carecentrix

Provider Newsflash
March 2024

FDA Recall – HeartMate Touch Communication System

Purpose of this communication:

- We are writing to inform you that effective immediately the FDA has issued a Class 1 recall of HeartMate Touch Communication System that monitors patients who have an implantable HeartMate 3 Left Ventricular Assist Device (LVAD), application (App) version 1.0.32 distributed from May 7, 2020 to December 18, 2023. The recall is due to an unexpected pump stop or start of the HeartMate 3 Left Ventricular Assist Device (LVAD). Issues may occur if the HeartMate Touch System is disconnected from a patient's HeartMate Controller while a "pump stop" command is running. When the HeartMate Touch is reconnected to the same or a new controller, depending on the status of the pump at connection the pump will either stop or start. If the pump was stopped at reconnection, the pump will restart. If the pump is running at reconnection, a pump stop will occur. There are no alarms or indications that warn the user that the "pump stop" command is still in the command queue.

What do I need to do?

- Please review the following recall notice: https://www.fda.gov/medical-devices/medical-device-recalls/abbott-recalls-heartmate-touch-communication-system-unintentional-pump-start-and-stop?utm_medium=email&utm_source=govdelivery
- Notify impacted patients and facilitate the repair, replacement and/or resolution of the recall, according to the guidelines issued by the manufacturer in the FDA notification.
- Confirm if you have any CareCentrix patients affected by this recall and notify the CareCentrix Quality Department by faxing information to: 919-792-6718 Attn: Quality Department.

Thank you in advance for your cooperation and continued partnership.