FSN Ref: 23001 FSCA Ref: 23001

Date: 2023-12-22

Urgent Field Safety Notice
icotec Torque Wrench
REF 42-702

For attention of operating room managers, users of the icotec Pedicle System

Contact details, manufacturer:

icotec ag
Industriestrasse 12
9450 Altstätten
Switzerland

Ramon Hüppi

ramon.hueppi@icotec.ch

Tel.: +41 76 816 57 36

Urgent Field Safety Notice (FSN)
icotec Torque Wrench
REF 42-702

Risk addressed by FSN

Information on Affected Device
1. Device type
The instrument is intended for tightening nut screws of the icotec Pedicle System. It has a torque limiting function.
2. Commercial name
icotec Torque Wrench
3. Primary clinical purpose of device
The Torque Wrench is intended for implantation of icotec Pedicle System implant devices. The instrument is intended for tightening the nut screws.
4. Device model/catalogue number
REF 42-702
5. Affected serial number range
All serial numbers

Reason for Field Safety Corrective Action (FSCA)
1. Description of the product problem
icotec has received notification of one revision that had to be carried out because nut screws had become loose. During the investigation of the device involved, it was detected that the torque limiting function of the wrench used to tighten the nut screws during implantation was not functioning correctly. Due to the malfunction, the nut screws may not have been tightened sufficiently. As long as the cause of the malfunction is not detected we recall all potentially affected instruments as a precaution.
2. Hazard giving rise to the FSCA
Where the affected instruments have been used in surgery, implant failure is possible: Nut screws may not have been tightened to the specified torque.
3. Predicted risk to patient
The construct may loosen or displace, and instability may occur resulting in patient symptoms that could require a revision surgery. Serious injury could occur due to the malfunction of this device.
4. Background on issue
Due to a known malfunction that has occurred in a single case, the nut screws may not have been tightened sufficiently. As long as the cause of the malfunction is not detected icotec recalls all potentially affected instruments as a precaution.
5. Other information relevant to FSCA
Replacement instrument will be made available.

Type of Action to Mitigate the Risk
1. Action to be taken by the user
Quarantine the device upon receival of this document. Decision on whether patient-level follow-up is required should be made by the physician. Arrange the return of the affected devices to icotec or the local icotec distributor as soon as possible.
2. Customer reply is required (form attached on the next page "Field Safety Notice Customer Reply Form, Customer Reply Form").
3. Action Being Taken by the Manufacturer
All affected devices will be removed from the market. Replacement instruments will be made available.
4. The FSN is not required to be communicated to the patient.

General Information	
1. FSN type	New
2. Further advice or information already expected in follow-up FSN?	No
3. Manufacturer information (for contact details refer to page 1 of this FSN)	
a. Company name	icotec ag
b. Address	Industriestrasse 12, 9450 Altstätten, Switzerland
c. Website address	www.icotec-medical.com
4. The national competent authority will be informed about this communication.	
5. Name / Signature	Jörg Schneider
	[redacted]

Transmission of this Field Safety Notice
This notice needs to be passed on to all those who need to be aware within your organisation or to any organisation where the potentially affected devices have been transferred. Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action. Please report all device-related incidents to the manufacturer and the national Competent Authority if appropriate, as this provides important feedback.

Field Safety Notice Customer Reply Form
Customer Reply Form

1. Field Safety Notice (FSN) Information	
FSN reference number	23001
FSN date	2023-12-22
Device name	icotec Torque Wrench
Product code	REF 42-702
Serial numbers	

2. Customer Details	
Healthcare organisation name	
Organisation address	
Department / unit	
Contact name	
Title or function	
Telephone number	
Email	

3. Customer Response	
☐	I confirm receipt of the Field Safety Notice and that I read and understood its content.
☐	The information and required actions have been brought to the attention of all relevant users and executed.
☐	I have checked our inventory and further use of the listed device(s) is prevented.
☐	The return of the instruments to icotec or the local icotec distributor is arranged.
☐	I do not have any affected devices.
☐	Other action (define):
Print Name	
Signature	
Date	

4. Return acknowledgement to sender	
Email	feedback@icotec.ch
Customer Helpline	+41 76 816 57 36
Postal Address	Industriestrasse 12, 9450 Altstätten, Switzerland
Web Portal	www.icotec-medical.com
Fax	+41 71 757 00 01
Deadline for returning the customer reply form	2023-12-22

It is important that your organisation takes the actions detailed in the FSN and confirms that you have received the FSN.

Your organisation's reply is the evidence we need to monitor the progress of the corrective actions.