2025-06-12

URGENT FIELD SAFETY NOTICE

Manufacturer SRN:	DE-MF-000020091
FSCA Reference:	1280465 – SPRINTER CART (XL) – Missing ‘Pushing prohibited’ label
FSN Type:	New
Affected Product:	INFUSION POLE (Mat. 701033599) SPRINTER CART (Mat. 701033456) SPRINTER CART XL (Mat. 701046022) SPRINTER CART (Mat. 701047813) SPRINTER CART XL (Mat. 701054184)
Unique Device Identifier:	04037691257860 04037691254920 04037691493473 04037691583273 04037691746289
Affected Serial No.:	All SPRINTER CART (XL) with an INFUSION POLE
For Attention of:	Users of the medical device listed above

Dear valued customer,

Maquet Cardiopulmonary GmbH (MCP) would like to inform users about a corrective action for mobile SPRINTER CARTs and SPRINTER CARTs XL equipped with the optional component INFUSION POLE that do not comply with the labelling requirements of international standard IEC 60601-1.

The mobile SPRINTER CART and SPRINTER CARTs XL are designed to support the ROTAFLOW Console, the Rotaflow II Base Unit, or the CARDIOHELP System and a heater unit during extracorporeal circulation either with or without an oxygenator. The INFUSION POLE can be used to hold 2 x 2 kg infusion bags at a maximum height of 2.2 m (Figure 1).

Problem Description

According to IEC 60601-1:2005+AMD1:2012+AMD2:2020, clause 9.4.2.3 ‘Instability from horizontal and vertical forces’, if an equipment overbalances when being pushed/ leaned on/ etc. with 15% of its weight, the medical electrical equipment shall be marked with a clearly legible warning, e.g., safety sign according to ISO 7010-P017 (Figure 1).

Starting April 21, 2021, MCP implemented a safety sign on newly produced INFUSION POLEs but did not correct INFUSION POLEs manufactured before this date. Therefore, all INFUSION POLEs manufactured before April 21, 2021, are affected by this issue.

Given the limited traceability of INFUSION POLEs to SPRINTER CARTs, along with the distribution methods used for the INFUSION POLEs, all SPRINTER CARTs and SPRINTER CARTs XL are considered to be potentially impacted and within the scope of this field action.

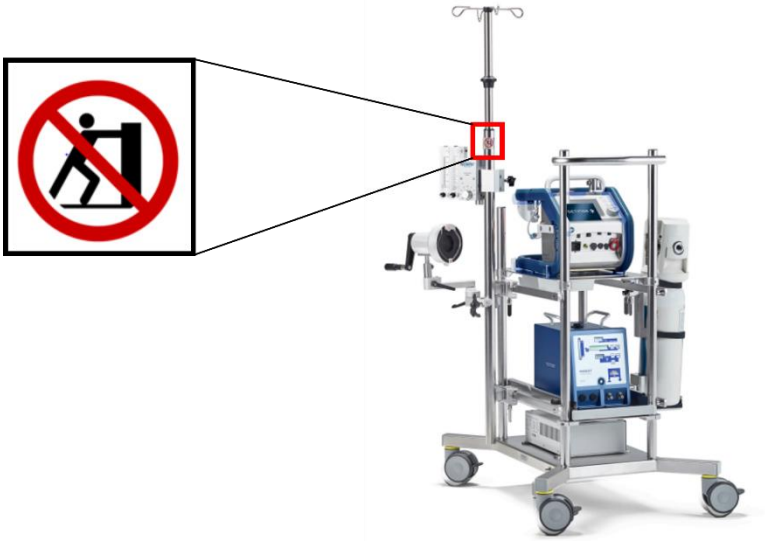


Figure 1: Figure showing Sprinter Cart system with Infusion Pole and indicating position of 'Pushing prohibited' label (see red marking)

Hazardous situation

In course of a Health Hazard Evaluation (HHE), Maquet Cardiopulmonary GmbH determined the following hazardous situations that may arise:

- The SPRINTER CARTs and SPRINTER CART XL may overbalance, which could damage the CARDIOHELP/ ROTAFLOW/ ROTAFLOW II or disconnect or damage the perfusion disposable and result in no or low blood flow to the patient

Potential harm

The possible immediate and/or long-range health consequences and risk levels of the nonconformance include the following (for further information please refer to Annex I):

- Ischemia (secondary to loss of blood flow) (medium)

Maquet Cardiopulmonary GmbH has received no complaints that can be linked to this issue.

