July 22, 2022

URGENT MEDICAL DEVICE REMOVAL EXPANSION
HLS Set Advanced

	Product Description:	Product Code/REF Number:	UDI Code:	Distributed Affected Lot Number(s)*:
Issue 1: Paper packaging of accessories	BEQ-HLS 5050 USA; HLS Set Advanced 5.0	70105.2797	04037691741543	3000183908
	BEQ-HLS 7050 USA; HLS Set Advanced 7.0	70105.2794	04037691773513	3000183172 through 3000184681
	Manufacturing Dates: July 14, 2021 to July 23, 2021			
	Distribution Dates: August 24, 2021 to January 6, 2022			
Issue 2: Punctures through the Tyvek lid	BEQ-HLS 5050 USA; HLS Set Advanced 5.0	70106.9077	04058863076355	3000192081 through 3000216172
	BEQ-HLS 7050 USA; HLS Set Advanced 7.0	70106.9078	04058863080383	3000190535 through 3000234522
	Manufacturing Dates: September 3, 2021 to April 12, 2022			
	Distribution Dates: October 22, 2021 to June 16, 2022			

***see full list of lots in Annex 1**

Dear Risk Manager,

Maquet Cardiopulmonary GmbH (MCP)/Getinge is expanding its voluntary Medical Device Removal initiated on November 6, 2020 for the HLS Set Advanced (disposable for Cardiohelp). Maquet Cardiopulmonary GmbH (MCP) has continued to receive customer complaints (a total of 34 as of July 15, 2022) of damage to the sterile barrier the HLS Set Advanced. Additional part numbers and lots are being added to the scope of this voluntary Medical Device Removal. Two issues have been identified with distinct root causes and affect different products, but they both can potentially cause a breach in the sterile barrier that may result in compromised product sterility.

The HLS Set Advanced is intended for use with and is part of the CARDIOHELP System and is a preconnected set used for extracorporeal respiratory and/or cardiovascular support.

The CARDIOHELP System is a blood oxygenation and carbon dioxide removal system used to pump blood through the extracorporeal bypass circuit for circulatory and/or pulmonary support for periods appropriate to cardiopulmonary bypass (up to six hours). It is also intended to

provide circulatory and/or pulmonary support during procedures not requiring cardiopulmonary bypass (for periods up to six hours).

The CARDIOHELP System in configuration with the HLS/HIT Set Advanced is intended to be used within the hospital environment and outside the hospital environment (for periods up to six hours), e.g. for intra- and inter-hospital transport.

MCP has not received any reports of adverse events due to damage to the sterile barrier system of the HLS Set Advanced.

Risk to Health:

Exposure to a non-sterile or potentially non-sterile medical device, or a delay in the procedure, may result in following immediate and/ or long-range health consequences:

- Inflammation,
- Infection,
- Sepsis,
- Ischemia

Issue 1: Paper packaging of accessories:

Identification of the issue:

MCP/Getinge has received 19 complaints since initiating a voluntary Medical Device Removal on November 6, 2020, reporting damage to the packaging. All of these reported complaints were related to the former medical paper packaging.

In September 2021, MCP/Getinge introduced a packaging design change to the U.S. variant of the HLS Set Advanced which switched from medical paper packaging to Tyvek. Design verification tests showed that medical paper is a weaker material than Tyvek, carrying a higher risk of being breached and thus compromising product sterility. Therefore, MCP/Getinge is removing all HLS Sets with the former medical paper packaging design from the market.

Actions to be taken by the Customer:

Our records indicate that you have received the HLS Set Advanced having the product codes/lot numbers that are potentially affected by this Medical Device Removal.

- Please examine your inventory immediately to determine if you have any of the affected HLS Set Advanced with the product codes and lot numbers listed on page 1 of this notice and acknowledge that you have received this notification by following the instructions below.
- If an affected device is already in use, please continue using according to normal practices.

- Should you have any un-used and un-expired affected product you should immediately return the affected product for credit. Please contact Getinge Customer Service at (888) 9GETUSA / (888) 943-8872 (press option 2) between the hours of 8:00 a.m. and 6:00 p.m. Eastern Standard Time to request a return authorization (RMA) and shipping instructions to return any affected product. Pack the product to be returned with the appropriate return documents and, using the shipping instructions provided, arrange for pickup with the designated delivery service provider.
- Please also enter the affected lot numbers, quantity and RMA number provided by Customer Service in the spaces provided on the Medical Device Removal Expansion - Response Form on Page 8-9 of this letter, if you are returning products to Maquet/Getinge.

Action by the Getinge:

Maquet Cardiopulmonary GmbH (MCP)/Getinge already implemented the more durable Tyvek accessory packaging in all product manufactured September 2021 and later.

Issue 2: Punctures through the Tyvek lid:

Identification of the issue:

MCP/Getinge has received 15 complaints reporting damage to the Tyvek cover. The position of the perforations were consistent across the complaints and corresponded with the tabs of the venous measuring cell within the packaging on either the left or the right side (see Figure 1, Figure 2 and Figure 3). The results of the product packaging investigation suggests that the Tyvek damage only occurs if the HLS Set is dropped upside down causing either the Velcro straps holding the HLS Module to come loose or the HLS Module to detach. A shift/movement of the HLS Module enables the venous measuring cell tab(s) to perforate the Tyvek cover and the sterile barrier system may be compromised.

