

April 19, 2013

Dear Nobel Biocare Partner:

Urgent Field Safety Notice

Procera Abutment Ab Ti f Astra Tech 4.5/5.0ST CAD (Article Nr.: 10-4056)

Procera Abutment Ab Ti f Astra Tech 4.5/5.0ST W-u (Article Nr.: 10-4057)

FSCA-identifier; April 2013

Type of action; device exchange

Our quality management systems have detected that the Procera Abutment Ab Ti f Astra Tech 4.5/5.0ST (W-u) (Article Nr.: 10-4056 and 10-4057) File N° xxxx (Customer specific) you received on 201x-xx-xx may have been manufactured from a raw material that should not have been used for the production of these abutments, is not designed to remain in the oral cavity and should be removed as soon as possible. The external raw material provider did supply the unsuitable material accompanied by a material certification indicating the material is according to the standard requested by NobelBiocare.

An initial clinical assessment by an external specialist showed, that the usage of the above mentioned abutment may affect the longevity and safety of the prosthetic reconstruction. We therefore kindly ask you to remove the prosthetic reconstruction and to replace the abutment with the exchange part supplied by us, which has been manufactured based on the above mentioned file.

Nobel Biocare will provide a complimentary exchange of the product in question including the new product, the costs for the removal and replacement, the costs for reproducing the prosthetic reconstruction and the shipping costs. You as our customer are an important intermediary to the clinician and ultimately to the patient. Therefore, as this is not a standard procedure we offer to all clinician who received abutments potentially resulting from said third-party sourced material blank, to have a Nobel Procera Specialist attending the removal procedure.

Nobel Biocare is committed to the highest Quality in all of its manufacturing processes and has a zero tolerance policy for product defects. We have, therefore, initiated immediate corrective action to prevent reoccurrence of such an event and improve our systems.

Nobel Biocare is following the highest Quality Standards and we are performing this Urgent Field Safety Notice in the interest of patients and care givers. We regret any inconvenience this may have caused you.

Thank you for your valuable partnership.

If you have further questions, please contact our customer service department at XXXXXX.

Yours sincerely,



Beatrice Oberle-Rolle
Global Head Regulatory Affairs



Patrick Haeuptli
Vice President Quality Management

Urgent Field Safety Notice Acknowledgment

AE 1315

Name: XXXXX
 Customer number: XXXXXX

| Product Number | File Number | Clinician name |
|----------------|-------------|---|
| 10-4056 | xxx | <i>To be filled out by the clinician during the visit</i> |
| 10-4057 | yyy | |

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 understood the instructions.

- I have read and understood the Urgent Field Safety Notice.
 I would like a Nobel Procera Specialist to contact the clinician.
- I have read and understood the Urgent Field Safety Notice.
 I would like a Nobel Procera Specialist to support me in contacting the clinician
- I have read and understood the Urgent Field Safety Notice.
 I would like to contact the clinician by myself.

 Signature

 Date