2024-03-07

URGENT FIELD SAFETY NOTICE

Manufacturer SRN:	DE-MF-000020091
FSCA Reference:	946576 Custom Tubing Packs – Potentially kinked tubing
FSN Type:	New
Affected Product:	BE-MECC 142000#NRP pack (Article no. 701076679)
Unique Device Identifier(s) (UDI-DI):	04058863304120
Affected Batch No.:	3000287584, 3000287583, 3000287574, 3000287575, 3000280257, 3000280256, 3000259047, 3000270181, 3000264003, 3000260955, 3000243680, 3000243103, 3000224821, 3000264004, 3000224820, 3000200513, 3000200502
For Attention of:	Users of the medical device listed above

Dear valued customer,

Maquet Cardiopulmonary GmbH (MCP) would like to inform you with this letter about a recall for the Custom Tubing Pack (CTP) BE-MECC 142000#NRP pack (Article no. 701076679) due to kinked tubing.

The intended use of the CTP is in extracorporeal circulation during cardiopulmonary bypass procedures for transporting blood and other fluids between the patient and the extracorporeal system.

Problem description

Maquet Cardiopulmonary GmbH became aware of this issue in course of customer complaints. It was reported that the venous tubing line is significantly kinked close to the oxygenator inlet connection (Figure 1, Figure 2).

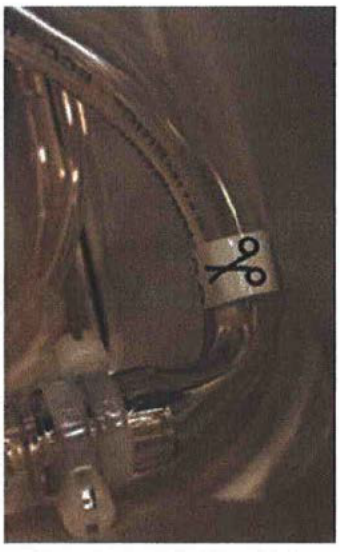

Figure 1: Example of bent tube

Figure 2: Example of bent tube

Hazardous situation

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

- Patient is exposed to inappropriately low blood flow
- Air enters the patient vascular system
- Product exchange/replacement, or modification

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 (Blood flow, Air embolism) (medium risk)

Maquet Cardiopulmonary GmbH has identified four customer complaints, however, none of them reported patient harm, serious injuries, or deaths due to failure mode described above.

Corrective Action:

- Return of affected devices

Action to be taken by the user:

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

Details of the 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 the affected Custom Tubing Packs in your inventory.
- If a product is already in use, it should remain in use.
- Please 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.
- Please **always** report any adverse events, e.g., infections 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 by **April 5, 2024,** the latest. Please give **FSCA-946576** as reference in the subject line of your email.

Action to be taken by the manufacturer:

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

- Inform all customers possessing the affected products **promptly** about this Field Action by sending the Field Safety Notice for Customers.

Packaging design with inherent safety

- Development of new packaging design for CTP

Enclosed documents:

- Customer response form
- 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 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, or send an e-mail to FSCA.cp@getinge.com.

Sincerely,

[redacted]

Signature: [redacted]

Electronically signed by: [redacted]
Reason: I approve this document
Date: Mar 14, 2024 08:13 GMT+8

Email:

[redacted]

Signature: [redacted]

Electronically signed by
Reason: I approve this document.
Date: Mar 8, 2024 10:44 GMT+1

Email:

Contact details of manufacturer

[redacted]

Email: FSCA.cp@getinge.com

CUSTOMER RESPONSE FORM

FSCA Reference:	946576 Custom Tubing Packs – Potentially kinked tubing
Affected Product:	BE-MECC 142000#NRP pack (Article no. 701076679)
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Please send this form at the latest by **April 5, 2024,** 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 for affected product Custom Tubing Pack. 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 Custom Tubing Packs in my inventory.
☐ I have following Custom Tubing Packs in my inventory:

Article No.	Description	Batch No.	Quantity

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 946576 Field Safety Notice.

Hazardous situation	Harm	S from part III	P from above	Risk		
				Low	Med	High
Patient is exposed to inappropriately low blood flow	Ischemia (Blood flow)	4	3	☐	☒	☐
Air enters the patient vascular system	Ischemia (Air embolism)	4	3	☐	☒	☐
Product exchange/replacement, or modification	User inconvenience	2	2	☒	☐	☐

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 946576 Field Safety Notice.

The tubing set BE-MECC 142000#NRP pack for the CARDIOHELP-i is a component of an extracorporeal system. The hazardous situation low blood flow can be detected with alarm system as per IFU CARDIOHELP II NONUS. The combined flow/bubble sensor is for flow measurement and arterial bubble monitoring.

IFU CARDIOHELP II EN-NONUS, Rev1.10.2, Page 20:

Flow monitoring

WARNING!

- Only use the CARDIOHELP-i with flow monitoring which triggers an alarm.

IFU, CARDIOHELP-I Tubing Set, G-261 NONUS, Rev04, Page 14:

- **Maquet Cardiopulmonary recommends using bubbles, direction of flow, temperature and pressure monitoring to enable safe perfusion.**

There is no design mechanism however according to the images above the defect is easily visually apparent to the user.

IFU, CARDIOHELP-I Tubing Set, G-261 NONUS, Rev04, Page 11:

- **When installing the tubes and preparing the device or pump, care must always be taken to ensure that there are no kinks, cracks, cuts, punctures or other damage to the tube system.**

IFU, CARDIOHELP-I Tubing Set, G-261 NONUS, Rev04, Page 12:

- **Mechanical forces may act on the components during the application. This can lead to blood loss, embolisms and inadequate patient support.**
  - **Secure all connections.**
  - **Avoid excessive tension and check the integrity and leak-tightness of the components immediately.**
  - **Ensure that the tubes are not kinked.**

IFU, CARDIOHELP-I Tubing Set, G-261 NONUS, Rev04, Page 13:

- **Kinking, clamping or any occlusion on the blood inlet side of the QUADROX-iR can lead to cavitation, particularly at high pump speeds. This can lead to an air embolism in the patient.**
  - **Avoid kinking, clamping and any occlusion on the blood inlet side of the QUADROX-iR.**
  - **If clamping is necessary, reduce the blood flow to below 0.6 l/min.**
  - **If possible, deactivate the LPM mode on the CARDIOHELP-i before clamping.**
  - **Always clamp the arterial and venous line at the same time.**

IFU, CARDIOHELP-I Tubing Set, G-261 NONUS, Rev04, Page 20:

⚠ WARNING!

Damage to the device or packaging.

A non-sterile or defective device can result in patient infections.

- **Perform a careful visual inspection of the sterile packaging before use. Pay particular attention to moisture, openings and soiling.**
- **Perform a careful visual inspection of the device before use. In particular, ensure there is no damage to the material, cracks, burrs or fissures.**