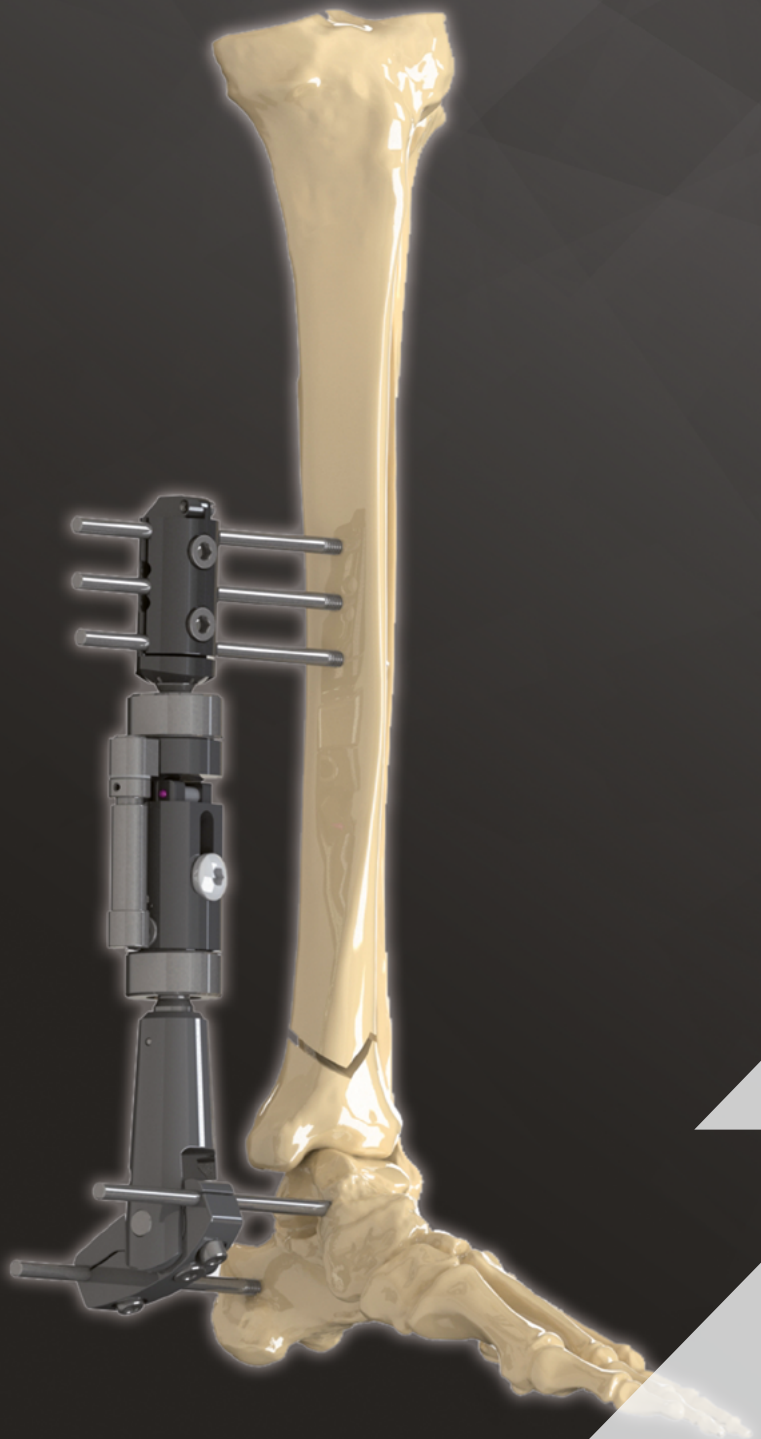
Operative Technique

Distal Tibial and Pilon Fractures with the Radiolucent Ankle Clamp



ORTHOFIX®

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Orthofix wishes to thank the following surgeons for their contribution to the development of the technique:
Dr. J.L. Marsh and Dr. F. Lavini

The surgical technique shown is for illustrative purposes only. The technique(s) actually employed in each case will always depend upon the medical judgment of the surgeon exercised before and during surgery as to the best mode of treatment for each patient. Please see the Instructions For Use for the complete list of indications, warnings, precautions, and other important medical information.

Please kindly refer to the product IFU PQEFS, to the Orthofix implantable devices and related instrument IFU PQSCR, and to the reusable medical devices IFU PQRMD that contain instructions for use of the product.

INTRODUCTION

Fractures of the distal tibial metaphysis, with extension into the articular region, or pilon fractures, are commonly due to vertical compression trauma, or, more rarely, to torsional forces that result in a spiral fracture of the distal tibia with extension into the ankle joint.

It is imperative to assess both the severity of joint involvement and the degree of metaphyseal comminution in order to determine the appropriate treatment strategy. Anatomic reconstruction of the articular surface is mandatory, but the degree of associated metaphyseal comminution will often mean that adequate support for the articular surface cannot be achieved without the introduction of an autologous bone graft.

While Type I fractures (articular fractures without significant displacement)[1] may in the majority of cases be reconstructed with minimal internal fixation, Type II fractures (articular fractures with significant disruption of the articular surface but minimal metaphyseal comminution), and Type III fractures (severely comminuted fractures with major joint involvement) require more extensive surgical intervention.

For many years, the recommended surgical treatment for these fractures has been open reduction coupled with rigid internal fixation with plates and screws[1,2,3,4,5].

