October 10, 2023

URGENT MEDICAL DEVICE REMOVAL

Reference Number: 8010762-10/06/2023-003-R

CARDIOHELP Emergency Drive

Product Name	CARDIOHELP Emergency Drive
Product REF Number	701048002 Emergency Drive 701076205 Emergency Drive
UDI	04037691643526
Distributed Affected Serial Numbers:	**701048002** 90425259 to 90425748 (Excluding 90425438, 90425443, 90425568, 90425570, 90425588, 90425716) **701076205** 90425438, 90425443, 90425568, 90425570, 90425588, 90425716, 90425747, 90425748
Manufacturing Dates:	August 11, 2022 through June 20, 2023
Distribution Dates:	September 14, 2022 through July 27, 2023

Dear Risk Manager,

Maquet Cardiopulmonary GmbH (MCP)/Getinge is initiating a voluntary Medical Device REMOVAL for the CARDIOHELP Emergency Drive, due to a possible blocking or impairment of the CARDIOHELP Emergency Drive. Getinge will be removing the affected emergency drives in order to repair the devices. There are loaner devices available so that you may continue to use your CARDIOHELP System while your device is being repaired.

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 CARDIOHELP Emergency Drive (Figure 1) is used in emergencies to manually drive the disposable if needed.

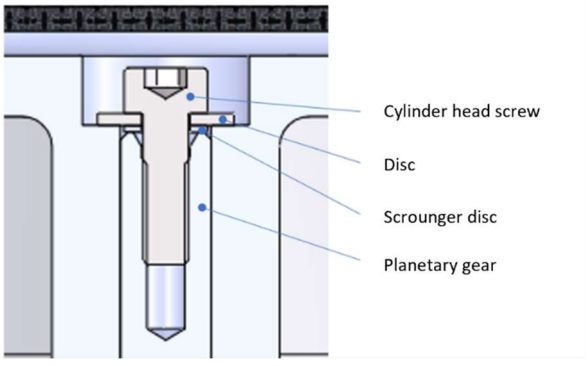

Figure 2: Draft of the position of the scrounger disc

Figure 1: CARDIOHELP with Emergency Drive on top

Identification of the issue:

Maquet Cardiopulmonary GmbH received a customer complaint that the rotation of the CARDIOHELP Emergency Drive hand crank was blocked or impaired. In the course of its investigation, it was found that the scrounger disc caused this issue. The scrounger disc was originally introduced to the CARDIOHELP Emergency Drive in order to lengthen the shaft of the Emergency Drive to reduce stiffness of movement caused by the assembly (Figure 2). The company determined that the removal of the scrounger disc will correct the issue and will have no adverse impact on patient safety.

Maquet Cardiopulmonary GmbH reviewed all complaints since the introduction of the scrounger disc to the Emergency Drive. The company identified four (4) complaints that involved a similar issue of difficulty rotating the Emergency Drive hand crank. None of these complaints involved patient harm, serious injury, or death.

Risk to Health:

Insufficient rotation due to an impaired or blocked CARDIOHELP Emergency Drive can lead to the following hazardous situation:

- The patient can be exposed to inappropriate low blood flow.

The potential immediate and/or long-range health consequences associated with an impaired function of the CARDIOHELP Emergency Drive may be any, all, or none of following harms:

- Ischemia
- Hypoxia

Actions to be taken by the Customer:

Our records indicate that you have received a CARDIOHELP Emergency Drive having a serial number that is affected by this voluntary Medical Device Field Action.

- Please examine your inventory immediately to determine if you have any affected CARDIOHELP Emergency Drives in your inventory.
- A representative from Getinge will contact you to ensure that you have received this information, have identified all of your Emergency Drives, and determined whether they fall under this field action. Getinge will arrange the supply of loaner replacements where needed and will arrange for the return of the affected Emergency Drives for repair.
- You may also request loaner Emergency Drive(s) from Getinge Technical Support at (888) 943-8872 (select option 1, option 2), Monday through Friday, between the hours of 8:00 a.m. and 6:00 p.m. (Eastern Time Zone)
- **If you have affected product that is currently being used in patient treatment, inform Getinge immediately at (888) 943-8872, option 1, option 1. Please ensure that an alternate means of emergency support is available at all times, which may include a nonaffected Emergency Drive (if available) or a fully charged backup CARDIOHELP console.**
- Please forward this information to all current and potential CARDIOHELP 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 4) to acknowledge that you have received this notification. Return the completed form to Getinge by e-mailing a scanned copy to Cardiohelpedrive2023.qrc@getinge.com or by faxing the form to 1-866-351-3477.

Action to be Taken by Getinge:

A Getinge representative will contact you to ensure that you have identified any affected Emergency Drives and to arrange for loaner devices to be provided as necessary while your device(s) are being corrected. Your unit(s) will be returned to you once the Emergency Drive has been corrected and arrangements will be made to have the loaner device(s) returned to Getinge.

This field action only affects the products listed on Page 1; no other products are affected by this issue.

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 Field Action 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 REMOVAL 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