QUICK REFERENCE GUIDE

THE ORTHOFIX HYBRID
FIXATION SYSTEM

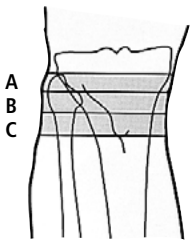
12

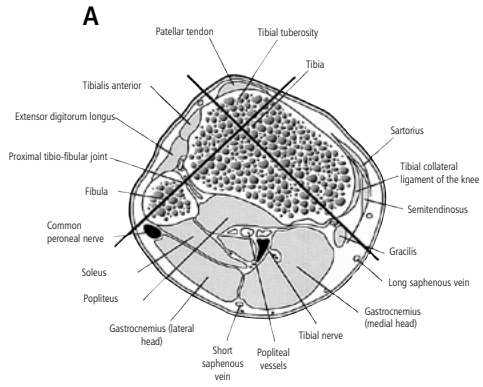
ORTHOFIX®

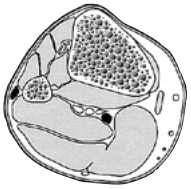
Please kindly refer to the product IFU PQSHH, to the Orthofix implantable devices and related instrument IFU PQSCR, and to the reusable medical devices IFU PQRMD that contain instructions for use of the product.

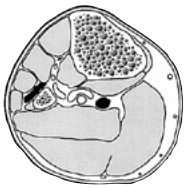
SAFE CORRIDORS FOR X-WIRE INSERTION

Proximal Tibia

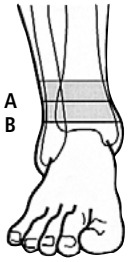


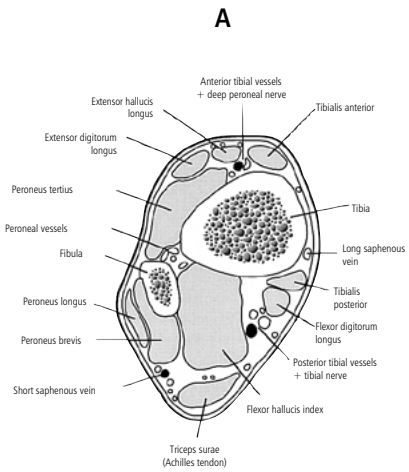


