

T2 Alpha™

Tibia Nailing System

Operative technique



T2 Alpha

T2 Alpha Tibia Nailing System, IMN Screws System and IMN Instruments System

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This publication sets forth detailed recommended procedures for using Stryker devices and instruments. It offers guidance that you should heed, but, as with any such technical guide, each surgeon must consider the particular needs of each patient and make appropriate adjustments when and as required. A workshop training is recommended prior to performing your first surgery. All nonsterile devices must be cleaned and sterilized before use.

Follow the instructions provided in our cleaning and sterilization guide (OT-RG-1). Multi-component instruments must be disassembled for cleaning. Please refer to the corresponding assembly/disassembly instructions.

Please remember that the compatibility of different product systems has not been tested unless specified in the product labeling.

See package insert (Instructions for Use) (L22000035, L22000044, L22000045, L22000007) for a complete list of potential adverse effects, contraindications, warnings and precautions.

The surgeon must discuss all relevant risks including the finite lifetime of the device with the patient when necessary.

CAUTION

Use instruments/implants only as described in this operative technique to avoid damage to instruments/implants, bone or soft tissue.

The terms 'all Stryker IM Nailing Systems' / 'all titanium-made Stryker IM Nailing Systems' (described in IFU L22000035 and L22000045) are defined as T2 Alpha Femur Antegrade GT/PF Nailing System and T2 Alpha Tibia Nailing System.

Indications and contraindications

This document applies to the devices of the T2 Alpha Tibia Nailing System, IMN Screws System and IMN Instruments System.

T2 Alpha Tibia Nailing System

Intended use

The T2 Alpha Tibia Nailing System is intended for temporary stabilization of bone segments or fragments until bone consolidation has been achieved.

Indications for Use (United States and Canada)

The indications for use of this internal fixation device include:

- Open and closed tibia fractures
- Pseudarthrosis and correction osteotomy
- Pathologic fractures, impending pathologic fractures, and tumor resections
- Nonunion and malunion
- Fractures involving osteopenic and osteoporotic bone

The End Cap Lower Extremity and the Nail Holding Screw Tibia / Femur PF may also be used in conjunction with the T2 Alpha Femur Antegrade GT/PF Nailing System.

Indications for Use (Europe and other countries)

The indications for use of this internal fixation device include:

- Open and closed tibial fractures
- Nonunion and malunion

The End Cap Lower Extremity and the Nail Holding Screw Tibia / Femur PF may also be used in conjunction with the T2 Alpha Femur Antegrade GT/PF Nailing System.

Contraindications

The physician's education, training and professional judgement must be relied upon to choose the most appropriate device and treatment. Conditions presenting an increased risk of failure include:

- Any active or suspected latent infection or marked local inflammation in or about the affected area
- Compromised vascularity that would inhibit adequate blood supply to the fracture or the operative site
- Bone stock compromised by disease, infection or prior implantation that can not provide adequate support and/or fixation of the devices
- Material sensitivity, documented or suspected
- Obesity. An overweight or obese patient can produce loads on the implant that can lead to failure of the fixation of the device or to failure of the device itself
- Patients having inadequate tissue coverage over the operative site
- Implant utilization that would interfere with anatomical structures or physiological performance
- Any mental or neuromuscular disorder which would create an unacceptable risk of fixation failure or complications in post-operative care
- Other medical or surgical conditions which would preclude the potential benefit of surgery

IMN Screws System

Intended use

The IMN Screws System is intended to stabilize the intramedullary nail-bone construct for temporary stabilization.

IMN Instruments System

Intended use

The IMN Instruments System is intended to enable the implantation and extraction of intramedullary nail and screw.

MRI Safety Information



T2 Alpha Tibia Nailing System (9-15mm nails)

Non-clinical testing has demonstrated that the T2 Alpha Tibia Nailing System and IMN Screws System are MR Conditional. A patient with this device can be safely scanned in an MR system meeting the following conditions:

- Static magnetic field of 1.5 T or 3.0 T
- Maximum spatial field gradient of 3,000 gauss/cm (30 T/m)
- Maximum MR system reported, whole body averaged specific absorption rate (SAR) of 2 W/kg (Normal Operating Mode)

Under the scan conditions defined above, the T2 Alpha Tibia Nailing System and IMN Screws System are expected to produce a maximum temperature rise of less than 1.5°C after 15 minutes of continuous scanning.

In non-clinical testing, the image artifact caused by the device extends approximately 27mm from the T2 Alpha Tibia Nailing System and IMN Screws System when imaged with a spin echo or gradient echo pulse sequence and a 3.0 T MRI system.

T2 Alpha Tibia Nailing System (8mm nails)

Non-clinical testing has demonstrated that the T2 Alpha Tibia Nailing System and IMN Screws System are MR Conditional. A patient with this device can be safely scanned in an MR system meeting the following conditions:

- Static magnetic field of 1.5 T or 3.0 T
- Maximum spatial field gradient of 3,000 gauss/cm (30 T/m)
- Maximum MR system reported, whole body averaged specific absorption rate (SAR) of 2 W/kg (Normal Operating Mode)
- Scan time restriction: maximum 6 minutes of continuous scanning

Under the scan conditions defined above, the T2 Alpha Tibia Nailing System and IMN Screws System are expected to produce a maximum temperature rise of less than 6.0°C after 6 minutes of continuous scanning.

In non-clinical testing, the image artifact caused by the device extends approximately 27mm from the T2 Alpha Tibia Nailing System and IMN Screws System when imaged with a spin echo or gradient echo pulse sequence and a 3.0 T MRI system.

▲ CAUTION

The MRI safety information provided is based on testing which did not include supplementary devices. If there are supplementary devices (i.e. plates, screws, wires, etc.) present in proximity to the T2 Alpha Tibia Nailing System and IMN Screws System, this could result in additional MRI effects and the information provided above may not apply.

Additional Information

T2 Alpha Tibia Nail

- **Nail diameters**
Ø8mm – Ø15mm*
- **Nail length**
240mm – 420mm in 15mm increments
- **Compression Screw Tibia****



- **End Cap Lower Extremity and End Caps Tibia**



IMN Screws

- **Locking Screw**
Ø5mm, 25mm – 120mm
Ø4mm, 20mm – 60mm for 8mm nails (distal screws only)
20mm – 60mm in 2.5mm increments
60mm – 120mm in 5mm increments



- **Advanced Locking Screw**
Ø5mm, 30mm – 100mm
Ø4mm, 27.5mm – 60mm for 8mm nails (distal screws only)
27.5mm – 60mm in 2.5mm increments
60mm – 100mm in 5mm increments



Drills

- 4.2mm - green
- 5.5mm - green (counterbore drill)
- 3.5mm - orange
- 4.5mm - orange (counterbore drill)

** Compression range	
Total length of slot	12mm
Less screw diameter	5mm
Max movement of screw	7mm



* Check with local representative regarding availability of implant sizes.
 Note: Screw length is measured from top of head to tip
 Note: The suprapatellar instrumentation can only be used with nails with a diameter of up to 13mm
 Note: 8mm nails require 4mm IMN Locking Screws or 4mm IMN Advanced 5 Locking Screws for distal locking.

Additional Information

Packaging

The implants in the T2 Alpha Tibia Nailing and IMN Screws Systems include packaging that minimizes user contact with the implant prior to implantation.

After the pouch is opened, all implants include a sheath that is introduced into the sterile field.

Example 1: Nail is removed from pouch, sheath is opened and attached to the targeting arm (fig. 1, 2, 3).



Fig. 1



Fig. 2



Fig. 3

Additional Information

Packaging

Example 2: After removal from pouch, screw (fig. 4, 5) or other implant (fig. 6, 7) is attached to the corresponding screwdriver.

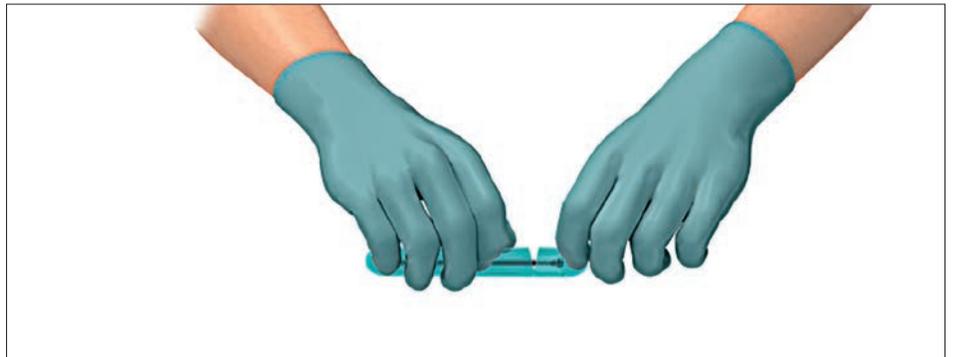


Fig. 4

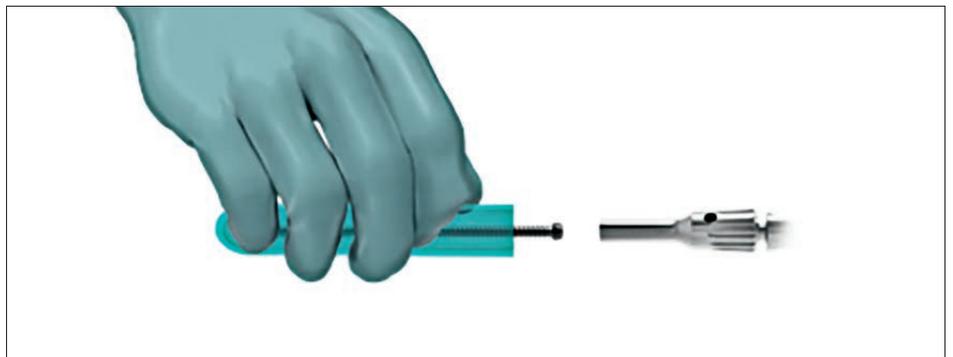


Fig. 5



Fig. 6



Fig. 7

Operative technique

Infrapatellar approach

Patient positioning and reduction

There are two options for patient positioning.

1. The patient is placed in the supine position on a radiolucent table and the knee of the injured leg is flexed.
2. The patient is placed in the supine position on a radiolucent fracture table and the leg is hyperflexed on the table with the aid of a leg holder (fig. 8).

The knee is flexed to $>90^\circ$.

A triangle may be used under the knee to accommodate flexion intra-operatively. It is important that the knee rest is placed under the posterior aspect of the lower thigh in order to reduce the risk of vascular compression and of pushing the proximal fragment of the tibia anteriorly.

Anatomical reduction can be achieved by internal or external rotation of the fracture and by traction, adduction or abduction, and must be confirmed under image intensification. Draping must leave the knee and the distal end of the leg exposed.

Incision

Based on radiological image, a paratendinous incision is made from the patella extending down approximately 1.5 – 4cm in preparation for nail insertion.

The patellar tendon may be retracted laterally or split

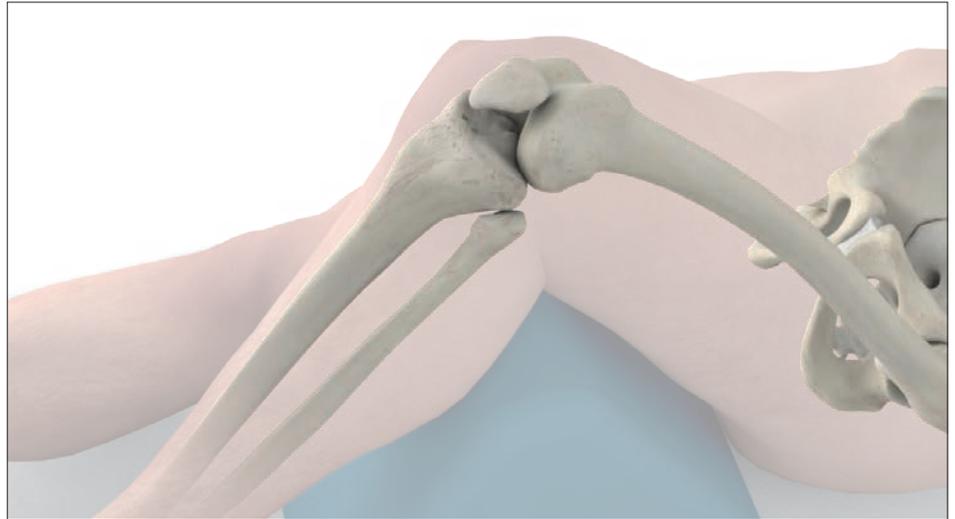


Fig. 8



Fig. 9

at the junction of the medial third, and lateral two-thirds of the patellar ligament. This determines the entry point (fig. 9).

Operative technique

Infrapatellar approach

Entry point

The medullary canal is opened through a superolateral plateau entry portal. The center point of the portal is located slightly medial to the lateral tibia spine as visualized on the A/P radiograph and immediately adjacent and anterior to the anterior articular margin as visualized on the true lateral radiograph. It is located lateral to the midline of the tibia by an average of 6 percent of the tibia plateau width.

Radiographic confirmation of this area is essential to prevent damage to the intra-articular structure during portal placement and nail insertion (fig. 10, 11).

