Rev 1: September 2018

FSN Ref: FSCA 003-2021 (ER21-0253) FSCA Ref: FSCA 003-2021 (ER21-0253

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

Rev 1: September 2018

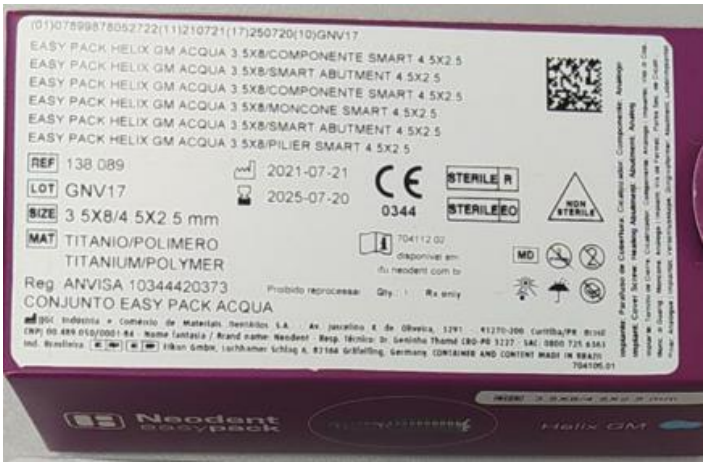
FSN Ref: FSCA 003-2021 (ER21-0253) FSCA Ref: FSCA 003-2021 (ER21-0253

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

1. Information on Affected Devices*

1. Device Type(s)*

138.089- Easypack Helix GM Acqua 3.5X8/Smart 4.5X2.5 / batch GNV17



2. Commercial name(s)

138.089 - Easypack Helix GM Acqua 3.5X8/Smart 4.5X2.5

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

Complete when this becomes available.

4. Primary clinical purpose of device(s)*

Through the combination of all of its components, the Easy Pack Set is indicated for the sequence of dental procedures of immediate or conventional loading, performed for installation and implant osseointegration, molding/scanning and making of provisional prosthesis.

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

138.089 - Easypack Helix GM Acqua 3.5X8/Smart 4.5X2.5

6. Software version

Only where relevant.

7. Affected serial or lot number range

ARTICLE	PRODUCT NAME	LOT	MANUFT.DATE	EXPIRY DATE
138.089	Easypack Helix GM Acqua 3.5X8/Smart 4.5X2.5	GNV17	July, 21th, 2021	July, 20th, 2025

8. Associated devices

Within context of the FSCA eg for IVD reagents and platforms.

	2 Reason for Field Safety Corrective Action (FSCA)*
2.	1. Description of the product problem*
	It has been identified that there is a mixture between two Easy Pack Lots. The information described in the carton box and the implant itself are different.
2.	2. Hazard giving rise to the FSCA*
	It has been identified that there is a mixture between two Easy Pack Lots. The information described in the carton box and the implant itself are different.
2.	3. Probability of problem arising
	The conducted investigation of the non-conformity identified that 100% of the lot shows discrepancies in the labelling between carton box and the implant itself. Two user product complaints have been received but no issue reported.
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, in cases where there is sufficient bone availability, the problem could cause bone compression or difficulty in installation, due to the site preparation being carried out 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. Further information to help characterise the problem
	Include any further relevant statistics to help convey the seriousness of the issue.
2.	6. Background on Issue
	JJGC received 2 complaints 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 complaints investigation, it was identified that the non-conformity was originated in the assembling operation, where the templates of the orders involved were exchanged. So, the implants with the measure 3.5x13mm followed the process incorrectly as the lot GNV17 (138.107 - Easypack Helix GM Acqua 3.5X8/Smart 4.5X2.5), committing 100% of the lot.
2.	7. Other information relevant to FSCA
	This field may only contain additional information that is deemed necessary by the manufacturer to supplement information relevant to the FSCA.

	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?	18/February/2022
3.	3. Particular considerations for: Choose an item. Is follow-up of patients or review of patients' previous results recommended? No Provide further details of patient-level follow-up if required or a justification why none is 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?	18/February/2022
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	Provide reference and date of previous FSN if relevant
4.	**3.** For Updated FSN, key new information as follows:	
	Summarise any key difference in devices affected and/or action to be taken.	
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:	
	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	**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.	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.