

**CUSTOMER
NAME
STREET No.
ZIP-CODE, PLACE**

Urgent Safety Notice
Recall
concerning the
1/3 Tubular Plate 3.5, 2 round holes, L29
1 / 3 Tubular Plate 3.5, 3 round holes, L41

Berlin, February 28, 2017

Reference-No.: CAPA 2017/005
Sender: aap Implantate AG, Lorenzweg 5, 12099 Berlin, Germany
Recipient: User, Head of Orthopedic Surgery, Head of Orthopedics; Clinical
Director, CEO, Sales Partner

Identification of medical devices affected:

Medical device: Osteosynthesis, trauma implant
Product description: 1/3 Tubular Plate 3.5, 2 round holes, L29
1 / 3 Tubular Plate 3.5, 3 round holes, L41

Product number: see Annex A
Lot code: see Annex A

Dear customer,

This letter is to inform you of the recall of certain batches of the titanium 1/3 Tubular Plate 3.5, 2 round holes and 1 /3 Tubular Plate 3.5, 3 round holes.

Description of the problem including the identified cause:

Description of the product

The plates affected by the recall are titanium 1 /3 Tubular Plate of the screw diameter 3.5 without a thread from our range of standard osteosynthesis implants.

Reason for the corrective measure

The item numbers and batches stated above were manufactured out of specification. The relevant plates may have micro fissures which could impair mechanical stability.

Batches other than those mentioned do not have this problem and are therefore not being recalled.

Risks to patients, users and third parties from the continued use of the product, including a risk assessment.

Level Probability	Despite microfissures, the implant possesses a basic stability which is sufficient to resist the low level of forces which arise in the use of these small plates.
Risk	There are no direct health risks (injury or disease) that could result from the use of the relevant product, or from being exposed to the relevant product.
	There are no long-term health risks (injury or disease) that could result from the use of the relevant product, or from being exposed to the relevant product.
Assessment	The affected products have been marketed since 2011. There have been no reports of fractured plates to date. The risk of implant failure can therefore be considered to be minor.

Low Probability	The prior damage to the implant results in premature failure of the plate which may impair the healing of the fracture.
Risk	The direct consequences of an implant failure could be delays in surgery or the need for surgical revision.
	No long-term health risks are anticipated.
Assessment	Replacement of a fractured implant in revision surgery restores the necessary status of treatment. No long-term damage is therefore anticipated.

Very minor Probability	Failure of the previously damaged implant causes unforeseen complications for the patient.
Risk	In very rare cases, indirect consequence to health may result due to the necessity for surgical revision.
	No long-term health risks are anticipated.
Assessment	Indications for the 2 and 3-hole one-third tubular plates basically include the treatment of very small bone defects. Consequently, no major complications are anticipated even in the event of failure.

Risks to patients treated with the affected products, including a risk assessment

Level Probability	Patients treated with an affected implant will in all probability not experience any problem since the implant retains sufficient basic stability.
Risk	There are no direct health risks (injury or disease) which could result from the use of the relevant product, or from being exposed to the relevant product.
	There are no long-term health risks (injury or disease) that could result from the use of the relevant product, or from being exposed to the relevant product.
Assessment	The affected products have been marketed since 2011. There have been no reports of fractured plates to date. The risk of implant failure can therefore be considered to be minor.

Low Probability	In rare cases, the plates may fracture if the forces exceed the residual mechanical stability of the affected products.
Risk	The direct consequences would entail further surgery to replace the damaged implant.
	No long-term health risks are anticipated.
Assessment	Due to the size and short length of the affected implants, they can only be used in regions of the body subject to minor stress. The probability of major force being exerted with the associated danger of implant failure it is therefore considered minor.

Very minor Probability	In very rare cases, additional complications may arise from revision surgery.
Risk	Direct consequences would be an extended treatment period.
	No long-term health risks are anticipated.
Assessment	In the very rare case of further complications associated with an implant fracture, short and medium-term impairment of health is probable.

What actions does the recipient now need to implement?

Please take the following actions without delay:

1. Please immediately remove all products (see Annex A) from your stock to ensure that they can not be used.
2. With this letter you will receive a confirmation form, please complete it completely, sign it and send it back to us 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 immediately to us.

Forwarding the safety notice:

1. Please ensure that all users of the specified products in your organization and all other applicable persons receive notification of this **"Urgent 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.
2. 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 "Urgent Safety Notice".

Contact:

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

aap Implantate AG
Lorenzweg 5
12099 Berlin, Germany

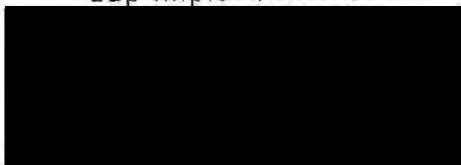
Denis Kühn
Medical Device Safety Officer
incident@aap.de

Tel. +49 (0)30 750 19 197

Fax +49 (0)30 750 19 111

Yours truly,

aap Implantate AG
aap Implantate AG



Denis Kühn
Director Quality Assurance
& Regulatory Affairs

**Confirmation of recall of
1/3 Tubular Plate 3.5, 2 round holes, L29 and 1 /3 Tubular Plate 3.5, 3 round
holes, L41 of the company *aap* Implantate AG**

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

- 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

I confirm the complete examination of our stocks

Clinic: _____

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**

Annex A

Item Number	Product Description		
	1/3 Tubular Plate 3.5, 2 round holes, L 29		
Item Number	Lot	Product Description	Material
PG 3513-02-2	L002	1/3 Tubular Plate 3.5, 2 round holes, L 29	Titanium
PG 3513-02-2	L006	1/3 Tubular Plate 3.5, 2 round holes, L 29	Titanium
PG 3513-02-2	L007	1/3 Tubular Plate 3.5, 2 round holes, L 29	Titanium
PG 3513-02-2	L008	1/3 Tubular Plate 3.5, 2 round holes, L 29	Titanium
	1/3 Tubular Plate 3.5, 3 round holes, L 41		
PG 3513-03-2	L001	1/3 Tubular Plate 3.5, 3 round holes, L 41	Titanium
PG 3513-03-2	L002	1/3 Tubular Plate 3.5, 3 round holes, L 41	Titanium
PG 3513-03-2	L003	1/3 Tubular Plate 3.5, 3 round holes, L 41	Titanium
PG 3513-03-2	L004	1/3 Tubular Plate 3.5, 3 round holes, L 41	Titanium
PG 3513-03-2	L006	1/3 Tubular Plate 3.5, 3 round holes, L 41	Titanium
PG 3513-03-2	L009	1/3 Tubular Plate 3.5, 3 round holes, L 41	Titanium
PG 3513-03-2	L010	1/3 Tubular Plate 3.5, 3 round holes, L 41	Titanium