

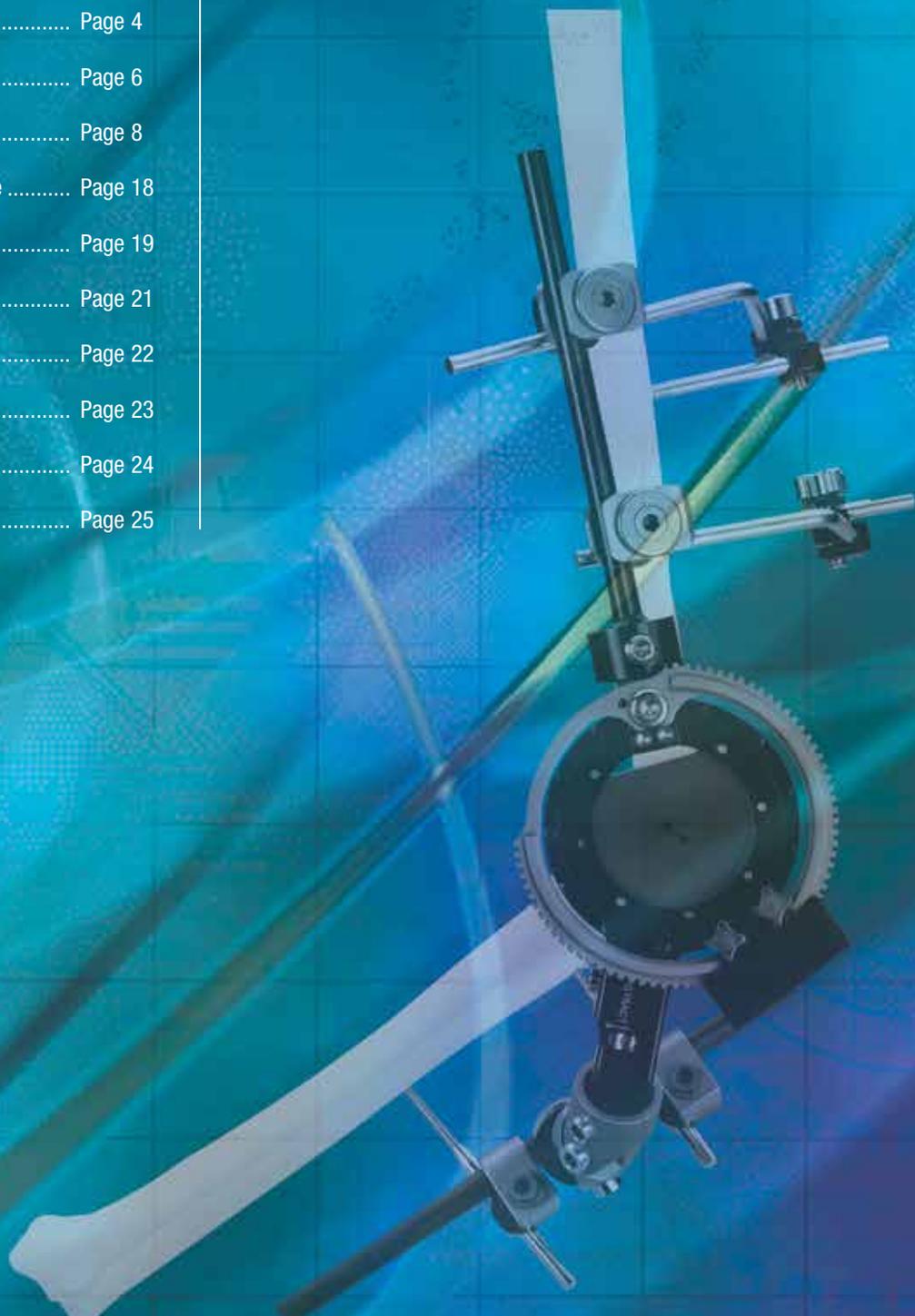
OptiROM® Elbow Fixator

Surgical Technique



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Introduction

The **OptiROM** Elbow Fixator was designed for use in the management of complex injuries of the elbow. It is well recognized that early range of motion can facilitate fracture healing, cartilage regeneration, and rehabilitate atrophic or contracted soft tissues. Early range of elbow motion is required soon after injury or surgery to prevent stiffness and achieve a maximum arc of motion. Unfortunately, surgical release of contractures or acute injuries can create instability that makes unprotected movements risky or impossible. External braces are poorly tolerated, inhibit motion and do not accurately reproduce the elbow axis. Several devices, external fixation and Continuous Passive Motion (CPM) machines have been described for treatment of these injuries.

The **OptiROM** Elbow Fixator supports the conventional method as well as a new conceptual method for determining the center of rotation. This new method relies on radiographic assessment to determine the center of rotation. Under either of these methods the **OptiROM** Elbow Fixator provides a controlled range of motion around a predetermined axis. This fixator provides excellent stability with a low profile monolateral design. Fixator components are remote from the zone of injury, which allows it to function like a skeletally fixed brace.