Figure 1

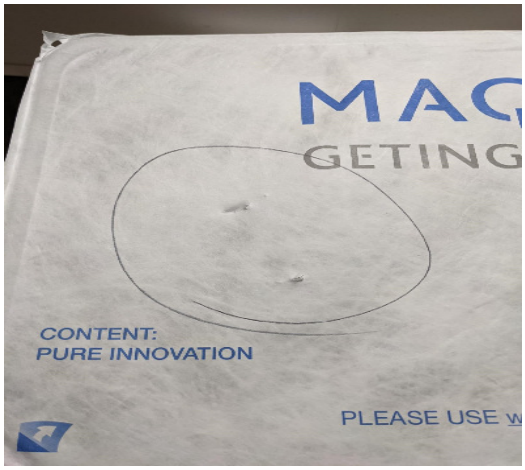

Figure 2

Figure 3

Figure 1: HLS Module with the venous measuring cell tabs

Figure 2: An example of holes as seen in the Tyvek cover

Figure 3: Positions of damage (either left or right side) based of position of HLS Module in the package

Actions to be taken by the Customer:

Our records indicate that you have received the HLS Set Advanced having the product codes/lot numbers that are potentially affected by this Medical Device Removal.

- Please examine your inventory immediately to determine if you have any of the affected HLS Set Advanced with the product codes and lot numbers listed on page 1 of this notice and acknowledge that you have received this notification by following the instructions below.
- If an affected device is already in use, please continue using according to normal practices.
- Due to a potential delay of replacement products there are two potential options you may take for these affected lots:
- Option 1:
    - Should you have any unused and unexpired affected product, you are eligible to return the affected product for credit/replacement. Please contact Getinge Customer Service at (888) 9GETUSA / (888) 943-8872 (press option 2) between the hours of 8:00 a.m. and 6:00 p.m. Eastern Standard Time to request a return authorization (RMA) and shipping instructions to return any affected product. Pack the product to be returned with the appropriate return documents and, using the shipping instructions provided, arrange for pickup with the designated delivery service provider.
    - Please also enter the affected lot numbers, quantity and RMA number provided by Customer Service in the spaces provided on the Medical Device Removal Expansion - Removal Response Form on Page 8-9 of this letter, if you are returning products to Maquet/Getinge.
- Option 2:
    - If the products are necessary based on expert clinical judgement, you can use the devices after following these inspection measures:
        1. Prior to use, the HLS Sets Tyvek covers must be checked visually for any damages, holes or tears in order to prevent the use of an unsterile medical device.
        2. After removing the tray from the secondary package (white cardboard box), position the tray in a well-lit area outside the sterile field.
        3. Check the integrity of the sterile barrier of the tray (Tyvek cover) before use.
            - If any doubt arises as to package integrity, then it should not be used. Any product with damaged packaging must be returned to Getinge.
            - Please contact Getinge Customer Service at (888) 9GETUSA / (888) 943-8872 (press option 2) between the hours of 8:00 a.m. and 6:00 p.m. Eastern Standard Time to request a return authorization (RMA) and shipping instructions to return any affected product. Pack the product to be returned with the

appropriate return documents and, using the shipping instructions provided, arrange for pickup with the designated delivery service provider.

- Please note that, until additional packaging design change can be implemented and released into manufacturing, all replacement product which you will receive will be packaged in the same design (released September 2021). This product has an “Inspection instruction” affixed on the white box along with a new label (see annex 2).
- Please forward this information to all current and potential HLS Set Advanced users within your hospital / facility.

Action by the Getinge:

MCP is working diligently on an additional packaging design change in order to reduce the shift/movement of the HLS Module. You will continue to receive the current packaging design until a packaging design change can be implemented and released into manufacturing.

The product you receive will be labeled on all four side panels indicating special instructions for shipment, handling and storage (see Figure 4). A more controlled shipment method will be utilized to limit the possibility of upside down drops. All HLS Sets will have an additional "Safety Notice” affixed on the white box, which will allow easier identification of the current packaging design as well as provide instruction to identify possible damage to the package prior to use.

Figure 4: Example of new box label

Information applying to both issues

If you are a distributor who has shipped any affected products to customers, please forward this document to their attention for appropriate action. If you are transporting product from the original ship-to location to another location, please utilize controlled shipment methods that will avoid upside down drops.

Whether you have affected product or not, please complete and sign the attached MEDICAL DEVICE REMOVAL EXPANSION – RESPONSE FORM (page 8-9) to acknowledge that you have received this notification. Return the completed form to Maquet/Getinge by e-mailing a scanned copy to acthlsset2022.US@getinge.com or by faxing the form to (877) 634-9232.

This voluntary Medical Device Removal only affects the products listed on page 1; no other products are affected by this voluntary Medical Device Removal.

Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA's MedWatch Adverse Event Reporting program using one of the following methods:

- **Online**: www.accessdata.fda.gov/scripts/medwatch/
- **Regular Mail**: Download form www.fda.gov/MedWatch/getforms.htm or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form
- **Fax**: 1-800-FDA-0178

We apologize for any inconvenience this voluntary Medical Device Removal may cause. If you have any questions, please contact your Getinge representative or call the Getinge Customer Support at (888) 9GETUSA / (888) 943-8872 (press option 2), Monday through Friday, between the hours of 8:00 a.m. and 6:00 p.m. (Eastern Time Zone).

This recall is being made with the knowledge of the U.S. Food and Drug Administration.

Sincerely,

Allison Jean Kaplan
Specialist II, Regulatory Affairs and Field Action Compliance
USA Shared Services
GETINGE
45 Barbour Pond Drive
Wayne, NJ 07470 USA