







Approved by



Intramedullary Nail System
Femur Nail Kit
Code 08040001





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This guide is designed to demonstrate the recommended techniques and applications for the use of the *ARZZT* intramedullary nail for femurs, meant for orthopedic traumatologists in the treatment of 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 fractures through intramedullary fixation with the biomechanical principle of internal splints or tutors.







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Introduction

The treatment of diaphyseal femoral fractures is currently based on closed- focus intramedullary nailing by virtue of its biological and biomechanical advantages.

The solid nails—drilled or not drilled—act as internal splints, serving as "bridge nails" between the proximal fragments, with both their distal and proximal locking being essential due to the fact that all efforts are transmitted and supported via the locking screws.

In cases of simple transverse fractures and short oblique fractures where the bone fragments are touching and there is no diastasis, the loads will be

transmitted through the bone and the work of the screws is limited to controlling rotational efforts.

The locked nail acts biomechanically as a "bridge osteosynthesis," with good stability in terms of flexion and rotation. In the more proximal and distal fractures, or more complex fractures, its fixation depends on the locking screws.

The non-drilled and locked solid titanium nails feature a low level of rigidity and a high resistance to fatigue even when thinner nails are used. Recently, cannulated titanium nails have been developed in order to achieve the placement of nails with a greater diameter and to facilitate the technique for their insertion, allowing them to be inserted by way of a guide rod after reaming.

One of the best features of the utilization of this kind of implant is the security of the distal locking screw, as the practicality and simplicity of the technique used allows one to maintain a constant symmetry between the instruments and the implant, which saves time spent in surgery, and decreases the need to use the image intensifier.

In the case of a significant separation among the fragments, a delay in bone consolidation (three months), or pseudoarthrosis, the system also offers the additional possibility of removing the proximal static locking screw in order to make the system more dynamic.

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.





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Implant Design

ARZZT solid and cannulated intramedullary nails for the femur are made with a titanium 6AI4V alloy, with two distal orifices for fixed locking and two for proximal locking (one fixed and one dynamic), in which one places locking screws with conical heads to achieve greater fastening in the cortex.

They have been designed for use in diaphyseal fractures with simple, complex or comminuted fragments up to 5 cm proximal to the distal metaphysis of the femur.

The solid nail is available in the following measurements:

- Diameter Ø 9 mm / longitude of 320 to 420 mm
- Diameter Ø 10 mm / longitude of 320 to 420 mm
- Diameter Ø 11 mm / longitude of 340 to 420 mm
- Diameter Ø 12 mm / longitude of 340 to 420 mm

The cannulated nail is available in the following measurements:

- Diameter Ø 9 mm / longitude of 320 to 420 mm
- Diameter Ø 10 mm / longitude of 320 to 420 mm
- Diameter Ø 11 mm / longitude of 340 to 420 mm
- Diameter Ø 12 mm / longitude of 340 to 420 mm

Diameter of cannulated orifice: 3.7 mm

Diameter of guide rod: 2.5 mm; longitude of 1,000 mm

Both nails offer increments of 20 mm between each of their lengths.

Titanium blocking screws: diameter of 4.9 mm; measurements of 30 to 80 mm with increments of 5 mm

Both nails feature a universal design for the left and right femur.

The end cap protects the proximal nail thread to facilitate its extraction. The solid nail is preferred for use with the non-drilling insertion technique.

The cannulated nail is used with or without the drilling technique, using a guide rod.

The *ARZZT* solid and cannulated femoral nails are used for the stabilization of diaphyseal, metaphyseal, segmental and comminuted fractures of the femur.





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Pre-operative Planning

The diameter and longitude of the nail are determined based on the measurement of the X-rays of the healthy extremity, taking into account the image magnification standards (which vary between 10 and 15%). Some surgeons use the image intensifier, superimposing the nail over the affected extremity in order to establish the longitude and to obtain a safe distance without affecting the articulation of the knee and hip. Another method is measuring from the point of the great trochanter to the articular interline of the knee, and subtracting 8 cm.

For very narrow bones, it is recommended to place the nail with a smaller diameter—at the surgeon's discretion—and, depending on the comminution and stability of the fracture, it is recommended to use a nail with a larger diameter with the aim of achieving greater fastening and stability.





