



LIVING
WITH
AN LVAD

Medtronic

WHAT IS HEART FAILURE?

Heart failure refers to a condition in which the heart muscle is weak and no longer able to efficiently pump enough blood to meet the body's needs. Heart failure affects an estimated 26 million people around the world.¹

Unfortunately, heart failure is progressive — so it can worsen over time, even if you are taking your recommended medication(s). In fact, about 10% of people with heart failure have an advanced condition.²

Symptoms of Heart Failure



Shortness of breath



Chronic lack of energy



Cough with frothy sputum



Swollen or tender abdomen with loss of appetite



Swelling of feet and legs



Difficulty sleeping at night due to breathing problems



Increased urination at night



Confusion and/or impaired memory

ABOUT YOUR HEART

If you have been diagnosed with heart failure, it means your heart muscle is weak. As a result, it cannot supply enough oxygen and nutrient-rich blood to your body's cells. Heart failure can develop slowly or quickly after an injury to the heart — and sometimes, the cause is unknown.

Knowing the basics of how a normal, healthy heart functions can help you better understand the condition and symptoms of heart failure.

For the heart to function properly, its four chambers must work together to pump blood to the lungs and to all the body's cells. With heart failure, as the heart muscle weakens, the chambers will compensate for lost pumping ability by getting larger, but it eventually results in inefficient pumping and a worsening condition.

The Heart Has 4 Chambers:

Two upper chambers

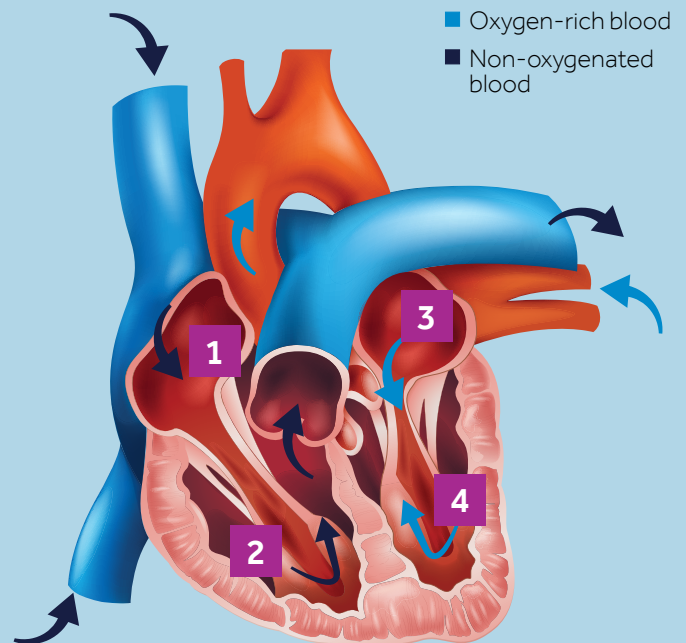
A right atrium and a left atrium

Two lower chambers

A right ventricle and a left ventricle

The right atrium

- 1** takes in oxygen-depleted blood from the rest of the body and sends it back out to the lungs through the right ventricle.
- 2** The lungs oxygenate the blood which travels to the left atrium,
- 3** and then on to the left ventricle,
- 4** which pumps oxygen-rich blood to the rest of the body.



LIVING WITH HEART FAILURE

Heart failure can severely limit a person's activity. That's because the body is not getting enough oxygen-rich blood and nutrients. Decreased mobility is also common due to fluid buildup in the lungs or legs.

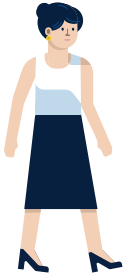
Medications and lifestyle changes can help to reduce symptoms in early stages of heart failure. Eventually, medications and treatments may no longer be effective, and more advanced treatments such as heart transplantation and a left ventricular assist device (LVAD) may be recommended by doctors to improve the health and quality of life for people with advanced heart failure.



Christian

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Classes of Heart Failure³



Class I

No limitation of physical activity. Ordinary physical activity does not cause undue fatigue, palpitation, or dyspnea (shortness of breath).



Class II

Slight limitation of physical activity. Comfortable at rest. Ordinary physical activity results in fatigue, palpitation, or dyspnea (shortness of breath).



Class III

Marked limitation of physical activity. Comfortable at rest. Less than ordinary activity causes fatigue, palpitation, or dyspnea.



Class IV

Unable to carry on any physical activity without discomfort. Symptoms of heart failure at rest. If any physical activity is undertaken, discomfort increases.

