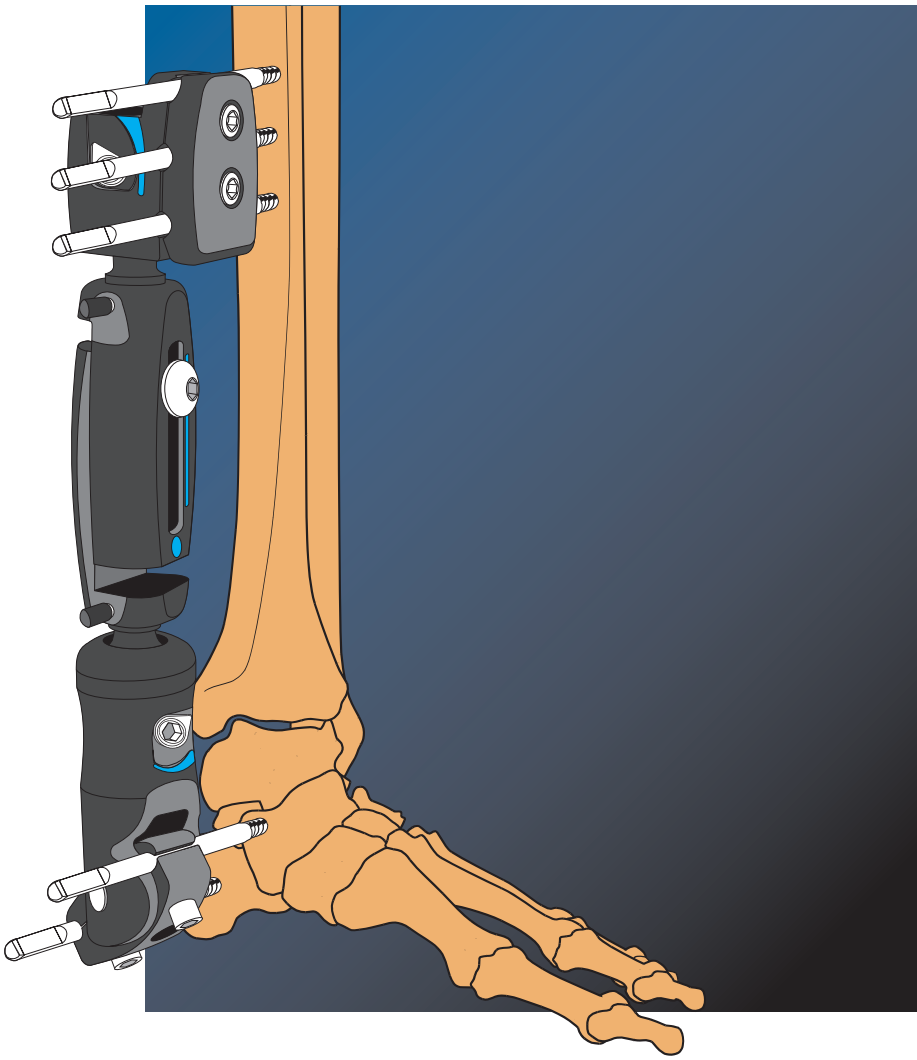
QUICK REFERENCE GUIDE



The XCaliber Articulated Ankle Fixator

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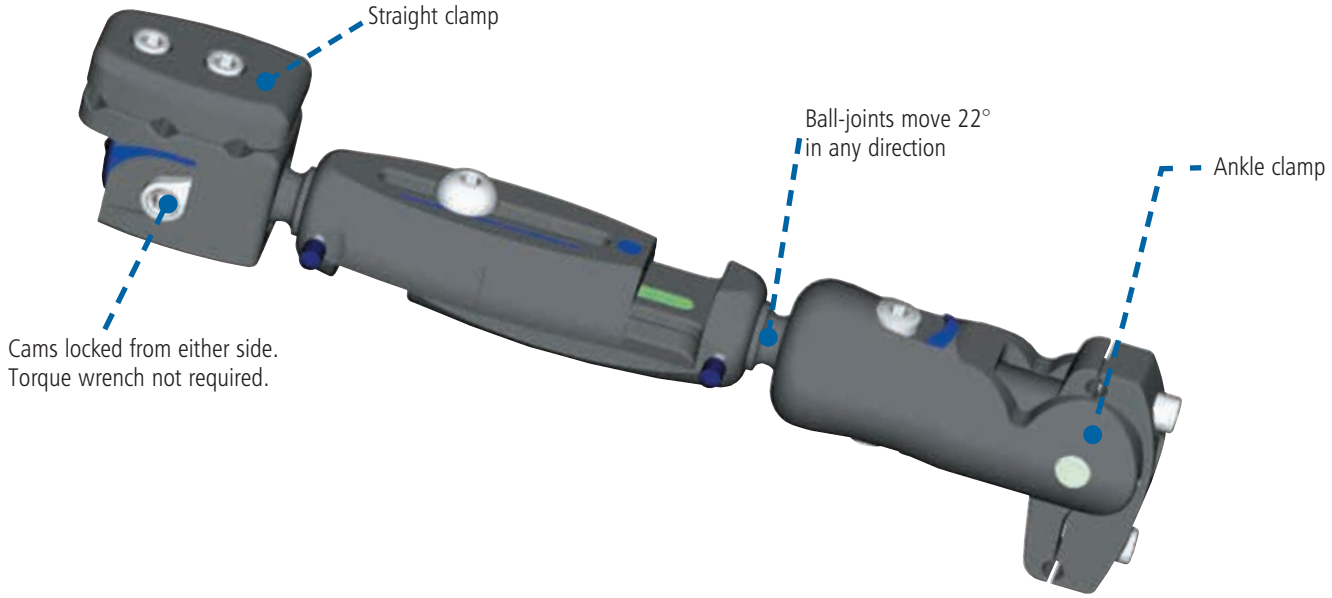
By Dr. S. Berki, Dr. V. Caiaffa, Dr. F. Lavini and Dr. M. Manca

ORTHOFIX®

GENERAL POINTS

The XCaliber Articulated Ankle Fixator is made of radiolucent material for unobstructed X-ray visualization. The metallic