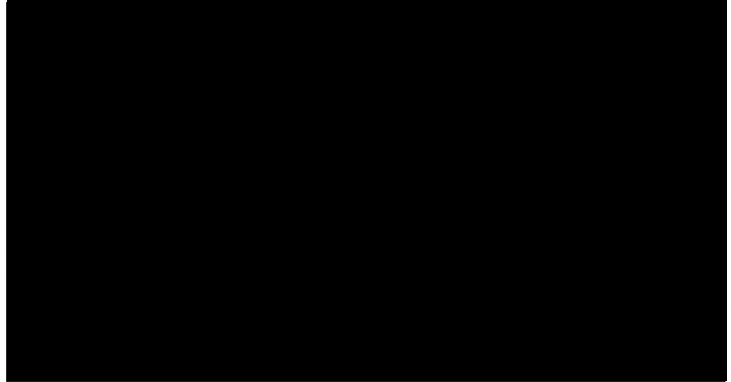


Cover letter for patient delivery



08.08.19

Recall – Important Safety Information

Dear Ladies and Gentleman,

As a quality supplier of urological products and auxiliary devices for the discharge incontinence care, patient safety and the reliability of our products are our top priorities. Therefore a transparent and open communication with you as the user is important for us. **Please forward this letter to the person who will change your catheter.** This ensures that the next catheter change can be performed correctly.

Description of the problem including the identified cause:

Today we would like to send you urgent safety information for urine collection trays (disposable kidney trays). These cardboard urine collection trays are part of several UROMED catheterisation kits. These sets are used when changing catheters, so sterile components are required to ensure patient safety. The supplier of the urine collection trays mentioned above has now informed us that irregularities occurred during the inspection of such sterile sets and that non-sterile urine collection trays were found.

This anomaly can cause recontamination of other components and medical devices used when using an affected set with an unsterile urine collection tray, leading to possible infection of patients.

The products concerned also include urinary drainage systems, since the catheterisation sets are part of the sets there. However, in the case of urinary drainage systems, only the **UROMED basic component** contained in the catheterisation kit is affected, but not the individually packaged sterile urine drainage systems and catheters. Furthermore, the Octenisept, the catheter sliding gel and the UROMED filling medium in the set can be used without any reservations.

In order to exclude the risk for you and your patients, we feel obliged to stop the distribution of the affected catheterisation kits and to recall the products still on the market as long as the anomalies and thus the risk cannot be excluded. This is a preventive measure in order not to endanger patient safety when using the products concerned.

For patients who have already been successfully treated with these products, there is no danger and no need for additional aftercare.

Affected medical devices:

- UROMED CATHETERIZATION KIT: REF 1560
 - **Affected components: Complete Set**
- UROMED CATHETERIZATION SET »PLUS«: REF 1565
 - **Affected component: UROMED base component included in the set**
- UROMED CATHETERIZATION SET »SILKA«: REF 1566
 - **Affected component: UROMED base component included in the set**
- UROMED CATHETERIZATION SET »BASIS«: REF 1567
 - **Affected component: UROMED base component included in the set**
- CYSTOBAG® urine drainage system:
 - REF 1144, 1145, 1146, 1147, 1148, 1149, 1150, 1151, 1152, 1155
 - **Affected component: UROMED base component contained in REF 1566 catheterization kit**
- FLUXOBAG® urine drainage system:
 - REF 1160
 - **Affected component: UROMED base component contained in REF 1567 catheterization kit**

Which measures have to be taken by the user?

Please check if you have products with the above article numbers. If this is the case, please stop using **only the affected component** immediately, so that further use of this component can be ruled out. If there are still affected products in your stock, please have them ready for collection.

Please inform us on the enclosed reply form **by 16.08.2019** of the available stocks so that we can arrange for a credit note to be issued. The form can be sent by fax to **the following number, +49 40/; 713 007 - 99**, or by **e-mail to the following address: service@uromed.de**

If you have any questions regarding the security information, please call our service team telephone number: **+49 40-713007-11**

The information described is passed on:

The Bundesinstitut für Arzneimittel und Medizinprodukte (BfArM) is informed about the procedure described here. Due to the regulations of the BfArM, we are bound by certain deadlines; we ask you to therefore, the form in the attachment as indicated within **one week until 16.08.2019** to us so that we can complete the complete corrective action as quickly as possible.

Please make sure that all users of the mentioned products and other information to be provided persons will be informed of this corrective measure. If you transfer the products to third parties please forward a copy of this information or contact the person listed below.

Please retain this information until the corrective action has been taken and the products can be marketed again.

We are convinced that in your interest we have acted in a transparent and consistent manner and ask you to apologize for the inconvenience caused.

We thank you in advance for the measures to be taken.

For further questions and information please do not hesitate to contact us.

Kind/Regards

