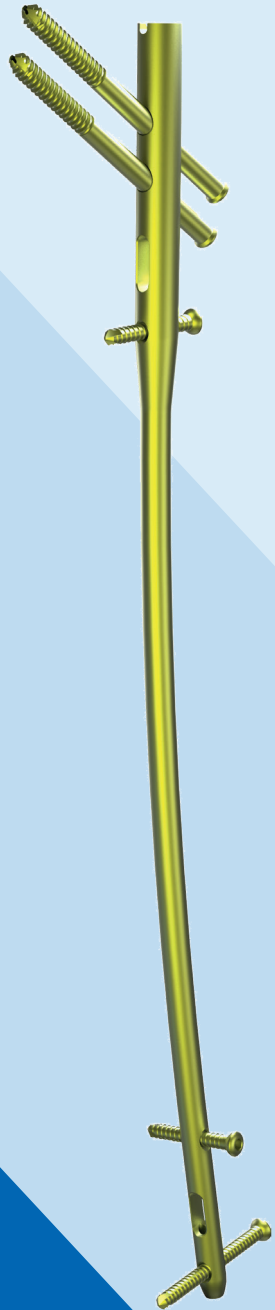
MARQUARDT
Medizintechnik



VITUS-FT Femur Nail System

Table of Contents

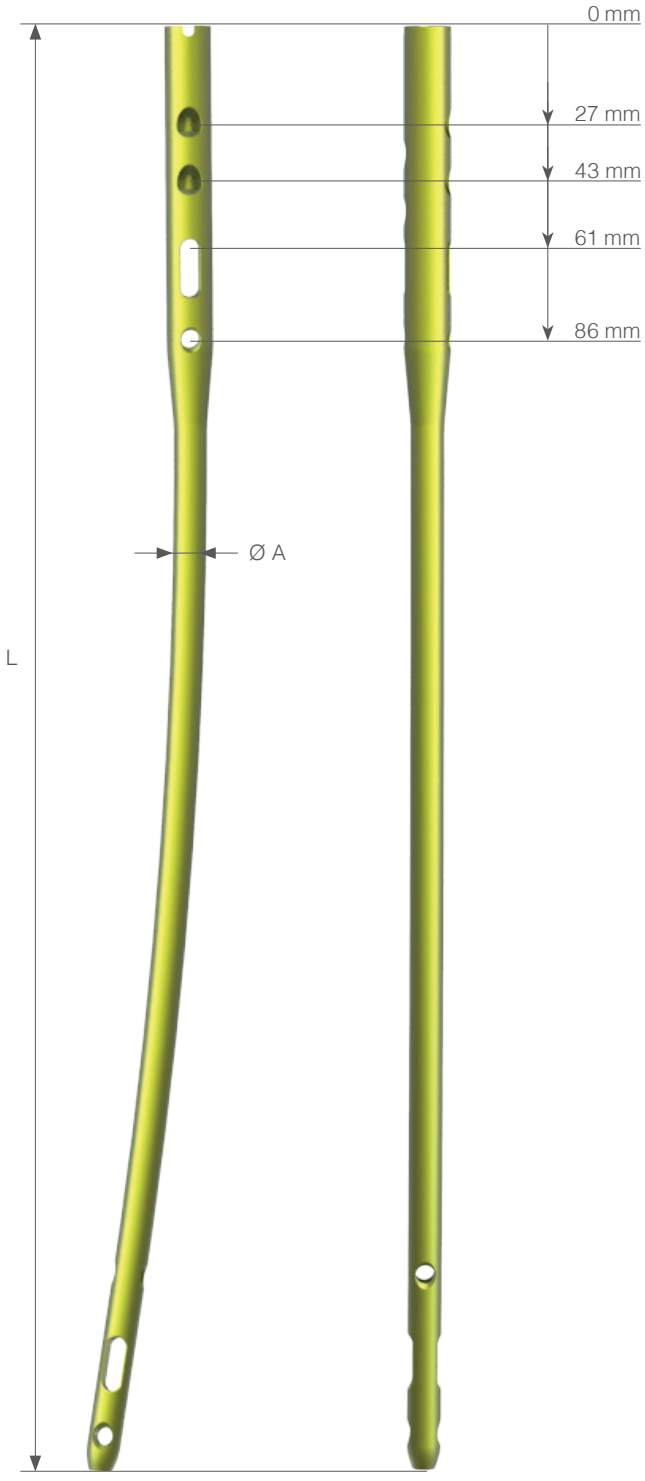
Note

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 Femur Nail:
  Two designs for the right and left femur
- Material:
  Ti6AL4V
- Diameter (A):
  Ø 9 mm – Ø 13 mm (1 mm – increment)
- Cannulated:
- Length (L):
  300 mm – 480 mm (20 mm - increment)
- Colour:
  gold



