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Urgent safety information

Recall regarding

BEGO Semados® SC 3.25 L13 (article no. 58163, LOT 034884)

Dear Dr _____

This letter is to inform you about a recall of one of our products.
The recall refers to the following implant:

BEGO Semados® SC 3.25 L13
Article no.: 58163
LOT no.: 034884

During the production of the implant, there was an error in the labelling on the packaging.
Instead of the text **BEGO Semados® SC 3.25 L13**, the label instead contains the text **BEGO Semados® SC 3.25 113**.

For you as the clinician this means:

When selecting the implant based on the label on the packaging, the erroneous label may lead to misunderstanding of the written text. Instead of the correct implant contained in the packaging of length 13 (L13), you may assume that the packaging instead contains an implant of the length 11.5 (113 or 11.5).

This may lead to you preparing the implant bed for a length of 11.5 and then inserting the implant deeper than the drilled cavity by applying greater force to obtain insertion flush with the bone (predominantly with cancellous bone / D4). This can cause damage to the nerve or other anatomical structures (such as the sinus membrane).



This may consequently lead to anatomical structures (such as the inferior alveolar nerve in the lower jaw) being compressed. If the patient presents with pain (apart from wound pain) or a feeling of numbness, the level of the implant should be corrected or the implant should be removed. If the patient does not have any symptoms, the implant can remain *in situ* and the treatment can proceed as usual. Regular recall appointments are recommended.

If the affected implant has been inserted, we would ask that you complete the attached complaints form and return it to us with a postoperative radiograph. Your contact person in the field service unit will happily assist you with this.

If you have any questions, we can be contacted at any time on +49 421 2028 201 or by email at kroesche@bego.com.

Yours truly

pp Dr Nina Chuchracky
Director of Product Marketing / Dentist
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