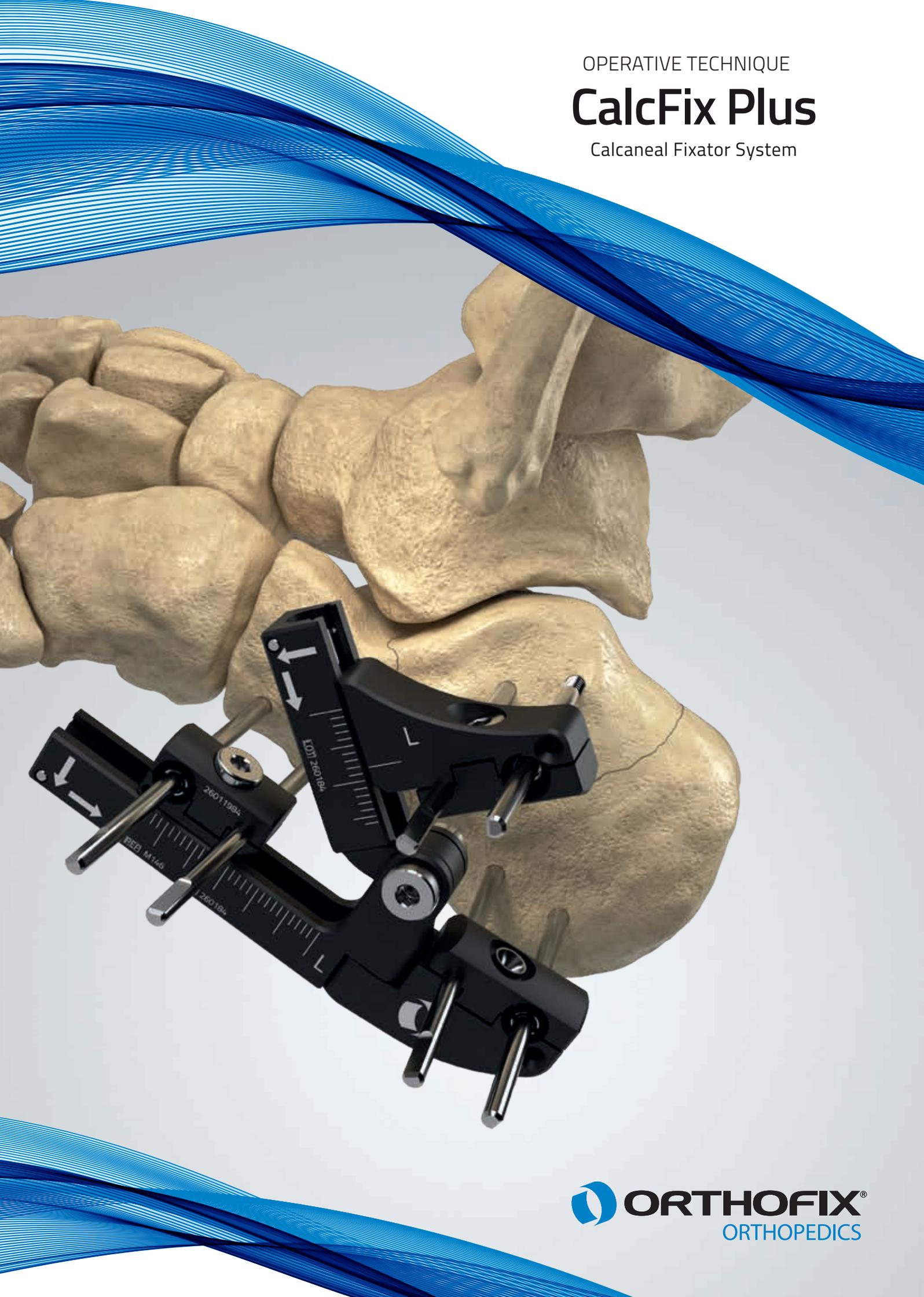


OPERATIVE TECHNIQUE

CalcFix Plus

Calcaneal Fixator System



CalcFix Plus

Calcaneal Fixator System

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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 kindly refer to the product IFU PQMIN and PQSCR and to the reusable medical devices IFU PQRMD that contain instructions for use of the product.

