

2020-12-16

**URGENT - FIELD SAFETY NOTICE**

**Subject:** FSCA-2020-12-07 VHK and VKMO Pediatric Sterile Barrier Integrity

**Affected Product:** - Pediatric Venous Hardshell Cardiotomy Reservoir  
 - Combination of Pediatric Venous Hardshell Cardiotomy Reservoir with QUADROX-i Pediatric Oxygenator

REF no.	Article no.	Product description
VKMO 30000	701050111	Quadrox-I Pediatric Oxygenator HMO 30000 with Pediatric Venous Hardshell Cardiotomy Reservoir VHK 31000
BO-VKMO 30000	701053454	Quadrox-I Pediatric Oxygenator HMO 30000 with Pediatric Venous Hardshell Cardiotomy Reservoir VHK 31000 with SOFTLINE Coating
VKMO 31000	701049185	Quadrox-I Pediatric Oxygenator HMO 31000 with Pediatric Venous Hardshell Cardiotomy Reservoir VHK 31000
BO-VKMO 31000	701053455	Quadrox-I Pediatric Oxygenator HMO 31000 with Pediatric Venous Hardshell Cardiotomy Reservoir VHK 31000 with SOFTLINE Coating
VHK 31000	701048595	Pediatric Venous Hardshell Cardiotomy Reservoir
BO-VHK 31000	701051432	Pediatric Venous Hardshell Cardiotomy Reservoir with SOFTLINE Coating
BO-VHK 31000-J	701054166	Pediatric Venous Hardshell Cardiotomy Reservoir, SOFTLINE coated, Japan
VKMO 30000	701070422	QUADROX-i Pediatric HMO 30000 with Pediatric Venous Hardshell Cardiotomy Reservoir VHK 31000

**Affected Lot No.:** see attached Annex I List of affected products

Dear valued customer,

The Pediatric Venous Hardshell Cardiotomy Reservoir (VHK) as its combination with the QUADROX-i Pediatric Oxygenator (VKMO) were developed for use during cardiopulmonary bypass operations. They are used in an extracorporeal circuit to collect, store and filter blood that is aspirated from the surgical field as well as drained from the patient by the venous line.

During verification testing of Pediatric VKMOs and VHKs a potential impairment of the sterile packaging barrier system was identified.

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 or reports of adverse events due to damage to the sterile barrier system of above mentioned products.

The products with lots listed in Annex I List of affected products are subject of this Field Safety Notice.

We apologize for any inconvenience caused and assure you that we are working with highest priority on a solution.

Template: CP-SOP-001-T-02\_V02, Effective date 2019-09-15

**Corrective Action:**

- According to our surveillance documentation, your current stock may include products affected by this action. Please refer to Annex I List of affected products.
- **Caution:** Please match lot numbers on labels in your stock with affected lots according to attached Annex I List of affected products.
- **Please return immediately all affected products in your stock to your local Getinge representative.**
- Please complete and sign the attached Letter of Acknowledgement for the customer and send it back to your local Getinge representative.
- Please contact your local Getinge representative for credit.

**Referenced documents/ attachments:**

- Annex I List of affected products
- Letter of Acknowledgement Customer

**Transmission of the Field Safety Notice:**

- This notice needs to be forwarded to all those who need to be aware within your organization or to any organization where the potentially affected devices have been further distributed.
- 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, or send an e-mail to [FSCA.cp@getinge.com](mailto:FSCA.cp@getinge.com).**

Sincerely,

**Managing Director**

**Safety Officer**

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