Rev 2: February 2020
FSN Ref: FSCA.011 FSCA Ref: FSCA.011

Date: 2025-10-09

Field Safety Notice
GM Helix Implant, Ti, 4.0X13

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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Packaging mix-up length of implant

1. Information on Affected Devices*	
1.	1. Device Type(s)*
	The Neodent GM Helix Implant is made of commercially pure titanium (Grade 4) and features a Grand Morse (GM) prosthetic interface with an internal hexagonal index, consistent across all implant diameters. Its macrogeometry includes a conical body and apex, double trapezoidal threads, a rounded apex, and the ability to compress bone during installation. The Helix GM implant has a rough surface created by abrasive blasting and acid etching, and Acqua, a hydrophilic surface applied to the base via a specialized physical-chemical process.
1.	2. Commercial name(s)*
	GM Helix Implant, Ti, 4.0X13
1.	3. Unique Device Identifier(s) (UDI-DI)
	7899878024569
1.	4. 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. It may be used with single-stage or two-stage procedures, for single- or multiple-unit restorations, and may be loaded immediately when good primary stability is achieved and with appropriate occlusal loading.
1.	5. Device Model/Catalogue/part number(s)*
	109.985 GM Helix Implant, Ti, 4.0X13
1.	6. Affected serial or lot number range

Article #	Product Name	Lot
109.985	GM Helix Implant, Ti, 4.0X13	JPZ75

1.	7. Associated devices
	N/A

2. Reason for Field Safety Corrective Action (FSCA)*	
2.	1. Description of the product problem*
	The manufacturer's investigation of a customer complaint identified a possible mix-up of Helix GM Implants with heights of 11.5 mm and 13 mm.
2.	2. Hazard giving rise to the FSCA*
	Due to a potential mix-up in manufacturing, it is possible that a package labelled as 109.985 GM Helix Implant, Ti, 4.0X13 lot JPZ75 may contain a 11.5mm implant instead of a 13 mm implant.
2.	3. Probability of problem arising
	The detectability of the differences in height is considered to be low.
2.	4. Predicted risk to patient/users
	In a worst-case scenario, the clinician would try to insert the shorter implant into an alveous prepared for a larger dimension. This situation could result in lack of primary

	stability or osseointegration failure. The overall severity for this situation is classified as moderate, and there are no health risks to the patient.
2.	5. Background on Issue
	The issue of potential mix-up of lengths of implant was identified during the investigation of a customer complaint.

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 1. Identify and segregate units in stock labelled article **109.985- GM Helix Implant, Ti, 4.0X13, lot JPZ75.** 2. Return the product for replacement or refund. 3. If the product has been installed, it is not necessary to remove the implant and additional patient follow-up is not required. 4. Complete and return the Customer Confirmation Form below.	
3.	2. By when should the action be completed?	15th November 2025
3.	3. Particular considerations for: Implantable device Is follow-up of patients or review of patients' previous results recommended? No If the product has been installed, 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	
3.	6. By when should the action be completed?	15th November 2025
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. 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 Oliviera, 3291 Brazil
	c. Website address	https://www.straumann.com/neodent/br/pt/profissionais.html
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.