Indiana State Department of Health
An Equal Opportunity Employer

Michael R. Pence
Governor

William C. VanNess II, MD
State Health Commissioner

DATE: March 5, 2014

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

FROM: A. Scott Gilliam, MBA, CP-FS
Director, Food Protection Program

SUBJECT: Thoratec Corporation - RECALL [Medical Device]

AFFECTED PRODUCT: **HeartMate II® LVAS Pocket System Controller (the "Pocket Controller")**

SUMMARY: **Unclassified Recall; This safety advisory is being issued because some patients and caregivers have experienced difficulties with the process of changing from a primary system controller to their backup system controller.**

The HeartMate II Pocket System Controller can be identified by the catalog number located on the labels of the various packaging configurations. The following device catalog numbers are affected by this action:

- **HeartMate II Implant Kit with Pocket Controller: Catalog Numbers 106015 and 106016**
- **Pocket Controller: Catalog Numbers 106762 and 106017**
- **HeartMate II LVAD Pump and Pocket Controller Kit: Catalog Number 107801**
- **Pocket Controllers that have been removed from packaging: Model Number 105109 (found on side of each unit)**

Distributed nationwide.

SUGGESTED ACTION: **For consumer inquiry only. Clinicians and patients with questions may contact the company at 1-800-528-2577, or if calling from outside the USA, 1-925-847-8600 (7 days a week, 8-5 Pacific Time).**

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Recall -- Firm Press Release

Thoratec Corporation Issues Worldwide Urgent Medical Device Correction
Letter to Update its Labeling Regarding the Use of the HeartMate II® LVAS
Pocket System Controller

Contact:
Consumer:
(800) 528-2577
http://www.thoratec.com

FOR IMMEDIATE RELEASE - March 4th, 2014 - Thoratec Corporation initiated a voluntary worldwide Medical Device Correction in order to update its labeling and training materials for the HeartMate II® LVAS Pocket System Controller (the "Pocket Controller"). This safety advisory is being issued because some patients and caregivers have experienced difficulties with the process of changing from a primary system controller to their backup system controller. These difficulties have resulted in four deaths and five reports of loss of consciousness or other symptoms of hypoperfusion. Of these nine events, eight occurred in patients who were converted to the Pocket Controller after being originally trained on an older model, the EPC System Controller. Two of the deaths occurred in patients who attempted to exchange system controllers while alone and, contrary to the labeling, without contacting the hospital first. The Urgent Medical Device Correction Letter sent to hospitals on March 4, 2014 communicated the reported incident rate over the past year and a half since the introduction of the Pocket System Controller in August 2012.

Thoratec's investigations of these reports have not revealed any failures of the devices to meet specifications or deficiencies in quality control procedures. No product needs to be returned to Thoratec.

Consumers who have the HeartMate II LVAS Pocket Controller should immediately contact their doctor for retraining on use of the device and to receive updated Patient Handbook information.

Physicians who prescribe the HeartMate II LVAS Pocket Controller should immediately review the updated labeling and training materials provided in the Urgent Medical Device Correction Letter with all clinical personnel responsible for training patients and caregivers on the use of the Pocket System Controller. All patients using the Pocket Controller and their caregivers should be retrained on the use of the device and be provided with updated Patient Handbook information.

The Urgent Medical Device Correction Letter applies to all HeartMate II LVAS Pocket Controllers manufactured and distributed to date in the United States and worldwide. Distribution was initiated in the European Union in August 2012, and in the United States and Canada in May 2013. The Pocket Controller has been prescribed for 2,142 patients either at the time of the implantation of the HeartMate II LVAD, or as a replacement for an older System Controller model. This latter patient population, those receiving the Pocket Controller as a replacement for an older model, is at a higher risk of experiencing difficulty in the controller exchange process. These

patients may not have received adequate training regarding the differences between the two controllers, especially differences related to the connection of the driveline.

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Hospitals with ongoing HeartMate II LVAS patients using the Pocket System Controller should contact Thoratec if they have any questions. A copy of this press release can be found in Thoratec's SEC filing dated March 4, 2014, available on Thoratec's website, www.thoratec.com, under Investors/SEC Filings.

Clinicians and patients with questions may contact the company at 1-800-528-2577, or if calling from outside the USA, 1-925-847-8600 (7 days a week, 8-5 Pacific Time).

Thoratec has informed the FDA and other national competent authorities of this action.

Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail or by fax.

- Online: http://www.fda.gov/medwatch/report.htm
- Regular Mail: use postage-paid FDA form 3500 available at: http://www.fda.gov/MedWatch/getforms.htm. Mail to MedWatch 5600 Fishers Lane, Rockville, MD 20852-9787
- Fax: 1-800-FDA-0178

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