AOS Advanced orthopaedic solutions



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10 V System

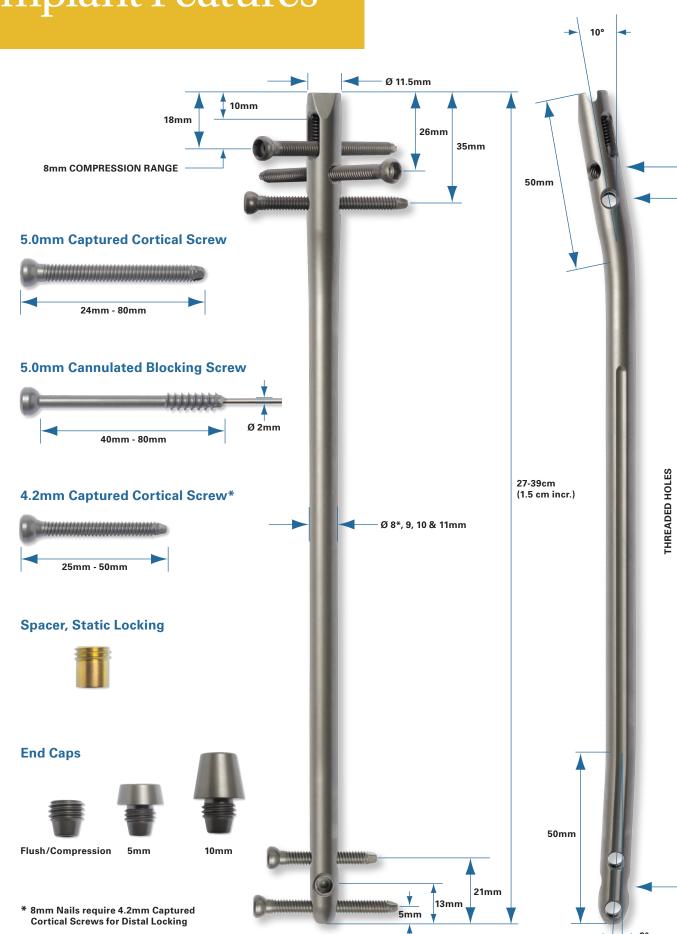
Surgical Technique

Contents

IMPLANT FEATURES	2
1. INDICATIONS	3
2. PATIENT POSITIONING	3
3. INCISION & ENTRY POINT	4-6
4. FRACTURE REDUCTION	7-8
5. REAMING	8
6. NAIL SELECTION	8
7. NAIL LENGTH SELECTION	8
8. NAIL INSERTION	9-12
9. NAIL LOCKING	13
10. PROXIMAL LOCKING	14
11. COMPRESSION LOCKING	14-20
12. DISTAL LOCKING	20-21
13. END CAP PLACEMENT	21
14. NAIL REMOVAL	22
15. BLOCKING SCREW TECHNIQUE: Incision & Entry Point22	
16. A/P BLOCKING SCREW INSERTION	22-23
17. M/L BLOCKING SCREW INSERTION	24
18. CONFIRMATION OF BLOCKING SCREW INSERTION	24

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.

Implant Features

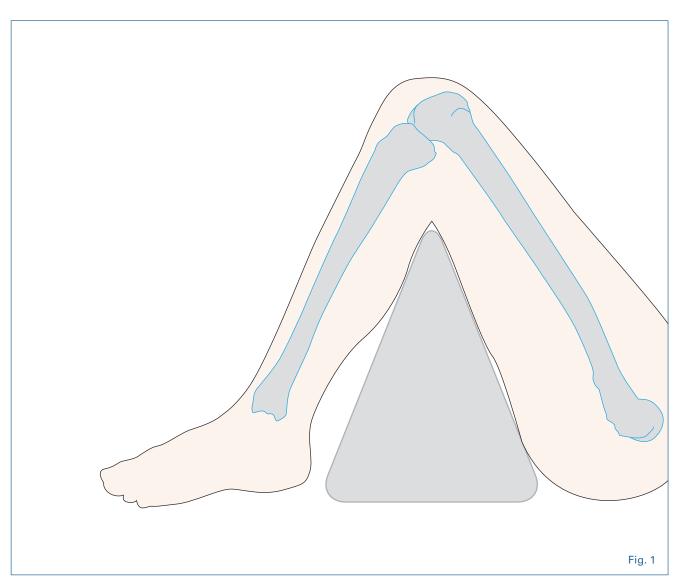


Tibial Nail System Surgical Technique

1. Indications

The AOS Tibial Nail System is intended to provide temporary stabilization of various types of fractures, malunions 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 fractures
- Fractures with bone loss and bone transport
- Open and closed fractures, pathologic fractures
- Corrective osteotomies
- Pseudarthrosis of the tibial shaft
- Non-unions, malunions, metaphyseal and epiphyseal fractures



