

2021-02-25

URGENT - FIELD SAFETY NOTICE

Subject: FSCA-2021-02-19 Tubing sets released without specified degassing time

Affected Product:	REF	Product Description	Article No.	Lot
	BO-HQV 15902	Adult Pack	70103.5634	92301649
	BE-S 2336	CH Heparine lijn	70105.5796	92312215

Affected Lot No.: See table above

Dear valued customer,

The products listed above were inadvertently shipped to your establishment before the degassing time after sterilization was fully elapsed.

Upon recognition of the issue and based on the risk associated with potential concentration of high Ethylene Oxide residuals on the device, our local Getinge Representative has contacted you to return the devices prior to issuance of this FSN.

You have already returned 33 of the products to your local Getinge Representative and have scrapped 1 of the products at your establishment. Based on our surveillance documentation you do not have any remaining units of the devices and no devices were used to treat patients.

Maquet Cardiopulmonary GmbH has not received any reports of serious injuries or death due to release of affected products to customers.

Corrective Action: Return the affected devices.

- Advice on action to be taken by the User**
- According to our surveillance documentation, your current stock of 33 devices have been returned to your local Getinge representative and you have scrapped 1 device at your establishment.
 - Please confirm that all devices returned to your local Getinge representative by completing and signing the attached Letter of Acknowledgement for the customer and sending it back to your local Getinge representative.
 - If you find any additional affected devices, please segregate the devices immediately to avoid mix-ups and immediately contact your local Getinge representative to arrange for the return of these devices.

- Referenced documents/ attachments:**
- Letter of Acknowledgement Customer

Transmission of the Field Safety Notice:

- This notice needs to be passed on to all those who need to be aware within your organization or to any organization where the potentially affected devices have been transferred.
- Please transfer this notice to other organizations on which the action has an impact.
- Please maintain awareness of 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 will provide 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,

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Maquet Cardiopulmonary GmbH
 Kehler Str. 31
 76437 Rastatt
 GERMANY

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