

Tibial Fractures

stryker®

Trauma & Extremities

T2® Tibia

Suprapatellar Instrument (SPI) System

Operative Technique



T2 Tibial Nailing System

Stryker acknowledges Joshua R. Langford, MD for support in the development of this technique guide.

This publication sets forth detailed recommended procedures for using Stryker Osteosynthesis 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 first surgery.

All non-sterile devices must be cleaned and sterilized before use. Follow the instructions provided in our reprocessing guide (L24002000). Multi-component instruments must be disassembled for cleaning. Please refer to the corresponding assembly/ disassembly instructions.

See package insert (L22000007 and L220105B6) 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.

Warning:

Fixation Screws:
Stryker Osteosynthesis bone screws are not approved or intended for screw attachment or fixation to the posterior elements (pedicles) of the cervical, thoracic or lumbar spine.

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Note:
For information regarding the Operative Technique for the standard T2 Tibial Instrumentation please refer to the Literature Number T2-ST-3.

Technical Details

Nails

T2 Nails

Diameters 8*–13mm

Sizes 240–420mm

Screws

Note:

Screw Length is measured from top of head to tip. Dimensions are nominal.



5.0mm Fully Threaded Locking Screws

L = 25–120mm

4.0mm Fully Threaded Locking Screws for 8mm Nails (Distal Holes Only)

L = 20–60mm



5.0mm Partially Threaded Locking Screws (Shaft Screws)

L = 25–120mm

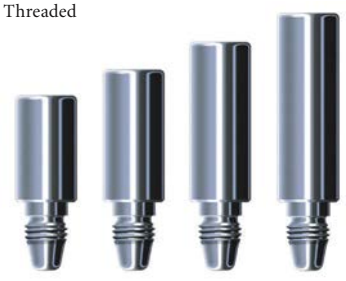


Tibia Advanced Compression Screw

End Caps



Fully Threaded | Standard | +5mm | +10mm | +15mm



+20mm | +25mm | +30mm | +35mm

Note:

The T2 Tibia Nail is also available in diameter 14mm and 15mm. Due to the sleeve sizes the Suprapatellar Approach can only be performed with T2 Tibia Nails up to a diameter of 13mm.



** Compression Range	
Total Length of Slot	12mm
Less Screw Diameter (-)	5mm
Maximum Movement of Screw	7mm

* 8mm nails require 4mm Fully Threaded Screws for Distal Locking

\+ Distal Nails are available as special order implants

Technical Details

Symbol coding on the instruments indicates the type of procedure, and must not be mixed.

Symbol

■ Square = Long instruments

▲ Triangular = Short instruments

Drills

Drills feature color-coded rings:

4.2mm = Green

For 5.0mm Fully Threaded Locking Screws and for the second cortex when using 5.0mm Partially Threaded Locking Screws (Shaft Screws).

5.0mm = Black

For the first cortex when using 5.0mm Partially Threaded Locking Screws (Shaft Screws).

3.5mm = Orange

For 4.0mm Fully Threaded Locking Screws for the distal holes only of the 8mm Tibial Nail.

Indications, Precautions & Contraindications

Indications

The T2 Tibial Nailing System is intended to provide temporary stabilization of various types of fractures, malunion and nonunion of the tibia. The nails are inserted using an opened or closed technique and can be statically, dynamically and compressed locked.

The T2 Tibial Nailing System is indicated for long bone fracture fixation, specifically tibial fracture fixation, which may include the following:

- Open and closed tibial fractures
- Pseudarthrosis and correction osteotomy
- Pathologic fractures, impending pathologic fractures and tumor resections
- Nonunion and malunion



Component	Material Name	Abbreviated Name
Nail Insertion Sleeve, Elastic	Pellethane 2363-90A	TPU
Drill Sleeve	Stainless Steel Polytetrafluroethylene (coated)	StSt PTFE
Fixation K-Wire	Stainless Steel Tungsten Hydrogen Carbide (coated)	StSt WCH or W-C:H

Note:
The above components contain listed materials.

Precautions

Stryker Osteosynthesis systems have not been evaluated for safety and use in MR environment and have not been tested for heating or migration in the MR environment, unless specified otherwise in the product labeling.

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 postoperative care
- Other medical or surgical conditions which would preclude the potential benefit of surgery

Pre-Operative Planning

An X-Ray Template (1806-0000 for Standard nails, 1806-0001 for Distal nails) is available for pre-operative planning. Thorough evaluation of preoperative radiographs of the affected extremity is critical. Careful radiographic examination can help prevent intra-operative complications.

For standard mid-shaft fractures, the proper nail length should extend from just below the Tibial Plateau at the appropriate medio-lateral position to just proximal to the Epiphyseal Scar of the ankle joint.

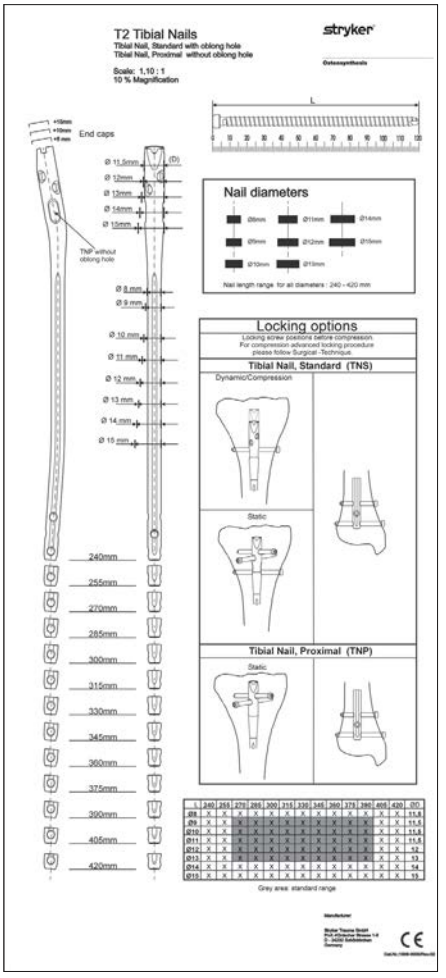
This allows the surgeon to consider the apposition / compression feature of the T2 Standard Tibial Nail and T2 Distal Tibial Nail knowing that 7mm of active apposition / compression is possible, prior to determining the final length of the implant. If apposition / compression is planned, the nail should be at least 7mm shorter.

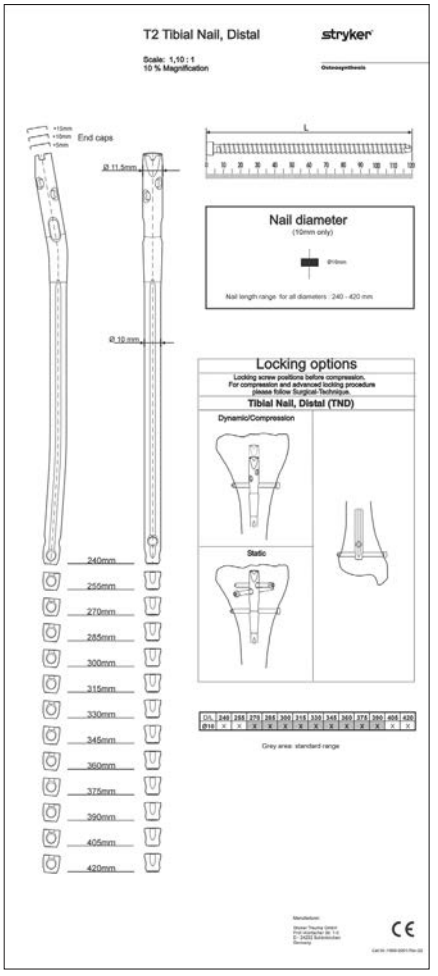
Note:

Check with local representative regarding availability of sizes and nail types.

Caution:

Smaller statured patients may require additional caution when using the suprapatellar instrumentation. Surgeons must always consider patient anatomy prior to utilization of any Stryker instrument or implant.





Operative Technique – Suprapatellar Insertion

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.1a).

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.1b).

Note:

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.1a

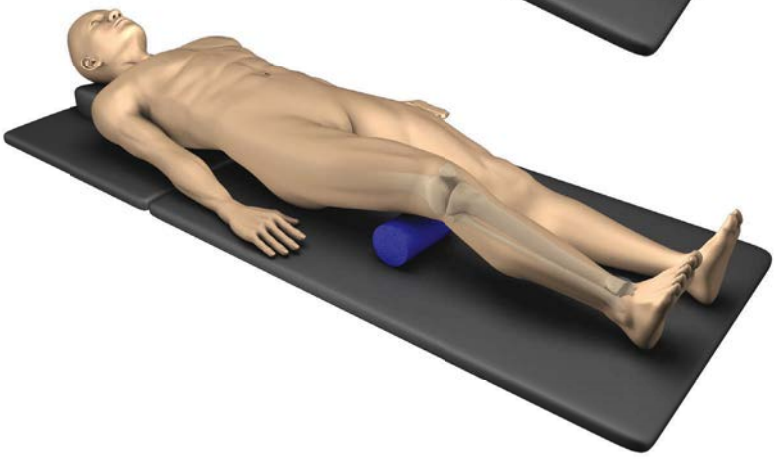


Fig.1b

Incision

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

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

Caution:

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

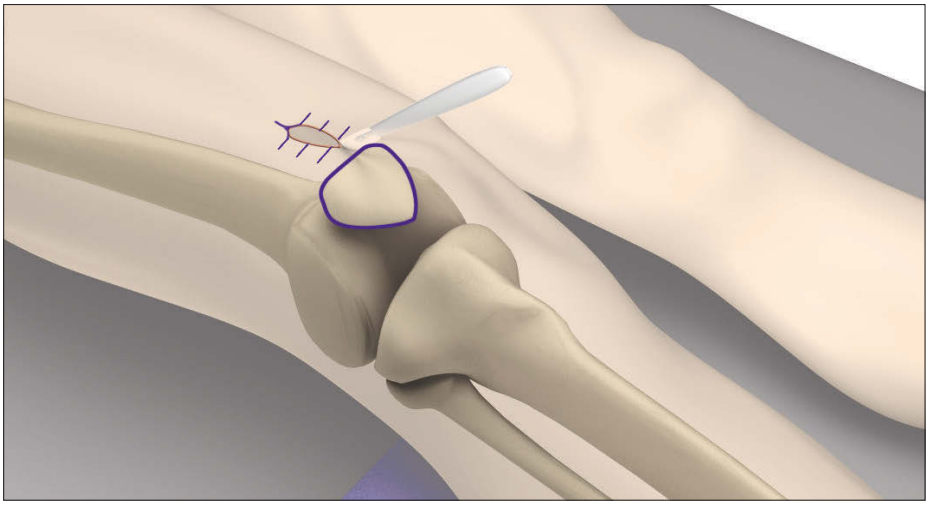


Fig.2

Operative Technique – Suprapatellar Insertion

Assembly: Modular Handle and Drill Sleeve

Assemble the Modular Handle (Fig.3) (1806-1412) by inserting the magnetically activated trigger.

