
Urgent!

Field Safety Notice (FSN)



August 10th, 2018

FSCA Number: FSCA-2018-08-07

FSCA Title: Closed de-airing connector of HLS Set

Affected Product: BE-HLS 7050# HLS Set Advanced 7.0

Affected product details: Material No.: 70104.7753

Lot: 70120207

Quantity: 56

Description of the problem:

Dear valued colleagues and business partners,
The HLS Set is delivered with a priming set, which allows a fast and safe priming of the entire HLS set.

The priming set consists of a priming bag, connecting tubes, quick coupling and a de-airing connector.

During the priming process, air is flushing out of the HLS Set into the priming bag and escapes by using the de-airing connector.

It has come to our attention that a tightly closed de-airing connector instead of an open de-airing connector has been mounted on the de-airing tube of the affected HLS Set. Therefore the de-airing of the affected HLS Set is not possible.

A closed de-airing connector can potentially lead to a delay in treatment.

Maquet Cardiopulmonary has not received any complaints associated to serious injuries or deaths due to a closed de-airing connector of the HLS Set.

Corrective Action:

Return immediately the affected products to your local Getinge representative.

Advice on action to be taken by the user:

- According to our post-market surveillance documentation, your current stock may include products affected by this action.
- Fill and sign the attached Letter of Acknowledgement for customer and send it back to your local Getinge representative
- Return immediately the affected products to your local Maquet representative

Referenced document/attachment:

- Letter of Acknowledgement

Transmission of the Field Safety Notice:

- This notice needs to be passed on to all those who need to be aware within your organization or to any organization where the potentially affected devices have been transferred.
- Please transfer this notice to other organizations on which the action has an impact.
- Please maintain awareness on the notice and resulting actions for an appropriate period to ensure effectiveness of the corrective action.
- According to our post-market surveillance documentation the following countries are directly affected by this FSCA: BE, FR, IN, NL, RS, SA, SE

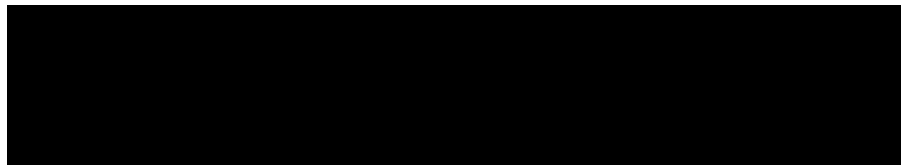
We apologize for any inconvenience this may cause you and we will do our utmost to carry through this action as swiftly as possible.

As required, we have provided this notification to the necessary Regulatory Agencies.

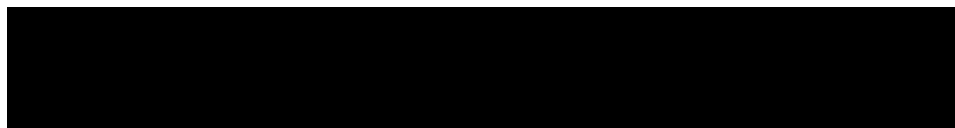
Should you have questions or require additional information, please contact your local Getinge representative.

Sincerely,

Managing Director



Safety Officer



Maquet Cardiopulmonary GmbH
Kehler Str. 31
76437 Rastatt
GERMANY