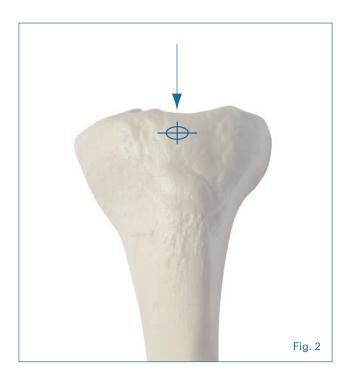
2. Patient Positioning

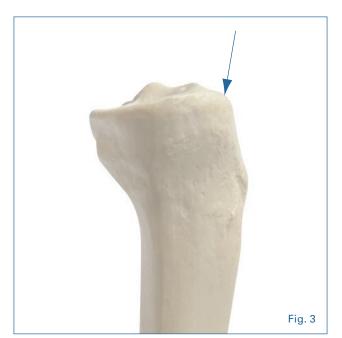
Position the patient supine on a radiolucent table. Knee flexion will assist with identification of the anatomic landmarks to allow accurate incision placement (Fig. 1). For ease of distal locking from the medial direction, it is helpful to place the C-arm on the opposite side of the injured limb.

3. 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 (Fig. 2), and in-line with the anterior cortex and intramedullary canal in the lateral view (Fig. 3). An entry point is made either with a 3.2mm x 33cm Guide Pin (0100) option 1 or a Curved Cannulated Awl (0213) option 2, based on surgeon preference.





Option 1:

The 3.2mm Guide Pin may be placed using the Entry Tube (0612) and 3.2mm Pin Guide (0310). Orientate the Entry Tube and Pin Guide into the proper position and insert the Guide Pin into the tibial metaphysis 1.5-3cm (Fig. 4). Use A/P and lateral fluoroscopic views to confirm accurate placement of the guide pin. For midshaft and distal tibia fractures, a central starting point in the A/P view is adequate. For more proximal fractures, however, a slightly lateral starting point is recommended to avoid proximal fragment malalignment.



Remove the Pin Guide from the Entry Tube and use the **12mm** Cannulated Entry Reamer (0228) through the Entry Tube to open the proximal tibia (Fig. 5). The entry reamer is marked Fluoroscopically verify the entry point and direction in both to identify the correct reaming depth depending on whether the A/P and lateral views then advance the 9.5mm Curved compression will be used. The tibial nail compression range Cannulated Awl (Fig. 6) in line with the tibial canal. is 8mm.



Option 2:



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 (0419) (Fig. 8).

Note: For option 1, place the Ball Nose Guide Wire directly into the entry site utilizing the Guide Wire Gripper.

4. Fracture Reduction

the fracture, into the region of the center distal epiphyseal scar, on both the A/P and lateral view. Once the Ball Nose Obtain appropriate anatomic reduction in order to restore Guide Wire is at the desired depth, detach the Guide Wire length, alignment and rotation of the injured limb. Gripper and remove.

To aid in manipulating the fracture fragments and passing To assist in removal of the Guide Wire Gripper slide the the Ball Nose Guide Wire, a 9.5mm **Reduction Tool (0811)** Obturator (0227) into the back of the Guide Wire Gripper (Fig. 9) is available. Insert the Reduction Tool into the canal during extraction in order to maintain the Ball Nose Guide and use the curved tip to direct the Ball Nose Guide Wire past Wire's position within the canal (Fig. 10A & Fig. 10B).









5. Reaming

Achieve excellent 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 (0235-080), 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. Use the Obturator to prevent the Guide Wire from backing out, as previously described.

6. Nail Selection

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.

7. Nail Length Selection

Slide the **Guide Wire Depth Gauge (0520)** 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. 11)**.





8. Nail Insertion

Depending on surgeon preference, two insertion guides are available.

Option 1:

The **Low-Profile Insertion Guide (1235)** 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 **(Fig. 12)**.

Option 2:

The **Extended Insertion Guide (1240)** offers an increased jig length for those who prefer a more percutaneous surgical approach (**Fig. 13**).





