
Urgent Safety Information

Recall concerning

Guide Wire Semislip UAS-35150-S

Achenmühle, 21.November 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-S:

Identification of relevant items:

LOT: C14-0625
14-0448

Quantity:

Description of problem including investigated cause:

Problem:

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

Cause:

The Pebax-tip or parts of Pebax-component may loosen on distal end, when it is pushed or pulled over sharp edges or metal objects.

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

Tel.: 0049 8032 973-425

Fax: 0049 8032-973-241

E-Mail: Patrick.leuschke@urovision.de

Kind regards,

Patrick Leuschke

Customer response form

FAX Number to reply 0049 8032-973-241

Recall for Urotech Guide wire

Item number	UAS-35150-S
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LOT:	

Following products are in our storage:
(Don't use the products, return them to Urotech please!)

Item number	LOT	Quantity
UAS-35150-S		

No products in our storage.

Vendor:

Person
responding:

Tel. No.

Remarks:

Please follow the procedure:

- 1. Please fill in this form completely, even if you have no more products in stock.**
- 2. Please send the filled form to Fax No.: +49 (0)8032-973-241**

date:

Signature / function

Please fax this form as quickly as possible