Abbott Recalls the HeartMate 3™ Left Ventricular Assist System Due to Potential Malfunction that may Lead to Graft Occlusion

The FDA has identified this as a Class I recall, the most serious type of recall. Use of these devices may cause serious injuries or death.

- Recalled Products: HeartMate 3™ Left Ventricular Assist System
- Model/Item Numbers: Catalog # 106524US (U.S. commercial), 106524 (U.S. Investigational Device Exemption number), 10652INT (international)
- Lot Numbers: All lots
- Manufacturing Dates: All
- Distribution Dates: September 2, 2014 to present
- Devices Recalled in the U.S.: 4,878 units nationwide

Device Use:

The HeartMate 3™ Left Ventricular Assist System helps deliver blood from the heart to the rest of the body. It is used for short-term support of patients who are at risk of death from end-stage left ventricular heart failure, such as patients awaiting a heart transplant. The system includes a blood pump that is implanted in the space around the heart (pericardium) along with an outflow graft that connects the pump to the aorta.

Reason for Recall

Abbott is recalling the HeartMate 3™ Left Ventricular Assist System due to a malfunction in the device's outflow graft assembly that may cause the outflow graft to twist and close up (occlusion) over time. Occlusion of the outflow graft can reduce or stop pump flow and set off a persistent low flow alarm in the system. A reduction in pump can lead to serious adverse events such as blood clots and death.

Who May be Affected

- All patients receiving cardiac support using the HeartMate 3™ Left Ventricular Assist System
- Health care providers and caregivers monitoring patients with the system

What to Do

Patients:

Patients experiencing a persistent low flow alarm should contact the physician managing their HeartMate 3™ Left Ventricular Assist System immediately. Abbott is recommending not to remove the device because of this issue.

Physicians:

Following communications on **April 5, 2018 (https://www.sjm.com/~/media/galaxy/hcp/resources-reimbursement/technical-resources/product-adviseries-archive/hm3/heartmate3-system-outflow-graft-twist-occlusion-doctor-letter-us.pdf?la=en)**, and **May 4, 2018 (http://abbott.mediaroom.com/press-releases?item=124269)**, respectively, Abbott sent an Urgent Medical Device Recall notification to physicians on May 21, 2018, alerting them again to the device malfunction and providing them with the following instructions for managing patients getting the device or patients who already have the device implanted.

- Patients should be followed per recommendations from the American Society of Echocardiography (J Am Soc Echocardiogr 2015;28:853-909), which states that "An LVAD surveillance echo exam should be considered at approximately 2 weeks after device implantation or before index hospitalization discharge (whichever occurs first), followed by consideration of surveillance transthoracic echo (TTE) at 1, 3, 6, and 12 months post implantation and every 6 to 12 months thereafter."
- TTE imaging is not a definitive tool to identify an outflow graft twist obstruction. However, it can be used as an indirect assessment of obstruction by imaging the size of the left ventricle, the mitral valve and aortic valve opening, and diastolic velocity (inflow or outflow).
- A decrease in flow over time may be an indicator of Outflow Graft twist obstruction. If such a trend in flow is observed, or if flow velocity anywhere in the Outflow Graft exceeds 2 meters/sec (J Am Soc Echocardiogr 2015;28:853-909), more frequent surveillance echo exams than listed above, or other investigative methods, may be necessary.
- If a persistent low flow alarm (i.e., a low flow alarm not resolved after all relevant patient medical conditions having been ruled out as the cause) occurs at any time following implant, a Computed Tomography (CT) angiogram should be urgently obtained, if there are no contraindications, to identify a possible outflow graft twist occlusion.
- In the event that surgical repair of the Outflow Graft is needed due to a twist occlusion, the Outflow Graft Bend Relief should be reattached in its original state or repaired to prevent bending, abrasion or occlusion of the outflow graft at the graft's attachment point to the pump.

Contact Information

Customers who want more information about this recall can contact their local Abbott Mechanical Circulatory Support (MCS) Clinical Specialist or MCS HeartLine at 1-800-456-1477, which is available 24 hours a day, 7 days a week.

Date Recall Initiated

April 5, 2018

How do I report a problem?

Health care professionals and consumers may report adverse reactions or quality problems they experience using these devices to **MedWatch: The FDA Safety Information and Adverse Event Reporting Program (https://www.accessdata.fda.gov/scripts/medwatch/index.cfm?action=reporting.home)** either online, by regular mail or by FAX to 1-800-FDA-0178.

More in Medical Device Recalls (/MedicalDevices/Safety/ListofRecalls/default.htm)

2018 Medical Device Recalls (/MedicalDevices/Safety/ListofRecalls/ucm590900.htm)

2017 Medical Device Recalls (/MedicalDevices/Safety/ListofRecalls/ucm535289.htm)

2016 Medical Device Recalls (/MedicalDevices/Safety/ListofRecalls/ucm480134.htm)