Urgent Medical Device Correction

HeartMate 3™ LVAS Kits
(Model Numbers: 106524US and 106524INT)

Heart Failure Division
Abbott Medical
6035 Stoneridge Drive
Plesanton, 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 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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- 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 and complete the attached acknowledgment form included with this letter and return it to Abbott.

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

Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail, or by fax. To submit your report:

- Complete the voluntary Form FDA 3500 online at https://www.fda.gov/safety/medical-product-safety-information/medwatch-forms-fda-safety-reporting.
- Download the form from FDA.gov or call 1-800-332-1088 to request a reporting form, then complete and return it to the address on the pre-addressed form or submit it by fax to 1-800-FDA-0178.

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