Connect the appropriate Drill Sleeve (1806-1408, 1806-1409) to the Modular Handle (Fig.5) by inserting the Drill Sleeve into the ring of the Modular Handle. The trigger of the handle can be pulled back to assemble or disassemble the Drill Sleeve. Note that the Drill Sleeve can be engaged on the Modular Handle every 90 degrees to suit surgeon preference. Use the Ø8-11 Drill Sleeve (1806-1408) for T2 Tibia Nails up to a diameter of 11mm, and the Ø8-13 Drill Sleeve (1806-1409) for T2 Tibia Nails up to a diameter of 13mm.

Note:

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



Fig.3

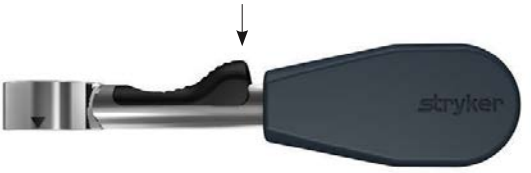


Fig.4

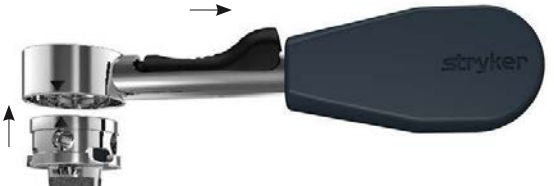
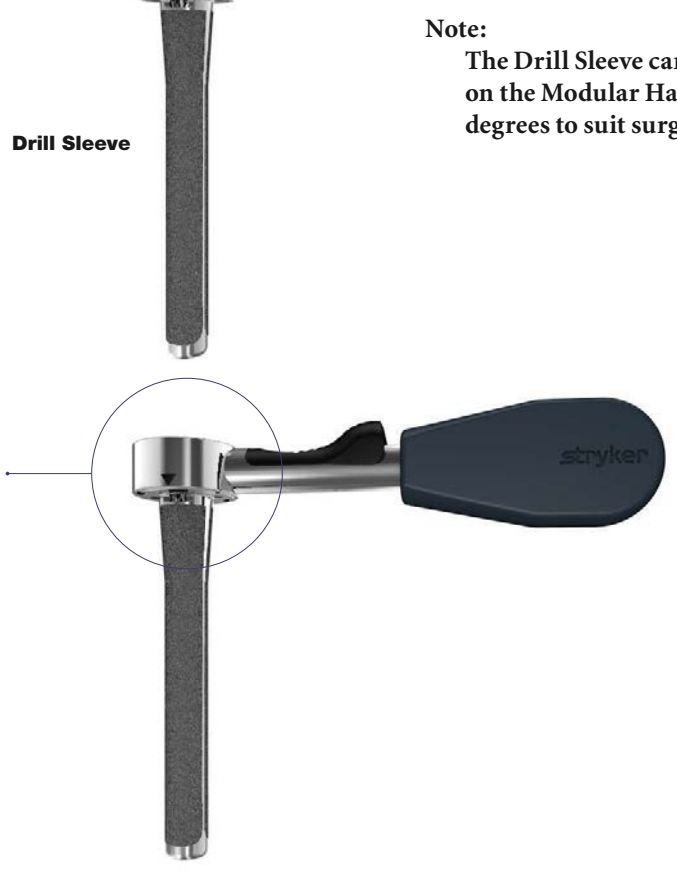


Fig.5

Note:

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



Final position of assembled Modular Handle and Drill Sleeve.

Fig.6

Operative Technique – Suprapatellar Insertion

Sleeve Insertion Technique: Overview

Two different sleeve insertion techniques can be used.

Note:

The standard technique can be carried out by either using the Elastic Nail Insertion Sleeve or the metal Nail Insertion Sleeve*.

The Elastic Nail Insertion Sleeve is single-use only while the metal Nail Insertion Sleeve* is reusable.

The standard technique will be described here. For the alternative technique, please go to page 31.

All sleeves and trocars are offered in two different sizes: Ø8-11 and Ø8-13.

The Ø8-11 sleeves and trocars can be used for T2 Tibia Nails up to a diameter of 11mm, and the Ø8-13 sleeves and trocars can be used for T2 Tibia Nails up to a diameter of 13mm.

Only sleeves and trocars of corresponding sizes can be used together.

Standard Technique

Components Used:

- Elastic Nail Insertion Sleeve (1806-1406S, 1806-1407S)
- Drill Sleeve (1806-1408, 1806-1409)
- Modular Handle (1806-1412)
- Trocar (1806-1414, 1806-1415)
- Plug (1806-1416)

Features:

- Elastic Nail Insertion Sleeve creates working channel for implant and instrument passages. The elastic sleeve is single-use only
- Placement of fixation K-Wires possible to prevent movement of Drill Sleeve relative to the tibial plateau during the opening and reaming processes
- Insertion of Plug into the Trocar is designed to facilitate sliding of the assembly over femoral condyles



Fig.7

*Metal Nail Insertion Sleeves are not available for sale in the US.

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 between the interface of the two sleeves (Fig.9). Note that the Drill Sleeve can be engaged on the Modular Handle every 90° to suit surgeon preference.

Then, advance the corresponding Trocar and Plug into the Drill Sleeve until it is locked.

Note:

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 tibial 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 their palm during insertion of the assembly.



Fig.8

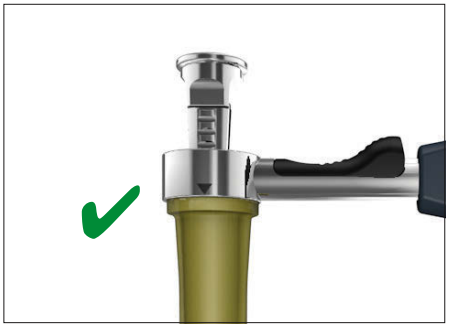


Fig.9



Fig.10

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 tibial plateau (Fig.11a).

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. See Figures 11a and 11b. Do not insert the sleeves as exhibited in figure 11c.

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.

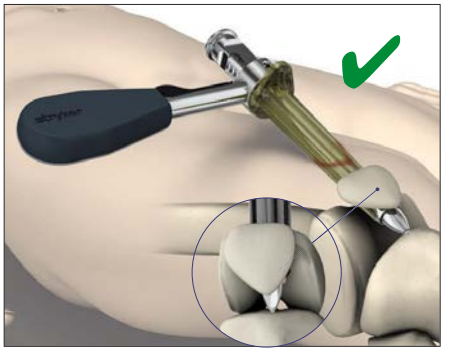


Fig.11a

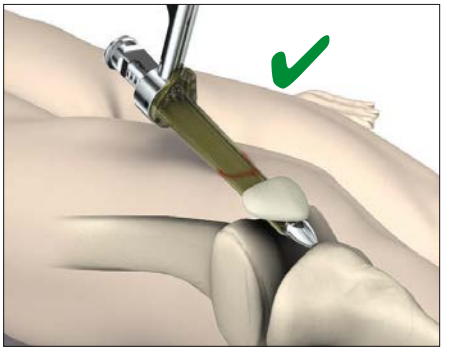


Fig.11b

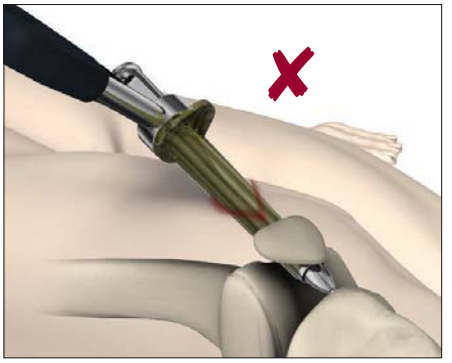


Fig.11c

Operative Technique – Suprapatellar Insertion

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 tibial spine as visualized on the A/P radiograph (Fig.12) and immediately adjacent and anterior to the anterior articular margin as visualized on the true lateral radiograph.

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

In an additional M/L radiograph (Fig.13) the correct positioning of the entry point in the sagittal plane should be confirmed.



Fig.12

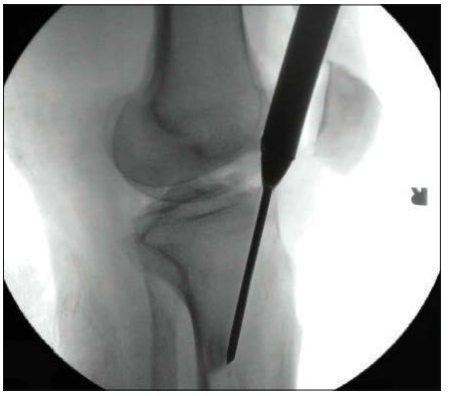


Fig.13

The opening should be directed with a central orientation in relation to the medullary canal in both (A/P and M/L) views. Use the central hole of the Trocar (1806-1414, 1806-1415) to determine the entry point by placing a central 3 x 285mm K-Wire (1806-0050S).

Note:

As an alternative to the standard 3 x 285mm K-Wire (1806-0050S), the 3 x 285mm Fixation K-Wire (1806-1417S) can be utilized as an entry point guide wire.

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

Multi-hole functionality

The off-center hole of the Trocar can be used either for initial guide wire placement or also 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 3 x 285mm K-Wire through the off-center hole of the Trocar (Fig.14). If an initial K-Wire had been used in the center hole, remove at this time.

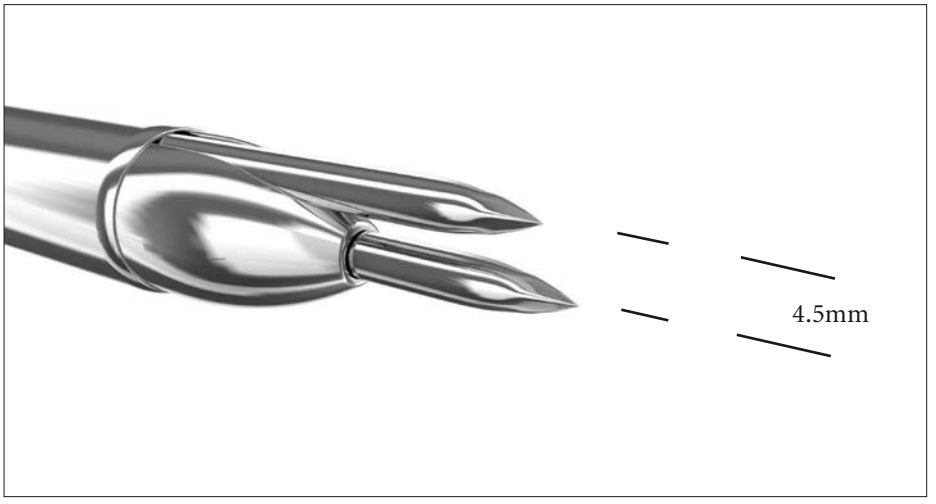


Fig.14

Note:

To ensure proper drill alignment when using the off-center hole, remove the Trocar and place it over the off-center 3 x 285mm K-Wire so that it goes through the center hole of Trocar.

