



July 21, 2017

URGENT FIELD SAFETY NOTICE

Identifier: FSCA JULY2017
Type of Action: IFU Update
Product: Jarvik 2000 Ventricular Assist System, Adult VAD, Post-Auricular Cable Model, JHI-001
Subject: Warning against use of oily or fatty substances near the Pedestal connector

To: Distributors & Users of the Jarvik 2000® Ventricular Assist System (VAS)

Jarvik Heart, Inc. has been requested by the French competent authority, ANSM, to issue a field safety corrective action (FSCA) based on two (2) incidents involving disconnection of the Pedestal Cable (JHI-201) resulting from the use of oily or fatty substances near the Pedestal connector. Both of these disconnections occurred in a hospital environment, activated an alarm, and were promptly addressed by a clinician re-connecting the cable with no harm to the patient. The cable was later replaced.

Jarvik Heart, Inc. is aware of only two (2) reportable incidents of this type in over five hundred (500) implants of the Post-Auricular Cable, JHI-001. Based on the reported events, the occurrence rate for this type of incident is 0.4%.

Affected Devices

All Jarvik 2000 Ventricular Assist System (VAS), Adult VAD, Post-Auricular Cable, JHI-001

Description of Potential Issue

The use of oily or fatty substances in the vicinity of the Pedestal connector has the potential for these substances to transfer onto the Pedestal connector and substantially reduce the retention force between the Pedestal Cable (JHI-201) and the Pedestal connector. This may result in a partial or complete disconnection of the Pedestal cable during normal use, and result in a pump stopped condition.





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If a disconnection should occur, the Pump Stopped Alarm will sound prompting immediate action to address the pump stopped condition. Re-connection of the cable in this case, will immediately resolve the pump stopped alarm, and re-start the VAD.

Recommended Actions

If a disconnection of the Pedestal Cable should occur due to the use of oily or fatty substances:

- Promptly reconnect the Pedestal Cable
- Apply a temporary bandage over the Pedestal Cable and connector, around the head, to keep them connected
- Return to the hospital or center where hospital staff should clean the Pedestal site per the Operator Manual and replace the Pedestal Cable with a fresh Pedestal Cable



Avoid the use of oily or fatty substances near the Pedestal connection site as these may affect the retention of the Pedestal Cable upon the Pedestal base. The use of such substances near the connector may result in a loose connection and increase the chances of accidental disconnection.

Jarvik Heart, Inc. is updating the Operator Manual, Patient Handbook, and Training (Surgical) Manual to include the above warning and expects to make these available by end of August 2017.

Transmission of this FSCA

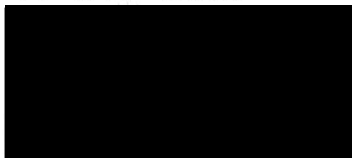
Please transfer this notice to anyone in your organization that may be impacted.

Please maintain awareness of this notice until updated labeling documents have been made available.

This notice has been submitted to all competent authorities worldwide in markets where the Jarvik 2000 Ventricular Assist System (VAS), Adult VAD, Post-Auricular Cable, JHI-001 has been distributed.

Thank you for your attention to this matter.

Contact Person



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 JULY2017, 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