There is, however, a high incidence of complications associated with this method of treatment, and reports of wound breakdown, superficial and deep infection and osteomyelitis are common[2,6,7,8,9,10,11,12]. Amputation is a significant risk in the more severe cases[13].

Recently, several authors[3,9,14,15,16] have reported decreased complication rates in severe pilon fractures using external fixation.

In view of the need to obtain accurate reconstruction of the articular surface in these circumstances, with minimal additional insult to the metaphyseal region where the soft tissue envelope is thin, limited open reduction of the articular fracture and fixation of the fragments with screws or Kirschner wires is indicated. Limited internal fixation may also be performed using the Orthofix Fragment Fixation System, which comprises a range of implants of varying thickness and thread length specifically designed for this purpose that can be introduced percutaneously and subsequently trimmed to length.

Use of the Orthofix Dynamic Axial Fixator with the RadioLucent Ankle Clamp has many advantages in this situation. The ankle module is applied medially to screws inserted in the talus and calcaneum, while the body of the fixator is attached to screws inserted into the tibial shaft. The telescopic feature of the fixator body provides the distraction necessary for adequate visualization of the joint while reconstruction of the articular surface is carried out. Unobstructed views of the distal tibial metaphysis and ankle joint can be obtained in any plane because of the radiolucency of the ankle clamp.

Reduction of the fragments in the metaphyseal region and the provision of adequate stability to maintain the integrity of the newly reconstructed joint surface can then be achieved by ligamentotaxis (exerting traction on the joint capsule and associated ligaments), again mediated via the telescopic facility of the fixator.

The articulated clamp is locked during the early stages of fracture healing, but can be unlocked at the appropriate time to allow gentle mobilization of the ankle about the center of rotation of the tibio-talar joint without loss of fracture reduction.

Saleh et al.[17] reported a series of 12 patients with severe pilon fractures (Rüedi and Allgöwer Types II and III) treated with the Orthofix Dynamic Axial Fixator with articulated clamp for the ankle. All required open reduction and minimal internal fixation of the joint surface. The authors considered the technique to be a safe, minimally invasive form of treatment for a difficult fracture.

Bonar and Marsh[18] reported their results in 21 patients with severe pilon fractures (Rüedi and Allgöwer Type II, 9; Type III, 12; 7 open fractures), treated with the Orthofix system, combined in 15 with limited internal fixation. Nineteen of the 21 cases healed. The two instances of non union were in cases where there was no attempt at articular reconstruction and no bone grafting. Despite the high degree of bone and soft tissue injury, there were no cases of wound infection, skin slough or osteomyelitis. The authors comment that the limited approach coupled with external fixation avoided the soft tissue stripping necessary to obtain rigid internal fixation.

More recently, Marsh et al.[19] have described the results of a prospective study in 49 displaced plafond fractures in 48 patients. The Orthofix articulated clamp for the ankle was used in all patients, with minimal internal fixation to reconstruct the articular surface in 40 cases. Average duration of external fixation was 12 weeks, and all fractures healed. This study was conducted in four different centers. There were no cases of wound breakdown or osteomyelitis, and no amputations.

In a prospective study randomized to traditional open reduction and internal fixation, or external fixation with minimal internal fixation, Wyrsch et al.[13] found that there were 28 additional operations, 6 wound breakdowns, 6 deep infections and 3 (16%) amputations in the 19 patients of the ORIF group, compared with 5 additional operations, no wound breakdowns, no deep infections and no amputations in the 20 external fixator patients, most of whom were treated with the Orthofix system. Furthermore, the functional assessment of the external fixator patients was significantly improved compared with the ORIF patients.

In a prospective study in Johannesburg, South Africa, Wisniewski and Radziejowski[20] treated 21 consecutive patients with tibial pilon fractures with the Orthofix system combined with limited internal fixation. There were no cases of wound breakdown, no deep infections and no amputations. All the fractures healed within 16 to 24 weeks.

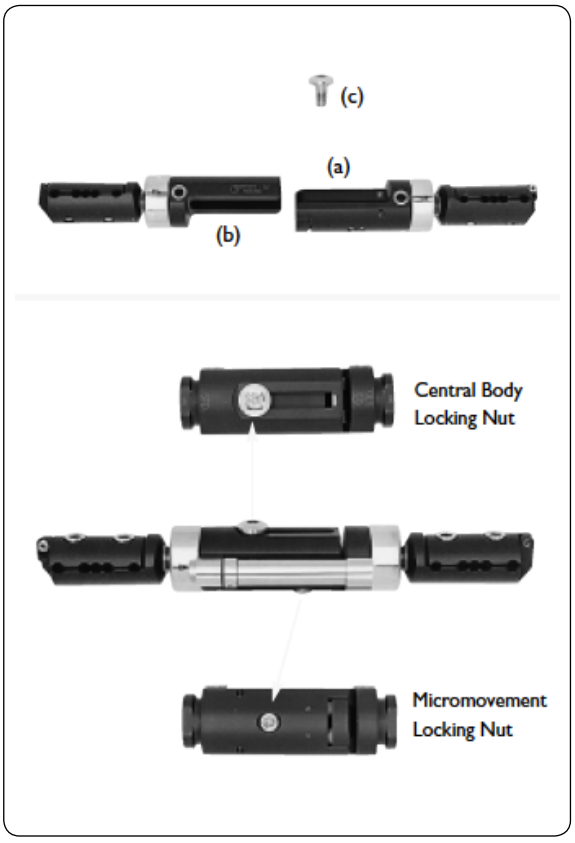
In the papers quoted above, a total of 123 patients with tibial pilon fractures have been treated with external fixation in seven different trauma units, the vast majority with Orthofix, without any wound breakdown, deep infection or amputation.

