42% of all heart transplant patients worldwide are bridge to transplant with a VAD.\(^1\)

Our commitment to advance the treatment of end-stage heart failure has never been stronger.

PROVEN.

The HeartWare HVAD System is the most widely studied implanted centrifugal ventricular device.

2000+ patients enrolled in HeartWare HVAD trials.

Growing HVAD Clinical Trial and Registry Experience*

*HVAD CE Mark Trial, ADVANCE CAP Trial, ENDURANCE Trial, ReVolve Registry, INTERMACS Registry, Japan HVAD Trial, ENDURANCE Supplemental Trial, MVAD Trial, LATERAL Trial
COMMITTED.

We continually learn and innovate, further advancing the treatment of end-stage heart failure, striving to improve patient outcomes and the clinical experience of your practice.

TRUSTED.

350 hospitals trust the HeartWare HVAD System.

47 countries around the world totaling more than 13,000 patients.*

*Source data on file with Medtronic
SMART TECHNOLOGY
SMART MANAGEMENT

The HeartWare HVAD System is designed with intuitive peripherals that help VAD centers more efficiently manage their MCS programs and give patients greater mobility.

Autologs™ On-demand Data Available with Every Patient Visit

Autologs is the latest addition to our industry-leading device management service, providing transparent data as an integral part of the user-friendly HeartWare HVAD System. Comprehensive logfile data is delivered to your computer in seconds. Now you can instantly access the data during the clinic visit, streamlining device management.

- Autologs reports provide in-depth information — a 14-day view — on VAD parameters, pump performance, battery usage, pulsatility, alarms and events
- Gain key insight into your patient’s condition to troubleshoot patient complications and guide on-the-spot therapy decisions
- Determine if your patients are not using their equipment properly, which can signal a need for additional training
- Monitor the pump’s function and identify any alarms the patient may have logged over the last two weeks
Controller 2.0

Our next-generation controller delivers class-leading ease of use, giving your patients greater freedom with fewer battery changes and associated alarms.

- New battery drain scheme designed to allow patients to go up to 14 hours before performing a battery exchange

- Simple-to-learn system helps patients more easily monitor their condition and pump performance

- Metal connectors designed to increase wear resistance and provide a natural, 12 o’clock orientation to give you and your patients more reliable connections

- Lightweight, portable equipment is designed to be more user-friendly, allowing for greater mobility

Waveforms: Real-time Data for Enhanced Device Management

- Accurate, reliable and real-time parameters
- Consistent flow accuracy
The HeartWare™ HVAD™ Pump is the world’s smallest, commercially available, full-support centrifugal VAD designed to be implanted completely within the pericardial space.

**Easy to Implant**

- The small size reduces the need for a pump pocket, which may lead to decreased bleeding and decreased blood product use\(^2\)
- Allows for less invasive exchange and explantation\(^2\)
- A 10mm outflow graft to the artery reduces the anastomotic size by approximately 50% compared to other devices, leading to flexibility of arterial landing sites
Determining which patients are candidates for a VAD — and which system is right for them — are key steps in treating advanced heart failure.

The unique integrated inflow cannula design offers the flexibility to fit into smaller framed patients and treat more complex patients. It also allows for stable inflow — even with body habitus changes eliminating complication of malposition.10

BECAUSE EVERY ADULT BTT PATIENT IS UNIQUE

The HeartWare HVAD Pump’s integrated inflow cannula is designed to treat more complex patients.

- Chemo-induced cardiomyopathy
- Post-partum cardiomyopathy
- Calcified apex
- Previous DOR procedures
- Congenital heart disease
- Frail
- Obese
- S/P AMI (heart attack)1-3

Determining which patients are candidates for a VAD — and which system is right for them — are key steps in treating advanced heart failure.
UNIQUELY DESIGNED

ENGINEERED FOR RELIABILITY AND DURABILITY

We are committed to partnering with you to advance end-stage heart failure therapies for your patients.

Passive maglev with hydrodynamic bearings means there’s no need for electronic sensors or mechanical bearings — resulting in a less complex system eliminating friction, heat, and component wear.¹¹

Dual motor stators enhance efficiency and provide redundancy to rotate the impeller, designed to maintain support even in single motor operation.¹⁰

HeartWare HVAD Pump
3 Blood Flow Paths

A patented, wide-blade impeller featuring 3 blood flow paths — primary, secondary, and tertiary — designed to enhance blood flow and reduce blood trauma while reducing the time blood travels through the device.\(^{12}\)

WE ARE COMMITTED TO PARTNERING WITH YOU TO ADVANCE END-STAGE HEART FAILURE THERAPIES FOR YOUR PATIENTS.
References


Brief Statement: HeartWare™ HVAD™ System

Indications
The HeartWare™ Ventricular Assist System is indicated for use as a bridge to cardiac transplantation in patients who are at risk of death from refractory end-stage left ventricular heart failure. The HeartWare System is designed for in-hospital and out-of-hospital settings, including transportation via fixed wing aircraft or helicopter.

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. 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 expose batteries to excessive shock or vibration since this may affect battery operation. Do not grasp the driveline cable as this may damage the driveline. Do not pull, kink or twist the driveline or the power cables, as these actions may damage the driveline. Special care should be taken not to twist the driveline including while sitting, getting out of bed, adjusting the controller or power sources, or when using the shower bag. Do not disconnect the driveline from the controller or the pump will stop. If this happens, reconnect the driveline to the controller as soon as possible to restart the pump.

Potential Complications
Implantation of a Ventricular Assist Device (VAD) is an invasive procedure requiring general anesthesia, a median sternotomy, a ventilator and cardiopulmonary bypass. There are numerous risks associated with this surgical procedure and the therapy including but not limited to, death, stroke, device malfunction, peripheral and device-related thromboembolic events, bleeding, 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.

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