HeartWare Recalls Ventricular Assist Device Controllers Due to Loose Connectors which may Prevent Alarm from Sounding and Pump Stops

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:

- HeartWare Ventricular Assist Device (HVAD) Controllers
- Serial Numbers: HW001 to HW11270, and HW20001 to HW 20296
- Product Codes: 1100, 1101, 1102, 1103, 1104, 1205
- Manufacturing Dates: March 6, 2006 to October 17, 2016
- Number of devices manufactured: 4586
- Devices Recalled in the U.S.: 91 units distributed nationwide

Figure: HeartWare Ventricular Assist Device Controller, a small computer that monitors the pump

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://medlineplus.gov/ency/imagepages/18081.htm) and a controller that controls the speed and function of the pump.

The HVAD is designed for use both in and out of hospital settings, including during patient transport.

Reason for Recall

HeartWare Inc. is recalling the HVAD controller due to a loose power connector which may cause the rear portion of the pump's driveline connector to become separated from the front portion of the driveline connector. A loose connector may allow moisture to enter the controller causing corrosion, electrical issues, reduced speaker volume and connection failures. If the speaker volume is decreased, the patient may not hear the alarm. If there is a loss of connection, the pump may stop which could cause serious adverse health consequences, including death.

HeartWare issued a related recall for the HVAD on July 29, 2016 (/MedicalDevices/Safety/ListofRecalls/ucm526212.htm).

Who May be Affected

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

What to Do

On June 8, 2016, HeartWare Inc. sent an "Urgent Medical Device Correction" letter to affected customers. The letter instructed providers who care for these patients to:

- Remind patients about the safe use of the HVAD System, particularly with regard to moisture and proper connection to power and data sources.
- Inspect controllers for loose connectors by gently pressing on each connector and feeling for atypical movement.

- If a loose connector is identified, replace with a controller from inventory and contact your local HeartWare representative
- If the loose controller is the patient's primary controller, perform a careful benefit risk analysis before using the device.
- Sign and return the "Acknowledgement Form" to HeartWare Quality Compliance via email at FSCA@heartware.com (mailto:FSCA@heartware.com), or fax it to (305) 364-2665 within 30 days.

Contact Information

Health care providers who have questions should contact their HeartWare representative or contact HeartWare Inc. at cs@heartware.com (mailto:cs@heartware.com) or 1-877-367-4823 with any questions related to this recall.

Date Recall Initiated:

February 29, 2016

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?action=reporting.home) either online, by regular mail or by FAX to 1-800-FDA-0178.

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