Medtronic, Inc. Recalls Instructions for Use and Patient Manual for HeartWare HVAD System to Update Information about Carrying Case, Driveline Cover, and Controller Power-Up Issues

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 Product

- HeartWare HVAD System Instructions for Use and Patient Manual that accompany components including HeartWare HVAD Pump, Controller, Driveline Cable, Driveline Cover, and Surgical Tool Kits
- Models:
    - HVAD Sterile Implant Kit, Model Numbers: 1100, 1101, 1102, 1103, 1104, 1104JP, 1205, MCS1705PU
    - HVAD Controller Kit, Model Numbers: 1403US, 1407AU, 1407CA, 1407CH, 1407DE, 1407GB, 1407IL, 1407IN, 1407IT, 1407JP, 1407KR, 1420, 1420JP
    - HVAD AC Adapter Controller, Model Numbers: 1430AR, 1430AU, 1430CA, 1430CH, 1430DE, 1430GB, 1430IL, 1430IN, 1430IT, 1430JP, 1430US
    - HVAD DC Adapter Controller: Model Number: 1440
    - HVAD DATA CABLE 1575- MONITOR, Model Number: 1575
    - HVAD Battery Pack, Model Numbers: 1650, 1650CA-CLIN, 1650DE
    - HeartWare Patient Pack, Model Number: 1475
    - HeartWare Waist Pack, Model Numbers: 2050, 2050IL, 2050OUS
    - HeartWare Shoulder Pack, Model Numbers: 2060, 2060IL, 2060OUS
- Distribution Dates: March 7, 2006 to present
- Devices Recalled in the U.S.: 130,716
- Date Initiated by Firm: February 26, 2021

Device Use

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The HeartWare Ventricular Assist Device (HVAD) System helps the heart continue to pump blood to the rest of the body. The HVAD System is used as a bridge to heart transplants in patients who are at risk of death from end-stage left ventricular heart failure, to give the heart tissue time to recover, or as a final, or destination, therapy for patients where new transplants are not planned.

Figure 1 - HeartWare System

Reason for Recall

Medtronic is recalling their HeartWare HVAD System to provide updated Instructions for Use (IFU) and Patient Manual (PM) due to safety issues with (1) Carrying Cases, (2) Driveline Cover Orientation and; (3) Controller Power-Up Sequence.

- **Carrying Case:** A drop of the carrying case, caused by damage to the case or improper wear, can disconnect the driveline and then interrupt pump power. **The IFU and PM will be updated to provide information about the lifespan for the carrying cases, and information about how to safely clean and wear the Convertible Patient Pack.**
- **Driveline Cover Orientation:** When the driveline cover is first installed during the surgical implant procedure, if installed properly it will always cover the driveline connector. However, if a patient removes the cover during a controller exchange, there is a possibility that the driveline cover could be put on backwards. In that reversed orientation, the fit of the cover inadvertently causes the driveline locking mechanism to be in the

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unlocked position, which could cause temporary or accidental driveline disconnects. **The PM will be updated to inform patients to keep the driveline cover on when disconnecting and reconnecting the driveline during a controller exchange.**

- **Controller Power-Up Sequence:** During power-up, the LED lights turn red and can be misunderstood as a "red alarm," leading to an unnecessary controller exchange. **The IFU and PM will be updated to make clear that the expected power-up sequence causes the alarm indicator LEDs and both sets of battery LEDs to turn red for 2.5 seconds while the controller LCD displays the power-on message.**

If using the HVAD system and (1) the carrying case breaks and the driveline pulls out of the controller as it drops, or (2) the driveline disconnects from backwards driveline cover orientation; or (3) a controller exchange is performed unnecessarily due to confusion of start-up behavior as a "red alarm" battery failure, this may cause serious patient harm, including death.

There has been 1 death and 64 injuries reported to the FDA for these issues.

Who May be Affected

- Health care providers using the affected HeartWare HVAD System
- Patients undergoing procedures using the affected device

What to Do

On February 26, 2021, Medtronic sent an Urgent Medical Device Notice to all affected customers informing them of upcoming labeling updates related to the issues with the HVAD System carrying cases, driveline cover orientation, and controller power up sequence. This notice also informed customers of labeling updates related to two other issues with the HVAD System, which were identified as Class II recalls (Z-1469-2021 (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfres/res.cfm?id=186390) and Z-1438-2021 (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfres/res.cfm?id=186391)). The notice included an Appendix with updated Instructions For Use (IFU) and Patient Manual (PM) that addressed all of these issues.

Medtronic asked customers to take the following actions:

- Review the updated IFU and PM steps as included in the notice and share with patients as needed.
- Share the notice with all those who need to be aware in the organization or in any organization where potentially affected patients have been transferred.
- Complete a Customer Confirmation Form (enclosed with the notice) and email it to RS.CFQFCA@medtronic.com (mailto:RS.CFQFCA@medtronic.com).

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Contact Information

Customers with questions about this recall should contact their Medtronic Field Representative or Medtronic Customer Service by phone at 877-367-4823.

Additional Resources:

- Medical Device Recall Database Entry (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRES/res.cfm?id=186062)
- Medtronic Urgent Medical Device Notice (https://www.medtronic.com/content/dam/medtronic-com/global/HCP/Documents/hvad/hvad-urgent-medical-device-notice-feb-2021.pdf) (http://www.fda.gov/about-fda/website-policies/website-disclaimer)

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.

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