

Date: 26.09.2025

URGENT SAFETY Notice
RECALL for medical devices

REF	designation	LOT
09.63030.110S	VITUS-Fi Distal Fibula Nail Ø 3.0 mm, L 110 mm	See appendix
09.63030.145S	VITUS-Fi Distal Fibula Nail Ø 3.0 mm, L 145mm	See appendix
09.63030.180S	VITUS-Fi Distal Fibula Nail Ø 3.0 mm, L 180mm	See appendix
09.63036.110S	VITUS-Fi Distal Fibula Nail Ø 3.6mm, L 110mm	See appendix
09.63036.145S	VITUS-Fi Distal Fibula Nail Ø 3.6mm, L 145mm	See appendix
09.63036.180S	VITUS-Fi Distal Fibula Nail Ø 3.6mm, L 180mm	See appendix

Dear Sir or Madam,

Marquardt Medizintechnik GmbH is initiating a voluntary product recall. This product recall covers the LOT numbers listed in the appendix.

The fibula nails in question are 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 products listed in the attachment. Please read this information carefully in order to respond to this safety measure (recall).

Reason for the voluntary medical device recall:

The listed LOT numbers are being recalled as a precautionary measure to check whether the proximal 4° bend of the nail complies with the technical specifications and has been performed in the correct direction. Marquardt has received a total of two reports in which deviations in the bend were detected. To ensure patient safety, all LOT numbers from the production period to be checked are therefore being voluntarily recalled.

Potential impact on patients:

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 another implant during surgery, which may also delay the surgical procedure.

Doctors who have treated patients with the affected LOT numbers should care for these patients postoperatively in the usual manner without any additional measures being necessary.

Required measures:

1. Please check your inventory immediately and withdraw all affected products from circulation until they are returned.
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. 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. Complete 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 notified 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)

Appendix:

REF	LOT	Description
09.63030.110S	20/125496	VITUS-Fi Distal Fibula Nail ø 3.0mm, L 110mm
09.63030.110S	20/126473	VITUS-Fi Distal Fibula Nail ø 3.0mm, L 110mm
09.63030.110S	20/126474	VITUS-Fi Distal Fibula Nail ø 3.0mm, L 110mm
09.63030.110S	20/128077	VITUS-Fi Distal Fibula Nail ø 3.0mm, L 110mm
09.63030.110S	21/130106	VITUS-Fi Distal Fibula Nail ø 3.0mm, L 110mm
09.63030.110S	21/131501	VITUS-Fi Distal Fibula Nail ø 3.0mm, L 110mm
09.63030.110S	21/132148	VITUS-Fi Distal Fibula Nail ø 3.0mm, L 110mm
09.63030.110S	21/134566	VITUS-Fi Distal Fibula Nail ø 3.0mm, L 110mm
09.63030.110S	21/136928	VITUS-Fi Distal Fibula Nail ø 3.0mm, L 110mm
09.63030.110S	21/138190	VITUS-Fi Distal Fibula Nail ø 3.0mm, L 110mm
09.63030.110S	21/139030	VITUS-Fi Distal Fibula Nail ø 3.0mm, L 110mm
09.63030.110S	21/139739	VITUS-Fi Distal Fibula Nail ø 3.0mm, L 110mm
09.63030.110S	21/140363	VITUS-Fi Distal Fibula Nail ø 3.0mm, L 110mm
09.63030.110S	22/141680	VITUS-Fi Distal Fibula Nail ø 3.0mm, L 110mm
09.63030.110S	22/142833	VITUS-Fi Distal Fibula Nail ø 3.0mm, L 110mm
09.63030.110S	22/143273	VITUS-Fi Distal Fibula Nail ø 3.0mm, L 110mm
09.63030.110S	22/144970	VITUS-Fi Distal Fibula Nail ø 3.0mm, L 110mm
09.63030.110S	22/145341	VITUS-Fi Distal Fibula Nail ø 3.0mm, L 110mm
09.63030.110S	22/145576	VITUS-Fi Distal Fibula Nail ø 3.0mm, L 110mm
09.63030.110S	22/147166	VITUS-Fi Distal Fibula Nail ø 3.0mm, L 110mm
09.63030.110S	22/148075	VITUS-Fi Distal Fibula Nail ø 3.0mm, L 110mm
09.63030.110S	22/150536	VITUS-Fi Distal Fibula Nail ø 3.0mm, L 110mm
09.63030.110S	22/152113	VITUS-Fi Distal Fibula Nail ø 3.0mm, L 110mm
09.63030.110S	23/154984	VITUS-Fi Distal Fibula Nail ø 3.0mm, L 110mm
09.63030.110S	23/154985	VITUS-Fi Distal Fibula Nail ø 3.0mm, L 110mm
09.63030.110S	23/156047	VITUS-Fi Distal Fibula Nail ø 3.0mm, L 110mm
09.63030.110S	23/159344	VITUS-Fi Distal Fibula Nail ø 3.0mm, L 110mm
09.63030.110S	23/160752	VITUS-Fi Distal Fibula Nail ø 3.0mm, L 110mm
09.63030.110S	24/164202	VITUS-Fi Distal Fibula Nail ø 3.0mm, L 110mm
09.63030.110S	24/166150	VITUS-Fi Distal Fibula Nail ø 3.0mm, L 110mm
09.63030.110S	24/167132	VITUS-Fi Distal Fibula Nail ø 3.0mm, L 110mm
09.63030.110S	24/169227	VITUS-Fi Distal Fibula Nail ø 3.0mm, L 110mm
09.63030.110S	24/169586	VITUS-Fi Distal Fibula Nail ø 3.0mm, L 110mm
09.63030.110S	24/170562	VITUS-Fi Distal Fibula Nail ø 3.0mm, L 110mm
09.63030.145S	20/126315	VITUS-Fi Distal Fibula Nail ø 3.0mm, L 145mm
09.63030.145S	20/126475	VITUS-Fi Distal Fibula Nail ø 3.0mm, L 145mm

