Field Safety Notice

HeartMate 3™ Left Ventricular Assist System
Catalog # 106524INT – HM3 LVAS KIT

April 5th, 2018

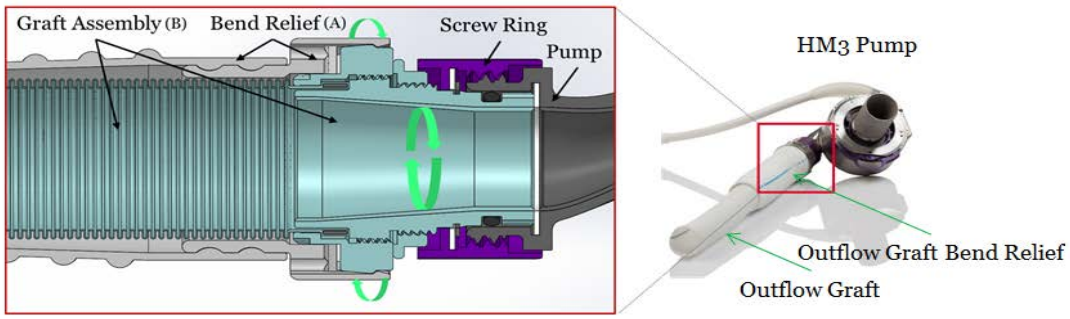
Dear Physician,

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.

Abbott Cardiovascular and Neuromodulation

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 Technical Service +46-8474-4147 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

CC: Chairman Medical Board and relevant Head of Departments