bolts and the cam and bush of 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

99-91245	XCaliber Articulated Ankle Kit with Dynamic Compression/ Distraction Unit, sterile
99-11947	Radiolucent Ankle Pin Guide, sterile
99-91038	Supplementary Screw Holder (Bar and Clamps), sterile
90037	Supplementary Screw Holder

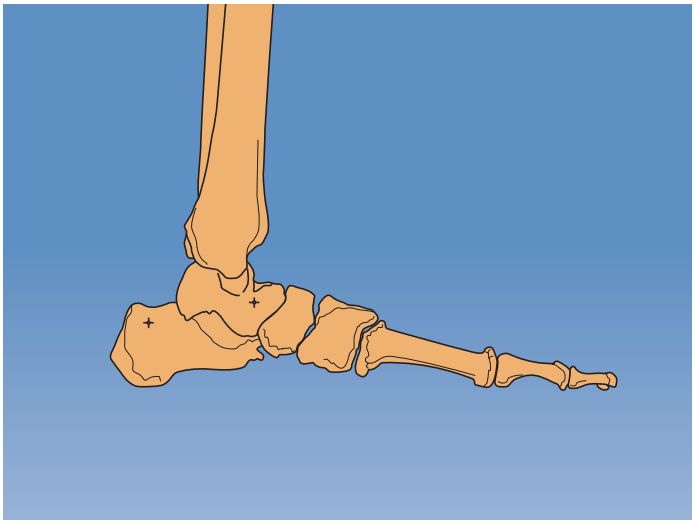
Standard Instrumentation for Screw Insertion

