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

CUSTOMER
NAME
STREET No.
ZIP CODE, CITY

Urgent safety information

Product recall for

aap Drill Guide LOQTEQ® VA with scale up to L 28, drill diam. 2.0, 0°

Berlin, 08/23/2017

Reference number:	21055513
Sender:	*aap* Implantate AG, Lorenzweg 5, 12099 Berlin
Addressees:	Users, orthopedic surgery management, orthopedic department managers; clinical directors, managing directors, sales partners

Identification of affected medical products:

Product category:	Instruments
Trade name:	LOQTEQ® VA drill guide with scale up to L 28, drill diam. 2.0, 0°
Product number:	**IU 8165-22**
Batch number:	All batch numbers I001 to I012

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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 customer,

We are sending you this letter to inform you of circumstances relating to the IU 8165-22 drill guide.

Description of the problem:

Background to the corrective measure, including description of the problem with the product
aap Implantate AG has initiated a recall of the IU 8165-22 drill guide. This relates to batch numbers I001 through I012.

In rare cases, jamming of the drill in the drill guide may occur in association with the use of the corresponding drill. It cannot be excluded that the drill or the drill guide can then no longer be re-used immediately. Depending on the number of instruments in the system, the length of time needed for surgery may be increased. In rare cases, the drill may also break.

The described scenario may have an adverse effect on the course of surgery, and therefore *aap* Implantate AG has decided to recall the above-mentioned drill guide.

Risks to patients, users and third parties with the continued use of the product, including assessment of the risk(s)

High probability	There is no increased risk of failure in normal use.
Risk	**No direct** consequences for health (injuries or illnesses), which could result from the use of, or exposure to, the affected product.
	No long-term consequences for health (injuries or illnesses), which could result from the use of, or exposure to, the affected product.
Assessment	The manufacturer has received a few complaints from the market which related to the scenario described above. At present, the probability of occurrence is categorized as very low.

Very low probability	The drill jams during use with the above-mentioned drill guide and may break.
Risk	**Direct** results may be a longer time needed for surgery, since a suitable replacement needs to be obtained.
	No long-term consequences for health (injuries or illnesses), which could result from the use of, or exposure to, the affected product.
Assessment	The previously known cases permit the conclusion of a very low probability.

What measures must be taken by the addressees?

1. Please remove all drill guides from batches I001 – I012 from your stock immediately, in order to ensure that these cannot be used.
2. As an alternative to the affected IU8165-22 drill guide (fenestrated drill guide) the IU8165-23 (closed drill guide) may continue to be used without problems.
3. With this letter, you will receive a confirmation form. Please complete this in full, sign it and return it to us on receipt of this information. If you do not have any of the affected products **please also fill in** the confirmation form and fax it to 0049 (0)30 750 19 111 or email it to incident@aap.de.
4. Please return all affected products to us immediately, hand them over to the aap Medical Product Advisor or contact your supplier to arrange for collection.

Recommendations for patients or for the treatment/follow-up of patients who have been treated with potentially affected products

There is no subsequent risk for patients who have already been treated. Follow-up treatment is not required.

Forwarding of the described information:

1. Please ensure that users of the products stated above and other persons who are to be informed within your organization are made aware of this **urgent safety information.** If you have passed on the product to others, please forward a copy of this information to them or inform the contact person stated below.
2. Please keep this information at least until all affected products have been returned to us.

The Federal Institute for Drugs and Medical Devices has received a copy of this "Urgent safety information".

Contacts:

In case of queries, please contact:

aap Implantate AG
Lorenzweg 5
12099 Berlin
Germany

Denis Kühn
Safety Representative for Medical Products
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Tel.: +49 (0)30 750 19 197
Fax: +49 (0)30 750 19 111

Yours sincerely
aap Implantate AG

[redacted]

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Denis Kühn
Director Quality Management

Confirmation form for product recall
Drill guide

Please return this form to us immediately by fax or e-mail, even if you no longer have any stocks of the listed product.

☐ We confirm receipt of this information. There are no longer any stocks of the affected product. This is indicated by **Quantity 0** in the "Number of items returned" column.

☐ We confirm receipt of this information. There are still stocks of the affected product These should be collected from us.

Please enclose this confirmation form with the return shipment.

Product name	Batch no.	Quantity delivered by *aap*	Quantity returned

I hereby confirm the complete check of our stocks:

Hospital:

Name in block letters:

Telephone number:

Signature/date/stamp:

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

Fax number: **030/750 19 111**
E-mail: **incident@aap.de**
Postal address: ***aap* Implantate AG**
Attn. Returns Department
Lorenzweg 5
12099 Berlin