

# USE OF THE HEARTWARE™ HVAD™ SYSTEM FOR A **PATIENT WITH A SMALL BODY SURFACE AREA**

Case Study:  
University of California  
San Francisco  
San Francisco, California

**Medtronic**  
Further. Together

## CASE STUDY:

### UNIVERSITY OF CALIFORNIA SAN FRANCISCO

#### CASE AT-A-GLANCE

Age: 42 years old  
Gender: Female  
Diagnoses: Cardiomyopathy, NYHA Class IV heart failure  
Complicating Factors: Small BSA (1.5), refractory ventricular tachycardia  
Treatment Approach: LVAD for BTT  
Treating Facility: University of California, San Francisco  
Device Selection Considerations: The patient's small frame required a device appropriate for her body

#### CASE HISTORY

A 42-year-old woman was diagnosed in 2010 with non-ischemic cardiomyopathy and then developed refractory ventricular tachycardia (VT). She was taking three medications to treat the recurrent VT and had previously received an implantable cardioverter-defibrillator (ICD). After an ablation procedure in June, she went into cardiogenic shock and was referred to UCSF. At the time of referral, her left ventricular ejection fraction was 10% and the patient was classified as INTERMACS 1. The patient was placed on extracorporeal membrane oxygenation (ECMO) support for approximately 15 days to stabilize her prior to implantation of a left ventricular assist device (LVAD).

#### TREATMENT APPROACH:

The patient's body surface area (BSA) and poor bi-ventricular function informed our VAD selection and treatment strategy. At 5'1" and 115 pounds, her small body frame would not be optimal for an LVAD placed in the abdominal cavity. Further, we were initially concerned that she would also require long term right ventricular (RV) support, which led us to select a VAD that was smaller and more versatile.

Durability was another consideration for our treatment decision. The patient's panel reactive antibody (PRA) titer was 90% for Class I and 98% for Class II. While the patient was listed with UNOS for a heart transplant, her high PRA score may make it significantly more difficult to find a suitable donor heart. As a result, we wanted a smaller-profile ventricular assist device that had proven length of support. For these reasons, we selected the HeartWare™ HVAD™ System.

The patient was supported by ECMO throughout the surgical procedure. Upon evaluation at the time of implant, only left ventricular (LV) support was needed, and the HeartWare™ HVAD™ Pump was implanted as previously described<sup>1</sup> with no complications. The pump speed was initially set at ~2400 RPM and was later increased to ~2600 RPM to provide adequate hemodynamic support given the extent of her LV dysfunction. The patient was monitored in the ICU for roughly seven days and then transferred to the telemetry unit before being discharged home. She remains on the transplant list and has returned to a near normal life while living with the HVAD System.

#### DISCUSSION:

Body habitus is an important consideration when devising a treatment strategy for advanced heart failure. Women can be particularly difficult to treat because of their small BSA and relatively shallow abdominal cavity. These factors may have contributed to the historical under-treatment of women with advanced heart failure using mechanical circulatory support. Even with the availability of newer devices, women continue to represent only about 21% of all VAD patients.

At UCSF, by taking advantage of the versatility offered by the HVAD System we have been able to increase significantly the proportion of women receiving a VAD. Its smaller size and pericardial placement eliminates the need for a pump pocket and fits smaller body types. As we treat a large Asian-American population, this is especially important and we are able to accommodate the needs of more patients with the HVAD Pump.

The patient's post-implant stay was lengthened by her poor state of health upon referral, requiring extensive physical therapy, but she was eventually discharged home. Now, living at home, the patient is able to participate in activities that she could not do before implant. Prior to implantation, she received ICD shocks on an almost daily basis, which significantly limited her activity. However, with the HVAD System she is able to participate in life again, including playing with her children, shopping, cooking, and enjoying her church community.

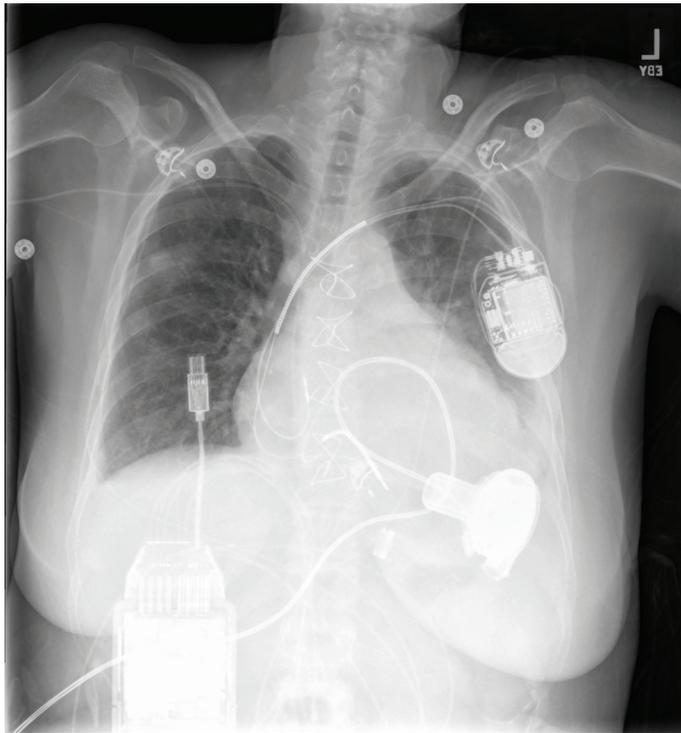
#### References

- <sup>1</sup>Slaughter MS. Implantation of the HeartWare Left Ventricular Assist Device. *Semin Thorac Cardiovasc Surg.* 2011; 23(3):245-7.
- <sup>2</sup>Joyce DL, Conte JV, Russell SD, et al. Disparities in access to left ventricular assist device therapy. *J Surg Res.* 2009; 152:111-7.
- <sup>3</sup>INTERMACS. Quarterly Statistical Report. 2014 1st Quarter.



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X-ray showing the position of the HVAD in the patient's relatively small frame

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**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**

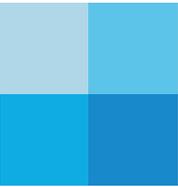
Proper usage and maintenance of the HVAD™ System is critical for the functioning of the device. Never disconnect from two power sources at the same time (batteries or power adapters) since this will stop the pump, which could lead to serious injury or death. At least one power source must be connected 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](http://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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