June 27, 2023

UPDATED URGENT MEDICAL DEVICE CORRECTION
HLS Set Advanced

Product Description:	Product Code/REF Number:	UDI Code:	Distributed Affected Lot Number(s):
BEQ-HLS 5050 USA; HLS Set Advanced 5.0	70106.9077	04058863076355	All Lot Numbers
BEQ-HLS 7050 USA; HLS Set Advanced 7.0	70106.9078	04058863080383	All Lot Numbers
Manufacturing Dates: September 3, 2021 to Ongoing			
Distribution Dates: October 22, 2021 to Ongoing			

Dear Risk Manager,

Maquet Cardiopulmonary GmbH (MCP)/Getinge sent you an Urgent Medical Device Correction letter on February 13, 2023 notifying you of the initiation of a voluntary Medical Device Correction for the HLS Set Advanced (disposable in the CARDIOHELP System) due to insufficient evidence of packaging sterility. This is an update to the initial notification.

The HLS Set Advanced is part of the CARDIOHELP System, which is intended to provide circulatory and/or pulmonary support (for periods up to six hours).

MCP/Getinge has not received any reports of complaints or adverse events due to this issue.

The previously issued Urgent Medical Device Removals (FDA Reference Numbers: Z-0632-2021 & Z-0633-2021, November 20, 2020 letter and Z-1764-2022 through Z-1767-2022, July 22, 2022 letter) are separate from and not affected by this Urgent Medical Device Correction and the already defined actions remain in effect.

Identification of the issue:

Through communications with one of the Regulatory Authorities, a gap was identified in packaging validation testing for HLS Set Advanced that may compromise sterility. This testing was performed in order to validate changes made in the packing design in order to prevent damage to the tray and pouches.

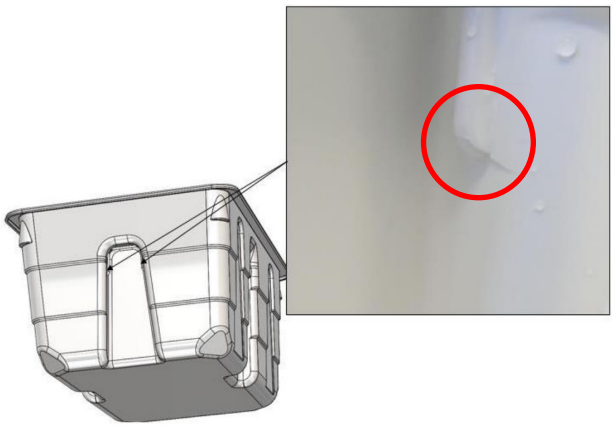
Because of this nonconformance, MCP/Getinge voluntarily established a quality shipping-hold on December 8th, 2022.

Potential packaging issues were previously identified during internal validation testing. Issue 1, damage to the tray and Issue 2, damage to the sterile accessory pouches, which may not be visible to the naked eye. Corrective actions were implemented on March 7, 2023 for each issue, consisting of a production process change and introducing 100% inspection.

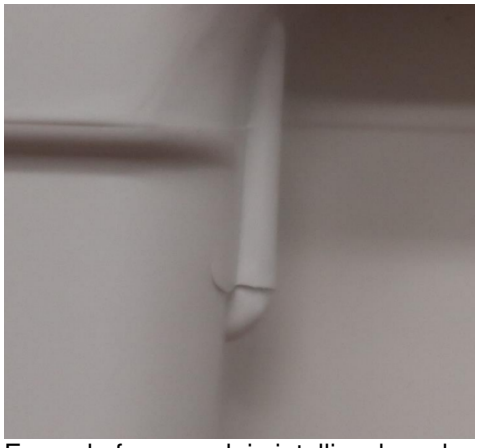
The packaging tests in question were immediately and successfully repeated on HLS Set Advanced from Getinge's inventory (product that is shipped to customers). This was the basis for resuming product shipments in late December. Although the company's testing in December 2022 confirmed effectiveness of the new packaging design per industry standard, the testing did not follow internal MCP/Getinge protocol for including the "worst case" sterilization (2 times ETO sterilization) and transport simulation. When the company repeated the testing in April 2023 per its internal protocol, the product failed testing in 1 of 45 samples tested. Specifically the product showed a leak at the same location as notified previously in our initial customer letter, dated February 13, 2023.

Example:
Issue 1 – Damage on the outside of the sterile intellipack tray that may occurr during the packaging assembly process and/or transport.

