

URGENT FIELD SAFETY NOTICE

Subject: 656504: HLS/ HIT Set - potentially compromised sterile barrier

Affected Product:

REF no.	Article no.	Product description
BE-HLS 7050	701069073	HLS Set Advanced 7.0 with BIOLINE Coating, for the NONUS market
BE-HLS 5050	701069076	HLS Set Advanced 5.0 with BIOLINE Coating, for the NONUS market
BO-HLS 7050	701069083	HLS Set Advanced 7.0 with SOFLINE Coating, for the CA market

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

Unique Device Identifier:

REF no.	Article no.	UDI
BE-HLS 7050	701069073	04058863005744
BE-HLS 5050	701069076	04058863078298
BO-HLS 7050	701069083	04058863020082

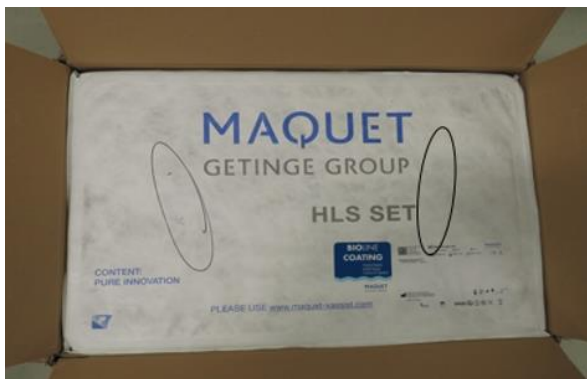
Dear valued customer,

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

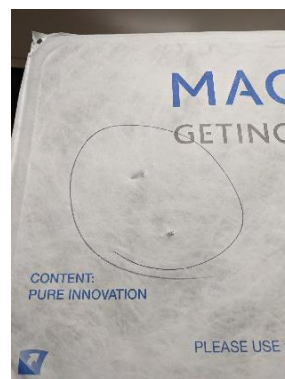
Maquet Cardiopulmonary GmbH (MCP) has received customer complaints of damage to the primary packaging of the HLS Set Advanced. In all customer complaints it was reported that the Tyvek cover was damaged. The appearance of the packaging failure can be hole(s) in the Tyvek. The damages are caused by the tabs of the venous probe holder within the packaging (picture 1). Consequently, depending on position of HLS module in the package, holes can appear either on the left or right side of the Tyvek (pictures 2 and 3), which corresponds to the position of the venous probe holder.



Picture 1: both tabs of the venous probe holder within HLS Module



Picture 2: position of potential damages either on left or right side, depending on position of HLS Module in the package



Picture 3: example of holes in the Tyvek cover

The results of the product packaging investigation suggest that the Tyvek damage only occurs, if the HLS Set drops with the topside facing down so that either the velcro straps, which hold the HLS Modules, come loose or the HLS Module detaches. A shift/ movement of the HLS Module affords the opportunity for the venous probe tab(s) to perforate the Tyvek cover and the sterile barrier system may be compromised.

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

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

Maquet Cardiopulmonary GmbH is working with urgency on the packaging design change in order to reduce the shift/ movement of the HLS Module. However, it takes time to perform such change based on all regulatory requirements. Therefore, we can provide to you at this time only devices with the same packaging design as possible replacement. The only changes in devices with old packaging design will be a better controlled transport condition against drops with the topside facing down and that all HLS Sets will have additional affixed "Inspection Instruction" on the white box. The affixed "Inspection Instruction" on the white box will help you to have a better traceability of the current packaging design. As soon as we have finalized the new packaging design change and have produced first lots, we will inform you about the first lot number.

