

2023-08-21

URGENT FIELD SAFETY NOTICE

Manufacturer SRN: DE-MF-000020091

FSCA Reference: 874275 – Custom Tubing Pack – Gas filter used in fluid lines

FSCA Type: New

Affected Product:

| REF no. | Article no. | Product description |
|---------------------|-------------|--------------------------------|
| HQV 3300 | 701004874 | Quadrox Complete Pack with HMO |
| S 1150 | 701019904 | Kondenzwasser-Falle |
| BO-HQV 51601 | 701041635 | Adult Pack OPEN |
| BO-HQV 27903 | 701053602 | Adult Pack |
| HQV 3003 | 701070115 | Pre-Connected Circuit |
| HQV 94500 | 701072923 | Cabaret de pompe Chicoutimi |
| BO-H 141906 | 701076649 | Rotaflow supply set Suction |

Affected Batch No.: See attached Annex I List of affected lots

Unique Device Identifier:

| REF no. | Article no. | UDI |
|---------------------|-------------|----------------|
| HQV 3300 | 701004874 | 04037691005003 |
| S 1150 | 701019904 | 04037691270234 |
| BO-HQV 51601 | 701041635 | 04037691380216 |
| BO-HQV 27903 | 701053602 | 04037691718156 |
| HQV 3003 | 701070115 | 04037691996325 |
| HQV 94500 | 701072923 | 04058863080284 |
| BO-H 141906 | 701076649 | 04058863303765 |

For Attention of: Users of the medical devices listed above

Template: CP-SOP-001-T-02 V02, Effective date 2019-09-15

Dear valued customer,

Maquet Cardiopulmonary GmbH (MCP) would like to inform you with this letter about a recall for the above-mentioned Custom Tubing Packs (CTP) due to inappropriately deployed gas filters in fluid-bearing lines of the product.

The Heart-Lung-Machine (HLM) CTP is a component of an extracorporeal system and may only be used in combination with other components (e.g., blood pumps, oxygenators, hemoconcentrators, heat exchangers). It is used to transport blood and other fluids between the patient and the extracorporeal system. The HLM CTP is intended for use in extracorporeal circulation during cardiopulmonary bypass procedures.

Problem description

Maquet Cardiopulmonary GmbH became aware of the issue in course of a customer complaint. It was reported that there was gas leaking from the cardioplegia line. The customer did not replace the product during treatment. No harm to any person has been reported. Upon investigation of the complaint, it was noted that the gas filter of the HLM CTP was not deployed as specified by the manufacturer (i.e., in gas-bearing line/tube).

Hazardous situations

In course of a Health Hazard Evaluation (HHE), MCP determined the following hazardous situations for the inappropriate deployment of the gas filters:

- Patient, user or other persons are exposed to pathogenic agents.
- The patient is exposed to inappropriate low blood flow.
- Patient is exposed to inappropriately high pressure.
- Product exchange/replacement.

Potential harms

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

- Inflammation
- Infection
- Sepsis
- Ischemia
- Hypertension
- User inconvenience

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

Corrective Actions

- Recall of all affected products

Action to be taken by the customer:

| | |
|---|---|
| <input checked="" type="checkbox"/> Identify Device | <input checked="" type="checkbox"/> Quarantine Device |
| <input checked="" type="checkbox"/> Return Device | <input type="checkbox"/> Destroy Device |

- 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 Custom Tubing Sets in your inventory.
- Please return immediately all affected products in your stock to your local Getinge representative.
- Alternative products are available. Upon return, Getinge will provide you with Credit Note. Replacements can be ordered as usual.
- If a product is already in use, it should remain in use.
- 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 **October 31, 2023, the latest**. Please give **FSCA-874275** as reference in the subject line of your email.

Action to be taken by the manufacturer

| | |
|---|--|
| <input checked="" type="checkbox"/> Product Removal | <input type="checkbox"/> On-site device modification/ inspection |
| <input type="checkbox"/> Software upgrade | <input type="checkbox"/> IFU or labelling change |
| <input type="checkbox"/> Other | <input type="checkbox"/> None |

- Inform all customers possessing the affected products **promptly** about this Field Action by sending the Field Safety Notice for Customers.
- Upon return of affected products, provide customer with credit note.

