August 15, 2016

Urgent Field Safety Notice

HeartWare® HVAD Pumps in Inventory

Identifier: FSCA JUL2016
Type of Action: Voluntary Recall
Product Name: HeartWare® HVAD Pumps in Inventory
Product Codes:

US Product:	**Model No.: 1103**
International Product:	**Model No.: 1104XX** **('XX" represents country designation)**

Ranges of Serial #s: Sterile, un-implanted stock in inventory with serial numbers prior to HW25838

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 notice to announce a voluntary recall of specified implant kits (pumps) in hospital inventory, which may be more susceptible to electrical faults if the driveline becomes contaminated.

Contamination of the driveline-to-controller connector can occur during the implant procedure or post operatively from fluid ingress into the driveline. HeartWare has implemented manufacturing process improvements designed to prevent driveline connector contamination in new implant kits.

Connector contamination of the driveline has been seen to occur most often in the first 30 days post implant. Affected devices that have already been implanted into a patient are not subject for removal. Patients that experience electrical faults due to driveline connector contamination should be addressed per HeartWare's HVAD Pump driveline connector cleaning procedure conducted by qualified HeartWare personnel, per the HeartWare Ventricular Assist System Instructions for Use section 3.24. Do not attempt to repair or service any components of the HeartWare System. If the HeartWare System equipment malfunctions, please promptly contact your local HeartWare representative.

Risk to Health

The presence of fluid or foreign material at the driveline/controller connector may impact the function of the pump and controller.

Specifically, foreign material at the driveline/controller connector could lead to electrical faults and connection failures. In these scenarios, potential risks include interruption of circulatory support due to a pump stop, which could cause serious injury or death.

Actions for the Clinician

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

1. **Identify affected product in hospital inventory**. Upon receipt of this notification, promptly review your HVAD pumps in inventory, and either:
   - Identify any affected product(s) and list them on the attached Acknowledgement Form; ***OR***
   - Check the box to confirm that "No affected HeartWare® HVAD Pump(s) have been identified in hospital inventory."
2. **Acknowledgement Form**. Complete and sign the attached "Acknowledgment Form" and return it to HeartWare per the instructions on the form. Upon receipt of the Acknowledgement Form, HeartWare Customer Service will generate the appropriate RGAs and process shipment of replacement product to you. In the event that no affected product is identified within hospital inventory, no further action is required.
3. **Forward this notice** to all those who need to be aware within your organization as well as to any other organization where affected HVAD pumps may have been transferred.
4. **Return affected product to HeartWare.** When replacement product has been received, return affected product to HeartWare via the appropriate RGAs.
5. **Completion Form.** Once affected product in inventory has been identified and returned, complete and return the attached "Completion Form" to your HeartWare representative no later than two (2) months from the date of this letter according to the instructions on the form.

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 the appropriate Regulatory Agencies. We regret any inconvenience that this may cause and appreciate your understanding as we take action to ensure patient safety and customer satisfaction.

Sincerely,

Mark Jackson
Vice President, Quality and Design Assurance

Attachments:

1. Acknowledgment Form (Required)
2. Completion Form (Required *ONLY IF* affected products are identified in inventory)

HeartWare®

Acknowledgement Form
URGENT MEDICAL DEVICE RECALL

(to be completed by the Site Representative)

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Clinical Institution / Hospital Name	

Please check appropriate box below:

☐ HeartWare® HVAD Pump(s) in inventory have been identified as affected product under FSCA JUL2016 and are listed below:

HVAD Pump Serial Number in Inventory under FSCA JUL2016	

☐ No affected HeartWare® HVAD Pump(s) have been identified in hospital inventory. (***If checked, no additional action is required***).

The undersigned hereby acknowledges receipt and understanding of HeartWare's Urgent Medical Device Recall, FSCA JUL2016.

Position / Title	Printed Name	Signature	Date

Please provide acknowledgement no later than 30 days from the date of this letter by doing one of the following:

- ***Return this signed form to your HeartWare representative; or***
- ***Email an electronic copy of this signed form to FSCA@Heartware.com; or***
- ***Fax the signed form to (305) 364-2665***

HeartWare®

Completion Form
URGENT MEDICAL DEVICE RECALL

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Clinical Institution / Hospital Name	

The undersigned hereby acknowledges:

Affected HeartWare® HVAD Pumps in inventory have been identified and have been returned to HeartWare.

Position / Title	Printed Name	Signature	Date

Please return no later than 2 months from the date of this letter by doing one of the following:

- ***Return this signed form to your HeartWare representative; or***
- ***Email an electronic copy of this signed form to FSCA@Heartware.com; or***
- ***Fax the signed form to (305) 364-2665***