

LIFE WITH A LEFT VENTRICULAR ASSIST DEVICE (LVAD)



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UNDERSTANDING ADVANCED HEART FAILURE

If you've been diagnosed with heart failure, you are not alone. In fact, heart failure affects at least **15 million people in Europe**.¹

The term "heart failure" refers to a condition in which the heart muscle is no longer able to efficiently pump enough blood to meet the body's needs. 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. Heart failure can develop slowly or quickly after an injury to the heart — and sometimes, the cause is unknown.

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. There are a limited number of donor hearts available and not everyone suffering from advanced heart failure is eligible for a heart transplant (due to other chronic diseases or advanced age for example). Another option for these people suffering from advanced heart failure is an LVAD.



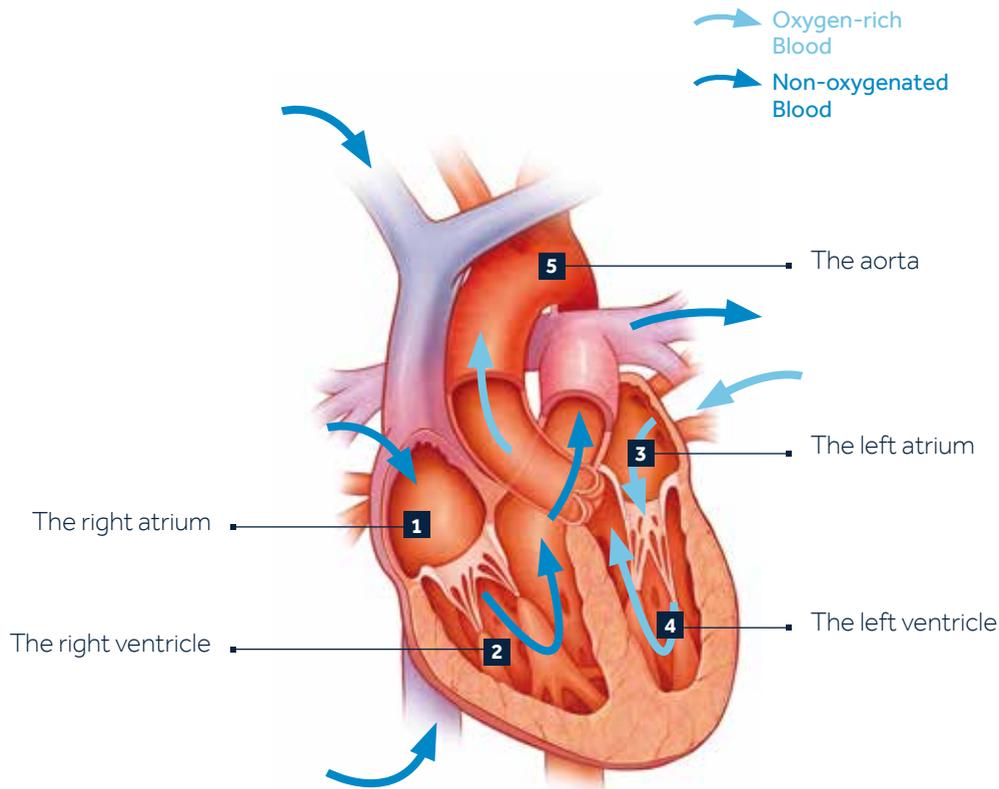
THE HEART

Knowing the basics of how a normal heart functions can help you better understand the condition and symptoms of heart failure. The heart is a fist-sized organ that acts as a pump to send oxygen-rich blood throughout the body. Regular, rhythmic electrical signals keep the heart pumping blood.

The heart has four 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 pushes it to the right ventricle (2) which then sends it to the lungs. The lungs oxygenate the blood which travels to the left atrium (3), and then onto the left ventricle (4), which pumps oxygen-rich blood to the rest of the body via the aorta (5).



For the heart to function properly, its four chambers must work together to pump blood to the lungs and to the rest of the body. With heart failure, as the heart muscle becomes weaker the chambers will compensate for losing pumping ability by getting larger, which eventually results in inefficient pumping and a worsening condition.



WHAT IS AN LVAD AND HOW DOES IT WORK?

