U.S. Food and Drug Administration
Protecting and Promoting *Your* Health

HeartWare Inc. Extends Recall to Include Batteries Used in the Ventricular Assist Device Due to Premature Power Depletion

The FDA has identified this as a Class I recall, the most serious type of recall. Use of these devices may cause serious injuries or death.

Recalled Product:

- Batteries used on HeartWare Ventricular Assist Device (HVAD)
- Serial numbers: BAT000001 to BAT199999
- Model number: 1650
- Manufacturing dates: May 19, 2013 to July 1, 2015
- Distribution dates: May 21, 2013 to July 31, 2015
- Devices recalled in the U.S.: 18,631 units nationwide, including Washington D.C.

Device Use

The HVAD helps deliver blood from the heart to the rest of the body. It is used in patients who are at risk of death from end-stage left ventricular heart failure and who are waiting for a heart transplant. The system includes a pump implanted in the space around the heart (**pericardium (https://www.nlm.nih.gov/medlineplus/ency/imagepages/18081.htm)**) and a controller that controls the speed and function of the pump.

Reason for Recall

HeartWare Inc. is recalling the batteries because they may lose power prematurely due to faulty cells. If the HVAD system is not connected to an additional power source shortly after the system sounds an alarm indicating a low battery level, the pump will stop working and the patient may experience serious adverse health consequences, including death.

Who May be Affected

- Patients receiving cardiac support using the HVAD system supplied with the defective batteries
- Health care providers and caregivers monitoring patients with a HVAD system supplied with the defective batteries

What to Do

On January 7, 2016, HeartWare Inc. sent an "Urgent: Medical Device Recall" letter to affected

customers. The letter instructed customers to:

- Complete and return the acknowledgement form attached with the letter
- Identify and quarantine affected batteries under patients' possession and in hospitals
- Arrange an appointment with a qualified representative for replacement batteries with improved cells
- Return the affected products to HeartWare Inc. along with the completion form attached with the letter
- Forward the notice to third affected customers

Contact Information

Customers can contact HeartWare Inc. at **cs@heartware.com (mailto:cs@heartware.com)** or via telephone by calling 1-877-367-4823.

Date Recall Initiated:

January 7, 2016

Additional Resources

- **HeartWare Ventricular Assist System (VAS) – Electrostatic Discharge May Cause Pump Failure (/MedicalDevices/Safety/ListofRecalls/ucm435811.htm)** (February 2015)
- **HeartWare Ventricular Assist System – Updated with Multiple Reasons for Recalls (/MedicalDevices/Safety/ListofRecalls/ucm451447.htm)** (April 2015)

How do I report a problem?

Health care professionals and consumers may report adverse reactions or quality problems they experienced using these devices to **MedWatch: The FDA Safety Information and Adverse Event Reporting Program (https://www.accessdata.fda.gov/scripts/medwatch/index.cfm)** either online, by regular mail or by FAX to 1-800-FDA-0178.

More in Medical Device Recalls (/MedicalDevices/Safety/ListofRecalls/default.htm)
2016 Medical Device Recalls (/MedicalDevices/Safety/ListofRecalls/ucm480134.htm)
2015 Medical Device Recalls (/MedicalDevices/Safety/ListofRecalls/ucm429489.htm)
2014 Medical Device Recalls (/MedicalDevices/Safety/ListofRecalls/ucm384921.htm)