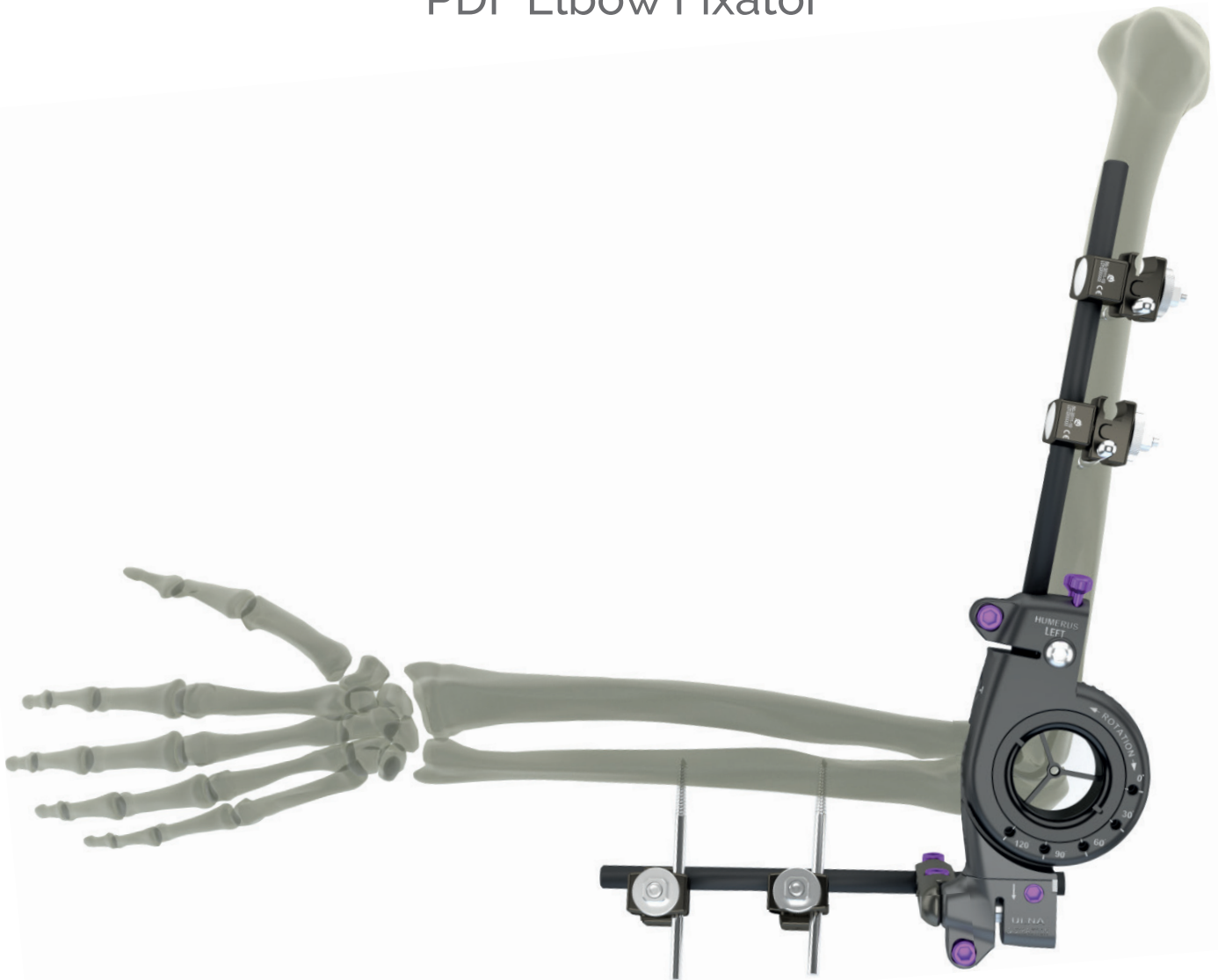




PDF Elbow Fixator



A WishBone Medical Company

Response Ortho is a global
orthopaedic trauma solutions manufacturer
offering premium products
created under its founding principles of
innovation, excellence by design
and functional superiority





CONTENTS

- 3** Introductions
- 4** Surgical Technique
- 10** Ordering Information
- 12** Notes

www.responseortho.com

Introductions

Elbow dislocations can be classified as simple or complex. Simple dislocations are characterized by the absence of fractures, while complex dislocations are associated with fractures of the radial head, olecranon, or coronoid process. If the elbow joint remains unstable after fracture fixation, UniX PDF Elbow Fixator will be a good solution to provide stability to the elbow joint, and to allow early mobilization. The latter may be important for preventing stiffness of the joint. The UniX PDF Elbow Fixator surgical technique relies on radiographic image assistance to determine the center of rotation.