If necessary, repeat the above mentioned steps accordingly.

Unlock the Trocar and push the Drill Sleeve and Elastic Nail Insertion Sleeve forward until the sleeve tip lies on the tibial plateau (Fig.15).

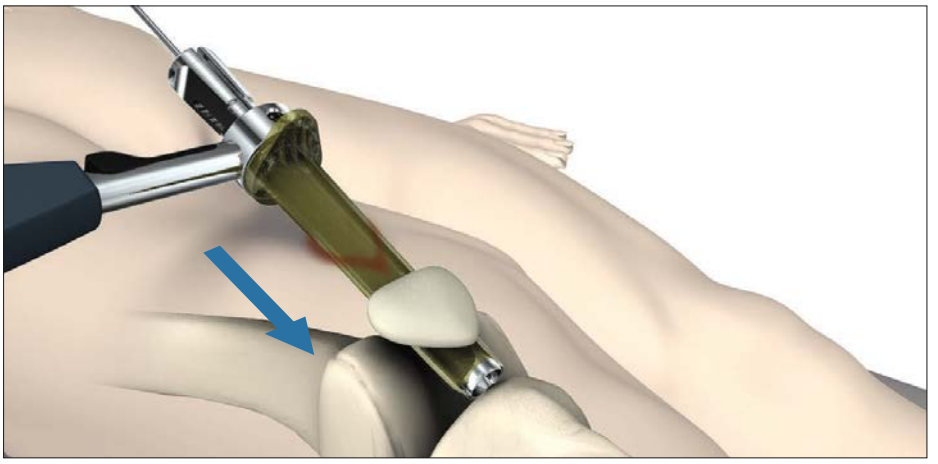


Fig.15

Fixation K-Wires

Two 3 x 285mm Fixation K-Wires (1806-1417S) can be used for fixation of the sleeves to the tibial plateau.

Insert the K-Wires through the slots in the Drill Sleeve (1806-1408, 1806-1409) (Fig.16).

The sleeve system is designed for enhanced fixation of the sleeves as well as to prevent anteriorization of the sleeves during the opening and subsequent reaming process.

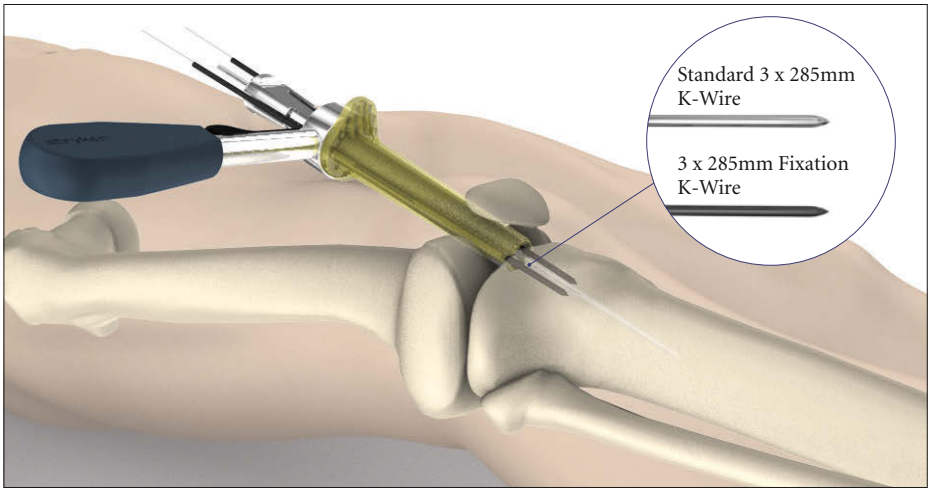


Fig.16

Note:

The 3 x 285mm Fixation K-Wires should extend into the tibia as shown in (Fig.18) to allow for proper fixation while avoiding potential interference during the subsequent reaming process.

Opening of Tibia

Remove the Trocar prior to opening of the tibia. The Opening Drill Ø12 (1806-1400) is used to access the medullary canal (Fig.17).

Note:

Opening Drilling should be performed through the Drill Sleeve with the Nail Insertion Sleeve (metal* or elastic) remaining in place.

Advance the Opening Drill until it stops.

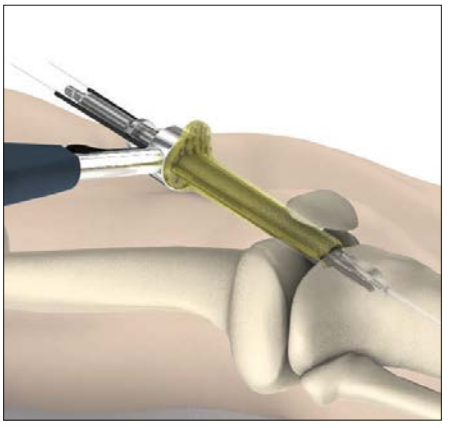


Fig.17

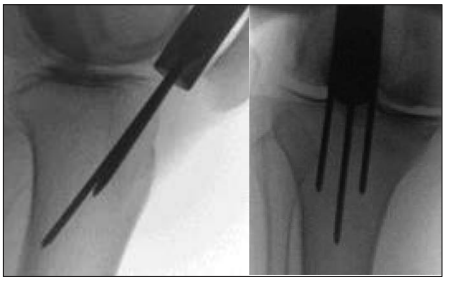


Fig.18

*Metal Nail Insertion Sleeves are not available for sale in the US.

Operative Technique – Suprapatellar Insertion

Unreamed Technique

The 3 x 285mm K-Wires and the Drill Sleeve (1806-1408, 1806-1409) can be removed now if an unreamed technique is performed.

The Elastic Nail Insertion Sleeve (1806-1406S, 1806-1407S) or the Nail Insertion Sleeve (1806-1410, 1806-1411)* remain in their place.

If an unreamed technique is preferred, the 3 x 800mm Smooth Tip Guide Wire (1806-0090S) is passed through the fracture site using the Guide Wire Handle (1806-1095 and 1806-1096) (Fig.19). The Universal Rod (1806-0110) with Reduction Spoon (1806-0125) may be used as a fracture reduction tool to facilitate Guide Wire insertion, and as a gauge to help determine the diameter of the medullary canal. The Universal Rod is 9mm diameter. Internal rotation during insertion will aid in passing the Guide Wire down the tibial shaft. The Guide Wire should lie in the center of the metaphysis and the diaphysis in both the A/P and Lateral views to avoid offset positioning of the nail. The Guide Wire handle is removed leaving the Guide Wire in place.



Fig.19

Reamed Technique

The Drill Sleeve (1806-1408, 1806-1409) and the 3 x 285mm Fixation K-Wires (1806-1417S) are not removed prior to performing a reamed technique. The Elastic Nail Insertion Sleeve (1806-1406S, 1806-1407S) or the Nail Insertion Sleeve (1806-1410, 1806-1411)* also remain in their place.

Note:

Reaming should be performed through the Drill Sleeve with the Nail Insertion Sleeve (metal* or elastic) remaining in place.

Use of the Suprapatellar Instrumentation increases the working length and may require longer reamer and guide wire lengths than those used with the standard infrapatellar technique approach (as described in Literature Number T2-ST-3). Please plan accordingly.



Fig.20

*Metal Nail Insertion Sleeves are not available for sale in the US.

Operative Technique – Suprapatellar Insertion

For reamed techniques, the central 3 x 285mm K-Wire is removed and a 3mm Ball Tip Guide Wire is inserted through the fracture site. Except for the 8mm Tibial Nails, use of the Ball Tip Guide Wire does not require a Guide Wire exchange.

The Universal Rod with Reduction Spoon may be used as a fracture reduction tool to facilitate Guide Wire insertion through the fracture site.

Note:

The Ball Tip at the end of the Guide Wire is designed to stop the reamer head.

Reaming is commenced in 0.5mm increments until cortical contact is appreciated. Final reaming should be 1mm-1.5mm larger than the diameter of the nail to be used.

Note:

- **Reaming may be completed over any Stryker 3mm Ball Tip Guide Wire. Use of the Suprapatellar Instrumentation may require longer reamer and guide wire lengths that those used with the standard infrapatellar approach. Please plan accordingly.**
- **The maximum reaming diameter for the Ø8-11 Drill Sleeve (1806-1408) is 12.5mm, for the Ø8-13 Drill Sleeve (1806-1409) 14.5mm.**

The Guide Wire Pusher can be used to help keep the Guide Wire in position during reamer shaft extraction. The metal cavity at the end of the handle pushed on the end of the power tool facilitates to hold the Guide Wire in place when starting to pull the power tool (Fig.21). When close to the Guide Wire end place the Guide Wire Pusher with its funnel tip to the end of the power tool cannulation (Fig.22).

The Guide Wire Pusher is designed to keep the Guide Wire in place while removing the power tool.

