1 September 2010

# URGENT FIELD SAFETY NOTICE

**Affected devices:** Thoratec HeartMate II® Left Ventricular Assist System (HM II LVAS) System Controllers
Model Numbers: 103695 (HM II Implant Kit, US labeling), 103693 (HM II Implant Kit, EU labeling), 103696 (System Controller, US labeling), 103692 (System Controller, EU labeling)
Serial Numbers: All serial numbers with "EPC" prefix

**Description of problem:** Thoratec has become aware of a recent trend in complaints related to the HM II System Controller. Bending fatigue has resulted in broken data communication wires in the power leads, and bent pins in the connectors between the System Controller and its power sources (batteries, Power Base Unit [PBU] or Power Module [PM]) have interfered with the connections to the System Controller power leads. Broken wires and bent connector pins have the potential to interrupt pump function.


As of August 2010, approximately 1% of patients supported with the HeartMate II LVAS have reported malfunctions that were attributed to bending fatigue resulting in broken wires in the power leads. Approximately 22% of patients on HeartMate II LVAS support have experienced bent pins in the power lead connections while changing from batteries to AC power or *vice versa*. No adverse clinical effects were reported for any of the incidents except for two patients who exhibited symptoms of reduced blood flow until the System Controller could be replaced. All incidents were successfully managed by replacing the System Controller (with a back-up controller provided to every patient) according to the Instructions for Use, Patient Handbook and other patient training.

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Tel 916-852-2833 Fax 916-638-3216

**Symptoms of problem:** Broken wires in the System Controller power leads or bent pins in the power lead connections result in various alarms, such as “Red Heart” hazard alarms, low battery, power cable disconnect, or inability to communicate with the System Monitor or Display Module. Alarms may be transient or continuous. Bent pins are readily visible in the power lead connectors when they are disconnected and may prevent connection of the power lead connectors. If alarms are generated or resolved by manipulation of the strain reliefs adjacent to the power lead connectors, one or more wires in the power leads may have broken.

**Immediate action to be taken:** You should contact all ongoing patients using the affected System Controllers (serial numbers starting with “EPC”) to determine if they are experiencing any unexplained intermittent alarms or have any bent pins in the connectors between the System Controller and the power sources. If so, you should request that they return to the hospital so that their power leads can be examined. If you need further assistance with this evaluation, please contact Thoratec Europe Ltd by phone at: +44 (0) 1480 455200.

**Preventive action:** Please review the attached addendum to the HeartMate II labeling with all VAD clinicians and ongoing HeartMate II LVAS patients. The information in the addendum is intended to prolong the useful life of the power leads. Additional instructions are also provided to prevent damage to the power lead connector pins when changing power sources.

**Acknowledgement:** Please complete and sign the attached Acknowledgement Form and fax it to Thoratec Regulatory Affairs at +44 (0) 1480 454126 or e-mail to europeaninfo@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. Once this Urgent Field Safety Notice has been reviewed and a signed Acknowledgement Form has been faxed, no additional action is required.

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 as well as to continuous improvement projects that could enhance product performance.

Sincerely,

THORATEC CORPORATION

Donald A. Middlebrook
Vice President, Corporate Quality and Regulatory Affairs

# Acknowledgement Form

**HeartMate II LVAS Percutaneous Lead**

**PLEASE COMPLETE ALL REQUESTED INFORMATION AND RETURN IMMEDIATELY**

Please check all boxes below before returning this form.

☐ I have reviewed the symptoms that may be associated with broken wires in the System Controller power leads or bent pins in the power lead connections, and emphasized the instructions for proper care with all of my ongoing patients.

☐ I understand the risk information that Thoratec has provided in this notice, and that the labeling for commercially distributed devices will be revised to reflect this new information from clinical experience. I also agree to carefully review this risk vs. benefit information with prospective patients.

