Urgent Product Defect Correction

FA-Q124-HF-1

HEARTMATE 3™ LVAS KITS & HEARTMATE 3 OUTFLOW GRAFTS
HEARTMATE II™ LVAS KITS & HEARTMATE II OUTFLOW GRAFTS

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Dear Valued Customer,

Abbott is writing to notify you of risk of "Extrinsic Outflow Graft Obstruction (EOGO)" associated with the HeartMate 3™ Left Ventricular Assist System (LVAS) and HeartMate II™ LVAS and our plan to update the IFU. Significant EOGO can manifest clinically as a persistent low flow alarm in some patients and under certain circumstances, 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.

Whilst very rare, there have been 249 complaints globally (including 209 serious injuries) concerning EOGO with HeartMate 3 between 2012 to 15 January 2024 including 19 deaths assessed to be likely associated directly or indirectly with EOGO. 77 complaints globally (including 70 serious injuries) have been reported for HeartMate II between 2012 and 26 October 2023 including 3 deaths assessed to be likely associated directly or indirectly with EOGO. 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. As of January 2024, no complaints have been reported for HeartMate 3 and HeartMate II associated with EOGO in Australia.

Abbott is initiating this action after consultation with the Therapeutic Goods Administration (TGA), Australia.

This letter contains important information on how to recognise EOGO and recommended steps to diagnose EOGO. Note that 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 and HeartMate II™ LVAS.

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. Abbott considers that medical benefits outweigh the risks of harm.

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 low flow alarms can point to EOGO, however this can also be due to other causes of pump flow obstruction such as twist or kink. Persistent unresolved low flow, if unrecognised or left untreated, can lead to the above-mentioned harms. Note that the IFU indicates that patients need to contact the hospital when there is a low flow alarm (HMII IFU page 7-15; HM3 IFU Page 7-13).

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 is in the process of updating the Instructions for Use (IFU) to include warning regarding EOGO as well as additional diagnostic recommendations related to persistent low flow and related risks associated with EOGO. The update to IFU is targeted to be completed by Q3, 2024.

In addition, Abbott is in the process of developing and qualifying a design solution to minimise the accumulation of biodebris on the outflow graft for HeartMate 3 outflow grafts; as previously communicated, HeartMate II LVAS has been discontinued.

Note that there is no need to return any product to Abbott.

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

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

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	ARTG #
105581INT	HeartMate 3™ Sealed Outflow Graft with Bend Relief	293807
106524INT	HeartMate 3™ LVAS Implant Kit	300895
103393	HeartMate II™ Sealed Outflow Graft with Bend Relief	217353 (Discontinued)
106016	HeartMate II™ LVAS Implant Kit	226356 (Discontinued)
104912	HEARTMATE II®, LVAS IMPLANT KIT (WITH SEALED GRAFTS)	226356 (Discontinued)
103693	HEARTMATE II®, LVAS IMPLANT KIT	172201 (Discontinued)