

«Name\_1»  
«Name\_2»  
«Street»  
«City», «Rg» «Postal»

April 22, 2015

Dear Nobel Biocare Partner:

**URGENT FIELD SAFETY NOTICE**

**Reference AE1504**

**Replace Select Tapered TiU NP 3.5x10mm**, ref. 29401 (Lot no. 13011366)  
**Replace Select Tapered TiU RP 4.3x11.5mm**, ref. 36107, (Lot no. 13011452)  
**Replace Select Tapered TiU WP 5.0x10mm**, ref 29423 (Lot no. 13012523)

Nobel Biocare Quality Management Systems observed an issue with a material used in the packaging of our implants. Our internal analysis has confirmed that this material is not according to our standards. Nobel Biocare is highly committed to integrate quality in all of our manufacturing processes and to provide the best customer and patient experience.

Based on our testing performed so far and our current knowledge the likelihood that the products listed above cause adverse health consequences is currently considered to be low.

As a precautionary measure, we herewith initiate a removal and exchange of the product(s) received by you listed above. You are, therefore, requested to return the product(s) with above lot number(s) not yet used to Nobel Biocare. You will receive a replacement product.

To acknowledge receipt of this letter, please complete the attached "Acknowledgement" form and fax to +442085736740 or joanne.irvine@nobelbiocare.com In case you have already placed implants, please provide the information in the chart below.

Please accept our apologies for any inconvenience this may cause.

Thank you for your valuable partnership.

If you have further questions, please contact your customer service department.

Yours sincerely,



Barbara Malitschek  
Global Head Regulatory Affairs



Patrick Haeuptli  
Vice President Quality Management

## Acknowledgment AE 1504

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«Name\_1»  
«Customer»

Product Number	Lot Number	Quantity Received	Quantity Sent Back	Quantity Placed
XXXX	XXXXX	XXXXX		

Please mark the appropriate box below, sign and date where indicated, and fax this page to Nobel Biocare as confirmation that you have received this communication and understand the instructions.

Return Email or send a signed copy to:  
**Local Customer Service**

<p><input type="checkbox"/> I have read and understood the Field Correction Letter.</p> <p><input type="checkbox"/> I have read the Field Correction Letter, but I need further assistance. Please contact me:</p> <p>_____</p> <p>(Name and phone number)</p> <p>Name (Print): _____</p> <p>Signature: _____                      Date: _____</p>
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