Urgent Product Correction

FA-Q124-HF-1

HEARTMATE 3™ LVAS KITS & HEARTMATE 3 OUTFLOW GRAFTS

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Dear Valued Customer,

Abbott is writing to notify you of a planned update to our Instructions for Use associated with observed outflow graft deformation known as “Extrinsic Outflow Graft Obstruction” (EOGO) associated with the HeartMate 3™ Left Ventricular Assist System (LVAS). Significant EOGO will manifest clinically as a persistent low flow alarm under certain circumstances in some patients, and in such cases, may impair the ability of the HeartMate LVAS to provide adequate hemodynamic support. Refer to Appendix A for a complete list of impacted product model numbers. Abbott is initiating this action after consultation with Medsafe, Ministry of Health, New Zealand.

This letter contains important information on how to recognise EOGO and recommended steps to diagnose EOGO. There is no need to return any product to Abbott.
EOGO is caused by the accumulation of biological materials (acellular biodebris) between the HeartMate Outflow Graft and the Outflow Graft Bend relief or a non-HeartMate component (such as a Gore-Tex/PTFE conduit or wrap added by the surgeon during implant). The biodebris accumulation happens over a long period of support (typically longer than 2 years) and has similar clinical effects between HeartMate 3™ LVAS. The HeartMate 3™ LVAS Kaplan Meier estimate of the rate of EOGO post-implant is 0.24% at 2 years and 2.06% at 5 years.

Impact and Associated Risks

Significant clinical manifestations of EOGO may include constriction of the outflow graft leading to persistent low flow alarms or low flow. Persistent low flow, if not treated, may result in: hemodynamic compromise, the need for surgical intervention, including possible pump replacement, and risk of death. Continued use of the HeartMate LVAS is safe with the guidance described in this letter. In summary, the intention of this letter is to provide information for the clinicians, and there is no need to return any product to Abbott.

Supplemental Guidance and Recommendations

It is important that clinicians continue to pay attention to low flow alarms as this is the first symptom of significant outflow obstruction. Persistent unresolved low flow, if unrecognised or left untreated, can lead to the above-mentioned harms.

The following information provides guidance on how to diagnose unresolved low flow associated with outflow graft obstruction and recommended actions. A clinical article published in 2018 (Mehra et al. J Heart Lung Transplant. 2018 Nov;37(11):1281-1284.) includes a suggested diagnostic algorithm to recognise outflow graft obstruction for HeartMate 3 LVAD in the context of outflow graft twist. This published approach is appropriate to determine if significant EOGO is present and contributing to observed low flow alarms that are not able to be resolved. **In summary, the Mehra et al. algorithm identifies the following approach for unresolved low flow alarms:**

- If the patient presents with symptoms such as a trend to reduced flow with no improvement back to baseline or persistent low flow alarms (with or without symptoms), the first step is to rule out other clinical conditions that could cause low flow.
- If the patient’s signs or symptoms persist, it is important to rule out compression of the outflow graft through imaging such as a CT Angiogram.

Upon diagnosing EOGO, the clinician has options to treat this condition, which include: patient monitoring, percutaneous intervention like outflow graft stenting, surgical decompression by opening the bend relief, or pump replacement. There are inherent risks to any procedure to address EOGO, dependent on the preoperative stability of the patient.

Abbott will update the Instructions for Use (IFU) to include additional diagnostic recommendations related to persistent low flow and related risks associated with EOGO.

In addition, Abbott is in the process of developing and qualifying a design solution to minimise the accumulation of biodebris on the outflow graft and will implement it upon completion of the qualification and receiving regulatory approvals. Initial investigation determined that histology of the material between the graft and bend relief after implementation of the proposed design solution differs from biodebris and is similar to the cellular collagenous connective tissue that surrounds the graft where no wrap exists and no EOGO has been observed. .

Please report any adverse reactions or quality problems experienced with the use of these products to your local Abbott representative.

Please distribute this notice to those who need to be aware of this information within your institution and complete the attached acknowledgement form. Abbott has notified applicable regulatory agencies about this issue. Should you have any questions about this communication, please contact your local Abbott representative.

Abbott is committed to providing the highest quality products and support. We sincerely apologise for any inconvenience this issue may have caused.

Sincerely,

Elizabeth Boltz
Divisional Vice President, Quality
Abbott Heart Failure

Abbott

Appendix A

Model Number	Model Name	WAND #
105581INT	HeartMate 3™ Sealed Outflow Graft with Bend Relief	191209-WAND-6TQSWK
106524INT	HeartMate 3™ LVAS Implant Kit	191209-WAND-6TQT15