In pilon fractures where the degree of comminution is less severe, bridging of the ankle joint may be avoided with use of the Orthofix Hybrid Fixator Assembly[21].

This system can also be used in non-articular fractures of the distal tibia where there is insufficient space for the application of a Metaphyseal Clamp or T-clamp with Orthofix screws.

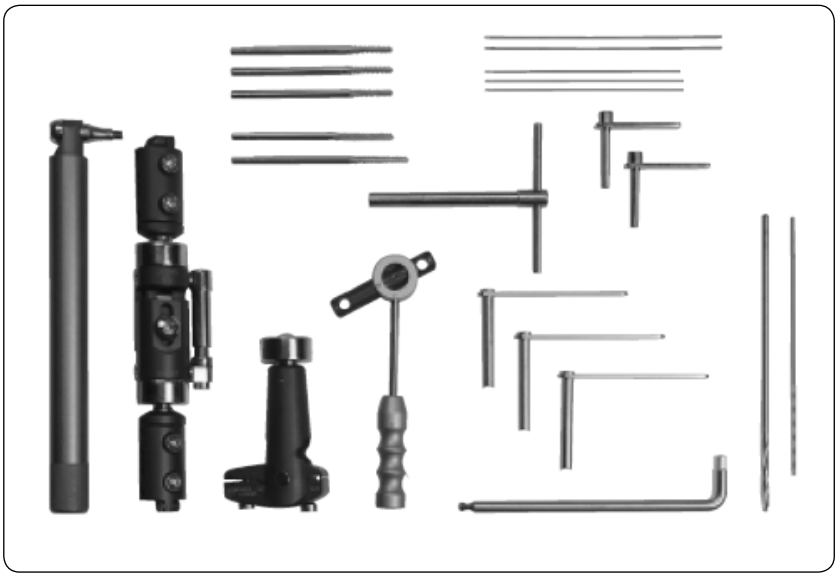
All the techniques and procedures described in this manual are illustrated with reference to the ProCallus Fixator (90000 Series). The Dynamic Axial Fixator (10000 Series) can also be used for this indication (see page 16). The body of the device can be combined with the RadioLucent Ankle Clamp (90046) to construct the assembly necessary for treating distal tibial and pilon fractures.

With this fixator, the male component (a) slides within a groove in the female component (b) for adjustment of body length. Movement between the male and female components of the fixator is prevented when the Central Body Locking Nut (c) is tightened. When loosened, the Micromovement Locking Nut unlocks a mechanism that allows limited cyclic micromovement on weightbearing, but prevents collapse of the fracture. Loosening the Central Body Locking Nut provides progressive loading of the fracture site, but should not be carried out until the fracture is stable enough for weightbearing.



USE OF THE RADIOLUCENT ANKLE CLAMP

EQUIPMENT REQUIRED



a) ProCallus Fixator Short Model (90028).

b) Radiolucent Ankle Clamp (90046).

c) Radiolucent Ankle Pin Guide (11947). This together with the RadioLucent Ankle Clamp is also available in a sterile kit (99-90646)*.

d) Four or five 6/5 mm cortical screws. Screw length and thread length can be estimated by reference to the patient's X-rays, using the Orthofix transparent X-ray overlay. Thread length should be such that about 5 mm of thread will remain outside entry cortex and about 2 mm will project beyond the second cortex.

e) Two Kirschner Wires, 1.5 mm diameter, 250 mm long (11014).

f) Three Kirschner Wires, 2.0 mm diameter, 150 mm long (11146).

g) One Cannulated Drill Bit, 3.2 mm diameter, 150 mm long (1101301). Cannulation 1.8 mm.

h) One Drill Bit, 4.8 mm diameter, 180 mm long (1100101).

i) One Drill Guide, 3.2 mm diameter, 40 mm long (11106).

j) One Drill Guide, 4.8 mm diameter, 40 mm long (11104).

k) Three Screw Guides, 60 mm long (11102).

l) One T-Wrench (11000).

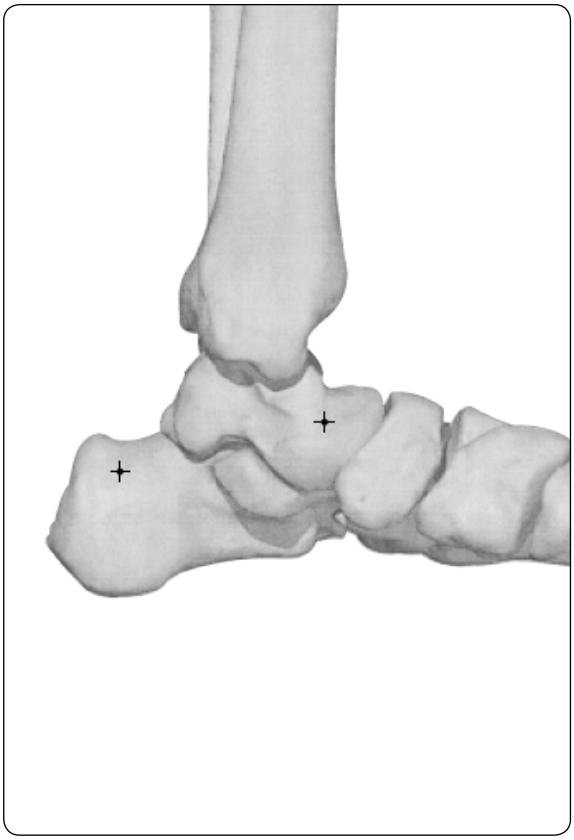
m) One Allen Wrench, 6 mm (10017).

n) One Torque Wrench (10025).

