November 13, 2023

URGENT MEDICAL DEVICE – Removal

Reference Number: 8010762-11/13/2023-004-R

CARDIOHELP-i Heart Lung Support System

Product Name	CARDIOHELP-i Heart Lung Support System
Product REF Number	Venous probe connection cable (REF 701069333 and 701048804), used with the Cardiohelp-i system (REF 701072780 and 701048012)
UDI-DI	04058863074863 and 04037691658384
Distributed Affected Serial Numbers:	All cables used with Cardiohelp-i system serial numbers prior to and including 90413927
Manufacturing Dates:	May 19, 2010, through March 5, 2021
Distribution Dates:	May 19, 2010, through March 5, 2021

Dear Risk Manager,

Maquet Cardiopulmonary GmbH (MCP)/Getinge is initiating a voluntary Medical Device Removal for the CARDIOHELP-i Heart Lung Support System, due to the potential that the now-obsoleted design of the venous probe connection cable may break, which could lead to the inability to transmit data from the venous probe to the CARDIOHELP-i System. This field action does not affect you if you already use the venous probe connection cable that is made with polyurethane and is of longer length (320 +/- 10mm) (See Figure 1 below for visual difference between the old and new cables).

The CARDIOHELP System is a blood oxygenation and carbon dioxide removal system used to pump blood through the extracorporeal bypass circuit for circulatory and/or pulmonary support for periods appropriate to cardiopulmonary bypass (up to six hours). It is also intended to provide circulatory and/or pulmonary support during procedures not requiring cardiopulmonary bypass (for periods up to six hours).

Identification of the issue:

MCP/Getinge has received complaints of breaks in the insulation, shielding or wires of the venous probe connection cable. These complaints were associated with an older and shorter version of the connection cable. See Figure 1 below showing the older version of the connection cable on the left. Starting in April 2019 the cable design was updated with a more durable material (polyurethane) and a longer length to reduce the bending forces, thus reducing the risk of breaking.

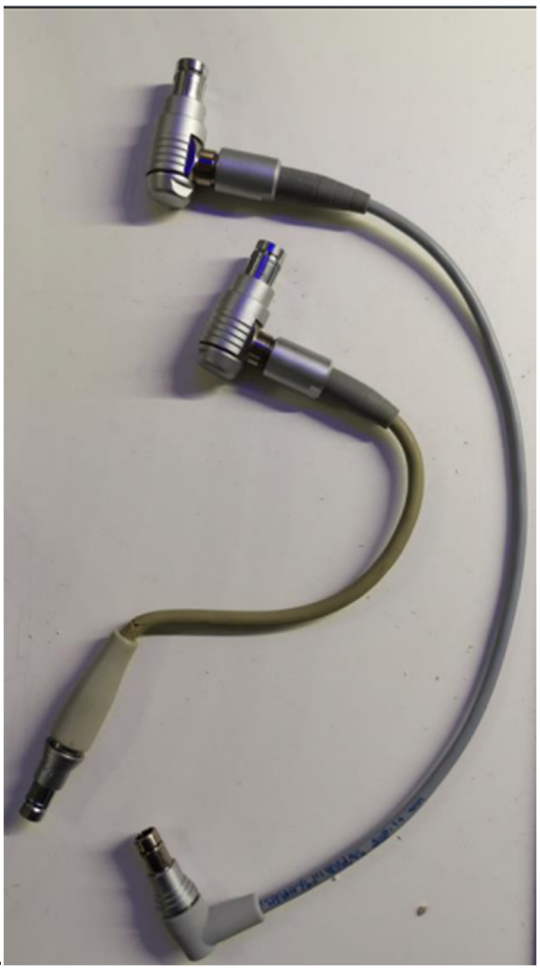

Figure 1 – Previous version of (short) cable (L), Current version of (long) cable (R). There are notable differences in length and in the end plug of the cables.

There have been no reports of adverse events due to this issue.

Risk to Health:

The Venous Probe of the CARDIOHELP-i measures SvO2, hemoglobin, hematocrit, and venous temperature values. The Venous Probe Connection Cable, which transmits the data from the Venous Probe to the user interface of CARDIOHELP-i, is the subject of this field action. Fracture of the venous probe cable may influence the management of extracorporeal support due to missing or incorrect values transmitted to the CARDIOHELP-i user interface. However, numerous clinical redundancies exist (e.g., arterial temperature available on CARDIOHELP-i, external blood gas measurement, esophageal temperature) that could mitigate the effect of a loss or incorrect reporting of these values.

The potential immediate and/or long-term health consequences (injuries or illnesses) that could result from use of, or exposure to, a defective venous probe connection cable may be any, some, or all of the following:

- Ischemia
- Hyperthermia
- Hemolysis
- Thromboembolism

- Brain Damage
- Hypothermia
- Cardiac Arrhythmia
- Coagulation disorder(s)
- Anemia

These health consequences relate to the patient being exposed to inappropriate blood flow, blood temperature, or hematocrit/hemoglobin levels as a result of the CARDIOHELP-i not receiving information from the venous probe.

Actions to be taken by the Customer:

Our records indicate that you have received a CARDIOHELP-i having a serial number that is affected by this voluntary Medical Device Removal.

- Please examine your inventory immediately to determine if you have any affected CARDIOHELP-i (i.e., using the older, short connection cable) in your inventory.
- If you have an older version of the venous probe connection cable (shown on the left in **Figure 1**, even if there are no visible signs of breakage, Getinge will replace the cable at no charge to your facility. If your venous probe connection cable shows any visible indication of breakage or if the CARDIOHELP-i displays an error instructing you to "replace venous probe or cable" (see Chapter 9.4.3 of the IFU), please discontinue use and contact Getinge Customer Support at (888) 943-8872 (select option 2), Monday through Friday, between the hours of 8:00 a.m. and 6:00 p.m. (Eastern Time Zone). Getinge will provide instructions on the return of the cable and arrange for a replacement to be sent at no charge to your facility.
- **Affected CARDIOHELP-i devices do not need to be returned while awaiting replacement of the venous probe cable. As noted in the Service Manual, please check whether there is any visible damage to the venous probe unit and cables before use.**
- **Please forward this information to all current and potential CARDIOHELP-i users within your hospital / facility.**
- **If you are a distributor who has shipped any affected products to customers, please forward this document to their attention for appropriate action.**
- Whether or not your facility has affected product(s) listed in this notice, please complete and sign the attached MEDICAL DEVICE- REMOVAL RESPONSE FORM (Page 5) to acknowledge that you have received this notification. Return the completed form to Getinge by e-mailing a scanned copy to cardiohelpvenousprobe2023.act@getinge.com or by faxing the form to 1-866-404-6853.

Type of Action by Getinge:

Getinge has been distributing a redesigned venous probe cable since April 2019.

Getinge will replace any affected venous probe connection cables at no cost to your facility.
This voluntary removal only affects the products listed on Page 1; no other products are affected by this voluntary removal.

Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail or by fax using the following:

- **Online**: www.accessdata.fda.gov/scripts/medwatch/
- **Regular Mail**: Download form www.fda.gov/MedWatch/getforms.htm or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form
- **Fax**: 1-800-FDA-0178

We apologize for any inconvenience this Medical Device Removal may cause. If you have any questions, please contact Getinge Customer Support at (888) 943-8872 (select option 2), Monday through Friday, between the hours of 8:00 a.m. and 6:00 p.m. (Eastern Time Zone).

This Medical Device Removal notice is being made with the knowledge of the U.S. Food and Drug Administration.

Sincerely,

Allison Jean Kaplan
Specialist, Regulatory Affairs and Field Action Compliance

Getinge