UROMED
PRODUKTE FÜR DIE UROLOGIE

UROMED Kurt Drews KG
Adress

Ihr Zeichen	Unser Zeichen	Durchwahl 040 / 713 007	Datum
		-0	22.09.2025

Field Safety Corrective Action

Recall

UROMED Silicone Balloon Catheter "INTEGRAL"

UROMED >>PROSIL<< DBK COUVELAIRE

UROMED-SUPRA-KATH-"INTEGRAL"

Identification of affected medical devices:

REF	Product name / description	LOT-Number
1110.16	UROMED Silicone Balloon Catheter "INTEGRAL"	D25040137
2170.18	UROMED >>PROSIL<< DBK COUVELAIRE	D25050709
2170.20	UROMED >>PROSIL<< DBK COUVELAIRE	D25041717
2955.20	UROMED-SUPRA-KATH-"INTEGRAL"	D25050638

Dear Sir or Madam,

We hereby send you the following Field Safety Corrective Action to inform you about a recall and measures to be taken.

Description of the problem including the identified cause

Within our quality controls, it was determined that for the above-mentioned products, the seal strength of individual sterile packages does not meet the required specifications and may therefore be insufficient.

Therefore, unintentional opening of the sterile packaging prior to use may occur, which may not ensure maintenance of sterility over the shelf life period indicated on the products.

Due to this risk, we have decided, in the interest of patient safety, to recall the above-mentioned products with the listed lot numbers.

We assume that there is no risk and no reason for additional medical follow-up for patients who have already been successfully treated with the products.

The affected seal seam is the side opposite the peel tab.

Measures to be taken

Please check your inventory to see if you have any products of the above item and lot numbers and sort them out to ensure that the products are not used. If there are still products in your inventory, please destroy them.

For the documentation of the field safety corrective action / the recall, we would also like to ask you to fill out the enclosed attachment for the response regarding the whereabouts of the products and return it to us by 17.10.2025 by e-mail to [redacted], [redacted] or by mail.

Disclosure of the information

Please ensure that all users of the above products in your organization and other persons to be informed are made aware of this field safety corrective action / recall. If you have passed products on to third parties, please forward a copy of this information or inform the contact person indicated below.

Please keep this information at least until the action has been completed at your site.

The competent authorities in the countries of distribution as well as the Federal Institute for Drugs and Medical Devices (BfArM) and our Notified Body have been informed about the safety corrective action in the field / the recall.

Contact person of the company UROMED Kurt Drews KG

[redacted]

We are convinced that we have acted transparently and consistently in your interest and apologize for any inconvenience. We thank you in advance for your attention and support regarding the measures to be taken.

Please do not hesitate to contact us if you have any further questions or require further information.

We sincerely thank you for your understanding and cooperation.

Yours sincerely

UROMED Kurt Drews KG

Enclosure: Response about the whereabouts of the products

Adress

UROMED Kurt Drews KG

Field Safety Corrective Action

Reply about the whereabouts of the products

1110.16	UROMED Silicone Balloon Catheter "INTEGRAL"	D25040137
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☐ The stock has been checked and there are none of the affected products in the warehouse.

☐ The inventory has been checked and all remaining affected products have been destroyed:

REF 1110.16	LOT D25040137	_____ pcs.
REF 2170.18	LOT D25050709	_____ pcs
REF 2170.20	LOT D25041717	_____ pcs
REF 2955.20	LOT D25050638	_____ pcs

Place Date Signature / practice stamp, if applicable

For necessary replacement deliveries or credit notes, please contact our customer service representatives in the office or in the field.