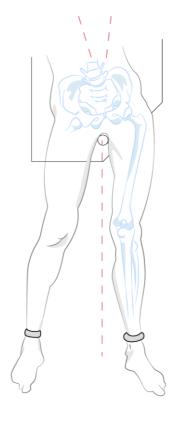


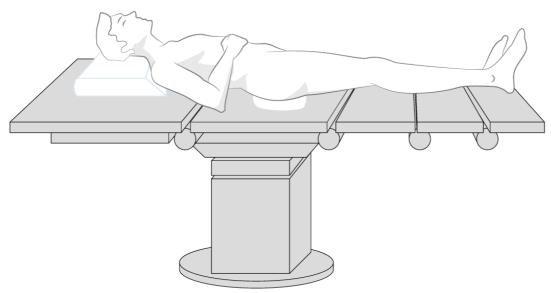
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Patient Positioning

The femoral fracture can be reduced in an open or closed manner, with the latter being the preferred method, placing the patient in a supine position on a fracture reduction table or a radiolucent surgical table. In order to allow for better access for the surgical approach, the trunk is inclined toward the side opposite the fracture at 25 degrees. With the trunk fixed, the healthy pelvic extremity is placed in a leg support with hip abduction to allow the image intensifier to have free access to the entirety of the fractured femur in terms of both lateral and AP projections, which include the hip and careful observation of the great trochanter.

The reduction and correction of the fracture rotation must be performed before beginning the surgical procedure.







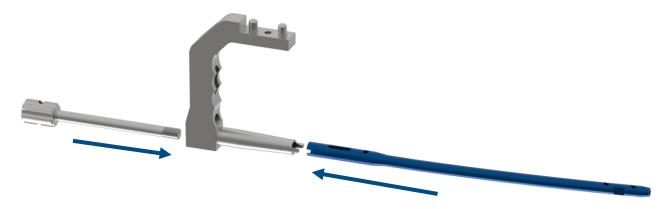


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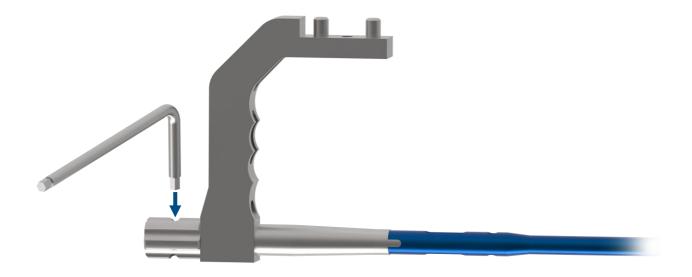
Preparing the nail and Instruments

The nail must be assembled and calibrated before it is used inside the femur in order to allow for the free passage of the screws and to create exact symmetry.

1. Position the nail in the insertion handle, ensuring that the grooves line up when fixing it with the nail connector.



2. Fasten the nail in the insertion handle with the nail connector and firmly tighten the handle using the L-handled hexagon key (Allen), introducing it into the handle's orifices.

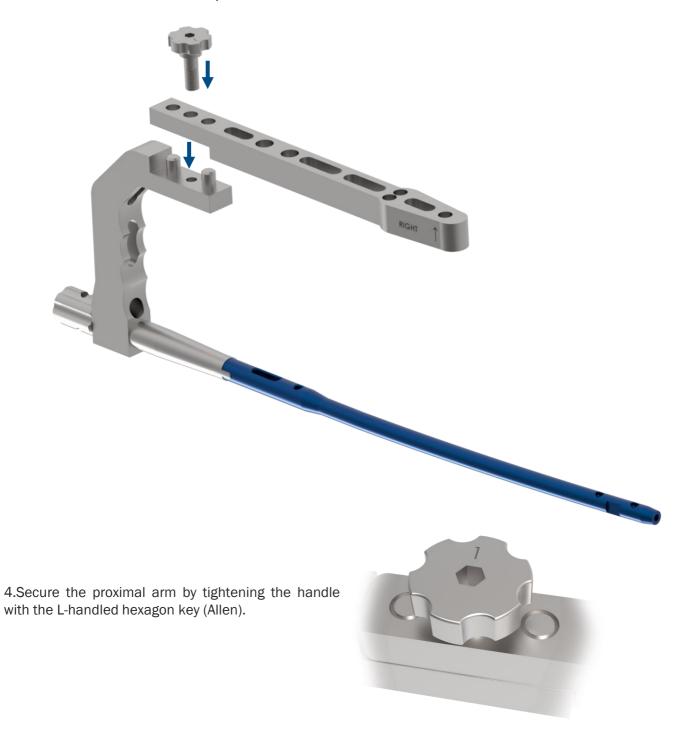






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3. Position the proximal arm in accordance with the longitude of the nail, lining up the arrows of the insertion handle with those of the proximal arm.

