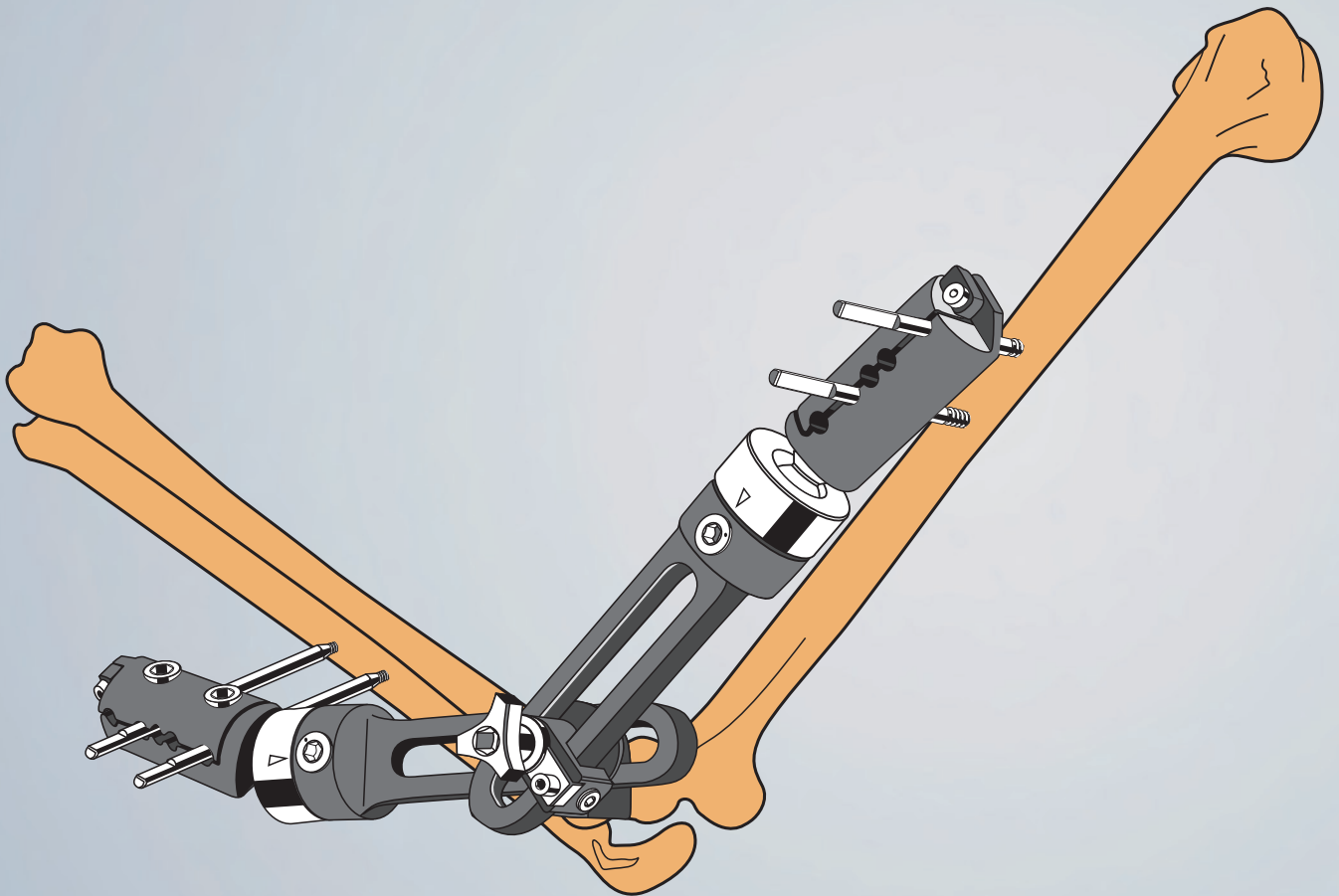
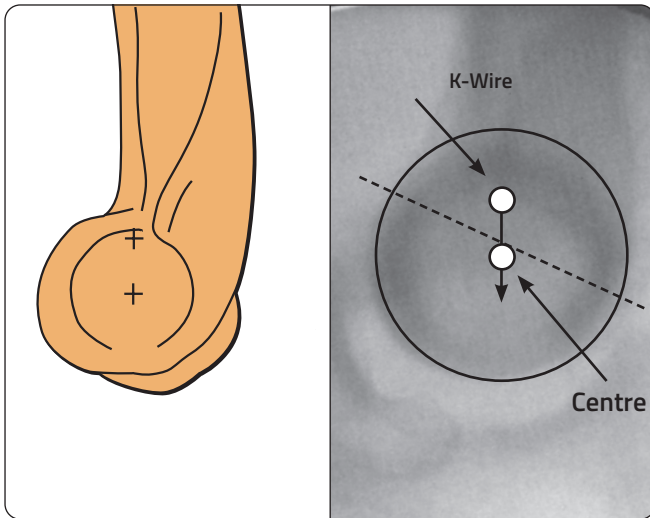


