Rev 1: September 2018

FSN Ref: Neodent 001/2023 (ER23-0024) FSCA Ref: Neodent 001/2023

Date: DD:MMM:YYYY.

Urgent Field Safety Notice
Device Commercial Name

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

	1. **Information on Affected Devices***
1.	1. Device Type(s)*
	109.958- Alvim CM Implant 3.5x10mm 
1.	2. Commercial name(s)
	109.958 - Alvim CM Implant 3.5x10mm
1.	3. Primary clinical purpose of device(s)*
	The Neodent Implant System is intended to be surgically placed in the bone of the upper or lower jaw to provide support for prosthetic devices, such as artificial teeth, to restore chewing function.
1.	4. Device Model/Catalogue/part number(s)*
	109.958- Alvim CM Implant 3.5x10mm
1.	5. Software version
	NA
1.	6. Affected serial or lot number range
	JJGC (Neodent) investigation of a customer complaint identified that with article 109.658- Alvim CM Implant 3.5x10mm, a few units of lot MCY64 during a manual reprocessing at bandarole step to change the damaged carton box, have been packaged with the carton box labelled as article 109.647- Alvim CM Implant 4.3x8mm, lot NCZ56. The non-conformity is about the use of incorrect carton box and not a mix between the lots. Therefore, the non-conformity affected only lot MCY64 and not lot NCZ46. JJGC (Neodent) decided to perform a Field Safety Corrective Action with the customers who received the item 109.658- Alvim CM Implant 3.5x10mm, lot MCY64.

In order to avoid misunderstanding with the customer, besides the affected lot, the customer also needs to check if they have both lots on their stock:

ARTICLE	PRODUCT NAME	LOT	MANUFT.DATE	EXPIRY DATE
109.647	Alvim CM Implant 4.3x8mm	NCZ56	August, 15th, 2022	August, 14th, 2027
109.658	Alvim CM Implant 3.5x10	MCY64	August, 16th, 2022	August, 15th, 2027

2 Reason for Field Safety Corrective Action (FSCA)*

2.1. Description of the product problem*

According to the investigation performed, JJGC (Neodent) determined that a few units of article 109.658- Alvim CM Implant 3.5x10mm, lot MCY64 during a manual reprocessing at bandarole step to change the damaged carton box, have been packaged with the carton box of the article 109.647- Alvim CM Implant 4.3x8mm, lot NCZ56.

2.2. Hazard giving rise to the FSCA*

It has been identified that there is a mix of the carton box. The information described in the carton box and the implant itself are different.

2.3. Probability of problem arising

The investigation of the non-conformity identified a carton box mix during a reprocessing of few units. The non-conformity shows discrepancies in the labelling between carton box and the implant itself.

2.4. Predicted risk to patient/users

The information stated on the carton package is used by the professional to select the implant that is going to be placed in the patient, during the scheduled surgical procedure. Considering the worst case scenario, in which an implant with bigger length is present in a package with smaller length label on box, in cases where there is sufficient bone availability, the problem could cause bone compression or difficulty in installation, due to the site preparation being done for an implant smaller length. On the other hand, in borderline cases, where the bone quality is low and/or the bone ridge has a maximum indication for the 8mm length implant without compromising anatomical structures, associated with the possibility of the professional does not notice the divergence previously, proceeding with its surgical installation, the procedure could cause damage to the patient, such as damage to nervous structures or communication with bone cavities.

2.5. Background on Issue

JJGC (Neodent) received 1 complaint of 5 units from the same customer in which the customer reported that the implant itself has a bigger length than described in the package. According to the complaint investigation, it was identified that the non-conformity was originated during manual reprocessing of the carton box, where the operator used an incorrect box. So, few units of the implant with the measure 3.5x10mm had been reprocessed incorrectly with a carton box of the implant measure 4.3x8mm.

	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 Provide further details of the action(s) identified.	
3.	2. By when should the action be completed?	14 April 2023
3.	3. Particular considerations for: Implantable device Is follow-up of patients or review of patients' previous results recommended? No, not necessary If the product has been installed and no issue/symptom was identified, it is not necessary to remove the implant and additional patient follow-up is not required	
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 Product is to be returned to local representative	
3	6. By when should the action be completed?	14 April 2023
3.	7. Is the FSN required to be communicated to the patient /lay user?	No

	4. General Information*	
4.	1. FSN Type*	New
4.	2. Further advice or information already expected in follow-up FSN? *	No
4.	3. Manufacturer information (For contact details of local representative refer to page 1 of this FSN)	
	a. Company Name	**NEODENT – JJGC INDÚSTRIA E COMÉRCIO DE MATERIAIS DENTÁRIOS S.A.**
	b. Address	**JUSCELINO KUBITSCHEK DE OLIVEIRA, 3291. CURITIBA, PARANÁ. BRAZIL.**
	c. Website address	**https://www.straumann.com/neodent/br/pt/profissionais.html**
4.	4. The Competent (Regulatory) Authority of your country has been informed about this communication to customers. *	
4.	5. 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.