The design is compatible with limited osteosynthesis techniques and can provide for unobstructed radiographic and operative access. The fixator is easily converted from a static frame to one allowing range of motion. Motion limits can be adjusted to fit the clinical scenario. Symmetric distraction of the elbow is possible if clinically indicated.



Introduction (Continued)

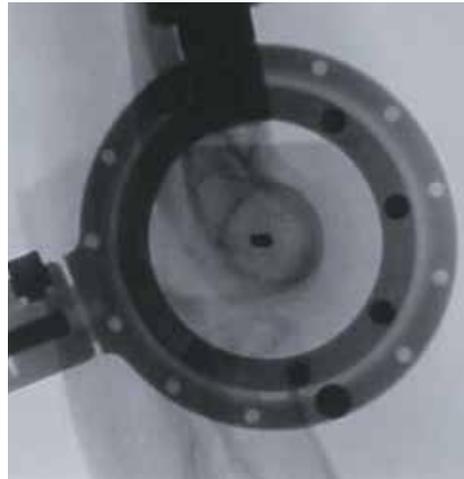
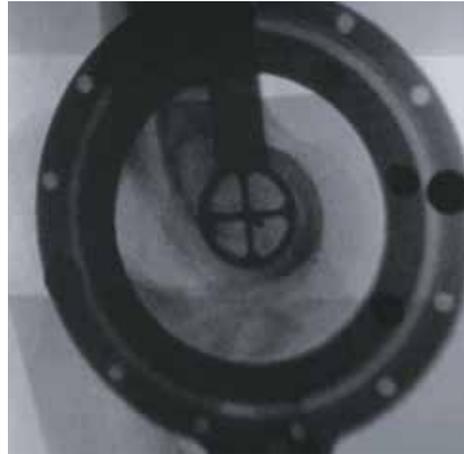
Procedures Associated With Fixator Application

Should the patient need soft tissue reconstruction for an unstable elbow, or release of a stiff elbow joint, multiple operative approaches are possible. Generally, the elbow reconstruction should be completed prior to fixator application.

If the surgeon intends to insert an axis pin to identify the axis of rotation, the wounds should be left open to facilitate direct visualization of the elbow joint and the anatomic landmarks. Should radiographic location of the axis of rotation be the preferred method, wounds should be closed in preparation for application of humeral bone screws.

In cases of fracture repair or treatment of acute elbow instability, a preliminary reduction should be performed prior to fixator application. Planned fracture fixation or soft tissue repairs should be completed prior to fixator application.

If distal humeral fixation is planned, the surgeon should be prepared for the effect this will have on locating the elbow axis of rotation.



Indications For Use

INDICATIONS

The OptiROM Elbow Fixator external fixation device intended for use in upper extremity treatment of bone and soft tissue conditions and other bone conditions amenable to treatment by use of the external fixation modality. Possible applications include:

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

CONTRAINDICATIONS

Patients with mental or neurologic conditions who are unwilling or incapable of following postoperative care instructions.

WARNING: This device is not approved for screw attachment or fixation to the posterior elements (pedicles) of the cervical, thoracic or lumbar spine.

Pre-Operative Planning

Each application of the **OptiROM** Elbow Fixator is indication specific. Generally, A/P, lateral and sometimes, oblique radiographs are indicated. In addition, CT scans will provide additional insight into intra articular pathology and should be considered. For the purposes of identifying the axis of rotation, as well as planning for adjunctive procedures, the surgeon must evaluate a lateral radiograph of the distal humerus to identify fractures or deformity.

Methods To Align Hinge With Elbow Axis Of Rotation

Achieving precise alignment of the circular hinge with respect to the axis of rotation of the elbow joint is the most critical step in applying the **OptiROM** Elbow Fixator. With perfect alignment, the resistance to motion is minimal. This increases post-operative motion and decreases forces transmitted to the fixator. Unfortunately, the elbow is not easily tolerant of off-axis alignments. Forces in the system and resistance to movement increase rapidly with off axis alignment. We have designed a fixator and an alignment technique that facilitates the surgeon's ability to achieve precise alignment of the fixator hinge with the elbow axis of rotation. There are two different techniques to accomplish this. The author suggests and exclusively utilizes a **radiographic technique of axis location** (Figure 1, Page 5). The author believes this technique to be more accurate, allowing for fine adjustment of the axis of rotation, and a more expeditious application than conventional targeting. The technique requires the surgeon to know the precise radiographic landmarks of the elbow when the fluoroscopic beam and the axis of rotation coincide in the same plane. These landmarks will be described.



