

Surgical Technique

Cannulated Tibial Interlocking Nail



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FDA U.S. FOOD & DRUG

Intramedullary Nail System Tibia Nail Kit Code 08060001



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The purpose of this guide is to demonstrate the technique and recommended indications for the use of *ARZZT* Intramedullary Nails in the treatment of diaphyseal tibia fractures.

The recommendations for their use do not presume to interfere with the surgeon's experience, nor the particular needs of each patient, and follow the basic norms for the treatment of diaphyseal fractures through fixation with locked intramedullary nails.



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Introduction

Currently, nearly all authors agree on intramedullary nailing as the treatment of choice for the majority of tibia fractures, thanks to its biological and biomechanical advantages. The locked nail acts biomechanically as a "bridge osteosynthesis," with good stability in terms of flexion and rotation. With more proximal and distal fractures, or more complex fractures, its fixation depends on the locking screws, and much less on bone-nail friction.

This is why Truemed has developed its solid and cannulated titanium blocking screw systems.





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Indications and Contraindications

Indications :

Ins Hilden Arzzt Nail Systems, consisting of intramedullary solid and cannulated nails, end cap and locking screws, are intended for fixation of fractures of different types: of the shaft, open and closed shaft fractures; and malunion and non-unions of the Femur, Tibia, and Humerus.

Cannulated nail:

- Tibia fracture classifications 42-A, 42-B, and 42-C (AO) $\,$

- Exposed tibia fractures I, II, and IIIA (Gustilo)

- Non-union or pseudoarthrosis of the tibia

Contraindications:

- Infections

- Open fracture types IIIB and IIIC (Gustilo).

Indications:

Solid nail:

- Tibia fractures classifications 42-A to 42-C (AO)
- Exposed tibia fracture types I, II, IIIA, IIIB, and IIIC (Gustilo)

Contraindications:

- Infections
- Non-union or pseudoarthrosis of the tibia





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Implant Design

Cannulated tibia nail

Material: TITANIUM 6AI4V

Available in the following measurements: With increments of 20 mm of longitude for all diameters.

- Diameter 8 mm with a longitude of 240 mm to 340 mm
- Diameter 9 mm with a longitude of 260 mm to 360 mm
- Diameter 10 mm with a longitude of 280 mm to 360 mm



Diameter of cannulated orifice: 3.7 mm Diameter of guide wire: 2.5 mm, longitude of 1,000 mm Titanium locking screws: 30 mm to 80 mm, with increments of 5 mm





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Implant Design

Solid tibia nail:

This is a solid nail that requires a manual reamer from the site of introduction to the tibial isthmus, which needs to be one millimeter larger in diameter than the nail used.

Available in the following measurements: With increments of 20 mm for each longitude:

- Diameter 8 mm with a longitude of 240 mm to 340 mm
- Diameter 9 mm with a longitude of 260 mm to 360 mm
- Diameter 10 mm with a longitude of 280 mm to 360 mm

The nail is made of TITANIUM 6AI4V







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Set of Instruments





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Surgical Planning

The diameter and longitude of the nail are determined based on the measurement of X- rays of the healthy extremity, taking into account the image magnification standards (which varies between 10 and 15 percent). Another method is the measurement in the healthy extremity of the distance between the anterior tuberosity of the tibia and the articulation of the ankle, subtracting 20 mm from the longitude obtained.





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System Calibration (for both system):

Attach the cannulated or solid nail to the insertion handle, aligning its tabs with the grooves of the implant, holding it firmly by the nail connector.



Secure the system using the L-handled hexagon key (Allen).



Place the proximal arm over the insertion nandle, ensuring that the longitude arrow for the selected nail meets the arrow located on the handle. Fasten the tibia module to the handle by tightening the fastening screw with the L-handled hexagon key (Allen).

Introduce the external sheath (for tissue protection) and the 5.2 mm internal sheath drill bit guide) in the most distal orifice of the locking guide.



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System Calibration (for both system):

Place the proximal arm over the insertion handle, ensuring that the longitude arrow for the selected nail meets the arrow located on the handle. Fasten the tibia module to the handle by tightening the fastening screw with the L-handled hexagon key (Allen).



Introduce the external sheath (for tissue protection) and the 5.2 mm internal sheath drill bit guide) in the most distal orifice of the locking guide.



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Insert the T-handled feeler gauge into the 5.2 mm external sheath (for tissue protection) and affix it to the spacer.



Place the distal arm, fastening it to the proximal arm with the fastening screw, using the L-handled hexagon key (Allen).





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Introduce the external tibia sheaths (for tissue protection) to the distal arm, along with the internal sheaths (3.5 mm drill bit guides).



Make sure that the bits pass freely through the nail's distal orifices.



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Once the system is calibrated, remove the spacer, the T-handled feeler gauge, and the 5.2 mm external sheath, as well as the other external sheaths and the internal sheaths (3.5 mm drill bit guides).



Detach the module from the fastener handle, leaving it in two pieces:

a) module with the distal arm and b) Insertion handle with the nail.





