URGENT MEDICAL DEVICE RECALL

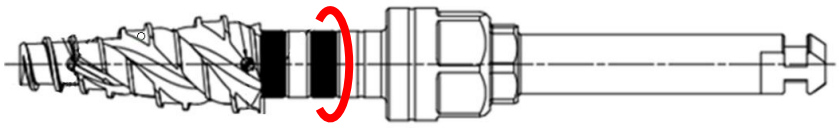
Date: 28th of July 2022
Identifier: PFA 2208
Product: Nobel Biocare N1 TiUltra TCC NP 3.5x13mm
To: Safety officer, vigilance officer, dentist, surgeon and other relevant staff members>

Dear Nobel Biocare Customer,

The purpose of this letter is to inform you that Nobel Biocare is recalling the following product(s):

Article number	Article name	Lot number
300859	Nobel Biocare N1 TiUltra TCC NP 3.5x13mm	12167337
		12167830
		12168184

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

Identification of the device	The affected product can be identified on the label by either material number and lot number, or by the following UDIs; (01)07332747161717(10)12167337(11)210119(17)251218 (01)07332747161717(10)12167830(11)210125(17)251224 (01)07332747161717(10)12168184(11)210128(17)251227
Problem description	For the affected products, there may be a burr present on the co-packed *OsseoShaper 1* around the waist of the device. *Figure 1* illustrates where the bur may be present (red).  *Figure 1. Illustration of the OsseoShaper 1 with potential burr location (red)* There is a risk that the burr can come loose from the device.
Potential hazard	The hazard is primarily identified as a risk of the patient inhaling the burr if coming lose from the OsseoShaper 1 during the clinical procedure. There is no risk to the implants or placement of the implants.
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 info.italy@nobelbiocare.com 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

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	another facility or organization, let that facility know of the recall by providing a copy of this notice.
Actions planned by Nobel Biocare	Nobel Biocare have implemented preventive actions, preventing this incident from re-occurring. Nobel Biocare will replace devices subject to this recall free of charge.
Further information and support	If you require any further information or support, please contact your local customer support representative at +39 800 53 93 28.

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 sincerely apologizes for the inconvenience this situation causes you and thank you for your understanding.

Best regards,

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

CUSTOMER ACKNOWLEDGMENT FORM

Identifier: PFA2208

Customer account number: <Insert account number>

Please complete and return this Acknowledgment Form within 5 working days of receipt of this letter, via email to info.italy@nobelbiocare.com 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 used	Quantity returned	Date returned
300859	12167337	*<enter quantity>*			
300859	12167830	*<enter quantity>*			
300859	12168184	*<enter quantity>*			

*Quantity purchased by your organization according to Nobel Biocare records.

Return Address;	Nobel Biocare Dist. Center B.V. Returns Department Popeweg 72 Venlo 5928SC The Netherlands

☐ I have a query, please contact me.

Organization name: _____

Organization address: _____

Contact name: _____

Title or function: _____

Telephone number: _____

Email: _____

_____ _____

Signature Date (mm/dd/yyyy)

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.

DISTRIBUTOR ACKNOWLEDGMENT FORM

Identifier: PFA2208

Distributor account number: <Insert account number>

Please complete and return this Acknowledgment Form within 5 working days of receipt of this letter, via email to info.italy@nobelbiocare.com, 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 used	Quantity returned	Date returned
300859	12167337	*<enter quantity>*			
300859	12167830	*<enter quantity>*			
300859	12168184	*<enter quantity>*			

**Quantity purchased by your organization according to Nobel Biocare records.*

Return Address;	Nobel Biocare Dist. Center B.V. Returns Department Popeweg 72 Venlo 5928SC The Netherlands

☐ I have a query, please contact me.

Organization name: _____

Organization address: _____

Contact name: _____

Title or function: _____

Telephone number: _____

Email: _____

_____ _____

Signature Date (mm/dd/yyyy)

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.