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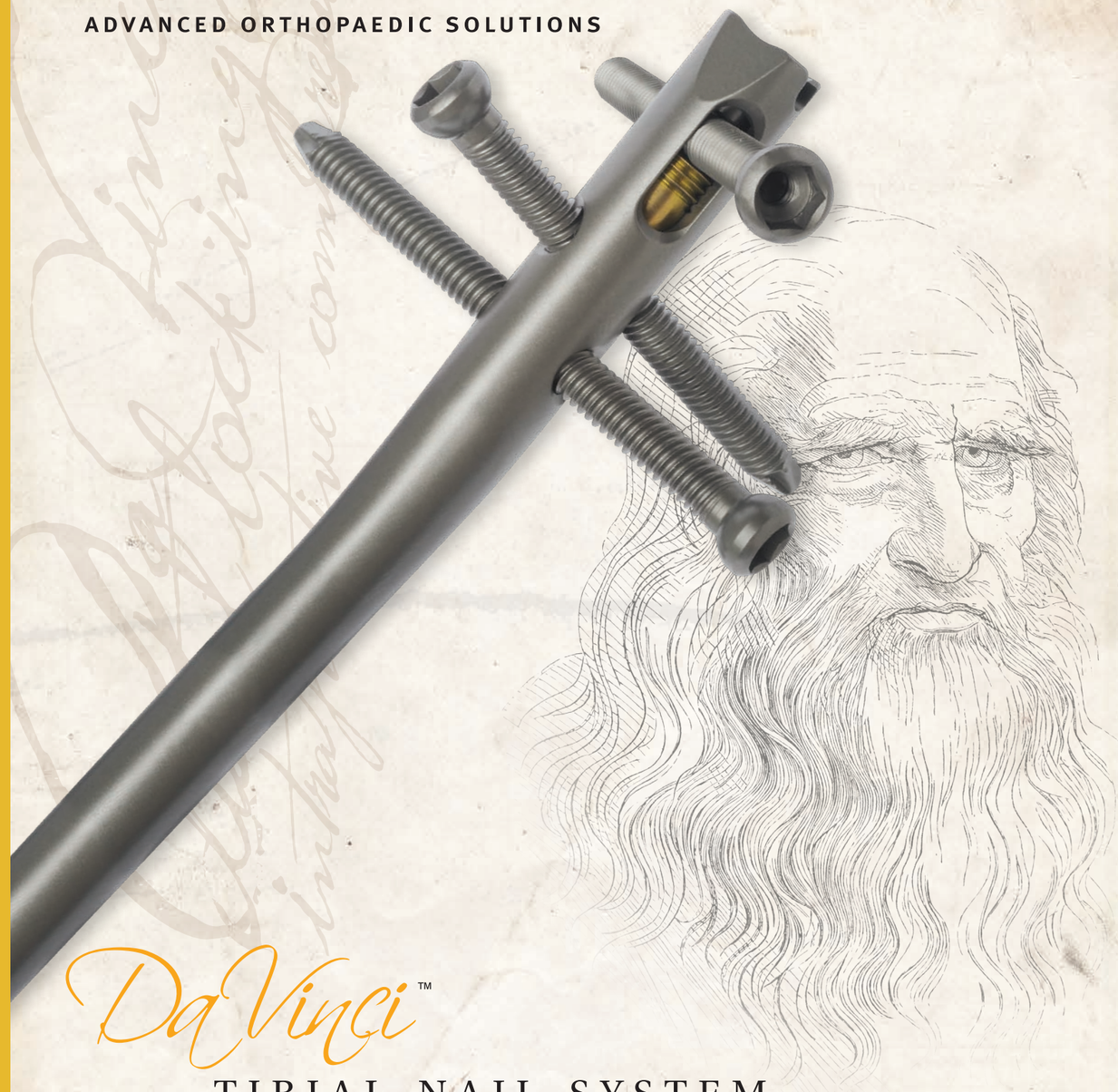


DaVinci™

TIBIAL NAIL SYSTEM

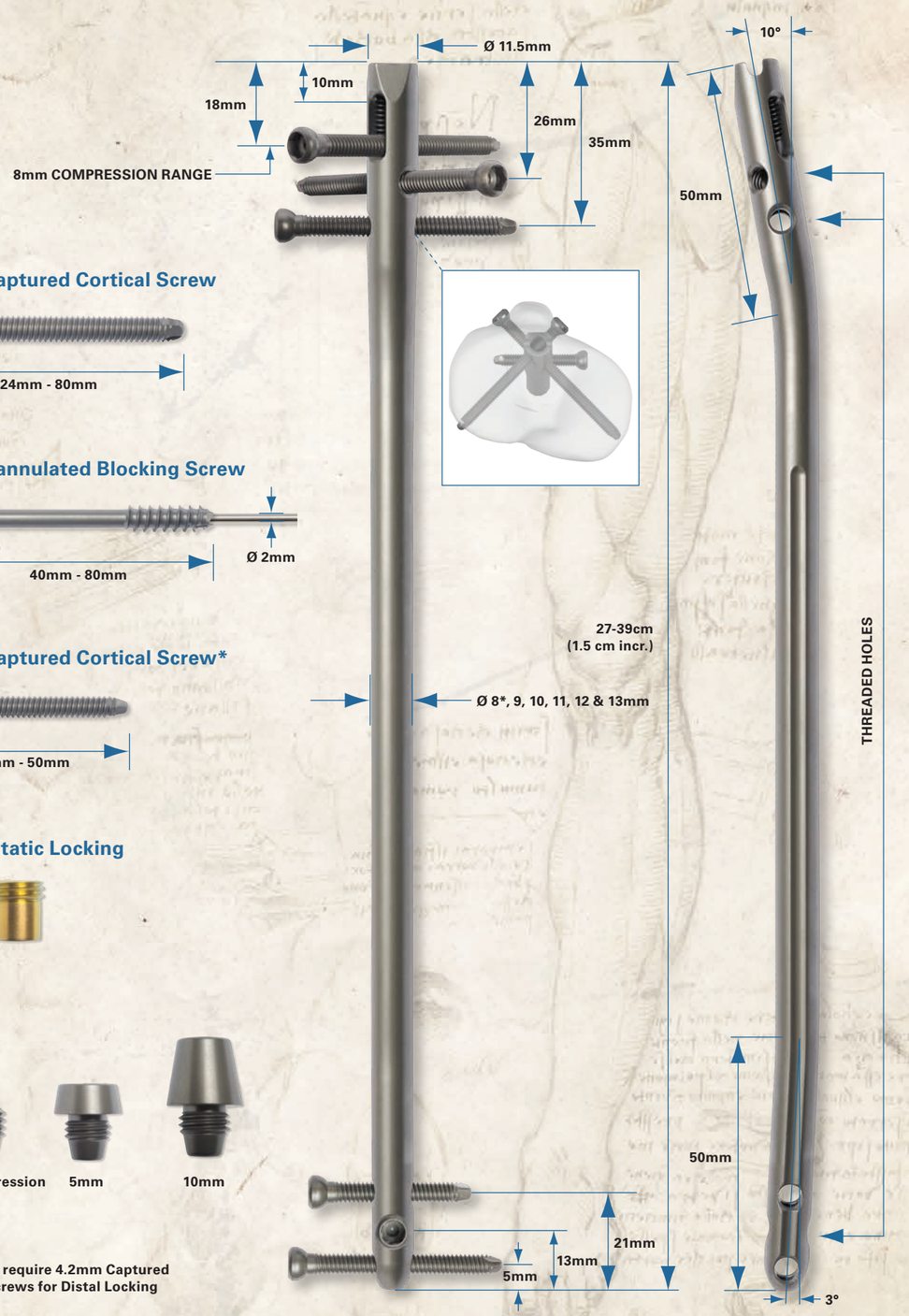
Standard & Suprapatellar Approach
Surgical Technique

Tibial Nail System
Standard Approach
Surgical Technique

This Surgical Technique sets forth detailed recommended procedures for using AOS devices and instruments. It offers guidance, 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. Surgeons must always rely on their own professional clinical judgement when deciding which products and surgical treatments to use with their patients. Refer to package insert for information on indications, warnings, precautions and contraindications.

