



HeartMate 3[™]
Left Ventricular Assist System

**Patient Information
Brochure**



HeartMate 3™ Left Ventricular Assist System (LVAS) Patient Information Brochure

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What is heart failure?

Heart failure is a serious condition. If you have heart failure, your heart muscle cannot pump enough blood to provide the body with oxygen. The disease will become worse over time. It is rarely cured. The condition is considered advanced when conventional treatments, such as drugs, no longer work.

Advanced heart failure patients usually have less than 2 years to live without heart transplantation or mechanical support. About 50,000 patients each year die from advanced heart failure in the United States. If you have advanced heart failure, you may be too tired to do your usual activities – walking, climbing stairs, eating. You may be short of breath even while lying down. You likely do not have enough blood flow and require special care.

Understanding your treatment options

The current standard of care for patients in advanced heart failure includes four treatment options:

1. Drugs for heart failure
2. Cardiac Resynchronization Therapy (CRT) and Implantable Cardioverter Defibrillators (ICD)
3. Heart Transplant
4. Mechanical Circulatory Support (MCS) – use of a blood pump machine

There are many ways of treating heart failure. Many drugs work well in the early stages of heart failure but in advanced heart failure, these drugs may not be enough.

One treatment is cardiac resynchronization therapy (CRT). CRT adjusts the electrical rhythms in the heart to make it pump more efficiently. Another treatment is implantable cardioverter defibrillators (ICD) which monitor heart rhythms. An ICD will deliver shocks if dangerous rhythms are detected. CRT and ICD therapy have become common treatments for some patients.

Some patients with advanced heart failure are candidates for a heart transplant. A heart transplant can improve survival and quality of life. Donor hearts are not always available. While waiting for a donor, the condition of the heart may continue to get worse.

Mechanical circulatory support (MCS) is a way to improve the circulation of blood through the body. A heart pump called a ventricular assist device (VAD) is used. Several types of heart pumps are currently approved by the FDA to treat advanced heart failure. Each heart pump has its own benefits and drawbacks. A patient should discuss these options with his/her doctor. The patient and their doctor should then select the method that best meets the patient's expectations and lifestyle.

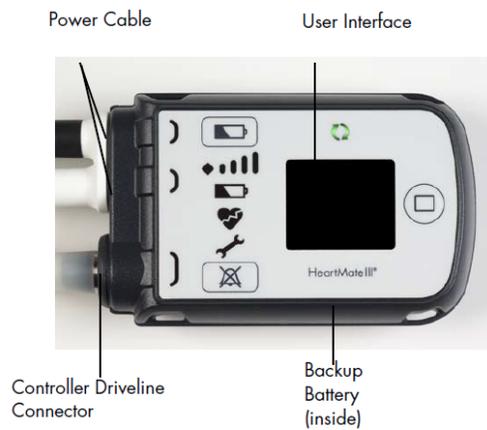
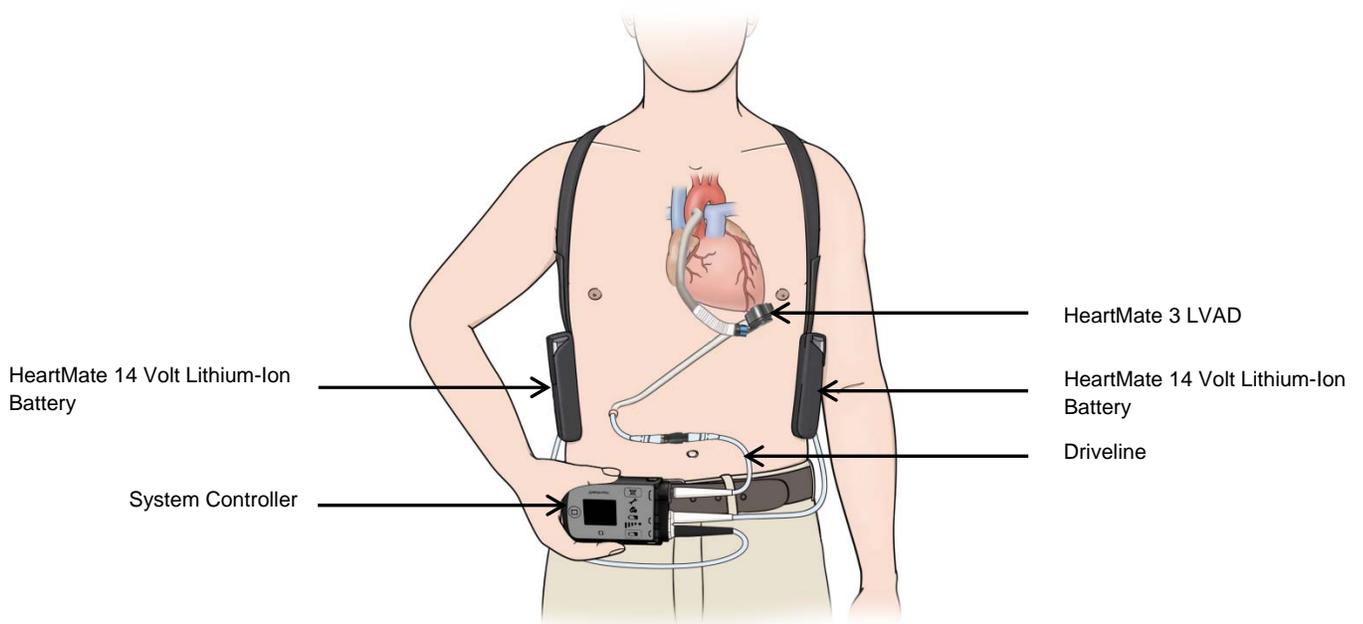
What is the HeartMate 3 Left Ventricular Assist System (LVAS)?

