MARQUARDT
Medizintechnik

VITUS-Fi
Fibula Nail System

Clinical Advisor

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Note:

The surgical technique outlined below reflect the surgical procedure usually chosen by the clinical advisor. However, each surgeon must decide which surgical method and which approach is the most successful for his patient.

Introduction

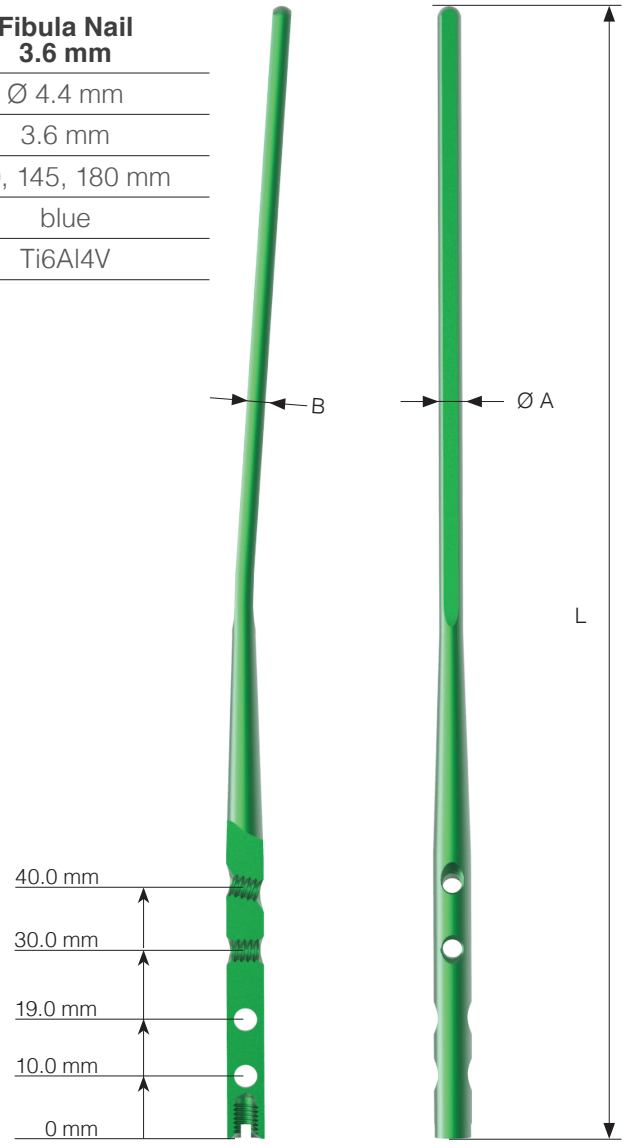
Product specification

The Marquardt ***VITUS-Fi*** Fibula Nail System serves for stable fixation and soft tissue sparing treatment of distal fibula fractures.

	Fibula Nail 3.0 mm	Fibula Nail 3.6 mm
Diameter (A)	Ø 3.8 mm	Ø 4.4 mm
Width (B)	3.0 mm	3.6 mm
Length (L)	110, 145, 180 mm	110, 145, 180 mm
Colour	green	blue
Material	Ti6Al4V	Ti6Al4V

Modular washer

The modular washer offers a safe, interlocking transfer of force to the cortical bone. This ensures pressure distributed fixation of the fragments.



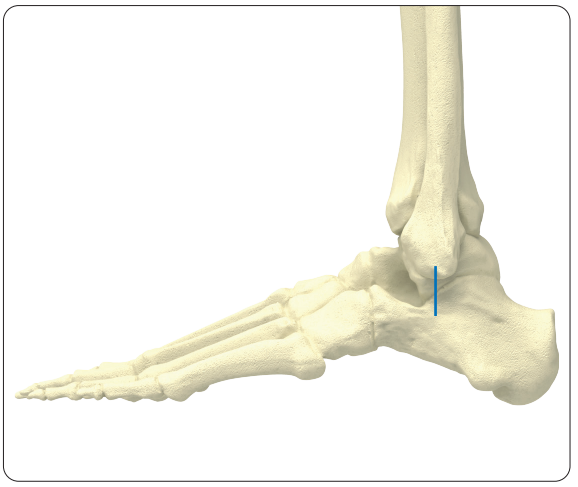
Indication

- Distal fibula shaft fractures in the case of a lower leg fracture.
- Low to moderate dislocated distal fibula fractures in the case of an ankle fracture.

