



Update to Voluntary Medical Device Recall Urgent

HeartMate 3™ LVAS Kits
(Model Number: 106524US)

February 2025

Dear Healthcare Professional,

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 authorization from Health Canada for a HeartMate 3™ Left Ventricular Assist System (LVAS) product update that will be implemented in 2025.

HeartMate 3™ LVAS Apical Seal Update

In 2024, Abbott sent a notification (included in this package) 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 early as the week of February 17th, 2025. 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 Canada 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.

Next Steps

In summary, by the end of Q2 2025, this update 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 included in this package, 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,

A handwritten signature in black ink, appearing to read 'Carolyn Tabion'.

Carolyn Tabion
Divisional Vice President, Quality
Abbott Heart Failure