Indications

The VITUS-FT Femur Nail with VITUS-FT Cap Screw and Ø 4.9 mm Locking Screws:

- Complex and simple femoral shaft fractures
- Sub-trochantric fractrures
- Pseudarthrosis and delayed union

The VITUS-FT Femur Nail in combination with Ø 6.5 mm Hip Screws:

- Shaft fractures in combination with femoral neck fractures or peritrochanteric fractures

Surgical Technique

1. Positioning of the Patient

- The patient is placed on a fracture or radiolucent table in the lateral decubitus or supine position.
- The uneffected leg is abducted in the leg holder as far as possible to ease image intensifier positioning.
- The C-arm must be adjusted so that the femur can be imaged in a lateral and anterior - posterior view along its entire length.

2. Repositioning of the Fracture

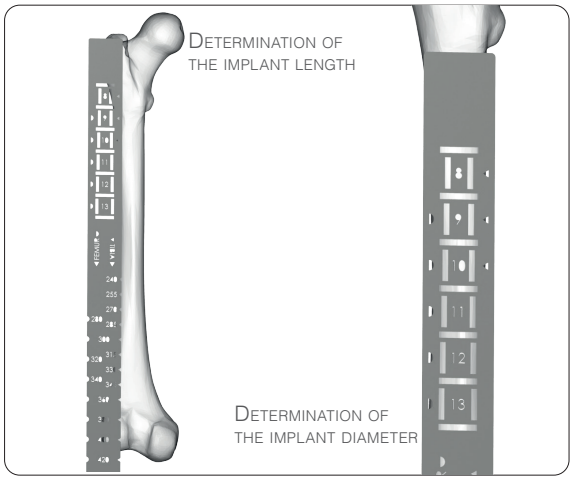
- Perform closed reduction manually by axial traction under image intensifier.

3. Implant Selection

Instruments

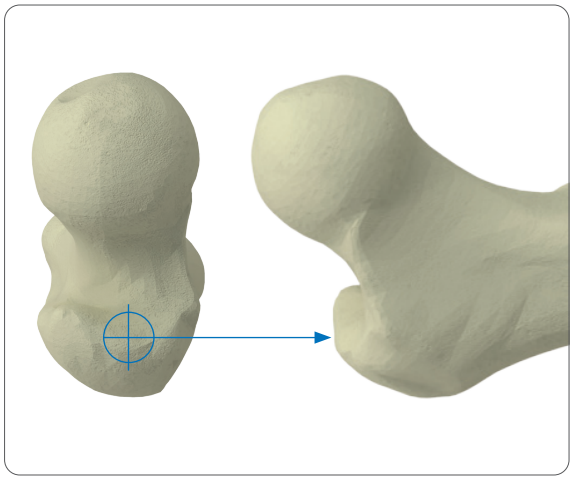
REF 09.20210.130 X-Ray Template

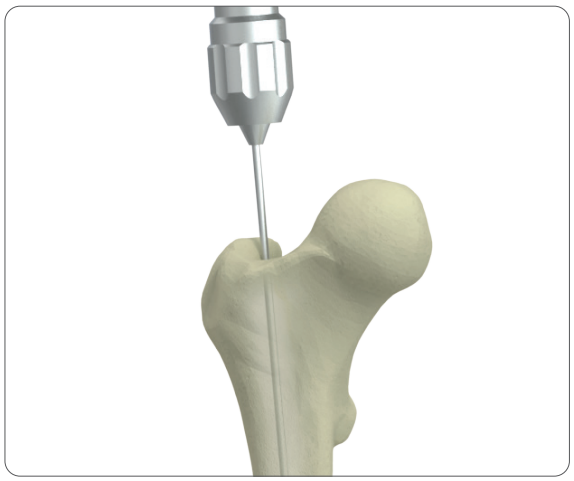
- The required nail length and diameter can be determined after reduction of the lower leg fracture using the x-ray template.



4. Access and Entry Point

- The tip of the greater trochanter can be identified by palpation.
- A longitudinal skin incision of about 40 mm is made starting just above the greater trochanter to the iliac crest.
- The incision is then deepened down to the gluteus maximus fascia longitudinally in the direction of the wound
- The underlying muscle fibers will be seperated and the tip of the greater trochanter palpated.
- The entry point of the femur nail is in the line with the medullary canal in the lateral view. In AP view, the entry point is slightly lateral to the tip of the greater trochanter.



