

Urgent !
Field Safety Notice (FSN)



DMS#
(DMS#)
2726679

Version
(Version)
V 01

Gültig ab
(valid from)
Last signature

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2019-08-27

FSCA Number: FSCA-2019-08-23

FSCA Title: QUART Arterial Filter – Sterile Barrier Integrity

Affected Product: QUART Arterial Filter with ref. no. 70100.4263, 70103.1617, 70100.2652, 70106.4969, 70101.2811, 70103.2033, 70104.8784

Affected product details: Sterile packaging of Quart Arterial Filter

Description of the problem:

Dear valued customers,

Maquet Cardiopulmonary has determined that the sterile barrier system of the QUART Arterial Filter may be compromised during transportation.

During verification testing of transportation simulation, the integrity of the sterile packaging of one sample of 48 tested resulted in a damaged sterile barrier system of the product.

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.

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).

Maquet Cardiopulmonary has not received any complaints associated with damage to the sterile barrier system or to serious injuries or death due to damage to the sterile barrier system of the Arterial Quart Filter.

Governing Procedure: SV 09.11

Print-outs and copies of this document have to be checked for validity and correctness before use.
FB-0078 / V 05

Gültig ab: 2018-06-25

FB-0087a
Version: 04
Gültig ab: 2018-09-18

Governing Procedure: SV 02.03

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In an abundance of caution, Maquet Cardiopulmonary is requesting you to please stop using the Arterial Quart Filter listed above 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 complete and sign the attached Letter of Acknowledgement for the customer and send it back to your local Getinge representative.
- Return immediately the affected products to your local Getinge representative for credit.
- To fulfill your future needs of single sterile arterial filters, we recommend to use a competitor product, such as the Medtronic Affinity Arterial Filter, Terumo Capiox Arterial Line Filter or the LivaNova Arterial Filter

Referenced

documents/attachments:

- Letter of Acknowledgement Customer

Governing Procedure: SV 09.11

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FB-0076 / V 06 Gültig ab: 2018-06-25

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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,

Managing Director

Safety Officer

Maquet Cardiopulmonary GmbH
Kehler Str. 31
76437 Rastatt
GERMANY

Governing Procedure: SV 09.11

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