

HEARTWARE™ HVAD™ VENTRICULAR ASSIST DEVICE **PRODUCT DATA SHEET**

The VAD of Choice

The HVAD™ System allows heart failure programs to treat a broad range of patients, improve patient survival and enhance quality of life.



HVAD SYSTEM IMPLANTABLES



HVAD™ PUMP

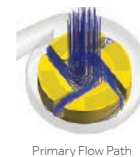
GENERAL CHARACTERISTICS

- Continuous flow
- Displaced volume = 50 cc, weight = 160 g
- Device size and integrated inflow cannula allow for pericardial placement, which eliminates the need for abdominal surgery and device pockets
- Can provide up to 10 L/min of flow*

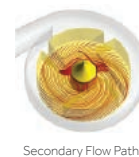


IMPELLER

- Magnetically and hydrodynamically suspended
- Wide-bladed
- Operates at speeds ranging from 1800 to 4000 rpm
- Provides multiple blood flow paths



Primary Flow Path



Secondary Flow Path



Tertiary Flow Path



DRIVELINE

- Percutaneously connects the HVAD Pump to an external controller
- Length = 119 cm
- Diameter up to 4.8 mm
- Constructed with conductor wires similar to those used in pacemakers
- Six individually insulated, fatigue-resistant cables, each encased within a silicon lumen with an outer sheathing
- Contains a portion that is wrapped with woven polyester fabric to encourage tissue in-growth



SEWING RING

- Designed to secure the HVAD Pump to the myocardium
- Composed of titanium and polyester



OUTFLOW GRAFT WITH STRAIN RELIEF

- 10 mm gel-impregnated polyester
- Articulating strain relief designed to prevent kinking

HVAD SYSTEM PERIPHERALS



HEARTWARE MONITOR

- Used by clinicians to set system parameters
- Touchscreen tablet PC computer
- Uses proprietary software to display real-time pump information, historical pump information and alarm conditions



HEARTWARE BATTERIES AND CHARGER

- Lithium ion battery pack
- Each battery allows up to six hours of operation when fully charged*
- Battery charger has capacity to charge four batteries simultaneously

*Bench test on file with HeartWare, Inc.



HEARTWARE CONTROLLER

- Microprocessor unit that regulates pump function and monitors the system
- Contains two-line LCD screen that displays parameters, alarms and recommended troubleshooting
- Each alarm has a unique sound, color-coded prioritization, visual display and message
- Requires power from two sources at all times
- Two batteries OR one battery and electricity from the wall (AC) or car outlet (DC)



PATIENT PACKS

- Available in three styles
- Designed to support an active lifestyle
- Lightweight, ultra-durable rip-stop nylon material
- Easy to clean material
- Magnetic closures allow easy access to equipment
- See-through controller window lets patients easily check the display



Brief Statement: 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.

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