Class I Medical Device Recall: Thoratec Corporation, HeartMate II Left Ventricular Assist System (LVAS)

U.S. Food & Drug Administration

Recall Class: Class I

Date Recall Initiated: February 23, 2012

Product: HeartMate II Left Ventricular Assist System (LVAS)

Model/catalog/lot numbers: 103393, 103695, 104692, 104911, 104912

Range of manufacturing and distribution dates: February 2010 – February 2012

Use: The HeartMate II LVAS is indicated for use as a bridge to transplantation in heart transplant candidates at risk of imminent death from non-reversible left ventricular failure. It is also indicated for use in patients with New York Heart Association (NYHA) Class IIB of IV end-stage left-ventricular failure who have received optimal medical therapy for at least 45 of the last 60 days and who are not candidates for heart transplantation.

The HeartMate II blood pump delivers blood from the dysfunctional left ventricle of the heart to the rest of the body. It is an axial-flow, rotary ventricular assist system and can generate blood flows up to 10 liters per minute (1 beat per minute). The device is intended to be used both inside and outside the hospital (e.g., at home), or during transportation of ventricular assist device patients by ground ambulance, airplane or helicopter.

Recalling Firm:
Thoratec Corporation
6035 Stoneridge Drive
Pleasanton, CA 94588

Reason for Recall: Detachment of the bend relief from its intended position around the proximal outflow graft may allow the graft to kink or deform, resulting in reduction of blood flow from the HeartMate II LVAS pump, pump/graft thrombosis, or perforation of the outflow graft. Additionally, the metal end of the bend relief may be sharp and cause erosion and cutting of the outflow graft. This product may cause serious adverse health consequences, including death.

Public Contact: 1-800-528-2577 or 925-847-8600 (7 days a week, 8-5 Pacific Time)

FDA District: San Francisco

FDA Comments: The firm states that the device labeling has been revised to provide instructions on how to verify the bend relief is fully engaged with the sealed outflow graft at the time of implant and new caution statement regarding the bend relief connection are included. Clinicians have been instructed to follow the revised instructions for use that clarify the recommended procedure for securing the bend relief to the outflow graft.

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 the MedWatch FDA Safety Information and Adverse Event Reporting Program [1] either online, by regular mail, by telephone, or by FAX.

SOURCE [2]

Source URL (retrieved on *07/10/2014 - 6:42pm*):
http://www.mdtmag.com/news/2012/04/class-i-medical-device-recall-thoratec-corporation-heartmate-ii-left-ventricular-assist-system-lvas?qt-most_popular=0

Links:
[1] http://www.fda.gov/Safety/MedWatch/HowToReport/default.htm
[2] http://www.fda.gov/MedicalDevices/Safety/RecallsCorrectionsRemovals/ListofRecalls/ucm298662.htm