Medtronic Recalls HeartWare HVAD Pump Outflow Graft and Outflow Graft Strain Relief Due to Risk of Breaks and Tears During Set Up

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 Pump Outflow Graft and Outflow Graft Strain Relief
- Model Numbers:
  - HVAD™ Pump Outflow Graft: 1125
  - HVAD™ Pump Implant Kit: 1103
  - HVAD™ Implant Accessories Kit: 1153
- Distribution Dates: March 1, 2018 to April 1, 2020
- Devices Recalled in the U.S.: 4,924
- Date Initiated by Firm: April 3, 2020

Device Use

The HeartWare HVAD Pump Outflow Graft and Outflow Graft Strain Relief, which are parts of the HeartWare Ventricular Assist Device (HVAD) System, help the heart deliver 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 where new transplants are not planned.

Reason for Recall

Medtronic is recalling their HeartWare HVAD Pump Outflow Graft and Outflow Graft Strain Relief because the outflow graft of the HVAD Pump may tear and the strain relief screw may break during assembly prior to implant but might not be observed until during or after the pre-implant pump assembly and attachment to the HVAD pump.

The use of the affected products may cause serious patient harm including dizziness, loss of consciousness, bleeding, fluid buildup around the heart, additional medical procedures and death.

Medtronic has received 92 complaints related to the pre-implant pump assembly process, which includes both the strain relief screw breaking and outflow graft tears.

Who May be Affected

- Health care providers using affected HeartWare HVAD Pump Outflow Graft and Outflow Graft Strain Relief devices
- Patients undergoing procedures using the affected device

What to Do

On April 3, 2020, Applied Medtronic sent an Important Medical Device Safety Alert to all affected customers. The notice instructed customers to:

- Review the steps listed in Appendix A for assembly and attachment of the outflow graft and strain relief for future HVAD™ System implants.
- Closely inspect the graft after assembly and before implantation for any possible tears.
- Continue to practice standard peri-operative and immediate post-operative patient management to detect for this issue.
- Complete the enclosed Physician Confirmation Form and either return it to your Field Representative or email to RS.CFQFCA@medtronic.com (mailto:RS.CFQFCA@medtronic.com) to indicate you received the notification.

Contact Information

Customers who need additional information about this recall can contact Medtronic Mechanical Circulatory Support Customer Service by phone at 877-367-4823 or mail:

8200 Coral Sea St., NE
Mailstop MVN61
Mounds View, MN 55112

Additional Resources:

- Medtronic Important Medical Device Safety Alert Letter (https://www.medtronic.com/content/dam/medtronic-com/global/HCP/Documents/physician-letter-hvad-outflow-graft-fca.pdf) (http://www.fda.gov/about-fda/website-policies/website-disclaimer)
- FDA Recalls Database (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRES/res.cfm?id=164298)

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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