2023-12-21

URGENT FIELD SAFETY NOTICE

Manufacturer SRN:	DE-MF-000020091
FSCA Reference:	946519 RF-32 – potentially compromised sterile barrier
FSN Type:	New
Affected Product:	Refer to Annex I
Unique Device Identifier(s) (UDI-DI):	Refer to Annex I
Affected Batch No.:	Refer to Annex I
For Attention of:	Users of the medical device listed above

Dear valued customer,

Maquet Cardiopulmonary GmbH (MCP)/Getinge is notifying you about a recall for the ROTAFLOW Centrifugal Pump (RF-32) due to a potentially compromised sterile barrier.

The RF-32 is intended to maintain the blood flow during extracorporeal circulation.

Description of the Problem

During retrospective internal testing, MCP/Getinge discovered narrow channels in the seal of the sterile bags used to package the RF-32. MCP/Getinge receives this sterile bag from a supplier that performs tests to verify sterility. Incomplete sealing can potentially lead to a breach of the sterile barrier.

To gauge the scope of affected products MCP/Getinge re-tested all lots of the supplier-provided packaging used for products that are still within shelf life. This testing demonstrated that three supplier batches of sterile bags were affected. Therefore, this Field Safety Notice is limited to products that contain sterile bags from the three affected supplier batches.

Hazardous situation / Risk to Health

The Nelipak bag is the primary sterile barrier for the RF-32.

- MCP/Getinge's Health Hazard Evaluation (HHE) determined that a breach of the sterile barrier of the RF-32 could expose patients to pathogenic agents.

This hazardous situation could result in the following potential harms (for further information, please refer to Annex II):

- Inflammation (medium risk)
- Infection (medium risk)
- Sepsis (medium risk)

There have been no adverse events or customer complaints reported related to the issue described above.

Corrective Action:

- Return of affected RF-32 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 RF-32 in your inventory.
- If a product is already in use, it should remain in use due to increased potential risk when disconnecting the product during ongoing therapy.
- Please immediately quarantine all affected products in your stock and return to your local Getinge representative
- Upon return of the affected products, you will receive a replacement or Credit Note.
- Replacement/ New products can be ordered as usual.
- Please **always** report any adverse events, e.g., infections potentially related to the affected products, to your Getinge representative.
- Whether or not you have affected product(s), duly fill out the enclosed Letter of Acknowledgement / Customer Response Form and return it to your local Getinge representative by **January 17, 2024,** the latest. Please give **FSCA-946519** 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.
- Arrange the return of the affected product and provide the customer with credit note.
- Implementing additional corrective and preventive measures with the supplier in order to prevent the issue from happening again.
- Verification testing for integrity of the sterile seal is now performed by MCP/Getinge in-house before the material is used in production.

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 any other persons that need to be informed are made aware of this Urgent Field Safety Notice.
- Please transfer this notice to other organizations that may be impacted by this action.
- If you have given the affected product(s) to third parties, please forward a copy of this information or inform the MCP/Getinge contact person indicated below.

Please remain aware of this notice and its accompanying 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,

CUSTOMER RESPONSE FORM

FSCA Reference:	946519 RF-32 – potentially compromised sterile barrier
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 RF-32. 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 RF-32 in my inventory.
☐ I have following RF-32 in my inventory and decided for the following option:

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 946519 Field Safety Notice.

