



نتقدم بثقة
Moving Forward
with Confidence



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 46 dated 31/3/2024 Regarding NCMDR Field Safety Notice of HeartMate 3 LVAS Kits 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



DSC
مركز سلامة الدواء
Drug Safety Center



ص.ب: ٣٩٣ مسقط - الرمز البريدي: ١٠٠ - هاتف: ٢٢٣٥٧١١١ - فاكس: ٢٢٣٥٨٤٨٩

P.O. Box: 393 Muscat - Postal Code: 100 - Tel: 22357111 - Fax: 22358489

☒ @DSCPHO Email: dscpho@moh.gov.om



Circular No. 46/2024

20 -09-1445 H
31 -03-2024

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Field Safety Notice of HeartMate 3 LVAS Kits from Abbott.

Source	NCMDR - National Center Medical Device Reporting- SFDA. https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&rid=20969
Product	HeartMate 3 LVAS Kits.
Description	Active Implantable Devices.
Manufacturer	Abbott.
Local agent	Muscat Pharmacy & Stores LLC.
The affected products	Model Numbers: 106524INT (UDI: 0081302401171)
Reason	Potential of blood leaking out of the left ventricle or air entering the left ventricle or Left Ventricle Assist Device (LVAD) which are attributed to a leak path at the seal interface between the HeartMate 3™ Left Ventricle Assist System (LVAS) inflow cannula and the titanium apical cuff.
Action	<ol style="list-style-type: none">1. Please follow the recommendation in the attachment.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



DSC
مركز سلامة الدواء
Drug Safety Center



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



Urgent Field Safety Notice

FA-Q124-HF-2
HeartMate 3™ LVAS Kits
Model Numbers: 106524INT
(UDI: 0081302401171)

Heart Failure Division
Abbott Medical
6035 Stoneridge Drive
Pleasanton, CA 94588

March 2024

Dear Valued Customer,

Abbott is notifying you that there have been complaints of blood leaking out of the left ventricle or air entering the left ventricle or Left Ventricle Assist Device (LVAD) which are attributed to a leak path at the seal interface between the HeartMate 3™ Left Ventricle Assist System (LVAS) inflow cannula and the titanium apical cuff. The blood leak or air entrainment has only been observed during the implantation procedure. Once the bleeding or air entrainment was resolved intraoperatively, the issue did not re-occur postoperatively. Abbott's investigation determined that in certain instances, routine manipulation of the pump or internal fluid pressures during implantation can result in a compressed sealing ring on one side, leading to a leak path on the opposite side.

As of February 18, 2024, Abbott has received a total of 81 complaints about the issue out of 33,795 implantations. Of these, the occurrence rate of serious adverse health consequences (death, irreversible right heart failure or cerebral or myocardial infarction due to air embolism) was 0.01%. The other reported harms of blood leakage or air entrainment were extended surgery time, bleeding, and hemorrhage.

This letter contains important information to reinforce implant instructions and standard surgical processes when observing blood leaking from the LVAD or air passing into the left ventricle and LVAD via any path including the interface between the inflow cannula and the apical cuff.

Impact and Associated Risks

During implantation of the HeartMate 3™ LVAS, if hemostasis is not achieved, blood leakage or air entrainment will impact the integrity of the blood pathway and may lead to the following while the integrity of the blood pathway is being restored by the surgeon: extended surgery time, bleeding, hemorrhage, right heart failure, air embolism, or potential death from hemorrhage or air embolism.

Recommendation

The product is not being removed from the field and unused product does not need to be returned. Abbott considers the medical benefits to outweigh the risk of harm and recommends continued use of the HeartMate 3™ LVAS per the Instructions For Use (IFU) and supplemental guidance provided below.

In most cases, blood leakage from, or air entrainment into, the left ventricle or LVAD at any interface, including at the interface between the pump and the apical cuff, is addressed by adjusting the pump position. In the remaining cases, leakage or air entrainment is addressed using conventional strategies for resolving air leaks or surgical bleeding.

If blood leak or air entrainment is suspected or observed, follow standard surgical processes and the existing IFU:

- Residual air must be completely evacuated from the device blood chamber prior to initiating the LVAD support.



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HeartMate 3™ LVAS Kits
Model Numbers: 106524INT
(UDI: 0081302401171)

Heart Failure Division
Abbott Medical
6035 Stoneridge Drive
Pleasanton, CA 94588

- Ensure that bleeding is assessed and ensure proper management of hemostasis before closing all wounds.
- Use conventional strategies for resolving air leaks or surgical bleeding, including: adjusting the pump position, waiting for the natural tendency of blood to coagulate or upon reversal of anticoagulation, adding surgical materials, and exchanging the apical cuff, the pump, or both.
- Always have a complete backup system (implant kit and external components) available on-site and in close proximity during the implantation procedure for use in the event of an emergency.

Next Steps

Abbott is developing and qualifying a change in the seal interface to address this issue and will implement it upon completion of the qualification and receiving regulatory approvals.

Please distribute this notice to those who need to be aware within your institution.

Abbott is in the process of notifying the applicable regulatory agencies about this issue.

We sincerely apologize for any difficulties or inconvenience this may cause you and your patients. Please know that Abbott is committed to providing the highest quality products and support, and we thank you for your partnership in assisting us with this process. Should you have any questions about this communication, please contact your local Abbott representative.

Sincerely,

Elizabeth Boltz
Divisional Vice President, Quality
Abbott Heart Failure