TREATMENT OPTIONS FOR ADVANCED HEART FAILURE

Heart transplant may be an option for advanced heart failure patients. However, there are a limited number of donor hearts available and not all advanced heart failure patients are eligible for a heart transplant. Another option for advanced heart failure patients is an LVAD. An LVAD is a mechanical pump that is surgically implanted in the left ventricle of the heart. The LVAD is designed to assist the left ventricle of the heart in pumping blood throughout the body to relieve the symptoms of advanced heart failure.



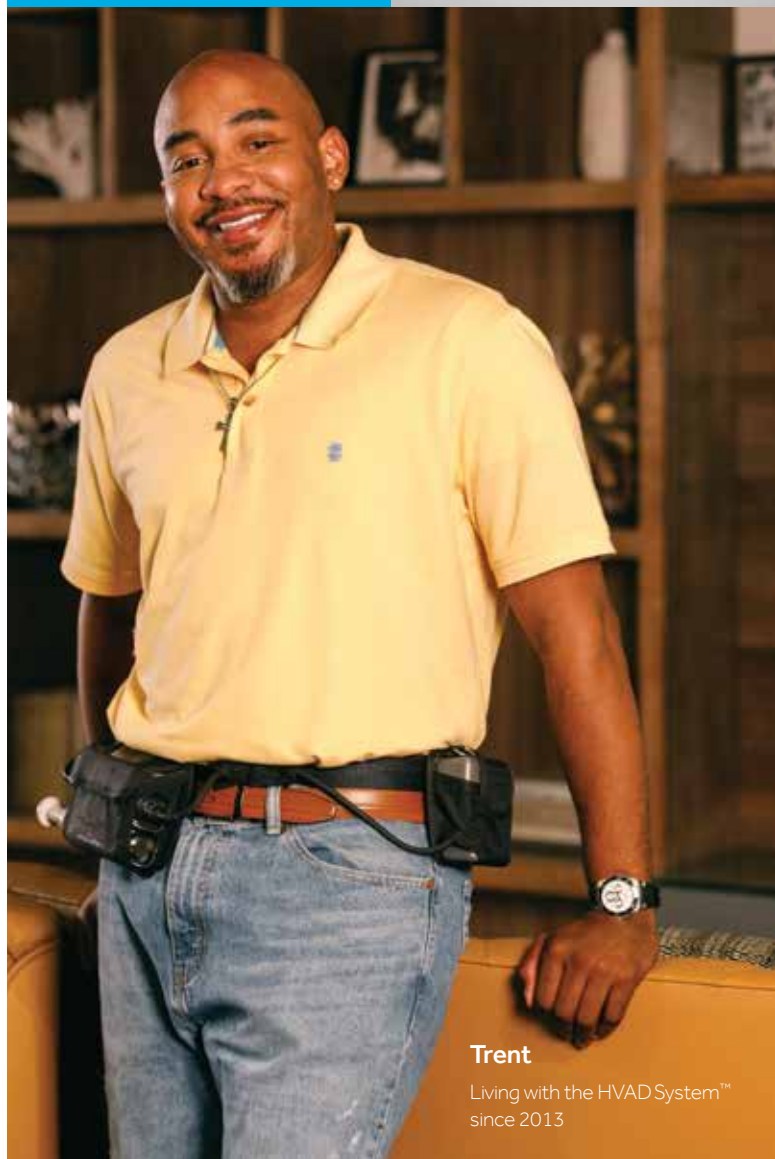
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ABOUT THE HEARTWARE™ HVAD™ SYSTEM

The HeartWare HVAD System is an LVAD intended for advanced heart failure patients as a bridge to a heart transplant or for patients who are not a candidate for a heart transplant. The HVAD™ Pump is the smallest LVAD currently available, and was first implanted in Europe in 2006. It received approval in the United States in 2012.

The HVAD System has been used to treat more than 18,000 patients with advanced heart failure demonstrating high survival and improved quality of life.⁴