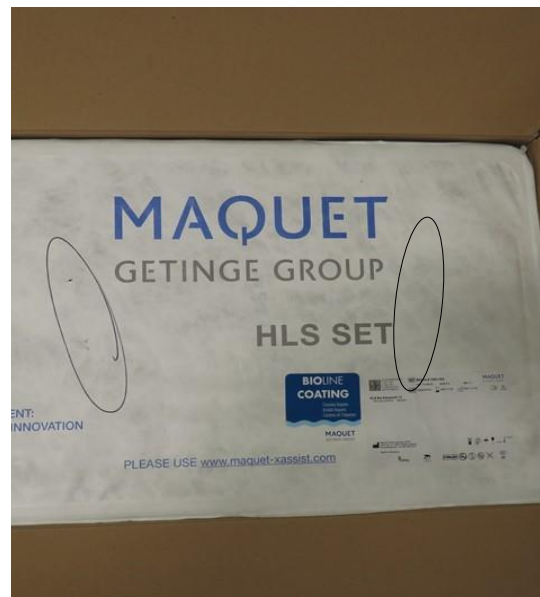
Please take care that you check all devices which you have in your stock **today and devices which you can receive soon, provided your national competent authority allows this,** based on the provided instructions, see option 2 in chapter "Action to be taken" below.

Action to be taken: Due to a potential delay of replacement products:**Option 1**

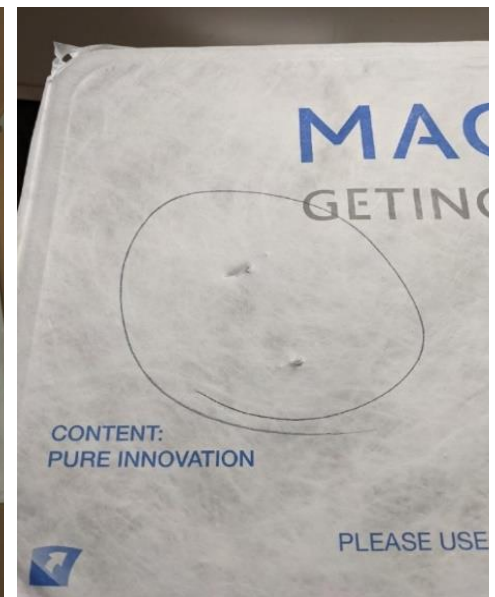
- Please return immediately all affected products in your stock to your local Getinge representative.
- In case of return of the affected products, please contact your local Getinge representative for credit or replacement.
- If a product is already in use, it should remain in use.

Option 2:

- If the products are necessary based on expert clinical judgement, you can use the devices after following these inspection measures:
 1. Prior to use, the HLS Sets Tray covers have to be checked visually for any damages, holes or tears in order to prevent the use of an unsterile medical device.
 2. After removing the tray from the secondary package (white cardboard box), position the tray in a well-lit area outside the sterile field.
 3. Check the integrity of the sterile barrier of the tray (Tyvek cover) before use. If any doubt arises as to package integrity, then it should not be used. Any product with damaged packaging must be returned to the local Getinge representative.



Picture 4: position of potential damages either on left or right side, depending on position of HLS Module in the package



Picture 5: typical appearance of damage

- **Please note**, that all products which you can receive at this time contains old packaging design and they have affixed "Inspection instruction" on the white box.

- 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 in regards to the affected products to your Getinge Representative.

Enclosed documents:

- 656504 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 with highest priority on a solution. 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,

Signature: *Dieter Engel*

Electronically signed by: Dieter Engel
Reason: I approve this document.
Date: Jul 20, 2022 08:19 GMT+2

Managing Director

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: Jul 19, 2022 22:58 GMT+2

Email: timur.guevercinci@getinge.com

Maquet Cardiopulmonary GmbH
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76437 Rastatt
GERMANY
Phone: +49 7222 932 - 0
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CUSTOMER RESPONSE FORM

Subject: 656504: HLS/ HIT Set - potentially compromised sterile barrier

Affected Product:

REF no.	Article no.	Product description
BE-HLS 7050	701069073	HLS Set Advanced 7.0 with BIOLINE Coating, for the NONUS market
BE-HLS 5050	701069076	HLS Set Advanced 5.0 with BIOLINE Coating, for the NONUS market
BO-HLS 7050	701069083	HLS Set Advanced 7.0 with SOFLINE Coating, for the CA market

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

- ☐ I have read and understand this Field Safety Notice for above mentioned affected products. We will take action as soon as possible according to given instructions.
- ☐ I confirm that I have distributed this Field Safety Notice to the affected personal.
- ☐ All affected products have been consumed.
- ☐ Following affected products in our inventory will be inspected and if a sterile barrier is compromised, we will return the product/s to you for credit/ replacement.
- ☐ Following affected products will be returned to you for credit/ replacement.

