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IMPORTANT MEDICAL DEVICE CORRECTION

Medtronic HeartWare™ HVAD™ System

Product	Model Numbers	Serial Number Range
Controller / Controller Kits	1403, 1407, 1420	CON300175 - CON320540

August 2018

Dear Physician or Healthcare Professional:

HeartWare, now a part of Medtronic, is voluntarily providing a communication for all HVAD System Controller units with Serial Numbers in the range of CON300175 – CON320540 (approximately 17,065 units distributed worldwide). Controller units in this range may not meet the labeled standard for protection against water or fluid ingress. Specifically, some units have the potential to develop hairline cracks at the power ports of the controller housing. Hairline cracks may allow for water ingress **if the patient does not follow the Instructions for Use and the Patient Manual, including use of a water-resistant shower bag to help protect the unit** (refer to Attachment A).

If a Controller develops a hairline crack and is unprotected from water or fluid exposure as described in the IFU (see Attachment A), the unit may experience water or fluid ingress. This can lead to varying degrees of controller malfunction, including pump stop.

Hairline cracks in the Controller housing at the power ports were found during manufacturer inspection of product under 10x magnification and are not visible without magnification. The root cause was determined to be a latent interaction between the materials used in the housing unit and the nitrile rubber gasket of the power port connector. Internal investigation estimates the risk of developing a hairline crack in a Controller unit is 0.36. The estimated probability of adverse events due to this issue is < 0.00007. Medtronic has since resolved this issue in the manufacturing process, and as of 23-Aug-2018, all newly distributed Controller units are no longer susceptible to this materials interaction. No other HVAD System components are susceptible to this issue.

Through 14-Aug-2018, there have been zero (0) confirmed complaints against HVAD Controllers in this serial number range associated with hairline cracking or related to reports of fluid ingress. Additionally, fluid ingress has not been observed during internal analysis of HVAD Controller units in this serial number range that were returned for reasons unrelated to this communication.

Patient Management Recommendations

We realize that each patient requires unique clinical considerations. In consultation with Medtronic's Independent Practitioner Quality Panel (IPQP), Medtronic and the IPQP do not recommend proactive controller exchanges as a result of this potential issue. We do, however, recommend the following Patient Manual instructions should be reinforced with your patients:

- **Patients currently supported by the HVAD System should follow all instructions in their Patient Manuals regarding water or fluid avoidance, which remain unchanged, and understand the importance of always using a shower bag when showering (refer to Attachment A of this letter).**
- If a patient encounters a situation in which their HVAD System Controller is exposed to water or fluid outside of conditions described in the IFU and Patient Manual, the patient should be advised to contact his/her VAD coordinator.
- If further assistance is needed, Clinicians should contact their local Medtronic HeartWare representative.

The IFU and Patient Manuals can be found at:
IFU: www.heartware.com/clinicians/instructions-use
Patient Manual (US website): www.heartware.com/patients-caregivers/resources/patient-manual-usa

Please complete the enclosed Clinician Confirmation Certificate and return via email to **RS.CFQFCA@medtronic.com**

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**

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,

Chris Harrold
Vice President, Quality and Regulatory
Medtronic Cardiac Rhythm and Heart Failure

See below for Attachment A: HVAD System with Controller Instructions for Use (IFU) and Patient Manual labeling related to protection against water damage.

ATTACHMENT A

HVAD System with Controller Instructions for Use (IFU) and Patient Manual labeling related to protection against water damage.

The information below is taken directly from the IFU or Patient Manual providing guidance on protecting the HVAD System and its components from water damage. Refer to the HVAD IFU or Patient Manual for a full list of precautions, warnings and potential complications.

