MARQUARDT
Medizintechnik

VITUS-FT Tibia Nail System

Table of Contents

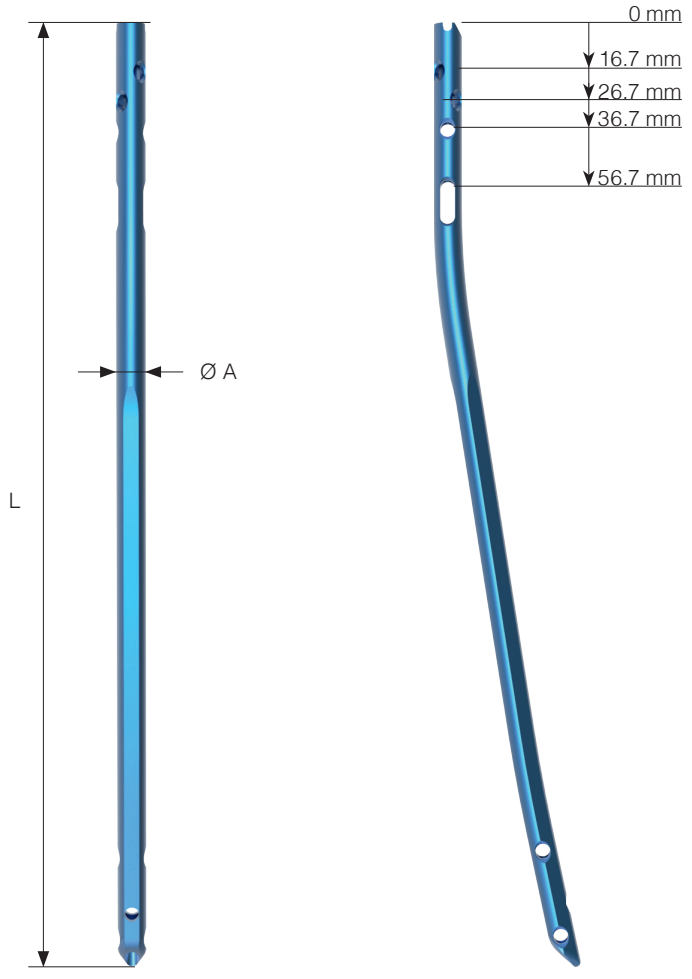
Note:

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

Implant Specifications

- VITUS-FT Tibia Nail:
  Universal design for the left and the right tibia
- Material:
  Ti6Al4V
- Diameter (A):
  Ø 8 mm – Ø 12 mm (1 mm – increment)
- Cannulation:
  Ø 8 mm (solid)
  Ø 9 mm – Ø 12 mm (cannulated)
- Length (L):
  240 mm – 420 mm
  240 mm – 360 mm (15 mm – increment)
  360 mm – 420 mm (20 mm – increment)
- Cross Section:
  3-phase
- Colour:
  blue



Indications

The VITUS-FT Tibial Nail is indicated for fractures in the tibial shaft as well as for metaphyseal and certain intraarticular fractures of the tibial head and the pilon tibiale:

- 41 - A2 / A3
- All shaft fractures
- 43 - A1 / A2 / A3
- Combinations of these fractures

Surgical Technique

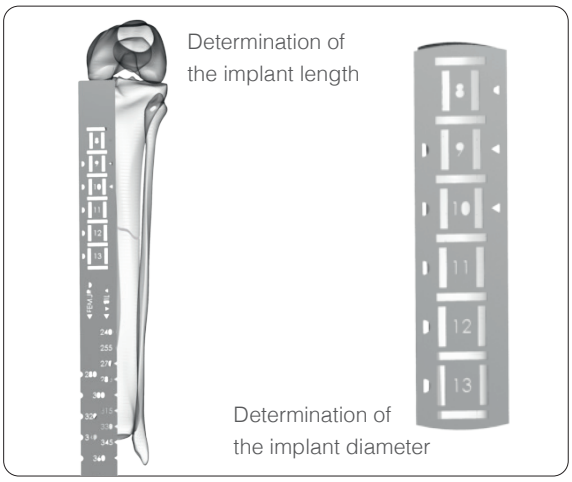
Positioning of the Patient

- Position the patient supine on the radiolucent table.
- Ensure that the knee of the injured leg can be flexed at least 90°. The use of a femoral holding device is helpful.
- In addition a small cushion can be placed below the pelvic of the fractured site.
- Little torsion of the hip can help to avoid external rotation.

- As an alternative the operating table can be let down. The flexion (> 90°) in the knee can be achieved by using an additional cushing below the upper leg.

Repositioning of the Fracture

- Perform closed reduction manually by axial traction under image intensifier.

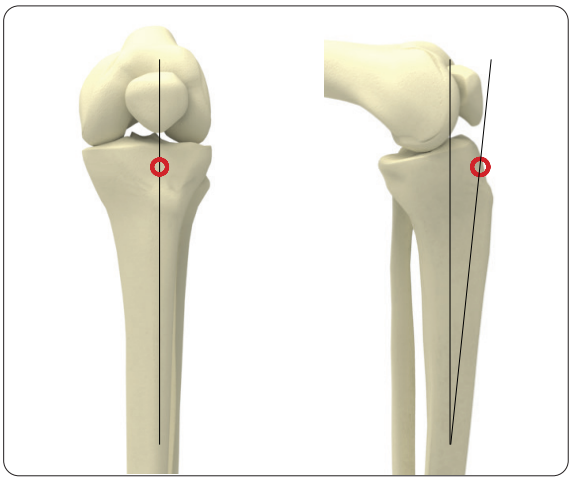


Implant Selection

Instruments

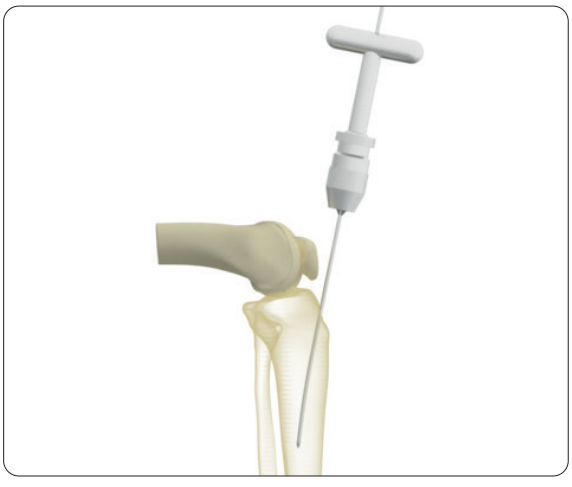
REF 09.20210.130 *X-Ray Template*

- The required nail length can be determined after reduction of the lower leg fracture using the x-ray template.



