



aap Implantate AG · Lorenzweg 5 · 12099 Berlin · Germany

**CUSTOMER
NAME
HOUSE No. STREET
POST CODE, CITY**

Field Safety Notice
about a field safety corrective action
- Recall -

Berlin, June 28, 2019

Reference number: 21059440
Recipients: All customers who have received deliveries based on the traceability of the sales data in the ERP System on the products in question.

Identification of the medical devices affected:

Medical device: Basic insert for load drill guide, LOQTEQ® 4.5, round hole
Product description: Part of an instrument for orthopedic fixation
Product/catalogue No.: IU 8167-45
Lot code: I011



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Dear customers,

We are writing to inform you of a recall/FSCA concerning the basic insert for load drill guide LOQTEQ® 4.5, round hole (IU 8167-45) and of the related corrective measures.

The diameter of the basic insert for load drill guide LOQTEQ® 4.5, round hole (IU8167-45; Lot I011) is too large to be used with a LOQTEQ® 4.5 (IU 8167-0X) load drill guide. This means that the function of the basic insert for load drill guide LOQTEQ® 4.5 (IU8167-45) is not fulfilled.

As a result and in accordance with medical device regulations, a recall/FSCA will be initiated for:

- 1) Basic insert for load drill guide, LOQTEQ® 4.5, round hole,
Catalogue number IU 8167-45, lot I011

The residual risks caused by the further use of the product/part affected have been checked and assessed by means of a corresponding risk analysis.

Risks to patients, users and third parties in the event that use has already been made of the product and of the further use of the product including an assessment of the risk(s)

Very low probability	The probability of a basic insert (IU 8167-45, Lot I011) with too large a diameter being used is very low due to the high probability of detection.
Risk	There is no risk to patient safety, user safety or third-party safety. The use of a basic insert (IU 8167-45, Lot I011) with too large a diameter, which makes combination with a load drill guide (IU 8167-0X) and hence compression drilling for locking screws impossible, poses no health risk.
Assessment	The intraoperative use of the basic insert (IU 8167-45, Lot I011) with too large a diameter always leads to the detection of the error, as it makes combination with a load drill guide (IU 8167-0X) and hence compression drilling for locking screws impossible. Alternatively, fracture compression using a double drill guide and standard screw is possible, which compensates for this malfunction. There are no health consequences for the patient or risks for users or third parties.
Decision	Taking into account all risks (and their probabilities and severities) and the possible consequences, the decision was made to carry out corrective actions/recall to prevent this happening again.

Please take the following actions immediately:

1. Please remove all products with the catalogue and lot number in question immediately from your warehouse to prevent further use.
2. With this letter you will receive a confirmation form, please fill it out completely, sign it and return it to us after receiving this information. If you have no affected products, **please** fill out the confirmation form **anyway** and fax it to 0049 (0) 30 750 19 111 or email it to incident@aap.de.
3. Please return all the products that you still have in stock to us immediately.



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Forwarding the corrective action:

Please ensure that all users of the affected products within your organization and other persons who are affected receive this information via the Field Safety Notice. If products are passed on to third parties, please also send these third parties a copy of the Field Safety Notice or inform our contact.

Please retain this information until the complete return of all affected products to aap Implantate AG.

The national authorities are being informed about this FSCA. The Federal Institute for Drugs and Medical Devices has received a copy of this Field Safety Notice.

Please do not hesitate to contact us if you have any questions.

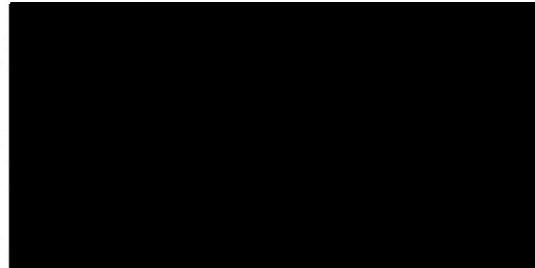
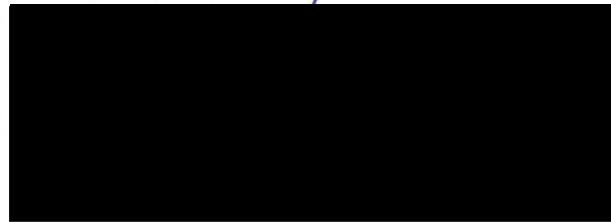
Contact:

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

aap Implantate AG
Lorenzweg 5
12099 Berlin
Germany

Robert Bednarek
Deputy Medical Device Safety Officer
incident@aap.de
Tel. +49(0)30-75019-194
Fax +49(0)30-75019-111

Best wishes,
aap Implantate AG /



Confirmation form for the recall relating to

- 1) the basic insert for load drill guide, LOQTEQ® 4.5, round hole,
catalogue number IU 8167-45, lot I011**

Please send this form back to us by fax or email immediately, even if you no longer have any of the product listed in stock.

- We confirm receipt of this information. We no longer have the product in question in stock. This has been marked with the **Quantity 0** in the "Quantity of returns in pcs" column.
- We confirm receipt of this information. We still have some of the product in question in stock that needs to be collected from us.

Please enclose this confirmation form with the return.

Product name	Lot No.	Quantity delivered by aap	Quantity of returns in pcs
Basic insert for load drill guide, LOQTEQ® 4.5, round hole, catalogue number IU 8167-45	I011		

I hereby confirm that we have checked all of our stocks:

Clinic: _____

Name in block capitals: _____

Telephone number: _____

Signature/date/stamp: _____

Please return this confirmation form to one of the following addresses:

Fax number: **+49 (0) 30 750 19 111**

Email: **incident@aap.de**

Postal address: **aap Implantate AG, Lorenzweg 5, 12099 Berlin, FAO Goods Received**