

2022-02-11

URGENT - FIELD SAFETY NOTICE

Subject: 575777 Pin on Transport Guard of Cardiohelp-i can come loose

Affected product: Cardiohelp-i (article number 701048012)
Cardiohelp-i (article number 701072780, US Variant)

Affected Serial No.: 90413945, 90414225, 90414226, 90414227, 90414228, 90414229, 90414232, 90414233, 90414234, 90414235, 90414236, 90414237, 90414258, 90414259, 90414260, 90414261, 90414272, 90414277, 90414278, 90414279, 90414280, 90414281, 90414282, 90414283, 90414284, 90414285, 90414286, 90414287, 90414288, 90414289, 90414292, 90414293, 90414294, 90414295, 90414296, 90414297, 90414299, 90414300, 90414302, 90414303, 90414304, 90414305, 90414306, 90414307, 90414308, 90414309, 90414310, 90414311, 90414312, 90414317, 90414318, 90414319, 90414327, 90414328, 90414329, 90414330, 90414336, 90414358, 90414360, 90414365, 90414366, 90414390

Dear valued customer,

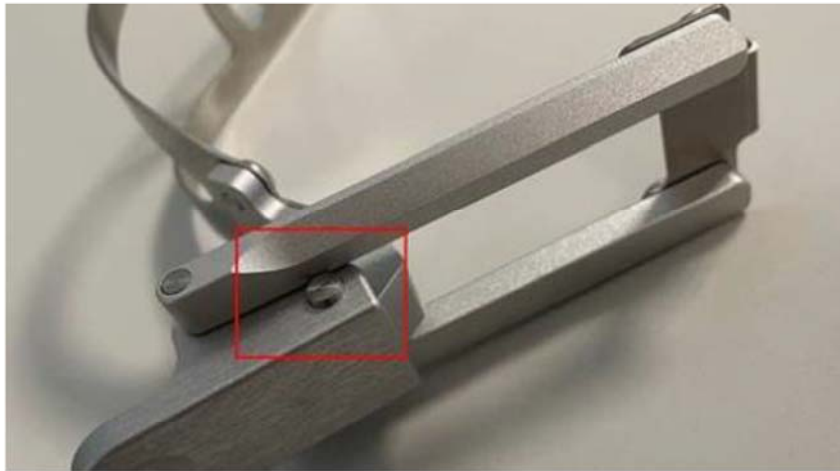
Maquet Cardiopulmonary GmbH has determined during the End of Life testing of a Cardiohelp-i, that the cylindrical pin in the upper part of the Transport Guard can come loose. The Transport Guard is an accessory of the Cardiohelp-i and secures the oxygenator to the drive during inter-hospital transportation or intra-hospital transportation if no Sprinter Cart/ Sprinter Cart XL is used.



Picture 1 Transport Guard with Disposable

The detected nonconformity is restricted only to Transport Guards distributed with above mentioned serial numbers of Cardiohelp-i. This issue can lead to either of two situations:

- If the locking mechanism jams, it may result in a failure to open the Transport Guard if/ when necessary, see picture 1.



Picture 2 Jamming of the Transport Guards due to loosened cylindrical pin. Opening of the Transport Guard is not possible.

- If the locking pin comes loose from the assembly of the Transport Guard, it may result in disassembly of the Transport Guard during use, see picture 2.



Picture 3 Disassembly of the Transport Guard due to loosened cylindrical pin.

If emergent opening is necessary while the Transport Guard is jammed, this can result in insufficient patient support resulting in ischemia.

If the Transport Guard disassembles during use it does not fulfil its function to hold the HLS module in the event of the Cardiohelp-i being dropped on the floor.

Maquet Cardiopulmonary GmbH has not received any complaints with serious injuries or death due to the described malfunction of the Transport Guard within Cardiohelp-i units.

Based on the associated risk to the above mentioned issue, a general decommissioning of the affected Cardiohelp-i is therefore not required.

- Corrective Action:**
- The Transport Guard within the affected Cardiohelp-i units with the serial numbers mentioned above will be checked by the Getinge authorized representative and replaced by a new one if required.
 - Pending the replacement of the Transport Guard, please check if Transport Guard can be opened and the mentioned pin is not loose.

- Advice on action to be taken by the User:**
- Duly fill out the enclosed Letter of Acknowledgement for Customers and return it as soon as possible to your local Getinge representative by mentioning **575777** as reference in order to organize the prompt checking or rather replacement of transport guard by our authorized Getinge service personnel.

- Referenced documents/ attachments:**
- 575777 Letter of Acknowledgement Customer

Transmission of the Field Safety Notice:

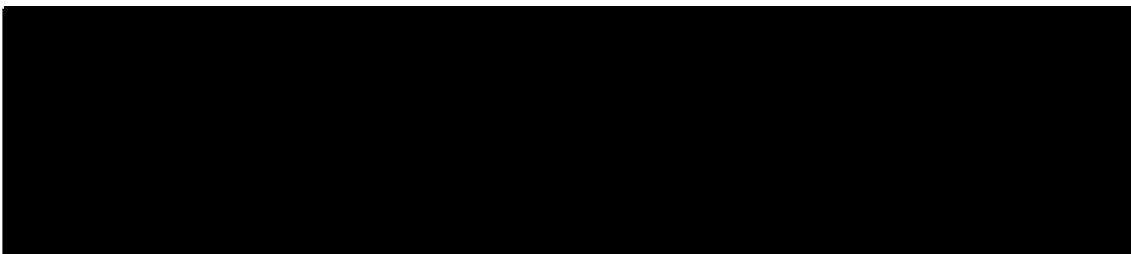
- This notice needs to be passed on to all those who need to be aware within your organization or to any organization where the potentially affected devices have been transferred.
- Please transfer this notice to other organizations on which the action has an impact.
- Please maintain awareness of the 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 will provide this notification to the necessary Regulatory Agencies.

Should you have questions or require additional information, please contact your local Getinge representative, or send an e-mail to FSCA.cp@getinge.com.

Sincerely,



Maquet Cardiopulmonary GmbH
Kehler Str. 31
76437 Rastatt
GERMANY