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 [enter local Getinge mail address](#) or via post [enter local Getinge address](#) or FAX>:

Annex I List of affected batches

This Annex I List of affected batches is considered as a supplementary attachment to the 656504 Field Safety Notice.

Below are listed all batches of products which are affected and have been distributed.

Table 1 general overview

REF	Article	Batch range
BE-HLS 7050	701069073	from 3000182107 to 3000234524
BE-HLS 5050	701069076	from 3000189274 to 3000227602
BO-HLS 7050	701069083	from 3000190163 to 3000192093

Table 2 all affected lots per country

Country	Article No.	Product Description	Batch
Argentina	701069073	BE-HLS 7050 #SHLS Set Advanced 7.0	from 3000187932 to 3000222885
Australia	701069073	BE-HLS 7050 #SHLS Set Advanced 7.0	from 3000182110 to 3000234524
Australia	701069076	BE-HLS 5050 #SHLS Set Advanced 5.0	3000189718
Austria	701069073	BE-HLS 7050 #SHLS Set Advanced 7.0	from 3000182112 to 3000220053
Austria	701069083	BO-HLS 7050 #S/ HIT Set Advanced 7.0	from 3000190163 to 3000192093
Belarus	701069073	BE-HLS 7050 #SHLS Set Advanced 7.0	3000208673
Belgium	701069073	BE-HLS 7050 #SHLS Set Advanced 7.0	from 3000182111 to 3000220052
Bosnia-Herzegovina	701069073	BE-HLS 7050 #SHLS Set Advanced 7.0	from 3000182111 to 3000199088
Brazil	701069073	BE-HLS 7050 #SHLS Set Advanced 7.0	from 3000189184 to 3000217603
Brazil	701069076	BE-HLS 5050 #SHLS Set Advanced 5.0	from 3000220058 to 3000222886
Brunei Darussal	701069073	BE-HLS 7050 #SHLS Set Advanced 7.0	from 3000190527 to 3000218622
Chile	701069073	BE-HLS 7050 #SHLS Set Advanced 7.0	from 3000207493 to 3000220051
China	701069073	BE-HLS 7050 #SHLS Set Advanced 7.0	from 3000205877 to 3000228851
China	701069076	BE-HLS 5050 #SHLS Set Advanced 5.0	from 3000199095 to 3000227602
Colombia	701069073	BE-HLS 7050 #SHLS Set Advanced 7.0	3000208678
Colombia	701069076	BE-HLS 5050 #SHLS Set Advanced 5.0	from 3000222886 to 3000223281
Costa Rica	701069073	BE-HLS 7050 #SHLS Set Advanced 7.0	from 3000182107 to 3000207493
Croatia	701069073	BE-HLS 7050 #SHLS Set Advanced 7.0	from 3000182117 to 3000217600

