May 24, 2016

URGENT FIELD SAFETY NOTICE

HeartWare® Controller

Identifier:	FSCA APR2016
Type of Action:	Safety Notification
Product Codes:	1407XX
Range of Serial #s:	HeartWare® Controllers

Dear HeartWare Clinician,

As part of HeartWare's ongoing product performance monitoring, we have received reports of loose power and data connectors on the HeartWare Controller, and are distributing this voluntary safety notification to reduce the potential occurrence of related issues.

Risks to Health

Presently, HeartWare Controllers are manufactured to possess a certain level of protection from water exposure. If a power or data connector becomes loose, Controllers could become more vulnerable to water damage.

Specifically, a loose connector could allow moisture to penetrate the surface of a Controller, which could lead to internal corrosion, electrical faults, reduced speaker volume and connection failures. In these scenarios, potential risks include:

- Interruption of circulatory support due to a pump stop, which could result in serious injury or death;
- Reduced ability to detect alarms; and
- Loss of communication between the Controller and HeartWare Monitor.

Loose connectors have been seen to develop over time during use of the Controller. HeartWare has observed an increase in reports of loose connectors with respect to Controllers that have been in use over one year.

Actions for the Clinician

After reviewing this notification, HeartWare requests that you complete the following actions:

1. Continue to remind your patients currently supported by the HVAD® System to follow all instructions in their Patient Manuals including alarm awareness, water avoidance and carefulness when connecting and disconnecting to power and data sources.

2. At your patients' regularly-schedule appointments, inspect Controllers for loose connectors by gently pressing on each connector and feeling for atypical movement. Do not press hard on the connectors or they could break. If a loose connector is identified, we recommend that you replace the affected Controller with a Controller from inventory and contact your local HeartWare representative. If the affected Controller is the patient's primary Controller, please use discretion as

to whether the risks of a Controller exchange outweigh the risks of a Controller with a loose connector.

3. Please sign and return the attached "Acknowledgement Form" to HeartWare within **30 days** and forward this notification to those individuals within your organization who need to be aware of its contents.

Questions

Should you have any questions or concerns, please contact your local HeartWare representative.

Thank you in advance for your cooperation. HeartWare is conducting this voluntary safety notice with acknowledgment from your local Regulatory Agency.

Sincerely,

Mark Jackson,
Vice President, Quality and Design Assurance

Attachments:

1. Acknowledgement Form

HeartWare®

Acknowledgement Form

URGENT FIELD SAFETY NOTICE

(to be completed by the Site Representative)

Identifier:	FSCA APR2016
Type of Action:	Safety Notification
Product Codes:	1407XX
Range of Serial #s:	All HeartWare® Controllers

Clinical Institution / Hospital Name	

The undersigned hereby acknowledges receipt and understanding of HeartWare's Urgent Medical Device Correction, FSCA APR2016.

Position / Title	Printed Name	Signature	Date

Please sign and return the Acknowledgment Form within 30 days from the date of this letter by doing one of the following:

- ***Email an electronic copy of this signed form to the HeartWare Quality Compliance team via FSCA@heartware.com email address; or***
- ***Fax the signed form to (305) 364-2665***