The HeartMate 3 LVAS is designed to take over the pumping function of a part of your heart called the left ventricle. The HeartMate 3 system includes an implanted heart pump. This heart pump is called the HeartMate 3 Left Ventricular Assist Device (LVAD). The LVAD contains an electric motor and a driveline.

The driveline exits through your skin and is connected to a small computer called the System Controller. The controller connects to an external power source. The controller sends power to the pump through the driveline.

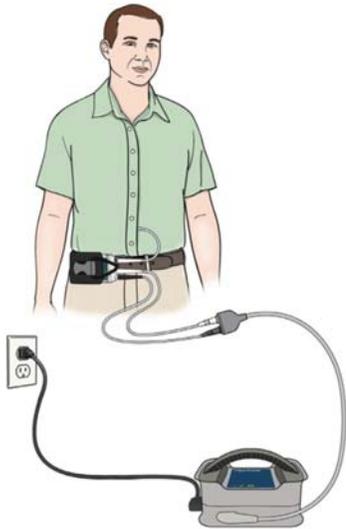
The controller also checks the pump every second to make sure it is working well. The controller provides pump information:

- The controller will alert you with lights, sounds, and messages on the display screen, if any changes occur in how the pump operates.
- The controller will show the pump speed and the amount of blood flow on the display screen.

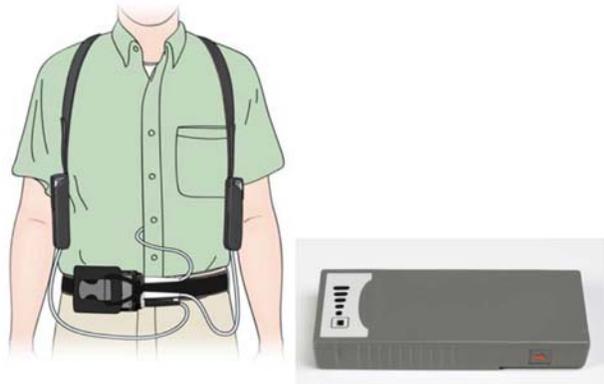


The System Controller is powered by:

- A Mobile Power Unit™ that is plugged into an electrical outlet, or
- Two rechargeable HeartMate 14 Volt Lithium-Ion batteries worn in a vest or shoulder bag.