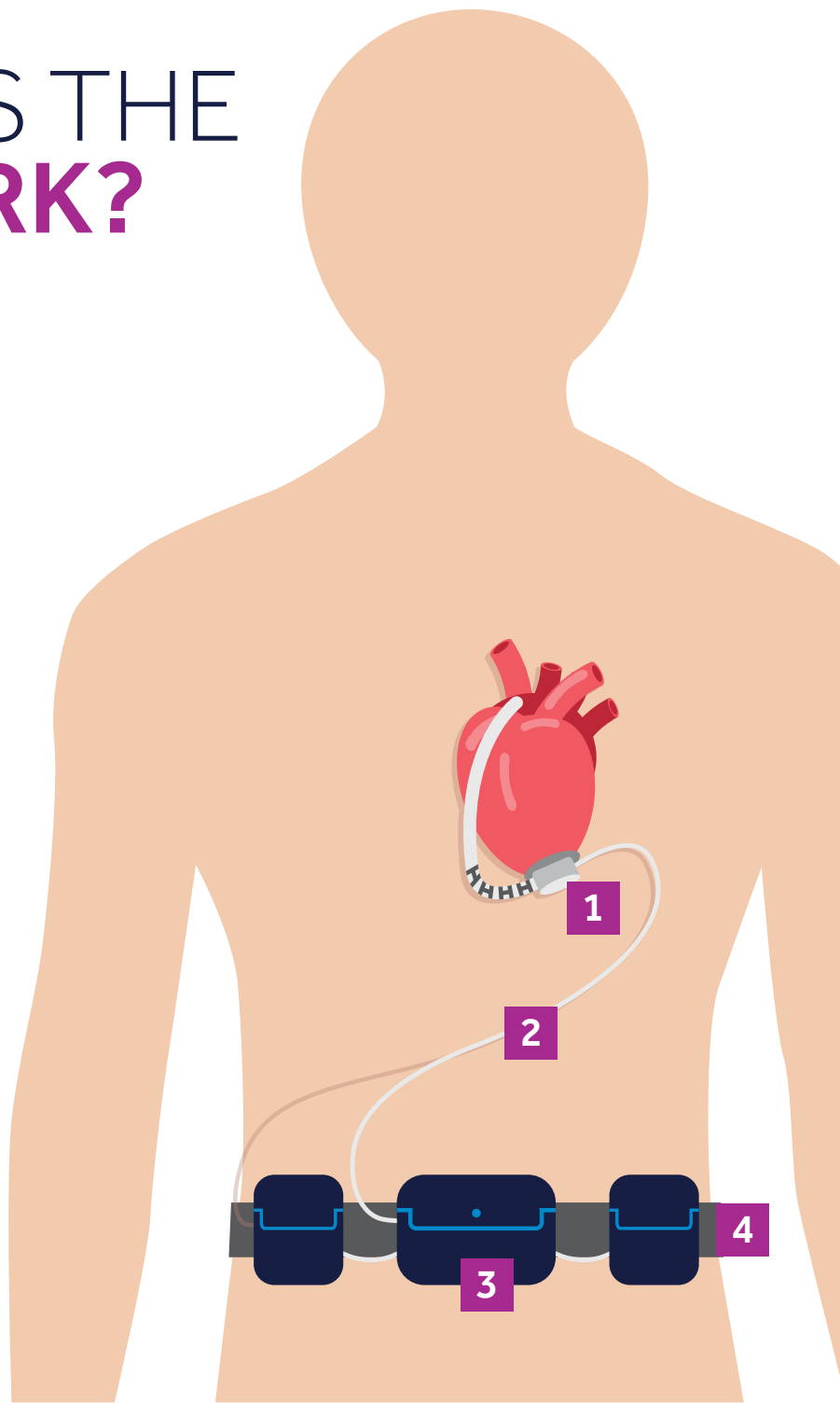


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HOW DOES THE HVAD WORK?

1. The HVAD Pump is implanted in your heart at the bottom of the left ventricle.
2. A driveline cable transfers power and information between the pump and the controller. Part of the driveline exits the body through a small incision in the skin.
3. The wearable controller monitors the pump, sending you information to tell you about how the system is working. Batteries, or an electrical (A/C) cable, are connected to the controller and continuously power the pump. **The driveline cable must be attached to the controller and two power sources at all times.**
4. A wearable pack holds the external equipment, allowing the patient to move about freely when A/C power is not required.





David

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Tyshell

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ABOUT THE SURGICAL PROCEDURE

The small size of the HVAD Pump allows it to be implanted using one of two surgical approaches — sternotomy or thoracotomy. Your doctor will perform the procedure using the approach that is best for you.



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Sternotomy is a surgical open-heart procedure in which a vertical inline incision is made along the sternum, after which the sternum is divided.



Thoracotomy is a less-invasive surgical approach. It requires two smaller incisions rather than one large sternal incision. This procedure may reduce the time you need to stay in the hospital after surgery, so you can get home sooner. Not everyone is a candidate for thoracotomy. Your surgeon will decide if the thoracotomy approach is right for you.