Country	Article No.	Product Description	Batch
Cyprus	701069073	BE-HLS 7050 #SHLS Set Advanced 7.0	from 3000190531 to 3000217596
Czech Republic	701069073	BE-HLS 7050 #SHLS Set Advanced 7.0	from 3000182110 to 3000220053
Czech Republic	701069076	BE-HLS 5050 #SHLS Set Advanced 5.0	from 3000215235 to 3000223281
Czech Republic	701069083	BO-HLS 7050 #S/ HIT Set Advanced 7.0	3000190163
Denmark	701069073	BE-HLS 7050 #SHLS Set Advanced 7.0	from 3000190526 to 3000220051
Denmark	701069076	BE-HLS 5050 #SHLS Set Advanced 5.0	from 3000193372 to 3000199095
Egypt	701069073	BE-HLS 7050 #SHLS Set Advanced 7.0	from 3000189186 to 3000190526
Estonia	701069073	BE-HLS 7050 #SHLS Set Advanced 7.0	from 3000189187 to 3000215329
Finland	701069073	BE-HLS 7050 #SHLS Set Advanced 7.0	from 3000182110 to 3000220052
France	701069073	BE-HLS 7050 #SHLS Set Advanced 7.0	from 3000182107 to 3000220052
France	701069076	BE-HLS 5050 #SHLS Set Advanced 5.0	from 3000189274 to 3000227601
Germany	701069073	BE-HLS 7050 #SHLS Set Advanced 7.0	from 3000182107 to 3000220053
Germany	701069076	BE-HLS 5050 #SHLS Set Advanced 5.0	from 3000189274 to 3000227600
Germany	701069083	BO-HLS 7050 #S/ HIT Set Advanced 7.0	from 3000190163 to 3000192093
Greece	701069073	BE-HLS 7050 #SHLS Set Advanced 7.0	from 3000182114 to 3000216178
Hong Kong	701069073	BE-HLS 7050 #SHLS Set Advanced 7.0	from 3000187932 to 3000222885
Hungary	701069073	BE-HLS 7050 #SHLS Set Advanced 7.0	from 3000189190 to 3000217593
Iceland	701069073	BE-HLS 7050 #SHLS Set Advanced 7.0	from 3000189188 to 3000217596
Iceland	701069076	BE-HLS 5050 #SHLS Set Advanced 5.0	from 3000220058 to 3000223281
India	701069073	BE-HLS 7050 #SHLS Set Advanced 7.0	from 3000190531 to 3000225894
Ireland	701069073	BE-HLS 7050 #SHLS Set Advanced 7.0	from 3000182108 to 3000220051
Israel	701069073	BE-HLS 7050 #SHLS Set Advanced 7.0	from 3000182110 to 3000216191
Italy	701069073	BE-HLS 7050 #SHLS Set Advanced 7.0	from 3000182107 to 3000220053
Italy	701069076	BE-HLS 5050 #SHLS Set Advanced 5.0	from 3000189274 to 3000223281
Japan	701069073	BE-HLS 7050 #SHLS Set Advanced 7.0	from 3000182115 to 3000227590
Jordan	701069073	BE-HLS 7050 #SHLS Set Advanced 7.0	from 3000182110 to 3000196202
Kosovo	701069073	BE-HLS 7050 #SHLS Set Advanced 7.0	3000193371 -

Country	Article No.	Product Description	Batch
Kuwait	701069073	BE-HLS 7050 #SHLS Set Advanced 7.0	from 3000182107 to 3000232542
Kuwait	701069076	BE-HLS 5050 #SHLS Set Advanced 5.0	3000215235 -
Latvia	701069073	BE-HLS 7050 #SHLS Set Advanced 7.0	from 3000195593 to 3000205876
Lebanon	701069073	BE-HLS 7050 #SHLS Set Advanced 7.0	from 3000223280
Lithuania	701069073	BE-HLS 7050 #SHLS Set Advanced 7.0	from 3000182110 to 3000208670
Luxembourg	701069073	BE-HLS 7050 #SHLS Set Advanced 7.0	from 3000187933 to 3000217600
Macedonia	701069073	BE-HLS 7050 #SHLS Set Advanced 7.0	3000217592
Malaysia	701069073	BE-HLS 7050 #SHLS Set Advanced 7.0	3000193367
Mexico	701069073	BE-HLS 7050 #SHLS Set Advanced 7.0	from 3000182118 to 3000217596
Nepal	701069073	BE-HLS 7050 #SHLS Set Advanced 7.0	3000190534
Netherlands	701069073	BE-HLS 7050 #SHLS Set Advanced 7.0	from 3000182107 to 3000220053
Netherlands	701069076	BE-HLS 5050 #SHLS Set Advanced 5.0	from 3000189718 to 3000223281
Netherlands	701069083	BO-HLS 7050 #S/ HIT Set Advanced 7.0	3000192093
New Zealand	701069073	BE-HLS 7050 #SHLS Set Advanced 7.0	from 3000187932 to 3000227573
Norway	701069073	BE-HLS 7050 #SHLS Set Advanced 7.0	from 3000182114 to 3000220051
Norway	701069076	BE-HLS 5050 #SHLS Set Advanced 5.0	from 3000193372 to 3000220050
Oman	701069073	BE-HLS 7050 #SHLS Set Advanced 7.0	3000223280
Pakistan	701069073	BE-HLS 7050 #SHLS Set Advanced 7.0	from 3000187932 to 3000216193
Panama	701069073	BE-HLS 7050 #SHLS Set Advanced 7.0	3000207497
Panama	701069076	BE-HLS 5050 #SHLS Set Advanced 5.0	3000215235
Philippines	701069073	BE-HLS 7050 #SHLS Set Advanced 7.0	from 3000182108 to 3000207489
Poland	701069073	BE-HLS 7050 #SHLS Set Advanced 7.0	from 3000182107 to 3000218626
Poland	701069076	BE-HLS 5050 #SHLS Set Advanced 5.0	3000193372
Poland	701069083	BO-HLS 7050 #S/ HIT Set Advanced 7.0	3000192093
Portugal	701069073	BE-HLS 7050 #SHLS Set Advanced 7.0	from 3000182110 to 3000220052
Portugal	701069076	BE-HLS 5050 #SHLS Set Advanced 5.0	from 3000189274 to 3000227601
Qatar	701069073	BE-HLS 7050 #SHLS Set Advanced 7.0	3000207507
Romania	701069073	BE-HLS 7050 #SHLS Set Advanced 7.0	from 3000182118 to 3000218616
Romania	701069076	BE-HLS 5050 #SHLS Set Advanced 5.0	from 3000193372 to 3000223281
Russian Federation	701069073	BE-HLS 7050 #SHLS Set Advanced 7.0	from 3000190528 to 3000199081
Saudi Arabia	701069073	BE-HLS 7050 #SHLS Set Advanced 7.0	from 3000182117