The use of HA-Coated Screws is strongly recommended for this application.

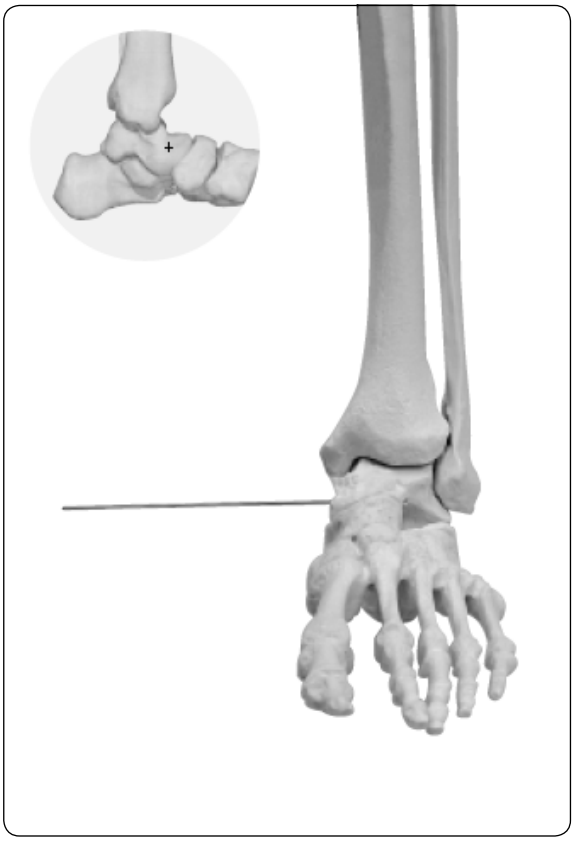
OPERATIVE TECHNIQUE

The distal screws are inserted first, one in the talus and one in the calcaneum. Screw localization is always in the center of the neck of the talus, and in the upper part of the posterior aspect of the tuberosity of the calcaneum. The screws must be inserted perpendicular to the axis of the tibia, when viewed in both the coronal and sagittal planes. The use of OsteoTite™ (HA-Coated) Bone Screws is strongly recommended in this application, especially in the talus and calcaneum.

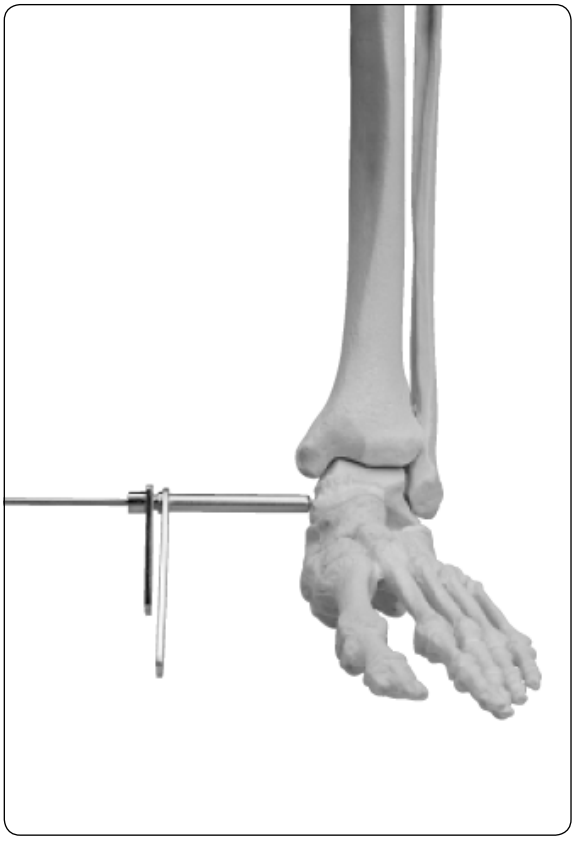


INSERTION OF THE TALAR SCREW

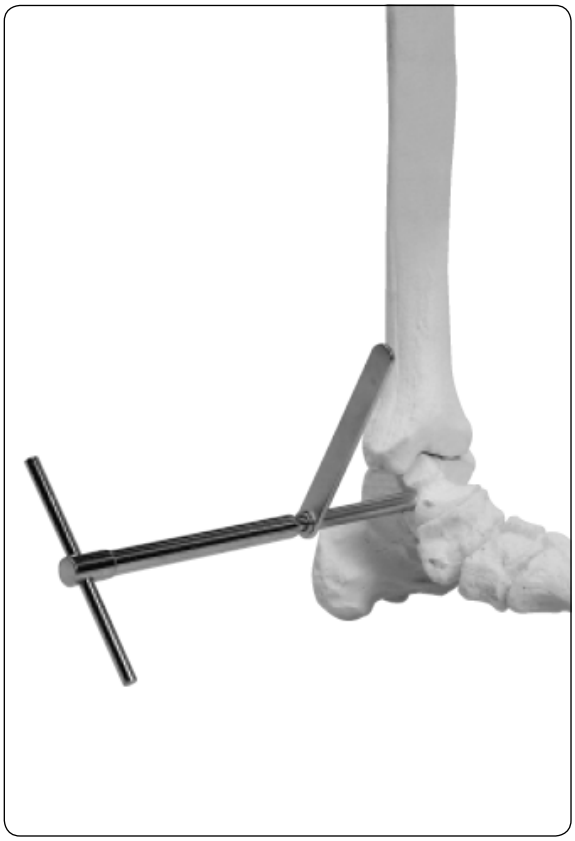
The first screw to be inserted is the talar screw. This screw may be inserted free-hand. A 1.5 mm Kirschner wire is inserted exactly in the position shown in the inset diagram, in the center of the neck of the talus, in a line parallel to the talar dome.