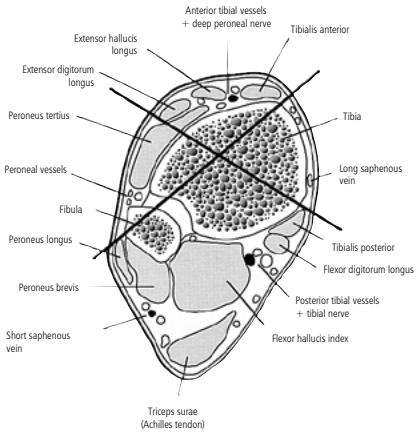




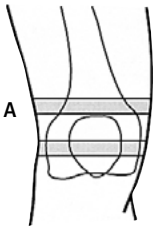
Distal Tibia

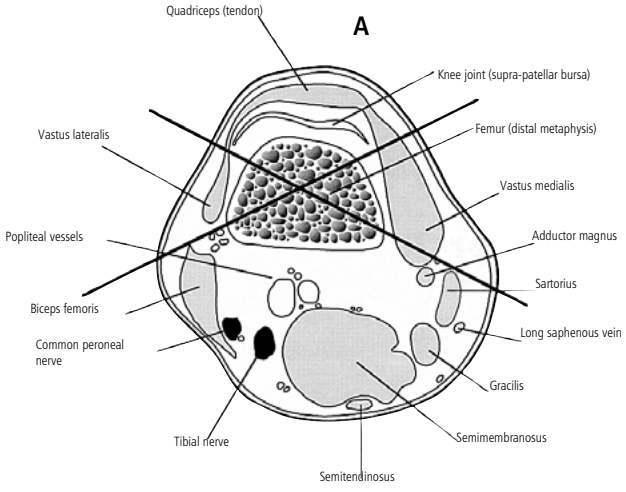


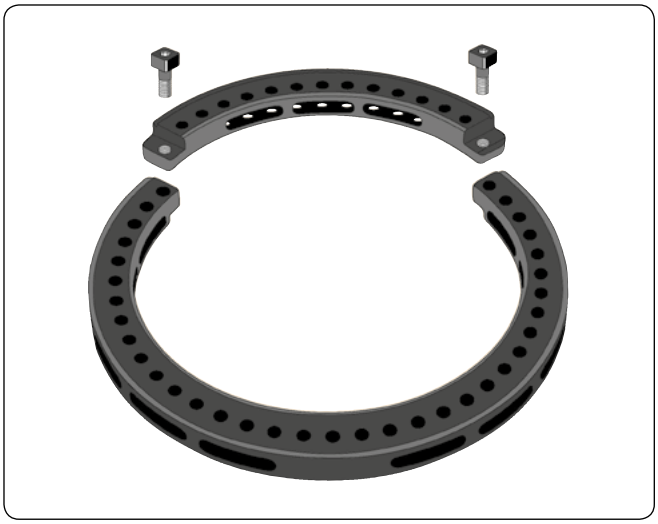




Distal Femur

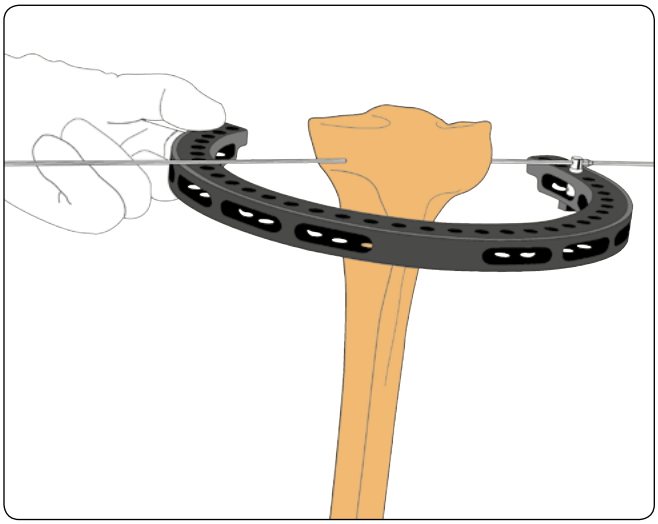






X-WIRE INSERTION

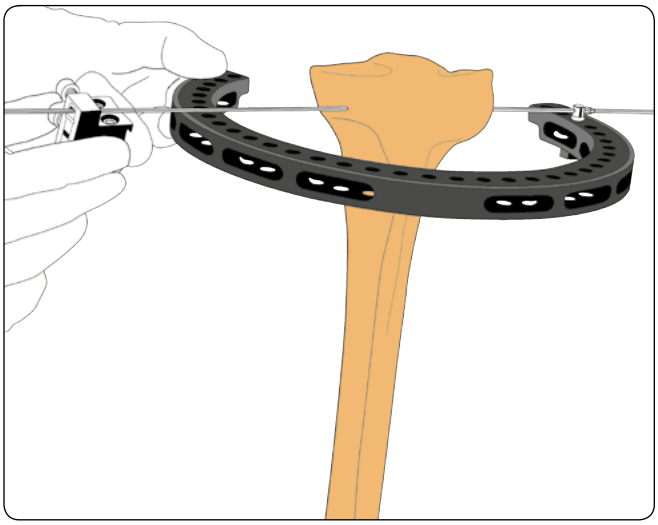
- Choose appropriate ring.
- Full circumference rings may be made by joining 1/3 and 2/3 rings together with locking screws.



- 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 X-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 centered 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.

