
Urgent Safety Information

Recall concerning

Guide Wire Semislip UAS-35150-S / UAS-35150-N

Achenmühle, 29. November 2016

Vendor:

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

Addressee:

User of below mentioned medical products

Distributor

Address

Post-Code City

Country

Dear Sir or Madam,

kindly note that we need to recall our product UAS-35150-S / UAS-35150-N

Identification of relevant items:

UAS-35150-N

LOT:

Quantity:

UAS-35150-S

LOT:

Quantity:

Description of problem including investigated cause:

Because of a lack in strength of the material, it could happen that the hydrophilic-coated Pebax tip gets loose from the core of the Guidewire. In this case, some fragments of the tip of the Guidewire could get loose and stay in the body of the patient. This would have another surgery required to remove the parts of the Guidewire from the body.

This problem occurred only once, but for the products described above it could be that some of the Guidewires from this batch could have the same problem and that parts of the tip could get loose in the body while manipulation and strong bending of the Guidewire in the body.

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 8032-973-394
or Email: Complaints@medi-globe.de

Recall for Urotech Guide wire

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

Item number	LOT	Quantity
UAS-35150-S		
UAS-35150-N		

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)8032-973-394 or
Email:Complaints@medi-globe.de**

date:

Signature / function

Please send this form as quickly as possible