2023-07-20

URGENT FIELD SAFETY NOTICE

Manufacturer SRN:	DE-MF-000020091
FSCA Reference:	856260 – HLS Cannula – Seal width out of specification
Affected Product:	PAL 1723 (Mat. 701047258) BO-PVL 2155 (Mat. 701053108) BO-PVL 2355 (Mat. 701053109)
Affected Batch No.:	3000249819 (7 units affected) 3000249793 (2 units affected) 3000249791 (2 units affected)
Unique Device Identifier(s) (UDI-DI):	04037691707600 04037691746968 04037691815077
For Attention of:	Users of the medical devices listed above

Dear valued customer,

Maquet Cardiopulmonary GmbH (MCP) would like to inform with this letter about a recall for the above-mentioned HLS Cannula due to out of specification packaging sealing.

The HLS Cannula (Figure 1) is a wire-reinforced, thin-wall cannula used to cannulate suitable target vessel(s) with the intention of providing systemic perfusion of the corpus via connection to extracorporeal circulation. The cannula is available with optional BIOLINE Coating or SOFTLINE Coating in sizes from 13 to 29 French with variable lengths.

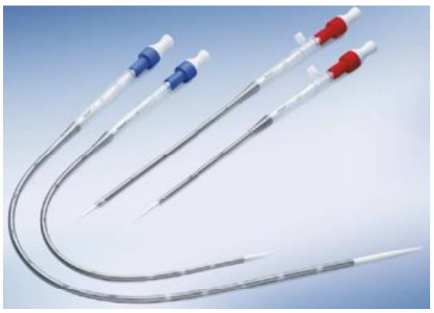

Figure 1: HLS Cannula (arterial and venous as long and short version)

The primary packaging in which an HLS Cannula is packed is a rectangle-shaped gas-permeable, Tyvek sterile pouch (Figure 2). The Tyvek sterile pouch rollstock features two short, unsealed and two long sides with a seam pre-sealed by the supplier. The Tyvek rollstock is cut to specific length and, subsequently, heat-sealed on the short sides by MCP.

Figure 2: Example of HLS Cannula primary and secondary packaging

Problem description

Maquet Cardiopulmonary GmbH became aware of defects in the seam width of the Tyvek sterile pouches (primary packaging). The seal width was lower than specified. A seam that is too narrow could result in a contamination of the product. As products with the affected Tyvek rollstock had already been shipped at the time the defect was discovered, this recall was initiated.

Hazardous situation and harm

Hazardous situation: Application of contaminated product

In course of a Health Hazard Evaluation (HHE), MCP assessed the application of a potentially contaminated HLS Cannula sterile pouch. The immediate and long-term health consequences may include any, some, all, or none of the following harms:

- Inflammation
- Infection
- Sepsis

It is assumed that some degree of user inconvenience would likely be experienced due to the possible exchange of the compromised product while attempting to place a patient on extracorporeal support.

Maquet Cardiopulmonary GmbH is working with all possible urgency on implementing the corrective actions. In the meantime, a 100% control of the material is performed preventively. Maquet Cardiopulmonary GmbH has not identified any complaints of patient harm, serious injuries, or deaths due to failure modes described above.

Corrective Actions	• Recall of all affected products
Actions to be taken by the customer	☒ Identify Device ☒ Return 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 any affected HLS Cannula in your inventory. • Report your stock to your local Getinge representative so that a possible return of the affected products can be organized. • 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 **September 1, 2023, the latest**. Please give FSCA-856260 as reference in the subject line of your email.
Actions to be taken by the manufacturer	• 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	• Letter of Acknowledgement Customer

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

Person Responsible for Regulatory Compliance (PRRC)

Contact details of manufacturer
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Email: FSCA.cp@getinge.com

CUSTOMER RESPONSE FORM

FSCA Reference:	856260 – HLS Cannula – seal width out of specification
Affected Product:	PAL 1723 (Mat. 701047258) BO-PVL 2155 (Mat. 701053108) BO-PVL 2355 (Mat. 701053109)
Affected Batch No.:	3000249819 3000249793 3000249791

Please send this form to your local Getinge representative at the latest by **September 1, 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 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 personnel.

☐ I do not have any affected products in my inventory.

☐ I have the following affected products in my inventory:

Article Number	Description	Batch number	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.