Is it time to consider a HEARTMATE™ LEFT VENTRICULAR ASSIST DEVICE (LVAD)?

A treatment for advanced heart failure.

See Important Safety Information referenced within.
What is HEART FAILURE?

Heart failure — sometimes called a weak heart — occurs when the heart is unable to pump enough blood to meet the body’s demands. When this occurs, blood pressure within the heart and lung blood vessels increases, eventually leading to congestive symptoms and shortness of breath. It is a disease that worsens over time and is rarely cured.

At its onset, heart failure is typically treated with changes in lifestyle and a combination of medications, which tend to be more effective when the disease is in its earlier stages. Advanced heart failure occurs when traditional heart therapies, such as medication, no longer work. As a patient with advanced heart failure, you may be too exhausted to participate in your usual activities of daily life, such as walking, climbing stairs, eating meals — even lying down may be challenging.
Treating Heart Failure

Your heart requires special care. As an advanced heart failure patient, your doctor may discuss your options, such as medication, a heart transplant, a heart pump (mechanical circulatory support device) or hospice. Patients with advanced heart failure experience significant limitations in normal activities and have a reduced quality of life. Some patients may also require hospitalizations and face a higher risk of death — with some studies showing a life expectancy of less than two years without heart transplantation or a medical device that provides mechanical support. Annually, approximately 50,000 Americans lose their lives due to advanced heart failure.

Left Ventricular Assist Devices (LVADs)

Heart transplantation is recognized as a viable treatment option for patients with advanced heart failure. However, there are a limited number of donor hearts available. A small implanted heart pump called an LVAD supports the pumping function of the heart and helps circulate oxygen-rich blood throughout the body for patients whose hearts are too weak to pump blood adequately on their own.

The HeartMate II™ Left Ventricular Assist Device (LVAD) is an option for patients with NYHA Class IIIB or IV heart failure. It can be used for Bridge to Transplantation support (for people waiting for a donor heart) or for Destination Therapy, sometimes called permanent support (for people who are ineligible for heart transplantation).

THE NYHA* CLASSES OF HEART FAILURE

CLASS I
No symptoms or limitations to physical activity.

CLASS II
Slight limitations of physical activity. Comfortable at rest; ordinary physical activity results in feeling tired and shortness of breath.

CLASS III
Significant limitations of physical activity. Less than ordinary activity causes results in feeling tired and shortness of breath.

CLASS IV
Unable to carry on any physical activity without discomfort. Tired and shortness of breath even at rest.

*NYHA (New York Heart Association) Heart Failure Class System

See Important Safety Information referenced within.
The HeartMate II™ LVAD had been FDA approved since 2008. To date, over 26,000 heart failure patients have received the HeartMate II LVAD. Many have passed the five-year milestone on therapy, with some patients still on therapy after 10 years.

Clinical studies have shown that HeartMate II LVAD can reverse symptoms of heart failure — improving long-term survival, functional status and quality of life for patients.
HELPING PATIENTS WITH ADVANCED HEART FAILURE
CELEBRATE MORE REBIRTHDAYS
with the HeartMate II™ LVAD

MAYRA
Living well on HeartMate II LVAD since 2008

See Important Safety Information referenced within.
HeartMate II™ LVAD
PROVEN CLINICAL RESULTS

More patients have been implanted with the HeartMate II™ LVAD than any other continuous flow LVAD. Today, thousands of patients around the world are living active, full lives with a HeartMate II LVAD.3-6

Long-Term Survival

Patients implanted with a HeartMate II LVAD have been shown in a clinical study to have a 2-year survival rate of 68%.8

2-YEAR SURVIVAL RATE OF 68%8

Reversed Heart Failure Symptoms

NYHA Class is a common scale that doctors use to measure heart failure symptoms (see page 3). In a long-term clinical study, all patients were in NYHA Class IIIB or IV heart failure before receiving the HeartMate II LVAD. After being implanted with the HeartMate II LVAD, more than 80% of patients improved to NYHA Class I or II by six months. This improvement was maintained by 78% of patients out to at least two years.4

> 80% OF PATIENTS IMPROVED to NYHA Class I or Class II by 6 months

≥ 78% OF PATIENTS REMAINED at NYHA Class I or Class II out to at least 2 years
Significant Improvement in Six-Minute Walk Distance and Quality of Life

The Six-Minute Walk Test (6MWT) is a common way to test for your ability to perform daily physical activities. In a clinical study, only 16% of patients tested were able to complete the six-minute walk test at an average of ~200 meters before receiving the HeartMate II™ LVAD. At six months after being implanted with the HeartMate II LVAD, 94% of those tested were able to complete the test at an average of ~340 meters — that’s more than the length of three football fields!

Additionally, using clinically validated quality of life assessment surveys, patients reported a median 39 points improvement in their quality of life at both 6 and 24 months after receiving their HeartMate II LVAD.

Risk and Adverse Event Information

As with any surgical procedure, there are risks for serious adverse events associated with LVAD therapy. The HeartMate II LVAD should not be used on patients who cannot tolerate, or who are allergic to, anticoagulation therapy (blood-thinning medication). It is important to understand, and discuss with your doctor, the risks associated with LVAD therapy.

Note: One football field = 91 m (100 yards)

†An improvement of 5 points or more is clinically meaningful.

See Important Safety Information referenced within.
UNDERSTAND THE HEARTMATE II™ LVAD SYSTEM

The HeartMate II™ LVAD is implanted by a trained cardiac surgeon. There are components placed inside and outside the body to help your heart.

1 **HEART PUMP (LVAD):** Connected to the left side of your heart and moves blood from your heart to the rest of your body.

2 **BATTERIES:** Provides up to 12 hours of uninterrupted power.

3 **DRIVELINE:** Transfers power and information between the controller and the LVAD. This component is partially outside of your body.

