Rev 1: September 2018

FSN Ref: 656504 V04 & 661861 V04 FSCA Ref: 656504 & 661861

Date: 12.08.2022

Urgent Field Safety Notice
HLS Set 7050 & HLS Set 5050

For Attention of*:Argentina, Austria, Australia, Belarus, Belgium, Bosnia-Herzegovina, Brazil, Brunei Darussal, Chile, China, Colombia, Costa Rica, Croatia, Cyprus, Czech Republic, Denmark, Egypt, Estonia, Finland, France, Germany, Greece, Hong Kong, Hungary, Iceland, India, Ireland, Israel, Italy, Japan, Jordan, Kosovo, Kuwait, Latvia, Lebanon, Lithuania, Luxembourg, Macedonia, Malaysia, Mexico, Nepal, Netherlands, New Zealand, Norway, Oman, Pakistan, Panama, Philippines, Poland, Portugal, Qatar, Romania, Russia, Saudi Arabia, Serbia, Singapore, Slovakia, Slovenia, South Africa, South Korea, Spain, Sweden, Switzerland, Thailand, Turkey, Ukraine, United Arab Emirates, United Kingdom, Vietnam.

Contact details of local representative (name, e-mail, telephone, address etc.)*
Timur Güvercinci Maquet Cardiopulmonary GmbH Kehler Str. 31 76437 Rastatt GERMANY Phone: +49 7222 932 - 0 Email: FSCA.cp@getinge.com

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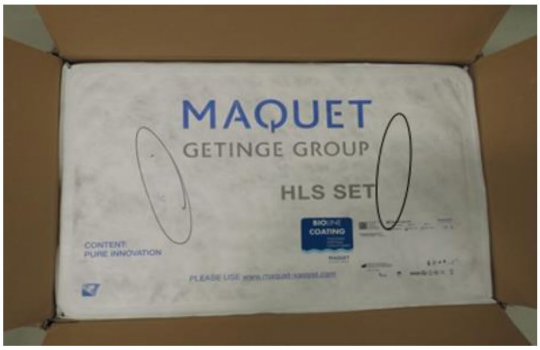
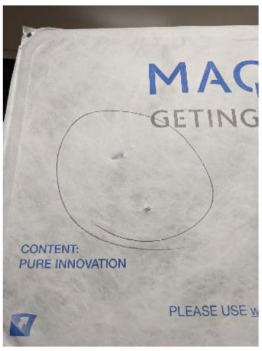
Urgent Field Safety Notice (FSN)
HLS Set 7050 & HLS Set 5050
Risk addressed by FSN

	1. Information on Affected Devices*
1.	1. Device Type(s)*
	The HLS Set Advanced (see figure 1) is intended for use in an extracorporeal circulation for cardiac support and/ or pulmonary support.  Figure 1: HLS Module Advanced
1.	2. Commercial name(s)
	BE-HLS 7050 (part number 701069073) BE-HLS 5050 (part number 701069076) BO-HLS 7050 (part number 701069083) BE-HLS 7050 USA (part number 701069078) BE-HLS 5050 USA (part number 701069077) BO-HLS 7050 CA (part number 701069065) BEQ-HLS 5050 CA (part number 701069068)
1.	3. Unique Device Identifier(s) (UDI-DI)
	04058863005744 (BE-HLS 7050, part number 701069073) 04058863078298 (BE-HLS 5050, part number 701069076) 04058863020082 (BO-HLS 7050, part number 701069083) 04058863080383 (BE-HLS 7050 USA, part number 701069078) 04058863076355 (BE-HLS 5050 USA, part number 701069077) 04058863300238 (BO-HLS 7050 CA, part number 701069065) 04058863304625 (BEQ-HLS 5050 CA, part number 701069068)
1.	4. Primary clinical purpose of device(s)*
	Intended Use: HLS Set Advanced / HIT Set Advanced, NONUS The HLS Set Advanced / HIT Set Advanced is intended for use in an extracorporeal circulation for cardiac support and/or pulmonary support. The maximum duration of use depends on the coating and the cannulae used, and is: - HLS Set Advanced, in conjunction with BIOLINE-coated HLS Cannulae: 30 days - HIT Set Advanced, in conjunction with SOFTLINE-coated HLS Cannulae: 5 days

