URGENT FIELD SAFETY NOTICE - Annex II Inspection Instruction

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

Affected Products:

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

1. Inspection of Intellipacks (plastic packaging component of the product)

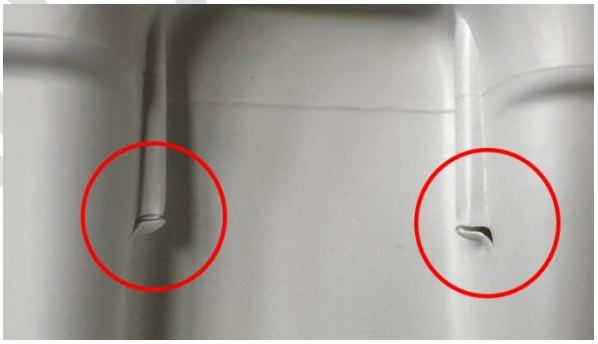
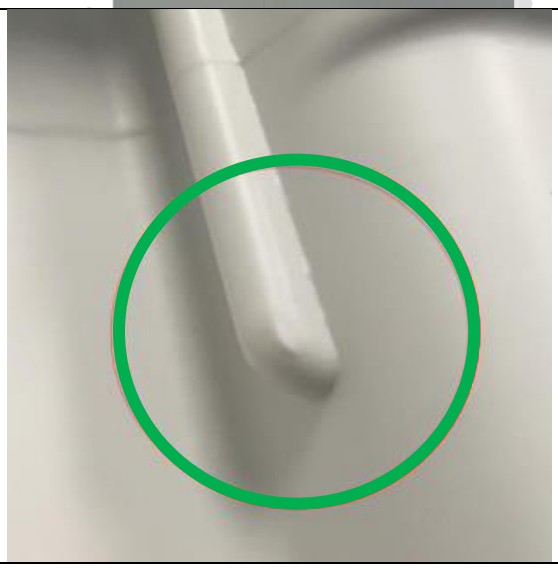
Before use, the holder for safety plates of the Intellipacks must be checked for possible damage.

(In Part 2, example pictures of conform and nonconforming parts are shown for assistance.)

For this purpose, the handles present in the outer packaging must be pressed in. As a result, the holder of the Safety plate is visible on the Intellipack.

Use a commercially available LED flashlight during the investigation to get a better view on the holder of the safety plates! Note: The holders for the safety plates are only present on one side.	

2. Exemplary pictures of conforming and not conforming products

	Material is undamaged (pictures 1 and 2) or shows white stress marks only (picture 3) and can be used	Material is damaged (with a visible breakthrough) and cannot be used
1		
2		
3		

2023-08-16

URGENT FIELD SAFETY NOTICE

Manufacturer SRN: DE-MF-000020091

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

FSN Type: Update

Affected Products:

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 Identifiers (UDI):

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) remain unchanged and the actions described below are to be taken in addition to the existing measures.

underlined: changes made from V04 to V05

Dear valued customer,

This is a revised version of the already distributed FSN. It shall inform about the current status of the Field Action including the negative outcome of the newly performed test under worst conditions (double sterilization), the temporary CE-suspension for HLS and PLS products as well as the respective derogation approval. Further, it will provide an updated inspection instructions for better identifying the described non-conformities. Please also contact your local Getinge representative for further information.

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

Historical background

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. This quality shipping-hold was then lifted on January 2nd, 2023, by issuing the initial version of this FSCA 745922.

The tests that were called into question were repeated with samples under market conditions. However, these tests were 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.

However, against MCP's expectation, this final evidence for sterile barrier integrity could not be obtained. An investigation determined that the planned corrective actions were not fully implemented.

Further, Maquet Cardiopulmonary´s Notified Body decided to suspend the CE Certificate until appropriate corrections can be implemented. The continue shipment of devices to the markets are currently permited only under special authorization. Please consult your local Getinge representative to verify the impact of this decision in your market.

