Indiana State Department of Health
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Michael R. Pence
Governor

Jerome M. Adams, MD, MPH
State Health Commissioner

DATE: September 17, 2015

TO: All Local Health Departments
Attn: Chief Food Inspection Officer

FROM: Laurie Kidwell, RRT Supervisor
Food Protection Program

SUBJECT: Thoratec Corporation – RECALL [Medical Device]

AFFECTED PRODUCT: **HeartMate II LVAS**

SUMMARY: **Unclassified Recall; The recall has been initiated because Thoratec received reports from several hospitals about a number of patients who encountered an advisory alarm due to the expiration of their System Controller backup batteries. Some of these patients who received the advisory alarm attempted to switch from their primary to backup System Controller, and of those, three were unable to connect their pump to their backup System Controller in a timely manner, resulting in two patient deaths and one serious injury.**

Urgent Medical Device Correction Letter to all hospitals who have patients supported with the HeartMate II LVAS reminding them to monitor the expiration date of the backup battery contained within the HeartMate II "Pocket" System Controller, as specified in the product Instructions for Use. This backup battery has a 36 month expiration date. If allowed to expire, an advisory alarm, indicated by a yellow wrench symbol, is triggered. This alarm occurs at 12:00 a.m. on the first day of the month in which the backup battery expires. It is important to note that exceeding the backup battery expiration and any associated advisory (or "yellow wrench") alarms do not affect normal HeartMate II LVAS function. While the HeartMate II LVAS Instructions for Use provides information on monitoring and changing the backup battery before it reaches the 36 month expiration date, Thoratec has recently received reports of patients experiencing advisory alarms for expired System Controller backup batteries.

SUGGESTED ACTION: **For consumer inquiry only. Patients with questions or who experience this issue should contact their doctor or VAD coordinator at their hospital. Clinicians with questions should contact their Thoratec representative or call Thoratec's 24-hour HeartLine at 1-800-456-1477.**

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Recall -- Firm Press Release

FDA posts press releases and other notices of recalls and market withdrawals from the firms involved as a service to consumers, the media, and other interested parties. FDA does not endorse either the product or the company.

Thoratec Issues Voluntary Device Correction

Contact:
Consumer:
1-800-456-1477

Media:
Neil Meyer
Senior Director Finance and Investor Relations
Thoratec Corporation
(925) 738-0029

FOR IMMEDIATE RELEASE - September 14, 2015 - PLEASANTON, CA - Thoratec Corporation (NASDAQ: THOR) today issued a voluntary Urgent Medical Device Correction Letter to all hospitals who have patients supported with the HeartMate II LVAS reminding them to monitor the expiration date of the backup battery contained within the HeartMate II "Pocket" System Controller, as specified in the product Instructions for Use. This backup battery has a 36 month expiration date. If allowed to expire, an advisory alarm, indicated by a yellow wrench symbol, is triggered. This alarm occurs at 12:00 a.m. on the first day of the month in which the backup battery expires. **It is important to note that exceeding the backup battery expiration and any associated advisory (or "yellow wrench") alarms do not affect normal HeartMate II LVAS function.** While the HeartMate II LVAS Instructions for Use provides information on monitoring and changing the backup battery before it reaches the 36 month expiration date, Thoratec has recently received reports of patients experiencing advisory alarms for expired System Controller backup batteries.

On September 1, 2015, Thoratec received reports from several hospitals about a number of patients who encountered an advisory alarm due to the expiration of their System Controller backup batteries. Some of these patients who received the advisory alarm attempted to switch from their primary to backup System Controller, and of those, three were unable to connect their pump to their backup System Controller in a timely manner, resulting in two patient deaths and one serious injury.

The Urgent Medical Device Correction Letter is intended to prevent the occurrence of certain preventable advisory alarms that may result in patients deciding to attempt a System Controller exchange. Thoratec is working with hospital staff to identify patients that may be close to reaching the 36-month expiration date of their System Controller backup battery in order to facilitate priority replacement and to ensure routine monitoring of backup battery lifetime during clinic visits, as specified in the product Instructions for Use.

What to do if you are a HeartMate II LVAS Patient:

If you are a HeartMate II LVAS patient and the serial number on your System Controller starts with the letters "EPC," you are not affected by this action and there is nothing you need to do. If you are a HeartMate II LVAS patient and the serial number on your System Controller starts with the letters "PC" (i.e. "Pocket Controller") and you received your device more than two years ago, please contact your doctor immediately to have the expiration date of the backup battery within your HeartMate II System Controllers (both primary and backup) checked and, if necessary, replaced. If you received your HeartMate II LVAS implant less than two years ago, please ask your doctor to check both your primary and backup HeartMate II System Controller backup batteries during each clinical visit. As a reminder the backup battery should be replaced approximately 6 months before expiration, dependent upon your clinic schedule.

> Important Note: If you are a HeartMate II LVAS patient with a Pocket System Controller and experience a Backup Battery Advisory alarm, follow the instructions for this alarm in your Patient Handbook and contact your hospital for further instructions. **For all advisory (yellow wrench) alarms, you should first call your hospital contact for instructions. Do not attempt to replace the System Controller unless instructed by your hospital.**

The Backup Battery Advisory alarm will occur at 12:00 a.m. on the first day of the month it will expire. The advisory alarm tone is a slow beep and the message displayed on the LCD user interface screen of your System Controller is dependent on the software version; the LCD will either show "Call Hospital Contact, Backup Battery Fault" + "Replace Controller, Backup Battery Fault" *or* it will show "Call Hospital Contact, Backup Battery Fault."

Patients with questions or who experience this issue should contact their doctor or VAD coordinator at their hospital. Clinicians with questions should contact their Thoratec representative or call Thoratec's 24-hour HeartLine at 1-800-456-1477.

Thoratec has advised the U.S. Food and Drug Administration (FDA) of this action. Adverse events or quality problems experienced with the use of this product may be reported to the FDA's MedWatch Adverse Event Reporting program:

Online: http://www.fda.gov/Safety/MedWatch/HowToReport/default.htm (form available to fax or mail), or
Phone: 1-800-FDA-1088.

About Thoratec Corporation:

Thoratec is a world leader in therapies to address advanced-stage heart failure. The company's products include the HeartMate II® and HeartMate 3™ LVAS (Left Ventricular Assist Systems) and Thoratec® VAD (Ventricular Assist Device) with more than 20,000 devices implanted in patients suffering from heart failure. Thoratec also manufactures and distributes the CentriMag®, PediMag®/PediVAS®, and HeartMate PHP™ product lines. HeartMate 3 and HeartMate PHP are investigational devices and are limited by US law to investigational use. Thoratec is headquartered in Pleasanton, California. For more information, visit the company's website at http://www.thoratec.com.

Investor and media contact:

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