



URGENT MEDICAL DEVICE CORRECTION

HeartMate 3™ Left Ventricular Assist System

Catalog #106524US LVAS KIT, HM3, UDI# 00813024013297

Outflow Graft Clip

Catalog #10012390GBL, UDI# 05415067030269.

October 17, 2018

Dear Physician,

In May 2018, we provided you information associated with HeartMate 3 (HM3) Outflow Graft twist occlusions and a forthcoming design improvement. Abbott is now informing our U.S. physician partners that we have recently received the FDA approval for this design improvement and the Outflow Graft Clip is now available.

The Outflow Graft Clip has been designed to prevent any rotation of the outflow graft, thus eliminating the safety concern reported in the May 2018 notice. The Outflow Graft Clip is intended to be used with all new patient implants and may be used on patient cases where an Outflow Graft twist is confirmed and surgical intervention is required.

All HM3 implanting centers are required to be trained on the proper attachment of the clip prior to use of the clip. New HM3 kits sent to you will include the Outflow Graft Clip, and clips will be provided at no charge for all HM3 inventory currently available at your implanting center. Abbott recommends the following updated patient management strategies for patients implanted with HM3.

Updated Patient Management – New Patients

- During implant, when attaching the Outflow Graft to the Pump Cover, a clicking sound will be heard as the Screw Ring is tightened. Continue turning the Screw Ring clockwise until it comes to a complete stop and stops clicking. To avoid damaging the Outflow Graft assembly, do not use tools to tighten the screw ring.
- **Once the screw ring is tightened, apply the Outflow Graft Clip according to the provided Instructions For Use.**

Updated Patient Management – Ongoing Patients

- For patients who are **not** experiencing any evidence of an outflow graft obstruction, Abbott recommends standard of care follow-up as previously outlined in the May 2018 notice without performing a surgical intervention to apply the Outflow Graft Clip.
- For patients previously implanted with the HM3 who are experiencing an outflow graft obstruction and require a surgical intervention to repair the obstruction, Abbott recommends applying the clip at the time of surgical intervention according to the Outflow Graft Instructions for Use.

As a reminder, this is not a new issue but a continuation of the previous communications related to field reports of Outflow Graft twist. The only actions requested of you and your institution is the return of the acknowledgement form included in this packet, as well as providing updated patient care based on the patient management recommendations outlined above.

If you have questions, please contact your local Abbott MCS Clinical Specialist or MCS HeartLine 1-800-456-1477, which is available 24 hours a day, 7 days a week.

Thank you for your continued support.

Sincerely,

A handwritten signature in black ink, appearing to read 'Lance Mattoon'.

Lance Mattoon
Divisional Vice President, Quality
Abbott Heart Failure