

Urgent Field Safety Notice

icotec ag Cannulated Taps

2018-08-30

Sender

icotec ag, Industriestrasse 12, 9450 Altstätten, Switzerland

Addressee

OR management, users of the icotec pedicle system

Dear user,

The purpose of this letter is to inform you about a safety-relevant corrective measure concerning a version of the icotec tap (see section 1. Identification of the Affected Product).

Our records show that we have delivered affected products to your clinic.

1. Identification of the affected product

REF number	Product	LOT numbers
42-621	Cannulated Tap, 5.5 mm	15/01 and 15/02
		

2. Description of the Problem Including the Identified Cause

There is a possibility that during the manufacture of the above-mentioned tap, the hole in the instrument tip was not drilled exactly in the centre. This can lead to a reduced wall thickness in the front area of the tip. The tip could thus break off under great stress.

3. Clinical Impact

During reprocessing, an instrument with a defective tip can be easily recognized and its use prevented while inspecting the instruments.

During OR preparation, a defective tip is easily recognizable. The defect is noticeable when the tap is passed between the OR personnel and the surgeon. It would be possible to switch to a different system.

If a defective instrument is not detected before a surgery and the damaged tap is used, this would likely not be noticeable to the user and in turn could cause the thread to be cut.

If, when using the tap, the tip breaks off in the bone, it can be localized on an X-ray or image converter and removed. The recovery of the tip could lead to a delay during the surgery.

If the tip were to break in the bone when using the tap, and this is not noticed, tissue irritation would be very unlikely due to the material and the size of the fragment. The need for further surgical intervention can be ruled out.

icotec is not aware of any adverse events related to this product defect.



4. What Measures Should Be Taken by the Addressee?

The affected product may no longer be used. Please store it separately to ensure that it is no longer used. Please complete the attached confirmation form and return it to icotec as soon as possible.

Your icotec representative will contact you shortly to coordinate the exchange of the affected devices.

5. Passing on This Information

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

Please retain this notice at least until this measure has been carried out.

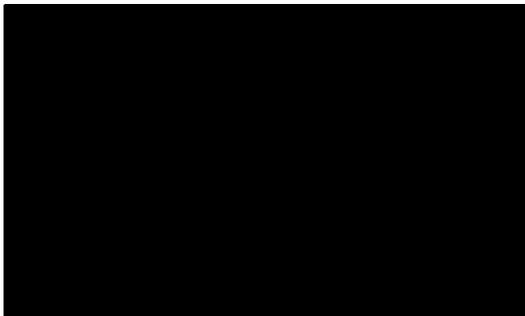
The competent national authorities have received a copy of this "Urgent Field Safety Notice".

6. Contact Persons

If you have any questions, please contact Mr. Alexander Dürr (Spine Portfolio Manager, alexander.duerr@icotec.ch, +49 (0)160 694 87 14).

We thank you for your assistance and support in the timely implementation of this measure and 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.

Yours sincerely,



Confirmation Form

regarding the urgent safety notice dated 08-30-2018

Identification of the affected product

REF number	Product	LOT number
42-621	Cannulated Tap, 5.5 mm	15/01 and 15/02
		

Please complete this form and send/fax/e-mail it back to icotec.

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

- We do have the affected item in our inventory:

Existing items (including quantity):

REF number	Product	LOT number	Stock quantity
42-621	Cannulated Tap, 5.5 mm	15/01	
42-621	Cannulated Tap, 5.5 mm	15/02	

Name of the clinic

Name/title (in block capitals)

Telephone number

Date, signature