2023-12-21

URGENT FIELD SAFETY NOTICE

Manufacturer SRN:	DE-MF-000020091
FSCA Reference:	946521 Hemoconcentrator assembled after its shelf-life had expired
FSN Type:	New
Affected Product:	Refer to Annex I List of affected products
Unique Device Identifier(s) (UDI-DI):	4037691057361, 4037691076041, 4037691149035, 4037691298351, 4037691563527
Affected Batch No.:	Refer to Annex I List of affected products
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 corrective action for the above-mentioned Hemoconcentrator due to assembly after its shelf-life had expired.

The primary function of a hemoconcentrator is the elimination of excess water, electrolytes, and/or metabolites from the vascular space of a patient during cardiac surgery. The secondary function is retention of formed cellular elements (red blood cells, platelets, etc.) and albumin in the vascular system. The tertiary function is the removal excess fluid to be drawn from the interstitial space of the patient thereby preventing and/or minimizing peripheral edema.

A hemoconcentrator permits the retention of corpuscular blood components and plasma proteins while allowing the removal of excess plasma water thereby concentrating vascular volume. Unbound, low molecular weight solutes are removed from the vascular system with excess water in the process of hemoconcentration.

Problem description

The component "Hemoconcentrator" was assembled into the finished product (Hemoconcentrator tubing set) after its shelf-life had expired

After internal testing, it was determined that only one component lot was affected. Therefore, this Field Action is limited to products that containing Hemoconcentrator of the one affected batch.

Hazardous situation

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

- Patient is exposed to inappropriate high Thrombogenicity
- Patient is exposed to inflammatory agents
- Patient is exposed to inappropriately high hemodilution

Potential harm

The possible immediate and/or long-range health consequences and risk levels of the non-conformance include the following:

- Coagulation disorder
- Ischemia (Thromboembolism)
- Bleeding
- Inflammation
- Anemia
- Hemodilution

Maquet Cardiopulmonary GmbH has not identified any complaints of patient harm, serious injuries, or deaths due to the failure modes described above.

Corrective Action:	• Return of affected product
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 Hemoconcentrator in your inventory.
- Please immediately quarantine all affected products in your stock and return to your local Getinge representative.
- Your local Getinge representative will contact you if you have an affected product in your inventory to organize the product return.
- Upon return you will be provided with credit note.
- 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 **January 17, 2024,** the latest. Please give **FSCA-946521** 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.
- A local Getinge representative will contact all customers with an affected product to organize the product return.
  Provide customer with credit note.

Enclosed documents:

- Customer response form
- Annex I List of affected products
- Annex II 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 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,

Managing Director

Signature: [redacted] *Electronically signed by: Dieter Engel*
Reason: I approve this document.
Date: Dec 21, 2023 08:46 GMT+1

Email: dieter.engel@getinge.com

Person Responsible for Regulatory Compliance (PRRC)
(on behalf of the PRRC)

Signature: [redacted] *Electronically signed by: Alexander Bernhardt*
Reason: I approve this document.
Date: Dec 21, 2023 09:10 GMT+1

Email: alexander.bernhardt@getinge.com

Contact details of manufacturer

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

CUSTOMER RESPONSE FORM

FSCA Reference:	946521 Hemoconcentrator assembled after its shelf-life had expired
Affected Product:	Refer to Annex I List of affected products
Affected Batch No.:	Refer to Annex I List of affected products

Please send this form at the latest by **January 17, 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 Hemoconcentrator. 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 Hemoconcentrator in my inventory.
☐ I have following Hemoconcentrator 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 List of affected products

This Annex I List of affected products is considered a supplementary attachment to the 946521 Field Safety Notice.

Canada:

Article no.	Item Description	Batch no.
701027710	H 52570#BC 140 Plus with Lines	3000273187
701035298	BO-H 48771#BC 140 Hemoconcentrator Plus	3000276250 3000277066

Czech Republic:

Article no.	Item Description	Batch no.
701005142	P-0400#Hemoconcentrator set incl. BC 140	3000273199

France:

Article no.	Item Description	Batch no.
701005142	P-0400#Hemoconcentrator set incl. BC 140	3000242892

Germany:

Article no.	Item Description	Batch no.
701005142	P-0400#Hämokonzentrator Set mit BC 140	3000242892 3000273199

Netherlands:

Article no.	Item Description	Batch no.
701048516	H 31471#Hemoconcentrator Set BC 140	3000247617
701030315	H 15981#Set BC 140 Plus	3000247619

Philippines:

Article no.	Item Description	Batch no.
701005142	P-0400#Hemoconcentrator set incl. BC140	3000273199

Portugal:

Article no.	Item Description	Batch no.
701005142	P-0400#Hemofiltration Set incl BC140Plus	3000242892

South Africa:

Article no.	Item Description	Batch no.
701005142	P-0400#Hemoconcentrator set incl. BC140	3000273199

Switzerland:

Article no.	Item Description	Batch no.
701005142	P-0400#Hämokonzentrator Set mit BC 140	3000242892 3000273199

United Arab Emirates:

Article no.	Item Description	Batch no.
701005142	P-0400#Hemoconcentrator set incl. BC 140	3000242892

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

This Annex II Further information regarding Hazardous situation, Harms and Risk Levels is considered a supplementary attachment to the 946521 Field Safety Notice.

Hazardous situation	Harm	S from part III	P from above	Risk		
				Low	Med	High
Patient is exposed to inappropriate high Thrombogenicity	Coagulation disorderb,c	3	3	☐	☒	☐
	Ischemia (Thromboembolism)b	4	3	☐	☒	☐
	Bleedingc	3	3	☐	☒	☐
Patient is exposed to inflammatory agents	Inflammation	3	3	☐	☒	☐
Patient is exposed to inappropriately high hemodilution	Anemia	3	3	☐	☒	☐
	Hemodilution	3	3	☐	☒	☐
Product exchange/replacement	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