

Company
Name Surname
Sample Street 1
1234 Sample City
Country

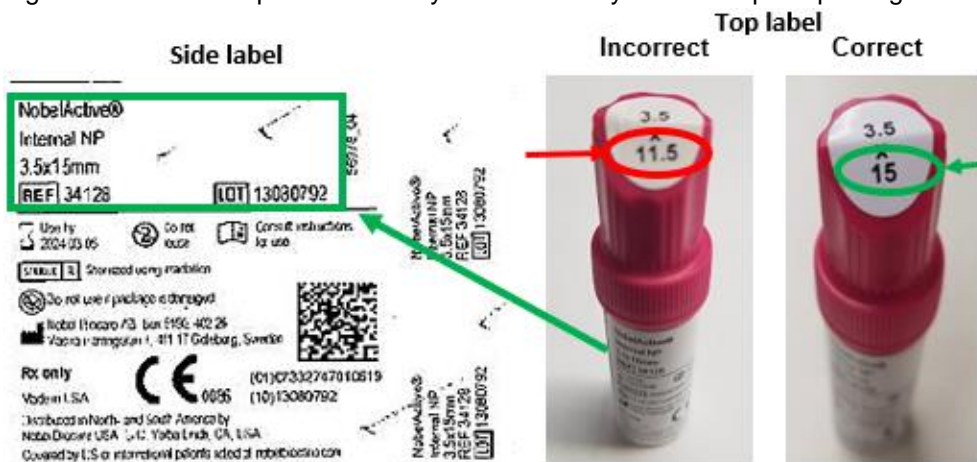
Date

URGENT MEDICAL DEVICE RECALL

NobelActive Internal NP 3.5x15mm
Ref 34128, Lot 13080792
Nobel Biocare Recall identifier: PFA1917

Dear Nobel Biocare Partner,

Nobel Biocare identified a labeling issue affecting article 34128, NobelActive Internal NP 3.5x15mm, lot 13080792. Our records indicate that you purchased a product that may potentially be affected. This letter 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.

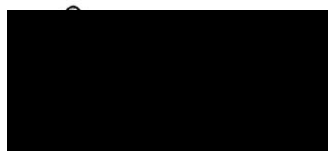
Issue / hazard description	<p>The top label of article 34128, lot 13080792 (NobelActive Internal NP 3.5x15mm) may incorrectly indicate an implant length of 11.5mm, which is shorter than the actual length of the implant (15mm). The side label does provide the correct information. Figure 1 shows examples of correctly and incorrectly labeled implant packages.</p>  <p>Figure 1: Article side and top label: incorrect top label (left) vs correct top label (right).</p>
Actions to be taken by customers	<ol style="list-style-type: none"> 1. Identify affected devices in your stock by confirming the information on the side label: NobelActive Internal NP 3.5x15mm, article 34128, lot 13080792. 2. Confirm the information on the top label as shown in figure 1 above. 3. Complete attached Customer Acknowledgment Form and return it to Nobel Biocare, via email to us.complaints@nobelbiocare.com or fax 714-282-5073, within 5 days of receipt of this letter. 4. Return incorrectly labeled products (top label <u>3.5x11.5</u>) to: Nobel Biocare Attn: Returns PFA1917 22715 Savi Ranch Pkwy Yorba Linda, CA 92887. Correctly labeled products (top label <u>3.5x15</u>) do not need to be returned.

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. Nobel Biocare will replace affected devices free of charge.
Transmission of this letter	This letter 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 Recall Letter. Nobel Biocare confirms that this information has been notified to the FDA.

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 1-800-322-5001 x.1527. 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 1917

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

Please complete and return this Acknowledgment Form within 5 days of receipt of this letter, via email to us.complaints@nobelbiocare.com or fax 714-282-5073.

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

Receipt of Recall Letter

- ☐ I confirm receipt of the Recall Letter and that I read and understood its content.
- ☐ I confirm receipt of the Recall Letter 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
34128	13080792	X			

Customer information

(Name and phone number)

Signature

Date