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IMPORTANT MEDICAL DEVICE SAFETY ALERT

Medtronic HeartWare™ HVAD™ System

Product	Models
HVAD™ Pump Outflow Graft	1125
HVAD™ Pump Implant Kit	1103
HVAD™ Implant Accessories Kit	1153

April 2020

Dear Physician or Healthcare Professional:

Medtronic is writing to alert you to important safety information related to the HVAD™ System and the potential for damage that can occur during the procedure. Specifically, the Outflow Graft may be subject to tears and the Strain Relief screw may break during the pre-implant pump assembly and attachment to the HVAD™ Pump. We are providing additional steps for assembly and attachment to reduce the risk of damage and tearing during the assembly procedure. No action is needed for patients currently implanted with an HVAD™ Pump since the potential for damage applies to the pre-implant Outflow Graft and Strain Relief assembly procedure. Medtronic is currently not retrieving product from the field. Appendix A (attached) includes excerpts from the IFU and describes additional steps for assembly and attachment to avoid potential damage.

Out of nearly 22,000 HVAD pumps distributed through March 5, 2020, Medtronic has received 92 complaints (0.42%) related to the pre-implant pump assembly process, which includes both outflow graft tears and strain relief screw damage. The number of events is broken down as follows:

- 54 complaints (0.25%) including 2 deaths related to outflow graft tears and 2 deaths related to subsequent complications following outflow graft intervention. These tears may result in bleeding and have led to critical patient harm at a rate of 0.13%. With outflow graft tears, there is a potential for peri-operative/post-operative bleeding. This possibility should be considered in patients being treated for post-operative bleeding.
- 38 complaints (0.17%) were related to broken strain relief screws. No patient harm has been reported due to broken strain relief screws. Product damage was identified prior to or during implant in 74 cases and post-implant in 18 cases.

Medtronic is working with the FDA for approval of a design change that is intended to reduce the risk of damage during the assembly of the outflow graft and strain relief and attachment onto the pump during the pre-implant procedure. Medtronic will provide training on this design change after the necessary regulatory approvals are obtained.

YOUR ACTIONS

- Please review the steps listed in Appendix A for assembly and attachment of the outflow graft and strain relief for future HVAD™ System implants.
- Graft should be closely inspected after assembly and before implantation for any possible tears.
- Physicians should continue to practice standard peri-operative and immediate post-operative patient management to detect for this issue.
- Please complete the enclosed Physician Confirmation Form and either return it to your Field Representative or email to RS.CFQFCA@medtronic.com, which indicates you received this notification.

Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail, or by fax.

- Complete and submit the report Online: www.fda.gov/medwatch/report.htm
- Regular Mail or Fax: Download form www.fda.gov/MedWatch/getforms.htm or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form, or submit by fax to 1-800-FDA-0178.

Please maintain a copy of this notice in your records. Medtronic will notify all applicable regulatory agencies about this matter. Please share this notification with others in your organization as appropriate. We sincerely regret any difficulties this may cause you and your patients. Medtronic remains dedicated to patient safety and will continue to monitor device performance to ensure we meet your needs and those of your patients.

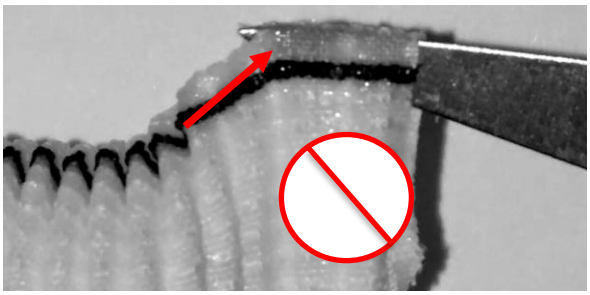
Sincerely,

Kirk Hauge
Vice President, Quality and Regulatory
Medtronic Cardiac Rhythm and Heart Failure

Appendix A: Outflow Graft Attachment excerpts from IFU (standard text) and Additional Steps (italicized underlined text)

1. Examine the outflow graft package. It must be unopened and without visible damage.
2. Open the package aseptically, taking care not to contaminate the sterile graft. Pass the outflow graft onto the sterile field.
3. Slide the strain relief over the outflow graft. Next, stretch the outflow graft over the HVAD™ Pump outflow conduit. Hemostats can be used to assist with the procedure.

