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**MR Information**

The Titanium Tibial Nail System has not been evaluated for safety and compatibility in the MR environment. It has not been tested for heating, migration or image artifact in the MR environment. The safety of the Titanium Tibial Nail System in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.
**Indications for the Titanium Tibial Nail**

The Titanium Solid Tibial Nail is intended to stabilize fractures of the tibia. Specifically, it is intended for Grades I and II open tibial diaphyseal fractures; high energy, unstable closed fracture patterns; comminuted fractures of tibias with small medullary canals; and certain pre- and postisthmic fractures.

The Titanium Cannulated Tibial Nail is intended to stabilize fractures of the tibia. Indications include, but are not limited to, open and closed tibial shaft fractures; certain pre- and postisthmic fractures; tibial malunions and tibial nonunions.
Proximal and distal locking hole configurations provide a choice of locking options, both static and dynamic, to accommodate the fracture pattern and soft-tissue injury:

**CASE 1**

**Diaphyseal fracture**
Locked dynamically, with proximal and distal locking bolts or locking screws in the frontal plane.

*Note:* Results from case reports are not necessarily predictive of results in other cases. Results in other cases may vary.
CASE 2

Fracture involving the proximal third component

Locked statically, the oblique superior locking bolt or locking screw improves control of proximal third fractures.
CASE 3

Distal fracture

Locked with distal locking bolts or locking screws in both the sagittal and frontal planes.

Distal AP interlocking allows placement of perpendicular bolts or screws for more secure fixation of the short distal fragment.
Use the preoperative planner ruler to determine nail length and nail diameter.

**Note:** There are two templates available for use: true size and 115% magnification. The template image is magnified 15% to account for average radiograph magnification; however, variations in magnification levels are common.

When selecting nail size, consider canal diameter, fracture pattern, and postoperative protocol.
INSTRUMENTS FOR OPENING THE TIBIA

- ComPact Air Drive II
  - 511.701

- Double Air Hose
  - 519.51S

- 2.5 mm Threaded Guide Wire
  - 900.723

- Jacob’s Chuck with Key
  - 511.73

- 11.0 mm Cannulated Drill Bit
  - 360.06

- 12.0 mm Drill Sleeve
  - 360.17

- Medullary Canal Length Gauge (optional)
  - 356.55

- Radiographic Ruler, for Tibial Nails
  - 356.59
Position the patient
Position the patient supine on a radiolucent operating table. Ensure that the knee of the injured leg can be flexed at least 90°, and x-ray visualization of the entire tibia is possible in both the AP and lateral views. Temporary reduction and stabilization can be accomplished by manual pressure at the fracture site, or by application of a sterile tourniquet or elastic bandage around the fracture. Alternatively, the Large Distractor may be used on the medial side, with the insertion of Schanz screws, in the frontal plane, as close as possible to each tibial end. At the surgeon's discretion, the procedure can be performed on a fracture table with the leg placed in traction.

Confirm nail length
Position the image intensifier for an AP view of the distal tibia. With a long forceps, hold the ruler alongside the leg, parallel to and at the same level as the tibia. Adjust the ruler until the distal tip is at the level of the physeal scar or the desired nail insertion depth. Mark the skin at the bottom of the ruler.

Move the image intensifier to the proximal tibia, replace the distal end of the ruler at the skin mark, and take an AP image of the proximal tibia. Read nail length directly from the ruler image, selecting the measurement at or just below the level of the anterior edge of the tibial plateau.

When using the Large Distractor, measure the distance from the inferior border of the distal pin to the superior border of the proximal pin to determine optimal nail length.

Precautions:
- Instruments and screws may have sharp edges or moving joints that may pinch or tear user's glove or skin.
- Handle devices with care and dispose worn bone cutting instruments in an approved sharps container.
Identify nail entry point
The entry point for the nail is in line with the medullary canal in the AP view, and is at the anterior edge of the tibial plateau. The location of the entry point in relation to the tibial tubercle varies with patient anatomy.

Make a longitudinal incision over the midline of the tubercle, extending proximally.