or

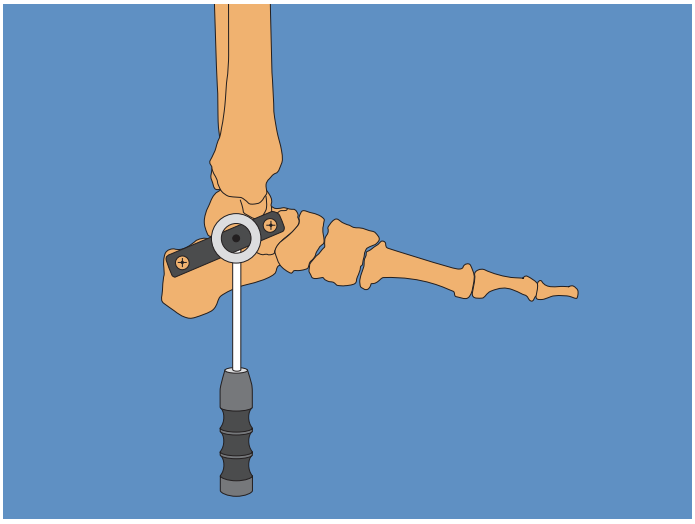
99-91647UE	XCaliber Ankle Complete Kit, sterile Consisting of:
	1x91150 Universal T Wrench
	1x91017 Universal Allen Wrench
	1x11106 Drill Guide 3.2x40mm
	1x11104 Drill Guide 4.8x40mm
	1x91047 XCaliber Ankle Fixator
	1x11947 Radiolucent Ankle Pin Guide
	3x11102 Screw Guide L 60mm
	1x91015 Dynamic Compression/Distraction Unit
	2x99-611540 XCaliber Osteotite Screw 150/40, sterile
	3x99-611530 XCaliber Osteotite Screw 150/30, sterile
	1x1101101 Cannulated Drill Bit 3.2x200mm
	2x11014 X-Wire without olive 1.5x250mm
	1x1100101 Drill Bit 4.8x180mm
99-91038	Supplementary Screw Holder (Bar and Clamps), sterile
90037	Supplementary Screw Holder

STERILE	R

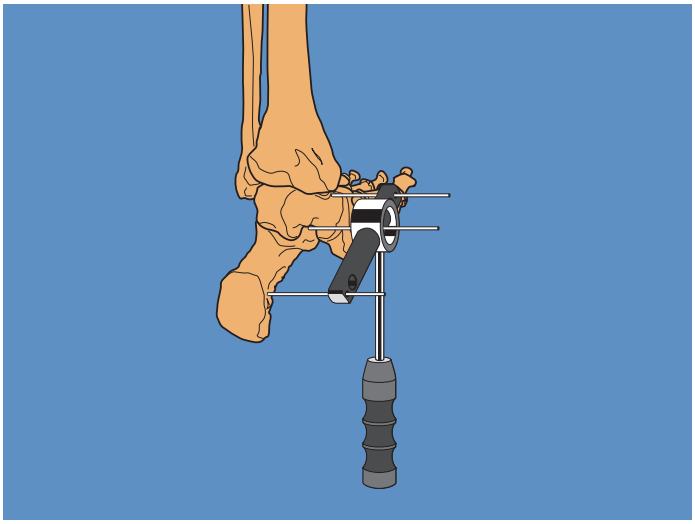
CAUTION: Federal (U.S.A.) law restricts this device to sale by or on the order of a physician. Contents sterile unless package opened or damaged; Do not use if package is opened or damaged.



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 calcaneum.

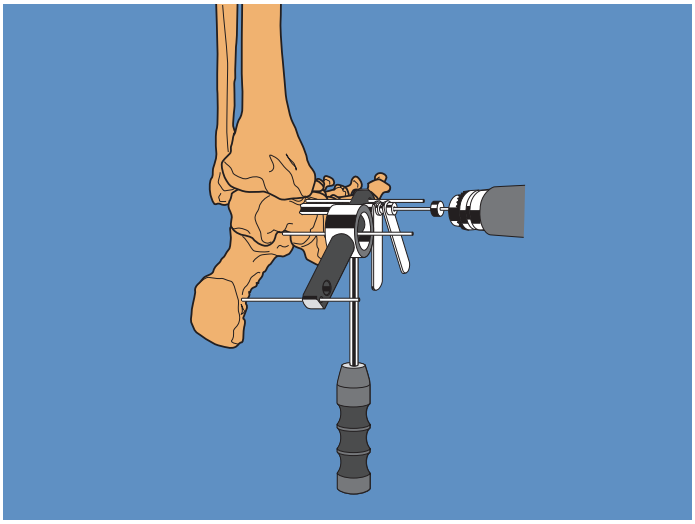


To identify the approximate centre of rotation of the tibio-talar joint, place the centre of the pin guide over the medial projection of the sinus tarsi, parallel to the dome of the talus in the AP projection. In the lateral view, the ring of the pin guide should match the curve of the dome of the talus. 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.



