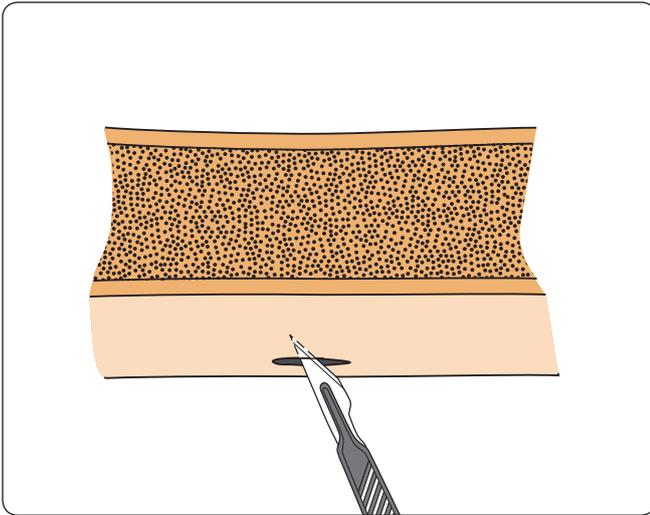


DIAPHYSEAL AND METAPHYSEAL FRACTURES

PART B: THE PROCALLUS FIXATOR (90000 SERIES)

BY DR. L. RENZI-BRIVIO AND DR. F. LAVINI



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.

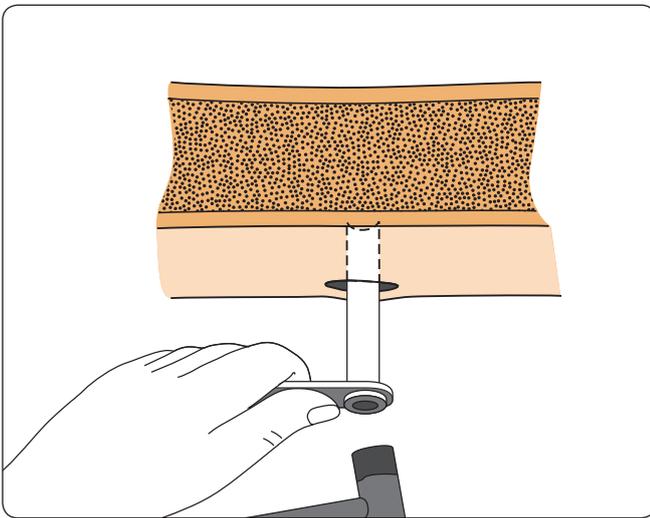
DIAPHYSEAL FRACTURES

TIBIA

Reduce the fracture as anatomically as possible, emphasizing rotational correction. A fixed position on a fracture table with a Steinman pin is recommended.

Screw Insertion

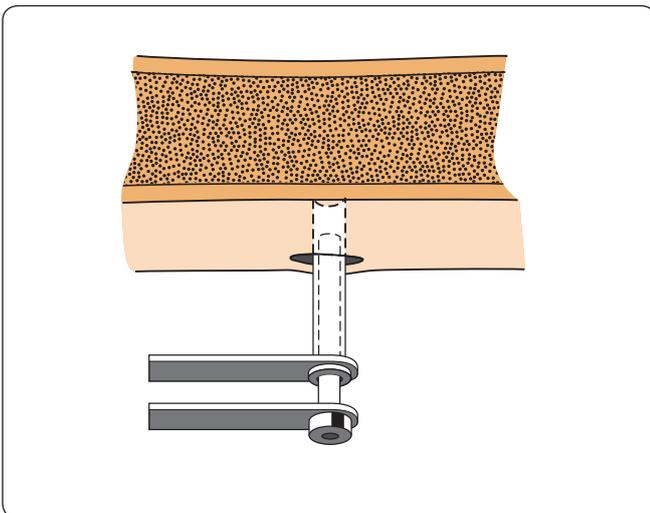
Insert screws into the shortest or most difficult segment first, from the anterior or antero-medial aspect of the tibia. Make a 15-20mm incision so that the skin around each screw is not too tight. The underlying tissues also require broad dissection down to the bone.



