



URGENT MEDICAL DEVICE RECALL

HeartMate 3™ Left Ventricular Assist System Catalog #106524US LVAS KIT, HM3

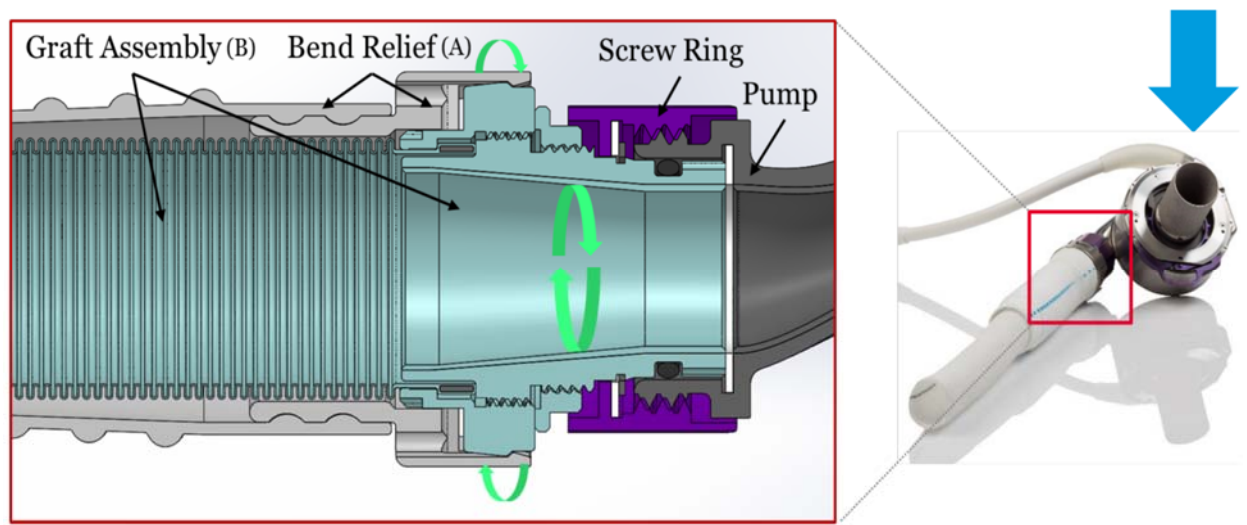
May 21, 2018

Dear Physician,

We are providing additional information to the letter we recently issued associated with HeartMate 3 (HM3) Outflow Graft twist occlusions. The prior letter, dated April 5th, 2018, pointed out that 0.72% of 4,467 implants worldwide have experienced a twist in the Outflow Graft known to result in patient injury or death. For your reference, the prior letter is included. This current communication provides further clarification on the origin of the outflow graft twist, the persistent low flow alarm, additional recommendations for patient management, and future mitigations that we will implement. We have formulated this communication in conjunction with the US Food and Drug Administration.

Origin of Outflow Graft Twist in HeartMate 3 LVAS

The HM3 is designed to allow for Outflow Graft connector rotation by the surgeon after connection to the pump, so that proper alignment of the Outflow Graft can be made during implantation without disconnecting the Outflow Graft connector from the pump. Appropriate tightening of the Screw Ring (see below) during implantation reduces, but does not eliminate, the propensity of the Outflow Graft connector to rotate. *In vivo*, normal forces can rotate the metallic Outflow Graft connector; if the rotation is in one direction only (instead of back-and-forth (clockwise/counter-clockwise)), then twist will accumulate in the graft. Accumulation of Outflow Graft twist can occur at any time point post-implantation. The twist may deform the Outflow Graft (a twist occlusion) and reduce or stop pump flow. The time course from the beginning of an accumulation of twist to an occlusion is unknown and may be variable among patients. Occlusion of the HM3 Outflow Graft often requires urgent surgical intervention.



Persistent Low Flow Alarm

During normal communication between the HM3 pump and controller, the HM3 pump calculates an estimated flow and sends the information to the controller once every second. The controller will trigger a low flow alarm if the estimated flow it receives from the pump is below 2.5 liters per minute (lpm) for more than 5 seconds.

A **persistent** low flow alarm presumed to be caused by Outflow Graft twist is one that is not resolved after addressing patient medical conditions such as hypertension, low preload, right heart dysfunction, inflow occlusion, volume status and arrhythmias.