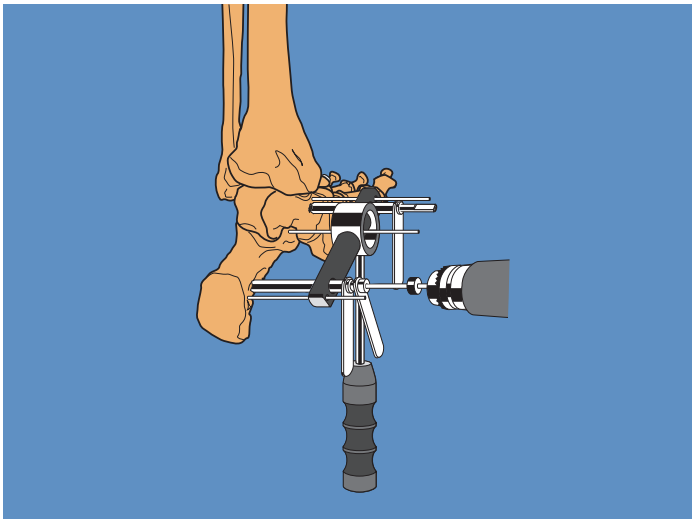
Insert a 2mm K-wire through the centre of the pin guide, down to the skin. Insert K-wires into the two small holes in the pin guide to stabilize it for screw insertion.

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



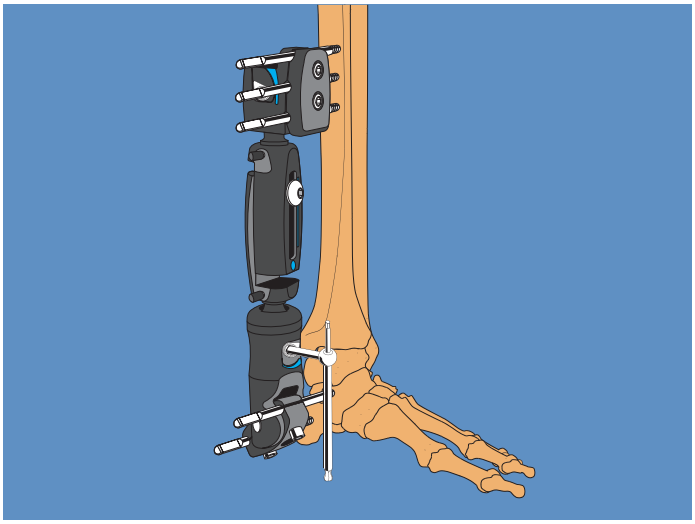
Insert a screw guide and 3.2mm drill guide through the anterior hole in the short arm of the pin guide. Check that it is in the centre of the bone. Drill the bone completely with a 3.2mm drill bit. Replace it with a 4.8mm drill guide and drill the first cortex only with a 4.8mm drill bit.

Note: The position of this screw can first be checked by inserting a 2mm Kirschner wire over the centre of the neck of the talus. Use a 2.0mm wire guide in the screw guide if available. 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.



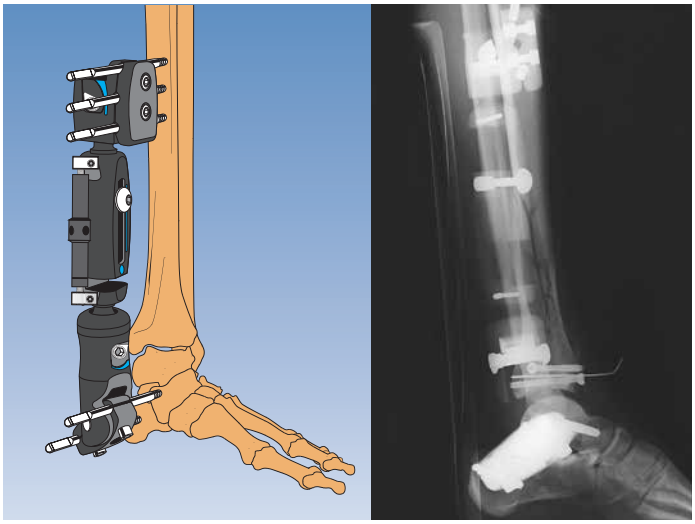
After removing the drill guide, insert the screw into the talus with the T-wrench or hand drill until it reaches the second cortex. A further 5 or 6 half turns are then normally required to ensure that about 2mm of the screw protrudes beyond the second cortex.
Note: Never insert the self drilling screws under power.
Repeat the same procedure for insertion of the second screw into the calcaneum.
If self-drilling XCaliber bone screws are being used, in the talus or calcaneum where the cortex is thin, a 3.2mm drill bit should be used.

