



October 5, 2018

URGENT FIELD SAFETY NOTICE

Identifier: FSCA OCTOBER2018
Type of Action: ADVICE ON CARE AND MAINTENANCE OF EXTERNAL CABLES
Product: JHI-212 Y Cable, JHI-202 Lithium-ion Battery Cable, JHI-201 Pedestal Cable, JHI-204 Extension Cable
Subject: USE OF EXTERNAL CABLES, MALE CONNECTORS

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

Jarvik Heart, Inc. is aware of complaints of damaged male connectors on external cables. A three year review showed more complaints were received on Y Cables and Li-ion Battery Cables than on other cables. Most of the items returned and investigated showed evidence of physical damage to the connector, the most common being a detached male connector housing. Other forms of damage observed include misaligned connector, cracked connector housing, and bent pins, etc. Many of these complaints suggest user damage related to use. Also observed in these complaints was improper use and maintenance of external cables.

In nearly all of these cases, the damaged external cable was safely replaced with a back-up cable in accordance with the Instructions For Use and no harm or injury to patient occurred. We are aware of one case where a clinician improperly taped together a detached connector housing instead of replacing the cable. A few weeks later the housing detached again resulting in a pump stop condition requiring hospitalization of a pump-dependent patient who had lost consciousness. In another case, a patient who usually does not use a Y Cable plugged a Li-ion Battery Cable directly into the Controller. The male cable connector housing of the Li-ion Battery Cable later became detached but was replaced with a back-up cable with no harm or injury to the patient.

Based on our review of complaints Jarvik Heart, Inc. would like centers to emphasize the importance of proper care and maintenance of external cables to all operators of the Jarvik 2000 VAS.

Affected Devices

JHI-212 Y Cable, JHI-202 Lithium-ion Battery Cable, JHI-201 Pedestal Cable, JHI-204 Extension Cable

No specific serial numbers are affected.

Description of Potential Issue

Investigation into complaints of this nature over the past three (3) years indicate an approximate 0.32% occurrence rate for all external cables and over the past year Jarvik Heart, Inc. has received eight (8) related complaints.

If excessive force is applied to the male connector during use, this can result in a detached connector housing, damage to the connector, disconnection of the cable, and a pump stopped



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condition. If a disconnection should occur, the Pump Stopped Alarm will sound prompting immediate action to address the pump stopped condition. Replacement of the cable with a back-up cable will immediately resolve the pump stopped alarm and re-start the VAD.

Jarvik Heart, Inc. has investigated the issue and determined that the manner the current cables are used by some patients is primarily responsible for these types of damaged connectors.

Please note that safe operation of the Jarvik 2000 system requires a trained operator and back-up equipment present at all times. Back-up equipment includes controllers, batteries, cables, & chargers. Per the Instructions For Use, operators are to return any failed or suspect component(s) to the Clinical Center for evaluation by Jarvik Heart, Inc.

Jarvik Heart, Inc. is requesting that all centers emphasize to all trained operators and patients, during routine cable changes, the following sections of the Jarvik 2000 VAS Operator Manual and respective Patient Handbook related to external cables:

Precautions and Warning

- The cables and connectors can break or short-circuit if over stressed or pulled and should always be protected from catching on objects, or being kinked, twisted, or tangled. Never lift or hang the FlowMaker Controller or batteries by the cables.

Changing a Battery

Note:	It is possible to plug the battery cable directly into the FlowMaker Controller without the use of a Y Cable. However, without the Y Cable, the Jarvik 2000 VAD will stop each time the battery is changed. Unless there is an emergency and a Y Cable is not available or is damaged, the Y Cable should be used at all times.
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Connecting the FlowMaker® Controller

	<ul style="list-style-type: none">• Never attempt to disconnect any connector by twisting• The connectors are attached and removed by a push-pull latch mechanism and not by a screw thread• Do not attempt to pull the connector apart by the wire or by the strain relief as doing so may cause damage to occur to the cable• Never force a connector together. If the plug does not go into the receptacle easily, gently rotate it until it is aligned properly. When it is fully engaged, a soft click will be heard.• If a connector is damaged or pins are bent, do not attempt to repair but replace the cable instead.
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Care and Maintenance of the Jarvik 2000

- All external equipment should be inspected weekly at a minimum.
- **Replace any cables or external equipment that appears damaged with a back-up component.** Immediately contact the implant center to have the back-up component replaced as soon as possible. All damaged equipment should be returned to the implant center. The implant center should then contact Jarvik Heart, Inc. to return the equipment for inspection.
- **Never try to service or fix a damaged or broken component. Always replace the component with a back-up component** and return the damaged or broken component to the implant center for return to Jarvik Heart, Inc.
- **All external cables should be replaced after 6 months of use.**

Recommended Actions

Jarvik Heart, Inc. recommends that all centers emphasize the importance of proper care and maintenance of external cables to all operators and patients during routine cable changes including:

- If disconnection of an external cable should occur during use due to a damaged connector, promptly replace it with a back-up cable.
- If an external cable is damaged in any way (e.g. detached connector housing, misaligned connector, cracked connector housing, bent pins, etc.), always replace it with a back-up cable
- Never try to repair or modify a damaged external cable or connector
- Always use approved configurations, this requires use of the Y-cable.

Important note: Not replacing damaged cables, repairing damaged cables, or not following approved configurations can result in serious injury.

Product improvements

As an additional improvement to reduce the chances of a detached male connector housing from occurring, Jarvik Heart, Inc. will add an epoxy bond to the threads of the male connector on all external cables during assembly to reinforce the connector. These cables will be phased into production during Q4 of 2018 and be available to the centers for routine cable changes.



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Transmission of this FSCA

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

This notice has been submitted to all competent authorities worldwide in markets where the Jarvik 2000 Ventricular Assist System (VAS), has been distributed.

Thank you for your attention to this matter.





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(to be completed by the site representative)

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Product: JHI-212 Y-Cable, JHI-202 Lithium-ion Battery Cable, JHI-201 Pedestal Cable, JHI-204 Extension Cable
Subject: USE OF EXTERNAL CABLES, MALE CONNECTORS

The undersigned hereby acknowledges having received and understood the urgent field safety notice FSCA OCTOBER2018, sent by Jarvik Heart, Inc.

Center:	
Country:	
Function/Title:	
Clinician 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