OptiROM on forearm in *flexion*



OptiROM on forearm in *extension*

If the surgeon chooses the radiographic method of alignment, the first step in the procedure will be placement of the humeral bone screws. Through an open incision, bone screws are inserted safely above the transition of the radial nerve on the lateral humerus.

The fixator is then attached to the humeral bone screws and an external axis finder is used to facilitate positioning. The axis of rotation of the elbow can also be aligned with the use of an **invasive axis pin technique** (Figure 2).

This step is accomplished separately utilizing percutaneous or open techniques. It requires that the surgeon know the anatomic landmarks of the periphery of the humerus over the axis of rotation.

Knowledge of the radiographic landmarks can supplement accurate insertion of the axis pin, and we strongly suggest that they be used. If the surgeon chooses to implement an axis pin, this will be the first step in the procedure, and the proximal humeral bone screws pins will be aligned off of the axis pin.



Figure 1. Radiographic technique of axis location

***A 3.2mm drill bit or guide wire is used only to aid radiographic interpretation.**



Figure 2. Invasive axis pin technique

Technique Overview

The **OptiROM** Elbow Fixator can be applied using two methods to achieve alignment of the axis of rotation to the elbow joint. Both methods assume a radiographic appearance of the landmarks of the elbow. When aligned properly, this image will show radiopaque circles centered on the axis of rotation as well as a radiodense line along the distal humeral metaphysis at the elbow joint.

Radiographic Method

The **radiographic method** of fixator application requires the surgeon to target the elbow axis of rotation without using an invasive guide wire. The fixator is then applied with reference to the center of rotation of the elbow joint and overview of the steps included in the radiographic method are illustrated here.

- Step 1:** Position targeting rod on the most distal screw of proximal bone screw cluster. Align rod and wire with use of fluoroscopy to identify radiographic landmarks and axis of rotation. The wire should rest on the skin and not penetrate soft tissue.
- Step 2:** With axis of rotation identified and rod locked to proximal bone screws, the wire is retracted and the central component of fixator is aligned to allow free passage of wire through radiolucent targeting disc. The axis of rotation of the fixator should now be aligned with the elbow axis.
- Step 3:** The distal component of the fixator is applied with independent bone screw placement in the ulna.



Step 1



Step 3

Invasive Targeting Method

The *invasive targeting method* of fixator application requires the surgeon to place a targeting guide wire through the center of rotation of the elbow joint. The fixator is then placed over the guide wire, the proximal and distal bone screw clusters are then templated accordingly. An overview of the steps included in the invasive targeting method are illustrated here.

Step 1: Guide wire is inserted at the pre-determined location using anatomic landmarks prior to application of the fixator.

Step 2: The fixator is slid over the guide wire and the proximal and distal bone screws are templated accordingly.

Step 3: The distal component of the fixator is applied with independent bone screw placement in the ulna.



Step 1



Step 2



Step 3

Surgical Technique

Patient Positioning

The patient is positioned supine utilizing a radiolucent hand table extension on the side of the extremity to be operated on.

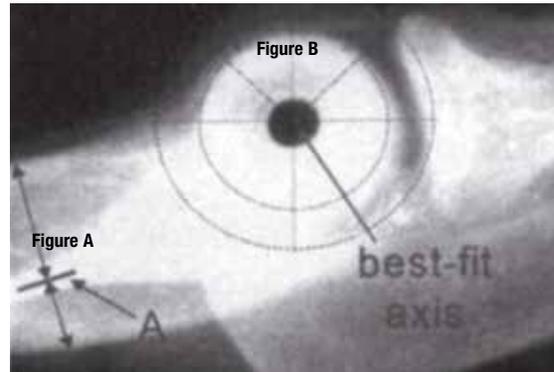
The arm should be parallel to the floor with the hand positioned in slight pronation. The arm should be prepped to the shoulder and draped in routine sterile fashion.

Radiographic Landmarks

Radiographic alignment of an external hinge requires precise knowledge of what the elbow looks like fluoroscopically when it is positioned exactly along the appropriate axis. The radiographic appearance of the elbow, when aligned, shows concentric radiopaque circles centered on the axis (Figure B) as well as a radiodense line along the distal humeral metaphysis (Figure A).

Two radiographic landmarks allow for the identification of the rotational axis of the elbow. Transverse plane orientation is determined by the position of a radiographically dense line projected over the distal humeral metaphysis (relative to the anterior/posterior cortex). This dense line will project an approximate 73% anterior to 27% posterior humeral cortex ratio (Figure A). Coronal plane orientation is determined by the concentric circular appearance of the superimposed medial trochlear flange and the capitellum/trochlear sulcus (Figure B).

Radiographic landmarks are helpful for both the radiographic method and the invasive axis pin method of axis location for fixator application.



