2020-06-19

URGENT - FIELD SAFETY NOTICE

Subject:	FSCA-2020-05-16
Affected Product:	Single holder for oxygenator neo./ped. as a supplement to holder arm (QUADROX-i, QUADROX) (Article No. 70104.7495, REF No. HKHZ 19)
Affected Batch No.:	70128207

Dear valued customer,

The holder (70104.7495) is being used as single holder for QUADROX-i Neonatal and QUADROX-i Pediatric oxygenators and can also be used in combination with the holder arm 016061 (70104.8947). This holder is designed specifically to hold an oxygenator for small patient, and is used in cardiopulmonary bypass procedures (CPB) in a pediatric patient population.

Maquet Cardiopulmonary GmbH became aware that the snapping function between Holder and oxygenator was not given. Only one specific Lot of Holder was affected.

Ischemic organ damage is a possible harm, which could be resulted from a de-connection of the oxygenator, with a consecutive fall to the floor and crack of the device with resulting compromised function of the oxygenator. As the oxygenator is however located only a very limited distance above the floor and in addition with tubes connected to the oxygenator a free fall with an acceleration of G = 9,81 m/s2 and potential increasing damage of the oxygenator with increasing height of fall is not expected/possible.

A complete disintegration of the device which would make it necessary to exchange the oxygenator device is not expected due to reasons explained earlier.

In case a malfunction of the snap-connection is detected already during assembly (which is expected in a majority of cases) the appropriate measure would be to exchange the holder with a spare model. The malfunction of the holder can be checked following the testinstruction. In case of unavailability of a spare model fixation at the snap site with tape is necessary. Both measures are expected to be of a very limited duration in time.

Please do not use the affected single holder for oxygenator neo./ped. and as a supplement to holder arm (QUADROX-i, QUADROX) and return them to your local Getinge representative.

Maquet Cardiopulmonary GmbH has not received any reports of serious injuries or death due to not given snapping mechanism between Holder and oxygenator.

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 note.
Referenced documents/ attachments:	• Letter of Acknowledgement Customer • Testinstruction

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 Getinge representative.

Sincerely,

Managing Director

Markus Medart, 2020-06-19 11:01:38+0200
Approved/Geprüft: u2895387
Managing Director

Safety Officer

Nursel Boelens, 2020-06-19 15:59:27+0200
Approved/Geprüft: u4015842
Director Regulatory Affairs

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