With Response Ortho 's valuable experience in external fixation, UniX PDF Elbow fixator was designed to provide highest stability with unilateral design. The circular central body design allows radiographic visualization of elbow joint.

The fixator has active or passive motion options and changing the active/passive motion mode is easy to manage. Fixation can be converted from the static frame to one allowing range of motion between 0°-120° with 30° increments.

Indications

1. Fracture dislocation with ligamentous instability
2. Comminuted intra-articular fractures
3. Post traumatic reconstruction for joint stiffness

Application Timing

Generally reconstruction is completed prior to application of the fixator. Ideally all wounds should be closed prior to radiological identification of the point of axial rotation or, if preferred the surgeon may identify the access of rotation using an open technique facilitated by direct visualisation of anatomical landmarks. In the case of fractures or floating elbow gross reduction of the fractures should be completed prior to applying the fixator.

Application

The position of the circular hinge with respect to the axis of rotation of the elbow joint is the most critical step in applying the UniX PDF Elbow Fixator to avoid resistance to motion.

Fixator Assembly

To ease positioning of the fixator, simplified identification of rotational axis and application of the humeral bone screws, the distal components of the fixator should be separated from the central component.

The radiographic method of fixator application requires the surgeon to target the elbow axis of rotation, and then fixing the centre of rotation by insertion of a 3.2mm guide wire. The centre of rotation of the fixator is aligned with this position.

Screw Insertion Technique



Select an appropriate length soft tissue guide. Having used the trocar to identify the centre of the bone, place the soft tissue guide on the humerus such that the two points of the trocar straddle the centre of the bone. This will help maintain the position of the soft tissue guide.



Using the non-dominant hand, maintain gentle pressure to ensure continuous contact between the soft tissue guide and the cortex of the bone. Remove the trocar and tap the soft tissue guide points with the bone.



Once this is done, insert the appropriate drill guide into the soft tissue guide and pre-drill both cortices in preparation for the bone screw. Drilling needs to be performed such that the axis of the drill is perpendicular to the long axis of the bone. This will result in the correct orientation of the bone screws.

Drill Guide	Drill Bit	Screw
4.8 mm	4.8 mm	6/5 mm Cortical
3.2 mm	3.2 mm	6/5 mm Cancellous
3.2 mm	3.2 mm	4.5/3.5 mm Cortical

(Bone screw diameter should not exceed 1/3 diameter of bone)

After bi-cortical penetration of the drill, the drill bit and drill guide are withdrawn. Maintain contact and position of the soft tissue guide.

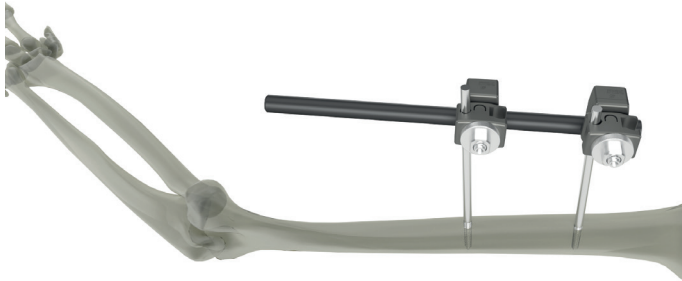


1. The appropriate 6/5mm bone screw is then inserted through the soft tissue guide using the Bone Screw T-wrench.

Note: Care must be taken to avoid over-penetration. Due to the tapered design the bone screws must not be backed out, or they will lose purchase.



Proximal Screws Placement



1. Make the incision at the location of the proximal bone screw, followed by blunt dissection to the surface of the bone.
2. Mark the position of the proximal screw in M/L position.
3. Insert the half pin.

Technical Note: Care needs to be taken to identify and isolate the Radial nerve on the lateral humerus, which is usually in the vicinity of the proximal bone screw insertion point. In case of any doubt, it is advisable to widen the incision in order to help locate and isolate the Radial Nerve. The proximal screw track can then be pre-drilled and the screw inserted free hand according to the following steps.

4. At this point the proximal clamp should be attached onto the first bone screw.
5. Insert the second soft tissue sleeve to confirm the second incision point. Again, use blunt dissection to open the soft tissues down to the level of the bone.
6. The distal bone screw is inserted in similar fashion using the soft tissue guide. Assure the screws are in parallel placement.

Technical Note: Bicortical penetration of the bone screws should be confirmed using image intensification, with two threads extending beyond the far cortex. Care should be taken to avoid over penetration when using tapered bone screws as they will lose purchase if they are backed out.

