

THE XCALIBER HYBRID FIXATOR

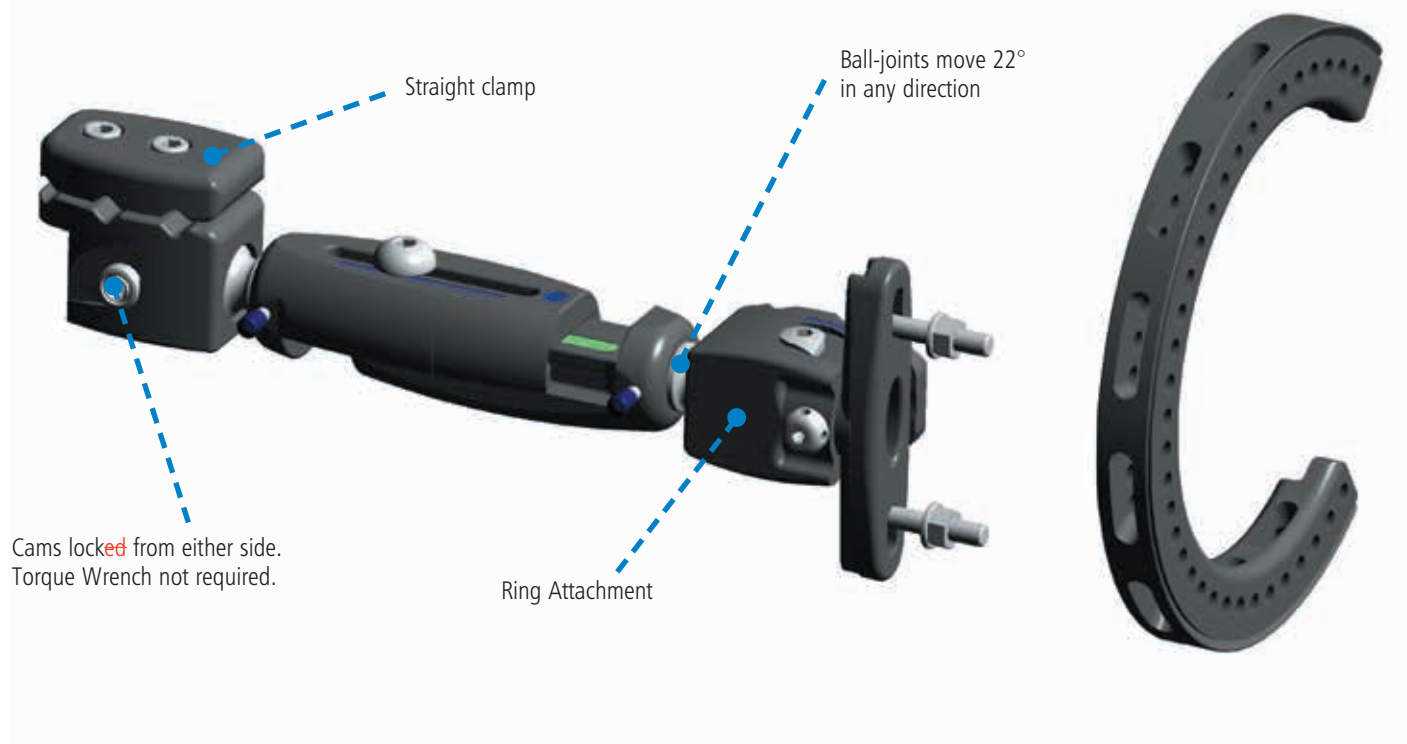
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The surgical technique shown is for illustrative purposes only. The technique(s) actually employed in each case will always depend upon the medical judgment of the surgeon exercised before and during surgery as to the best mode of treatment for each patient. Please kindly refer to the product IFU PQSHH and PQXCA, 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.

GENERAL POINTS

The XCaliber Fixator is made of radiolucent material for unobstructed X-ray visualization. The metallic bolts, and the cam and bush of each ball-joint 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. Also, the joint is sealed and cannot be dismantled for cleaning.

The XCaliber Fixator is strictly single patient use.