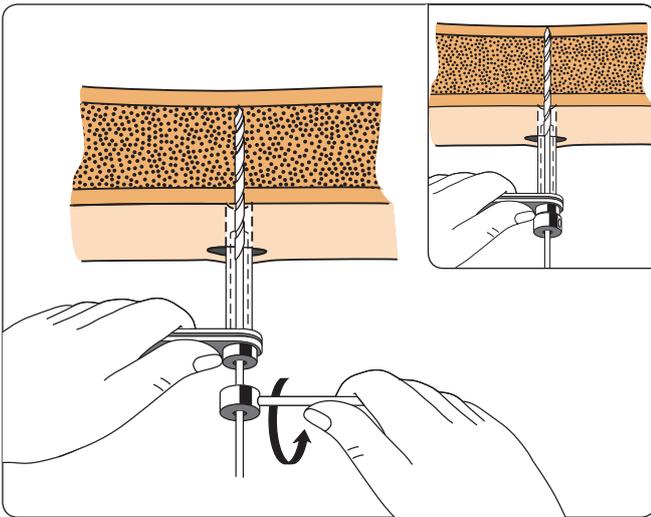
Insert a screw guide perpendicular to the longitudinal axis of the bone. Use a trocar to locate the midline by palpation. Keep the screw guide in contact with the cortex by gentle pressure, withdraw the trocar, and tap the screw guide lightly to anchor its distal end.

If the placement of this screw is critical because it is close to a joint, the position can first be checked by inserting a 2mm Kirschner wire. A screw guide can be centered over the wire by using a Ruland wire guide.

WARNING: During screw and wire insertion, do not enter the joints or the growth plates in pediatric patients to avoid joint damage or growth impairment.

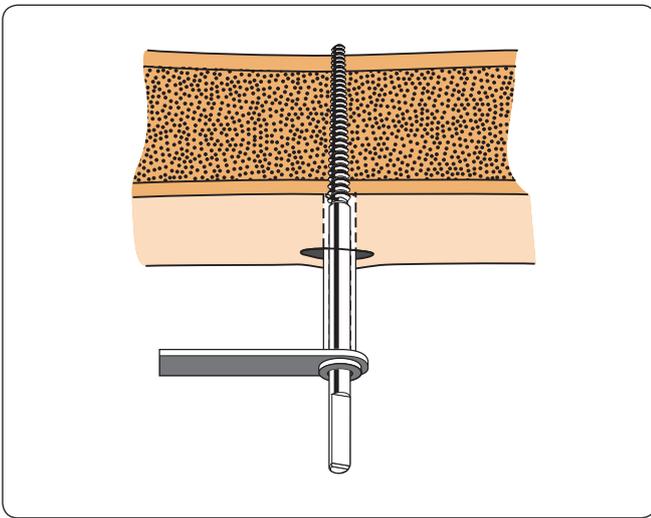


Insert the correct drill guide into the screw guide. Use screw guides for every screw insertion to minimize soft tissue trauma. We recommend a 3.2mm drill bit for cancellous bone, and a 4.8mm drill bit for cortical bone.



Drill at 500-600 rpm through the first cortex with the correct drill bit and drill stop, checking that the drill bit is at right angles to the bone. The force applied to the drill should be firm and the drilling time as short as possible to avoid thermal damage. Stop at the second cortex, offset the stop collar by 5mm, and continue through the bone. Ensure that the drill bit completely penetrates the second cortex. If a preliminary K-wire has been used, a cannulated drill bit can be used over the wire.

Kirschner wires which are used for this purpose and cannulated drill bits should NEVER be reused.



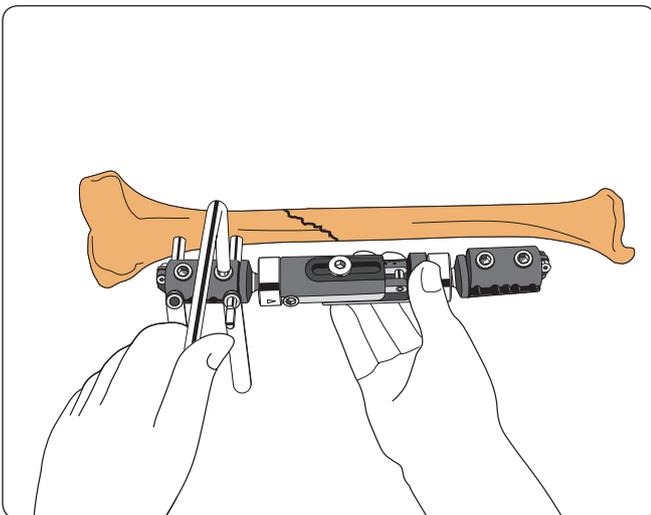
Remove the drill bit and drill guide, keeping pressure on the handle of the screw guide. Insert the selected screw and turn it with the T-wrench until it reaches the second cortex. A further 5 or 6 half turns are then normally required to ensure that about 2mm of the screw protrudes beyond the second cortex.



WARNING: As the thread is tapered, repositioning the screw by turning counterclockwise will loosen the bone-screw interface.

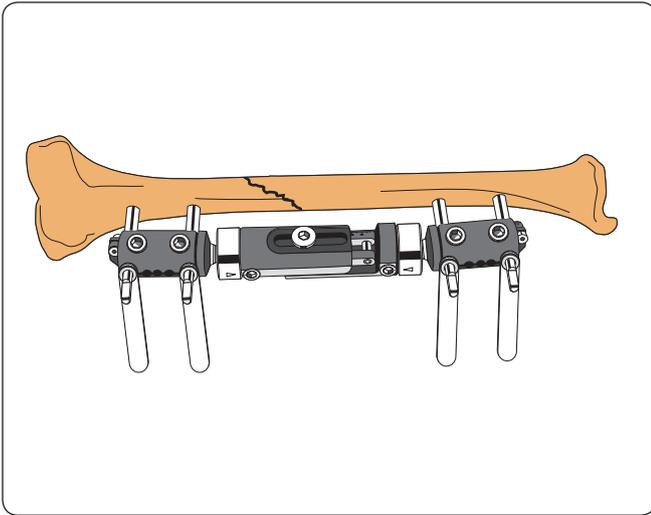


PRECAUTION: Any attempt to back out an Orthofix conical screw once it has been inserted may cause it to become loose.

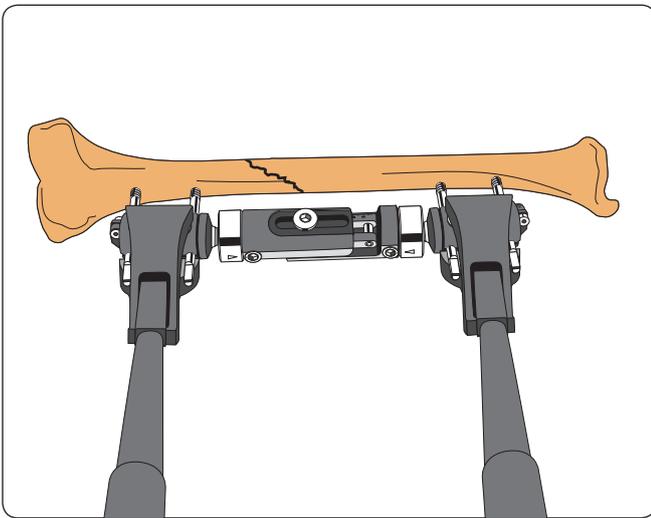


Fixator Application

Leave the screw guide in position and apply the ProCallus Fixator, with the micromovement locking nut tightened, and the central body locking nut and cams loosened. Check that all nuts and cams face away from the bone so that they can be tightened. Insert a second screw guide, as far as possible from the first for maximum stability; make the incision, and insert it down to the bone. Tighten both clamp locking screws firmly with the Allen wrench to ensure that the bone screws will be parallel. Repeat the screw procedure as before.



Before screw insertion into the second bone fragment, adjust the fixator body to the correct length, making sure that it is neither completely closed nor fully open. This will allow for final reduction. Insert screw guides through the second clamp down to the bone; tighten the clamp locking screws and insert the bone screws as before.



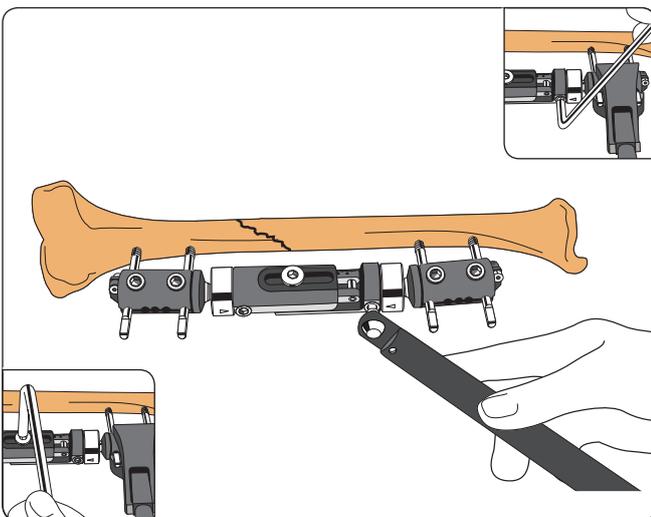
Partially loosen the clamp locking screws and remove the screw guides. Position the ProCallus fixator at least 2cm from the skin to allow for post-operative swelling and cleaning. Align the body parallel to the major axis of the segment being treated. Fully tighten the clamp locking screws. Obtain final reduction with manipulation forceps.



WARNING: The fixator should be applied at a sufficient distance from the skin to allow for post-operative swelling and for cleaning, remembering that the stability of the system depends upon the bone-fixator distance. If the fixator is sited at a distance of more than 4cm from the bone, the use of 3 screws per clamp is advisable.



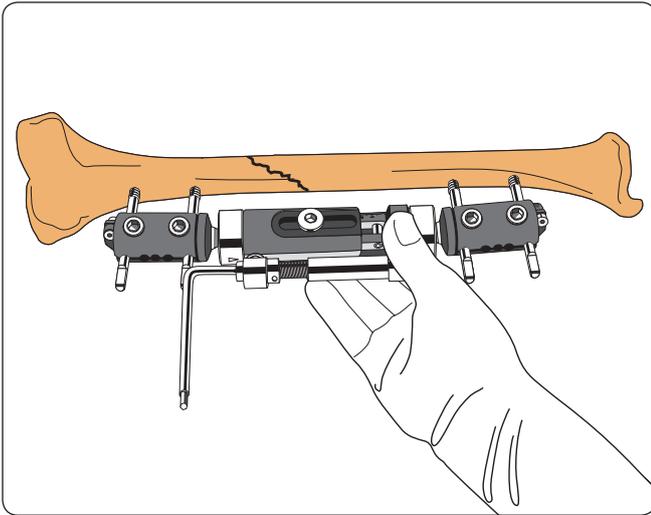
WARNING: Axial displacement may occur if the body of the fixator is not in line with and parallel to the bone.



Hold the reduction in a good position, while an assistant tightens the cams and the central body locking nut with an Allen wrench. Lock the cams definitively with a torque wrench, a "click" indicating the correct torque. Use the torque wrench only to tighten the cams, and never use it to loosen anything.



WARNING: Any attempt to unlock the cam or any screw using the torque wrench will damage its gearing.



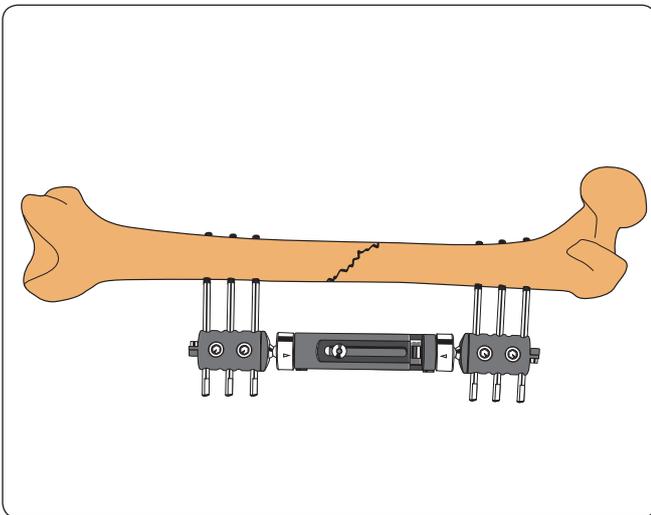
With the Central Body Locking Nut loosened, compression or distraction can be achieved using the compression-distraction unit fitted into the cams. The Allen wrench is used to turn the screw of compression-distraction unit either clockwise or counterclockwise. (one full turn = 1mm). Compression is never recommended in a fresh fracture. Release any skin tension around the screws by extending the skin incision.



WARNING: For increased stability the compression-distraction unit may be applied to the fixator body and locked into place.

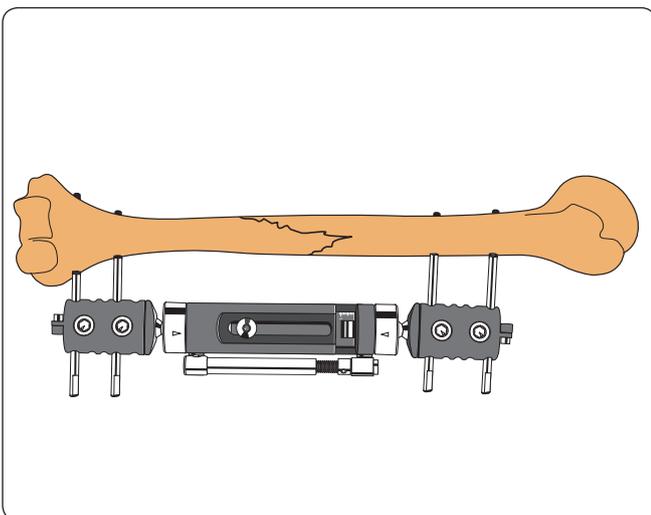


WARNING: Compression is never recommended in a fresh fracture.



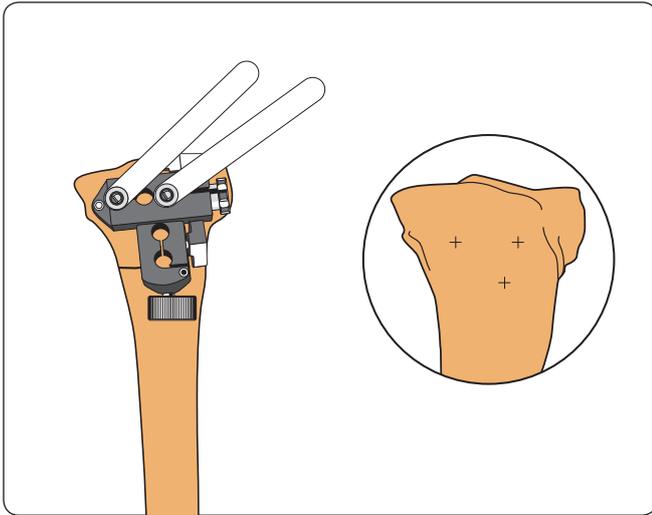
FEMUR

Reduce the fracture approximately, and any rotational displacement as completely as possible. Apply a ProCallus Fixator (standard or long model) to the lateral aspect of the femur. Insert 6 screws, 3 in each clamp, in the shortest segment first, using screw and drill guides. Position the second group of screws to allow the body of the fixator to be open a minimum of 1cm. Screws should never be less than 2cm from the fracture line. Obtain final reduction using manipulation forceps with the fixator in place. Lock the fixator as above, again using a torque wrench for the cams only.



HUMERUS

Reduce fracture approximately, and any rotational displacement as completely as possible. Apply a ProCallus fixator (standard or short model) to the lateral aspect of the bone. Insert 4 screws, 2 in each clamp, with screw and drill guides. Insert the most distal screw first, 1cm proximal to the lateral epicondyle. The second distal screw should be in the fourth seat of a standard clamp. To avoid risk of damage to the radial nerve, use an open procedure. Position the proximal screws to allow the telescopic body of the fixator to be open a minimum of 1cm. Reduce and lock as before.



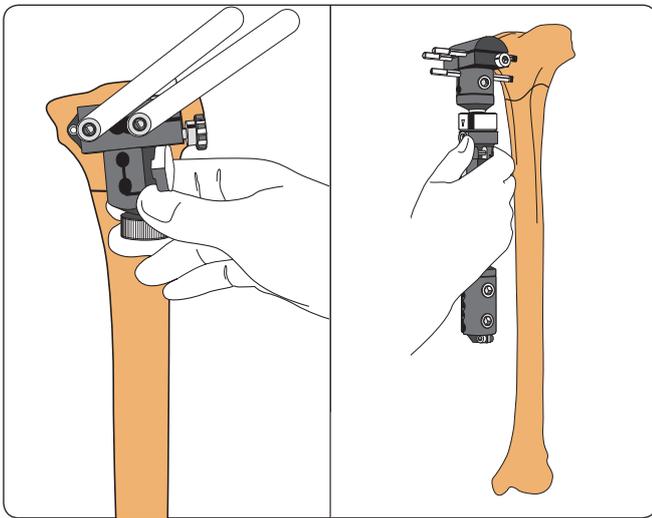
METAPHYSEAL FRACTURES

TIBIA: Proximal Metaphyseal Fractures

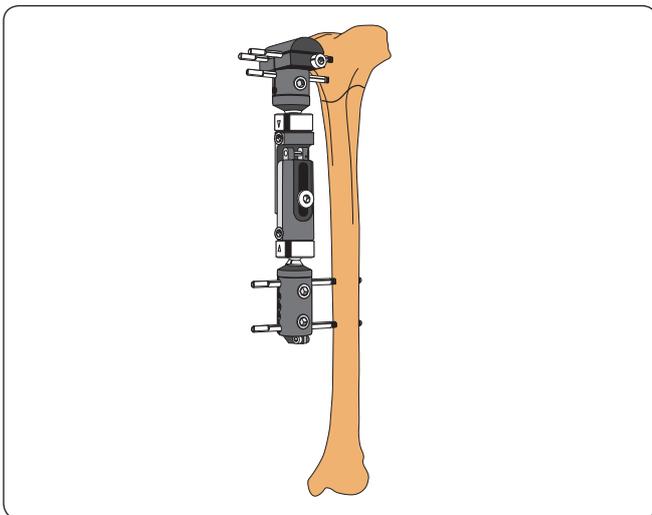
Use of Metaphyseal Clamp

Apply the ProCallus fixator (standard or short model with the Metaphyseal Clamp) antero-medially. Insert most anterior proximal screw first, freehand, 2cm distal to the knee joint. Apply metaphyseal clamp template and insert second proximal screw in 3rd or 4th seat of the horizontal component.

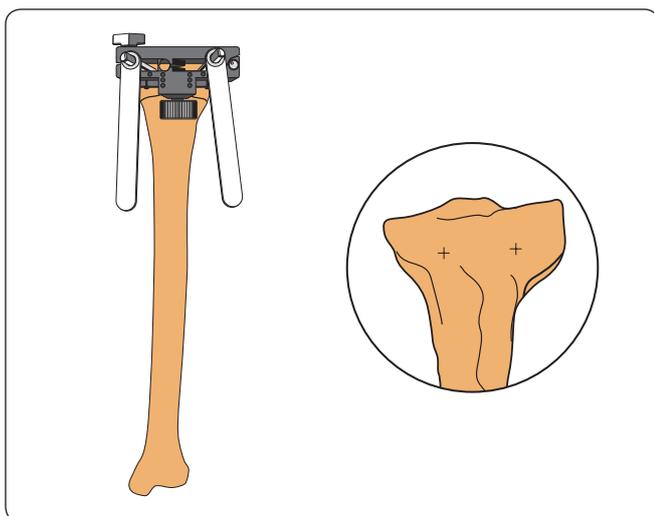
OsteoTite™ (HA-Coated) bone screws may be useful in this application.



Rotate vertical component of metaphyseal clamp template to find most favourable position for remaining metaphyseal screw, and insert it. Replace template with definitive metaphyseal clamp attached to a ProCallus fixator with a straight clamp.



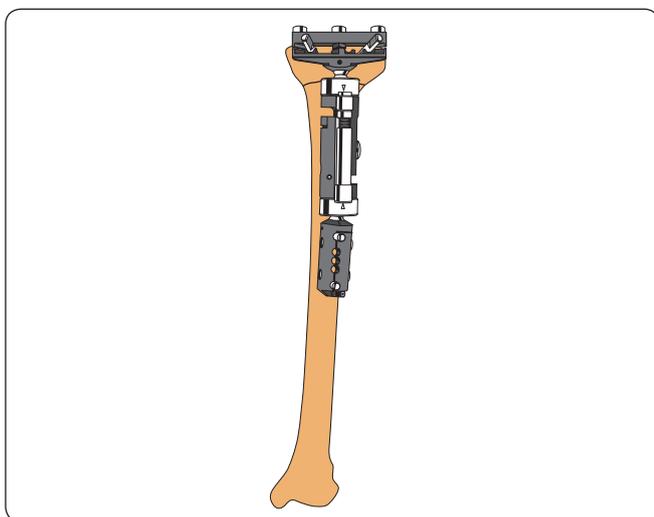
Insert the diaphyseal screws, again checking that the fixator body is not completely closed.



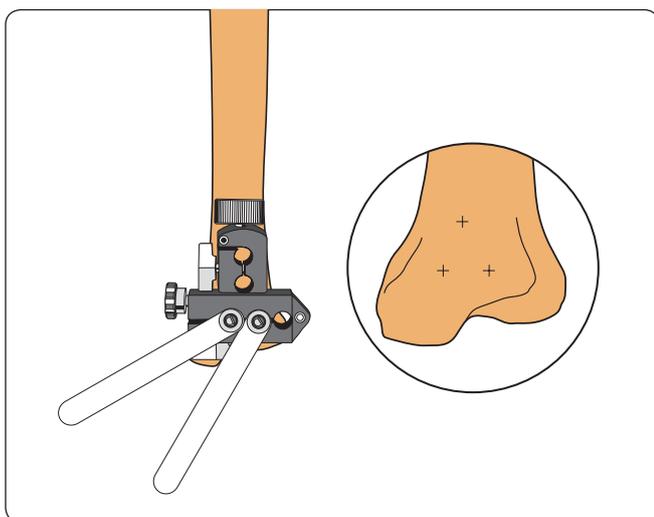
Use of Torbay-Garches Clamp

Apply the ProCallus fixator (standard or short model with the Torbay-Garches clamp) using an antero-medial or anterior approach. Temporarily anchor the Torbay-Garches clamp template to the proximal tibia with Kirschner wires. Insert the most posterior screw first in antero-medial applications, then the more anterior screw, to converge slightly with the first.

OsteoTite (HA-Coated) bone screws may be useful in this application.



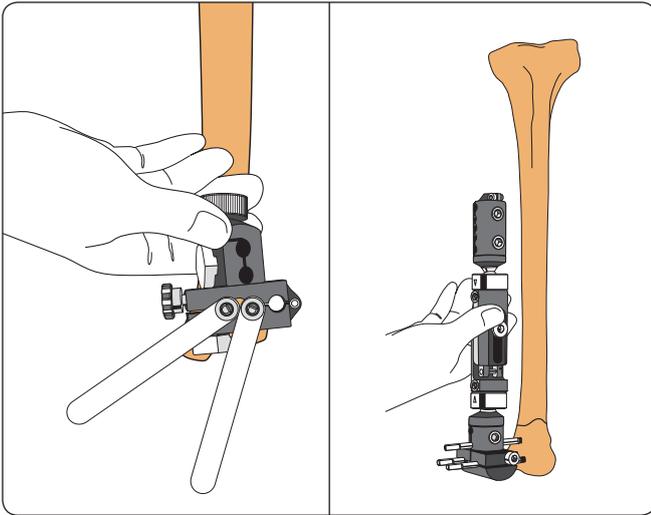
Replace the Torbay-Garches Clamp template with definitive Torbay-Garches Clamp. Attach the body of the ProCallus and insert the diaphyseal screws, ensuring that the fixator body is not completely closed.



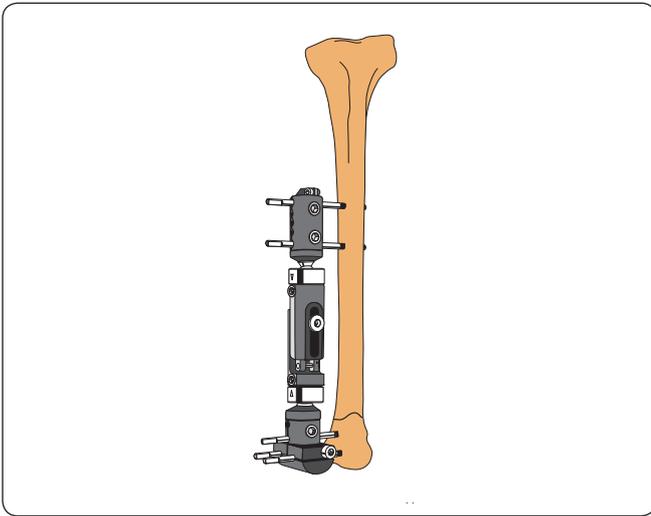
TIBIA: Distal Metaphyseal Fractures

Apply the ProCallus fixator (standard or short model with the Metaphyseal Clamp) antero-medially. Insert the most posterior distal screw first, freehand, immediately anterior to the medial malleolus. Apply the metaphyseal clamp template and insert a second distal screw in the 3rd or 4th seat of the horizontal component.

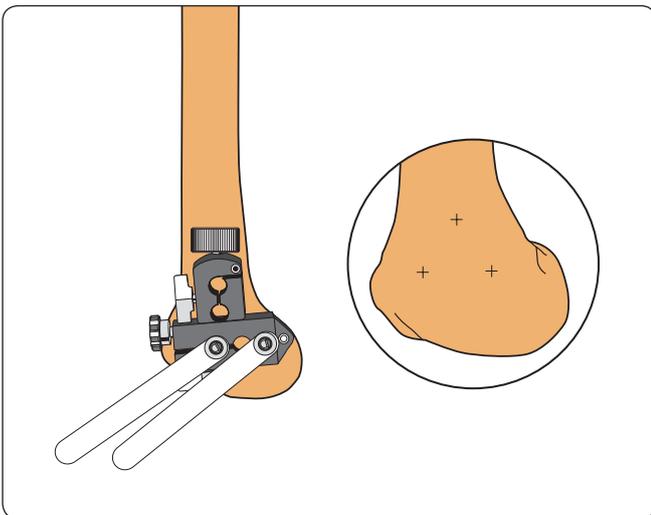
OsteoTite (HA-Coated) bone screws may be useful in this application.



Rotate the vertical component of the metaphyseal clamp template to the most favourable position, and insert the remaining metaphyseal screw. Replace the template with the definitive metaphyseal clamp attached to a ProCallus fixator with a straight clamp. Alternatively a T-Clamp may be used distally.



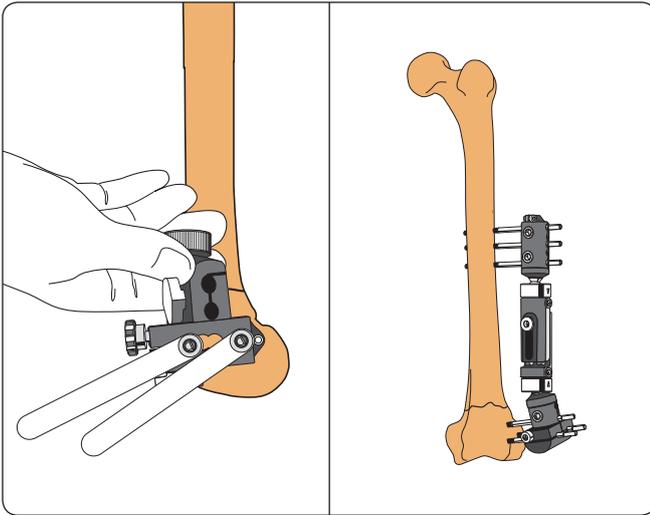
Insert the diaphyseal screws. Check that the fixator body is not fully closed.



FEMUR: Distal Metaphyseal Fractures

Apply the ProCallus fixator (standard or short model with the Metaphyseal Clamp) laterally, inserting the most anterior distal screw first, about 1cm behind the anterior edge of the lateral condyle. With the metaphyseal clamp template firmly closed, insert the second distal screw in the 3rd or 4th seat of the horizontal component.

OsteoTite (HA-Coated) bone screws may be useful in this application.



Rotate the vertical component of the metaphyseal clamp template to insert the remaining metaphyseal screw in the most favourable position. Replace the template with the definitive metaphyseal clamp attached to a ProCallus fixator with a straight clamp. Insert the diaphyseal screws, checking that the fixator body is open at least 1cm.

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

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