REF	LOT	Description
09.63036.110S	20/125497	VITUS-Fi Distal Fibula Nail ø 3.6mm, L 110mm
09.63036.110S	20/128079	VITUS-Fi Distal Fibula Nail ø 3.6mm, L 110mm
09.63036.110S	21/131503	VITUS-Fi Distal Fibula Nail ø 3.6mm, L 110mm
09.63036.110S	21/133845	VITUS-Fi Distal Fibula Nail ø 3.6mm, L 110mm
09.63036.110S	21/135635	VITUS-Fi Distal Fibula Nail ø 3.6mm, L 110mm
09.63036.110S	21/137422	VITUS-Fi Distal Fibula Nail ø 3.6mm, L 110mm
09.63036.110S	21/138706	VITUS-Fi Distal Fibula Nail ø 3.6mm, L 110mm
09.63036.110S	22/140875	VITUS-Fi Distal Fibula Nail ø 3.6mm, L 110mm
09.63036.110S	22/141683	VITUS-Fi Distal Fibula Nail ø 3.6mm, L 110mm
09.63036.110S	22/143276	VITUS-Fi Distal Fibula Nail ø 3.6mm, L 110mm
09.63036.110S	22/143856	VITUS-Fi Distal Fibula Nail ø 3.6mm, L 110mm
09.63036.110S	22/145577	VITUS-Fi Distal Fibula Nail ø 3.6mm, L 110mm
09.63036.110S	22/148078	VITUS-Fi Distal Fibula Nail ø 3.6mm, L 110mm
09.63036.110S	22/152116	VITUS-Fi Distal Fibula Nail ø 3.6mm, L 110mm
09.63036.110S	23/154990	VITUS-Fi Distal Fibula Nail ø 3.6mm, L 110mm
09.63036.110S	23/154992	VITUS-Fi Distal Fibula Nail ø 3.6mm, L 110mm
09.63036.110S	23/156049	VITUS-Fi Distal Fibula Nail ø 3.6mm, L 110mm
09.63036.110S	23/159347	VITUS-Fi Distal Fibula Nail ø 3.6mm, L 110mm
09.63036.110S	24/164204	VITUS-Fi Distal Fibula Nail ø 3.6mm, L 110mm
09.63036.110S	24/164759	VITUS-Fi Distal Fibula Nail ø 3.6mm, L 110mm
09.63036.110S	24/166357	VITUS-Fi Distal Fibula Nail ø 3.6mm, L 110mm
09.63036.110S	24/170565	VITUS-Fi Distal Fibula Nail ø 3.6mm, L 110mm
09.63036.110S	25/173934	VITUS-Fi Distal Fibula Nail ø 3.6mm, L 110mm
09.63036.145S	20/127080	VITUS-Fi Distal Fibula Nail ø 3.6mm, L 145mm
09.63036.145S	20/128307	VITUS-Fi Distal Fibula Nail ø 3.6mm, L 145mm
09.63036.145S	21/130762	VITUS-Fi Distal Fibula Nail ø 3.6mm, L 145mm
09.63036.145S	21/130952	VITUS-Fi Distal Fibula Nail ø 3.6mm, L 145mm
09.63036.145S	21/133846	VITUS-Fi Distal Fibula Nail ø 3.6mm, L 145mm
09.63036.145S	21/134569	VITUS-Fi Distal Fibula Nail ø 3.6mm, L 145mm
09.63036.145S	21/135043	VITUS-Fi Distal Fibula Nail ø 3.6mm, L 145mm
09.63036.145S	21/135849	VITUS-Fi Distal Fibula Nail ø 3.6mm, L 145mm
09.63036.145S	21/137423	VITUS-Fi Distal Fibula Nail ø 3.6mm, L 145mm
09.63036.145S	21/138489	VITUS-Fi Distal Fibula Nail ø 3.6mm, L 145mm
09.63036.145S	21/139033	VITUS-Fi Distal Fibula Nail ø 3.6mm, L 145mm
09.63036.145S	21/140365	VITUS-Fi Distal Fibula Nail ø 3.6mm, L 145mm
09.63036.145S	22/141684	VITUS-Fi Distal Fibula Nail ø 3.6mm, L 145mm