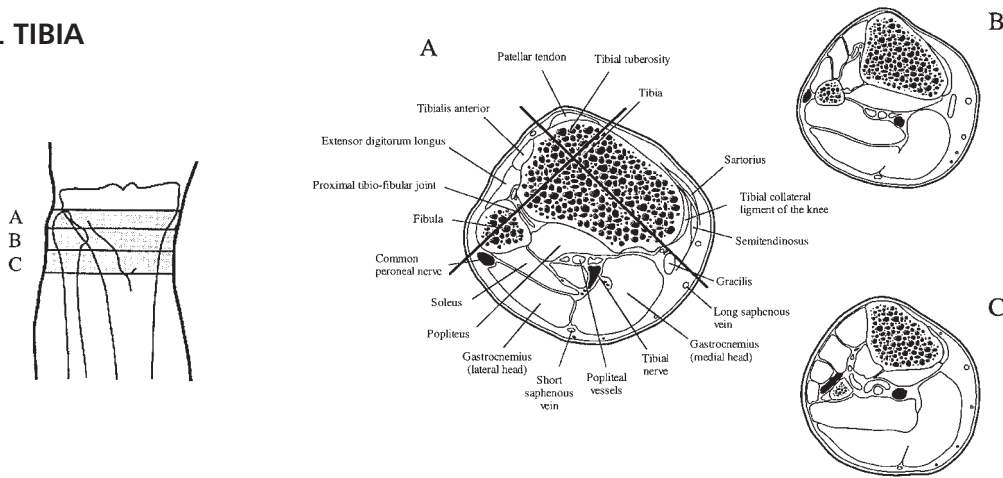


EQUIPMENT REQUIRED

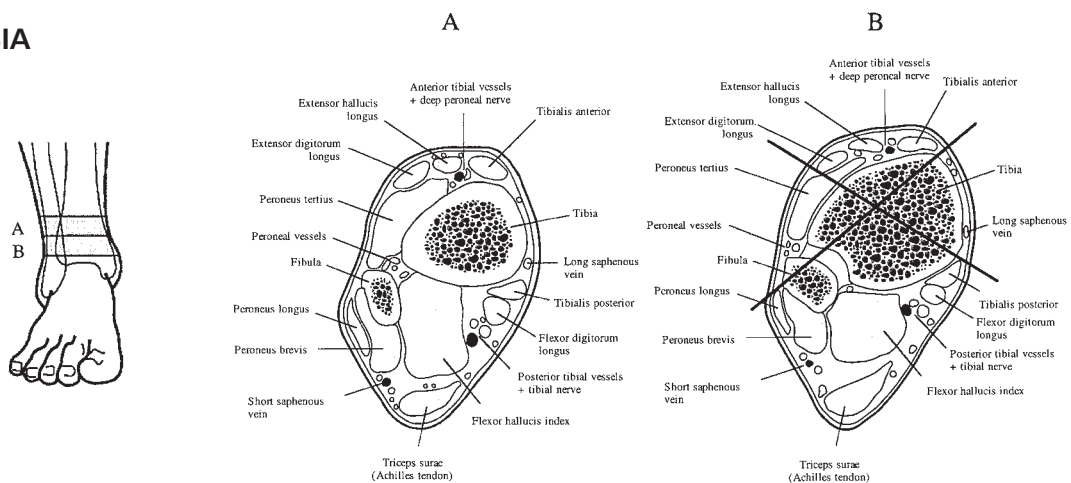
99-91080	XCaliber Hybrid Kit, sterile
81043	Supplementary Screw Holder Bar Radiolucent, 300mm
90038	Supplementary Screw Holder Clamp
80042	Post, 50mm
80044	Post, 100mm
Radiolucent Rings are available in the following diameters: 125mm, 150mm, 175mm, 190mm, 220mm.	
Standard Instrumentation for Wire and Screw Insertion.	