Contents

Implant Features



5.0mm Captured Cortical Screw

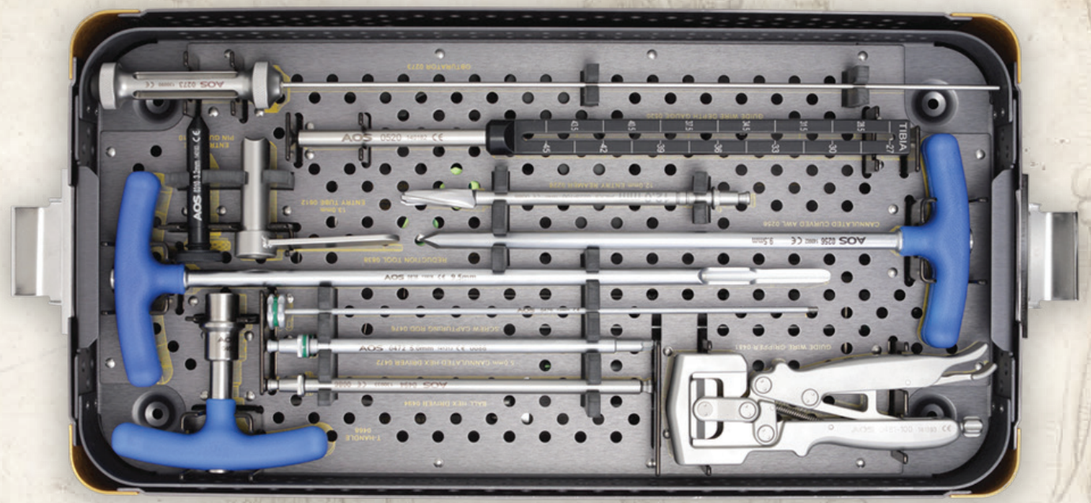
5.0mm Cannulated Blocking Screw

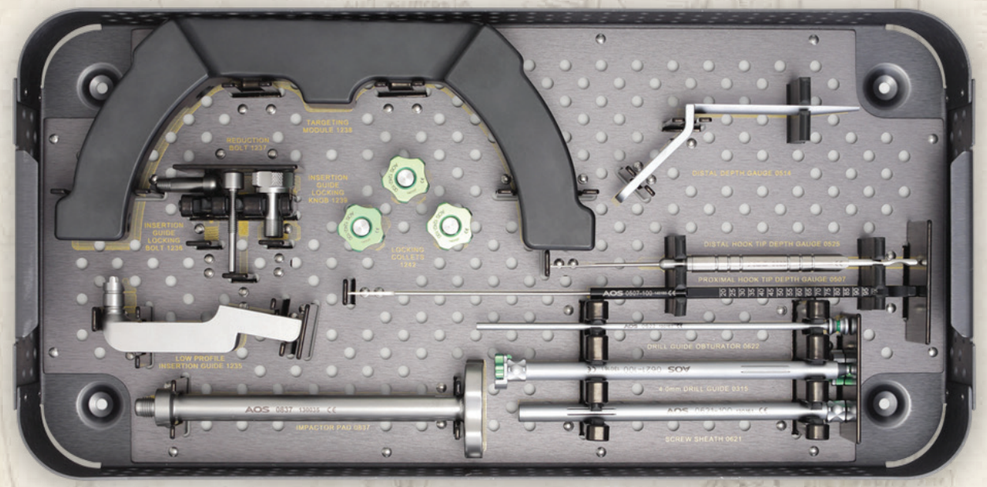
4.2mm Captured Cortical Screw*

Spacer, Static Locking

End Caps

* 8mm Nails require 4.2mm Captured Cortical Screws for Distal Locking





Tibial Nail System

Standard Approach
Surgical Technique

1. Indications

The AOS Tibial Nail System is intended to provide temporary stabilization of various types of fractures, mal-unions, and non-unions of the tibia. It is intended for long bone fracture fixation of tibial fractures, which may include the following:

- Transverse, oblique, spiral, segmental and comminuted fracture
- Fractures with bone loss and bone transport
- Open and closed fractures, pathologic fractures
- Corrective osteotomies
- Pseudarthrosis of the tibial shaft
- Non-unions, mal-unions, metaphyseal and epiphyseal fractures.

NOTE: Depending on surgeon preference, two surgical approaches are described in the surgical technique: Standard Medial Parapatellar Approach and Suprapatellar Approach

Fig. 1

2. Patient Positioning

Position the patient supine on a radiolucent table. Knee flexion will assist with the identification of the anatomic landmarks to allow accurate incision placement **(Fig. 1)**. For ease of distal locking from medial direction, it is helpful to place the C-arm on the opposite side of the injured limb.

NOTE: To confirm adequate visualization and reduction capabilities, take preliminary radiographic images before the patient is fully prepped and completely draped.

3. Incision & Entry Point

A patellar splitting or medial parapatellar incision, 1.5-3cm in length, is made in-line with the intramedullary canal.

The entry point into the tibial intramedullary canal is located just medial to the lateral tibial eminence in the A/P view **(Fig. 2)**, and in-line with the anterior cortex in the intramedullary canal in the lateral view **(Fig 3)**. Based on surgeon preference, an entry point is made with one of the following two options:

Option 1:
use the **3.2mm x 33cm Guide Pin (0100-000)**,
or
Option 2:
use the **Curved Cannulated Awl (0256-000)**.

Intramedullary Entry Option 1 (Pin Guide):
The 3.2mm Guide Pin may be placed using the **Entry Tube (0612-100)** and **3.2mm Pin Guide (0310-000)**. Orient the Entry Tube and Pin Guide into the proper position and insert the Guide Pin into the metaphysis 1.5-3cm **(Fig. 4)**.

Use A/P and lateral fluoroscopic views to confirm accurate placement of the guide pin.

NOTE: For mid-shaft and distal tibia fractures, a central starting point in the A/P view is adequate. For more proximal fracture, however, a slight lateral starting point is recommend to avoid proximal fragment malalignment.

Fig. 2

Fig. 3

Fig. 4

Remove the Pin Guide from the Entry Tube and use the **12mm Cannulated Entry Reamer (0228-100)** through the Entry Tube to open the proximal tibia **(Fig. 5)**.

NOTE: The entry reamer is marked to identify the correct reaming depth depending on whether the compression will be used.

NOTE: The tibial nail compression range is 8mm.

Fig. 5

Intramedullary Entry Option 2 (Curved Cannulated Awl):
Fluoroscopically verify the entry point and direction in both the A/P and lateral views, then advanced the **9.5mm Curved Cannulated Awl (Fig. 6)** in line with the tibial canal.

Once access to the tibial canal has been gained, place the **3.0mm Ball Nose Guide Wire (0101-900)** through the Curved Cannulated Awl **(Fig. 7)** into the entry site utilizing the **2.0/3.0mm Guide Wire Gripper (0481-100) (Fig. 8)**.

Fig. 6

Fig. 7

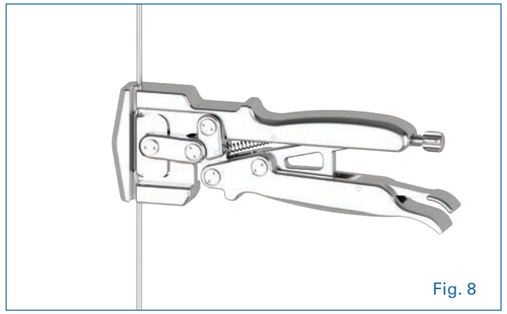


Fig. 8

4. Fracture Reduction

Obtain appropriate anatomic reduction in order to restore length, alignment and rotation of the injured limb. To aid in manipulating the fracture fragments and passing the **Ball Nose Guide Wire**, a **9.5mm Reduction Tool (0838-000) (Fig. 9**) is available.

Insert the Reduction Tool into the canal and use the curved tip to direct the Ball Nose Guide Wire past the fracture, into the region of the center distal epiphyseal scar, on both the A/P and lateral view. Once the Ball Nose Guide Wire is at the desired depth, detach the Guide Wire Gripper and remove.

Fig. 9

5. Reaming

Achieve proper alignment of the injured limb prior to reaming and maintain it throughout the reaming process to avoid eccentric reaming. Commence reaming by placing the **8mm Monobloc Reamer (0251-080)**, **Flexible Shaft (0233)** and **9.0-12.5mm Reamer Heads (0234- 090/125)** over the Ball Nose Guide Wire. Ream the canal in half-millimeter increments to a size 1.0mm to 1.5mm larger than the selected nail. Monitor the reaming procedure using image intensification to avoid eccentric or excessive cortex reaming.

6. Nail Selection

NOTE: Generally, a nail diameter 1mm less than the final reamer diameter is chosen. When treating distal tibia fractures with a tibial nail, stresses are increased on the nail's distal portion. For distal tibia fractures, it is recommended that the surgeon use the largest nail diameter that will fit in the canal, without excessive thinning of the cortex.

Slide the **Guide Wire Depth Gauge (0520-000)** onto the Ball Nose Guide Wire until it contacts the bone. Read the measurement that lines up with the etch mark on the guide wire to determine the nail length **(Fig. 10)**.

