The Impella® Ventricular Support Systems

A New Way to Treat Left Heart Failure

A Guide for Families and Caregivers

ABIOMED

About This Booklet

This booklet is for people like you who have a family member, relative or another significant person in your life suffering from failure of the left side of the heart (***left heart failure***), who have not been helped by medication or other treatments. The doctor treating your family member, relative or significant other can explain how the Impella® Ventricular Support Systems can be used to treat this life threatening condition.

The booklet explains:

- How the heart works
- What heart failure means
- What the Impella® Ventricular Support Systems is
- What are the possible risks and benefits of someone having this treatment

Please read this booklet carefully. 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® Ventricular Support Systems 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

Acute myocardial infarction: commonly known as a heart attack, this condition occurs when blood flow stops to part of the heart causing damage to the heart muscle

Aorta: a large artery (blood vessel) in the chest that blood flows through as it travels from the heart to the body

Aortic Valve: a heart valve that blood flows through as it exits the heart

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

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.

***Cardiogenic shock**:* a dire condition of the heart, such that it can no longer pump enough blood to meet the body's basic needs

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

***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 artery*:** a large artery (blood vessel) in the groin area

***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.

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

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

Intra-aortic balloon pump: a medical device used to treat left heart failure

***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

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

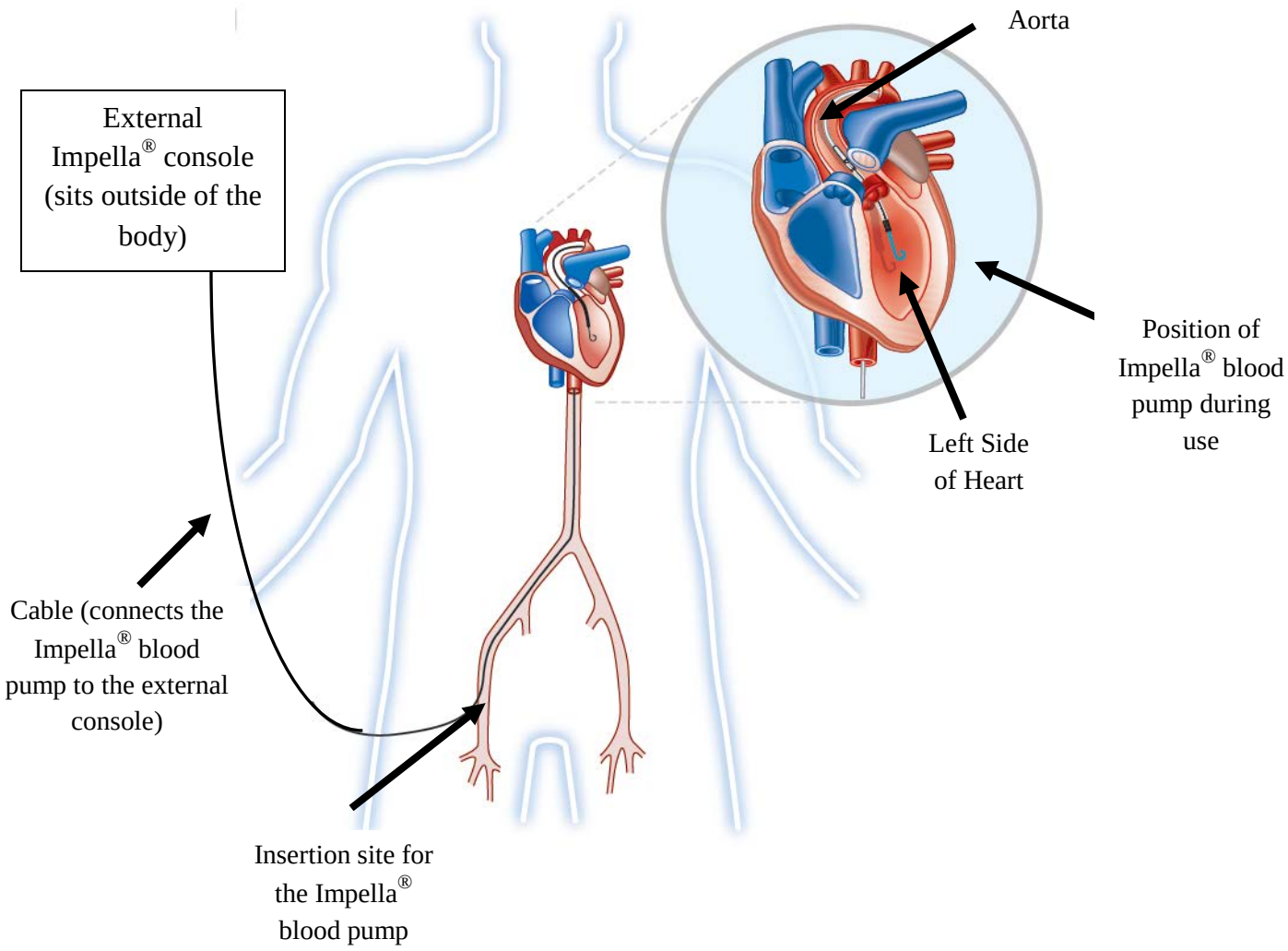
Warning: A statement describing an action or situation that could seriously harm the patient

