Company Name/Logo

Rev 2: February 2020

FSN Ref: Manufacturer's ref number

FSCA Ref: CAPA-0000357

Date: 2026-07-09

Field Safety Notice

Bone Level Tapered Implant, Ø 4.1mm RC, SLActive® 12mm, Roxolid®, Loxim 021.5312 lot ZPME8

For Attention of*: Identify either by name or role who needs to be aware of the hazard and/or take action. If this is multiple recipients then include full list.

Contact details of local representative (name, e-mail, telephone, address etc.)*
This could be a distributor or local branch of the manufacturer. To be added at the appropriate stage in the different local languages.

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Field Safety Notice (FSN)
Device Commercial Name
Risk addressed by FSN

1. Information on Affected Devices*

1. 1. Device Type(s)*

Straumann® Roxolid® SLActive® / SLA® and titanium SLA® implants are part of the Straumann® Dental Implant System, which is an integrated system of endosseous dental implants with corresponding abutments and healing components, as well as instruments and prosthetic parts.Straumann® dental implants are solid-screw implants with a bone anchorage surface that is large-grit sandblasted and acid-etched.

1. 2. Commercial name(s)*

Bone Level Tapered Implant, Ø 4.1mm RC, SLActive® 12mm, Roxolid®, Loxim

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

0763003170002Q6

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

Straumann® dental implants are intended for oral implantation to provide a support structure for connected prosthetic devices. Straumann® dental implants are indicated for the functional and esthetic oral rehabilitation of the upper or lower jaw of edentulous or partially edentulous patients. Unless stated in specific indications, they can be used for immediate, early or late implantation following the extraction or loss of natural teeth. The implants can be placed with immediate function for single-tooth and/or multiple-tooth restorations when good primary stability is achieved and with appropriate occlusal loading to restore chewing function

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

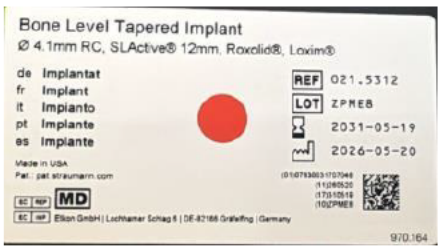
021.5312

1. 6. Software version

N/A

1. 7. Affected serial or lot number range

Article	Lot	Product name	Mfg date	Expiry date
021.5312	ZPME8	Bone Level Tapered Implant, Ø 4.1mm RC, SLActive® 12mm, Roxolid®, Loxim	2026-05-20	2031-05-19



1. 8. Associated devices

N/A

2. Reason for Field Safety Corrective Action (FSCA)*	
2.	1. Description of the product problem*
	Due to a manufacturing error, a partial mix-up has occurred between two (2) lots of BLT implants. As a result, lot ZPME8, article 021.5312, BLT Ø4.1mm RC, SLActive®, 12mm TiZr, NTP has been found to contain implants that are 14mm in length instead of 12 mm.
2.	2. Hazard giving rise to the FSCA*
	Lot ZPME8, article 021.5312, BLT Ø4.1mm RC, SLActive®, 12mm TiZr, NTP contains a number of implants that are 14mm in length instead of 12mm, consequently these devices are mislabelled. Without the correct label information, the user is unable to identify actual implant length, which in turn can result in the customer placing a 14mm implant into an implant bed prepared for a 12mm implant.
2.	3. Probability of problem arising
	Visual detectability by the end user of a mix-up between a 12 mm and 14 mm implant is considered to be low, especially if only one (1) implant is being used (no opportunity for comparison). The dentist could therefore proceed with the insertion of the implant with greater length (14mm) into the implant bed prepared for an, as planned, 12mm implant. Based on the preliminary investigation at the manufacturing site, it is considered that 50% of lot ZPME8 is potentially affected, based on this evaluation and considering the low detectability, the occurrence rate is assessed as probable. To date, one (1) complaint has been received in relation to this deviation, no patient harm was reported as part of this event (refer to section 6. Background on issue).
2.	4. Predicted risk to patient/users
	The information stated on the device packaging is used by the health care professional to select the implant that is going to be placed in the patient, during a scheduled surgical procedure. In case the implant is longer than indicated on the device labelling, the user may proceed to insert a 14mm implant into an implant bed prepared for a shorter, 12mm implant, this could result in bone compression, nerve damage or sinus perforation. To date, no patient harm has been reported in relation to this issue.
2.	5. Further information to help characterise the problem
	Based on the preliminary investigation at the manufacturing site, it is considered that 50% of lot ZPME8 is potentially affected.
2.	6. Background on Issue
	Institut Straumann has received one (1) complaint (ID 1001961017) from a customer who placed three BLT 4.1 x 12 mm implants labelled as 021.5312 lot ZPME8 in a patient, but one (1) of the placed implants was found to be 14mm in length. Preliminary manufacturing investigation determined that a partial mix-up occurred between 2 lots during successive packaging operations. More specifically a mix of components occurred between lot ZPME8, art. 21.5312 BLT Ø4.1mm RC, SLActive® 12mm, TiZr, NTP and lot ZVFV5, art. 021.5314 BLT Ø4.1mm RC, SLActive® 14mm, TiZr, NTP. Lot ZPME8 has been distributed to customers in the EU, lot ZVFV5 was distributed exclusively in the US and is therefore out of scope of this FSN.
2.	7. Other information relevant to FSCA
	To date, no harm to patients or users has been reported

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?	30th September 2026
3.	3. Particular considerations for: Implantable device Is follow-up of patients or review of patients' previous results recommended? No If the customer has used the product and there was no unexpected clinical occurrence during implant procedure, then manufacturer does not recommend a special follow up outside of the dentist's standard follow up procedure.	
3.	4. Is customer Reply Required? * (If yes, form attached specifying deadline for return)	Yes
3.	**5. 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.	6. By when should the action be completed?	30th September 2026
3.	7. Is the FSN required to be communicated to the patient /lay user?	No
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?	
	Choose an item.	Choose an item.

4. General Information*		
4.	1. FSN Type*	New
4.	2. For updated FSN, reference number and date of previous FSN	N/A
4.	3. For Updated FSN, key new information as follows:	
	N/A	
4.	4. Further advice or information already expected in follow-up FSN? *	Not planned yet
4.	5. If follow-up FSN expected, what is the further advice expected to relate to:	
	Eg patient management, device modifications etc.	
4.	6. Anticipated timescale for follow-up FSN	For provision of updated advice.
4.	7. 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.	8. The Competent (Regulatory) Authority of your country has been informed about this communication to customers. *	
4.	9. List of attachments/appendices:	If extensive consider providing web-link instead.
4.	10. 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.