JOLINE GmbH & Co. KG • Neue Rottenburger Str. 50 • D-72379 Hechingen

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Urgent Field Safety Notice

Voluntary product recall

concerning

High Flow Double Lumen ST Catheter 13 Fr

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FSCA-No.: 01-2025

Hechingen, 2025-03-19

Joline GmbH & Co. KG is voluntarily recalling the following batches of the product “High Flow Double Lumen ST Catheter 13 Fr” as a field safety corrective action (FSCA):

Affected medical devices:

REF	Lot	UDI
PKHF13PH150	514993	(01)04250203929530(17)280228(10)514993
PKHF13PH150	514994	(01)04250203929530(17)280228(10)514994
PKHF13PH150R	514995	(01)04250203929547(17)280228(10)514995

Description of the problem:

During internal quality controls, it was determined that there may be deviations in the behavior of the catheter material and that in very unfavorable constellations it is possible that a part of the “shotgun” tip of the catheter may tear off or partially tear off when bent strongly.
Particularly when the catheter is implanted via the left jugular vein into the Vena cava superior or into the right atrium of the heart, there is an increased risk that the “shotgun” tip of the catheter will be severely bent due to the prevailing anatomical conditions and may tear. Intraoperative and/or final imaging may not be able to detect such a tear or other changes to the catheter tip during or at the end of the procedure (e.g. if the catheter shaft is tight against the vessel wall).
In the case of a slight tear, increased mechanical hemolysis may occur at this point. In the event of increased tearing, it cannot be ruled out that the tip may tear off completely, especially with increasing length of stay, leading to a foreign body embolism with subsequent surgical intervention.
Through due diligence, Joline was able to inform all affected distributors quickly, so that at the time of this report no products left the distributors warehouse and subsequently no patients had been implanted with an affected catheter.

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Actions to be taken by the distributor:

Please ensure in your organization that all users of the above mentioned products and other persons to be informed are aware of this Urgent Filed Safety Notice.

Locate all affected products in your warehouse and quarantine them. Joline's Customer Service will support you in removing the affected products from your organization.

Please complete the FSCA customer response form on page 3 immediately due to the time-critical measure and send it by FAX to +49 7471 9881 111 or by e-mail to JL_complaint@joline.de.

Please keep this information at least until the measure has been completed.

The Federal Institute for Drugs and Medical Devices (BfArM) of Germany has received a copy of this letter. The corresponding local competent authority in your country will be informed by them.

Contact person:

Dr. Marian Wenzel will answer any questions you may have:

Phone: +49 7471 9881 162 or by E-Mail: marian.wenzel@joline.de

We regret the inconvenience this will cause you and ask for your understanding and cooperation in the interest of patient safety.

Thank you for your support,

JOLINE GmbH & Co. KG • Neue Rottenburger Str. 50 • D-72379 Hechingen

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Customer response form

FSCA-No. 01-2025

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Please read this appendix carefully together with the Urgent Safety Notice FSCA No. 01-2025 and return the completed and signed customer response form as soon as possible, at the latest by 31.03.2025, to

FAX: +49 7471 9881 111 or email: JL_complaint@joline.de

Please fill in the following table accordingly:

Affected Batch No.	**Number of secured and returned products**

By signing below, you confirm that you have read and understood this notice in full and that all recommended measures have been implemented as required.

Name and address of the facility	
Name	
Function	
Contact data (phone / email)	
Date	
Signature	