Surgical Technique

Access

- Obtain access via an incision of approx. 1 to 2 cm length from the fibula tip distally.
- Then reposition the fracture, as required, using reduction forceps by means of stab incisions.

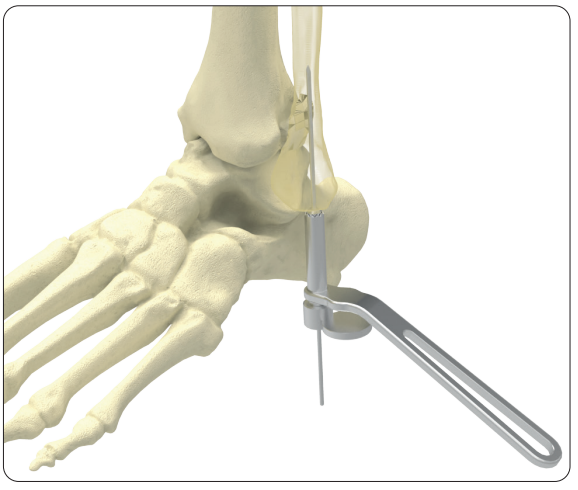


Nail Entry Point

Instruments

REF 11.90018.150	*Kirschner Wire Ø 1.8 mm, L 150 mm*
REF 09.20310.245	*VITUS-Fi Protection Sleeve 8.0/7.0*
REF 09.20310.246	*VITUS-Fi Reduction Sleeve 6.0/2.0*

- Firstly place the protection sleeve on the fibula tip incl. the reduction sleeve.
- Drill K-wire through the reduction sleeve into the fibula and position the proximal fragment in the medullary canal.
- Radiologically control the K-wire in the a.p. and lateral X-ray view.
- Then remove reduction sleeve.

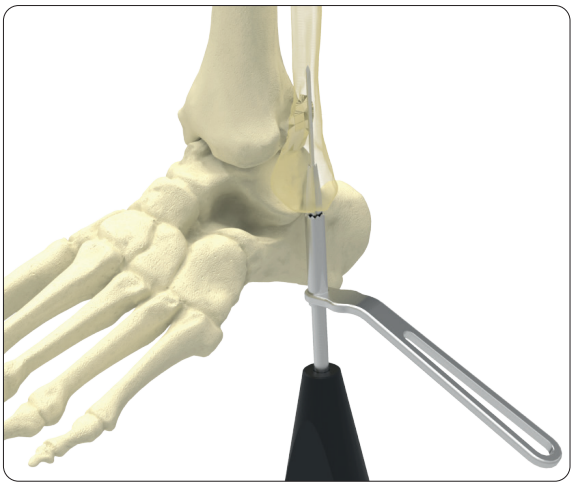


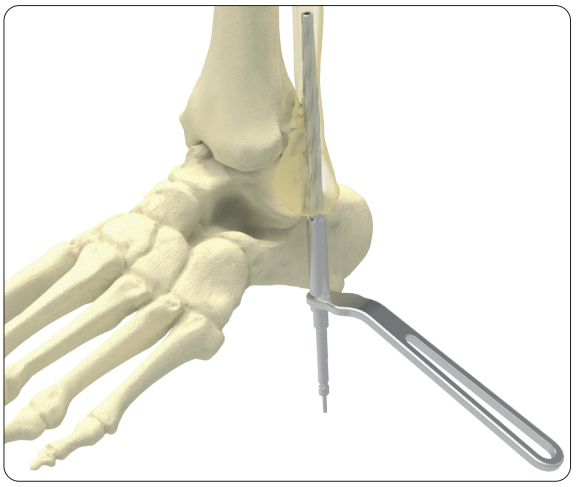
Opening the Medullary Canal

Instruments

REF 09.20310.401	*Awl, cannulated Ø 2.0 mm*

- Open the medullary canal with the cannulated awl via the K-wire (facultative).



