

HOFER GMBH & CO KG

Jahnstrasse 10-12
A 8280 FürstenfeldT: +43 3382 53388
F: +43 3382 53093M: office@hofer-medical.com
W: www.hofer-medical.com

Urgent Field Safety Notice

Fürstenfeld, 02.06.2022

Dear Sirs / Madams,

we would like to inform you that we are performing a field safety correction action (FSCA) for the following products:

Article Number	Article Description	Batch
775-132-151-003	INTEOS Radius M3 ext pal T 9/3 SR	2101003
775-132-150-003	INTEOS Radius M3 ext pal T 9/3 SL	2101002
775-112-151-003	INTEOS Radius M3 pal T 9/3 SR	2101007
775-112-150-003	INTEOS Radius M3 pal T 9/3 SL	2101006
775-112-150-003	INTEOS Radius M3 pal T 9/3 SL	2101449

Reason for Field Safety Notice

The action is taken due to findings in internal standardized screwing tests. Tests were conducted to check locking performance of the system. However, it was discovered that the likelihood of screws being screwed through the plate is increased in the affected batches. Investigations have revealed that the reason is a manufacturing error. The possibility of screwing the screw through the plate exists with orthogonal screwing (angulation = 0°).

Clinical Consequences

If a screw is screwed through the plate, there is no connection between the plate and the screw and the screw is implanted singularly. The screw can either be removed or remain in the body. If the single screw prevents successful reduction, it is rarely necessary to remove the implanted system and repeat the reduction with a new system. For the patient, this results in a longer operation time and additional removal of bone material (additional drilling).

Required Measures

Please take the following actions:

- Check if you have any of the affected batches in stock
- Please complete the enclosed response form and confirm that you have received and acknowledged the Field Safety Notice.
- When using the affected batches, ensure that screws are not screwed in orthogonally (angulation > 0°)

If you have any of the above batches in stock, replacement with a new batch is possible at any time.

If you have any questions regarding this Field Safety Notice, please contact your Hofer Medical Solutions sales representative or our Person Responsible for Regulatory Compliance (PRRC).

DI Christian Maier**Tel.: +43 3382 53388 / e-mail: office@hofer-medical.com**

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We regret any inconvenience this product error may have caused and assure you that we will take appropriate corrective and preventive action to avoid such incidents in the future.

Sincerely,
Hofer GmbH & Co KG
HOFALL 2 GmbH



DI Christian Maier
(CEO, PRRC)

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Field Safety Notice – Response Form

Please complete this response form and send it within 10 days to

Fax: +43 3382 53093 / E-Mail: office@hofer-medical.com

According to our traceability documentation, you received INTEOS Radius M3 (ext) pal plates from the affected batches between January 2022 and May 2022.

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775-112-150-003	INTEOS Radius M3 pal T 9/3 SL	2101449

- There are _____ [quantity] of affected products in our facility that we will return to you.
- There are _____ [quantity] of affected products in our facility. We will not return the affected products.
- There are none of the affected products in our facility.

We have received the information and ensured that all users of the above-mentioned products and other persons to be informed have been made aware of this Field Safety Notice. The measures described therein have been implemented accordingly.

_____ Date

_____ Health facility

_____ Name in block capitals

_____ Signature