Enclosed documents

- Customer response form
- Annex I List of affected lots

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 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 or send an e-mail to FSCA.cp@getinge.com.

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Sincerely,

Signature:

Email:

Signature:

Email:

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

CUSTOMER RESPONSE FORM

FSCA Reference: 874275 – Custom Tubing Pack – Gas filter used in fluid lines

Affected Product:

| REF no. | Article no. | Product description |
|---------------------|-------------|--------------------------------|
| HQV 3300 | 701004874 | Quadrox Complete Pack with HMO |
| S 1150 | 701019904 | Kondenzwasser-Falle |
| BO-HQV 51601 | 701041635 | Adult Pack OPEN |
| BO-HQV 27903 | 701053602 | Adult Pack |
| HQV 3003 | 701070115 | Pre-Connected Circuit |
| HQV 94500 | 701072923 | Cabaret de pompe Chicoutimi |
| BO-H 141906 | 701076649 | Rotaflo supply set Suction |

Affected Batch No.: See attached Annex I List of affected batches

Please send this form to your local Getinge representative at the latest by **October 31, 2023**.

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 CTP 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 CTP in my inventory.
- I have following affected CTP in my inventory and will send them back for credit:

| Product Name | Article Number | Batch Number | Quantity |
|--------------|----------------|--------------|----------|
|--------------|----------------|--------------|----------|

Your Comments:

Country

Hospital / Clinic (full address)

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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>:

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Annex I List of affected lots

This Annex I List of affected lots is considered as a supplementary attachment to the 874275 Field Safety Notice.

Below are listed all lots of products which are affected and have been distributed.

| Material Number | Material Description | Lot Number | Country |
|-----------------|---|------------|---------|
| 701004874 | HQV 3300#Quadrox Complete Pack with HMO | 3000147946 | Canada |
| 701004874 | HQV 3300#Quadrox Complete Pack | 3000148855 | Canada |
| 701004874 | HQV 3300#Quadrox Complete Pack with HMO | 3000172880 | Canada |
| 701004874 | HQV 3300#Quadrox Complete Pack with HMO | 3000199082 | Canada |
| 701004874 | HQV 3300#Quadrox Complete Pack with HMO | 3000221116 | Canada |
| 701041635 | BO-HQV 51601#Adult Pack OPEN | 3000162713 | Canada |
| 701041635 | BO-HQV 51601#Adult Pack OPEN | 3000192526 | Canada |
| 701041635 | BO-HQV 51601#Adult Pack OPEN | 3000206013 | Canada |
| 701041635 | BO-HQV 51601#Adult Pack OPEN | 3000209354 | Canada |
| 701070115 | HQV 3003#Pre-Connected Circuit | 3000252905 | Canada |
| 701072923 | HQV 94500#Cabaret de pompe Chicoutimi | 3000141558 | Canada |
| 701072923 | HQV 94500#Cabaret de pompe Chicoutimi | 3000159328 | Canada |
| 701072923 | HQV 94500#Cabaret de pompe Chicoutimi | 3000171796 | Canada |
| 701072923 | HQV 94500#Cabaret de pompe Chicoutimi | 3000194211 | Canada |
| 701004874 | HQV 3300#Quadrox Complete Pack with HMO | 92302793 | Germany |
| 701004874 | HQV 3300#Quadrox Complete Pack with HMO | 3000162011 | Germany |
| 701053602 | BO-HQV 27903#Adult Pack | 3000156733 | Germany |
| 701072923 | HQV 94500#Cabaret de pompe Chicoutimi | 92312197 | Germany |
| 701072923 | HQV 94500#Cabaret de pompe Chicoutimi | 3000144901 | Germany |
| 701004874 | HQV 3300#Quadrox Complete Pack with HMO | 92311752 | Ireland |
| 701004874 | HQV 3300#Quadrox Complete Pack with HMO | 92311966 | Ireland |
| 701004874 | HQV 3300#Quadrox Complete Pack with HMO | 3000196717 | Ireland |
| 701004874 | HQV 3300#Quadrox Complete Pack with HMO | 3000196719 | Ireland |
| 701004874 | HQV 3300#Quadrox Complete Pack | 3000214150 | Ireland |
| 701004874 | HQV 3300#Quadrox Complete Pack with HMO | 3000219309 | Ireland |
| 701019904 | S 1150#Kondenzwasser-Falle | 3000210366 | Ireland |
| 701019904 | S 1150#Kondenzwasser-Falle | 3000231129 | Ireland |
| 701019904 | S 1150#Kondenzwasser-Falle | 3000233559 | Ireland |
| 701019904 | S 1150#Kondenzwasser-Falle | 3000236120 | Ireland |
| 701019904 | S 1150#Kondenzwasser-Falle | 3000239972 | Ireland |
| 701041635 | BO-HQV 51601#Adult Pack OPEN | 3000196716 | Ireland |
| 701041635 | BO-HQV 51601#Adult Pack OPEN | 3000202555 | Ireland |