Retract the patellar tendon laterally, or split the tendon, depending on surgeon preference and patient anatomy. Insert the 2.5 mm Threaded Guide Wire [900.723] through the incision to the entry point. Under an AP image intensification view, center the guide wire in line with the medullary canal.

Note: For treatment of fractures involving the proximal third component refer to the section titled Fractures Involving Proximal Third Component (page 20).
Open the canal

With a power drill or hand chuck, insert the 2.5 mm guide wire through the metaphysis and into the medullary canal. Direct the wire so it is parallel to the anterior cortex and closely approximates the 9° angulation of the proximal nail. To ensure correct wire placement, hold a sterile nail anterior to the tibia and use it as an angle guide. Confirm wire placement with the image intensifier.

Place the 11.0 mm Cannulated Drill Bit into a cannulated drill and place the 12.0 mm Drill Sleeve [360.17] over the guide wire. Place the drill bit over the 2.5 mm guide wire and through the drill sleeve. Drill an opening into the medullary canal to a depth of approximately 100 mm. Remove the drill, guide wire and drill sleeve.

Confirm nail length (optional)

Insert the Medullary Canal Length Gauge [356.55] into the tibia. Use the C-arm to verify insertion depth. Read nail length directly from the gauge at the entry site.
Under image intensification, reduce the fracture and insert the appropriate reaming rod into the canal to the level of the distal metaphysis.

Ream in 0.5 mm increments, and advance the reamer with steady, moderate pressure. **Do not force the reamer.** Partially retract the reamer often to clear debris from the medullary canal.

Ream to a diameter 0.5 mm to 1.0 mm greater than nail diameter.

After reaming, remove the reaming assembly. Pass the Medullary Tube [355.006] down the reamed canal, over the reaming rod.

Remove the reaming rod and insert the Guide Rod, with smooth tip, through the Medullary Tube.

Remove the Medullary Tube, leaving the guide rod in position for insertion of the cannulated nail.
INSTRUMENTS FOR INSERTING THE NAIL

Titanium Tibial Nail Insertion Handle
356.511

Combination Wrench
321.16

Slotted Hammer
332.20

Insertion Bolt for Titanium Solid Tibial Nails
356.542

Inserter-Extractor for Titanium Tibial and Humeral Nails
356.49

Insertion Bolt for Titanium Cannulated Tibial Nails
356.544

Cannulated Socket Wrench
355.14

Driving Head
355.18
Assemble the insertion instruments
Orient the insertion handle anteriorly, and match the flats on the handle and nail.

For solid nails, select the Insertion Bolt for Titanium Solid Tibial Nails [356.542]. For cannulated nails, select the Insertion Bolt for Titanium Cannulated Tibial Nails [356.544].

Place the insertion bolt into the insertion handle and thread it into the proximal nail end. Tighten the insertion bolt with the Cannulated Socket Wrench [355.14], but do not overtighten.

Thread the Inserter-Extractor onto the threaded post of the insertion handle.

Note: Do not attach the aiming arm for nail insertion.
For solid nails, place the nail into the tibial opening with the insertion handle oriented anteriorly.

For cannulated nails, place the nail over the guide rod and into the tibial opening with the insertion handle oriented anteriorly.

Verify fracture reduction and insert the nail as far as possible by hand. Monitor nail passage across the fracture under image intensification.

With the leg in flexion, use light blows of the slotted hammer on the Inserter-Extractor until the top of the nail is at or below the tibial opening.

**Note:** The nail must be fully inserted in flexion.
INSTRUMENTS FOR LOCKING PROXIMALLY

FOR ALL TIBIAL NAILS

- ComPact Air Drive II
  511.701
- Quick Coupling for Drill Bits
  511.75
- Locking Bolt Measuring Device
  357.792
- Hexagonal Screwdriver
  314.75
- Hose
   519.51S
- 11.0 mm/8.0 mm Protection Sleeve
  355.70
- 8.0 mm Trocar
  355.75
- Titanium Tibial Nail Insertion Handle
  356.511
- Titanium Tibial Nail Aiming Arm
  356.521
For 8 mm and 9 mm diameter Tibial Nails
(3.9 mm Locking Bolts)

