

Urgent Field Safety Notice (FSN)
Product recall concerning:
UROMED catheterisation kit

Manufacturer:

UROMED Kurt Drews KG
Meessen 7/11
22113 Oststeinbek
Germany

Addressee:

Customers who have been supplied with the products listed below

Identification of the medical devices concerned:

UROMED catheterisation kit
REF No.: 1560 All lot numbers with valid expiration date

Description of the problem including identified cause:

Ladies and Gentlemen,

Based on the information available to us, the sterilisability of the cardboard kidney trays contained in the above mentioned catheterisation kit with REF No. 1560 cannot be guaranteed. The sets are therefore not sterile and may not be used.

Because of this risk and in the interest of patient safety we have decided to recall all products with the above reference number. This letter aims to inform you about the recall.

Which measures have to be taken by the addressee?

Please check if you have products with the above REF number and block them so that further use is excluded. If there are still products in your stock please report them back to us. We will immediately take care of collection.

Other measures (if applicable):

For documentation purposes we would also ask you to complete the attached form (see appendix) and send it back to us within one week by fax (+49 (0) 40/713-007-99) or email (service@uromed.de)

Passing on the information described here:

Please ensure in your organization that all users of the above product and other persons to be informed are aware of this urgent safety information. If you have provided products to third parties, please forward a copy of this information or contact the person listed below.

Please keep this information at least until the action has been completed by the manufacturer.

The Federal Institute for Drugs and Medical Devices, (BfArM), Germany, has a copy of this "Urgent Field Safety Notice".

Contact person of the company UROMED Kurt Drews KG:

Frank Venzke
Safety Officer according to MPG §30 (German Medical Device Law)
Meessen 7/11
22113 Oststeinbek

Phone: +49 (0) 40/ 713-007-0
Fax: +49 (0) 40/ 713-007-99
E-Mail: vigilanz@uromed.de

o thank you for your understanding and cooperation.

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Appendix:
Response form