QUICK REFERENCE GUIDE

Elbow Fixator

PART B: POST-TRAUMATIC STIFFNESS

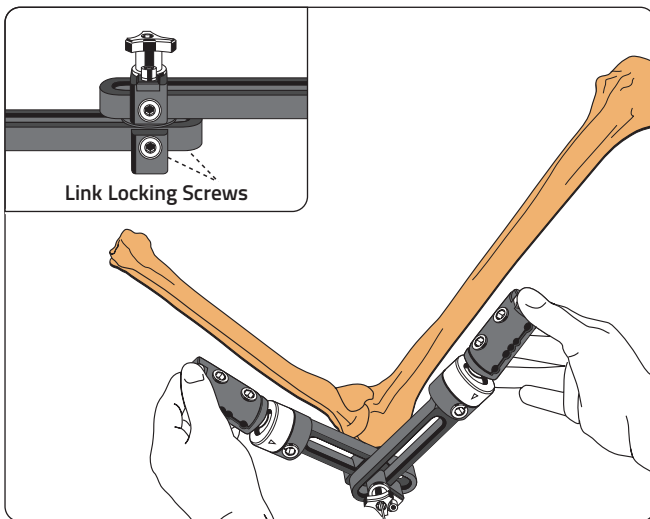




Please kindly refer to the product IFU PQEFS, to the Orthofix implantable devices and related instrument IFU PQSCR, and to the reusable medical devices IFU PQRMD that contain instructions for use of the product.

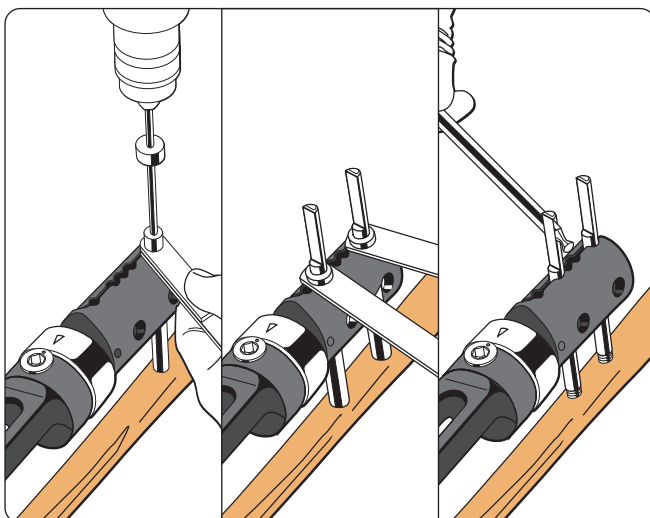
The Elbow Fixator is compatible with: Standard bone screws, Titanium bone screws, Standard coated bone screws, Self-drilling coated bone screws, Self-drilling bone screws, Transfixing Pins, Implantable wires.

Insert a 2mm Kirschner wire at the proximal border of the trochlea ring structure as seen in a true lateral X-ray. After distraction the position of the Kirschner wire will be at the centre of rotation.



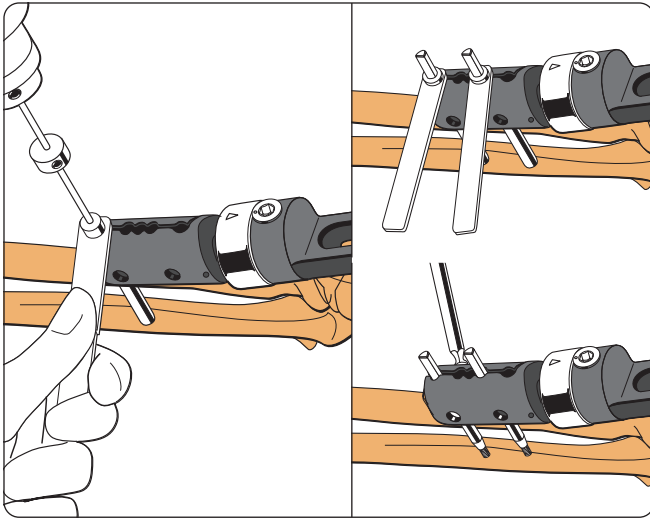
Slide the fixator over the 2mm Kirschner wire. Adjust the position of the humeral link so that a minimum space of about 15mm is available distal to the central unit.