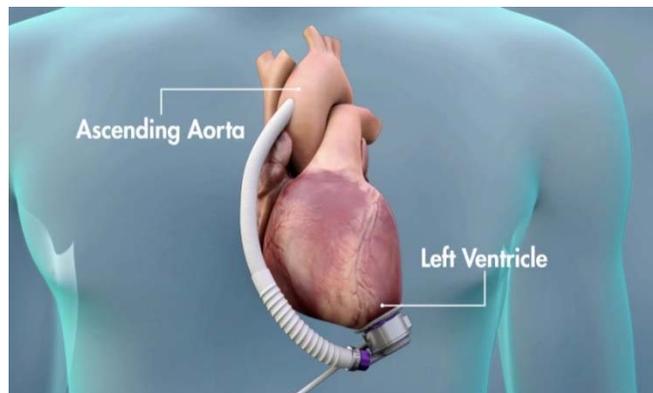
Mobile Power Unit



HeartMate 14 Volt Lithium-Ion Batteries

How does it work?

The HeartMate 3 pump is surgically implanted just below the heart. Blood enters the pump through a tube placed in the left ventricle. A small motor inside the pump turns the rotor and this motion moves the blood out of the pump into a tube connected to the aorta. The aorta is the main artery that delivers blood to the entire body. The pump helps your heart by taking over the work of your left ventricle. The pump also helps your heart by pumping oxygen-rich blood to the body.



Who should use the HeartMate 3 LVAS?

The HeartMate 3 may help advanced heart failure patients who are not responding to other treatments. Patients might receive a HeartMate 3 as a temporary pump while they wait for:

- A heart transplant or,
- The natural heart to recover

What happens before the procedure?

Before surgery, your doctor will talk to you and your family about possible risks and complications. Blood tests and X-rays will be performed. An LVAD Coordinator may visit you. This person will help you with your care after the operation. The night before the operation, you will not be allowed to eat or drink anything after midnight.

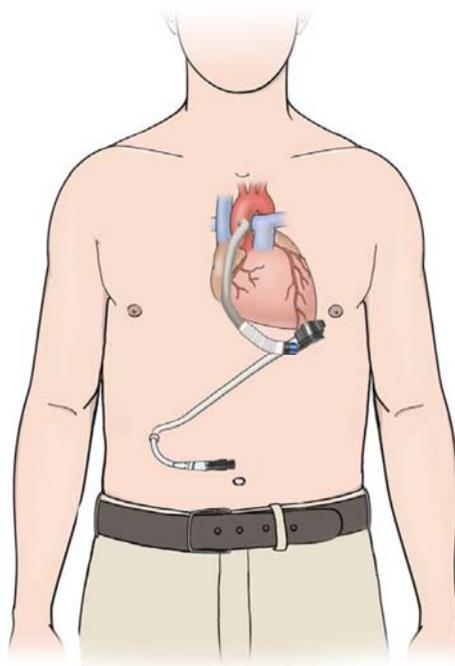
What happens during the implant procedure?

You and your medical team may decide that you should get a HeartMate 3 LVAS. If so, you will undergo open-heart surgery. Once you have been put to sleep, the surgeon will open your chest to place the heart pump. A small incision is also made on the belly. This incision allows the HeartMate driveline to exit the body. A heart-lung bypass machine does the work of your heart and lungs while the surgeon is implanting the pump.

The HeartMate 3 LVAD will be placed below your heart. It will be attached to your left ventricle and to the aorta. Once the pump is implanted, the driveline is connected to the System Controller. After the pump is working, the following will occur:

- The heart-lung bypass machine is removed.
- The chest incision is closed.
- The chest incision and driveline exit site are covered with a bandage.

The operation usually takes 3 to 6 hours.



What happens after the implant procedure?

