

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

March 19, 2015

Dear Nobel Biocare Partner:

**IMPORTANT – FIELD CORRECTION Reference AE1504**  
**Product name (product # / lot # -> specific letter for each customer)**

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 «phone number» or «e-mail». 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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Product List,  
FSCA, Nobel Biocare, PAE1504

Material No.	Lot No.	Description	Date Manufacturing	Expiry date
29401	13011446	Replace Select Tapered TiU NP 3.5x10mm	27.01.2015	26.12.2019
29401	13011544	Replace Select Tapered TiU NP 3.5x10mm	03.02.2015	02.01.2020
29401	13011366	Replace Select Tapered TiU NP 3.5x10mm	05.02.2015	04.01.2020
29402	13010895	Replace Select Tapered TiU NP 3.5x13mm	26.01.2015	25.12.2019
29403	13012695	Replace Select Tapered TiU NP 3.5x16mm	05.03.2015	01.02.2020
29423	13012523	Replace Select Tapered TiU WP 5.0x10mm	03.03.2015	30.01.2020
29423	13012525	Replace Select Tapered TiU WP 5.0x10mm	03.03.2015	30.01.2020
29423	13012987	Replace Select Tapered TiU WP 5.0x10mm	04.03.2015	31.01.2020
29424	13011341	Replace Select Tapered TiU WP 5.0x13mm	03.02.2015	02.01.2020
29424	13013046	Replace Select Tapered TiU WP 5.0x13mm	05.03.2015	01.02.2020
32215	13011622	NOBELREPLACE® Tapered Groovy RP 4.3x8mm	26.01.2015	25.12.2019
32215	13013239	NOBELREPLACE® Tapered Groovy RP 4.3x8mm	05.03.2015	01.02.2020
32216	13012851	NOBELREPLACE® Tapered Groovy RP 4.3x10mm	05.03.2015	01.02.2020
32223	13010360	NOBELREPLACE® Tapered Groovy 6.0 6x8mm	05.03.2015	01.02.2020
36103	13010001	NobRpl Tapered Groovy 6.0mm 6x11.5mm	05.02.2015	04.01.2020
36105	13011317	Replace Select Tapered TiU NP 3.5x11.5mm	27.01.2015	26.12.2019
36107	13011452	Replace Select Tapered TiU RP 4.3x11.5mm	22.01.2015	21.12.2019
36107	13011453	Replace Select Tapered TiU RP 4.3x11.5mm	26.01.2015	25.12.2019
36700	13011142	NobelReplace CC NP 3.5x10mm	27.01.2015	26.12.2019
36700	13010972	NobelReplace CC NP 3.5x10mm	27.01.2015	26.12.2019
36700	13010976	NobelReplace CC NP 3.5x10mm	27.01.2015	26.12.2019
36700	13010971	NobelReplace CC NP 3.5x10mm	27.01.2015	26.12.2019
36700	13011771	NobelReplace CC NP 3.5x10mm	27.01.2015	26.12.2019
36700	13011772	NobelReplace CC NP 3.5x10mm	27.01.2015	26.12.2019
36700	13011830	NobelReplace CC NP 3.5x10mm	09.02.2015	08.01.2020
36700	13011828	NobelReplace CC NP 3.5x10mm	09.02.2015	08.01.2020
36700	13012480	NobelReplace CC NP 3.5x10mm	03.03.2015	30.01.2020
36700	13012481	NobelReplace CC NP 3.5x10mm	04.03.2015	31.01.2020
36700	13012482	NobelReplace CC NP 3.5x10mm	04.03.2015	31.01.2020
36700	13012640	NobelReplace CC NP 3.5x10mm	05.03.2015	01.02.2020
36701	13010794	NobelReplace CC NP 3.5x11.5mm	23.01.2015	22.12.2019
36701	13010795	NobelReplace CC NP 3.5x11.5mm	23.01.2015	22.12.2019

