November 22, 2017

URGENT FIELD SAFETY NOTICE	
Identifier:	**FSCA NOVEMBER2017**
Type of Action:	**Re-inspection**
Product:	**Jarvik 2000 Ventricular Assist System, Adult VAD, Abdominal Cable Model, JHI-002**
Subject:	**Drive Cable Connector requires X-ray inspection to confirm presence of all three (3) connector pin crimps**

To: Distributors & Users of the Abdominal Driveline Jarvik JHI-002 VAD

Jarvik Heart, Inc. is aware of one (1) incident in Japan in which a patient supported by the Jarvik 2000 VAD, Abdominal Cable, JHI-002 started to experience short controller alarm beeps after one (1) year post-implant. The alarm beeps occasionally occurred, even after external equipment had been replaced. Several months later the patient started to experience intermittent pump stopped alarm conditions requiring evaluation at the hospital. Some of these events lasted a couple of seconds or more, and were accompanied by observations of the wattmeter momentarily spiking up to 10 or 13 watts. The hospital treated the patient's intermittent pump stopped conditions by replacing the external equipment and modifying anticoagulation treatment. After several weeks in the hospital, the patient was released and returned home.

A couple of months later the patient was found unconscious at home while taking a shower and while the caregiver was away. The patient went into cardiac arrest and was rushed to the hospital. Because a trained caregiver was not present, no attempt was made to replace equipment with back-up equipment, and no back-up equipment was taken to the hospital. Neither the paramedic nor the hospital staff was able to resuscitate the patient who later passed away. All of the external equipment and the VAD at the time of the event were returned to Jarvik Heart, Inc. for analysis and it was determined that three wires inside one (1) of three (3) pins in the drive cable connector was not crimped.

Jarvik Heart, Inc. is aware of one (1) incident in four hundred fifty four (454) manufactured devices of the Abdominal Cable, JHI-002 where a missing pin crimp was found on the drive cable connector. Based on the reported event, the occurrence rate for this type of incident is 0.2%.

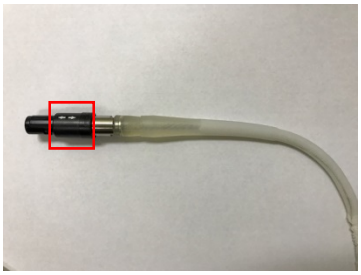
Affected Devices

Only four (4) devices outside Japan are affected: S/N 1560, SN 1265, SN 1789, SN1832

Description of Potential Issue

All drive cable connectors have three (3) wires inside each of three (3) pins, and each pin is required to be manually crimped by an operator during the assembly process. If one pin is not crimped, it is possible for the VAD to run normally so long as one of the three (3) wires inside

the pin makes electrical contact with the pin. However, if the drive cable is manipulated in such a way that **all** three (3) wires inside the pin do not make electrical contact with the pin, intermittent operation of the VAD or a pump stopped condition may occur.



Abdominal Drive Cable connector showing location of pin crimps

Recommended Actions

Jarvik Heart, Inc. is aware of only one (1) missing crimp on a drive cable connector pin out of 454 manufactured JHI-002 devices and believes the risk of a similar incident is extremely low.

As a precaution to confirm the presence of pin crimps on **all** drive cable connectors of JHI-002 Abdominal Cable VADs we recommend:

- all implanted patients have an X-ray inspection of their drive cable connector and images sent to Jarvik Heart, Inc. QA to review and confirm presence of pin crimps.
    - Jarvik Heart will provide a procedure for X-ray inspection of the connector

- all packaged JHI-002 VADs be quarantined until X-ray inspection of the drive cable connector can be performed by Jarvik Heart, Inc. to confirm presence of pin crimps.

Transmission of this FSN

Please transfer this notice to anyone in your organization that may be impacted.

This notice has been submitted to all relevant competent authorities worldwide in markets where the Jarvik 2000 Ventricular Assist System (VAS), Adult VAD, Abdominal Cable, JHI-002 has been distributed.

Thank you for your attention to this matter.

Contact Person

Kamal Gandhi

VP Quality & Regulatory

Jarvik Heart, Inc.

Attachment: Acknowledgment of receipt form

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(to be completed by the site representative)

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The undersigned hereby acknowledges having received and understood the urgent field safety notice FSCA NOVEMBER 2017, sent by Jarvik Heart, Inc.

Function/Title	**Name (please print)**	**Signature**	**Date**
_____	_____	_____	_____

No later than 30 days from the date of this notice, please:

- Return this signed form to your Jarvik Heart, Inc. representative; or
- Send by email an electronic copy of this signed form to returns@jarvikheart.com

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