Access and Entry Point

- In AP view the entry point is in line with the axis of the intramedullary canal and with the lateral tubercle of the intercondylar eminence.
- In lateral view the entry point is at the ventral edge of the tibial plateau.
- The incision starts proximally at the distal third of the patella along the patellar ligament down to the tibial tuberosity.



Insertion of the Intramedullary Tibia Nail

Insertion of the Guide Rod

Instruments

REF 09.20210.090 *Guide Wire Ø 3.0 mm, L 365 mm*
REF 06.20050.045 *Universal Chuck*

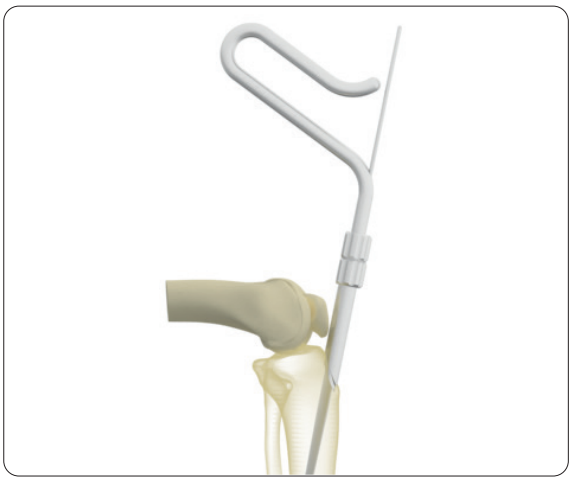
- The guide wire is clamped into the universal chuck.
- The tip of the guide wire is placed at the entry point and driven forward, about 150 mm into the medullary canal.
- Finally, the universal chuck is removed and the correct position of the guide wire in both planes is confirmed with the image intensifier.

Openning of the Medullary Canal

Instruments

REF 09.20210.040 *Awl Ø 10mm*
REF 09.20210.050 *Tissue Protection Sleeve 12.0/10.0*
REF 09.20210.070 *Tissue Protection Sleeve 14.0/12.0*

- The tissue protection sleeve Ø 14.0/12.0 is inserted over the guide wire unitl the peaks of the sleeve are fixed in the bone.
- Next, the tissue protection sleeve Ø 12.0/10.0 is inserted into the tissue protection sleeve Ø 14.0/12.0.
- The cannulated awl is driven forward over the guide wire, with light rotating movements until the stop on the tissue protection sleeve Ø 12.0/10.0 is reached.

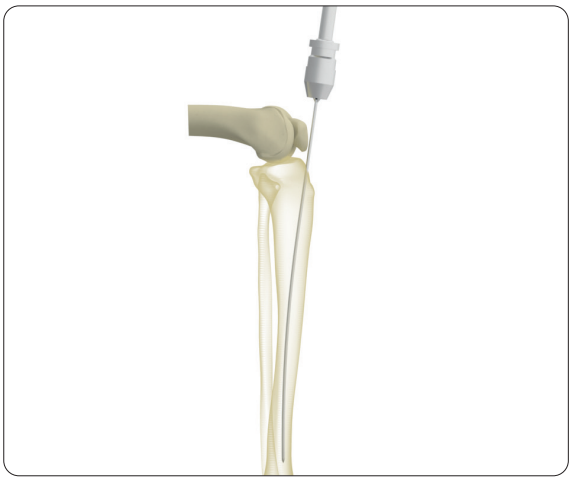


Insertion of the Guide Wire

Instruments

REF 06.20050.045 *Universal Chuck*

- After removal of the Awl and the tissue protection sleeve, the guide wire is inserted into the medullary canal with the universal chuck.
- Using image intensifier in both planes, the guide wire is pushed forward into the distal fragment and positioned centrally in the distal tibial metaphysis.

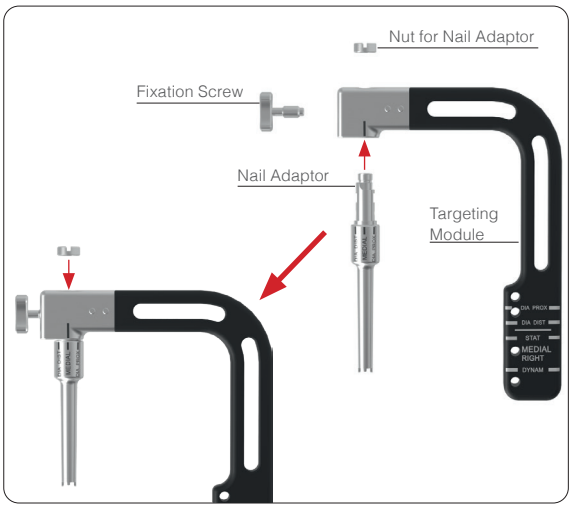


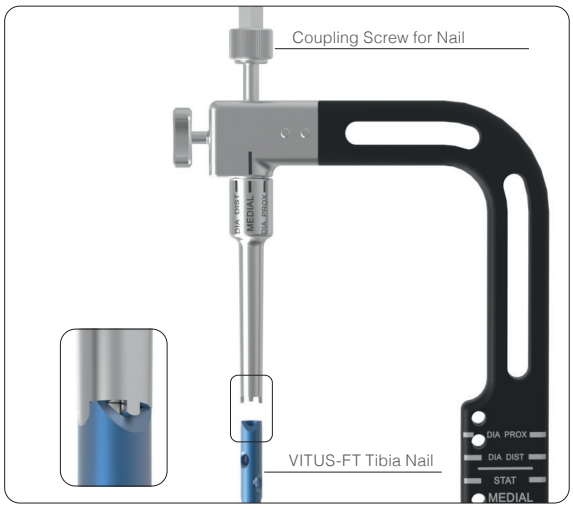
Assembly of the Targeting Device

Instruments

REF 04.20040.099 *Combination Wrench Ø 11 mm*
REF 09.20210.010 *Targeting Module*
REF 09.20210.011 *Nail Adaptor*
REF 09.20210.012 *Nut for Nail Adaptor*
REF 09.20210.013 *Fixation Screw*
REF 09.20210.165 *Adaptor for Targeting Device Assembly*

