



INFORMED CONSENT FOR LEFT VENTRICULAR ASSIST DEVICE INSERTION FOR
LONG-TERM CIRCULATORY SUPPORT

Patient Name: _____

Introduction

Your heart is weak and unable to pump enough blood to meet all the needs of your body. This may make you feel tired and can lead to organ dysfunction, organ failure and/or death. Implanting a Left Ventricular Assist Device (LVAD) can play an important role in correcting this situation, either as a means of keeping you alive until a new heart becomes available, known as Bridge to Transplant (BTT), or as a definitive option, known as Destination Therapy (DT).

Left Ventricular Assist Device (LVAD) implantation is major surgery with significant risks and benefits. It is critical to understand the procedure, the potential complications, and the obligations you will face living with the device. This form documents that you were informed of these issues, had all your questions answered, and are willing to proceed with the LVAD implant surgery.

LVAD as BTT: Many patients with end-stage heart failure are candidates for heart transplantation. If you are waiting for a new heart and start to get sicker, or if a very long wait time is anticipated, an LVAD can be implanted to keep you alive until a new heart becomes available. This is known as using an LVAD as a Bridge to-Transplant.

LVAD as DT: Not all patients with end-stage heart failure are best served by a heart transplant. If you are such a patient, a permanent mechanical pump can be implanted. This use of an LVAD is called Destination Therapy, and it should allow you to live a fulfilling life for many years to come.

The LVAD

An LVAD is a blood pump designed to help restore the flow of blood through the body. It works in concert with your heart, but does not replace it. The HeartMate 3 is the durable LVAD pump used at Hartford Hospital. This device is approved by the Food and Drug Administration (FDA) for both BTT and DT indications. The systems has the following components:

- The heart pump
- A driveline (power cord) which passes through the skin
- An external power source
- A small computer (controller) that controls pump operation

After the implant surgery, you and your caregiver(s) will be taught more details about the operation and care of the LVAD. You and a companion will need to be sufficiently knowledgeable about the operation of the system and you will need to demonstrate that you can safely perform emergency procedures.

The heart pump: The LVAD is designed to support the left ventricle, which is the main pumping chamber of the heart. The HeartMate 3 is about the size of a hockey puck, and weighs a little less than half a pound. This pump is attached directly to the bottom of the left ventricle. It drains blood from the left ventricle and pumps blood into the aorta, the main artery that delivers blood to the rest of the body. You may hear a mechanical hum as the pump operates.

The driveline: The driveline is the “power cord” of the pump. It exits the skin on either the right or left side of your abdomen and it must be covered at all times by a sterile dressing. The driveline connects the pump inside your body to its external power source and the controller that keeps the pump running properly. The exit site



dressings on your abdomen need to be changed using meticulous sterile technique. You and your caregiver(s) will be instructed on how to change the dressing before you are discharged from the hospital or rehab facility.

The external power source: The HeartMate 3 pump is powered by batteries or by being connected directly to a unit that delivers power from a wall outlet to the pump. Two portable batteries that power the pump can be worn in either a special holster or shoulder bag, allowing considerable mobility. You will be instructed on how to switch power sources and how to charge the batteries. You will need to demonstrate your competency with these tasks before you are discharged from the hospital or rehab facility.

The controller: The controller is a small computer that tells the pump how fast to spin. It also continually monitors the pump and will provide audible and visual alarms in the event of a problem.

LVAD Implant Procedure

The pump is implanted during open-heart surgery, which typically takes between 4 to 8 hours. An incision will extend from the top of the breast bone to just below the ribcage. A heart-lung machine will pump blood through your body during the operation. After the LVAD is implanted, the heart-lung machine will be weaned off and the LVAD and your heart will take over/assist your circulation. After the incision is closed, you will be taken to the Intensive Care Unit (ICU) to recover. You will be on a breathing machine (ventilator) with a breathing tube in your windpipe until you are strong enough to breathe on your own; this could be in a matter of hours or it could take several days or more. While the tube is in place you will not be able to speak, but you will be able to communicate by other means. You will also receive the medication you will need to feel comfortable.

