



T H O R A T E C[®]
C O R P O R A T I O N

FOR USE ANYTIME

CONTACT: Susan Benton Russell
310.697.3488
susan@bentoncommunications.com

Learning About The HeartMate II® LVAD

What is an LVAD?

LVAD stands for Left Ventricular Assist Device. It is a mechanical device that circulates blood throughout the body when the heart is too weak to pump blood adequately on its own. It is sometimes called a “heart pump” or “VAD.” HeartMate II is a small implantable LVAD that represents a breakthrough in medical technology and has rapidly become the most widely used device of its kind in the world.

Is HeartMate II an artificial heart?

No. HeartMate II is not an artificial heart, nor is it a heart replacement. The patient’s native heart is not removed. HeartMate II attaches to the heart and is designed to assist – or take over - the pumping function of the patient’s left ventricle - the main pumping chamber of the heart.

How does HeartMate II work?

HeartMate II is designed to supplement the pumping function of the heart. The device is placed just below the diaphragm in the abdomen. It is attached to the left ventricle, and the aorta, the main artery that carries oxygenated blood from the left ventricle to the entire body. An external, wearable system that includes a small controller and two batteries is attached by an external driveline. The wearable system is either worn under or on top of clothing.

How does HeartMate II help a heart failure patient?

HeartMate II is designed to restore blood flow throughout the body, enabling the patient to breathe more easily and feel less fatigued. The patient’s organs will receive more blood than they did before receiving the LVAD, and this will likely improve their organ function. After receiving an LVAD, patients generally feel more energetic and are able to resume normal activities that they were unable to do prior to receiving the device.

How active can patients be with the HeartMate II?

Because patients are in a severe stage of heart failure before receiving the device, they are very debilitated and typically very limited in terms of activity level. After receiving HeartMate II, the majority of patients can return to their favorite daily activities, with the primary limitation being water immersion. Many patients are able to return to work and resume hobbies that they haven't been able to do for years. Moreover, in May 2013, the FDA approved Thoratec's next-generation HeartMate II Pocket Controller™, which is lighter and more compact than previous LVAD system controllers, and is designed to support the active lifestyles that patients with HeartMate II LVADs are leading.

How is HeartMate II used?

HeartMate II may be used to support patients and improve their quality of life while they wait for a donor heart to become available. This is known as "Bridge-to-Transplantation." It may also be used as a permanent option for patients who are not eligible for heart transplantation, due to age or other medical conditions. Usage of the device in this manner is known as "Destination Therapy." In either situation, without the option of an LVAD, advanced heart failure patients have poor prospects for survival and significantly limited lifestyles.¹²

Is HeartMate II a good treatment option for advanced heart failure patients?

Yes. The use of an LVAD, such as the HeartMate II, is considered an appropriate treatment option in cases of advanced heart failure. Studies have shown that patients treated with an LVAD can live longer and enjoy a much-improved quality of life compared with those being treated with drug therapy alone.³⁴ There are approximately 50,000 – 100,000 advanced heart failure patients who could benefit from an LVAD in the U.S.⁵

How long can HeartMate II be used?

Recipients have lived for years with HeartMate II; in fact, some are living more than eight years post implant.⁶

How long do the batteries last?

The latest generation of batteries used to support LVADs may last up to 12 hours before needing to be recharged.

¹ Pagani FD, Miller LW, Russell SD, et al. Extended Mechanical Circulatory Support With a Continuous-Flow Rotary Left Ventricular Assist Device. *J Amer Coll Cardiol* 2009;54(4):312-321.

² Park, S., et. al. Outcomes in Advanced Heart Failure Patients with Left Ventricular Assist Devices for Destination Therapy. *Circ Heart Fail* 2012.

³ Rose E., et. al. Long-Term Use of a Left Ventricular Assist Device for End-Stage Heart Failure. *N Engl J Med* 2001; 345: 1435-43.

⁴ Rogers JC, et. al. Chronic Mechanical Circulatory Support for Inotrope-Dependent Heart Failure Patients Who Are Not Transplant Candidates: Results of the INTrEPID Trial. *J Amer Coll Cardiol* 2007; 50:741-7.

⁵ American Heart Association, HeartMate II: A Reliable Destination; Feb. 2010

⁶ Data on file, Pleasanton, Calif., Thoratec Corporation

Who can get a HeartMate II?

Patients suffering from advanced heart failure and who have exhausted the limitations of medical therapies may be candidates to receive a HeartMate II. Due to the device's ability to allow the patient's heart to rest and supplement the pumping function, it has been shown that the LVAD provides the opportunity for a weakened heart to regain some of its own function. Patients should consult a physician to find out if they are a candidate for LVAD therapy.

How many patients receive heart transplants and how many are ineligible for transplants?

Though transplants offer hope for approximately 2,000 advanced heart failure patients each year in the U.S., over 250,000 patients have no viable treatment option and are considered at high risk for repeated hospitalizations, poor quality of life and even death.⁷

Does someone with a HeartMate II still have a pulse?

A patient who is implanted with a HeartMate II usually has a dampened pulse. The reason for this is that HeartMate II moves blood from the heart to the body continuously along with the heartbeat. The "strength" of the patient's pulse will depend on how much assistance the LVAD is providing to the heart.

Is HeartMate II FDA approved?

Yes. HeartMate II has been approved for both Bridge-to-Transplantation and Destination Therapy. HeartMate II is the most widely used and extensively studied LVAD available today.

When should a patient/family be told about LVAD therapy?

Interviews with over 200 patients and caregivers indicate they would have preferred to be informed about LVAD technology when the diagnosis of congestive heart failure was first given. The earlier people know what their options may be, the better and less frustrated in their decision making.

How big are LVADs?

LVADs vary in size, but the HeartMate II measures approximately 3 inches in length and weighs approximately 10 ounces. It has one moving part, a continuously spinning rotor that helps circulate blood.

Where can I find out what it is like for people to live with HeartMate II from people who have been implanted?

Many of Thoratec's patients have shared their story about how the HeartMate II has impacted their lives. You can view these stories on Thoratec's website: <http://www.thoratec.com/vad-trials-outcomes/patient-stories/index.aspx>

Where can I get an LVAD?

There are more than 300 centers worldwide that are implanting HeartMate II. For a list of centers visit: <http://www.thoratec.com/patients-caregivers/about-heartmatell.aspx>

⁷ Advanced Heart Failure Treated with Continuous-Flow Left Ventricular Assist Device. Slaughter, M.S., Rogers, J.G., et al. N Engl J Med. 2009 Dec 3; Vol 361:2241-2251

How many people have a HeartMate II?

More than 15,000 people have received HeartMate II.

HEART FAILURE

What is heart failure?

Heart failure is a widespread, chronic condition that develops when the heart muscle weakens and is unable to pump a sufficient amount of blood throughout the body. Heart failure worsens over time and is typically caused by persistent high blood pressure, heart attack, valve disease and other forms of heart disease or birth defects. Left untreated, the lack of adequate blood flow causes the organs to progressively fail, resulting in numerous medical complications that deteriorate a person's quality of life and often leads to death.

How common is heart failure?

According to the American Heart Association (AHA) and the Heart Failure Society of American (HFSA), more than five million Americans are living with heart failure, and 670,000 new cases are diagnosed each year. In the United States, the number of deaths from this condition has more than doubled since 1979, averaging 250,000 annually⁸.

Where can I go to find out more information on heart failure?

Visit www.hearthope.com for more information on heart failure and to find out if early-or advanced-stage heart failure therapy is an option for you.

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⁸ American Heart Association web site