

U.S. Food and Drug Administration
Protecting and Promoting Your Health

Serious Adverse Events with Implantable Left Ventricular Assist Devices (LVADs): FDA Safety Communication

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Date Issued: August 5, 2015

Audiences:

- Health care providers treating heart failure patients
- Patients with a LVAD
- Caregivers of patients with a LVAD

Specialties: Cardiology, Cardiac Surgery, Heart Failure, Heart Transplantation

Product:

Implantable LVADs help the left ventricle (the main pumping chamber of the heart) circulate blood throughout the body in patients with advanced heart failure. The devices consist of a blood pump, power pack and controller. The blood pump is implanted inside a patient's body and attached to the heart's left ventricle and to the aorta. The power pack and controller are connected to the blood pump and carried by the patient outside the body.

LVADs are approved for bridge-to-transplant (BTT) or destination therapy (DT). BTT refers to providing circulatory support to a patient at risk of imminent death from non-reversible left ventricular heart failure until a donor heart becomes available for a heart transplant. DT refers to providing circulatory support to a patient with end-stage left ventricular heart failure who is not candidate for a heart transplant.

To date, there are two implantable LVADs approved by the FDA:

- The HeartMate II Left Ventricular Assist System manufactured by Thoratec Corporation, approved for BTT in 2008 and DT in 2010 and
- The HeartWare Ventricular Assist System HVAD manufactured by HeartWare, Inc., approved only for BTT in 2012.

Purpose: The FDA is alerting health care providers, patients, and caregivers about serious adverse events associated with LVADs. These adverse events include an increased rate of pump thrombosis (blood clots inside the pump) with Thoratec's HeartMate II and a high rate of stroke with the HeartWare HVAD since approval of the devices. We are also aware of bleeding complications associated with both devices.

Summary of Problem and Scope:

The FDA is aware of serious adverse events associated with both devices.

Thoratec HeartMate II:

The FDA has received reports and information from a variety of sources indicating an increase in the rate of pump thrombosis events in patients implanted with the HeartMate II. Information also shows that patients are experiencing pump thrombosis events earlier than observed during the clinical trials conducted to support the product's approvals in 2008 (BTT) and 2010 (DT). For example, two analyses in the scientific literature reported the confirmed (after explant) HeartMate II pump thrombosis rate as high as 8.4% of implanted devices at 3 months ([Starling et al, 2013](http://www.nejm.org/doi/full/10.1056/NEJMoa1313385)) and 6% of implanted devices at 6 months ([Kirklin et al, 2014](http://www.sciencedirect.com/science/article/pii/S105324981301526X)). This is compared to 1.6% of implanted devices at one year during the BTT clinical trial and 3.8% of implanted devices at 2 years during the DT clinical trial. Pump thrombosis is a serious complication that can require repeat surgery to replace the pump or can lead to death.

HeartWare HVAD:

The FDA is aware of [recently reported](http://ir.heartware.com/phoenix.zhtml?c=187755&p=irol-eventDetails&EventId=5188781) results from a clinical trial designed to evaluate the safety and effectiveness of the HeartWare HVAD when used for the DT indication. Investigators reported 28.7% of HVAD patients experienced one or more strokes over two years, compared to 12.1% among patients implanted with the control device (HeartMate II). Although the HVAD is not currently approved for DT, it is the same device approved for the BTT indication.

Stroke is a serious complication that can lead to permanent patient disability and death.

Thoratec HeartMate II and HeartWare HVAD:

The FDA is aware of bleeding complications related to both the Thoratec HeartMate II and HeartWare HVAD, through adverse event reports and information from a variety of sources. The cause of bleeding complications is not fully understood, but is likely due to many different factors. One possible factor may be modification to blood thinning (anticoagulation) therapy in an attempt to lower the risks of pump thrombosis and [embolic stroke](http://www.nlm.nih.gov/medlineplus/ency/article/000726.htm).

Bleeding is a serious complication that can lead to death.

Recommendations:

The FDA recognizes that LVADs are life-sustaining, life-saving devices for patients with advanced left ventricular heart failure. When used for the currently approved indications in appropriately selected patients, we believe the benefits of these LVADs continue to outweigh the risks. However, the FDA also believes it is important for health care providers and patients to be aware of this important information when considering the use of these devices and clinical management of their patients.

Health Care Providers:

- Perform a thorough clinical evaluation, assessing the benefit-risk profile of each patient in determining the most appropriate treatment plan and, if necessary, selecting a device.
- Consider the risks for pump thrombosis, stroke, and bleeding when determining the appropriate therapy for individual patients.
- Review the current device labeling prior to making treatment decisions if you are considering using either of these devices.
- Return all explanted LVAD devices and components to their respective manufacturer. In the case of LVAD-related pump thrombosis and other adverse events, manufacturer evaluation of the affected device is critical to better understand the reasons for these adverse events.