Operative Technique Contributing Surgeons:

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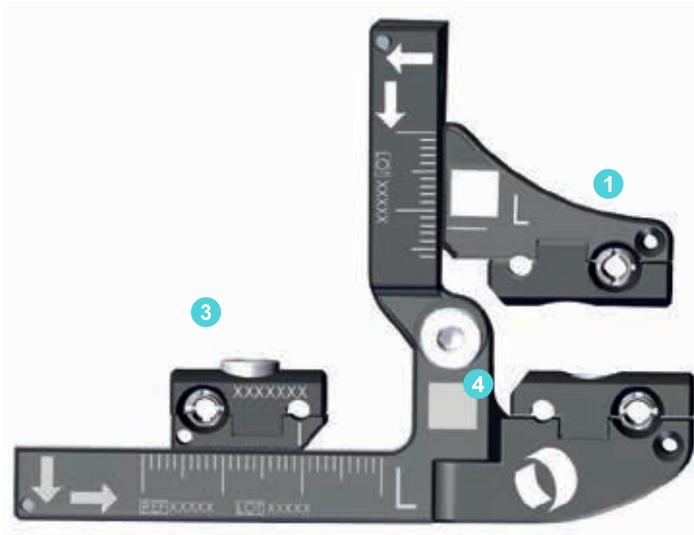
GENERAL DESCRIPTION

The CalcFix Plus Calcaneal Fixator is connected to the bone by means of bone screws .

The calcaneal fixator body is provided already assembled consisting of:

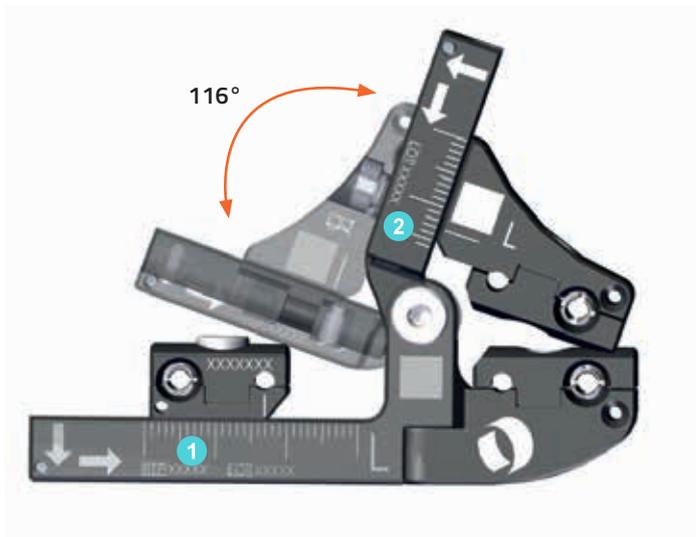
THREE CLAMPS

1. Superior Clamp
2. Posterior Clamp
3. Anterior Clamp
4. Central Hinge



TWO ARMS

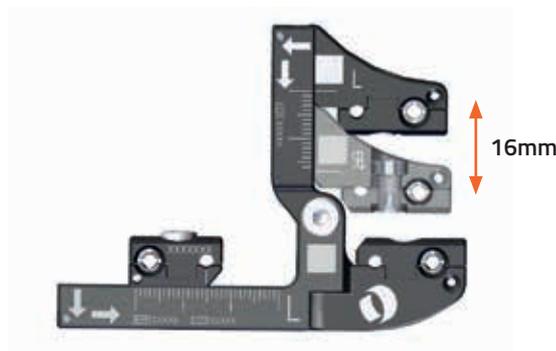
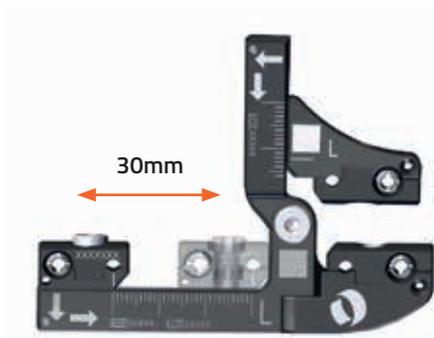
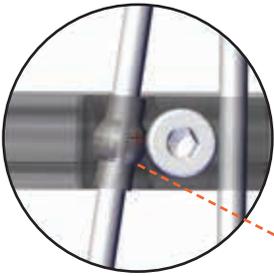
1. Horizontal arm containing the horizontal rail
2. Swiveling arm containing the subtalar rail