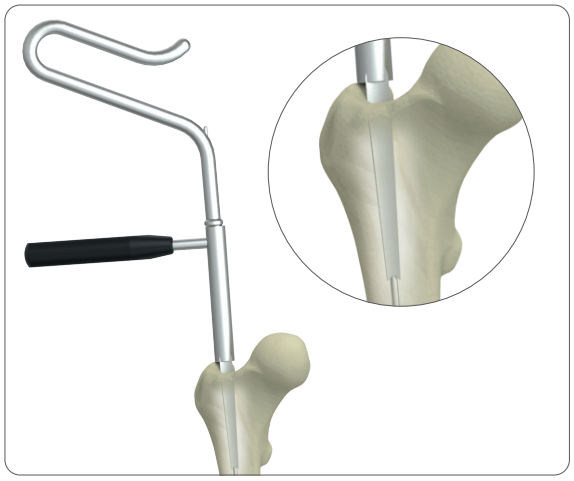


4. Opening of the Medullary Canal

Instruments

REF 06.20050.045 *Universal Chuck*
REF 09.20210.090 *Guide Wire Ø 3.0 mm*

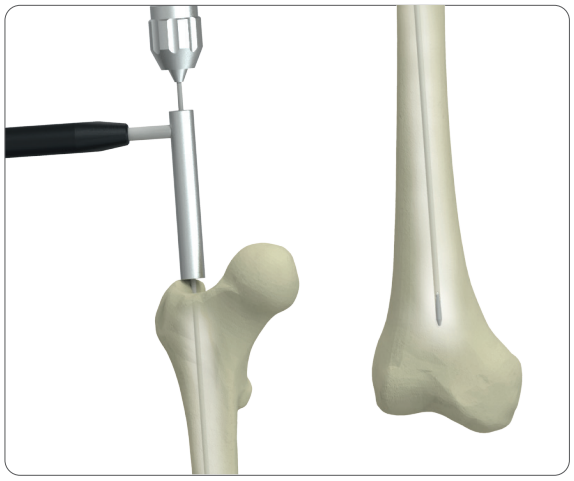
- The guide wire is clamped into the universal chuck.
- The tip of the guide wire is placed at the entry point and driven forward, about 150 mm into the medullary canal.
- Finally, the universal chuck is removed and the correct position of the guide wire in both planes is confirmed with the image intensifier.



Instruments

REF 09.20210.060 *Tissue Protection Sleeve Ø 15.0 / 13.0 mm*
REF 09.20210.260 *Awl Ø 13.0 mm*

- The tissue protection sleeve is inserted over the guide wire.
- The cannulated awl is driven forward over the guide wire, with light rotating movements until the stop on the tissue protection sleeve is reached.



5. Insertion of the Guide Wire

Instruments

REF 06.20050.045 *Universal Chuck*
REF 09.20210.060 *Tissue Protection Sleeve Ø 15.0 / 13.0 mm*
REF 09.20120.900 *Guide Wire Ø 3.0 mm, L 900 mm*

- After removal of the awl, the guide wire is inserted into the medullary canal with the universal chuck.

Optional

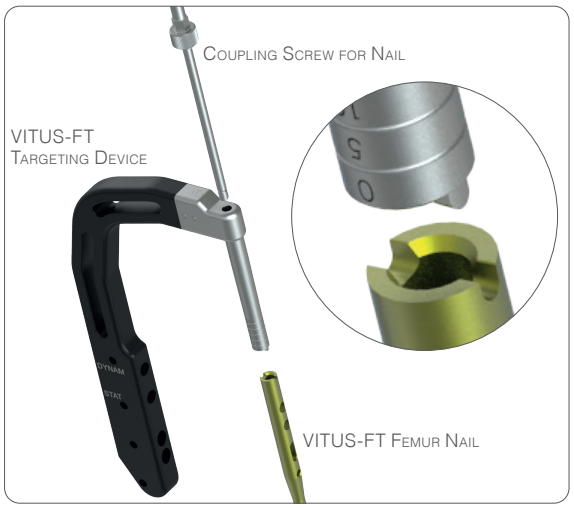
- Insert the guide wire (L 900 mm) through the tissue protection sleeve into the medullary canal with the universal chuck.
- Place the guide wire (L 900 mm) centrally in the distal metaphyseal area of the femur.

6. Insertion of the VITUS-FT Femur Nail

Instruments

REF 04.20040.099 *Combination Wrench Ø 11.0 mm*
REF 09.20210.020 *Targeting Device*
REF 09.20210.250 *Coupling Screw for Nail*

- The nail is put on the targeting device and fixed with the help of the coupling screw.
- The cams of the targeting device have to fit exactly into the grooves of the nail.
- The coupling screw will be tightened using the combination wrench.