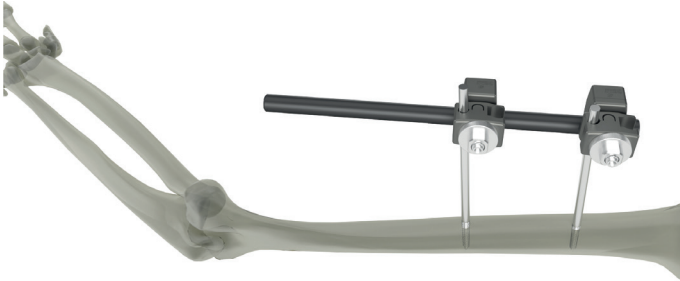
Positioning and Attaching the Central Component

1. Attach the targeting rod on the most distal screw of proximal bone screw cluster. Confirm the alignment with the axis of rotation of the elbow.

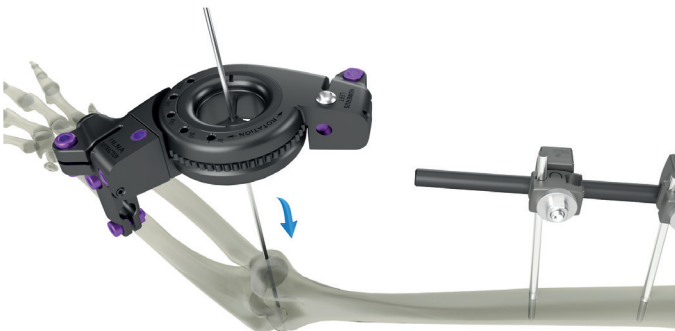


2. Fine positioning is then achieved by placing the 3.2mm drill bit or guide wire through the axis finder, allowing it to rest on the lateral epicondyle and adjust the alignment rod until the wire or drill appears as a dot in the centre of the capitellum. Once positioning is confirmed drill the guide-wire into position.

3. Now confirm the position of the elbow has not changed in relation to the fluoroscopic beam by checking the radiographic landmarks.
4. Now remove the alignment rod from the K-wire, ensuring it maintains its position.



5. The central component of the UniX PDF ELbow Fixator can now be brought down over the guide wire and attached to the proximal clamp. Adjust the position of the central component until the targeting disc can slide smoothly into the UniX PDF ELbow Fixator central component.



6. Once this position is achieved lock all the proximal component connectors. Reconfirm the correct position of the K-Wire under fluoroscopy. The centre of rotation of the frame should be securely positioned over the axis of rotation of the elbow.



7. Once the axis of rotation is confirmed to be correct, and all locking bolts on the proximal section are locked, the distal component of the fixator is applied with independent bone screw placement in the ulna.



Ulnar Component Attachment

1. Loosen the locking serrations of the distal component of the fixator, and slide the bar into the ulnar rod slot. Tighten the ulnar fixation bolt and remaining ulnar bone screws.
2. The bar of the distal component of the fixator should be aligned parallel to the anatomical axis of the ulna and adjacent to the subcutaneous border. This will assist in placement of the ulna screws perpendicular to the shaft.

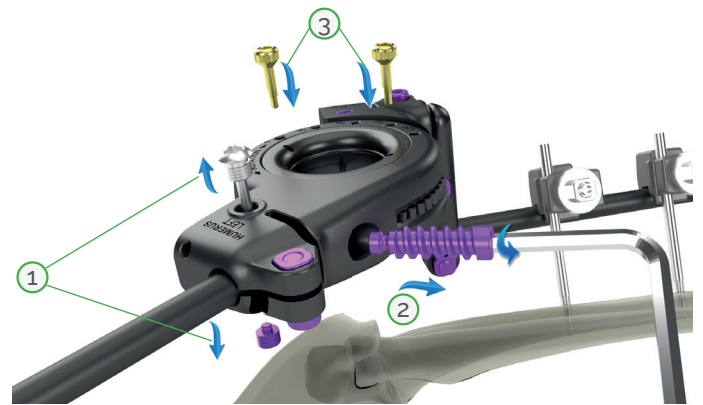


3. Mark the pin hole positions on the skin. Place distal component next to ulna.
4. The distal components of the fixator are then temporarily removed to allow screw placement before being reattached definitively. Ulnar screws are placed using standard technique.



Technical Note: In most applications, the 3.2mm drill guide and drill bit will be used in the ulna. Appropriate length of 4.5/3.5mm screw used. Prior to final tightening the frame the surgeon should ensure that the ulna is accurately aligned to the humerus

Post-operative Free Range of Motion

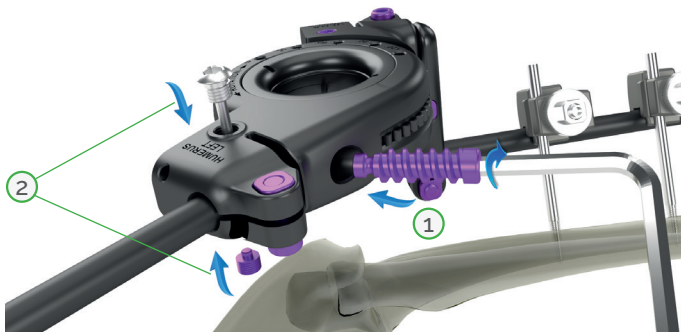


The exact postoperative motion program will depend on the clinical requirements of the patient. Should mobility be possible, then test the elbow through a range of motion after fixator application. If the hinge of the fixator is well aligned it should be stable through a full arc of motion. Motion can begin the day after fixator application. Active movement and gentle passive distraction are generally adopted.

