



## **URGENT MEDICAL DEVICE RECALL**

HeartMate 3™ Outflow Graft  
Catalog #105581, #105581US

HeartMate 3™ Left Ventricular Assist System (LVAS) kit  
Catalog #106524, #106524US LVAS KIT, HM3

March 30, 2019

Dear Clinician,

To help ensure the safety of patients, Abbott is notifying HeartMate 3 implanters of an issue related to the HeartMate 3 Outflow Graft. This issue is separate from the one announced in May 2018, involving twisting of the HeartMate 3 Outflow Graft. Abbott has received 19 (0.23%) worldwide reports of the HeartMate 3 Outflow Graft leaking at its pump connection during implantation because the Screw Ring either disconnected or did not tighten completely. To date, we have not received reports of patient injury or adverse patient outcomes related to this issue. The HeartMate 3 Outflow Graft is available as a standalone accessory (Catalog #105581, #105581US) and as a component of the HeartMate 3 Left Ventricular Assist System (LVAS) kit (Catalog #106524, #106524US).

Investigation has determined that the issue is caused by the C-Ring within the Outflow Graft assembly to have been improperly seated during manufacturing. If the C-Ring is insufficiently seated, it renders the device nonfunctional because the Outflow Graft connection will leak during the implant procedure.

### **Clinical Impact**

There have been no adverse patient outcomes reported to us. All reported issues were detected either during the connection of the Outflow Graft to the pump, or after the Outflow Graft was connected to the pump and the device was activated. Testing has demonstrated that when this issue is present, there is readily detectable leaking at the Screw Ring while the patient is still on cardiopulmonary bypass. In such situations, the Outflow Graft would need to be replaced with a backup Outflow Graft.

### **Recommendations and Next Steps**

Abbott is recalling 208 HeartMate 3 Outflow Graft units globally (87 within the US). An Abbott Representative will be contacting you within the coming weeks to identify the specific units that are impacted in your inventory and replace them.

In the interim, continued implants with the current HeartMate 3 Outflow Grafts can still be conducted with standard implant procedures by following the HeartMate 3 Instructions for Use. However, in addition to following the existing instruction of checking for blood leaks and bleeding at the Outflow Graft "When the flow through the blood pump is satisfactory," we now recommend that adequate performance of the Screw Ring attachment to the pump be evaluated before the device is brought to the surgical field. If the Screw Ring does not function properly, the Outflow Graft should be replaced with a backup Outflow Graft.

### **Patient Management Recommendations**

For patients implanted with the HeartMate 3 Left Ventricular Assist System (LVAS), Abbott confirms there is no risk due to this issue. Patients should be managed per standard clinical practice.

Please complete the acknowledgement form included in this packet and return to Abbott. If you are a consignee of this letter within your organization, please notify all users of the device within your organization.

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](http://www.fda.gov/medwatch/report.htm)
- Regular Mail or Fax: Download form [www.fda.gov/MedWatch/getforms.htm](http://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 form, or submit by fax to 1-800-FDA-0178

We apologize for any difficulties this may cause you and your patients. Abbott is committed to providing the highest quality products and support.

Sincerely,



Lance Mattoon  
Divisional Vice President, Quality  
Abbott Heart Failure