Update to Urgent Medical Device Correction

HeartMate 3™ LVAS Kits & Outflow Grafts
(Model Number: 106524US, 105581US)

Heart Failure Division
Abbott Medical
6305 Stoneridge Dr.
Pleasanton, CA 94588

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Dear Valued Customer,

The Heart Failure division of Abbott is committed to delivering the highest quality products and services to assist clinicians in treating heart failure. We are pleased to inform you that Abbott has received FDA approval for two HeartMate 3™ Left Ventricular Assist System (LVAS) product updates that will be implemented in 2025.

HeartMate 3™ LVAS Apical Seal Update

In 2024, Abbott sent a notification (https://www.cardiovascular.abbott/us/en/hcp/products/heart-failure/left-ventricular-assist-devices/heartmate-3/indications-safety-warnings/advisories.html) to inform you that there had been complaints of blood leaking from or air entering the left ventricle or Left Ventricular Assist Device (LVAD) because of a leak at the seal interface between the HeartMate 3™ LVAS inflow cannula and the titanium apical cuff.

Abbott has started to manufacture the newly approved apical seal into the HeartMate 3™ LVAD, and the new design has started to be incrementally phased in as of December 27th, 2024. While Abbott works diligently to increase our newly designed apical seal inventory, we recommend continued use of the existing HeartMate 3™ LVAS apical seal in the interim and believe the clinical benefits outweigh the risk of harm. With your support, we expect adequate inventory to initiate replacement of all remaining inventory in the field within the United States by the end of Q2 2025. This stepwise approach ensures a continued supply of LVAS kits to patients and provides you with the new design as quickly as possible. Your local Heart Failure representative will work closely with you to ensure a smooth transition.

HeartMate 3™ LVAS Outflow Graft Bend Relief Update

Additionally, in 2024, Abbott sent another notification (https://www.cardiovascular.abbott/us/en/hcp/products/heart-failure/left-ventricular-assist-devices/heartmate-3/indications-safety-warnings/advisories.html) to inform you of an issue related to observed outflow graft deformation known as “Extrinsic Outflow Graft Obstruction” (EOGO), caused by the accumulation of biological materials, such as 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).

Abbott has started to manufacture a modified Outflow Graft Bend Relief with perforation features distributed along the Bend Relief length and circumference. This design solution is for HeartMate 3™ LVAS Outflow Grafts only. Abbott will initiate the replacement of existing HeartMate 3™ LVAS Outflow Grafts in the United States by the end of Q2 2025. Your local Heart Failure representative will work closely with you to ensure a smooth transition.

Next Steps

In summary, by the end of Q2 2025, both updates will be included in the HeartMate 3™ LVAS kits. The activities described above demonstrate Abbott’s commitment to quality and our dedication to the patients we serve. Please read the previous notifications, in the links above, to review the recommendations regarding the use of current HeartMate 3™ LVAS configurations.

An acknowledgment form must be completed and returned to your Heart Failure representative to confirm receipt and acknowledgment of this letter. Please contact your Heart Failure representative for more information regarding these updates or our services. We deeply appreciate your partnership and patience as we work to provide you and your patients with these updates. We look forward to continuing to provide you with lifesaving Heart Failure solutions.

Sincerely,

Carolyn Tabion
Divisional Vice President, Quality
Abbott Heart Failure