REF	LOT	Description
09.63030.145S	20/128078	VITUS-Fi Distal Fibula Nail ø 3.0mm, L 145mm
09.63030.145S	20/128899	VITUS-Fi Distal Fibula Nail ø 3.0mm, L 145mm
09.63030.145S	21/130107	VITUS-Fi Distal Fibula Nail ø 3.0mm, L 145mm
09.63030.145S	21/131837	VITUS-Fi Distal Fibula Nail ø 3.0mm, L 145mm
09.63030.145S	21/132149	VITUS-Fi Distal Fibula Nail ø 3.0mm, L 145mm
09.63030.145S	21/134310	VITUS-Fi Distal Fibula Nail ø 3.0mm, L 145mm
09.63030.145S	21/134567	VITUS-Fi Distal Fibula Nail ø 3.0mm, L 145mm
09.63030.145S	21/135634	VITUS-Fi Distal Fibula Nail ø 3.0mm, L 145mm
09.63030.145S	21/137421	VITUS-Fi Distal Fibula Nail ø 3.0mm, L 145mm
09.63030.145S	21/138192	VITUS-Fi Distal Fibula Nail ø 3.0mm, L 145mm
09.63030.145S	21/138486	VITUS-Fi Distal Fibula Nail ø 3.0mm, L 145mm
09.63030.145S	21/140364	VITUS-Fi Distal Fibula Nail ø 3.0mm, L 145mm
09.63030.145S	21/140384	VITUS-Fi Distal Fibula Nail ø 3.0mm, L 145mm
09.63030.145S	22/141681	VITUS-Fi Distal Fibula Nail ø 3.0mm, L 145mm
09.63030.145S	22/142834	VITUS-Fi Distal Fibula Nail ø 3.0mm, L 145mm
09.63030.145S	22/143854	VITUS-Fi Distal Fibula Nail ø 3.0mm, L 145mm
09.63030.145S	22/144971	VITUS-Fi Distal Fibula Nail ø 3.0mm, L 145mm
09.63030.145S	22/146061	VITUS-Fi Distal Fibula Nail ø 3.0mm, L 145mm
09.63030.145S	22/147167	VITUS-Fi Distal Fibula Nail ø 3.0mm, L 145mm
09.63030.145S	22/150537	VITUS-Fi Distal Fibula Nail ø 3.0mm, L 145mm
09.63030.145S	22/150962	VITUS-Fi Distal Fibula Nail ø 3.0mm, L 145mm
09.63030.145S	22/152114	VITUS-Fi Distal Fibula Nail ø 3.0mm, L 145mm
09.63030.145S	23/153466	VITUS-Fi Distal Fibula Nail ø 3.0mm, L 145mm
09.63030.145S	23/154754	VITUS-Fi Distal Fibula Nail ø 3.0mm, L 145mm
09.63030.145S	23/154987	VITUS-Fi Distal Fibula Nail ø 3.0mm, L 145mm
09.63030.145S	23/156048	VITUS-Fi Distal Fibula Nail ø 3.0mm, L 145mm
09.63030.145S	23/157243	VITUS-Fi Distal Fibula Nail ø 3.0mm, L 145mm
09.63030.145S	23/159345	VITUS-Fi Distal Fibula Nail ø 3.0mm, L 145mm
09.63030.145S	23/161592	VITUS-Fi Distal Fibula Nail ø 3.0mm, L 145mm
09.63030.145S	24/167134	VITUS-Fi Distal Fibula Nail ø 3.0mm, L 145mm
09.63030.145S	24/169229	VITUS-Fi Distal Fibula Nail ø 3.0mm, L 145mm
09.63030.145S	24/169587	VITUS-Fi Distal Fibula Nail ø 3.0mm, L 145mm
09.63030.145S	24/170563	VITUS-Fi Distal Fibula Nail ø 3.0mm, L 145mm
09.63030.145S	25/176847	VITUS-Fi Distal Fibula Nail ø 3.0mm, L 145mm
09.63030.180S	20/126476	VITUS-Fi Distal Fibula Nail ø 3.0mm, L 180mm
09.63030.180S	20/127079	VITUS-Fi Distal Fibula Nail ø 3.0mm, L 180mm
09.63030.180S	20/128744	VITUS-Fi Distal Fibula Nail ø 3.0mm, L 180mm

