08.05.2015

HAZARD ALERT

HeartWare® Ventricular Assist System (HVAD)

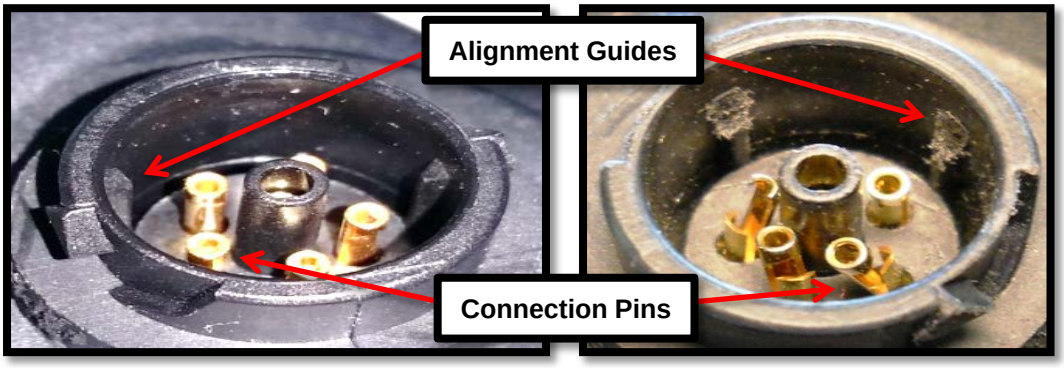
Identifier:	FSCA APR2015A
Type of Action:	Hazard Alert
Product Codes:	1100, 1101, 1102, 1104, 1205
Range of Serial #s:	All HeartWare® HVAD Systems currently in use

Dear HeartWare Clinician,

As part of HeartWare's ongoing product performance monitoring, we have reviewed certain complaints related to the HVAD® System, and are distributing this Hazard Alert to help reduce the occurrence of avoidable injuries as patients remain on the device for increasingly long periods of time.

1. Worn Alignment Guides

Take care when connecting to power sources. The alignment guides in the power supply connector ports may wear down over time. Worn alignment guides may allow the power supply connectors to rotate or move while the metallic connection pins are still engaged. If this happens, the connection pins could become damaged or bent. The following pictures show what to look for when evaluating whether alignment guides are worn down:



Unworn Alignment Guides (Good) *Worn Alignment Guides (Use Caution)*

HeartWare has initiated a program to improve the strength of the alignment guides to reduce possible damage to the connection pins. Patients should inspect the power supply ports on their Controllers for potential wear or damage to the alignment guides or connection pins. If damage is found, (i) care should be taken when connecting power sources so as not to twist or bend the connection pins and (ii) patients should contact their healthcare provider to schedule an appointment and possibly arrange for a replacement Controller.

Risks:
Damage from wear and tear to power supply connectors over time could result in the inability to connect to a power source. Delay in power maintenance could result in battery discharges or pump stops, which could cause death or serious injury.

2. Internal "Double Disconnect Alarm" Battery

Never disconnect from both power sources at the same time. The Controller has an internal battery with a sole purpose of powering an alarm in the unlikely event that both power sources are simultaneously disconnected. Like all batteries, this battery may fail with age. If there is a complete interruption of power and the internal battery is dead or underpowered, there may be no audible alarm. Patients should be reminded to always follow their Patient Manuals when changing power sources. Patients should NEVER disconnect from both power sources at the same time and should ensure that a caregiver is always nearby when changing power sources. A solution to the internal battery failure is currently being investigated by HeartWare.

Risks:
A failure of the internal battery has no impact on normal functionality of the Controller and is unlikely to have a clinical impact, *provided* patients follow the Patient Manual and NEVER disconnect from both power sources at the same time and ensure that a caregiver is always nearby when changing power sources. Failure to follow the Patient Manual could result in serious injury or death.