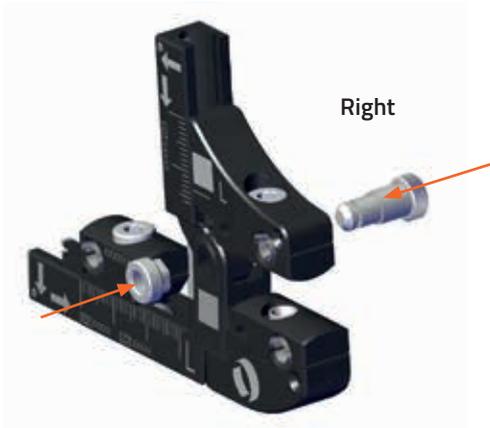
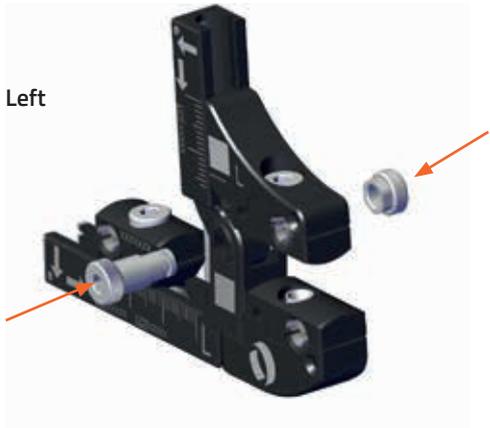
Varus-valgus orientation of the posterior clamp.



The external half-pins can be positioned with a converging angle up to $\pm 15^\circ$.



The fixator can be applied on either side, left or right foot.



SALES CONFIGURATION

99-M1460 CalcFix Plus Calcaneal Fixator Set Sterile

Part #	Description
10012	ALLEN WRENCH, 3mm
M210	T-WRENCH FOR BONE SCREWS
M211	DRIVER FOR 3mm SHAFT SCREWS
M146	CALCFIX PLUS CALCANEAL FIXATOR
M315	SELF-DRILLING, CORTICAL SCREW, LENGTH 70/25mm D 3.0-2.5mm
M317	SELF-DRILLING, CORTICAL SCREW, LENGTH 100/30mm D 3.0-2.5mm
1371501	KIRSCHNER WIRE LENGTH 150mm DIAMETER 1.5mm



The standard configuration in the sterile set is for LEFT application. To change the configuration for RIGHT application, the bolt of the central hinge has to be removed and mounted on the opposite side of the fixator body, to keep the hexagon accessible to the dedicated Allen Wrench.

PATIENT POSITIONING

The patient may be positioned either in a lateral decubitus or prone position (**Fig. 1 and Fig. 2**). The latter is very useful for radiographic projections, being simpler. The prone position is also useful in cases of bilateral fractures, as it allows the surgeon to work within a single operative field.



Fig. 1 Prone position axial view

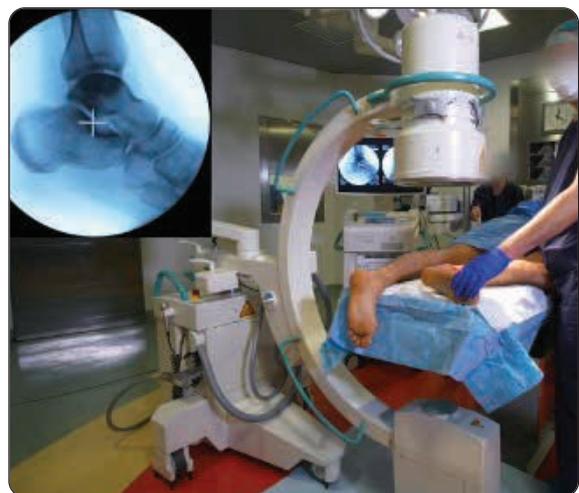


Fig. 2 Prone position lateral view

SURGICAL TECHNIQUE

FRACTURE REDUCTION

Depending on its complexity, there are various ways of reducing a calcaneal fracture. Here are some examples:

1. Simple fractures, for example Sanders II without articular surfaces involvement: closed manual reduction, with external maneuvers only.
2. Complex fractures, for example Sanders Types III and IV: by using 2.5-3mm Kirschner wires. The first wire is introduced in a posterior-anterior direction, limiting the introduction to the posterior fragment. This wire is used as a joystick to control 3 planes and achieves a reduction of the axes and volume, with an imaging check in both axial and lateral projections. A second wire is then passed through the fracture up to the anterior apophysis of the calcaneus or in some cases the cuboid (**Fig. 3**). The first K-wire is then removed.

