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

HeartWare Ventricular Assist System - Damaged Alignment Guides / Connection Pins May Cause Pump to Stop

Recall Class: Class I

Date Recall Initiated: April 29, 2015

Devices:

HeartWare Ventricular Assist System (VAS)

- Product Codes: 1101, 1103
- Serial Numbers: All Heartware systems currently in use
- Manufacturing and Distribution Dates: January 2008 to March 2015
- Devices recalled in the US: 1763

Use: The HeartWare VAS 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 (http://www.nlm.nih.gov/medlineplus/ency/imagepages/18081.htm)**) and a controller that controls the speed and function of the pump.

Recalling Firm:
HeartWare
14400 NW 60th Avenue
Miami Lakes, FL 33014

Reason for Recall: The alignment guides in the power supply connector ports may wear down over time. This can cause the connection pins to become twisted or bent, and eventually prevent the patient from connecting the device controller to their VAS. An interruption in this electrical connection would cause the pump to stop, which could cause serious patient injury or death.

The company has reported 33 reports of malfunction and one serious injury related to this problem.

Public Contact:

- Patients with questions about this recall should contact their health care provider or the VAD (Ventricular Assist Devices) Coordinator at their hospital center.
- Health care providers who have questions should contact their HeartWare representative or contact HeartWare's 24-hour Clinical Support at 1-888-494-6365, or email **FSCA@heartware.com (mailto:FSCA@heartware.com)**.

FDA District: Florida District Office

More Information about this Recall:

HeartWare sent their customers an Urgent Medical Device Correction notice on May 25, 2015 to alert them of the problem and actions to take. HeartWare will replace all defective controllers by the end of June 2016.

Health Care Providers:

1. Forward HeartWare's voluntary safety notice to those individuals within your organization who need to be aware of its content.
2. Identify the patients currently supported by the HVAD System.
3. Distribute the patient communication to those patients directly by FedEx or other traceable communication method. Contact your HeartWare representative for any assistance with this process.
4. Make appointments to see the patients subject to this recall as soon as possible, and inspect their device's power supply connector ports for wear, twisting, or bending. Consider replacing the controller if necessary.
5. Continue to reinforce the messages described in HeartWare's voluntary safety notice with your patients during their regularly scheduled appointments.
6. Complete, sign, and return the "Acknowledgement and Completion Form" to your HeartWare representative within 30 days of receipt of this letter or by email at **FSCA@heartware.com (mailto:FSCA@heartware.com)**.

Patients:

Inspect the power supply ports on your controllers for potential wear or damage to the alignment guides or connection pins. If damage is found, use care when connecting power sources to avoid twisting or bending the power connection pins. Contact your health care provider as soon as possible to schedule an appointment and possibly arrange for a replacement controller.

HeartWare wants to remind patients to use your device safely:

1. Never disconnect from both power sources at the same time.
2. Take care when connecting to power sources.
3. Keep the outer sheath of your driveline protected from excessive sunlight.
4. Beware of accidental snagging or pulling of your driveline.

About Class I Recalls:

Class I recalls are the most serious type of recall and involve situations in which there is a reasonable probability that use of these products will cause serious adverse health consequences or death.

Health care professionals and consumers may report adverse reactions or quality problems they experienced using these products 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.

Additional Resources

- Firm Press Release (http://ir.heartware.com/phoenix.zhtml?c=187755&p=irol-newsArticle&ID=2057393) (/AboutFDA/AboutThisWebsite/WebsitePolicies/Disclaimers/default.htm)

More in Medical Device Recalls (/MedicalDevices/Safety/ListofRecalls/default.htm)

2015 Medical Device Recalls (/MedicalDevices/Safety/ListofRecalls/ucm429489.htm)

2014 Medical Device Recalls (/MedicalDevices/Safety/ListofRecalls/ucm384921.htm)

2013 Medical Device Recalls (/MedicalDevices/Safety/ListofRecalls/ucm384618.htm)