MARQUARDT
Medizintechnik

Date: 05.08.2025

For the attention of the surgical management team:
URGENT SAFETY Notice
MEDICAL DEVICE RECALL concerning:
REF: 09.63030.110S, Lot: 25/175120

REF	Description	LOT	UDI-PI
09.63030.110S	VITUS-Fi Fibulanail Ø 3.0 mm, L 110 mm	25/175120	(01)04250185298303 (17)300531 (10)25/175120

Dear Sir or Madam,
Marquardt Medizintechnik GmbH is initiating a voluntary product recall. This product recall covers the REF: 09.63030.110S, LOT: 25/175120, which is listed in the table above.

The affected fibula nail is intended for Stable Fixation and soft tissue sparing treatment of distal fibula fractures.

Our records indicate that you or your institution have received one or more units of the above-listed products. Please read these instructions carefully in order to respond to this safety measure (recall).

Reason for voluntary medical device recall:
The affected LOT number is being recalled due to a manufacturing defect. This manufacturing defect resulted in the proximal 4° bend of the nail being made in the wrong direction. Note: Marquardt Medizintechnik has determined that not all nails with the affected LOT number are affected. However, to ensure patient safety, all nails with the affected LOT number are being recalled.

Potential impact on the patient:
It is likely that the user will notice the manufacturing defect when mounting the implant on the target instrument and before insertion. This will probably cause the user to use another nail of the same design, which may delay the surgical procedure.
If the manufacturing defect is not detected when mounting the implant on the target instrument, it will not be possible to insert the implant completely and it will be necessary to switch to a different implant during surgery, which may also delay the surgical procedure.
Doctors who have treated patients with the aforementioned LOT number should care for these patients postoperatively in the usual manner without the need for additional measures.

Dieter Marquardt
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78549 Spaichingen, Germany

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Telefax +49 7424 501441
info@marquardt-medizintechnik.de
www.marquardt-medizintechnik.de

Geschäftsführer: Dieter Marquardt,
Kim Marquardt Stoll, Timo Dietrich
Handelsregister: Amtsgericht Stuttgart
HRB 460719

Required measures:

1. Please check your inventory immediately and withdraw all affected products from circulation until they are returned to Marquardt Medizintechnik.

2. Please ensure that all users of the above-mentioned products and other persons who need to be informed are made aware of this urgent safety information within your organisation.

3. Please ensure that this notice is observed in your facility until all necessary internal measures have been completed.

4. Please inform Marquardt Medizintechnik if affected products have been passed on to other facilities. Please provide us with the contact details so that Marquardt Medizintechnik can inform the recipients accordingly.

5. Inform Marquardt Medizintechnik of any adverse events related to the use of the affected products.

6. Comply with all national laws and regulations regarding the reporting of adverse events to the competent supervisory authority in your country.

7. Fill out the enclosed return form and send it back to the specified fax number or email address.

8. Please return the completed form to us within 3 calendar days of the date of receipt.

9. Please retain this information at least until the measure has been completed.

We confirm that the competent national authorities in your country have been informed of this safety-related corrective measure for users and that the Federal Institute for Drugs and Medical Devices (BfArM) has received a copy of this 'Urgent Safety Information'.

We apologise for any inconvenience caused by this product recall and thank you for your cooperation.

Yours sincerely

Volker Bühler (Dip. Ing. FH.)
(QMB / PRRC)

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RETURN FORM

If you have any questions, please contact us at:

Dieter Marquardt-Medizintechnik GmbH
Robert-Bosch-Str.1
78549 Spaichingen

Tel: +49/7424/95810
FAX: +49/7424/501441
E-Mail: info@marquardt-medizintechnik.de

Your personal contact person for this matter is listed below. If you have any questions about this measure, please contact your contact person directly.

Name: Volker Bühler, Funktion: Leiter QMB/PRRC, Tel. +49/7424/958115 oder 0170/1629820
Email: v.buehler@marquardt-medizintechnik.de

Hospital: _____

Postcode, town: _____

Contact person (name, position): _____

Telephone number:_____

Please tick the appropriate box::

☐ I have received the notification from Dieter Marquardt Medizintechnik GmbH regarding the products listed below.

☐ I have checked our inventory and confirm that we do not have any affected products in stock.

☐ I have checked our inventory. The listed products are in our inventory.

Quantity	REF	Descripion	LOT
_____ piece	09.63030.110S	VITUS-Fi Fibulanaill Ø 3.0 mm, L 110 mm	25/175120

Please arrange for a new delivery or collection in the following department:

_____

☐ We have forwarded/sold items to the following institutions:

_____

_____

(Name, address, contact person and telephone number of the institution)

Please complete this form in full, even if you have already used up/destroyed the aforementioned products, and fax or email it to the number below.

_____

(Date / legally valid signature of a person from the medical facility))

Please fax or email this reply form to:
+49 /7424 / 501441 or by Email to info@marquardt-medizintechnik.de
Please ensure that, when returning the form,
proof of decontamination is enclosed, if necessary

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