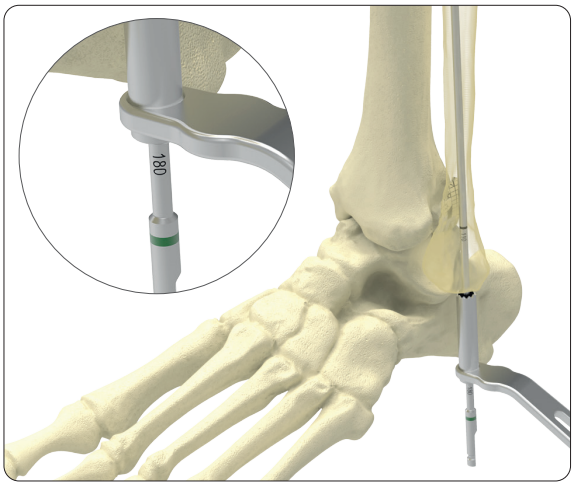


Drilling

Instruments

REF 09.20310.220 *VITUS-Fi Medullary Reamer Ø 6.1 mm*

- Ream the medullary canal in the distal fragment with the Ø 6.1 mm medullary reamer with stop via the K-wire using the protection sleeve.
- Drill the medullary reamer up to the stop on the protection sleeve.
- Then remove the medullary reamer and K-wire.



Expanding the Medullary Canal of the Proximal Fragment

Instruments

REF 09.20310.230 *VITUS-Fi Medullary Reamer Ø 3.1 mm*
REF 09.20310.240 *VITUS-Fi Medullary Reamer Ø 3.7 mm*

- Insert the Ø 3.1 mm or Ø 3.7 mm medullary reamer through the protection sleeve into the distal fragment and push it into the proximal fragment.
- Ream the medullary canal of the proximal fragment.
- Use the Ø 3.1 mm medullary reamer (green marking) for the 3.0 mm fibula nail. Use the Ø 3.7 mm medullary reamer (blue marking) for the 3.6 mm fibula nail.
- The drilling depth corresponds to the intended nail length. Observe the scaling for this purpose.

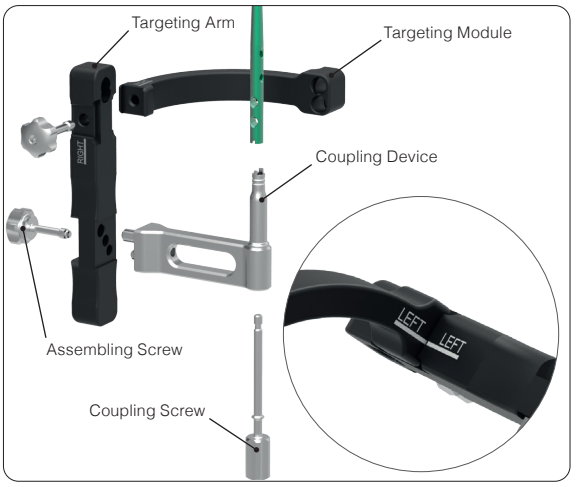
Note:

If necessary, the repositioned fracture should be held with the reduction forceps while expanding the medullary canal.

