP, if your doctor decides that you need it after your surgery.

During the Procedure

At the beginning of the procedure, your doctor will numb your leg so no pain is felt when the Impella® RP is inserted. The Impella® RP will be inserted into your ***femoral vein*** through a small incision in your leg. Then it will be advanced through the vein 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. The Impella® RP will remain in place and will continue pumping while your heart rests.

After the Procedure

After the Impella® RP is inserted you will be moved to the ***Intensive Care Unit*** of the hospital where you will be closely monitored by your doctors and nurses. A breathing tube will probably be used for 1-3 days to help your lungs function properly. Your doctors and nurses will use the console to check on the Impella® RP. Since the Impella® RP will be connected to the console, you will not be able to get out of bed or sit up until the Impella® RP is removed.

When you become stronger, you will be moved to a regular hospital room. You may experience some pain from the surgical incisions that were part of the medical procedure of putting in the Impella® RP. Your medical team will give you medication for your heart and pain medication as necessary. Nurses and physical therapists will work with you to help you regain your strength and freedom of movement.

When your doctor determines that your heart has recovered, he or she will gradually lower the pumping speed of the Impella® RP and allow your heart to take over. When your heart is

pumping properly, without the help of the Impella® RP, the device will be removed. Your doctor may decide to give you general anesthesia (making you sleep), while the device is being removed, so that you will not experience any discomfort. The insertion site on your leg will be closed and bandaged.

You will not be able to leave the hospital until the Impella® RP is removed and your doctor determines you are well enough to go home. It is not possible to leave the hospital while you are being treated with the Impella® RP.

Impella® RP Clinical Experience

Summary of Clinical Trial Data

An FDA approved clinical trial of the Impella® RP was conducted in 2014. The trial was called the RECOVER RIGHT study. It was designed to evaluate the safety and probable benefit of the Impella® RP. The study focused on patients who:

- Had right heart failure
- Did not get better taking medications
- Needed support to correct their heart failure

The study included 30 patients who were treated at 8 different hospitals in the United States.

The ***primary endpoint*** (desired outcome) of the trial was one of the following events:

- Patient survival at 30 days
- Hospital discharge
- Bridge to the next therapy

These are the most important results of the study:

- Approximately 3 out of 4 patients survived to either 30 days or to hospital discharge
- The Impella® RP was successfully implanted in 9 out of 10 patients suffering from right heart failure
- The rate of problems seen during the study was not excessively high, compared to that seen for other similar therapies

Although it was a relatively small study, the results of RECOVER RIGHT were promising, and showed that the Impella® RP's properties could be used successfully to treat right heart failure in the selected patients.

After reviewing the results of the RECOVER RIGHT study, the FDA approved the Impella RP for use in patients as a Humanitarian Use Device.

Warnings and Precautions

Warnings for Patients and their Families
 Portable and mobile radio frequency devices, such as cell phones, may affect your external console. Take special care when you or your family members are operating their portable devices near your console. If you suspect that one of these devices is interfering with your console, turn off the portable device and contact your nearest caregiver.

About the Heart

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.

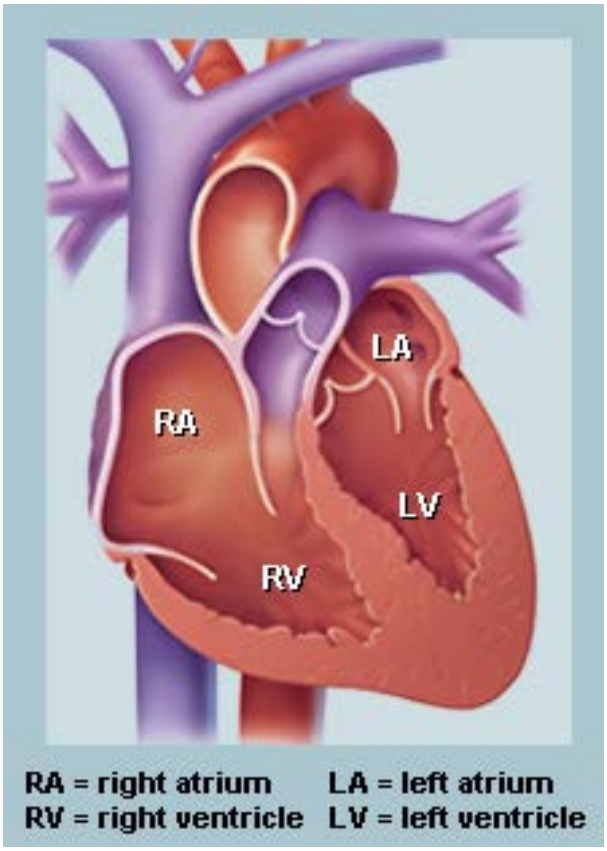
Blood pumped by the heart brings oxygen and food to every part of the body. It also removes carbon dioxide and other waste produced by the body. A healthy body depends on the heart pumping enough blood to deliver oxygen and food and to remove waste.