☐ I acknowledge that I have received Thoratec's Urgent Field Safety Notice (dated 1 September 2010) concerning the System Controller power leads and connectors for the Thoratec HeartMate II LVAS and that I understand the contents and have communicated the contents to the appropriate personnel.

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☐ (Optional) I need more information. Please contact me at the number listed below.

Name (print) _____

Signature: _____

Facility Name: _____

Date: _____

Phone Number: _____

E-mail : _____

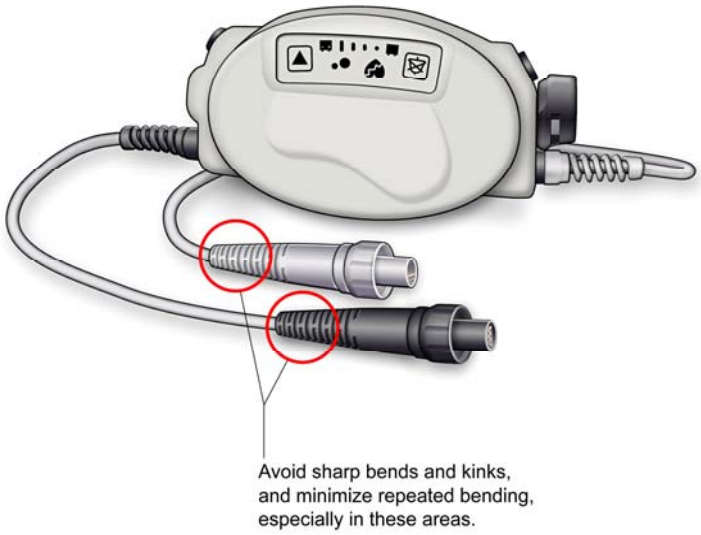
**PLEASE FAX THIS ACKNOWLEDGEMENT FORM TO**
**THORATEC CORPORATION**
**ATTN: REGULATORY AFFAIRS**
**Fax: +44 (0) 1480 454126 or e-mail: europeaninfo@thoratec.com**

## Caring for the System Controller Power Leads

While your heart pump should allow you to return to many of your daily activities, it is extremely important to protect your power leads, especially if you are active. Always keep your power leads protected from sharp bends, kinking and repetitive bending. Damage to the power leads, depending on the degree, may cause the pump to stop.

Remember to follow these recommendations:

- Do not severely bend your power leads, especially at the strain reliefs near the System Controller connectors.
- When transporting your System Controller, avoid placing it in bags or accessories that cause the power leads, especially near the connectors, to have sharp bends.
- If you carry your System Controller in a carrying case, don't "catch" the power leads in the zipper.
- Minimize repeated bending of the power leads, especially near the connectors.
- Do not let the power leads become twisted.




## *Making and Breaking Connections to Battery Power*

While changing from the AC power supply (Power Module [PM] or Power Base Unit [PBU]) to batteries (and vice versa) is a routine procedure for HeartMate patients, it is important to use care when making or breaking connections. When making or breaking connections to battery power, be sure to:

- Line up the "half moon" connectors, as shown in **Figure 1**.
- Gently bring the connectors together, turning them slightly to make the connection, if needed.
- Never pull, twist, or turn the strain relief portion of the connectors (where the connector and cable meet).
- When you feel the connectors engage, push them together firmly until fully connected – WITHOUT twisting or forcing the connectors.
- Once they are fully connected, secure the connection between the connectors by turning *the nut* on the connector (**Figure 2**). Hand tighten the nut; do NOT use tools. Do NOT twist the connectors when turning the nut.
- When disconnecting, turn *the nut* on the connector until the connection is loose and then gently pull the connectors apart.
- Never twist connectors or pull them apart at an angle.

Figure 1

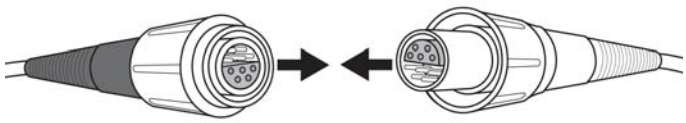


Figure 2