

hVAD[®] System

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. This makes the HVAD System the VAD of choice for heart failure programs around the world.

HVAD System Implantables

HVAD[®] PUMP



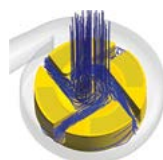
General Characteristics

- 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

Market Approvals

European Commercial approval in January 2009.

US ADVANCE Bridge-to-Transplant (BTT) approval in November 2012.

Canada Bridge-to-Transplant (BTT) approval in April 2015.

HVAD System Implantables (continued)

OUTFLOW GRAFT WITH STRAIN RELIEF



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

SEWING RING



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

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

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

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)

*Bench test on file with HeartWare, Inc.

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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