Urgent Field Safety Notice

Pedicle Screw - icotec ag

2017-10-11

Sender
icotec ag, Industriestrasse 12, 9450 Altstätten, Switzerland

To the attention of
Operating Room Manager, user of the icotec Pedicle System

PLEASE DISTRIBUTE THIS INFORMATION TO THE APPROPRIATE PERSONNEL AT YOUR FACILITY WHO MAY USE THE PRODUCT WHICH IS THE SUBJECT OF THIS NOTICE

Dear Sir/Madam,

icotec has initiated a Field Safety Corrective Action for certain sizes of the icotec Carbon/PEEK Pedicle Screws. Our records indicate that you may have inventory that is impacted by this Field Safety Notice.

1. Identification of the affected product

<table>
<thead>
<tr>
<th>REF No.</th>
<th>Product</th>
<th>LOT No.</th>
</tr>
</thead>
<tbody>
<tr>
<td>16-5721-57535</td>
<td>icotec Carbon/PEEK Pedicle screw, Ø7.5 × 35 mm</td>
<td>14/04</td>
</tr>
<tr>
<td>16-5721-57560</td>
<td>icotec Carbon/PEEK Pedicle screw, Ø7.5 × 60 mm</td>
<td>14/03</td>
</tr>
</tbody>
</table>

2. Reason for this Field Safety Corrective Action

The affected screws were not assembled in accordance with icotec specifications by a contract supplier.

The screw shank of the pedicle screw REF 16-5721-57535 is 60 mm long and contradictory to the 35 mm length indicated on the packaging label.

The screw shaft of the pedicle screw REF 16-5721-57560 is 35 mm long and contradictory to the 60 mm length indicated on the packaging label.

3. Clinical implication

During a surgery, the affected product is easily detectable by surgical staff or the surgeon after un-packaging the implant and when the screw is handed over (35 mm screw shaft length vs. 60 mm screw shaft length).

Upon detection of this subject screw, the screw can be replaced with a correct one. There may be a short delay of the surgery.

If the subject screw is not detected before, the position of the screw/the screw tip can be verified radiologically.
Implantation of a longer than planned screw could lead to damage of vessels or neurological structures. A longer surgical procedure would be required to treat such damages. If a shorter than planned screw will be implanted, there is only a low risk for reduction of construct stability with subsequent pseudoarthrosis, because a short screw is also adequate to provide anchorage in the pedicle. An additional surgical procedure could become necessary. No far icotec is not aware of adverse events related to these subject screws.

4. Action to be taken by the user
Stop using the affected products immediately. Quarantine the products in a manner that ensures the affected products will not be used.

Your icotec representative will contact you shortly to coordinate the return of the affected implants. Please return the completed reply form (attached) to your designated icotec agency/distributor.

5. Transmission of this Field Safety Notice
This notice needs to be distributed to appropriate staff within your organisation or to any organisation where the potentially affected devices have been transferred.

Please maintain a copy of this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action.

icotec has informed the required Regulatory Agencies about this Field Safety Corrective Action.

6. icotec Representative
Should you have any inquiries, please do not hesitate to contact your designated icotec agency/distributor for this action directly:

icotec is committed to distribute only products of the highest quality standards and to provide any required support.

We apologize for any inconvenience that this Field Safety Notice may create and greatly appreciate your attention to this matter.

Sincerely,

Marina Heß
CQO
icotec ag

icotec ag
innovative composite technology
Industriestrasse 12
9450 Altstätten, Switzerland
Telephone +41 71 757 00 00
Telefax +41 71 757 00 01
E-mail info@icotec.ch
Internet www.icotec-medical.com
**Reply Form**

**Urgent Field Safety Notice of 2017-10-11**

**Identification of the affected product**

<table>
<thead>
<tr>
<th>REF-No</th>
<th>Product</th>
<th>LOT-No</th>
<th>Quantity</th>
</tr>
</thead>
<tbody>
<tr>
<td>16-5721-57535</td>
<td>icotec Carbon/PEEK-Pedicle Screw, Ø7.5 × 35 mm</td>
<td>14/04</td>
<td></td>
</tr>
<tr>
<td>16-5721-57560</td>
<td>icotec Carbon/PEEK- Pedicle Screw, Ø7.5 × 60 mm</td>
<td>14/03</td>
<td></td>
</tr>
</tbody>
</table>

Please complete and return this form to your designated icotec agency/distributor:

- □ in our facility we do not have any of the affected products in stock.
- □ we have the identified products in stock:

<table>
<thead>
<tr>
<th>REF-No</th>
<th>Product</th>
<th>LOT-No</th>
<th>Quantity</th>
</tr>
</thead>
<tbody>
<tr>
<td>16-5721-57535</td>
<td>icotec Carbon/PEEK-Pedicle Screw, Ø7.5 × 35 mm</td>
<td>14/04</td>
<td></td>
</tr>
<tr>
<td>16-5721-57560</td>
<td>icotec Carbon/PEEK- Pedicle Screw, Ø7.5 × 60 mm</td>
<td>14/03</td>
<td></td>
</tr>
</tbody>
</table>

Name of the facility: .................................................................

Name/title (in block letters): ................................................................

Telephone number: .............................................................................

Date, signature: ..................................................................................