Once the position of this Kirschner wire has been confirmed using image intensification, a screw guide with a 3.2 mm drill guide is inserted over the Kirschner wire and the bone drilled with the 3.2 mm cannulated drill bit, held exactly parallel to the top of the dome of the talus. The Kirschner wire and drill guide are replaced with a 4.8 mm drill guide, and the entry cortex enlarged with a 4.8 mm drill bit.

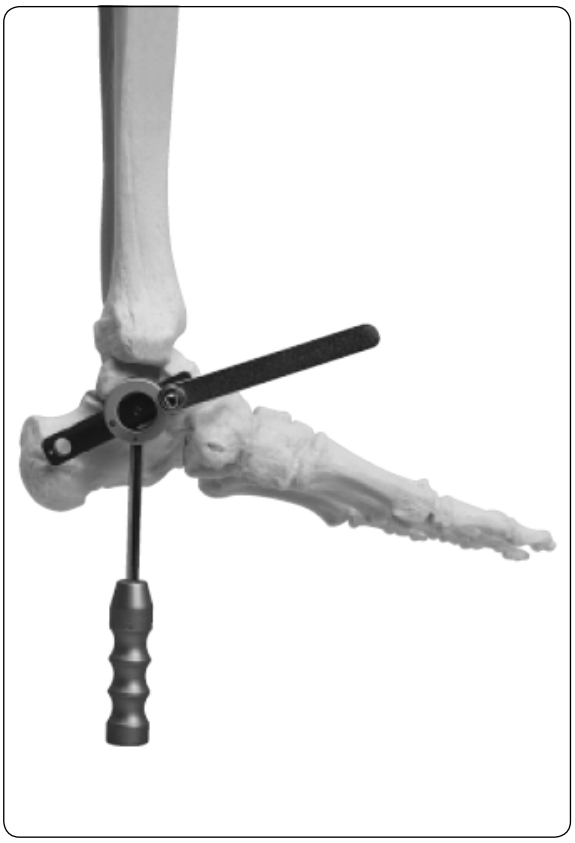


The talar screw is inserted in the usual manner, using image intensification to confirm penetration of the second cortex.

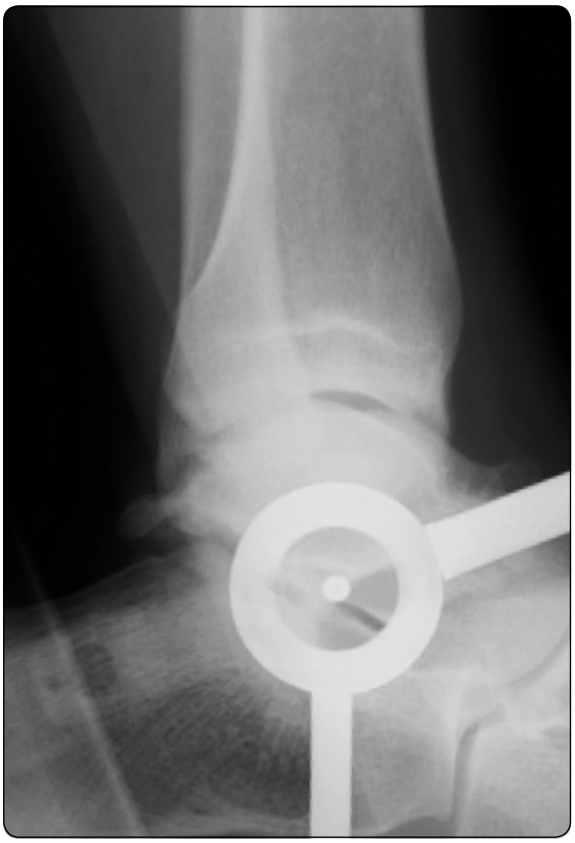


PRECAUTION: During and after insertion, ensure correct positioning of the implants under image intensification.

The screw guide is now removed and the radiolucent pin guide applied over the talar screw. The screw guide is then re-applied. The handle of the pin guide should be aligned close to the axis of the tibia, to ensure correct screw positioning for a later full range of ankle mobilization.



