Date: 2025-04-14

Urgent Field Safety Notice
Plus Initial Drill 103.170 lot LNWT8

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

Urgent Field Safety Notice
Plus Initial Drill 103.170 lot LNWT8

Missing depth Markings

1. Information on Affected Devices*	
1.	1. Device Type(s)*
	The Plus Initial Drill 103.170 is a rotary instrument indicated for drilling of bone tissue or dentin. This product is a surgical instrument used for demarcation and rupture of the cortical bone with the purpose of Implant bed preparation for insertion of the Implant chosen. At its active end there is a spear-shaped tip, with high cutting power. At the other there is a handle that is designed to fit a Contra-Angle for transmission of torque. Laser markings determine the drilling depth in accordance with the surgical planning.
1.	2. Commercial name(s)*
	Plus Initial Drill
1.	3. Unique Device Identifier(s) (UDI-DI)
	7898237561967
1.	4. Primary clinical purpose of device(s)*
	The Plus Initial Drill 103.170 is a rotary instrument indicated for drilling of bone tissue or dentin. This product is a surgical instrument used for demarcation and rupture of the cortical bone with the purpose of Implant bed preparation for insertion of the Implant chosen
1.	5. Device Model/Catalogue/part number(s)*
	103.170 Plus Initial Drill
1.	6. Affected serial or lot number range

Article #	Product Name	Lot
103.170	Plus Initial Drill	LNWT8

103.170 – Batch LNWT8
Non-conforming Product

103.170 – Example
Conform Product

1.	7. Associated devices
	N/A

2. Reason for Field Safety Corrective Action (FSCA)*	
2.	1. Description of the product problem*
	The 103.170 Plus Initial Drill was produced without the laser engraving of 7mm, as shown in section 1.6 This is an isolation issue affecting the above-listed article lot only.
2.	2. Hazard giving rise to the FSCA*
	The absence of one of the laser-engraved markings on the active portion of the Drill may impair the measurement of the bone milling, since this is crucial for the professional when preparing the

	surgical bed that will receive the implant. In borderline cases, where the bone ridge has a maximum height indication without compromising noble anatomical structures, the procedure could cause harm to the patient, such as injury to nerve structures, communication with bone cavities, bone plate fractures, or fenestrations.
2.	3. Probability of problem arising
	In the work instructions there is no instruction for the dentist to check the depth markings on the drill. Therefore, the likelihood of detection of the missing depth markings is remote.
2.	4. Predicted risk to patient/users
	The risk assessment has determined that due to the lack of detectability of the defect, the risk of too deep drilling is considered occasional.
2.	5. Background on Issue
	The manufacturer JJGC (Neodent) identified the issue internally with article 103.170. Bounding by the manufacturing site identified that 103.170 lot LNWT8 was impacted and has been distributed to customers.

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. Search your inventory and/or surgical kits in use for units of item 103.170 – PLUS INITIAL DRILL - Lot LNWT8. The lot is identified on the part, use Figure 2 below as a support for batch identification.
2. Identify and separate **all units of this lot**, whether open or closed.
3. If the product was used and no complications or problems were identified, or the patient did not present symptoms, there is no need for any additional action with the patient.
4. Identified product is to be returned to address listed on FSN
   - Send the product(s) to the us. ATTENTION! When sending the product, if any unit is open, place it in surgical paper and decontaminate it before shipping.
5. If the product is not found in your stock, indicate this on the Customer Confirmation Form.
6. In all cases, complete, sign and return the Customer Confirmation Form for Field Action.

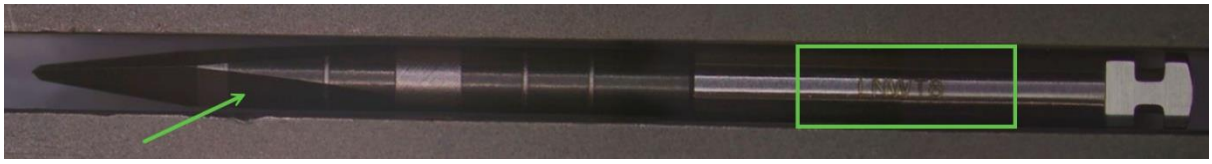

Figure 1 - Identify the initial drill without the 7mm marking and confirm the LNWT8 batch on the

3.	2. By when should the action be completed?	30.04.2025
3.	3. Is customer Reply Required? * (If yes, form attached specifying deadline for return)	Yes
3.	**4. 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.	5. By when should the action be completed?	10.07.2025
3.	6. 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.