

This Annex II is considered as a supplementary attachment to the FSN of FSCA-2020-10-30

Subject: Instruction for inspection of the Devices subject of this Field Safety Notice

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
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
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 5050-CA	70106.4848	HLS Set Advanced 5.0 for extracorporeal cardiac and/or pulmonary support with BIOLINE Coating, for the Canadian market

Affected Lot No.: see attached Annex I of FSN List of affected products

If expert Clinical judgement concludes that the use of the product is necessary then the following instructions must be followed and understood.

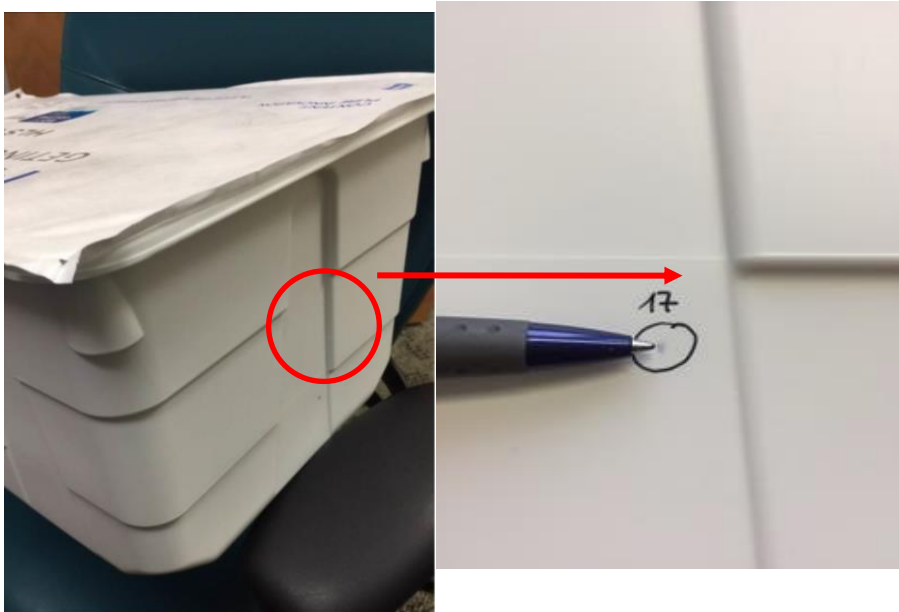
Visual Inspection:

1. After removing the tray from the secondary package (cardboard box), position the tray in a well-lit area outside the sterile field. Before opening the package, inspect the seal under light to assess its integrity.
2. Check the exterior package (including Tyvek cover and tray) before opening. If any doubt arises as to the package integrity it should not be used. Any product with damaged packaging must be returned to the Getinge local representative.

Inspection of HLS Set - tray defects:



Picture 1: HLS Set tray



Picture 2 : HLS Set - pinholes in tray

Inspection of HLS Set - Tyvek defects:



Picture 3 : HLS Set – defects in Tyvek

3. Make sure that the area where you will perform this verification is properly lit. You may use an inspection magnifier in case you have it.
4. Open the product. Completely remove the Tyvek cover. Inspect the Tyvek cover against a light source to ensure its integrity. After taking out the contents of the product, check the empty packaging for defects in the surface of the tray, compromising the sterile barrier.
5. Discard the package after thorough visual inspection yields a satisfactory result.

If a product package is determined to be damaged in any of these steps, please return to the Getinge local representative.

6. Before returning the package to the local Getinge representative, include all removed parts back in the package and close the package again using a clear tape.
7. If the integrity of the package has been confirmed through inspection, the HLS Set Advanced may be used. Please make sure that once the tray is open all its content must be used/ applied immediately for the priming and set-up procedure.

NOTE: Do not set aside or shelve the accessories for later use because the integrity of any of the individual packages may be compromised by defects that may be imperceptible; however, the “emergency prime line” may be retained for the duration of the application of the therapy to be used in case of an emergency as deemed necessary by the treating clinician.

We apologize for any inconvenience caused and assure you that we are working with highest priority on a solution.