



IMPORTANT MEDICAL DEVICE ADVISORY

HeartMate 3™ Coring Tool
GTIN: 00813024013075
Catalog #10005872

March 08, 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.

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.

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.

Should you have questions regarding this notice, please contact your local Abbott MCS Sales or Clinical Representative or the emergency MCS Hotline +32 22006645, 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>

Thank you for your continued support.

Sincerely,

.....