

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

HeartWare, Inc., Heartware Ventricular Assist System - Locking Mechanism of Pump Driveline Connector May Fail to Engage

Recall Class: Class I

Date Recall Initiated: Dec. 6, 2013

Product: HeartWare Ventricular Assist System

Catalog Numbers: 1100, 1101, 1102, 1103, 1104, and 1205.

Serial Numbers: HW001 to HW 11270 and HW20001 to HW 20296.

Affected products were manufactured from March 6, 2006 through October 17, 2013 and distributed from March 17, 2006 through November 29, 2013.

Use: The HeartWare Ventricular Assist System is used as a bridge to cardiac transplantation in patients who are at risk of death from advanced heart failure. The System includes various internal and external components including but not limited to the internal pump, external controller, power sources, and the driveline connecting the pump to the controller. The HeartWare Ventricular Assist System, also known as HeartWare Ventricular Assist Device (HVAD), is designed for in-hospital and out-of-hospital settings, including transportation by fix-wing aircraft or helicopter.

Recalling Firm:

HeartWare Inc.
14400 NW 60th Avenue
Miami Lakes, Florida 33014

Reason for Recall:

The company received reports where the driveline connector locking mechanism has failed to engage as a result of a faulty manufacturing assembly process. This failure could result in the pump stopping and potentially lead to serious adverse health consequences, including death.

Public Contact:

Physicians with questions related to this recall or have affected products and need to schedule a driveline connector repair should contact HeartWare Clinical Support at (888) 494-6365, 24 hours a day, seven days a week, or by email at FSCA@heartware.com (<mailto:FSCA@heartware.com>).

Patients: See below.

FDA District: Florida District Office

More Information about this Recall:

On December 12, 2013, HeartWare, Inc. sent an initial Urgent Medical Device Correction letter to their customers.

The firm will be sending an updated Urgent Medical Device Correction letter to physicians affected by this recall. This letter will provide updated actions to be taken by the physician. Letters for patients will be sent to physicians to be hand-delivered to their patients.

ACTIONS TO BE TAKEN:

PATIENTS:

If the driveline becomes disconnected from the patient controller, a "VAD Stopped" (high priority) alarm will alert you. As instructed in the Patient Manual, immediately reconnect the driveline to the controller and contact your doctor or VAD Coordinator.

Your driveline connection will be inspected by your doctor or VAD Coordinator. Should the inspection identify a locking mechanism that fails to engage, your physician will arrange for a permanent repair by a HeartWare Clinical Engineer as soon as possible. Once the driveline connector has been checked or repaired, the locking mechanism should function properly. Do NOT attempt to disconnect or inspect the driveline yourself.

PHYSICIANS:

Please promptly arrange a follow up visit with patients having the affected HVAD to inspect the driveline connector.

At implant and at each routine clinic visit, please inspect the patient's driveline connector for proper locking and to ensure that the connector assembly remains secure. During the inspection, pull back the protective boot and slide the locking mechanism back and forth to verify free movement of the mechanism. If the locking mechanism of the driveline connector does not move freely or fails to engage, please push the connector back into the controller and immediately contact a HeartWare Clinical Engineer to perform a permanent field repair.

Please give the patient recall letter to your patients who have an affected device and explain what they should do if an unintentional driveline disconnect occurs.

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/>) either online, by regular mail or by FAX.

Additional Resources:

- **Firm Press Release** (<http://www.prnewswire.com/news-releases/heartware-issues-reminder-to-december-2013-driveline-connector-device-correction-256606471.html>)  (<http://www.fda.gov/AboutFDA/AboutThisWebsite/WebsitePolicies/Disclaimers/default.htm>)