

Urgent !
Field Safety Notice (FSN)



Version
(Version)
V 01

Gültig ab
(valid from)
See last signature

Page 1 of 4

2019-09-11

FSCA Number: FSCA-2019-09-10

FSCA Title: VHK and VKMO(D) Adult/Small Adult Accessories –Sterile Barrier Integrity

- Affected Product:**
- 701067941 - VKMO 78000 #SQUADROX-i HMO 70000+VHK7000
 - 701067942 - VKMO 70000 #SQUADROX-i HMO 70000+VHK71000
 - 701067948 - BO-VKMO 70000 #SQUADR-i HMO70000+VHK71000
 - 701067949 - VKMO 71000 #SQUADROX-i HMO 71000+VHK71000
 - 701067951 - BO-VKMO 71000 #SQUADR-i HMO71000+VHK71000
 - 701067956 - BE-VKMO 70000 #SQUADR-i HMO70000+VHK71000
 - 701067962 - BO-VKMOD 71000 #SQUADROX-iD 71000+VHK71000
 - 701067966 - VKMO 50000 #SQUADROX-i HMO 50000+VHK71000
 - 701067968 - BO-VKMO 50000 #SQUADR-i HMO50000+VHK71000
 - 701067969 - VKMO 51000 #SQUADROX-i HMO 51000+VHK71000
 - 701063859 - BE-VHK 71000#Venöses Reservoir VHK 71000
 - 701062605 - VHK 71000#Venöses Reservoir VHK 71000

Affected product details:

See attached Annex I

Description of the problem:

Dear valued customers,

During verification testing of Adult/Small Adult VKMOs and VHK a potential impairment of the sterile packaging pouches of the accessories was detected, for products manufactured after March 4th 2019. Under unfavorable transport conditions, excessive movement of the device and its accessories in the carton can lead to stress points that could compromise the sterile barrier of the packaging pouches.

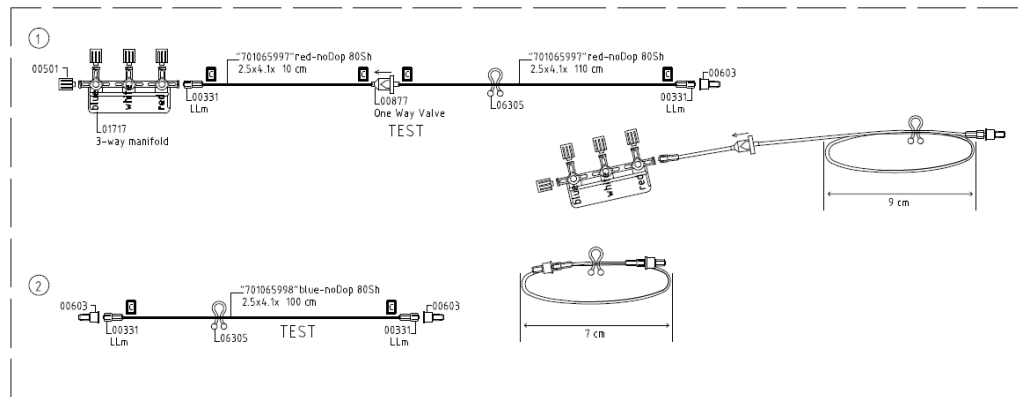
Please note that this relates only to the accessories supplied. No compromised pouches containing the VKMO and VHKs were detected.

Urgent !
Field Safety Notice (FSN)

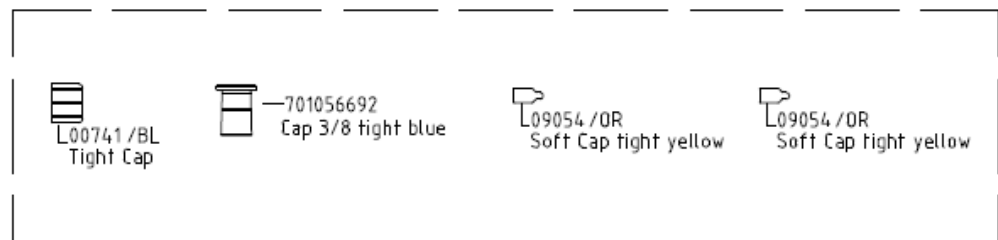
Due to the potential impairment of the sterile packaging pouches of the accessories, **do not use the accessories of VKMO Adult/Small Adult and VHK** within this package or of the affected lot numbers.

The VKMO(D) 70000/71000/78000 and VKMO 50000/51000 is a combination of the venous hard shell reservoir (VHK) and the QUADROX-i Adult/Small Adult.

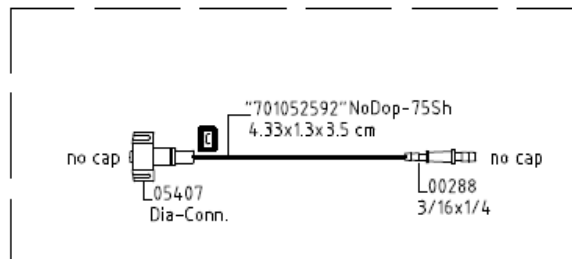
VKMOs and VHKs are supplied with additional accessories packed in separate pouches:



3-way manifold line



Tight caps



Adapter for recirculation line

Urgent !
Field Safety Notice (FSN)



Version
(Version)
V 01

Gültig ab
(valid from)
See last signature

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).

A comprehensive complaint review resulted in no reports concerning the pouch integrity of the accessories and no complaints were received in relation to fever, inflammatory reaction or SIRS as a consequence of using Adult/Small Adult VKMOs or VHK accessories.

Should you not be able to use VKMO Adult/Small Adult and VHK without the supplied accessories or suitable substitutes, please return the affected products to your local Getinge representative for credit.

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

**Corrective
Action:**

- Remove and do not use the **accessories**, 3-way manifold line, Tight caps and Adapter for recirculation line
- In case you do not want to use this product without the accessories, 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 VKMO(D)70000/71000/78000 , VKMO 50000/51000 and VHK 71000, for the specific lots, listed in attached Annex I.
- 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.
- Prior to ordering new VKMOs, please fill out the attached letter "Confirmation of order under consideration of Field Safety Notice of FSCA 2019-09-10"

Urgent !

Field Safety Notice (FSN)



Version
(Version)
V 01

Gültig ab
(valid from)
See last signature

Page 4 of 4

Referenced documents/ attachments:

- Annex I: List of affected products
- Letter of Acknowledgement Customer
- Customer acknowledgement of FSN prior taking order ("Confirmation of order under consideration of Field Safety Notice of FSCA 2019-09-10")

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

Managing Director

Safety Officer

Maquet Cardiopulmonary GmbH
Kehler Str. 31
76437 Rastatt
GERMANY

Governing Procedure: *SV 09.11*

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

Print-outs and copies of this document have to be checked for validity and correctness before use
FB-0076 / V 05 Gültig ab: 2018-06-25

Governing Procedure: *SV 02.03*