2021-05-10

URGENT - FIELD SAFETY NOTICE

Subject: FSCA-2021-05-07 Sterile Barrier Integrity issue of the accessory tight caps of the VHK and VKMO Neonatal

Affected Product:

- Combination of Neonatal Venous Hardshell Cardiotomy Reservoir with QUADROX-I Neonatal Oxygenator with or without coating
- Neonatal Venous Hardshell Cardiotomy Reservoir

Ref. No.	Article number	Product Description
VHK 11000	701048596	Neonatal Venous Hardshell Cardiotomy Reservoir
BO-VHK 11000	701051430	Neonatal Venous Hardshell Cardiotomy Reservoir, SOFTLINE coated
BO-VHK 11000-J	701054173	Neonatal Venous Hardshell Cardiotomy Reservoir, SOFTLINE coated, Japan
VKMO 10000	701050109	QUADROX-i Neonatal HMO 10000 with Neonatal Venous Hardshell Cardiotomy Reservoir VHK 11000
BO-VKMO 10000	701053443	QUADROX-i Neonatal HMO 10000 with Neonatal Venous Hardshell Cardiotomy Reservoir VHK 11000, SOFTLINE
VKMO 11000	701049279	QUADROX-i Neonatal HMO 11000 with Neonatal Venous Hardshell Cardiotomy Reservoir VHK 11000
BO-VKMO 11000	701053444	QUADROX-i Neonatal HMO 11000 with Neonatal Venous Hardshell Cardiotomy Reservoir VHK 11000, SOFTLINE
BO-VKMO 11000 -J	701063847	QUADROX-i Neonatal HMO 11000 with Neonatal Venous Hardshell Cardiotomy Reservoir VHK 11000, SOFTLINE, Japan
VKMO 10000	701070440	QUADROX-i Neonatal HMO 10000 with Neonatal Venous Hardshell Cardiotomy Reservoir VHK 11000
VKMO 11000	701070444	QUADROX-i Neonatal HMO 11000 with Neonatal Venous Hardshell Cardiotomy Reservoir VHK 11000
BO-VKMO 11000	701071077	QUADROX-i Neonatal HMO 11000 with Neonatal Venous Hardshell Cardiotomy Reservoir VHK 11000, SOFTLINE

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

Dear valued customer,

The Neonatal Venous Hardshell Cardiotomy Reservoir (VHK) as its combination with the QUADROX-i Neonatal 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 design verification testing of neonatal VKMOs and VHKs a potential impairment of the sterile package of the accessory part “tight caps” was identified. Figure 1 shows the affected pouch that contains the tight caps.

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Figure 1: Sterile pouch that contains the tight caps.

Figure 2 and 3 show the VKMO and accessories placed in the Styrofoam inlay inside the cardboard box.

Figure 2: VKMO packed in Styrofoam inlay

Figure 3: The rolled pouch that contains the tight caps in the Styrofoam inlay

The affected tight caps are packed in an individual sterile package placed outside the VKMO/VHK. The tight caps are used to replace vented caps during vacuum assisted venous drainage (VAVD) procedures and post-operative vacuum-assisted wound drainage. These caps are required to be sterile in both applications as they are in contact with the blood path.

The exposure of either the blood path or sterile (operative) field to nonsterile tight caps may cause none, some, or all of the following immediate and/or long-range health consequences (injuries or illnesses):

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- Exposure of the sterile (operative) field to an unsterile product which could compromise the entire surgical field.
- Exposure of a patient's vascular system to an unsterile product resulting in inflammation and/or infection.
- Sepsis due the unmitigated and unknown propagation of an infection to other regions of the corpus.

Maquet Cardiopulmonary has not received any complaints or reports of adverse events due to damage to the sterile barrier system of tight caps by above mentioned products.

Corrective Action:

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

Due to the fact that no replacement products are available, please consider:

- If the package containing the tight caps is not opened and discarded and the tight caps are not needed, e.g. if gravity venous drainage is favored instead of vacuum assisted venous drainage (VAVD) or no vacuum assisted wound drainage is required based on Clinical expertise and judgement, the products can be safely used.

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 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 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.

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Sincerely,

Managing Director

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