Fig. 10

7. Nail Insertion

Depending on surgeon preference, two insertion guides are available for the Standard Medial Parapatellar Approach.

Nail Insertion Guide Option 1:
The **Low-Profile Insertion Guide (1235-100) (Fig. 11)** is designed to avoid patellar impingement for those who prefer a low-profile approach. The Low-Profile Insertion Guide may also be used if placing the leg in extension is desired by surgeon.

Nail Insertion Guide Option 2:
The **Extended insertion Guide (1240-100) (Fig. 12)** offers an increase jig length for those who prefer a more percutaneous surgical approach.

Fig. 11

Fig. 12

Place the selected Insertion Guide onto the nail, assuring the correct orientation, by aligning the bevel surfaces on the nail and Insertion Guide (**Fig. 13**). Place the tibial nail **Targeting Module (1238-100)** on the selected Insertion Guide. Insert the **Locking Bolt (1236-000)** and tighten in a clockwise direction using the **Ball Hex Driver (0494-000)** connected to the **T-Handle (0468-000)**. The **Impactor Pad (0837-000)** should be used if impaction is necessary **(Fig. 14)**.

Insert the nail over the Ball Nose Guide Wire and into the canal. If the nail does not enter the tibia easily, use a **Slotted Mallet (0805-000)** and strike against the Impactor Pad surface.

CAUTION: Take care not to strike the Targeting Module with the Slotted Mallet.

CAUTION: Avoid excessive force when inserting the nail. If the nail jams in the canal while inserting, extract it and choose the next-smaller diameter nail or prepare the canal appropriately.

Fig. 13

Fig. 14

Confirm fracture reduction and ensure appropriate nail insertion depth proximally and distally with M/L and A/P fluoroscopy. Verify nail position to ensure that it has not rotated during insertion. The bevel on the nail's proximal end should be centered on the tibia **(Fig. 15)**.

NOTE: If fracture dynamization or compression is desired, countersink the nail by at least 10mm to avoid impingement in the knee joint. The jig is marked by two grooves to indicate static and dynamic or compression placement. Seat the nail to the proximal groove for dynamic locking or to the distal groove for static locking **(Fig. 16)**.

Fig. 15

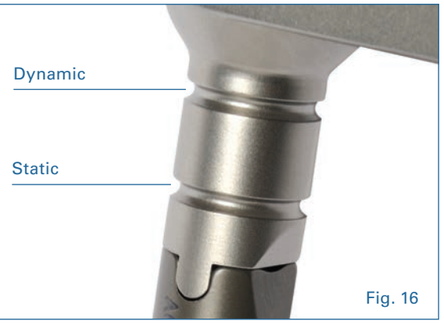


Fig. 16

Nail Locking

Once the nail has been inserted, remove the Ball Nose Guide Wire. Prior to locking both proximally and distally, compress the fracture and check rotational alignment. The nail can be locked either distally or proximally first, depending on surgeon preference. For fracture compression intra-operatively, use the **Reduction Bolt (1237-000) (Fig. 17)**, or the capturing Flush/Compression End Cap **(Fig. 18)** may be used after removal of the Insertion Guide.

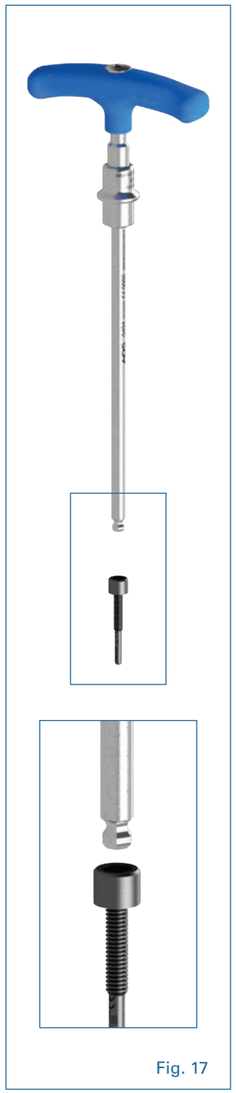


Fig. 17

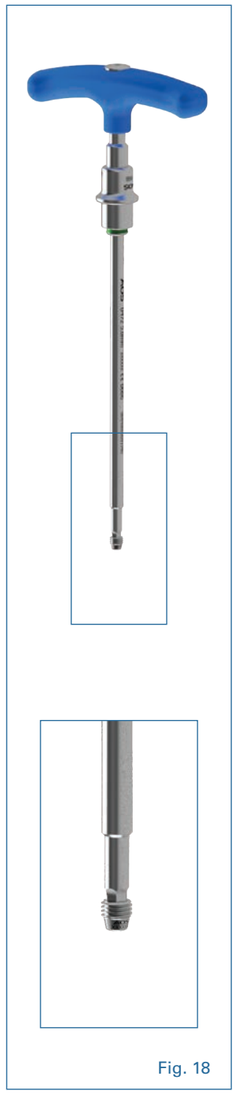


Fig. 18

8. Proximal Locking

Proximal locking includes two (2) statically locked threaded holes and one (1) slot that allows for fracture dynamization, apposition or compression.

9. Compression Locking

A proximal dynamic slot has been incorporated in the nail with an 8mm range of controlled compression. If using compression, countersink the nail by at least 10mm to avoid backing out into the joint. The jig is marked by grooves to indicate static and dynamic compression placement **(see Fig. 16**). Seat the nail to the proximal groove for compression locking.

Compression Locking Option A:
If compression is required it is achieved intra-operatively. Conduct proximal locking in the dynamic mode within the slot and then perform distal locking. Use the Compression Bolt threaded into the Locking Bolt of the Insertion Guide and turn clockwise to push against the proximal screw within the slot, drawing the distal segment towards the fracture site **(Fig. 19A)**.

Alternatively, the Flush/Compression End Cap may be used for compression after removal of the Insertion Guide.

Compression Locking Option B:
If static locking is required in the dynamic slot, conduct proximal locking in the static mode **(Fig. 19B)**.

Compression Locking Option C:
If static locking is required in the superior aspect of the dynamic slot, conduct proximal locking in the static mode utilizing the gold Static Spacer **(Fig. 19C)**.

Fig. 19A

Fig. 19B

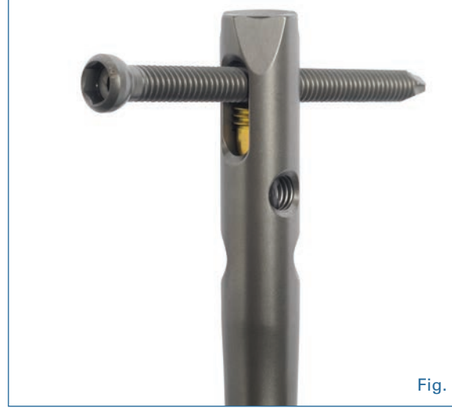


Fig. 19C

Ensure the Targeting Module is securely fastened to the selected Insertion Guide. Tighten the Targeting Module using the self-contained bolt within the Insertion Guide.

Insert the green **Locking Collet (1242-100)** into the locking hole in the Targeting Module and thread in until the clear anodized portion is placed within the Targeting Module locking hole **(Fig. 20A)**. The Locking Collet is now free to place the Sheath and Trochar. After positioning the Sheath and Trochar, turn the Locking Collet clockwise to lock
(Fig. 20B). Alternatively, the Sheath and Trochar may be used freely without utilizing the Locking Collet **(Fig. 20C)**.

NOTE: The Targeting Module is marked to indicate which hole should be used for dynamic or static locking and left or right.

Place the protective **Distal Sheath (0621-100)**, **4.0mm Distal Drill Guide (0315-100)** and **Obturator (0622-000)** through the appropriate locking hole with Locking Collet in the Targeting Module. Make a stab incision and bluntly dissect to the bone **(Fig. 21A)**. When the Trochar is placed against the bone cortex, lock the Sheath and Trochar by turning the green Locking Collet in a clockwise direction until tight. Remove the Trochar.

NOTE: The Drill Guide extends past the Screw Sheath to allow a smaller incision and a more percutaneous approach. When the Drill Guide is assembled in the Screw Sheath, the Drill Guide will sit on bone; the Sheath will not.

Drill the bone using the **4.0mm Calibrated Drill (0219-100)** through the Drill Guide and Sheath, across the tibial canal until the far cortex is penetrated **(Fig. 21B)**. Read the calibration line on the drill bit that lines up with the Drill Guide to determine screw length.

Verify fluoroscopically to assure the proper screw length selection and remove the Calibrated Drill and Drill Guide.

