2019-04-01

FSCA Number: FSCA-2019-03-29

FSCA Title: Sterility assurance level of 3-way stopcock cannot be assured in various customized tubing sets

Affected Product: Custom Tubing Sets with ref. no. 70102.8429; 70105.2149; 70105.5796; 70105.6052; 70106.7687; 70106.9210; 70107.1484

Affected product details: Additional product information incl. affected Lot no., ref. to Annex 1

Description of the problem:

Dear valued customers,

Maquet Cardiopulmonary has determined that the sterility assurance level (SAL) requirement of 10^{-5} of the 3-way stopcock which is included in the HLM Custom Tubing Sets cannot be assured in the above listed Custom Tubing Sets for the specific lot numbers in Annex 1.

A review of all specific HLM Custom Tubing Set design drawings revealed that in various Custom Tubing Sets the orientation of the 3-way stopcock can restrict air flow into the downstream port of the stopcock. In situations where a non-vented cap is used on the downstream port, the flow of humidity and gas for sterilization can be restricted into the space of the stopcock port. This restriction of flow into the port creates a challenge to the sterilization process for the 3-way stopcock included in the Custom Tubing Set.

In this case the sterility assurance level of the respective 3-way stopcock port cannot be assured.

Individuals undergoing extracorporeal circulation usually develop inflammatory response due to the fact that human blood cells are exposed to foreign surface with a release of inflammatory mediators as the consequence. The most severe form is called systemic inflammatory response Syndrome (SIRS).

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.

Maquet Cardiopulmonary has not received any complaints associated to serieus injuries or death due toa not assured sterility assurance level of the 3-way stopcock.

Please stop using the HLM Custom Tubing Set listed in Annex I and follow the actions to be taken in this notification.

Corrective Action:

- Please return immediately all affected products in your stock to your local Getinge representative.

Advice on action to be taken by the user:

- According to our surveillance documentation, your current stock may include products affected by this action.
- Please 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 Getinge representative.

Referenced documents/attachments:

- Annex 1: List of affected products
- Letter of Acknowledgement Customer

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 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 Maquet representative.

Sincerely,

……..

Maquet Cardiopulmonary GmbH
Kehler Str. 31
76437 Rastatt
GERMANY