

aap Implantate AG · Lorenzweg 5 · 12099 Berlin · Germany

**CUSTOMER**

**NAME**

**STREET HOUSE No.**

**POSTAL CODE, CITY**

**Field Safety Notice**

- containing user information as a field safety corrective action -

Berlin, 09.09.2019

**Reference number:** 21059309

**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:** LOQTEQ® Distal Lateral Femur Plate PP

**Product description:** Product to treat fractures of the distal femur and periprosthetic fractures of the femur.

**Product/catalog no.:** PF 4520-09-2, PF 4521-09-2, PF 4520-11-2, PF 4521-11-2,  
PF 4520-13-2, PF 4521-13-2, PF 4520-15-2, PF 4521-15-2,  
PF 4520-17-2, PF 4521-17-2

**Lot code:** all lots

Dear users and customers,

We are writing to give you some important information on the use of the LOQTEQ® Distal Lateral Femur Plate PP.

Because of cases of failure following the field use of LOQTEQ® Distal Lateral Femur Plate PP, this letter is intended to give you some important information on the use of this product which may help minimize the risk of plate failure.

**Information on the use of the LOQTEQ® Distal Lateral Femur Plate PP which may help minimize the risk of plate failure:**

- Adhere to the concept of biological osteosynthesis whenever reasonably possible (“no touch” technique in the fracture zone, minimally invasive methods, MIPO)
- Optimize the biomechanical environment by using long bridging plate structures and optimized motion paths (thereby optimizing the distribution of stress on the implant)
- Use bicortical screw fixation on both sides of the fracture (by using additive plates or polyaxial screws)
- Perform double-plate osteosynthesis or use strut grafts in cases of complex fractures or poor bone quality
- If partial weight bearing cannot be guaranteed because the patient is not expected to comply, current studies recommend using the concept of double-plate osteosynthesis to allow complete weight bearing immediately
- The decision in favor of full weight bearing should be made on a case-by-case basis, taking the patient and his or her compliance and situation (age, weight, comorbidities, previous diseases) into account

The residual risks caused by the further use of the product/part concerned have been reviewed and assessed by an appropriate risk analysis.

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

**Risk assessment:**

Patients who have received a LOQTEQ® Distal Lateral Femur Plate PP are at greater risk of implant failure if the application notes on page 2 has not been followed.

There is no increased risk of implant failure for future patients treated with a LOQTEQ® Distal Lateral Femur Plate PP provided that the above recommendations on the use of the LOQTEQ® Distal Lateral Femur Plate PP are followed.

**Decision:**

In light of all of the risks and potential consequences, a decision has been made to send a Field Safety Notice to users containing important user information which must be followed to prevent future incidents in the field.

Please take the following actions immediately:

1. Please read the information on the use of the LOQTEQ® Distal Lateral Femur Plate PP included with this letter (see page 2).
2. Confirm that you have received, read and understood the information on the use of the LOQTEQ® Distal Lateral Femur Plate PP.

When forwarding the information on the use of the LOQTEQ® Distal Lateral Femur Plate PP:

Please ensure that all users of the products concerned within your organization and other persons concerned 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 notify our contact person.

Please retain this information.

The national authorities are being informed about this Field Safety Notice. 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

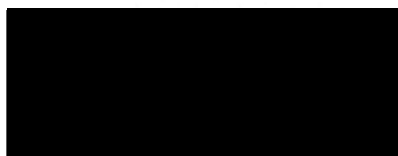
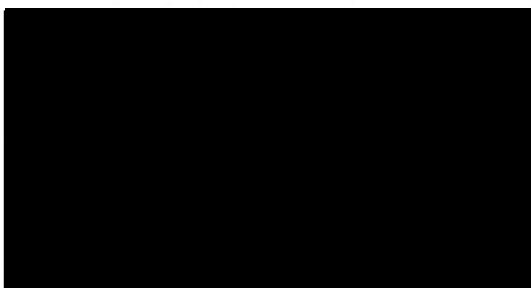
Deputy Medical Device Safety Officer

[incident@aap.de](mailto:incident@aap.de)

Tel. +49(0)30-75019-194

Fax +49(0)30-75019-111

Kind regards,  
aap Implantate AG



Robert Bednarek  
*Deputy Head of Quality Management &  
Deputy Medical Device  
Safety Officer*

### Confirmation form

that the information on the use of the LOQTEQ® Distal Lateral Femur Plate PP has been received, read and understood

Product: LOQTEQ® Distal Lateral Femur Plate PP with the catalog numbers (all lots)

PF 4520-09-2	PF 4521-09-2
PF 4520-11-2	PF 4521-11-2
PF 4520-13-2	PF 4521-13-2
PF 4520-15-2	PF 4521-15-2
PF 4520-17-2	PF 4521-17-2

Please return this confirmation form to us by fax, e-mail, or postal mail as soon as possible.

- We confirm that we have received, read and understood the information on the use of the LOQTEQ® Distal Lateral Femur Plate PP.

**Please return this confirmation form to one of the addresses listed below.**

Hospital: \_\_\_\_\_

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**

E-mail: **incident@aap.de**

Mailing address: **aap Implantate AG, Lorenzweg 5, D-12099 Berlin,  
Attn: Quality Management [z. Hd. Qualitätsmanagement]**