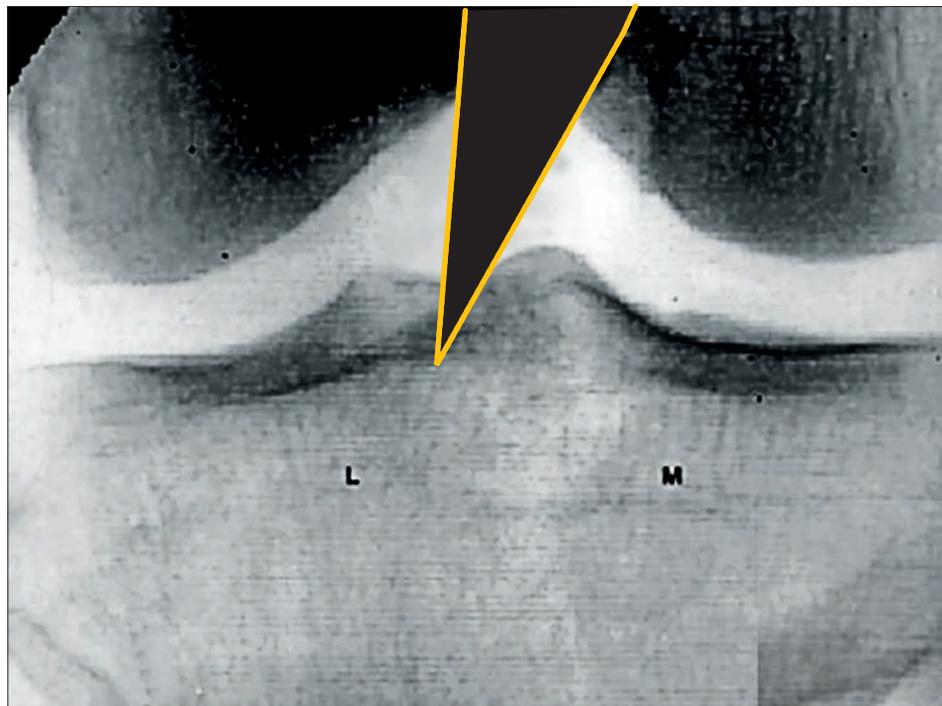


Fig. 10

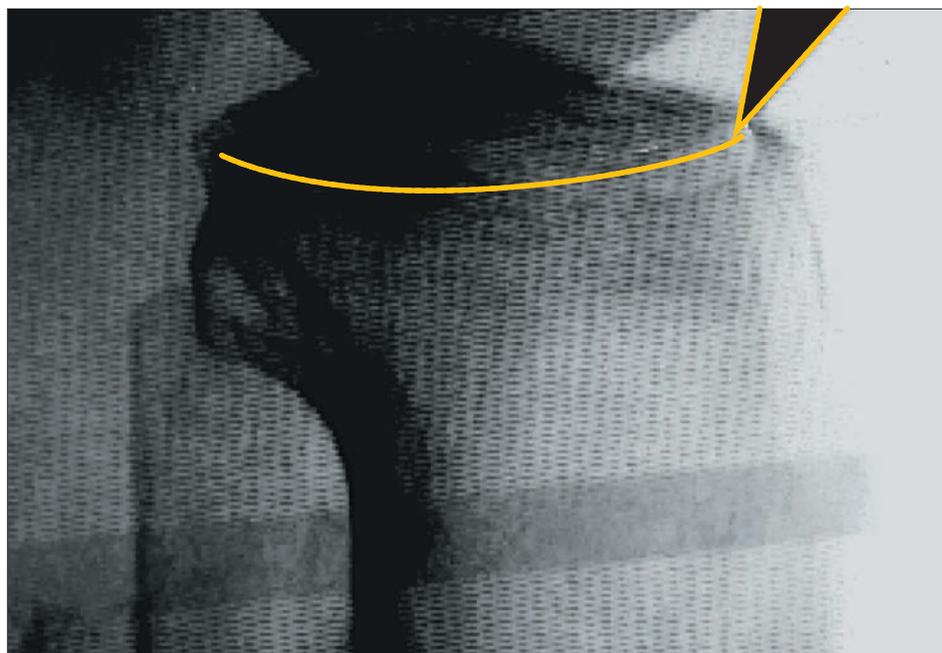


Fig. 11

Operative technique

Infrapatellar approach

Opening

The opening should be directed with a central orientation in relation to the medullary canal.

Insert the 3x285mm K-wire at the identified entry point and into the medullary canal.

Assemble the Opening Reamer Handle and Opening Reamer Sleeve, 11.5, and together with the Opening Trocar, 11.5 (fig. 12), guide the assembly over the K-wire until the Opening Trocar is fully seated on the bone. It is recommended to orient the sleeve so that the convex tips are positioned anteriorly/posteriorly and the concave ends are positioned medially/laterally.

If the initial K-wire is not optimally positioned, the off-center holes of the Opening Trocar can be used to correct the entry point by inserting a second K-wire. To utilize, rotate the trocar into the desired position and place a second K-wire through one of the off-center holes. The distance from the center hole is 4mm (fig. 13). Once the second K-wire is positioned as desired, remove the initial K-wire and the Opening Trocar.

NOTICE

As an alternative to the standard 3x285mm K-wire, the 3x285mm Fixation K-wire can be utilized as an entry point guide wire.

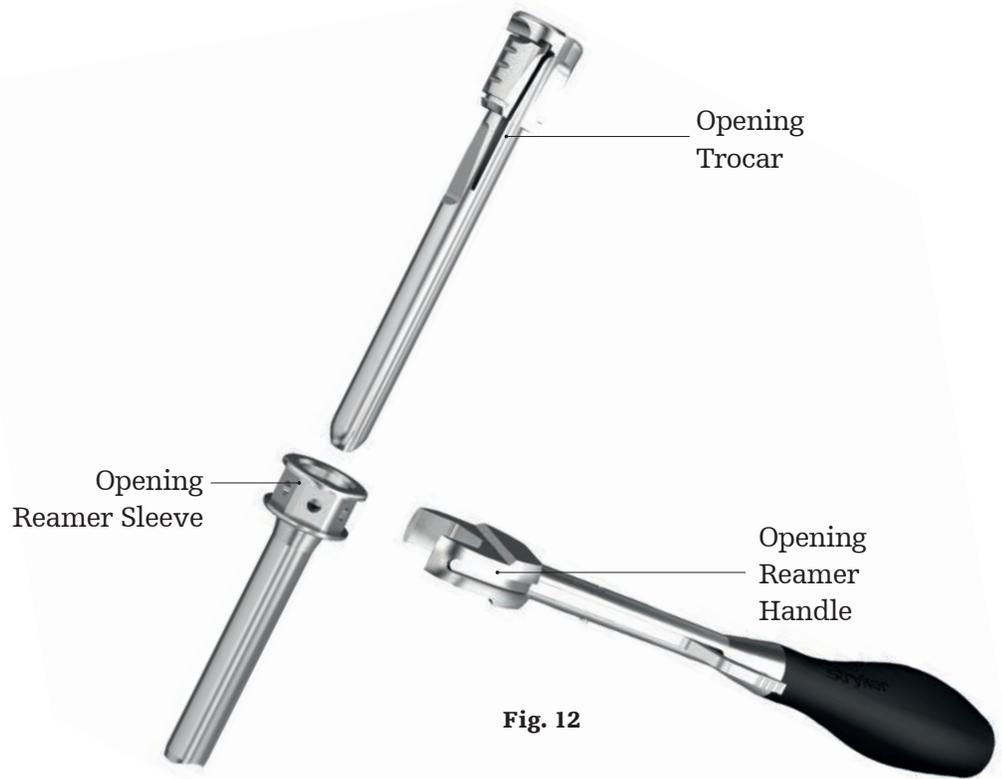


Fig. 12

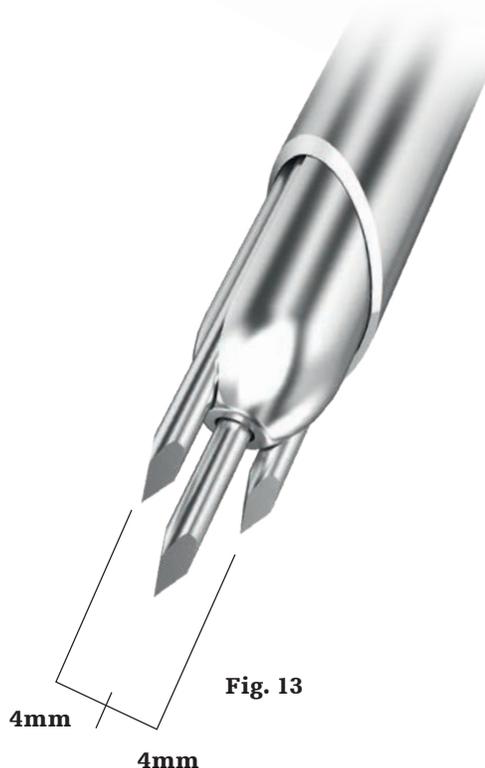


Fig. 13

Operative technique

Infrapatellar approach

If more than 4mm of correction is required, 8mm of correction can be achieved by removing the sleeve and trocar assembly from the initial K-wire and reinserting the assembly over the K-wire through one of the off-center holes of the trocar. Then insert a second K-wire through the remaining off-center hole. Once the second K-wire is positioned as desired, remove the initial K-wire and trocar.

After verifying that the Opening Reamer Sleeve is fully seated on the bone, advance the Opening Reamer on power and ream over the K-wire through the Opening Reamer Sleeve to open the medullary canal (fig. 14a). If hand reaming is preferred, attach the Opening Reamer to the Quick-Lock Delta Handle and rotate the reamer assembly. Remove the K-wire.

As an alternative, the cortex can be opened with the Curved Awl (fig. 14b). If the Curved Awl is used, the Opening Reamer or Bixcut Reamer must be utilized to widen the entry portal. If using the Bixcut Reamer, ensure that the diameter of the selected reamer is at least as large as the diameter of the proximal end of the nail. The proximal diameter of the 9-11mm nails is 11.5mm; nail sizes 12-15mm have a constant diameter. Ream far enough to accommodate the proximal section of the nail. Use X-ray to confirm depth.



Fig. 14a



Fig. 14b

⚠ CAUTION

Verify correct entry point prior to opening the cortex.

⚠ CAUTION

The Opening Reamer is a front and side cutting instrument and should be used with care to ensure that the sharp edges of the reamer do not inadvertently damage bone or soft tissue. Use of the Opening Reamer Sleeve is recommended.

⚠ WARNING

Do not touch sharp edges of drill bits, reamer heads and cutting tools with surgical gloves. Take care when handling sharp edges of packaging and instruments.

Operative technique

Suprapatellar approach

Patient positioning options and reduction

The patient is placed in the supine position on a radiolucent table and the leg is flexed approximately 15°. To create this necessary flexion in the knee, a cushion can be placed underneath the tibia to create the appropriate angle (fig. 15a).

This positioning elevates the fractured tibia out of the same plane as the opposite tibia, allowing for easier lateral X-ray imaging. In addition, it provides support under the fractured tibia throughout the procedure.

Alternatively, a triangle or other “bumps” may be placed under the posterior aspect of the lower thigh to accommodate flexion intra-operatively (fig 15b).

NOTICE

Increasing the knee flexion may limit the available space within the joint and the opportunity to maneuver the sleeves during insertion.

Anatomical reduction can be achieved by internal or external rotation of the fracture and by traction, adduction or abduction, and must be confirmed under image intensification. Draping must leave the knee and the distal end of the leg exposed.

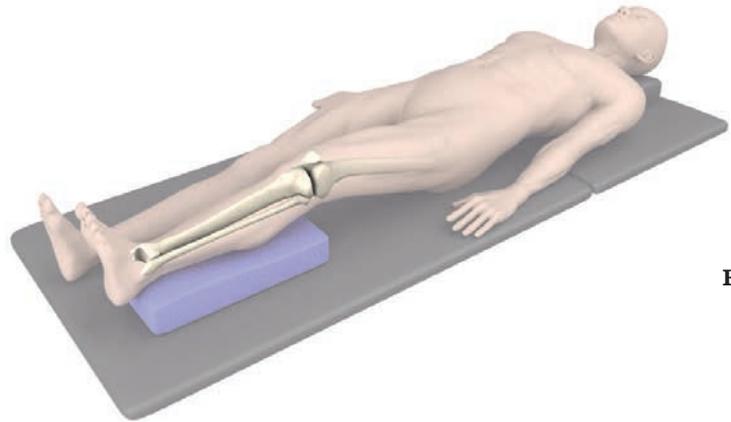


Fig. 15a

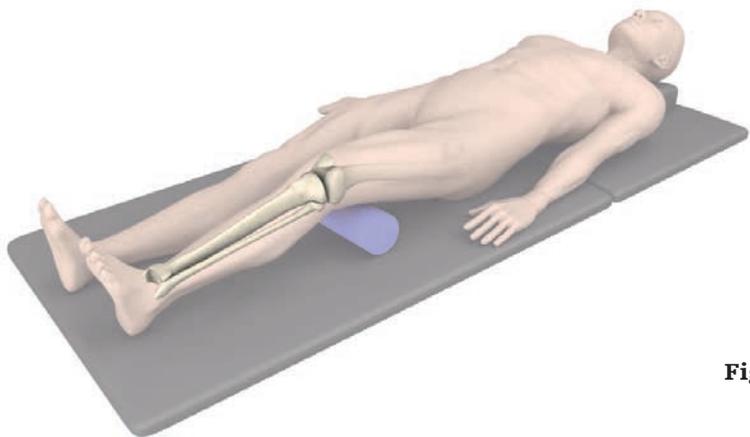


Fig. 15b

Operative technique

Suprapatellar approach

Incision

A longitudinal incision is made directly proximal to the patella, measuring approximately 2-3cm (fig. 16).

Then, a longitudinal split of the quadriceps tendon is performed along its midline.

⚠ CAUTION

Surgeons must evaluate the available joint space. Switching to a parapatellar approach is recommended if space within the joint is too limited to permit smooth sleeve insertion.