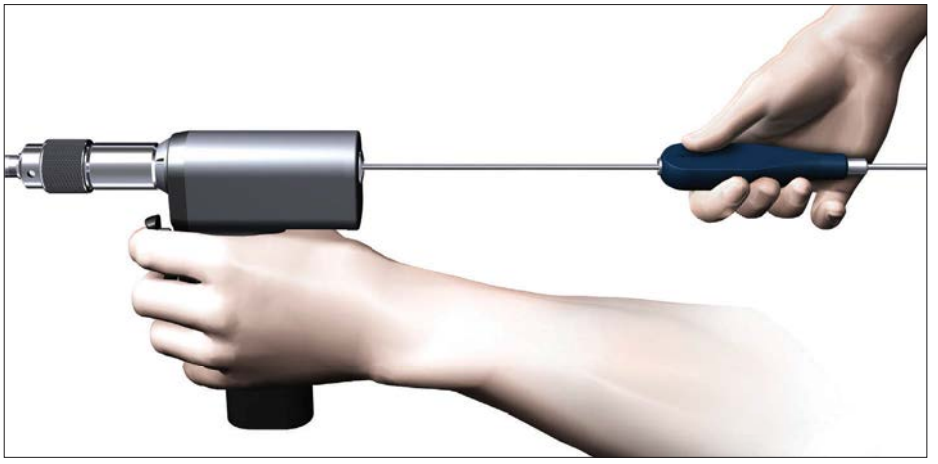


Fig.21

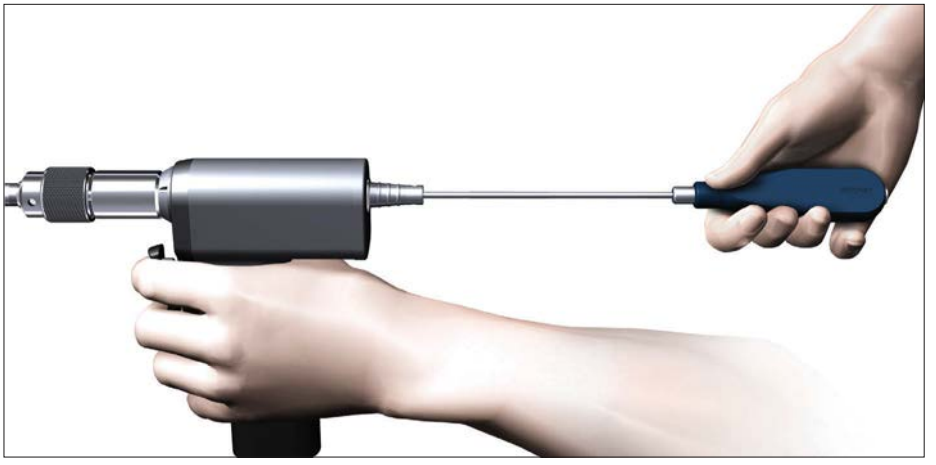


Fig.22

Note:

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

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.

Note:

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

Caution:

8mm Tibial Nails cannot be inserted over the 3mm Ball Tip Guide Wires. The Ball Tip Guide Wire must be exchanged for a 3mm Smooth Tip Guide Wire prior to nail insertion. Use the Teflon Tube (1806-0073S) for the Guide Wire exchange.

Note:

Depending on the location of the fracture, use of the Teflon Tube for Guide Wire exchange with Suprapatellar Instrumentation may potentially be limited when using nails longer than 330mm.

Operative Technique – Suprapatellar Insertion

Nail Selection

Diameter

The diameter of the selected nail should be 1-1.5mm smaller than that of the last reamer used.

Length

The X-Ray Ruler (1806-0010) may be used to determine nail diameter and length. The X-Ray Ruler may also be used as a guide to help determine final Locking Screw positions (Fig.23).

Note:

X-Ray Ruler also features Distal Hole Configurations.

Alternatively, nail length may be determined by measuring the remaining length of the Guide Wire. The Guide Wire Ruler (1806-0022) is placed on the Guide Wire and the correct nail length is read at the end of the Guide Wire on the Guide Wire Ruler (Fig.24).

Caution:

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

The Guide Wire Ruler is calibrated for 800mm and 1000mm Guide Wires with markings for the Tibia, Femur and Humerus.

Upon completion of reaming, the appropriate size nail is ready for insertion.

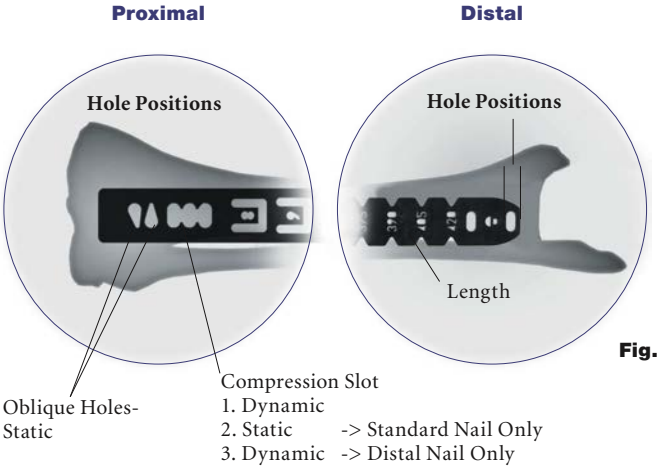
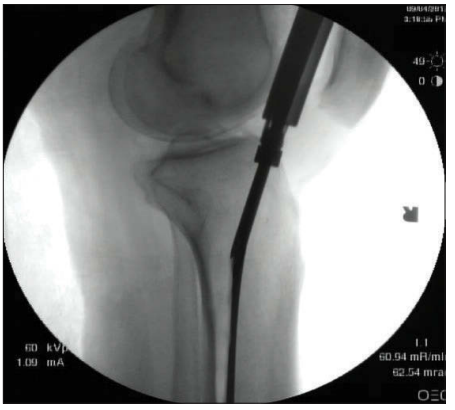


Fig. 23



Note:

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

End of Guide Wire Ruler
is the measurement reference

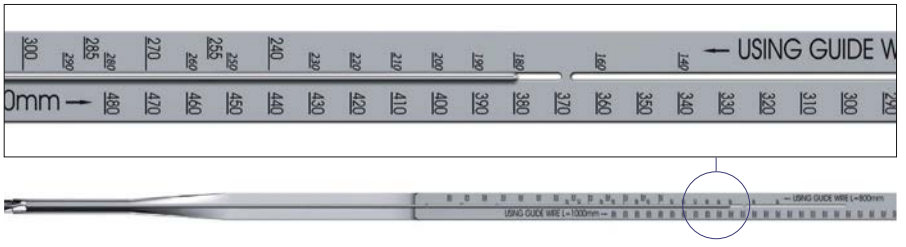


Fig. 24



Fig. 25

The Guide Wire Ruler can be easily folded and unfolded.

Nail Insertion

Remove the 3 x 285mm Fixation K-Wires (1806-1417S) and then the Drill Sleeve (1806-1408, 1806-1409) prior to nail insertion. The Elastic Nail Insertion Sleeve (1806-1406S, 1806-1407S) or Nail Insertion Sleeve (1806-1410, 1806-1411)* is used to perform nail insertion through a sleeve.

The selected nail is assembled onto the SPI Nail Adapter (1806-1402) with the SPI Nail Holding Screw (1806-1401) (Fig.26). Securely tighten the Nail Holding Screw with the Insertion Wrench (1806-0135) so that it does not loosen during nail insertion.

To attach the SPI Nail Adapter to the Targeting Arm, turn the Quick-Lock Ring on the Targeting Arm clockwise. Triangles on the Quick-Lock Ring and the Targeting Arm indicate the correct position to attach the Nail Adapter when both triangles are in line with each other.

Caution:

Prior to insertion:

1. **Recheck that the Nail is tightly secured to the SPI Nail Adapter.**
2. **Ensure that both the head of the Nail Holding Screw and the driving end of the nail completely align with the Nail Adapter.**
3. **Verify the hole pattern and appropriate locking options for the nail type selected. This is extremely important since the proximal hole patterns are different among the Standard and Distal Nails.**
4. **Check correct alignment by inserting a drill bit through the assembled Tissue Protection and Drill Sleeve placed in the required holes of the targeting device.**

Note:

T2 Tibial Nails with diameters 9mm–15mm do not require a Guide Wire exchange.

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



Fig. 26

*Metal Nail Insertion Sleeves are not available for sale in the US.

Operative Technique – Suprapatellar Insertion

Note:

If Fixation K-Wires have been utilized, they must be removed followed by removal of the drill sleeve prior to nail insertion. In addition, the Targeting Arm should be removed from the SPI Nail Adapter prior to nail insertion.

If a Guide Wire is used, it is important to note that only the 8mm Tibial Nails require exchanging the 3 x 800mm Ball Tip Guide Wire (1806-0080S) for the 3 x 800mm Smooth-Tip Guide Wire (1806-0090S) prior to insertion. Use the Teflon Tube (1806-0073S) to facilitate the Guide Wire exchange.

The Strike Plate (1806-0150) is threaded into the SPI Nail Adapter next to the Nail Holding Screw.

The nail is inserted by hand over the 3 x 800mm Ball Tip Guide Wire (if used) through the femoropatellar joint and into the entry site of the proximal tibia (Fig.27). Gently raise your hand to ensure concentric entry into portal so as to not take off any bone of the anterior tibia. In addition, gently manipulate the nail to help avoid penetration of the posterior cortex.

The Nail is advanced through the ventry point past the fracture site to the appropriate level. Remove the Guide Wire once the nail is past the fracture site.

The Slotted Hammer can be used on the Strike Plate (Fig.28) if dense bone is encountered or, alternatively, the Universal Rod may be attached to the Strike Plate and used in conjunction with the Slotted Hammer (1806-0170) to insert the nail (Fig.29).



Fig. 27



Fig. 28



Fig. 29

Operative Technique – Suprapatellar Insertion

The three circumferential grooves on the insertion post act as a guide while inserting the nail to the correct depth. When locking the Tibial Nail in the Static Mode, the nail is countersunk a minimum of 2mm to the chondral surface (Fig.30).

When the implant is inserted in the Dynamic Mode, with active apposition/compression or in the Advanced Locking Mode, the recommended insertion depth is 7mm or 12mm based on how much active compression is to be applied (Fig.31). The final nail depth should be well below the chondral surface to minimize irritation to the Patellar Tendon.

If the nail has been inserted too far, it has to be repositioned. Repositioning of the nail should be carried out either by hand or by using the Strike Plate attached to the SPI Nail Adapter. The Universal Rod and Slotted Hammer may then be attached to the Strike Plate to carefully and smoothly retract the assembly. DO NOT hit on the Target Device.

Attach the Targeting Arm to the SPI Nail Adapter by rotating the spring loaded Quick-Lock Ring on the Targeting Arm clockwise while connecting it to the knob on the end of the SPI Nail Adapter (Fig.32).

Note:

Remove the Guide Wire prior to drilling holes and inserting the Locking Screws.

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. Depth of insertion may be visualized with the aid of fluoroscopy.

Caution:

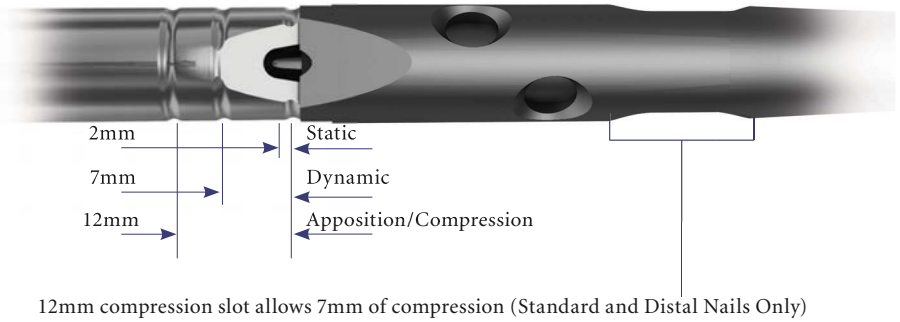
The Compression Slot on the Distal Nail is located 7mm further distal than on the Standard Nail.



