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

Patient Name: ___________________________________

Introduction

Because your heart is sick and weak, it is unable to pump enough blood to meet all the needs of your body’s organs. This may make you feel tired and can lead to organ dysfunction or 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 an alternative to transplantation, known as Destination Therapy (DT).

Ventricular Assist Device (VAD) implantation is major surgery with significant risks, as well as benefits. Therefore, it is critical that you understand the procedure, the potential for complications, and the obligations you will face living with the device. This form will document that you have been informed of these issues, have had all your questions answered, and are willing to proceed with the implant surgery.

LVAD as BTT: Many patients with end-stage heart failure are candidates for heart transplantation. Unfortunately, the waiting time for a new heart can be long and unpredictable. 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. This gives you the added advantage of not having to spend the waiting period in the hospital.

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 as an alternative to a transplant. 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

The 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. For patients receiving a VAD for Destination Therapy, we use the HeartMate II LVAD, made by the Thoratec Corporation (www.thoratec.com) and approved by the Food and Drug Administration (FDA) for this indication. For patients receiving a VAD as bridge to transplant, the HeartMate II or the HeartWare HVAD (www.heartware.com) are used, both of which are approved by the FDA for BTT. Both systems have the same main 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 II pump is about the size and shape of a large pear, and it weighs a little over one pound. It is implanted in a space behind your ribs and just below your heart. The HVAD is about the size of a hockey puck, and weighs a little less than half a pound. It is attached directly to the bottom of the left ventricle. Both pumps drain blood from the tip of the left ventricle and pump blood into the aorta, the main artery which 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 will exit 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 to the controller that keeps the pump running properly. The exit site dressing on your abdomen needs to be changed using meticulous sterile technique. You and your caregiver(s) will be instructed in how to change the dressing before you are discharged from the hospital.

The external power source: The HeartMate II LVAD may be powered by batteries or by being connected directly to a Power Module (PM) that delivers power from a grounded wall outlet to the pump. Two portable batteries that can power the pump for up to 10 hours at a time are worn in either a special holster or shoulder bag, allowing you considerable mobility. The HeartWare HVAD may also be powered by batteries, which can power the pump for about 4 hours, and which also can be worn in a special holster or shoulder bag. The HeartWare controller can be attached to an AC or DC adapter for use when you are relaxing or sleeping. You will be instructed in 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.

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 while we work on the heart. After the LVAD is implanted, the heart-lung machine will be weaned off and the LVAD and your heart will take over 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
- Need for reoperation
- High blood pressure
- 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)
- Prolonged ICU and/or hospital stay
- Psychiatric problems (disturbances in thought processes or emotions, behavioral changes)
- Infection (due to the device)
- Hemolysis (the destruction of blood cells)
- Heart attack
- Right heart failure (the right side of the heart is weak and fails to pump blood)
- Mechanical pump failure (the pump or its parts may stop working or malfunction)
- Arrhythmia (heart may beat irregularly or stop beating)
- Excessive bleeding
- Liver dysfunction (the liver fails to filter blood)
- Kidney failure
- Need for mechanical ventilation (having a breathing tube and a machine to help you breathe)
- Neurological dysfunction (brain or nerve damage resulting in difficulty or inability to wake up or difficulty moving parts of the body)
- Pulmonary dysfunction (the lungs fail to oxygenate the body)
Potential Benefits
Most patients benefit from LVAD implantation. The LVAD helps your heart pump more blood to your body. The increase in cardiac output 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. They can also improve kidney function. Sometimes patients who are not transplant candidates can become transplant 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 VAD pump demonstration models and have a basic understanding of the device components, including batteries, power module, 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. I understand that I cannot be alone after I receive a VAD until given permission by the VAD team.

Improved circulation of blood after VAD 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 a VAD. There are some activities that should be avoided during VAD 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 VAD and your home environment must be satisfactory to adequately support the VAD equipment. You must have consistent electricity and phone services. VAD equipment must only be plugged into grounded, 3-pronged electrical outlets. A visiting nurse will come to your home before surgery to ensure these requirements are met.

Furthermore, you will need to adhere to meticulous medical care after VAD 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 VAD and its components by preventing trauma, kinks or damage to the driveline and maintaining clean equipment

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 VAD implantation 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 have read all of the above information. I have also received a patient manual describing the function of the Thoratec HeartMate II LVAD/ HeartWare HVAD (circle one).

I understand the risks and benefits of the procedure, as well as the lifestyle changes that I must make to be successful with my VAD. I have had an opportunity to ask questions, and I have 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 [ ] because:

____________________________________________________________________________

_____________________________________ M.D.  Date:___________ Time:_____________