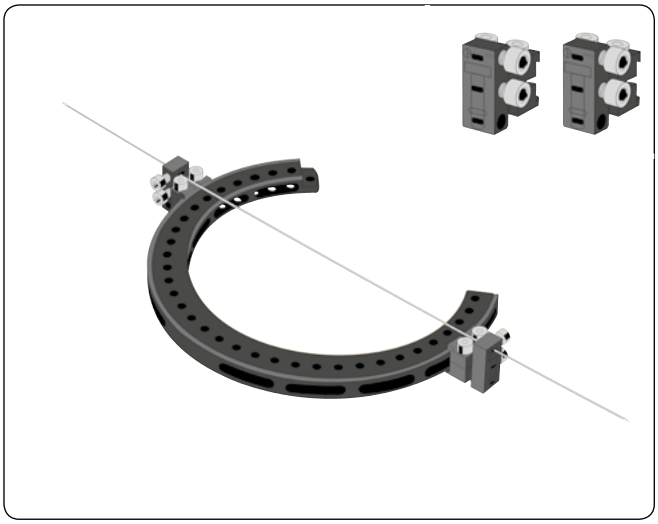
PRECAUTION: When wires are inserted for use with a ring based frame, whether hybrid or a full circular frame, they should be tapped through the soft tissues and drilled through the bone; they should never be drilled through soft tissues.

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.



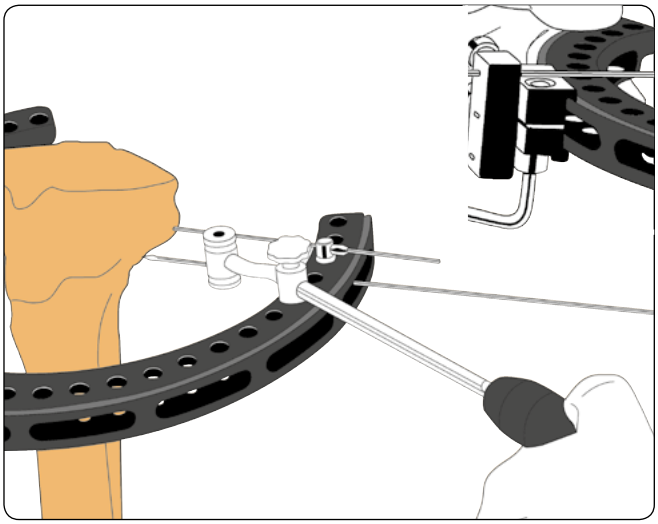
Wire may be drilled above, below or through the ring for best position relative to fracture and joint capsule.

- 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.

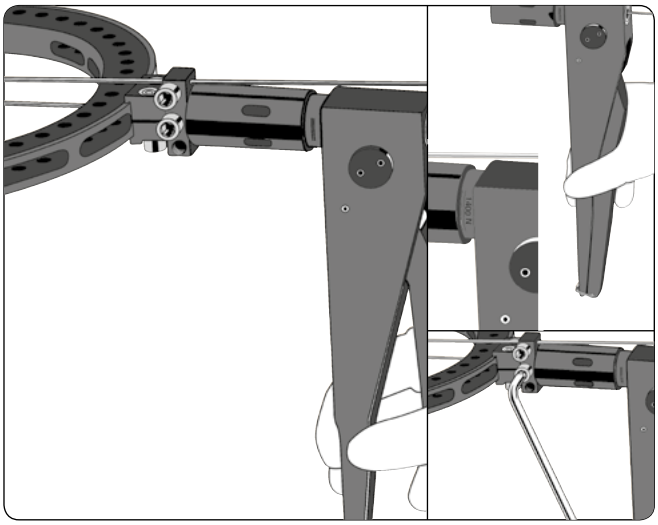


First wire may be inserted free-hand. Use a X-Wire without olive and attach it to ring using a three-hole wire clamp slider unit at each end.

- Tighten both slider units to ring, then tighten wire clamp screw on one end of wire.