Motion limit pin holes are available on the central portion of the fixator and motion range can be adjusted according to patient requirements. The frame can be partially restricted by the Stopper Pins (50-6050-00) or, can be locked by the Passive Distraction Component (50-6052-00) dependent on the needs and comfort of the patient.

The locking bolt should be removed (counterclockwise) from the slot (1) and remove passive distraction component (2). Insert motion limit pins into the holes (3) if necessary

Passive Distraction



The Passive Distractor is designed to allow gradual distraction of the elbow for flexion or extension to heal elbow stiffnesses.

The passive distraction component (50-6052-00) should be inserted (clockwise) in the slot (1) and locked by the locking bolt (2).

After tightening the bolts (2), the passive distraction component will provide flexion or extension by turning.



Articular Distraction



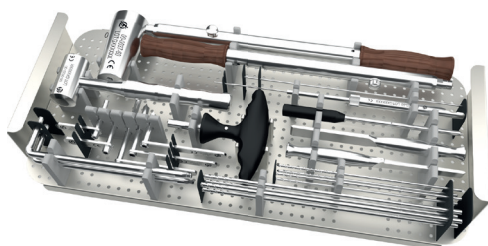
If articular surface distraction is necessary, the distraction unit on the central component will allow joint distraction for 15mm.

The unit should be placed 90° or perpendicular to the line drawn from the tips of the olecranon and coronoid processes.





00-9069-06	UniX PDF Elbow Fixator Set	1
00-8109-06	Unix PDF Elbow Fixator Case	1
50-3011-10	Multiaxial Large Bar Clamp, 6/10/10	16
50-3023-15	150mm Carbon Fiber Rod w/marker	4
50-3023-20	200mm Carbon Fiber Rod w/marker	4
50-5029-00	Unix Supplemental Rod Clamp	2
50-6012-00	Elbow Fixator Targeting Rod	1
50-6012-03	3.2mm Threaded Tip Guide Wire	2
50-6050-00	UniX PDF Elbow, Angular Stopper Pin	4
50-6051-00	UniX PDF Elbow, Fixator Body	2
50-6052-00	UniX PDF Elbow, Passive Dist. Component	2
50-6053-00	UniX PDF Elbow, Ulnar Height Adjuster	2



00-8109-00	External Fixator General Instrument Case	1
00-0022-00	Hammer (Light)	1
00-3321-20	Quick Release Drill, 3.2mm Ø, 200mm Length	2
00-3323-20	Quick Release Drill, 3.2mm Ø, 200mm Length, Cannulated	1
00-3481-03	Quick Release Drill, 4.8mm Ø, 280mm Length	2
00-3483-28	Quick Release Drill, 4.8mm Ø, 280mm Length, Cannulated	1
00-0041-32	Drill Guide 3.2mm	2
00-0041-48	Drill Guide 4.8mm	2
00-0052-40	Soft Tissue Guide, 40mm	2
00-0052-60	Soft Tissue Guide, 60mm	2
00-0050-00	Trocar	1
00-2035-19	Allen Wrench, 5mm/190mm	2
00-2036-00	T-Wrench for Bone Screws	1
00-0130-13	Osteotome, 13mm Wide Blade	1
00-0130-19	Osteotome, 19mm Wide Blade	1
00-7057-00	2.0mm X 250mm Non-Threaded Guide Wire	4
00-0013-90	Depth Gauge, 4.5/6.0mm Range, 90mm length	1
00-0037-60	Low Profile Rod Cutter, 6mm (modular handle)	1

CLICK 2 CORRECT



Click2Correct™ Web App

Click2Correct™ Preoperative Planning and Templating Software offers reduced planning time, the easiest user interface possible and an improved template library.



Web Based Interface



Multi Platform Support



Touch Screen Compatible



Unlimited Cloud Storage



Multi User Support

www.click2correct.com



PDF Elbow Fixator



www.responseortho.com

ITOSB, 10. Cadde, No:1, Tepeoren
Tuzla, Istanbul, 34959, TURKEY
Phone : +90 (216) 314 11 04
Fax : +90 (216) 365 37 36
e-mail: info@responseortho.com

CE₂₁₉₅