- 8.0 mm/3.2 mm Drill Sleeve
  - 355.72

For 10 mm – 13 mm diameter Tibial Nails
(4.9 mm Locking Bolts)

- 8.0 mm/4.0 mm Drill Sleeve
  - 357.71

- 4.0 mm Three-Fluted Calibrated Drill Bit,
  - 215 mm, 80 mm calibration, quick coupling
  - 356.982

For 8 mm and 9 mm diameter Tibial Nails
(3.9 mm Locking Bolts)

- 3.2 mm Three-Fluted Calibrated Drill Bit,
  - 215 mm, 80 mm calibration, quick coupling
  - 356.97
Proximal locking can be achieved with the leg in full extension. This neutralizes the deforming forces on proximal fragments caused by the quadriceps mechanism and relieves the pressure on soft tissue usually associated with tibial nail insertion instruments. This position also facilitates assessment of rotational alignment prior to locking.

**Note:** If, after primary static fixation, callus formation fails to occur and/or in the event of fragment diastasis, secondary dynamisation is carried out, normally by removal of the proximal static locking bolts. This should be carried out approximately 6–8 weeks after implantation, depending on fracture stability and callus formation.

**Locking Options**
- **Stat 1** for static, transverse locking.
- **Stat 2** for static, transverse locking. Allows locking of very proximal fractures.
- **Dynamic** for immediate dynamization.
- **Oblique** for the most superior proximal locking option.

**Attach the Aiming Arm**
For transverse locking, orient the aiming arm for medial to lateral locking bolt or locking screw insertion. For interlocking through the oblique locking hole, attach the aiming arm to the insertion handle for an anterolateral or anteromedial approach. Tighten the spring-loaded connecting knob to secure the aiming arm to the insertion handle. Confirm that the insertion handle is securely fastened to the nail. Tighten the insertion bolt if necessary.
Lock proximally
Choose the appropriate insertion hole, as marked on the aiming arm. Insert the 11.0 mm/8.0 mm Protection Sleeve and 8.0 mm Trocar into the aiming arm, and through a stab incision to the bone.

To interlock 8 mm and 9 mm nails:
Interlock the blue 8 mm and 9 mm nails with the blue 3.9 mm locking bolts or 4.0 mm locking screws. Remove the trocar and insert the 8.0 mm/3.2 mm Drill Sleeve into the protection sleeve. The drill sleeve will snap into place when properly seated in the protection sleeve.

Drill both cortices with the 3.2 mm Calibrated Drill Bit, stopping the drill immediately after penetrating the far cortex.

To interlock 10 mm, 11 mm, 12 mm, and 13 mm nails:
Interlock the 10, 11, 12, and 13 mm green tibial nails with the green 4.9 mm locking bolts or 5.0 mm locking screws. Use the 8.0 mm/4.0 mm Drill Sleeve and drill with the 4.0 mm calibrated drill bit.

Note: There is no need to calculate locking bolt or locking screw length because the calibrated drill bit provides a direct measurement. However, since drill bit position directly represents locking bolt or locking screw position in bone, the locking bolt or screw will be too long if the drill bit is overinserted, or if the drill sleeve is not pressed down to the cortex.

Confirm drill bit position radiographically. Be sure the drill sleeve is pressed firmly to the cortex, and read locking bolt or screw length from the calibrated drill bit at the back of the drill sleeve.
When using the Locking Bolt Measuring Device, remove the drill sleeve and the outer sleeve of the measuring device. Place the measuring slider and needle through the protection sleeve and measure for locking bolt or screw length. Locking bolt or screw length is read directly from the measuring device at the back of the protection sleeve.

Insert the locking bolt or screw through the protection sleeve using the screwdriver.

Repeat the procedure for a second transverse proximal locking bolt or locking screw.
Apply Large Distractor
The Large Distractor is applied on the medial side. The distractor will help to keep the fracture out to length and aid reduction. To correct overlapping fragments, which are usually posterior, it may be necessary to introduce a Schanz screw into the floating fragment and pull it into reduction.
Identify nail entry point
For fractures in the proximal third of the tibia, it is essential to select an entry site for the nail which is as superior as possible and in line with the lateral intercondylar eminence.