If the result is unsatisfactory, a percutaneous approach can also be used.

Through a small lateral incision, a lever is introduced into the fracture site to elevate the articulating surface of the subtalar joint.

The second method for reduction is the most common as the reduction should primarily aim to recover the volume and axes of the calcaneus.

The fixation stabilizes the reduction obtained, with a limited possibility of subsequent reduction; after application, the fixator can recover the length and height of the calcaneus.



Fig. 3 Fractures reduction with K-wires

HALF-PINS FINAL FIXING POINTS



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

The calcaneal fixator is positioned depending on the size of the calcaneus and the fracture pattern. The body of the fixator is used as a template, placing the device directly over the calcaneus and checking the position under fluoroscopy.

The final fixing points of the half-pins must be located (**Fig. 4**):

1. at the level of the posterior apophysis of the calcaneus
2. at the level of the subtalar surface
3. at the level of the anterior calcaneal apophysis. Depending on the calcaneus size, fracture pattern, or in cases of severe comminution of the anterior calcaneal apophysis, it may be necessary to insert one or both anterior clamp half-pins into the cuboid (**Fig. 5**).



Fig. 4 Position of half-pins



Fig. 5 Position of anterior clamp half-pins in the cuboid

Wire Placements

Check that the calcaneal fixator is mounted according to the laterality of the foot that has to be treated (left or right). Verify that the letter on the swiveling arm is the same of the one marked on the horizontal arm ("L" or "R"). Finally check that the hexagon of the central bolt is accessible to the dedicated Allen Wrench before inserting the wires

It is recommended to start the application of the fixator with both anterior clamp and superior clamp at half-run of the rails to allow compression or distraction maneuvers in the last steps of the surgery. In the sterile set both clamps are provided at the end of their run; adjust them in the mid-position by turning the appropriate worm-screw on top of the rail with the 3mm Allen wrench.

Once checked with fluoroscopy, having located the ends of the calcaneus, the fixator is held in place by inserting the K-wires in the appropriate holes of the anterior, posterior and superior clamps of the device (**Fig. 6**).

A useful tip is to insert the first wire in the clamp that will engage the smallest bone fragment (**Fig. 7**).

The varus-valgus hinge can be used to contour the shape of the foot, being sure to reach the bone with all the wires and half-pins.

Half-pin Placements

Part #	Description
10012	3mm Allen Wrench
M210	T-Wrench
M211	Driver

Open the clamps with the 3mm Allen Wrench.

Insert the three innermost half-pins through the clamp holes (**Fig. 8**).

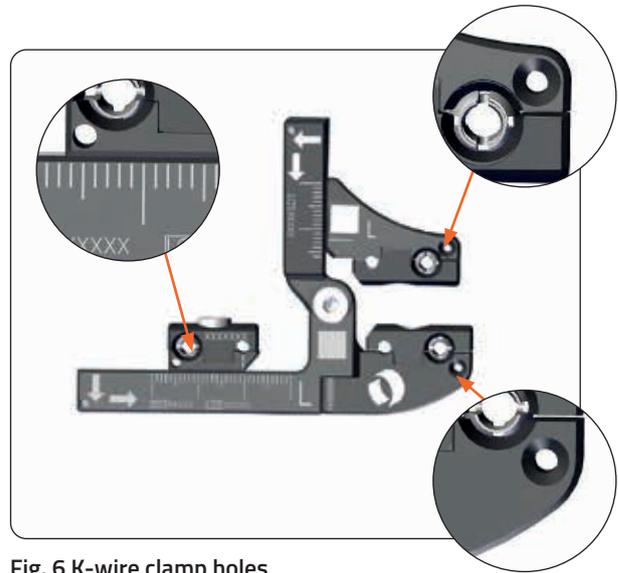


Fig. 6 K-wire clamp holes



Fig. 7 Positioning K-wires



Fig. 8 Positioning inner half-pins

It is recommended to start fixing the smallest fragment with the first half-pin.

