

Medtronic Recalls HeartWare Splice Kit Intended to Repair the Driveline of its Ventricular Assist Device Because it May Cause Electrical Issues or 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:

- Product Name: HeartWare Ventricular Assist System Pump Driveline Splice Kit
- Product Codes: ASY00116 and ASY00281
Affected Lots: All driveline splice repair kits that were used prior to April 2015
- Distribution Dates: January 11, 2011 to May 23, 2014
- Devices Recalled in the U.S.: 9 nationwide

Device Use:

The HeartWare Ventricular Assist Device (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). It also includes a driveline cable that goes through the skin. The driveline connects the pump to an external controller that regulates the speed and function of the pump. The system is powered with batteries or power adapters. The HVAD is designed for use both in and out of hospital settings, including during patient transport.

The driveline splice kit is intended to repair the driveline once an electrical break has been identified. These repairs are limited to the section of the driveline that is outside of the patient.

Reason for Recall:

Medtronic is recalling the driveline splice kit due to a design problem that would prevent the repaired cable assembly from withstanding excessive force or pull (e.g. accidental dropping of controllers or snagging driveline cables). The excessive force or pull could cause damage to the cable assembly and interrupt electrical connection. The company issued these kits between April 2010 and March 2015 to repair previous HVAD driveline cable connector assembly issues.

An interruption in electrical connection may cause the pump to stop, which may lead to serious adverse health consequences, including death.

Who May be Affected:

Healthcare providers who used the HeartWare Ventricular Assist System Pump Driveline Splice Kit prior to April 2015. All patients that underwent driveline splice repairs prior to April 2015

What to Do:

On March 16 2017, Medtronic informed affected customers that there is a new HVAD Driveline Splice Kit now available via an Urgent Medical Device Recall notice. The notice asked customers to:

- Review the notice and ensure appropriate staff is aware of the notice.
- Determine whether performing a re-splice procedure is appropriate for patients who had a driveline repair performed with the original splice kit.
 - Healthcare providers should weigh the benefits of using the new HVAD Driveline Splice Kit against the risks of a re-splice procedure, during which the pump will temporarily have to stop. This may expose the patient to the risk of serious adverse events or death.
 - If the decision is made to perform a driveline re-splice, healthcare providers should contact their local HeartWare representative to schedule the procedure. The driveline splice procedure must only be performed by a minimum of two trained HeartWare technicians in a controlled clinical setting to reduce the potential risk of damage to the driveline and subsequent serious injury or death.
 - All patients that underwent driveline splice repair after April 2015 have been spliced with the improved HVAD Splice Kit and are not affected by this issue.
- Complete, sign, and return the acknowledgement form to the HeartWare representative or by email at [FSCA@heartware.com \(mailto:FSCA@heartware.com\)](mailto:FSCA@heartware.com) within 30 days of receipt of the notice.

Contact Information:

Customers with questions are instructed to contact their local HeartWare representative with any questions related to this recall.

Date Recall Initiated:

March 10, 2017

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 either online, by regular mail or by FAX to 1-800-FDA-0178.

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

2017 Medical Device Recalls [\(/MedicalDevices/Safety/ListofRecalls/ucm535289.htm\)](/MedicalDevices/Safety/ListofRecalls/ucm535289.htm)

2016 Medical Device Recalls [\(/MedicalDevices/Safety/ListofRecalls/ucm480134.htm\)](/MedicalDevices/Safety/ListofRecalls/ucm480134.htm)