



Abbott

# LIVING A MORE **ACTIVE** **LIFE**

with the  
HeartMate 3™ LVAD



**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.

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.<sup>1</sup> 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.



VIVIAN  
HeartMate 3™ LVAD  
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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.<sup>2</sup> 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 50,000 Americans lose their lives due to advanced heart failure.<sup>2</sup>

## Heart Failure and 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. An implanted heart pump called a left ventricular assist device (LVAD) can help the heart pump oxygen-rich blood throughout the body and meaningfully improve the symptoms of advanced heart failure.<sup>2</sup>

The HeartMate 3™ Left Ventricular Assist Device (LVAD) is an option for patients with advanced heart failure. The HeartMate 3 LVAD is intended for a broad range of advanced heart failure patients and is designed to restore blood flow and improve survival, functional status and quality of life for short-term support.

## 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.

\*American Heart Association Classes of Heart Failure 2017.



**HeartMate 3™ Left  
Ventricular Assist Device**  
with Full MagLev™  
Flow Technology

## Getting to know the **HEARTMATE 3™ LVAD**

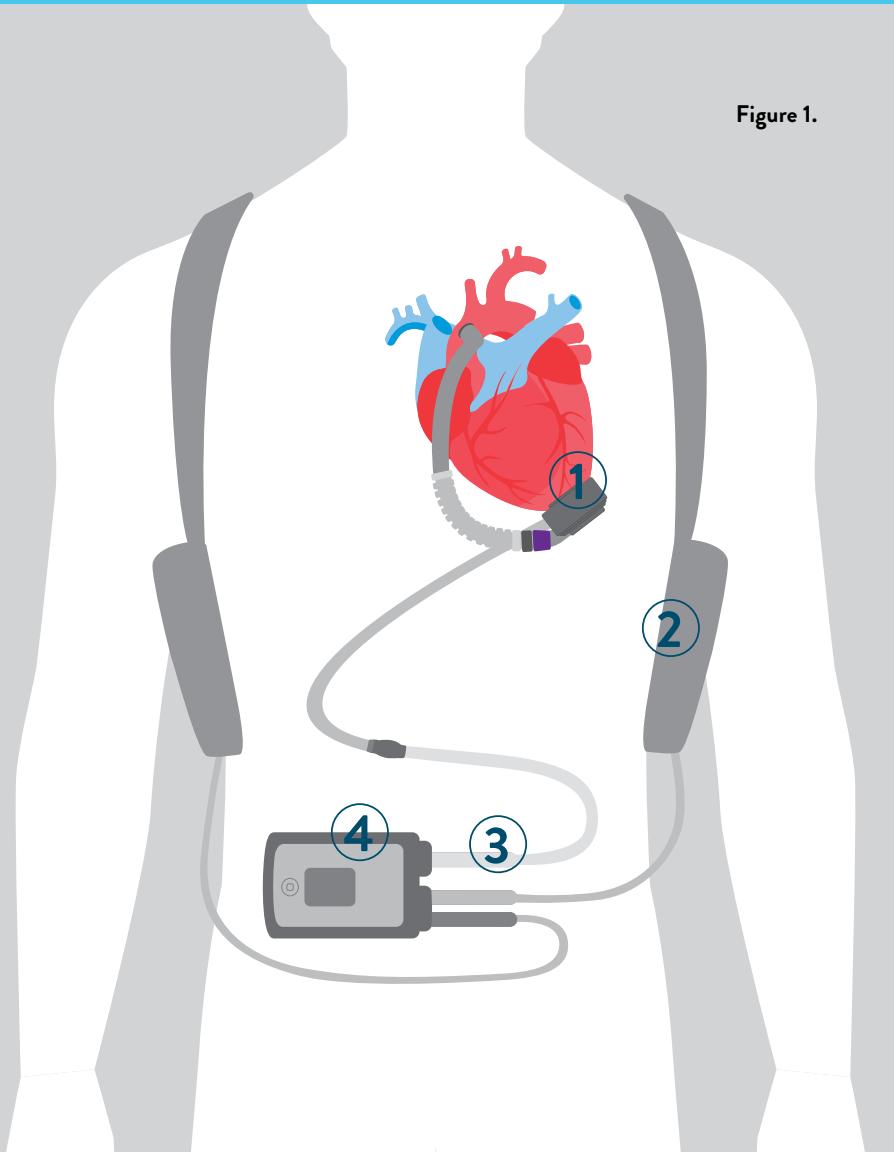
The HeartMate 3™ LVAD is a small implantable device that is designed to support the pumping function of the heart and helps circulate blood throughout the body for patients whose hearts are too weak to pump blood adequately on their own.<sup>3</sup> It is placed in your chest by an experienced heart surgeon.

The HeartMate 3 LVAD offers significant improvement in survival and quality of life<sup>4</sup> with fewer complications\*\* than similar devices, partly due to its Full MagLev™ Flow Technology, which helps protect the blood as it flows through the pump.

# Getting to know your HeartMate 3™ LVAS

- 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.

Figure 1.



## 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™

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.

