

Company
Name Surname
Sample Street 1
1234 Sample City
Country

Date

URGENT FIELD SAFETY NOTICE

NobelParallel CC NP 3.75x10mm
Ref 37965, Lot 12129104
Nobel Biocare Recall identifier: PFA1925

Dear Nobel Biocare Partner,

Nobel Biocare identified a labeling issue affecting article 37965, NobelParallel CC NP 3.75x10mm, lot 12129104. Our records indicate that you purchased a product that may potentially be affected. This notice is intended to inform you about the issue, the actions that should be taken and the actions planned by Nobel Biocare to correct the issue.

Issue description The top label of article 37965, lot 12129104 (NobelParallel CC NP 3.75x10mm) may incorrectly indicate an implant length of 7mm, which is shorter than the actual length of the implant (10mm). The side label does provide the correct information. Figure 1 shows examples of correctly and incorrectly labeled implant packages.



Figure 1: Incorrect top label (left), correct top label (right) and the correct side label

Potential hazard If the incorrect length is not noticed prior to implant placement, the following potential hazards are foreseen:

- (1) A second surgical procedure may be required to complete the treatment with the correct size implant.
- (2) Implant replacement surgery may be required if the incorrect length is discovered after the implant had been placed.
- (3) While considered unlikely, if placed in the posterior lower jaw, the implant may damage the inferior alveolar nerve canal or perforate a small artery requiring immediate removal of the implant.

**Actions to be
taken by
customers**

1. Identify affected devices in your stock by confirming the information on the side label: NobelParallel CC NP 3.75x10mm, article 37965, lot 12129104.
2. Confirm that both the side and top label indicate 3.75x10mm as shown in figure 1 on page 1 of this notice.
3. Complete attached Customer Acknowledgment Form and return it to Nobel Biocare, via email to [xxxxx](#) or fax [xxxxx](#), within 5 days of receipt of this notice.
4. Return incorrectly labeled products (top label 3.75x7mm) to:

[Nobel Biocare xxxx](#)

[Attn: Returns PFA1925](#)

[xxxxx](#)

[xxxxx](#)

Correctly labeled products (top label 3.75x10mm) do not need to be returned.

5. Nobel Biocare will replace returned devices free of charge.

**Actions planned
by Nobel Biocare**

Nobel Biocare reviewed the packaging and labeling processes, has implemented corrective actions and will initiate preventive actions to ensure a high level of safety and quality of its medical devices.

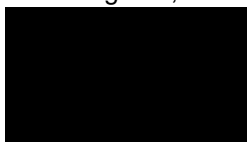
**Transmission of
this notice**

This notice needs to be passed on to all those who need to be aware within your organisation or to any organisation where the potentially affected devices have been transferred.

We kindly ask you to follow instructions provided in this notice. Nobel Biocare confirms that this information is being notified to the appropriate Regulatory Agency.

Please be assured that maintaining a high level of safety and quality is our highest priority. If you require any further information or support, please contact your customer support representative at [xxxxx](#). We are sorry for the inconvenience and we thank you for your understanding.

Best regards,



Sophie Vaillot, Head Global Regulatory Affairs

Customer Acknowledgment Form

PFA 1925

Name **xxxx**
Customer no. **xxxxx**

Please complete and return this Acknowledgment Form within 5 days of receipt of this notice, via email to **xxxxx** or fax **xxxxx**.

Please complete this form even if you do not have any affected stock.

Receipt of Field Safety Notice

- ☐ I confirm receipt of the Field Safety Notice and that I read and understood its content.
- ☐ I confirm receipt of the Field Safety Notice and that I read and understood its content. However, I have additional questions and wish to be contacted.

Customer actions

The table below indicates the items purchased by you according to our records. Please indicate how many you will be sending back, how many you confirm to be correct and how many were used.

Article Number	Lot Number	Quantity Received	Quantity of incorrect items (please send back)	Quantity of correct items (keep in stock)	Quantity used
37965	12129104	X			

Customer information

(Name and phone number)

Signature

Date