Coronal plane best fit axis and transverse plane orientation

Radiographic Targeting And Alignment Of Hinge

After the humeral bone screws have been inserted, the fluoroscopy machine should be repositioned and brought in from the head of the table, perpendicular to the radiolucent hand table. The arm should be positioned with the shoulder abducted 90° and the elbow in full extension. Sterile bumps should be utilized on the medial side of the elbow to ensure that the arm is parallel to the floor and to adjust abduction/adduction in the axis identification process.

The fluoroscopy machine is then rotated so that the beam is approximately 60° off of the plane of the floor. The C-arm is then internally and externally rotated to determine the radiographic dense line of the medial humeral ridge. Ideal position dictates that this dense line should rest 27% from the posterior cortex and approximately 73% from the anterior cortex. Abduct and adduct the arm in the plane of the fluoroscopic beam until the shadows of the trochlea and capitellum are in concentric alignment.



Patient positioning - **lateral view** with fluoroscopy machine positioning



Patient positioning - **superior view** with fluoroscopy matching positioning

Surgical Technique (Continued)

Technique For Radiographic Method

The radiographic method requires application of the proximal component of the fixator as the first step. The position of the humeral bone screws is determined by identifying the lateral epicondyle, centering the circular hinge over it and tracing the appropriate position of the proximal component on the skin. Plan the position with the component slightly pre-extended. The screws should be applied directly in the lateral to medial plane. Avoiding posterolateral screw positioning will minimize proximity to the radial nerve.

Fixator Preparation

To facilitate fixator positioning for identification of rotational axis and for application of humeral bone screws, the distal component of the fixator should be removed from the central proximal component of the frame. Using the 5mm Allen Wrench, the rotational locking set screw is loosened and the distal component of the fixator is separated.



Marking of humerus for placement of proximal component bone screws



Loosening locking nut for removal of distal component



Insertion Of Proximal Component Bone Screws

After marking the skin for placement of the proximal bone screw cluster, an incision is made and dissection is continued to the bone for placement of the distal screw in the proximal bone screw clamp. An open incision for the humeral bone screws is recommended to identify and avoid the radial nerve. The trocar and appropriate length soft tissue guide are then utilized to identify the center of the bone and to establish the orientation of the screw tract to be pre-drilled. The orientation and insertion of the bone screws should be perpendicular to the long axis of the bone. Once the screw site is selected, use gentle pressure to maintain contact between the soft tissue guide and the cortex of the bone. Remove the trocar and tap the soft tissue guide with a mallet to engage the soft tissue guide with the bone. The appropriate drill guide and drill bit are then inserted into the soft tissue guide and drilled bicortically. In most applications, the 4.8mm drill guide and drill bit will be used to prepare for 6/5mm tapered cortical screws.

To assure that accurate bone screws selection, the width of the humerus should be measured and the appropriate bone screw selected, understanding that the diameter of the bone screw should not exceed 1/3 the diameter of the bone.

The drill bit is then removed and gentle pressure is maintained on the soft tissue guide to prevent losing the pre-drilled hole. The appropriate 6/5mm screw is then inserted into the soft tissue guide using the Bone Screw T-wrench.



Trocar and soft tissue guide are used to identify the center of bone and orient bone screw tract



Bicortical penetration made with matching drill bit and drill guide through soft tissue guide

Surgical Technique (Continued)

Bicortical penetration of the bone screws is assured using image intensification, with two threads beyond the far cortex.

Care should be taken to avoid over penetration as the bone screws are tapered and will lose purchase if they are backed out.

The proximal bone screw is inserted in similar fashion using the bone screw clamp as template to assure parallel placement. Using the 5mm Allen Wrench, the clamp cover screws are loosened to accommodate insertion of both soft tissue guides. The bone screw clamp/soft tissue guide assembly is then placed over the existing bone screw.

At this point using the existing incision site, preparation can be made for insertion of the proximal humeral bone screw repeating steps for the distal bone screw placement.

After insertion of both proximal bone screws, the soft tissue guides are removed and the clamp cover screws are then re-tightened to assure parallel bone screw placement. Approximately three centimeters of clearance between the skin and fixator is recommended for adequate soft tissue hygiene. Once the humeral bone screws are locked into the clamp, the wounds may be closed.



Appropriate length bone screw inserted through soft tissue guide



Tightening clamp cover of proximal component over bone screws

Alignment Of The Axis Finder With The Axis Of Rotation Of Elbow

Place the external axis finder over one of the humeral bone screws. Bring the distal part of the axis finder over the capitellum and confirm its position radiographically (Refer to page 8). Fine-tune the position by placing the 3.2mm drill bit or guide wire through the axis finder, allowing it to rest on the lateral epicondyle. This pin is not inserted into the bone. Fine tune radiographic alignment by adjusting the pin and axis finder position until the pin appears as a dot radiographically. This dot must be in the center of the capitellum depicting the center of rotation for the joint.

