HVAD® System
The VAD of Choice

HeartWare®

www.heartware.com
The HVAD System difference

SIMPLE
Developed with the needs of the patient & MCS team in mind, making it simple to implant, manage and learn.

VERSATILE
Designed to be used in the broadest range of patients, while allowing the greatest surgical flexibility of any VAD on the market.

SMART
Created to deliver instant and actionable information to help provide a clear clinical picture.
An **Essential Part** of every heart failure program

The HVAD System is changing the way heart failure is treated due to excellent survival, low complication rates and improved quality of life. Recent publications have shown the HVAD System offers:

**HIGH SURVIVAL RATES**

Highest survival of any US BTT pivotal clinical trial\(^1\)

- **99%** 30 DAY SURVIVAL
- **94%** 180 DAY SURVIVAL
- **86%** 1 YEAR SURVIVAL

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**LOW COMPLICATION RATES**

Low rates of bleeding and infection compared to other BTT clinical trials

- Driveline infection and sepsis were very low at 0.25 and 0.23 events/patient-year, respectively\(^5\)
- Extremely low rates of bleeding requiring transfusions or reoperations at 0.19 events/patient-year\(^5\)
- 84% of patients were free from GI bleeding events at 1 year\(^3\)
- Very low rate of device exchange for thrombus at 0.04 events/patient-year\(^2\)
- Comparable rates of neurologic events to contemporary devices in both clinical trial and commercial use\(^4,5\)

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**IMPROVED QUALITY OF LIFE**

At follow up, patients implanted with the HVAD\(^\circ\) Pump reported significant improvements in quality of life and more than 3\(\times\) the distance they were able to walk in 6 minutes\(^5\)

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![Consistent Survival with HVAD\(^\circ\) System vs. Projected Survival](chart)

![Quality of Life Improvements](chart)
Uniquely Designed HVAD System

The most proven durable centrifugal device.

PROVEN RELIABILITY WHERE IT COUNTS

99.98% Reliability of implanted components in clinical and commercial use.

Robust Driveline

0 Exchanges due to internal driveline fractures in 5000 implants.

Contactless Design

Enhanced Blood Flow

• Magnetic & hydrodynamic bearings
• Designed for reduced damage to blood cells

3 blood flow paths lead to low shear stress

Powerful and Compact

10 l/min : 50 cc

• Full flow to meet patient’s physiologic needs
• Responsive to patient activity and hemodynamic condition

Reappearance of a Normal Circadian Rhythm after HVAD Pump Implantation

Accommodates the Broadest Range of procedures and patient types

One of the most important steps in the treatment of advanced heart failure is determining which patients are candidates for a VAD and which system is right for them. Everything from body size and frame to potential changes in body composition are considerations when making the decision.

PATIENT BODY TYPES

The unique integrated inflow cannula of the HVAD Pump allows it to fit into small framed patients, yet the HVAD Pump is powerful enough to support large framed or obese patients. The pericardial placement ensures a stable position in the left ventricle even with ventricular and body changes that occur after implant.8

PORTABLE EQUIPMENT FOR AN ACTIVE LIFESTYLE

Mobility
- Lightest weight patient system available today
- Simple “plug and play” adapters provide mobility at home, in the car or on the go
- A pair of batteries provides mobile power for up to 12 hours
- Total weight for travel is 50% less than other commercially available VAD systems

Ease of use
- First controller with intuitive instructions via text-based display

Minimal maintenance
- No daily system checks, no battery calibration, and no power module19

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<thead>
<tr>
<th>Competitor19</th>
<th>HeartWare18</th>
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<tr>
<td>21.7 LBS</td>
<td>10.7 LBS</td>
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Unrivaled Versatility with ease of implantation

Every patient is unique – both in terms of anatomy and physiology. This requires surgeons to evaluate and adjust their approach to ensure proven outcomes. The HV AD Pump’s novel design accommodates different patient needs by allowing for a versatile surgical approach in a simple 3-step procedure done within the pericardial space.  

**THE HVAD ADVANTAGE**

**Pericardial Placement:**
- Pump *position stability* even with changes to body habitus
- Less extensive incision
- Elimination of pump pocket
- Driveline exit site options

**Surgical Flexibility:**
- Compact design allows for *alternative placement* in patients with
  - congenital heart disease
  - complex LV anatomy
  - previous cardiac surgery
- Elimination of a pump pocket *minimizes concern* about prior or future abdominal surgeries

**SIMPLE 3-STEP TREATMENT**

Customized surgical tools and accessories facilitate a simple, 3-step implantation procedure.

"In my experience, implantation of the HVAD System is easy to perform and causes minimal surgical trauma. I also find the HVAD Pump to be suitable for implantation in the broadest range of patient types."

— Prof. Dr. med. Thomas Krabatsch
Senior Physician, Department of Cardi thoracic and Vascular Surgery
The German Heart Institute, Berlin
Enables clinicians to more effectively manage their patients

The smart design of the HVAD System makes it simple to learn and manage for both the patient and their support team. The intelligent interface and supporting diagnostics offer MCS teams the tools and essential information they need to effectively manage their patients.

A BETTER WAY TO LEARN, TRAIN, AND MANAGE.

- Clear and actionable instructions
- Customizable alarms provide early warning of potential issues
- Self monitoring controller alerts for issues
- Real time data allows the MCS team to optimize patient management
- Historical device trends available for review as needed
- Log files provide additional information to enhance understanding of the clinical scenario and to troubleshoot patient and equipment issues
- 24 hour support and analysis from HeartWare experts

“The HVAD System not only has excellent clinical outcomes, but it is easy to use and simple for patients to learn. The user-friendly system is unique among LVAD technologies, providing valuable real-time information about pump function which can be used to optimize device performance and improve patient management.”
— Jeffrey Teuteberg, MD
Assistant Professor, Heart Failure/Cardiac Transplantation
Medical Director, Artificial Heart Program
University of Pittsburgh Medical Center

“The HeartWare peripherals reduce training time because the controller is easy to understand. The simple connections and clear messages allow patients and caregivers to quickly gain confidence with the system.”
— Laura Blue, RN, MSN, NP
VAD Coordinator, Duke University Medical Center
The VAD of Choice

The HVAD System allows heart failure programs to treat a broad range of patients, improve patient survival and patient quality of life. This makes the HVAD System the VAD of choice for heart failure programs around the world.

Learn more about why the HVAD System is an essential part of any heart failure program.

Call your HeartWare representative today.

WARNING: Serious and life threatening adverse events, including stroke, have been associated with use of this device. A user must fully consider the risks of this device with that of other treatment modalities before deciding to proceed with device implantation.

In the USA the HVAD System is intended for use as a bridge to cardiac transplantation in patients who are at risk of death from refractory end-stage left ventricular heart failure.

CAUTION: Federal Law (USA) restricts this device to sale by or on the order of a physician. Refer to the “Instructions for Use” for complete indications for Use, Contraindications, Warnings, Precautions, Adverse Events and Instructions prior to using this device.

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References
4. Strueber M, et al Results of the Registry to Evaluate the HeartWare Left Ventricular Assist System (The REVOLVE Registry) Presentation at ISHLT 2012, Montreal, Canada April 2012: manuscript submitted for publication.
7. Data on file with manufactures, HeartWare Inc, Framingham, MA.

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For full prescribing information please see the IFU

Instructions For Use can be found at:
www.heartware.com/clinicians/instructions-use

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