Place the selected Insertion Guide onto the nail assuring the correct orientation by aligning the bevel surfaces on the nail and Insertion Guide (Fig. 14). Place the tibial nail **Targeting Module (1238)** on the selected Insertion Guide. Insert the Locking Bolt (1236) and tighten in a clockwise direction using the Ball Hex Driver (0406) connected to the **T-Handle (0411)**. The Impactor Rod (0810) should be used if impaction is necessary (Fig. 15).





Insert the nail over the Ball Nose Guide Wire into the canal. If the nail does not enter the tibia easily use a Slotted Mallet (0805) and strike against the Impactor Rod surface. Take care not to strike the Targeting Module with the Slotted Mallet. Avoid excessive force when inserting the nail. If the nail jams in the canal, extract it and choose the next-smaller diameter nail or prepare the canal appropriately.

Confirm fracture reduction and ensure appropriate nail insertion depth proximally and distally with $\ensuremath{\text{M/L}}$ 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. 16).





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. 17).

9. 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 (1237) or the capturing Flush/Compression End Cap may be used after removal of the Insertion Guide (Fig 18A & Fig. 18B).



10. Proximal Locking

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

11. 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 (Fig 19). Seat the nail to the proximal groove for 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 conduct 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.

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

Option B:

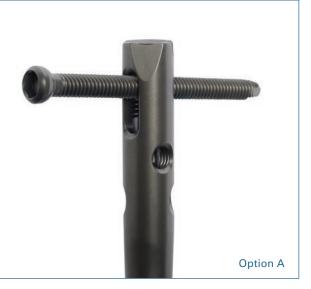
If static locking is required in the dynamic slot, conduct proximal locking in the static mode.

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.







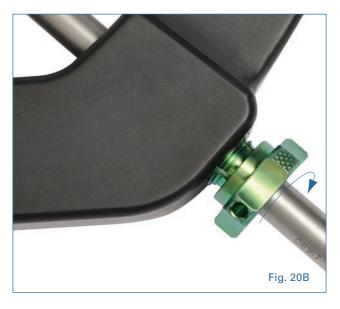


Ensure the Targeting Module is securely fastened to the selected Insertion Guide. Tighten the Targeting Module using the self-contained bolt within the Insertion Guide.

Insert the green Locking Collet (1242) 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 postioning 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).









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

Place the protective Sheath (0600), 4.0mm Drill Guide (0308) and Trochar (0608) through the appropriate locking hole with Locking Collet in the Targeting Module. Make a stab incision and bluntly dissect to the bone (Fig. 21). 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.



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

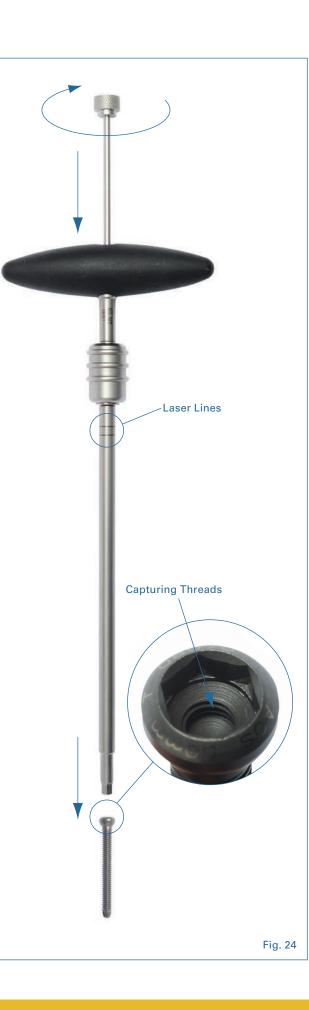




Alternatively, screw length may be determined using the **Proximal Hook Tip Depth Gauge (0507) (Fig. 23)**. Read the calibration line on the Hook Tip Depth Gauge that lines up with the Screw Sheath.

Using the **5.0mm Cannulated Hex Driver (0421)**, **Screw Capturing Rod (0422)** and T-Handle attach the screw to the driver (**Fig. 24**). 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. 25**). The Cannulated Hex Driver is etched with two laser lines. When these align with end of Sheath the screw head is seated against bone.







12. Distal Locking

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

Use 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. 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) with green color band (Fig. 26). For 4.2mm Captured Cortical Screws use the 3.2mm Drill (0229) with red color band (Fig. 27). Drill until the second cortex is penetrated.