Make sure the position of the elbow in relation to the fluoroscopic beam has not changed by checking the radiographic landmarks. Rotating the C-Arm in the position previously described (Page 9) will facilitate locating of the radio dense along the distal humeral metaphysis. Abducting and adducting the elbow will facilitate location of the concentric circles of the capitellum and trochlea. After positioning is confirmed, tighten the targeting coupler to secure the position of the axis finder on the humeral bone screws. This will lock the position with respect to the axis of rotation of the elbow.



Oblique view of target rod over capitellum



Radiographic representation (lateral view) of target rod over capitellum

Surgical Technique (Continued)

Alignment Of Hinge With Axis Finder

Position the central component of the frame with the targeting disc under the axis finder by partially withdrawing the 3.2mm drill bit/guide wire. Adjust the position until the guide wire will drop smoothly through the central hole of the targeting disc. Sequentially tighten the locking connectors of the proximal component of the frame. When securely locked, the hinge should be centered over the axis of rotation and the ulnar side of the frame can be attached.

Ulnar Component Placement

Using the 5mm Allen Wrench, the distal component of the fixator is then reattached to the central portion of the frame. The locking serrations of the distal component of the fixator should be loosened to approximate alignment of the bar and targeting of the ulnar bone screws. The bar of the distal component of the fixator should be aligned parallel to the long axis, as well as adjacent to the subcutaneous border of the ulna to facilitate bone screw placement perpendicular to the long axis of the shaft. Once location of the ulnar screws has been identified, the skin should be marked and the fixator moved away in preparation for independent bone screw placement. Ulnar bone screw placement can vary based on the clinical scenario or surgeon preference.



Adjustment of central component to allow target wire to pass through center of target disc



Reattachment of distal component to fixator

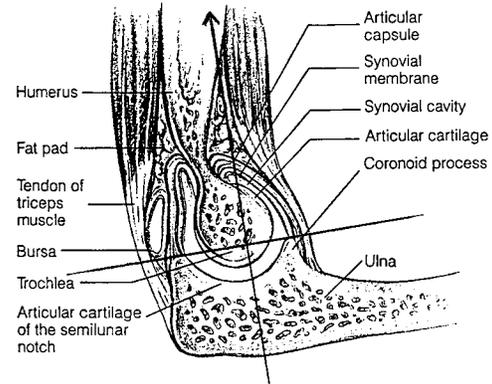
Distraction unit should be placed 90° or perpendicular to a line drawn from the tips of the olecranon and coronoid processes.

Independent bone screw placement into the ulna is made possible with the use of a pin-to-bar system incorporated into the design of the distal component. Percutaneous placement of the ulnar bone screws is recommended at the marked points along the subcutaneous border of the ulna. The trocar is inserted into the soft tissue guide and the center of the bone is identified. The appropriate drill guide and drill bit are then inserted into the soft tissue guide. In most applications, the 3.2mm drill guide and drill bit will be used. Under image intensification, the bone is drilled bicortically.

The drill bit is then removed and gentle pressure is maintained on the soft tissue guide. The appropriate screw 4.5/3.5mm is then inserted into the soft tissue guide using the Bone Screw T-wrench. Bicortical penetration of the bone screws is recommended and should be confirmed under image intensification, with no less than two threads beyond the far cortex.

After bone screw insertion, the distal component of the fixator is attached. Prior to tightening the frame, be certain that the ulna is accurately aligned to the humerus.

Final tightening of all components of the fixator completes the frame application.



Lateral view of distal component alignment with ulna



Placement of proximal ulna bone screw

Surgical Technique (Continued)

Technique For Invasive Axis Pin

Utilizing this method, an axis pin is inserted at the pre-determined location using anatomic landmarks prior to application of the fixator.

Drilling The Axis Pin

With direct visualization of the joint space and under image intensification, a 3.2mm guide pin is inserted through the capitellum, parallel to the articular surface of the distal humerus. Care should be taken to protect and retract the ulnar nerve to avoid impingement. The anatomic landmarks for pin position laterally are, 1) the center of the lateral epicondyle and 2) the steep slope on the anterior inferior surfaces of the medial epicondyle. Placement of the guide pin should be confirmed radiographically on the A/P and lateral views. Once the axis has been determined and the surgeon is comfortable with the placement of the targeting pin, the **OptiROM** Elbow Fixator is then applied. We strongly recommend radiographic confirmation of pin position.

NOTE: As the 3.2mm wire is for guidance only, there is no need for extended penetration, or bicortical penetration of guide wire.



Placement of targeting wire through center axis of rotation



Lateral view of placement of central component over target wire

Applying The Fixator

Using the radiolucent targeting disc, the frame is applied over the shank of the guide pin. The locking serrations of the proximal fixator arm should be loosened to approximate targeting of the humeral bone screws. Again, using the open technique, the radial nerve should be identified and protected to avoid impingement with the drill bit. The proximal arm of the fixator should be aligned to facilitate bone screw placement perpendicular to the long axis of the shaft of the humerus. Once location of the humeral screws has been identified, the fixator should be locked. The proximal clamp should be 1-2cm's pre-extended to screw placement proximal to the radial nerve. In large patients an 8cm clamp can be substituted for a 5cm clamp to allow for more proximal pin positioning.