Fig. 30



Fig. 31



12mm compression slot allows 7mm of compression (Standard and Distal Nails Only)



Fig. 32

Guided Locking Mode

(via Target Device)

Before locking the nail proximally, recheck that the SPI Nail Holding Screw is securely tightened by using the Insertion Wrench, and check that the Targeting Arm is properly attached to the SPI Nail Adapter. The Target Device is designed to provide four options for proximal locking when using the Standard Tibial Nail (Fig.33-Fig.34).

In Static Locking Mode all three indicated holes may be used (Fig.33).

1. Static
2. Static
3. Static

The dynamic hole is used to lock the nail in the controlled Dynamization or Apposition/Compression Modes (Fig.34).

Both the dynamic and more proximal of the two oblique locking holes are used in the Advanced Locking Mode.

Proper placement of the Advanced Compression Screw against the transverse Partially Threaded Locking Screw (Shaft Screw) will block the more distal of the two oblique locking holes even if fully compressed (Fig.35).

4. Dynamic
1. Static

Caution:
Any attempt to drill across the more distal of the two oblique locking holes may result in particulate debris generation or a broken drill.

The Long Tissue Protection Sleeve (1806-0185) together with the Long Drill Sleeve (1806-0215) and the Long Trocar (1806-0315) is inserted into the Target Device by pressing the safety clip (Fig.36). The mechanism is designed to keep the sleeve in place and prevent it from falling out. It is also designed to prevent the sleeve from sliding during screw measurement. To release the Tissue Protection Sleeve, the safety clip must be pressed again and held while removing the sleeve.

Caution:
The location of the oblong hole on the Distal Tibial Nail is 7mm more distal than the hole location for the Standard Tibial Nail. If a Distal Tibial Nail is implanted, do not attempt to drill through the Dynamic M/L hole on the Target Device or you will hit the nail. Only use the static hole numbered 1, 2, and 3 (Fig.33).

Caution:
Any loads placed on the device may affect accuracy of proximal locking targeting.



Fig.33



Fig.34



Caution:
For Standard and Distal Nail only.

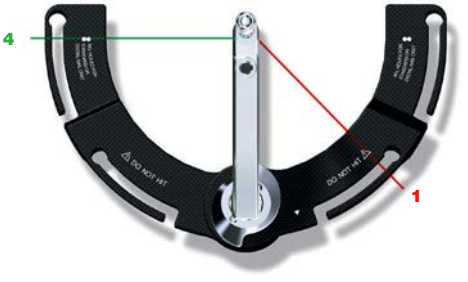
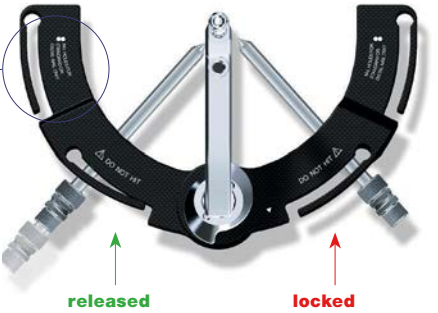


Fig.35



There are four safety clips **Fig.36**

Static Locking Mode

For static locking of the Standard Tibial Nail, both proximal oblique screws and the M/L Locking Screw may be used. In highly unstable, comminuted fractures the M/L screw is placed in the static position of the oblong hole. This may further improve stability of the proximal fragment.

If secondary dynamization is planned, the M/L screw may be inserted in the dynamic position of the oblong hole on the Target Device. This allows controlled dynamization of the fracture in cases of delayed union after removal of the proximal oblique screws.

Caution:

If secondary dynamization is used with the Distal Tibial Nail, the M/L screw has to be inserted through the distal most part of the oblong hole of the Target Device. (The oblong hole on the Distal Tibial Nail is 7mm more distal than on the Standard Tibial Nail).

Always start with the most distal oblique Fully Threaded Locking Screw. The Long Tissue Protection Sleeve (assembled with the Long Drill Sleeve and Trocar) is positioned through the static locking hole on the Target Device. A small skin incision is made, and while pressing the safety clip, the Tissue Protection Sleeve is pushed through until it is in contact with the anterior cortex (Fig.37).



Fig.37



Fig.38

Caution:

Make sure the Tissue Protection Sleeve/Drill Sleeve Assembly is seated on bone prior to selecting final screw length.

The Long Trocar is removed, with the Tissue Protection Sleeve and Drill Sleeve remaining in position.

Operative Technique – Suprapatellar Insertion

For accurate drilling and easy determination of screw length, use the center-tipped, calibrated Ø4.2 x 340mm Drill (1806-4260S).

The centered Drill is forwarded through the Drill Sleeve and pushed onto the cortex.

After drilling both cortices, the screw length may be read directly off of the calibrated Drill at the end of the Drill Sleeve. If measurement with the Screw Gauge, Long is preferred, first remove the Drill Sleeve, Long and read the screw length directly at the end of the Tissue Protection Sleeve, Long (Fig.38 - Fig.39).

The position of the end of the Drill as it relates to the far cortex is equal to where the end of the screw will be. Therefore, if the end of the Drill is 3mm beyond the far cortex, the end of the screw will also be 3mm beyond.

The Screw Gauge, Long, is calibrated so that with the bend at the end pulled back flush with the far cortex, the screw tip will end 3mm beyond the far cortex (Fig.39).

Alternatively, stop the drill when it engages the far cortex and measure the drill bit depth off of the calibrated Drill. Add 5mm to this length to obtain the correct screw length.

When the Drill Sleeve is removed, the correct Locking Screw is inserted through the Tissue Protection Sleeve using the Long Screwdriver Shaft AO (1806-0227) with the Teardrop Handle (702429).

Caution:

The coupling of Elastosil handles contains a mechanism with one or multiple ball bearings. In case of applied axial stress on the Elastosil handle, those components are pressed into the surrounding cylinder resulting in a complete blockage of the device and possible bending.

To avoid intra-operative complications and secure long-term functionality, we mandate that Elastosil handles be used only for their intended use. DO NOT HIT on them.



Fig. 39

*Dimensions are Nominal

Operative Technique – Suprapatellar Insertion

Alternatively, the 3.5mm Hex Self-Holding Screwdriver or Long (1806-0233) can be used for the screw insertion.

The screw is advanced through both cortices. The screw is near its proper seating position when the groove around the shaft of the screwdriver is approaching the end of the Tissue Protection Sleeve (Fig.40).

Repeat the locking procedure for the more proximal oblique Locking Screw (Fig.41 - Fig.42).



Fig. 40

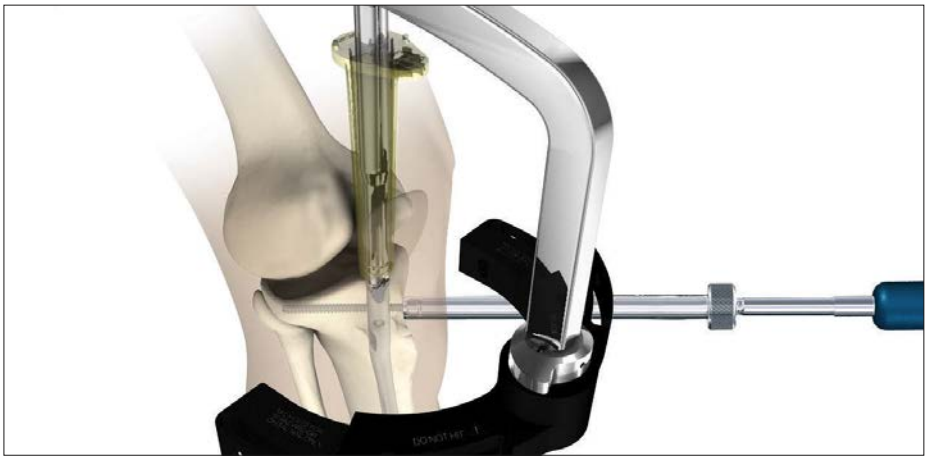


Fig. 41



Fig. 42

Freehand Distal Locking

The freehand technique is used to insert Locking Screws into both the M/L and A/P holes in the nail. Rotational alignment must be checked prior to locking the nail statically.

Multiple locking techniques and radiolucent drill devices are available for freehand locking. The critical step with any freehand locking technique is to visualize a perfectly round locking hole with the C-Arm.

The center-tipped Ø4.2 x 130mm Drill (1806-4280S) is held at an oblique angle pointing to the center of the locking hole (Fig.43 - Fig.44). Upon X-Ray verification, the Drill is placed perpendicular to the nail and drilled through the medial cortex. Confirm in both the A/P and M/L planes by X-Ray that the drill passes through the hole in the nail.

The Screw Gauge, Long (1806-0331) can be used to determine the screw length (Fig.45).

As detailed in the proximal locking section (Fig.39, page 22), the position of the end of the drill is equal to the end of the screw as they relate to the far cortex.

Routine Locking Screw insertion is employed (Fig.46) with the assembled Screwdriver Shaft and Teardrop Handle.

Alternatively, the 3.5mm Hex Self-Holding Screwdriver can be used for the screw insertion.

Note:

A fully threaded End Cap is available to lock down on the most proximal screw and create a fixed angle construct.

Caution:

Distal locking should always be performed with two screws, locking the hole nearest the fracture site first. On the Standard Tibial nails, always lock the most proximal M/L hole. The most distal hole of both types is M/L.

