LIVING A MORE ACTIVE LIFE

with the HeartMate 3™ LVAD for the treatment of advanced heart failure

RON
HeartMate 3™ LVAD Recipient
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.

In its early stages, heart failure can often be managed with medication and a healthy lifestyle. As the disease progresses and the heart becomes weaker, treatment gets more complex. Compared with medications or pacemakers, ventricular assist devices (VADs) improve quality of life to a far greater degree. Advanced heart failure is a term used when conventional heart therapies and symptom management strategies are no longer working. 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 an overwhelming challenge.
Treating Heart Failure

As an advanced heart failure patient, you and your heart require special care. Your doctor may discuss treatment options with you such as medications, a heart transplant, a heart pump (mechanical circulatory support device) or hospice. Patients with advanced heart failure are frequently hospitalized and have a reduced quality of life. These patients 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 270,000 Americans lose their lives due to advanced heart failure.

Left Ventricular Assist Devices (LVADs)

Heart transplant 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 3™ LVAD is an option for patients with NYHA Class IIIB or IV heart failure. It can be used for both short-term and long-term heart support, such as:

- Bridge to Transplantation (for people waiting for a donor heart)
- 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 having shortness of breath.

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

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

The HeartMate 3™ LVAD received FDA approval in 2017 and is the latest innovation in LVAD therapy. Clinical study has shown that the HeartMate 3 LVAD can reverse symptoms of heart failure — improving long-term survival, functional status and quality of life for patients.6

HeartMate 3 LVAD outcomes are made possible with Full MagLev™ Flow Technology, which helps protect the blood as it flows through the pump.
GETTING BACK TO
LIFE’S IMPORTANT MOMENTS
with the HeartMate 3™ LVAD

FLYNN
HeartMate 3™ LVAD Recipient
HeartMate 3™ LVAD

PROVEN CLINICAL RESULTS

MOMENTUM 3, the largest LVAD trial ever conducted**, studied the safety and effectiveness of the HeartMate 3™ LVAD in patients with advanced refractory left ventricular heart failure and who were indicated for mechanical circulatory support with an LVAD.

Long-Term Survival

Patients implanted with a HeartMate 3 LVAD have been shown in a clinical study to have a two-year survival rate of 83%.6

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 3 LVAD. After being implanted with the HeartMate 3 LVAD, more than 78% of patients improved to NYHA Class I or II by six months. This improvement continued in 79% of patients through two years.4
Significant Increase in Six-Minute Walk Distance

The Six-Minute Walk Test is a common way to test for your ability to perform daily physical activities. Patients who received the HeartMate 3™ LVAD had a significant improvement in six-minute walk distance. Before receiving the device, patients were able to walk an average of 154 meters (about 168 yards) in six minutes. Twenty-four months after receiving the HeartMate 3 LVAD, patients were able to walk an average of 308 meters (about 337 yards) in six minutes. That’s two times farther in distance.

RISK AND ADVERSE EVENT INFORMATION

There are serious adverse events associated with LVAD therapy. It is important to understand these risks and discuss them with your doctor. The HeartMate 3 LVAD should not be used on patients who cannot tolerate, or who are allergic to, anticoagulation therapy (blood-thinning medication). Other than the risks normally associated with major surgery and having general anesthesia, the potential complications of having a HeartMate 3 LVAD are listed below.

ADVERSE EVENTS THAT ARE EXPECTED TO OCCUR AT LESS THAN OR EQUAL TO THE FOLLOWING RATES AT TWO YEARS:

- Major infection (55%)
- Bleeding (43%)
- Cardiac arrhythmia (38%)
- Right heart failure (32%)
- Respiratory failure (24%)
- Renal dysfunction (13%)
- Stroke (10%)
- Other neurological event (12%)
- Hepatic dysfunction (4%)
- Psychiatric episode (5%)
- Venous thromboembolism (5%)
- Hypertension (6%)
- Arterial non-CNS thromboembolism (2%)
- Pericardial fluid collection (2%)
- Myocardial infarction (1%)
- Wound dehiscence (1%)
- Hemolysis (not associated with suspected device thrombosis) (1%)
- Suspected device thrombosis (1%)
- Other adverse events (70%)
UNDERSTAND THE HEARTMATE 3™ LVAD SYSTEM

The HeartMate 3™ 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:** Provide up to 17 hours of uninterrupted power.

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

4 **CONTROLLER:** Powers and checks the pump and driveline. This easy-to-wear controller weighs less than 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.

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**Powering a Better Life**

**RECHARGEABLE BATTERIES**
are lightweight and long-lasting, weighing less than one pound each. A pair of batteries offers up to 17 hours of uninterrupted support — almost twice as long as batteries in similar devices.

**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.
The HeartMate 3™ 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 that 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 (Figure 1).

After the surgery, you may stay in the hospital for two to four 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 3 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 3 LVAD implant.
Is the HeartMate 3™ LVAD FDA approved?

Yes. The HeartMate 3™ LVAD is approved for both short-term and long-term heart support. This can include 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).

Am I a candidate for HeartMate 3 LVAD therapy?

You may be a candidate if you have NYHA Class III B 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 3 LVAD?

Most patients describe a marked improvement in their functional status and quality of life with the HeartMate 3 LVAD. 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.
What are the risks with LVAD therapy?
Like any major surgery, getting an LVAD comes with risks. Talk to your doctor to understand the risks and benefits.

Is the LVAD procedure covered by health insurance or Medicare?
The procedure may be covered by health 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.HeartMate3.com for more information and educational resources and to locate a HeartMate™ LVAD implant center near you. To see patient information on the FDA website, visit https://bit.ly/2MXWa77, scroll down to the section titled, “Labeling” and click on “Labeling part 2.”

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 support groups. Your medical team may be able to put you in touch with groups in your area.

For more information visit www.HeartMate3.com
**Ongoing evaluation of over 2,000 patients on short- and long-term therapy.
***Your advanced heart failure center will guide you on which activities you may need to avoid once you have your HeartMate 3™ Left Ventricular Assist Device. This includes swimming or water sports since some components of the system are outside of the body and cannot be submerged in water.


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HeartMate3.com
St. Jude Medical is now Abbott.

Rx Only

Important Safety Information

Brief Summary: Prior to using these devices, please review the Instructions for Use for a complete listing of indications, contraindications, warnings, precautions, potential adverse events and directions for use.

Indications: The HeartMate 3™ Left Ventricular Assist System is indicated for providing short- and long-term mechanical circulatory support (e.g., as bridge to transplant or myocardial recovery, or destination therapy) in patients with advanced refractory left ventricular heart failure.

Contraindications: The HeartMate 3 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 3 Left Ventricular Assist System are: death, bleeding, cardiac arrhythmia, localized infection, right heart failure, respiratory failure, device malfunctions, driveline infection, renal dysfunction, sepsis, stroke, other neurological event (not stroke-related), hepatic dysfunction, psychiatric episode, venous thromboembolism, hypertension, arterial non-central nervous system (CNS) thromboembolism, pericardial fluid collection, pump pocket or pseudo pocket infection, myocardial infarction, wound dehiscence, hemolysis (not associated with suspected device thrombosis) or device thrombosis.

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