6 January 2015

URGENT MEDICAL DEVICE RECALL

Product:	HeartWare® Controller
Identifier:	FSCA APR2013.1
Type of Action:	Recall of HeartWare® Controller
Product Codes:	1400, 1401XX
Range of Serial #s:	CON000001 through CON005472

Dear HeartWare Clinician,

In 2013, HeartWare advised you on measures to take in relation to patient safety risks associated with electrostatic discharge (ESD).

Following further analysis of complaint data and ongoing risks, HeartWare is expanding its voluntary Field Safety Corrective Action, FSCA APR2013, by initiating a Medical Device Recall of older HeartWare Controllers (product codes 1400 and 1401XX) with Serial Numbers CON000001 through CON005472. Our records indicate that your facility received these older Controllers.

The affected Controllers exhibit a higher susceptibility to ESD than newer Controllers. Since the 2013 Field Safety Corrective Action, we have received reports of one additional death and one additional serious injury in which ESD may have caused or contributed to data corruption in older Controllers resulting in the loss of commutation to pump motors, which ultimately led to pump stops.

As a reminder, the 2013 Field Safety Corrective Action indicated that ESD is a known risk for electronic equipment and identified techniques to reduce the risk of exposure to ESD. The HeartWare® Ventricular Assist System Instructions for Use (IFU) and Patient Manual also address ESD awareness and Controller alarm management. As stated in the 2013 Field Safety Corrective Action, patients can reduce the risk of ESD by avoiding dry environments, certain fabrics and materials such as silk clothing and carpeting, electronic devices prone to static electricity and certain activities such as vacuuming and removing clothes from a dryer. Patients are instructed to carry backup Controllers at all times and are trained on how to perform a Controller exchange in emergency situations.

HeartWare has made design enhancements to the Controller to improve the Controller's immunity to ESD. This recall only applies to the Controllers (product codes 1400 and 1401XX) with Serial Numbers CON000001 through CON005472. Although HeartWare introduced the enhanced design prior to the 2013 Field Safety Corrective Action, HeartWare only recently accumulated sufficient complaint data to quantify and support the conclusion that enhanced Controllers reduce ESD risk to a level that potentially justifies an intentional pump stop inherent in the exchange of an older Controller.

Risks to Health

- Affected Controllers have a probability of an ESD event of 4% after twelve months of use according to analyzed complaint data. For comparison, the newer Controllers have a probability of an ESD event of 0.1% after twelve months of use. No serious adverse health consequences have been reported in connection with the newer Controllers.

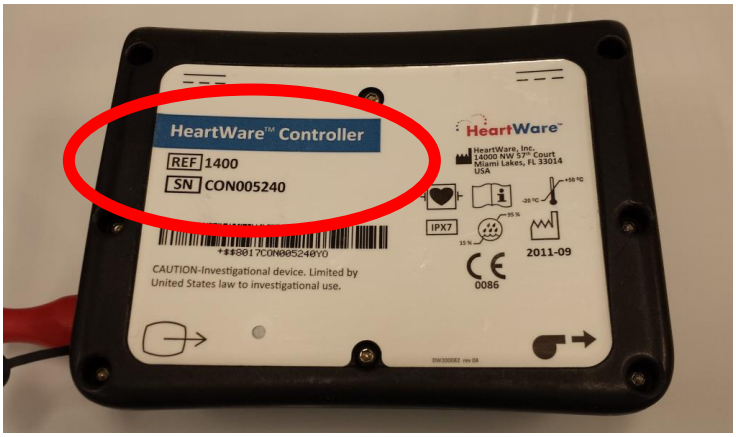
- The risk of injury associated with ESD includes the interruption of circulatory support due to a pump stop. According to analyzed complaint data with respect to affected Controllers, approximately 25% of ESD events may cause or contribute to a pump stop requiring a Controller exchange.

- As described in the HeartWare IFU and Patient Manual, an ESD event may necessitate a Controller exchange. A brief pump stop during a Controller exchange poses a risk of injury in some patients, ranging from minimal temporary symptoms of hypoperfusion to cardiopulmonary arrest or death. In patients with a high risk of catastrophic cardiovascular collapse (*e.g.* patients with a fused aortic valve, patients with an aortic valve that has been sewn shut due to aortic valve regurgitation, patients with very poor endogenous ventricular function, etc.), ESD poses an elevated risk due to the patients' low tolerance of even a temporary pump stop. For reference, when looking at complaint data, only 2.9% of patients who underwent a brief pump stop (not necessarily related to ESD) experienced a serious adverse event or required additional intervention such as inotropic therapy.