CLINICIAN Instructions for Use

www.heartware.com/clinicians/instructions-use

1.4 Warnings (continued)

WARNINGS

9. **WARNING!** DO NOT plug the controller into an AC wall outlet during showers; to eliminate the possibility of a severe electrical shock, it should be connected to two batteries
10. **WARNING!** DO NOT allow patients to take a bath or swim, as this may damage HeartWare™ HVAD™ System components and/or result in driveline exit site infection.
11. **WARNING!** DO NOT submerge HeartWare™ HVAD™ System components in water or other fluid as this may damage them. If this happens, contact HeartWare.
12. **WARNING!** DO NOT allow water or other fluids to enter the controller, power adapters, batteries, battery charger or connectors, as this may damage HeartWare™ HVAD™ System components. If this happens, contact HeartWare.
13. **WARNING!** DO NOT use any components other than those supplied by HeartWare with the HeartWare™ HVAD™ System, as this may affect HeartWare™ HVAD™ System operation.
14. **WARNING!** Damaged equipment should be reported to HeartWare and inspected.
15. **WARNING!** DO NOT rely only on flow estimation to assess cardiac output. An average estimated flow on the monitor or Controller Display of less than 2.0 L/min, or greater than 10.0 L/min may indicate an electrical fault, incorrect hematocrit entry or an occlusion and/or thrombus or other materials (e.g. tissue fragments) in the device. Inaccurate assessment of HVAD® Pump flow may lead to less than optimal treatment.
16. **WARNING!** DO NOT grasp the driveline cable as this may damage the driveline. To remove the driveline from the controller, first pull back the driveline cover then grasp and pull the driveline connector.
17. **WARNING!** DO NOT disconnect the driveline from the controller or the pump will stop. If this happens, reconnect the driveline to the controller as soon as possible to restart the

2.6 Carrying Cases and Shower Bag (continued)

HeartWare® Shower Bag

A shower bag is available for use in conjunction with the HeartWare™ HVAD™ System. To ensure safe and appropriate use of the shower bag, all patients and caregivers should be trained on shower bag operation prior to use.

WARNING! DO NOT allow patients to shower until they have received permission from their clinician to do so. Patients who shower must use the HeartWare® Shower Bag.

WARNING! DO NOT allow hearing impaired patients to shower unless their caregiver is close by to hear alarms.

WARNING! DO NOT plug the controller into an AC wall outlet during showers; to eliminate the possibility of a severe electrical shock, it should be connected to two batteries.

WARNING! DO NOT allow patients to take a bath or swim, as this may damage HeartWare™ HVAD™ System components and/or result in driveline exit site infection.

WARNING! DO NOT submerge HeartWare™ HVAD™ System components in water or other fluid as this may damage them. If this happens, contact HeartWare.

WARNING! DO NOT allow water or other fluids to enter the controller, power adapters, batteries, battery charger or connectors, as this may damage HeartWare™ HVAD™ System components. If this happens, contact HeartWare.

WARNING! DO NOT use any components other than those supplied by HeartWare with the HeartWare™ HVAD™ System, as this may affect HeartWare™ HVAD™ System operation.

WARNING! Damaged equipment should be reported to HeartWare and inspected.

PATIENT MANUAL Instructions for Use

www.heartware.com/patients-caregivers/resources/patient-manual-usa

6.0 Living with the HeartWare™ HVAD™ System

6.4 Washing and Showering

Your clinician will let you wash your incisions after your wounds have healed. When you wash, the controller, batteries and connectors must be protected from water and you should take care so that water doesn't run along the driveline into the controller. The exit site should also be kept as dry as possible. Keeping the exit site dry helps avoid infections.

Your clinician will decide if it is safe for you to shower. If your clinician gives you permission to shower, you must use the HeartWare® Shower Bag to protect the controller and batteries.

WARNING! DO NOT shower until your clinician tells you it is safe to do so. If you receive permission to shower, you must use the HeartWare® Shower Bag. If your hearing is impaired and/or you cannot hear the controller alarms without the use of a hearing aid, make sure your caregiver will be close by to hear alarms.

WARNING! DO NOT plug the controller into an AC wall outlet during showers; it should be connected to two batteries.

WARNING! DO NOT take a bath or swim.

WARNING! DO NOT submerge any HeartWare™ HVAD™ System component in water.

WARNING! DO NOT allow water or other fluids to enter the controller, power (AC/DC) adapters, batteries, battery charger, or connectors. If this happens, contact your clinician.

HeartWare® Shower Bag

The HeartWare® Shower Bag provides the ability to comfortably and securely shower with your HeartWare™ HVAD™ System. The shower bag is water resistant, not water proof, and protects the controller and batteries from direct water spray and moisture. The shower bag permits one (1) controller and two (2) batteries to be placed into a single compartment.

Figure 13

For additional information on using the shower bag, see Section 6.5.