It is important to align the guide wire with the lateral spine of the tibial plateau. Hyperflexion of the proximal fragment assists placement of the nail as anterior and parallel to the anterior cortex as possible. The sagittal plane entry site is critical.

Insert and lock the nail
When the nail has been fully inserted as indicated in the “Inserting the Nail” section on page 13, the leg can be placed in extension. Locking is then performed with the fractured leg in full extension.

Proximal locking can be performed as described in the previous sections.

Note: The nail must be fully inserted in flexion. Once the nail is fully inserted, extension may be accomplished.
USE THE RADIOLUCENT DRIVE

Align image
Align the image intensifier with the most distal hole in the nail until a perfect circle is visible.

Determine incision point
Place a knife blade on the skin to determine the incision point, and make a stab incision. Carefully dissect the underlying tissues to reduce the risk of saphenous vein perforation.

Center drill bit in locking hole
Under image intensification, insert the tip of the radiolucent drive drill bit through the incision and place it onto the bone. Keep the drill bit oblique to the x-ray beam until the tip is centered in the locking hole.
Locking Distally

Important:
- Use the 3.2 mm radiolucent drive drill bit [511.414] for 8 mm and 9 mm nails.
- Use the 4.0 mm radiolucent drive drill bit [511.417] for 10 mm–13 mm nails.

Drill
Tilt the drive until the drill bit is in line with the beam and appears centered in the outer ring. The drill bit will virtually fill the locking hole image. Hold the drill firmly in this position and drill through both cortices.

Measure
Measure for the locking bolt or locking screw using the Locking Bolt Measuring Device. Locking bolt or screw length is read directly from the device.

Insert locking bolt or locking screw
Insert the appropriate size titanium locking bolt or screw using the screwdriver and holding sleeve.

For standard freehand technique:
Use the standard drill bit to perform freehand distal locking.
- Use the 3.2 mm drill bit [356.97] for 8 mm and 9 mm nails.
- Use the 4.0 mm drill bit [356.982] for 10 mm–13 mm nails.
Remove the nail insertion instruments. Select the appropriate end cap or end cap extension piece. Align the end cap with the proximal nail end, and insert it into the coupling threads with the screwdriver. Turn the end cap until it is fully seated within the nail.

If an excessively short nail has been inserted too deeply and locked and if no secondary dynamisation is planned, the End Cap with 15 mm extension (458.110) can be used. Over-insertion of the nail is not possible if the Titanium Tibial Nail Insertion Handle is used.

**Precaution:** To avoid irritation of the patellar ligament an end cap with extension should not be used in such cases.
Remove locking bolts or locking screws and end cap
Clean tissue ingrowth from the hex of the end cap and locking bolts or locking screws. Use the screwdriver to remove the end caps and locking bolts or locking screws.

Notes:
- Before removing the last locking bolt or screw, thread the Extraction Screw into the proximal nail end. This will prevent the nail from rotating in the medullary canal.
- Ingrown bone tissue in the diagonal hole can prevent insertion of the extraction screw and must first be pushed out from the proximal end of the nail using a Steinmann pin. Be careful not to damage the nail thread during this procedure.

Remove the nail
Insert the Extraction Screw for the Titanium Tibial Nail and thread it into the proximal nail end. Tighten the Extraction Screw with the 11 mm Combination Wrench [321.16]. Thread the Inserter-Extractor onto the connecting screw, and remove the nail with reverse blows of the Slotted Hammer.
**TITANIUM TIBIAL NAILS**

**Material:**
Titanium-6% aluminum-7% niobium alloy

**Color-Coded:**
- 8 mm and 9 mm nails are blue for use with blue 3.9 mm locking bolts or 4.0 mm locking screws.
- 10 mm–13 mm nails are green for use with green 4.9 mm locking bolts or 5.0 mm locking screws.

