Abbott-Thoratec Recalls HeartMate II LVAS Pocket System Controller Due to Risk of Patient Injury and/or Death during Backup Controller Exchange

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(s)

- HeartMate II Left Ventricular Assist (LVAS) Pocket System Controller
- Model/Item Numbers: 105109, 106015, 106762, 107801
- Manufacturing Dates: July 2012 to December 2016
- Distribution Dates: July 2012 to March 2017
- Devices Recalled in the U.S.: 28,882 Nationwide

Device Use

The Pocket System Controller is a power supply that connects to the implanted HeartMate II LVAS pump through a lead (driveline) under the skin. The controller helps power the LVAS system, a mechanical device that circulates blood throughout the body when the heart is too weak to pump blood adequately on its own. The controller is powered by batteries or connected to a main power supply.

The HeartMate II LVAS Pocket System Controller is intended for use inside or outside of the hospital. A back-up system controller is provided to each patient for use in case of a device alarm or malfunction. Instructions and training are provided on how to switch from one system controller to the other.

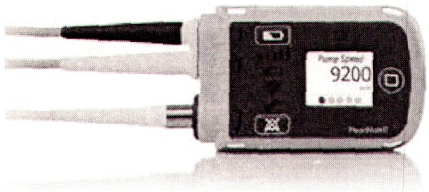

Image of a HeartMate II LVAS Pocket System Controller

Reason for Recall

Patients may sometimes need to change to their backup back-up system controller during the course of ventricular assist therapy. The change should be done quickly and in the hospital, because it can present a significant challenge to patients that are elderly and/or untrained. For these patients, a slow or improper driveline changeover places them at risk of serious injury or death.

Abbott-Thoratec has received a total of 70 reports of incidents, including 19 injuries and 26 deaths. All of the deaths occurred when patients attempted to exchange controllers while away from the hospital.

To address this issue, Abbott-Thoratec is providing all HeartMate II LVAS with Pocket Controller users with new software and hardware updates to assist patients in successfully changing their pocket controller in emergency situations.

Who May be Affected

- Patients with a HeartMate II LVAS Pocket System Controller
- Health care providers treating patients with left ventricular heart failure using the HeartMate II LVAS Pocket System Controller

What to Do

On March 29, 2017, Abbott-Thoratec sent an "Urgent Medical Device Correction" letter to affected customers. The letter identified the following actions to be taken:

- New HeartMate II LVAS Pocket System Controller patients will receive upgraded hardware and software (to include a fully upgraded system controller with new yellow alignment markings and new lead/driveline) from their ventricular assist device (VAD) coordinator.
- Existing HeartMate II LVAS Pocket System Controller patients will receive updated device software and alarm guides for both their primary and back-up controllers.
  - If existing patients need their controller replaced (if damaged or an old model controller), Abbott-Thoratec will replace the controller at no cost, but the patient's implanted drive line will not be changed to have matching yellow markings.
- Abbott-Thoratec will contact all affected health care providers to coordinate office visits, and receipt of software updates and updated labeling. Each office visit should include:
  - Software updates on the primary and backup System Controllers with support from authorized Abbott representatives.
  - Explanation of the latest software update to the patient and caregiver(s).
    - The alarm notification system has been updated to remove advisory alerts on the patient's System Controller. These are noncritical alerts that will be seen by the physician on the System Monitor when the patient goes in for the next routine appointment.
  - A reminder to patients to contact their VAD coordinator in the event an alarm appears on their System Controller, and reinforce that System Controller exchanges are to be performed by their VAD Coordinator in the hospital.
  - Signing and returning the Acknowledgement Form attached to the "Urgent Medical Device Correction" letter.

Contact Information

Customers with questions about this recall may contact Abbott's Heartline at: 800-456-1477.

Date Recall Initiated

March 30, 2017

Additional Resources

- **Thoratec Corporation, HeartMate II LVAS Pocket System Controller - Insufficient Labeling and Training for Patients Switched from the EPC Controller (*Class I Recall: Originally Issued April 1, 2014*) (http://wayback.archive-it.org/7993/20170112083856/http:/www.fda.gov/MedicalDevices/Safety/ListofRecalls/ucm391322.htm)**

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 (/Safety/MedWatch/HowToReport/default.htm)**. Health care professionals employed by facilities that are subject to **FDA's user facility reporting requirements (/MedicalDevices/DeviceRegulationandGuidance/PostmarketRequirements/ReportingAdverseEvents/default.htm)** should follow the reporting procedures established by their facilities.

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

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

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