Alternatively, screw length may be determined using the **Proximal Hook Tip Depth Gauge (0507-100) (Fig. 21C)**. Read the calibration line on the Hook Tip Depth Gauge that lines up with the Screw Sheath.

Fig. 20A

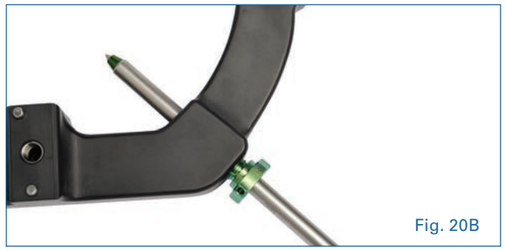


Fig. 20B

Fig. 20C

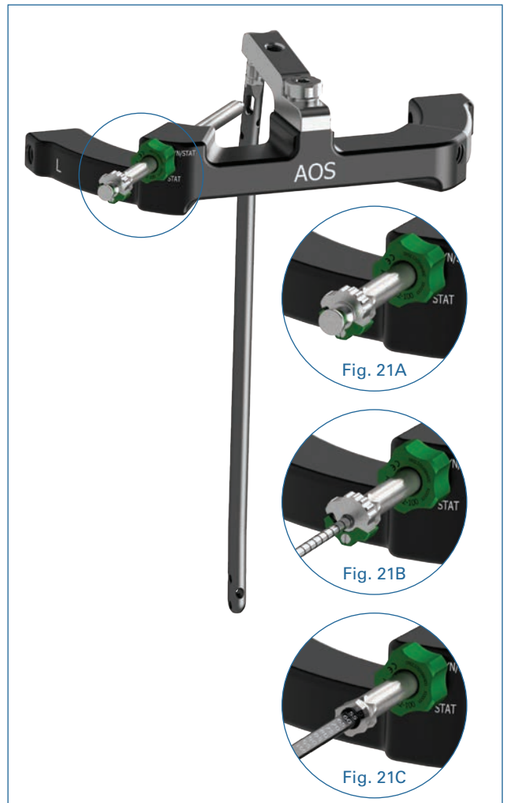


Fig. 21A

Fig. 21B

Fig. 21C

Using the **5.0mm Cannulated Hex Driver (0472-000)**, **Screw Capturing Rod (0476-000)** and T-Handle, attach the screw to the driver **(Fig. 22)**. The screw is captured by threading the Capturing Rod into the head of the screw. Insert the 5.0mm Captured Cortical Screw through the Sheath **(Fig. 23)**. The Cannulated Hex Driver is etched with two laser lines. When these align with the end of the Sheath, the screw head is seated against bone.

Fig. 22

Fig. 23

10. Distal Locking

Distal locking includes two (2) M/L holes and one (1) threaded A/P hole.

Using the 5.0mm Captured Cortical Screw for tibial nails 9mm-11mm diameters. For the 8mm tibial nail diameter, utilize the 4.2mm Captured Cortical Screw.

Distal locking is typically approached from the medial side. Use Fluoroscopy to conduct distal locking utilizing the standard free-hand technique.

NOTE: Accurate C-arm position is confirmed when the distal nail hole appears to be a perfect circle.

Once correct placement has been verified fluoroscopically, make a stab wound in direct alignment with the distal hole.

For 5.0mm Captured Cortical Screws use the **4.0mm Drill (0210-200)** with green color band **(Fig. 24)**. For 4.2mm Captured Cortical Screws use the **3.2mm Drill (0229-000)** with red color band **(Fig. 25)**.

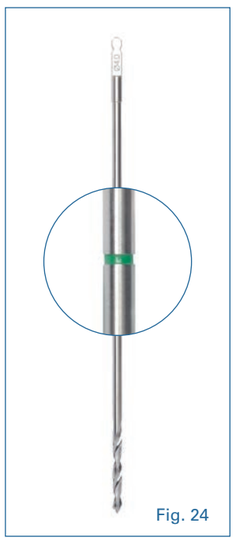


Fig. 24

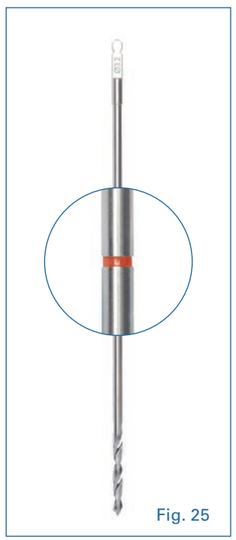


Fig. 25

Drill until the far cortex is penetrated. Verify the drill bit position fluoroscopically prior to taking any measurements. Place the **Distal Depth Gauge (0514-200)** onto the drill bit and advance down to the bone. Read the colored calibration line on the drill bit that corresponds to the calibrations indicated on the Distal Depth Gauge **(Fig. 26)**. Remove the drill bit and advance the selected screw using the Cannulated Hex Driver, Screw Capturing Rod and T-Handle. Repeat above steps for additional screw placement **(Fig. 27)**.

Fig. 26

Fig. 27

11. End Cap Placement

Flush, 5mm and 10mm End Caps are provided in the system to prevent bony in-growth and add length when needed. The Flush End Cap may also be used for compression by pushing against the most proximal screw within the dynamic slot.

Note: End cap placement is made easier using the 5.0mm Cannulated Hex Driver, Screw Capturing Rod and T-handle to capture the selected end cap during insertion **(Fig. 28)**.

Irrigate the joint to ensure that no debris remains. Close the wound.

12. Nail Removal

If the surgeon deems it appropriate to remove the nail, an **Easy-Out Extractor (0812-100)** is used with the impactor Rod to aid in nail extraction.

Locate the top of the nail through an appropriate incision. Remove the End Cap using the 5.0mm Cannulated Hex Driver.

Make the appropriate incisions and remove all locking screws. Remove all overgrown bone around the nails proximal aspect to avoid iatrogenic fracture during nail extraction. Once locking screws are removed, attach the Easy-Out Extractor to the Impactor Rod and use the conical thread to engage the nail threads and cannula. Use the Slotted Mallet to remove the nail.

NOTE: Leaving in one locking screw prior to removal can help to securely fasten Easy-Out Extractor to the nail.

Fig. 28

Blocking Screw Technique

13. Incision and Entry Point

A 1.5-3cm patellar splitting or medial parapatellar incision is made in-line with the intramedullary canal.

The entry point is located just medial to the lateral tibial eminence in the A/P view **(see Fig. 2)** and in-line with the anterior cortex and intramedullary canal in the lateral view **(see Fig. 3)**.

Insert the Curved Cannulated Awl manually to a depth just proximal to the fracture.

NOTE: When creating the initial entry point, ensure the trajectory of the Awl is in line with the axis of the tibia. The correct awl trajectory in the proximal fragment must be established prior to the alignment with the axis of the distal fragment. This ensures accurate fracture reduction when the nail is inserted.

14. A/P Blocking Screw Insertion

In order to prevent varus or valgus malalignment of the proximal fragment, 5.0mm Cannulated Blocking screws may be placed in the A/P plane. Attach the **Blocking Screw Target Arm (1241-000)** to the Curved Cannulated Awl and slide it into the desire position in the A/P plane **(Fig. 29)**. Generally, for proximal third fracture, the A/P Guide Pin is placed on the lateral side.

Finger tighten the Tart Arm to the Awl and insert the **2.0mm Pin Guide (1243-100)** in the appropriate location for the desired nail size (8, 9, 10, or 11mm) **(Fig. 29A)**. Tilt the Target Arm block to determine blocking screw position.

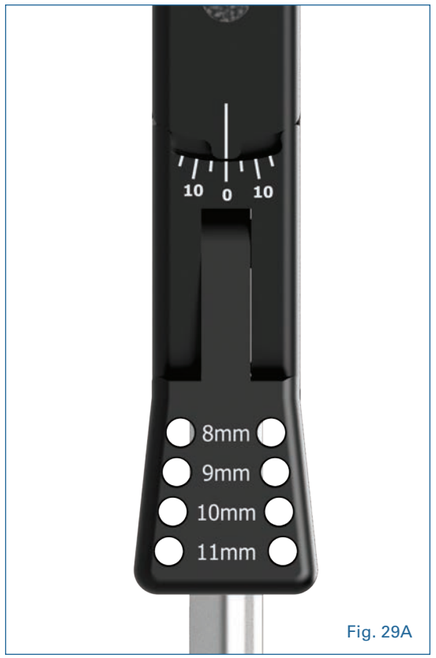


Fig. 29A

Fig. 29

Place a **2.0mm x 30cm Guide Pin (0102-300)** through the Pin Guide and drill both cortices **(Fig. 30)**. Detach the Target Arm for the Awl, then remove the Awl from the proximal tibia. Once the nail is inserted, the Guide Pins can be exchanged for Cannulated Blocking Screws. Screw length is determined using the **Distal Depth Gauge (0514-200)** and reading from the calibrated line on the Guide Pin **(Fig. 31)**. Insert the selected Cannulated Blocking Screw over the Guide Pin with the **5.0mm Cannulated Hex Driver (0472-000)** and T-Handle until the screw engages the far cortex.