SAFE CORRIDORS FOR KIRSCHNER WIRE INSERTION

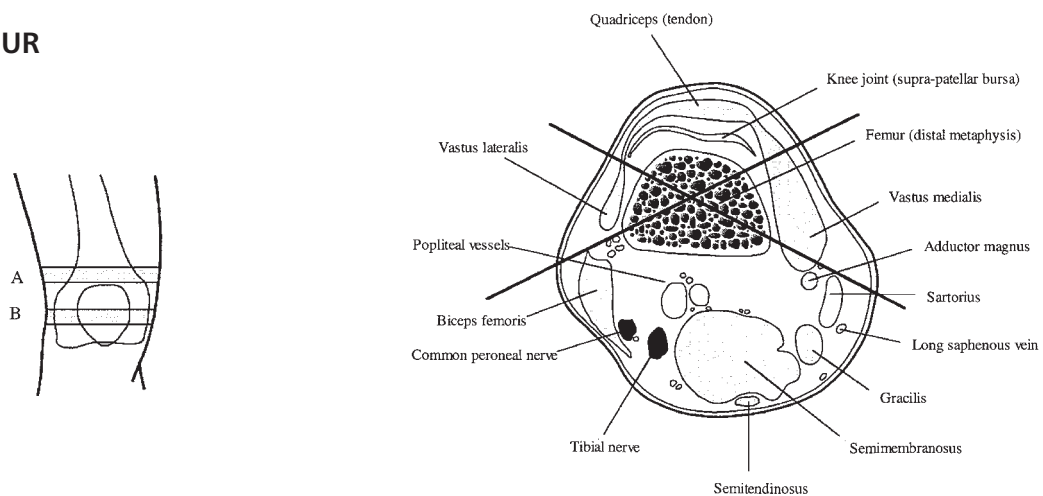
PROXIMAL TIBIA



DISTAL TIBIA



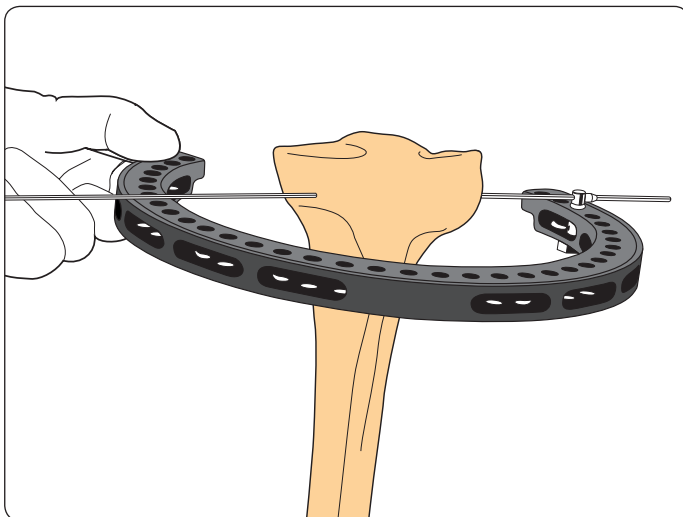
DISTAL FEMUR





KIRSCHNER WIRE INSERTION

Choose appropriate ring. Full circumference rings may be made by joining 1/3 and 2/3 rings together with locking screws.



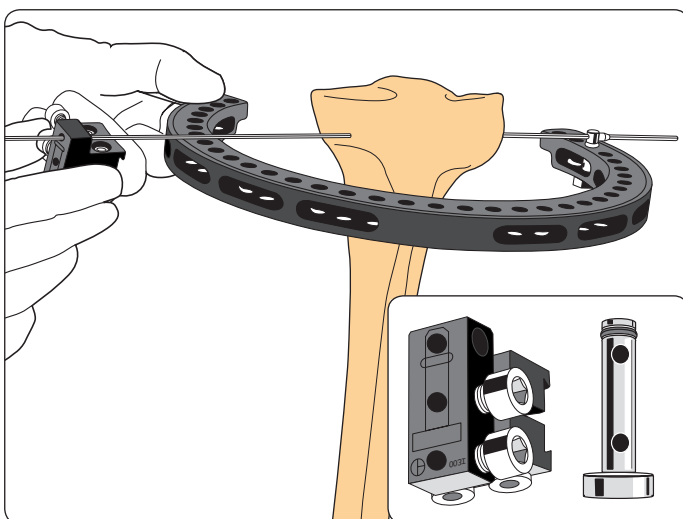
Reference anatomically safe corridors on cross-section of limb. Insert wire closest to the joint first. Insert a two-hole securing pin into appropriate hole in ring.