4 **CONTROLLER:** Powers and checks the heart pump and driveline. This easy-to-wear controller weighs approximately one pound and discreetly slips into a front pocket. The controller uses alerts to tell you how the system is working and includes 15 minutes of emergency backup power.

---

**Powering an Active Life**

**RECHARGEABLE BATTERIES** are lightweight and long-lasting, weighing approximately one pound each. A pair of batteries offers up to 12 hours of uninterrupted support.

**MOBILE POWER UNIT** (not shown) can be plugged into an electrical socket to provide power while you are indoors, at rest or asleep. Small, lightweight and as mobile as you are, the unit is designed to be extremely durable.

See Important Safety Information referenced within.
About the HeartMate II™ LVAD

PROCEDURE

The HeartMate II™ LVAD is implanted by a trained cardiac surgeon in a hospital using standard surgical procedures and care.

During the surgery, your surgeon places the LVAD inside your chest and attaches it to the left ventricle of the heart and to the aorta (a large blood vessel which carries blood from your heart to the rest of the body). After the LVAD is in place, a tube (the driveline) is passed through the skin of your abdomen and connected to the controller and a power supply — see Figure 1.

After the surgery, you may stay in the hospital for 2-4 weeks for close monitoring and recovery (hospital stay varies by patient). You and your caregiver will also learn about post-surgical care and how to operate and live with the HeartMate II LVAD System.

After you leave the hospital, there will be regular checkups with the LVAD care team. You will be able to return to an active lifestyle and many of the normal activities you enjoy (with few exceptions**).

It is important to fully understand the risks of LVAD implantation. Together with your doctor, make sure you ask questions and understand the risks of having a HeartMate II LVAD implant.

**Your advanced heart failure center will guide you on which activities you may need to avoid once you have your HeartMate II LVAD. This includes swimming or water sports since some components of the system are outside of the body and cannot be submerged in water.
Is the HeartMate II™ LVAD FDA approved?

Yes. The HeartMate II™ LVAD has been approved by the FDA for Bridge-to-Transplantation since 2008 and for Destination Therapy since 2010.

Am I a candidate for HeartMate II™ LVAD therapy?

You may be a candidate if you have NYHA Class IIIB or IV heart failure and continue to have heart failure symptoms despite taking medications. It may be used for Bridge to Transplantation support (if waiting for a donor heart) or for Destination Therapy, sometimes called permanent support (if ineligible for heart transplantation).

Further evaluation by an advanced heart failure doctor will help determine whether you are a candidate who may benefit from LVAD therapy.
Can I do normal activities with the HeartMate II™ LVAD?
Most patients describe a marked improvement in their functional status and quality of life with the HeartMate II™ LVAD.4–6 Yet it is a big change for both recipients and caregivers. There is much to learn and it will take some time for you both to adjust. Today’s LVADs are lightweight and smaller than earlier models, so you’ll be able to move around fairly easily, get moderate exercise and enjoy an active lifestyle.††

Is the LVAD procedure covered by health insurance or Medicare?
The procedure may be covered by insurance or Medicare. If your care team at the advanced heart failure center determines you are a candidate for LVAD therapy, they can help explain your coverage options.

How can I learn more?
Visit www.HeartMate.com for more information and to locate a HeartMate™ LVAD implant center near you.

††Your advanced heart failure center will guide you on which activities you may need to avoid with your device. This includes swimming or water sports since some components of the HeartMate II™ Left Ventricular Assist System are outside of the body and cannot be submerged in water.

IMPORTANT INFORMATION
The information in this brochure is provided for educational purposes. Individual experiences, symptoms, situations and circumstances may vary. Please consult your physician or qualified health provider regarding your condition and appropriate medical treatment.

Remember, the more you know, the more confident you can be about your decision. Some people find it helpful to talk with local patient support groups. Your medical team may be able to put you in touch with groups in your area.

For more information visit www.HeartMate.com

See Important Safety Information referenced within.
**Important Safety Information:** Prior to using these devices, please review the Instructions for Use (IFU) for a complete listing of indications, contraindications, warnings, precautions, potential adverse events and directions for use.

**Indications:** The HeartMate II™ Left Ventricular Assist System is indicated for use as a “bridge to transplantation” for cardiac transplant candidates who are at risk of imminent death from non-reversible left ventricle failure. It is also indicated for use in patients with New York Heart Association (NYHA) Class IIIB or IV end-stage left ventricular failure, who have received optimal medical therapy for at least 45 of the last 60 days, and who are not candidates for cardiac transplantation. The HeartMate II Left Ventricular Assist System is intended for use both inside and outside of the hospital, or for transportation of Left Ventricular Assist Device patients via ground ambulance, airplane, or helicopter.

**Contraindications:** The HeartMate II Left Ventricular Assist System is contraindicated for patients who cannot tolerate, or who are allergic to, anticoagulation therapy.

**Adverse Events:** Adverse events that may be associated with the use of the HeartMate II Left Ventricular Assist System are listed below. Adverse events are listed in decreasing order of frequency, except for death, which appears first because it is a non-reversible complication: Death, Bleeding (perioperative or late), Cardiac arrhythmia, Local infection, Respiratory failure, Device malfunction, Sepsis, Right heart failure, Driveline or pump pocket infection, Renal failure, Stroke, Neurologic dysfunction, Psychiatric episode, Peripheral thromboembolic event, Hemolysis, Hepatic dysfunction, Device thrombosis, Myocardial infarction.

Refer to the User’s Manual for detailed indications, contraindications, warnings, precautions and potential adverse events.

™ Indicates a trademark of the Abbott group of companies.

© 2018 Abbott. All Rights Reserved.

26719-SJM-HM-0718-0120 | Item approved for U.S. use only.