

Urgent Field Safety Notice

HeartWare™ Ventricular Assist Device (HVAD™) System Retrieval Instructions

July 2021

Medtronic reference: FA981 Phase II

Dear VAD Coordinator/Healthcare Professional,

Medtronic is providing this letter as a follow-up to our June 2021 customer communication titled "Urgent Field Safety Notice: Notification Letter Medtronic HVAD™ System" (attached). The June 2021 communication announced our decision to stop the distribution and sale of the HeartWare Ventricular Assist Device (HVAD)™ System and advised physicians to immediately stop new implants of the Medtronic HVAD System. This communication serves as the retrieval instructions for the Medtronic HVAD System and other components. There is no change to the Patient Management Recommendations outlined in the June 2021 communication.

Please return the following product:

Model Number	Product Description
1104	HVAD™ Pump Implant Kit
MCS1705PU	HVAD™ Pump Implant Kit
1125	HVAD™ Pump Outflow Graft
MCS1725OG	HVAD™ Pump Outflow Graft
1153	HVAD™ Pump Implant Accessories
MCS1753AK	HVAD™ Pump Implant Accessories
100	Driveline Extension Cable

Medtronic is recommending that you **do not** return peripherals or HVAD Surgical Tools needed to manage patients currently on support. Medtronic will continue to support these products and you may order them as needed. If your Center has no active patients on HVAD support, Medtronic requests you return all HVAD products to Medtronic.

Your Actions

- Return all unused affected product (listed in the table above) in your inventory to Medtronic. Your local Medtronic Representative can assist you in the return of affected product.
- For any other questions or concerns, including if you are having trouble locating an alternative device for your patient during this transitional period, please contact the Medtronic Office of Medical Affairs at rs.mcsmedicalaffairs@medtronic.com.
- Please forward this notice to all those who need to be aware within your organization.

The Competent Authority of your country has been notified of this action.

Medtronic remains dedicated to patient safety and will continue to monitor device performance to ensure we meet your needs and those of your patients. If you have any questions, please contact your local Medtronic Representative or Medtronic.

Sincerely,

Hussein Khaldieh,

Sr Sales Manager, SH, KSA

Enclosure: June 2021 Urgent Field Safety Notice

Urgent Field Safety Notice

Medtronic HVAD™ System

Notification Letter

June 2021

Medtronic reference: FA981

Dear Physician / Health Care Professional / Valued Customer,

Medtronic is issuing a global communication announcing our decision to stop the distribution and sale of the HeartWare Ventricular Assist Device (HVAD)™ System. **Physicians should immediately stop new implants of the Medtronic HVAD™ System. Prophylactic explant of the HVAD™ System is not recommended at this time.**

CUSTOMER ACTIONS

Medtronic is requesting customers take the following actions: physicians should:

1. Stop new implants of the Medtronic HVAD™ System.
2. Continue normal use of peripherals and contact Medtronic for replacement of peripheral components (for example: Controllers, batteries AC/DC Adapters, Carrying Case).

BACKGROUND

A growing body of observational clinical comparisons demonstrate a higher frequency of neurological adverse events and mortality with the HVAD™ System as compared to other commercially available durable left ventricular assist devices (LVAD). Considering these findings and given the availability of alternative devices such as the Abbott HeartMate™ 3, Medtronic has made the decision to stop the distribution and sale of the HVAD™ System. Medtronic advises that there be no further implantations of the HVAD System.

In addition, in December 2020, Medtronic issued an Urgent Field Safety Notice informing physicians of an issue where the HVAD™ pump may experience a delay to restart or a failure to restart. The Communication explained that a subset of HVAD™ devices included an internal pump component from three (3) specific lots that increased the risk of restart failure. Medtronic has not been able to pinpoint a root cause for each pump restart failure.

Consistent with the December 2020 notice, the rate of failure among pumps outside of the subset of 3 specific lots currently remains at ~0.4%. Between January 2009 and April 22, 2021 Medtronic received a total of 106 complaints involving delay or failure to restart with the HVAD™ pump. Twenty-six (26) of these complaints involved HVAD™ devices operating under normal conditions (dual stator mode), while 80 involved devices operating in a back-up mode (single stator mode) that allows for continued pump function if electrical continuity between the pump and controller is interrupted. Of the 26 complaints that occurred under normal conditions, 4 resulted in patient death and 5 led to urgent explant. Of the 80 complaints that occurred in single stator mode, 10 deaths and 8 explants were reported to Medtronic. Although Medtronic has identified the root cause and mitigations for pumps within the 3 specific lots, we have not been able to pinpoint a root cause for the other restart failures reported with the HVAD™ pumps.

MEDTRONIC'S ACTIONS

We are committed to patient safety and to serving the needs of the approximately 4,000 HVAD™ patients currently implanted with the device. We recognize this information may be concerning for patients and their caregivers, and Medtronic is committed to supporting them, in coordination with their physicians.