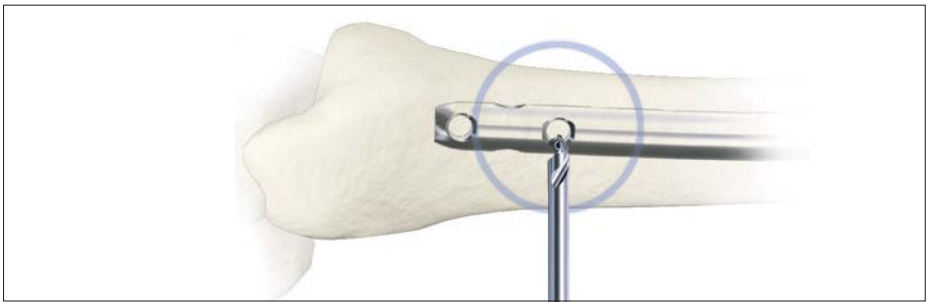


Fig.43

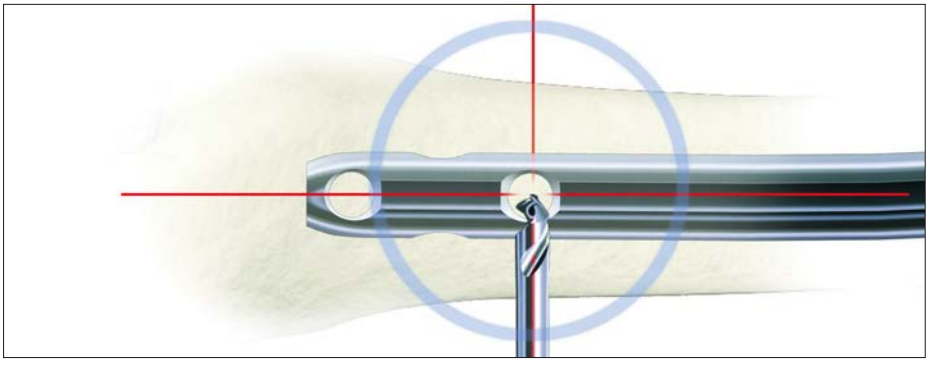


Fig.44



Fig.45

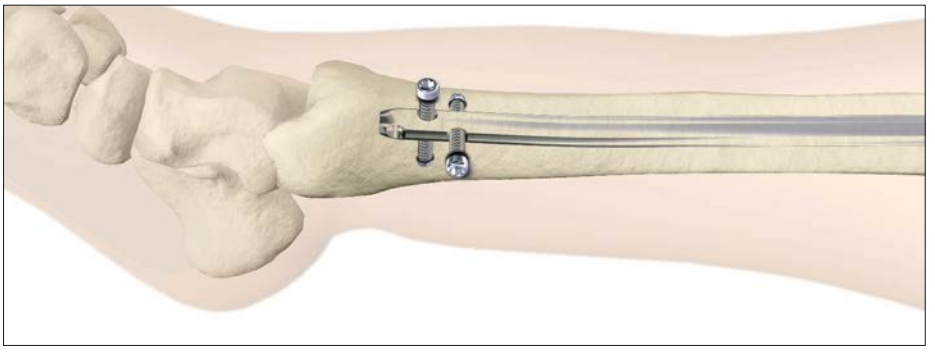


Fig.46

The next most proximal hole on both nails is A/P. The Standard Nails have a third more proximal M/L hole.

8mm Tibial Nails must always be locked distally with 4mm Fully Threaded Screws.

For the 8mm Tibial Nails, the Ø3.5 x 130mm Drill (1806-3550S) is used to drill both cortices prior to inserting the 4mm Fully Threaded Locking Screws in the distal holes. With all sizes of T2 Tibial Nails, the 8mm Nails use 5.0mm Screws proximally.

End Cap Insertion

End Cap insertion is performed through the Elastic Nail Insertion Sleeve (1806-1406S, 1806-1407S) or a Nail Insertion Sleeve (1806-1410, 1806-1411).

After removal of the Target Device, an End Cap is used. Nine different sizes of End Caps are available to adjust nail length and to reduce the potential for bony ingrowth into the proximal threads of the nail (Fig.47).

Note:

Fully Threaded or Standard End Caps can optionally be inserted through the SPI Nail Adapter after removal of the SPI Nail Holding Screw. For additional details please refer to the Standard T2 Tibia Operative Technique.



Fig.47

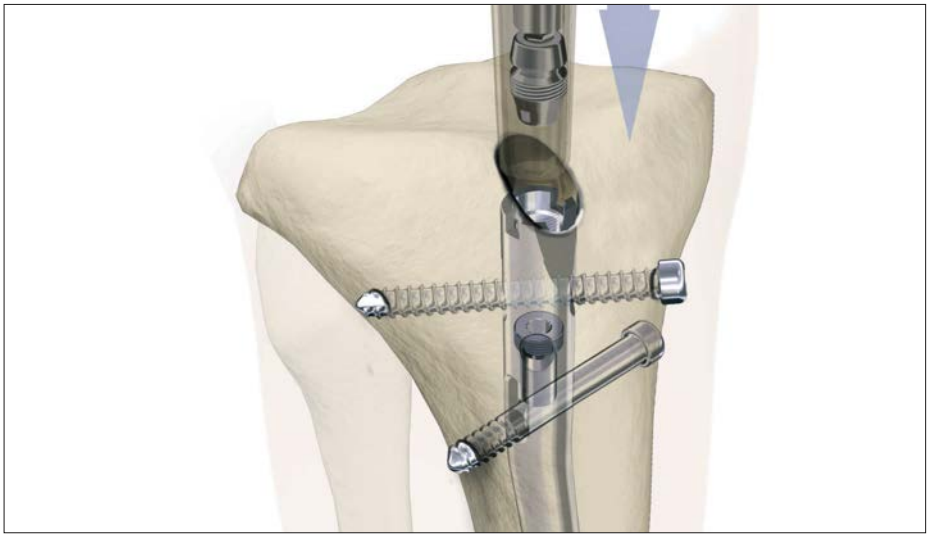


Fig.48

The End Cap is inserted with the Screwdriver, Self-Holding, Long (3.5mm) after intra-operative radiographs show satisfactory reduction and hardware implantation (Fig.48-Fig.49). If the self-holding screwdriver is not available, the Screwdriver Shaft and Teardrop Handle can also be utilized.

Fully seat the End Cap to minimize the potential for loosening (Fig.49). Thoroughly irrigate the wound to prevent debris from remaining within the knee joint. Close the wound using standard technique.

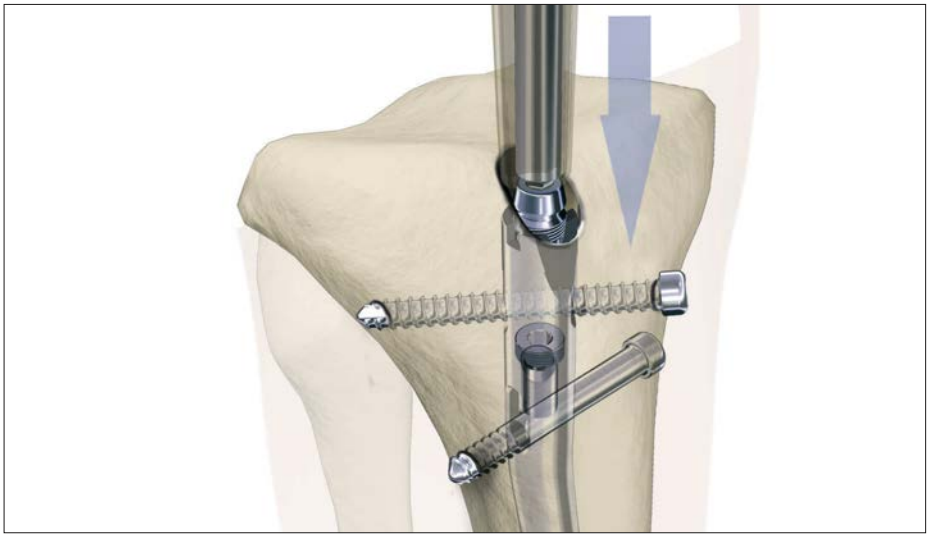


Fig.49

Dynamic Locking Mode

When the fracture profile permits, dynamic locking may be utilized for transverse, axially stable fractures. Controlled dynamization is performed by statically locking the nail distally with at least two screws in a freehand technique (Fig.50)

Note:

The Standard Nails have one A/P and two M/L distal screw hole options. The Distal Nail has one M/L (the most distal) and one A/P distal screw hole.



Fig. 50

In the Dynamic Locking Mode of the Standard Tibial Nail, the Partially Threaded Locking Screw (Shaft Screw) is placed in the dynamic position of the M/L oblong hole. The two oblique proximal screws are not inserted. This allows the nail to move relative to the Partially Threaded Locking Screw (Shaft Screw) and the fracture to settle while maintaining torsional stability (Fig.51).

For screw insertion, follow the procedure described above.



Fig. 51

Caution:

When using the Distal Tibial Nail, the M/L screw has to be inserted in the static position of the oblong hole on the Targeting Device. It is important to note that the position of the oblong hole of this nail is 7mm more distal than on the Standard Nail.

When using the Distal Tibial Nail, static locking of the proximal M/L oblong hole can only be performed freehand.

The proximal end of the nail must be buried at least 7mm–12mm into the bone to reduce the potential for impingement or irritation of the Patellar Tendon if the nail migrates during dynamization.

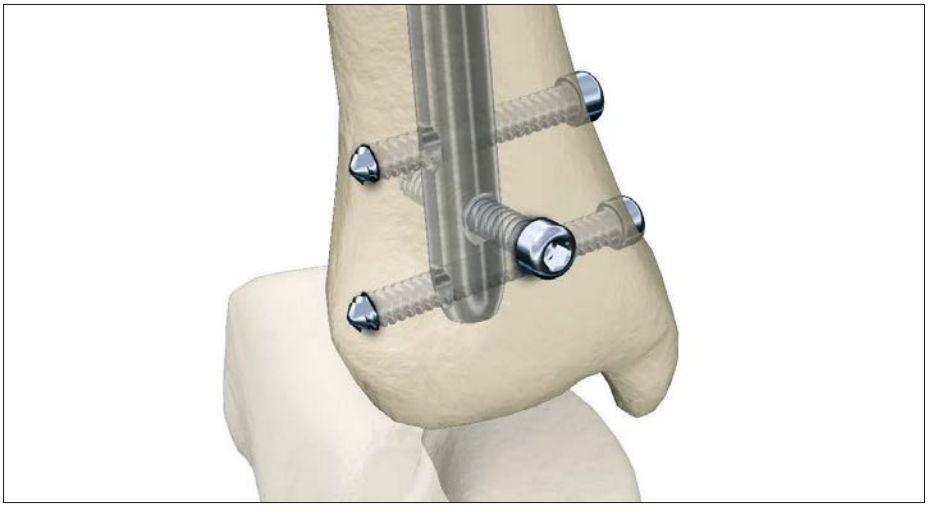


Fig. 52

Apposition/Compression Locking Mode

In transverse or axially stable fracture patterns, active apposition/compression increases fracture stability[1]. The T2 Standard Tibial Nail and T2 Distal Tibial Nail provide the option to treat a tibial fracture with active mechanical apposition/compression prior to leaving the operating room.

