2025-02-17

URGENT FIELD SAFETY NOTICE

Manufacturer SRN:	DE-MF-000020091
FSCA Reference:	1227741 – CTP – Connector with incorrect coating installed
FSN Type:	New
Affected Product:	BO-HQV 129001#Ossigenatore Adult (Mat. 701074297)
Unique Device Identifier:	04058863181400
Affected Batch No.:	3000422274, 3000408738, 3000405719
For Attention of:	Users of the medical device listed above

Dear valued customer,

Maquet Cardiopulmonary GmbH (MCP) would like to inform users about a recall that pertains to connectors with incorrect coating being installed in certain Custom Tubing Packs (CTPs).

A CTP is intended for use in extracorporeal circulation during cardiopulmonary bypass procedures. The maximum duration of use is 6 hours.

There are two variants of coating available, BIOLINE and SOFTLINE. While SOFTLINE coating does not have any known contraindications, medical devices with BIOLINE coating surfaces should not be used on:

- Patients with known hypersensitivity to heparin (heparin allergy).
- Patients suffering from or with a history of type II heparin-induced thrombocytopenia (HIT).

Problem description

The manufacturer became aware of this issue due to an production employee report. It was found that a BIOLINE coated connector was installed into a SOFTLINE otherwise coated CTP.

An internal investigation has shown that all products manufactured according to versions 2 and 3 of the associated technical drawing are affected, however, no products were produced according to version 2. Therefore, this FSCA is limited to all products manufactured according to version 3 of the associated technical drawing.

Hazardous situation

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

- Patient is exposed to allergenic agents

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):

- Sensitization (low)
- Allergic response/reaction (low)
- Anaphylactic response (medium)

Maquet Cardiopulmonary GmbH has not identified any reports of patient harm, serious injuries, or deaths due to the incorrect coating.

Corrective Action:

- Recall of all affected products

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.
- Please quarantine and return immediately all affected products in your stock to your local Getinge representative.
- Upon return of the affected products, please contact your local Getinge representative for credit or replacement.
- 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, but no later than March 7, 2025,** quoting **FSCA-1227741** 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.
- Upon return of the affected products, provide the customer with credit or replacement.

Enclosed documents:

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

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: *Electronically signed by: Dieter Engel*
Reason: I approve this document.
Date: Feb 20, 2025 08:11 GMT+1

Email: dieter.engel@getinge.com

Person Responsible for Regulatory Compliance (PRRC)

Signature: *Electronically signed by: Alexander Bernhardt*
Reason: I approve this document.
Date: Feb 17, 2025 11:41 GMT+1

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:	1227741 – CTP – Connector with incorrect coating installed
Affected Product:	BO-HQV 129001#Ossigenatore Adult (Mat. 701074297)
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Please send this form at the latest by **March 7, 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.

☐ All affected products have been consumed and I do not have any affected products in my inventory.

☐ Following affected products will be returned to you for credit or replacement:

Article Number	Description	Lot 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 as a supplementary attachment to the 1227741 Field Safety Notice.

Hazardous Situation	Harm	S (from Part III)	P (from above)	Risk		
				Low	Med	High
Patient is exposed to allergenic agents	Sensitization	1	4	☒	☐	☐
	Allergic response/reaction	3	3	☒	☐	☐
	Anaphylactic response	4	3	☐	☒	☐

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