# GETTING BACK TO LIFE'S IMPORTANT MOMENTS

with the  
HeartMate 3™ LVAD



**FLYNN**  
HeartMate 3™ LVAD  
Recipient

# THE HEARTMATE 3™ LVAD CAN HELP PATIENTS WITH ADVANCED HEART FAILURE LIVE ACTIVE, FULLER LIVES, WITH FEW LIMITATIONS.\*\*\*

## What to Know About Your Surgical Procedure

The surgery to implant your heart device will be done using standard surgical procedures and care. Your surgeon will perform open-heart surgery to place the pump below your heart. The pump will attach to your aorta (a large blood vessel which carries blood from your heart to the rest of your body) and to the left side of your heart.

After the pump is in place, there will be a tube passing through the skin of your abdomen that connects to the power cable. The power cable is connected to the small monitor called the controller and then to a special power supply: 1) two batteries, together can last up to 17 hours, 2) a power module which is plugged into an AC wall outlet, or 3) a mobile power unit, which is also plugged into a wall outlet. (See figure 1.)

It is important to fully understand the risks of LVAD implantation. Together with your doctor, make sure you completely understand the risks of having a HeartMate 3 LVAD implant.



\*\*\*Your advanced heart failure center will guide you on which activities you may need to avoid once you have your HeartMate 3 LVAD. This includes swimming or water sports since some components of the system are outside of the body and cannot be submerged in water.

# HeartMate 3™ LVAD Clinical Trial: THE MOMENTUM 3 STUDY

A clinical trial called MOMENTUM 3 studied the safety and effectiveness of the HeartMate 3 LVAD. The trial involved 69 medical sites and 1,028 patients who had advanced refractory left ventricular heart failure and who were indicated for mechanical circulatory support with an LVAD.

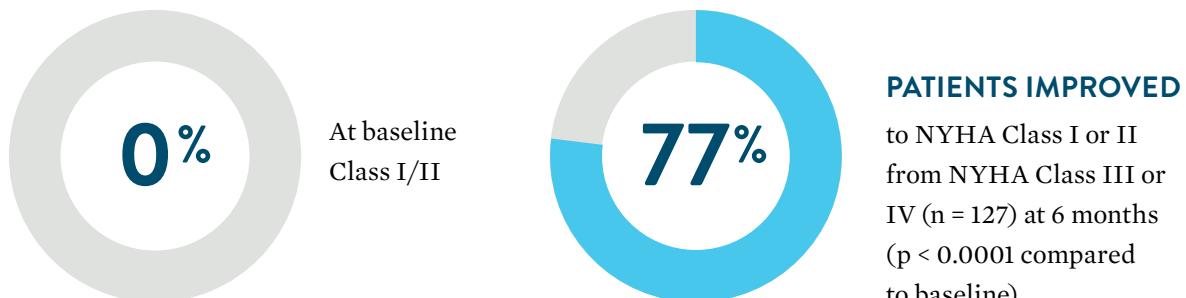
## Significant Survival and Quality of Life Improvements<sup>4</sup>

During the MOMENTUM 3 clinical trial, patients experienced significant improvements in survival: at 180 days after implant, overall survival with the HeartMate 3 LVAD was 89 percent. These patients also experienced significant improvements in quality of life, as defined by two common quality of life measurement scales.<sup>4</sup>



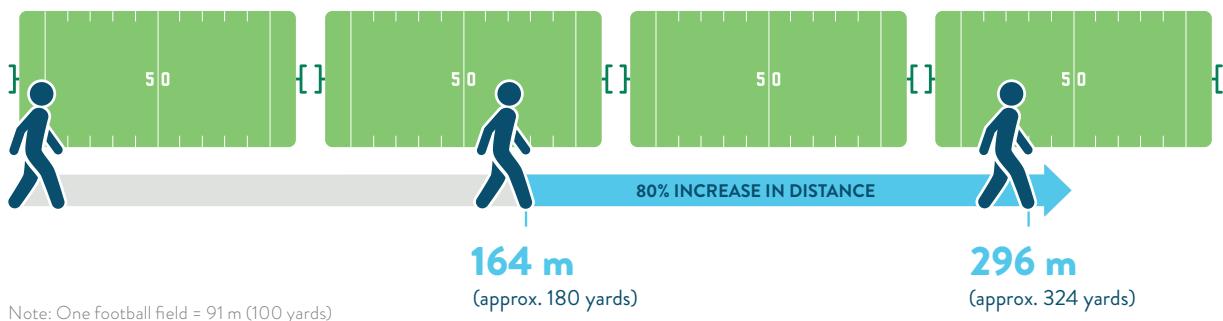
## Meaningful NYHA Class Improvement<sup>4</sup>

NYHA is a common scale that doctors use to measure heart failure. Patients who received the HeartMate 3™ LVAD had a significant improvement in their NYHA class – 100 percent of patients prior to receiving the device were in NYHA Class IIIB or IV, which are considered more severe stages of heart failure. Six months after receiving the HeartMate 3 LVAD, 77 percent of patients improved to NYHA Class I or II, which are considered more mild stages of heart failure.<sup>4</sup>



## Significant Increase in Six-Minute Walk Distance<sup>3</sup>

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 164 meters (about 180 yards) in six minutes. Six months after receiving the HeartMate 3 LVAD patients were able to walk an average of 296 meters (about 324 yards) in six minutes. That's an 80 percent improvement in distance.