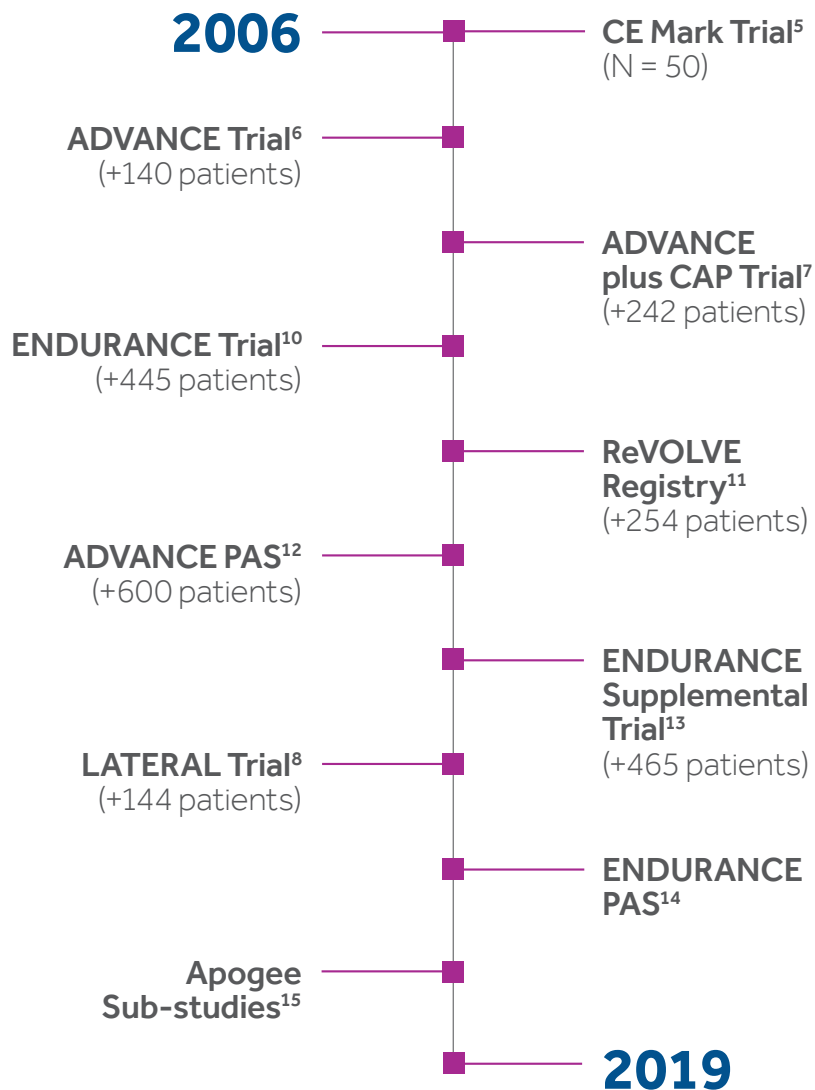
Despite the HVAD Pump's relatively small size, it can pump enough blood every minute to decrease heart failure symptoms. The speed of the HVAD Pump can be adjusted to deliver the right amount of blood for the body's needs.

An HVAD Pump is prescribed by your doctor and is not for everyone. Talk with your doctor to see if it is right for you. Your doctor should discuss all potential benefits and risks with you. Although many patients benefit from the use of an HVAD Pump, results may vary.



HEARTWARE HVAD CLINICAL TIMELINE

For more than a decade, the safety and efficacy of the HVAD System has been studied in clinical trials and real-world registries.



HVAD LATERAL TRIAL CLINICAL EVIDENCE^{8,9}

Offering a Less-invasive Surgical Approach

The HVAD Lateral study is the first multicenter trial ever conducted to examine implanting an LVAD via thoracotomy surgical technique.

The trial included 144 patients implanted with HVAD via a thoracotomy approach at 26 hospitals in North America.

The HeartWare HVAD Lateral Trial 2-year Results Demonstrated:

- 95% freedom from disabling stroke
- 87% unprecedented survival
- 30% reduced length of stay for patients implanted with HVAD using this less-invasive surgical approach
- Less bleeding requiring reoperation
- Significant improvements in quality of life and functional capacity

95%

FREEDOM FROM
DISABLING STROKE
AT 2 YEARS



87%

UNPRECEDENTED
SURVIVAL AT
2 YEARS



30%

REDUCED LENGTH OF
STAY FOR PATIENTS



FREQUENTLY ASKED QUESTIONS

How do I know if I am a candidate for VAD therapy?