Patients/Caregivers:

- Discuss openly and in detail the benefits and risks of any therapy being considered by your heart failure specialist, cardiologist and surgical team. This discussion should include:
 - your risks of developing an adverse event like a blood clot or stroke and the potential side effects if you do experience an adverse event.
 - how the benefits and risks of the device compare to other non-LVAD medical therapies.

- If you have any concerns regarding your device, discuss them with the health care providers managing your heart failure.

FDA Actions:

Thoratec HeartMate II:

The FDA has extensively evaluated all available information, including adverse event reports received by FDA, data from Thoratec, data from the scientific literature, and data from the Interagency Registry for Mechanically Assisted Circulatory Support (**INTERMACS** (<http://www.uab.edu/medicine/intermacs/>)). Our analysis did not identify discrete, device-specific reasons for the reported rise in pump thrombosis. The FDA acknowledges the risks of pump thrombosis for HeartMate II have increased since the time of approval. However, careful review of all available data suggests the benefits of the device, when used in appropriately selected patients, continue to outweigh the risks for the currently approved indications.

The FDA has been working with Thoratec to better understand and explain the increased incidence of pump thrombosis. On August 5, 2014, the FDA approved updated **labeling** (http://www.thoratec.com/assets/download-tracker/HMII/10000987/10000987_A_HMII_DTPASThrombosis_Addendum.pdf) for the HeartMate II that includes the risk of pump thrombosis.

Thoratec is currently conducting a prospective, multi-center, non-randomized study designed to assess the incidence of HeartMate II pump thrombosis and to identify the risk factors associated with pump thrombosis events. Details of this study can be found on the National Institutes of Health ClinicalTrials.gov website: <https://clinicaltrials.gov/show/NCT02158403> (<https://clinicaltrials.gov/show/NCT02158403>).

HeartWare HVAD:

The FDA is concerned about the reported stroke rates but at this time, believes the benefits of using the device continue to outweigh the risks for the currently approved BTT indication. The FDA also believes it is appropriate to continue the clinical investigation of this device in the DT population with the careful monitoring procedures currently in place. The FDA continues to evaluate all available information, including adverse event reports received by FDA, data from HeartWare, data from the scientific literature, and data from INTERMACS for the currently approved BTT indication, as well as the data from the DT clinical trial. As more information about the risks associated with the device becomes available, the FDA will work with HeartWare to identify any future actions that may be appropriate.

HeartWare is currently conducting a prospective, randomized, controlled, unblinded, multi-center study to assess whether optimal blood pressure management can help lower the incidence of stroke in DT patients implanted with an HVAD. Details of this study can be found on the National Institutes of Health ClinicalTrials.gov website: <https://clinicaltrials.gov/show/NCT01966458> (<https://clinicaltrials.gov/show/NCT01966458>).

Reporting Problems to the FDA:

Prompt reporting of adverse events can help the FDA identify and better understand the risks associated with LVADs.

If you suspect or experience a problem with an LVAD, we encourage you to file a voluntary report through **MedWatch, the** (<http://www.fda.gov/Safety/MedWatch/HowToReport/default.htm>) **FDA Safety Information and Adverse Event Reporting program** (<http://www.fda.gov/Safety/MedWatch/HowToReport/default.htm>). Health care personnel employed by facilities that are subject to **FDA's user facility reporting requirements** (<http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/PostmarketRequirements/ReportingAdverseEvents/default.htm>) should follow the reporting procedures established by their facilities.

Additional Resources:

- **Thoratec Corporation: HeartMate II Instructions for Use and Manuals (USA)** (http://www.thoratec.com/assets/download-tracker/HMII/10000987/10000987_A_HMII_DTPASThrombosis_Addendum.pdf)
- **HeartWare, Inc.: HVAD System Instructions for Use and Manuals (USA)** (<http://www.heartware.com/clinicians/instructions-use>)
- **Kirklin JK, Naftel DC, Kormos RL, et al.: Interagency Registry for Mechanically Assisted Circulatory Support (INTERMACS) analysis of pump thrombosis in the HeartMate II left ventricular assist device. J Heart Lung**

[Transplant 2014;33:12-22.](#)



<http://www.sciencedirect.com/science/article/pii/S105324981301526X>



- [Starling RC, Moazami N, Silvestry SC, et al.: Unexpected abrupt increase in left ventricular assist device thrombosis. N Engl J Med 2013;370:33-40.](#)
<http://www.nejm.org/doi/full/10.1056/NEJMoa1313385>
- [Interagency Registry for Mechanically Assisted Circulatory Support](#)
<http://www.uab.edu/medicine/intermacs/> (INTERMACS)

Contact Information:

If you have questions about this communication, please contact CDRH's Division of Industry Communication and Education (DICE) at DICE@FDA.HHS.GOV (<mailto:DICE@FDA.HHS.GOV>), 800-638-2041, or 301-796-7100.

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