- The nail adaptor is pushed into the targeting module with light rotational movements. The lasermarking „MEDIAL“ has to match with the lasermarking on the targeting module.
- The fixation screw is tightened hand-tight and afterwards the fixing nut is also tightened hand-tight by using the adaptor and the combination wrench.



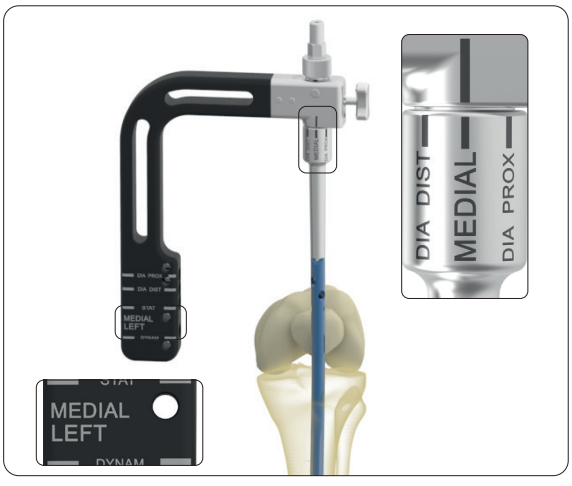


Connecting the Nail to the Targeting Device

Instruments

REF 04.20040.099	*Combination Wrench Ø 11 mm*
REF 09.20210.250	*Coupling Screw for Nail*

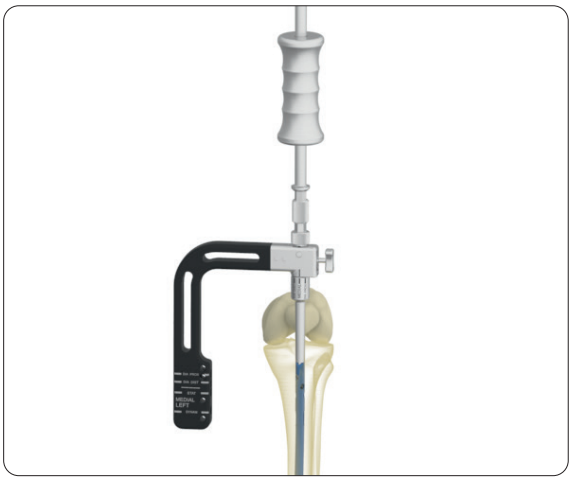
- The nail is put on the nail adaptor and fixed with the help of the coupling screw.
- The cams of the nail adaptor have to fit exactly into the grooves of the nail.



Insertion of the Nail with the Targeting Device

- For insertion of the nail, the laser marking „MEDIAL“ of the nail adaptor has to match with the laser marking of the targeting module.
- On the targeting module the laser marking „MEDIAL LEFT“ can be seen (for a right nail it must show „MEDIAL RIGHT“).
- The fixation screw is tightened hand-tight before insertion.
- The nail should be inserted by hand over the guide wire into the medullary canal with light rotational movements.
- Check the final position with AP and lateral x-rays.

Please note:
Using the non cannulated Ø 8 mm VITUS-FT Tibia Nail, the guide wire has to be removed first.



Optional Instruments for Insertion of the Nail

Instruments

REF 09.20210.170	*Slide Hammer*
REF 09.20210.180	*Extractor for Nail*
REF 09.20210.190	*Driving Head*

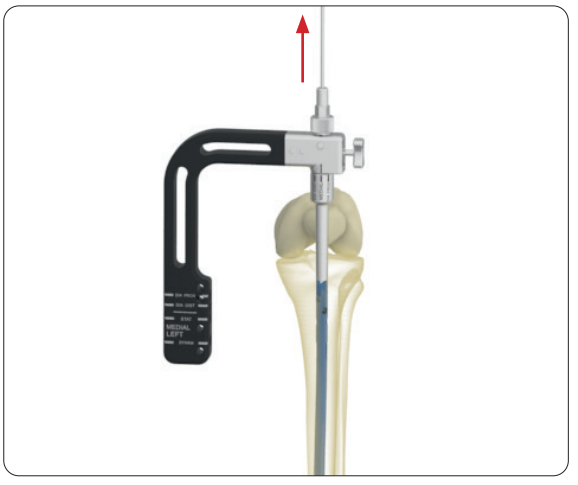
- If necessary, the tibia nail can be driven into the medullary canal with light, controlled blows.
- Therefore, the extractor is screwed onto the coupling screw and the slide hammer is mounted onto the extractor.
- Finally the driving head is screwed onto the extractor.

Please note:
It is important that the nail advances into the medullary canal with each blow. If this is not the case, the impaction must be stopped and the cause determined using the image intensifier.

- If necessary, use a nail with a smaller diameter.
- The driving of the intramedullary nail through the fracture zone and the final phase of the insertion should be carried out using the image intensifier. Therefore, the extractor, the slide hammer and the driving head should be removed from the coupling screw.
- After using the slide hammer make sure that the nail is still connected properly to the targeting device.
- The correct position of the nail should be confirmed in both planes with the image intensifier.

Removal of the Guide Wire

Please note:
If it is difficult to remove the guide wire, the slide hammer can be used in combination with the upside-down connected universal chuck.