Fig. 30

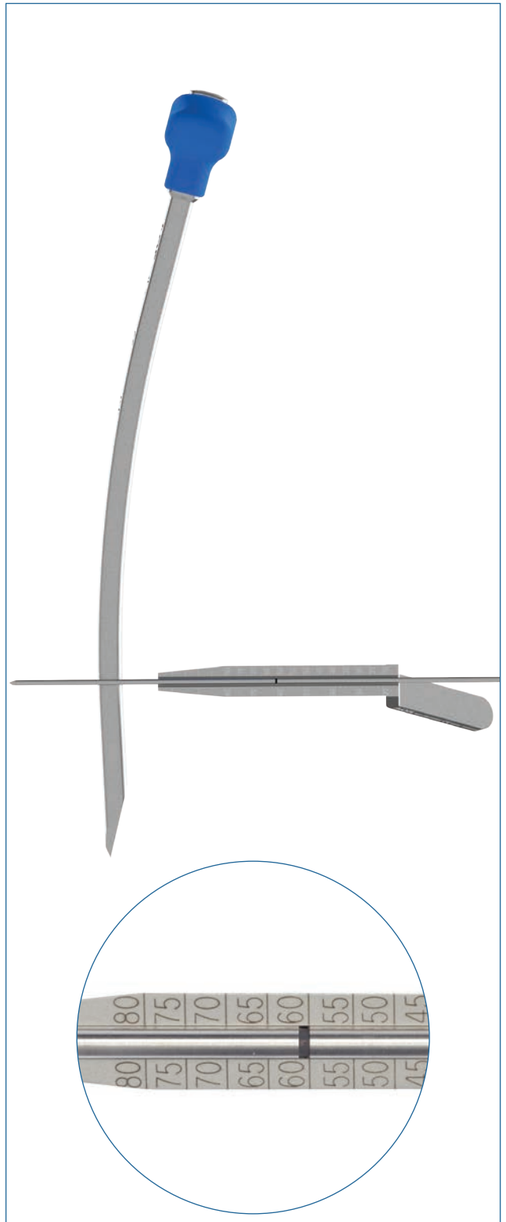


Fig. 31

15. M/L Blocking Screw Insertion

In order to prevent anterior or posterior malalignment of the proximal fragment, 5.0mm Cannulated Blocking screws may be placed in the M/L plane. Attach the Blocking Screw Target Arm to the Curved Cannulated Awl and slide it into the desire position in the M/L plane **(Fig. 32)**. Generally, for proximal third fracture, the A/P Guide Pin is placed on the lateral side.

Finger tighten the Target Arm (A) to the Awl and insert the **2.0mm Pin Guide (1243-100)** in the appropriate location for the desired nail size (8, 9, 10, or 11mm) **(Fig. 32A)**. Tilt the Target Arm block to determine blocking screw position.

Place a 2.0mm x 30cm Guide Pin through the Pin Guide and drill both cortices **(Fig. 33)**. Detach the Target Arm from the Awl, then remove the Awl from the proximal tibia. Once the nail is inserted, the Guide Pins can be exchanged for Cannulated Blocking Screws.

Fig. 32A

Fig. 32

Screw length is determined using the Distal Depth Gauge and reading from the calibrated line on the Guide Pin **(see Fig. 31)**. Insert the selected Cannulated Blocking Screw over the Guide Pin with the 5.0mm Cannulated Hex Driver and T-Handle until the screw engages the far cortex.

16. Confirmation of Blocking Screw Insertion

After implantation of the Cannulated Blocking Screws, obtain both A/P and M/L radiographic images to confirm accurate placement.

Re-inserting the AWL provides a good indication of the nail's insertion trajectory based upon the positon of the Cannulated Blocking Screws. Following of proper screw placement, proceed with nail insertion. Alternatively, the nail can be inserted with the Guide Pins in position, which can be exchanged for Cannulated Blocking Screws.

Fig. 33

Tibial Nail System
Suprapatellar Approach
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Surgical Technique

17. Patient Positioning

The patient is positioned in the supine position on a radiolucent table with the unaffected limb extended away from the affected limb. Using the semi-extended technique, the affected limb should be in 10-20° of flexion and positioned to permit visualization of the fracture with radiography **(Fig. 34)**.

NOTE: To confirm adequate visualization and reduction capabilities, take preliminary radiographic images before the patient is fully prepped and completely draped.

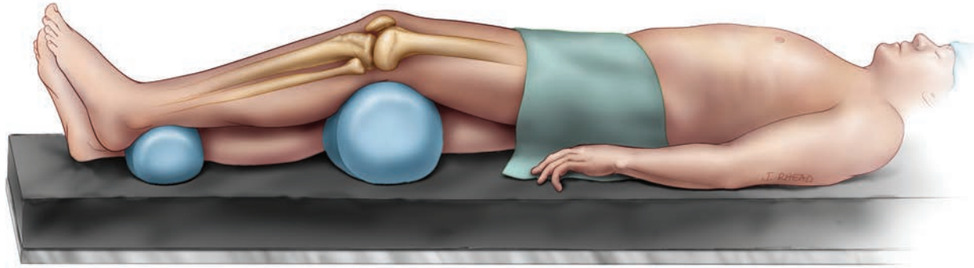

Fig. 34

18. Incision & Entry Point

Make a midline skin incision approximately 1.5 inches in length from upper pole of the patella to the middle of the patella **(Fig. 35)**. Make a second deep incision medial to the patella, cutting the superior two-thirds of the medial retinaculum, but leaving the cuff intact.

Extend the incision 1-2 cm into the quadriceps tension. The incision is through the medial one-third of the quadriceps tendon. Sublux the patella laterally.

The entry point into the tibial intramedullary canal is located just medial to the lateral tibial eminence in the A/P view **(see Fig. 36)**, and in line with the anterior cortex and intramedullary canal in the lateral view **(see Fig. 4)**. Based on surgeon preference, an entry point is made with one of the following two options:

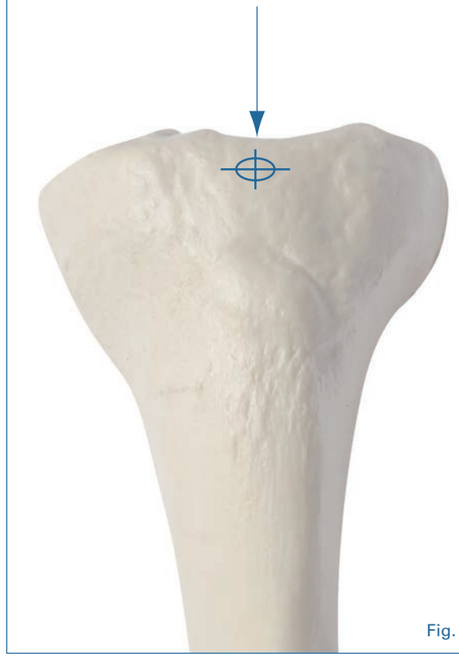

Fig. 35

Option 1: use the **3.2mm x 33cm Guide Pin (0100-000)**,
or
Option 2: use the **Curved Cannulated Awl (0256-000)**.

NOTE: For mid-shaft and distal tibia fractures, a central starting point in the A/P view is adequate. For more proximal fracture, however, a slight lateral starting point is recommend to avoid proximal fragment malalignment.

Fig. 36

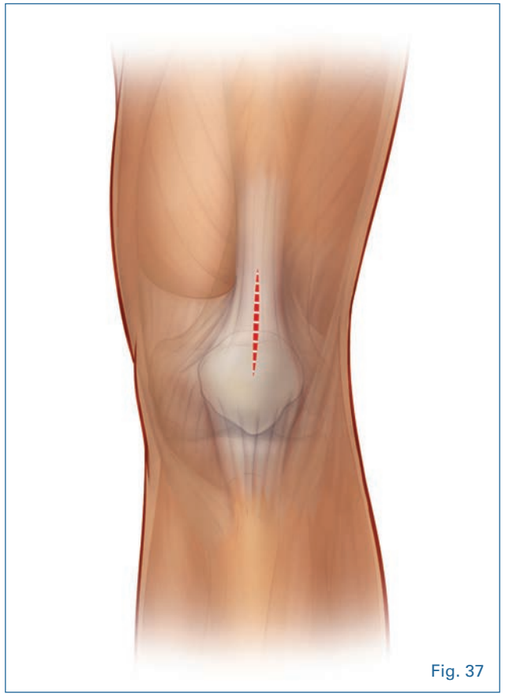

Fig. 37

Intramedullary Entry Option 1 (Pin Guide):
Assemble the Pin Guide (0346-100), **Sheath Handle Assembly (0641-000)**, and **Suprapatellar Entry Sheath (0642-000) (Fig. 38A & 38B)**.