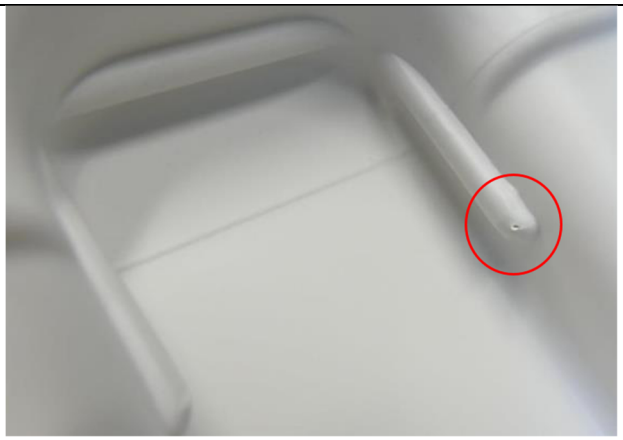
Undamaged, unstressed intellipack packaging tray



Area on the intellipack packaging tray where the failure was detected with example of crack



Example for a crack in intellipack packaging tray



Example for a crack in intellipack packaging tray

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

Symptoms may include but are not limited to localized and/or systemic inflammatory reaction, pyrogenic reaction (fever), stimulation of humoral immune response (SIRS), activation of coagulation and complement cascade and/or release of inflammatory molecules, e.g. cytokines.

Actions to be taken by the Customer:

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

- Please examine your inventory immediately to determine if you have any of the affected HLS Set Advanced with the product codes listed on page 1 of this notice and acknowledge that you have received this notification by following the instructions below.
- Should you continue to use affected product, the potential risk of exposure that may lead to immediate and/ or long range health consequences is listed in Risk to Health above.
- If an affected device is already in use, please use according to normal practices. Monitor the patient for signs and symptoms as listed above under Risk to Health and, if detected, treat according to clinical protocols.
- Please note that all available and newly produced devices are affected by this Urgent Medical Device Recall Correction. Should you need to continue to use and / or purchase this product for use you will continue to receive product affected by this potential issue until validation testing is concluded.

There are two potential options you may take for affected inventory:

- Option 1 (stop use / return product):
    - Should you have any unused and unexpired affected product, you are eligible to return all 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 Correction - Response Form on Page 7 of this letter, if you are returning products to Maquet/Getinge.

- Option 2 (continued use of product should you have no alternative product):
    - If you do not have alternative product available for use, you may continue use of this product, however please review the information provided under Risk to Health in this letter. Monitor the patient for signs and symptoms as listed above under Risk to Health and, if detected, treat according to clinical protocols.
    - Perform a visual inspection of the primary packaging, check for visible stress marks or damages in the packaging as shown above (Example: Issue 1). In case of visible stress marks in the packaging, do not use the product and return for replacement or credit note.

  - Please note that there is a possibility that packaging defects may not be detectable by the naked eye.
  - Continue to use in accordance with Instructions for Use G-660 Revision 4, Section 6.1 Warning – Damage to the device or packaging.
  - The use of non-sterile or defective devices can result in infection of the patient, user and third parties. See Section 4.1 (Basic Safety Instructions) in the Instructions for Use G-660 Revision 4.
    – Only use the device if it is sterile.
    – Do not use the device if it or the sterile packaging is damaged.
    – Observe the use-by date on the packaging.
    – Always observe strict asepsis when handling
  - Stacking the product in its primary packaging can damage the sterile barrier.
    – Do not stack sets on top of each other in their primary packaging.
  - Follow all other instructions on the packaging and the instructions for use.

- Please report any adverse events, e.g. infections potentially related to the affected products to 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 and to FDA as listed below.
- Please forward this information to all current and potential HLS Set Advanced users within your hospital/facility. This may include teams in the ICU, CT Surgery, Cath Lab, Patient Transport, and/or others.
- If you are a distributor who has shipped any affected products to customers, please forward this document to their attention for appropriate action.
- Whether you have affected product or not, please complete and sign the attached MEDICAL DEVICE CORRECTION– RESPONSE FORM (Page 7) to acknowledge that you have received this notification. Return the completed form to Maquet/Getinge by e-mailing a scanned copy to acthlsset2023.US@getinge.com or by faxing the form to (877) 665-2398.

Action by the Getinge:

As noted in our initial letter, MCP/Getinge is conducting visual inspection to identify any damaged units prior to final distribution, and also has implemented “white glove” transportation conditions to ensure that devices remain sterile during the distribution process.

MCP/Getinge is currently working on a long-term redesign of the tray and safety plate with the tray supplier. MCP/Getinge is also working on any additional mitigations and containment that may provide added assurance of sterility with the current design.

Please note that you will continue to receive product affected by this potential issue until which time these activities have concluded.

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

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 Correction 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