FSN Ref: 2020-10-09_USER

FSCA Ref: 2020-10-09

Date: 12. October 2020

Urgent Field Safety Notice

Geistlich Bio-Oss Pen®

Recall of Geistlich Bio-Oss Pen® due to functional issue

For Attention of Geistlich Bio-Oss Pen® User

Dent-Med Materials B.V. Antwoordnummer 634 1700 VB Heerhugowaard Tel. 0226-360 150 .....

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1. Information on Affected Devices

Device Type(s)

Geistlich Bio-Oss Pen® (GBOP) is a product variant providing ease of use in a syringe-like dispenser configuration. The pen contains natural bone mineral for filling of bone defects in maxillofacial surgery, implantology, and periodontology.

Commercial names
Geistlich Bio-Oss Pen® 0.25-1mm 0.25g
Geistlich Bio-Oss Pen® 0.25-1mm 0.5g
Geistlich Bio-Oss Pen® 1-2mm 0.5g

Primary clinical purpose of devices
The pen contains natural bone mineral for filling of bone defects in maxillofacial surgery, implantology, and periodontology

Device Model/Catalogue/part numbers
30661.1, 30662.1, 30671.1, 500606, 500607, 500608

Affected serial or lot number range

Geistlich Bio-Oss Pen 0.25-1mm 0.25g (0.5cc):

82000125; 82000472; 82000541; 81901652

Geistlich Bio-Oss Pen 0.25-1mm 0.5g (1.0cc):

82000126; 82000471; 82000597; 81901653

Geistlich Bio-Oss Pen 1-2mm 0.5g (1.5cc)

82000148; 82000545; 81901074; 81901654

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2. Reason for Field Safety Corrective Action (FSCA)

Description of the product problem
Geistlich Pharma was informed that in individual cases it was difficult to expel the Geistlich Bio-Oss® (GBO) granules from the pen. It was also reported that the resistance could suddenly drop and the granules may be expelled all at once. These appear to be isolated incidents, related to the plunger function of the GBOP. The sudden expulsion of the Bio-Oss granules could affect the surrounding tissue, particularly if used in the sinus lift indication, and while unlikely, could pose a risk for patient harm. Further medical intervention may, in this case be necessary. In an abundance of caution Geistlich Pharma will recall specific lots of GBOP from the customers. Cases that have already been successfully treated with GBOP, do not require any action. *The quality of the Geistlich Bio-Oss® granules is not affected by this issue.*

Hazard giving rise to the FSCA
The sudden expulsion could affect the surrounding tissue, and when used in sinus floor elevation a rupture of the Schneiderian membrane could occur. In this situation some GBO particles could enter the maxillary sinus cavity and would need to be surgically removed. In addition, antibiotic therapy would need to be implemented to prevent further complications. In an abundance of caution Geistlich Pharma will recall specific lots of GBOP from the customers. Cases that have already been successfully treated with GBOP do not require any action. *The quality of the Geistlich Bio-Oss® granules is not affected by this issue.*

3. Type of Action to mitigate the risk

Action to be taken by the User

1. Complete and return the separate FSN Customer Reply Form by **31.10.2020.**

2. If you still have Geistlich Bio-Oss Pen® with the affected lot numbers (see above) on stock, please immediately discontinue use. **After your distribution partner contacted you**, return all affected pens to them. Geistlich Pharma will replace the Geistlich Bio-Oss Pen® with Geistlich Bio-Oss® spongiosa granules or other Geistlich products.

3. If you have experienced this issue and have not reported this to date, please report as a customer complaint to your distribution partner.

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4. General Information

FSN Type: New

Further advice or information already expected in follow-up FSN? Not yet planned

The Competent (Regulatory) Authority of your country has been informed about this communication to customers.

List of attachments/appendices: - Customer Reply Form

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Transmission of this Field Safety Notice

This notice needs to be passed on all those who need to be aware within your organisation or to any organisation where the potentially affected devices have been transferred. (As appropriate)

Please transfer this notice to other organisations on which this action has an impact. (As appropriate)

Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action.

Please report all device-related incidents to the manufacturer, distributor or local representative, and the national Competent Authority if appropriate, as this provides important feedback.

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