2023-01-31

URGENT FIELD SAFETY NOTICE

Subject: FSCA 745922 - HLS & PLS Set - potentially compromised sterile barrier

Affected Product:

REF no.	Article no.	Product description
BE-PLS 2050	701068386	PLS Set
BE-PLS 2051	701068389	PLS Set Plus
BO-PLS 2051	701068390	HIT Set PLS Plus
BE-PLS 2050	701076706	PLS China
BE-HLS 7050	701069073	HLS Set Advanced 7.0
BE-HLS 5050	701069076	HLS Set Advanced 5.0
BO-HLS 7050	701069083	HIT Set Advanced 7.0
BO-HLS 5050	701069079	HIT Set Advanced 5.0
BEQ-HLS 7050-CA	701069065	HLS Set Advanced 7.0
BEQ-HLS 5050-CA	701069068	HLS Set Advanced 5.0
BEQ-HLS 7050 USA	701069078	HLS Set Advanced 7.0
BEQ-HLS 5050 USA	701069077	HLS Set Advanced 5.0

Affected Batch No.: See Annex I List of affected batches included below

Unique Device Identifier:

REF no.	Article no.	UDI
BE-PLS 2050	701068386	04058863006635
BE-PLS 2051	701068389	04058863006666
BO-PLS 2051	701068390	04058863006673
BE-PLS 2050	701076706	04058863304533
BE-HLS 7050	701069073	04058863005744
BE-HLS 5050	701069076	04058863078298
BO-HLS 7050	701069083	04058863020082
BO-HLS 5050	701069079	04058863078502
BEQ-HLS 7050-CA	701069065	04058863300238
BEQ-HLS 5050-CA	701069068	04058863304625
BEQ-HLS 7050 USA	701069078	04058863080383
BEQ-HLS 5050 USA	701069077	04058863076355

The previous FSCAs 713001 (PLS), 656504(HLS) and 661861(HLS) are not affected by this FSCA and the already defined actions remain unchanged in place.

underlined: changes made from V02 to V03

2023-01-31

Dear valued customer,

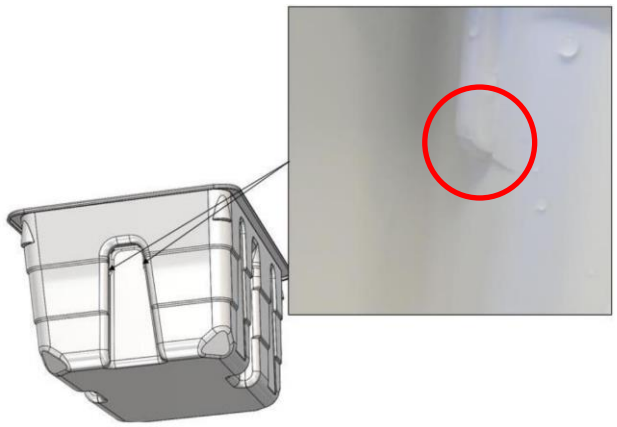
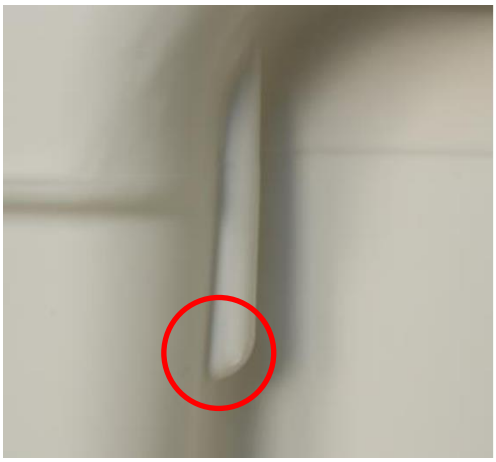
The HLS Set Advanced and the PLS Set are intended for use in an extracorporeal circulation for pulmonary and/ or cardio-circulatory support.