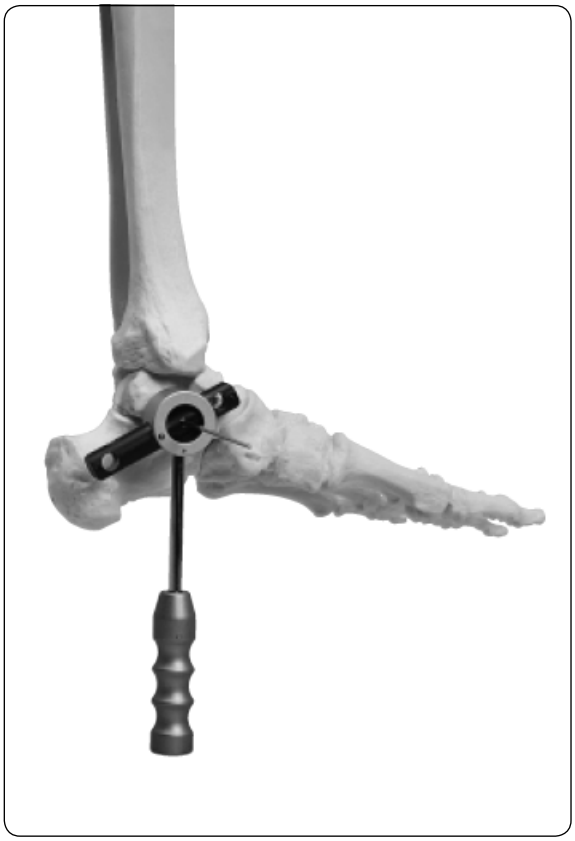
The pin guide is centered over the approximate center of rotation of the tibio-talar joint by aligning the radio-opaque circle of the pin guide with the center of the circle described by the dome of the talus.



ALTERNATIVE TECHNIQUE

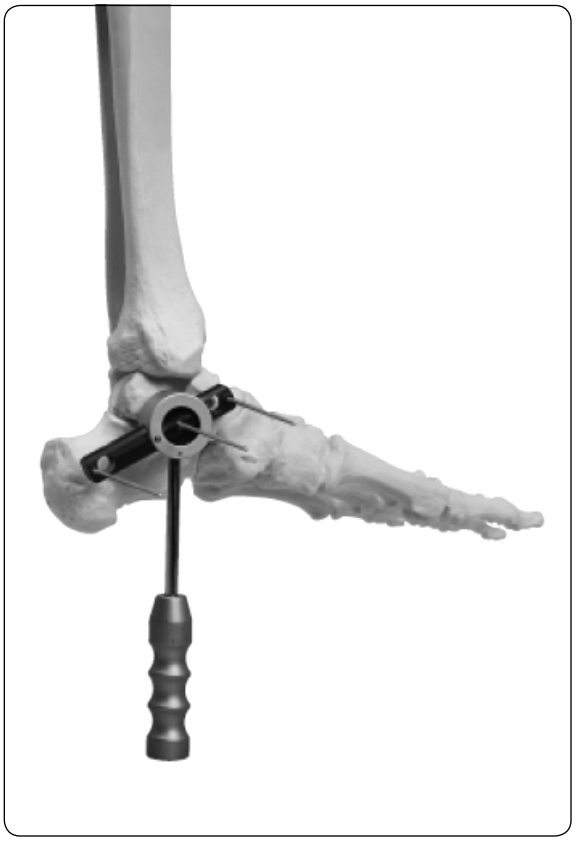
As an alternative to free-hand placement, the talar screw may be inserted using the pin guide as follows:

- The exact position of the sinus tarsi is identified on the lateral aspect of the foot by palpation with the index finger. The thumb is then used to identify the projection of the sinus tarsi on the medial side of the foot.
- The pin guide is now centered over the medial projection of the sinus tarsi and a 2 mm Kirschner wire inserted through the center of the guide, down to the skin, so that it is parallel to the dome of the talus in the AP projection.

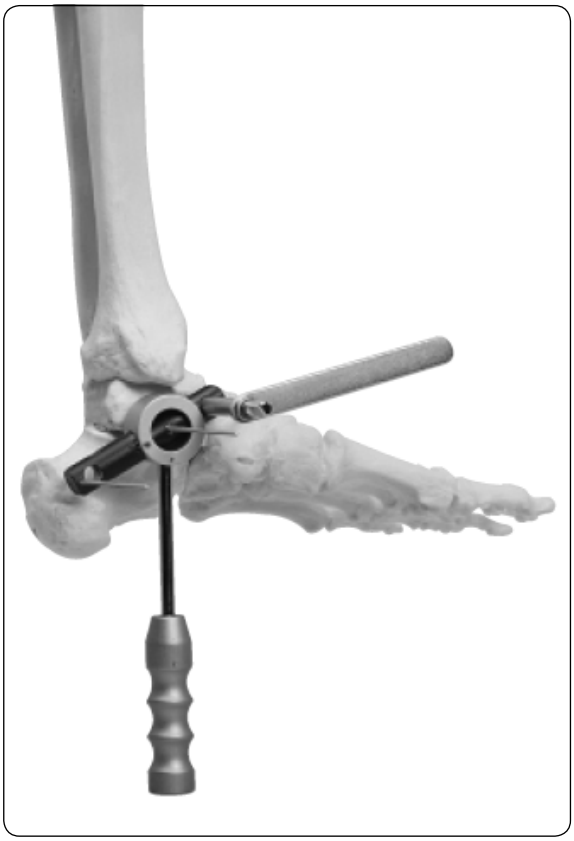


PRECAUTION: During and after insertion, ensure correct positioning of the implants under image intensification.

The handle of the pin guide is aligned close to the axis of the tibia, to ensure correct screw positioning for a full range of later ankle mobilization. Accurate positioning of the distal screws is aided by the fact that the pin guide is radiolucent, allowing unobstructed views on image intensification. A 2 mm Kirschner wire is inserted into each of the two small holes in the pin guide, parallel to the dome of the talus, to stabilize the pin guide in the correct position.



