Rev 2: February 2020
FSN Ref: ER25-0064 FSCA Ref: ER25-0064

Date: 2025-03-06

Urgent Field Safety Notice
TLX/TLX Guided Implant Driver 037.3002 lot GLKJ9 and lot LGMZ8

For Attention of*:ENTER CUSTOMER NAME AND ADDRESS

Contact details of local representative (name, e-mail, telephone, address etc.)*
ENTER NAME AND ADDRESS OF LOCAL DISTRIBUTION ORGANISATION INCLUDING NAME, TELEPHONE NUMBER AND EMAIL

Rev 2: February 2020
FSN Ref: ER25-0064 FSCA Ref: ER25-0064

Urgent Field Safety Notice (FSN)
037.3002 TLX/TLC Guid.Imp.Driv. ratchet,SP,SST (lot GLKJ9)
037.3002 TLX/TLC Guid.Imp.Driv. ratchet,SP,SST (lot LGMZ8)

Missing depth Markings

1. Information on Affected Devices*

1. 1. Device Type(s)*

The TLX/TLC Guided Implant Drivers for ratchet SP are used for guided placement of dental implants of the Straumann® Dental Implant System. The TLX/TLC Guided Implant driver for ratchet SP is used to remove the implant from its packaging and to proceed to implant placement in a guided manner through a surgical template. The depth marks on the driver are used to place the implant at the correct depth. The TLX/TLC Guided Implant Driver is delivered non-sterile and is made from stainless steel. The TLX/TLC Guided Implant driver has a handle designed to fit with the ratchet to transmit torque. According to Straumann Surgical and Prosthetic Instruments, Care and Maintenance (702000/en) All instruments must be cleaned, disinfected and sterilized before every use. This also applies to new instruments removed from protective transport packaging and single-use devices that are delivered non-sterile. Before every use, the device must be carefully checked for proper function and damage.

1. 2. Commercial name(s)*

TLX/TLC Guided Implant Driver, ratchet, SP

1. 3. Unique Device Identifier(s) (UDI-DI)

07630031750587

1. 4. Primary clinical purpose of device(s)*

The TLX/TLC Guided Implant Driver serves to pick up and remove the implant from the implant vial and to proceed with implant placement in a guided manner through a surgical template.

1. 5. Device Model/Catalogue/part number(s)*

037.3002 TLX/TLC Guided Implant Driver, ratchet, SP

1. 6. Affected serial or lot number range

Article Number	Description	Packaging lot number	Lot Number engraved on part	Lot number located on head of Driver
037.3002 	TLX/TLC Guid.Imp.Driv. ratchet,SP,SST	**LGMZ8**	HTXT5	
037.3002 	TLX/TLC Guid.Imp.Driv. ratchet,SP,SST	**GLKJ9**	HTXT5	

1. 7. Associated devices

N/A

2. Reason for Field Safety Corrective Action (FSCA)*	
2.	1. Description of the product problem*
	Due to a manufacturing error the TXL/TLC Guided Implant Driver was not laser marked with the required depth markings to indicate the H2, H4 and H6 T-sleeve positions. This is an isolation issue affecting the above-listed article and lots only.
2.	2. Hazard giving rise to the FSCA*
	Without the depth markings the user cannot assess the implant placement depth. The most critical foreseeable sequence of events is if the surgeon does not notice depth markings are missing and proceeds with implant placement deeper than initially intended.
2.	3. Probability of problem arising
	Before every use, the device must be carefully checked for proper function and damage. Under normal use, absence of the depth markings would be detected and the device not used. As part of the guided surgery protocol the 3 depth markings also need to be verified to ensure correct implant placement. In case the Guided Implant driver is used without the depth markings it could result in placing the implant deeper than initially intended. A significantly too-deep placement would be physically prevented, as the handle of the torque instrument would touch and be retained by the sleeve. The high detectability of the defect is confirmed by the initial complaint where the defect was detected prior to use in patient. No patient/user harm has been reported to date.
2.	4. Predicted risk to patient/users
	This risk assessment has determined that due to the high detectability of the defect, the risk of too deep implant placement is considered remote. No patient/user harm has been reported to date.
2.	5. Background on Issue
	Institut Straumann has received one (1) complaint from a customer reporting that the TLX/TLX Guided Implant driver, art. 037.3002 from lot GLKJ9 is missing the required laser marking lines which serve as depth markings (complaint ID 1001302218). Bounding by the manufacturing site has indicated that 3 lots of art. 037.3002 have been affected by this issue, LGMZ8, GLKJ9 and LNMG3. Items from lots LGMZ8 and GLKJ9 have already been distributed to 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 Complete and return the Distributor / Customer Response Form	
3.	2. By when should the action be completed?	06.04.2025
3.	3. Is customer Reply Required? * (If yes, form attached specifying deadline for return)	Yes

3.	**4. Action Being Taken by the Manufacturer*** ☒ Product Removal ☐ On-site device modification/inspection ☐ Software upgrade ☐ IFU or labelling change ☐ Other ☐ None Provide further details of the action(s) identified.	
3.	5. By when should the action be completed?	06.05.2025
3.	6. Is the FSN required to be communicated to the patient /lay user?	No

4. General Information*		
4.	1. FSN Type*	New
4.	2. Manufacturer information (For contact details of local representative refer to page 1 of this FSN)	
	a. Company Name	Institut Straumann AG
	b. Address	Peter Merian-Weg 12, Basel
	c. Website address	https://www.straumann.com/
4.	3. The Competent (Regulatory) Authority of your country has been informed about this communication to customers. *	
4.	4. Name/Signature	Insert Name and Title here and signature below.

	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. (As appropriate) Please transfer this notice to other organisations on which this action has an impact. (As appropriate) 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, distributor or local representative, 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.