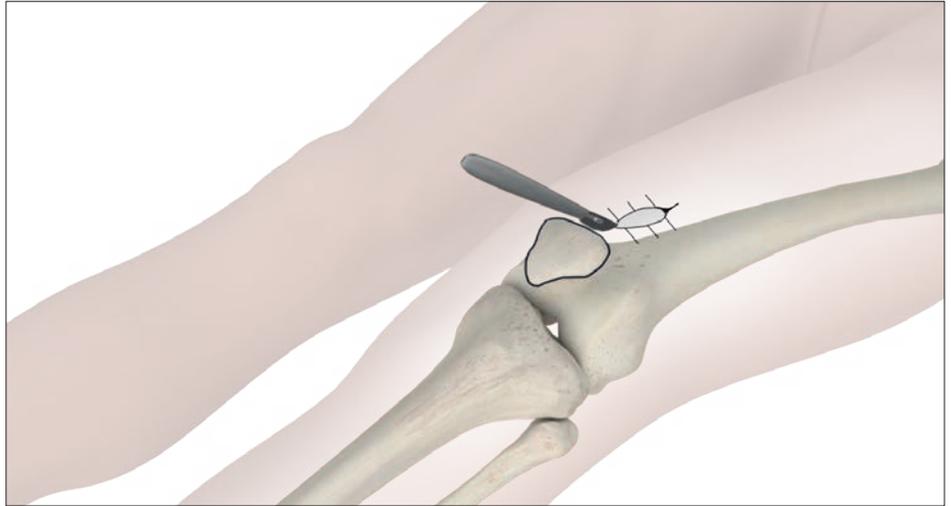


Fig. 16

Operative technique

Suprapatellar approach

Assembly: Modular Handle and Drill Sleeve

Assemble the Modular Handle (fig. 17a) by inserting the magnetically activated trigger.

Connect the appropriate Drill Sleeve to the modular handle by inserting the Drill Sleeve into the ring of the modular handle (fig. 17b). The trigger of the handle can be pulled back to assemble or disassemble the Drill Sleeve.

NOTICE

It is recommended to visibly inspect the Drill Sleeve before use, as it may become damaged over time.

NOTICE

The Drill Sleeve can be engaged on the modular handle every 90 degrees to suit surgeon preference.

CAUTION

Due to the sleeve sizes the suprapatellar approach can only be performed with T2 Alpha Tibial Nails up to a diameter of 13mm.



Fig. 17a

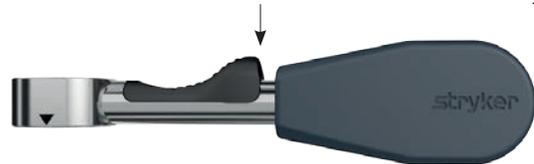


Fig. 17b



Fig. 17c

Final position of assembled Modular Handle and Drill Sleeve.

The Modular Handle, Drill Sleeves, Trocars, Plug and Elastic Nail Insertion Sleeves are existing components of the T2 System.

Operative technique

Suprapatellar approach

Sleeve insertion technique

The Elastic Nail Insertion Sleeve is single-use only. All sleeves and trocars are offered in two different sizes: Ø8-11 and Ø8-13. The Ø8-11 sleeves and trocars can be used with the T2 Alpha Tibial Nails up to a diameter of 11mm and the Ø8-13 sleeves and trocars can be used with the T2 Alpha Tibial Nails up to a diameter of 13mm. Only sleeves and trocars of corresponding sizes can be used together.

Assemble the appropriate Drill Sleeve, Reamer Sleeve, Elastic Nail Insertion Sleeve, Trocar and Plug (fig. 18)



Fig. 18

Operative technique

Suprapatellar approach

Sleeve insertion technique

Make sure that the Elastic Nail Insertion Sleeves are correctly aligned with the Drill Sleeve. When the sleeves are correctly aligned, there will be no gap (fig. 19) between the interface of the two sleeves.

Then, advance the corresponding trocar and plug into the Drill Sleeve until it is locked.

NOTICE

During the sleeve insertion procedure, ensure the off-center hole of the trocar is lateral or medial to the center hole in order to facilitate smooth insertion. Be sure to maintain this position until the trocar tip sits on the tibia plateau, at which point the trocar can then be rotated again as desired.

The plug is not fixed in the trocar. Therefore, the surgeon should press the plug with his or her palm during insertion of the assembly.



Fig. 19

Operative technique

Suprapatellar approach

Sleeve insertion technique

Guided by the femoral condyles, insert the entity comprised of the Elastic Nail Insertion Sleeve, Drill Sleeve, Trocar and Plug into the patellofemoral joint until the tip of the Trocar sits on the tibia plateau (fig. 20a). Ensure that the handle is positioned so that the K-wire slots in the Elastic Nail Insertion Sleeve are positioned in the frontal plane during sleeve insertion. Do not insert the sleeves in any orientation other than what is pictured in Figures 20a and 20b. Do not insert the sleeves as exhibited in Figure 20c.

⚠ CAUTION

Proceed with caution to not cause harm to the patella, intercondylar notch, and surrounding tissues.

The Plug can be removed from the Trocar at this time.



Fig. 20a



Fig. 20b



Fig. 20c

Operative technique

Suprapatellar approach

Entry point

The medullary canal is opened through a superolateral plateau entry portal.

The center point of the portal is located slightly medial to the lateral tibia spine as visualized on the A/P radiograph (fig. 21a) and immediately adjacent and anterior to the anterior articular margin as visualized on the true lateral radiograph (fig. 21b).

The entry point is located lateral to the midline of the tibia by an average of 6 percent of the tibia plateau width. Radiographic confirmation of this area is essential to prevent damage to the intra-articular structure during portal placement and nail insertion.

The off-center hole of the Trocar can be used either for guide wire placement or to correct an initially misplaced entry point through the center hole. The distance between the center and the off-center hole is 4.5mm.

To utilize the off-center hole, rotate the Trocar into the desired position and place either an initial or second 3x285mm K-wire through the off-center hole of the Trocar (fig. 22). If an initial K-wire was used in the center hole, remove at this time.

In an additional M/L radiograph (fig. 16), the correct positioning of the entry point in the sagittal plane should be confirmed.

The opening should be directed with a central orientation in relation to the medullary canal in both (A/P and M/L) views.

NOTICE

Do not use a bent K-wire for entry point definition.



Fig. 21a



Fig. 21b

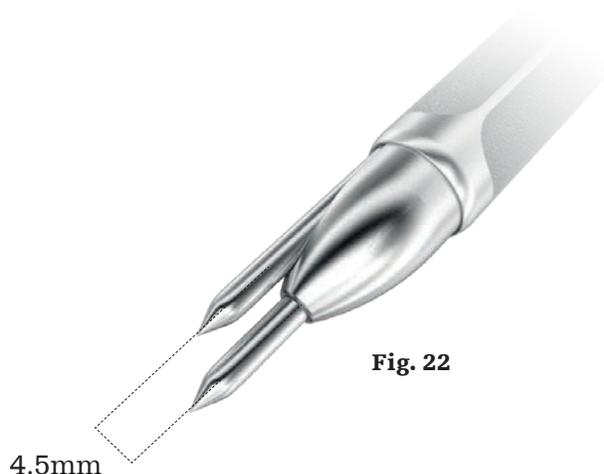


Fig. 22

4.5mm

Operative technique

Suprapatellar approach

Unlock the Trocar and push the Drill Sleeve and Elastic Nail Insertion Sleeve forward until the sleeve tip lies on the tibia plateau (fig. 23).

Fixation K-wires

Two 3x285mm fixation K-wires can be used for fixation of the sleeves to the tibia plateau.

Insert the K-wires through the holes in the Drill Sleeve (fig. 24).

NOTICE

The 3x285mm fixation K-wire should extend into the tibia as shown (fig. 24) to allow for proper fixation.

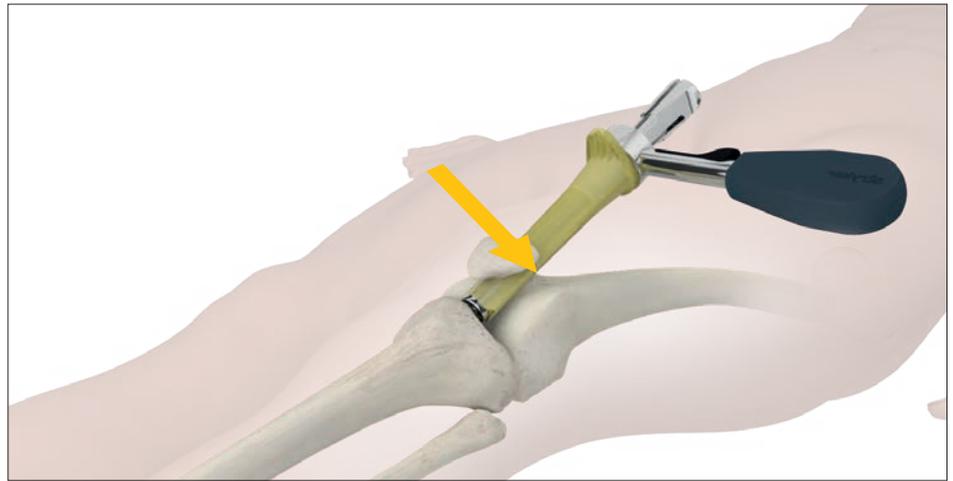


Fig. 23

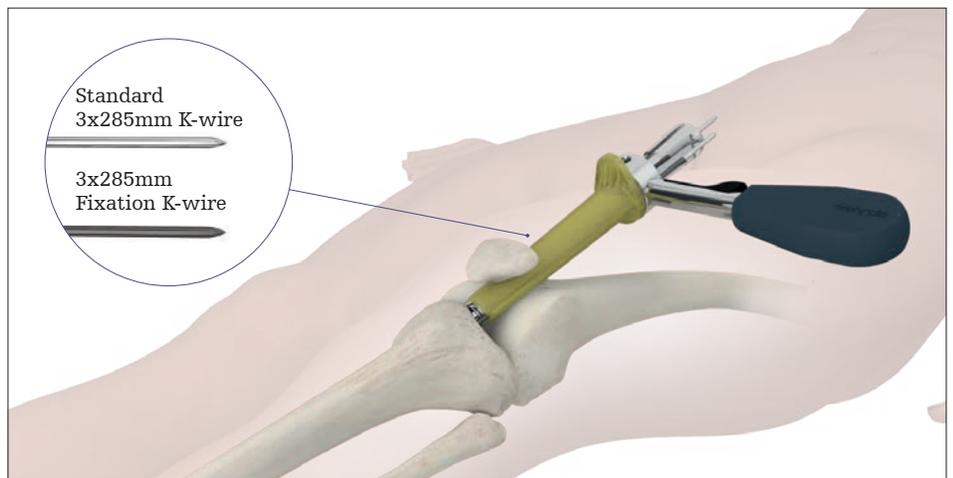


Fig. 24

Operative technique

Suprapatellar approach

Opening

Remove the Trocar prior to opening of the tibia. The Opening Drill Ø12 is used to access the medullary canal (fig. 25a).

Reamed technique

The Drill Sleeve and the 3x285mm Fixation K-wires are not removed prior to reaming. The Elastic Nail Insertion Sleeve also remains in place.

The remaining operative steps for both the infrapatellar and suprapatellar approach are the same unless otherwise indicated. All of the following pictures are shown using the infrapatellar approach unless otherwise indicated.

⚠ CAUTION

Use of the suprapatellar instrumentation decreases the working length and may require longer reamer and guide wire lengths than those used with the infrapatellar approach. Please plan accordingly.

⚠ CAUTION

Opening drilling should be performed through the drill sleeve with the Elastic Nail Insertion Sleeve or the Nail Insertion Sleeve SPI remaining in place. Advance the opening drill until it stops.



Fig. 25a



Fig. 25b

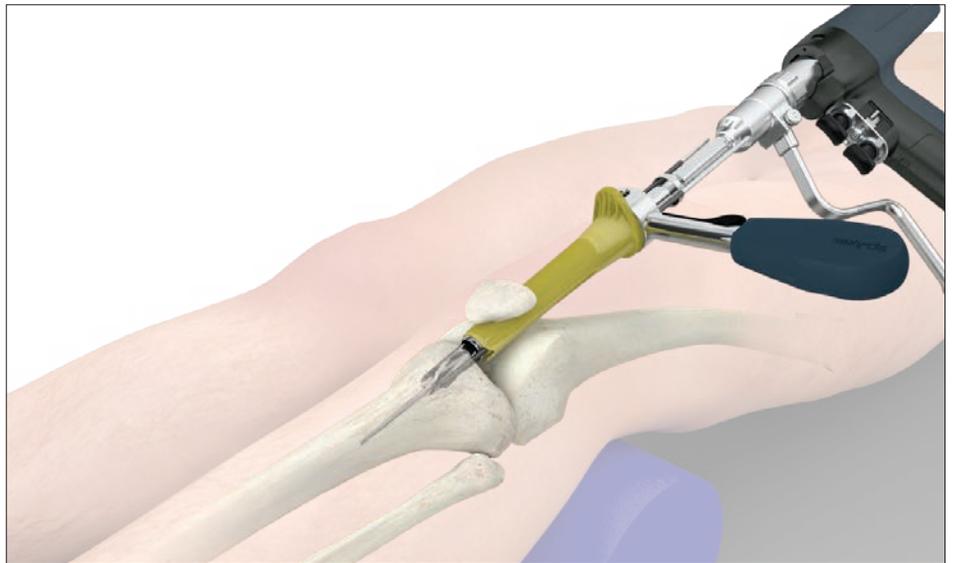


Fig. 26

Operative technique

Guide wire insertion

Insert the Ball Tip Guide Wire 3x800mm through the Guide Wire Handle (fig. 27a). Adjust the handle as desired and lock the assembly by closing the fixation lever.

