2023-06-21

URGENT FIELD SAFETY NOTICE

Manufacturer SRN:	DE-MF-000020091
Subject:	812435 - Replacement of Rotaflow II drive closing cover
Affected Product:	701074622 Rotaflow II drive (flex) 701074623 Rotaflow II drive (compact)
Affected Serial No.:	See Annex I
Unique Device Identifier:	701074622 - 04058863229263 701074623 - 04058863229256

Dear valued customer,

The technical function of the Rotaflow II Drive (Fig. 1) is to drive disposable ROTAFLOW centrifugal pump (RF-32 disposable) within an extracorporeal circulation. This RF32-disposable is retained inside the Rotaflow II Drive by a locking mechanism (yellow locking mechanism, shown in Figure 1).

The Rotaflow II Drive is mandatory in a Rotaflow II System and can be used as accessory on a HL40 system. It comes in two different holder variants: flexible or compact.

Figure 1: Rotaflow II Drive

Problem description

In October 2022 Maquet Cardiopulmonary received a complaint on issues connected to the yellow locking mechanism unlocking on patient transfer and requiring a low force to unlock.

An internal investigation identified that material behavior (strain, rigidity, etc.) is subject to change over time and a reduction of unlocking force over multiple use cycles occurs.

- **ATTENTION! As this error can end treatment and is a potential risk for patients, please do not use this product until corrective servicing is performed.**

Hazard giving rise to the Field Safety Corrective Action (FSCA)

The noticed error can potentially cause an accidental release of the RF-32 disposable, falling out of the drive and causing pause or end of treatment.

This can cause the harm of: **Ischemia**

Population most at risk

Patients with impaired or unstable circulatory system are at most risk.
In the event extracorporeal support is disrupted due to disengagement of the RF-32 disposable from the Rotaflow II Drive, a delay (or interruption) of extracorporeal support may exacerbate the critical condition of a rapidly deteriorating patient (i.e. one who is hemodynamically instable/collapsing or who is highly dependent on extracorporeal support). In some situations, a delay or disruption in support could induce global hypoxia and/or local ischemia, depending on the period of disruption and complicating comorbidities.

Immediate and/or long-range health consequences of the non-conformance

If the yellow locking mechanism opens due to upwards forces, the magnetic coupling between the Rotaflow II Drive and the RF-32 disposable may be lost, resulting in a reduction (or stoppage) of blood flow. A reduced blood flow, or no blood flow, can result in ischemia. The possibility and subsequent degree of ischemia depends on the duration and/or the extent of the blood flow reduction (or stoppage).

Risk Mitigating Clinical Factors

There are no foreseeable risk mitigating clinical factors (per se) that may serve to moderate/mitigate the risks/harms described in the corresponding Health Hazard Evaluation.

However, in the Instruction for Use before every application a function test is prescribed. This test checks the function of mechanical components including the yellow locking mechanism.

- **ATTENTION! As this error can end treatment and is a potential risk for patients, please do not use this product until corrective servicing is performed.**

Action to be taken by manufacturer:	• replacement of yellow locking mechanism with the black Rotaflow I locking mechanism by Getinge representatives (the black locking mechanism is equivalent to the Rotaflow I Drive locking mechanism)
Action to be taken by user:	• **ATTENTION! As this error can end treatment and is a potential risk for patients, please do not use this product until corrective servicing is performed.** • According to our post-market surveillance documentation, your current stock may include products affected by this action • Choose one of the 2 options: 1.) replacement of yellow locking mechanism with the black Rotaflow I locking mechanism by Getinge representatives (the black locking mechanism is equivalent to the Rotaflow I Drive locking mechanism) 2.) return the affected products (in case of Rotaflow II system: the whole system) to your local Getinge representative. • **For customer without maintenance contract:** A local Getinge representative will get in contact with customer. • Please report any adverse events related to the affected products to your Getinge representative. • Regardless of the option you choose, please complete and sign the attached customer response form and send it back to your local Getinge representative.
Enclosed documents:	• Customer response form • Annex I affected product details

Transmission of the Field Safety Notice

- Please ensure in your organization that all users of the above-mentioned products and other persons to be informed are made aware of this Urgent Field Safety Notice.
- Please transfer this notice to other organizations on which the action has an impact.
- If you have given the products to third parties, please forward a copy of this information or inform the contact person indicated below.
- Please maintain awareness on the notice and resulting actions for an appropriate period to ensure effectiveness of the corrective action.

We apologize for any inconvenience this may cause you and we will do our utmost to carry through this action as swiftly as possible.

As required, we have provided this notification to the necessary Regulatory Agencies.

Should you have questions or require additional information, please contact your local Getinge representative.

Sincerely,

…

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76437 Rastatt
GERMANY
Phone: +49 7222 932 - 0
Email: FSCA.cp@getinge.com

CUSTOMER RESPONSE FORM

Subject: 812435 - Replacement of Rotaflow II drive closing cover

Affected Product: See Annex I

By completing this document and signing it, I acknowledge that I have read and understand the following associated points:

- I have read and understand this Field Safety Notice 812435. We will take action as soon as possible according to given instructions.
- I confirm that I have distributed this Field Safety Notice to the affected personal.

Choose one:

☐ Below listed products require service by Getinge representatives.

☐ Below listed products will be returned to manufacturer.

Article Number	Product Name	Serial Number

Your Comments:

Country

Hospital / Clinic (full address)

Date

Name (Function)

Signature

Please return the completed form to your local Getinge representative by email, mail or FAX under Reference of 812435 Field Safety Notice.

Annex I List of affected products

This Annex I List of affected products is considered as a supplementary attachment to the 812435 Field Safety Notice.

Below are listed all lots of products which are affected and have been distributed.

Article Number	Product Name	Serial Number
701074622	Rotaflow II drive (flex)	All products are affected
701074623	Rotaflow II drive (compact)	All products are affected