Abbott

URGENT MEDICAL DEVICE RECALL

HeartMate 3™ Coring Tool
Catalog #10005872

March 7, 2019

Dear Clinician,

To help ensure the safety of patients, Abbott is alerting HeartMate 3 implanters that the company has become aware of an issue related to the HeartMate 3 Coring Tool that has been available since November of 2018.

We were recently notified of one event following use of the Coring Tool where a physician reported observing a small black plastic particle in the left ventricle during the implant procedure. While we received no reports of patient injury related to this issue, an internal investigation has confirmed that the particle came from the Coring Tool's plastic blade cover.

Abbott has proactively initiated removal of all lots and serial numbers of the HeartMate 3 Coring tool from customer inventory. Stop use, quarantine and return any units on hand within your centers to Abbott. The HeartMate 3 Coring Tool will not be available until the issue is resolved. We estimate approximately 70 units have been used in procedures in the United States.

The HeartMate 3 Coring tool is an optional accessory for coring of the heart during implantation of a HeartMate 3 LVAD and is sold separately from the HeartMate 3 Kit.

The HeartMate 3 LVAD is NOT impacted by this voluntary recall. In addition, the Coring Knife supplied with the HeartMate 3 Kit is not impacted by this notice, nor are the Mini Apical Cuff and Holding Tool. **The Coring Knife supplied with the HeartMate 3 Kit, which is compatible with both the Apical Cuff and Mini Apical Cuff, should be used in lieu of the optional HeartMate 3 Coring Tool.**

Clinical Impact

Although there have been no reported injuries, we believe recalling the device will ensure patients are not exposed to any potential risk that may result from the presence of residual particles in the ventricle.

Patient Management Recommendations

Abbott has consulted with our Medical Advisory Board regarding this issue. For patients previously implanted with the HeartMate 3 device and where the optional HeartMate 3 Coring Tool was utilized, Abbott recommends close vigilance for potential harm which could include concerns such as infection or thromboembolism.

Please complete the acknowledgement form included in this packet and return to Abbott, as noted on the acknowledgement form.

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

A copy of this letter is available on
https://www.cardiovascular.abbott/us/en/hcp/resources/product/advisories.html

Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail, or by fax.

- Complete and submit the report Online: www.fda.gov/medwatch/report.htm
- Regular Mail or Fax: Download form www.fda.gov/MedWatch/getforms.htm or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed from, or submit by fax to 1-800-FDA-0178

Thank you for your continued support.

Sincerely,

Lance Mattoon
Divisional Vice President, Quality
Abbott Heart Failure