A screw guide and a 3.2 mm drill guide guide are inserted into the anterior screw seat of the pin guide through a skin incision, after separation of the underlying soft tissues down to the bone. The talar screw is then inserted using the same procedure described above.

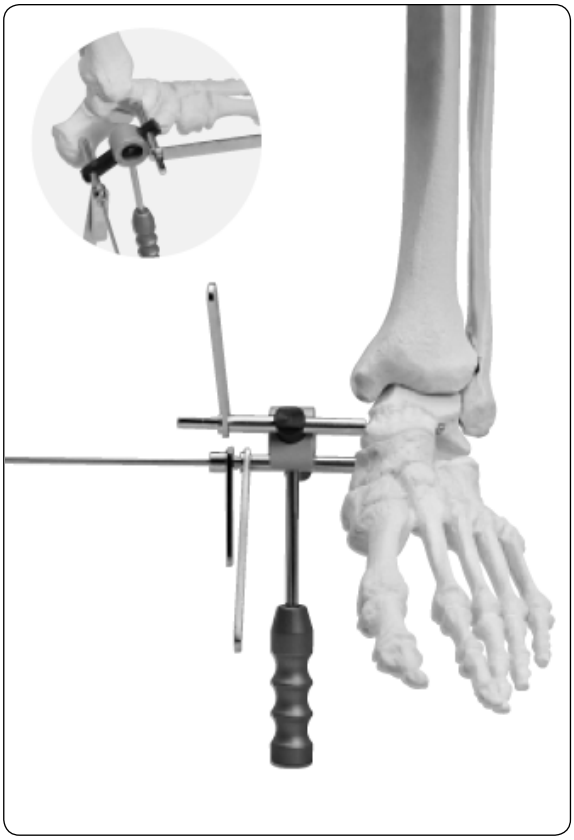


PRECAUTION: Screws and wires must be inserted with full knowledge of the safe corridors to avoid damage to the anatomical structures.

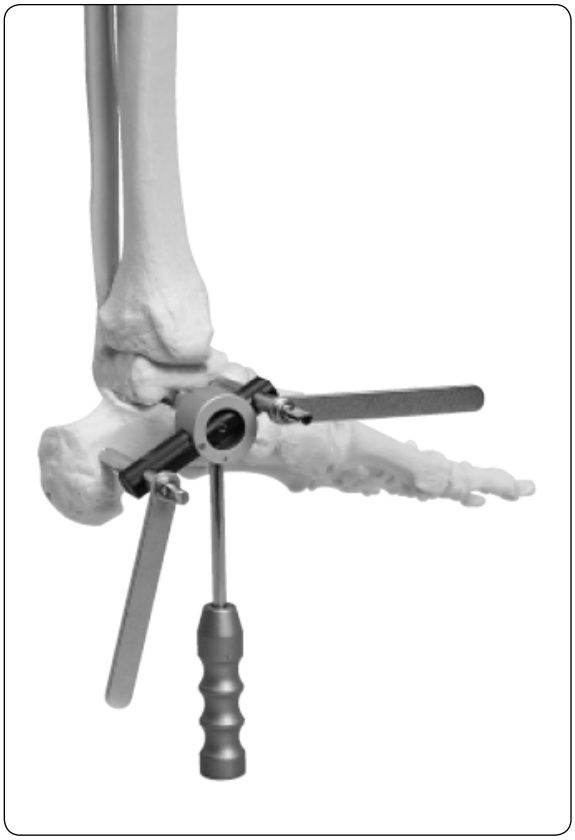
INSERTION OF THE CALCANEAL SCREW

The calcaneal screw is now inserted. Placement of the calcaneal screw in the superior aspect of the calcaneum allows some dorsi-flexion of the ankle at the appropriate time in the post-operative phase (see page 14). If the handle of the pin guide is held in line with the axis of the tibia, this screw will normally be in the correct position.

A screw guide and 3.2 mm drill guide are inserted into the posterior screw seat and the 3.2 mm drill bit used to drill the bone, parallel to the top of the dome of the talus. The proximal cortex is enlarged with a 4.8 mm drill bit, as for the talar screw.



The drill bit and drill guide are now removed and the calcaneal screw inserted. Correct positioning of the distal screws should be checked by image intensification, using an AP view of the lateral border of the talus for the talar screw, and an axial view of the hindfoot for the calcaneal screw.

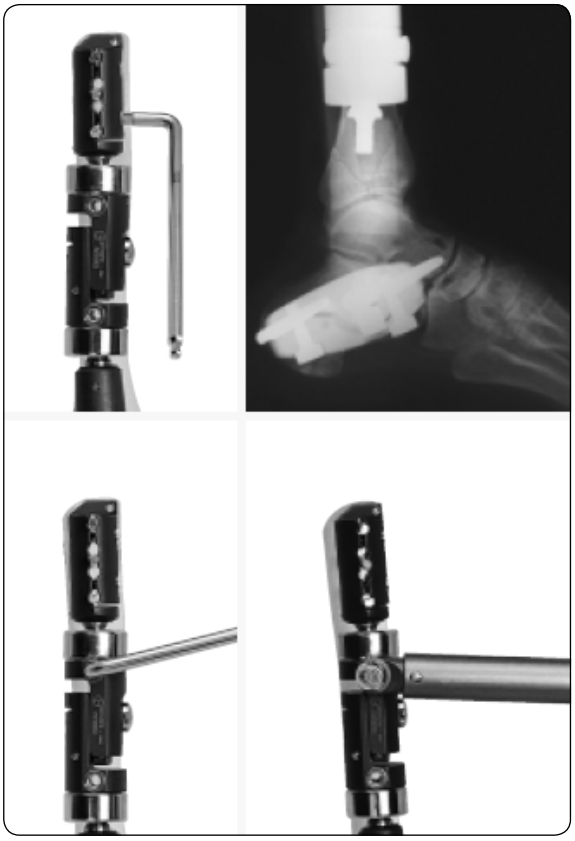


PRECAUTION: During and after insertion, ensure correct positioning of the implants under image intensification.

