

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.

Template: CP-SOP-001-T-02 V02, Effective date 2019-09-15

**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,

**Managing Director**

GETINGE 

Markus Medart, 2020-11-06 17:36:25+0100  
Approved: u2895387, Managing Director

**Safety Officer**

GETINGE 

Nursel Boelens, 2020-11-06 17:12:13+0100  
Approved: u4015842, Director Regulatory Affairs

Maquet Cardiopulmonary GmbH  
Kehler Str. 31  
76437 Rastatt  
GERMANY

Country	Article No.	Product Description	Lot
Sweden	701048127	BE-HLS 5050#HLS Set Advanced 5.0	70133518
Sweden	701048127	BE-HLS 5050#HLS Set Advanced 5.0	70133620
Sweden	701048127	BE-HLS 5050#HLS Set Advanced 5.0	70135594
Sweden	701048127	BE-HLS 5050#HLS Set Advanced 5.0	70137755
Sweden	701048127	BE-HLS 5050#HLS Set Advanced 5.0	70138863
Sweden	701048127	BE-HLS 5050#HLS Set Advanced 5.0	70139803
Switzerland	701047753	BE-HLS 7050#HLS Set Advanced 7.0	70127926
Switzerland	701047753	BE-HLS 7050#HLS Set Advanced 7.0	70128090
Switzerland	701047753	BE-HLS 7050#HLS Set Advanced 7.0	70128103
Switzerland	701047753	BE-HLS 7050#HLS Set Advanced 7.0	70128193
Switzerland	701047753	BE-HLS 7050#HLS Set Advanced 7.0	70128582
Switzerland	701047753	BE-HLS 7050#HLS Set Advanced 7.0	70129238
Switzerland	701047753	BE-HLS 7050#HLS Set Advanced 7.0	70129239
Switzerland	701047753	BE-HLS 7050#HLS Set Advanced 7.0	70129240
Switzerland	701047753	BE-HLS 7050#HLS Set Advanced 7.0	70129389
Switzerland	701047753	BE-HLS 7050#HLS Set Advanced 7.0	70129630
Switzerland	701047753	BE-HLS 7050#HLS Set Advanced 7.0	70129633
Switzerland	701047753	BE-HLS 7050#HLS Set Advanced 7.0	70130061
Switzerland	701047753	BE-HLS 7050#HLS Set Advanced 7.0	70130204
Switzerland	701047753	BE-HLS 7050#HLS Set Advanced 7.0	70130368
Switzerland	701047753	BE-HLS 7050#HLS Set Advanced 7.0	70130369
Switzerland	701047753	BE-HLS 7050#HLS Set Advanced 7.0	70130879
Switzerland	701047753	BE-HLS 7050#HLS Set Advanced 7.0	70130880
Switzerland	701047753	BE-HLS 7050#HLS Set Advanced 7.0	70130882
Switzerland	701047753	BE-HLS 7050#HLS Set Advanced 7.0	70131078
Switzerland	701047753	BE-HLS 7050#HLS Set Advanced 7.0	70131082
Switzerland	701047753	BE-HLS 7050#HLS Set Advanced 7.0	70131158
Switzerland	701047753	BE-HLS 7050#HLS Set Advanced 7.0	70131404
Switzerland	701047753	BE-HLS 7050#HLS Set Advanced 7.0	70131583
Switzerland	701047753	BE-HLS 7050#HLS Set Advanced 7.0	70131970
Switzerland	701047753	BE-HLS 7050#HLS Set Advanced 7.0	70131974
Switzerland	701047753	BE-HLS 7050#HLS Set Advanced 7.0	70132101
Switzerland	701047753	BE-HLS 7050#HLS Set Advanced 7.0	70132431
Switzerland	701047753	BE-HLS 7050#HLS Set Advanced 7.0	70132651
Switzerland	701047753	BE-HLS 7050#HLS Set Advanced 7.0	70132843
Switzerland	701047753	BE-HLS 7050#HLS Set Advanced 7.0	70132899
Switzerland	701047753	BE-HLS 7050#HLS Set Advanced 7.0	70132902
Switzerland	701047753	BE-HLS 7050#HLS Set Advanced 7.0	70133054
Switzerland	701047753	BE-HLS 7050#HLS Set Advanced 7.0	70133090
Switzerland	701047753	BE-HLS 7050#HLS Set Advanced 7.0	70133092
Switzerland	701047753	BE-HLS 7050#HLS Set Advanced 7.0	70133480
Switzerland	701047753	BE-HLS 7050#HLS Set Advanced 7.0	70133745
Switzerland	701047753	BE-HLS 7050#HLS Set Advanced 7.0	70133975