Assembly of the Targeting Device

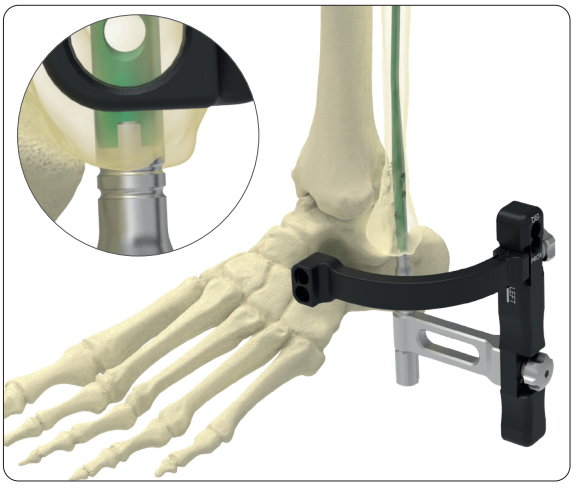
Instruments

REF 09.20310.010	*VITUS-Fi Coupling Device*
REF 09.20310.015	*VITUS-Fi Targeting Arm*
REF 09.20310.020	*VITUS-Fi Targeting Module*
REF 09.20310.030	*VITUS-Fi Coupling Screw*
REF 09.20310.035	*VITUS-Fi Assembling Screw*
REF 14.30060.165	*Pin Wrench, hex 3.5 mm*



- Firstly the targeting arm with the coupling device is assembled using the assembling screw.
- Then also fix the left/right targeting module on the targeting arm with the assmebling screw. The laser marking on the targeting module and the targeting arm has to coincide.
- The coupling screws have to be tightened with the pin wrench.
- Finally connect the appropriate fibula nail with the coupling screw on the coupling device. The slots on the nail prevent incorrect assembling.

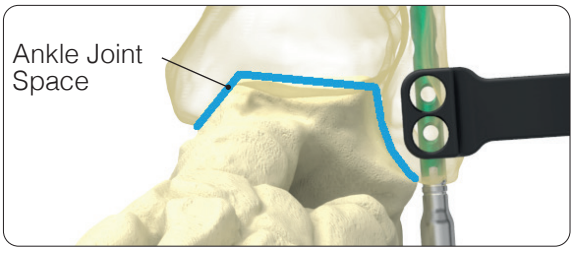
Insertion of the Nail

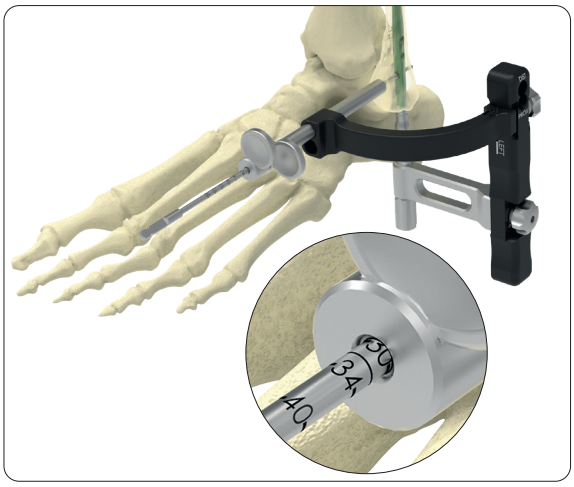


- The fibular nail assembled on the targeting device is inserted into the medullary canal.
- The correct rotation setting of the nail is essential for positioning the two proximal locking screws. For this, a slight external rotation is to be set.
- Set the ankle joint space correctly using the X-ray a.p. view (mortise view with 15° internal rotation of the leg).
- Then place the nail to the correct depth (coupling point between nail and coupling device at the level of the fibula tip).

Note:

- With the ankle joint space (shown in blue) set correctly, both holes of the target module must project above the two distal locking holes of the nail in the a.p. view.
- An inward rotation of the targeting device must be prevented as the screws could run past the dorsal tibial edge. A slight outward rotation is acceptable.