The Guide Wire Handle can accommodate guide wires and K-wires with diameters from 1.8mm – 4mm. If necessary, loosen or tighten the adjustment wheel to increase or decrease the diameter of the insertion hole.

Advance the Ball Tip Guide Wire through the fracture site and to the desired insertion depth. The guide wire should lie in the center of the metaphysis and the diaphysis in both the AP and Lateral views to avoid offset positioning of nail.

The Reduction Rod and Quick-Lock Delta Handle Assembly may be used as a fracture reduction tool to facilitate guide wire insertion through the fracture site (fig. 27b).

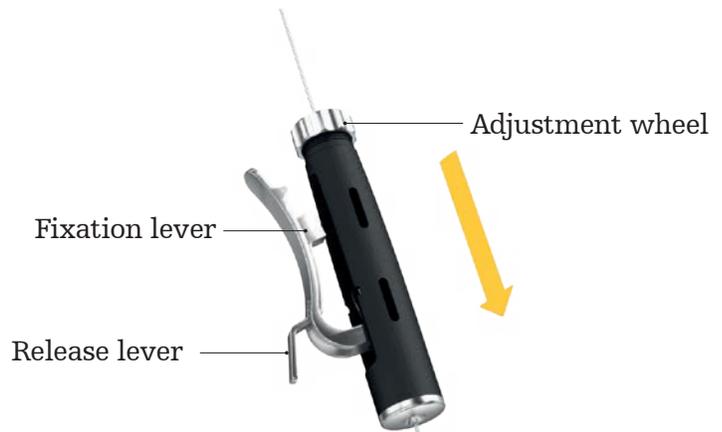


Fig. 27a

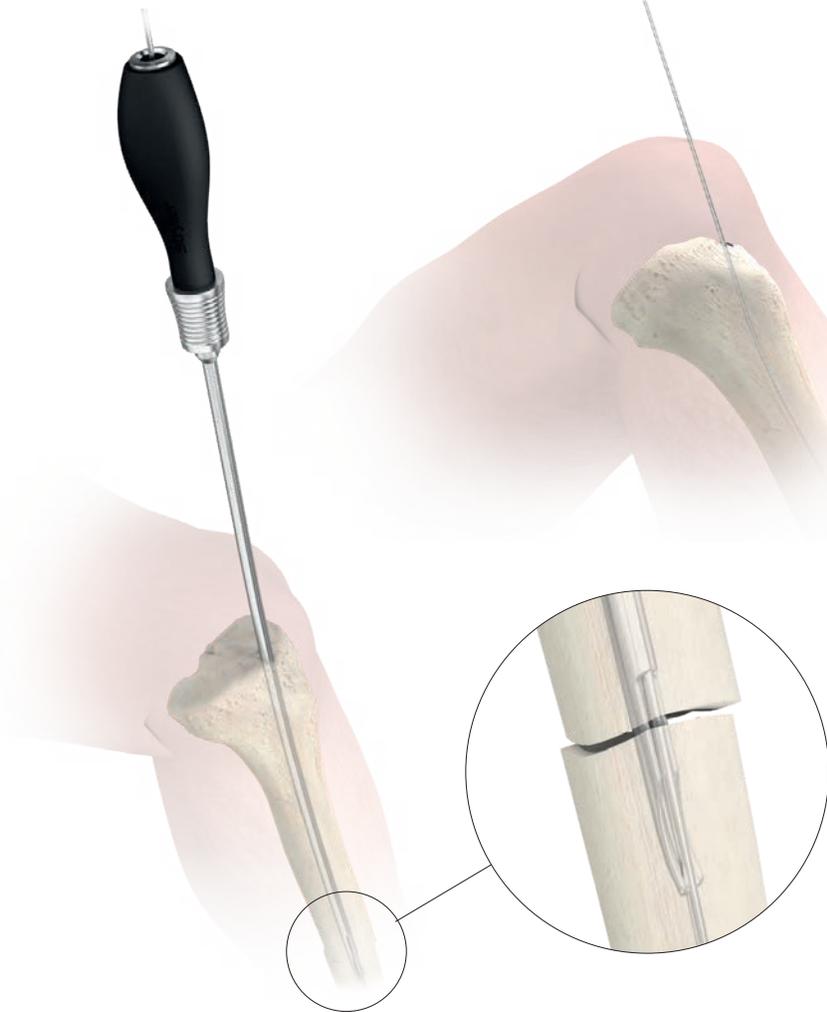


Fig. 27b

NOTICE

The ball tip at the end of the guide wire will stop the reamer head.

NOTICE

Do not use bent guide wires.

CAUTION

Confirm correct position of Ball Tip Guide Wire prior to reaming.

Operative technique

Reaming

Commence reaming (fig. 28) in 0.5mm increments until the desired diameter has been achieved.

To help maintain the position of the guide wire during reamer shaft extraction, press the funnel tip end of the Guide Wire Pusher (fig. 29) at the end of the wire while extracting the reamer from the medullary canal.

The diameter of the selected T2 Alpha Tibial Nail should be 1 - 1.5mm smaller than that of the last reamer used.

Alternatively, the diameter of the nail may be determined by using the X-ray Ruler under fluoroscopy before or after guide wire insertion. To determine diameter, use the ruler at the smallest diameter of the medullary canal (fig. 30).

If operating via the suprapatellar approach, remove the fixation K-wires and Drill Sleeve once reaming has been completed. The Elastic Nail Insertion Sleeve remains in place for nail insertion.

NOTICE

The diameter of the selected T2 Alpha Tibial Nail must be at least 1mm - 1.5mm smaller than the last reamer used.

NOTICE

In the suprapatellar approach, the maximum reaming diameter for the Ø8-11 Drill Sleeve is 12.5mm, for the Ø8-13 Drill Sleeve 14.5mm.



Fig. 28



Fig. 29

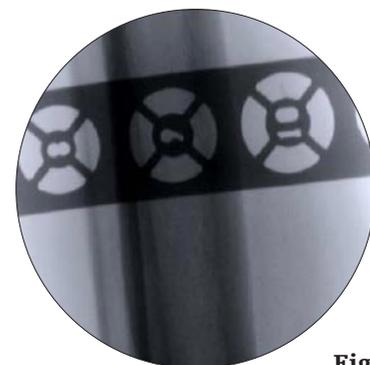


Fig. 30

Image indicates an estimated canal/diameter width of 9mm.

NOTICE

To ensure proper positioning of the Guide Wire tip during reaming, the Guide Wire Pusher may be replaced with any other Stryker 3mm Guide Wire.

NOTICE

The smallest diameter nail available is 8mm. The diaphyseal bone must be large enough to allow for reaming of the medullary canal up to at least 9mm.

CAUTION

Excessive heat generation during reaming/drilling may cause soft tissue or bone damage.

CAUTION

The proximal diameter of the 8mm-11mm diameter nails is 11.5mm. Additional metaphyseal reaming may be required to facilitate nail insertion. Nail sizes 12-15mm have a constant diameter.

WARNING

Care must be taken to ensure that the entry portal is not extended anteriorly during reaming. This could lead to an offset position for the nail and a risk of shaft fracture.

Operative technique

Nail selection

Determine appropriate nail length by measuring the remaining length of the Ball Tip Guide Wire. Remove the Opening Reamer Sleeve and place the Guide Wire Ruler through the Opening Reamer Sleeve (fig. 31a) and on the Ball Tip Guide Wire and read the correct nail length at the end of the Ball Tip Guide Wire on the Guide Wire Ruler. Ensure that the tip of the Guide Wire Ruler is fully seated on the bone (fig. 31b) prior to determining measurement. If the Ball Tip Guide Wire is between two length markings, use of the shorter nail is recommended.

End of Guide Wire Ruler is the measurement reference

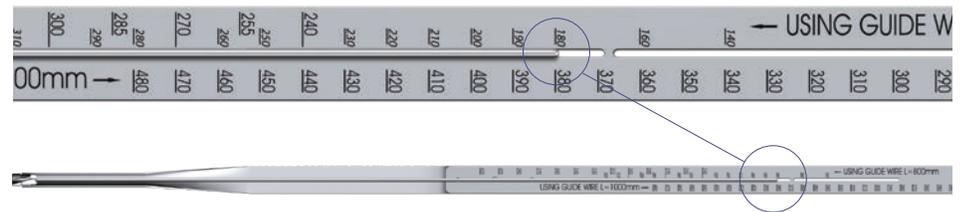


Fig. 31

NOTICE

The end of the guide wire ruler should align with the proximal end of the nail once inserted.

CAUTION

If the fracture is suitable for apposition/compression the implant selected should be at least 7-12mm shorter than measured to help avoid migration of the nail beyond the insertion site.

CAUTION

The Guide Wire Ruler is calibrated for 800mm and 1000mm Guide Wires.

CAUTION

Use fluoroscopy to ensure that the Ball Tip Guide Wire and Guide Wire Ruler are correctly positioned and verify nail length measurement prior to nail insertion.

Operative technique

Nail insertion

The selected nail is assembled onto the Nail Adapter Tibia with the Nail Holding Screw Tibia / Femur PF (fig. 32a).

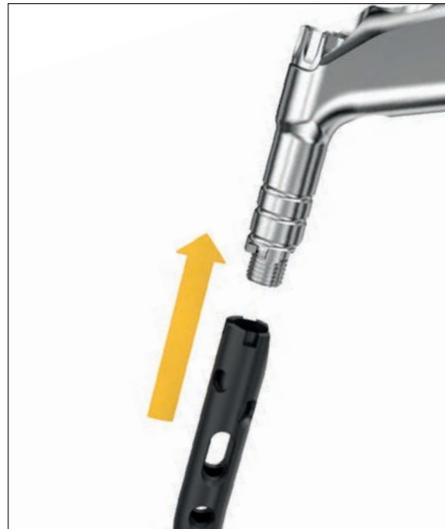
If operating via the suprapatellar approach, the Nail Adapter Tibia SPI and the Nail Holding Screw Tibia SPI must be used to assemble the nail (fig. 32b).

Pre-tighten the screw to the nail by hand and then use the Ball Tip Screwdriver to tighten the assembly (fig. 33a, 33b).

⚠ CAUTION

Prior to nail insertion, ensure that the following measures are taken:

1. Verify that the nail is tightly secured to the Nail Adapter Tibia or Nail Adapter Tibia SPI
2. Ensure that both the head of the Nail Holding Screw PF / Tibia or Nail Holding Screw Tibia SPI and the driving end of the nail completely align with the appropriate nail adapter
3. Verify correct alignment by inserting a drill through the sleeve and targeting arm assembly. The drill must pass through the holes of the nail (fig. 33c)
4. If guided distal locking is to be performed, follow the pre-operative assembly instructions as described in this operative technique.



Nail Adapter Tibia and Nail Holding Screw Tibia / Femur PF is shown and is used with the infrapatellar approach.

Fig. 32a



Nail Adapter Tibia SPI and Nail Holding Screw Tibia SPI is shown and is used with the suprapatellar approach.

Fig. 32b



Fig. 33a



Fig. 33b



Fig. 33c

Operative technique

Nail insertion

Insert the nail by hand over the Ball Tip Guide Wire and into the entry site of the proximal tibia (fig. 34a, fig. 34b).

Gently manipulate the nail to help avoid penetration of the posterior cortex. If the nail is deflected towards the posterior cortex, remove the nail and hyperflex the knee. Under image control, use a straight reamer to ream an anterior tract in the proximal fragment. Advance the nail past the fracture site to the appropriate level. Remove the guide wire once the nail is past the fracture site.

If dense bone is encountered, first confirm that sufficient reaming has been achieved.

If hammering is desired, thread the Delta Strike Plate into the Nail Adapter Tibia or Nail Adapter Tibia SPI and deliver light blows with the Slotted Hammer to further insert the nail (fig. 35). Alternatively, the T2 Strike Plate can be used for nail insertion. Do not hit the Nail Adapter Tibia or Nail Adapter Tibia SPI. Do not hit the Nail Adapter Tibia or Nail Adapter Tibia SPI.

The nail depth should be well below the chondral surface to minimize irritation to the patellar tendon.

NOTICE

If Fixation K-wires have been utilized, they must be removed followed by removal of the drill sleeve prior to nail insertion.



Fig. 34a

Infrapatellar approach



Fig. 34b

Suprapatellar approach: Nail is inserted through the Elastic Nail Insertion Sleeve



Fig. 35

CAUTION

Do not impact or backslap the nail with the Targeting Arm, Tibia attached to the Nail Adapter Tibia or Nail Adapter Tibia SPI.

WARNING

Do not apply excessive force during reaming and nail insertion. If severe resistance is encountered, removal of the nail and additional reaming or selection of a nail with a smaller diameter is recommended.

Operative technique

Nail insertion

If the nail has been inserted too far, reposition as needed. Repositioning of the nail should be carried out either by hand or by using the Delta Strike Plate. Backslapping may be performed using the Slotted Hammer to extract the assembly. Alternatively, the T2 Universal Rod may be used.

A chamfer is located on the proximal end of the nail to help identify the junction of the nail and insertion post under fluoroscopy. Three circumferential grooves are located on the insertion post of the target device assembly at 2mm, 7mm and 12mm from the proximal end of the nail (fig. 36). Depth of insertion may be visualized with the aid of fluoroscopy. When the T2 Alpha Tibia Nail is inserted in the dynamic mode, or when it is inserted with active apposition / compression, the recommended depth of insertion is at least 7mm to avoid protrusion of the T2 Alpha Tibial Nail.

To attach the Targeting Arm Tibia to the Nail Adapter Tibia or Nail Adapter Tibia SPI, ensure that the knob on the Targeting Arm Tibia is in the open position and slide the arm down the shaft of the Nail Adapter Tibia or Nail Adapter Tibia SPI until it hits the stop. Turn the knob to lock (fig. 37).