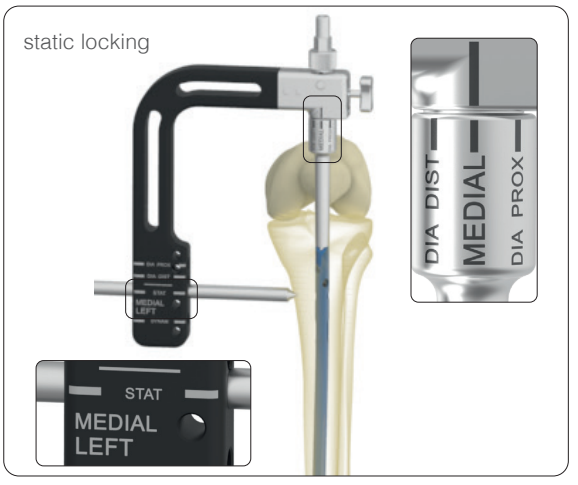


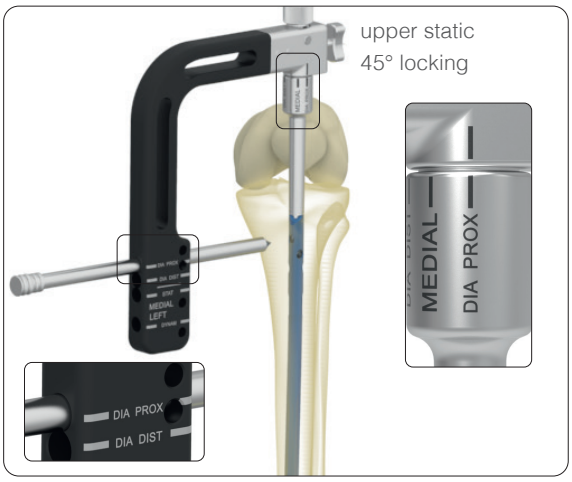
Options for Proximal Locking

Static Locking

For static locking, there are three possible screw positions:

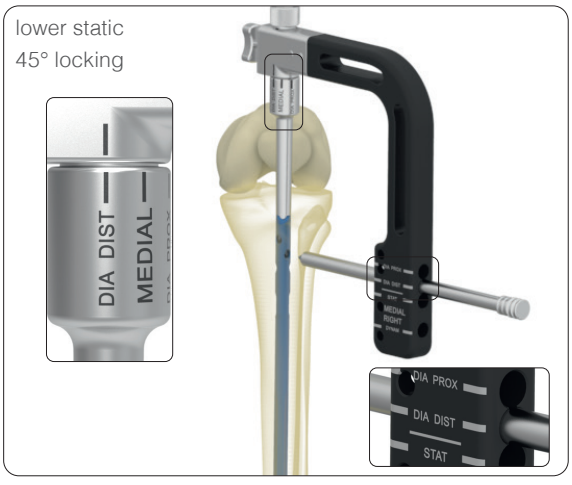
- Medial Locking: Drill hole in the targeting module which is parallel to the anterior plane, marked with STAT.
- 45° Diagonal locking: Drill holes in the targeting module which are oriented in an angle of 45° to the anterior plane marked with DIA PROX and DIA DIST.
- Combination of medial and 45° diagonal locking.





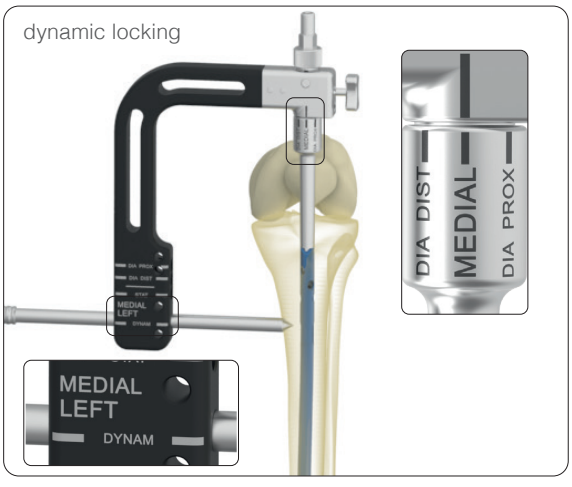
Use of the upper static proximal 45° locking (DIA PROX)

- The fixation screw must be untightened before turning of the targeting device.
- Then the targeting device can be rotated around the axis of the nail until the lasermarking „DIA PROX“ on the nail adaptor matches with the lasermarking of the targeting device.
- After reaching the target position „DIA PROX“ the fixation screw must be tightened hand-tight.
- The upper locking screw can now be drilled and will be oriented diagonal to the anterior plane by 45°.



Use of the lower static proximal 45° locking (DIA DIST)

- The fixation screw must be untightened before turning of the targeting device.
- Then the targeting device can be rotated around the axis of the nail until the lasermarking „DIA DIST“ on the nail adaptor matches with the lasermarking of the targeting device.
- After reaching the target position „DIA DIST“ the fixation screw must be tightened hand-tight.
- The lower locking screw can now be drilled and will be oriented diagonal to the anterior plane by 45°.



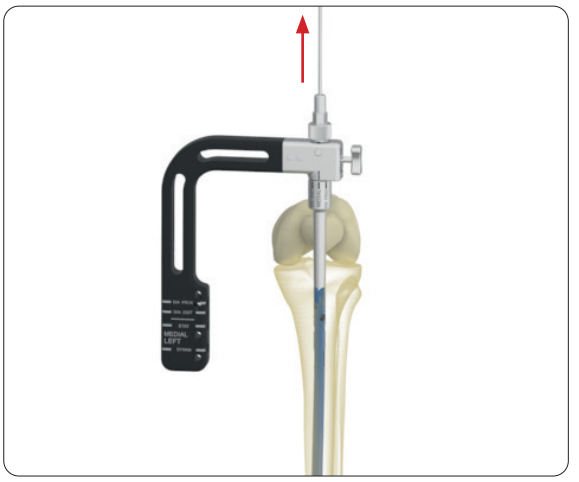
Dynamic Locking

- For dynamic locking, the distal hole on the targeting module marked DYNAM is used.