Introduce tip of K-wire with lateral olive through the two-hole securing pin. Push wire through soft tissues and drill through bone, while assistant maintains ring parallel to joint with limb centred within it. Avoid joint capsule. When wire has exited far cortex, stop drilling and ensure wire is parallel to ring and joint line. Continue to advance wire by tapping it with mallet, until lateral olive is against securing pin.

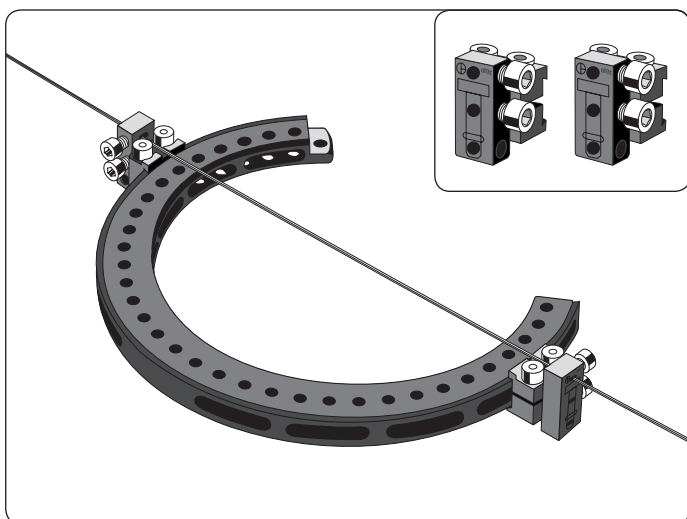
Wire may be drilled above, below or through the ring, for best position relative to fracture and joint capsule.



WARNING: During screw and wire insertion, do not enter the joints or the growth plates in pediatric patients to avoid joint damage or growth impairment.

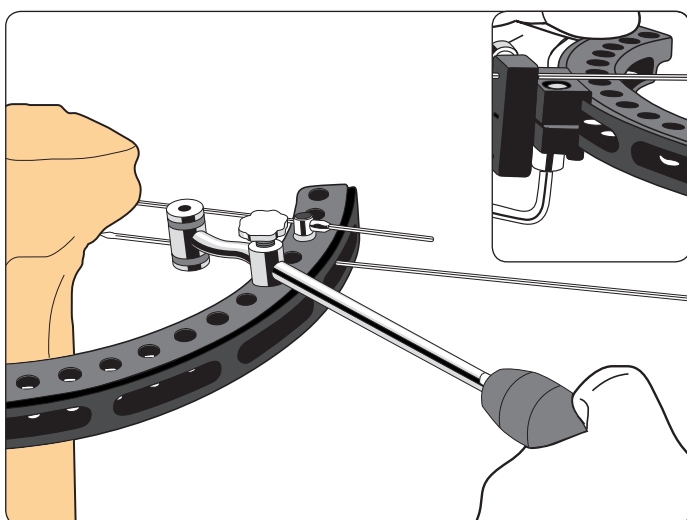


Loosen all screws of three-hole wire clamp slider unit. Orient clamp in same direction as securing pin. Introduce wire into appropriate hole in slider unit.

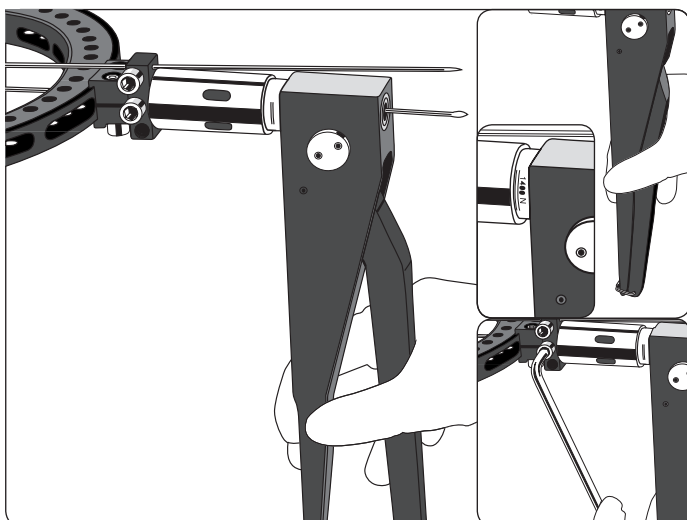


If a K-wire without olive is used attach it to ring using a three-hole wire, clamp slider unit at each end. Tighten both slider units to ring. Tighten wire clamp screw on one end of wire.

