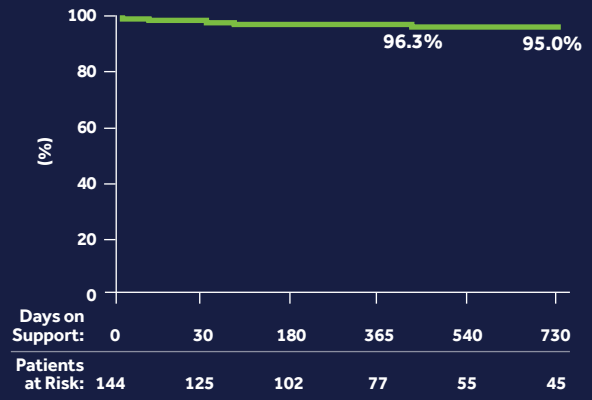
# THE WORLD'S SMALLEST CENTRIFUGAL VAD

with more than 18,000 implants worldwide and clinical evidence to prove its safety and effectiveness when used in a less-invasive thoracotomy approach.[1,3]

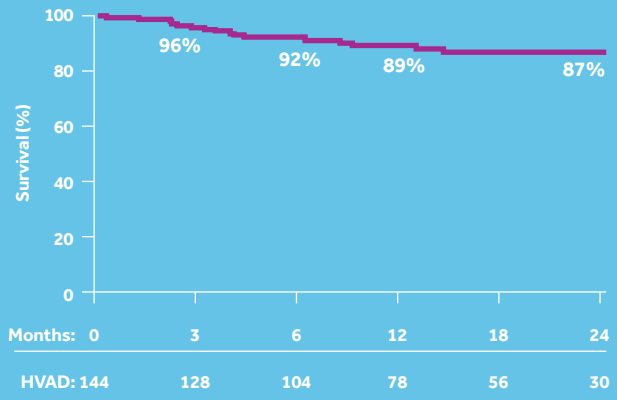
### 95% Freedom From Disabling Stroke at 2 Years.[2]




**95%**

**Freedom from Disabling Stroke**

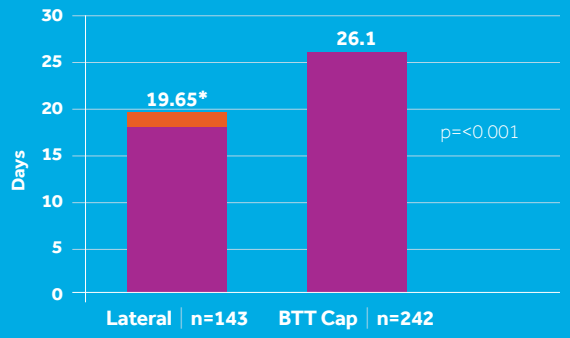
### 87% Unprecedented Survival at 2 Years.[1]




**87%**

**Unprecedented Survival**

### 30% reduced length of stay[1]




*Upper Boundary of 95% Confidence interval

**30%**

**Reduced Length of Stay**

**References:**

**1.** 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.

**2.** Wieselthaler G, et al. Temporal Adverse Event Profile following LVAD Implantation via a Thoracotomy Approach: 2 Year Follow-up of the LATERAL Trial. Presented at ASAIO 2019, San Francisco, CA.

**3.** Medtronic data on file as of July 2019, and data extrapolated based on source data from: HVAD System Instructions for Use. HeartWare Inc., Framingham, MA, USA 07/18. HeartMate 3 Left Ventricular Assist System, Instructions for Use. Thoratec Corporation, Pleasanton, CA, USA 02/27.

## Brief Statement: HeartWare™ HVAD™ System

Indications for Use

The HeartWare Ventricular Assist System is indicated for hemodynamic support in patients with advanced, refractory left ventricular heart failure; either as a Bridge to Cardiac Transplantation (BTT), myocardial recovery, or as Destination Therapy (DT) in patients for whom subsequent transplantation is not planned.

Contraindications

The HVAD™ System is contraindicated in patients who cannot tolerate anticoagulation therapy

Warnings/Precautions

Proper usage and maintenance of the HVAD™ System is critical for the functioning of the device. Serious and life threatening adverse events, including stroke, have been associated with use of this device. Blood pressure management may reduce the risk of stroke. Never disconnect from two power sources at the same time (batteries or power adapters) since this will stop the pump, which could lead to serious injury or death. At least one power source must be connected 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 devices and conditions that may induce strong static discharges as this may cause the VAD to perform improperly or stop. Magnetic resonance imaging (MRI) could cause harm to the patient or could cause the pump to stop. The HVAD™ Pump may cause interference with automatic implantable cardioverter-defibrillators (AICDs), which may lead to inappropriate shocks, arrhythmia and death. Chest compressions may pose a risk due to pump location and position of the outflow graft on the aorta - use clinical judgment. If chest compressions have been administered, confirm function and positioning of HVAD Pump post CPR.

Potential Complications

Implantation of a VAD is an invasive procedure requiring general anesthesia and entry into the thoracic cavity. There are numerous known risks associated with this surgical procedure and the therapy including, but not limited to, death, stroke, neurological dysfunction, device malfunction, peripheral and device-related thromboembolic events, bleeding, right ventricular failure, infection, hemolysis and sepsis. Refer to the "Instructions for Use" for detailed information regarding the implant procedure, indications, contraindications, warnings, precautions and potential adverse events prior to using this device. The IFU can be found at www.heartware.com/clinicians/instructions-use.

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