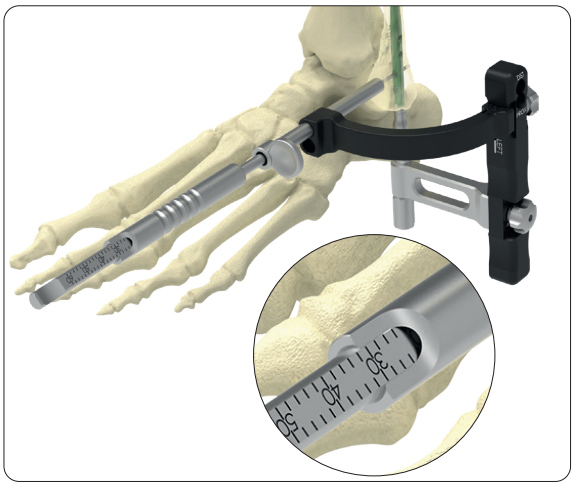


A/P Fixation

Instruments

REF 09.20310.055	*VITUS-Fi Protection Sleeve 8.0/7.0*
REF 09.20310.060	*VITUS-Fi Drill Guide 7.0/2.8 mm*
REF 09.20310.090	*Drill Bit Ø 2.8 mm, scaled*

- Firstly mark the skin incision with the trocar positioned over the respective guides of the targeting module and perform a stab incision here.
- Insert the protection sleeve and drill guide through the respective hole in the targeting device and place on the bone.
- Then use the drill bit to drill up to the 2nd cortical bone.
- The screw length required can be measured on the scale of the drill.

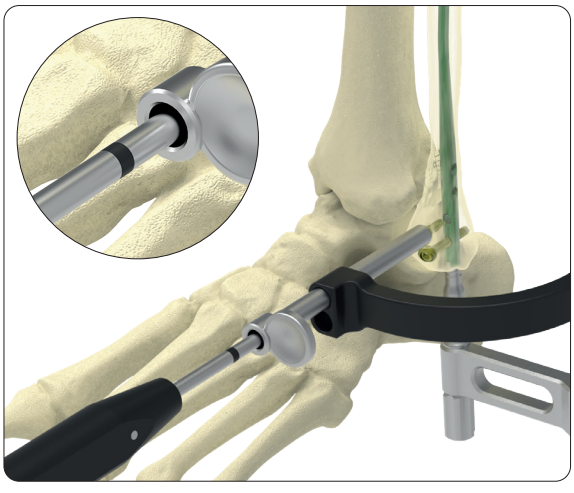


A/P Fixation - Measuring the Screw Length

Instruments

REF 009.20310.125	*VITUS-Fi Length Determination Instrument, for Screws up to 60 mm*

- Alternatively, the length determination instrument is introduced via the protection sleeve and the slider is pushed to the second cortical bone.
- The screw length required can then be read off from the scale of the length determination instrument.



A/P Fixiaton - Insertion of the Screws

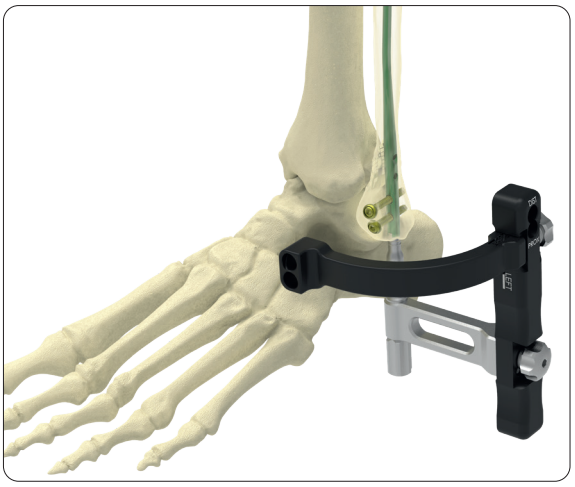
Instruments

REF 09.20310.120	*VITUS-Fi Screwdriver, hex 2.5 mm*

- Both a.p. screws are tightened by hand with the screwdriver.
- In order to avoid alteration of the peroneal tendons, the screws should stand max. 1 to 2 mm above the dorsal cortical bone.
- The modular washer fixed to the screw prevents the screw head from sinking in.
- With the protection sleeve seated correctly on the bone, the marking on the screwdriver shaft shows whether the screw head runs onto the ventral cortical bone with the washer.