The first wire may be inserted free-hand.

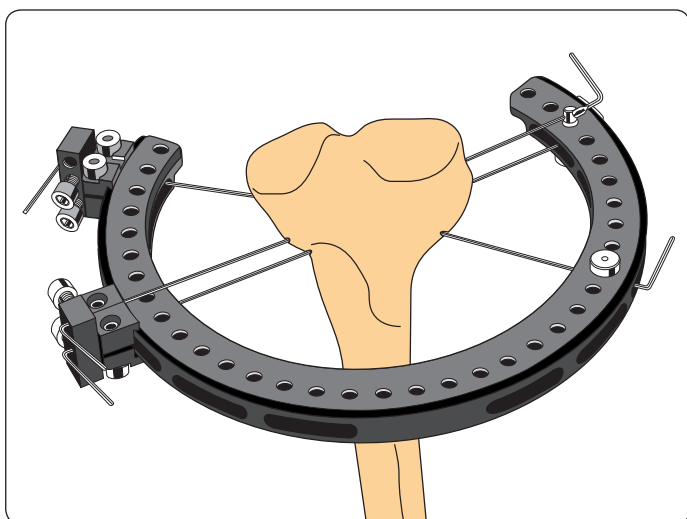


Insert parallel wire next through second hole in securing pin, using wire guide. Disconnect the slider unit temporarily from the ring and then insert it over both wires. Tighten slider unit on to ring fully, using 3mm Allen Wrench. Position limb in centre of ring.



To tension wires, open handle of wire tensioning device to fullest extent. Insert wire through the device and position it against face of slider unit. Tension wire to minimum of 1200 N, in two stages if necessary. Tighten wire clamp screws with 5mm Allen Wrench. Cut and/or bend wire and apply wire cover.

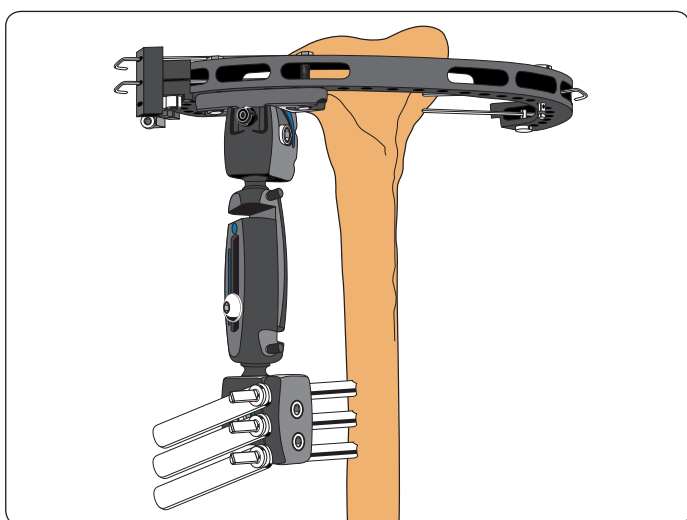
Where K-wires without olive have been used in conjunction with two three-hole wire clamp slider units, tighten wire clamp screws at one end, and tension at the other as above.



Insert crossing wires at widest angle neurovascular structures will permit (usually between 50°-70°). For optimal ring stability wires should cross in the centre of the tibia. Insert the securing pin into the ring, upside-down relative to the first securing pin to prevent wires from intersecting in bone.



PRECAUTION: Screws and wires must be inserted with full knowledge of the safe corridors to avoid damage to the anatomical structures.



