



URGENT MEDICAL DEVICE CORRECTION

HeartMate II[®] System Controller, Model No. 105109 (Pocket Controller[™]), All Serial Numbers. Catalog Numbers 106016 and 106017

March 29, 2017

Dear Physician,

As follow-up to our most recent communication in September, 2015, we are advising you that Thoratec Corporation, an Abbott Laboratories company, is updating its alert guides, conducting a software upgrade and adding controller alignment markings for the HeartMate II[®] System Controller as part of a continued effort to ensure patients are successfully able to exchange their pocket controller in emergency situations.

A number of training and education improvements were completed in 2014 upon a voluntary field correction regarding the patient controller exchange process. As a result, we saw an 80% reduction in adverse event rates for System Controller exchanges, and a 90% shift of System Controllers being exchanged at home to being completed in the hospital, which is consistent with the instructions for use. Despite this, patients continue to experience a very low level of adverse events (including serious injury or death), at a rate of 0.1%, as a result of unnecessary patient controller exchanges. System Controller exchanges are best conducted by medical professionals in a controlled environment.

The current updates include:

- Updated labeling and alarm guides, which will be provided to you by an Abbott representative and included with the system controller packaging.
- A software upgrade that simplifies the System Controller alarm messaging by removing some advisory alerts on the patient's System Controller. These are non-critical alerts that will be seen by you and your staff on the System Monitor when patients come in for their next appointment. Removing these advisory alerts from the System Controller will further reduce the chance that a patient will react to such an alert by attempting to change System Controllers unnecessarily.
- Enhanced connector alignment markings on the System Controller and the LVAD's driveline connector to provide clearer aids in aligning the connectors during insertion/removal.



- The System Controller with new yellow markings will be provided to all newly implanted patients.
- Some existing patients will need to have their controller replaced (i.e. damaged or old model controller). In these cases, we will replace the controller at no cost; however, in such a case, the patient's implanted driveline will not be changing and will not have matching yellow markings.

All ongoing HeartMate II LVAS patients should receive software updates and the updated labeling and alarm guides from you and your VAD Coordinator. An Abbott representative will be in contact with you to assist in scheduling these updates. This office visit should include:

1. Software updates on the primary and backup System Controllers, with support from authorized Abbott representatives.
2. Explanation of the latest software update to the patient (and caregivers).
 - The alarm notification system was updated to remove advisory alerts on the patient's System Controller. These are non-critical alerts that will be seen by the physician on the System Monitor when the patient goes in for the next routine appointment.
3. 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.

Should you have questions regarding this notice, please contact Abbott Technical Services at +46-8474-4147, which is available 24 hours a day, 7 days a week. Alternatively, your Abbott Sales Representative is available to answer any questions you may have.

We apologize for any difficulties this may cause you and your patients. Abbott is committed to providing the highest quality products and support.

Thank you for your continued support.

Sincerely,



Susan Jezior Slane

Divisional Vice President, Quality Assurance and Compliance
Abbott Cardiovascular and Neuromodulation