3. Power Management Software Upgrade

Treat all battery alarms in accordance with the patient manual and Instructions for Use ("IFU"). In addition to previous enhancements to improve battery performance, HeartWare is developing a software upgrade to improve how the Controller manages a transient loss of communication between it and the batteries, which can sometimes contribute to premature "battery switching" or false battery alarms. In many cases during a transient loss of communication, power is not lost to the Controller and there is no loss of functionality. Until the software upgrade is available, patients should treat all battery alarms in accordance with the Patient Manual.

Risks:
Unnecessary battery switching and false battery alarms do not increase risk to patients, but may result in increased battery changes or alarms.

4. Driveline Outer Sheath Discoloration and Cracking

Keep driveline outer sheaths protected from excessive ultra violet light. Patients should be aware that the driveline outer sheath may crack or become discolored over time. This outer, protective covering contains a plastic material that may degrade if exposed to excessive ultra violet light, such as direct sunlight or tanning beds, while the internal driveline conductors remain protected and intact. Although HeartWare is aware of a few instances where a driveline exit site infection occurred with respect to a patient with a cracked outer sheath, the rate of patients with exit site infections and discolored or cracked outer sheaths is no greater than the rate of patients with exit site infections and no discolored or cracked outer sheaths. To help prevent unnecessary exposure to ultra violet light, patients should keep their driveline protected under their clothing while in direct or indirect sunlight. If patients do cover their driveline with clothing, they should take care not to limit access to the Controller connection in a way that would interfere with a Controller exchange should one be necessary.

Risks:
Patients with discolored or cracked drivelines had comparable rates of driveline-related infections when compared to patients without discolored or cracked drivelines.

5. Snagging or Pulling of the Driveline

Beware of inadvertent snagging or pulling of the driveline. As a reminder, patients should take care when managing their driveline to avoid accidental snagging or pulling, which could result in excessive force being placed on the driveline's connection to the Controller. For example, patients should avoid having an exposed loop in the driveline that could catch on hazards such as door knobs, seat belts or brake handles. Patients should not pull, kink or twist the driveline. If a patient inadvertently damages his or her

driveline, the patient should NOT attempt to repair the driveline as it may lead to inadvertent injuries. The patient should contact his or her healthcare provider to determine whether a driveline repair should be performed by a HeartWare technician.

Risks:
If a driveline is severely damaged or disconnected from the Controller, electrical issues or pump stops are possible, which could lead to serious injury or death.

Actions to be Taken

HeartWare requests that you complete the following actions:

1. **Review** the enclosed notice and "Patient Communication" and familiarize yourself with its contents.
2. **Forward** this notice to those individuals within your organization who need to be aware of its contents.
3. **Identify** your patients currently supported by the HVAD® System.
4. **Distribute** the "Patient Communication" to your patients in person, via FedEx or some other reliable means of communication. Please contact your HeartWare representative should you need any assistance with this process.
5. Continue to **reinforce** the messages described in this notice with your patients during their regularly scheduled appointments.
6. **Complete, sign and return** the "Acknowledgement and Completion Form" to HeartWare within **30 days** of receipt of this letter.

If any of your patients implanted with the HeartWare HVAD® System could have been transferred from your hospital to another, please immediately let that hospital know of the Recall for the Hazard Alert. It would be appreciated if you would then telephone – long distance callers reverse charge – the nearest company office indicated below so that we can make contact with the hospital supplied from your hospital.

Should you have any questions or concerns, please contact your local HeartWare representative, Craig Armstrong at +614 0348 1802.

Company Address:
HeartWare Pty Ltd.
68 Pitt Street Level 10
Sydney, NSW 2000
Australia

Telephone: +612 8078 6164
Fax: +612 8078 4314
Email: FSCA@heartware.com
Customer Service Email: csaustralia@heartware.com

HeartWare is distributing this voluntary safety notice to the appropriate Regulatory Agencies consistent with applicable regulations.

Sincerely,

[redacted]

Mark Jackson
Vice President, Quality & Design Assurance

Attachments:
1. Acknowledgement and Completion Form
2. Patient Communication

HeartWare®

Acknowledgement and Completion Form

HAZARD ALERT

(to be completed by the Site Representative)

Identifier: FSCA APR2015A
Type of Action: Hazard Alert
Product Codes: 1100, 1101, 1102, 1104, 1205
Range of Serial #s: All HeartWare® HVAD Systems currently in use

Clinical Institution / Hospital Name	

The undersigned hereby acknowledges receipt and understanding of HeartWare's Hazard Alert, FSCA APR2015A, and certifies that the "Patient Communication" attached to the notice has been distributed to all affected patients.

