



IMPORTANT MEDICAL DEVICE ADVISORY
Update to December 2, 2019 Communication
HeartMate 3™ Modular Cables
(Catalog #106525INT and 106525)
HeartMate 3™ Left Ventricular Assist System (LVAS) Kit
(Catalog #106524INT and 106524)

Abbott Heart Failure

August 31, 2020

Dear Clinician,

In a communication dated December 2, 2019, Abbott informed physicians and VAD coordinators that we received reports of the HeartMate 3™ modular cable being improperly inserted during controller exchange causing erroneous electrical contact, and potentially resulting in a blown fuse, confusion for the patient, and triggering controller alarms.

We have had no additional reports of incorrect insertion since the December 2, 2019 communication, which was at a rate of 1% worldwide.

This communication is to inform you that our newly designed modular cable is available (per applicable regulatory approvals). **It has been designed to prevent erroneous electrical contact if the modular cable is incorrectly inserted into the controller.** Reference Appendix A for images of new modular cable design.

The previous cable design remains acceptable for use with proper controller exchange technique as described in our December 2, 2019 communication and IFU, which means a replacement for the new model is not required for proper performance for the modular cable.

If clinicians desire to exchange to the new design modular cable for existing patients which are supported with the previous version (see pictures on next page), the exchange should be done on a case by case basis with the following considerations:

- **Replacement of the modular cable for a HeartMate 3 patient should be completed at the discretion of the treating clinician, based on the risk per patient condition.**
- **Exchanging the modular cable requires a pump stop where there will be no power to the pump for a brief period. The patient's native heart should be able to support circulation during the pump stop.**

Treating clinicians must assess each patient's current health status prior to an exchange. The replacement of current cables is not part of the considerations for Patient Management recommendations; therefore, if the decision is made to replace the cable for ongoing patients, the new modular cable will need to be purchased by the customer.

Please maintain a record of this notice to ensure effectiveness of this communication. If product potentially affected by this notification has been transferred from your institution to another hospital, please forward a copy of this update to the respective physician or institution. The competent (regulatory) authority for your country has been notified of this action.

Abbott remains committed to patient safety and providing the highest quality products and services. If you have questions regarding this notice, please contact your Abbott Sales Representative.

Thank you for your continued support.

Sincerely,

A handwritten signature in blue ink, appearing to read 'Lance Mattoon', is written over a blue horizontal line.

Lance Mattoon
Divisional Vice President, Quality
Abbott Heart Failure

Appendix A – Modular Cable Visual Differences

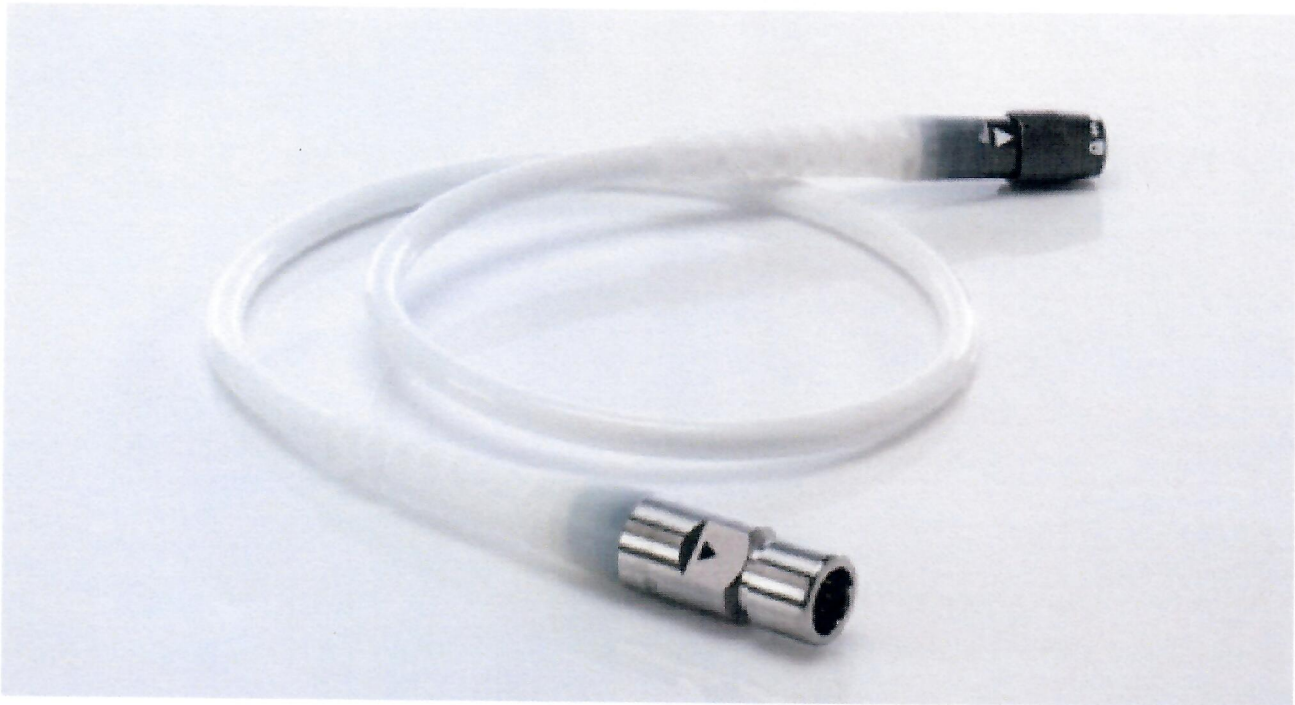
Note: Cable versions are visibly identifiable on product labels.

New Modular Cable Design – Catalog #106525INT, ZFIN 10010875



Visual Characteristics: White Arrow, Alignment Mark

Previous Modular Cable Design – Catalog #106525/106525INT, ZFIN 100159732, 106525, 106525INT



Visual Characteristics: Black Arrow