# HeartWare<sup>®</sup>

# **Urgent Field Safety Notice**

## Medtronic HeartWare<sup>™</sup> HVAD<sup>™</sup> System

Important device information

August 2018

Medtronic reference: FA837

Dear Physician, 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 can be found at: www.heartware.com/clinicians/instructions-use

Please share this notification with others in your organization as appropriate.

Medtronic has notified the Competent Authority of your country of this action.

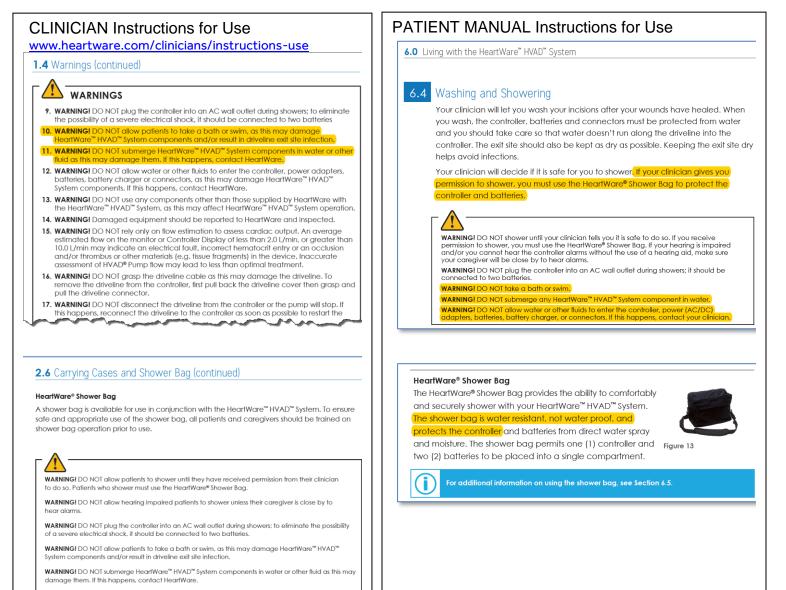
We sincerely regret any difficulties this may cause you and your patients. Medtronic remains dedicated to patient safety and will continue to monitor device performance to ensure we meet your needs and those of your patients. If you have any questions, please contact your Medtronic Representative.



### 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.



WARNINGI DO NOT allow water or other fluids to enter the controller, power adapters, batteries, bat

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.