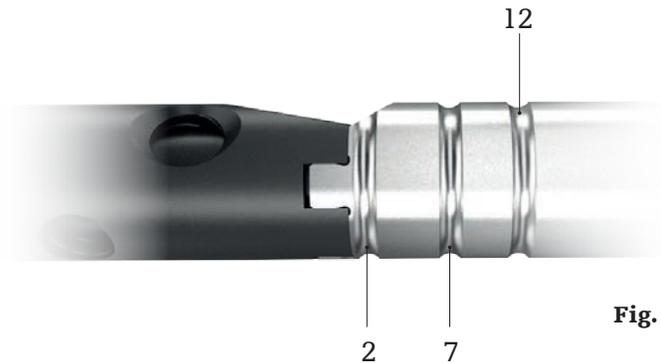


Fig. 36



Fig. 37

NOTICE

Do not hit the Nail Adapter Tibia or Nail Adapter Tibia SPI with the Slotted Hammer; only hit the Strike Plate.

CAUTION

Remove Ball Tip Guide Wire prior to drilling.

CAUTION

Final implant position must be confirmed by X-ray.

CAUTION

Ensure by fluoroscopy that curvature, length and diameter of selected nail fit the patient's anatomy.

Operative technique

Guided proximal locking

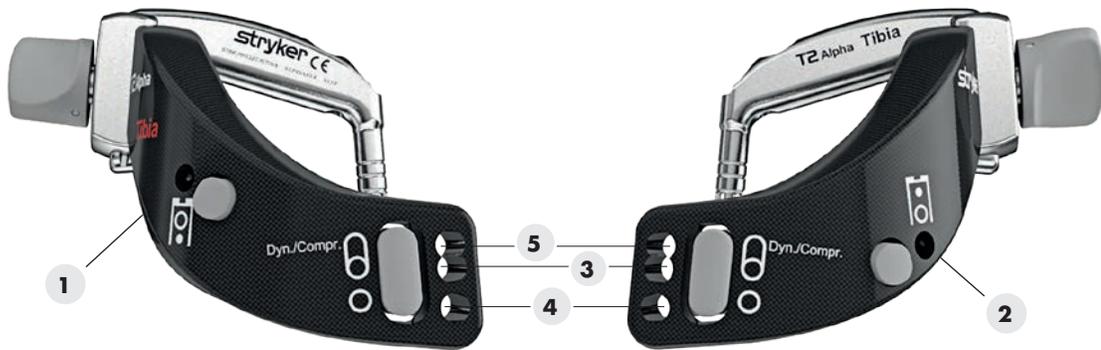
Before locking the nail proximally, verify that the Nail Holding Screw Tibia / Femur PF is securely tightened and that the Targeting Arm Tibia is properly attached to the nail adapter. The Targeting Arm Tibia is designed to provide four options for proximal locking.

NOTICE

Numeric markings are for illustration only. The targeting device is not marked with numbers. All circles marked on targeting device indicate static locking. Dynamic/compression locking options are marked accordingly.



Proximal locking hole options - top view



Proximal locking hole options - front view

Operative technique

Guided proximal locking

Option 1

Static locking mode

All four indicated holes may be used.

- 1 Oblique static
- 2 Oblique static
- 3 ML static
- 4 ML static



Option 2:

Controlled dynamization or apposition / compression mode

The dynamic hole is used to lock the nail in the controlled dynamization or apposition/compression modes.

The dynamic hole is indicated on the targeting arm.

- 5 Dynamic



⚠ CAUTION

Dynamic locking might be associated with bone shortening during the healing period.

Operative technique

Guided proximal locking

Option 3:

Internal apposition/ compression

In the internal apposition/
compression mode, use of the
dynamic hole is required.
Use of an additional ML static
screw and/or the most proximal
oblique screw is recommended.
In the internal apposition/
compression mode, the more
distal oblique screw cannot be
used as the compression screw
blocks this hole in the nail.

- 5 Dynamic
- 4 ML static (recommended)
- 1 Oblique static (optional)



Option 4:

External apposition/ compression

In the external apposition/
compression mode, use of the
dynamic hole is required.
Use of an additional ML static
screw is recommended.

- 5 Dynamic
- 4 ML static (recommended)
- 1 Oblique static (optional)
- 2 Oblique static (optional)



All circles marked on targeting
device indicate static locking.
Dynamic/compression locking
options are marked accordingly.

Operative technique

Static locking mode

For static locking of the T2 Alpha Tibial Nail, both proximal oblique screws and both proximal M/L locking screws may be used. If secondary dynamization is planned, the M/L screw may be inserted in the dynamic position of the oblong hole of the Targeting Arm, Tibia. This allows controlled dynamization of the fracture. Insert the Tissue Protection Sleeve together with the Locking Drill Sleeve and Locking Trocar through the appropriate hole of the Targeting Arm Tibia (fig. 38a, 38b). Make a small skin incision at the sleeve entry point.

Advance the sleeve assembly through the incision until it is in contact with the cortex. Fully seat the Tissue Protection Sleeve on the cortex. This will drive the head of the Locking Trocar from the sleeve assembly (fig. 39).

⚠ CAUTION

Ensure sleeve assembly is seated on bone prior to drilling and screw length measuring. Verify correct position of sleeve under imaging prior to drilling. The gray friction lock mechanism is designed to maintain the position of the drill sleeves. To remove the sleeve assembly from the Targeting Arm Tibia, press the gray mechanism while pulling the sleeves and trocar.



Fig. 38a



Fig. 38b



Fig. 39

⚠ CAUTION

Applying excessive force may result in breakage of the drill which could require recovery. Recovery could result in an iatrogenic fracture and/or bone damage may occur.

⚠ WARNING

Drilling past the far cortex may damage soft tissue.

Operative technique

Static locking mode

Advance the Locking Drill, 4.2 x 360mm through the Locking Drill Sleeve, Long and onto the cortex. Drill both cortices (fig. 40a, 40b).

Position the drill tip at the desired final position of the screw tip. Determine screw measurement by rotating the grip of the Locking Drill Sleeve, Long and pulling the sleeve towards the drill attachment until the sleeve hits the stop.

Read the measurement on the Locking Drill Sleeve, Long at the junction of the Tissue Protection Sleeve, Long (fig. 41)

Alternatively, the Guided Depth Gauge can be used through the Tissue Protection Sleeve, Long to read off the length at the end of the sleeve (fig. 42).

NOTICE

5.0mm Locking Screws and Advanced Locking Screws require the 4.2mm drill (green color-coded drill).

⚠ WARNING

Damage of the nail during drilling may reduce the fatigue strength of the implant which could cause the nail to fail.



Fig. 40a

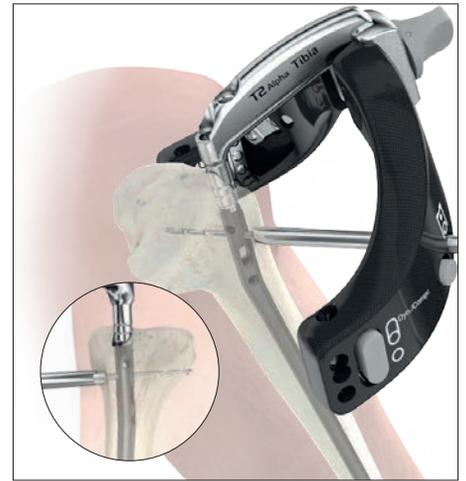


Fig. 40b



Fig. 41



Fig. 42

Operative technique

Static locking mode

Remove the Locking Drill and Locking Drill Sleeve, Long and insert the selected Locking Screw through the Tissue Protection Sleeve, Long using the Screwdriver Bit, Long and Quick-Lock Delta Handle (fig. 43, 44a). Advance the screw through both cortices until the screw is fully seated. When the marking on the screwdriver (fig. 44b) nears the head of the Tissue Protection Sleeve, Long, the screw is close to its final position. Use imaging to confirm placement of the screw.

The paddle tip of the Tissue Protection Sleeve, Long allows the user to visually verify that the screw head is seated on the bone under X-ray without retracting the sleeve from the bone.

Alternatively, the sleeve can be pulled away from the bone to verify that the screw is fully seated.

Repeat the locking procedure for the second oblique screw (fig. 46) and/or the static or dynamic ML screws as appropriate.

Dynamic locking mode

When the fracture pattern permits, dynamic locking may be utilized for transverse, axially stable fractures. Controlled dynamization is performed by statically locking the nail distally (see Guided Distal Locking or Freehand Distal Locking Sections).



Fig. 43

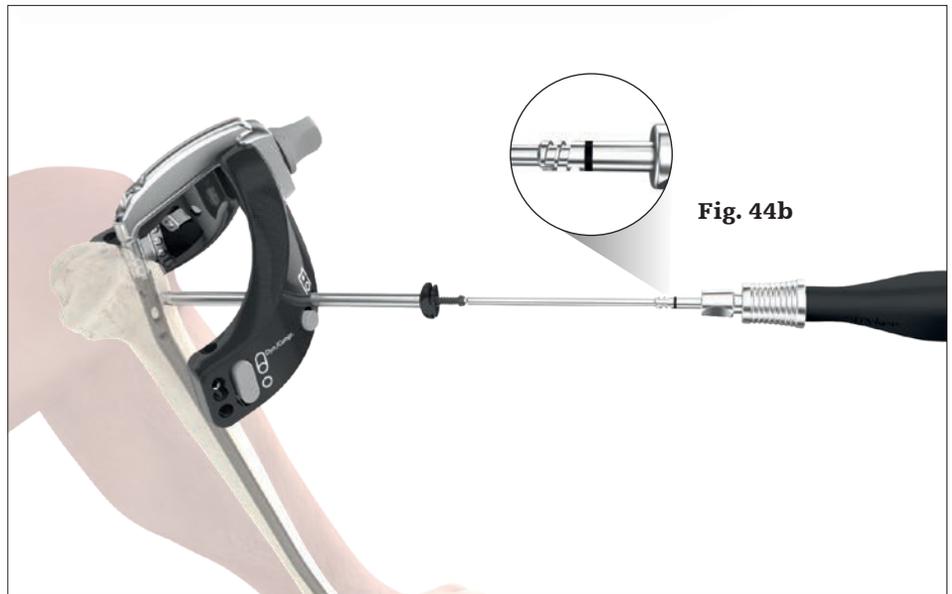


Fig. 44a

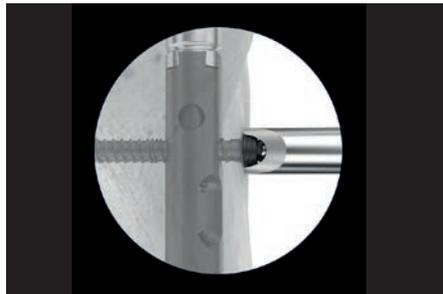


Fig. 45

After distal locking has been performed, place a locking screw in the dynamic position of the ML oblong hole following the aforementioned steps for screw insertion.

Do not insert the two proximal oblique or the static ML screws as this prevents nail movement relative to the locking screw and the fracture to settle while maintaining torsional stability.



Fig. 46

T2 Alpha Tibial Nail with two oblique screws

Operative technique

Internal apposition/compression mode

In transverse, axially stable fracture patterns, active mechanical apposition/compression may be desired.

The Compression Screw Tibia can be used to apply apposition/compression.

When compressing the nail, the implant must be inserted at a safe distance from the entry point to accommodate for the 7mm of active compression.

The three grooves on the insertion post help attain accurate insertion depth of the implant.

After distal locking has been performed, insert a Locking Screw proximally in the dynamic position of the oblong hole.

To apply compression, attach the Compression Screw Tibia to the Compression Screwdriver and Quick-Lock Delta Handle assembly. Insert the Compression Screwdriver through the Nail Holding Screw Tibia / Femur PF or Nail Holding Screw Tibia SPI and apply apposition/compression (fig. 47).

Once apposition/compression has been applied, the compression screwdriver may be removed (fig. 48). Insertion of a second proximal ML screw or the most proximal oblique screw is recommended.

When using the Compression Screw Tibia, the more distal of the two proximal oblique locking screws cannot be used.



Fig. 47



Fig. 48

NOTICE

Initial signs of screw bending indicate that sufficient compression has been achieved.

CAUTION

Apposition/compression must be carried out under X-ray control. Over-compression may cause the nail or screw to fail.

CAUTION

The Compression Screw Tibia must be screwed in correctly and with reasonable forces to provide desired function and to avoid damage of implants / instruments. Deformation of the locking screw may indicate unreasonable force.

Operative technique

External apposition/compression mode

As an alternative to internal compression, the External Compression Device Tibia can be used to apply apposition / compression.

After two static screws have been inserted distally, insert a Locking Screw proximally in the dynamic position of the oblong hole.

To apply compression, attach the External Compression Device Tibia to the Quick-Lock Delta Handle (fig. 49) and insert the External Compression Device Tibia through the Nail Holding Screw Tibia / Femur PF or Nail Holding Screw Tibia SPI to engage the internal threads of the nail. Rotate to apply compression (fig. 50, 51).

When compressing the fragments, the implant must be inserted at a safe distance from the entry point to accommodate up to 7mm of active compression. The three grooves on the insertion post help attain accurate insertion depth of the implant.

The lines marked on the shaft of the External Compression Device, Tibia are designed to aid in determining the amount of compression that has been achieved. The two distal lines are used in the infrapatellar approach, and the two proximal lines are used for the suprapatellar approach. When the first black line passes the proximal end of the nail holding screw, compression is being applied.