Though we will stop distribution and sale of the HVAD™ System, patients who currently have an HVAD™ implant may require support for many years. We will continue to provide ongoing product support, including the Pioneer controller and peripherals, and we will work diligently to mitigate potential risks associated with the HVAD™ System.

- Medtronic is moving as quickly as possible to create a plan to guide the ongoing support for patients, caregivers, and health care professionals who participate in their care. This plan will include a support program for patients, caregivers, physicians, and VAD coordinators. The specifics of the program are still in development, with guidance from a panel of physician advisors.
- Medtronic will prepare an information sheet that physicians can provide to their patients currently supported with the HVAD who have questions about use and safety of their device.
- We also are working closely with manufacturers of other commercial LVAD devices to help ensure that alternative device options are available for patients who may be candidates for an LVAD device.

PATIENT MANAGEMENT RECOMMENDATIONS

In response to the recent restart failure issue and the evolving data about potential neurologic risks associated with the HVAD™ pump, Medtronic engaged an Independent Practitioner Quality Panel (IPQP) composed of cardiologists, surgeons and VAD coordinators to advise on recommendations for appropriate patient management. Based on information collected to-date and IPQP input, Medtronic's current recommendation is that physicians continue following best clinical practices and manage patients implanted with HVAD™ pump according to the recommendations in the Instructions for Use (IFU).

- **Prophylactic explant of the HVAD™ device is not recommended**, as risks associated with explantation may outweigh the potential benefits. The decision regarding explant and exchange of the HVAD™ pump should be made by physicians on a case-by-case basis, considering the patient's clinical condition and surgical risks. If a physician determines that pump exchange is appropriate, we recommend exchanging to an alternative commercial LVAD.

Patients on HVAD Support

- For existing patients on HVAD™ support, physicians should follow instructions provided in the IFU and adhere to current best clinical practices including closely managing blood pressure and International Normalized Ratio (INR).

BP Recommendations (Ref US IFU00625 and OUS IFU00593)

- Blood pressure management goals should be individualized to the patient conditions. The following are recommended blood pressure management practices:
 - Prior to discharge, patients and/or caregivers should be trained to obtain blood pressure readings and record values.
 - For patients with a palpable pulse, MAP targets should be ≤ 85 mmHg.
 - For patients without a palpable pulse, a manual cuff and a doppler is the preferred method with a MAP target of ≤ 90 mmHg.
 - Patients should be provided specific MAP targets for notification of their clinician for possible intervention as part of their discharge instructions.

Anticoagulation Recommendations (Ref US IFU00625 and OUS IFU00593)

- Long term oral anticoagulation regimen recommendation of combination of warfarin (with INR target 2.0-3.0) and daily ASA > 81mg.
- Continue to use Autologs™ and HVADLogs to better understand pump performance and support clinical decision making.
- Patients should continue normal use of the HVAD™ System peripherals (for example: Pioneer controllers, batteries, AC/DC adapters, and carrying case) consistent with the IFU and should contact their clinic for replacement as needed. Patients also should be reminded to never disconnect the pump from two power sources at the same time and to always have a back-up controller and fully charged spare batteries available.

Patients in Need of LVAD Placement

- **If your center implants alternative commercial LVADs besides HVAD™, use an alternative commercial LVAD, such as the Abbott HeartMate™ 3 LVAD.**
- If you are unable to access an alternative commercial LVAD for your patients in urgent need following this communication, a Patient Information form is required to be completed by you and your patient to acknowledge the risks of an HVAD implant prior to implanting your HVAD inventory.
- If you are an “HVAD only” implanting center, Medtronic is available to facilitate training on an alternative device, such as the Abbott HeartMate™ 3 LVAD. We also are available to work with you and your staff to develop a transition plan for moving from HVAD™ to an alternative LVAD.
- For any other questions or concerns, including if you are having trouble locating an alternative device for your patient during this transitional period, please contact your local Medtronic Representative or Medtronic .

We are working with Abbott to ensure continuity of supply to support future implants of the HeartMate™ 3 LVAD. Medtronic will contact each site to coordinate a product retrieval following this communication.

ADDITIONAL COMMUNICATION

The Competent Authority of your country has been notified of this action. Please share with anyone in your organization that needs to be aware or to whom you have transferred product.

Patient safety is our first concern. There is nothing more important than the safety and well-being of patients. We know the greatest commitment we make to doctors and patients is to consistently make safe medical technologies that alleviate pain, restore health, and extend life.

If you have any questions, please contact your local Medtronic Representative or Medtronic.

We appreciate your time and attention in reading this important notification and will continue to inform you of any additional recommendations.

Sincerely,

Hussein Khaldieh,

**Operating Unit Manager | CS and MCS
Saudi Arabia**