URGENT FIELD SAFETY NOTICE

Product:	Nobel Biocare N1 TiUltra Implants
Date:	16-Dec-24
Identifier:	PFA2420
To:	Safety officer, vigilance officer, dentist, surgeon and other relevant staff members

Dear Nobel Biocare Customer,

The purpose of this letter is to inform you that Nobel Biocare is conducting a recall on the following product(s):

Product name	Catalog number	Lot number	UDI-DI
Nobel Biocare N1 TiUltra TCC NP 3.5x9mm	300857	12253670 12253671	07332747161694
Nobel Biocare N1 TiUltra TCC NP 3.5x11mm	300858	12253066 12254352 12254353	07332747161700
Nobel Biocare N1 TiUltra TCC RP 4.0x7mm	300860	12255165	07332747161724
Nobel Biocare N1 TiUltra TCC RP 4.0x9mm	300861	12252015 12253672 12253673 12255677	07332747161731
Nobel Biocare N1 TiUltra TCC RP 4.0x11mm	300862	12253448 12254209 12254210 12255392 12255393 12255939	07332747161748
Nobel Biocare N1 TiUltra TCC RP 4.0x13mm	300863	12253619 12253620 12254212 12254213	07332747161755
Nobel Biocare N1 TiUltra TCC RP 4.0x15mm	301170	12254404	07332747171143

We kindly ask you to follow the instructions provided in this letter.

Identification of the device	The affected products and lot numbers which are listed in the table above can be identified by checking the label of the products you may have in your stock.
Problem description and potential hazard	Nobel Biocare became aware through internal quality control of an issue related to multiple **Nobel Biocare N1 TiUltra Implants.** One of the plastic components of the packaging that is used to hold the OsseoShaper in place may contain a manufacturing error. This results in a sharp edge that could puncture the blister packaging, thereby breaching the sterile barrier. Consequently, for those articles where the packaging is damaged, the sterility is not guaranteed. Exposure to a non-sterile dental implant or drill could result in a local inflammatory reaction. In rare cases, this may turn into a systemic infection. No complaints of damaged packaging or clinical complications have been received for the potentially affected articles at the time of initiating this recall.

Nobel Biocare AB
PO Box 5190, 402 26
Västra Hamngatan 1
Göteborg, 411 17 Sweden
PRO 187036_603_00

PMS@nobelbiocare.com
nobelbiocare.com

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Date: 16-Dec-24
Identifier: PFA2420
To: Safety officer, vigilance officer, dentist, surgeon and other relevant staff members

Actions to be taken by the user	Customer We kindly ask you to follow the instructions below: 1. Inspect your stock and quarantine affected devices. 2. Complete attached **Customer Acknowledgment Form**, even if you do not have any affected stock, and return it to Nobel Biocare, via email to *<insert email address>*, within 5 days of receipt of this notice. 3. Return all affected stock on hand to Nobel Biocare using the shipping label attached to this notice. 4. Ensure relevant staff members are informed of this recall. If you have supplied or transferred any potentially affected product to another facility or organization, let that facility know of the recall by providing a copy of this notice. Distributor We kindly ask you to follow the instructions below: 1. Inspect your stock and quarantine affected devices. 2. Inform your customers of this recall by sending them a copy of this letter and make sure they act accordingly. 3. Complete attached **Distributor Acknowledgment Form** with information collected from your end users and return it to Nobel Biocare, via email to *<insert email address>*, within 5 days of receipt of this notice. 4. Return all affected devices on hand and devices returned by your end customers to Nobel Biocare using the shipping label attached to this notice.
Need to inform the patient	This safety notice is being issued as a precautionary measure. To date, we have not received any reports of damaged packaging or clinical complications related to this issue. At this time, no specific actions are required beyond adhering to the standard follow-up procedures established by your office or hospital. Decisions regarding whether to inform patients should be made at the clinician's discretion, based on individual case assessments and professional judgment.
Actions planned by Nobel Biocare	Nobel Biocare reviewed the manufacturing processes at the supplier of the component, 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.
Further information and support	If you require any further information or support, please contact your local customer support representative at *<insert phone number, e-mail address>*. Please maintain awareness of this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action.

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	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.

Nobel Biocare confirms that this information is being notified to the appropriate regulatory authority.

Please be assured that maintaining a high level of safety and quality is our highest priority. We apologize for the inconvenience, and we thank you for your understanding.

Best regards,

Stefan Trampler
Vice President Regulatory Affairs, Quality Assurance and Design Assurance

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CUSTOMER ACKNOWLEDGMENT FORM

Identifier: PFA2420

Customer name

Customer account number:

Please complete and return this Acknowledgment Form within 5 working days of receipt of this letter via email, even if you do not have any affected devices in stock.

☐ I confirm receipt of the recall letter and that I read and understood its content.

☐ The information in the recall letter has been brought to the attention of all relevant staff members

☐ I have performed or will perform the actions described in the recall letter and confirm that:

- ☐ I no longer have any affected devices in stock.
- ☐ The following devices have been or will be returned to Nobel Biocare:

Catalog number	Lot Number	Quantity purchased*	Quantity returned	Date returned

☐ I have a query, please contact me.

Organization name: _____

Organization address: _____

Contact name: _____

Title or function: _____

Telephone number: _____

Email: _____

_____ _____

Signature Date (indicate the month in letters)

It is important that your organization takes the actions detailed in the recall letter and confirms that you have received the recall letter.

Your organization's reply is the evidence we need to monitor the progress of the corrective actions.

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DISTRIBUTOR ACKNOWLEDGMENT FORM

Identifier: PFA2420

Distributor account number:

Please complete and return this Acknowledgment Form within 5 working days of receipt of this letter via email, even if you do not have any affected devices in stock.

☐ I confirm receipt of the recall letter and that I read and understood its content.

☐ I have checked my stock and quarantined inventory.

☐ I have identified customers that received or may have received this device and have informed the identified customers of this recall.

☐ I have received a response from all identified customers.

- ☐ If not, specify further action taken: _____

  _____

☐ I confirm that:

- ☐ Neither I nor any of my customers have any affected devices in stock.
- ☐ The following devices have been or will be returned to Nobel Biocare or destroyed. Please indicate the quantity and the date:

Catalog number	Lot Number	Quantity purchased*	Quantity returned	Quantity destroyed	Date returned/ destroyed

☐ I have a query, please contact me.

Organization name: _____

Organization address: _____

Contact name: _____

Title or function: _____

Telephone number: _____

Email: _____

_____ _____

Signature Date (indicate the month in letters)

It is important that your organization takes the actions detailed in the recall letter and confirms that you have received the recall letter.

Your organization's reply is the evidence we need to monitor the progress of the corrective actions.

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