

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

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

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27.09.2021

Urgent safety information

Recall concerning

MR-414815 Magnetic Black Star (Batch Number G2014010)

Dear Ladies and Gentlemen,

With this letter we would like to inform you about a recall of our product **MR-414815** and ask you to take note:

Identification of the medical devices concerned:

Article number (REF.)	Batch number (LOT.)	Quantity
MR-414815	G2014010	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 that the affected batch had a stent length 5 cm longer than specified. The test results so far show that only the batch listed is affected. The internal risk assessments show that there are no increased risks to patient care.

Since, according to current knowledge, the entire batch is affected, we are conducting a voluntary recall of this batch.

Patient risk & recommendation for further action:

The ureteral stent length of +5 cm is within the range of common stent length variants. The affected batch has a specified length of 15 cm. There are variants of the affected product with specified lengths from 10 to 26 cm. Since the user can only estimate the necessary length of a ureteral stent prior to placement in the patient, a position check is always indicated after placement. Choosing a stent that is too long may result in a larger protrusion of the stent into the bladder. This has no influence on the functionality of the stent. It may have an impact on patient comfort.

Managing Director: Christian Klein, Martin Lehner

Commercial Register/Registration: HRB 12518 Local Court Traunstein

Hypo Vereinsbank, Rosenheim

DZ Bank AG, Munich

IBAN: DE 67 7112 0077 0021 9404 70

IBAN: DE 22 7016 0000 0000 1438 62

VAT ID No.: DE129359282

BIC (SWIFT): HYVEDEMM448

BIC (SWIFT): GENODEFF701

For patients who have received a ureteral stent from the affected batch number, 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 email **immediately, but no later than 12.10.2021**, 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:

Beate Ragg
Medi-Globe-Str. 1-5
D-83101 Achenmühle

Tel.: 08032 973 337
Email: export@urotech.com

With kind regards



Dr Markus Schönberger, PRRC

Reply form
via e-mail to export@urotech.com

Product recall MR-414818 G2014010

☐ 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
MR-414815	G2014010	

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 send the completed reply form to the following e-mail address: export@urotech.com

Please shorten to 1 page if possible!

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