2024-08-15

URGENT FIELD SAFETY NOTICE

Manufacturer SRN:	DE-MF-000020091
FSCA Reference:	1094156 BO (Softline) coating out of specifications
FSN Type:	New
Affected Product:	See Annex I
Unique Device Identifier(s) (UDI-DI):	See Annex I
Affected Batch No.:	See Annex I
For Attention of:	Users of the medical device listed in Annex I

Dear valued customer,

Maquet Cardiopulmonary GmbH (MCP) is initiating a recall for the Custom Tubing Set due to the Softline coating being out of specifications.

The QUADROX-i is a hollow fiber membrane oxygenator with microporous membrane and heat exchanger. The designation QUADROX-i refers to all available versions and sizes, unless stated otherwise.

The QUADROX-i essentially consists of two membrane packages. The first chamber contains the plastic fibers of the heat exchanger and the microporous oxygenation fibers arranged in crosswise mats. The second chamber contains solely mats made of oxygenation fibers.

The QUADROX-i with integrated arterial filter is able to filter air bubbles and particles larger than 40 µm out of the blood flow. Large amounts of air can be removed via the de-airing valve. The QUADROX-i can be used as follows:

- In a closed system with a venous softbag reservoir
- In an open system with a venous hardshell cardiotomy reservoir
- In a minimized extracorporeal circulation

The device may only be operated by trained physicians or trained perfusionists experienced in extracorporeal circulation. The device is intended to be used in the operating room. Within the specified flow rate, the device can be used for all patients irrespective of age, body weight and gender.

Problem description

Maquet Cardiopulmonary's monthly inspection of oxygenators for the presence of the Softline coating revealed that two out of ten oxygenators tested did not pass. The Softline coating is a vital component in the biocompatibility of blood contact components used in extracorporeal circulation. This means that the oxygenators installed in the Annex I products do not have the Softline coating.

Hazardous situation

A Health Hazard Evaluation (HHE) performed by Maquet Cardiopulmonary GmbH determined the following hazardous situations may arise due to the nonconformance:

- Patient is exposed to insufficient gas exchange
- Patient is exposed to systemic thrombotic event
- Final product with degraded coating properties is used

Potential harm

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

- Hypoxemia (Medium)
- Hypercapnia (Medium)
- Ischemia (Thromboembolism) (Medium)
- Hemolysis (Medium)
- Inflammation (Medium)

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 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.
- Please **always** report any adverse events, e.g., clotting 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 **September 18, 2024,** at the latest. Please give **FSCA- 1094156** 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.

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:

Email: dieter.engel@getinge.com

Person Responsible for Regulatory Compliance (PRRC)

Signature:

Email: alexander.bernhardt@getinge.com

Contact details of manufacturer

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

CUSTOMER RESPONSE FORM

FSCA Reference:	1094156 – BO (Softline) coating out of specifications
Affected Product:	See Annex I
Affected Batch No.:	See Annex I

Please send this form at the latest by **September 18, 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 all products. 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 following affected products 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 1094156 Field Safety Notice.

Canada:

Article No.	Article Description	UDI	Batch No.
701067942	VKMO 70000 #SQUADROX-i HMO 70000+VHK7100	04058863007229	3000358089

China:

Article No.	Article Description	UDI	Batch No.
701067941	VKMO 78000 #SQUADROX-i HMO 70000+VHK7000	04058863017792	3000358091

Ireland:

Article No.	Article Description	UDI	Batch No.
701067942	VKMO 70000 #SQUADROX-i HMO 70000+VHK7100	04058863007229	3000358089

Italy:

Article No.	Article Description	UDI	Batch No.
701055823	BO-HQV 94100#Circuito per Minicec	04037691771687	3000358220
701067948	BO-VKMO 70000 #SQUADR-i HMO70000+VHK7100	04058863003245	3000358090
701074465	BO-HQV 36210#Custom Pack	04058863189574	3000358294 3000355333

Spain:

Article No.	Article Description	UDI	Batch No.
701004884	HQV 7503#Quadrox Complet Pack	04037691047522	3000358219
701028619	HQV 37701#HL Pack, Adult	04037691034836	3000358296
701050545	HQV 81500#Set Donante Asistolia	04037691639482	3000358226
701067942	VKMO 70000 #SQUADROX-i HMO 70000+VHK7100	04058863007229	3000358089
701067948	BO-VKMO 70000 #SQUADR-i HMO70000+VHK7100	04058863003245	3000358090
701076373	BO-HQV 32400#HL - Pack	04058863301259	3000358224

United Kingdom:

Article No.	Article Description	UDI	Batch No.
701069392	HQV 49400#Adult Perfusion Pack	04037691982557	3000358218

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 1094156 Field Safety Notice.

Hazardous situation	Harm	S from part III	P from above	Risk		
				Low	Med	High
Patient is exposed to insufficient gas exchange	Hypoxemia	3	3		X	
	Hypercapnia	3	3		X	
Patient is exposed to systemic thrombotic event	Ischemia	4	3		X	
Final product with degraded coating properties is used	Hemolysis	4	3		X	
	Ischemia	4	3		X	
	Inflammation	3	3		X	
Replacement/exchange of product	User inconvenience	2	1	X		

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