Your physician will discuss potential benefits and risk of implant surgery with you and your family, as well as what it's like to live with a VAD. Together, you can decide if VAD therapy is an option for you. Your physician may suggest that you talk with a patient who has a VAD to hear a real-life perspective of living with a VAD.

How long is the recovery from the surgery?

Major heart surgery is required to implant the HVAD Pump and recovery can take three to six months. The VAD team will provide information on all aspects of preparing for surgery and recovering from surgery, with a clear plan for leaving the hospital and setting follow-up appointments.

How will I manage my equipment?

It's important to learn how to properly manage the HVAD System equipment and care for the driveline cable exit site. The VAD team at your hospital will provide you and your caregiver with extensive training before you leave the hospital.

Is the HeartWare HVAD System safe and effective?

The HeartWare HVAD System was approved by Health Canada in 2015 as a bridge to transplant for advanced heart failure patients. Health Canada approval was extended to patients who are not candidates for a heart transplant in 2018.

What limitations in my lifestyle can I expect with the HeartWare HVAD System?

Some of the components of the HeartWare HVAD System are outside the body and cannot be submerged in water. Your physician and VAD care team will guide you on which activities you may need to avoid with your device. This includes swimming or water activities.

How do I manage a power outage?

Your VAD team will instruct you on managing your battery supply by having extra batteries charged and ready and by notifying your local power company of your LVAD implant prior to you being discharged from the hospital.



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References

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- ⁵ Strueber M, O'Driscoll G, Jansz P, Khaghani A, Levy WC, Wieselthaler GM; HeartWare Investigators. Multicenter evaluation of an intrapericardial left ventricular assist system. *J Am Coll Cardiol*. March 22, 2011;57(12):1375-1382.
- ⁶ Aaronson K, Slaughter MS, Miller LW, et al. Use of an intrapericardial, continuous-flow, centrifugal pump in patients awaiting heart transplantation. *Circulation*. June 26, 2012;125(25):3191-3200.
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- ⁸ Wieselthaler G, et al. Temporal Adverse Event Profile following LVAD Implantation via Thoracotomy Approach; 2 Year Follow-up of the Lateral Trial. Presented at ASAIO 2019; San Francisco, CA.
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- ¹¹ Schmitto JD. Presented at EACTS 2018; Milan, Italy.
- ¹² Medtronic clinical data on file.
- ¹³ Milano CA, Rogers JG, Tatóoles AJ, et al. HVAD: The ENDURANCE Supplemental Trial. *JACC Heart Fail*. September 2018;6(9):792-802.
- ¹⁴ First enrollment 2018.
- ¹⁵ First enrollment 2019.

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Additional Device Information

The HeartWare™ HVAD™ System assists a failing heart and relieves the symptoms of advanced heart failure. It may be used in advanced heart failure patients, whether or not a subsequent heart transplant is planned. You should not receive an HVAD System if you are pregnant or cannot tolerate blood thinning medications.

Implantation of the HVAD System requires major surgery. Risks associated with the implant surgery and with HVAD System use include, but are not limited to, death, stroke, device malfunction, blood clots, bleeding, other types of heart failure, infection, red blood cell destruction, and total body infection. Managing your blood pressure may reduce the risk of stroke.

The HVAD System includes external components that connect to and provide power to the heart pump inside your body. After receiving an HVAD System, you will have some limitations. You will not be able to swim, or otherwise submerge external components in water. You will not be able to shower until your clinician tells you it is safe to do so. If you receive permission to shower, you must use the HeartWare shower bag. You may need to modify or perhaps avoid interactions with some sources of electromagnetic interference, electric or gas-powered appliances, and tools. Magnetic resonance imaging (MRI) should not be used, as it could cause severe harm to you and the pump. You must keep mobile phones at least 20 inches (50 centimeters) away from the controller, as mobile phones may interfere with controller operation.

Proper use and upkeep of the HeartWare HVAD System is required to keep the system working well. Never remove both power sources (batteries or power adapters) from the controller at the same time because this will stop the pump, which could lead to serious injury or death. At least one power source must be connected to the controller at all times. Always keep a spare controller and fully charged spare batteries available at all times in case of an emergency. Do not disconnect the driveline from the controller or the pump will stop. Avoid kinking or twisting your driveline.

This treatment is prescribed by your physician. This treatment is not for everyone. Please talk with your doctor to see if it is right for you. Your physician should discuss all potential benefits and risks with you. Although many patients benefit from the use of this treatment, results may vary.

See the HeartWare HVAD System Patient Manual for detailed information regarding instructions on operating the HeartWare HVAD System and on necessary medical care. If you have any questions after reading the manual, please ask your clinician.