Corrective Action:

- Verify presence of 'Pushing prohibited' label on each INFUSION POLE of SPRINTER CART/ SPRNTER CART XL **during next service visit**
- If not present, affix 'Pushing prohibited' label to INFUSION POLE of SPRINTER CART/ SPRNTER CART XL **during next service visit**

Action to be taken by user:

☒ Identify Device
☐ Quarantine Device
☐ Return Device
☐ Destroy Device

Details on further action(s):

- According to our post-market surveillance documentation, you may have products affected by this action. Please examine your inventory **immediately** to determine, if you have any affected product in your inventory.
- Patients should be monitored as appropriate according to your facility's standard of care.
- Please **always** report any adverse events potentially related to the affected products, to your Getinge representative.
- Duly fill out the enclosed Letter of Acknowledgement and return it to your local Getinge representative **as soon as possible, latest by 2025-07-11,** by mentioning **FSCA-1280465** as reference in the subject line of your mail.

Actions to be taken by the manufacturer:

☐ Product Removal
☒ On-site device modification/ inspection
☐ Software Upgrade
☐ IFU or labeling change
☒ Other
☐ None

- Inform all customers possessing the affected products promptly about this Field Action by sending the Field Safety Notice for Customers.
- Ensure that the above-mentioned Corrective Actions are carried out by Getinge representative.

Enclosed documents:

- Letter of Acknowledgment Customer
- Annex I Further information regarding Hazardous situation, Harms and Risk Levels
- Annex II Excerpts from IFUs

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 sincerely 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,

Vice President

Signature: Dieter Engel
Electronically signed by: Dieter Engel
Reason: I approve this document.
Date: Jun 12, 2025 15:50 GMT+2

Email: dieter.engel@getinge.com

Person Responsible for Regulatory Compliance (PRRC)

Signature: Alexander Bernhardt
Electronically signed by: Alexander Bernhardt
Reason: I approve this document.
Date: Jun 12, 2025 15:35 GMT+2

Email: alexander.bernhardt@getinge.com

Contact details of manufacturer
Maquet Cardiopulmonary GmbH
Kehler Str. 31
76437 Rastatt
GERMANY
Phone: +49 7222 932 - 0
Email: FSCA.cp@getinge.com

CUSTOMER RESPONSE FORM

FSCA Reference:	1280465 – SPRINTER CART (XL) – Missing ‘Pushing prohibited’ label
Affected Product:	INFUSION POLE (Mat. 701033599) SPRINTER CART (Mat. 701033456) SPRINTER CART XL (Mat. 701046022) SPRINTER CART (Mat. 701047813) SPRINTER CART XL (Mat. 701054184)
Affected Serial No.:	All SPRINTER CART (XL) with an INFUSION POLE

Please send this form at the latest by **July 11, 2025**, to your local Getinge representative.

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. 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.

☐ I do not have any affected products in my inventory.

☐ I have the following affected products in my inventory:

Article Number	Description	Serial Number	Quantity
XXXXX.XXXX	<SAP Product name>		

Your Comments:

Country

Hospital / Clinic (full address)

Date	Name (Function)
	Signature

Please return the completed form to your local Getinge representative by email enter local Getinge mail address or via post enter local Getinge address or FAX>:

Annex I Further information regarding Hazardous situation, Harms and Risk Levels

This Annex I Further information regarding Hazardous situation, Harms and Risk Levels is considered a supplementary attachment to the 1280465 Field Safety Notice.

Hazardous Situation	Harm	S (from Part III)	P (from above)	Risk		
				Low	Med	High
Overbalance of the Cart, Cardiohelp, Rotaflow, Rotaflow II damage, disconnection or damage of the perfusion disposable – No or low blood flow	Ischemia (blood flow)[a]	4	1	☐	☒	☐

a. Ischemia (secondary to loss of blood flow) may occur under the following circumstances:
- Failure of device
- Disconnection or damage of the perfusion disposable.