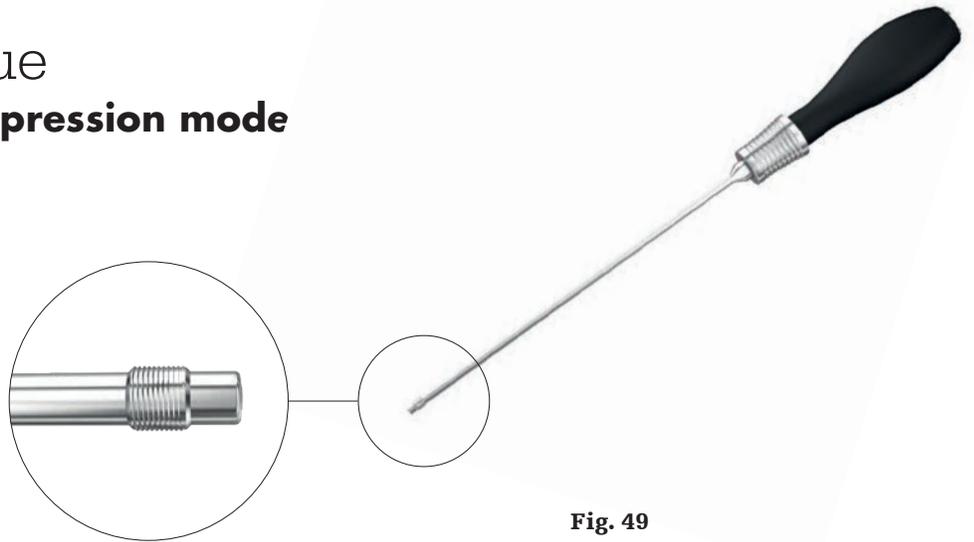


Fig. 49



Fig. 50



Fig. 51

Once the second black line is at the same height as the Nail Holding Screw, 7mm of compression has been achieved and no additional forces should be applied.

Once apposition/compression has been applied, insertion of a second proximal ML screw is recommended. Once the second screw has been inserted, the External Compression Device Tibia can be detached.



Fig. 52

Operative technique

Guided distal locking

Guided distal locking

Use of the T2 Alpha Tibia Distal Targeting Device is recommended when performing distal locking of the ML screws. The distal AP screw requires freehand distal locking.



Fig. 53

Operative technique

Assembly

Pre-operative assembly is recommended prior to nail insertion. Assembly steps are as follows:

1. Attach the Adapter Tibia / Femur Retrograde to the Distal Targeting Arm Tibia

The length of the selected nail determines the attachment point. Insert the center pin of the Adapter Tibia / Femur Retrograde into the hole of the Distal Targeting Arm Tibia that corresponds with the selected nail. Turn knob to secure (fig. 54, 55).



Fig. 54



Fig. 55

2. Attach Adjusting Device, Tibia to the Distal Targeting Arm, Tibia

Insert the center pin of the Adjusting Device Tibia through the appropriate hole of the Distal Targeting Arm Tibia. Left/Right markings on the targeter indicate which hole should be used (fig. 56, 57). Once inserted, turn knob to secure.



Fig. 56



Fig. 57

Operative technique

Pre-operative assembly

3. Attach Distal Targeting Arm Assembly to Nail Adapter, Tibia/ Nail Adapter Tibia SPI

Slide the Adapter Tibia / Femur Retrograde down the shaft of Nail Adapter Tibia or Nail Adapter Tibia SPI (fig. 58a), tibia until the stop is felt. Turn knob to secure (fig. 58b).

Insert the Tissue Protection Sleeve, Long into the most proximal of the distal locking holes of the Adjusting Device Tibia to confirm that the device has been assembled to accommodate the selected nail length (fig. 59).

If the sleeve is properly positioned, remove the sleeve from the Adjusting Device Tibia and disassemble the distal targeting assembly from the Nail Adapter Tibia or Nail Adapter Tibia SPI and place on the back table. Do not disassemble the Adjusting Device Tibia or Adapter Tibia / Femur Retrograde from the Distal Targeting Arm Tibia.



Fig. 58a



Fig. 58b



Fig. 59

Operative technique

Distal drilling and locking

Proceed with nail and screw insertion as described in this operative technique. Once the nail insertion has been performed, re-attach the Distal Targeting Arm Tibia to the Nail Adapter Tibia or Nail Adapter Tibia SPI as described in the preassembly steps. Depending on the preferred locking configuration, proximal screw insertion may be performed prior to distal locking.

Insert the sleeve assembly through the appropriate hole of the adjusting device (fig. 60). The sleeves should not contact the skin of the patient. Do not make an incision until the C-arm and sleeves are correctly positioned as described in the following steps.

The following three steps must be taken prior to drilling:

1. Oblique positioning of C-arm
2. Height and orbital rotation adjustment of the C-arm
3. Sleeve adjustment to the nail position

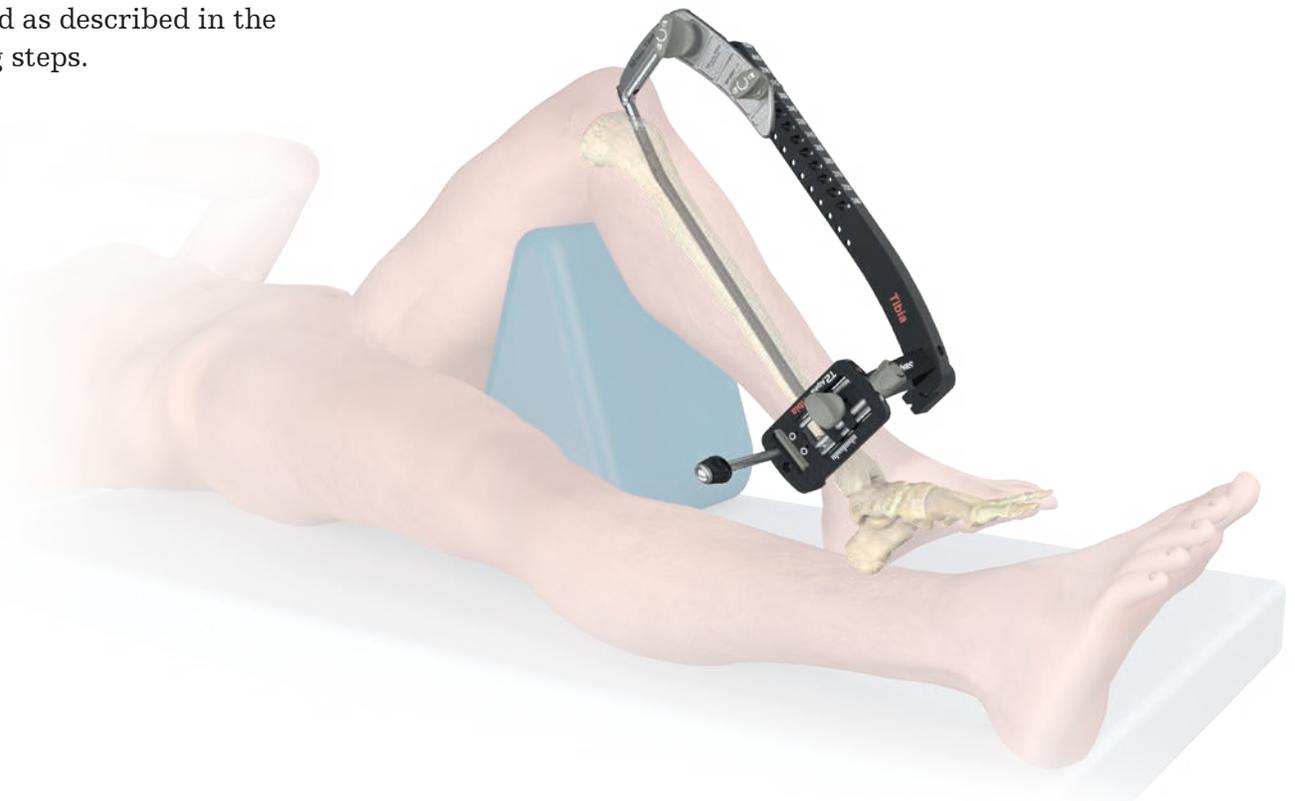


Fig. 60

Operative technique

Distal drilling and locking

1. Oblique positioning of the C-arm

To perform guided distal locking, it is essential to place the X-ray beam of a C-arm approximately 30° oblique to the axis of the drill sleeve assembly.

As an option, the K-wire 3x285mm can be inserted into the more proximal K-wire hole of the adjusting device (fig. 61). This wire indicates 30° oblique to the axis of the drill sleeve assembly and helps to adjust the C-arm.

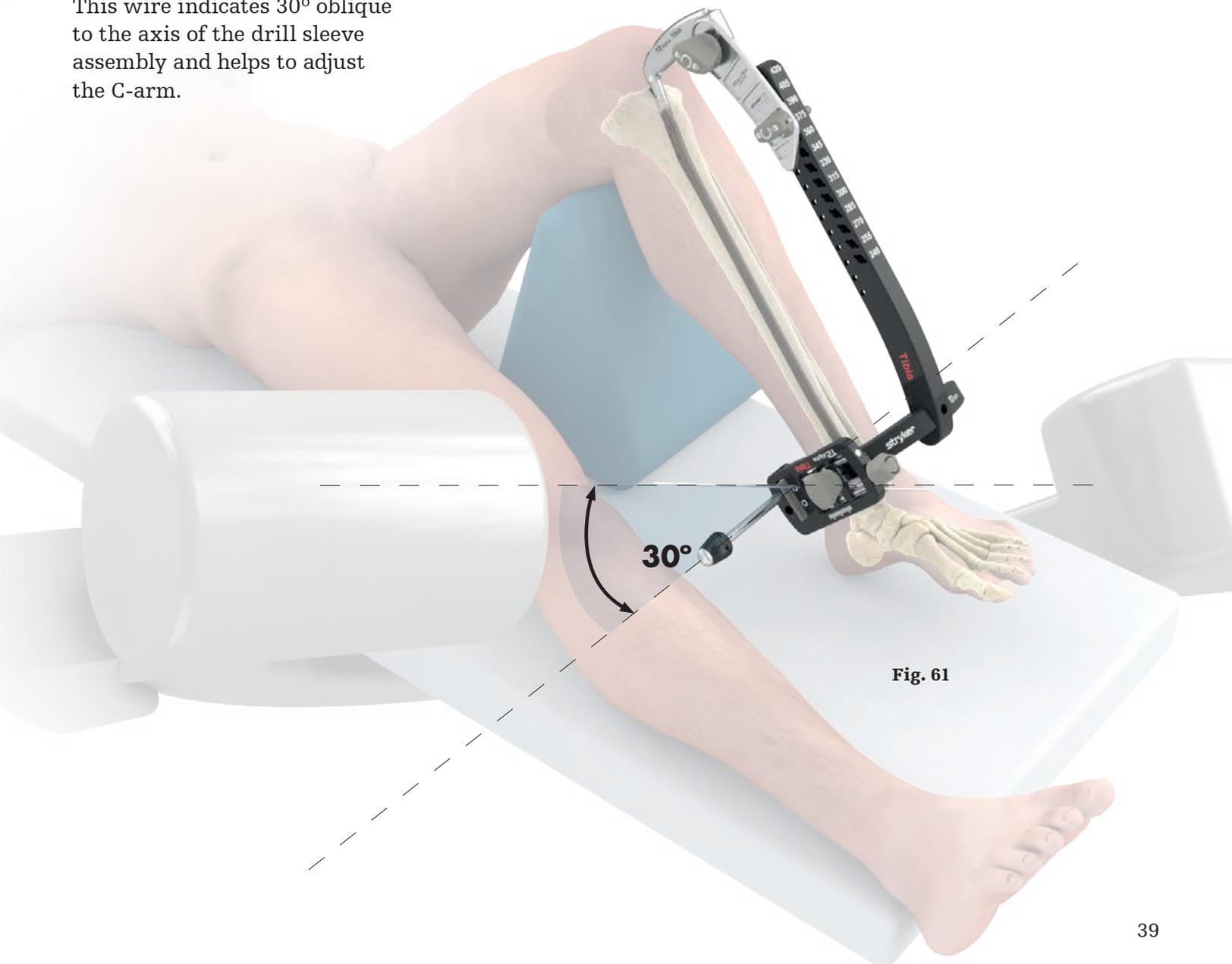


Fig. 61

Operative technique

Distal drilling and locking

2. Height and orbital rotation of the C-arm

In this step, it is important to position the C-arm so that the nail tip and the sleeve tip are seen parallel on the fluoroscopic image.

After oblique C-arm positioning, adjust the height and orbital rotation of the X-ray beam at the same plane as the Drill Sleeve assembly (fig. 62). Take an X-ray.

If the sleeve and nail tip are parallel (fig. 63a) or colinear (fig. 63b) in the X-ray image, the C-arm is correctly positioned and no adjustments to the C-arm position are necessary (fig. 63).

If the sleeve and nail are not parallel or colinear, the C-arm is incorrectly positioned.

Adjust the C-arm rotation as per the following instructions until the correct position is achieved.

This step requires appropriate C-arm positioning only. Do not turn the Adjusting Device Tibia before the nail and the sleeve are parallel.



