



Urgent Medical Device Recall (Correction)

For Certain Serial Numbers of Apical Coring Knife and
HeartMate 3 LVAD Kits

(Models: 1050, 106524US)

GTIN: 00813024010227, 00813024013297

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

September 2023

Dear Valued Customer,

Abbott notified customers in August 2023 of complaints related to the inability to start and/or complete resecting heart tissue 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 were not affected by the notice.

Abbott is continuing to work with our Apical Coring Knife vendor to supply knives that do not present this issue. However, the supply of unaffected Apical Coring Knives continues to be limited. Therefore, Abbott is making additional Left Ventricular Assist System (LVAS) kits (Model 106524US) with the affected Apical Coring Knives available. The intent of this cover letter is to notify customers that due to limited supply and the need to continue supporting planned implants, Abbott has identified additional LVAS kit affected serial numbers for shipment which are now included in the scope of the Apical Coring Knives Field Notification described in the original letter dated August 2023.

The recommendations remain the same as the original communication letter. A copy of the customer letter and associated appendices (Appendix A as of August 2023 and Appendix A Expanded Scope as of September 2023) with the specific serial numbers that are affected can be found on the Abbott Product Advisory website: [HeartMate 3 LVAD Product Advisories | Abbott \(cardiovascular.abbott\)](https://www.heartmate3lvad.com/HeartMate-3-LVAD-Product-Advisories-Abbott-cardiovascular.abbott). Please continue to refer to the website for the serial numbers in scope as you receive additional HeartMate 3 LVAS Kits.

Sincerely,

A handwritten signature in black ink that reads 'Elizabeth Boltz'.

Elizabeth Boltz
Divisional Vice President, Quality
Abbott Heart Failure