Sultanate of Oman
Ministry of Health
Directorate General of Pharmaceutical
Affairs and Drug Control
Muscat

سلطنة عُمان
وزارة الصحة
المديرية العامة للصيدلة
والرقابة الدوائية
مسقط

To:
THE DIRECTOR GENERAL OF HEALTH SERVICES IN ALL GOVERNORATES
Commanding Officer, Armed Forces Hospital (Al Khoudh & Salalah)
Director General of Engineering Affairs, MOH
Director General of Royal Hospital
Director General of Khoula Hospital
Director General of Medical Supplies (MOH)
Director General of Pvt. Health Est. Affairs (to kindly arrange distribution to all Pvt. Hospitals)
Hospital Director (Al Nahda Hospital)
Hospital Director (Al Massara Hospital)
The Head of Medical Services in SQU Hospital
The Head of Medical Services in Royal Oman Police
The Head of Medical Services in Ministry of Defence
The Head of Medical Services in The Diwan
The Head of Medical Services in The Sultan's Special Force
The Head of Medical Services in Internal Security Services
The Head of Medical Services in Petroleum Development of Oman
The Head of Medical Services in LNG Oman
ALL PRIVATE PHARMACIES & DRUG STORES

After Compliments,

Please find attached our Circular No 31 **dated** 3/3/24 **Regarding NCMDR Field Safety Corrective Action of Heartmate II & 3 LVAS Kits & Heartmate II & 3 Outflow Grafts from (mfr: Abott).**

Copy to:

- **Director, Office of H.E. The Undersecretary for Health Affairs**
- **Director of Medical Device Control, DGPA&DC**
- **Director of Pharmacovigilance & Drug Information Dept, DGPA&DC**
- **Director of Drug Control Department, DGPA&DC**
- **Director of Pharmaceutical Licensing Department, DGPA&DC**
- **Director of Central Quality Control Lab., DGPA&DC**
- **Supdt. of Central Drug Information**

PADC
المديرية العامة للصيدلة والرقابة الدوائية
Directorate General of Pharmaceutical Affairs & Drug Control
ISO 9001:2015 Certified

ص.ب: ٣٩٣ مسقط - الرمز البريدي: ١٠٠ - هاتف: ٢٢٣٥٧١١١ - فاكس: ٢٢٣٥٨٤٨٩
P.O. Box: 393 Muscat - Postal Code: 100 - Tel: 22357111 - Fax: 22358489
dgpa_dc Email: dg-padc@moh.gov.om

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مسقط

Circular No. 31 / 2024

22 -08-1445 H

03 -02-2024

Field Safety Corrective Action of Heartmate II & 3 LVAS Kits & Heartmate II & 3 Outflow Grafts from Abbott.

Source	NCMDR - National Center Medical Device Reporting- SFDA. https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&rid=19937
Product	Heartmate II & 3 LVAS Kits & Heartmate II & 3 Outflow Grafts.
Description	Axial-flow rotary ventricular assist system.
Manufacturer	Abbott.
Local agent	Muscat Pharmacy & Stores LLC.
The affected products	Please refer to "Appendix A" in the attachment.
Reason	Potential for 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.
Action	1. The Instructions for Use (IFU) will be updated by Abbott to include additional diagnostic recommendations related to persistent low flow and related risks associated with EOGO, please refer to the attachment for more information. 2. Contact the local agent for remedial action.
comments	Healthcare professionals are encouraged to report any adverse events Suspected to be associated with the above device or any other medical device to Department of Medical Device Control through the E-mail: Med-device@moh.gov.om

Dr. Mohammed Hamdan Al Rubaie

Director General

PADC
المديرية العامة للصيدلة والرقابة الدوائية
Directorate General of Pharmaceutical Affairs & Drug Control

ص.ب: ٣٩٣ مسقط - الرمز البريدي: ١٠٠ - هاتف: ٢٢٣٥٧١١١ - فاكس: ٢٢٣٥٨٤٨٩
P.O. Box: 393 Muscat - Postal Code: 100 - Tel: 22357111 - Fax: 22358489
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Heart Failure Division
Abbott Medical
6035 Stoneridge Drive
Pleasanton, CA 94588
USA

URGENT Field Safety Notice

FA-Q124-HF-1

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

February 2024

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) 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.

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.

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 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, HeartMate II LVAS will be discontinued.

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 apologize for any inconvenience this issue may have caused.

Sincerely,

Elizabeth Boltz

Elizabeth Boltz
Divisional Vice President, Quality
Abbott Heart Failure

Appendix A

Model Number	Model Name	GTIN Number
106524	HeartMate 3 LVAS Implant Kit	N/A
106524INT	HeartMate 3™ LVAS Implant Kit	00813024011712
106015	HeartMate II™ LVAS Implant Kit	00813024011224
106016	HeartMate II™ LVAS Implant Kit	00813024011231
102139	Thoratec® HeartMate II® LVAS Implant Kit	N/A
103695	HEARTMATE II®, LVAS IMPLANT KIT	00813024010616
104912	HEARTMATE II®, LVAS IMPLANT KIT (WITH SEALED GRAFTS)	00813024010821
103693	HEARTMATE II®, LVAS IMPLANT KIT	00813024010623