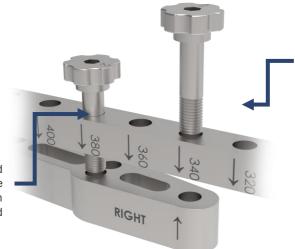






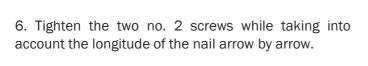
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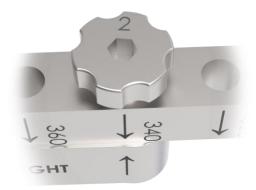
5. Position the second module (aiming arm) depending on the leg to be operated on (left or right), following the direction of the arrow on the module.

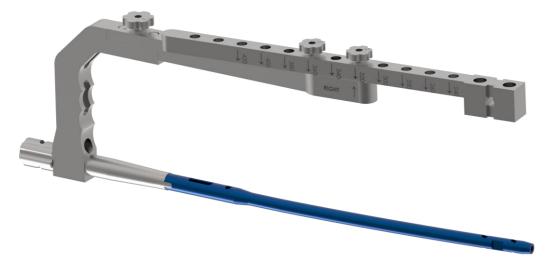


Upon positioning the proximal fastening screw on the distal module for the retrograde femoral nail, it should coincide with the length of the nail.

The distal fastening screw is to be placed in the corresponding hole next to the fracture, which is why the proximal arm is marked with the words "left" and "right" to avoid confusion.





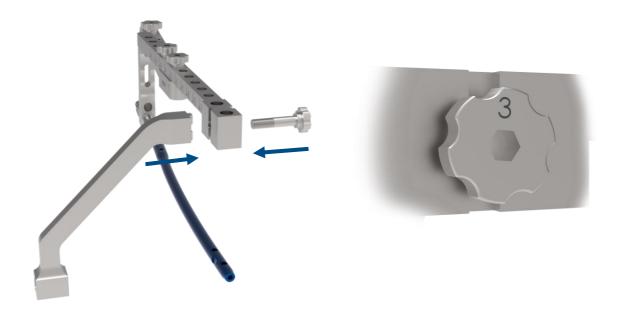






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- 7. Position the aiming arm in order to insert the T-handled feeler gauge, tightening it with fastening screw no.
- 3.



8. Position the internal sheath (drill bit guide) for the 5.2 mm bit, which must touch the distal groove.



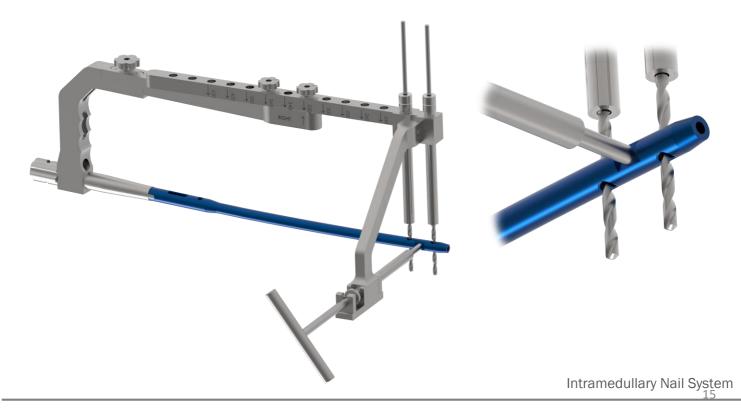


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9. Remove the internal sheath (drill bit guide) and position the feeler gauge, affixing and fastening it to the module with the different spacers (to lock it in), depending on the diameter of the nail.



10. Position the external sheaths (for tissue protection) and internal sheaths (distal drill bit guides) through the distal arm and verify that the 4 mm bit passes through the orifices without any problem.