	- All versions of the HLS Set Advanced, in conjunction with cannulae from other manufacturers: 6 hours Intended Use: HLS Set Advanced / HIT Set Advanced, CA Same as above in NONUS with the following applicable restriction: The maximum duration of use is 6 hours. Intended Use: HLS Set Advanced / HIT Set Advanced, AUS with BIOLINE Coating Same as above in NONUS with the following applicable restriction: HLS Set Advanced, in conjunction with BIOLINE coated HLS cannulae: To be used in extracorporeal circulation during cardiopulmonary bypass procedures for a duration not to exceed 6 hours. Any use up to 30 days is limited to patients with acute respiratory failure or acute cardiopulmonary failure where other available treatment options are no longer supportive alone, and continued clinical deterioration is expected or the risk of death is imminent. HLS Set Advanced, in conjunction with cannulae from other manufacturers: 6 hours Intended Use: HLS Set Advanced / HIT Set Advanced, AUS with SOFTLINE Coating Same as above in NONUS with the following applicable restriction: HIT Set Advanced, in conjunction with SOFTLINE coated HLS cannulae: 5 days HIT Set Advanced, in conjunction with cannulae from other manufacturers: 6 hours Indication for Use: HLS Set Advanced / HIT Set Advanced, US The HLS Set Advanced / HIT Set Advanced is part of the CARDIOHELP System. For the indication for use, refer to the CARDIOHELP System Instructions for Use.
1.	5. Device Model/Catalogue/part number(s)*
	BE-HLS 7050 #SHLS Set Advanced 7.0 (part number 701069073) BE-HLS 5050 #SHLS Set Advanced 5.0 (part number 701069076) BO-HLS 7050 #S/ HIT Set Advanced 7.0 (part number 701069083) BEQ-HLS 7050 USA #SHLS Set Advanced 7.0 (part number 701069078) BEQ-HLS 5050 USA #SHLS Set Advanced 5.0 (part number 701069077) BEQ-HLS 7050-CA #SHLS Set Advanced 7.0 (part number 701069065) BEQ-HLS 5050-CA #SHLS Set Advanced 5.0 (part number 701069068)
1.	6. Affected serial or lot number range
	See Attachment 01 (Att01_HLS Set_affected Lot#_FSCA FSCA 656504 & 661861)

	2 Reason for Field Safety Corrective Action (FSCA)*
2.	1. Description of the product problem*
	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 (figure 2). Consequently, depending on the orientation of the Tyvek cover on HLS tray, holes can appear either on the left or right side of the Tyvek (figure 3 and 4), which corresponds to the position of the venous probe holder.  *Figure 2: both tabs of the venous probe holder within HLS Module*  *Figure 3: position of potential damages either on left or right side, depending on position of HLS Module in the package*  *Figure 4: example of holes in the Tyvek cover* Causality Chain: 1. The damages can only occur if the device is dropped **upside down** from **above of 0,8 meter** height 2. If the device is dropped upside down from 0,8 meter height, the packaging is reversible deformed by the impact force, which leads to movement of oxygenator relative towards to Tyvek cover and pierce the Tyvek primary packaging, creating one or two punch holes with the size of 6mm to 16mm .The damages of the primary packaging can occur either on the left or the right side, depending on the orientation of Tyvek cover. Loss of product sterility.
2.	2. Hazard giving rise to the FSCA*
	Direct harm can only occur if the packaging is compromised but the damages are **not detected** prior to use. **Indirect harm** can only occur if the packaging is compromised and the damages are **detected** prior to use, which results in unavailability of the device. All reported complaints are connected identification of damages in primary packaging during opening of the device. All identified holes coming either from the complaint devices or internal investigations have the size between 5 mm and 20 mm. This indicates a high rate of detection. Possible **direct harm** if device with damaged primary packaging is used: **Hazardous Situation: Patient is exposed to pathogenic agents** 1. **Harm:** Inflammation (Severity of Harm: **Critical**) 2. **Harm:** Infection (Severity of Harm: **Catastrophic**) 3. **Harm:** Sepsis (Severity of Harm: **Catastrophic**) Possible **indirect harm** if device is not available for use, because it has a damaged packaging): **Hazardous Situation: delay of procedure** 1. **Harm:** Ischemia (Severity of Harm: **Catastrophic**) 2. **Harm:** User inconvenience (Severity of Harm: **Low**)

2.	3. Background on Issue

Maquet Cardiopulmonary got aware of this topic by customer complaints where it was reported, that the primary packaging was observed be damaged during unpacking of the device.

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Root Causes:

- Outer packaging (tertiary packaging) used for transportation of HLS Sets from the SSU to the customer (especially in USA), lack appropriate transport handling marks, clearly highlighting the correct upright position of the delivered product. In USA outer packaging (tertiary packaging) is used for all HLS Sets, this is not always the case for rest of the world. The number of complaints per sold devices coming from USA correlates with that root cause.

  The absence of labeling on the outer packaging increases the probability of rough handling of the devices. The missing directional labels can lead to an overhead transportation. If the device is transported upside down and is dropped from over 0,8 meters, it may get damaged. The directional labels are part of the risk mitigation file as a risk mitigation measure. The use of outer packaging without application of similar labels leads to an ineffective risk mitigation measure.

- The current packaging is not designed to withstand inappropriate handling during transport (e.g. box is dropped upside down from carrying height (approximately 0,8 meters).