REF	LOT	Description
09.63036.145S	22/143857	VITUS-Fi Distal Fibula Nail ø 3.6mm, L 145mm
09.63036.145S	22/144787	VITUS-Fi Distal Fibula Nail ø 3.6mm, L 145mm
09.63036.145S	22/144973	VITUS-Fi Distal Fibula Nail ø 3.6mm, L 145mm
09.63036.145S	22/145578	VITUS-Fi Distal Fibula Nail ø 3.6mm, L 145mm
09.63036.145S	22/147169	VITUS-Fi Distal Fibula Nail ø 3.6mm, L 145mm
09.63036.145S	22/150067	VITUS-Fi Distal Fibula Nail ø 3.6mm, L 145mm
09.63036.145S	22/150963	VITUS-Fi Distal Fibula Nail ø 3.6mm, L 145mm
09.63036.145S	22/152117	VITUS-Fi Distal Fibula Nail ø 3.6mm, L 145mm
09.63036.145S	23/154993	VITUS-Fi Distal Fibula Nail ø 3.6mm, L 145mm
09.63036.145S	23/156050	VITUS-Fi Distal Fibula Nail ø 3.6mm, L 145mm
09.63036.145S	23/158816	VITUS-Fi Distal Fibula Nail ø 3.6mm, L 145mm
09.63036.145S	23/160754	VITUS-Fi Distal Fibula Nail ø 3.6mm, L 145mm
09.63036.145S	24/164205	VITUS-Fi Distal Fibula Nail ø 3.6mm, L 145mm
09.63036.145S	24/164760	VITUS-Fi Distal Fibula Nail ø 3.6mm, L 145mm
09.63036.145S	24/167137	VITUS-Fi Distal Fibula Nail ø 3.6mm, L 145mm
09.63036.145S	24/169231	VITUS-Fi Distal Fibula Nail ø 3.6mm, L 145mm
09.63036.145S	24/171047	VITUS-Fi Distal Fibula Nail ø 3.6mm, L 145mm
09.63036.145S	24/173001	VITUS-Fi Distal Fibula Nail ø 3.6mm, L 145mm
09.63036.145S	25/173935	VITUS-Fi Distal Fibula Nail ø 3.6mm, L 145mm
09.63036.180S	20/125498	VITUS-Fi Distal Fibula Nail ø 3.6mm, L 180mm
09.63036.180S	20/128080	VITUS-Fi Distal Fibula Nail ø 3.6mm, L 180mm
09.63036.180S	21/130763	VITUS-Fi Distal Fibula Nail ø 3.6mm, L 180mm
09.63036.180S	21/130953	VITUS-Fi Distal Fibula Nail ø 3.6mm, L 180mm
09.63036.180S	21/133847	VITUS-Fi Distal Fibula Nail ø 3.6mm, L 180mm
09.63036.180S	21/135636	VITUS-Fi Distal Fibula Nail ø 3.6mm, L 180mm
09.63036.180S	21/138707	VITUS-Fi Distal Fibula Nail ø 3.6mm, L 180mm
09.63036.180S	21/139034	VITUS-Fi Distal Fibula Nail ø 3.6mm, L 180mm
09.63036.180S	22/140876	VITUS-Fi Distal Fibula Nail ø 3.6mm, L 180mm
09.63036.180S	22/141685	VITUS-Fi Distal Fibula Nail ø 3.6mm, L 180mm
09.63036.180S	22/143282	VITUS-Fi Distal Fibula Nail ø 3.6mm, L 180mm
09.63036.180S	22/143858	VITUS-Fi Distal Fibula Nail ø 3.6mm, L 180mm
09.63036.180S	22/144974	VITUS-Fi Distal Fibula Nail ø 3.6mm, L 180mm
09.63036.180S	22/145579	VITUS-Fi Distal Fibula Nail ø 3.6mm, L 180mm
09.63036.180S	22/150068	VITUS-Fi Distal Fibula Nail ø 3.6mm, L 180mm
09.63036.180S	22/150964	VITUS-Fi Distal Fibula Nail ø 3.6mm, L 180mm
09.63036.180S	22/152118	VITUS-Fi Distal Fibula Nail ø 3.6mm, L 180mm
09.63036.180S	23/154991	VITUS-Fi Distal Fibula Nail ø 3.6mm, L 180mm