The link locking screws are provisionally tightened at this point.



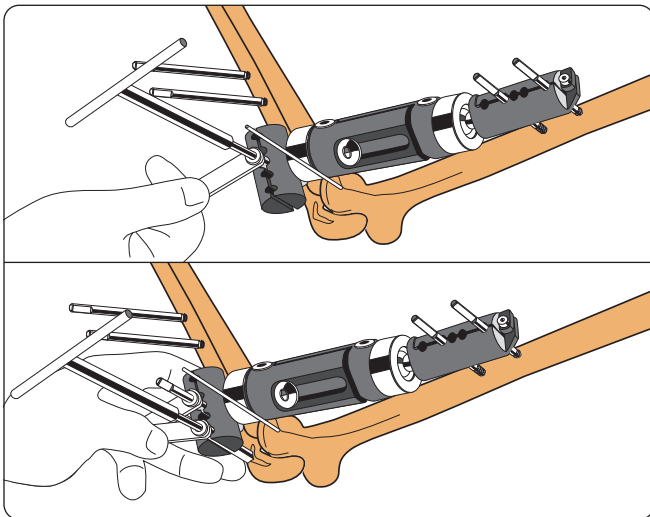
Expose the lateral aspect of the humerus by blunt dissection in order to avoid damage to the radial nerve. After pre-drilling with a 4.8mm drill bit, insert two 100/30 or 110/30 6-5mm diameter screws. In small humeri, where the diameter of the bone is less than 20mm, use screws with a smaller thread diameter, 4.5-3.5mm.

The most proximal screw should be placed at the distal insertion of the deltoid muscle.



With the forearm in the neutral position, apply the ulnar screws from the dorsal side, placing them as centrally as possible to avoid weakening the bone. After pre-drilling with a 3.2mm drill bit, insert the most distal screw first. Always use 120/20 or 100/20 4.5-3.5mm diameter screws in clamp seats 1 and 4. Bicortical purchase is required. In very heavy patients or in the case of a severely stiff elbow, use a third screw.

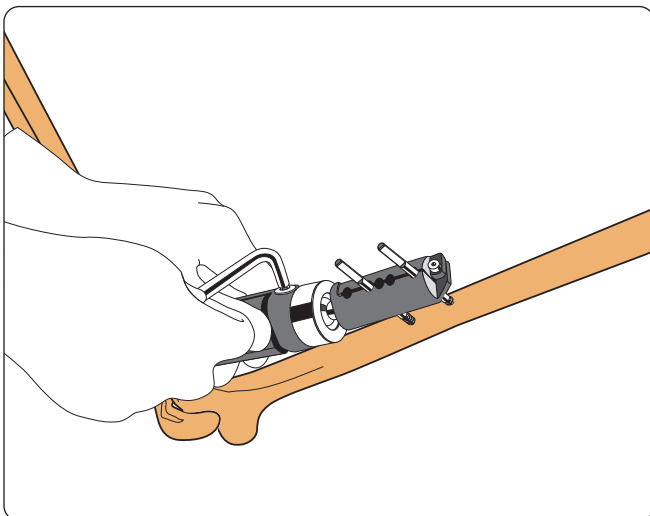
Open exposure is advisable. An Extended Range Clamp should be used if it is not possible to place both screws in the exact centre of the bone axis.