Proximal Component Placement

Refer to Surgical Technique page 11.

Distal Component Placement

Refer to Surgical Technique page 14.



Superior view of placement of fixator over target wire

Posterior Humeral Insertion Technique

Applying The OptiROM Elbow Fixator Anchored With Posterior Humeral Pins

Once the guide pin has been placed through the axis of rotation of the elbow, the preassembled **OptiROM** Elbow External Fixator frame can be placed along the lateral aspect of the upper extremity.

Attention can be turned to the posterior aspect of the humerus at this time. The triceps muscle overlies the posterior humerus along essentially its entire length. The musculotendinous junction extends relatively proximal to about the middle third of the humerus, and the tendinous elements of the triceps are slightly more on its lateral aspect. Further appreciating this anatomy, it should also be observed that there is relatively little triceps excursion as it nears its insertion on the ulna even through the full flexion extension arc of motion of the elbow. It is for these reasons that longitudinal dissection in line with fibers that permit placement of pins through the muscle and into the posterior aspect of the humerus can be done without significant compromise and relatively little damage to this important extensor of the elbow.

In this safe zone, two or more posterior pins can be placed. They can be placed anywhere from directly lateral to nearly medial being bordered by the area of travel of the ulnar nerve. However, we favor a nearly direct posterior insertion because of multiple factors – primarily since there is no apparent loss of frame stability and greater margin of safety.

The incisions are carried carefully down to the posterior aspect of the humerus. The tracts are enlarged by careful spreading or simply by extending the deeper dissection in line with the fibers of the triceps tendon. Soft tissue protector sleeves are utilized to gain access to the posterior cortex of the humerus.



The appropriate size drill is utilized to drill through the posterior and anterior cortices of the humerus. Self-tapping, terminally threaded pins are employed.

Two small (approximately 1.5cm) skin incisions are made through the skin of the posterior brachium.

There are no specific subcutaneous structures of significant concern, but care should be exercised to avoid any superficial sensory nerves or large veins. These incisions, and eventual pin insertions, should be performed in the “safe zone”, along the posterior aspect of the humerus. We have defined this region as that area from approximately 6cm proximal to the olecranon tip to approximately 20-25cm proximal to the olecranon tip. Of course, these distances and ranges are variable with different patient sizes and injuries to the surrounding structures.

The safe zone is bordered proximally by the radial nerve which crosses obliquely from medial to lateral. Distally, the tapering of the intramedullary canal (which typically terminates approximately 4cm proximal to the roof of the olecranon fossa) is the defining features.

Once two or more bone screws are placed, the proximal aspect of the frame can be assembled. In order to provide monolateral frame position, “outriggers” have been designed to attach to both the posterior pins and the frame. Appropriate pin-to-bar clamps are employed to establish the relationship between the bone screws and the outriggers. The extensions are positioned to accommodate the girth of the brachium, which may be swollen from trauma. The frame is attached to the outriggers by specially designed clamps that allow facile manipulation and many degrees of freedom for exact positioning.

Post-Operative Care

Dry sterile gauze is wrapped around the shanks of the bone screws to prevent pistoning of the soft tissues. Sterile saline should be used on the pin sites until the wounds have healed and the sutures are removed. The patients are then instructed to shower on a daily basis using an antibacterial soap and water as a means for routine bone screw hygiene. Screw sites should be monitored during subsequent clinic visits. All fixator fittings should be evaluated for tightness during subsequent clinic visits.

The exact postoperative motion program will depend on the clinical condition and surgeon preference. Carefully test the elbow through a range of motion after fixator application. If the hinge is well aligned it should be stable through a full arc of motion. Motion can begin the day after fixator application, usually with the help of a physical therapist. Active and gentle passive movements are permitted. Motion limits are typically not set, although the frame permits this if desired by the surgeon. Patients are given a 5mm Allen Wrench, which allows them to lock the frame for comfort.



Application of range of motion limit pins

Post-Operative Care (Continued)

If the surgeon wants to distract the articular surfaces, the central distraction unit allows joint distraction of up to 1mm. During application the unit should be placed 90° or perpendicular to a line drawn from the tips of the olecranon and coronoid processes.

Fixator removal can be accomplished in the outpatient clinic without sedation. The timing of fixator removal depends on the elbow condition being treated.

NOTE: The use of CPM machines in conjunction with the fixator should be prohibited as the center of rotation on the CPM may be different from the center of rotation on the fixator. Following this suggestion will eliminate unnecessary stressing of the bone screw interface and fixator components.