Caution:

Distal freehand static locking with at least two screws must be performed prior to applying active, controlled apposition/compression to the fracture site.

If active apposition/compression is required for the T2 Standard Tibial Nail, a Partially Threaded Locking Screw is inserted via the Target Device in the dynamic position of the of the oblong hole. The Distal Tibial Nail uses the static position of the oblong hole. This will allow for a maximum of 7mm of active, controlled apposition/compression using the Advanced Compression Screw. In order to insert the Partially Threaded Locking Screw (Shaft Screw), drill both cortices with the Ø4.2 x 340mm Drill (1806-4260S). Correct screw length may be read from the calibration on the Drill at the end of the Drill Sleeve. The near cortex ONLY is overdrilled using the Ø5 x 230mm Drill (1806-5000S).

Note:

It may be easier to insert the Compression Screw prior to fully seating the nail. Once the nail tip has cleared the fracture site, the guide wire (if used) is withdrawn. With the proximal portion of the nail still not fully seated and extending out of the bone, the Nail Holding Screw is removed and the Compression Screw is inserted. Care should be taken that the shaft of the Compression Screw does not extend into the area of the oblong hole.

Another alternative is that after the Partially Threaded Locking Screw (Shaft Screw) is inserted, the Nail Holding Screw securing the nail to the insertion post is removed, leaving the insertion post intact with the nail. This will act as a guide for the Compression Screw (Fig.53).

The Compression Screw is inserted with the SPI Compression Screwdriver Shaft (1806-1403) assembled on the Teardrop Handle through the insertion post. When the ring on the SPI Compression Screwdriver Shaft is close to the Target Device, it indicates the engagement of the apposition/compression feature of the nail.

The Long Tissue Protection Sleeve is removed and the Compression Screw is gently tightened utilizing the two-finger technique. As the Compression Screw is advanced against the 5.0mm Partially Threaded Locking Screw (Shaft Screw), it draws the distal fracture segment towards the fracture site, employing active apposition/compression. Image intensification will enable the surgeon to visualize active apposition/compression. Some bending of the Partially Threaded Locking Screw may be seen.

Caution:

Prior to compressing the fracture, the nail must be countersunk 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.

Apposition/compression should be carried out under fluoroscopy. Overtightening of the Compression Screw onto the Partially Threaded Locking Screw (Shaft Screw) may result in screw failing.



Fig.53

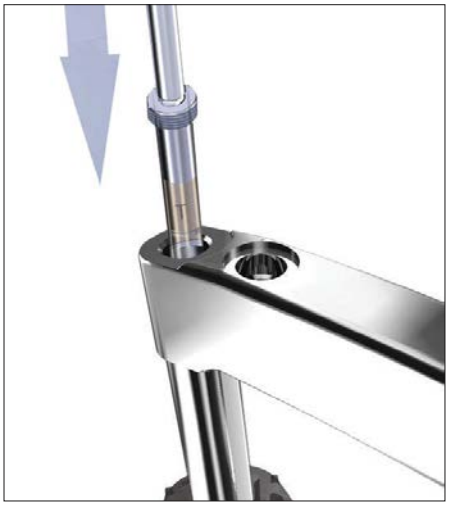


Fig.54



Fig.55

Advanced Locking Mode

In order to achieve additional fixation, and to reduce the load on the Partially Threaded Locking Screw, the design of the T2 Standard Tibial Nail and T2 Distal Tibial Nail provides the opportunity to insert an additional Fully Threaded Locking Screw into the more proximal of the two oblique holes after the optimum amount of apposition/compression is attained.

Affix the Compression Screw onto the self-retaining SPI Compression Screwdriver Shaft. Remove the SPI Nail Holding Screw leaving the Target Device in place. Advance the Compression Screw through the Target Device until the ring on the SPI Compression Screwdriver Shaft is close to the Target Device and compression is applied (Fig.56).

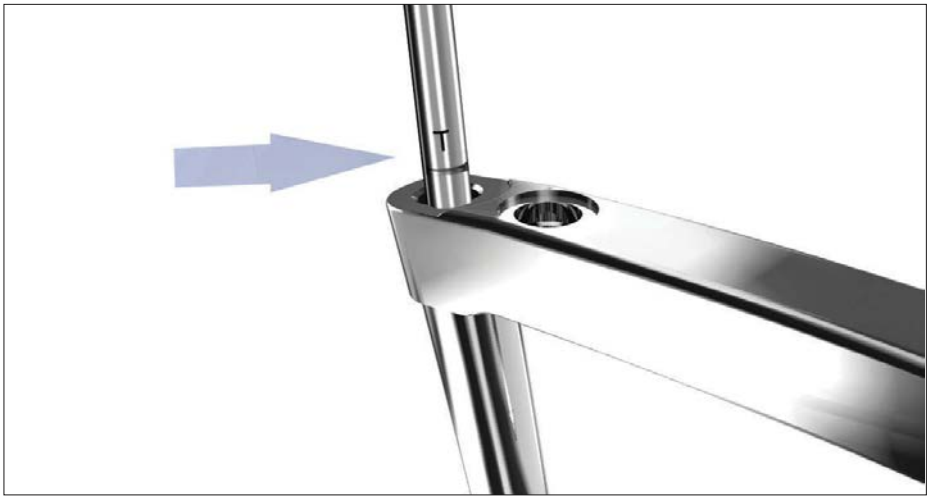


Fig. 56

To insert the Advanced Compression Screw, follow the procedure on page 27.

Note:

As previously described, it may be easier to insert the Compression Screw prior to fully seating the nail.

To reattach the Target Device, detach the Teardrop Handle from the SPI Compression Screwdriver Shaft and screw the Nail Holding Screw over the Compression Screwdriver Shaft back into position.

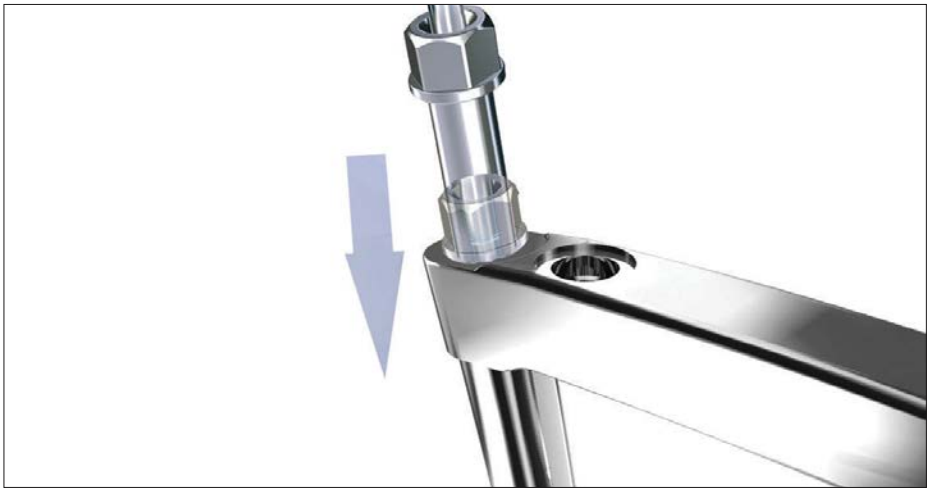


Fig. 57

Prior to guided locking via the Target Device, the SPI Nail Holding Screw must be securely tightened with the Insertion Wrench.

Caution:

When using the Advanced Compression Screw, only the more proximal oblique hole can be locked with a screw. The more distal oblique hole will be partially blocked by the top of the Advanced Compression Screw regardless of the amount of compression applied to the Shaft Screw in the M/L oblong hole.

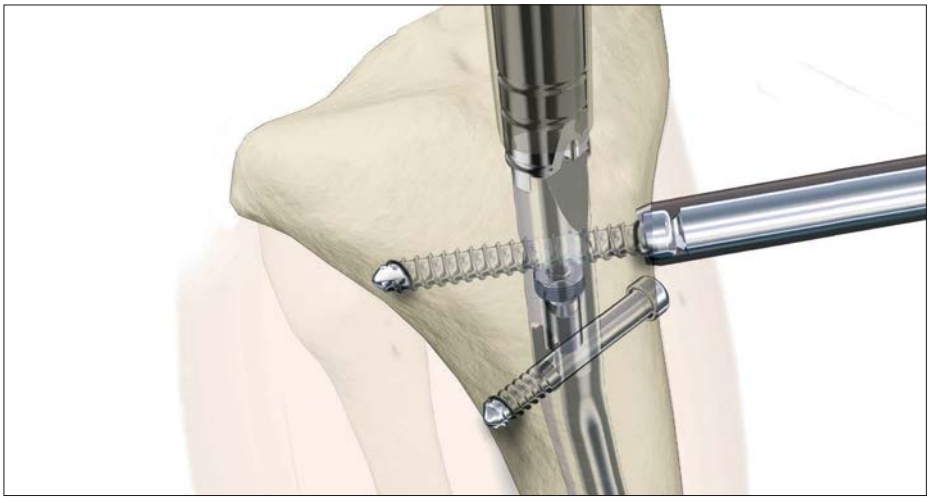


Fig. 58

To insert the proximal oblique Fully Threaded Locking Screw, follow the locking procedure for static locking.

Nail Removal

Explantation, for any reason, is at the surgeon's discretion when weighing patient benefit to the risks that accompany all general surgical procedures. Nail removal can be performed via an infra- or supra-patellar approach.

Caution:

In the case of infection (suspected or proven) nail removal should not be performed via the suprapatellar approach.

If needed, the End Cap and Advanced Compression Screw are removed with the Self-Holding Screwdriver or the Screwdriver Shaft and Teardrop Handle. If the Advanced Locking Mode was utilized, first remove the End Cap, then the most proximal screw, and then the Advanced Compression Screw can be removed (Fig.59).

Note:

As an alternative to removing the Advanced Compression Screw (if used), it can be just disengaged from the Partially Threaded Locking Screw (Shaft Screw) by turning the Compression Screwdriver one full turn in a counter-clockwise direction. There is no need to remove it from the nail.

Caution:

DO NOT remove the last proximal Locking Screw prior to attaching the Universal Rod to the proximal end of the nail. Doing so may result in the nail moving posteriorly, making it difficult to attach the Universal Rod to the nail.

The Universal Rod is inserted into the driving end of the nail. All Locking Screws are removed with the Long Screwdriver Shaft and Teardrop Handle(Fig.60). Alternatively, the 3.5mm Hex Self-Holding Screwdriver Long (1806-0233) or Extra Short (1806-0203) can be used for the screw removal. The Slotted Hammer or optional Sliding Hammer is used to extract the nail in a controlled manner (Fig.61).

