IMPORTANT MEDICAL DEVICE ADVISORY

HeartMate 3™ Left Ventricular Assist System
Catalog # 106524INT – LVAS KIT, HM 3
105581INT – Packaged assembly Outflow, HM3(INT)

DATE, 2017

Dear Physician,

Abbott has observed cases in which the outflow graft bend relief (OGBR) on the HeartMate 3 (HM3) Left Ventricular Assist System (LVAS) was not fully and evenly secured to the outflow graft. As a result, we conducted an internal review of x-rays from both the U.S. MOMENTUM 3 IDE and Continuous Access Protocol (CAP) studies, and identified additional cases where the OGBR was not properly secured.

At this time, we are providing you this letter to notify you of updated patient management recommendations and a new training to reinforce the OGBR connection technique described in the HM3 LVAS Instructions for Use (IFU).

Estimation of Rate of OGBR Disconnect

We have observed 33 cases worldwide (approximately 1.01%) where the OGBR was not fully and evenly secured to the outflow graft. Specific rates are as follows:

- *Commercial Distribution (OUS): Total number of separations: 2 filed as complaints. Number shipped OUS 2083 (through Feb 2017). Rate: (0.1%)*
- *IDE (US): Total number of separations: 28 (24 identified from Abbott review of 448 x-rays, remaining 4 from study sites). 28/452 (6.20%)*
- *CAP (US): Total number of separations: 3 (2 from Abbott review of 75 x-rays, 1 from surgeon x-ray review). 3/76 (3.95%)*

Clinical Impact

There may be no symptoms associated with an OGBR that is not fully and evenly connected; however, there is potential: (1) for kinking of the outflow graft leading to a low flow state that may result in heart failure symptoms and reoperation; or (2) for mechanical wear and tear of the outflow graft leading to intra-pericardial bleeding potentially causing hemodynamic compromise that may require emergency surgery.

Please see the cautionary statement in Appendix A.

Training

Abbott's Mechanical Circulatory Support (MCS) field team and clinical specialists will be scheduling time to conduct training with surgeons who are implanting HM3 at your center. Training will emphasize the OGBR connection to the outflow graft and will include a hands-on demonstration on how to fully and evenly secure the connection and guidance on evaluating post-implant chest x-rays to assess whether the OGBR connection is successful.

All training should be scheduled and completed by August 31, 2017.

Patient Management Recommendations

Currently implanted patients

- For patients already implanted with the HM3 LVAS, please review a current x-ray to ensure the OGBR is fully and evenly secured to the outflow graft. Where images of the outflow graft and bend relief are not available, please take images at the patient's next visit and review to ensure the OGBR is properly secured.

Newly implanted patients

- For newly implanted patients, please take an x-ray one day post-implant and review it to ensure the OGBR is fully and evenly secured.

Disconnected OGBR identified during x-ray review

- If a disconnected OGBR is identified during x-ray review, physicians should determine patient care recommendations based on each unique clinical case. Additionally, review with your Abbott clinical specialist to file a complaint through the normal complaint process.

Please see Figure 1 and Figure 2 in Appendix A for the cautionary statement included in the HM3 LVAS IFU and photos of bend relief connections.

Please sign and return the attached acknowledgment form.

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 MCS 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

Appendix A

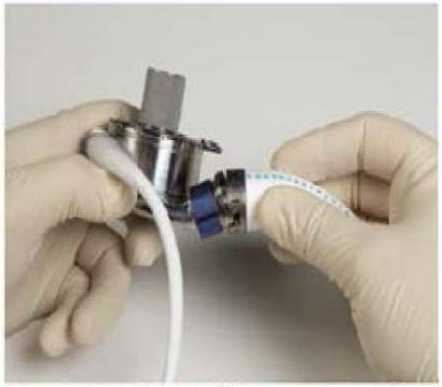
Figure 1

CAUTION !

- Failure to connect the bend relief to the sealed Outflow Graft 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 Left Ventricular Assist Device flow and/or bleeding.
- Care should be taken to ensure that the sealed Outflow Graft bend relief remains connected during sternal closure.
- Once the Left Ventricular Assist Device is activated, reduce cardiopulmonary bypass flow rapidly to provide ample blood flow to the Left Ventricular Assist Device. Whenever possible, maintain the HeartMate III at a pump flow greater than 3 lpm and a pump speed greater than 4,000 rpm.

Figure 2

Correct: Fully Connected



Incorrect: Not Fully Connected