Surgical Steps for Proximal Locking

Please note:
If fracture compression is required, the distal locking should be completed first. In this case the knee must not be extended. The soft tissues could be damaged and the nail could break through the proximal cortex due to a levering effect in the anterior direction.

Removal of the guide wire and confirmation that the coupling screw is firmly fastened.



Insertion of the Tissue Protection Sleeve with the Trocar

Instruments

REF 09.20210.120	*Trocar Ø 8.0 mm*
REF 09.20210.330	*Tissue Protection Sleeve 10.0/8.0*

Depending on the fracture a static (STAT) or dynamic (DYNAM) locking should be achieved.

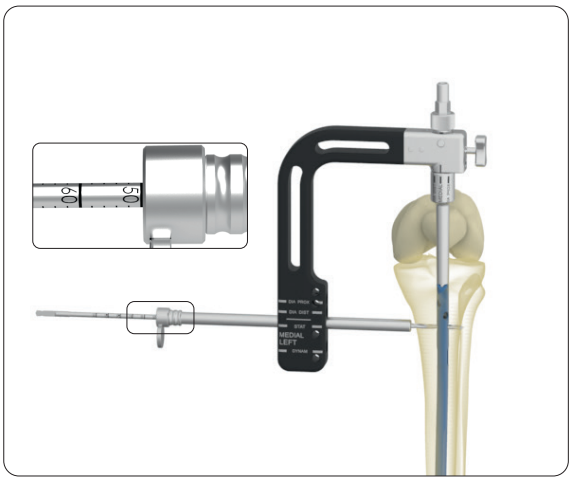
- The tissue protection sleeve with trocar, is introduced into the appropriate guide hole of the targeting device.
- The skin is incised at the appropriate location and dissected bluntly to the bone.
- The trocar is then removed and the tissue protection sleeve is inserted until it is in close contact with the bone surface.

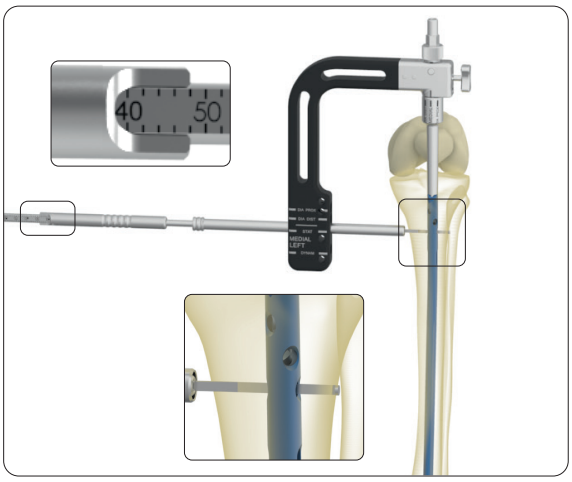
Drilling of the Locking Holes

Instruments

REF 09.20210.110	*Drill Sleeve 8.0/4.0 mm*
REF 09.20210.155	*Drill Bit Ø 4.0 mm*
REF 09.20210.330	*Tissue Protection Sleeve 10.0/8.0*

- The drill guide is inserted into the tissue protection sleeve
- Both cortices are carefully drilled with the three-fluted drill bit.
- The screw length can be read off the drill directly. For precise measuring it is important that the tip of the drill protrudes from the far corticalis minimally.





Measuring of the Screw Length

Instruments

REF 09.20210.220 *Length Determination Instrument, for Screws up to 100 mm*

- The screw length is determined by the length determination instrument for locking screws.
- Ensure the tissue protection sleeve is in contact with the bone and the hook grasps the far cortex.
- Read the screw length directly from the depth gauge.
- Verify screw length and ensure that the locking screw reaches through both cortics for a bicortical fixation.

Insertion of the Locking Screw

Instruments

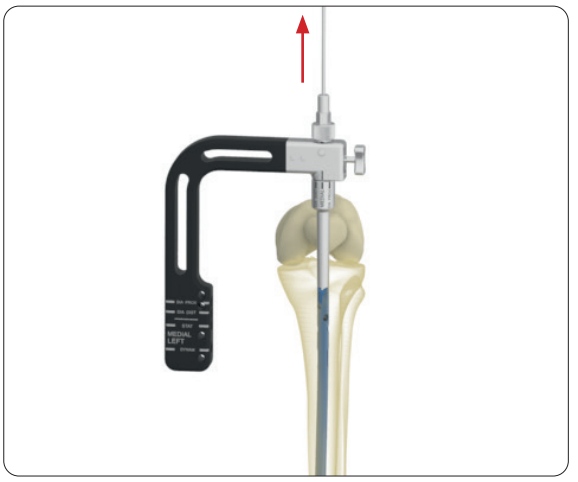
REF 09.20210.200 *Screwdriver, hex 3.5mm*

- The previously determined locking screw Ø 4.9 mm is inserted through the tissue protection sleeve with the screwdriver.
- The correct placement of the inserted locking screws must be confirmed in both planes with the image intensifier.

For inserting additional proximal locking screw, repeat the previously described steps.

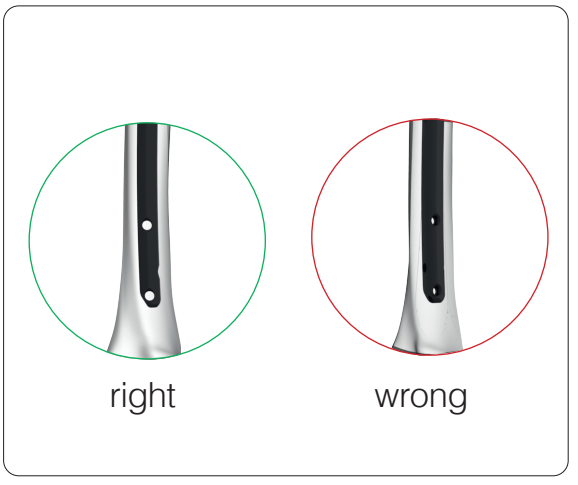
Distal Locking

Please note:
Distally, at least two locking screws must be inserted.
Make sure that the guide wire was removed before distal locking.