Fracture Repositioning

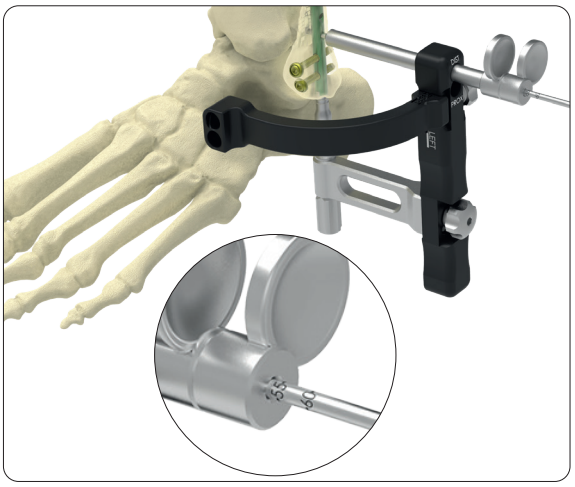
- With the a.p. locking screw in place, the fracture can still be repositioned, particularly to set the correct fibula length.



Lateral Fixation - Drilling

Instruments

REF 09.20310.055	*VITUS-Fi Protection Sleeve 8.0/7.0*
REF 09.20310.060	*VITUS-Fi Drill Guide 7.0/2.8 mm*
REF 09.20310.090	*Drill Bit Ø 2.8 mm, scaled*



- Lateral screw fixation takes place analogous to a.p. screw placement.
- Use the drill bit to also drill through the lateral cortical bone of the tibia.

Note:

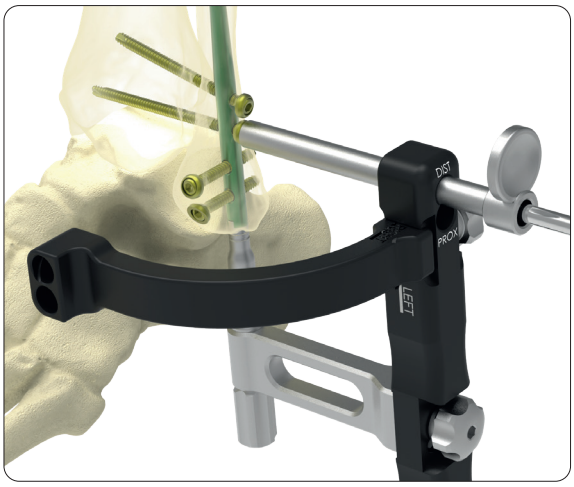
The upper hole in the target device (labeled “DIST”) serves for distal-lateral screw placement.
The lower hole in the target device (labeled “PROX”) is intended for proximal-lateral screw placement.

Lateral Fixation - Measuring the Screw Length

Instruments

REF 009.20310.125	*VITUS-Fi Length Determination Instrument, for Screws up to 60 mm*

- The screw length can be read off from the scale of the drill bit if the protection sleeve is corrected seated on the bone.
- Alternatively, the screw length can be determined with a length determination instrument.



Lateral Fixation - Insertion of the Screws

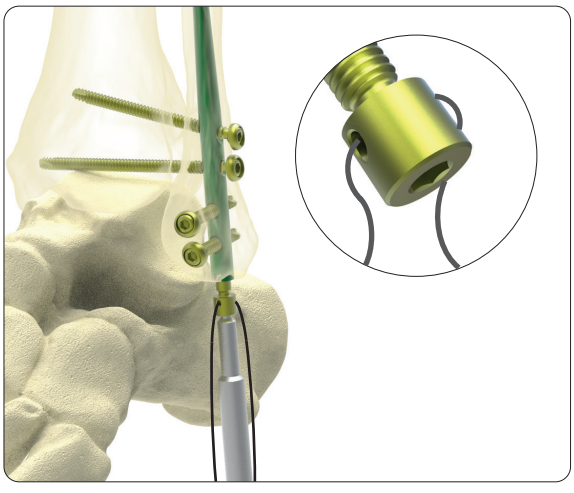
Instruments

REF 09.20310.120 *VITUS-Fi Screwdriver, hex 2.5 mm*

- Both lateral screws are tightened by hand with the screwdriver.
- With the protection sleeve seated correctly on the bone, the marking on the screwdriver shaft shows the correct depth position of the screw (washer lies on the lateral cortical bone).
- The target device is released from the nail and removed by loosening the coupling screw.