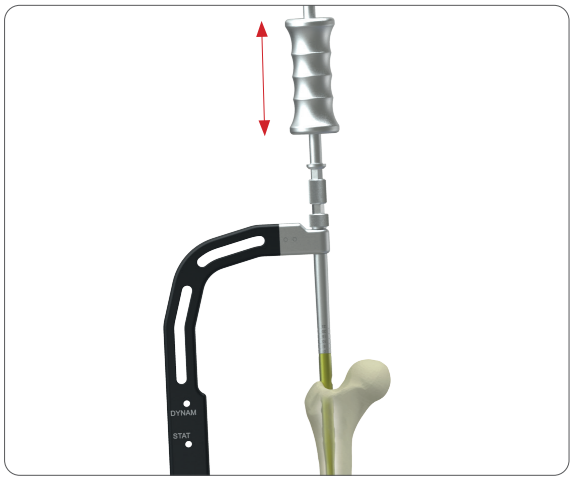


- The nail should be inserted by hand over the guide wire into the medullary canal with light rotational movements.
- Check the final position with AP and lateral x-rays.

Instruments

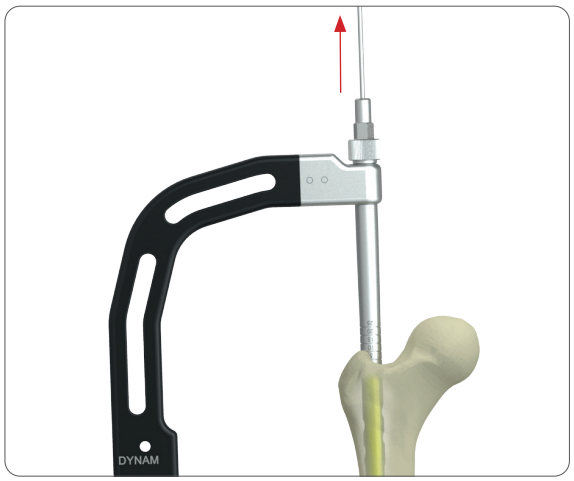
REF 09.20210.170 *Slide Hammer*
REF 09.20210.180 *Extractor for Nail*
REF 09.20210.190 *Driving Head*

- If necessary, the 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.



Attention

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 a nail with a smaller diameter must be used.



- After the insertion of the nail remove the driving head, the slide hammer and the extractor from the coupling screw.
- Remove the guide wire while the coupling screw remains firmly attached to the nail and the targeting device.
- If it is difficult to remove the guide wire, the slide hammer can be used in combination with the upside-down connected universal chuck.

7. Proximal Locking

Instruments

REF 09.20210.120	*Trocar Ø 8.0 mm*
REF 09.20210.330	*Tissue Protection Sleeve Ø 10.0 / 8.0 mm*
REF 14.30060.040	*Eccentric Fixation Bolt*

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 pushed forward until it is in close contact with the bone surface.
- The tissue protection sleeve is locked with the fixation bolt.

Instruments

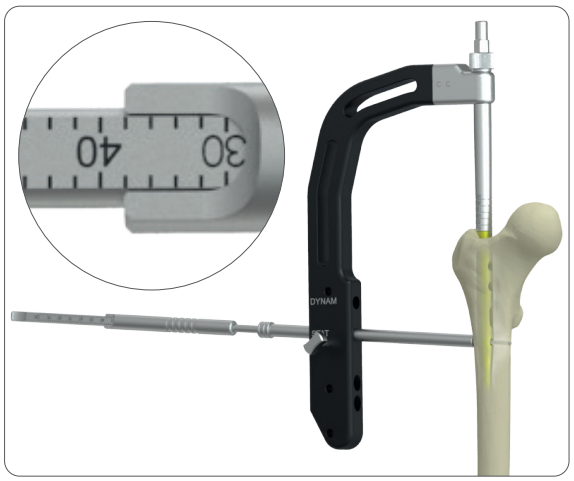
REF 09.20210.110	*Drill Guide Ø 8.0 / 4.0 mm*
REF 09.20210.155	*Drill Bit Ø 4.0 mm*

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

Instruments

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

- Alternatively 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 length determination instrument.
- Verify screw length and ensure that the locking screw reaches through both cortics for a bicortical fixation.