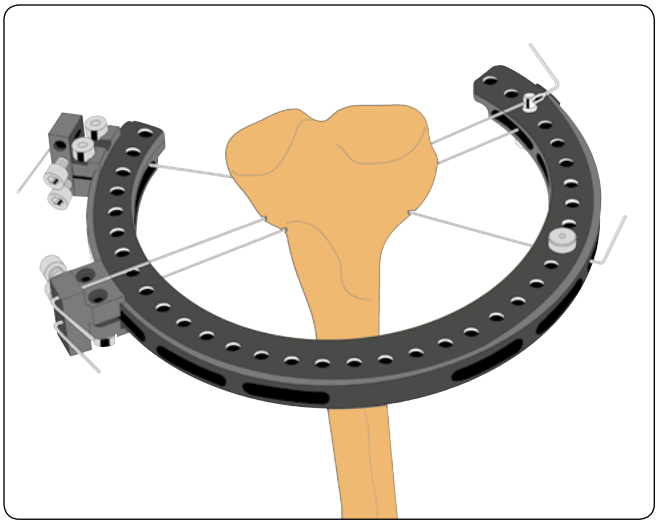
- Insert parallel wire next through second hole in securing pin, using wire guide.
- Disconnect the slider unit temporarily from the ring and then insert it over both wires.
- Tighten slider unit onto ring fully, using 3mm Allen Wrench.
- Position limb in center of ring.



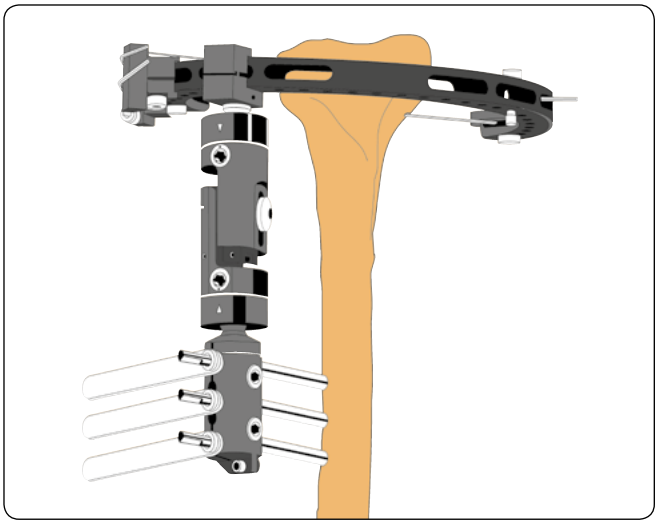
- To tension wires, open handle of wire tensioning device to fullest extent.
- Fully insert wire through the device sliding it up against face of slider unit.
- Tension wire to minimum of 1200 N, in two stages if necessary.
- Tighten wire clamp screws with 5mm Allen Wrench.
- Cut and/or bend wire and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

PRECAUTION: To avoid causing injury: the ends of wires should be protected with special covers or bent at the ends as soon as they are tensioned.

Where X-Wires without olive have been used in conjunction with three-hole wire clamp slider units at each end, apply tensioning device to end of wire that has not yet been tightened in its slider unit and tension 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 center 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.