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

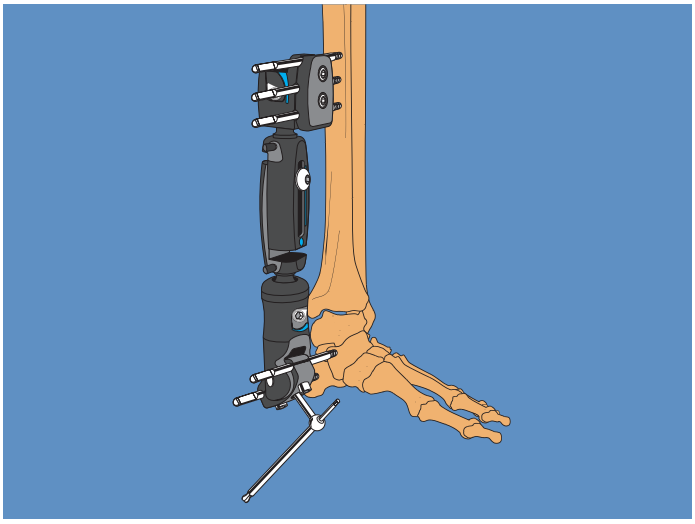


Remove the K-wires and pin guide and place the fixator over the distal screws. Use the fixator as a template for placement of the tibial screws, after checking that the fixator body is not completely closed. Diaphyseal bone screws should always be inserted in the centre of the bone axis, to avoid weakening it after pre-drilling with a 4.8mm drill bit through a 4.8mm drill guide.
In all cases the surgeon should be mindful of the amount of torque required to insert the screw. If it seems tighter than usual, it is safer to remove the screw and clean it, and drill the hole again with a 4.8mm drill bit, even if it has already been used. Lock the clamp cover locking screws firmly and reduce the fracture. PARTIALLY tighten the cams with the Allen wrench. Check reduction and lock the cams definitively with the Allen wrench.

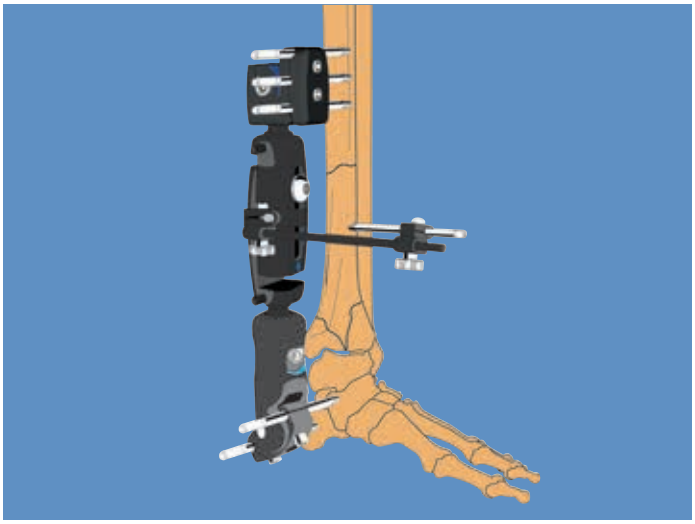
Note: The cams can be locked from either side of the clamp. They should be turned towards the thicker section of the coloured insert until tightly closed, and the cam is at least 50% of the way across the recess.



Once fibular length has been restored, distract the ankle joint further under image intensification by an additional 4-5mm,
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. A 6mm Allen wrench should be used to tighten the supplementary screw holder clamps. A supplementary screw can also be used to stabilize a third fragment. This screw should be removed before the fixator is dynamized.

Orthofix wishes to thank

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for their invaluable help in the preparation
of this Quick Reference Guide
and their contribution to the design
and refinement of the equipment described.

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) as amended in 2007/47/EC
- International Standards ISO 13485 / ISO 9001 for external fixator devices, implants for osteosynthesis and related instruments.

See "Orthofix External Fixation System" instruction leaflet (PQ EXF) prior to use.

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