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Surgical Technique

The surgical technique described as follows is used for the placement of both implants, with the variants for the insertion of each particular nail specified.

Patient positioning:

Place the patient in a prone supine position with the knee of the injured extremity flexed at 70° to 90° degrees, supported by a pillow or surgical pack.





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Surgical Technique

Approach:

Make a longitudinal incision over the medial line of the patellar tendon, from the inferior pole of the patella to the anterior tuberosity of the tibia, freeing subcutaneous cellular tissue until the patella tendon is identified. Intramedullary Nail System

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Locate the entirety of the patella tendon and its borders to avoid injuring it, then separate the patellar tendon at its medial border using blunt dissection and displace the tendon laterally, exposing the site of the nail's introduction.

Penetrate the medullar canal, introducing the awl in the intermediate point between the knee joint and the anterior tuberosity of the tibia.



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Solid nail: If you are going to use a solid nail, this procedure must be followed:

Introduce the manual reamers progressively, beginning with the 8 mm caliber reamer, until you reach the one a millimeter greater in diameter than the nail to be used.





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Cannulated nail: If you are going to use a cannulated nail, this procedure must be followed:

Introduce the 1,000 mm guide rod, ensuring at all times that it is in the medullar canal at both ends of the fracture.

Position the external sheath (for tissue protection) and the skin protector without removing the guide wire, and begin the medullar drilling progressively with the 8 mm reamer, until reaching the diameter of the nail to be used.







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Nail Insertion

Solid nail: Introduce the nail, adjust the impactor/extractor to the nail fastener of the insertion handle, and tap it lightly until the frame of the insertion handle is level with the border of the introduction orifice.

Cannulated nail: Adjust the impactor/extractor to the nail of the insertion handle, slide the nail into the medullar canal through the guide wire, following its direction. Tap it lightly, introducing the implant until the frame of the insertion handle is level with the border of the introduction orifice.





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Nail Insertion

Distal blocking (both systems):

Remove the impactor/extractor and the guide wire (in the event that you're using the cannulated nail), and fit the tibia module and the distal arm to the insertion handle. Use the fastening screw to secure the system. Introduce the external sheath (for tissue protection) and the internal sheath (5.2 mm drill bit guide) into the module's most distal orifice. Incise the skin at the site marked by the external sheath (5.2 mm, for tissue protection).





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Perform the blunt dissection of the tissues until the 5.2 mm external sheath is in contact with the anterior tibial cortex. Place the punch and drive it against the anterior cortex. Swap the punch with the internal sheath (5.2 mm drill bit guide), and perforate the anterior tibial cortex once with the 5.2 mm drill bit.





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Position the spacer, securing the T-handled feeler gauge, and then position the 3.5 mm external sheaths (for tissue protection) in the orifices of the distal arm. Incise the skin at the areas marked by the external sheaths (for tissue protection).



Position the internal sheaths (3.5 mm drill bit guides), and use the 3.5 mm bit to perforate both the medial and lateral cortex. Remove the internal sheaths (drill bit guides), and introduce the depth gauge in order to determine the longitude of the screw. Introduce the screws chosen for the distal blocking of the nail.



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Proximal locking (both systems): remove the tibia module along with the distal arm, and proceed to set up the proximal arm, fastening it to the insertion handle with the fastening screw.



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Introduce the external sheaths (3.5 mm, for tissue protection) into the orifices of the proximal arm. Incise the skin at the areas marked by the external sheaths (for tissue protection). Position the internal sheaths (3.5 mm drill bit guides), and perforate.

Remove the internal sheaths (3.5 mm drill bit guides), and use the depth gauge to determine the longitude of the locking screw. Posteriorly, remove the insertion handle, and position the sealing cap with the T-handled screwdriver.

Wash with saline solution and close in layers. The surgical event is complete.







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Implant Extraction

Make a small incision approximately 1 cm above the head of each distal and proximal locking screw. Via dissection, locate the blocking screws, remove the fibrous and bone tissue from the hexagonal recesses of the screws. Remove the screws with ARZZT screwdriver, leaving one in order to maintain the fixation of the nail.

Continue with the patient in a supine prone position, and with the knee of the injured extremity flexed at 70 to 90 degrees.

Make a longitudinal cutaneous incision of 3–4 cm. Use the previous surgical approach for the placement of the nail at the anterior surface of the knee, at the level of the patellar tendon, separating it longitudinally at its midpoint until you locate the sealing cap. Remove the excess fibrous and bone tissue from the hexagon, and remove the sealing cap with the ARZZT screwdriver.

Assemble the insertion handle with the nail connector, tightening them firmly using the L-handled hexagon key (Allen) in order to avoid the rotation or displacement of the nail back underneath the tibial condyle. You must be careful to avoid damaging the thread of the nail during this procedure. Remove the remaining blocking screw and extract the nail using the impactor/extractor.

Suture the proximal wound in layers with vicryl 2.0, the skin with nylon 3-0, and the wounds from where the screws were removed with nylon 3-0. Cover the wounds with sterile dressing and bandage the extremity.

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