Symmetric joint distraction



Locking range of motion capabilities of frame with arm in flexion

System Components

Passive Distractor

Design Overview

The Passive Distractor (P/N 09650) is a useful tool to allow incremental, gradual distraction of the elbow for flexion or extension, and is commonly utilized for elbow contractures.



OptiROM Elbow
Passive Distractor

Application of this device is demonstrated below. (Figures 1-4)



Figure 1



Figure 2



Figure 4

Left And Right Application

The passive distraction gear can be flipped to ensure usage in both right and left elbow applications. This is done by simply manipulating the gear box into the smooth section of the gear. The two **silver** bolts are removed and the gear box is flipped as demonstrated below.



Equipment Required

Bone Screws

These are suggested bone screw sizes; however, each patient should be evaluated preoperatively and bone screws should be chosen based on individual patient needs. Bone screw diameter should never exceed 1/3 the diameter of the bone.

Humeral Bone Screws

6/5mm Tapered, Cortical Bone Screws with 6mm Shank
P/N's A60-11030 (110mm Overall Length, 30mm Thread Length),
A60-11040, A60-12040

Ulnar Bone Screws

4.5/3.5 Tapered, Cortical Bone Screws with 6mm Shank
P/N's A45-08030 (80mm Overall Length, 30mm Thread Length),
A45-10020, A45-10040, A45-12040

OptiROM Elbow Fixator is provided in a loaner bank system (P/N 00040).*

The loaner bank includes:

1. **OptiROM Proximal Assembly** (P/N 09600)
 - 1A. Central Component (P/N 09575)
 - 1B. Proximal Arm (P/N 09630)
2. Targeting Disc (P/N 09580)
3. Right Knuckle**
4. Left Knuckle**
5. 150mm Carbon Fiber Rod** (P/N 14160)
6. 6mm Bone Screw Clamps** (P/N 14040)
7. 40mm Soft Tissue Sleeves (P/N 03080)
8. 60mm Soft Tissue Sleeves (P/N 03085)
9. 3.2mm Targeting Wire (P/N 09595)
10. Targeting Coupler (P/N 09590)
11. Targeting Rod (P/N 09585)
12. 3.2mm Drill Guide (P/N 03065)
13. 4.8mm Drill Guide (P/N 03060)
14. 3.2mm Drill Bit (P/N 03035)
15. 4.8mm Drill Bit (P/N 03025)
16. Ulnar Bone Screws (see above)
17. Humeral Bone Screws (see above)
18. T-Wrench For Bone Screws (P/N 03125)
19. 5mm Allen Wrench (P/N 03110)
20. Passive Distractor (P/N 09650)



*Not shown are the Proximal *Posterior* Components:
Long Assembly (P/N 09567), Short Assembly (P/N 09569),
Small Bent Bar (P/N 09655) and Large Bent Bar (P/N 09660).

Part of **OptiROM Distal Assembly (Right-P/N 09610, Left-P/N 09605).

*OptiROM Elbow Fixator Case Study**

Unstable Elbow Dislocation



Film #1: 35-year-old male presents with posterior lateral dislocation of the right elbow. A/P radiograph shows that radial head is non-congruent with capitellum. In addition, signs of a type I or type II coronoid process fracture fragment is evident.



Film #2: A/P radiograph after closed reduction. While joint looks better, suspicion exists for medial side incongruity between trochlea and olecranon process as well as a wide presentation of the radial/capitellum joint space.



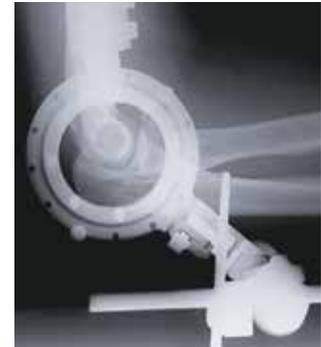
Film #3: Lateral radiograph after closed reduction. Joint appears concentrically reduced. Coronoid process fracture is evident.



Film #4:OptiROM



Film #5: A/P radiograph after **OptiROM** Elbow Fixator application. Image shows concentric appearance at the trochlea/ulnar joint.



Film #6: Lateral radiograph after **OptiROM** Elbow Fixator application. Image shows concentric reduction of both aspects of the elbow joint.



Film #7: Lateral radiograph of right elbow 10 weeks after injury/4 weeks after fixator removal. Image shows concentrically reduced joint. Coronoid process fracture is evident. Patient has 30-110° range of motion of the elbow joint.

Sterilization Recommendations

STERILITY

The OptiROM Elbow Fixator is provided non-sterile and must be sterilized prior to use. All packaging materials must be removed prior to sterilization. All components should be sterilized in a loosened state such that components may move freely.

The following steam sterilization parameters are recommended:

Cycle: Vacuum Steam

Temperature: 270°F (132°C)

Time: 8 minutes

Note: Allow for cooling

Repeated sterilization of carbon fiber reinforced epoxy is not recommended.