The half-pins can be inserted using a low-revolution power drill using the dedicated Driver, or manually with the specific T-Wrench.

Hold the fixator body about 15–20mm from the skin (Fig. 9).

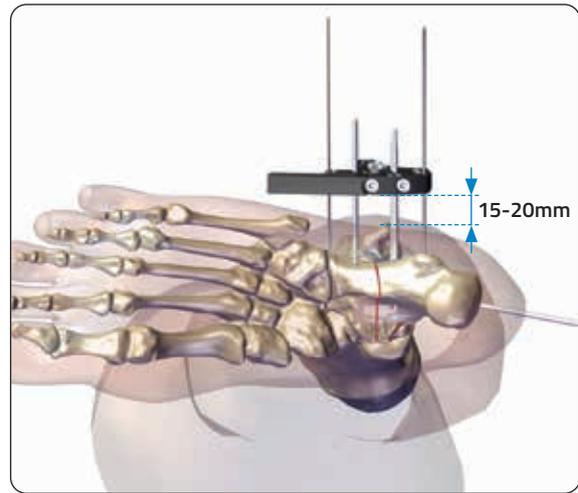


Fig. 9 Positioning fixator body

The external half-pins can be oriented with a converging angle up to $\pm 15^\circ$. (Fig. 10).

If it is necessary to angle a half-pin, remove the adjacent wire first.

Changing the distance between the skin and the fixator body will no longer be possible after inserting a single angled half-pin.



WARNING: The fixator should be applied at a sufficient distance from the skin to allow for postoperative swelling and for cleaning, remembering that the stability of the system depends upon the bone-fixator distance.



Fig. 10 Orientation of external half-pins

Insert the remaining half-pins through the external holes of the clamps (Fig. 11).



Fig. 11 Positioning external half-pins

Once all six half-pins have been inserted, remove the wires and close the clamps by tightening the cover-locking screws, using the 3mm Allen Wrench (**Fig. 12**).



Fig. 12 Locking of clamps

It is possible to perform a minor adjustment in varus-valgus of the body of the calcaneus by unlocking the varus-valgus hinge (**Fig. 13**) and rotating the posterior clamp of the fixator (**Fig. 14**). To allow the clamp to be angled for the varus/valgus adjustments, the main rail of the fixator must be slightly distracted.



Fig. 13 Unlocking of varus-valgus hinge

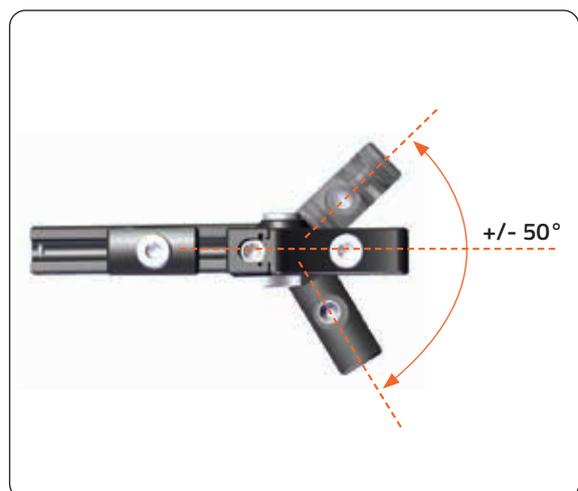


Fig. 14 Posterior clamp rotation

Once the varus-valgus adjustment/correction has been achieved, lock the varus-valgus hinge by tightening the set screw with the 3mm Allen Wrench (**Fig. 15**).

Once the final position of the fixator body has been reached, lock the central hinge and the varus-valgus hinge of the device using the 3mm Allen key.

