

CONSIDER REFERRING FOR VAD THERAPY

TRIGGERS FOR IDENTIFYING HEART FAILURE PATIENTS WHO MAY BENEFIT FROM VAD THERAPY



Two readmissions
within the past year¹



Inotropes
considered²



Medical therapy
optimized³



EF < 35%¹

LATEST CLINICAL EVIDENCE FROM THE HVAD LATERAL TRIAL

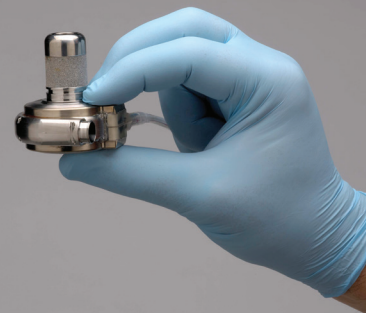
95% freedom from disabling stroke at 2 years⁵

87% unprecedented 87% survival at 2 years.⁴

30% reduced length of stay post-thoracotomy
implantation⁴



HVAD™ is the only full-support durable VAD with clinical evidence to prove its safety and effectiveness when used in a less-invasive thoracotomy approach.



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References

- ¹ Yancy CW, Januzzi JL Jr, Allen LA, et al. 2017 ACC Expert Consensus Decision Pathway for Optimization of Heart Failure Treatment: Answers to 10 Pivotal Issues About Heart Failure With Reduced Ejection Fraction: A Report of the American College of Cardiology Task Force on Expert Consensus Decision Pathways. *J Am Coll Cardiol*. January 16, 2018;71(2):201-230.
- ² Ginwalla M, Tofovic DS. Current Status of Inotropes in Heart Failure. *Heart Fail Clin*. October 2018;14(4):601-616.
- ³ Peura JL, Colvin-Adams M, Francis GS, et al. Recommendations for the use of mechanical circulatory support: device strategies and patient selection: a scientific statement from the American Heart Association. *Circulation*. November 27, 2012;126(22):2648-2667.
- ⁴ 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.
- ⁵ 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.

Brief Statement

HeartWare™ HVAD™ System

Indications for Use

The HeartWare™ HVAD™ 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 HeartWare 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.

Caution: Federal law (USA) restricts these devices to sale by or on the order of a physician.

Medtronic

Medtronic Canada
99 Hereford Street
Brampton, Ontario L6Y 0R6
Tel: 905-460-3800
Toll free: 1-800-268-5346

medtronic.ca

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