Current status

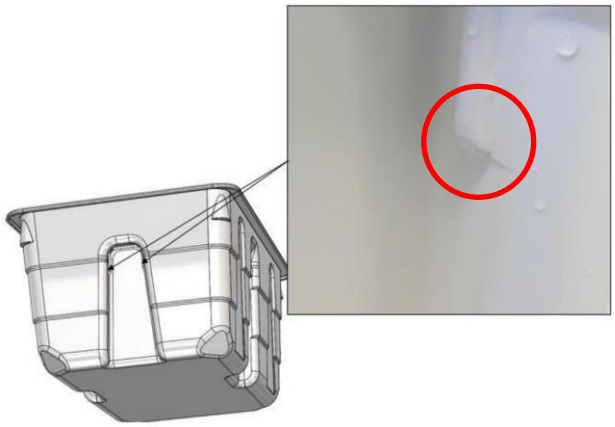
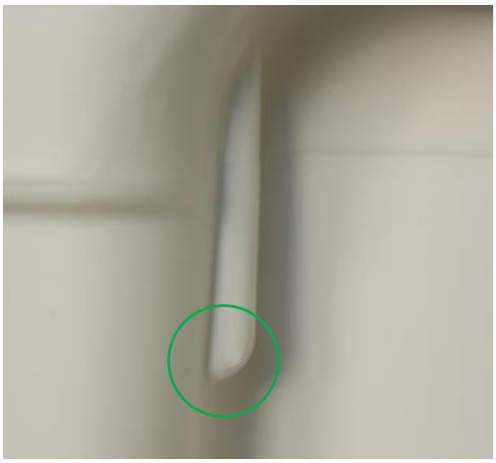
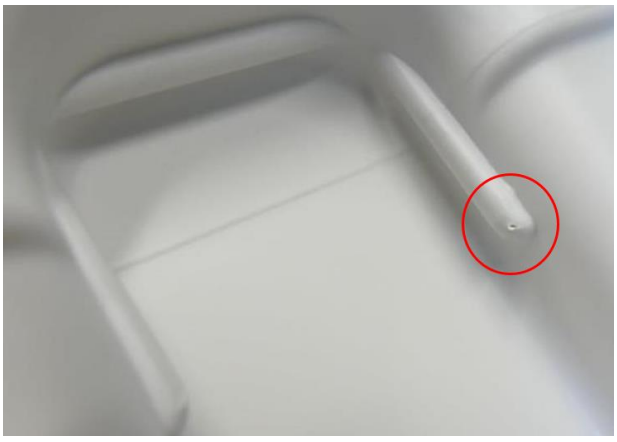
In the meantime, MCP has conducted further investigation into the error cases, specifically, the "white stress marks". All samples used passed through a real transport route and were tested for integrity afterwards. The tests have shown no evidence that the "white stress marks" have a negative impact on sterility. In addition, none of the retrospectively inspected sets returned from customers have shown any breaches in sterile barrier. In conclusion, there is no increased risk for patients or users due to the "white stress marks".

Following this investigation, MCP has updated Annex II Instruction for visual inspection to define products with "white stress marks" as conforming and suitable for use.

Hereinafter, the possible packaging nonconformities are listed.

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

In course of sterile barrier system integrity tests, MCP has determined a defect (visible cracks) in the intellipack packaging tray that can occur during production. Cracks may compromise the integrity of the sterile barrier of the HLS/PLS sets.

Corrective Action implemented on 2023-03-07: Change of production process and introduction of 100% inspection.</td>
<td> 
Area on the intellipack packaging tray where the failure was detected with crack</td>
</tr>
<tr>
<td> 
Conform: Undamaged, unstressed intellipack packaging tray</td>
<td> 
Conform: White stress marks on intellipack packaging tray</td>
</tr>
<tr>
<td> 
Not conform: Crack in intellipack packaging tray</td>
<td> 
Not conform: Hole in intellipack packaging tray</td>
</tr>
</table>

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.) Corrective Action implemented on 2023-03-07: Change of packaging process and implementation of 100% inspection.	

Health-Hazard-Evaluations (HHEs) were re-performed to assess the risk of the non-conformities, including the results of the newly performed packaging verification tests.

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 resolving the non-conformities. However, this requires implementation and reperforming of the necessary tests. Thereafter, we will reassess whether further measures need to be taken to ensure patient safety.

Therefore, at this time we can only provide you with devices with the non-conformities 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) remain unchanged and the actions described below are to be taken in addition to the existing measures.

Action to be taken: **Due to an unavailability 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-conformities described above, this applies also to newly produced devices.
- Regardless of the decision you make (Option 1 or 2), please complete and sign the attached customer response form and send it back to your local Getinge representative.
- For PLS: In case you received 2-for-1 PLS sets as per ongoing **FSCA 713001 (PLS)**, please return both PLS sets.
- 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 damages (cracks, holes etc.) in the packaging according to error case 1 (HLS + PLS) and 2 (HLS) described above. In case of visible damages in the packaging, do not use the product and return for replacement or credit note. Please refer to Annex II for a detailed instruction on how to check your products for the respective error cases.
- 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-conformities described above, this applies also to newly produced devices.
- Regardless of the decision you make (Option 1 or 2), 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
- Annex II Instruction for visual inspection v2

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
(on behalf of the Managing Director)

Signature: Johannes Schlenker *Electronically signed by: Johannes Schlenker Reason: I approve this document. Date: Aug 16. 2023 16:35 GMT+2*

Email: johannes.schlenker@getinge.com

Person Responsible for Regulatory Compliance (PRRC)
(on behalf of PRRC)

Signature: Alexander Bernhardt *Electronically signed by: Alexander Bernhardt Reason: I approve this document. Date: Aug 16. 2023 16:55 GMT+2*

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Phone: +49 7222 932 - 0
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CUSTOMER RESPONSE FORM

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

Affected Product:

REF no.	Article no.	Product description
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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

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
BO-HLS 5050	701069079	All batches affected
BEQ-HLS 7050-CA	701069065	All batches affected
BEQ-HLS 5050-CA	701069068	All batches affected
BEQ-HLS 7050 USA	701069078	All batches affected
BEQ-HLS 5050 USA	701069077	All batches affected