

Name 1
Name 2
Address 1
Address 2

January 16, 2018

URGENT FIELD SAFETY NOTICE
IPS CaseDesigner™ 1.3

Dear Partner,
Thank you for your valuable partnership and trust in our products.

Nobel Biocare wants to inform you that our quality management systems have detected a bug in the version 1.3 of the IPS CaseDesigner™ software which might lead to designing an incorrect intermediate splint to be used during surgery.

The risk mentioned above can only be identified in a very specific scenario:

- 1) A surgery is planned in the version 1.2 of IPS CaseDesigner™, using the maxilla rotation point function - moving it from its default position;
- 2) The user updates the software to the version 1.3;
- 3) The user opens the planning previously made in the version 1.2 with the version 1.3;
- 4) The maxilla rotation point will move back to its default position, changing the plan originally made by the user and originating a file for the creation of an intermediate splint in an incorrect position compared to the one originally designed by the user;
- 5) The user saves the planning in the version 1.3;
- 6) The user orders the splints (intermediate and final) according to the revised planning without noticing the change.

The bug does not affect surgery plans created and opened with the same version of the IPS CaseDesigner™ software – e.g. a surgery plan for which the rotation point for the maxilla has been moved by the user from its default position that is created and saved in version 1.3 and reopened in the same software version at a later date will not be affected by this bug.

A bugfix for this issue is available in the version 1.3.4 of the IPS CaseDesigner™ software.

Our records show that you have installed the version 1.3 of the IPS CaseDesigner™ software affected by the bug. The next time you will open the IPS CaseDesigner™ software, you will receive a pop-up window with the following message:

Update available

Dear IPS CaseDesigner User,

This update contains an important bug fix relating to patient safety. The bug only appears in Maxilla first cases which have been planned in version 1.2 and additionally a custom rotation point of the Maxilla was chosen. The custom rotation point is reset when the planning is opened in version 1.3. This can lead to different planning values or results which can possibly change the originally splint design if not noticed by the User.

The update to version 1.3.4 is therefore mandatory because of potential patient safety risks.

Please do the following:

1. Complete the attached “Quality Message Acknowledgement” form to confirm receipt of this letter;
2. Download the new version 1.3.4 of IPS CaseDesigner™ once prompted the next time you will open the software;
3. If you have planned a treatment on version 1.2 and selected a custom rotation point for the maxilla, and have updated the IPS CaseDesigner™ software to version 1.3.2 or 1.3.3 in the meantime, you are requested to carefully check the plan already saved and the splints potentially ordered and to redo the surgery planning in the new version 1.3.4.

Please send the completed form by fax to +32.15.44.32.09 / +49.7461.706-350 or by email to softwaresupport@nobelbiocare.com or support.ips@klsmartin.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 mandatory update in the interest of our customers and their patients.

Thank you for your support. If you have further questions, please contact our customer service department at +32.15.444.111 (Nobel Biocare) or +49.7461.706-428 / +49.7461.706-449 (KLS Martin).

Yours sincerely,

Barbara Malitschek
Global Head Regulatory Affairs

Daniel Verstappen
Vice President Regulatory Affairs, Quality Assurance
and Design Assurance

Quality Message Acknowledgment

PAE 1729

Name
Customer no.

IPS CaseDesigner™ 1.3

Please tick the 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:
+32.15.44.32.09 / +49.7461.706.350 or softwaresupport@nobelbiocare.com - support.ips@klsmartin.com

I have read and understood the Quality Message.

(Name and phone number)

Signature

Date