**Titanium Solid Tibial Nails** (blue and green)

- **Size:**
  - Diameters: 8, 9 and 10 mm
  - Lengths: 255–360 mm, in 15 mm increments; 380–420 mm, in 20 mm increments

**Titanium Cannulated Tibial Nails** (green)

- **Size:**
  - Diameters: 10, 11, 12, and 13 mm
  - Lengths: 255–360 mm, in 15 mm increments; 380–420 mm, in 20 mm increments

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**Oblique locking hole close to proximal nail end for stable interlocking of proximal-third fractures**

**Dynamic slot for 1 cm of controlled, axial dynamization**

**Stat 1 transverse locking hole**

**Stat 2 transverse locking hole**

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**Three distal locking holes, for locking in both frontal and sagittal planes, allow perpendicular bolt or screw fixation of distal fractures.**
Titanium End Cap, for Titanium Cannulated Tibial Nails [458.120]
- 8 mm diameter
- Protects nail threads from tissue ingrowth
- Sits flush with proximal nail end

Titanium End Cap 15 mm Extension, for Titanium Solid Tibial Nails [458.110]
- Extends length of nail by one size
- Negates reinsertion of a longer nail

Titanium End Cap, for Titanium Solid Tibial Nails [458.10]
- 6 mm diameter
- Protects nail threads from tissue ingrowth
- Sits flush with proximal nail end

3.9 mm Titanium Locking Bolt (blue) [458.xx]
- Lengths: 18–80 mm, in 2 mm increments
- 3.25 mm core diameter
- Fully threaded
- Self-tapping trocar tip
- 3.5 mm hexagonal drive

4.9 mm Titanium Locking Bolt (green) [459.xx]
- Lengths: 26–60 mm, in 2 mm increments
  64–80 mm, in 4 mm increments
  85–100 mm, in 5 mm increments
- 4.25 mm core diameter
- Fully threaded
- Self-tapping trocar tip
- 3.5 mm hexagonal drive

4.0 mm Titanium Locking Screw (blue) [458.8xx]
- 3.3 mm core diameter

5.0 mm Titanium Locking Screw (green) [458.9xx]
- 4.3 mm core diameter
TITANIUM TIBIAL NAIL INSERTION AND LOCKING SET (105.570)
TITANIUM TIBIAL NAIL INSERTION AND LOCKING SET, WITH LOCKING SCREWS (105.572)

### Instruments

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<td>Hexagonal Screwdriver</td>
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<td>356.982</td>
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<td>8.0 mm/4.0 mm Drill Sleeve, 105 mm</td>
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<td>Locking Bolt Measuring Device, 16 to 80 mm</td>
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<td>12.0 mm Drill Sleeve</td>
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### Implants

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<td>3.9 mm Titanium Locking Bolts, 2 mm increments, 2 ea.</td>
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<td>4.0 mm Titanium Locking Screws, 2 mm increments, 2 ea.</td>
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<td>458.926 .960 †</td>
<td>5.0 mm Titanium Locking Screws, 2 mm increments, 2 ea.</td>
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<td>458.964 .980 †</td>
<td>5.0 mm Titanium Locking Screws, 4 mm increments, 2 ea.</td>
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†Included in set 105.570
‡Included in set 105.572

For detailed cleaning and sterilization instructions, please refer to www.synthes.com/cleaning-sterilization or sterilization instructions, if provided.
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**Also Available**

- 150.060 Flexible Reamer Set for IM nails
- 105.954 Small Battery Drive with 14.4 V Battery Pack Set
- 351.02 Small Awl, 210 mm
- 351.06 4.0 mm Centering Pin, 400 mm
- 351.24 11.0 mm Cannulated Cutter
- 351.26 Protection Sleeve, for Cannulated Cutter
- 351.706S 2.5 mm Reaming Rod with ball tip, 950 mm, sterile
- 351.707S 2.5 mm Reaming Rod with ball tip and extension, 950 mm, sterile
- 355.006 Medullary Tube
- 355.042◊ 2.5 mm Guide Rod with smooth tip, 950 mm
- 399.42 Hammer, 500 grams
- 511.30 Radiolucent Drive
- 511.414 3.2 mm Three-Fluted Drill Bit, brad point, 150 mm
- 511.417 4.0 mm Three-Fluted Drill Bit, brad point, 150 mm
- 511.701 Compact Air Drive II
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To order (USA): 800-523-0322
To order (Canada): 855-946-8999

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