Treating the Heart with the Impella® Ventricular Support Systems

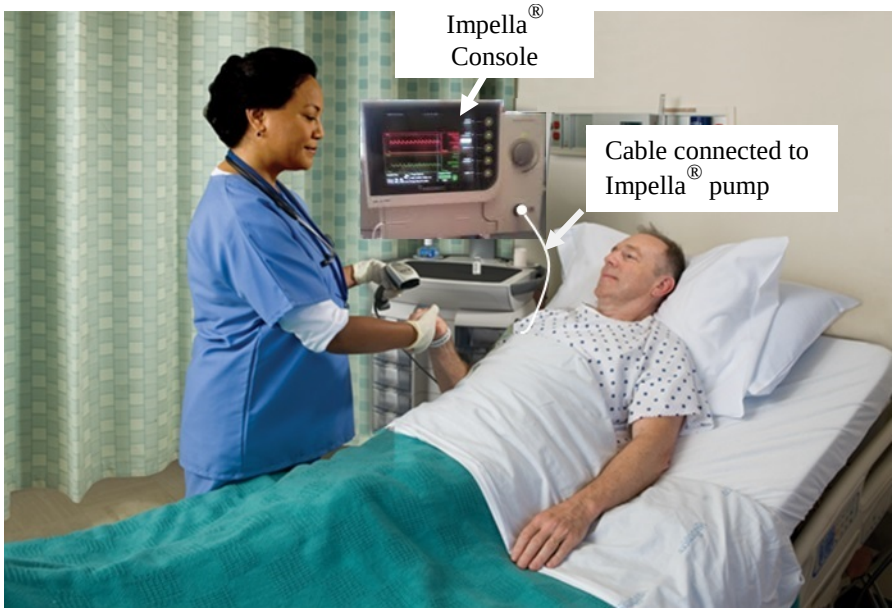
The Impella® Ventricular Support Systems

The Impella® Ventricular Support Systems have a small blood pump at the end of a thin, flexible tube (***catheter***). It is usually inserted through a blood vessel in a patient's leg (called the ***femoral artery***). Once implanted, it pumps blood for the left side of the heart. It does this by pumping blood from inside the heart, from the main left heart chamber, the ***left ventricle***, to the main blood vessel exiting to the heart, called the ***aorta*** (as shown in the picture below).

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



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



Who Should Use the Impella® Ventricular Support Systems

The Impella® Ventricular Support Systems may help patients who need emergency support of the left heart. Typical patients who may use the Impella® Ventricular Support Systems include:

- Patients whose left heart fails because of a heart attack
- Patients whose left heart fails during heart surgery

The Impella® Ventricular Support Systems must be used in a hospital. Patients who receive an Impella® Ventricular Support Systems must remain in the hospital until it is removed.

The Impella® Ventricular Support Systems is Not Right for Everyone

Who May Not be Able to be Treated with the Impella® Ventricular Support Systems

People with the conditions listed below, may not be able to be treated with the Impella® Ventricular Support System. The doctor choosing the best treatment for each patient will determine whether she/he has any of these conditions:

- Loosely attached clot(s) inside the ***left ventricle***, which may break off while the pump is in use and result in harm
- A replacement ***heart valve*** or other heart device, which could block the open area available for the pump to pass
- Severe narrowing of a ***heart valve***, which could block the open area available for the pump to pass
- A problem with a ***heart valve*** that allows blood to leak back into the ***left ventricle*** from the ***aorta***—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
- 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 severe problem with the ***right ventricle,*** which was caused it to fail to efficiently pump blood.
- A severe problem with the lungs, which prevents them from providing oxygen to your blood circulation.
- If external heart massage (CPR) is being administered.
- A defect, such as a small channel in the heart, which could shunt the blood flow between its chambers and reduce the pump output.
- A split or rupture of the **left ventricle**, which results in the leakage of blood out of the **left ventricle.**
- A build-up of blood into the space surrounding the heart, which blocks its ability to fill (with blood).