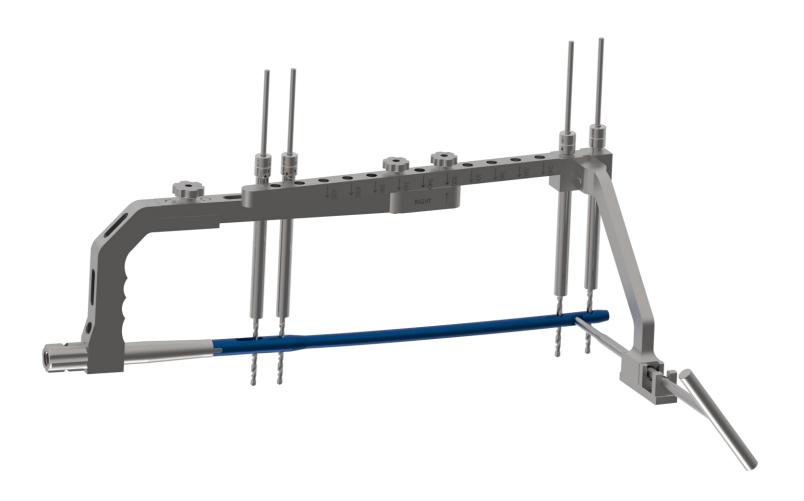






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11. Introduce the external sheaths (for tissue protection) and the internal sheaths (distal drill bit guides) into the proximal orifices, and verify that the bit passes through the proximal orifices without any problem.



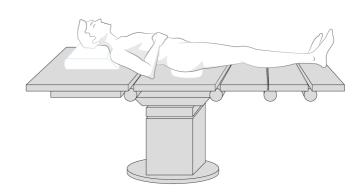


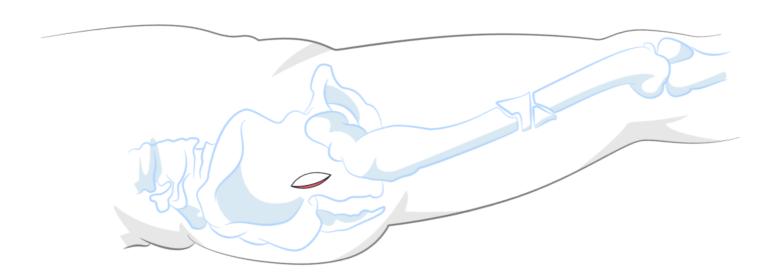


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Antegrade Surigcal Technique for the Arzzt Solid Femoral Nail

Once the patient is on the operating table, with the fracture reduction closed, the image intensifier in position, following asepsis and antisepsis the surgical area is delimited with drapes, and the surgeon proceeds to perform a proximal cutaneous incision (10–15 cm), with respect to the great trochanter (3 cm in longitude), and to palpate the tip of the great trochanter through the gluteal musculature.







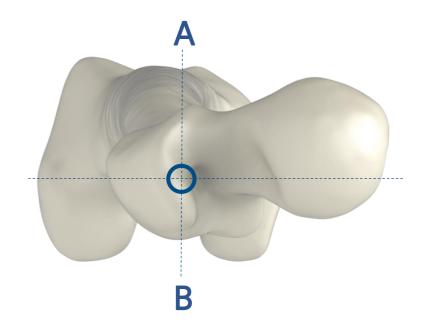


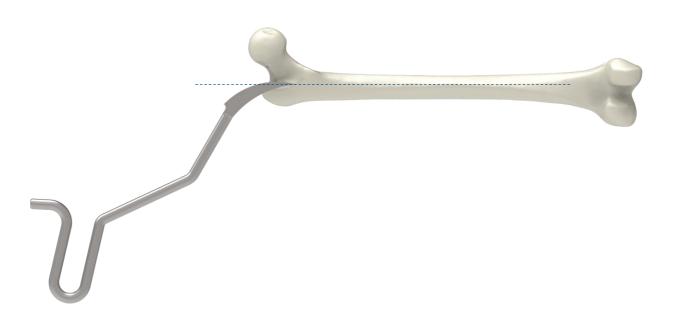
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Antegrade Surigcal Technique for the Arzzt Solid Femoral Nail

The point of entry must be aligned with the medullar canal on the AP and lateral projections, situated on the piriform fossa or the tip of the great trochanter (it should never be too medial in order to ensure that the circumflex femoral artery is not damaged).

Once the insertion point has been located, the medullar canal is opened with the primer punch, placing the tip of same on the piriform fossa. Verify the exact spot with the image intensifier, and begin its introduction with soft turns until a depth of 5–10 cm is reached.









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Remove the primer punch and, with control, using the image intensifier, introduce a hand reamer of a lesser diameter in order to make the medullar canal permeable until the level of the fracture line. Remove the reamer and proceed with the introduction of the chosen femoral nail.

The diameter of the nail must be 1.5 mm to 2 mm less than the diameter of the medullar canal at the level of the femoral isthmus.