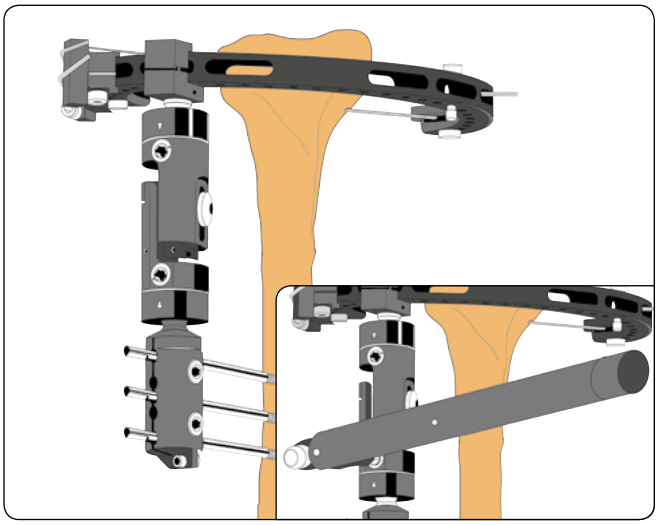


DIAPHYSEAL SCREW INSERTION

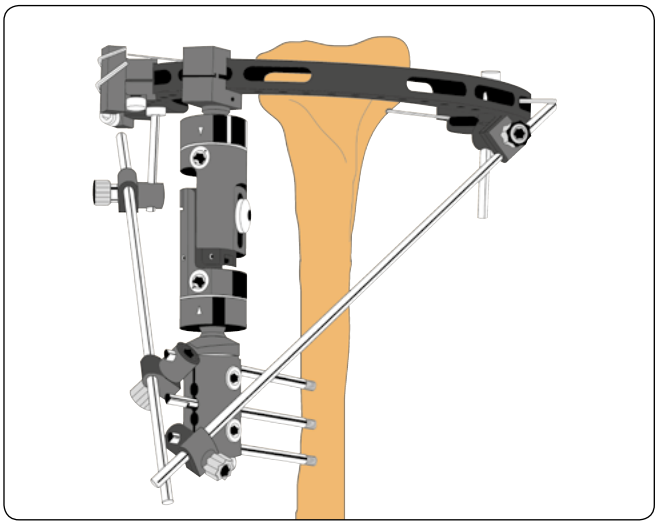
- Reduce fracture further by manipulation of ring and limb.
- Attach fixator to ring using the coupling with ball-joint, and lock with 3mm Allen Wrench.
- Position fixator parallel to long axis of bone with cams and all locking nuts accessible for tightening. Make sure fixator body is neither fully closed nor fully open.
- Clamp acts as its own template for screw insertion. Insert bone screws in standard manner. Where two screws are inserted, use clamp seats 1 and 5; where three are inserted, use seats 1, 3 and 5.

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

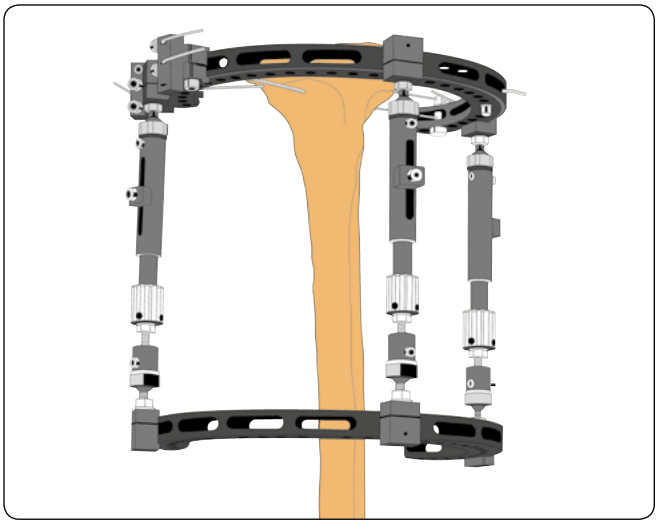
WARNING: Medial or lateral translation may occur if the body of the fixator is not placed parallel to the diaphysis.



- Confirm fracture reduction.
- Lock micromovement locking nut, central body locking nut and ball-joints of the fixator with the 6mm Allen Wrench.
- Use torque wrench for final locking of ball-joints only.

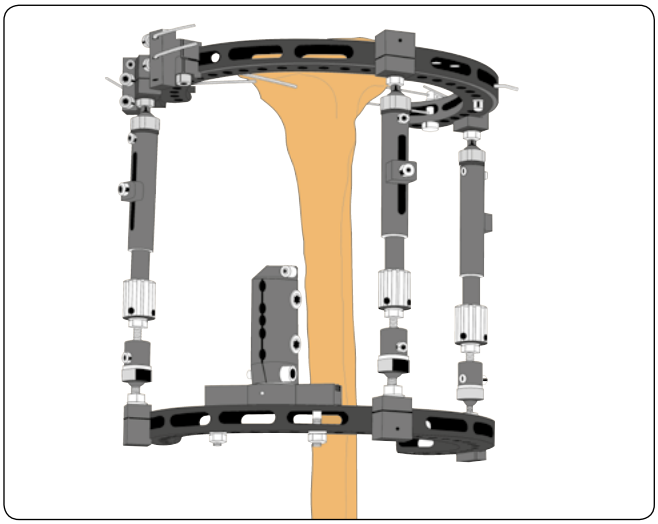


- Reinforcement bars may be added to increase stability.
- Insert post through ring and attach bar using a supplementary screw holder clamp.
- Attach opposite end of bar to bone screw using another supplementary screw holder clamp.
- As healing progresses, remove reinforcement bars to increase load sharing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