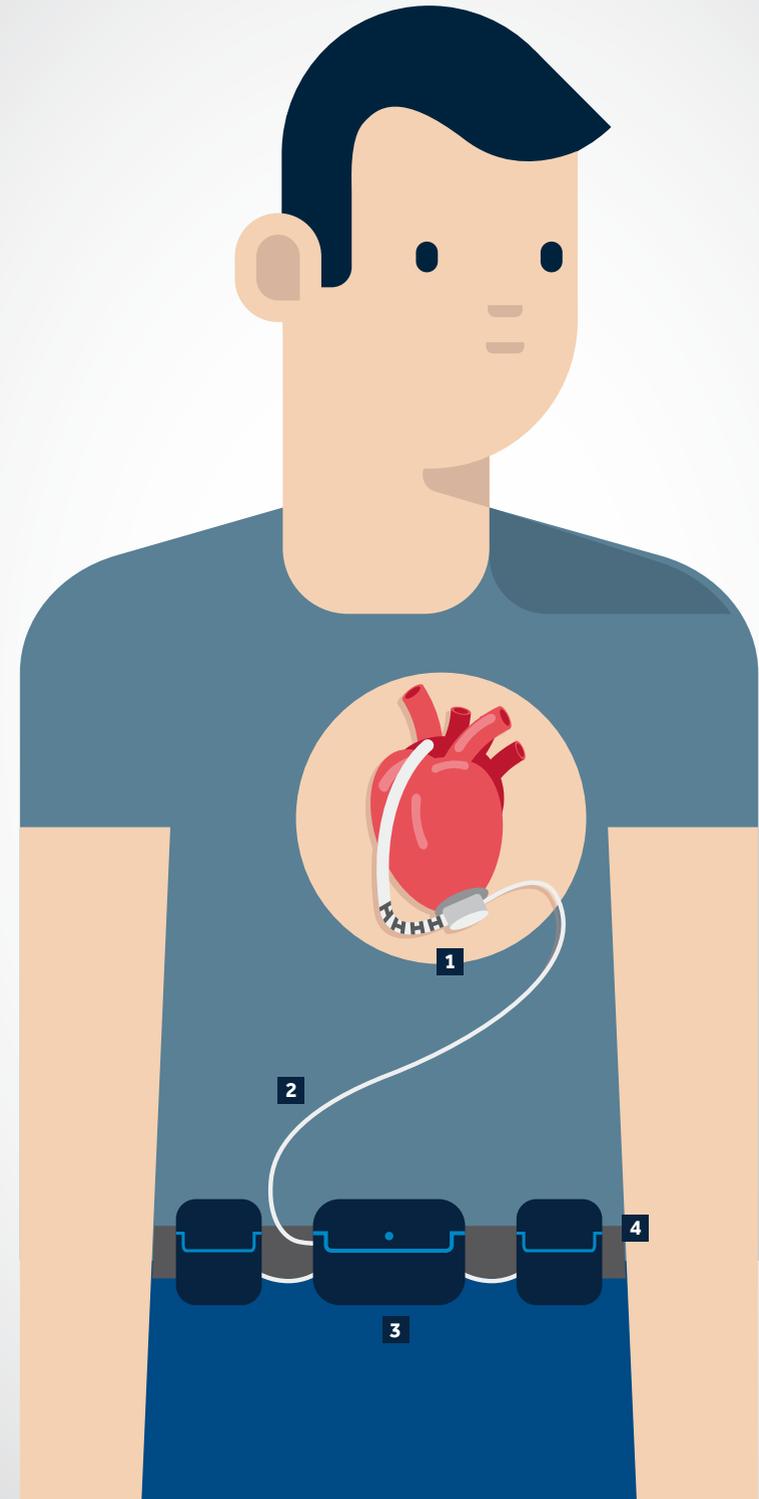
A **left ventricular assist device** or **LVAD** is a battery-operated mechanical pump. It is designed to assist the heart in pumping blood throughout the body to relieve the symptoms of advanced heart failure.

An LVAD system is 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.

An LVAD is surgically implanted through heart surgery under general anesthesia.

Current LVADs are smaller and more durable than the previous generation of devices. Despite devices being compact in size, they can pump enough blood every minute to decrease heart failure symptoms.

1. An LVAD Pump is implanted in your heart at the bottom of the left ventricle.
2. A driveline cable attached to the pump exits the body through a small incision in the skin and attaches to a controller outside of the body.
3. The controller is a mini-computer that monitors the pump. It provides text messages and audible alarms to help you manage the system. 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 power sources at all times.
4. A wearable pack holds the external equipment, allowing you to move about freely when A/C power is not required.



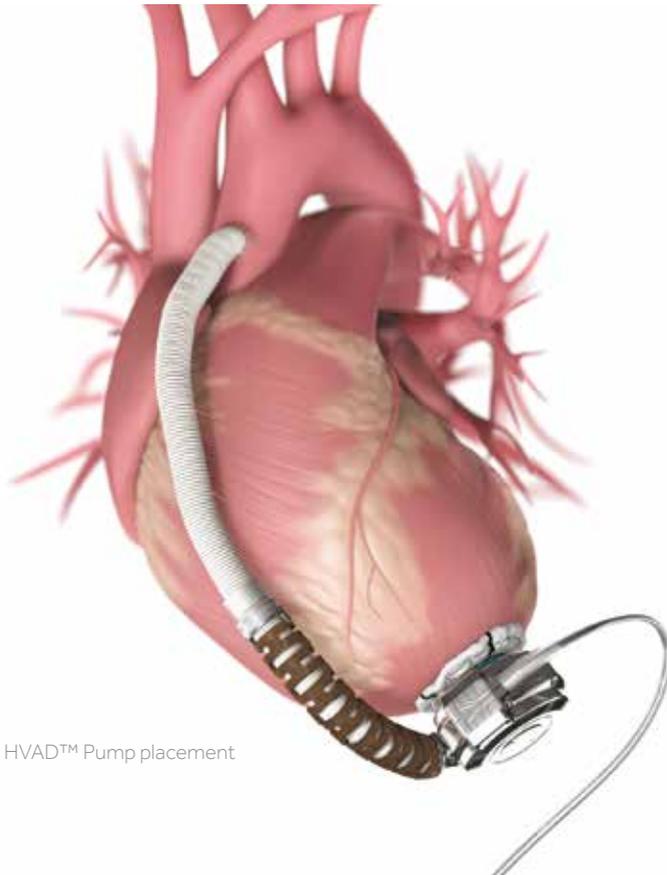
THE HVAD™ SYSTEM FOR ADVANCED HEART FAILURE

