OPERATIVE TECHNIQUE

Pertrochanteric

Fixator

1010



06/05L

220/40

2010

Pertrochanteric

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Fixator

The Orthofix Pertrochanteric Fixator comprises

Surgical steps

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 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.

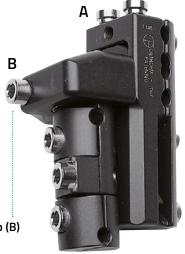
Operative Technique Contributing Surgeons: Dr. E. Alcivar Dr. F. Lavini Dr. L. Renzi Brivio

THE ORTHOFIX PERTROCHANTERIC FIXATOR COMPRISES

---- A posterior clamp (A)

For the screws that are inserted along the femoral neck. This has fixed screw seats **(1)** machined at an angle of 115° to the longitudinal axis to enable one screw to be inserted along the axis of the neck (right or left femur), and a single swivelling seat to enable a second screw to be inserted in a convergent mode **(2)**.





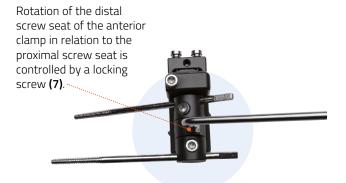
Anterior Clamp (B)

Which has proximal (3) and distal (4) screw seats for insertion of diaphyseal screws in the subtrochanteric region.



Movement of the anterior clamp in the frontal plane is controlled by locking screws **(5)**.

Rotation of the screw seats in the anterior clamp is controlled by a locking screw **(6)**.



Description	Qty.
Pertrochanteric Fixator complete with Allen Wrench 5mm	1
	Pertrochanteric Fixator complete with Allen

INSTRUMENTATION				
Part #	Description	Qty.		
11126	Special Pertrochanteric Screw Guide	1		
Not include	ed in the box:			
91150	Universal T-wrench	1		
91120	Hand Drill	1		
91101	Bone Screw Cutter	1		
SCREWS	;*			

99-612630	XCaliber Osteotite Bone Screws 260/30, sterile	2
99-612640	XCaliber Osteotite Bone Screws 260/40, sterile	2

* The screws listed are the most commonly used. Selection of correct total screw length and thread length is based upon the criteria described under Operative Technique. Note that bone screws are for single use only and must not be reused.

For the Pertrochanteric Fixator INSTRUMENTATION see General Catalogue.

SURGICAL STEPS

The fracture must be reduced in both planes under image intensification before application of the fixator.

Insertion of Femoral Neck (Self-Drilling) Screws

The thread length is selected to ensure that it passes through and beyond the fracture site.

The most proximal screw is inserted first. A 2mm Kirschner Wire is inserted along the femoral neck at an angle of 110° to 130° to the long axis of the diaphysis. The path of this wire must be within 5mm of the superior border of the femoral neck, and must be perfectly central when viewed axially. Correct positioning of this wire is essential, since it will determine the final position of the first proximal screw. In osteoporotic bone, this screw should be in contact with the superior cortex of the femoral neck (Fig 1).

A 1cm incision is made distal to the K-wire through the tissues following the direction of the wire. The 6.0mm trocar inserted into the special screw guide is used to locate the bone, sliding the upper, cannulated section of the screw guide over the K-wire (Fig 2).

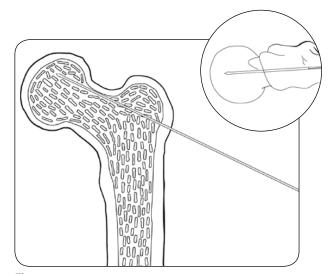


Fig. 1

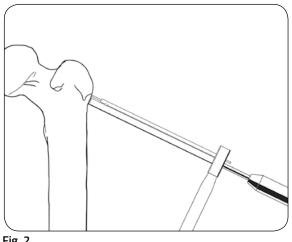
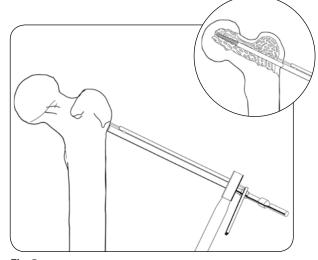


Fig. 2

The first XCaliber Screw 260/30 is inserted using the T-wrench or the Hand Drill (not included in the box) . Image intensification is used to ensure that the screw path is perfectly parallel to that of the K-wire and the tip of the screw lies no closer than 1cm to the articular surface (Fig 3).

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





The Kirschner Wire and special screw guide are now removed, and the screw is positioned in one of the two fixed screw seats in the posterior clamp of the fixator, depending upon the width of the femoral neck. A screw guide, with the 6mm trocar, is inserted into the posterior clamp distal to the swiveling screw seat through a second incision down to the lateral aspect of the femur. Its position is adjusted according to shape of the femoral neck, and ideally so that it is slightly convergent with respect to the first Screw. The trocar is then replaced by the second XCaliber screw 260/30, which is inserted down to the bone, and its position confirmed under image intensification. After positioning the posterior clamp 2cm from the skin, its cover is tightened firmly **(Fig 4)**.