Fig. 62

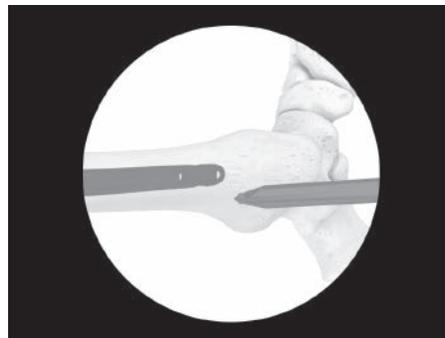


Fig. 63a

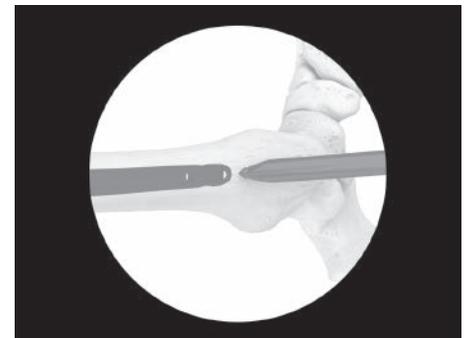


Fig. 63b

Operative technique

Examples of incorrect C-arm positioning

Example 1: When the tip of the sleeve and nail point down (fig. 64a), move the X-ray tube up (fig. 64b) until the nail and sleeve are seen in parallel.

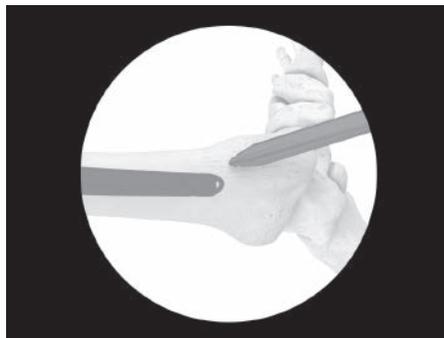


Fig. 64a



Fig. 64b

Example 2: When the tip of the sleeve and the tip of the nail point up (fig. 65a), move the X-ray tube down (fig. 65b) until the nail and sleeve are seen in parallel.

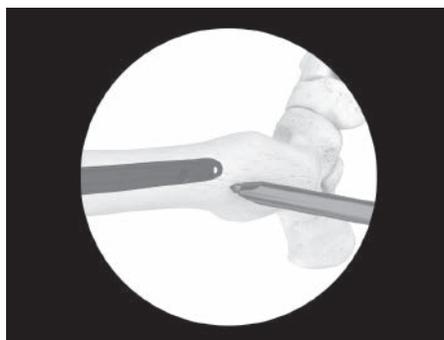


Fig. 65a



Fig. 65b

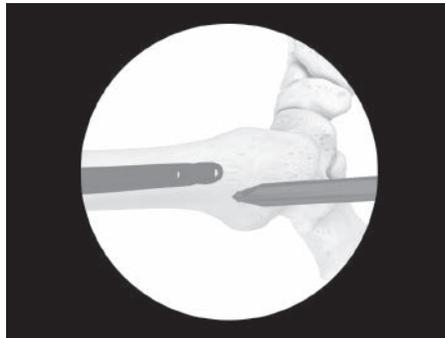
Operative technique

Distal drilling and locking

3. Sleeve adjustment to the nail position

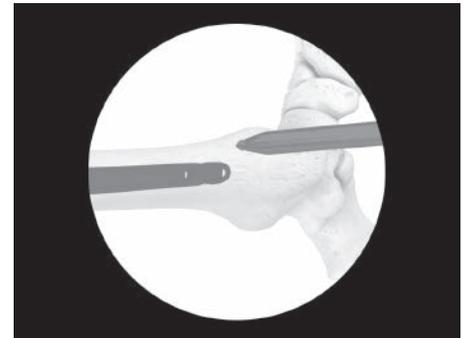
Once the C-arm has been adjusted so that nail and sleeve are shown parallel, the deviated image may show the sleeve either above or below the nail (fig. 66a and fig. 66b). If the sleeve and the nail tip are shown colinear, (fig. 66c) no further adjustment of the Adjusting Device Tibia is needed.

If the sleeve and nail tip are not colinear on the same axis (fig. 66a, 66b) sleeve adjustment is required by turning the adjusting screw of the Adjusting Device, Tibia (fig. 67). By turning the adjusting screw, the sleeve moves anteriorly or posteriorly.



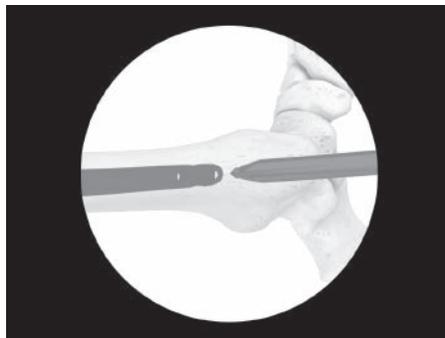
Nail tip and sleeve parallel but not in the same axis. Turn the knob of the adjusting device counterclockwise to move the sleeve up.

Fig. 66a



Nail tip and sleeve parallel but not in the same axis. Turn the knob of the adjusting device clockwise to move the sleeve down.

Fig. 66b



Sleeve and nail tip are colinear. No adjustment of the adjusting device is needed.

Fig. 66c.



Fig. 67

Operative technique

Distal drilling and locking

Once the nail and sleeve are colinear, make a small skin incision at the sleeve entry point. Ensure that the incision is straight to avoid forces on the sleeve.

Advance the Locking Tissue Protection Sleeve Long, Locking Drill Sleeve Long and Locking Trocar Long assembly through the incision until the sleeve tip is close to the cortex. Do not force the chamfers of the sleeve into the bone as this could cause deviations. Take an X-ray to confirm correct position of the sleeve as sleeve alignment could be compromised by soft tissue or slippage on the bone. Adjust sleeve position if needed.

Once sleeve position has been confirmed, commence distal drilling and screw insertion (fig. 68, 69) as outlined in the proximal locking section. Repeat these steps for the insertion of the second ML screw.

NOTICE

Patient anatomy, entry point or other factors may result in excessive nail bending that cannot be compensated with the adjusting device. In these instances, freehand distal locking must be performed.

NOTICE

4mm Locking Screw and 4mm Advanced Locking Screw require the 3.5 drill (orange color-coded drill).



Fig. 68



Fig. 69

CAUTION

Take care to avoid capturing soft tissue during freehand drilling.

CAUTION

Avoid applying soft tissue pressure to the sleeve assembly; do not make a skin incision.

WARNING

4mm Locking Screw or 4mm Advanced Locking Screws are used exclusively for distal locking of the 8mm T2 Alpha Tibial Nails.

8mm T2 Alpha Tibia Nails require the use of 5.0mm screws proximally.

Operative technique

Freehand distal locking

As an alternative to guided distal locking, the freehand technique may be used to insert the distal ML screws, and must be used to insert the distal A/P screw.

The critical step with any freehand locking technique is to adjust the C-arm until a perfectly locking hole is visualized with the C-arm.

Once the C-arm is correctly positioned, Make an incision (fig. 70c) and hold the freehand drill at an oblique angle to the center of the locking hole (fig. 70d). Upon X-ray verification, the drill is placed perpendicular to the nail and drilled through the lateral and medial cortex. Confirm in both the anterior and lateral planes by X-ray that the freehand drill passes through the hole in the nail.

Use the Screw Scale with the drill to read off the screw length directly at the color coded marking (fig. 71) Alternatively, the Freehand Depth Gauge, Long or Freehand Depth Gauge Short may be used after drilling to determine the required screw length (fig. 72).

Repeat steps as needed to insert additional screw(s).



**Locking hole is not perfectly circular.
The C-arm is incorrectly positioned.**
Fig. 70a



**Locking hole is perfectly circular.
The c-arm is correctly positioned.**
Fig. 70b



Fig. 70c



Fig. 70d

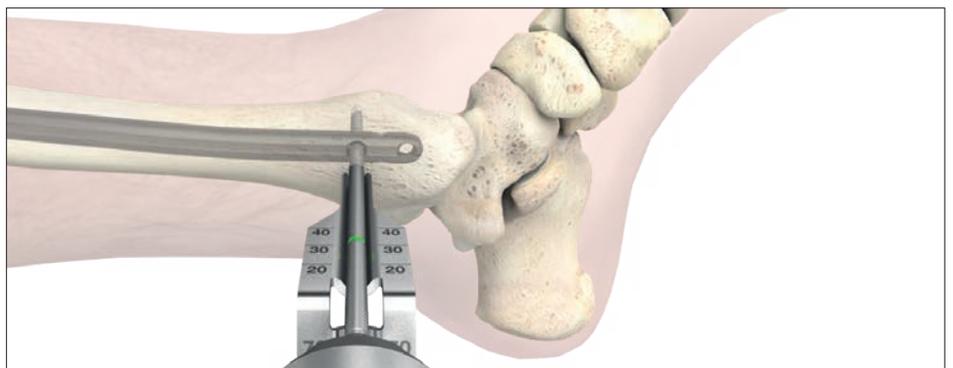


Fig. 71

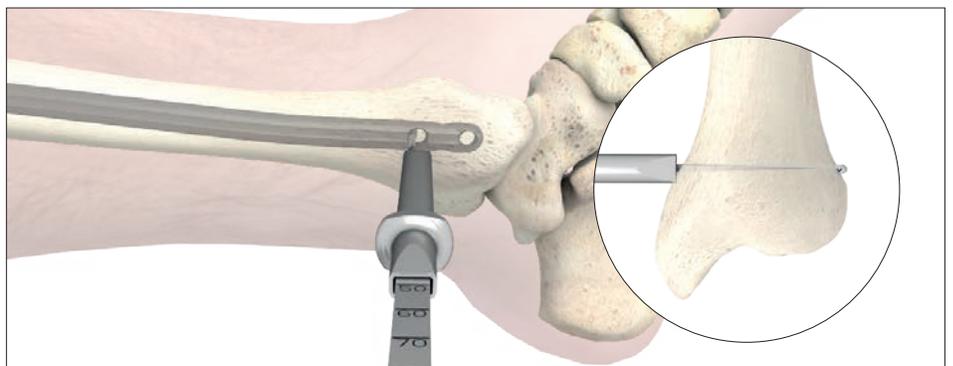


Fig. 72

Operative technique

Freehand distal locking

The self-retaining screwdriver assembly may be used to facilitate freehand locking. To use, assemble the Self-Retaining Screwdriver Sleeve to the Self-Retaining Screwdriver Bit/Quick-Lock Delta Handle Assembly (fig. 73) and attach the screwdriver to the screw and secure the connection by turning the screwdriver sleeve counterclockwise.

Routine screw insertion is employed to insert the screw (fig. 74).



Fig. 73

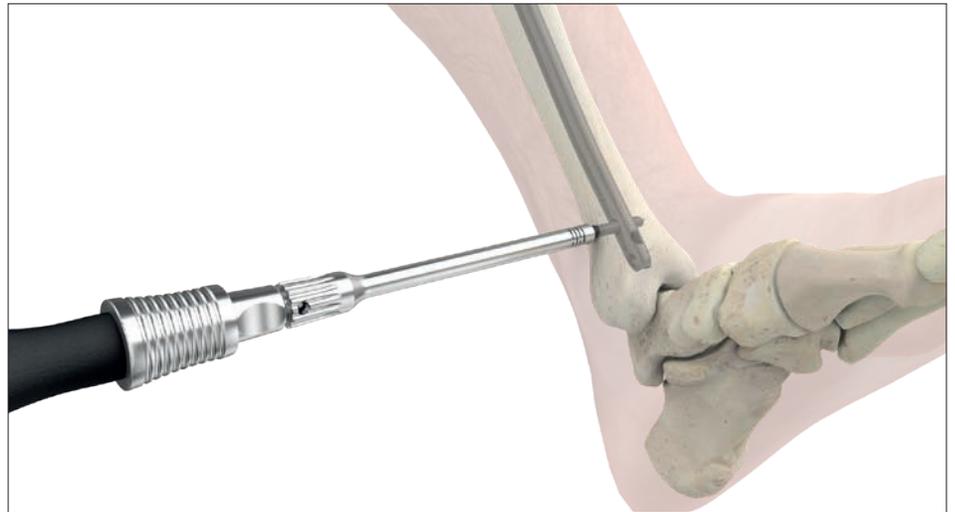


Fig. 74



Operative technique

Advanced locking screws

Advanced Locking Screws can be used as an alternative to the IMN Locking Screws.

The Advanced Locking Screws are designed with oversized threads (fig. 75, 75a) that engage with the internal threads of the T2 Alpha Tibial Nail while maintaining bicortical purchase.

Overdrilling of the near cortex must be performed to create a path for the screw.

Advanced Locking Screws may be preferred in instances of poor bone quality and in other instances when axial stability is desired.

Advanced Locking Screws may be inserted in any circular hole of the nail. They cannot be used in the dynamic / oblong holes (fig. 76).

The Advanced Locking Screws are inserted in a guided locking technique via the Targeting Arm Tibia and/or the Distal Targeting Arm Tibia or using a distal freehand technique.

Guided technique:

When using a guided technique, drilling and insertion of the Advanced Locking Screws is performed through the sleeve(s) of the proximal targeting arm tibia or distal targeting arm.

⚠ CAUTION

Overdrilling with the Counterbore Drill must be performed prior to Advanced Locking Screw Insertion.



Fig. 75

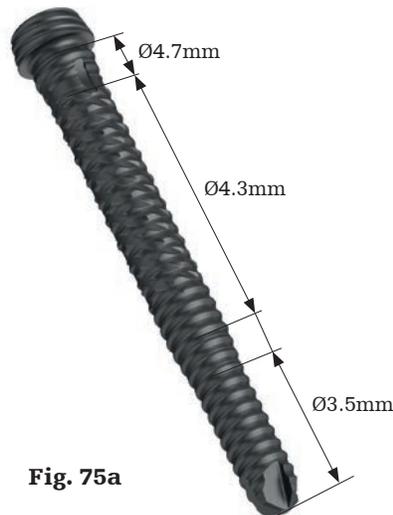


Fig. 75a



Fig. 76

Colored screws indicate where Advanced Locking Screws can be utilized. Advanced Locking Screws are not accepted in the oblong hole.