The Sheath Handle Assembly is placed in the proper position over the tibia canal entry point. Once the assembly is placed, the 3.2mm Guide Pin can be inserted through the cannula of the Pin Guide. The guide pin is oriented to the proper position and inserted 1.5-3cm into the tibial metaphysis **(Fig 39)**.

NOTE: Use A/P and lateral fluoroscopic views to confirm accurate placement of the guide pin. If additional stability is desired or needed, the Sheath Handle Assembly can be secured to the femur with pins placed in the selected holes **(Fig. 40)**.

With the guide pin in position and secure, the Pin Guide can be removed from the Entry Tube by rotating the handle counter-clockwise until the threads are disengaged. Then pull the Pin Guide from the Sheath Handle Assembly and Entry Sheath **(Fig. 41)**.

Fig. 38A Fig. 38B

Fig. 39

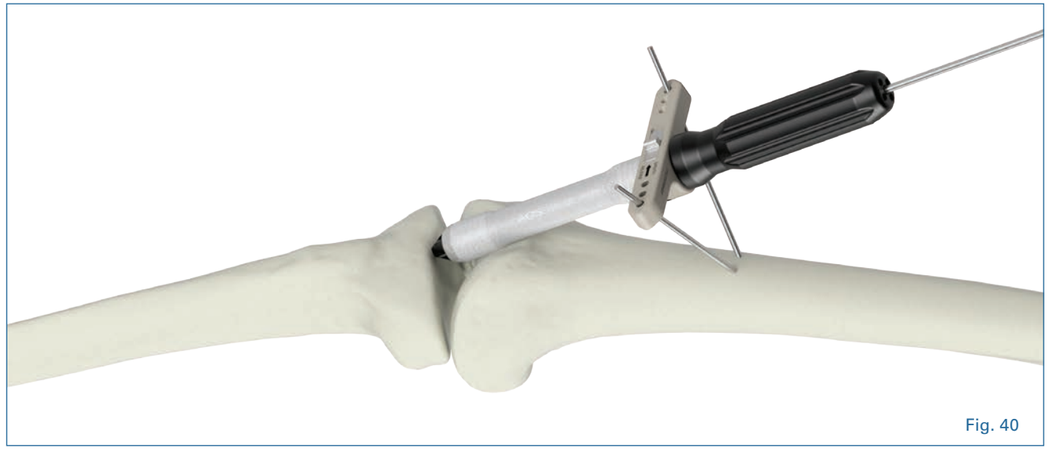

Fig. 40

Fig. 41

Once the Pin Guide is removed from the Suprapatellar Entry Sheath, use the **12mm Cannulated Entry Reamer (0228-100)** through the Suprapatellar Entry Sheath to open the proximal tibia **(Fig. 42)**.

NOTE: The entry reamer is marked to identify the correct reaming depth depending on whether the compression will be used.

Fluoroscopically verify the entry point and direction in both the A/P and lateral views. Once access to the tibial canal has been gained, remove the Guide Pin and place the **3.0mm Ball Nose Guide Wire (0101-900)** into the entry site utilizing the **2.0/3.0mm Guide Wire Gripper (0481-100) (Fig.43)**.

NOTE: The tibial nail compression range is 8mm.

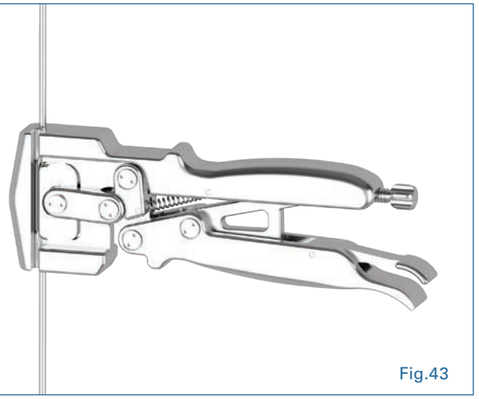

Fig.43

Fig.42

Fig. 44

Fig. 45

Intramedullary Entry Option 2 (Curved Cannulated Awl):
Fluoroscopically verify the entry point and direction in both the A/P and lateral views, then advanced the 9.5mm Curved Cannulated Awl **(Fig. 44)** through the Suprapatellar Entry Sheath and in line with the tibial canal.

Once access to the tibial canal has been gained, place the **3.0mm Ball Nose Guide Wire (0101-900)** through the Curved cannulated Awl **(Fig. 45)** in to the entry site utilizing the **2.0/3.0mm Guide Wire Gripper (0481-100) (see Fig. 43)**.

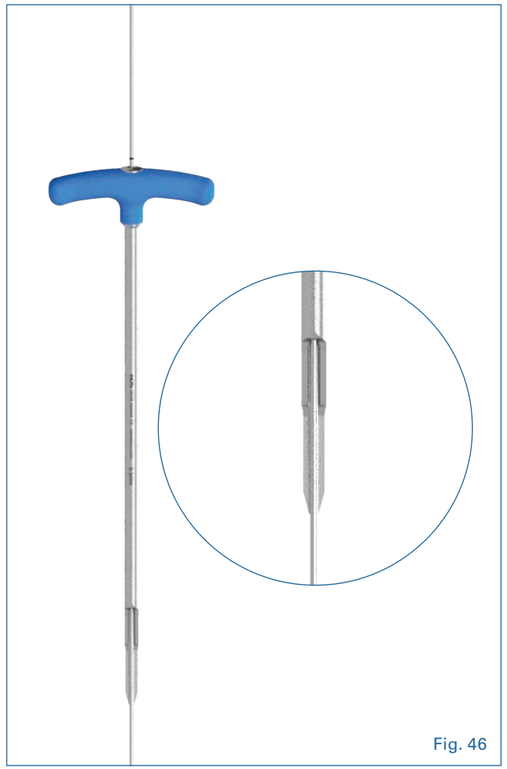

Fig. 46

19. Fracture Reduction

Obtain appropriate anatomic reduction in order to restore length, alignment and rotation of the injured limb. To aid in manipulating the fracture fragments and passing the Ball Nose Guide Wire, a **9.5mm Reduction Tool (0838-000) (Fig. 46)** is available.

Insert the Reduction Tool into the canal and use the curved tip to direct the Ball Nose Guide Wire past the fracture, into the region of the center distal epiphyseal scar, on both the A/P and lateral view. Once the Ball Nose Guide Wire is at the desired depth, detach the Guide Wire Gripper and remove.

20. Reaming

Achieve proper alignment of the injured limb prior to reaming and maintain it throughout the reaming process to avoid eccentric reaming. Commence reaming by placing the **8mm Monobloc Reamer (0251-080)**, **Flexible Shaft (0233)** and **9.0-12.5mm Reamer Heads (0234- 090/125)** over the Ball Nose Guide Wire and through the Suprapatellar Entry Sheath. Ream the canal in half-millimeter increments to a size 1.0mm to 1.5mm larger than the selected nail. Monitor the reaming procedure using image intensification to avoid eccentric or excessive cortex reaming.

21. Nail Selection

NOTE: Generally, a nail diameter 1mm less than the final reamer diameter is chosen. When treating distal tibia fractures with a tibial nail, stresses are increased on the nail's distal portion. For distal tibia fractures, it is recommended that the surgeon use the largest nail diameter that will fit in the canal, without excessive thinning of the cortex.

Slide the **Green Guide Wire Depth Gauge (0520-100)** onto the Ball Nose Guide Wire until it contacts the bone. Read the measurement that lines up with the etch mark on the guide wire to determine the nail length **(Fig. 47)**.