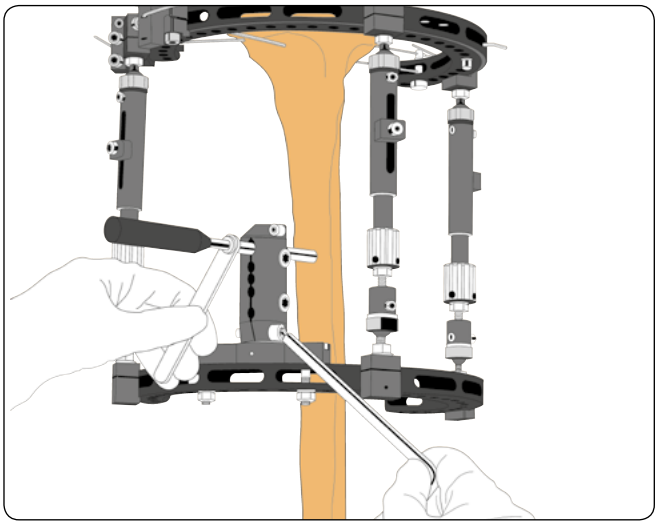
DIAPHYSEAL SCREW INSERTION

- Attach diaphyseal ring using three reduction units (antero-laterally, postero-laterally and postero-medially).
- All rings in one frame should be the same size.
- The telescopic and micrometric mechanisms of the reduction units should be partially open and spaced evenly around the circumference of the rings.
- Ensure that reduction units are perpendicular to the rings with the telescopic bodies oriented in the same way.
- Tighten all cams and locking screws.

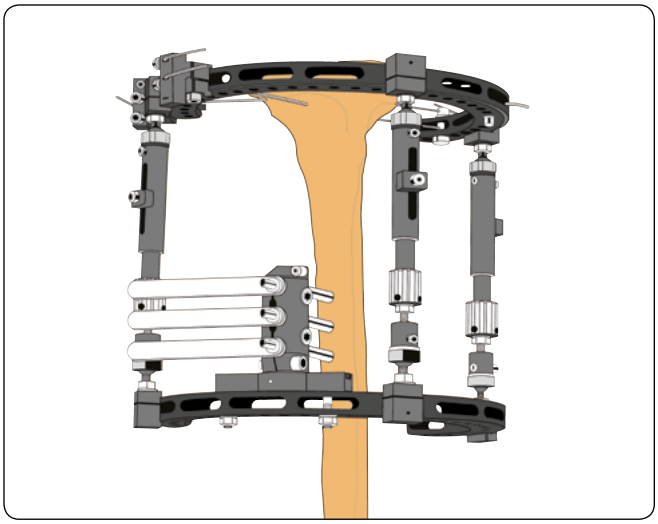


- A Sheffield Clamp is attached to the diaphyseal ring antero-medially using 10mm spanner.
- When a full ring is being used, the rings should always be orientated so that the Sheffield Clamp is mounted on the 2/3 component.
- Confirm fracture reduction.