After surgery, you will recover in the surgical intensive care unit (ICU). Here you will be carefully watched while your body recovers. When you wake up, you will have tubes and IV (intravenous) lines that were inserted during surgery. The breathing tube is usually removed the morning after surgery, once you are able to breathe on your own. The other tubes and IV lines are usually removed within the first few days after surgery. You will have a short stay in the ICU. You will then be moved into a regular hospital room.

After surgery, your doctor will check to make sure the HeartMate 3 LVAS settings are right for your needs. Your medical team will also teach you and your caregivers about:

- Living with the HeartMate 3
- How to care for the equipment
- Who to contact in case of an emergency

The Patient Handbook includes review procedures and a checklist to help you remember the information. You will always have to be connected to either batteries or an AC power supply to keep your pump running. Your doctor will prescribe medications. You will need to take these medications after the HeartMate 3 implant. It is important that you take your anticoagulation (blood thinners) and high blood pressure medications as directed. You not only take these medications for your health, but they also keep the pump working well.

After you are discharged, you will still have regular checkups with your personal physician. You will also have regular checkups with the medical team at the hospital where the HeartMate 3 LVAS was implanted. HeartMate 3 patients often enjoy traveling, as having the pump does not limit such activities. However, talk with your VAD Coordinator and doctor before making travel plans. They will work with you to make sure you are prepared to travel safely.

You will not be able to do some things with a HeartMate 3 LVAS:

- You will not be able to go swimming or take a tub bath after the HeartMate 3 LVAS is implanted. If your doctor says you can take showers you will need to use a special bag to keep the equipment dry.
- You will not be able to play contact sports or jumping games while you have the HeartMate 3 LVAS. Contact sports or jumping can damage the pump or cause bleeding.
- You must not become pregnant while you have the HeartMate 3 LVAS. A growing, unborn baby could push the pump out of place, which could cause the pump to fail, severe bleeding, or death. Also, most HeartMate 3 LVAS patients need to take blood thinners, which are not allowed during pregnancy because they can cause birth defects.

Benefits of the HeartMate 3 LVAS

The HeartMate 3 LVAS may help you to:

- Live longer
- Have a better quality of life
- Have reduced heart failure symptoms

Who should not have the procedure?

The HeartMate 3 Left Ventricular Assist System should not be used in patients who cannot tolerate medications to prevent blood clots (sometimes called blood thinners).

HeartMate 3 Clinical Study

A clinical trial was conducted from 2014 to 2016 at 69 hospitals in the United States. The trial was called the MOMENTUM 3 study. It was designed to study how safe and how well the HeartMate 3 LVAS works in patients like you who had advanced heart failure.

Over 1,000 patients participated in the study.

- Half of the patients were implanted with the HeartMate 3 LVAS.
- Half of the patients were implanted with another blood pump, the HeartMate II LVAS. (The HeartMate II LVAS was approved by the FDA in 2008.)

The pump that each patient received was randomly assigned (like a flip of a coin) and the results in the HeartMate 3 patients were compared to the results in the HeartMate II patients. The study focused on patients who:

- Had advanced heart failure.
- Did not get better taking medication or with other treatments.

The desired outcome for the patients in the trial was one of the following events after implanting the HeartMate 3 LVAS:

- Planned heart transplantation.
- Living with the HeartMate 3 LVAS implanted and not being disabled by a stroke or needing a reoperation to remove or replace the pump.
- Removal of the HeartMate 3 LVAS because the patient's natural heart recovered enough to not need a mechanical blood pump.

HeartMate 3 Clinical Study Outcome Results

The results of the study were analyzed after the first 294 patients in the study had been implanted with the HeartMate 3 LVAS for at least six months (short-term support). The most important results were:

- 86% of the HeartMate 3 patients had one of the desired outcomes.
- 89% of the HeartMate 3 patients were alive six months after the implant.
- The percent of patients who died was similar between the HeartMate 3 and the HeartMate II LVAS.
- The percent of patients who had strokes was similar between the HeartMate 3 and the HeartMate II LVAS.
- The percent of patients who had most other adverse events was similar between the HeartMate 3 and the HeartMate II LVAS. But more HeartMate 3 patients had a serious driveline infection.

