Medtronic

HeartWare™ HVAD™ System

The Medtronic HeartWare™ HVAD™ System is a left ventricular assist device (LVAD) that helps the heart pump and increases the amount of blood that circulates through the body.

The HVAD System is approved in the U.S., Canada, and in CE Marked countries for patients with advanced heart failure who are not candidates for heart transplants. Many patients with end-stage heart failure have other medical conditions or health histories that make them ineligible for a heart transplant. The HVAD System is also available in these geographies as well as in Japan as a bridge to heart transplant in eligible patients.

The HVAD System is also approved in the U.S., Canada, and in CE Marked countries for a less-invasive implant procedure called a thoracotomy. A thoracotomy involves two small incisions between the patient's ribs, and this implant approach has been shown to lead to shorter hospital stays.[i]

The HVAD System features the world's smallest, commercially available, centrifugal flow pump. Weighing only 160 grams, the HVAD System's continuous flow pump is 30 percent thinner and has 38 percent less volume than other centrifugal-flow devices.[ii, iii]

LVAD therapy has been demonstrated to extend life, augment heart function, and improve quality of life in patients with advanced heart failure for whom the device is indicated.[iv] Worldwide, more than 18,000 patients have received the HVAD System since it was first approved in Europe in 2009.

How the HVAD System Works

The HVAD System consists of the pump; an external controller, which is a small computer that controls and manages the pump; a cable that connects the pump to the controller; and power sources that run the pump and controller. The HVAD Pump fits in the area around the heart known as the pericardial space. It is connected directly to the heart at the bottom of the left ventricle. There it draws oxygen-rich blood through the pump and pushes it into the aorta where it flows to the rest of the body. The system can pump enough blood every minute to decrease heart failure symptoms.[v] A physician programs the system to deliver the proper amount of flow for the body's needs.

HVAD System Clinical Data

The HVAD System was evaluated in the destination therapy patient population of the ENDURANCE and ENDURANCE Supplemental trials. Data from these trials support the safety and effectiveness of the HVAD System for destination therapy in patients with advanced heart failure for whom subsequent transplantation is not planned.

In the multicenter ENDURANCE trial, 445 patients with end-stage heart failure who were ineligible for cardiac transplantation were randomized in a two-to-one ratio to receive the HVAD System or an alternative LVAD approved by the FDA for destination therapy. The trial met its primary

endpoint, demonstrating non-inferiority of the HVAD System to the control device. Results were published in *The New England Journal of Medicine* in 2017.

The ENDURANCE Supplemental trial was a follow-up trial to the ENDURANCE trial. This prospective, randomized, controlled, multicenter trial evaluated the impact of enhanced blood pressure management on patient outcomes in destination therapy patients receiving the HVAD System. A total of 465 patients were randomized in a two-to-one ratio to receive the HVAD System or a control device, i.e., an alternative LVAD approved by the FDA for destination therapy. While the study did not meet its primary endpoint, it did demonstrate that careful attention to blood pressure management may reduce the risk of stroke in patients with an HVAD System.

Similarly, FDA approval for HVAD implantation via thoracotomy was based on data from the prospective LATERAL clinical trial, which enrolled 144 patients with end-stage heart failure who were eligible for heart transplant. Long-term results from the trial show that after two years of follow up, 95 percent of HVAD patients implanted via thoracotomy were free from disabling stroke.[vi] The key secondary endpoint revealed a 30 percent reduction in total length of hospital stay. Overall survival among patients receiving an HVAD via the thoracotomy procedure was 87 percent at two years.

Today, Medtronic continues efforts to improve HVAD patient outcomes through the Destination Therapy Post Approval Study (DT PAS) and Apogee Study, the latter of which is evaluating how blood pressure management, anticoagulation/antiplatelet therapy and implant procedures affect the 12-month rate of overall major adverse events, including infection, bleeding, device malfunction, stroke or death.

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[i] McGee E. Danter M, et al. Evaluation of a lateral thoracotomy implant approach for a centrifugal-flow left ventricular assist device: The LATERAL clinical trial. JHLT. 2019;38(4):344-351.
[ii] HVAD System Instructions for Use. HeartWare, Inc., Framingham, MA, USA. 01/17.
[Iii] HeartMate 3 Left Ventricular Assist System, Instructions for Use. Thoratec Corporation, Pleasanton, CA, USA (2/2015).
[iv] Emin A, et al. Quality of life of advanced chronic heart failure: medical care, mechanical circulatory support and transplantation. Eur J Cardiothorac Surg. 2016;50(2):269-73.
[v] Gupta S, et al. Normalisation of Haemodynamics in Patients with End-stage Heart Failure with Continuous-flow Left Ventricular Assist Device Therapy. Heart Lung Circ 2014;23: 963–969.
[vi] Wieselthaler G, et al. Temporal Adverse Event Profile following LVAD Implantation via a Thoracotomy Approach: 2 Year Follow-up of the LATREAL Trial. Presented at ASAIO 2019, San Francisco, CA.