Rev 2: February 2020
FSN Ref: ER25-0116 FSCA Ref: ER25-0116

Date: 2025.04.03

Field Safety Notice
064.4522S WB XL Anat. HA XC,Ø6.5,GH1.5,H4.5
064.4523S WB XL Anat. HA XC,Ø6.5,GH2.5,H5.5

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

Field Safety Notice (FSN)
064.4522S WB XL Anat. HA XC,Ø6.5,GH1.5,H4.5
064.4523S WB XL Anat. HA XC,Ø6.5,GH2.5,H5.5
Labeling error

1. Information on Affected Devices*

1. 1. Device Type(s)*

Straumann® Anatomic Healing Abutments are part of the Straumann® Dental Implant System. Anatomic Healing Abutments are designed for intra-oral scanning. They are available in a variety of shapes and sizes to fit individual patient needs. All AHAs are delivered in a sterile package.

1. 2. Commercial name(s)*

WB XL Anatomic Healing Abutments XC, Ø6.5

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

07630031775856
07630031775863

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

Straumann® sterile healing components are intended for use with implants of the Straumann® Dental Implant System (SDIS) to protect the inner configuration of the implant and maintain, stabilize and form the soft tissue during the healing process. The device is intended to be used as a temporary healing abutment.

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

064.4522S WB XL Anat. HA XC,Ø6.5,GH1.5,H4.5
064.4523S WB XL Anat. HA XC,Ø6.5,GH2.5,H5.5

1. 6. Software version

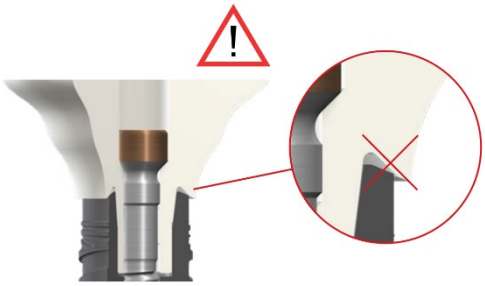
N/A

1. 7. Affected serial or lot number range

Material	Description	Batch
064.4522S	WB XL Anat. HA XC,Ø6.5,GH1.5,H4.5	GNNA2
064.4522S	WB XL Anat. HA XC,Ø6.5,GH1.5,H4.5	JZYZ3
064.4522S	WB XL Anat. HA XC,Ø6.5,GH1.5,H4.5	KRJA6
064.4523S	WB XL Anat. HA XC,Ø6.5,GH2.5,H5.5	GJXT4
064.4523S	WB XL Anat. HA XC,Ø6.5,GH2.5,H5.5	JLLP9
064.4523S	WB XL Anat. HA XC,Ø6.5,GH2.5,H5.5	KCKL1
064.4523S	WB XL Anat. HA XC,Ø6.5,GH2.5,H5.5	KPRE4
064.4523S	WB XL Anat. HA XC,Ø6.5,GH2.5,H5.5	LWZM6

1. 8. Associated devices

N/A

2. Reason for Field Safety Corrective Action (FSCA)*	
2.	1. Description of the product problem*
	The blister label for the XL Anatomic Healing Abutments says “RB/WB” instead of “WB”, where “RB” and “WB” refer to the compatibility with the prosthetic connection (Regular Base and Wide Base). 
2.	2. Hazard giving rise to the FSCA*
	While the label on the product box is correct, due to the incorrect blister label the use of the mislabelled WB abutments on RB implants cannot be excluded, in which case the abutment connection would exceed the implant shoulder. This could potentially lead to food trap and potential biological complications (e.g. inflammation, infection and bone loss). 
2.	3. Probability of problem arising
	The probability is remote. The affected articles will originally be ordered by the user for a planned implant procedure using a WB Implant. The inadvertent placement of a WB-abutment onto an RB Implant is therefore considered unlikely. Nevertheless, in case the healing abutment is not used and returned to storage without its Original Sales Unit Carton, this may lead to inadvertent misuse at a later stage. No patient/user harm has been reported to date.
2.	4. Predicted risk to patient/users
	Potential biological complications (e.g. inflammation, infection)
2.	5. Further information to help characterise the problem
	N/A
2.	6. Background on Issue
	Institut Straumann AG became aware of the issue via a customer complaint. No other similar complaints have been registered to date. Investigation showed that the mistake comes from an incorrect label specification for articles 064.4522S and 064.4523S.
2.	7. Other information relevant to FSCA
	N/A

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?	04.05.2025
3.	3. Particular considerations for: Implantable device Is follow-up of patients or review of patients' previous results recommended? Yes In case a WB Anatomical Healing Abutment has been placed onto an RB Implant and is still in situ at the time of this FSCA, it is recommended that the device is removed and replaced with an RB Anatomical Healing Abutment.	
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 Patient management recommendations are provided.	
3.	6. By when should the action be completed?	03.06.2025
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?	
	N/A	

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? *	No
4.	5. If follow-up FSN expected, what is the further advice expected to relate to:	
	N/A	
4.	6. Anticipated timescale for follow-up FSN	N/A
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:	"ER25-0116 FSN Customer Letter"
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.

