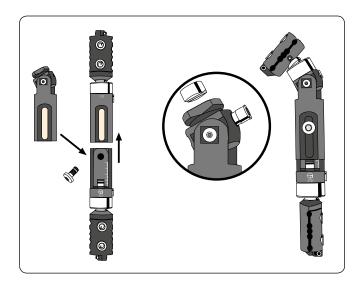


ARTHRODIATASIS

ARTICULATED JOINT DISTRACTION

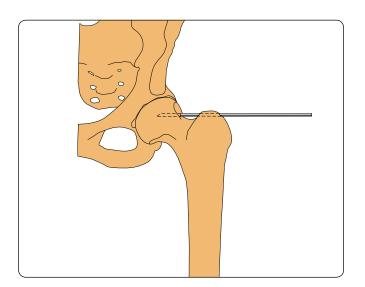




Please kindly refer to the product IFU PQEFS, to the Orthofix implantable devices and related instrument IFU PQSCR, and to the reusable medical devices IFU PQRMD that contain instructions for use of the product.

ARTHRODIATASIS OF THE HIP

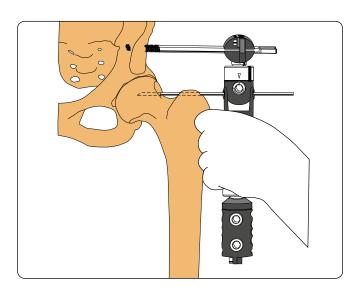
To prepare the assembly, remove the female component and replace it with the ProCallus articulated body for the hip. Remove cam and bush from the female component, fit them to the ProCallus articulated body for the hip, and attach a T-clamp. Lock the micromovement locking nut.



After any additional surgery has been carried out, apply the fixator so that the hinge on the articulated body is aligned accurately with the flexion/extension axis of the hip joint. Insert a guide wire at right angles to the long axis of the bone, to locate the centre of the femoral head, using Image Intensifier control.

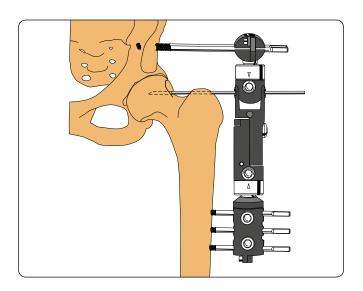


PRECAUTION: During and after insertion, ensure correct positioning of the implants under image intensification.

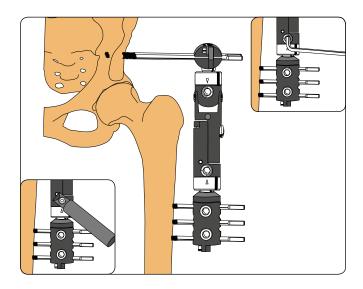


Slide the articulated module over the guide wire. With the hip held in 10°-15° of abduction, insert the proximal (pelvic) screws first, ideally in the dense bone just above the acetabular roof. Avoid penetration of the hip joint. Engage both the inner and outer tables. If possible, insert the second screw in the 3rd or 4th seat posterior to the first screw, so that a third intermediate screw may be applied if necessary.

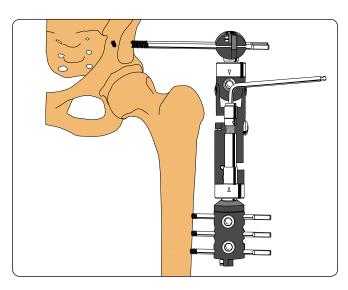
Use long screw guides for these proximal screws. OsteoTite $^{\text{TM}}$ bone screws are strongly recommended for this application. Always use a third screw if bone quality is poor.



Insert three femoral screws. Use screw seats 1, 3 and 5 in the clamp for maximum stability.



Lock cams using the 6mm Allen wrench. Complete locking of the cams with the torque wrench. Finally, remove the guide wire.



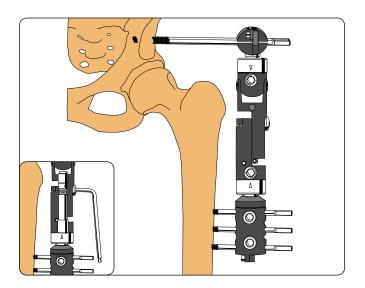
Attach the compression-distraction unit and distract the hip until 5mm joint space is seen. Flex hip and knee to 90° and perform further releases around the screw sites if necessary. Check carefully that movement is occurring at the hip. If the leg moves but the hinge does not, it means that movement is occurring at the spine rather than the hip. If hip flexion is limited, it may be due to soft tissue tension under the distractional force or malposition of the hinge. Reduce the distractional force and if the range of movement does not improve, take an X-ray to assess position of the hinge. If the hinge has been incorrectly sited and this cannot be corrected, remove the fixator.