Country	Article No.	Product Description	Lot
Switzerland	701047753	BE-HLS 7050#HLS Set Advanced 7.0	70133982
Switzerland	701047753	BE-HLS 7050#HLS Set Advanced 7.0	70133983
Switzerland	701047753	BE-HLS 7050#HLS Set Advanced 7.0	70133984
Switzerland	701047753	BE-HLS 7050#HLS Set Advanced 7.0	70133987
Switzerland	701047753	BE-HLS 7050#HLS Set Advanced 7.0	70133996
Switzerland	701047753	BE-HLS 7050#HLS Set Advanced 7.0	70134740
Switzerland	701047753	BE-HLS 7050#HLS Set Advanced 7.0	70134741
Switzerland	701047753	BE-HLS 7050#HLS Set Advanced 7.0	70134743
Switzerland	701047753	BE-HLS 7050#HLS Set Advanced 7.0	70135651
Switzerland	701047753	BE-HLS 7050#HLS Set Advanced 7.0	70135653
Switzerland	701047753	BE-HLS 7050#HLS Set Advanced 7.0	70135659
Switzerland	701047753	BE-HLS 7050#HLS Set Advanced 7.0	70135663
Switzerland	701047753	BE-HLS 7050#HLS Set Advanced 7.0	70135668
Switzerland	701047753	BE-HLS 7050#HLS Set Advanced 7.0	70136153
Switzerland	701047753	BE-HLS 7050#HLS Set Advanced 7.0	70136157
Switzerland	701047753	BE-HLS 7050#HLS Set Advanced 7.0	70136161
Switzerland	701047753	BE-HLS 7050#HLS Set Advanced 7.0	70136170
Switzerland	701047753	BE-HLS 7050#HLS Set Advanced 7.0	70136555
Switzerland	701047753	BE-HLS 7050#HLS Set Advanced 7.0	70136558
Switzerland	701047753	BE-HLS 7050#HLS Set Advanced 7.0	70136561
Switzerland	701047753	BE-HLS 7050#HLS Set Advanced 7.0	70136562
Switzerland	701047753	BE-HLS 7050#HLS Set Advanced 7.0	70137239
Switzerland	701047753	BE-HLS 7050#HLS Set Advanced 7.0	70137241
Switzerland	701047753	BE-HLS 7050#HLS Set Advanced 7.0	70137794
Switzerland	701047753	BE-HLS 7050#HLS Set Advanced 7.0	70137796
Switzerland	701047753	BE-HLS 7050#HLS Set Advanced 7.0	70137801
Switzerland	701047753	BE-HLS 7050#HLS Set Advanced 7.0	70137940
Switzerland	701047753	BE-HLS 7050#HLS Set Advanced 7.0	70138042
Switzerland	701047753	BE-HLS 7050#HLS Set Advanced 7.0	70138044
Switzerland	701047753	BE-HLS 7050#HLS Set Advanced 7.0	70138277
Switzerland	701047753	BE-HLS 7050#HLS Set Advanced 7.0	70138282
Switzerland	701047753	BE-HLS 7050#HLS Set Advanced 7.0	70138810
Switzerland	701047753	BE-HLS 7050#HLS Set Advanced 7.0	70138811
Switzerland	701047753	BE-HLS 7050#HLS Set Advanced 7.0	70139141
Switzerland	701047753	BE-HLS 7050#HLS Set Advanced 7.0	70139146
Switzerland	701047753	BE-HLS 7050#HLS Set Advanced 7.0	70139659
Switzerland	701047753	BE-HLS 7050#HLS Set Advanced 7.0	70140476
Switzerland	701047753	BE-HLS 7050#HLS Set Advanced 7.0	70140478
Switzerland	701047753	BE-HLS 7050#HLS Set Advanced 7.0	70140523
Switzerland	701047753	BE-HLS 7050#HLS Set Advanced 7.0	70140719
Switzerland	701047753	BE-HLS 7050#HLS Set Advanced 7.0	70140720
Switzerland	701047753	BE-HLS 7050#HLS Set Advanced 7.0	70141282
Switzerland	701048127	BE-HLS 5050#HLS Set Advanced 5.0	70128879