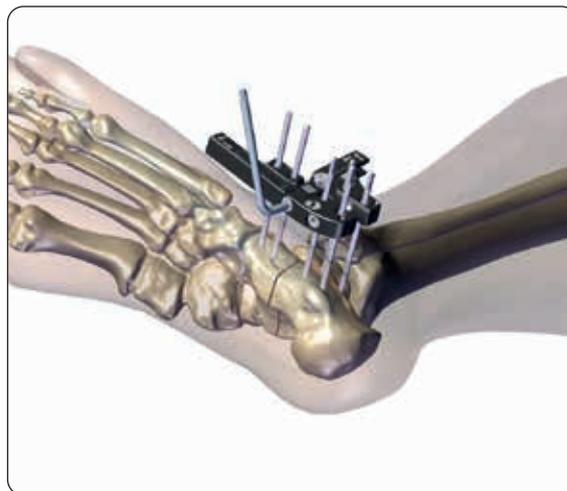


Fig. 15 Locking of varus/valgus hinge

Calcaneus Volume Recovery

Part #	Description
10012	3mm Allen Wrench

If a radiological check reveals the necessity for further distraction of the fragments, the following procedure can be followed:

1. The main rail is distracted, separating the posterior and anterior fragments, and unlocking the comminuted fragments from the depressed area. The amount of distraction is usually between 5 and 10mm; or as soon as a good resistance is felt.
2. After the main rail has been distracted, the subtalar rail is distracted by 3–7mm, or as soon as a good resistance is felt.

An axial x-ray of the calcaneus should reveal a parallel posterior and middle facet joint, while a lateral view will show a reduction in the angles (Bohler, Costa-Bertani and Gissane).

Stability can be verified with the motion of the subtalar joint and ankle. No crepitation should be felt and motion should be almost equal to the contralateral limb.

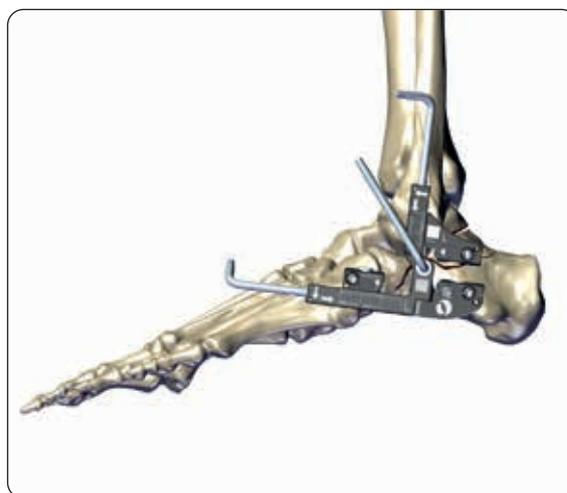


Fig. 16 Procedure for volume recovery

Device Removal

Part #	Description
10012	3mm Allen Wrench
M210	T-Wrench
M211	Driver

Open the three clamps of the fixator by loosening their cover-locking screws with the 3mm Allen Wrench (**Fig. 17**) and remove the body of the fixator (**Fig. 18**).



Fig. 17 Loosening of fixator clamps



Fig. 18 Removal of fixator body

Remove all half-pins manually with the T-Wrench or power drill (**Fig. 19**).



Fig. 19 Removal of half-pins

If the external half-pins are angled, remove the half-pins before removing the body of the fixator (**Fig. 20**).

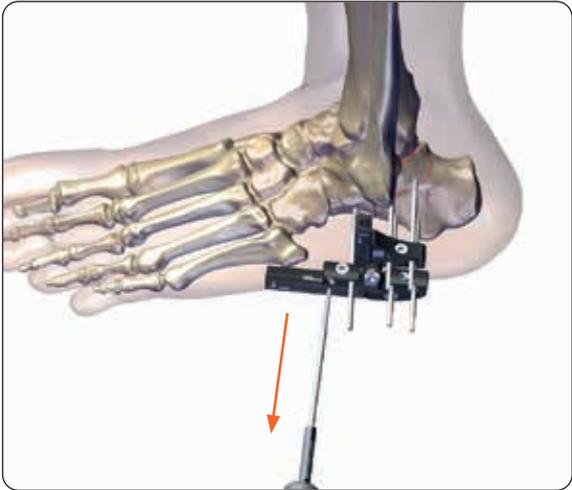


Fig. 20 Removal with angulated half-pins

Please refer to the "Instructions for Use" supplied with the product for specific information on indications for use, contraindications, warnings, precautions, possible adverse events, MRI (Magnetic Resonance Imaging) safety information 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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