Introduction of the nail

12. Before positioning the nail, verify that the system is properly calibrated, checking the firmness of all the fastening screws, removing the spacer (used to lock it in), the T-shaped feeler gauge, and the modules. Introduce the prepared femoral nail (already affixed to the fastening handle) by hand, using rotational movements to insert it as deep as possible, always with control and with the aid of the image intensifier, until you reach the fracture line. Touch the tip of the nail to the distal fragment of the fracture, ensuring the correction reduction of the fracture, driving the nail with the impactor (hammer) until you introduce the proximal end of the nail (10 mm deep with respect to the tip of the great trochanter). Proceed to position the modules.



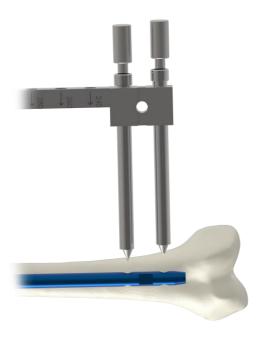




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Distal and Proximal Blocking

13. Position the proximal arm and the aiming arm. The insertion handle must be oriented laterally, parallel to the external surface of the thigh. Fix the distal arm and introduce the external sheath (for tissue protection), using the punch to mark the site, and make an incision of about 0.5 mm on the anterior and distal surface of the thigh. Perform a blunt dissection in layers, separating and pushing the external sheath (for tissue protection) and the punch until you make contact with the anterior cortex of the femur. Remove the punch, position the internal sheath (drill bit guide), and introduce the 5.2 mm bit through the first cortex to the nail. Remove the bit and introduce the T-handled feeler gauge, blocking it with the spacer in accordance with the diameter of the nail selected by the orthopedic surgeon.







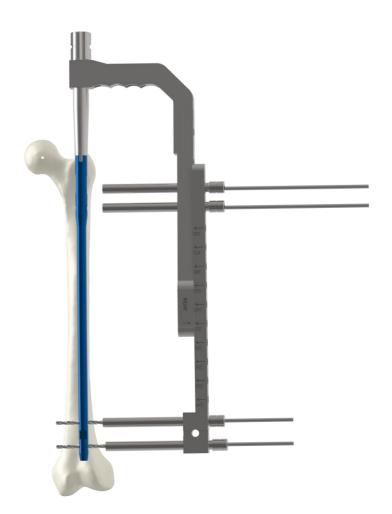


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14. Position the external sheaths (for tissue protection), the internal sheaths (drill bit guides), and bit on the external surface of the thigh. Mark the places where the incisions are to be made. Using small incisions, dissect in layers in order to allow the passage of the external sheaths (for tissue protection), internal sheaths (drill bit guides), and bit, until you locate the lateral cortex of the femur. Perforate with the 4.0 mm bit until you perforate the second cortex. Beginning with the most distal orifice, verify that the orifice corresponds to the orifice of the nail. Remove the bit and internal sheath, and introduce the depth gauge, obtaining the longitude of the blocking screw. Using the tap, make a path for the thread pitch through to the second cortex, remove it, and position the 5.0 mm screw with the appropriate screwdriver. Verify that it is inside the nail, and that the 5.0 mm screw passes through to the second cortex. Repeat the maneuver for the most proximal of the distal orifices.

You can opt to remove the second arm or leave it, and then proceed to perform the same maneuvers. For the static locking, introduce a 5.0 mm screw through the round orifice. If you require greater rotational control, insert a locking screw in the slot or dynamic orifice. For immediate dynamization of the system, simply insert a blocking screw into the slot or dynamic orifice next to the nail.

15. Remove the system and position the end cap on the proximal part of the nail. Suture the layers of the surgical wound above the great trochanter with vicryl no. 1, suture the skin with nylon 3-0, and the screw wounds with nylon 3-0. In accordance with the preferences of the orthopedic surgeon, place dressing and elastic bandaging. Remove the patient from the fracture table.





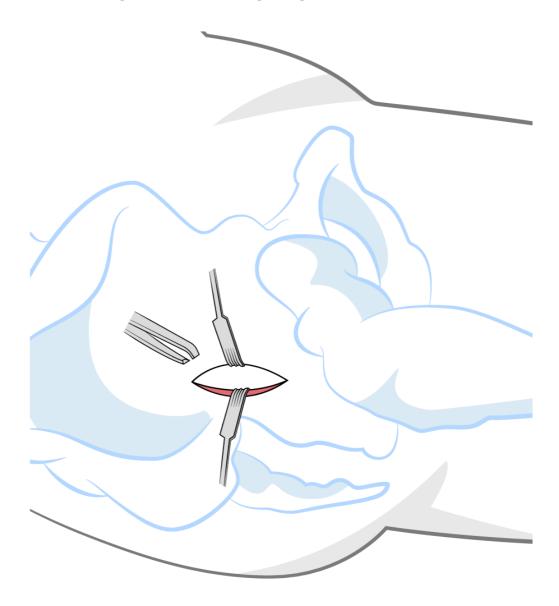




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Surgical Technique for the Arzzt Cannulated Femoral Nail, Employed Principally with the Drilling Technique Using a Guide Rod

