

October 12, 2023

**URGENT MEDICAL DEVICE – Correction**

**Reference Number: 8010762-09/06/2023-002-C**

**CARDIOHELP-i Heart Lung Support System**

|   |  |
|---|--|
| <b>Product Name</b>                         | CARDIOHELP-i Heart Lung Support System     |
| <b>Product REF Number</b>                   | 701072780                                  |
| <b>UDI</b>                                  | 04058863074863                             |
| <b>Distributed Affected Serial Numbers:</b> | 90414355 through 90414864                  |
| <b>Manufacturing Dates:</b>                 | October 12, 2021 through February 14, 2022 |
| <b>Distribution Dates:</b>                  | November 10, 2021 through March 03, 2023   |

Dear Risk Manager,

Maquet Cardiopulmonary GmbH (MCP)/Getinge is initiating a voluntary Medical Device Correction for the CARDIOHELP-i Heart Lung Support System, due to an insufficient fixation (weld) of the slide rail plate.

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).

The slide rails are located on the lateral aspects of the CARDIOHELP system. They are attached to the housing of the CARDIOHELP system with the slide rail holder (see red marks in Figure 1). As shown in Figure 2, the slide rail holder consists of a nut bolt welded onto a plate.

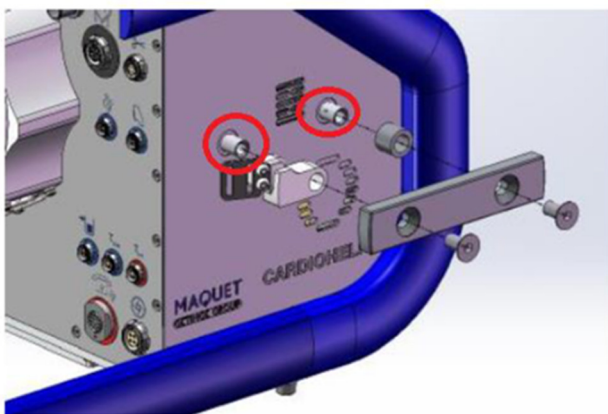


Figure 1: CARDIOHELP slide rail- exploded view

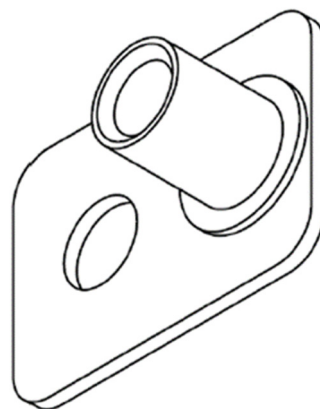


Figure 2: Draft of slide rail holder

**Identification of the issue:**

The fixation (weld) applied by the supplier to fixate the nut bolt to the slide rail plate was insufficient. The deficient weld allows the nut bolt to break off from the slide rail plate with slight manual force.

There have been no reported adverse events associated with this issue.

**Risk to Health:**

Insufficient securement of the slide rails to the lateral aspects to CARDIOHELP allows for the possibility that both/either the Transport Guard and/or the Emergency Drive (with the holder) to detach from CARDIOHELP. Detachment in either scenario could produce an unexpected outcome (e.g., disengagement of the HLS Module from the CARDIOHELP drive during transport, or detachment of both the Emergency Drive and holder resulting to injury to the user, third party, or the patient).

The potential immediate and/or long-range health consequences associated with a detachment of either the Transport Guard or the Emergency Drive when connected to the slide rail holder may result in any, all, or none of following harms to a patient supported on CARDIOHELP or to a user operating CARDIOHELP at the time the nonconformance is encountered:

- Ischemia
- User inconvenience
- Hypovolemia
- Fracture, cut/laceration, bruise (User/Third party)

**Actions to be taken by the Customer:**

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

- Please examine your inventory immediately to determine if you have any affected CARDIOHELP System(s) in your inventory.
- Should you have any affected CARDIOHELP-i System(s), your unit(s) will need to be returned to Getinge for correction. Getinge will contact your facility to arrange the return of your unit for correction. A CARDIOHELP loaner can be provided if needed.
- **Please do not fixate any accessory at the slide rail until the slide rail holders have been replaced.**
- **Affected CARDIOHELP-i can be used for intra-hospital transport only when placed on a Sprinter cart.**
- **Inter-hospital transport is not permitted until the slide rail holders have been replaced.**
- **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- CORRECTION RESPONSE FORM (Page 4)

to acknowledge that you have received this notification. Return the completed form to Getinge by e-mailing a scanned copy to [Cardiohelpsliderail2023.act@getinge.com](mailto:Cardiohelpsliderail2023.act@getinge.com) or by faxing the form to 1-866-313-4049.

**Type of Action by Getinge:**

A Getinge representative will contact you to arrange for the repair of your CARDIOHELP -i unit(s). Getinge will correct your CARDIOHELP -i unit(s) upon receipt and will return your unit(s) once correction has been completed.

This voluntary correction only affects the products listed on Page 1; no other products are affected by this voluntary correction.

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/](http://www.accessdata.fda.gov/scripts/medwatch/)
- **Regular Mail:** Download form [www.fda.gov/MedWatch/getforms.htm](http://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 Correction may cause. If you have any questions, please contact Getinge Technical Support at (888) 943-8872 (select option 4,2,1), Monday through Friday, between the hours of 8:00 a.m. and 6:00 p.m. (Eastern Time Zone).

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

Sincerely,



Marylou Insinga  
Senior Specialist, Regulatory Affairs and Field Action Compliance  
Getinge