   Use of a sharp-tipped instrument to expand graft diameter may damage graft material fibers, leading to leakage around the outflow graft and/or bleeding. Only use blunt-ended hemostats to assist with the procedure. Do not use excessive force during stretching as this may cause outflow graft tears.

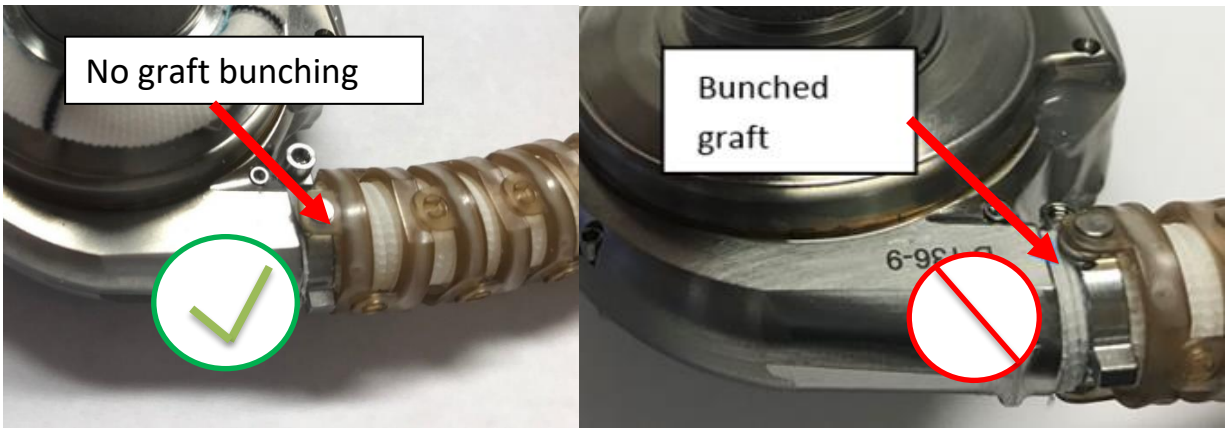


4. Verify that the outflow graft is not kinked or twisted. If necessary, reattach graft if kinking or twisting occurs.

   Carefully observe the outflow graft for any damage. If damage is noted, consider using a replacement outflow graft. Prior to installing the strain relief clamp over the pump outflow conduit, ensure that the clamp screw is fully loosened, but not falling out of the clamp body.

5. Place the graft clamp over the lip of the HVAD™ Pump outflow conduit.

   Avoid "bunching" of graft corrugations between the strain relief clamp and the pump body.
   While maintaining the fully loosened strain relief clamp over the pump outflow conduit, gently pull on the outflow graft to reduce corrugation bunching between clamp and pump body. Extra corrugations from the graft may prevent the strain relief clamp from being flush against the pump body, leading to the strain relief clamp being positioned over the pump outflow conduit ridge, potentially resulting in graft laceration while tightening.



6. Verify that the clamp screw is on the outflow conduit and attached to the graft clamp. If the clamp screw is completely removed or if it falls out, be sure to re-insert it correctly as the clamp has threads on only one side.
7. Position the clamp screw so that it is located on the inner side of the outflow conduit. Tighten the clamp screw until resistance is met.

   Use caution when tightening. It is possible to break the outflow graft strain relief screw when tightening with excessive force; do not use excessive force. Tightening beyond initial resistance may cause the clamp screw to break.

8. Gently pull on the outflow graft to verify secure placement of the graft clamp to the outflow conduit.
9. Inspect the outflow graft and strain relief for any kinks or twisting. Reattach the outflow graft, if necessary.

   Inspect the outflow graft for any bunching, damage, or tears. If damage is found, consider using a replacement outflow graft.

10. Clamp the HVAD™ Pump outflow graft with a vascular clamp, then wrap it all in a clean towel.