Patient Management – Ongoing Patients

Abbott consults with a Medical Advisory Board (MAB) to help address patient management. Based on input from the MAB, Abbott recommends the following for existing HM3 patients:

- Patients should be followed per recommendations from the American Society of Echocardiography (J Am Soc Echocardiogr 2015;28:853-909), which states that “An LVAD surveillance echo exam should be considered at approximately 2 weeks after device implantation or before index hospitalization discharge (whichever occurs first), followed by consideration of surveillance transthoracic echo (TTE) at 1, 3, 6, and 12 months post implantation and every 6 to 12 months thereafter.”
- TTE imaging is not a definitive tool to identify an outflow graft twist obstruction. However, it can be used as an indirect assessment of obstruction by imaging the size of the left ventricle, the mitral valve and aortic valve opening, and diastolic velocity (inflow or outflow).
- A decrease in flow over time may be an indicator of Outflow Graft twist obstruction. If such a trend in flow is observed, or if flow velocity anywhere in the Outflow Graft exceeds 2 meters/sec (J Am Soc Echocardiogr 2015;28:853-909) more frequent surveillance echo exams than listed above, or other investigative methods, may be necessary.
- If a persistent low flow alarm, as defined above (i.e., a low flow alarm not resolved after all relevant patient medical conditions having been ruled out as the cause), occurs at any time following implant, a Computed Tomography (CT) angiogram should be urgently obtained, if there are no contraindications, to identify a possible Outflow Graft twist occlusion.
- In the event that surgical repair of the Outflow Graft is needed due to a twist occlusion, the Outflow Graft Bend Relief should be reattached in its original state or repaired to prevent bending, abrasion or occlusion of the Outflow Graft at the graft’s attachment point to the pump.

Patient Management – New Patients

During implant, when attaching the Outflow Graft to the Pump Cover, a clicking sound will be heard as the Screw Ring is tightened. Continue turning the Screw Ring clockwise until it comes to a complete stop and stops clicking. Firmly hand-tightening the Screw Ring may reduce the risk of Outflow Graft twisting by increasing the resistance to metallic Outflow Graft connector rotation. To avoid damaging the Outflow Graft assembly, do not use tools to tighten the screw ring. This updated information (see Appendix 1) has been incorporated into the Instructions for Use.

Future System Enhancements

Future mitigations to prevent Outflow Graft twist occlusion for future interventions or implantations are being investigated and will be implemented after design verification and validation are complete and regulatory approval is received. We will promptly inform you when these mitigations become available.

Please complete the acknowledgement form included in this packet and return it to Abbott, as noted on the acknowledgement form.

If you have questions, please contact your local Abbott MCS Clinical Specialist or MCS HeartLine 1-800-456-1477 which is available 24 hours a day, 7 days a week.

Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail, or by fax.

- Complete and submit the report Online: www.fda.gov/medwatch/report.htm
- Regular Mail or Fax: Download form www.fda.gov/MedWatch/getforms.htm or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form, or submit by fax to 1-800-FDA-0178

Thank you for your continued support.

Sincerely,



Lance Mattoon
Divisional Vice President, Quality
Abbott Heart Failure

Appendix 1: Updated IFU Information

Surgical Procedures 5

Attaching the Sealed Outflow Graft to the Pump

FOR THIS TASK YOU NEED:

- 1 sealed Outflow Graft with bend relief (attached to the Aorta)
- 1 Pump (inserted into the Apical Cuff)

TO ATTACH THE SEALED OUTFLOW GRAFT:

1. Remove the thread protector from the Pump and the Outflow Graft. Using the Screw Ring, attach the Outflow Graft to the Pump Cover, turning the ring clockwise. You will hear a clicking sound as you tighten the Screw Ring (this is normal). Continue turning the ring clockwise until it comes to a complete stop and stops clicking. See **Figure 5.34**.

CAUTION !

Firmly hand-tighten the Screw Ring to ensure sufficient resistance to Outflow Graft twisting. To avoid damaging the assembly, do not use tools to tighten the Screw Ring.

WARNING !

- Twisting of the Outflow Graft has been identified in some patients post-operatively. Occurrences of twisting have resulted in graft occlusion, thrombosis, and/or death. The accumulation of twist within the graft is related to rotation of the metallic Outflow Graft connector within the attached Outflow Graft Bend Relief connector.
- Firmly hand-tightening the Screw Ring may reduce the risk of Outflow Graft twisting by increasing the resistance to metallic Outflow Graft connector rotation. Hand-tightening will not eliminate metallic Outflow Graft connector rotation.
- Twisting of the Outflow Graft can manifest as persistent low flow unexplained by other causes. It may be confirmed by appropriate imaging, such as computed tomography (CT) angiography.
- In the event that surgical intervention of the Outflow Graft is used to correct an Outflow Graft twist, the Outflow Graft Bend Relief should either be reattached in its original state or suitably repaired to prevent subsequent kinking of the Outflow Graft.

Appendix 1: Updated IFU Information (continued)

5 Surgical Procedures



Figure 5.34 Attach the Graft

2. Verify that the graft is not twisted or kinked by checking the position of the black line on the graft above and below the bend relief. The line should be straight.