DIAPHYSEAL SCREW INSERTION

Reduce fracture further by manipulation of ring and limb. Attach fixator to ring using the nuts and washers. Tighten them with the Open End Wrench (81031). Position fixator parallel to long axis of bone with cams and all locking nuts accessible for tightening. Make sure fixator body is neither fully closed nor fully open. Clamp acts as its own template for screw insertion. Insert bone screws in standard manner (See Manual 1, "Basic Considerations"). Where two screws are inserted, use clamp seats 1 and 3. Generally in adults three screws are recommended.



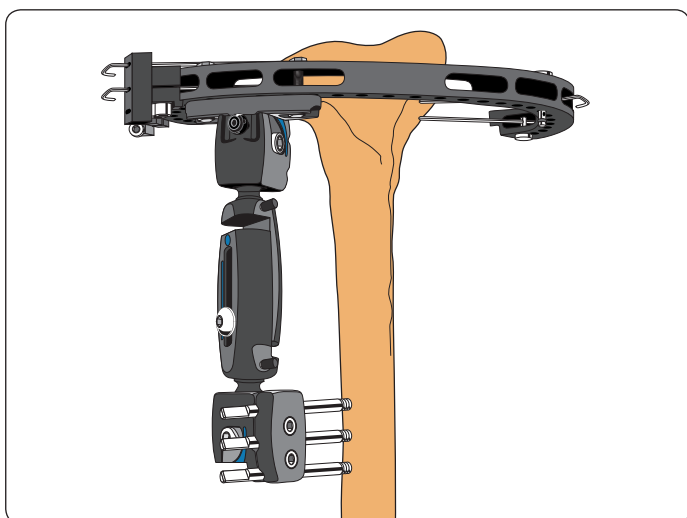
WARNING: Axial displacement may occur if the body of the fixator is not in line with and parallel to the bone.



WARNING: Medial or lateral translation may occur if the body of the fixator is not placed parallel to the diaphysis.



PRECAUTION: Diaphyseal bone screws should always be inserted perpendicular to and in the centre of the bone axis to avoid weakening it.



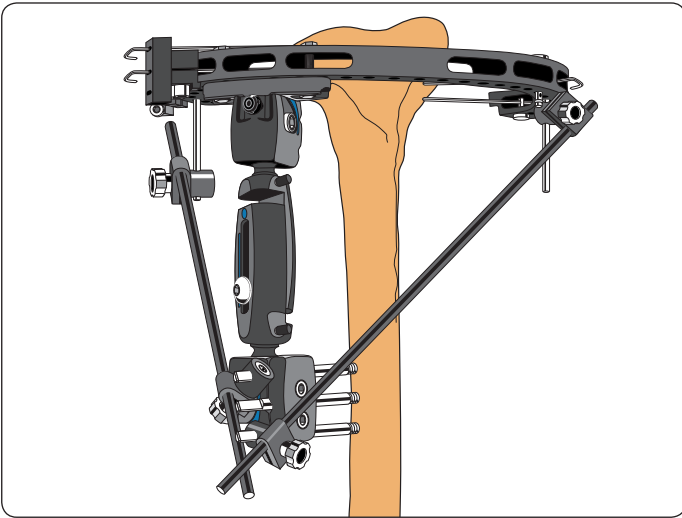
Confirm fracture reduction. Accurate reduction is aided by the fact that the fixator is radiolucent, allowing unobstructed views on image intensification.



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

Hold the reduction in a good position, while an assistant PARTIALLY tightens the cams and central body locking nut with the Allen Wrench. Tighten the central body locking nut. Check reduction and lock the cams definitively with the Allen Wrench.

Final locking of the ball-joints is achieved with the Allen Wrench; a torque Wrench is not required. 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.



Reinforcement bars may be added to increase stability, and are advised if the fracture is unstable.



PRECAUTION: When an unstable fracture is treated with the Sheffield Ring, reinforcement bars should be used.

Insert post through ring and attach bar using a supplementary screw holder clamp. Attach opposite end of bar to bone screw using another supplementary screw holder clamp. As healing progresses, remove reinforcement bars to increase load sharing at the fracture site.



PRECAUTION: Dynamization by loosening the micromovement locking nut and/or the central body locking nut of the monolateral fixator is not recommended in hybrid frames.

Operative Technique Contributing Surgeon:

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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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