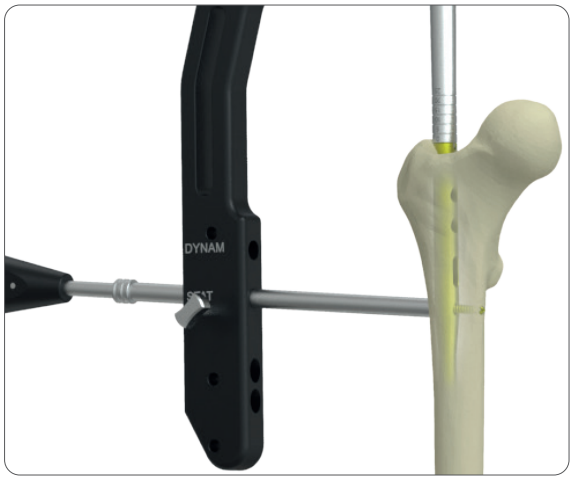


Instruments

REF 09.20210.200 *Screwdriver, hex 3.5 mm*

- The previously determined locking screw 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 an additional proximal locking screw, repeat the previously described steps.

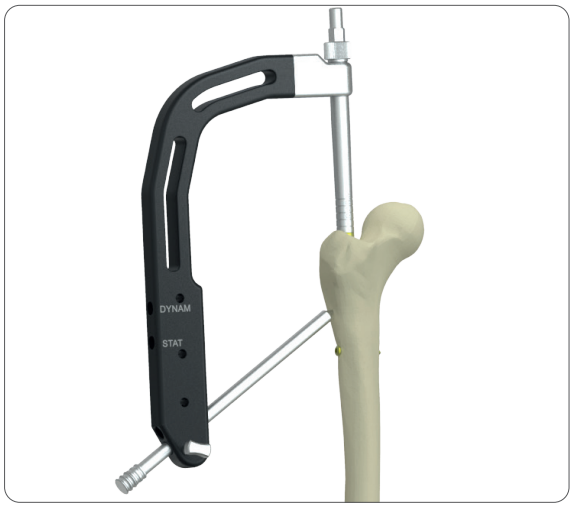


8. Cervical Locking

Instruments

REF 09.20210.120 *Trocar Ø 8.0 mm*
REF 09.20210.330 *Tissue Protection Sleeve Ø 10.0 / 8.0 mm*
REF 14.30060.040 *Eccentric Fixation Bolt*

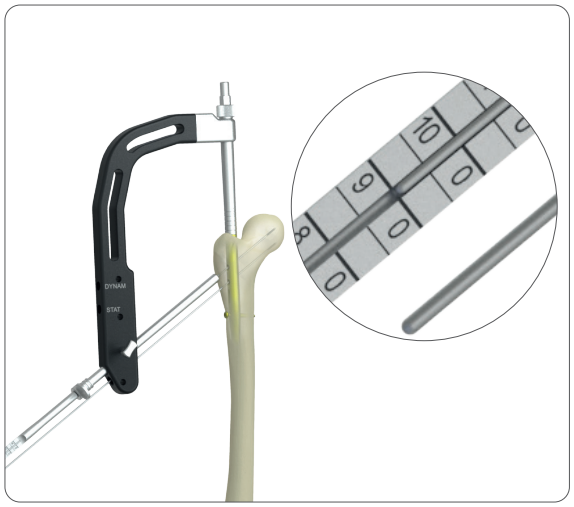
- In AP View the exact position of the nail depth should be determined.
- Next, the distal guide wire needs to be placed first through the distal targeting device hole.
- Therefore the tissue protection sleeve with trocar is introduced into the distal guide hole of the targeting device.
- The skin is 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.



Instruments

REF 09.20210.310 *Drill Guide Ø 8.0 / 2.0 mm*
REF 09.20210.320 *Guide Wire Ø 2.0 mm, L 440 mm*

- Insert the drill guide into the tissue protection sleeve.
- The first guide wire for the distal hip screw is inserted through the drill guide approx. 4 mm past the cortex at the Shenton's arch and up to about 2 mm before the cortex of the femoral band.
- Avoid penetrating the subcortical bone.
- The guide wire needs to be parallel to the femoral neck axis.
- Confirm the correct placement of the guide wire in both planes under the image intensifier.



Instruments

REF 09.20210.280 *VITUS-FT Length Determination Insturment, for Guide Wires Ø 2.0 mm*
REF 09.20210.310 *Drill Guide Ø 8.0 / 2.0 mm*
REF 09.20210.320 *Guide Wire Ø 2.0 mm, L 440 mm*

- Next, the proximal guide wire needs to be placed through the proximal targeting device hole.
- Therefore, repeat the two previous surgical steps using the proximal targeting device hole.
- The length of the inserted proximal guide wire is measured with the length determination instrument for guide wires.
- The distal guide wire should be maintained while the proximal guide wire is introduced.

