
Urgent Safety Information

Recall concerning

Guide Wire Semislip UAS-35150-SS

Achenmühle, 12. September 2014

Vendor:

Urotech GmbH
Medi-Globe-Strasse 1 – 5
83101 Achenmühle
Germany

Addressee:

User of below mentioned medical products

Klinik, Praxis
Adresse
Ggf Postfach

PLZ Ort

Dear Sir or Madam,

kindly note that we need to recall our product UAS-35150-SS:

Identification of relevant items:

LOT: C14-0625
14-yyyy

Quantity:

Description of problem including investigated cause:

Problem:

The Pebax-component on wire tip may partly loosen during application in ureteric urethral genitalia and stay in human body.

Cause:

Parts of Pebax-component can loosen on distal end when bending the wire sharply.

If surgery takes place without loosening parts of Pebax-component on wire there is no risk for patient.

What measures need to be achieved by addressee?

We kindly ask you to inform us using attached document how many of above items with relevant batch number you have not yet used. Please send back these goods along with the filled in document. As far as possible we ask you the check already used wires for completeness.

Please make sure that all relevant persons get to know of this urgent security information.

In case you've handed over above items to a third party please make sure to forward them this information and inform below mentioned contact person.

The authorities for drugs and medical items received a copy of this urgent security information.

Contact person at Urotech:

Patrick Leuschke
Medi-Globe-Strasse 1 – 5

83101 Achenmühle

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or

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E-Mail: a.eberl@urotech.com

Kind regards,

Patrick Leuschke

Angelika Eberl-Spicker