Once the patient is on the operating table, with the fracture reduction closed, the image intensifier in position, following asepsis and antisepsis the surgical area is delimited with drapes, and the surgeon proceeds to perform a proximal cutaneous incision (10–15 cm), with respect to the great trochanter (3 cm in longitude), and to palpate the tip of the great trochanter through the gluteal musculature.



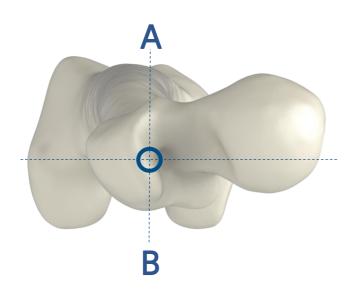




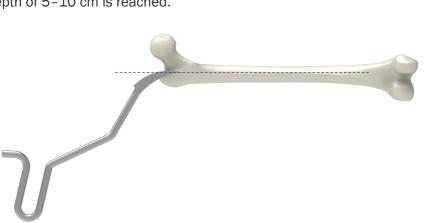
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Surgical Technique for the Arzzt Cannulated Femoral Nail, Employed Principally with the Drilling Technique Using a Guide Rod

The point of entry must be aligned with the medullar canal on the AP and lateral projections, situated on the piriform fossa or the tip of the great trochanter (it should never be too medial in order to ensure that the circumflex femoral artery is not damaged).



Once the insertion point has been located, the medullar canal is opened with the primer punch, placing the tip of same on the piriform fossa, verifying the exact spot with the image intensifier, and beginning its introduction with soft turns until a depth of 5–10 cm is reached.









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Remove the awl and, with control, using the image intensifier, introduce the guide wire (2.5 mm / 1,000 mm in longitude). Using the image intensifier (AP and lateral projections), check the direction in the medullar canal in order to thread the distal portion of the already-aligned fracture line.



Drilling The Medullar Cavity

In order to obtain secure and stable fixation, one must combine the maneuvers for reducing the fracture with the guide rod for the drilling.

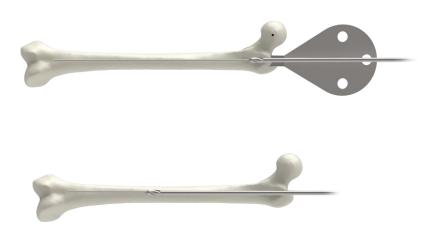
After having achieved the reduction of the fracture, and with the guide rod introduced into the medullar canal, the drilling begins.

Starting with the smallest reamer (9.0 mm), and incrementing the drilling by 0.5 mm, the longitude of the drilling must be identical to the longitude of the chosen nail.

You must use a skin protector (soft tissue protector) in order to avoid damaging the tissues adjacent to the insertion point.

Without turning, insert the drilling system into the medullar cavity over the guide wire. Proceed to drill the medullar cavity in accordance with standard procedure.

Once the full longitude of the medullar cavity has been drilled, extract the reamer, supporting the guide rod with the fastening pliers in the correct place so that the reduction is not lost.







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Continue with drilling of the medullar canal, increasing the reamer in increments of 0.5 mm until you feel contact with the femoral cortex. The final drilling must be 1.5–2 mm greater than the diameter of the nail to be used.

Nail selection: the diameter of the nail must be 1.5–2 mm less than the diameter of the last reamer used. The longitude can be determined by measuring the remaining longitude of the guide rod.

12.Introduction of the nail

Before positioning the nail, verify that the system is properly calibrated, checking the firmness of all the fastening screws, removing the spacer (used to lock it in), the T-shaped feeler gauge, and the modules.

Introduce the prepared femoral nail (already affixed to the fastening handle) by hand with light turns. The insertion handle must be oriented laterally, and using the image intensifier with control, verify the passage of the nail through the fracture. If necessary, hit the nail with the impactor to drive it through to the distal metaphysis, leaving the proximal end of the nail level with or just beneath the tip of the great trochanter (10 mm). Confirm the correct reduction of the fracture, remove the guide rod, and proceed to place the modules.