Country	Article No.	Product Description	Batch
			to 3000232542
Saudi Arabia	701069076	BE-HLS 5050 #SHLS Set Advanced 5.0	from 3000189718 to 3000223281
Serbia	701069073	BE-HLS 7050 #SHLS Set Advanced 7.0	from 3000182111 to 3000217600
Singapore	701069073	BE-HLS 7050 #SHLS Set Advanced 7.0	from 3000182116 to 3000218622
Slovakia	701069073	BE-HLS 7050 #SHLS Set Advanced 7.0	from 3000192085 to 3000210637
Slovenia	701069073	BE-HLS 7050 #SHLS Set Advanced 7.0	from 3000182115 to 3000212854
South Africa	701069073	BE-HLS 7050 #SHLS Set Advanced 7.0	from 3000187933 to 3000217597
South Africa	701069076	BE-HLS 5050 #SHLS Set Advanced 5.0	300022005
South Korea	701069073	BE-HLS 7050 #SHLS Set Advanced 7.0	from 3000187932 to 3000232542
Spain	701069073	BE-HLS 7050 #SHLS Set Advanced 7.0	from 3000182107 to 3000220053
Spain	701069076	BE-HLS 5050 #SHLS Set Advanced 5.0	from 3000189274 to 3000227600
Sweden	701069073	BE-HLS 7050 #SHLS Set Advanced 7.0	from 3000182107 to 3000220053
Switzerland	701069073	BE-HLS 7050 #SHLS Set Advanced 7.0	from 3000189188 to 3000220052
Switzerland	701069083	BO-HLS 7050 #S/ HIT Set Advanced 7.0	from 3000190163 to 3000192093
Thailand	701069073	BE-HLS 7050 #SHLS Set Advanced 7.0	from 3000195070 to 3000218617
Turkey	701069073	BE-HLS 7050 #SHLS Set Advanced 7.0	from 3000182110 to 3000218617
United Arab Emirates	701069073	BE-HLS 7050 #SHLS Set Advanced 7.0	from 3000190527 to 3000232542
United Arab Emirates	701069076	BE-HLS 5050 #SHLS Set Advanced 5.0	3000223281
United Kingdom	701069073	BE-HLS 7050 #SHLS Set Advanced 7.0	from 3000182107 to 3000218622
United Kingdom	701069076	BE-HLS 5050 #SHLS Set Advanced 5.0	from 3000189718 to 3000220058
Vietnam	701069073	BE-HLS 7050 #SHLS Set Advanced 7.0	from 3000182115 to 3000212850
Vietnam	701069076	BE-HLS 5050 #SHLS Set Advanced 5.0	3000215235