Risks Related to Use of the Impella Ventricular Support System

All cardiac surgical procedures have risks. Many of the risks with the Impella® Ventricular Support Systems are the same as those with the placement of any pump used to help the heart. However, because of the way the Impella Catheter is placed, some of these surgical risks may be lessened. Other problems that may happen with the Impella® Ventricular Support Systems are the same as those that occur with any major heart surgery procedure done with general anesthesia (when you are completely unconscious).

Risks

- Patients treated with the Impella blood pump are very sick, and may die during their therapy
- Patients may have a bleeding event, which can result in requiring blood being to be put back into their bodies (transfusion)
- Patients may have damage to their blood cells, which may be caused by the Impella blood pump or other pumps used during surgery
- Patients may have a stroke, which is a condition when decreased blood flow to the brain causes death of brain cells
- Patients may have reduced blood flow to their leg, where the Impella blood pump is inserted
- Patients may have an allergic reaction to the medication, for instance a blood thinner called heparin, which is used in conjunction with the Impella® blood pump device
- Blood clots may develop, which can travel through patients' blood vessels and block the blood flow to other organs, including their lungs making breathing difficult
- Patients may develop an infection, which could be localized or spread throughout their body
- Patients' heart tissues may be irritated or injured by the device as it is placed into the heart or during the time it sits inside the heart
- Patients' kidneys may not receive enough blood to function efficiently and may not function normally
- Patients' liver may not receive enough blood to function efficiently and may not function normally
- After patients' hearts are allowed to rest through the entire therapy, they may not recover enough strength to pump without help from the Impella® blood pump

What Happens If the Impella® Ventricular Support Systems Works Poorly or Fails?

Since your family member, relative or another significant person in your life will be in the hospital, his/her doctors and nurses will be able to continuously monitor the performance of the Impella® Ventricular Support Systems. If the Impella® blood pump begins to work poorly or fails, the doctor can usually make changes to fix the problem. If the problem cannot be fixed, the Impella® blood pump will be removed. The doctor will decide if a new Impella® blood pump should be used.

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

Benefits

How the Impella® Ventricular Support Systems Can Help Patients

Doctors consider treating patients, like your family member, relative or significant other, with the Impella® Ventricular Support Systems because the muscle on the left side of their heart (the left ventricle) has become very weak following a heart attack or open heart surgery and cannot pump enough blood on its own despite the usual treatments. This condition is the result of a sudden injury to the heart muscle and is called acute left heart failure.

When patients have acute left heart failure that occurs following a heart attack or open heart surgery that has not responded to the usual treatments, their doctors may decide to insert an Impella blood pump into their heart to help pump blood to the body and rest the heart muscle in the left ventricle to allow it to potentially recover from the injury. Depending on each patient's condition, the Impella blood pump may be left in place for one to several days to continue providing support to their heart until it recovers its ability to pump blood without help.

Based on what we currently know, it appears that the benefits of using the Impella® Ventricular Support Systems include:

- Allowing the left ventricle to rest by performing some of the heart's work
- Improving a patient's heart function
- Allow the patient to be a candidate for a different or longer term pump
- Giving a patient's heart a chance to recover after the Impella® blood pump is removed

Other Left Blood pumps are More Invasive

There are other blood pumps that can be used to treat the left side of the heart. However, to use these other pumps, doctors have to open a patient's chest to allow direct access to their heart. This is called ***open-heart surgery*** and is invasive. These pumps also require a second ***open-heart surgery*** for removal.

The Impella® Ventricular Support Systems is Minimally Invasive

With the Impella® Ventricular Support Systems, doctors do not have to perform surgery to open the chest. The device is inserted into a leg or a chest artery, and moved up the artery until it reaches the heart. An incision in your leg or chest is needed.

If the chest has already been opened (for ***open-heart surgery***), an Impella device may be placed in the heart through the ***aorta***.

Because the Impella® blood pump procedure is less invasive, patients may experience fewer complications during their treatment. They may also recover more quickly.

What Does the Treatment Involve

Before the Procedure

Before the Impella® blood pump is inserted, doctors will review each patient's medical information with their family members, relatives or significant other, to make sure the Impella® Ventricular Support Systems is the right option. The use of the Impella® blood pump is being considered because the patient's own heart function is failing and not responding to other available medical therapies.

