Heart Failure Division
Abbott Medical
6035 Stoneridge Drive
Plesanton, CA 94588
USA

Urgent Medical Device Recall (Correction)

For Certain Serial Numbers of Apical Coring Knife and HeartMate 3 LVAD Kits
(Models: 1050, 106524US)
GTIN: 00813024010227, 00813024013297

August 2023

Dear Valued Customer,

Abbott is notifying customers of a finding with the HeartMate Apical Coring Knife provided with the HeartMate 3 Left Ventricular Assist System (LVAS) kits (Model 106524US) and the Apical Coring Knife (Model 1050) separately distributed for use during HeartMate 3 or HeartMate II LVAS (Models 106015, 106016, and 107801) implant procedures. Note that distributed HeartMate II Implant Kits are not affected by this notice.

Starting in April 2023, Abbott has received complaints regarding inability of the Apical Coring Knife to start and/or complete resecting heart tissue when the physician was preparing the patient's heart for implantation of the Left Ventricular Assist Device (LVAD). As of August 3, 2023, a total of eight (8) complaints had been reported about this issue, corresponding to an overall complaint rate of about two percent (2%). There has been no patient harm reported beyond extended surgical time/procedure time with these complaints. In all these events, the physician was able to complete the procedure by using an Apical Coring Knife from the backup LVAS implant kit or an alternate surgical tool.

Please review Appendix A for the specific serial numbers within the scope of this notification.

Impact and Associated Risks

The Apical Coring Knife is used during implantation of the HeartMate 3 and HeartMate II LVADs to cut through the myocardium when the surgeon creates the apical ventriculotomy for the implantation of the LVAD into the left ventricle.

Inability to start and/or complete the coring procedure due to inadequate sharpness of the Apical Coring Knife could result in an extended procedure or surgical time while the backup coring knife is acquired. No patient injury or harm has been reported, but potential additional risks include a remote risk of hemodynamic compromise and/or thromboembolism/thromboembolic event, and improbable risk of stroke and/or death.

Recommendation

At this time, this product is not being removed from the field and does not need to be returned. While Abbott continues to investigate the root cause of the issue and implements appropriate corrective actions, clinicians can continue to use the Apical Coring Knife provided with the HeartMate 3 LVAS kits and the separately distributed Apical Coring Knives listed above at their discretion until further notice. Abbott is reinforcing the following warning in the Instructions for Use when utilizing the Apical Coring Knife:

- During the implant process, a complete backup system (implant kit and external components) must be available on-site and in close proximity for use in the event of an emergency.

Additionally, if unusual resistance is encountered during the coring procedure, immediately stop coring and complete using the backup Apical Coring Knife (from the LVAS kits or a separately distributed Apical Coring Knife, if available). Please continue to report any difficulties you encounter with the Apical Coring Knife.

Please complete the acknowledgement form included with this letter and return to Abbott. 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.

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
- Download form from FDA.gov or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form or submit by fax to 1-800-FDA-0178.

Abbott is continuing its investigation on this matter and working diligently to resume normal supply. We will communicate as new information becomes available. We sincerely apologize for any difficulties or inconvenience that 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