The 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 available² and its small size allows it to be implanted using one of two surgical approaches - sternotomy or thoracotomy.

Your doctor will explain the difference and perform the procedure using the approach that is best for you.

The HVAD™ System has been used to treat many people with advanced heart failure demonstrating **high survival** and **improved quality of life**².



HVAD™ Pump placement



HVAD™ size vs golf ball

LIVING WITH AN LVAD

You can live an active, fulfilling life with an LVAD - doing things you enjoy and spending time with the people you love.

Your doctor 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.

Leaving the hospital and returning home can feel challenging. Your doctor will make sure you and your family are **fully prepared** and **feeling secure**. They will create a safe plan in the event of an emergency.

Don't hesitate to ask your doctor about any question you may have about living with an LVAD, washing and showering, activities you can perform or returning to work for example.

Living with an LVAD includes managing the equipment that runs the pump and care for the driveline cable exit site. You may have to make some changes to account for the driveline and external equipment. **It's important that the driveline doesn't get pulled, caught or kinked.**

Your doctor will make sure you are fully informed and understand how to manage the equipment.

It may take time for you to become comfortable living with an LVAD. **Be patient with yourself.**

COMMONLY ASKED QUESTIONS

WHAT ARE THE BENEFITS OF LVAD THERAPY?

The benefit of LVAD therapy depends on each individual health condition but most people report **feeling stronger, less short of breath, having more energy and being more active** than before. LVADs have been shown to **increase survival and improve quality of life²**.

HOW DO I DECIDE IF LVAD THERAPY IS AN OPTION FOR ME?

Your doctor will discuss this option with you and your family. Together, you can decide if LVAD therapy is right for you. Your doctor may also suggest that you talk with someone who has an LVAD to hear their perspective of living with an LVAD.

IS AN LVAD THE SAME AS AN ARTIFICIAL HEART?

An LVAD is different from an artificial heart. An artificial heart replaces the failing heart completely whereas an LVAD works with the heart to help it pump more blood with less work.

WHAT ABOUT SURGERY?

Heart surgery is required to implant the LVAD system and recovery can differ between people. Your doctor 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 DO I LEARN TO MANAGE MY EQUIPMENT?

It's important to learn how to properly manage the LVAD system equipment and care for the driveline cable exit site. Your doctor will provide you and your caregiver with extensive training before you leave the hospital.

WHAT ABOUT ACTIVITIES AND INTIMACY?

Your doctor will guide you on which activities you may need to avoid with your device. This includes swimming, water activities, playing contact sports or any activity with a high risk of falls or injury.

Intimacy is a normal part of life. We understand people resume sexual activity when they feel comfortable. Discuss with your doctor as it is important that the driveline doesn't get pulled, caught or kinked.

CAN I GET AN MRI?

Discuss this with your doctor. You can get a CT scan or an X-Ray but you will not be able to get an MRI.

CAN I TRAVEL WITH AN LVAD ?

Travelling with an LVAD is of course possible and requires a bit of preparation. You will have to take all your device equipment with you.

Flying is perfectly safe for people with LVADs (there are no issues with pressurization or altitude). When flights are too long considering the battery life of your device, you should break your trip into shorter legs.

You should avoid the airport security equipment as this may interfere with your LVAD System. Simply request a hand search and ask to pay attention to the driveline cable exit site. Always consult your doctor before making any travel arrangements. They can provide you with the addresses of hospitals in the countries you are visiting in case you need to see a doctor.

You can find more information about life with an LVAD here:

www.mylvad.com



References:

- 1 HF Policy Network handbook (<http://www.hfpolicynetwork.eu/handbook>)
- 2 McGee E Jr, Danter M, Strueber M, et al. Evaluation of a lateral thoracotomy implant approach for a centrifugal-flow left ventricular assist device: The LATERAL clinical trial. J Heart Lung Transplant. April 2019;38(4):344-351.

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 since 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.



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Medtronic

Europe

Medtronic International
Trading Sàrl.
Route du Molliau 31
Case postale
CH-1131 Tolochenaz
Tel. +41 (0)21 802 70 00
Fax +41 (0)21 802 79 00

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