Dear Healthcare Professional Letter

FA-Q124-HF-1

28 February 2024

Dear Healthcare Professional,

cc: Chairman Medical Board and relevant Head of Departments

HeartMate 3™ LVAS Kits & HeartMate 3 Outflow Grafts, HeartMate II™ LVAS Kits & HeartMate II Outflow Grafts – Extrinsic Outflow Graft Obstruction (EOGO)

Abbott and Thoratec Corporation are issuing this letter to inform 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) and HeartMate II™ 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.

This letter contains important information on how to recognize EOGO and recommended steps to diagnose EOGO. There is no need to return any product to Abbott.

Background/ Description of Problem

The HeartMate 3 Left Ventricular Assist System is intended to provide long term hemodynamic support in patients with advanced, refractory left ventricular heart failure. It is intended either for temporary support, such as a bridge to cardiac transplantation (BTT), or as permanent destination therapy (DT). The HeartMate 3 is intended for use inside or outside the hospital.

The HeartMate II Left Ventricular Assist System is intended for use as a bridge to transplantation in cardiac transplant candidates at risk of imminent death from non-reversible left ventricular failure. The HeartMate II LVAS is also indicated for use in patients with New York Heart Association (NYHA) Class IIIB or IV end-stage left ventricular failure who have received optimal medical therapy for at least 45 of the last 60 days, and who are not candidates for cardiac transplantation. The HeartMate II LVAS is intended for use both inside and outside the hospital, or for transportation of ventricular assist device (VAD) patients via ground ambulance, fixed-wing aircraft, or helicopter.

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. 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.

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. 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.

Advisory to Healthcare Professionals

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 unrecognized 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 recognize 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 minimize 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. This design solution will be developed only for HeartMate 3 outflow grafts; as previously communicated in 2023 in a Marketing communication, HeartMate II LVAS will be discontinued.

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.

There are other identifiers affected globally; please contact your Abbott representative if you need to verify the affected products.

Reporting of Adverse Event

The Health Sciences Authority has been notified of this issue. Healthcare professionals are advised to report any adverse events and/or suspected adverse reactions associated with these devices to our distributor, Joey Loh from Transmedic Ptd Ltd via joey.loh@transmedicgroup.com or your local Abbott Representative. Alternatively, healthcare professionals may report the adverse events to the Medical Devices Cluster, Health Products Regulation Group, HSA at Tel: 6866 1048, or report online at www.hsa.gov.sg/adverse-events. Events that are reported to Transmedic Ptd Ltd or Abbott will be investigated and subsequently reported to HSA.

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

Sincerely,

Elizabeth Boltz
Divisional Vice President, Quality
Abbott Heart Failure

Appendix A

Model Number	Model Name	GTIN Number
105581INT	HeartMate 3™ Sealed Outflow Graft with Bend Relief	00813024011675
106524INT	HeartMate 3™ LVAS Implant Kit	00813024011712
103393	HeartMate II™ Sealed Outflow Graft with Bend Relief	00813024010807
106015	HeartMate II™ LVAS Implant Kit	00813024011224
103695	HEARTMATE II®, LVAS IMPLANT KIT	00813024010616
104911	HEARTMATE II®, LVAS IMPLANT KIT (WITH SEALED GRAFTS)	00813024011170
104912	HEARTMATE II®, LVAS IMPLANT KIT (WITH SEALED GRAFTS)	00813024010821