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

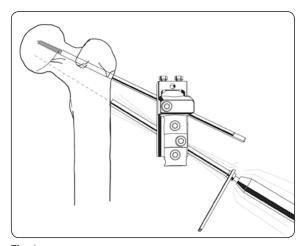


Fig. 4

The second femoral neck screw is inserted in the same manner as the first. The screw guide is now removed and the screw positioned in the swiveling screw seat, after which the posterior clamp locking screws are definitively tightened. The image intensifier is again used to ensure that the tip of the screw lies no closer than 1cm to the articular surface, and that it is central in the axial view **(Fig 5)**.

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

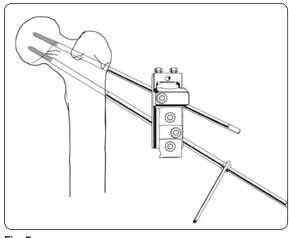
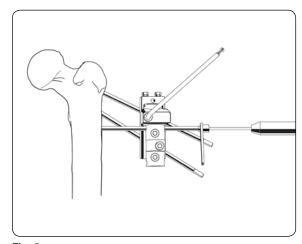


Fig. 5

Insertion of Femoral Diaphysis Screws

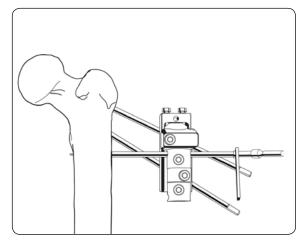
These screws may be inserted perpendicular to the long axis of the femur or obliquely by rotating the anterior clamp in the frontal plane and locking it in the desired position using the appropriate screws (5) (see components picture). A screw guide and trocar are inserted into the proximal seat of the anterior clamp down to the bone through an appropriate incision and positioned over the center of the diaphysis. The upper locking screw of the anterior clamp (6) (see components picture) is tightened to prevent any further rotational movement of the clamp, and the clamp cover is now partially tightened over the screw guide (**Fig 6**).



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Although the XCaliber Bone Screws are selfdrilling in predrilling is recommended in diaphyseal bone, using a 4.8mm drill bit when the bone is hard and a 3.2mm drill bit; when the bone quality is poor. The pilot hole is drilled using the correct drill guide, and a 260/40 XCaliber screw inserted until it is just protruding from the second cortex. After insertion, the Screw guide is removed and the clamp cover definitively tightened (**Fig 7**).

WARNING: Do not excessively penetrate the second cortex with any type of screws to avoid soft tissue damage. Do not penetrate the entry cortex with the smooth shank to avoid damage to the bone.





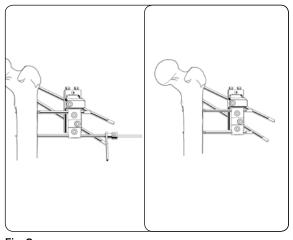
The distal diaphyseal screw is now inserted through a screw guide after pre-drilling as before. The distal screw seat of the anterior clamp can rotate axially in relation to the proximal screw seat to enable ideal positioning of this second diaphyseal screw in the center of the bone. The clamp is locked in this position by tightening the locking screw (7) (see components table). After inserting the second diaphyseal screw the screw guide is removed and the clamp cover definitively tightened. At the end of the procedure, confirm that the fracture is reduced, the cephalic screw tips are central in the head in the lateral view and about 10mm from the articular surface, and the diaphyseal screws fully engage both cortices. All locking screws are finally tightened using the long arm of the Allen Wrench. The fixator should be about 20mm from the skin to allow for pin site care. The screw shafts should now be cut with the bone screw cutter close to the fixator clamps, leaving about 6mm of screw shank protruding from the fixator, and the cut ends protected with screw caps. The arms of the cutter should be extended for greater efficiency, and the outer end of the screw held to prevent it from causing injury (Fig 8).



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PRECAUTION: When using screws, avoid cutting after screw insertion without the fixator applied. Cutting inserted screws without the fixator applied could transfer the cutting force to the bone.

PRECAUTION: XCaliber™ Screws should be cut before screw insertion or after they have all been inserted with the fixator applied and the clamp locking screws firmly tightened. Cutting must be performed with the appropriate cutter.





This fixator configuration can be used where the fracture line extends beyond the trochanteric region and is obtained by rotating the posterior clamp through 180°. In these circumstances, the proximal femoral neck screw is inserted in the swiveling screw seat, and the distal femoral neck screw in one of the fixed seats (**Fig 9**).

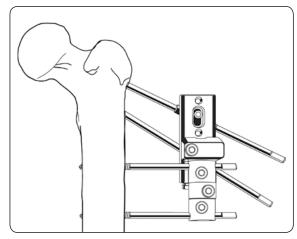


Fig. 9

Traction is then discontinued, and flexion and extension of the hip and knee performed to make sure that there is no tethering of the skin around the bone screws. If necessary make releasing incisions. Dressings are now applied around the pin sites so as to exert gentle compression to stabilise the skin and help prevent haematoma formation. The dressings may be soaked before application in a non irritant antiseptic if desired.

Please refer to the "Instructions for Use" supplied with the product for specific information on indications for use, contraindications, warnings, precautions, adverse reactions 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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