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36701	13010977	NobelReplace CC NP 3.5x11.5mm	30.01.2015	29.12.2019
36701	13011241	NobelReplace CC NP 3.5x11.5mm	30.01.2015	29.12.2019
36701	13011242	NobelReplace CC NP 3.5x11.5mm	29.01.2015	28.12.2019
36701	13011370	NobelReplace CC NP 3.5x11.5mm	02.02.2015	01.01.2020
36701	13011556	NobelReplace CC NP 3.5x11.5mm	09.02.2015	08.01.2020
36701	13011836	NobelReplace CC NP 3.5x11.5mm	09.02.2015	08.01.2020
36701	13012139	NobelReplace CC NP 3.5x11.5mm	04.03.2015	31.01.2020
36701	13012755	NobelReplace CC NP 3.5x11.5mm	04.03.2015	31.01.2020
36701	13012840	NobelReplace CC NP 3.5x11.5mm	03.03.2015	30.01.2020
36701	13012841	NobelReplace CC NP 3.5x11.5mm	03.03.2015	30.01.2020
36702	13011775	NobelReplace CC NP 3.5x13mm	29.01.2015	28.12.2019
36702	13011776	NobelReplace CC NP 3.5x13mm	03.02.2015	02.01.2020
36702	13011774	NobelReplace CC NP 3.5x13mm	03.02.2015	02.01.2020
36702	13011826	NobelReplace CC NP 3.5x13mm	04.02.2015	03.01.2020
36702	13011896	NobelReplace CC NP 3.5x13mm	12.02.2015	11.01.2020
36702	13012487	NobelReplace CC NP 3.5x13mm	03.03.2015	30.01.2020
36704	13011378	NobelReplace CC RP 4.3x8mm	04.02.2015	03.01.2020
36704	13011664	NobelReplace CC RP 4.3x8mm	05.02.2015	04.01.2020
36704	13011379	NobelReplace CC RP 4.3x8mm	05.02.2015	04.01.2020
36705	13011154	NobelReplace CC RP 4.3x10mm	22.01.2015	21.12.2019
36705	13011155	NobelReplace CC RP 4.3x10mm	22.01.2015	21.12.2019
36705	13011380	NobelReplace CC RP 4.3x10mm	26.01.2015	25.12.2019
36705	13011202	NobelReplace CC RP 4.3x10mm	28.01.2015	27.12.2019
36705	13011619	NobelReplace CC RP 4.3x10mm	09.02.2015	08.01.2020
36705	13011621	NobelReplace CC RP 4.3x10mm	09.02.2015	08.01.2020
36705	13012148	NobelReplace CC RP 4.3x10mm	04.03.2015	31.01.2020
36705	13012150	NobelReplace CC RP 4.3x10mm	05.03.2015	01.02.2020
36705	13012520	NobelReplace CC RP 4.3x10mm	04.03.2015	31.01.2020
36707	13011157	NobelReplace CC RP 4.3x11.5mm	22.01.2015	21.12.2019
36707	13011158	NobelReplace CC RP 4.3x11.5mm	23.01.2015	22.12.2019
36707	13011204	NobelReplace CC RP 4.3x11.5mm	26.01.2015	25.12.2019
36707	13011459	NobelReplace CC RP 4.3x11.5mm	27.01.2015	26.12.2019
36707	13011461	NobelReplace CC RP 4.3x11.5mm	03.02.2015	02.01.2020
36708	13011199	NobelReplace CC RP 4.3x13mm	23.01.2015	22.12.2019

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36708	13011200	NobelReplace CC RP 4.3x13mm	27.01.2015	26.12.2019
36708	13012501	NobelReplace CC RP 4.3x13mm	04.03.2015	31.01.2020
36708	13012514	NobelReplace CC RP 4.3x13mm	04.03.2015	31.01.2020
36710	13013146	NobelReplace CC RP 5.0x8mm	04.03.2015	31.01.2020
36711	13011136	NobelReplace CC RP 5.0x10mm	26.01.2015	25.12.2019
36711	13011367	NobelReplace CC RP 5.0x10mm	27.01.2015	26.12.2019
36711	13011450	NobelReplace CC RP 5.0x10mm	29.01.2015	28.12.2019
36711	13012929	NobelReplace CC RP 5.0x10mm	03.03.2015	30.01.2020
36713	13010964	NobelReplace CC RP 5.0x13mm	22.01.2015	21.12.2019
36713	13011549	NobelReplace CC RP 5.0x13mm	04.02.2015	03.01.2020
37287	13011140	NobelReplace CC PMC NP 3.5x11.5mm	26.01.2015	25.12.2019
37288	13010297	NobelReplace CC PMC NP 3.5x13mm	05.02.2015	04.01.2020
37290	13011562	NobelReplace CC PMC RP 4.3x8mm	04.03.2015	31.01.2020
37291	13011148	NobelReplace CC PMC RP 4.3x10mm	05.02.2015	04.01.2020
37296	13010961	NobelReplace CC PMC RP 5.0x10mm	11.02.2015	10.01.2020
37296	13013308	NobelReplace CC PMC RP 5.0x10mm	04.03.2015	31.01.2020
37298	13010296	NobelReplace CC PMC RP 5.0x13mm	27.01.2015	26.12.2019