Instruments

REF 09.20210.290 *Step Reamer Ø 6.5 / 4.5 mm*

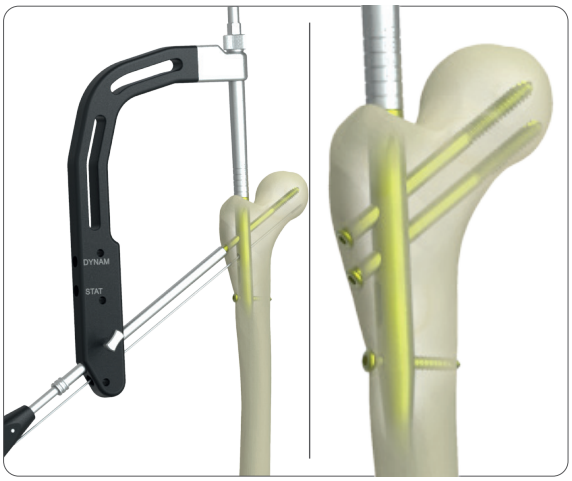
- Remove the length determination instrument and the drill guide.
- Drilling is done over the guide wire through the tissue protection sleeve with the step reamer into the femoral neck until the predetermined length of the screw is reached.

Attention

Drilling has to be done with caution and not any deeper than previously measured.

Instruments

REF 09.20210.200 Screwdriver, hex 3.5 mm



- Using the cannulated screwdriver, the cannulated hip screw is screwed in over the guide wire through the tissue protection sleeve (left).
- Afterwards the guide wire is removed.
- The correct placement of the inserted hip srew should be confirmed in both planes under the image intensifier.
- For the distal hip srew repeat the three previous surgical steps (right).

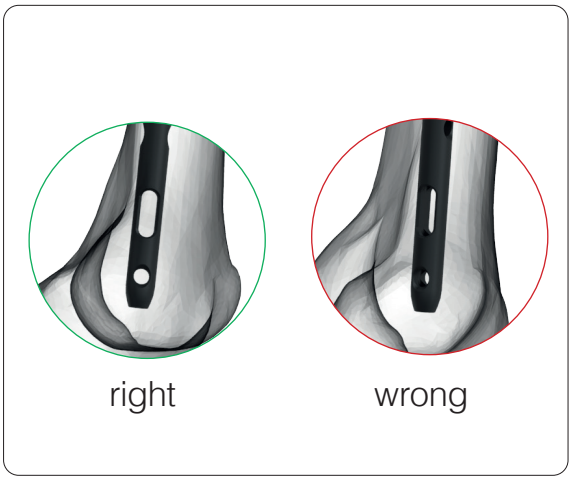
Attention

If the cervical locking is used, always two hip screws must be inserted in the nail.

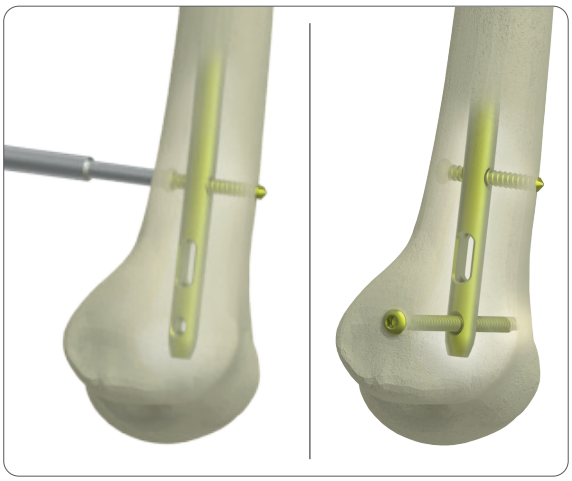
If hip screws are inserted proximal dynamic locking cannot be done.

However, it is possible to insert a second proximal locking screw into the proximal end of the proximal dynamic locking hole.

9. Distal Locking



- 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.
- 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.



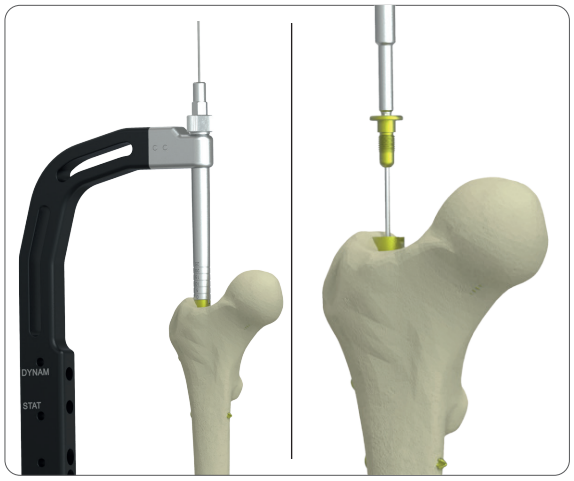
Instruments

REF 09.20210.150	*Drill Bit Ø 4.0 mm*
REF 09.20210.200	*Screwdriver, hex 3.5 mm*
REF 09.20210.220	*Length Determination Instrument, for Screws up to 100 mm*

- The procedure for the distal locking screws is the same as described in the surgical step 7.
- In order to perform static distal locking at least two screws should be inserted.