Acknowledgement Form

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

HeartMate 3™ Left Ventricular Assist System
Catalog #106524US LVAS KIT, HM3

By signing below I acknowledge that I understand the information that Abbott has provided in this Field Safety Notification related to Outflow Graft twist obstructions, and that the IFU for commercially distributed devices will be revised to reflect this new information.

Name (print): _____
Title (print): _____
Signature: _____
Facility Name: _____
Date: _____
Phone Number: _____
E-mail: _____

**PLEASE RETURN THIS ACKNOWLEDGEMENT FORM TO
Abbott Cardiovascular and Neuromodulation
Email: HM3Notices@Abbott.com**



IMPORTANT MEDICAL DEVICE ADVISORY

HeartMate 3™ Left Ventricular Assist System Catalog #106524US LVAS KIT, HM3

April 5th, 2018

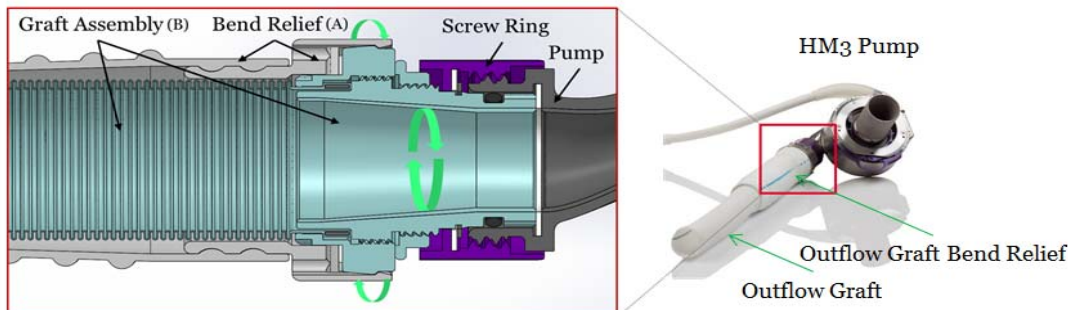
Dear Physician,

In an effort to keep you informed of important device updates that can help ensure the safety of your patients, Abbott is advising our physician partners that we have received reports of outflow graft twist occlusions in the HeartMate 3 (HM3) Left Ventricular Assist System. As a result, patients whose devices experience these outflow graft occlusions will experience a **persistent** low flow alarm.

Currently, we are aware of 32 total reports associated with outflow graft twisting in the HM3 device, an occurrence of 0.72 percent based on 4,467 implants worldwide. Outflow graft twists can result in serious adverse events such as hemodynamic compromise, thrombus, and death.

Description of Outflow Graft Twisting in HeartMate 3 LVAS

The Outflow Graft is the conduit for blood flow from the HM3 pump to the ascending Aorta.



Normal *in vivo* forces associated with heart beats, respiration and patient activity can cause small rotations between the Outflow Graft Bend Relief (A) and the pump. These rotations are expected and appear to be 'back and forth' without accumulation in either direction. However, there is the potential for these forces to be preferentially translated to the outflow graft (B) in either the 'back' or 'forth' direction which may deform the outflow graft and reduce pump flow. The accumulation of outflow graft twist can occur at any point beyond implant. Postoperative twisting and occlusion of the HM3 outflow graft may result in the need for surgical intervention following the original implant procedure.

Patient Management for Physicians

Below is information for physicians managing patients that will be implanted or already implanted with HM3 devices:

- During implant, when attaching the Outflow Graft to the Pump Cover, a clicking sound will be heard as the Screw Ring is tightened. Continue turning the Screw Ring clockwise until it comes to a complete stop and stops clicking for a firm hand tightened connection.
- If a low flow alarm persists at any time following implant, and other potential causes such as hypertension, low preload, right-heart failure and inflow occlusion have been considered for cause, a Computed Tomography (CT) angiography should be taken to identify the possibility of an outflow graft twist occlusion.
- In the event surgical repair of the outflow graft is needed due to a twist occlusion, the Outflow Graft Bend Relief should be reattached in its original state or repaired to prevent further kinking or occlusion of the graft.

Physicians managing patients that exhibit a persistent low flow alarm should determine patient care recommendations based on each unique clinical case.

We apologize for difficulties this may cause you and your patients. Abbott remains committed to patient safety and providing the highest quality products and services.

If you have questions, please contact your local Abbott MCS Clinical Specialist or MCS HeartLine 1-800-456-1477 which is available 24 hours a day, 7 days a week.

Thank you for your continued support.

Sincerely,



Lance Mattoon
Divisional Vice President, Quality
Abbott Heart Failure