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

Patient Communication

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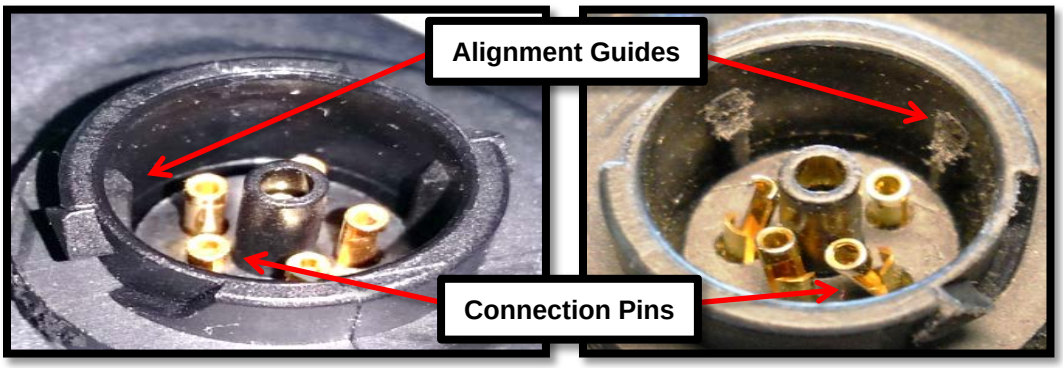
***Reason for this Letter*:**

HeartWare wants to make sure that patients with an HVAD® System know how to use their device safely. The purpose of this letter is to remind you of some important information about your HVAD® System.

1. **Never Disconnect from Both Power Sources at the Same Time**. If your Controller's internal battery is weak or dead, your Controller may not alarm if you disconnect from both power sources at the same time. Therefore, take care to always follow your Patient Manual. Remember to NEVER disconnect from both power sources at the same time and make sure that someone else is always with you when changing power sources.

2. **Take Care when Connecting to Power Sources**. The ports, or sockets, on the Controller may wear down over time causing power source connections to loosen or become difficult. Look at your power supply ports on your Controllers for wear or damage to the alignment guides or connection pins. The following pictures show what to look for:



Unworn Alignment Guides (Good) *Worn Alignment Guides (Use Caution)*

If damage is found, (a) be careful when connecting to power sources so as not to twist or bend the connection pins (shown above) and (b) contact your doctor to schedule an appointment and possibly arrange for a replacement Controller. Your doctor has also received this notice and is aware of this issue. Damage to power supply connectors could make it difficult to connect to a power source, which could lead to serious injury or death.

3. **Keep the Outer Sheath of your Driveline Protected from Excessive Sunlight**. Be aware that the driveline's outer sheath may become discolored or show signs of cracking over time. The outer covering of the driveline is made of a material that may break down if the material is exposed to excessive ultra violet light, such as direct sunlight or tanning beds. To avoid discoloration or cracking, keep your driveline protected under your clothing. If you cover your driveline with your clothing, be

careful not to get in the way of the Controller connection in a way that would interfere with a Controller exchange should one be necessary.

4. **Beware of Accidental Snagging or Pulling of your Driveline**. Avoid catching your driveline on things like door knobs, seat belts or brake handles. Do not pull, kink or twist your driveline. If you damage your driveline, DO NOT attempt to repair the driveline as it may lead to injuries. You should call your doctor to see if a repair is necessary and if necessary, to schedule a repair by a HeartWare technician. If a driveline is severely damaged or disconnected from the Controller, electrical issues or pump stops are possible, which could lead to serious injury or death.

Questions?

If you have any questions about your HeartWare® System or this notice, please contact your doctor or VAD team.

HeartWare is distributing this voluntary safety notice to the appropriate Regulatory Agencies consistent with applicable regulations.