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)**.