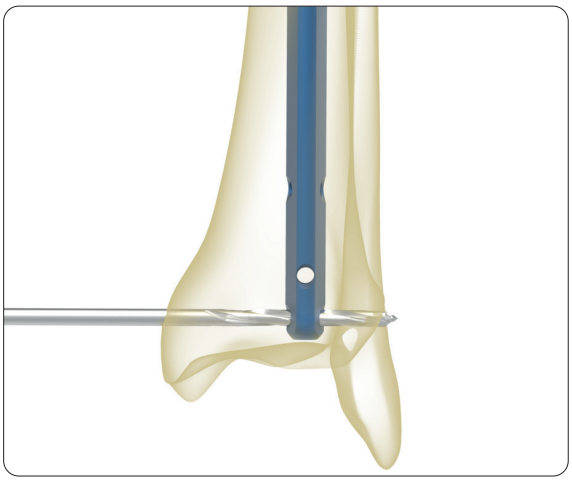
Positioning of the C-arm

- The C-arm needs to be positioned so that the locking hole into which the screw is to be inserted appears circular on the monitor and is situated approximately in the center of the image.



Incision of the Skin and Drilling of the Locking Holes

- The skin is incised over the selected hole.
- The bone is then exposed by splitting the soft tissues.
- Using the C-arm and radiolucent drill equipment.
- The tip of the drill bit is centered above the appropriate locking hole.
- Afterwards a hole is drilled through both cortices.

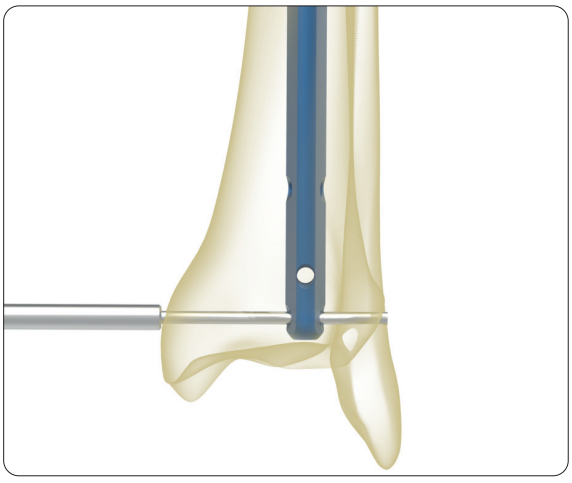


Please note:

Instruments

REF 09.20210.140 *Drill Bit Ø 3.2 mm*
REF 09.20210.150 *Drill Bit Ø 4.0 mm*

- For the Ø 8 mm and Ø 9 mm intramedullary nails the Ø 3.9 mm distal locking screws (drill bit Ø 3.2 mm) must be used.
- For all other intramedullary nails the Ø 4.9 mm distal locking screws (drill bit Ø 4.0 mm) must be used.

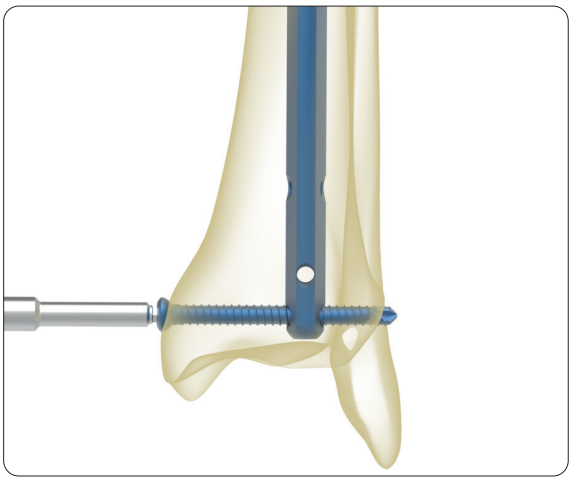


Measuring of the Screw Length

Instruments

REF 09.20210.220 *Length Determination Instrument, for Screws up to 100 mm*

- The screw length is determined by the length determination instrument for locking screws.



Insertion of the Locking Screw

Instruments

REF 09.20210.200 *Screwdriver, hex 3.5 mm*

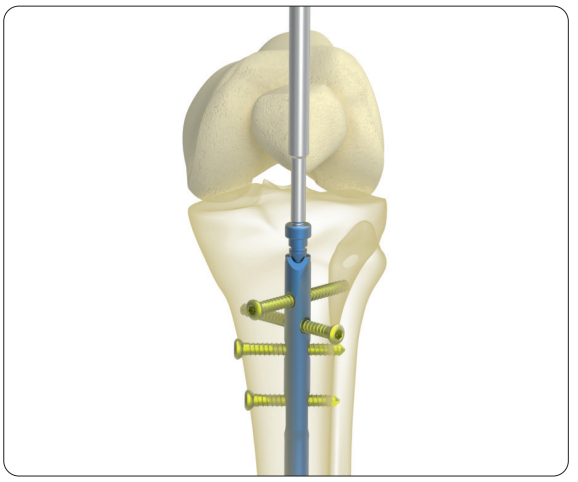
- The previously determined self-tapping locking screw is inserted into the predrilled hole using the screwdriver.
- The correct placement of the inserted locking screws must be confirmed in both planes with the image intensifier.

For inserting additional distal locking screws, repeat the previously described steps.

Insertion of the Cap Screw

- If the top of the tibial nail is located too deep in the medullary canal, a cap screw may be inserted to fill the gap.
- The cap screws are available in lengths from 0 to 25 mm (in 5 mm increments.