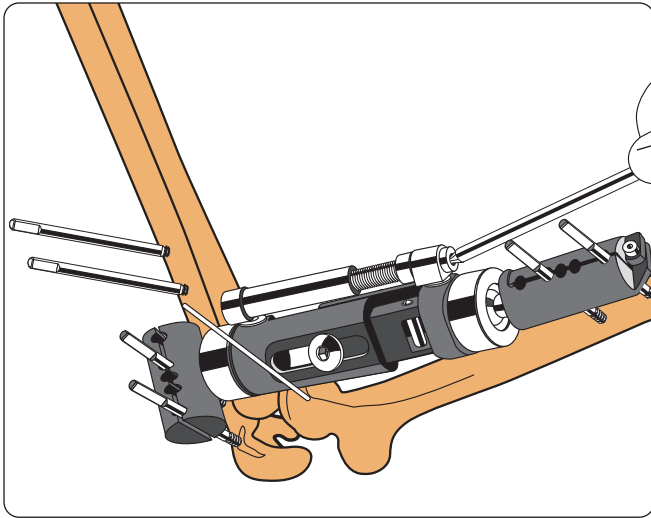
Remove the fixator and apply a standard ProCallus Fixator on the humeral screws, close to the skin. After pre-drilling with a 3.2mm drill bit, insert two distal screws in the ulna: the more distal one at the level of the coronoid process and the more proximal at the level of the olecranon groove. Use 120/20 4.5-3.5mm diameter screws.



WARNING: During screw insertion do not enter the joints to avoid joint damage.



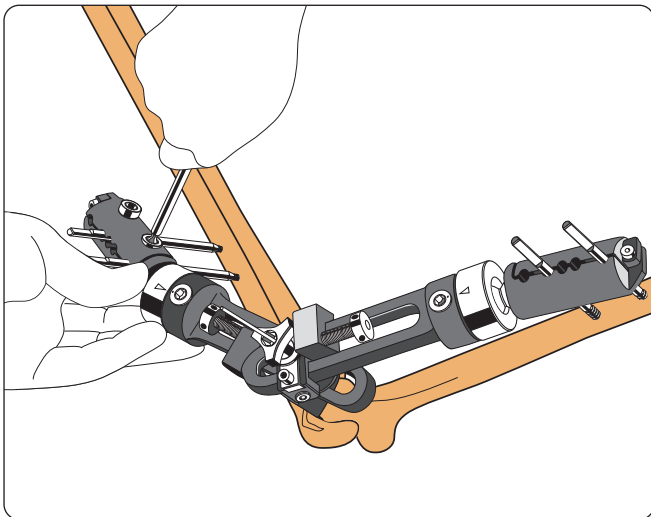
Tighten the clamp screws and cams with a 6mm Allen Wrench.



Insert the compression-distraction unit and with the central body locking nut loosened, apply 15mm of joint distraction slowly over 10 minutes. Release the distraction and then reapply it.

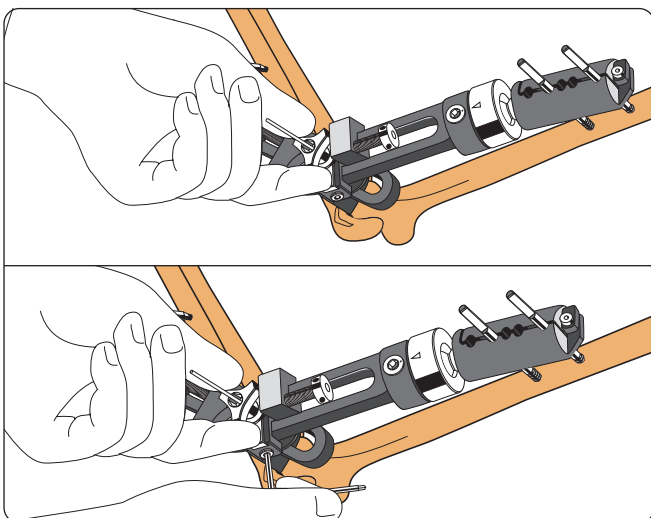


PRECAUTION: If opening of the joint cannot be achieved, consider a soft tissue release.

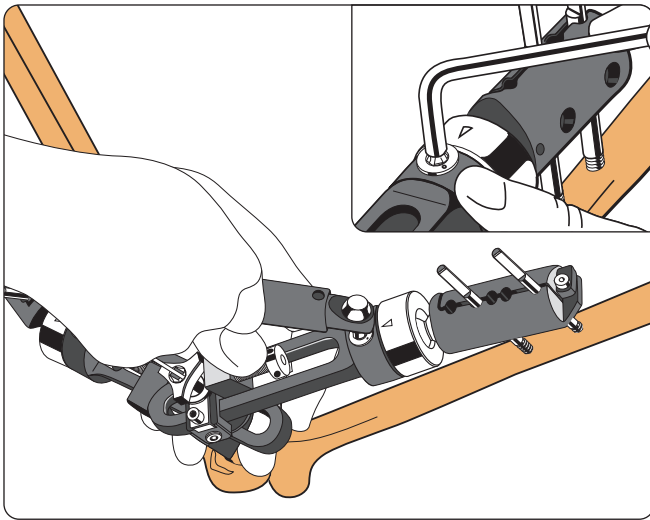


Remove the ProCallus™ Fixator and the proximal ulnar screws. Re-apply the elbow fixator over the Kirschner wire. Tighten the humeral and ulnar clamps with a 6mm Allen wrench, avoiding any bending of the Kirschner wire.