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 lungs. The left side of the heart pumps blood through the rest of the body. 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*** receives blood from the body and delivers it to the right ventricle.
- The ***right ventricle*** 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*** receives blood from the lungs and delivers it to the left ventricle.
- The ***left ventricle*** pumps blood through the rest of the body. As blood travels through the body, it releases oxygen for the body to use. It also picks up carbon dioxide that the body has produced as waste.



Heart Failure

Heart failure occurs when the heart is not able to pump enough blood to meet the needs of the body. Common symptoms include shortness of breath, being unusually tired and swelling in the legs. Shortness of breath is usually worse when you exercise, lie down or sleep at night. You may not be able to do a lot of exercise.

Heart failure usually happens because the left side of the heart is not working properly. This is called ***left heart failure***. Left heart failure may happen when the left ventricle is damaged by a heart attack, or when the valves that control blood flow through the left side of the heart do not work well.

However, in some patients, heart failure occurs because the right side of the heart is not working properly. This is called ***right heart failure***. Right heart failure may happen when the right ventricle is damaged by a heart attack or when the valves that control blood flow through the right side of the heart do not work well.

Treating Your Heart Failure

Your doctor will treat your heart failure by finding ways to make you feel better and keep your heart failure from getting worse. Your treatment may include:

- Changing what you eat and drink
- Increasing how much you exercise
- Taking medications
- Receiving a ***medical device***
- Receiving a ***heart transplant***

Your doctor will first suggest that you eat a healthier diet and exercise as much as possible. Your doctor will also prescribe medications to help your heart work better and to relieve your heart failure symptoms.

You may also receive a medical device such as a ***pacemaker***, ***defibrillator*** or ***heart pump***, to help your heart work better.

- A pacemaker is a device that keeps your heart beat regular
- A defibrillator is a device that corrects your heart beat if it becomes abnormal
- A heart pump is a device that pumps blood for your heart when it is severely damaged

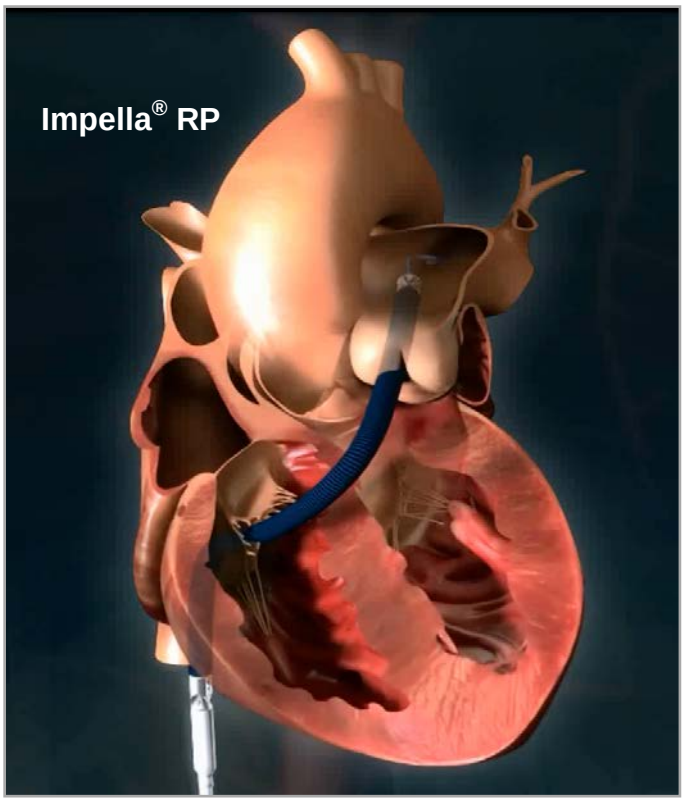
If your condition is very severe, your doctor may consider heart transplantation.

Online Resources

Abiomed, Inc.
visit: www.abiomed.com

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® RP to your doctor.

Rx only.



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