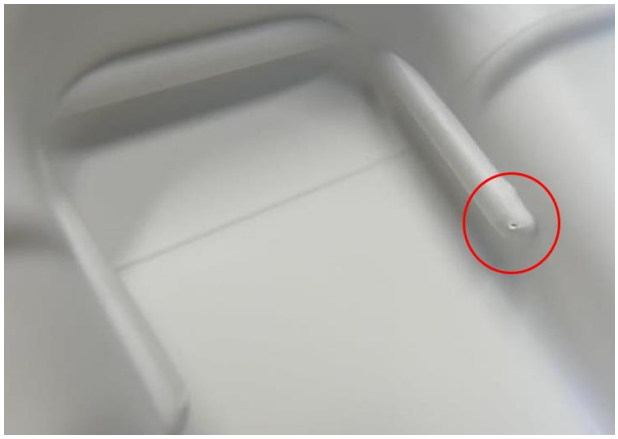
Maquet Cardiopulmonary GmbH (MCP) has received a communication from a regulatory body in which the conformity of the products mentioned above was called into question due to not adequately performed packaging tests. Due to this non-conformity, Maquet Cardiopulmonary GmbH (MCP) voluntarily decided to establish a quality shipping-hold of the aforementioned products on December 8th, 2022.

Hereinafter possible packaging nonconformities are listed. All of those nonconformities have been already addressed and corrected. However the adequacy of packaging verification is called in to question by regulatory body.

<table>
<tr>
<td>Error case 1 (HLS+PLS): Damage on primary packaging (intellipak) caused by production process failure

In course of sterile barrier system integrity tests MCP has determined a defect (visible stress marks and cracks) in the intellipack packaging tray during production. This defect may compromise the integrity of the sterile barrier of the HLS/PLS sets.

Corrective Action: Change of production process and introduction of 100% inspection.</td>
<td> 
Area on the intellipack packaging tray where the failure was detected with example of crack</td>
</tr>
<tr>
<td> 
Undamaged, unstressed intellipack packaging tray</td>
<td> 
White stressmarks on intellipack packaging tray</td>
</tr>
</table>

 Example for a crack in intellipack packaging tray	 Example for a crack in intellipack packaging tray
Error case 2 (HLS): Damage on secondary packaging caused by production process error in combination with worst case transport condition. Damage of the component Tyvek pouches. Combination of production process error and transport stress can lead to perforation of the secondary packaging. This defect may compromise the integrity of the secondary sterile barrier of the HLS sets. (The picture is merely for visualization of ink testing under laboratory conditions and was included for completeness purposes. No actions from the user are required.) Corrective Action: Change of packaging process and implementation of 100% inspection.	

The tests that were called into question were repeated with samples under market conditions. The samples were conditioned as described in the current market specification; single sterilized and transport conditioned according to ASTM D4169-22. Those tests confirmed the effectivity of above mentioned corrective actions and sterile barrier integrity for products produced under market condition. However, these tests are not sufficient to eliminate the non-conformity of adequacy of packaging verification.

To obtain final evidence of sterile barrier integrity under regulation conditions these tests have to be performed with samples that cover the assumed worst condition of sterilization impact. As a consequence the test samples need to face not just one, but two sterilization cycles.

Health-Hazard-Evaluations (HHEs) were performed to assess the risk of the non-conformities, including the results of the newly performed packaging verification tests. The outcome of the HHE states, that the residual risk which results from the non-conformity is justifiable according to the current product Risk Management. As a result the risk benefit analysis from the Risk Management Report is still valid and states that the benefit outweighs the risk.

The HHEs documented as possible risks:

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*
- *User Inconvenience*

Maquet Cardiopulmonary GmbH is working with all possible urgency on the finalization of the required tests also in the case of double sterilization to cover the worst-case condition of sterilization impact. However, these test results will be available earliest in April 2023. Thereafter, we will reassess whether further measures need to be taken to ensure patient safety. Based on the preliminary test results under market configuration, we are confident to confirm the conformity of the affected products.