COUNTRY	ITEM	UDI	LOT OR SERIAL #	ITEM DESCRIPTION
Australia	701005308	4037691085364	3000284766	RF-32#Centrifugal Pump with FLOWPROBE
Belgium	701005308	4037691085364	3000284766	RF-32#Centrifugal Pump with FLOWPROBE
Belgium	701005308	4037691085364	3000282219	RF-32#Centrifugal Pump with FLOWPROBE
Brazil	701005308	4037691085364	3000282219	RF-32#Centrifugal Pump with FLOWPROBE
Canada	701018652	4037691079875	3000286569	BEQ-RF-32#RotaFlow Zentrifugal
Canada	701018652	4037691079875	3000323073	BEQ-RF-32#RotaFlow Zentrifugal
China	701005308	4037691085364	3000280888	RF-32#Centrifugal Pump with FLOWPROBE
Colombia	701005308	4037691085364	3000284766	RF-32#Centrifugal Pump with FLOWPROBE
Czech Republic	701005308	4037691085364	3000280888	RF-32#Centrifugal Pump with FLOWPROBE
Czech Republic	701005308	4037691085364	3000282219	RF-32#Centrifugal Pump with FLOWPROBE
Finland	701005308	4037691085364	3000284766	RF-32#Centrifugal Pump with FLOWPROBE
France	701005308	4037691085364	3000284766	RF-32#Centrifugal Pump with FLOWPROBE
France	701005308	4037691085364	3000282219	RF-32#Centrifugal Pump with FLOWPROBE
Germany	701032035	4037691253879	3000282220	BO-RF-32#RotaFlow Zentrifugalpumpe
Germany	701005308	4037691085364	3000284766	RF-32#RotaFlow Zentrifugal
Germany	701005308	4037691085364	3000282219	RF-32#RotaFlow Zentrifugal
Germany	701032035	4037691253879	3000319810	BO-RF-32#RotaFlow Zentrifugalpumpe
India	701005308	4037691085364	3000280888	RF-32#Centrifugal Pump with FLOWPROBE
Italy	701032035	4037691253879	3000282220	BO-RF-32#RotaFlow Centriflugal pump
Italy	701005308	4037691085364	3000284766	RF-32#Centrifugal Pump with FLOWPROBE
Italy	701005308	4037691085364	3000282219	RF-32#Centrifugal Pump with FLOWPROBE
Italy	701032035	4037691253879	3000319810	BO-RF-32#RotaFlow Centriflugal pump
Japan	701032035	4037691253879	3000282220	BO-RF-32#RotaFlow Centriflugal pump
Japan	701005308	4037691085364	3000284766	RF-32#Centrifugal Pump with FLOWPROBE
Japan	701032035	4037691253879	3000319810	BO-RF-32#RotaFlow Centriflugal pump
Japan	701032035	4037691253879	3000322589	BO-RF-32#RotaFlow Centriflugal pump
Japan	701032035	4037691253879	3000323708	BO-RF-32#RotaFlow Centriflugal pump
Korea, Republic of (South Korea)	701005308	4037691085364	3000284766	RF-32#Centrifugal Pump with FLOWPROBE
Netherlands	701032035	4037691253879	3000282220	BO-RF-32#RotaFlow Centriflugal pump
Netherlands	701032035	4037691253879	3000319810	BO-RF-32#RotaFlow Centriflugal pump
Netherlands	701032035	4037691253879	3000322589	BO-RF-32#RotaFlow Centriflugal pump
Poland	701005308	4037691085364	3000284766	RF-32#Centrifugal Pump with FLOWPROBE
Poland	701005308	4037691085364	3000282219	RF-32#Centrifugal Pump with FLOWPROBE
Portugal	701005308	4037691085364	3000280888	RF-32#Centrifugal Pump with FLOWPROBE

Spain	701005308	4037691085364	3000284766	RF-32#Centrifugal Pump with FLOWPROBE
Spain	701005308	4037691085364	3000282219	RF-32#Centrifugal Pump with FLOWPROBE
Taiwan, Republic Of China	701005308	4037691085364	3000280888	RF-32#Centrifugal Pump with FLOWPROBE
Taiwan, Republic Of China	701005308	4037691085364	3000284766	RF-32#Centrifugal Pump with FLOWPROBE
Taiwan, Republic Of China	701005308	4037691085364	3000282219	RF-32#Centrifugal Pump with FLOWPROBE
Turkey	701005308	4037691085364	3000284766	RF-32#Centrifugal Pump with FLOWPROBE
United States	701047554	4037691530864	3000286570	BEQ-RF-32-USA#Centrif. Pump w FLOWPR.
United States	701047553	4037691650326	3000283239	BO-RF-32-USA#RotaFlow Zentrifugalpumpe
United States	701047553	4037691650326	3000330438	BO-RF-32-USA#RotaFlow Zentrifugalpumpe
United States	701047554	4037691530864	3000325568	BEQ-RF-32-USA#Centrif. Pump w FLOWPR.

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 946519 Field Safety Notice.

Hazardous situation	Harm	S from part III	P from above	Risk		
				Low	Med	High
Patient is exposed to pathogenic agents	Inflammation	3	3		☒	
	Infection	4	3		☒	
	Sepsis	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