Urgent Field Safety Notice

Drill from icotec ag: Concerns the icotec Anterior Cervical Plate System

2018-10-11

Sender
icotec ag, Industriestrasse 12, 9450 Altstätten, Switzerland

Addressee
Surgical Management, users of the icotec Anterior Cervical Plate system

Dear user

We would like to inform you about a safety-relevant corrective measure concerning a version of the icotec drill (see section 1: Identification of the Affected Product).

Our records show that we delivered affected products to you.

1. Identification of the Affected Product

Reference number	Product	Lot numbers
39-3-13	Drill, AO coupling, Ø 3 mm for 13 mm screw	12/01 and 14/01
		

2. Description of the Problem

There is a possibility that the stated drilling depth of the aforementioned drill (13 mm) does not correspond to the actual drilling depth (15 mm). When a drill with the described defect is used, drilling goes 2 mm deeper than intended.

3. Clinical Impact

If a defective drill is used during surgery, in the worst-case scenario, this could lead to injury of the dura or the myelon, possibly resulting in neurological deficits. An additional surgical procedure may be required.

icotec is not aware of any adverse incidents associated with this product defect.

4. What Measures Does the Addressee Need to Take?

The affected product must <u>not</u> be used any longer. Please store it in a separate place in order to ensure that it is no longer used.

Please complete the attached confirmation form and return it to icotec immediately.

The responsible icotec representative will get in touch to arrange the further course of action with you.

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5. Disclosure of the Information Provided Herein

Please ensure within your organization that all users of the aforementioned products and other persons to be notified receive this urgent field safety notice. If you have passed the products on to any third parties, please forward a copy of this notice to them, or inform one of the contact persons stated below.

Please retain this notice at least until the corrective measure is complete.

The competent national authorities have received a copy of this urgent field safety notice.

6. Contact Persons

If you have any questions regarding the product or its use, please contact Alexander Dürr (Spine Product Manager, alexander.duerr@icotec.ch, +49 160 694 87 14), and if you have any questions about how the corrective measure will proceed, please contact Jörg Schneider (Manager Regulatory Affairs, joerg.schneider@icotec.ch, +41 71 575 00 25).

Thank you for your assistance and support in the timely implementation of this measure. We apologize for any inconvenience caused. We can assure you that icotec is doing its utmost to ensure that our products meet our stringent internal quality requirements.

Kind regards

Jörg Schneider
Manager Regulatory Affairs
icotec ag

Confirmation Form

regarding

the Urgent Field Safety Notice Dated 2018-10-11

Identification of the Affected Product

Reference number	Product	Lot numbers
39-3-13	Drill, AO coupling, Ø 3 mm for 13 mm screw	12/01 and 14/01
		

Please complete this form and return it to icotec by mail/fax/e-mail.

☐ We do not have the affected item in our inventory.

☐ We have the affected item in our inventory and we have ensured that it will no longer be used. (Please enter the quantities you have in your inventory in the table below)

Reference number	Product	Lot number	Quantity in inventory
39-3-13	Drill, AO coupling, Ø 3 mm for 13 mm screw	12/01	
39-3-13	Drill, AO coupling, Ø 3 mm for 13 mm screw	14/01	

Name of hospital, department: .....

Name, title (in printed letters): .....

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

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