Stop New Implants of the Medtronic HVAD System – Letter to Health Care Providers

June 3, 2021

The U.S. Food and Drug Administration (FDA) is alerting health care providers that Medtronic has stopped the sale and distribution of the Heartware Ventricular Assist Device (HVAD) System because:

- There is an increased risk of neurological adverse events and mortality associated with the internal pump.
- There is a potential for the internal pump to stop. If the internal pump stops, it may delay restarting or fail to restart.

Both problems may lead to death or serious injuries. Therefore, health care providers should no longer implant the Medtronic HVAD System. Health care providers should continue to manage care of patients with a previously implanted Medtronic HVAD System according to the instructions in the Medtronic Urgent Medical Device Communication Notification letter.

Today, Medtronic issued an Urgent Medical Device Communication Notification Letter (https://www.medtronic.com/content/dam/medtronic-com/global/HCP/Documents/hvad-urgent-medical-device-notice-june-2021.pdf) (http://www.fda.gov/about-fda/website-policies/website-disclaimer) to inform health care providers that Medtronic has stopped the distribution and sale of the HVAD System. The FDA is issuing this letter to health care providers to ensure that health care providers are informed of this action.

Recommendations

- Follow all instructions provided in Medtronic's Urgent Medical Device Communication Notification Letter (https://www.medtronic.com/content/dam/medtronic-com/global/HCP/Documents/hvad-urgent-medical-device-notice-june-2021.pdf) (http://www.fda.gov/about-fda/website-policies/website-disclaimer):
    - Stop new implants of the Medtronic HVAD pump.
    - For patients currently implanted with an HVAD pump:

    - Continue with existing procedures and protocols for the device and contact Medtronic for necessary replacement of peripheral components (for example, controllers, batteries, AC/DC adapters, carrying case), which will continue to be made available by Medtronic.
    - Continue to follow instructions provided in the IFU and adhere to current best clinical practices, including strict management of blood pressure and International Normalized Ratio (INR), and the use of system log files to support clinical decision making related to pump performance.
- For new left ventricular assist devices (LVAD) implants, use an alternative, such as the Abbott HeartMate 3 LVAD instead of the Medtronic HVAD System.
- Discuss with patients that elective removal of an implanted Medtronic HVAD System is not recommended at this time. In general, the risks associated with explant will outweigh the potential benefits. Decisions about removing and/or exchanging the Medtronic HVAD System should be made by health care providers and patients on a case-by-case basis, considering the patient's clinical status and surgical risks.
- Report any adverse events or suspected events experienced with the Medtronic HVAD System through MedWatch, the FDA Safety Information and Adverse Event Reporting program (/safety/medwatch-fda-safety-information-and-adverse-event-reporting-program/reporting-serious-problems-fda).

Background

The Medtronic HVAD system is a durable LVAD that includes peripheral components (such as controllers, batteries, AC/DC adapters, carrying case) and was first approved for commercial use in the United States in November 2012. It is approved as a bridge to heart transplantation in patients who are at risk of mortality from end-stage left ventricular heart failure, for heart tissue recovery, and as destination therapy in patients for whom a heart transplant is not planned. Medtronic reports there are currently about 2,000 patients implanted with the device in the United States.

There is a growing body of observational clinical comparisons that demonstrates a higher frequency of neurological adverse events and mortality among HVAD System patients as compared to those who receive other commercially available durable LVADs.

Medtronic reports there are over 100 complaints involving a delay or failure to restart of the HVAD internal pump, which led to a total of 14 deaths and 13 pump removals. Medtronic recently recalled a subset of HVAD internal pumps for delayed or failure to restart. For details, see the recall notice, Medtronic Voluntarily Recalled the HVAD Pump Implant Kits Due to Delayed or Failed Restart After the Pump Is Stopped (/medical-devices/medical-device-recalls/medtronic-recalls-hvad-pump-implant-kits-due-delayed-or-failed-restart-after-pump-stopped).

FDA Actions

The FDA is working with Medtronic and Abbott to ensure optimal LVAD patient care remains a priority and an adequate supply of non-Medtronic LVADs are available for future patients. The FDA is working with Medtronic to ensure current patients with a Medtronic HVAD implant continue to receive appropriate follow-up monitoring.

The FDA has monitored the performance of the Medtronic HVAD System since it was approved in 2012, including monitoring neurological adverse event rates. Although Medtronic has stopped the sale and distribution of new HVAD Systems, the FDA will continue to monitor the safety and effectiveness of the HVAD Systems that remain implanted.

The FDA will keep health care providers and the public informed if new or additional information becomes available.

Reporting Problems to the FDA

The FDA encourages health care providers to report any adverse events or suspected adverse events experienced with the Medtronic HVAD System.

- Voluntary reports can be submitted through MedWatch, the FDA Safety Information and Adverse Event Reporting program (/safety/medwatch-fda-safety-information-and-adverse-event-reporting-program/reporting-serious-problems-fda).
- Device manufacturers and user facilities must comply with the applicable Medical Device Reporting (MDR) regulations (/medical-devices/postmarket-requirements-devices/mandatory-reporting-requirements-manufacturers-importers-and-device-user-facilities).
- Health care personnel employed by facilities that are subject to the FDA's user facility reporting requirements (/medical-devices/postmarket-requirements-devices/mandatory-reporting-requirements-manufacturers-

importers-and-device-user-facilities) should follow the reporting procedures established by their facilities.

Prompt reporting of adverse events can help the FDA identify and better understand the risks associated with medical devices.

Additional Resources

- Medtronic's Press Release (https://news.medtronic.com/2021-06-03-Medtronic-to-Stop-Distribution-and-Sale-of-HVAD-TM-System) (http://www.fda.gov/about-fda/website-policies/website-disclaimer)
- Abbott's Press Release (https://abbott.mediaroom.com/2021-06-03-Abbott-Confirms-Capacity-to-Support-Expanded-Use-of-HeartMate-3-TM-Heart-Pump) (http://www.fda.gov/about-fda/website-policies/website-disclaimer)

Contact Information

If you have questions about this letter, contact the Division of Industry and Consumer Education (/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) (DICE).