February 23, 2012

URGENT: MEDICAL DEVICE CORRECTION

Affected devices: All lot numbers of the Thoratec HeartMate II® Left Ventricular Assist System (HM II LVAS) Sealed Outflow Graft Short Bend Relief (Catalog No. 104692) and Thoratec HeartMate II Sealed Outflow Graft (Catalog No. 103393). All serial numbers of the Thoratec HeartMate II Implant Kit with Sealed Grafts (Catalog Nos. 104911 and 104912).

Description of problem:

Thoratec has become aware of a recent trend in reports of disconnection of the bend relief from the sealed outflow graft, a component of the HeartMate II LVAS. The bend relief is a tube of ePTFE surrounding the outflow graft proximal to the pump that is designed to prevent kinking of the outflow graft as shown in Figures 1 and 2.

Figure 1. HeartMate II LVAS, Implantable and External Components
Thoratec has distributed 3,852 Sealed Outflow Grafts since the introduction of the product in February 2010. As of February 6, 2012, Thoratec has received five (5) reports of patients undergoing surgical interventions for symptoms such as low pump flow, hemolysis, fluctuations in pump flow, speed and/or power, or worsening symptoms of heart failure where the outflow graft bend relief was found to be disconnected from the outflow graft. As of the date of this letter, four (4) of these patients continue on VAD support, and one (1) died of multi-organ failure after several days of ECMO support; however, it is not clear as to what extent the disconnected outflow graft bend relief may have caused or contributed to this patient’s condition.

Disconnection of the bend relief from the outflow graft may allow the graft to kink or otherwise deform, possibly resulting in the observed symptoms. Thoratec has received an additional twenty-four (24) reports of disconnected bend reliefs that were observed in x-ray images or during surgical procedures (e.g. transplant, explant, pump exchange) unrelated to any symptoms likely to be associated with disconnected bend reliefs. In three (3) of the total of 29 reports serious bleeding occurred during surgery, likely caused by abrasion of the graft by the disconnected bend relief.

The incidence of surgical interventions possibly related to disconnected outflow graft bend reliefs is 0.13% (5/3852). The incidence of bleeding possibly related to abrasion of the graft is 0.08% (3/3852). The overall incidence of disconnected outflow graft bend reliefs is 0.75% (29/3852).

**Symptoms of problem:**

Most reports of detached bend reliefs have not been associated with symptoms. The detachment of the bend relief was observed during an unrelated surgical procedure or during review of routine x-ray images. As described above, disconnected bend reliefs have the potential to allow outflow graft kinking and/or graft abrasion. Symptoms associated with a kinked outflow graft may include low pump flow, hemolysis, bleeding, fluctuations in pump flow, speed and/or power, or worsening symptoms of heart failure.
Immediate action to be taken:

1) For all new HeartMate II LVAS implant procedures, attach the bend relief to the outflow graft in accordance with the revised instructions attached to this letter (Attachment A).

   CAUTION: Failure to connect the bend relief so that it is fully and evenly connected can allow kinking and abrasion of the graft, which may lead to serious adverse events such as low LVAD flow and/or bleeding.

   CAUTION: Care should be taken to ensure the sealed outflow graft bend relief remains connected during sternal closure.

2) If a HeartMate II LVAS patient exhibits symptoms such as low pump flow, hemolysis, bleeding, fluctuations in pump flow, speed and/or power, or worsening symptoms of heart failure, the possibility of a disconnected outflow graft bend relief should be considered. Treat the patient according to best clinical judgment and your institution’s standard clinical practice guidelines. Report any such cases involving a disconnected bend relief to your local Thoratec representative.

Preventive action:

1) Review the attached revision to the HeartMate II LVAS labeling, including the new caution statements, with all surgical personnel responsible for implanting the HeartMate II LVAS. If the bend relief cannot be attached to the outflow graft during implantation of the HeartMate II LVAS, replace the graft and the bend relief.

2) Review the possible symptoms of disconnected outflow graft bend reliefs as described in this notice with all personnel responsible for the clinical management of HeartMate II LVAS patients.
Acknowledgement: Please complete and sign the attached Acknowledgement Form and fax it to Thoratec Regulatory Affairs at (925) 847-8571. 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 Medical Device Correction has been reviewed and a signed Acknowledgement Form has been returned to Thoratec, no additional action is required.

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
Acknowledgement Form
HeartMate II LVAS Sealed Outflow Graft Bend Relief

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 disconnected bend reliefs

☐ 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 Medical Device Correction (dated February 23, 2012) concerning the bend relief for the HeartMate II LVAS Sealed Outflow graft and that I understand the contents and have communicated the contents to the appropriate personnel.

☐ (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
(925) 847-8571
ATTACHMENT A
**Important Information Update**

**Attaching the Sealed Outflow Bend Relief to the Sealed Outflow Graft**

Slide the bend relief over the metal fitting of the sealed outflow graft toward the locking screw ring until it snaps into place. Visually inspect that the bend relief is fully connected and seated to the sealed outflow graft (see Figure 1). This is confirmed by performing both of the following steps:

a. Trying to unseat the connected bend relief from the metal fitting by gently pulling the bend relief back toward the anastomosis.  
   **AND**  
   b. Trying to rotate the connected bend relief by rotating the metal clip around the entire circumference of the metal fitting. If the bend relief has been fully and evenly connected, the metal clip should rotate with ease and not detach from the snap ring metal fitting.

**NOTE:**
Ensure when you are rotating the bend relief that you do not rotate/twist the sealed graft. Verify that the sealed graft is not twisted or kinked by checking the alignment of the black line on the graft.

**CAUTION!**
Failure to connect the bend relief so that it is fully and evenly connected can allow kinking and abrasion of the graft, which may lead to serious adverse events such as low LVAD flow and/or bleeding.

![Correct and Incorrect Bend Relief Connection](image)

**Figure 1. The Bend Relief Connection to the Sealed Outflow Graft (Correct and Incorrect)**
Securing the Pump and Connections

Once the flow through the blood pump is satisfactory, assure that all sealed inflow and sealed outflow connections are dry and secure. Obtain hemostasis and close all wounds in the standard fashion. Prior to leaving the O.R., immobilize the percutaneous lead with a stabilization belt or abdominal binder.

CAUTION!!

Care should be taken to ensure the sealed outflow graft bend relief remains connected during sternal closure.