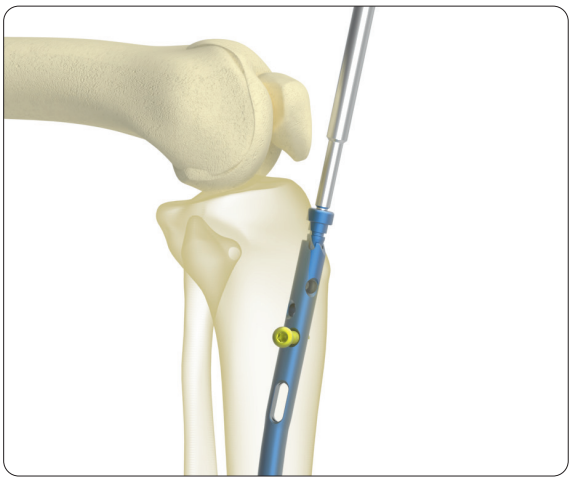
Please note:
The Insertion of a cap screw is generally recommended because it prevents bone ingrowth into the VITUS-FT Tibia Nail.



Instruments

REF 09.20210.230	*Guide Wire Ø 2.0 mm, L 440 mm*
REF 09.20210.200	*Screwdriver, hex 3.5 mm*

- The guide wire is inserted into the nail through the coupling screw of the targeting device.
- The coupling screw and the targeting device are removed. The inserted guide wire remains in the nail.
- The previously selected cap screw is inserted over the guide wire with the cannulated screwdriver.
- The correct position of the cap screw in the intramedullary nail is confirmed with the image intensifier.
- Finaly the guide wire will be removed.

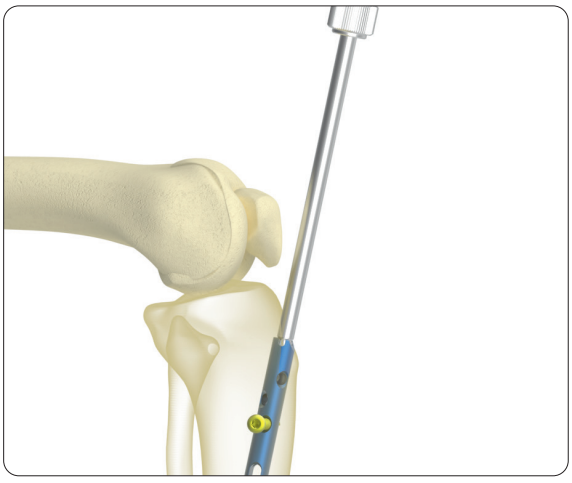


Removal of the Tibia Nail

Instruments

REF 09.20210.200 *Screwdriver, hex 3.5 mm*

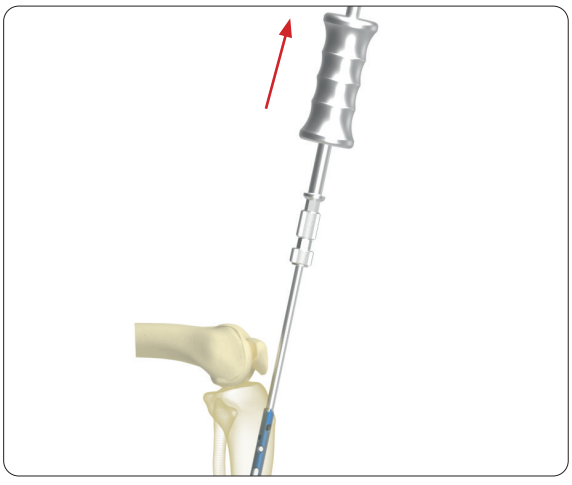
- Remove the end cap with the screwdriver.
- Next, remove all locking screws except one of the proximal locking screws using the screwdriver.



Instruments

REF 09.20210.250 *Coupling Screw for Nail*

- Assemble the coupling screw with the nail and tighten it to prevent rotation or displacement of the nail.



Instruments

REF 09.20210.170 *Slide Hammer*
REF 09.20210.180 *Extractor for Nail*
REF 09.20210.190 *Driving Head*
REF 09.20210.200 *Screwdriver, hex 3.5 mm*

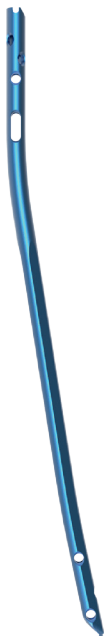
- Attach the slide hammer and the driving head to the extractor.
- Remove the remaining locking screw with the screwdriver.
- Extract the nail by applying gentle blows with the slide hammer.

Product Information

Implants

VITUS-FT Tibia Nail, solid

Ø 8 mm	
Article Number *	**Length**
09.43008.240	240 mm
09.43008.255	255 mm
09.43008.270	270 mm
09.43008.285	285 mm
09.43008.300	300 mm
09.43008.315	315 mm
09.43008.330	330 mm
09.43008.345	345 mm
09.43008.360	360 mm
09.43008.380	380 mm
09.43008.400	400 mm
09.43008.420	420 mm



VITUS-FT Tibia Nail, cannulated

Ø 9 mm	Ø 10 mm	Ø 11 mm	Ø 12 mm	
Article Number *	**Article Number ***	**Article Number ***	**Article Number ***	**Length**
09.43009.240	09.43010.240	09.43011.240	09.43012.240	240 mm
09.43009.255	09.43010.255	09.43011.255	09.43012.255	255 mm
09.43009.270	09.43010.270	09.43011.270	09.43012.270	270 mm
09.43009.285	09.43010.285	09.43011.285	09.43012.285	285 mm
09.43009.300	09.43010.300	09.43011.300	09.43012.300	300 mm
09.43009.315	09.43010.315	09.43011.315	09.43012.315	315 mm
09.43009.330	09.43010.330	09.43011.330	09.43012.330	330 mm
09.43009.345	09.43010.345	09.43011.345	09.43012.345	345 mm
09.43009.360	09.43010.360	09.43011.360	09.43012.360	360 mm
09.43009.380	09.43010.380	09.43011.380	09.43012.380	380 mm
09.43009.400	09.43010.400	09.43011.400	09.43012.400	400 mm
09.43009.420	09.43010.420	09.43011.420	09.43012.420	420 mm