Operative technique

Advanced locking screws

Drill both cortices and determine screw length in a guided or freehand manner as previously described in this operative technique (fig. 77). Once screw length has been determined, open the near cortex using the Counterbore Drill. Freehand locking requires use of the Counterbore Drill, Short, and guided locking requires use of the Counterbore Drill, Long.

Ensure that the counterbore drill is centered within the pre-drilled hole and the hole of the nail prior to insertion, and then drill until the stop is felt (fig. 78). Verify under imaging.

The Counterbore Drill widens the near cortex to allow for insertion of the Advanced Locking Screw (fig. 79).

In some instances, thick cortex or strong trabecular bone stock may prevent the counterbore drill from fully clearing the pathway to the nail. When this occurs, use the Counterbore Drill Manual in combination with the Delta Quick-Lock Handle to ensure that the passage to the nail is sufficiently widened (fig. 80). To use, insert the drill into the path created by the first counterbore drill and turn the drill in a gentle clockwise motion with moderate axial pressure until the pathway to the nail has been opened.

NOTICE

Do not use the Counterbore Drill, Manual with the power tool.

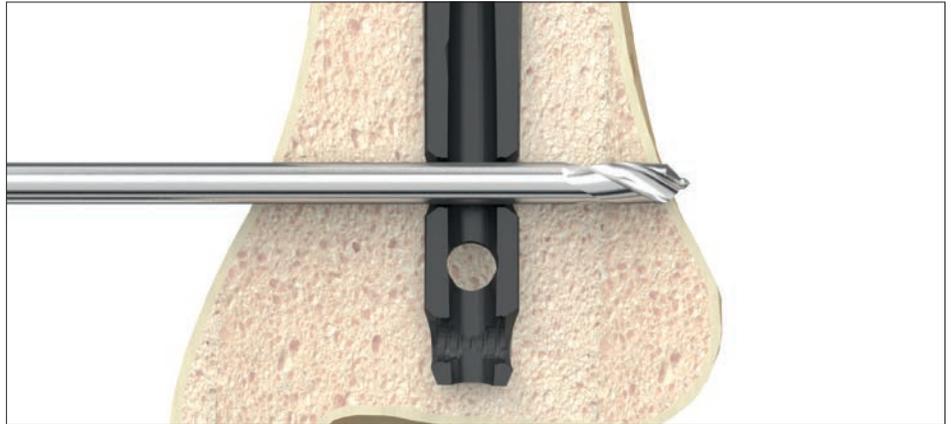


Fig. 77

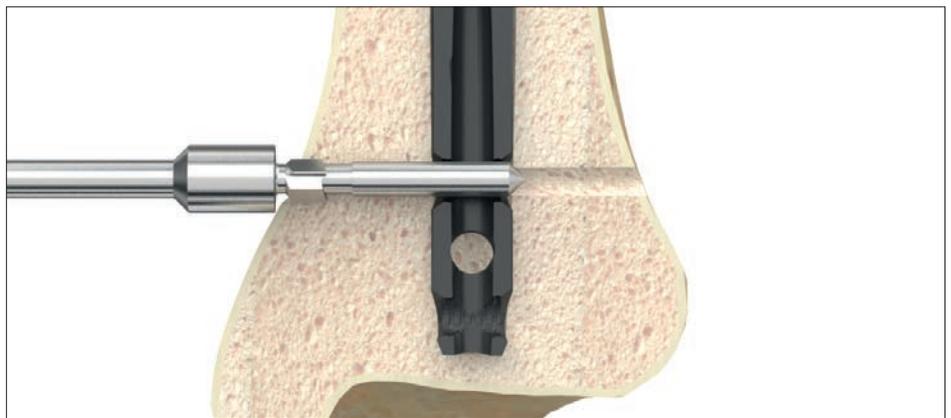
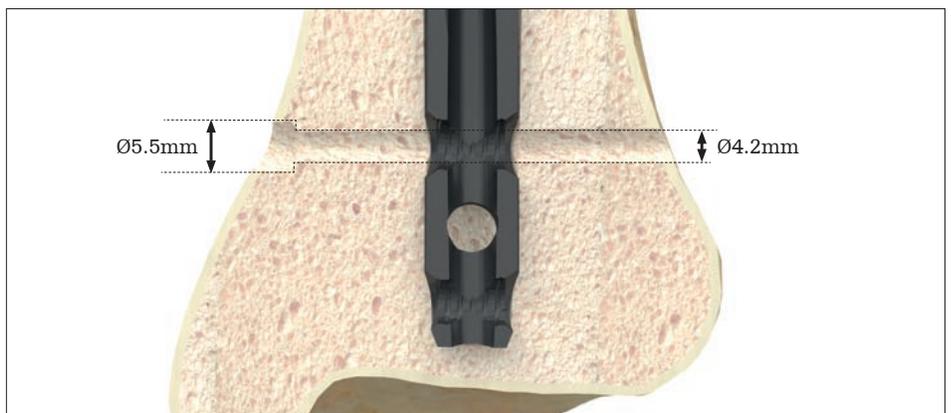


Fig. 78



Upon completion of drilling, the near cortex is over-drilled to 5.5mm while the far cortex is drilled to 4.2mm (pictured). If using the 4.0mm Advanced Locking Screws, the near cortex is Over-drilled to 4.5 while the far cortex is drilled to 3.5mm.

Fig. 79

Operative technique

Advanced locking screws

Once drilling has been completed, insert the Advanced Locking Screw with gentle axial force using the appropriate screwdriver through the near cortex without turning the screw while ensuring that the axis of the screw is aligned with the corresponding locking hole. Push the screw until the leading tip is engaged with the nail hole. X-ray verification can be used to confirm position.

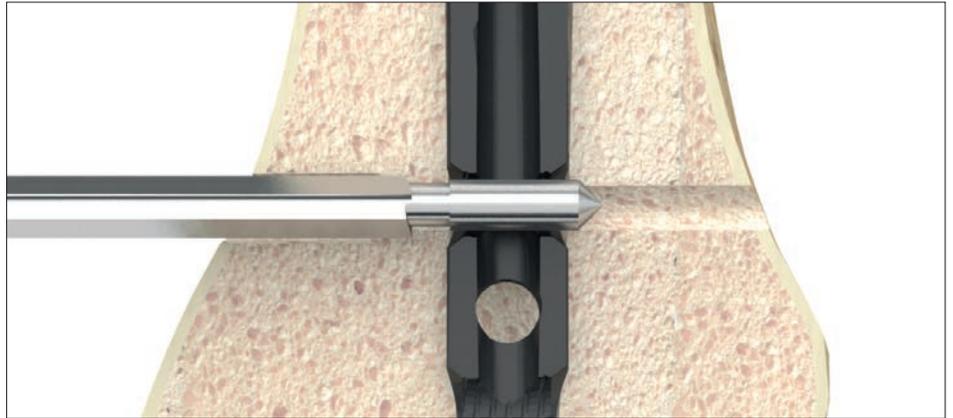


Fig. 80

To confirm correct starting point and axial alignment of the screw, rotate the screw counterclockwise while applying gentle axial force (fig. 81). A click sound or snapping of the thread indicates that the screw is in the correct position.

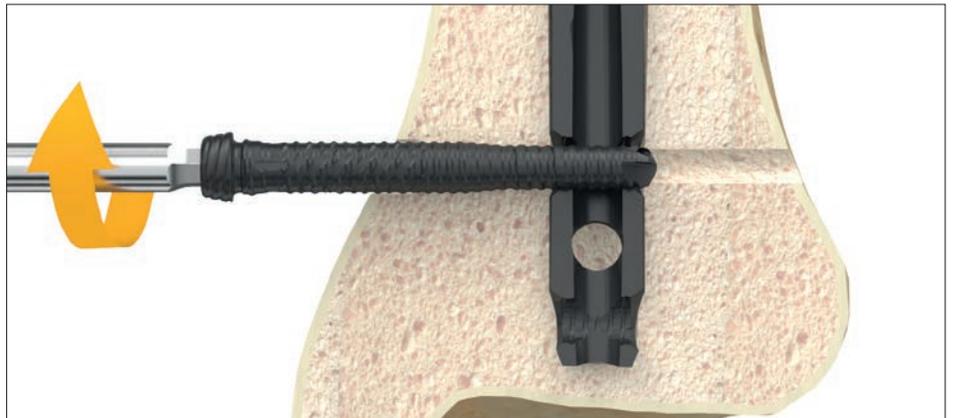


Fig. 81

Once position has been confirmed, insert the screw by rotating clockwise until the screw is fully seated (fig. 82). Use X-ray to confirm.

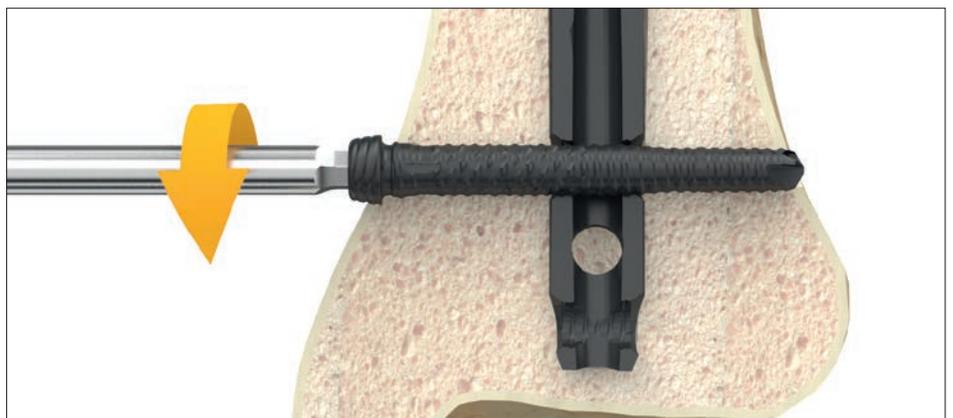


Fig. 82

⚠ CAUTION

The Advanced Locking Screw must be inserted using reasonable force. to provide desired function and to avoid damaging the screw. If unreasonable insertion torque is noticed, stop insertion, turn the screw counterclockwise and then attempt to insert the screw. If unreasonable insertion torque is still noticed, remove the screw and proceed with a Locking Screw.

Operative technique

End cap insertion

After removal of the Targeting Arm Tibia, the End Cap Tibia (+5, +10, +15, +20, +25) or End Cap Lower Extremity is available to adjust nail length and/or protect the threads of the nail. After imaging confirms satisfactory reduction and hardware implantation, an end cap can be inserted with the Screwdriver Bit and Quick-Lock Delta Handle assembly. If using the +5, +10, +15, +20, +25 End Caps, the Compression Screwdriver may also be used. (fig. 83, 84).

Ensure that the end cap is fully seated to minimize the potential risk for loosening.

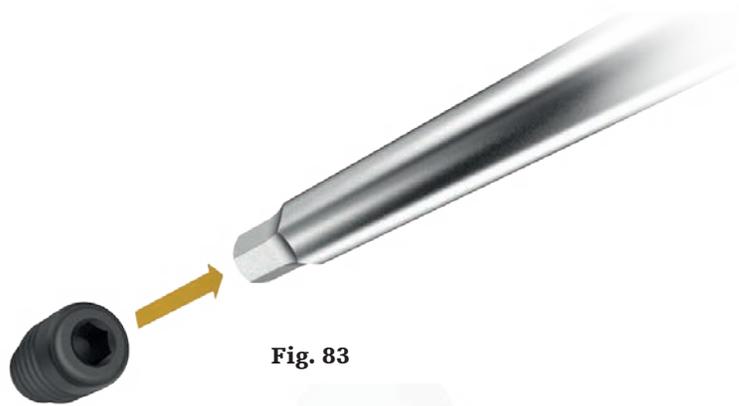


Fig. 83



Fig. 84

Operative technique

Nail removal

The End Cap Tibia or End Cap Lower Extremity is removed with the Screwdriver Bit Long and Quick-Lock Delta Handle assembly. To remove the nail, first assemble the Extraction Shaft and the Delta Strike Plate by threading the Delta Strike Plate into the Extraction Shaft. The cannulated Extraction Shaft is inserted into the driving end of the nail (fig. 85). If the most proximal oblique screw was used, it must be removed prior to assembling the Extraction Shaft to the nail.

All IMN Screws are removed with the Screwdriver Bit (fig. 86). If the Compression Screw Tibia was used, it must be removed prior to assembly of the Extraction Shaft. Unlock and remove the Compression Screwdriver.

Use the Slotted Hammer to extract the nail in a controlled manner (fig. 87). Alternatively, the T2 Universal Rod may be connected to the Extraction Shaft.

⚠ CAUTION

Stryker offers a universal implant extraction set that is not compatible with the T2 Alpha Tibial Nail. Use of the T2 Alpha Extraction Shaft is Required for removal. The universal implant extraction set may be used for removal of IMN Screws or other internal fixation systems.



Fig. 85



Fig. 86

⚠ WARNING

The T2 Alpha Tibial nail is not intended for full weight bearing in patients with complex unstable fractures until bone consolidation is confirmed in the follow-up X-rays.

⚠ WARNING

The T2 Alpha Tibial nail is designed for temporary implantation until bone consolidation occurs. If bone consolidation does not occur or if the consolidation is insufficient, the implant may break. The aim of post-operative care must be to ensure the promotion of bone consolidation.



Fig. 87

Notes

This document is intended solely for the use of healthcare professionals. A surgeon must always rely on his or her own professional clinical judgment when deciding whether to use a particular product when treating a particular patient. Stryker does not dispense medical advice and recommends that surgeons be trained in the use of any particular product before using it in surgery.

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Content ID: T2-ST-20, Rev 4, 10.2019

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CE 0123

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