Actions to mitigate the risk:

1. Reactivation of ineffective risk mitigation measure. Application transportation conditions labeling to outer packaging. – Implemented

Actions to improve detectability:

2. Application of an inspection instruction to every HLS set to show the location of possible damages resulting from this nonconformity.
   Inform all customers regarding the possible damages on the HLS Set primary packaging.

Further Actions to remove unknown improper handling from the transportation.

3. Specify the logistics conditions
   - Restrict parcel shipment
   - Allow only following shipment from Getinge distribution centers:
     - On pallet with proper fixation, preventing upside down transport
     - With sensitive freight carrier and instructed driver how to handle the HLS Set.

Packaging design with inherent safety

4. Development of a design solution which can withstand the upside down drop from 0,8 meters height. Currently not available.

Actions 2 and 3 will be obsoleted with the implementation of inherent safe packaging design.

With implemented actions 1-3 the product is considered as **safe**.

3. Type of Action to mitigate the risk*

3. 1. Action To Be Taken by the User*

☐ Identify Device ☐ Quarantine Device ☒ Return Device ☐ Destroy Device

☒ On-site device modification/inspection

☐ Follow patient management recommendations

☐ Take note of amendment/reinforcement of Instructions For Use (IFU)

☐ Other ☐ None

Actions to be taken by Customer
Due to a potential delay of replacement products, the user can choose between two options:

Option 1 (Return Device)
1. Please return immediately all affected products in your stock to your local Getinge representative.
2. In case of return of the affected products, please contact your local Getinge representative for credit or replacement.
3. If a product is already in use, it should remain in use.

Option 2 (on-site device inspection):
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.
4. **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.
5. Regardless of the decision you make, please complete and sign the attached customer response form and send it back to your local Getinge representative.
6. Please report any adverse events in regards to the affected products to your Getinge Representative.

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.

Action to be taken by distributor

- Please inform all affected end customers about this field action by sending the Field Safety Notice for Customer with related enclosed documents.
- Please attach the provided Field Safety Notice for Customer to all affected products in your stock, prior to sending them to the end customers. If this was already done by your Getinge Representative (see figure 7), you do not need to do it.

Figure 7: Attachment affixed by SSU to every white box

- Please affix highly visible the transport label in the outer side of each shipment box prior to transport the goods. Your local Getinge representative will provide you such labels on request.

Figure 8: Example of transport label for forwarder

- Please use „white glove“ forwarder, specialized on sensitive goods, or dedicated drivers or provide the boxes in palettes.

	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.	
3.	2. Is customer Reply Required? * (If yes, form attached specifying deadline for return)	Yes Deadline: 2022-11-01

	4. General Information*	
4.	1. FSN Type*	Update
4.	2. For updated FSN, reference number and date of previous FSN	FSN to FSCA 656504 V03 (2022-08-15) FSN to FSCA 661861 V03 US & CA (2022-08-15)
4.	**3.** For Updated FSN, key new information as follows:	
	Add of primary clinical purpose of the device, causality chain of the problem, hazard giving rise to the FSCA, probability of problem arising, predicted risk to patient/users, further information to help characterise the problem and other information relevant to FSCA Updated of background on Issue, Type of Action to mitigate the risk and general Information	
4.	4. Further advice or information already expected in follow-up FSN? *	No
4.	5. Manufacturer information (For contact details of local representative refer to page 1 of this FSN)	
	a. Company Name	Maquet Cardiopulmonary GmbH
	b. Address	Kehler Str. 31 76437 Rastatt Germany
	c. Website address	https://www.getinge.com/
4.	6. The Competent (Regulatory) Authority of your country has been informed about this communication to customers. * Relevant authorities were informed regarding this Field Action.	
	7. List of attachments/appendices:	Att01_HLS Set_affected Lot#_FSCA FSCA 656504 & 661861 Att02_HHE-2022-05-002_HLS Set Advanced_HIT Set Advanced Tyvek Defects Att03_Customer Response Form to FSCA 656504 (affected Lots included) Att04_Distributor Response Form to FSCA 656504 (affected Lots included)

		Att05_Customer Response Form to FSCA 661861 (affected Lots included) Att06_Safety relevant information HLS FSCA 661861_656504
4.	8. Name/Signature	Dieter Engel (Managing Director)
		Timur Güvercinci (PRRC)

	Transmission of this Field Safety Notice
	This notice needs to be passed on all those who need to be aware within your organisation or to any organisation where the potentially affected devices have been transferred. (As appropriate) Please transfer this notice to other organisations on which this action has an impact. (As appropriate) Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action. Please report all device-related incidents to the manufacturer, distributor or local representative, and the national Competent Authority if appropriate, as this provides important feedback..*

Note: Fields indicated by * are considered necessary for all FSNs. Others are optional.