***** All implants are also available in sterile. Therefor, add suffix "S" to article number.

Implants

VITUS-FT End Cap für Tibia Nail

- Material: Ti6AL4V
- Colour: blue
- Prevents bone ingrowth into the proximal end of the VITUS-FT Tibia Nail
- Canulated
- 0 mm – flush with the proximal end of the VITUS-FT Tibia Nail
- 5 mm, 10 mm, 15 mm, 20 mm and 25 mm – extension if the VITUS-FT Tibia Nail is located too deep in the medullary canal

0 mm 5 mm 10 mm 15 mm 20 mm 25 mm

Article Number *	Length
09.01010.000	0 mm
09.01010.005	5 mm
09.01010.010	10 mm
09.01010.015	15 mm
09.01010.020	20 mm
09.01010.025	25 mm

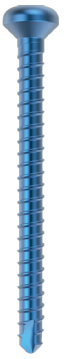
***** All implants are also available in sterile. Therefor, add suffix "S" to article number.

Implants

Article Number *	Length
09.03839.024	24 mm
09.03839.026	26 mm
09.03839.028	28 mm
09.03839.030	30 mm
09.03839.032	32 mm
09.03839.034	34 mm
09.03839.036	36 mm
09.03839.038	38 mm
09.03839.040	40 mm
09.03839.042	42 mm
09.03839.044	44 mm
09.03839.046	46 mm
09.03839.048	48 mm
09.03839.050	50 mm
09.03839.052	52 mm
09.03839.054	54 mm

VITUS-FT Locking Screw Ø 3.9 mm, self-tapping

- Thread diameter: 3.9 mm
- Core diameter: 3.4 mm
- Head diameter: 8.0 mm
- Hexagon socket: 3.5 mm
- Material: Ti6Al4V



Article Number *	Length	Article Number *	Length
09.03949.024	24 mm	09.03949.052	52 mm
09.03949.026	26 mm	09.03949.054	54 mm
09.03949.028	28 mm	09.03949.056	56 mm
09.03949.030	30 mm	09.03949.058	58 mm
09.03949.032	32 mm	09.03949.060	60 mm
09.03949.034	34 mm	09.03949.064	64 mm
09.03949.036	36 mm	09.03949.068	68 mm
09.03949.038	38 mm	09.03949.072	72 mm
09.03949.040	40 mm	09.03949.076	76 mm
09.03949.042	42 mm	09.03949.080	80 mm
09.03949.044	44 mm	09.03949.085	85 mm
09.03949.046	46 mm	09.03949.090	90 mm
09.03949.048	48 mm	09.03949.095	95 mm
09.03949.050	50 mm	09.03949.100	100 mm

VITUS-FT Locking Screw Ø 4.9 mm, self-tapping

- Thread diameter: 4.9 mm
- Core diameter: 4.3 mm
- Head diameter: 8.0 mm
- Hexagon socket: 3.5 mm
- Material: Ti6Al4V

***** All implants are also available in sterile. Therefor, add suffix "S" to article number.

Instruments

09.20210.090 Guide Wire Ø 3.0 mm, threaded tip, L 365 mm

09.20210.230 Guide Wire Ø 2.0 mm, for Cap Screws, L 440 mm

09.20210.210 Cleaning Wire Ø 2.0 mm, L 435 mm

09.20210.140 Drill Bit Ø 3.2 mm, AO-Coupling, L 250/220 mm

09.20210.150 Drill Bit Ø 4.0 mm, AO-Coupling, L 250/220 mm

09.20210.155 Drill Bit Ø 4.0 mm, scaled, AO-Coupling, L 355/325 mm

09.20210.050 VITUS-FT Tissue Protection Sleeve 12.0/10.0, for Tibia

09.20210.070 VITUS-FT Tissue Protection Sleeve 14.0/12.0 for Tibia

09.20210.110 VITUS-FT Drill Sleeve 8.0/4.0

09.20210.120 VITUS-FT Trocar Ø 8.0 mm

09.20210.330 VITUS-FT Tissue Protection Sleeve 10.0/8.0

09.20210.220 VITUS-FT Length Determination Instrument, for Screws up to 100 mm

09.20210.170 VITUS-FT Slide Hammer for REF 09.20210.180

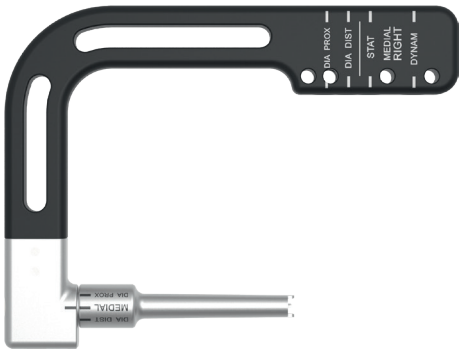
09.20210.180 VITUS-FT Extractor for Nail, Tibia / Femur

09.20210.250 VITUS-FT Coupling Screw for Nail, Tibia / Femur

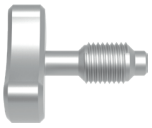
09.20210.190 VITUS-FT Driving Head for REF 09.20210.180

Instruments

09.20210.001 VITUS-FT Targeting Device for Tibia



09.20210.013 VITUS-FT Fixation Screw for REF 09.20210.001



09.20210.165 VITUS-FT Assembling Adaptor for Targeting Device

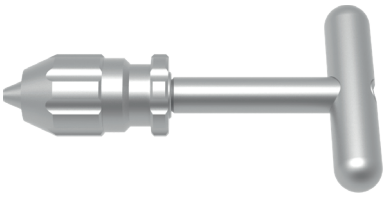
09.20210.340 VITUS-FT Fixation Bolt for Tissue Protection Sleeve

09.20210.040 VITUS-FT Awl Ø 10 mm, cannulated, for Tibia

09.20210.130 VITUS-FT X-Ray Template, Tibia / Femur

09.20210.200 VITUS-FT Screwdriver, hex 3.5 mm, cannulated

06.20050.045 Universal Chuck, T-Handle, cannulated



04.20040.099 Combination Wrench Ø 11 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 F2503-20 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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