Therefore, at this time we can only provide you with devices with the non-conformity described above, this applies also to newly produced devices. We apologize for any inconvenience this may cause.

The previous FSCAs 713001 (PLS), 656504(HLS) and 661861(HLS) are not affected by this FSCA and the already defined actions remain unchanged in place.

Action to be taken: **Due to a potential delay of replacement products:**

Option 1:

- Return all affected products in your stock to your local Getinge representative.
- In case of return of the affected products, please contact your local Getinge representative for credit.
- If a product is already in use, it should remain in use.
- At this time we can only provide you with devices with the non-conformity described above, this applies also to newly produced devices.
- Regardless of the decision you make, please complete and sign the attached customer response form and send it back to your local Getinge representative.
- Please report any adverse events, e.g. infections potentially related to the affected products to your Getinge representative.

Option 2:

- Perform a visual inspection of the primary packaging, check for visible stress marks or damages in the packaging. In case of visible stress marks in the packaging, do not use the product and return for replacement or credit note.
- The use of non-sterile or defective devices can result in infection of the patient, user and third parties.
  – 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
- The user must carry out a risk assessment regarding the risk of using a potentially non-sterile medical device compared to non-use of the medical device with the consequence of treatment for a patient. This risk assessment is to be considered as an individual assessment and for the respective patient before each application. We recommend documenting this in writing in the patient file.
- 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.
- At this time we can only provide you with devices with the non-conformity described above, this applies also to newly produced devices.
- Regardless of the decision you make, please complete and sign the attached customer response form and send it back to your local Getinge representative.
- Please report any adverse events, e.g. infections potentially related to the affected products to your Getinge representative.

Enclosed documents:

- customer response form
- Annex I List of affected batches

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 may 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 caused and assure you that we are working on a solution with highest priority. 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,

Managing Director

Signature: Dieter Engel *Electronically signed by: Dieter Engel Reason: I approve this document. Date: Jan 31, 2023 15:47 GMT+1*

Email: dieter.engel@getinge.com

Person Responsible for Regulatory Compliance (PRRC)

Signature: Timur Güvercinci *Electronically signed by: Timur Güvercinci Reason: I approve this document. Date: Jan 31. 2023 16:08 GMT+1*

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CUSTOMER RESPONSE FORM

Subject: 745922 - HLS & PLS Set - potentially compromised sterile barrier

Affected Product:

REF no.	Article no.	Product description
BE-PLS 2050	701068386	PLS Set
BE-PLS 2051	701068389	PLS Set Plus
BO-PLS 2051	701068390	HIT Set PLS Plus
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BO-HLS 5050	701069079	HIT Set Advanced 5.0
BEQ-HLS 7050-CA	701069065	HLS Set Advanced 7.0
BEQ-HLS 5050-CA	701069068	HLS Set Advanced 5.0
BEQ-HLS 7050 USA	701069078	HLS Set Advanced 7.0
BEQ-HLS 5050 USA	701069077	HLS Set Advanced 5.0

Affected Batch No.: See Annex I List of affected batches included below

Mandatory:

☐ I have read and understand this Field Safety Notice for above mentioned affected products.

☐ I confirm that I have distributed this Field Safety Notice to the affected personal.

Select minimum one (1) applicable option:

☐ All affected products have been consumed.

☐ Option 1: Following affected products will be returned to you for credit.

☐ Option 2: Products will be used by following the instruction for use.

REF	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

Annex I List of affected batches

This Annex I List of affected batches is considered as a supplementary attachment to the 745922 Field Safety Notice.

Below are listed all batches of products which are affected.

Table 1 general overview

REF	Article	Batch range
BE-PLS 2050	701068386	All batches affected
BE-PLS 2051	701068389	All batches affected
BO-PLS 2051	701068390	All batches affected
BE-PLS 2050	701076706	All batches affected
BE-HLS 7050	701069073	All batches affected
BE-HLS 5050	701069076	All batches affected
BO-HLS 7050	701069083	All batches affected
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BEQ-HLS 5050 USA	701069077	All batches affected