Risks

There are risks associated with any major surgical procedure. Potential complications that may occur with LVAD support and the implant procedure include, but are not limited to, the following:

- Death □□ Infection (due to the device) □ Excessive bleeding □□ Need for reoperation
- Hemolysis (the destruction of blood cells) □□ Liver dysfunction (the liver fails to filter blood)
- High blood pressure □ Heart attack □ Kidney failure
- Thromboembolism (blood clots that form and can travel to other parts of the body; this could result in a stroke or loss of a limb or organs and could require surgery)

- Right heart failure (the right side of the heart is weak and fails to pump blood)

- Need for mechanical ventilation (having a breathing tube and a machine to help you breathe) □ Prolonged ICU and/or hospital stay

- Mechanical pump failure (the pump or its parts may stop working or malfunction)
- Neurological dysfunction (brain or nerve damage resulting in difficulty or inability to wake up or difficulty moving parts of the body)

- Psychiatric problems (disturbances in thought processes or emotions, behavioral changes)
- Arrhythmia (heart may beat irregularly or stop beating)
- Pulmonary dysfunction (the lungs fail to oxygenate the body)

_____ Patient Initial



Potential Benefits

Most patients benefit from LVAD implantation. The LVAD helps your heart pump more blood to your body. The increase in blood flow gives you more energy, improving your quality of life and prolonging it as well.

Sometimes an LVAD will lower pressures inside your lungs which otherwise could make you NOT a candidate for a heart transplant. An LVAD may also improve kidney function. Sometimes patients who are not transplant candidates can become candidates after prolonged LVAD support. Your physicians will monitor your progress after LVAD insertion and will let you know if your candidacy for heart transplantation changes.

Lifestyle and Body Image Changes

I have seen an LVAD pump model and have a basic understanding of the device components, including batteries, power unit, driveline, and controller. I have seen a picture of a patient wearing the controller and batteries. I have also seen a picture of a driveline exit site (where the device exits the body on the abdomen). I understand that I will need a 24-hour caregiver following discharge from the hospital and that I should not be alone after I receive an LVAD until given permission by the LVAD team.

Improved circulation of blood after LVAD insertion should enable you to return to your daily life with few restrictions. With time, you should be comfortable with all aspects of living with an LVAD. There are some activities that should be avoided during LVAD support because the equipment is electrical and is outside the body. Examples of some restrictions include:

- No submersion in water (no tub baths, hot tubs/jacuzzis, or swimming)
- No contact sports
- No participation in impact activities that may cause trauma to the device or driveline
- No sleeping with electric blankets or pads
- No dusting computer or television screens or vacuum cleaning (they have strong static electricity which can cause electric shock, can damage electrical parts of the pump and its components, or cause the system to stop) □ Do not become pregnant

Discharge Home

To be discharged to your home, you must demonstrate mastery of the LVAD and your home environment must be satisfactory to adequately support the LVAD equipment. You must have consistent electricity and phone services. Some LVAD equipment must only be plugged into a grounded, 3-pronged electrical outlet. A home evaluation will be done before surgery to ensure these requirements are met and in most cases, a visiting nurse will be requested to visit the home for a formal evaluation prior to hospital discharge.

You will need to adhere to meticulous medical care after LVAD implant, including:

- Lifetime follow-up appointments and testing to monitor organ function, medications and VAD function
- Lifetime sterile dressing changes of driveline exit site by your designated caregiver
- Lifetime care for the LVAD and its components by preventing trauma, kinks or damage to the driveline and maintaining clean equipment

_____ Patient Initial



Financial

The following financial matters were discussed:

- Ongoing cost of medications and dressing change supplies
- Potential for denial of additional health, disability or life insurance coverage
- Future health issues related to LVAD implantation that may not be covered by current insurance
Alternative financial resources that may be available

Alternative Treatments

If you decide you do NOT want an LVAD, you can choose to be treated with other therapies that include conventional medications. Your heart failure cardiologist can discuss those options with you.

Patient Acknowledgement

I read all of the above information. I also received a patient manual describing the function of the **HeartMate 3**. I understand the risks and benefits of the procedure and the lifestyle changes I must make to be successful with my LVAD. I have had an opportunity to ask questions and received answers to all my questions about my condition, risks and benefits of the procedure(s), potential complications, alternative options, and lifestyle and body image changes.

This consent may be revocable by me at any time, except to the extent it has already been relied upon.

_____ M. D. Signed: _____
(Patient or legally authorized representative)

Date: _____ Time: _____ Date: _____ Time: _____

Interpreter responsible for explaining procedures and special treatment:

_____ (Interpreter)

Patient unable to sign prior to surgery [<input type="checkbox"/>] because:	
_____ M.D.	Date: _____ Time: _____