

UROMED Kurt Drews GmbH · Meessen 7/11 · D-22113 Oststeinbek



Ihr Zeichen

Ihre Nachricht

Unser Zeichen
kn/ru

Durchwahl 040 / 713 007 -
-31

Datum

Oststeinbek, Oktober 2010

Corrective Actions concerning UROMED Silicone-Balloon-catheter »SOFT« REF 1095

Dear Customer,

UROMED Kurt Drews GmbH would like to inform you about corrective actions that have to be effected concerning **UROMED Silicone-Balloon-Catheter »SOFT« REF 1095** and kindly ask for your support:

Products concerned:

REF 1095: all models with following LOT:
100511 100602 100709

Malfunction:

After an intensive analysis of this product we unfortunately had to find out that the integrated catheter plug might break upon removal and the tip remains inside the funnel as a result.

All articles that are on stock have already been examined and we were able to identify one specific LOT number of catheter plugs for the problematic reason. The defective product has been placed at disposal.

The end user will recognize the defect at once upon first use or exchange of the silicone balloon catheter. Due to a broken catheter plug it is obviously visible respectively no urine flows, there is no influence on the health of the patient.

But we would like to avoid extra burden due to the removal of the broken plug from the funnel.

Therefore we kindly ask you to give us your support upon effecting the corrective actions as follows:

Corrective Actions:

Preventatively we recall all **UROMED Silicone-Balloon-Catheter »SOFT« REF 1095** with the LOT number in concern i.e. please send back the corresponding products and we will perform an intensive examination of each single article. The products concerned have been delivered from the beginning of June 2010 until middle of September 2010.

Another possibility we offer is to remove and throw away the defective plug before application of the catheter. Upon request we will send you new catheter plugs REF 1510 free of charge separately.

Please inform us per attached response form about your warehouse stock and the further proceeding you would prefer until 11th October 2010.

Kindly return the defective products on our expense.

Page - 2 - Corrective Actions concerning UROMED Silicone-Balloon-Catheter »SOFT« REF 1095

Evidence of corrective actions:

The corrective actions have to be done until 29th October 2010.

Please ensure that all end users of the products concerned and other people of interest have been informed about this corrective actions.

If products have been sold to third parties kindly forward a copy of this information letter or contact the below stated contact person.

The Federal Institute for Drugs and Medical Devices (BfArM in Germany) has been informed about the proceedings herein mentioned.

As a supplier for urological products the safety of the patients and reliability of our products are our most important concerns.

We are convinced that we have acted in your interest transparently and consequently and kindly ask to accept our apologies for the inconvenience caused.

Thank you very much in advance for your attention concerning the arrangements to be effected.

In case of questions or if you require further information please do not hesitate to contact:
UROMED Kurt Drews GmbH, Meessen 7/11, 22113 Oststeinbek, Tel. 0049 40 713007-0.

With best regards,

UROMED Kurt Drews GmbH



Director Research and Development



Safety officer for medical devices

Enclosure

UROMED Corrective Actions REF 1095



Sender:

Customer:.....

Address:

Contact Person:

Tel. / E-Mail:

Product Description: Silicone-Balloon-Catheter REF 1095

| Stock : | Ch.: | Pieces: |
|-----------------|-------|---------|
| LOT-No.: 100511 | | |
| LOT-No.: 100602 | | |
| LOT-No.: 100709 | | |

No Stock (please tick)

Further steps:

- We will return the corresponding products. Please send exchange delivery.
- We will exchange the catheter plugs independently
 - We have adequate stock amount of catheter plugs.
 - Please send piece(s) catheter plugs free of charge.

Signature/Stamp/Date

Please return this form until 11.10.2010 to

UROMED: Fax +49 40 713 007-99