



oop Implantate AG · Lorenzweg 5 · D-12099 Berlin · Germany

CUSTOMER
NAME
STREET No.
ZIP-CODE, PLACE

Field Safety Notice

about a FSCA

- Recall-

Berlin, Jan 31th, 2019

Reference-No.: Call# 21058944

Recipient: All customers according to lot vs. sales data from the traceability run in our ERP-System

Identification of medical devices affected:

Medical device: 1) Cortical Screw 3.5, small head, self-tapping, L 20, Titan
2) Cortical Screw 3.5, self-tapping, L 26, Titan

Product description: 1) and 2) self-tapping Titan Screws for use during surgery

Product/Article #: 1) SK 3512-20-2
2) SK 3510-26-2

Lot code: 1) 1077
2) L097

Dear valued customer,

we hereby inform you of a recall regarding cortical screws 3.5 as well as the potential cause and corrective measures in this context.

In the course of a customer complaint, it has been noticed that cortical screws 3.5 have been incorrectly packaged. Shorter screws (20mm) have been incorrectly packed into packaging for longer (26mm) screws as well as longer (26mm) screws have been incorrectly packed into packaging for shorter (20mm) screws.

The cause of the incorrect packaging of cortical screws 3.5 is very likely to be due to a transposition during the packaging process.

Due to the cause, the following corrective measures are carried out by aap Implantate AG:

- 1) Recall Cortical Screw 3.5, small head, self-tapping, L 20, Titan,
Article # SK 3512-20-2, Lot 1077

- 2) Recall Cortical Screw 3.5, self-tapping, L 26, Titan,
Article # SK 3510-26-2, Lot L097

Remaining risks caused by the ongoing use of the non-conforming product/article are checked and evaluated by the subsequent risk analysis of the product/article.

| | |
|----------------------|--|
| very low probability | The application of a screw that is too short or too long occurs with a very low probability. Pre-and intraoperative control measures are highly likely to prevent the use of too short or too long screws. |
| Risk | With a very low risk, there could be the health consequence of insufficient osteosynthesis. |
| Evaluation | Due to pre-and intraoperative control measures, the probability of detection for the application of too short or too long screws is very high. This ensures a high level of patient safety. |
| Decision | Evaluation of all risks (probability and severity) and possible consequences lead to the decision for the FSCA (Recall) of all parts in the field to prevent any further occurrence. |

Please take the following measures without delay:

1. Please remove immediately all products of the affected article- and lot-numbers from your warehouse to prevent further use.
2. With this letter you will receive a confirmation form, please complete it completely, sign it and send it back to us immediately after receiving this information. If you do not have any affected products, please also fill out the confirmation form and fax it to 0049 (0) 30 750 19 111 or mail it to incident@aap.de.
3. Please return all affected products/articles immediately to us.

Forwarding the Field Safety Notice:

Please ensure that all users of the specified products in your organization and all other applicable persons receive notification of this "Field Safety Notice". If the products have been transferred to third parties, please forward a copy of this "Field Safety Notice" or inform the contact person specified below.

Please retain this information at least until all affected products have been returned to us.

The national regulators have been informed of this action.

The Federal Institute for Drugs and Medical Devices has received a copy of this "Field Safety Notice".



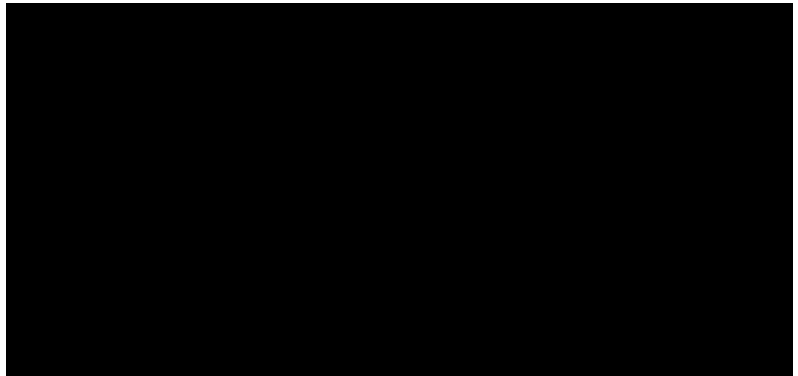
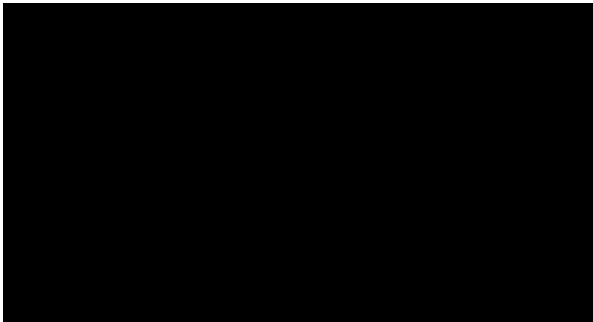
aap Implantate AG · Lorenzweg 5 · D-12099 Berlin · Germany

Contact: Should you have any queries, please do not hesitate to contact:

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12099 Berlin, Germany

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Tel. +49 (0)30 750 19 194
Fax +49 (0)30 750 19 111

Yours truly,
aap Implantate AG



Confirmation of FSCA

1. Cortical Screw 3.5, small head, self-tapping, L 20, Titan, Article # SK 3512-20-2, Lot 1077
2. Cortical Screw 3.5, self-tapping, L 26, Titan, Article # SK 3510-26-2, Lot L097

Please return this form by fax or mail to us immediately. Even if you have any affected products/articles on your stock, please return too!

- O** We confirm the receipt of this information. There is no stock of the product concerned. In the column "Return quantity in pieces" this was noted with the quantity 0.
- D** We confirm the receipt of this information. There is still stock of the product concerned, which will be collected from us.

Please enclose this form of confirmation of receipt/FSCA to the returned products/articles.

| Product description | Lot-number | Quantity of aap supplied | Return quantity in pieces |
|---|------------|--------------------------|---------------------------|
| Cortical Screw 3.5, small head, self-tapping, L 20, Titan, Article # SK 3512-20-2 | 1077 | | |
| Cortical Screw 3.5, self-tapping, L 26, Titan, Article # SK 3510-26-2 | L097 | | |

I confirm the complete examination of our stocks.

Clinic/Physician: _____

Print Name: _____

Telephone number: _____

Signature/Date/Stamp _____

Please return this form to one of the following addresses:

Fax number: 030/750 19 111
 E-Mail: incident@aap.de
 Postal address: aap Implantate AG, Lorenzweg 5, 12099 Berlin
 Attn: department for incoming goods