Note:

It is recommended to always used lateral screw placement irrespective of the mechanical instability of the syndesmosis.

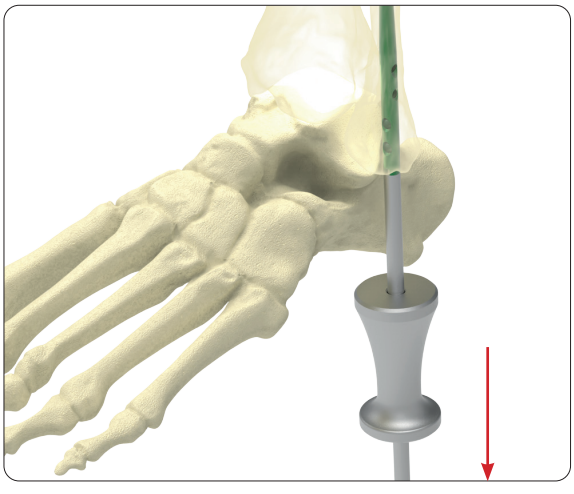


Insertion of the Cap Screw

Instruments

REF 09.20310.120 *VITUS-Fi Screwdriver, hex 2.5 mm*

- If the top of the tibial nail is located too deep in the medullary
- canal, the cap screw may be inserted to fill the gap.
- To ensure that the screwdriver and the cap screw are secured during insertion, suture material is pulled through the openings in the cap screw.
- Then the cap screw is placed on the screwdriver and held with the ends of the suture material against the screwdriver.
- Finally, the cap screw is inserted into the nail end and the sutures are removed.



Removal of the Nail

Instruments - Optional

REF 09.20310.145 *Extractor for Nails*
REF 14.30060.146 *Slide Hammer for Extractor*
REF 03.20040.025 *Screwdriver, hex 2.5 mm*

- The cap screw such as all locking screws except a lateral locking screw are removed with the screwdriver.
- Slide the slide hammer onto the extractor and then screw the extractor to the nail.
- Remove the last lateral locking screw with the screwdriver.
- Remove the nail under light strokes with the slide hammer.

Product Information

Implants

VITUS-Fi Fibula Nail Ø 3.0 mm

Article Number	Length
09.63030.110S	110 mm
09.63030.145S	145 mm
09.63030.180S	180 mm

VITUS-Fi Fibula Nail Ø 3.6 mm

Article Number	Length
09.63036.110S	110 mm
09.63036.145S	145 mm
09.63036.180S	180 mm

Article Number	Length
09.31635.010S	10 mm
09.31635.012S	12 mm
09.31635.014S	14 mm
09.31635.016S	16 mm
09.31635.018S	18 mm
09.31635.020S	20 mm
09.31635.022S	22 mm
09.31635.024S	24 mm
09.31635.026S	26 mm
09.31635.028S	28 mm
09.31635.030S	30 mm
09.31635.032S	32 mm
09.31635.034S	34 mm
09.31635.040S	40 mm
09.31635.045S	45 mm
09.31635.050S	50 mm
09.31635.055S	55 mm
09.31635.060S	60 mm

VITUS-Fi Locking Screw Ø 3.5 mm

- Thread diameter: 3.5 mm
- Core diameter: 2.7 mm
- Hexagon socket: 2.5 mm
- Material: Ti6Al4V