During the Procedure

At the beginning of the procedure, the doctor will numb the patient's leg, so no pain is felt when the Impella® blood pump is inserted. The Impella® blood pump is inserted into the ***femoral artery*** through a small incision in the leg. The Impella® blood pump can also be inserted into the ***subclavian artery*** through a small incision in the chest. Then it is advanced through the patient's artery to their 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® blood pump will remain in place and will continue pumping while the patient's heart rests.

If the chest has already been opened (for ***open-heart surgery***), an Impella device may be placed in the heart through the ***aorta***.

After the Procedure

After the Impella® blood pump is inserted; a patient is usually moved to the ***Intensive Care Unit*** of the hospital where she/he is closely monitored by their doctors and nurses. A breathing tube may be used for to help the patient's lungs function properly. Doctors and nurses will use the console to check on the Impella® blood pump. Since the Impella® blood pump will be connected to the external console, patients usually cannot get out of bed until the Impella® blood pump is removed. When the Impella® is inserted into the ***subclavian artery*** in the chest, the patient may be able to sit up in bed.

When a patient becomes stronger, she/he can be moved to a regular hospital room. They may experience some pain from the surgical incisions that were part of the medical procedure of putting in the Impella® blood pump. The medical team may give patients medication for their hearts and pain medication as necessary. Nurses and physical therapists will work with patients to help them regain your strength and freedom of movement.

When the doctor determines that each patient's heart has recovered, he or she will gradually lower the pumping speed of the Impella® blood pump and allow the recovered heart to take over. When the heart is pumping properly, without the help of the Impella® blood pump, the device will be removed. The doctor may decide to give a patient general anesthesia (making you sleep), while the device is being removed, so that they do not experience any discomfort. The insertion site on the patient's leg will be closed and bandaged.

Patients are not be able to leave the hospital until the Impella® blood pump is removed and their doctor determines they are well enough to go home. It is not possible for patients to leave the hospital while they are being treated with the Impella® blood pump.

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 blood pumps blood by expanding and contracting (beating) about 100,000 times each day.

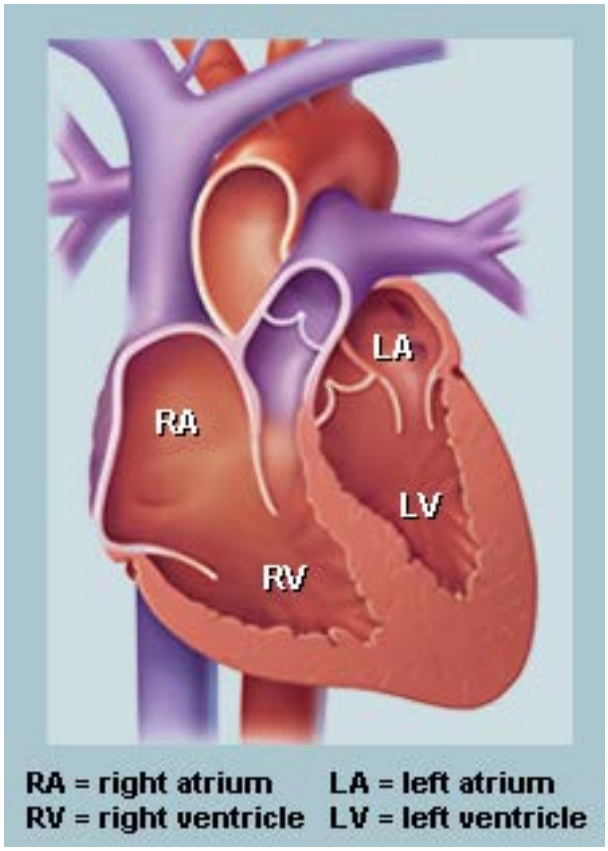
Blood pumped by the heart brings oxygen and food to every part of the body. It also carries carbon dioxide and other waste produced by the body. A healthy body depends on the heart pumping enough blood to deliver oxygen and food and to remove waste.

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 blood pumps blood through lungs. The left side of the blood 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. This can happen for many reasons. One cause of heart failure is that the heart has been injured, and cannot work efficiently. This may happen after a heart attack or either planned or emergency cardiac surgery.

Heart failure usually happens because the left side of the heart is not working properly. This is called ***left heart failure***.

Treating Your Left Heart Failure

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

- Taking medications
- Receiving a ***medical device*** called an ***intra-aortic balloon pump***, which is inserted through a vessel in your leg.

If this initial treatment does not work, and your heart continues to fail, your doctor may consider treating you with the Impella Ventricular Support Systems.

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® Ventricular Support Systems to the physician, who is treating your family member, relative or another significant person in your life.

Rx only.

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