

Company
 Name Surname
 Sample Street 1
 1234 Sample City
 Country

July 30, 2019

URGENT FIELD SAFETY NOTICE

Titanium abutments
 Nobel Biocare FSCA identifier: PFA1914

Dear Nobel Biocare Partner,

Nobel Biocare identified a packaging issue affecting the following medical devices:

Product number	Product description	Lot number
36662	Temporary Abutment Non-Engaging CC RP	13078005
36664	Temporary Abutment Engaging CC RP	13077622
36669	Esthetic Abutment CC RP 1.5mm	13077560
36683	Snappy Abutment 5.5 CC RP 3mm	13077700
38214	Universal Base CC RP 1.5mm	13076822
38761	Temporary Snap Abut Eng CC RP 1.5mm	13077550 13077551

Our records indicate that you purchased a device 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

Packages of abovementioned abutment lots may contain an incorrect screw. The figure below shows an example of a correct and incorrect screw.



Figure 1: Incorrect screw (left, article 37893: Screw Multi-unit Abut Angled CC RP/WP) versus correct screw (right, article 37892: Clinical Screw CC RP/WP)

Potential hazard

The screw will tighten, however it cannot be guaranteed that the screw will not loosen. In case the screw loosens the abutment should be retightened with the correct screw. While unforeseen, if damage to the internal threads of the implant were to occur this would typically require the implant to be removed and replaced with another implant.

**Actions to be taken
by customers**

1. Identify all devices in your stock from the affected lots. Attached Customer Acknowledgment Form indicates which of the lots you purchased according to our records.
2. Do not use devices from the affected lots.
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 all devices from the affected lots to:
Nobel Biocare
Attn: Returns PFA1914
xxxxx
xxxxx
5. Nobel Biocare will replace the devices free of charge.

**Actions planned by
Nobel Biocare**

Nobel Biocare reviewed the packaging 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 organization or to any organization where the potentially affected devices have been transferred.

We kindly ask you to follow instructions provided in this Field Safety Notice. Nobel Biocare confirms that this information has been 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 (phone number)**. We are sorry for the inconvenience and we thank you for your understanding.

Best regards,



Customer Acknowledgment Form

PFA 1914

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				
<input type="checkbox"/> I confirm receipt of the Field Safety Notice and that I read and understood its content.				
<input type="checkbox"/> 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				
<p>The table below indicates the items purchased by you according to our records. Please indicate how many you will be sending back and how many were used.</p>				
Article Number	Lot Number	Quantity Received	Quantity Used	Quantity Sent Back
x	x	x		
Customer information				
<hr style="border: 0; border-top: 1px solid black; margin-bottom: 5px;"/> (Name and phone number)				
<hr style="border: 0; border-top: 1px solid black; margin-bottom: 5px;"/> Signature			<hr style="border: 0; border-top: 1px solid black; margin-bottom: 5px;"/> Date	