INSERTION OF THE DIAPHYSEAL SCREWS

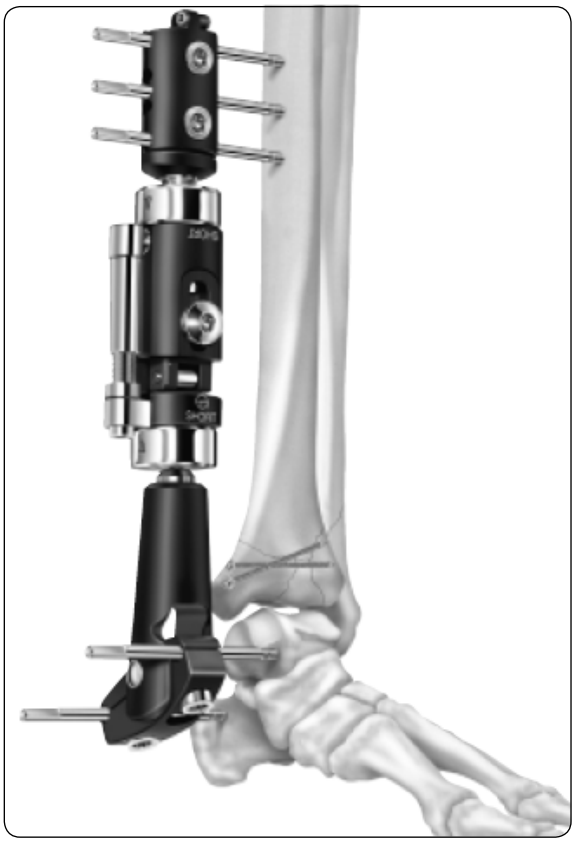
The pin guide is removed together with the screw guides, and the fixator with radiolucent ankle clamp fitted, ensuring that the telescopic body is open by about 1.0 cm. When applying the ProCallus, the Micromovement Locking Nut should be TIGHTENED, and the Central Body Locking Nut LOOSENED. Application sites for two or three cortical screws are now established in the medial face of the tibia, and these screws should now be inserted at right angles to the long axis of the tibia. Screws should be in positions 1 and 5 (two screws) or 1, 3 and 5 (three screws). It is not necessary to use a separate template for insertion of the diaphyseal screws. This is because the ProCallus straight clamp allows for the insertion of screw guides. Screw guides are inserted into the clamp and a 4.8 mm drill guide and drill bit used to drill the bone.

Once all the screws have been inserted, the screw guides are removed, the clamp cover screws tightened with the Allen wrench and reduction obtained. Accurate reduction is aided by the fact that the ankle clamp is radiolucent, allowing unobstructed views on image intensification. The ball-joints are then tightened using the Allen wrench. Final locking of the ball-joints is performed with the torque wrench.



The fixator is now distracted by 4 to 5 mm under image intensification, using the compression-distraction unit. Once distraction of the tibio-talar joint has been achieved, the Central Body Locking Nut should also be TIGHTENED. This distraction produces ligamentotaxis at the ankle joint, and will help to reduce bone fragments with soft tissue attachments. Because the ankle clamp is radiolucent, full Image Intensifier views of the fracture site are available in all planes.

If reduction cannot be fully achieved using a closed procedure, limited internal fixation of the articular surface may be carried out either percutaneously or through small incisions, using Kirschner wires, lag screws or the Orthofix Fragment Fixation System. Visualization of the articular surface for limited internal fixation may be aided by temporarily increasing the distraction. Bone grafting is often necessary for metaphyseal defects and is accomplished through small incisions. In some cases internal fixation of the fibula through a separate incision may be indicated, particularly if the fibula fracture extends into the ankle joint, or if there is a tibio-fibular diastasis.



The foot is now placed in the neutral position and the articulation locking nut on the ankle clamp tightened.

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ORTHOFIX OPERATIVE TECHNIQUE MANUALS

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Please refer to the "Instructions for Use" supplied with the product for specific information on indications for use, contraindications, warnings, precautions, adverse reactions and sterilization.

Electronic Instructions for use available at the website http://ifu.orthofix.it

Electronic Instructions for use - Minimum requirements for consultation:
- Internet connection (56 Kbit/s)
- Device capable to visualize PDF (ISO/IEC 32000-1) files
- Disk space: 50 Mbytes

Free paper copy can be requested from customer service (delivery within 7 days):
tel +39 045 6719301, fax +39 045 6719370,
e-mail: customerservice@orthofix.it

Caution: Federal law (USA) restricts this device to sale by or on the order of a physician. Proper surgical procedure is the responsibility of the medical professional. Operative techniques are furnished as an informative guideline. Each surgeon must evaluate the appropriateness of a technique based on his or her personal medical credentials and experience.

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