Two small distractors will be required. One should be applied on each link with the screw completely undone so that the distractor body is touching the hinge unit.

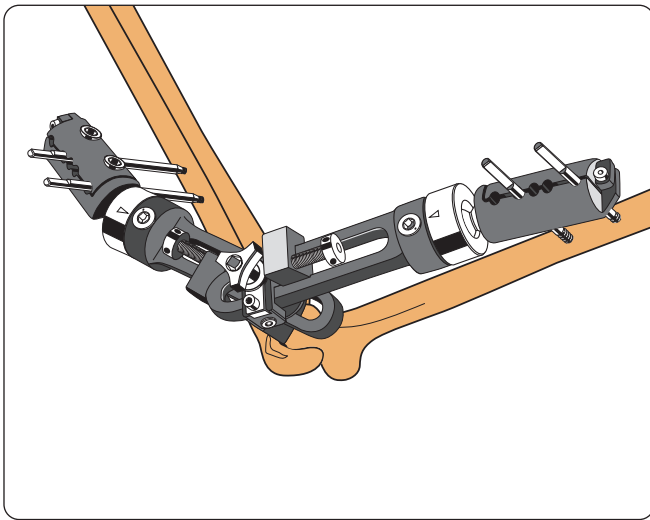


Lock the triangular knob and then each of the link locking screws.

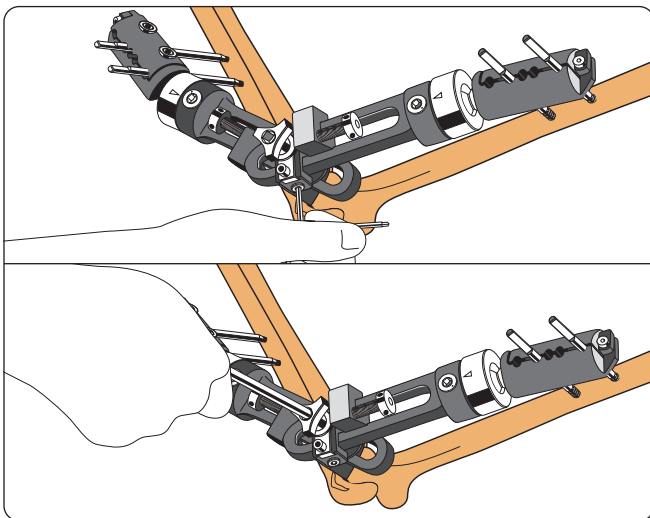


Tighten the ball-joints with a 6mm Allen Wrench and finally, lock them with a torque wrench.

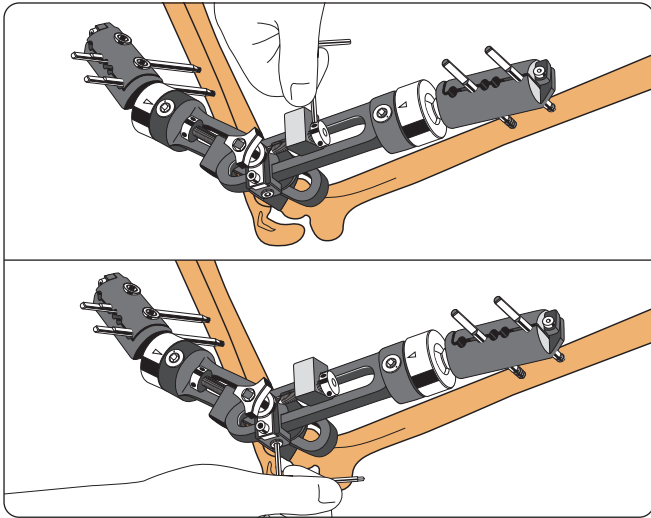
Follow this sequence strictly otherwise the links may bend or jam.