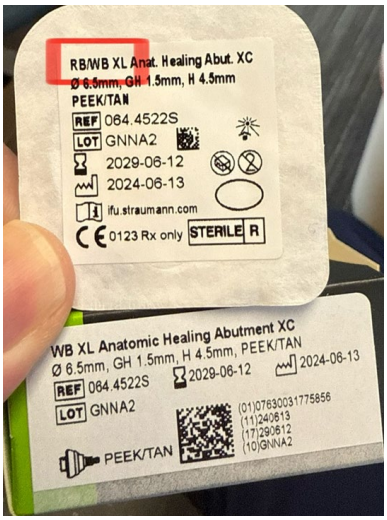
Urgent Field Safety Notice

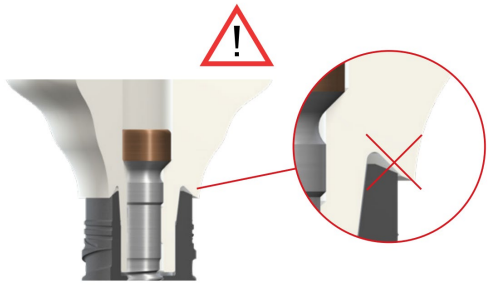
Commercial Name : ***(Insert article and lot number)***
FSCA identifier: ***ER25-0116***
Type of Action: ***Recall***

Dear Customer (insert name)

We would like to inform you that the ***(Insert article and lot number)*** which you have received from Institut Straumann ***presents a labeling error and should not be used.***

Description of Problem
Institut Straumann AG has received a complaint from a customer informing us that that the blister label for the WB XL Anatomic Healing Abutments says "RB/WB" instead of "WB", where "RB" and "WB" refer to the compatibility with the prosthetic connection (Regular Base and Wide Base).
While the label on the product box is correct, due to the incorrect blister label the use of the mislabeled WB abutments on RB implants cannot be excluded, in which case the abutment connection would exceed the implant shoulder. This could potentially lead to food trap and potential biological complications (e.g. inflammation and infection).





Institut Strauman has decided to voluntarily initiate a Field Safety Corrective Action to address this.

According to our records you have received ***xx (enter quantity***) pieces of ***(Insert article and lot number)***

Action to be taken:

1. Check you inventory for the affected article lot numbers. If the article (***Insert article and lot number)*** is still in your inventory, then stop use / distribution of the product immediately and quarantine / segregate physically. Please return the affected items to the attention of (***insert local contact details here***) for credit or replacement as indicated on the **Customer Confirmation Form**

2. If you have used the ***(Insert article and lot number), please identify in your records the implant type that received this Anatomic Healing Abutment. The implant product name contains an identifier for the connection to show whether a particular abutment is compatible with the implant being restored.***
   Implants with WB in description = COMPATIBLE (continue acc to point 3)
   Implants with RB in description = NON-COMPATIBLE (continue acc. to point 4)

3. If you have used the ***(Insert article and lot number)*** on a compatible WB implant, the device has been used as intended and **no patient action is required**. In this case, please complete **Customer Confirmation Form** accordingly and return it to ***(insert local contact details here)***

4. If you have used the WB Anatomic Healing Abutment with an RB implant, based on the current patient situation we recommend you take the following action:
   a. If the WB Anatomic Healing Abutment has already been removed and replaced with a permanent restoration successfully, no further patient action is required. We advise to monitor the patient situation as part of your routinely planned check-ups.
   b. In case the WB Anatomic Healing Abutment is still in situ, invite the patient to return to the practice for replacement with a compatible RB Anatomic Healing Abutment. Please contact (insert local contact) for details of when replacement RB Anatomic Healing Abutment is available BEFORE scheduling your patient's visit.

5. For all cases please complete and return the enclosed **Customer Confirmation Form to *(insert contact details)***

Transmission of the Field Safety Notice
This notice needs to be passed on to all those who need to be aware within your organization or to any organization where the affected devices have been transferred.

The competent authority of your country has been informed about this Field Safety Corrective Action.

We apologize for any inconvenience that this may cause.

Kind regards,

(insert name)