

Urotech GmbH, Medi-Globe-Str. 1-5, 83101 Rohrdorf / Achenmühle, Germany

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20.07.2021

Urgent safety information

Recall concerning

TU-570828 *Yellow Star Double-J Tumour Stent*
TU-360828 *Yellow Star Double-J Tumour Stent Set*
(Please remove any that do not apply!)

Dear Ladies and Gentlemen,

With this letter we would like to inform you about a recall of our product
TU-570828 / TU-360828 (please remove where not applicable!) and ask you to take note:

Identification of the medical devices concerned:

| Article number (REF.) | Batch number (LOT.) | Quantity |
|--------------------------|------------------------|----------------|
| TU-570828 | G2022128 | Enter quantity |
| TU-570828 | G2020574 | Enter quantity |
| TU-360828 | G2021763 | Enter quantity |
| TU-360828 | G2022859 | Enter quantity |

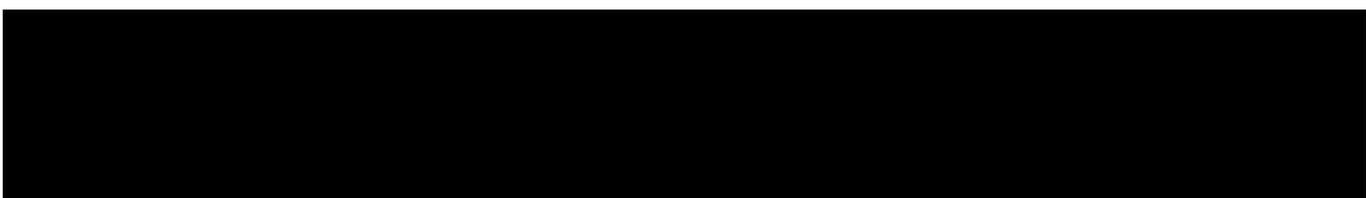
Please only enter the articles and quantities that the respective customer has also received!
Please remove any that do not apply!

Description of the problem:

We were informed of an incident in the market that in a single application of our ureteral stent >5 days after insertion into the patient of the stent, the renal pigtail spontaneously detached from the shaft. The renal pigtail remained in the kidney. The shaft including the bladder-side pigtail slipped out of the ureter into the bladder.

The problem at hand is due to a defective welded joint between the pigtail and the shaft.
Although the results of the investigation so far show that this is a singular event, we are conducting a voluntary recall for the potentially affected batches

Patient risk & recommendation for further action:



Spontaneous failure / fragmentation of the ureteral stent after insertion and positive position control may result in initially unnoticed renal urinary retention with the need for subsequent surgical or endoscopic removal of the components. This possible complication is described in the instructions for use.

For patients who have received a ureteral stent from the affected batch numbers, we recommend as a precautionary measure a close-meshed, symptom-related sonographic control until the regular removal, whether a renal urinary stasis is present. Furthermore, we recommend a regular position check according to the instructions for use.

What measures are to be taken by the addressee?

Upon tracing, we have determined that you have received affected products.
For this reason, we ask you for the following support:

1. please check if you still have products in stock from the above batch numbers (LOT).
2. Set the use of all affected lot numbers (LOT) in your possession.
3. Separate the batch numbers concerned (LOT) to avoid unauthorised access.
4. forward this "**Urgent Safety Information**" to all persons in your institution who need to be informed. If you have passed on the product, please identify the facilities/departments concerned and forward this notification to them immediately.

Please keep this information at least until the measure has been completed. The Federal Institute for Drugs and Medical Devices has received a copy of this "**Urgent Safety Information**".

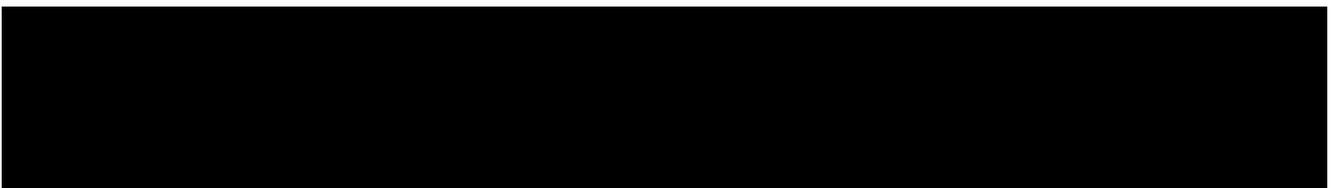
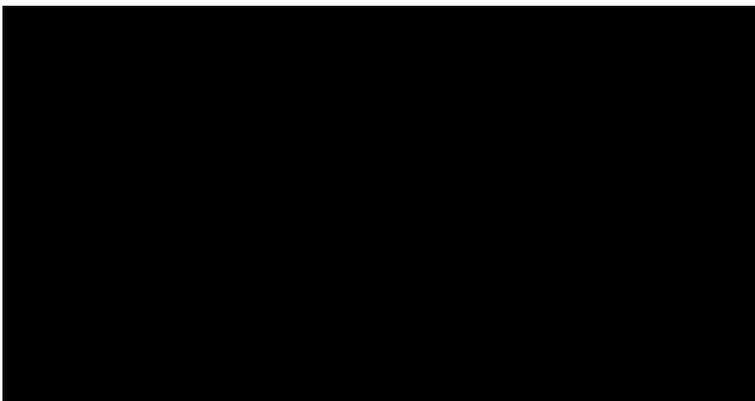
5. Please complete the attached **reply form** and return it by fax or email **immediately, but no later than 05.08.2021**, in order to be able to offer you an alternative as quickly as possible or to coordinate the return shipment of the affected items.

Please do not hesitate to contact us if you have any questions.

Contact person at the company Urotech:

Lisa Winter
Medi-Globe-Str. 1-5
D-83101 Achenmühle

Tel / Fax / Email etc.



Reply form
FAX number for reply +49 (0)8032 973 41 1
or by e-mail to Kundenservice@urotech.com

Product recall Yellow Star Double-J tumour stent

- We have the following number of affected products in stock:
 (Please do not continue to use products and return them to UROTECH!)

| Article number | LOT | Number |
|----------------|-----------------|--------|
| TU-570828 | G2022128 | |
| TU-570828 | G2020574 | |
| TU-360828 | G2021763 | |
| TU-360828 | G2022859 | |

Please only enter the articles and batches that the respective customer has also received!
Please remove any that do not apply!

- We do **not** have **any** affected product in our inventory.

Sender:

Contact person:

Tel. no.

Remark:

 Date:

 Signature / Function



Please proceed as follows:

1. **Complete the reply form in full, even if you no longer have any products in stock.**
2. **Please fax the completed reply form to the following fax number: +49 (0)8032 973 41 1 or to the following e-mail address: *Kundenservice@urotech.com***

Please shorten to 1 page if possible!