

I.T.S. GmbH

Autal 28, 8301 Lassnitzhöhe, Austria

Tel.: +43 316 211 21 0

Fax: +43 316 211 21 20

office@its-implant.com

www.its-implant.com

Urgent Notice

09.05.2019

MEDICAL DEVICE RECALL - 01/2019

Rim Plate, Left, 10-Hole, PRS RX System

Identification of the affected device:

Rim Plate, Left, 10-Hole, PRS RX System

Article Number: 21206-10

Lot Number: 26/F42778

Dear Sir/Madam,

This letter is to inform you that I.T.S. GmbH has initiated a voluntary Recall of mentioned articles.

In order to exclude the risk of confusion, the affected batch is exchanged.

Our records indicate that you may have inventory of the affected product. I.T.S. GmbH is issuing this notice to make users aware of this letter and the corrective actions and request them to distribute this notice immediately to the appropriate people within your hospital/company..

Please confirm the receipt of this letter. Furthermore, kindly complete the attached "Fax-Back Response Form" and return without delay to the address below via Fax or E-Mail.

If you have any questions, please do not hesitate to contact me directly.

Phone: +43 316 211 0

Fax: +43 316 211 20

E-Mail: office@its-implant.com

Thank you for your support.

Reason for the Recall:

The I.T.S. GmbH has been informed that the above mentioned plate is marked with 21206-14, but in fact it is article 21206-10, as also correctly indicates the label. The discrepancy in the laser marking of the article could be limited to one single batch.

Potential hazard:

There are no risks to the patient or user due to the product. The packaging label indicates the user that the product is a 10-hole rim plate, which is the actual content. However, the laser marking shows a 14-hole rim plate.

It is possible to identify the discrepancy when the plate is placed in the sterilization tray and thus before the cleaning and disinfecting process and the actual surgery. If the plate is used in the operating room, the user orientates himself to the geometry and length of the implant, whether it is suitable for the type of fracture and not on the article number.

At the current time we have received no information with patient participation.

Customer immediate actions:

- 1. Immediately review your inventory to identify and quarantine all affected products listed above in a manner that ensures the affected products will not be used.**
- 2. Review, complete, sign and return the attached reply form of this letter and send it back within 5 business days of receipt of this notification.**
- 3. Return any affected product as soon as possible, but within 30 business days and include a copy of this notification.**
- 4. Forward this notice to anyone in your facility that needs to be informed about this recall.**
- 5. If any of the affected products has been forwarded to another facility, contact that facility to arrange return and provide them with a copy of this notification.**
- 6. Keep a copy of this letter.**

It is the goal of I.T.S. GmbH, only to deliver products of the highest quality standard and to ensure full cooperation.

We apologize for any inconvenience that this field safety notification may create and appreciate your cooperation with our request.

Should you have any queries, please do not hesitate to contact your I.T.S. GmbH sales consultant..

FAX-BACK RESPONSE FORM

| Article description | Article Number | LOT Number |
|---|----------------|------------|
| Rim Plate, Left, 10-Hole, PRS RX System | 21206-10 | 26/F42778 |

- Hereby, I confirm that I acknowledged this notification and distributed this notice to the appropriate people within my hospital / company.
- We have checked our inventory and confirm, that we have no affected product in stock. We will keep a copy of this letter for our records.
- We have checked our inventory and secured the listed product and send it back to the mentioned address.
We will keep a copy of this letter for our records.

| Article Number | Lot-No. | Qty. | Comment |
|----------------|-----------|------|---------|
| 21206-10 | 26/F42778 | | |

Hospital / Company

Adress

Name

Function / Pos.

E-Mail

Phone

Date

Signature / Stamp