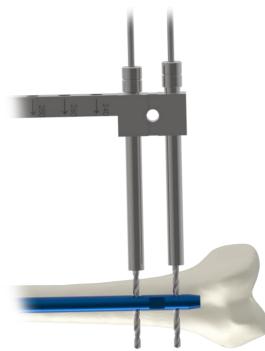


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Proximal and Distal Blocking

13. Position the proximal arm and the aiming arm. The insertion handle must be oriented laterally and parallel to the external surface of the thigh. Fix the distal arm and introduce the external sheath (for tissue protection). Using the punch, mark the site and incision make an approximately 0.5 mm on the anterior and distal surface of the thigh. Perform a blunt dissection in layers, separating and pushing the external sheath (for tissue protection) and the punch until you make contact with the anterior cortex of the femur. Remove the punch and position the internal (drill bit guide). sheath Introduce the 5.2 mm bit, passing through the first cortex until you reach the nail. Remove the bit and the T-handled introduce feeler gauge, using the spacer to block it accordance with the diameter of the nail chosen by the orthopedic surgeon.





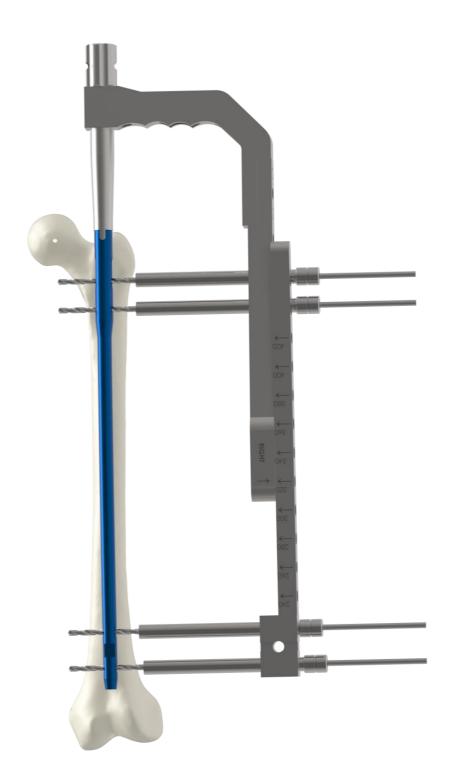




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14. Position the external sheaths (for tissue protection), the internal sheaths (drill bit guides), and the rod on the external surface of the thigh. Mark the places where the incisions are to be made. Using small incisions, dissect in layers in order to allow for the passage of the external sheaths (for tissue protection), internal sheaths (drill bit guides), and rod, until you locate the lateral cortex of the femur. Perforate with the 4.0 mm bit until you perforate the second cortex. Beginning with the most distal orifice, verify that the orifice corresponds to the orifice of the nail. Remove the bit and the internal sheath. Introduce the depth gauge, obtaining the longitude of the blocking screw. Using the tap, make a path for the thread pitch through to the second cortex, remove it, and position the 5.0 mm screw with the appropriate screwdriver. Verify that it is inside the nail, and that the 5.0 mm screw passes through to the second cortex. Repeat the maneuver for the most proximal of the distal orifices.

You can opt to remove the second arm or leave it, and then proceed to perform the same maneuvers. For the static locking, introduce a 5.0 mm screw through the round orifice. If you require greater rotational control, insert a blocking screw in the slot or dynamic orifice. For immediate dynamization of the system, simply insert a blocking screw into the slot or dynamic orifice next to the nail.

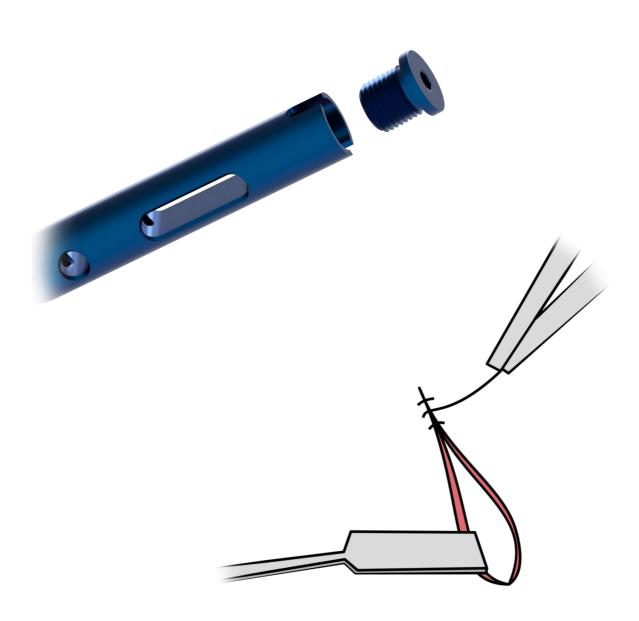






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15. Remove the system and position the sealing cap on the proximal part of the nail. Suture the layers of the surgical wound above the great trochanter with vicryl no. 1, suture the skin with nylon 3-0, and the screw wounds with nylon 3-0. In accordance with the preferences of the orthopedic surgeon, place dressing and elastic bandaging. Remove the patient from the fracture table.







