PETER BREHM GmbH • Am Mühlberg 30 • 91085 Weisendorf • Germany

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Urgent safety notice for users

Notification of a voluntary product recall

Dear Customers,

the company PETER BREHM GmbH is carrying out a voluntary product recall of one batch number of "Titanium Flat-head Spongiosa screw Ø 6,5 x 40 mm" implants.
According to our documentation, you have been supplied with at least one of the affected products.

The competent authority has been informed of this corrective action. Please read the following detailed information carefully and follow the procedure described therein.

Please return the filled out fax reply for our documentation of this process by 22.12.2020.

Finally, we would like to apologize for the inconvenience and thank you very much for your understanding and cooperation.

With best regards

PETER BREHM GmbH

Claus Windisch
Head of Product Development

Jan Birkholz
Safety Officer Medical Devices

Attachment:
FSCA
Reply Fax

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Field Safety Corrective Action

Notification of a voluntary product recall

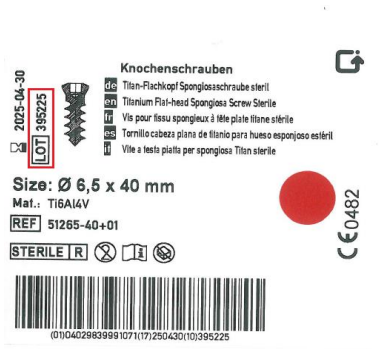
Reference	R-20201002-5

Affected products

Article Number	Designation	LOT
51265-40+01	Titanium Flat-head Spongiosa screw Ø 6,5 x 40 mm	395225

Description of situation

Due to a complaint out of the field, it is known that a Titanium Flat-head Spongiosa screw Ø 6,5 with a length of 30 mm was inadvertently included in the packaging of a Titanium Flat-head Spongiosa screw Ø 6,5 with a length of 40 mm.
As a precautionary measure, PETER BREHM GmbH has decided to recall all products of the affected batch of the Titanium Flat-head Spongiosa screw Ø 6,5 x 40 mm from the field.



The Titanium Flat-head Spongiosa screw Ø 6,5 x 40 mm; Article number: 51265-40+01 with the **LOT: 395225** is recalled (picture).

Clinical effects

In case of that the incorrectly packed Titanium Flat-head Spongiosa screw being identified intraoperatively due to its shorter length, it will result in an operating time extension of < 30 minutes. An intraoperative system change or abortion of the operation can be ruled out, as each screw length is available several times in loan shipments and consignment stores, so that a replacement product is available.

If the surgeon does not identify the wrong screw length, soft tissue irritation or injury to vessels and nerves can be ruled out. The reason for this is the length, which is shorter compared to the required screw length, and thus bicortical protrusion can be excluded.

The risk of revision surgery due to loosening of the implant can also be excluded, as the surgeon can clearly assess the mechanical stability of the restoration by screwing it in and the torque required for this.

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Measures to be implemented

- Please ensure that this safety information is brought to the attention of all the users of the products mentioned above as well as all other persons who are to be informed in your organization.
- Please check your stocks immediately and ensure that the affected products are no longer used.
- Please return all the affected products to the following address. You will receive a free replacement immediately afterwards.

  PETER BREHM GmbH
  Reklamationsmanagement
  Am Mühlberg 30
  D-91085 Weisendorf

- Please return the enclosed fax response to us within 5 workdays for documentation of this Safety Information, even if you do not have any of the listed products on stock. This measure ensures that we do not unnecessarily send you any further messages about this topic.
- If you have any further questions on this measure or on substitute products, please contact the sales agent who is responsible for you.

Contacts

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