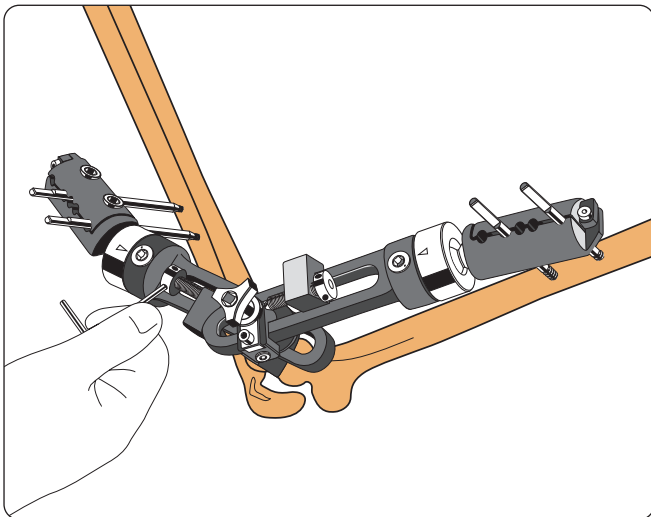
Remove the 2mm Kirschner wire. Ensure that the small humeral distractor is in contact with the central unit, tighten its locking screw and mark the position of both the distractor and the hinge unit on the link.



Loosen the humeral link locking screw and the triangular knob.

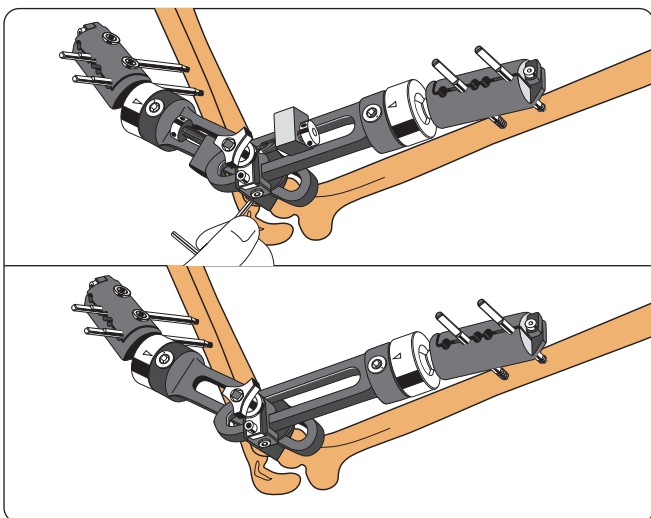


Distract for 12mm (the full length of the small distractor screw). Tighten the humeral link locking screw.

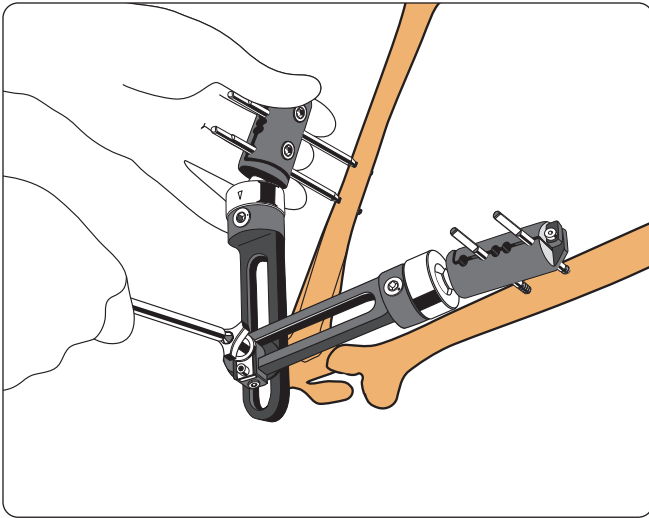


If the coronoid process impinges on the trochlea, use the small ulnar distractor to distance the coronoid process from the humerus, distracting 2-3mm.

If the olecranon tip impinges, the small distractor should be mounted on the ulnar link proximal to the hinge unit. To do this, the distraction screw must be removed and inserted from the other side of the distractor body.



After tightening of the ulnar link locking screw, remove both small distractors.



Test flexion and extension. The range of movement may be improved over time with the compression-distraction unit. Lock the fixator in 100°–110° of flexion.



PRECAUTION: Decompression of the ulnar nerve is generally recommended. In flexion contracture, full extension is best achieved slowly in the post-operative period, since the median and radial nerve as well as the brachial artery may be affected by immediate extension.

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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