March 21, 2024 via FedEx 2-Day delivery

URGENT MEDICAL DEVICE – CORRECTION
FSCA 8010762-01/08/2024-001-C
HLS Sets – Emergency Priming Line

Product Number(s)	Product Name	UDI DI
701069077	HLS Set Advanced 5.0, Small Adult, BIOLINE Coating (BEQ-HLS 5050 USA; HLS Set Advanced 5.0)	04058863076355
701069078	HLS Set Advanced 7.0, Adult, BIOLINE Coating (BEQ-HLS 7050 USA; HLS Set Advanced 7.0)	04058863080383
Distributed Affected Lot Numbers:	**701069077**: 3000301222, 3000319782, 3000327602, ***3000333098, 3000352360, 3000357174*** **701069078**: 3000280906, 3000280907, 3000280908, 3000380909, 3000282253, 3000282254, 3000282255, 3000291127, 3000300688, 3000314506, 3000316206, 3000316600, 3000317531, 3000317532, 3000318850, 3000318851, 3000318852, 3000318853, 3000319748, 3000319749, 3000319750, 3000319751, 3000319778, 3000319781, 3000323082, 3000323084, 3000323085, 3000324495, 3000324496, 3000324497, 3000324499, 3000325557, 3000325558, 3000325559, 3000327120, 3000327121, 3000328404, 3000328405, ***3000330091, 3000330092, 3000330094, 3000330095, 3000330096, 3000333095, 3000333096, 3000333097, 3000334409, 3000334410,*** 3000334413, 3000334414, 3000336487, ***3000336488, 3000337834, 3000342904, 3000342905, 3000342906, 3000342907, 3000342908, 3000344446, 3000344447, 3000344471, 3000344472, 3000344474, 3000346048, 3000346049, 3000346050, 3000346051, 3000346052, 3000348543, 3000348546, 3000348552, 3000348553, 3000349793, 3000349795, 3000349796, 3000349797, 3000352614, 3000352615, 3000352616, 3000352617, 3000353439, 3000353440***
Manufacturing Dates:	November 18, 2022, through ***November 27, 2023***	
Distribution Dates:	March 6, 2023, through ***March 1, 2024***	

Dear Risk Manager,

Maquet Cardiopulmonary GmbH (MCP)/Getinge is notifying customers of additional lots of the Emergency Priming Line, a component of the HLS Set, that are affected by a voluntary Medical Device Correction (originally initiated on January 16, 2024) due to a potentially compromised sterile barrier. These additional lots are provided in ***bold italicized*** text in the above list, along with the related manufacturing and distribution date ranges that have been updated accordingly.

Figure 1: Emergency Priming Line

The HLS Set is intended for use in an extracorporeal circulation for cardiac support and/or pulmonary support. The Emergency Priming Line (Figure 1) is used in emergency situations only for removing air in the blue line which has not yet reached the HLS Module. The Emergency Priming Line is first packaged in a sterile bag from Nelipak (Figure 1), which is itself packaged with other HLS Set components in a tray that serves as, the primary barrier.

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Emergency Priming Lines affected by this Medical Device Correction notice may only be used immediately after opening a new HLS Set because the Emergency Priming Line is sterile immediately upon opening of the tray. If an Emergency Priming Line is needed at a later time, a new HLS Set will need to be opened to ensure sterility of the Emergency Priming Line.

As of March 11, 2024, Getinge has not received any complaints or adverse event reports related to this issue.

Identification of the Issue:

The Emergency Priming Lines (Figure 1 above) are packaged in sterile bags provided to MCP/Getinge from its supplier, Nelipak. MCP/Getinge initially identified three batches of Nelipak bags that exhibited nonconformities at their seal, which could potentially compromise the sterile barrier of the Emergency Priming Line contained within them. The January 16, 2024 Medical Device Correction was limited to products that contained sterile bags from those three affected batches. MCP/Getinge is now expanding the scope of this Medical Device Removal to include product packaged in two additional batches of Nelipak bags that were identified as nonconforming during further investigation of the issue. Both the originally identified and newly added affected product are listed above.