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| | | | |
|-----------|---|------------|-------------|
| 701041635 | BO-HQV 51601#Adult Pack OPEN | 3000213283 | Ireland |
| 701041635 | BO-HQV 51601#Adult Pack OPEN | 3000215267 | Ireland |
| 701053602 | BO-HQV 27903#Adult Pack | 3000239973 | Ireland |
| 701053602 | BO-HQV 27903#Adult Pack | 3000239974 | Ireland |
| 701053602 | BO-HQV 27903#Adult Pack | 3000266352 | Ireland |
| 701072923 | HQV 94500#Cabaret de pompe Chicoutimi | 3000141837 | Ireland |
| 701072923 | HQV 94500#Cabaret de pompe Chicoutimi | 3000143122 | Ireland |
| 701072923 | HQV 94500#Cabaret de pompe Chicoutimi | 3000143297 | Ireland |
| 701072923 | HQV 94500#Cabaret de pompe Chicoutimi | 3000144304 | Ireland |
| 701076649 | BO-H 141906#Rotaflow supply set Suction | 3000270194 | Ireland |
| 701004874 | HQV 3300#Quadrox Complete Pack with HMO | 3000177705 | Netherlands |
| 701004874 | HQV 3300#Quadrox Complete Pack with HMO | 3000178795 | Netherlands |
| 701004874 | HQV 3300#Quadrox Complete Pack with HMO | 3000188694 | Netherlands |
| 701004874 | HQV 3300#Quadrox Complete Pack with HMO | 3000190250 | Netherlands |
| 701004874 | HQV 3300#Quadrox Complete Pack with HMO | 3000214157 | Netherlands |
| 701041635 | BO-HQV 51601#Adult Pack OPEN | 92302824 | Netherlands |
| 701041635 | BO-HQV 51601#Adult Pack OPEN | 3000141561 | Netherlands |
| 701041635 | BO-HQV 51601#Adult Pack OPEN | 3000183012 | Netherlands |
| 701041635 | BO-HQV 51601#Adult Pack OPEN | 3000185421 | Netherlands |
| 701041635 | BO-HQV 51601#Adult Pack OPEN | 3000196030 | Netherlands |
| 701041635 | BO-HQV 51601#Adult Pack OPEN | 3000209132 | Netherlands |
| 701041635 | BO-HQV 51601#Adult Pack OPEN | 3000212338 | Netherlands |
| 701041635 | BO-HQV 51601#Adult Pack OPEN | 3000215247 | Netherlands |
| 701053602 | BO-HQV 27903#Adult Pack | 3000144965 | Netherlands |
| 701053602 | BO-HQV 27903#Adult Pack | 3000164620 | Netherlands |
| 701053602 | BO-HQV 27903#Adult Pack | 3000251718 | Netherlands |
| 701053602 | BO-HQV 27903#Adult Pack | 3000251719 | Netherlands |
| 701072923 | HQV 94500#Cabaret de pompe Chicoutimi | 92305551 | Netherlands |
| 701072923 | HQV 94500#Cabaret de pompe Chicoutimi | 92307328 | Netherlands |
| 701072923 | HQV 94500#Cabaret de pompe Chicoutimi | 3000144964 | Netherlands |
| 701041635 | BO-HQV 51601#Adult Pack OPEN | 3000160122 | Norway |
| 701070115 | HQV 3003#Pre-Connected Circuit | 92304922 | Norway |
| 701072923 | HQV 94500#Cabaret de pompe Chicoutimi | 92311980 | Norway |

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