Medtronic

March 1, 2017

URGENT FIELD SAFETY NOTICE

HeartWare® Ventricular Assist Device (HVAD) System

Identifier	FSCA JAN2017
Type of Action	Safety Notification and Medical Device Removal
Product Codes / Range of Serial Numbers	All HeartWare® HVAD Controllers with Serial Numbers below CON300000 and all HeartWare® 1435 DC Adapters (all Serial Numbers)

Dear HeartWare Clinician,

This communication is to inform you that HeartWare, now a part of Medtronic, has developed an updated HeartWare® HVAD System Controller as part of our continuous improvement initiatives following two previously communicated Urgent Field Safety Notices that occurred in April 2015 and April 2016.

With the introduction of the updated HVAD Controller, also referred to as Controller 2.0, HeartWare is initiating removal procedures for previous generation HeartWare HVAD Controllers with serial numbers lower than CON300000, and all HeartWare DC Adapters, product code 1435 (all serial numbers), which are incompatible with the new HVAD Controller. The removal of these HVAD Controllers and DC Adapters will occur concurrently with the introduction of the new HVAD Controller.

As described in the previous Urgent Field Safety Notices from April 2015 and April 2016, there was the potential for the following safety issues associated with the current HeartWare® HVAD System Controller, including:

1. Worn alignment guides, which could allow connectors to rotate or move, potentially resulting in damaged connector pins.
2. Internal "double disconnect (no power) alarm" battery failure, which could prevent the controller from sounding an alarm in the event of a complete interruption of power.
3. Loose power and data connectors, which could allow the ingress of fluid, resulting in controller malfunction.

The new HVAD Controller includes enhancements to address these potential safety issues, including:

1. Strengthened power and serial port alignment guides to reduce the incidence of wear that could lead to damaged connector pins.
2. Functionality that monitors internal battery performance and sounds an alert when the internal battery is nearing its end of life.
3. Redesigned connectors and housing to prevent the risk of connectors loosening and moisture ingress.

In addition, the new HVAD Controller introduces upgraded internal circuitry designed to improve overall device reliability.

With the introduction of the HVAD Controller modifications described above, HeartWare requires that your site be trained by your local HeartWare representative on the new HVAD Controller prior to allowing distribution and use to occur at your hospital and with your patients. Your HeartWare Representative will work with you to identify a time that is best for your facility. HeartWare requests that you complete the following actions in the order noted in the Hospital and Clinician Actions section below.

> While HeartWare recommends that all patient HVAD Controllers be exchanged, clinicians should weigh the benefits of the updated HVAD Controller against the risks of a controller exchange procedure. Based on data reported to HeartWare, 0.2% of patients who underwent a controller exchange experienced a serious adverse event that required additional intervention. Serious adverse events reported were inclusive of neurological event, events requiring resuscitative efforts, and death due to pump failing to re-start after the controller exchange.

As a reminder, as with all HVAD Controllers, continue to reinforce the following with your patients and staff at all opportunities:

- Patients should continue to have a backup HVAD Controller ready at all times in the event of a primary HVAD Controller failure.
- *Staff only:* The driveline extension cable is to be used during the pre-implant test only. It is not intended to be used after the pump is implanted in the patient.

Hospital and Clinician Actions (to be executed in the following order):

1) **Review** the enclosed notice and forms, and **forward** the notice to those individuals within your organization who need to be aware of its contents.

2) **Complete, sign,** and **return** the "Acknowledgement Form" to HeartWare within thirty (30) days of receipt of this letter.

3) **Complete Training.** Training will cover the new product labeling including the Instructions for Use and Patient Manual. This training will be scheduled and conducted by your HeartWare Representative and is required before new HVAD Controllers will be distributed to your hospital. There may be a period of weeks to months between receipt of this letter and the date individuals at your site are trained.

   Patients must be educated on using the new HVAD Controller by hospital staff who have received training from a HeartWare representative. Do not exchange current HVAD Controllers and DC Adapters until after your site is trained.

4) **Quarantine and replace** affected HVAD Controllers, DC Adapters, Instructions for Use, Emergency Responder Guides and Patient Manuals in hospital inventory after training is complete.

   For every patient, quarantine and replace the following under clinical supervision in an environment where appropriate support equipment is readily available:
   - Primary and Backup HVAD Controller;
   - Affected DC Adapters; and
   - Patient Manual and Emergency Responder Guide.

   Clinicians are reminded not to perform an HVAD Controller exchange during an active electrical fault alarm as the HVAD Pump will be running a single stator. If an electrical fault is present, download patient log files and contact your HeartWare representative to resolve the electrical fault before executing the controller exchange.

5) **Return** all quarantined HVAD Controllers and DC Adapters to HeartWare. Your HeartWare representative will assist you with this process.

6) **Completion Form.** Once affected product in inventory has been identified and returned, complete and return the attached "Completion Form" to con2.0@medtronic.com or your HeartWare representative no later than twelve (12) months from the date of this letter according to the instructions on the form.

Please contact your local HeartWare Representative with questions. We regret any inconvenience that this action may cause and appreciate your understanding as we take action to ensure patient safety and customer satisfaction. Thank you in advance for your cooperation.

Sincerely,

Tim Samsel
Vice President, Quality, CRHF
Medtronic

Attachments
Attachment 1: Acknowledgement Form
Attachment 2: Completion Form

Medtronic

Acknowledgement Form

URGENT FIELD SAFETY NOTICE

(To be completed by site representative)

Identifier	FSCA JAN2017
Type of Action	Safety Notification and Removal
Product Codes / Range of Serial Numbers	All HeartWare® HVAD Controllers with Serial Numbers below CON300000 and all HeartWare® 1435 DC Adapters (all Serial Numbers)

Clinical Institution / Hospital Name:

The undersigned hereby acknowledges receipt and understanding of HeartWare's Urgent Field Safety Notification, FSCA JAN2017.

Position / Title	Printed Name	Signature	Date

No later than 30 days from the date of this notification, please:

- Return this signed form to your HeartWare representative; or
- Email an electronic copy of this signed form to con2.0@medtronic.com.

Medtronic

Product Return Completion Form

URGENT FIELD SAFETY NOTICE

(To be completed by site representative)

Identifier	FSCA JAN2017
Type of Action	Safety Notification and Removal
Product Codes / Range of Serial Numbers	All HeartWare® HVAD Controllers with Serial Numbers below CON300000 and all HeartWare® 1435 DC Adapters (all Serial Numbers)

Clinical Institution / Hospital Name:

_____

The undersigned hereby acknowledges:

- That all affected controllers and DC adapters in inventory and from current patients (if any) have been identified, quarantined, and replaced (or not replaced due to clinician judgment), and
- That quarantined controllers have been returned to HeartWare.

Position / Title	**Printed Name**	**Signature**	**Date**
_____	_____	_____	_____

Please provide this form upon return of all impacted hospital and patient controllers. Please:

- Return this signed form to your HeartWare representative; or
- Email an electronic copy of this signed form to con2.0@medtronic.com.