Rev 2: February 2020
FSN Ref: FSCA.010 ER25-0135 FSCA Ref: FSCA.010

Date: 2025-04-16

Field Safety Notice
HELIX GM IMPLANT 4.0X11.5 ACQUA

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.

Field Safety Notice (FSN)
HELIX GM IMPLANT 4.0X11.5 ACQUA

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)*
	HELIX GM IMPLANT 4.0X11.5 ACQUA
1.	3. Unique Device Identifier(s) (UDI-DI)
	7899878025290
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)*
	140.984 HELIX GM IMPLANT 4.0X11.5 ACQUA
1.	6. Affected serial or lot number range

Article #	Product Name	Lot
140.984	HELIX GM IMPLANT 4.0X11.5 ACQUA	JPZ21

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 140.984 HELIX GM IMPLANT 4.0X11.5 ACQUA lot JPZ21 contains a 13mm HELIX GM IMPLANT instead of a 11.5mm 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 borderline cases, where the bone quality is low and/or the bone ridge has a maximum indication of implant height without compromising noble anatomical structures, proceeding with the surgical installation of a 13 mm long implant instead of an 11.5mm long implant could cause harm to the patient such as injury to nerve structures, communication with bone cavities and/or fracture of the alveolar bone plate.
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 **140.984 - HELIX GM IMPLANT 4.0X11.5 ACQUA, lot JPZ21.** 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?	23rd May 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 Provide further details of the action(s) identified.	

3.	6. By when should the action be completed?	July 18th 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 OLIVEIRA, 3291. CURITIBA, PARANÁ. 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.