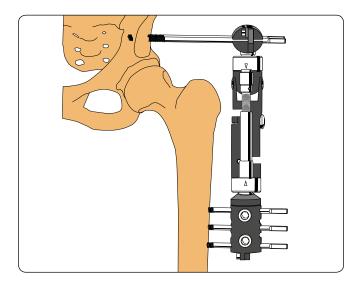
WARNING: For increased stability the compressiondistraction unit may be applied to the fixator body and locked into place.



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

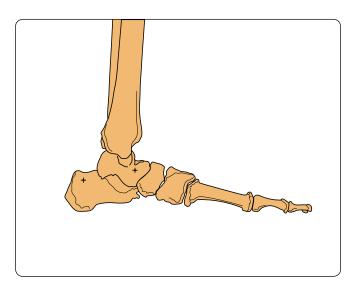


Tighten the central body locking nut and remove the compressiondistraction unit to make the assembly lighter.



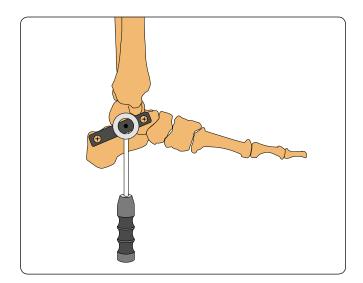
Where control of a flexion deformity is desired, or when taking controlled X-rays of the hip post-operatively, block hip movement by attaching the compression-distraction unit across the hinge.

Full weightbearing should be avoided while the hip is distracted.



ARTHRODIATASIS OF THE ANKLE

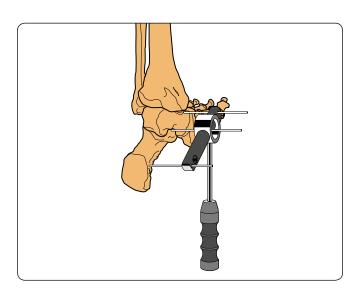
Debridment of the joints may be done either by opening the tibiotalar joint or by arthroscopy. In the latter case, debridment is done after application of the fixator; in the former, beforehand. Insert the distal screws first: one in the talus and one in the calcaneum.



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 AP projection. 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.

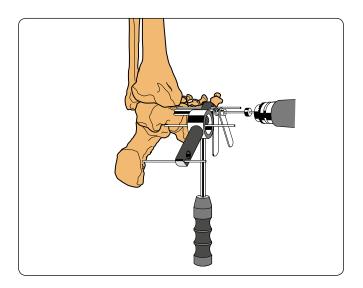


PRECAUTION: During and after insertion, ensure correct positioning of the implants under image intensification.

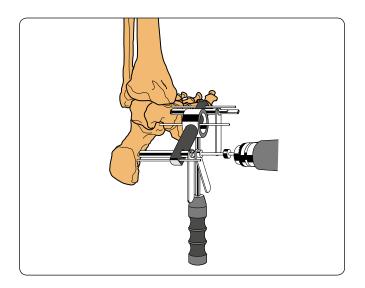


Insert a 2mm K-wire through the centre of the pin guide, down to the bone. Insert two K-wires into the small holes in the pin guide to stabilise it for screw insertion.

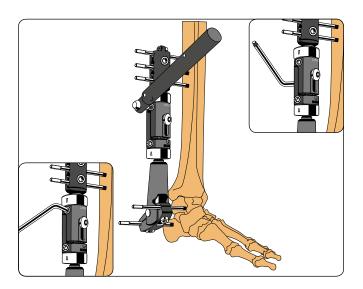
Anterior screw hole in pin guide should be over centre of neck of talus.



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 bone. Drill bone with a 3.2mm drill bit. Replace with a 4.8mm drill guide and drill the first cortex only with a 4.8mm drill bit.

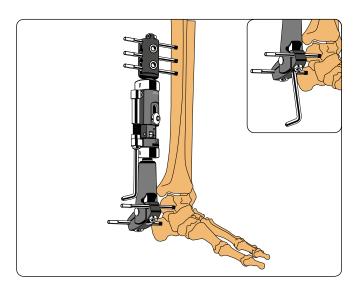


After removing the drill guide insert a screw into the talus. Repeat the same procedure for insertion of the second screw into the calcaneum.

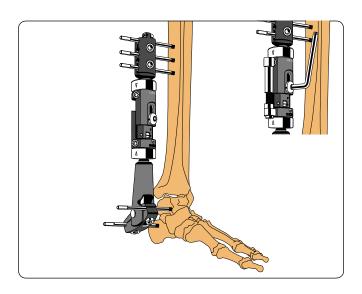


Remove K-wires and pin guide and place fixator over distal screws. Use fixator as template for placement of tibial screws.

Lock cams and micromovement locking nut using the 6mm Allen wrench. Finally, lock the cams with the torque wrench.



Attach the compression-distraction unit and distract the tibio-talar joint until 7-10mm joint space is seen. Check that joint movement is adequate. Tighten the articulation locking nut with the ankle plantigrade.



Tighten the central body locking nut and remove the compression-distraction unit to make the assembly lighter.

The use of OsteoTite bone screws, especially in the foot is advised in this application, particularly if the bone quality is poor.

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



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