The original January 16, 2024 Medical Device Correction, and this update to it, are distinct from an earlier Medical Device Removal issued by MCP/Getinge dated July 22, 2022 (reference FDA recall numbers Z-1764-2022, Z-1765-2022, Z-1766-2022, and Z-1767-2022), and an earlier Medical Device Correction issued by MCP/Getinge dated February 13, 2023 (with a later update issued June 27, 2023) (reference FDA recall number Z-1188-2023) related to issues with the primary sterile barrier for the HLS Set packaging (i.e., the Tyvek cover of the Intellipack tray). While HLS Sets are subject to both the past and current field actions, this current field action is not related to the primary sterile barrier and applies only to the secondary packaging of the Emergency Priming Line contained in the affected HLS Sets.

Risk to Health:

MCP/Getinge's Health Hazard Evaluation (HHE) determined that a breach of the sterile barrier of the Emergency Priming Line could expose patients to pathogenic agents.

This hazardous situation could result in the following potential harms:

- Inflammation
- Infection
- Sepsis

Actions to be taken by the Customer:

Our records indicate that you have received an HLS Set with a lot number that is affected by this voluntary Medical Device Correction (see Page 1).

- Please examine your inventory immediately to determine if you have any affected product. Dispose of any Emergency Priming Line from a previously opened, affected HLS Set.
- Whether or not your facility has affected product(s) listed in this notice, and even if your facility has previously provided a response to the earlier January 16, 2024 Medical Device Correction, please complete and sign the attached MEDICAL DEVICE - CORRECTION RESPONSE FORM provided herein (Page 4) to acknowledge that you have received this notification. Return the completed form to Getinge by e-mailing a scanned copy to HLSemprimingline2024.act@getinge.com or by faxing the form to 1-800-878-6921.
- **Please forward this information to all current and potential HLS Set users within your hospital / facility.**
- **If you are a distributor who has shipped any affected products to customers, please forward this document to their attention for appropriate action.**
- **As described in Section 4.3.2 of the HLS Set Instructions for Use (IFU), device users should always have an HLS Set in stock and available at the ready to use as a backup during therapy.**

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Please check your inventory to ensure you have at least one backup HLS Set before you begin treatment. If you do not have a backup HLS Set, please contact Getinge Customer Support to purchase a backup HLS Set.

- If you need to use the Emergency Priming Line:
    - Only use the Emergency Priming Line from a newly opened HLS Set.
    - The remaining components of the backup HLS Set must be disposed of after extraction of the Emergency Priming Line.
    - Please reach out to Getinge Customer Support (see contact information below) for the issuance of a replacement HLS Set at no cost.
- If you prefer to return your unopened/unexpired affected HLS Sets, please contact Maquet/Getinge Customer Support to request a return authorization (RMA) number and shipping instructions. We will provide unaffected replacement product at no charge. Replacement product will ship based on product availability. The remaining shelf life of the replacement product will be equal to or greater than that of the returned product.
- If an affected Emergency Priming Line is already in use, it should remain in use due to increased potential risk of stopping this emergency procedure. Please monitor the patient closely for any signs of infection.

Adverse events or quality problems experienced with the use of any of the products identified on Page 1 may be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail or by fax using the following:

- **Online**: www.accessdata.fda.gov/scripts/medwatch/
- **Regular Mail**: Download form at 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 (1-800-332-0178)

Type of Action Taken by Getinge:

Getinge is informing all customers to whom the affected products have been distributed via this Medical Device Correction notification.

This Medical Device Correction only affects the products listed on Page 1; no other products are affected.

If you have any questions, please contact your Getinge representative or call Getinge Customer Support at (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 Medical Device Correction is being made with the knowledge of the U.S. Food and Drug Administration.

Sincerely,

Allison Jean Kaplan
Specialist, Regulatory Affairs and Field Action Compliance
Getinge

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