REF	LOT	Description
09.63030.180S	21/131502	VITUS-Fi Distal Fibula Nail ø 3.0mm, L 180mm
09.63030.180S	21/134568	VITUS-Fi Distal Fibula Nail ø 3.0mm, L 180mm
09.63030.180S	21/136929	VITUS-Fi Distal Fibula Nail ø 3.0mm, L 180mm
09.63030.180S	21/138487	VITUS-Fi Distal Fibula Nail ø 3.0mm, L 180mm
09.63030.180S	21/139032	VITUS-Fi Distal Fibula Nail ø 3.0mm, L 180mm
09.63030.180S	22/141682	VITUS-Fi Distal Fibula Nail ø 3.0mm, L 180mm
09.63030.180S	22/143855	VITUS-Fi Distal Fibula Nail ø 3.0mm, L 180mm
09.63030.180S	22/144972	VITUS-Fi Distal Fibula Nail ø 3.0mm, L 180mm
09.63030.180S	22/146062	VITUS-Fi Distal Fibula Nail ø 3.0mm, L 180mm
09.63030.180S	22/147168	VITUS-Fi Distal Fibula Nail ø 3.0mm, L 180mm
09.63030.180S	22/150538	VITUS-Fi Distal Fibula Nail ø 3.0mm, L 180mm
09.63030.180S	22/152115	VITUS-Fi Distal Fibula Nail ø 3.0mm, L 180mm
09.63030.180S	23/153467	VITUS-Fi Distal Fibula Nail ø 3.0mm, L 180mm
09.63030.180S	23/154988	VITUS-Fi Distal Fibula Nail ø 3.0mm, L 180mm
09.63030.180S	23/154989	VITUS-Fi Distal Fibula Nail ø 3.0mm, L 180mm
09.63030.180S	23/159346	VITUS-Fi Distal Fibula Nail ø 3.0mm, L 180mm
09.63030.180S	23/160753	VITUS-Fi Distal Fibula Nail ø 3.0mm, L 180mm
09.63030.180S	23/162879	VITUS-Fi Distal Fibula Nail ø 3.0mm, L 180mm
09.63030.180S	24/164758	VITUS-Fi Distal Fibula Nail ø 3.0mm, L 180mm
09.63030.180S	24/167136	VITUS-Fi Distal Fibula Nail ø 3.0mm, L 180mm
09.63030.180S	24/170564	VITUS-Fi Distal Fibula Nail ø 3.0mm, L 180mm
09.63030.180S	24/172998	VITUS-Fi Distal Fibula Nail ø 3.0mm, L 180mm

REF	LOT	Description
09.63036.180S	23/154994	VITUS-Fi Distal Fibula Nail ø 3.6mm, L 180mm
09.63036.180S	23/159348	VITUS-Fi Distal Fibula Nail ø 3.6mm, L 180mm
09.63036.180S	23/160755	VITUS-Fi Distal Fibula Nail ø 3.6mm, L 180mm
09.63036.180S	23/161596	VITUS-Fi Distal Fibula Nail ø 3.6mm, L 180mm
09.63036.180S	24/166358	VITUS-Fi Distal Fibula Nail ø 3.6mm, L 180mm
09.63036.180S	24/169232	VITUS-Fi Distal Fibula Nail ø 3.6mm, L 180mm
09.63036.180S	24/170566	VITUS-Fi Distal Fibula Nail ø 3.6mm, L 180mm
09.63036.180S	25/175125	VITUS-Fi Distal Fibula Nail ø 3.6mm, L 180mm



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: vigilance@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: QMB/PRRC, Tel. +49/7424/958115

Email: vigilance@marquardt-medizintechnik.de

Cutomer number: _____

Hospital: _____

Postcode, town: _____

Contact person (name, position): _____

Telephone number: _____

Please tick the appropriate box::

- ☐ I have received the notification of the recall from Dieter Marquardt Medizintechnik GmbH.
- ☐ 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	designation	LOT
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☐ 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 vigilance@marquardt-medizintechnik.de

Please ensure that, when returning the form,
proof of decontamination is enclosed, if necessary

