Central Drugs Standard Control Organization
Directorate General of Health Services
Ministry of Health and Family Welfare
Government of India
(Medical Devices and Diagnostics Division)
Email: ddcimd-cdsco@nic.in
Food & Drugs Administration Bhawan,
Kotla Road, New Delhi.

F.No.29/Misc/03/2021-DC(316) **Date: 17th Sep 2021**

MEDICAL DEVICE ALERT

DEVICE

HeartWare™ HVAD System

BACKGROUND

The HeartWare Ventricular Assist Device (HVAD) System is used to help the heart continue to pump blood to the rest of the body. The HVAD systemis used as a bridge to cardiac transplants in patients who are at risk of death from end-stage left ventricular heart failure, for heart tissue recovery, oras destination therapy (DT) in patients for whom heart transplants are not planned.

Reason for Recall

Medtronic is stopping the distribution and sale of the Heartware HVAD System because:

- There is an increased risk of neurological adverse events and mortality associated with the internal pump.
- If the internal pump stops, it may delay restarting or fail to restart.
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IMMEDIATE ACTION TO BE TAKEN BY USER

- Field representatives may assist customers with the return of unused product (sold) and the timely return of the customer signed Customer Confirmation Form.
- Field representatives may assist customers with the timely return of the customer signed Customer Confirmation Form.
- Other associated Corrective/Preventive Actions established in associated CAPA.
- Further, the firm is deploying a permanent corrective action to address the two issues described in the recall notice.

Important Note: CDSCO have not received any complaints from the market on this issue.

FURTHER DETAILS & CONTACTS

M/s India Medtronic Pvt. Ltd, Gurugram, Haryana had issued a Field Safety Notice which is attached herewith this alert.

M/s India Medtronic Pvt. Ltd.
4th Floor, Tower A & B SAS Tower
Medanta The Medicity Complex
Sector 38, Gurugram 122001
Haryana, India
www.medtronic.co.in
Tel +91-124-4709800
Fax +91-124-4206850

Medtronic Stops Distribution and Sale of HeartWare HVAD System Due to Risk of Neurological Adverse Events, Mortality, and Potential Failure to Restart

The recall described in this notice is the same one that was announced in the Stop New Implants of the Medtronic HVAD System – Letter to Health Care Providers (/medical-devices/letters-health-care-providers/stop-new-implants-medtronic-hvad-system-letter-health-care-providers) on June 3, 2021.

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.

The recall described in this notice is the same one that was announced in the Stop New Implants of the Medtronic HVAD System – Letter to Health Care Providers (/medical-devices/letters-health-care-providers/stop-new-implants-medtronic-hvad-system-letter-health-care-providers) on June 3, 2021.

Recalled Product

- HeartWare HVAD System
- Model Numbers: See Full List of Affected Devices
- Distribution Dates: August 30, 2016 to June 3, 2021
- Devices Recalled in the U.S.: 4,620
- Date Initiated by Firm: June 3, 2021

Device Use

The HeartWare Ventricular Assist Device (HVAD) System is used to help the heart continue to pump blood to the rest of the body. The HVAD system is used as a bridge to cardiac transplants in patients who are at risk of death from end-stage left ventricular heart failure, for heart tissue recovery, or as destination therapy (DT) in patients for whom heart transplants are not planned.

Reason for Recall

Medtronic is stopping the distribution and sale of the Heartware HVAD System because:

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

Both problems may lead to death or serious patient harm including stroke, heart attack, worsening heart failure, the need for additional procedures and hospitalizations.

There is a growing body of observational clinical comparisons showing a higher frequency of neurological adverse events and mortality among HVAD System patients as compared to those who receive other commercially available durable left ventricular assist devices (LVAD).

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.

Who May be Affected

- Health care providers using the Heartware HVAD System
- Patients who have procedures with the Heartware HVAD System

What to Do

On June 3, 2021, Medtronic issued an Urgent Medical Device communication to health care providers recommending physicians:

- Stop new implants of the HeartWare HVAD System.
- Continue normal use of peripherals and contact Medtronic for replacement of peripheral components (for example: Controllers, batteries AC/DC Adapters, Carrying Case)
- Complete a Customer Confirmation Form and email to rs.cfqfca@medtronic.com (mailto:rs.cfqfca@medtronic.com)

The communication offered several patient management recommendations, including:

- For existing patients on HVAD support:

- Do not remove already implanted HVAD devices. Risks associated with removing the devices may outweigh the potential benefits. The decision regarding removal and exchange of the HVAD pump should be made on a case-by-case basis, considering the patient's clinical condition and surgical risks.
- Continue to follow instructions provided in the instructions for use (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. Specific details about these clinical practices can be found in the Urgent Medical Device Communicatio (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)n
- 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.

