

Urgent Field Safety Notice

Name of affected product: HeartAttendant Interface Cable

FSCA Identifier: FSCA-April 24, 2015 HeartAttendant Interface Cable

Type of Action: Device Exchange

Date: April 24, 2015

Attention: Implant Centers

Details on affected devices:

HeartAttendant Interface Cables Part Number M10035.

Lots:

Part Number M10035

001010580 (EU) 4 units

001010769 (EU) 8 units

001010824 (EU) 2 units

001010919 (EU) 4 units

Description of Device Component

The HeartAttendant Interface Cable is a 12-foot cable used to connect the HeartAttendant with the Conquest Controller, two sub-components of the HeartAssist 5 VAD System. This recall is limited to only the Interface Cable and not to any other component of the HeartAssist 5 VAD System.

Description of the problem:

During the investigation into a complaint received from a European hospital, it was determined that the HeartAttendant Interface Cable could short circuit causing faulty flow readings. The problem has been isolated to the wires within the Interface Cable, which may not be properly secured to the external connector. Use of a faulty Cable could disable certain functions in either the HeartAttendant or Controller, although the blood pump will continue to operate.

Advise on action to be taken by the user:

ReliantHeart requests that you return the units identified on the Returned Goods Authorization (RGA) Provided to each facility.

Step 1

1) Replacement cables will be provided to each facility to assure no impact to patient care.

Step 2

2) Identify and quarantine the cables

3) Return the cables referencing the RGA number on the shipping package complete and return the RGA form provided to ReliantHeart.

Transmission of this Field Safety Notice:

This notice will be passed on to the competent authorities of each impacted country as well as the United States Food and Drug Administration.

Contact reference person:

Cindy McKelroy

VP Regulatory / Quality

ReliantHeart Inc.

8965 Interchange Drive

Houston, Texas 77054

cmckelroy@reliantheart.com

The undersigned confirms that this notice has been submitted to the affected National Competent Authorities in Europe.



8965 Interchange Drive * Houston, Texas 77054

p: +1 713-592-0913 * f: +1 713-665-0963

www.reliantheart.com

ReliantHeart has successfully resolved this manufacturing deficiency with our supplier to eliminate future concerns on the performance of this cable.

Sincerely,



Cindy McKelroy