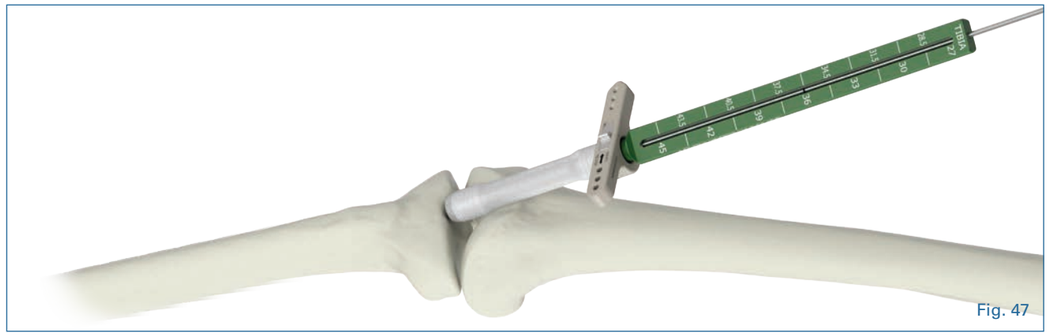

Fig. 47

22. Nail Insertion

The **Suprapatellar Extended Insertion Guide (1255-000) (Fig. 48)** offers an increased jig length and must be used when performing this procedure via the Suprapatellar approach.

Place the Suprapatellar Extended Insertion Guide onto the nail, assuring the correct orientation, by aligning the bevel surfaces on the nail and Insertion Guide **(Fig. 49)**. Place the tibial nail **Targeting Module (1238-100)** on the selected Insertion Guide. Insert the **Locking Bolt (1256-000)** and tighten in a clockwise direction using the **Ball Hex Driver (0494-000)** connected to the **T-Handle (0468-000)**. The **Impactor Pad (0837-000)** should be used if impaction is necessary **(Fig. 50)**.

Insert the nail over the Ball Nose Guide Wire and into the canal. If the nail does not enter the tibia easily use a **Slotted Mallet (0805-000)** and strike against the Impactor Rod surface.

CAUTION: Take care not to strike the Targeting Module with the Slotted Mallet.

CAUTION: Avoid excessive force when inserting the nail. If the nail jams in the canal while inserting, extract it and choose the next-smaller diameter nail or prepare the canal appropriately.

Fig. 48

Fig. 49

Fig. 50

Confirm fracture reduction and ensure appropriate nail insertion depth proximally and distally with M/L and A/P fluoroscopy. Verify nail position to ensure that it has not rotated during insertion. The bevel on the nail's proximal end should be centered on the tibia **(Fig. 51)**.

NOTE: If fracture dynamization or compression is desired, countersink the nail by at least 10mm to avoid impingement in the knee joint. The jig is marked by two grooves to indicate static and dynamic or compression placement. Seat the nail to the proximal groove for dynamic locking or to the distal groove for static locking **(Fig.52)**.

Nail Locking

Once the nail has been inserted, remove the Ball Nose Guide Wire. Prior to locking both proximally and distally, compress the fracture and check rotational alignment. The nail can be locked either distally or proximally first, depending on surgeon preference. For fracture compression intra-operatively, use the **Compression Bolt (1257-000) (Fig. 53)**, or the capturing Flush/Compression End Cap **(Fig. 54)** may be used after removal of the Insertion Guide.

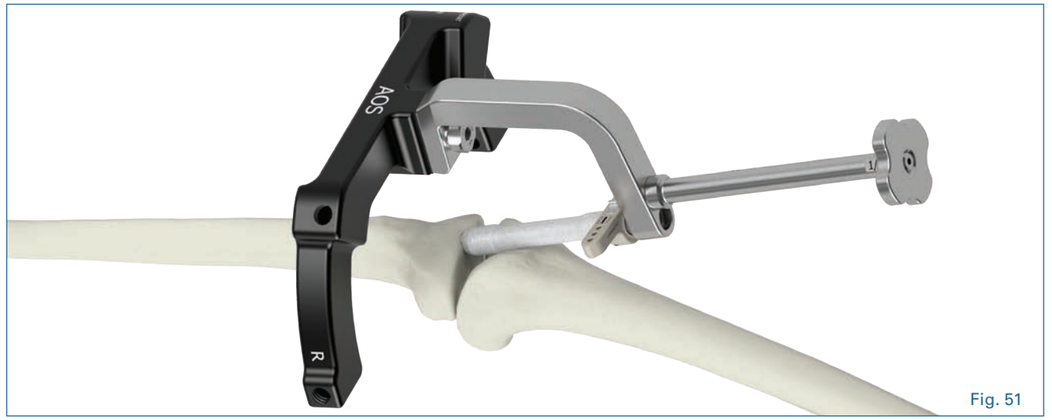

Fig. 51

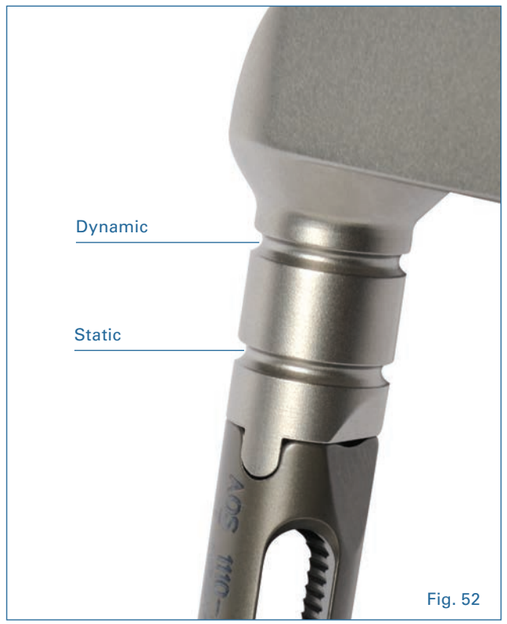

Fig. 52

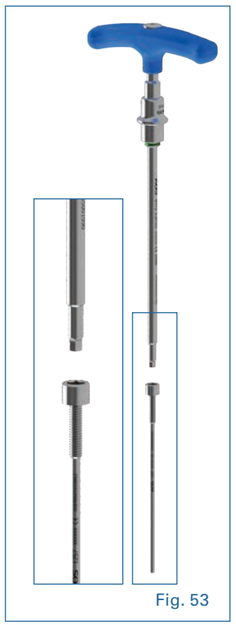

Fig. 53

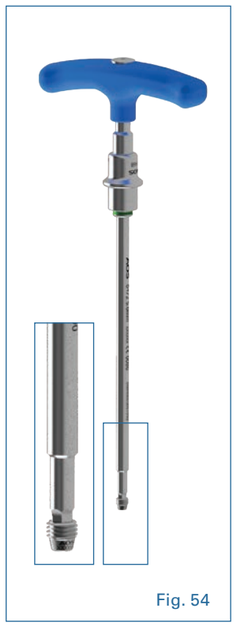

Fig. 54

23. Proximal Locking

Proximal locking includes two (2) statically locked threaded holes and one (1) slot that allows for fracture dynamization, apposition or compression.

24. Compression Locking

A proximal dynamic slot has been incorporated in the nail with an 8mm range of controlled compression. If using compression, countersink the nail by at least 10mm to avoid backing out into the joint. The jig is marked by grooves to indicate static and dynamic compression placement **(see Fig. 49)**. Seat the nail to the proximal groove for compression locking.

Compression Locking Option A:
If compression is required, it is achieved intra-operatively. Conduct proximal locking in the dynamic mode within the slot and then perform distal locking. Use the Compression Bolt threaded into the Locking Bolt of the Insertion Guide and turn clockwise to push against the proximal screw within the slot, drawing the distal segment towards the fracture site **(Fig. 55A)**.

Alternatively, the Flush/Compression End Cap may be used for compression after removal of the Insertion Guide.

Compression Locking Option B:
If static locking is required in the dynamic slot, conduct proximal locking in the static mode **(Fig. 55B)**.

Compression Locking Option C:
If static locking is required in the superior aspect of the dynamic slot, conduct proximal locking in the static mode utilizing the gold Static Spacer **(Fig. 55C)**.

Ensure the Targeting Module is securely fastened to the selected Insertion Guide. Tighten the Targeting Module using the self-contained bolt within the Insertion Guide.


Fig. 55A


Fig. 55B


Fig. 55C

Insert the green **Locking Collet (1242-100)** into the locking hole in the Targeting Module and thread in until the clear anodized portion is placed within the Targeting Module locking hole **(Fig. 56A)**. The Locking Collet is now free to place the Sheath and Trochar. After positioning the Sheath and Trochar, turn the Locking Collet clockwise to lock **(Fig. 56B)**. Alternatively, the Sheath and Trochar may be used freely without utilizing the Locking Collet **(Fig. 56C)**.

NOTE: The Targeting Module is marked to indicate which hole should be used for dynamic or static locking and left or right.

Place the protective **Distal Sheath (0621-100)**, **4.0mm Distal Drill Guide (0315-100)** and **Obturator (0622-000)** through the appropriate locking hole with Locking Collet in the Targeting Module. Make a stab incision and bluntly dissect to the bone **(Fig. 57A)**. When the Trochar is placed against the bone cortex, lock the Sheath and Trochar by turning the green Locking Collet in a clockwise direction until tight. Remove the Trochar.