Although HeartWare recommends that all affected Controllers be exchanged, it is the treating physician's responsibility to assess a patient's status and determine if the risk of a pump stop due to a Controller exchange is greater than the risk of a pump stop due to an ESD event. Controller exchanges may not be suitable for all patients. It is recommended that Controller exchanges be performed in a controlled setting under medical supervision.

Actions to be Taken by the Clinician

1. **Quarantine Affected Controllers**. Immediately review and quarantine all affected Controllers (product codes 1400 and 1401XX, Serial Numbers CON000001 through CON005472) in your possession, including "hospital training" Controllers. The serial number is located on the white label on the back of the Controller as indicated here:



2. **Acknowledgement Form**. Complete and return the attached "Acknowledgement Form" no later than **30 days** from the date of this letter to your HeartWare representative or to email address FSCA@heartware.com (even if you have no affected patients or Controllers).

3. **Identify Affected Patients**. Review your current patients' equipment records and identify those patients who may possess affected Controllers (both primary and backup).

4. **Primary Controllers**. For each current patient using an affected Controller as their ***primary*** Controller, review the applicable risks with the patient as soon as reasonably possible and, if medically advisable, exchange the affected Controller under medical supervision with a new Controller (serial number CON005473 or higher).

5. **Backup Controllers**. For each patient using an affected Controller as their ***backup*** Controller, contact the patient and arrange to have the backup Controller replaced with a new Controller (serial number CON005473 or higher).

6. **Return Controllers to HeartWare**. Return all quarantined, affected Controllers to HeartWare. Your HeartWare representative will contact you to assist with this process and to help replace affected Controllers as may be necessary.

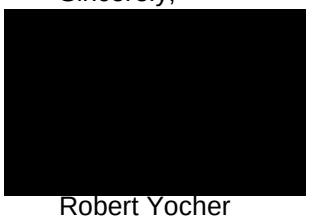
7. **Completion Form**. Complete and return the attached "Completion Form" no later than **6 months** from the date of this letter to your HeartWare representative (or to email address FSCA@heartware.com) with the assistance of your HeartWare representative, as needed.

Please forward this notice to those individuals within your organization who need to be aware of this notice, and to any other organization to which you may have transferred affected Controllers.

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

The undersigned confirms that this notice will be provided to the appropriate Regulatory Agencies consistent with applicable regulations.

Sincerely,



Robert Yocher
Senior Vice President, Regulatory Affairs

Attachments:
Attachment 1: Acknowledgement Form
Attachment 2: Completion Form

HeartWare®

Acknowledgement Form
URGENT MEDICAL DEVICE RECALL

(to be completed by the Site Representative)

Identifier: FSCA APR2013.1
Product Name: HeartWare® Controller
Catalog #: 1400, 1401XX
Serial #: CON000001 through CON005472

Clinical Institution / Hospital Name	

Number of affected Controllers that have been identified and quarantined from site supply (if none, record "0").	
If affected Controllers have been transferred to another organization, provide contact details below. If not applicable, leave this section blank.	

The undersigned hereby acknowledges receipt and understanding of HeartWare's Urgent Medical Device Recall, FSCA APR2013.1.

Position / Title	Printed Name	Signature / Date

Please sign and return this form no later than 30 days from the date of this letter to your HeartWare representative or to email address FSCA@heartware.com.

HeartWare®

Completion Form
URGENT MEDICAL DEVICE RECALL

(to be completed by the Site Representative or the HeartWare Representative (as applicable))

Identifier: FSCA APR2013.1
Product Name: HeartWare® Controller
Catalog #: 1400, 1401XX
Serial #: CON000001 through CON005472

Clinical Institution / Hospital Name	

Site Supply Returned to HeartWare	
Number of affected Controllers that have been identified in site supply (including "hospital training" Controllers) and returned to HeartWare (if none, record "0").	
RGA number(s):	

Site Supply Retained by Site for Training	
Number of affected Controllers that have been identified in site supply as "hospital training" Controllers and marked "**Not For Human Use**" by a HeartWare Representative (if none, record "0").	

Patient Supply Returned to HeartWare	
Number of affected Controllers used as primary or backup Controllers of current patients and returned to HeartWare (if none, record "0").	
RGA number(s):	

Name & Signature of HeartWare Representative (if applicable)	**Date of Completion**

~ To be completed by Hospital / Clinical Representative ~
The undersigned hereby confirms the above information in connection with HeartWare's Urgent Medical Device Recall, FSCA APR2013.1. Unless indicated otherwise on this form, all affected Controllers shipped to this site and not accounted for above are presumed to have been destroyed, discarded or previously returned to HeartWare.

Position / Title	Print Name	Signature / Date

Please sign and return this form no later than 6 months from the date of this letter to your HeartWare representative or to email address FSCA@heartware.com.