Address

-0 14.04.2022

Field Safety Corrective Action

Recall

UROMED-Einmal-Nelaton-Katheter

UROMED-Einmal-Tiemann-Katheter

Identification of affected medical devices:

REF	Product name	LOT Number
3595.10	UROMED-Einmal-Tiemann-Katheter	405.903
3595.14		548.908
3595.16		059.802
3595.18		547.908
3595.22		505.907
3595.06	UROMED-Einmal-Nelaton-Katheter	546.908
3565.12		698.912
3565.16		678.911
3565.22		682.912

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 of individual sterile packages does not meet the required specifications and may therefore be insufficient.

Therefore, there is a possibility that sterile packages are not completely sealed, so that sterility of the products cannot ensured.

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.

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 the above-mentioned products are in your inventory, please destroy them immediately.

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 **29.04.2022** by e-mail to **vigilanz@uromed.de**, fax to +49 40 71 30 07-99 or by post.

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 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

Janina Rumker / Rainer Klatt
Person responsible for regulatory compliance in accordance with Regulation (EU) 2017/745
Meessen 7/11
22113 Oststeinbek
Phone: +49 (0) 40/ 713-007-0
Fax: +49 (0) 40/ 713-007-99
E-mail: **vigilanz@uromed.de**

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
Meessen 7 / 11
D-22113 Oststeinbek

Field Safety Corrective Action

Reply about the whereabouts of the products

REF 3595.10 / 14 / 16 / 18 / 22	UROMED-Einmal-Tiemann-Katheter
REF 3565.06 / 12 / 16 / 22	UROMED-Einmal-Nelaton-Katheter

☐ The stock has been checked and there are none of the affected products in the warehouse.

☐ The inventory has been checked and the following affected products have been destroyed:

REF number	LOT number	Quantity destroyed
REF 3595.10	LOT 405.903	_____Pcs.
REF 3595.14	LOT 548.908	_____Pcs.
REF 3595.16	LOT 059.802	_____Pcs.
REF 3595.18	LOT 547.908	_____Pcs.
REF 3595.22	LOT 505.907	_____Pcs.
REF 3565.06	LOT 546.908	_____Pcs.
REF 3565.12	LOT 698.912	_____Pcs.
REF 3565.16	LOT 678.911	_____Pcs.
REF 3565.22	LOT 682.912	_____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.