- Patients implanted with the HeartMate 3 LVAS were less likely to need a reoperation to replace their pump or need an emergency heart transplantation than patients implanted with the HeartMate II LVAS.

The results of the study were analyzed again after the first 366 patients in the study had been implanted with the HeartMate 3 LVAS for at least two years (long-term support). The most important results were:

- 78% of the HeartMate 3 patients vs. 58% of the HeartMate II patients had one of the desired outcomes.
- 83% of the HeartMate 3 patients vs. 76% of the HeartMate II patients were alive two years after the implant.
- Patients implanted with the HeartMate 3 LVAD were less likely to need a reoperation to replace their pump or need an emergency heart transplantation than patients implanted with the HeartMate II LVAD.

Medical complications after the HeartMate 3 LVAS Implant

The table below lists the serious complications that occurred in the clinical study patients within the first six months after the pump was implanted.

Complications Within 6 Months After HeartMate LVAS Implant	HeartMate 3 Patients	HeartMate II Patients
Death	11 out of 100 patients	13 out of 100 patients
Major infection	37 out of 100 patients	30 out of 100 patients
Bleeding	30 out of 100 patients	37 out of 100 patients
Right heart failure	30 out of 100 patients	25 out of 100 patients
Abnormal heartbeat	26 out of 100 patients	33 out of 100 patients
Trouble or inability to breathe	22 out of 100 patients	17 out of 100 patients
Kidney function problems	11 out of 100 patients	9 out of 100 patients
Stroke	8 out of 100 patients	11 out of 100 patients
Other brain injuries	6 out of 100 patients	6 out of 100 patients
Liver function problems	5 out of 100 patients	2 out of 100 patients
Blood clots in veins	4 out of 100 patients	5 out of 100 patients
Psychiatric problems	3 out of 100 patients	5 out of 100 patients
Blood clots in arteries	2 out of 100 patients	2 out of 100 patients
High blood pressure	2 out of 100 patients	1 out of 100 patients
Fluid collection around the heart	2 out of 100 patients	3 out of 100 patients
Heart attack	1 out of 100 patients	1 out of 100 patients
Surgical wound opening	1 out of 100 patients	1 out of 100 patients
Blood cell damage	1 out of 100 patients	1 out of 100 patients
Suspected blood clots in the HeartMate 3 LVAD	0 out of 100 patients	10 out of 100 patients
Other complications	48 out of 100 patients	35 out of 100 patients

The table below lists the serious complications that occurred in the clinical study patients within the first two years after the pump was implanted.

Complications Within 2 Years After HeartMate LVAS Implant	HeartMate 3 LVAS Patients	HeartMate II LVAS Patients
Death	16 out of 100 patients	21 out of 100 patients
Major infection	50 out of 100 patients	50 out of 100 patients
Bleeding	41 out of 100 patients	51 out of 100 patients
Right heart failure	32 out of 100 patients	28 out of 100 patients
Abnormal heartbeat	33 out of 100 patients	37 out of 100 patients
Trouble or inability to breathe	24 out of 100 patients	23 out of 100 patients
Kidney function problems	13 out of 100 patients	11 out of 100 patients
Stroke	10 out of 100 patients	19 out of 100 patients
Other brain injuries	12 out of 100 patients	9 out of 100 patients
Liver function problems	4 out of 100 patients	4 out of 100 patients
Blood clots in veins	4 out of 100 patients	4 out of 100 patients
Psychiatric problems	3 out of 100 patients	6 out of 100 patients
Blood clots in arteries	2 out of 100 patients	3 out of 100 patients
High blood pressure	4 out of 100 patients	5 out of 100 patients
Fluid collection around the heart	2 out of 100 patients	5 out of 100 patients
Heart attack	1 out of 100 patients	1 out of 100 patients
Surgical wound opening	1 out of 100 patients	1 out of 100 patients
Blood cell damage	1 out of 100 patients	2 out of 100 patients
Suspected blood clots in the LVAD	1 out of 100 patients	16 out of 100 patients
Other complications	67 out of 100 patients	54 out of 100 patients

Functional Status

Functional status is an individual's ability to perform normal daily activities required to meet basic needs, fulfill usual roles, and maintain health and well-being. The HeartMate 3 patient functional status improved after being implanted with the pump.