Individuals or hospitals not using the recommended method, temperature, and time are advised to validate any alternative methods or cycles using an approved method or standard.

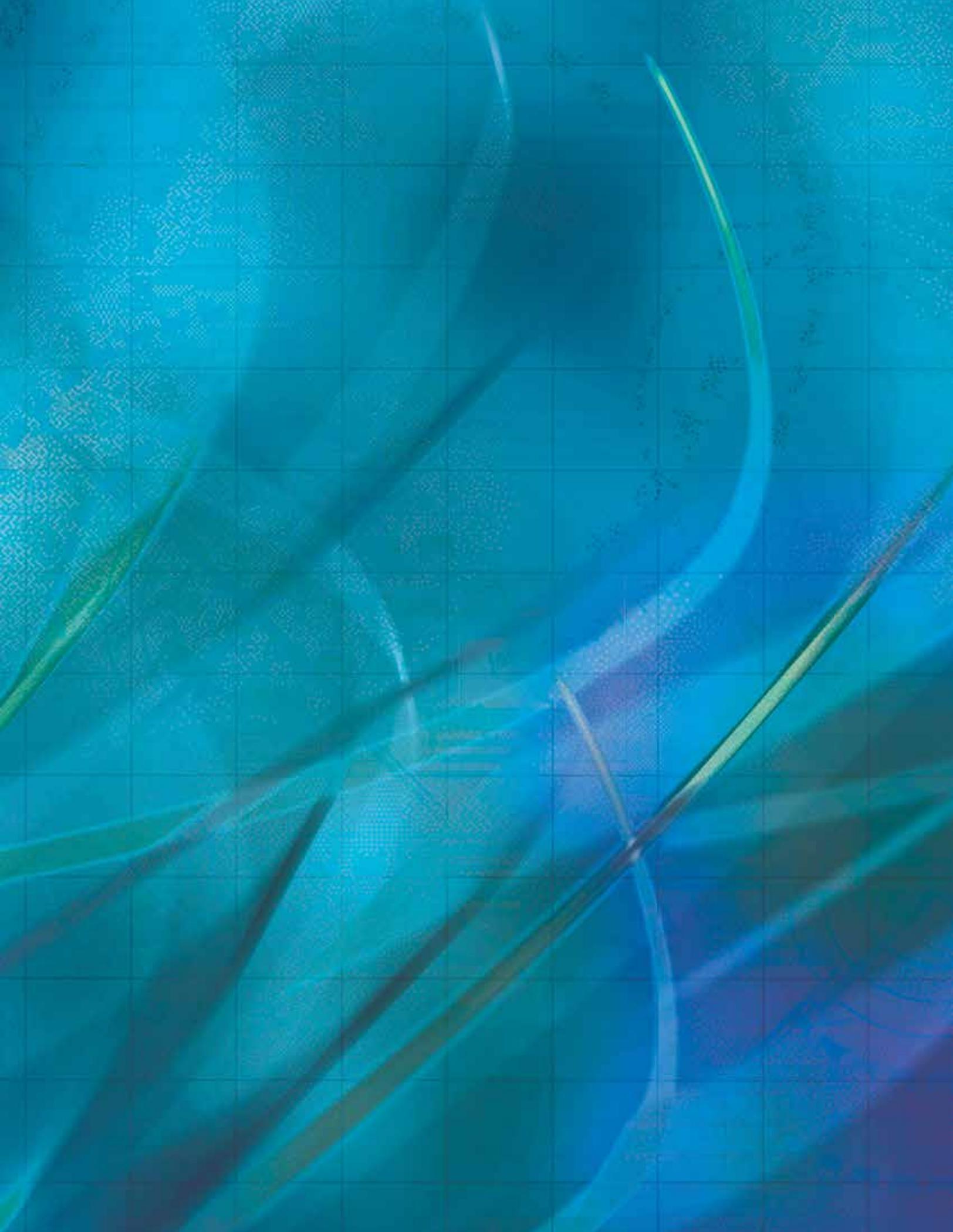
Further Information

This brochure describes the technique used by J. Lawrence Marsh, M.D., Professor of Orthopaedics, University of Iowa Hospitals and Clinics, Iowa City, IA. Biomet Trauma would also like to acknowledge Dr. Randall W. Culp, M.D. of Thomas Jefferson University Hospital, Philadelphia, PA and Dr. Thomas Graham, M.D. of The Curtis National Hand Center in Baltimore, MD for their contributions to this technique.

Biomet Trauma, as the manufacturer of this device, and their surgical consultants do not recommend this or any other surgical technique for use on a specific patient. The surgeon who performs any implant procedure is responsible for determining and utilizing the appropriate techniques for implanting the device in each patient. Biomet Trauma and their surgical consultants are not responsible for selection of the appropriate surgical technique to be utilized for an individual patient.

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