2020-11-06

URGENT - FIELD SAFETY NOTICE

Subject: FSCA-2020-10-30 HLS Set Sterile Barrier Integrity

Affected Product:

REF no.	Article no.	Product description
BE-HLS 7050	70104.7753	HLS Set Advanced 7.0 for extracorporeal cardiac and/or pulmonary support. with BIOLINE Coating, for the region NONUS
BO-HLS 7050	70104.9134	HIT Set Advanced 7.0 for extracorporeal cardiac and/or pulmonary support with SOFTLINE Coating, for the region NONUS
BE-HLS 5050	70104.8127	HLS Set Advanced 5.0 for extracorporeal cardiac and/or pulmonary support with BIOLINE Coating, for the region NONUS
BEQ-HLS 7050-CA	70106.4847	HLS Set Advanced 7.0 for extracorporeal cardiac and/or pulmonary support with BIOLINE Coating, for the Canadian market
BEQ-HLS 5050-CA	70106.4848	HLS Set Advanced 5.0 for extracorporeal cardiac and/or pulmonary support with BIOLINE Coating, for the Canadian market
BEQ-HLS 7050 USA	70105.2794	HLS Set Advanced 7.0 with BIOLINE Coating, for the US market
BEQ-HLS 5050 USA	70105.2797	HLS Set Advanced 5.0 with BIOLINE Coating, for the US market

Affected Lot No.: see attached Group 1 Countries Annex I List of affected products

Dear valued customer,

The HLS Set Advanced is intended for use in an extracorporeal circulation for cardiac support and/or pulmonary support.

During verification testing and a review of customer complaints for the HLS Set Maquet Cardiopulmonary (MCP) identified a potential impairment of the sterile packaging barrier system. Under the transport simulation verification tests, movements of the device and its accessories inside the plastic tray have been identified. As a result, the sterile barrier system may be compromised.

Exposure to a non-sterile or potentially non-sterile medical device may result in infection causing inflammatory like syndromes thereby deteriorating the clinical state of the patient. Additionally, infection may occur if the device is connected to the central circulatory system.

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

The products listed in Group 1 Countries Annex I List of affected products are subject of this Field Safety Notice.

We apologize for any inconvenience caused and assure you that we are working with highest priority on a solution.

Action to be taken:

- **Please return immediately all affected products in your stock to your local Getinge representative.**

  - According to our surveillance documentation, your current stock may include products affected by this action. Please refer to Group 1 Countries Annex I List of affected products.
  - Please complete and sign the attached Letter of Acknowledgement for the customer and send it back to your local Getinge representative
  - In case of return of the affected products, please contact your local Getinge representative for replacement or credit.
  - If a product is already in use, it shall remain in use.

Referenced documents/ attachments:

- Group 1 Countries Annex I List of affected products
- Letter of Acknowledgement Customer

Transmission of the Field Safety Notice:

- This notice needs to be forwarded to all those who need to be aware within your organization or to any organization where the potentially affected devices have been further distributed.
- 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.

Sincerely,

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Maquet Cardiopulmonary GmbH
Kehler Str. 31
76437 Rastatt
GERMANY