May 08, 2015

URGENT FIELD SAFETY NOTIFICATION

HeartWare® Driveline Cable Splice Assembly

Identifier: FSCA APR2015B
Type of Action: Safety Notification
Product Codes: ASY00116, ASY00281
Range of Serial #s: All Patients with Driveline splice repair

Dear HeartWare Clinician,

This is the second of two (2 of 2) Safety Notifications that you are receiving related to retraction of connector pins; however, this notification is specific to a subset of patients that have undergone splice repair of the HVAD Driveline. Our records indicate that you have one or more patients that have undergone a splice repair of their HVAD® Driveline. These patients are identified in the Acknowledgement and Completion Form on page 3 of this notification.

As part of HeartWare's ongoing product performance monitoring, we have received a limited number of complaints relating to the retraction of connector pins within the driveline splice assembly following a splice repair. We believe that the retraction of the splice assembly connector pins may be the result of excessive force applied to the driveline from accidental dropping of Controllers or snagging of drivelines on items such as door handles or other hazards.

Between April 2010 and March 2015, 35 patients underwent a splice repair. Retraction of the splice assembly connector pins occurred 15 times, likely due to the application of excessive force to the driveline. Of these failures, 2 may have contributed to a patient death.

HeartWare is finalizing enhancements designed to increase the strength of the splice assembly to avoid the retraction of splice assembly connector pins. HeartWare will notify clinicians when an improved repair kit is available. We are targeting to release the repair kit within the next few months.

Risk:
Accidental pulling or snagging of the driveline may result in excessive force being placed on the splice assembly. This can result in the retraction of the splice assembly connector pins and may lead to electrical faults or pump stops. Pump stops can result in death or serious injury.

Damaged to Splice Assembly Connector Pins			
Total Complaints	No Serious Adverse Event	Serious Adverse Event	Death
15	12	1	2

Actions to be taken by the Patient:
Patients should take care when managing their driveline to avoid accidental dropping of Controllers or snagging of drivelines, which could result in excessive force being placed on the splice repair. 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 should inadvertently damage his or her driveline or splice assembly, the patient should NOT attempt to repair the driveline as it may lead to inadvertent injuries, but should contact his or her clinician IMMEDIATELY for instructions and to schedule an appointment for a new splice repair by a HeartWare technician.

Actions to be taken by the Clinician

HeartWare requests that you complete the following actions:

1. **Review** this notice and the attached "Patient Communication" and familiarize yourself with its contents.

2. **Forward** this notice to those individuals within your organization who need to be aware of this notice.

3. **Verify** the list of patients in the "Acknowledgement and Completion Form," showing your patients who have undergone a splice repair according to HeartWare records.

4. **Distribute** the "Patient Communication" to your affected 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 or to schedule a splice repair by a HeartWare technician.

5. Continue to **reinforce** the messages set forth in this notice with your patients who have experienced a splice repair 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.

This notice needs to be passed on all those who need to be aware with your organization or to any organization where the potentially affected devices have been transferred. Please transfer this notice to other organizations on which this action has an impact.

Please maintain awareness on this notice and resulting action to ensure effectiveness of the corrective action.

Should you have any questions or concerns, please contact your local HeartWare representative. Our 24-Hour Clinical Support personnel are also available at +49 511 676936911 (Germany) or +44 7534 245492 (UK). HeartWare may also be reached via the European Authorized Representative, MedPass International Ltd., on +44 (0) 1452 619 222 (telephone and fax) and MedPass.AR@medpass.org (email).

HeartWare is distributing this voluntary safety notice with the knowledge of the Regulatory Agencies consistent with applicable regulations.

Sincerely,

[redacted]

Vice President, Quality & Design Assurance

Attachments:

1. Acknowledgement and Completion Form
2. Patient Communication

HeartWare

Acknowledgement and Completion Form
URGENT FIELD SAFETY NOTIFICATION

(to be completed by the Site Representative)

Identifier: FSCA APR2015B
Type of Action: Safety Notification
Product Codes: ASY00116, ASY00281
Range of Serial #s: All Patients with Driveline splice repair

Clinical Institution / Hospital Name	

Our records indicate that the following patient(s) at your site have undergone a splice repair and should receive the attached "Patient Communication":

Patient ID	**Implant Date**

The undersigned hereby acknowledges receipt and understanding of HeartWare's Medical Device Correction, FSCA APR2015B, and certifies that the "Patient Communication" attached to the notice has been distributed to all of site's patients who have received splice repairs.

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
URGENT FIELD SAFETY NOTIFICATION

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***Reason for this Letter*:**

You have been identified as a patient currently using an HVAD® System who may have undergone a driveline splice repair. We have received a limited number of complaints related to damaged connector pins located within the splice assembly. We believe that this damage may be caused by excessive pulling on drivelines from things like dropping the Controller or snagging the driveline on door knobs or brake handles. Damaged drivelines following a splice repair may result in electrical connection issues or even pump stops. Therefore, please:

1. **Contact your Doctor or VAD Coordinator to Schedule an Appointment**. An additional repair to your Driveline Cable Splice Assembly by a HeartWare technician may be required.

2. **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 accidental injuries.

Possible Risks:

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

Questions?

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

Thank you for your cooperation. HeartWare is distributing this voluntary safety notice with the knowledge of the Regulatory Agencies consistent with applicable regulations.