- For patients in need of LVAD placement
  - Use an alternative commercial LVAD, such as the Abbott HeartMate 3 LVAD.
  - If no alternative commercial LVAD is available for patients in urgent need, physicians and patient must complete a Patient Information form to acknowledge the risks of the Medtronic HVAD implant
  - For "HVAD only" implanting centers, Medtronic is available to facilitate training on an alternative device, such as the Abbott HeartMate 3 LVAD. Medtronic will also work with these centers to develop a transition plan to an alternative LVAD.

On July 7, 2021, Medtronic issued a follow up Urgent Medical Device Communication (https://www.medtronic.com/content/dam/medtronic-com/global/HCP/Documents/hvad-urgent-medical-device-notice-july-2021.pdf) (http://www.fda.gov/about-fda/website-policies/website-disclaimer) to provide instructions for returning some HVAD inventory including pump implant kits and accessories, outflow grafts, and driveline extension cables. The company noted that peripherals and HVAD surgical tools should be kept and used to manage patients currently on support, if any. If not, those items should also be returned. Clinical sites should follow the instructions in Medtronic's follow up Urgent Medical Device Communication (https://www.medtronic.com/content/dam/medtronic-com/global/HCP/Documents/hvad-urgent-medical-device-notice-july-2021.pdf) (http://www.fda.gov/about-fda/website-policies/website-disclaimer) issued on July 7, 2021 and only return certain components of the HeartWare HVAD System at this time.

On August 10, 2021, Medtronic issued a letter to healthcare professionals to inform them that Medtronic will be issuing a separate communication about the decision to Halt HVAD Distribution to all Medtronic HVAD™ patients.

The FDA also recommends:

- 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)
- For new 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.

Contact Information

Patients with questions should contact their doctor and review is the information available at www.Medtronic.com/HVADsafety (//www.Medtronic.com/HVADsafety) (http://www.fda.gov/about-fda/website-policies/website-disclaimer).

Healthcare providers with questions about this recall should contact:

- Medtronic Customer Service (mailto:rs.mcscustomerservice@medtronic.com), 1-877-367-4823 for product return questions.
- Medtronic Office of Medical Affairs (mailto:rs.mcsmedicalaffairs@medtronic.com) for medical questions, including help finding an alternative device for a patient during the transition.

Full List of Affected Devices

All HeartWare HVAD Systems are affected by this recall.

The following unused HeartWare HVAD System components in your inventory should be returned to Medtronic at this time:

Model Number	Product Description
1103	HVAD Pump Implant Kit

1104	HVAD Pump Implant Kit
1104JP	HVAD Pump Implant Kit
MCS1705PU	HVAD Pump Implant Kit
1125	HVAD Pump Outflow Graft
MCS1725OG	HVADPump Outflow Graft
1153	HVAD Pump Implant Accessories
MCS1753AK	HVAD Pump Implant Accessories
100	Driveline Extension Cable
100US	Driveline Extension Cable

Additional Resources:

- Medtronic Patient Information Regarding the HVAD System (https://www.medtronic.com/us-en/e/hvad-system-transition.html?cmpid=vanity_url_medtronic_com_hvadsafety_CVG_MCS_FY22) (http://www.fda.gov/about-fda/website-policies/website-disclaimer)
- Medtronic Urgent Medical Device Communication to Healthcare Providers (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 System – Letter to Healthcare Providers (/medical-devices/letters-health-care-providers/stop-new-implants-medtronic-hvad-system-letter-health-care-providers)
- Medical Device Recall Database Entries: (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRES/res.cfm?start_search=1&event_id=&productdescriptiontxt=Heartware&productcode=&IVDProducts=&rootCauseText=&recallstatus=&centerclassificationt
  - HeartWare HVAD Outflow Graft, REF MCS1725OG (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRES/res.cfm?id=188077)
  - HeartWare HVAD Implant Kit, REF MCS1705PU (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRES/res.cfm?id=188076)
  - HeartWare HVAD Implant Kit, REF 1104JP (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRES/res.cfm?id=188075)
  - HeartWare HVAD Driveline Extension Cable, REF 100US (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRES/res.cfm?id=188074)
  - HeartWare HVAD Pump Accessories, REF MCS1753AK (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRES/res.cfm?id=188078)
  - HeartWare HVAD Pump Implant Kit, REF 1153 (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRES/res.cfm?id=188072)
  - HeartWare HVAD Pump Implant Kit, REF 1125 (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRES/res.cfm?id=188071)
  - HeartWare HVAD Pump Implant Kit, REF 1104 (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRES/res.cfm?id=188069)
  - HeartWare HVAD Pump Implant Kit, REF 1103HeartWare HVAD Driveline Extension Cable, REF 100 (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRES/res.cfm?id=188073)

How do I report a problem?

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