Verify the drill bit position fluoroscopically prior to taking any measurements. Place the Distal Depth Gauge (0514) 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. 28). 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. 29).





13. 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.

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. 30).

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



14. Nail Removal

If the surgeon deems it appropriate to remove the nail, an Easy Out Extractor (0812) 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 nail's 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 the Easy Out Extractor to the nail.

15. Blocking Screw Technique: Incision and Entry Point

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

The entry point is located just medial to the lateral tibial eminence in the A/P view (See Page 4, Fig. 2) and in-line with the anterior cortex and intramedullary canal in the lateral view (See Page 4, 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 alignment with the axis of the distal fragment. This ensures accurate fracture reduction when the nail is inserted.

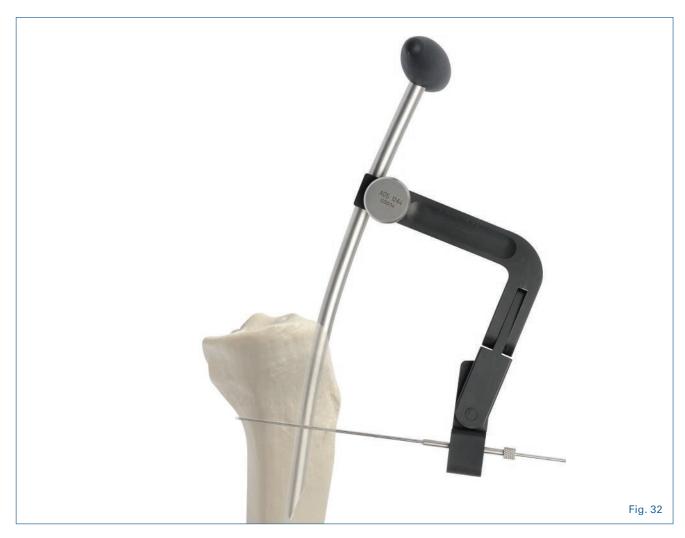
16. A/P Blocking Screw Insertion

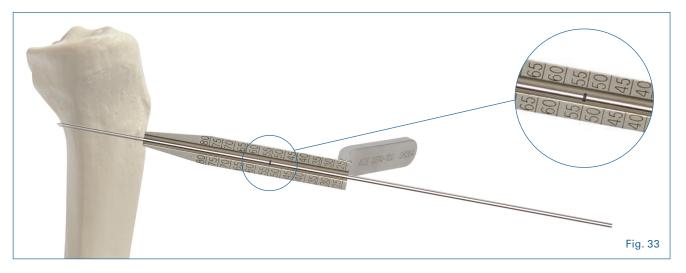
In order to prevent varus or valgus malalignment of the proximal fragment 5.0mm Cannulated Blocking Screws may be placed in the A/P plane. Attach the Blocking Screw Target Arm (1241) to the Curved Cannulated Awl and slide it into the desired position in the A/P plane (Fig. 31). Generally, for proximal third fractures 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) in the appropriate location for the desired nail size (8, 9, 10, or 11mm) (Fig. 31A). Tilt the Target Arm block to determine blocking screw position.



Place a 2.0mm x 30cm Guide Pin (0102-300) through reading from the calibrated line on the Guide Pin (Fig. 33). the Pin Guide and drill both cortices (Fig. 32). Detach the Insert the selected Cannulated Blocking Screw over the Guide Pin with the 5.0mm Cannulated Hex Driver (0421) and Target Arm from the Awl, then remove the Awl from the proximal tibia. Once the nail is inserted, the Guide Pins can T-Handle until the screw engages the far cortex. be exchanged for Cannulated Blocking Screws. Screw length is determined using the Distal Depth Gauge (0514) and





17. 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 desired position in the M/L plane (**Fig. 34**). Generally, on proximal third fractures the Guide Pin is placed posteriorly to the nail (medial to lateral).

Finger tighten the Target Arm to the Awl and insert the 2.0mm Pin Guide in the appropriate location for the desired nail size (8, 9, 10 or 11mm) (**Fig. 34A**). 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. 35**).



Detach the Target Arm from the Awl, then remove the Awl from the proximal tibia. Screw length and insertion follows the previously described technique.

Note: Due to the curvature of the Awl, flouroscopy is used to verify the selected hole location for the Guide Wire.

18. 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 position of the Cannulated Blocking Screws. Following confirmation 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.