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Post-Operative Care

Place an elastic bandage from the feet to the point nearest the origin of the thigh (groin area). Keep the extremity elevated. The patient may flex and extend in accordance with what is tolerable. The administration of analgesics and antibiotics is at the discretion of each orthopedic surgeon.

Walking and the need for support will be up to the surgeon in question, but walking with partial support can being in two weeks, following an X-ray inspection.

X-ray inspections take place every four weeks. The suture stiches are removed after two or three weeks. Treatments can be performed on demand and at the discretion of the orthopedic surgeon in question.

Depending on the evolution of the fracture consolidation, a dynamization of the nail can be performed by removing one of the proximal screws (removing the screw in the round orifice).





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Set of Instruments









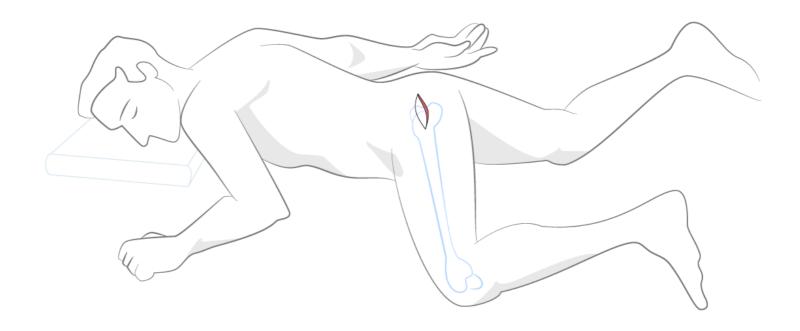


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Implant Extraction

Patient positioning

The simple extraction of the nail requires placing the patient in a lateral prone position, which does not require a special surgical table. This position allows one to obtain a light abduction of the hip, improving the exposure of the great trochanter and facilitating the removal of the nail.







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Implant Extraction

Surgical technique

- 1. Remove the proximal locking screws using the previous incisions.
- 2. Before proceeding to remove the distal blocking screws, one must make sure to position the nail connector, thus avoiding the rotation of the nail, which makes its removal more difficult.
- 3. It is recommended to use the previous proximal surgical incision posterolaterally, with an incision between five and 10 cm, as this reduces the risk of cutaneous necrosis and facilitates the extraction of the implant, unless the planning includes the performance of another kind of approach in cases where the previous incision is located outside the surgical zone.









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Perform a layered dissection, separating the subcutaneous cellular tissue, the fascia lata, and the insertion of the gluteus minimus and gluteus medius, until one can feel the point of the trochanter and the digital fossa of the femur.

- 4. Carefully remove the fibrous tissue located at the piriform fossa, obtaining a direct view of the implant. If you encounter bone tissue over the nail, use the guide punch until the implant is located.
- 5. Extract the sealing cap from the nail.
- 6. Remove the distal screws in the same manner that the proximal screws were removed.



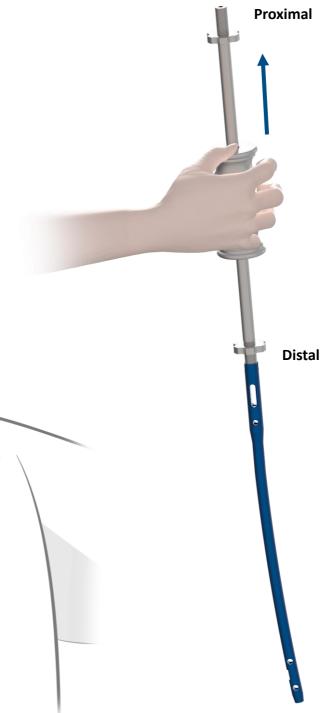






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- 7. Proceed with the extraction of the nail, using the impactor in a retrograde fashion.
- 8. Use a saline solution to wash the medullar canal, a perform an adequate surgical debridement.
- 9. Proceed to close the wound in layers. Cover it with sterile gauze. Depending on the surgical bleeding, you may drain the wound.





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