Severity Definitions:

Negligible (1) Inconvenience or temporary discomfort of patient, user or third party. No medical intervention or follow-up treatment is required

Low (2) Temporary injury or disability of patients, users or third parties. No medical intervention or follow up treatment is required.

Critical (3) Temporary injury or disability of patients, users or third parties. Medical intervention or follow-up treatment is required.

Catastrophic (4) Permanent injury or disability (e.g., loss of a body part), a life-threatening situation or death of patients, users or third parties

Probability Definitions:

Improbable (1) Harm is not likely.

Remote (2) Harm occurs infrequently

Occasional (3) Harm may occur occasionally / intermittent

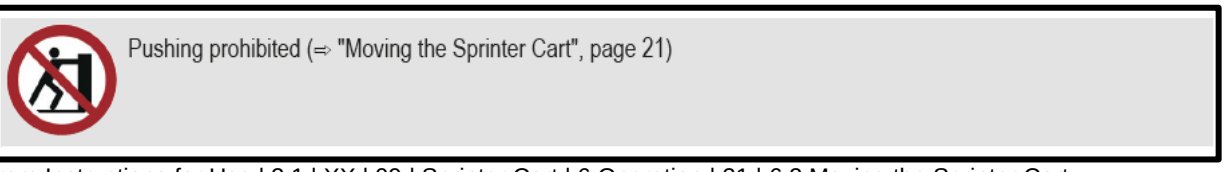
Probable (4) Harm may occur often

Frequent (5) Harm will occur repeatedly

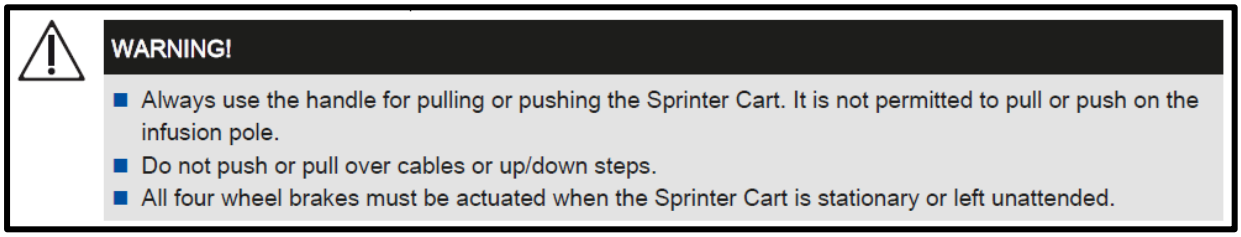
Annex II Excerpts from IFUs

This Annex II Excerpt from IFUs is considered a supplementary attachment to the 1280465 Field Safety Notice.

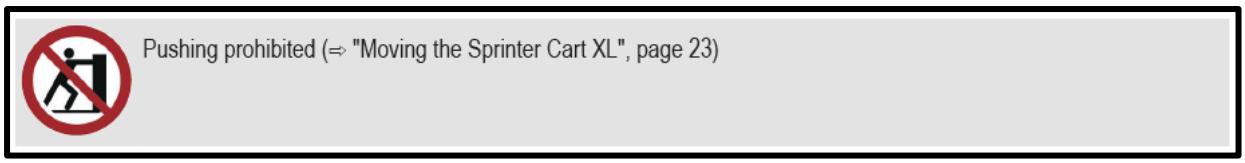
From Instructions for Use | 2.1 | XX | 09 | Sprinter Cart | 2 Safety | 12 | 2.7 Symbols:



From Instructions for Use | 2.1 | XX | 09 | Sprinter Cart | 6 Operation | 21 | 6.2 Moving the Sprinter Cart:



From Instructions for Use | 2.1 | XX | 11 | Sprinter Cart XL | 2 Safety | 12 | 2.7 Symbols:



From Instructions for Use | 2.1 | XX | 09 | Sprinter Cart | 6 Operation | 21 | 6.3 Moving the Sprinter Cart XL: