

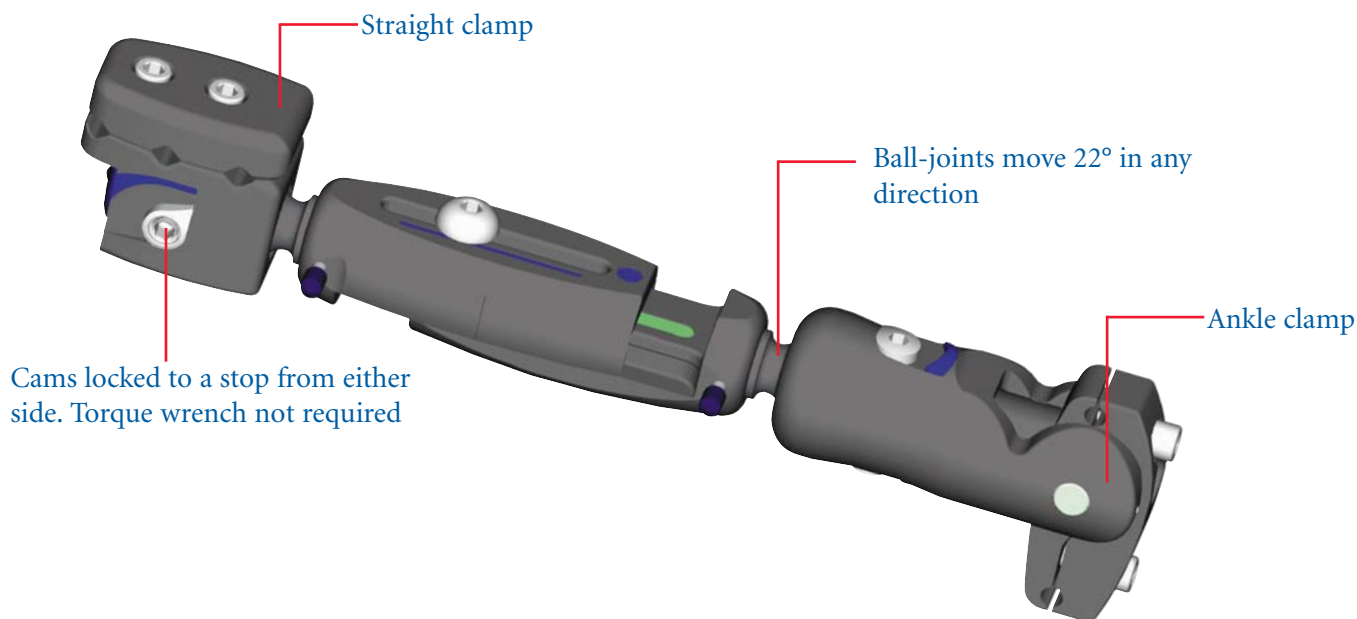
# The XCaliber Articulated Ankle Fixator

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## GENERAL POINTS

The XCaliber Articulated Ankle Fixator is made of radiolucent material for unobstructed X-ray visualization. The metallic bolts, the bush in each ball-joint the clamp cover and the base of the ankle clamp are the only radio-opaque components. Because it is radiolucent and made of a composite material, the ball-joint deforms after repeated tightening. It can be adjusted on the patient if repositioning of the fracture is required, but will not be strong enough for use on a second patient. In addition the joint is sealed and cannot be dismantled for cleaning.

**The XCaliber Fixator is strictly single patient use.**



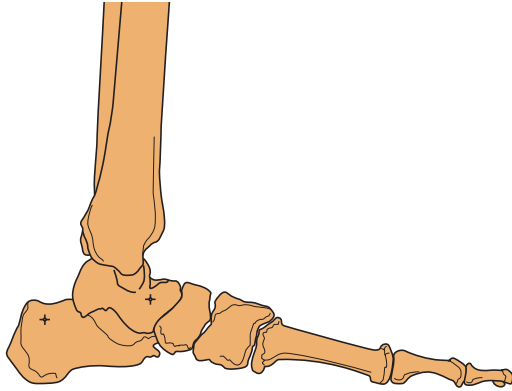
## EQUIPMENT REQUIRED

99-91047	XCaliber Articulated Ankle Kit, Sterile
99-11947	Radiolucent Ankle Pin Guide, Sterile
99-91010	XCaliber Static Compression-Distractor Unit, Sterile
99-91015	XCaliber Dynamic Compression-Distractor Unit, Sterile
91060	XCaliber Color Inserts
90037	Supplementary Screw Holder
99-91038	Supplementary Screw Holder, Sterile
91039	Supplementary Screw Holder Bar Radiolucent, 150 mm

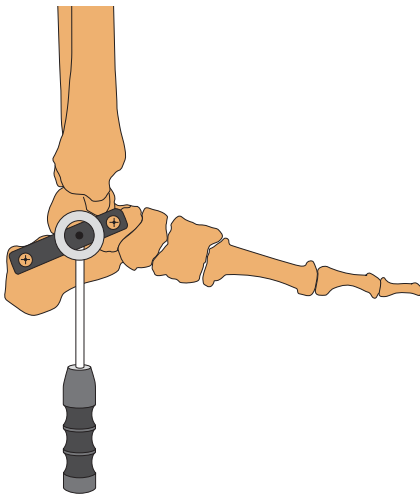
*Standard Instrumentation for Screw Insertion*

**STERILE EO**

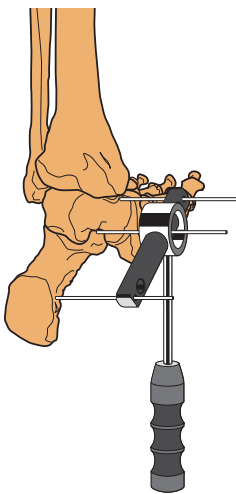
**CAUTION:** Federal (U.S.A.) law restricts this device to sale by or on the order of a physician. Contents sterile unless package opened or damaged; Do not use if package is opened or damaged.



- This application provides cross joint fixation for severe articular and pilon fractures of the distal tibia. It is designed to be minimally invasive.
- Insert the distal screws first: one in the talus and one in the calcaneus.

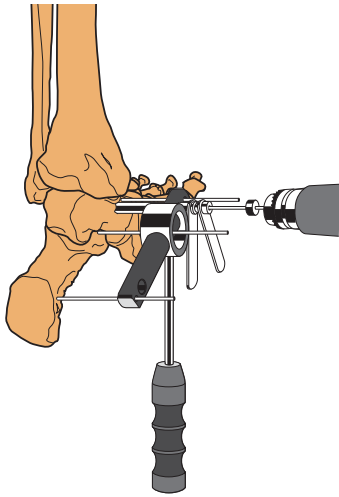


- To identify the approximate center of rotation of the tibio-talar joint, place the center of the pin guide over the medial projection of the sinus tarsi, parallel to the dome of the talus in the AP projection. In the lateral view, the ring of the pin guide should match the curve of the dome of the talus. Identify the ideal position of the anterior screw by moving the pin guide about its axis under image intensification. Align the handle of the pin guide with the axis of the tibia.



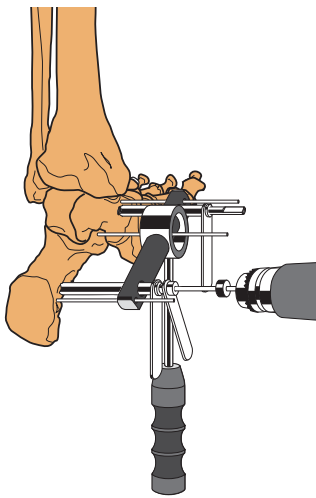
- Insert a 2 mm K-wire through the center of the pin guide, down to the skin. Insert K-wires into the two small holes in the pin guide to stabilize it for screw insertion.

*Note: The anterior screw hole in the pin guide should be over the center of the neck of the talus.*



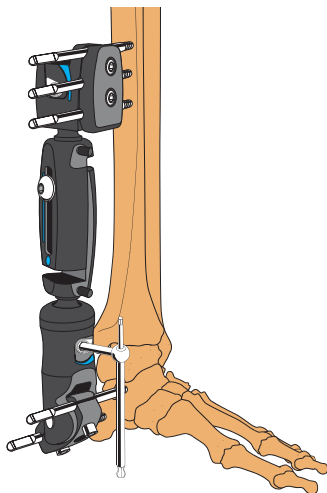
- Insert a screw guide and 3.2 mm drill guide through the anterior hole in the short arm of the pin guide. Check that it is in the center of the bone. Drill the bone completely with a 3.2 mm drill bit. Replace it with a 4.8 mm drill guide and drill the first cortex only with a 4.8 mm drill bit.

*Note: The position of this screw can first be checked by inserting a 2 mm Kirschner wire over the center of the neck of the talus. A cannulated drill bit can then be used over the wire. Kirschner wires which are used for this purpose and cannulated drill bits should NEVER be reused.*



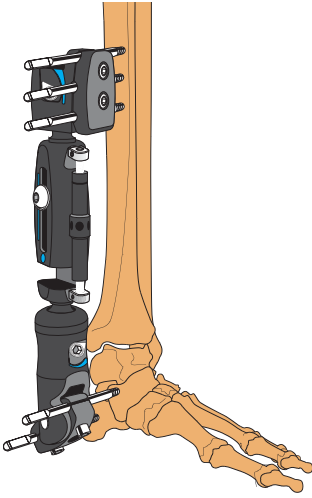
- After removing the drill guide, insert the screw into the talus. Repeat the same procedure for insertion of the second screw into the calcaneus.

*Note: OsteoTite (HA-Coated) bone screws are strongly recommended for this application.*

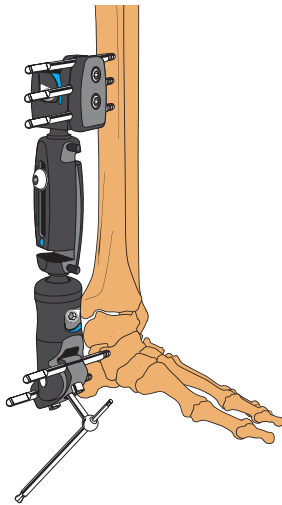


- Remove the K-wires and pin guide and place the fixator over the distal screws. Use the fixator as a template for placement of the tibial screws, after checking that the fixator body is not completely closed. Lock the clamp cover locking screws firmly and reduce the fracture. PARTIALLY tighten the cams (about halfway). Check reduction and lock the cams definitively. A torque wrench is not required.

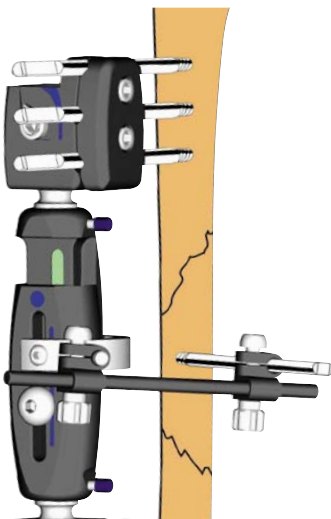
*Note: The cams are fully tightened by turning them towards the thickest part of the color insert until the flat surface reaches the edge of the recess.*



- Once the fibular length has been restored, distract the ankle joint further under image intensification by an additional 4-5 mm, using the compression-distraction unit. This will aid reduction by ligamentotaxis, and improve joint access for the fixation of small bone fragments. Because the fixator is radiolucent, full Image Intensifier views of the fracture site are available in all planes. The ankle joint should not be left in excessive distraction post-operatively. The body locking nut should be tightened and the compression-distraction unit removed.



- Lock the distal clamp articulation locking nut so that the ankle is plantigrade.



### SUPPLEMENTARY SCREWS

- A fracture will be held in a more stable position if the nearest bone screws are applied fairly close to the fracture margin, and if these distances are equal on both sides of the fracture. A minimum of 2 cm is recommended between the fracture and the nearest screw. A supplementary screw holder is supplied to achieve this. Using the screw guide, a screw should be inserted into the tibial shaft so as to even the distance between the fracture and the nearest bone screws. This screw is attached to the fixator either with a clamp over the fixator body, or over the nearest convenient bone screw. This screw should be removed before the fixator is dynamized.

The Orthofix Quality System has been certified to be in compliance with the requirements of:

- Medical Devices Directive 93/42/EEC, Annex II - (Full Quality System)
- International Standards EN 46001/ISO 9001

for orthopaedic external fixator systems including bone screws, nails and wires, sterile external and internal fixation systems.



See “Orthofix External Fixation System” instructions leaflet (PQ EXF) and appropriate Operative Manual prior to use.