## HeartMate 3™ LVAD 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 SIX MONTHS:

- Death (11%)
- Major infection (37%)
- Bleeding (30%)
- Right heart failure (30%)
- Abnormal heartbeat (26%)
- Trouble or inability to breathe (22%)
- Kidney function problems (11%)
- Stroke (8%)
- Other brain injuries (6%)
- Liver function problems (5%)
- Blood clots in veins (4%)
- Psychiatric problems (3%)
- Blood clots in arteries (2%)
- High blood pressure (2%)
- Fluid collection around the heart (2%)
- Heart attack (1%)
- Surgical wound opening (1%)
- Blood cell damage (1%)
- Suspected blood clots in the HeartMate 3 LVAD (0%)
- Other complications (48%)



The HeartMate 3™ LVAS

## Frequently Asked **QUESTIONS**

### Is the HeartMate 3™ LVAD safe and effective?

The HeartMate 3 Left Ventricular Assist System is indicated for providing short-term hemodynamic support (e.g., bridge to transplant or bridge to myocardial recovery) in patients with advanced refractory left ventricular heart failure.

### What kind of relief does the HeartMate 3 LVAD provide to people with advanced heart failure?

In a clinical study, patients with the HeartMate 3 LVAD could walk an average of 296 meters in six minutes (six months post-LVAD surgery). Before receiving their implanted heart pump, those patients could walk only 164 meters in six minutes.<sup>4</sup>

HeartMate 3 LVAD also significantly improved the NYHA class, or severity of disease, for clinical study patients. At six

months post-LVAD surgery, 77 percent of patients improved from NYHA Class IIIB or IV (more severe stages of heart failure) to NYHA Class I or II (more mild stages of heart failure). The HeartMate 3 LVAD also provided significant relief of heart failure symptoms and improved quality of life in many patients in the study.<sup>4</sup>

### What happens before, during and after surgery?

Before surgery, your doctor at the HeartMate 3 LVAD implant center will talk to you and your family about possible risks and complications. During open-heart surgery, the HeartMate 3 LVAD will be implanted in an operation that usually takes about three to six hours. After surgery, your doctor will check to make sure the device and equipment settings are appropriate for your needs. Your medical team will also teach you and your caregivers about living with the HeartMate 3 LVAD.

## Are there other risks?

Like any major surgery, getting an LVAD comes with risks. Talk to your doctor to understand the risks and benefits.

## What about a power outage?

Having extra batteries charged and ready will keep you prepared for a power outage. The system controller also has 15 minutes of backup power. The Mobile Power Unit™ is portable, so you can connect your HeartMate 3 LVAD system wherever power is available. When you leave the hospital, your local power company will be told of your medical device.

This is a precaution in the event of a power outage. If an outage occurs, you would be placed on a high-priority list to have your power restored.

## What happens when I return home?

You will continue your regular checkups with your physician and the medical team at the HeartMate 3 LVAD implant center. You will return to daily life with few limits and you may have more energy to do the things you enjoy.<sup>†</sup>

<sup>†</sup>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 3™ Left Ventricular Assist System are outside of the body and cannot be submerged in water.

## HOW TO LEARN MORE

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](http://www.HeartMate3.com)**

## IMPORTANT INFORMATION

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\*American Heart Association Classes of Heart Failure 2017.

\*\*Blood-related, hemocompatibility complications – Mehra paper, ISHLT 2017.

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1. <http://HeartMateII.com/understanding-heart-failure.aspx>
2. Peura JL, Colvin-Adams M, Francis GS, et al. Recommendations for the use of mechanical circulatory support: device strategies and patient selection: a scientific statement from the American Heart Association. *Circulation*. 2012;126(22):2648-2667.
3. HeartMate 3 LVAD Patient Handbook. Document 10002833.B. Published September 2015.
4. Mehra MR, Naka Y, Uriel N, et al; for the MOMENTUM 3 investigators. A fully magnetically levitated circulatory pump for advanced heart failure. *N Engl J Med*. 2017;376:440-450.

### Abbott

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HeartMate3.com  
St. Jude Medical is now Abbott.

### Rx Only

**Brief Summary:** Prior to using these devices, please review the User's Manual 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-term hemodynamic support (e.g., bridge to transplant or bridge to myocardial recovery) in patients with advanced refractory left ventricular heart failure.

**Contraindications:** The HeartMate 3™ LVAS 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 listed below. Adverse events are listed in anticipated decreasing order of frequency, except for death, which appears first as it is a non-reversible complication: 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), possible pump thrombosis (has not occurred with HeartMate 3™ in the MOMENTUM 3 short term clinical study through 180 days).

Please refer to the HeartMate 3 LVAS Instructions for Use for additional warnings and precautions.

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