



Corporate Headquarters  
6035 Stoneridge Drive, Pleasanton, CA 94588 (800) 528-2577

4 March 2014

## URGENT: FIELD SAFETY NOTICE

**Affected devices:** All serial numbers of the HeartMate II<sup>®</sup> System Controller, Model No. 105109 (Pocket Controller<sup>™</sup>), provided within the following packaging configurations: HeartMate II LVAS Implant Kit with Sealed Grafts (Cat. Nos. 106015, 106016), HeartMate II System Controller (Cat. Nos. 106762, 106017) and HeartMate II LVAS Implant Kit (Cat. No. 107801).

### **Description of problem:**

Thoratec has become aware of a recent trend in reports of serious injuries and deaths associated with the process of changing from a primary System Controller to their back-up System Controller in patients using the "Pocket" System Controller model. The System Controller is the external unit that controls the function of the implanted HeartMate II Left Ventricular Assist Device (LVAD, see Figure 1).

The HeartMate II LVAS Pocket System 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 controller model (EPC System Controller). As of February 4, 2014, Thoratec has received four (4) reports (0.2% of the patient population) of patient deaths that occurred during attempts to exchange one Pocket System Controller for another. Two (2) of the deaths occurred when patients attempted to exchange controllers while alone and, contrary to the labeling, without contacting the hospital first. Another five (5) patients (0.2% of the patient population) experienced temporary loss of consciousness or other symptoms of hypoperfusion while exchanging Pocket System Controllers. Thoratec's investigations of these reports have not revealed any failure of the devices to meet specifications or deficiencies in quality control procedures.

Thoratec's analysis has shown that eight out of nine (8/9) of the events occurred in patients who were converted to the Pocket System Controller after being originally trained on the EPC System Controller at the time of their HeartMate II LVAS implant. The risk of serious injury or death when exchanging Pocket System Controllers is likely associated with the inability of the patient and/or caregiver to make a complete connection between the driveline and the Pocket Controller in a timely manner. For newly implanted patients, training on the HeartMate II LVAS is quite intensive over the course of several weeks between implantation and discharge from the hospital. However, patients who are converted from the EPC System Controller to the Pocket System Controller typically have only a relatively short period of training on the new controller during outpatient clinic visits. These patients may not have received adequate training regarding the differences between the two controllers, especially differences related to connection of the driveline.

EN - EU

[www.thoratec.com](http://www.thoratec.com)

The current labeling and training for the HeartMate II LVAS anticipates that a patient may need to exchange System Controllers during the course of VAD support. The process of exchanging System Controllers requires a brief interruption of pump function; however, this is a well-known risk and accepted aspect of VAD therapy. The patient labeling instructs patients to sit or lie down while changing System Controllers because they may become dizzy when pump function is interrupted. In addition, both the labeling and the user interface on the System Controller also instruct patients to call the hospital for assistance when confronted with a "Replace System Controller" alarm message.

The HeartMate II LVAS labeling and training materials will be updated with the following information:

- Clarification of the procedure for connecting the driveline to the Pocket System Controller
- Reinforcement of instructions that patients should follow all Pocket System Controller advisory alarms and call their hospital when prompted to do so by the controller's user interface.
- System Controller exchanges, if at all possible, should not be attempted without the immediate presence and assistance of a trained, competent caregiver.
- Recommendations for periodic refresher training and assessment of the continued capability of patients and/or caregivers to complete a System Controller exchange in a timely manner, and demonstration of competency with simulated devices.
- Factors that should be taken into account if the physician is giving consideration to converting a patient from the EPC to the Pocket System Controller.

**Immediate action to be taken:**

- 1) Review the attached revision to the HeartMate II LVAS labeling (Addendum to Instructions for Use and Addendum to Patient Handbook) with all personnel responsible for training patients and caregivers on the Pocket System Controller. Please complete and sign the attached Acknowledgement Form and return it to Thoratec via fax (+44 (0) 1480 454126) or e-mail a scanned copy to [europaeaninfo@thoratec.com](mailto:europaeaninfo@thoratec.com). If you feel that you should not be signing this form, please have the appropriate person sign it and forward it to Thoratec.
- 2) Retrain and reassess all ongoing patients and caregivers on exchanging Pocket System Controllers using the revised labeling. Highest priority should be given to retraining patients that were converted to the Pocket Controller from a previous model of System Controller. Once you have trained all appropriate clinical personnel and on-going patients on the contents of this Field Safety Notice, please sign the attached Training Confirmation Form and return it to Thoratec via fax (+44 (0) 1480 454126) or e-mail a scanned copy to [europaeaninfo@thoratec.com](mailto:europaeaninfo@thoratec.com). An Example Patient Training Documentation Form is included for your convenience.

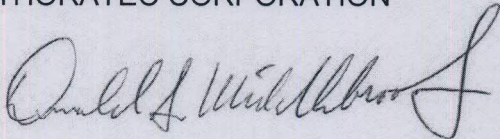
After the Acknowledgement and Training Confirmation forms have been returned to Thoratec no additional action is required.

This Field Safety Notice is being initially distributed in English. If English is not the official national language in your country, a translation will be provided to you as soon as possible for distribution to all appropriate personnel. The undersigned confirms that the national competent authorities have been informed about this Field Safety Notice.

Thank you for your cooperation in this matter. Thoratec is committed to keeping you informed of product-related clinical information that could help to optimize patient outcomes.

Sincerely,

THORATEC CORPORATION



Donald A. Middlebrook  
Vice President, Corporate Quality and Regulatory Affairs  
tel: (925) 730-4117  
e-mail: dmiddlebrook@thoratec.com

Attachments:

- A – Addendum to Instructions for Use (Document #110237)
- B – Addendum to Patient Handbook (Document #110249)
- C – Patient Training Documentation Form