2019-02-18

FSCA Number: FSCA-2019-02-15

FSCA Title: Pre-Bypass Filter Labelling Integrity not ensured

Affected Product: All Pre-Bypass Filters used for Customized Tubing Packs Production (Ref.No. 701021039 – 1/2 x 3/8 – without vent, 701021040 - 1/2 x 3/8 – with vent, 701031084 – 3/8 x 3/8 without vent, 701031086 – 3/8 x 3/8 – with vent)

Affected product details: See attached list of distributed affected products (Annex I)

Description of the problem:

Dear valued customers,

The Pre-Bypass Filter is a product which is supplied integrated within heart lung machine tubing sets.

Maquet Cardiopulmonary has been informed that the printed information on the front and back side of the pre-bypass filter, showed incomplete print quality.

Internal investigations have revealed that the print on the filters had already been partially removed out of the packaging or it was also detected that the printing could be removed by touching with hands. The print does not necessarily come off during transport. Even if the print is still fully intact it could be an affected device. The print may be removed when touched without any solvent used.

Maquet Cardiopulmonary has not received any complaints for this issue. There have been no reports associated to serious injuries or death due to improper or delaminating print of the pre-bypass filter.

Should you wish to use the tubing set with a pre-bypass filter showing incomplete instructions or potentially delaminating print, we kindly request you to inform all clinical staff who use the product to follow the information and instructions that are normally printed on the Pre-Bypass-Filter:

“0.2 micron filter
For priming cardiopulmonary bypass circuits
Warning: not for use with cellular blood products. Follow instructions for use. Do not reuse.”

Using the pre-bypass filter not following the warning can result in flow obstruction, a replacement of the circuit and ultimately a delay in the surgery and potential cardio-pulmonary deterioration in an emergency situation.

Furthermore all clinical staff touching the Pre-Bypass Filter should exchange their sterile gloves after removal of the Pre-Bypass Filter from the primed circuit. This will reduce the potential risk of cross-contamination of erased ink into the blood stream or the surgical field of the patient.

Corrective Action:

- All clinical staff using these products should read and follow the information and instructions that are normally printed on the Pre-Bypass Filter, listed above
- All clinical staff touching the Pre-Bypass Filter needs to exchange their sterile gloves after removal of the Pre-Bypass Filter from the primed circuit
- In case you do not want to use the entire tubing set containing a potentially affected pre-bypass filter, please return the product to your local Getinge representative

Advice on action to be taken by the user:

- The scope of this FSN encompasses all Maquet Cardiopulmonary GmbH (MCP) products listed in Annex I containing a pre-bypass filter (Ref.No. 701021039 – 1/2 x 3/8 – without vent, 701021040 - 1/2 x 3/8 – with vent, 701031084 – 3/8 x 3/8 without vent, 701031086 – 3/8 x 3/8 – with vent)
- 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

Referenced documents/attachments:

- Annex I: List of affected distributed 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 on 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 have provided this notification to the necessary Regulatory Agencies.

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

Sincerely,

Managing Director

i.A. Timothy J. Talcott 2019-02-18
Sr. Director of Quality Improvement Programs

Safety Officer

Approved / Geprüft	Signatory:	Signature / Unterschrift
UTC 2019-02-18, 14:48:58	Nursel Boelens (Director of Regulatory Affairs)	

Maquet Cardiopulmonary GmbH
Kehler Str. 31
76437 Rastatt
GERMANY