Fig. 56A

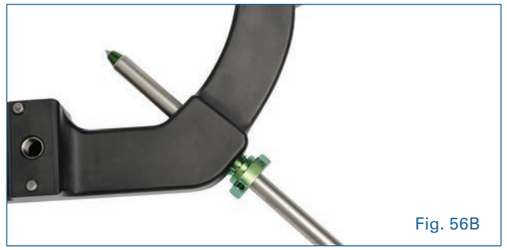
Fig. 56B


Fig. 56C

NOTE: The Drill Guide extends past the Screw Sheath to allow a smaller incision and a more percutaneous approach. When the Drill Guide is assembled in the Screw Sheath, the Drill Guide will sit on bone; the Sheath will not.

Drill the bone using the **4.0mm Calibrated Drill (0219-100)** through the Drill Guide and Sheath, across the tibial canal until the far cortex is penetrated **(Fig. 57B)**. Read the calibration line on the drill bit that lines up with the Drill Guide to determine screw length.

Verify fluoroscopically to assure the proper screw length selection and remove the Calibrated Drill and Drill Guide.

Alternatively, screw length may be determined using the **Proximal Hook Tip Depth Gauge (0507-100) (Fig. 57C)**. Read the calibration line on the Hook Tip Depth Gauge that lines up with the Screw Sheath.

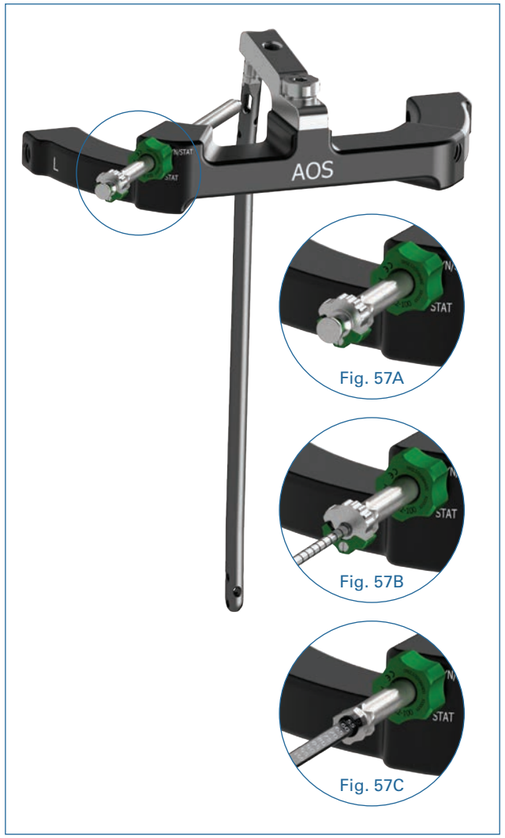

Fig. 57A
Fig. 57B
Fig. 57C

Fig. 58

Using the **5.0mm Cannulated Hex Driver (0472-000)**, **Screw Capturing Rod (0476-000)** and T-Handle, attach the screw to the driver **(Fig. 58)**. The screw is captured by threading the Capturing Rod into the head of the screw. Insert the 5.0mm Captured Cortical Screw through the Sheath **(Fig. 59)**. The Cannulated Hex Driver is etched with two laser lines. When these align with the end of the Sheath, the screw head is seated against bone.

Fig. 59

25. Distal Locking

Distal locking includes two (2) M/L holes and one (1) threaded A/P hole.

Using the 5.0mm Captured Cortical Screw for tibial nails 9mm-11mm diameters. For the 8mm tibial nail diameter, utilize the 4.2mm Captured Cortical Screw.

Distal locking is typically approached from the medial side. Use fluoroscopy to conduct distal locking utilizing the standard free-hand technique.

NOTE: Accurate C-arm position is confirmed when the distal nail hole appears to be a perfect circle.

Once correct placement has been verified fluoroscopically, make a stab wound in direct alignment with the distal hole.

For 5.0mm Captured Cortical Screws use the **4.0mm Drill (0210-200)** with green color band **(Fig. 60)**. For 4.2mm Captured Cortical Screws use the **3.2mm Drill (0229-000)** with red color band **(Fig. 61)**.

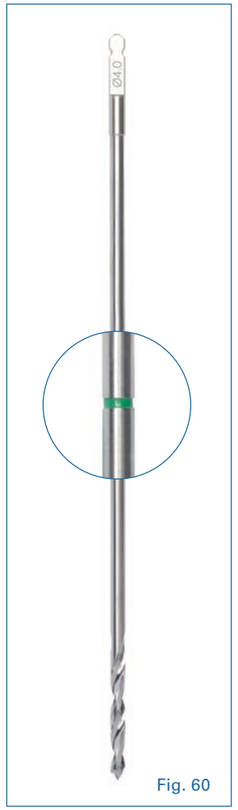

Fig. 60

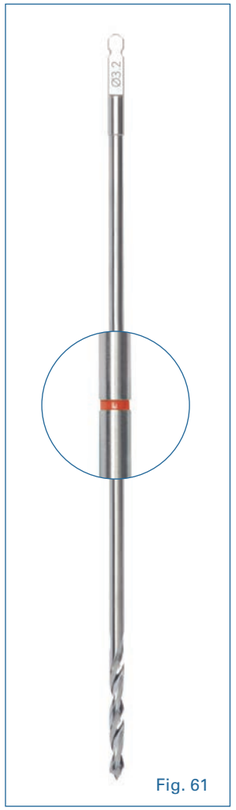

Fig. 61

Drill until the far cortex is penetrated. Verify the drill bit position fluoroscopically prior to taking any measurements. Place the **Distal Depth Gauge (0514-200)** onto the drill bit and advance down to the bone. Read the colored calibration line on the drill bit that corresponds to the calibrations indicated on the Distal Depth Gauge **(Fig. 62)**. Remove the drill bit and advance the selected screw using the Cannulated Hex Driver, Screw Capturing Rod and T-Handle. Repeat above steps for additional screw placement **(Fig. 63)**.

Fig. 62

Fig. 63

26. End Cap Placement

Flush, 5mm and 10mm End Caps are provided in the system to prevent bony in-growth and add length when needed. The Flush End Cap may also be used for compression by pushing against the most proximal screw within the dynamic slot.

Note: End cap placement is made easier using the 5.0mm Cannulated Hex Driver, Screw Capturing Rod and T-handle to capture the selected end cap during insertion **(Fig. 64)**.

Irrigate the joint to ensure that no debris remains. Close the wound.

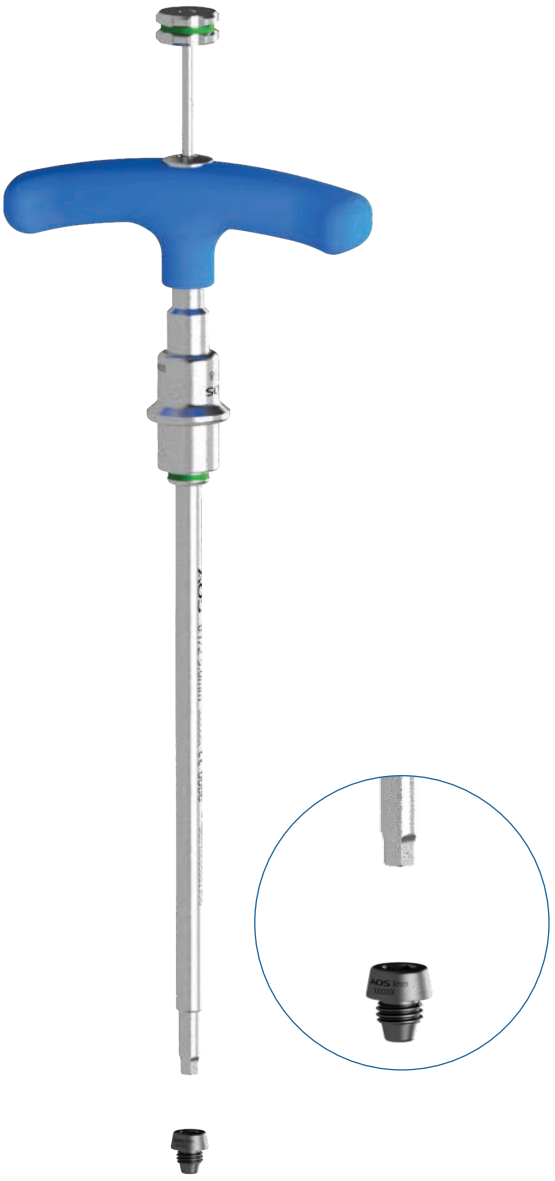

Fig. 64