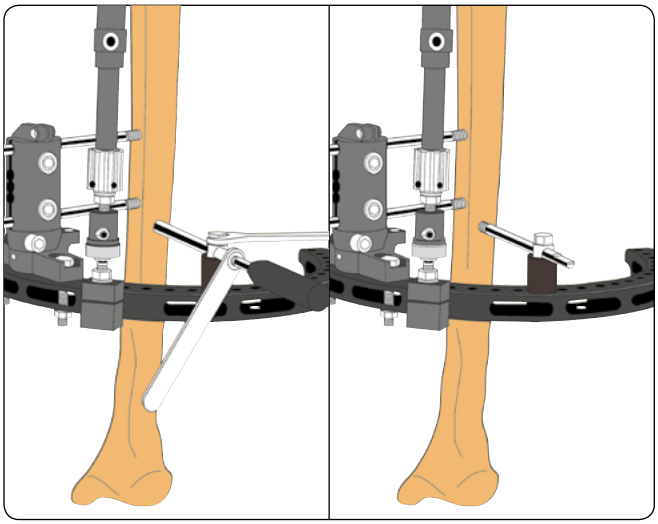
PRECAUTION: During and after insertion, ensure correct positioning of the implants under image intensification.



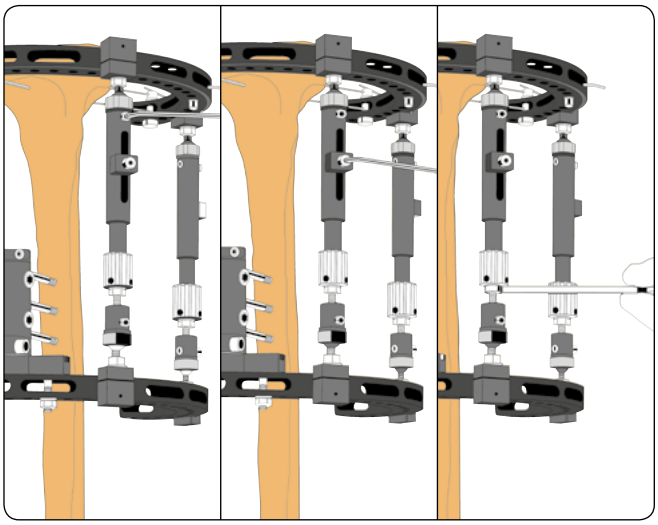
- Clamp can be rotated to establish ideal position for diaphyseal screws.
- Clamp cover locking screws should face anteriorly.
- Clamp acts as its own template for screw insertion.
- Using a trocar, identify desired bone screw orientation and tighten rotational locking screw with 6mm wrench.



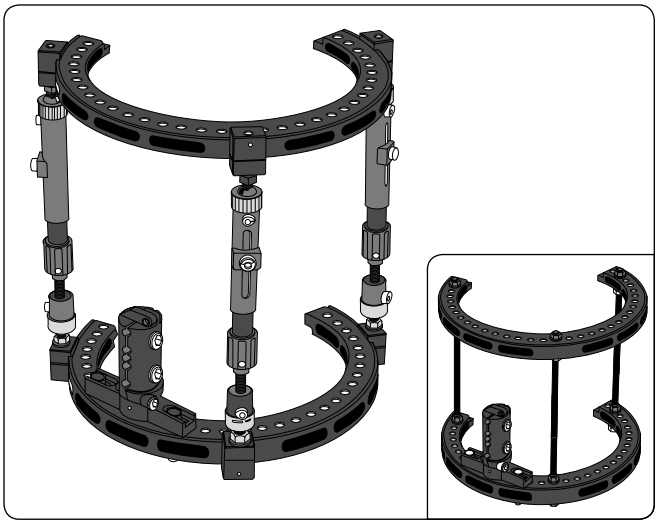
- Screws are inserted in the standard manner.
- Where two screws are inserted, use clamp seats 1 and 5; where three are inserted, use seats 1, 3 and 5.



- An additional screw may be inserted at 45°-90° to the first group using a single screw clamp attached to the diaphyseal ring.
- Where this screw is used, only two screws would normally be inserted through the Sheffield Clamp.
- This clamp can rotate for optimal screw placement.



- Final fracture reduction can be made using the distraction and ball-joint facilities of the three reduction units after loosening the cams and locking screws.
- After reduction, ensure that all cams and locking screws are fully tightened.
- The micrometric mechanism may be used for post-operative length correction of the fracture.



- Standard frame may be preconstructed before inserting the X-Wires.

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
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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. 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.

www.orthofix.com

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