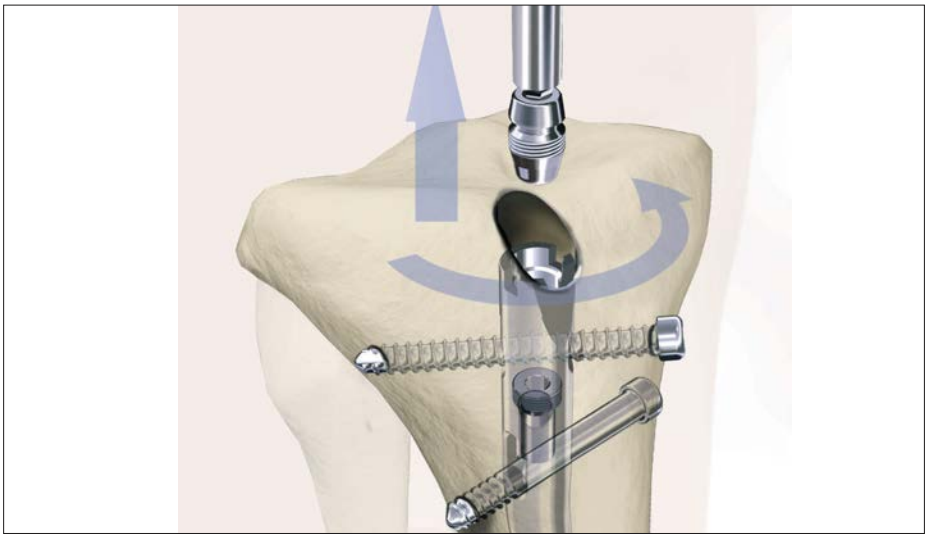


Fig. 59



Fig. 60



Fig. 61

Note:

Stryker also offers a special Extraction Set for the removal of internal fixation systems and associated screws.

For more information, please refer to the Implant Extraction Set guide.

Close the wound in the usual manner.

Blocking Screw Technique (optional)

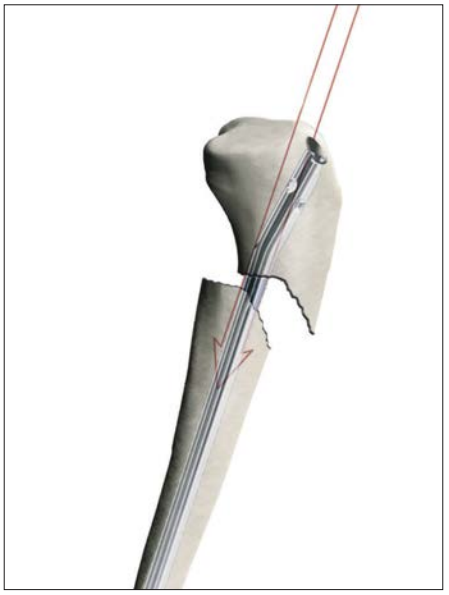


Fig.62

The nail often sits against the posterior cortex which causes anterior angulation of the fracture because the shaft position is fixed by the nail (Fig. 62).

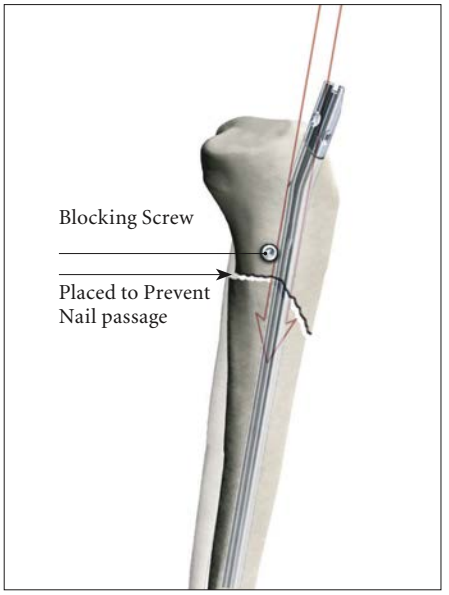


Fig.63

The principle of the use of a Blocking Screw is to prevent posterior nail passage by decreasing the effective diameter of the canal and directing the nail more anterior as shown (Fig. 63).



Fig.64

Using the superolateral entry point and with the Blocking Screw in place, the nail accurately aligns the shaft (fracture) (Fig. 64.)



Fig.65a

For Varus/Valgus Adjustment

One of the advantages of the very proximal bend in the nail, is its usefulness in correcting varus/valgus angulation. Do not lock the nail distally until after angular correction.

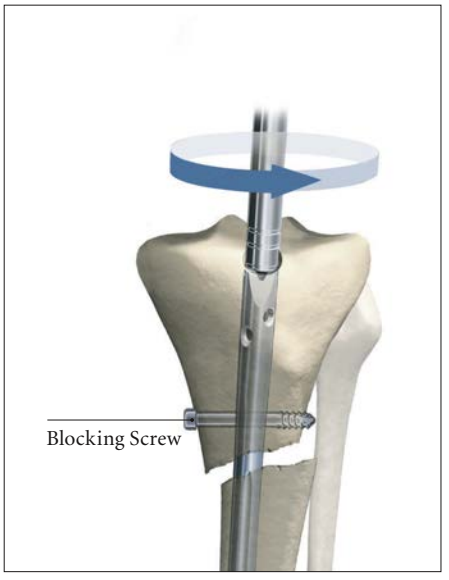


Fig.65b

Place the Blocking Screw at the level of the Proximal (Herzog) Bend. In cases where a Blocking Screw is used, simple rotation of the nail will allow the Herzog Bend to correct the angulation.

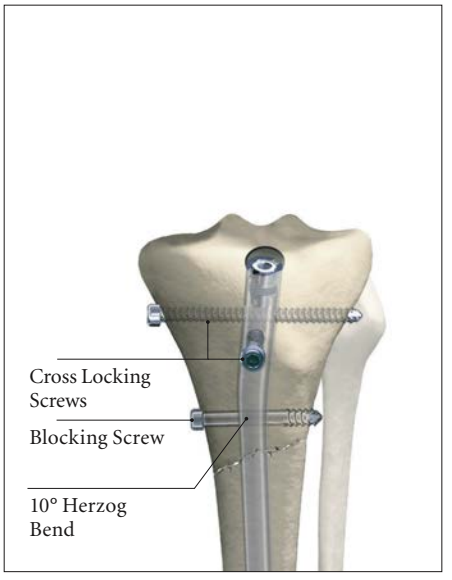


Fig.65c

Note:

As an option, or in an exchange/ revision nailing with a more distal entry portal, this principle can also be applied with a Lateral Blocking Screw placed A/P as an alternative method to help prevent Varus/ Valgus deformity.

Alternative Technique

Alternative Sleeve Insertion Technique

Components Used:

- Elastic Nail Insertion Sleeve (1806-1406S, 1806-1407S)
- Trocar (1806-1414, 1806-1415)
- Drill Sleeve (1806-1408, 1806-1409)
- Modular Handle (1806-1412)
- Plug (1806-1416)

Features:

- Elastic Nail Insertion Sleeve creates working channel for implant and instrument passages. The elastic sleeve is single-use only (Fig.66)
- Placement of fixation K-Wires is possible to prevent movement of Drill Sleeve relative to the tibial plateau during the opening and reaming processes
- Smaller during initial sleeve insertion than Standard Technique because only Trocar and Elastic Nail Insertion Sleeve are inserted together (smaller insertion diameter)
- Insertion of Plug into the Trocar is designed to facilitate sliding of the assembly over femoral condyles



Fig.66

Operative Technique – Suprapatellar Insertion

Alternative Sleeve Insertion Technique

1. Fully insert the corresponding Trocar and Plug into the Elastic Nail Insertion Sleeve (Fig.68).

Note:

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

Note:

The Plug is not fixed in the Trocar. Therefore, the surgeon should press the plug with their palm during insertion of the assembly.

Guided by the femoral condyles, insert the entity comprised of Elastic Nail Insertion Sleeve, Trocar, and Plug into the patellofemoral joint until the tip of the Trocar sits on the tibial plateau (Fig.67).

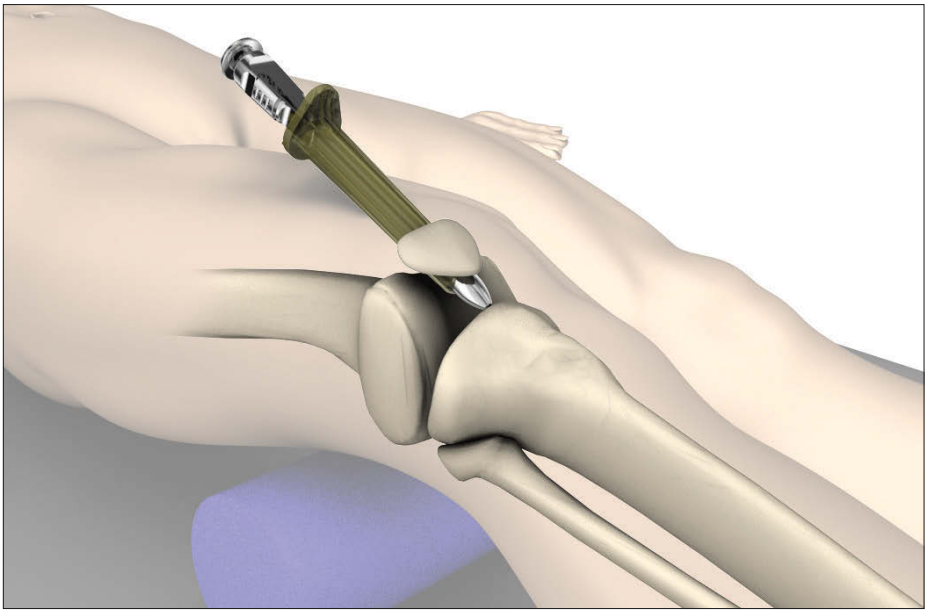


Fig.67

2. Remove the Trocar and Plug (Fig.69).

3. Advance the corresponding Trocar into the already assembled Drill Sleeve and Modular Handle entity until it is locked (Fig.70).

Insert the entity comprised of the Drill Sleeve and Trocar into the already placed Elastic Nail Insertion Sleeve until the tip of the Trocar sits on the tibial plateau.

Make sure that the sleeves are correctly aligned.

Caution:

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

4. Continue with entry point section on page 12.



Fig.68

Fig.69



Fig.70

References

1. O. Gonschorek, G. O. Hofmann, V. Bühren, Interlocking Compression Nailing: a Report on 402 Applications, Arch. Orthop. Trauma Surg (1998), 117: 430-437.

Notes

Notes

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