10. Dynamic Distal Locking

- If a secondary dynamic distal locking is required, a locking screw can be inserted in the distal end of the distal dynamic locking hole.
- The procedure corresponds to the surgical step 7.
- To activate the dynamic distal locking, the distal static locking screws have to be removed.



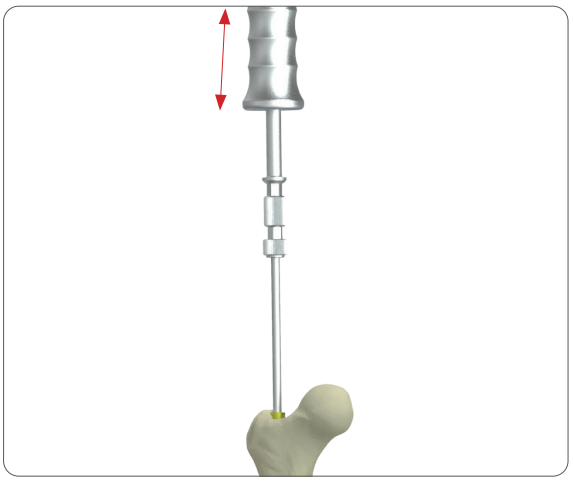
11. Insertion of the Cap Screw

Instruments

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

- The guide wire is inserted into the nail through the coupling screw of the targeting device (left).
- Next, the coupling screw and the targeting device will be removed. The inserted guide wire remains in the nail.
- The selected cap screw is insterted over the guide wire using the screwdriver (right).
- The guide wire is removed.

12. Removal of the VITUS-FT Femur Nail



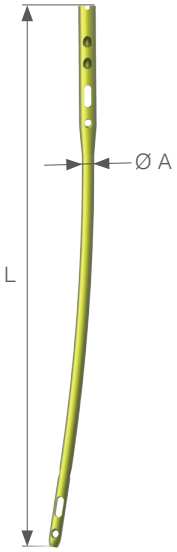
Instruments

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*

- Remove the end cap with the screwdriver.
- Next, remove all locking screws except one of the proximal locking screws using the Screwdriver.
- Assemble the coupling screw with the nail and tighten it to prevent rotation or displacement of the nail.
- 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.

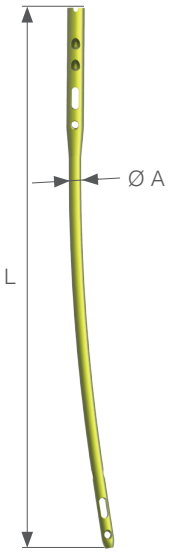
Product Informations

Implants



Vitus-FT Femur Nail, right, cannulated

L mm	Ø A: 9 mm	Ø A: 10 mm	Ø A: 11 mm	Ø A: 12 mm	Ø A: 13 mm
	Article Number	Article Number	Article Number	Article Number	Article Number
300	09.53109.300	09.53110.300	09.53111.300	09.53112.300	09.53113.300
320	09.53109.320	09.53110.320	09.53111.320	09.53112.320	09.53113.320
340	09.53109.340	09.53110.340	09.53111.340	09.53112.340	09.53113.340
360	09.53109.360	09.53110.360	09.53111.360	09.53112.360	09.53113.360
380	09.53109.380	09.53110.380	09.53111.380	09.53112.380	09.53113.380
400	09.53109.400	09.53110.400	09.53111.400	09.53112.400	09.53113.400
420	09.53109.420	09.53110.420	09.53111.420	09.53112.420	09.53113.420
440	09.53109.440	09.53110.440	09.53111.440	09.53112.440	09.53113.440
460	09.53109.460	09.53110.460	09.53111.460	09.53112.460	09.53113.460
480	09.53109.480	09.53110.480	09.53111.480	09.53112.480	09.53113.480

