Name 1
Name 2
Address 1
Address 2

March 10, 2017

<p style="text-align:center">URGENT FIELD SAFETY NOTICE
Multi-unit abutment Plus CC RP 2.5mm
Reference #: 38882 Lot #: 12076345</p>

Dear Nobel Biocare Partner,

Thank you for your valuable partnership and trust in Nobel Biocare.

Nobel Biocare want to inform you that our quality management systems have detected that a few parts of the lot # 12076345 of **Multi-unit abutment Plus CC RP 2.5mm** (product # 38882) carry a product label where parts of the information, e.g. lot number and expiry date are missing. Except for this missing information all products within this lot are according to specification and safe to use.

Nobel Biocare is committed to the highest quality standards in all of its manufacturing processes. Nobel Biocare has a zero tolerance policy for product deviations and we have initiated corrective actions to prevent reoccurrence of such an event and improve our systems.

Our records show that you received product(s) from this specific lot # 12076345. We kindly ask you to review your inventory of **Multi-unit abutment Plus CC RP 2.5mm** (product # 38882). After you have reviewed your inventory, please do the following:

1. Complete the attached "Quality Message Acknowledgement" form to confirm receipt of this letter. If you have received parts with the correct label, as illustrated in Figure 1, please check the first box. If you have received parts with incorrect label, as illustrated in Figure 2, please check the second box. If you have questions and wish to be contacted, check the third box.

2. If you have received parts with the correct label, as illustrated in Figure 1, you do not need to take any further actions. Only return the completed form to the address indicated below.

3. If you have received parts with incorrect label, as illustrated in Figure 2, we kindly ask you to immediately return these parts to your Nobel Biocare customer service, together with the completed form, for immediate replacement.

Please send the completed form by fax to XXXXXXXX or by email to XXXXXXXX@nobelbiocare.com

Please accept our sincerest apologies for the inconvenience this has caused. Since Nobel Biocare is committed to the highest quality standards, we are performing this recall/ field action in the interest of our patients and care givers.
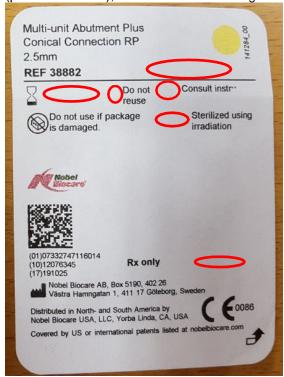
Thank you for your support. If you have further questions, please contact our customer service department at XXXXXXXXX.

Yours sincerely,

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………………..   .

Figure 1. The photo shows the <u>correct</u> product label for the **Multi-unit abutment Plus CC RP 2.5mm** (product # 38882), lot # 12076345.

Figure 2. The photo shows the <u>incorrect</u> product label for the **Multi-unit abutment Plus CC RP 2.5mm** (product # 38882), lot # 12076345. Missing information highlighted in red.

Quality Message Acknowledgment
PAE 1701

Name
Customer no.

Multi-unit abutment Plus CC RP 2.5mm
Reference #: 38882 *Lot #:* 12076345

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Product Number	Lot Number	Quantity received	Quantity to replace
38882	**12076345**	Qty XX	Qty XX

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

Return Fax or Email to:
XXXXXXXXXX or XXXXXXX@nobelbiocare.com

☐   I have read and understood the Quality Message. The product(s) in my inventory is correct.

☐   I have read and understood the Quality Message. The product(s) in my inventory carry an incorrect product label and I send it/them back as requested. I need a replacement product per immediate notice.

☐   I have read and understood the Quality Message. I have questions regarding replacement and return. I request to be contacted.

_____
(Name and phone number)

_____   _____

Signature   Date