Article Number	Length
09.63006.005S	5 mm

Cap Screw Ø 6.0 mm

- Hexagon socket: 2.5 mm
- Material: Ti6Al4V

Instruments

11.90018.150 Kirschner Wire Ø 1.8 mm, trocar tip, L 150 mm, stainless steel

09.20310.090 Drill Bit Ø 2.8 mm, scaled, AO Coupling, L 210/180 mm

09.20310.220 VITUS-Fi Medullary Reamer Ø 6.1 mm, cannulated, AO Coupling

09.20310.230 VITUS-Fi Medullary Reamer Ø 3.1 mm, scaled, AO Coupling

09.20310.240 VITUS-Fi Medullary Reamer Ø 3.7 mm, scaled, AO Coupling

09.20310.055 VITUS-Fi Protection Sleeve 8.0/7.0

09.20310.060 VITUS-Fi Drill Guide 7.0/2.8 mm

09.20310.065 VITUS-Fi Trocar Ø 2.6 mm

09.20310.245 VITUS-Fi Protection Sleeve 8.0/6.2

09.20310.246 VITUS-Fi Reduction Sleeve 6.0/2.0

09.20310.125 VITUS-Fi Length Determination Instrument, for Screws up to 60 mm

14.30060.165 Pin Wrench, hex 3.5 mm

09.20310.120 VITUS-Fi Screwdriver, hex 2.5 mm

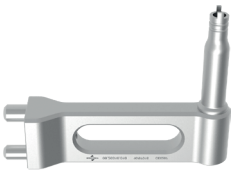
09.20310.401 Awl, cannulated Ø 2.0 mm

12.20050.020 Handle with AO Coupling

MARQUARDT Medizintechnik

Instruments - VITUS-Fi Targeting Device

09.20310.010 VITUS-Fi Coupling Device for Targeting Device

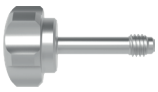


09.20310.015 VITUS-Fi Targeting Arm for REF 09.20310.010

09.20310.020 VITUS-Fi Targeting Module for REF 09.20310.015

09.20310.030 VITUS-Fi Coupling Screw for Nail

09.20310.035 VITUS-Fi Assembling Screw for Targeting Device



Instruments - Optional

09.20310.145 Extractor for Nails

14.30060.146 Slide Hammer for Extractor

03.20040.025 Screwdriver, hex 2.5 mm

MRI Safety Information

Non-clinical testing has demonstrated that the Intramedullary Nails range from Marquardt Medizintechnik is MR Conditional in accordance with the ASTM F2503 standard definitions. A patient with this device can be safely scanned in an MR system meeting the following conditions:

- Cylindrical-bore
- Horizontal magnetic field (B_0)
- Spatial field gradient lower than or equal to
  - **1.5 T:** 23.45 T/m (2345 G/cm)
  - **3.0 T:** 11.75 T/m (1175 G/cm)
- Radiofrequency (RF) field exposure:
  - RF excitation: Circularly Polarized (CP)
  - RF transmit coil: whole-body transmit coil
  - RF receive coil type: whole-body receive coil
  - Maximum permitted whole-body averaged specific absorption rate (SAR): Normal Operating Mode, 2 W/kg.
  - Scan duration and wait time:

    1.5 T: 2 W/kg whole-body average SAR for **10min and 55s** of continuous RF (a sequence or back-to-back series/scan without breaks) followed by a wait time of **10min and 55s** if this limit is reached.

    3.0 T: 2 W/kg whole-body average SAR for **7min and 54s** of continuous RF (a sequence or back-to-back series/scan without breaks) followed by a wait time of **7min and 54s** if this limit is reached.
- The Intramedullary Nails are expected to produce a maximum temperature rise of 6.2 °C at 1.5 T and 6.5 °C at 3 T both after the scanning periods presented above.
- The presence of this implant may produce an image artifact. Some manipulation of scan parameters may be needed to compensate for the artifact. In non-clinical testing, the image artifact caused by the device extends approximately 83 mm from the device edge when imaged with a spin echo pulse sequence and 65 mm with a gradient echo, both at 1.5 T.
- Patients with uncompromised thermoregulation and under uncontrolled conditions or patients with compromised thermoregulation (all persons with impaired systemic or reduced local thermoregulation) and under controlled conditions (a medical doctor or a dedicated trained person can respond instantly to heat induced physiological stress).

Note:

Undergoing an MRI scan, there is a potential risk for patients with a metallic implant. The electromagnetic field created by an MRI scanner can interact with the metallic implant, resulting in displacement of the implant, heating of the tissue near the implant, or other undesirable effects.

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