Country	Article No.	Product Description	Lot
Switzerland	701048127	BE-HLS 5050#HLS Set Advanced 5.0	70131143
Switzerland	701048127	BE-HLS 5050#HLS Set Advanced 5.0	70131169
Switzerland	701048127	BE-HLS 5050#HLS Set Advanced 5.0	70132193
Switzerland	701048127	BE-HLS 5050#HLS Set Advanced 5.0	70132661
Switzerland	701048127	BE-HLS 5050#HLS Set Advanced 5.0	70133177
Switzerland	701048127	BE-HLS 5050#HLS Set Advanced 5.0	70133518
Switzerland	701048127	BE-HLS 5050#HLS Set Advanced 5.0	70133529
Switzerland	701048127	BE-HLS 5050#HLS Set Advanced 5.0	70133620
Switzerland	701048127	BE-HLS 5050#HLS Set Advanced 5.0	70135518
Switzerland	701048127	BE-HLS 5050#HLS Set Advanced 5.0	70135519
Switzerland	701048127	BE-HLS 5050#HLS Set Advanced 5.0	70135593
Switzerland	701048127	BE-HLS 5050#HLS Set Advanced 5.0	70135594
Switzerland	701048127	BE-HLS 5050#HLS Set Advanced 5.0	70136126
Switzerland	701048127	BE-HLS 5050#HLS Set Advanced 5.0	70137755
Switzerland	701048127	BE-HLS 5050#HLS Set Advanced 5.0	70138864
Switzerland	701048127	BE-HLS 5050#HLS Set Advanced 5.0	70138867
Switzerland	701048127	BE-HLS 5050#HLS Set Advanced 5.0	70139336
Switzerland	701048127	BE-HLS 5050#HLS Set Advanced 5.0	70139803
Switzerland	701048127	BE-HLS 5050#HLS Set Advanced 5.0	70139875
Switzerland	701048127	BE-HLS 5050#HLS Set Advanced 5.0	70140298
Switzerland	701049134	BO-HLS 7050#HIT Set Advanced 7.0	70130298
Switzerland	701049134	BO-HLS 7050#HIT Set Advanced 7.0	70132343
Switzerland	701049134	BO-HLS 7050#HIT Set Advanced 7.0	70134720
Turkey	701047753	BE-HLS 7050#HLS Set Advanced 7.0	70127796
Turkey	701047753	BE-HLS 7050#HLS Set Advanced 7.0	70130368
Turkey	701047753	BE-HLS 7050#HLS Set Advanced 7.0	70131584
Turkey	701047753	BE-HLS 7050#HLS Set Advanced 7.0	70132651
Turkey	701047753	BE-HLS 7050#HLS Set Advanced 7.0	70133744
Turkey	701047753	BE-HLS 7050#HLS Set Advanced 7.0	70136171
Turkey	701047753	BE-HLS 7050#HLS Set Advanced 7.0	70136559
Turkey	701047753	BE-HLS 7050#HLS Set Advanced 7.0	70137239
Turkey	701047753	BE-HLS 7050#HLS Set Advanced 7.0	70138273
Turkey	701047753	BE-HLS 7050#HLS Set Advanced 7.0	70138282
Turkey	701047753	BE-HLS 7050#HLS Set Advanced 7.0	70140717
Turkey	701048127	BE-HLS 5050#HLS Set Advanced 5.0	70128879
Turkey	701048127	BE-HLS 5050#HLS Set Advanced 5.0	70133529
Turkey	701048127	BE-HLS 5050#HLS Set Advanced 5.0	70135519
Turkey	701048127	BE-HLS 5050#HLS Set Advanced 5.0	70136126
Turkey	701048127	BE-HLS 5050#HLS Set Advanced 5.0	70137755
Turkey	701048127	BE-HLS 5050#HLS Set Advanced 5.0	70138863
Turkey	701048127	BE-HLS 5050#HLS Set Advanced 5.0	70140057
United Kingdom	701047753	BE-HLS 7050#HLS Set Advanced 7.0	70127796
United Kingdom	701047753	BE-HLS 7050#HLS Set Advanced 7.0	70128089