FSN Ref: 22001 FSCA Ref: 22001

Date: 2022-11-16

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 Jörg Schneider joerg.schneider@icotec.ch Tel.: +41 71 757 00 25

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Risk addressed by FSN

	1. Information on Affected Devices*
1.	1. Device Type(s)*
	The instrument is intended for tightening Nut Screws of the icotec Pedicle System. It has a torque limiting function.
1.	2. Commercial name(s)
	icotec Torque Wrench
1.	3. Unique Device Identifier(s) (UDI-DI)
	07640164844589
1.	4. Primary clinical purpose of device(s)*
	The Torque Wrench is intended for implantation of icotec Pedicle System implant devices. The instrument is intended for tightening the Nut Screws.
1.	5. Device Model/Catalogue/part number(s)*
	REF 42-702
1.	6. Affected serial or lot number range
	SN 200221-038, 200221-046
1.	7. Associated devices
	icotec Pedicle System

	2 Reason for Field Safety Corrective Action (FSCA)*
2.	1. Description of the product problem*
	During internal testing (at manufacturer site) of the two torque wrench devices it was detected that the torque limiting function was out of specification. The specified torque limiting value is 12 Nm. The measuring results for both instruments were 4 Nm.
2.	2. Hazard giving rise to the FSCA*
	The affected instruments were used during surgeries. Implant failure possible: Nut Screws may not have been tightened to the required torque; construct may be unstable or could loosen/displace or instability could occur. None of the devices affected are present on site any more.
2.	3. Probability of problem arising
	-
2.	4. Predicted risk to patient
	Construct is unstable or could become loose/displaced or instability could occur which might lead to patient symptoms, that could make a revision surgery necessary.
2.	5. Background on Issue
	During internal testing (at manufacturer site) of the two torque wrench devices it was detected that the torque limiting function was out of specification. The specified torque limiting value is 12 Nm. The measuring results for both instruments were 4 Nm. All deficient instruments came from one single batch. The removal for this batch was initiated. The supplier has not yet completed its root cause investigation.
2.	6. Other information relevant to FSCA
	Replacement instruments are sent to the customers.

	3. Type of Action to mitigate the risk*		
3.	**1. Action To Be Taken by the User*** ☐ Identify Device ☐ Quarantine Device ☐ Return Device ☐ Destroy Device ☐ On-site device modification/inspection ☐ Follow patient management recommendations ☐ Take note of amendment/reinforcement of Instructions For Use (IFU) ☒ Other: None of the devices affected are present on site. Decision on whether patient-level follow-up is required should be made by the physician. ☐ None		
3.	2. By when should the action be completed?	-	
3.	3. Particular considerations for: Implantable device Is follow-up of patients or review of patients' previous results recommended? Decision on whether patient-level follow-up is required should be made by the physician.		
3.	4. Is customer Reply Required? * (If yes, form attached specifying deadline for return)		No
3.	**5. Action Being Taken by the Manufacturer** ☒ Product Removal ☐ On-site device modification/inspection ☐ Software upgrade ☐ IFU or labelling change ☒ Other: Customer information. Delivery of replacement instruments. Devices that are at the manufacturer's site are quarantined. Further use is prevented. ☐ None		
3.	6. By when should the action be completed?	2022-11-30	
3.	7. Is the FSN required to be communicated to the patient /lay user?		Choose an item.
3.	8. If yes, has manufacturer provided additional information suitable for the patient/lay user in a patient/lay or non-professional user information letter/sheet?		
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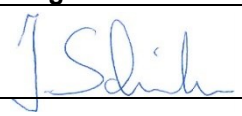
4. General Information*	
1. FSN Type*	New
2. For updated FSN, reference number and date of previous FSN	-
3. For Updated FSN, key new information as follows:	
-	
4. Further advice or information already expected in follow-up FSN? *	No
5. If follow-up FSN expected, what is the further advice expected to relate to:	
-	
6. Anticipated timescale for follow-up FSN	**-**
7. Manufacturer information (For contact details of local representative 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
8. The Competent (Regulatory) Authority of your country has been informed about this communication to customers. *	
9. List of attachments/appendices:	**-**
10. Name/Signature	**Jörg Schneider**
	

Transmission of this Field Safety Notice
This notice needs to be passed on 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. *

Note: Fields indicated by * are considered necessary for all FSNs. Others are optional.