Almost all of the patients were tired and short of breath (even while resting) before they were implanted with the HeartMate 3 LVAS. Six months after the implant, less than 1 out of 4 patients were still short of breath when doing mild physical activity, such as walking. The results were the same 2 years after the implant.

Patients were asked to walk as far as possible in the hospital hallways for six minutes to measure functional status. Less than half of the patients could take the test before they were implanted with the HeartMate 3.

Six-Minute Walk – Before HeartMate 3 LVAS Implantation

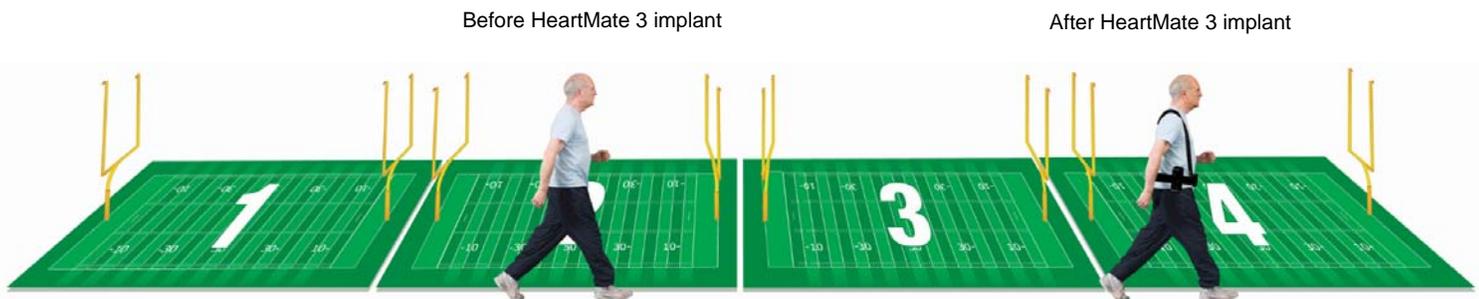
Average distance that patients could walk = 170 - 179 yards (less than two football fields)

Six-Minute Walk – Six Months after HeartMate 3 LVAS Implantation

Average distance that patients could walk = 328 yards (more than three football fields)

Six-Minute Walk – Two Years after HeartMate 3 LVAS Implantation

Average distance that patients could walk = 319 yards (more than three football fields)



Quality of Life

HeartMate 3 patients experienced major improvements in quality of life. Quality of life was measured by asking patients about the following:

- Their mobility
- Ability to take care of themselves
- Usual activities
- Pain/discomfort
- Anxiety/depression
- Symptoms of heart failure

What are the potential complications?

There are some serious complications associated with LVAD therapy. These complications are in addition to the risks normally associated with major surgery and having general anesthesia. It is important to understand these risks and discuss them with your doctor. The potential complications associated with use of the HeartMate 3 LVAS are listed below:

- Death
- Bleeding
- Abnormal heartbeat
- Infections
- Right heart failure
- Trouble or inability to breathe
- Device malfunctions
- Kidney function problems
- Severe blood infection
- Stroke and other brain injuries
- Liver function problems
- Psychiatric problems
- Blood clots in arteries and veins
- High blood pressure
- Fluid collection around the heart
- Heart attack
- Surgical wound opening
- Blood cell damage
- Blood clots in the HeartMate 3 blood pump

Additional Information

This patient guide is not intended to explain everything you need to know about your treatment options for advanced heart failure. Please discuss any questions you have about the HeartMate 3 LVAS or other treatment options with your doctor.