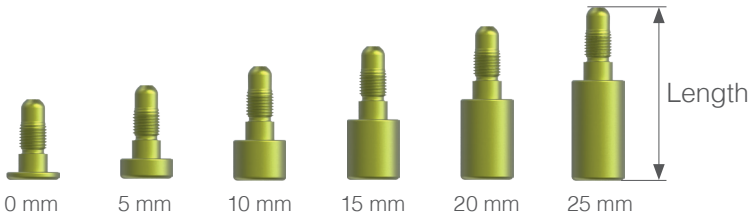


Vitus-FT Femur Nail, left, cannulated

L mm	Ø A: 9 mm	Ø A: 10 mm	Ø A: 11 mm	Ø A: 12 mm	Ø A: 13 mm
	Article Number	Article Number	Article Number	Article Number	Article Number
300	09.53209.300	09.53210.300	09.53211.300	09.53212.300	09.53213.300
320	09.53209.320	09.53210.320	09.53211.320	09.53212.320	09.53213.320
340	09.53209.340	09.53210.340	09.53211.340	09.53212.340	09.53213.340
360	09.53209.360	09.53210.360	09.53211.360	09.53212.360	09.53213.360
380	09.53209.380	09.53210.380	09.53211.380	09.53212.380	09.53213.380
400	09.53209.400	09.53210.400	09.53211.400	09.53212.400	09.53213.400
420	09.53209.420	09.53210.420	09.53211.420	09.53212.420	09.53213.420
440	09.53209.440	09.53210.440	09.53211.440	09.53212.440	09.53213.440
460	09.53209.460	09.53210.460	09.53211.460	09.53212.460	09.53213.460
480	09.53209.480	09.53210.480	09.53211.480	09.53212.480	09.53213.480

Vitus-FT Cap Screw for Vitus-FT Femur Nail

- Material: Ti6AL4V
- Colour: gold
- Prevents ingrowing of soft tissue into the proximal end of the VITUS-FT Femur Nail
- Cannulated
- 0 mm – flush with the proximal end of the VITUS-FT Femur Nail
- 5 mm, 10 mm, 15 mm, 20 mm und 25 mm – extension for the VITUS-FT Femur Nail



Article Number	Length
09.01013.000	0 mm
09.01013.005	5 mm
09.01013.010	10 mm
09.01013.015	15 mm
09.01013.020	20 mm
09.01013.025	25 mm

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

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

Hip Screw Ø 6.5 mm, Cannulated, Self-Tapping

- Thread diameter: 6.5 mm
- Core diameter: 4.5 mm
- Cannulation: 2.2 mm
- Head diameter: 8.0 mm
- Hexagon socket: 3.5 mm
- Material: Ti6Al4V

Length	Article Number
60 mm	09.03865.060
65 mm	09.03865.065
70 mm	09.03865.070
75 mm	09.03865.075
80 mm	09.03865.080
85 mm	09.03865.085
90 mm	09.03865.090
95 mm	09.03865.095
100 mm	09.03865.100
105 mm	09.03865.105
110 mm	09.03865.110
115 mm	09.03865.115
120 mm	09.03865.120
125 mm	09.03865.125
130 mm	09.03865.130
135 mm	09.03865.135
140 mm	09.03865.140

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

09.20210.320 Guide Wire Ø 2.0 mm, threaded tip, L 440 mm

09.20210.210 Cleaning Wire Ø 2.0 mm, L 435 mm

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

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

09.20210.290 Step Reamer Ø 6.5 / 4.5 mm, cannulated, scaled, Quick Coupling

09.20210.110 VITUS-FT Drill Sleeve Ø 8.0 / 4.0 mm

09.20210.120 VITUS-FT Trocar Ø 8.0 mm

09.20210.310 Drill Sleeve Ø 8.0 / 2.0 for Guide Wires

09.20210.330 VITUS-FT Tissue Protection Sleeve Ø 10.0 / 8.0

09.20210.060 VITUS-FT Tissue Protection Sleeve Ø 15.0 / 13.0, for Femur

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

09.20210.280 VITUS-FT Length Determination Instrument, for Guide Wires Ø 2.0 mm x 440 mm

09.20210.170 VITUS-FT Slide Hammer for REF 09.20210.180

09.20210.180 VITUS-FT Extractor for Nail, Tibia / Femur

09.20210.190 VITUS-FT Driving Head for REF 09.20210.180

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

14.30060.040 Eccentric Fixation Bolt

09.20210.200 VITUS-FT Screwdriver, hex 3.5 mm, cannulated

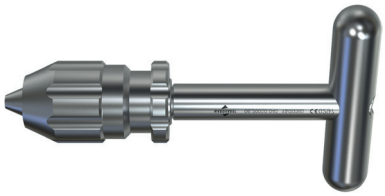
09.20210.130 VITUS-FT X-Ray Template, Tibia / Femur

09.20210.260 VITUS-FT Awl Ø 13 mm, cannulated, for Femur

09.20210.020 VITUS-FT Targeting Device, for Femur

04.20040.099 Combination Wrench Ø 11 mm

06.20050.045 Universal Chuck, T-Handle, cannulated



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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MARQUARDT
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