2026-07-27

URGENT FIELD SAFETY NOTICE

Manufacturer:	Maquet Cardiopulmonary GmbH (SRN: DE-MF-000020091)
FSCA Reference:	1573818 – PIK – Potentially compromised sterile barrier
FSN Type:	New
Affected Product:	PIK 100#Insertion Kit, Guidewire 100 cm (Mat. 701047384) PIK 100-USA#Insertion Kit Guidewire 100 (Mat. 701053068) PIK 150#Insertion Kit, Guidewire 150 cm (Mat. 701047385) PIK 150-USA#Insertion Kit Guidewire 150 (Mat. 701053069) PIK dilator S# (Mat. 701054606) PIK dilator set L# (Mat. 701054427)
Unique Device Identifier:	04037691519883 04037691730660 04037691519876 04037691730677 04037691746500 04037691746517
Affected Batch No.:	All
For Attention of:	Users of the medical device listed above

Dear valued customer,

The purpose of this letter is to advise you that Maquet Cardiopulmonary GmbH (MCP), a subsidiary of Getinge, is voluntarily recalling the Percutaneous Insertion Kits (PIK) due to a potentially compromised sterile barrier.

The PIK is used for preparing the cannulation of vessels for extracorporeal circulation. Surgical procedures can be performed under visual control or with percutaneous cannulation using the Seldinger technique. The device is available with guidewire lengths of 100 cm and 150 cm.

As accessories to the PIK, there are two sets with additional dilators available: Dilator Set L with larger dual step dilators (18/20, 20/22, 22/24Fr) for a better vessel dilation in the cases where cannulae are in use bigger than 23Fr. Dilator Set S contains a smaller dilator (8/10Fr), dedicated for the insertion of the smaller cannulae like 13Fr.

Problem description

The manufacturer became aware of this issue during retrospective review of historical packaging verification documentation. It was identified that there have been failures in sterile barrier integrity verification testing. As these failures were not previously addressed in accordance with packaging verification requirements, the packaging may not consistently maintain sterile barrier integrity.

Therefore, this FSCA is limited to all products of the PIK line within shelf-life.

Hazardous situation

In course of a Health Hazard Evaluation (HHE), Maquet Cardiopulmonary GmbH determined the following hazardous situations that may arise from a compromised sterile barrier:

- Patients are exposed to pathogens in/on the medical device in direct (or indirect) contact to the vascular system

Potential harm

The possible immediate and/or long-range health consequences and risk levels of the nonconformance include the following (for further information please refer to Annex I):

- Infection

Maquet Cardiopulmonary GmbH has identified two associated customer complaint reports detected during unpacking of the product before clinical use, none report patient harm, serious injuries, or deaths.

Corrective Action:

- Return the affected products to your local Getinge representative

Action to be taken by user:

☒ Identify Device ☒ Quarantine Device
☒ Return Device ☐ Destroy Device

Details on further action(s):

- According to our post-market surveillance documentation, you may have products affected by this action. Please examine your inventory **immediately** to determine, if you have any affected product in your inventory.
- Please quarantine and return immediately all affected products in your stock to your local Getinge representative.
- Upon return of the affected products, please contact your local Getinge representative for credit.
- Products currently in use may continue to be used in accordance with the instructions for use.
- Patients should be monitored in accordance with the care standards at your facility.
- Please **always** report any adverse events, e.g., infections, potentially related to the affected products, to your Getinge representative.
- Regardless of whether you have affected product(s) or not, duly fill out the enclosed Letter of Acknowledgement and return it to your local Getinge representative **as soon as possible, but no later than August 31, 2026,** by mentioning **FSCA-1573818** as reference in the subject line of your mail.

Actions to be taken by the manufacturer:

☒ Product Removal ☐ On-site device modification/ inspection
☐ Software Upgrade ☐ IFU or labeling change
☒ Other ☐ None

- Inform all customers possessing the affected products **promptly** about this Field Action by sending the Field Safety Notice for Customers.
- Upon return of the affected products, provide the customer with credit.

Enclosed documents:

- Letter of Acknowledgment Customer
- Annex I Further information regarding Hazardous situation, Harms and Risk Levels

Transmission of the Field Safety Notice:

- Please ensure in your organization that all users of the above-mentioned products and other persons to be informed are made aware of this Urgent Field Safety Notice.
- Please transfer this notice to other organizations on which the action has an impact.
- If you have given the products to third parties, please forward a copy of this information or inform the contact person indicated below.
- Please maintain awareness on the notice and resulting actions for an appropriate period to ensure effectiveness of the corrective action.

We sincerely 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 Getinge representative.

Sincerely,

Vice President

Signature:

Email:

Person Responsible for Regulatory Compliance (PRRC)

Signature:

Email:



Contact details of manufacturer
Maquet Cardiopulmonary GmbH
Kehler Str. 31
76437 Rastatt
GERMANY
Phone: +49 7222 932 - 0
Email: FSCA.cp@getinge.com

CUSTOMER RESPONSE FORM

FSCA Reference:	1573818 – PIK – Potentially compromised sterile barrier
Affected Product:	PIK 100#Insertion Kit, Guidewire 100 cm (Mat. 701047384) PIK 100-USA#Insertion Kit Guidewire 100 (Mat. 701053068) PIK 150#Insertion Kit, Guidewire 150 cm (Mat. 701047385) PIK 150-USA#Insertion Kit Guidewire 150 (Mat. 701053069) PIK dilator S# (Mat. 701054606) PIK dilator set L# (Mat. 701054427)
Affected Batch No.:	All

Please send this form at the latest by **August 31, 2026**, to your local Getinge representative.

By completing this document and signing it, I acknowledge that I have read and understand the following associated points:

- I have read and understand this Field Safety Notice. We will take action as soon as possible according to given instructions.
- I confirm that I have distributed this Field Safety Notice to the affected personnel.

☐ All affected products have been consumed.

☐ Following affected products will be returned to you for credit or replacement:

Article Number	Description	Lot Number	Quantity
XXXXX.XXXX	<SAP Product name>		

Your Comments:

Country

Hospital / Clinic (full address)

Date

Name (Function)

Signature

Please return the completed form to your local Getinge representative by email enter local Getinge mail address or via post enter local Getinge address or FAX>:

Annex I Further information regarding Hazardous situation, Harms and Risk Levels

This Annex I Further information regarding Hazardous situation, Harms and Risk Levels is considered as a supplementary attachment to the 1573818 Field Safety Notice.

Hazardous situation	Harm	S from Medical	P from above	Risk		
				Low	Med	High
Patients are exposed to pathogens in/on the medical device in direct (or indirect) contact to the vascular system	Minor infection	2	5	☐	☒	☐
	Major infection	3	4	☐	☒	☐
	Serious infection	4	3	☐	☒	☐

Severity Definitions:
Negligible (1) Inconvenience or temporary discomfort of patient, user or third party. No medical intervention or follow-up treatment is required
Low (2) Temporary injury or disability of patients, users or third parties. No medical intervention or follow up treatment is required.
Critical (3) Temporary injury or disability of patients, users or third parties. Medical intervention or follow-up treatment is required.
Catastrophic (4) Permanent injury or disability (e.g., loss of a body part), a life-threatening situation or death of patients, users or third parties

Probability Definitions:
Improbable (1) Harm is not likely.
Remote (2) Harm occurs infrequently
Occasional (3) Harm may occur occasionally / intermittent
Probable (4) Harm may occur often
Frequent (5) Harm will occur repeatedly