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

CUSTOMER
NAME
STREET No.
ZIP-CODE, PLACE

Field Safety Notice

about a FSCA

- Recall -

Berlin, Jan 10th, 2019

Reference-No.:	Call# 21058886
Recipient:	All customers according to lot vs. sales data from the traceability run in our ERP-System

Identification of medical devices affected:

Medical device:	Lambotte chisel, 20mm
Product description:	Chisel for manipulation/fixation of the bone slit during an osteotomy treatment
Product/Article #:	IU 3000-20
Lot code:	IU 3000-20 Lot# I011 IU 3000-20 Lot# I012 IU 3000-20 Lot# I013 IU 3000-20 Lot# I014 IU 3000-20 Lot# I015 IU 3000-20 Lot# I016 IU 3000-20 Lot# I017

aap Implantate AG | Lorenzweg 5 | D-12099 Berlin | Germany
Tel.: +49-30-75019-0 | Fax: +49-30-75019-111 | www.aap.de
Vorstand: Bruke Seyoum Alemu · Marek Hahn | Vorsitzender des Aufsichtsrats: Biense Visser
AG Charlottenburg HRB 64083 | VAT: DE 812 290 416 | Steuernummer: 29/532/00534
Deutsche Bank AG
Konto: 160 350 500 | BLZ: 100 700 00
IBAN: DE19 1007 0000 0160 3505 00 | BIC/SWIFT: DEUTDEBB
Commerzbank AG
Konto: 523 330 900 | BLZ: 100 400 00
IBAN: DE98 1004 0000 0523 3309 00 | BIC/SWIFT: COBADEFF

Dear valued customer,

due to a recent complaint by one of our customers regarding a broken Lambotte chisel we realized a non-conformity. The evaluation of this non-conformity indicated the suspicion for a systematic deviation. Therefore, we initiated a serious and detailed preventive inspection of all chisels in stock.

After detailed analysis of the available products we were able to identify the root cause of the original complaint as well as a systematic deviation caused by a supplier of us.

The break of the welded piece parts "chisel body" and "knocking plate" was caused by an unauthorized change of the welding technology by the supplier of these parts.

We also counterchecked parts welded in accordance with the ordered and confirmed specification and got proof again that correct manufactured parts are still safe and effective.

Even if the number of delivered articles is very small, we are obliged to prevent any further occurrence of break during treatment procedures and with this, the risk of procedure prolongation or harm to patients and other parties involved in the treatment procedure.

In consequence we have opened a CAPA-case in accordance with the regulations for medical devices and initiated immediately this FSCA.

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.

high probability	The chisel parts will loose integrity (break into two piece parts) during treatment (hammering to the knocking plate)
Risk	**Short-term** health consequences: contamination of the treatment area, additional injury of tissue/bone. Contusion of the holding hand of the user with a risk for contamination.
	Long-term health consequences: inflammation caused by contamination
Evaluation	The loose part may remain on a small rest of the welded structure, may drop down the floor or in worst case into the treatment area. In worst case (low probability) the part can be taken-off by e.g. a forceps. Even this would occur in a cleaned surrounding additional injury could be caused and inflammation in consequence of contamination could occur. In very seldom cases a contusion of the holding hand including contamination is thinkable. The remaining chisel body can be removed by an additional tool or the hammer itself and/or smooth through and back motions. This has also a low probability of additional injury of tissue or bone but is to be estimated not higher than the risk during the normal treatment itself.
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.

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Please take the following measures without delay:

1. Please immediately remove all products/articles of the affected lot numbers from your stock to secure any 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 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 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".

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

aap Implantate AG
Lorenzweg 5
12099 Berlin, Germany

Robert Bednarek
Deputy Safety Officer Medical Devices
incident@aap.de
Tel. +49 (0)30 750 19 197
Fax +49 (0)30 750 19 175

Yours Sincerely,
aap Implantate AG

[redacted]

Confirmation of FSCA

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!

☐ 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**.

☐ 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 recall of the return.

Product description	Lot-number	Quantity of *aap* supplied	Return quantity in pieces
IU 3000-20	I011		
IU 3000-20	I012		
IU 3000-20	I013		
IU 3000-20	I014		
IU 3000-20	I015		
IU 3000-20	I016		
IU 3000-20	I017		

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
attn: Return Department
Lorenzweg 5
12099 Berlin

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