ACUMED®
Innovative Solutions

Elbow Plating System

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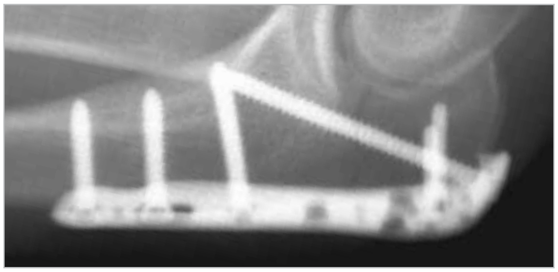
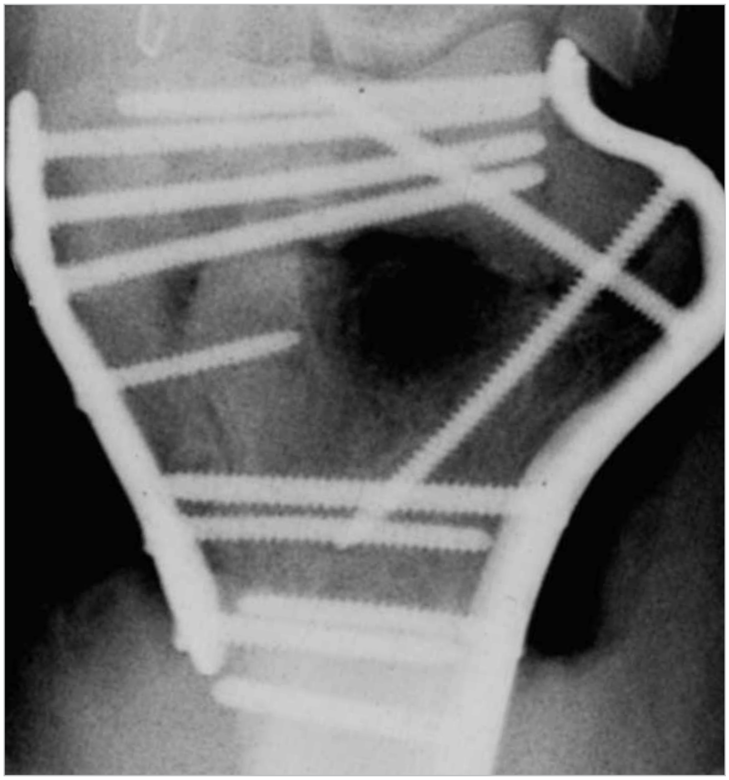
Acumed is a global leader of innovative orthopaedic and medical solutions.

We are dedicated to pioneering products, service methods and approaches that improve patient care.





CONTENTS

Orthopaedic surgeons are continually developing improved methods of fracture fixation and rehabilitation. Acumed® recognizes that often these new fixation methods require changes and advancements in orthopaedic implants and technology. Our goal is to design implants and instrumentation that address new fixation techniques, solve issues with current fixation methods and provide the best possible outcome for the patient.

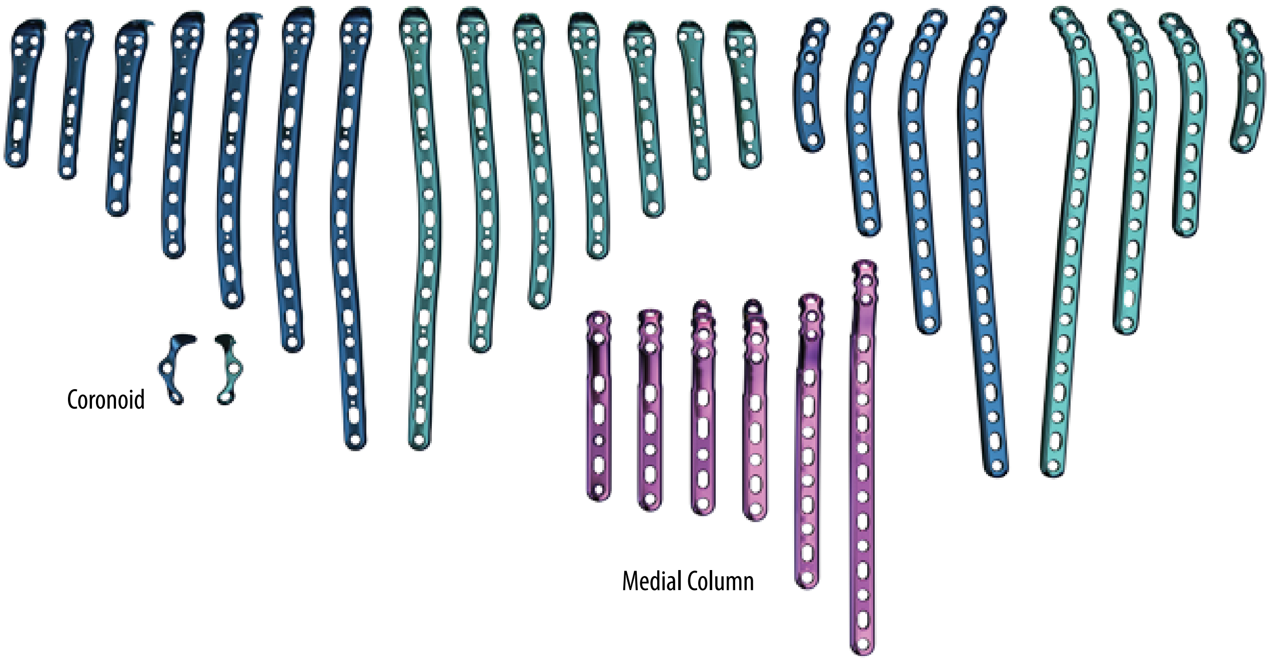
Designed to address fractures of the distal humerus, olecranon and coronoid, the Elbow Plating System offers precontoured, indication specific plates. The system features an innovative low-profile Olecranon Plate design with increased anatomic features and instrumentation to ease plate and screw insertion. The system features the Hexalobe Screw System with variable angle Tap-Loc® Technology for the Distal Humerus Plates.

The Elbow Plating System, designed in conjunction with Shawn W. O'Driscoll, Ph.D., M.D., has revolutionized the way orthopaedic surgeons treat and manage elbow fractures since its market release in 2001. Dr. O'Driscoll's experience has shown that the "parallel" plate placement on the distal humerus, combined with increased plate strength over standard reconstruction plates[1], allows for early rehabilitation and preservation of elbow function and motion.

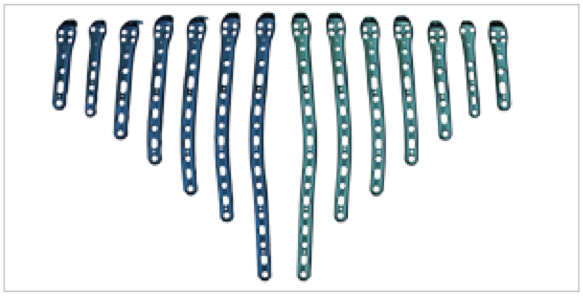
Precontoured Plate design eliminates the need for surgeons to bend the plates to match the anatomy of the patient. For complex fractures, the plates act as a template to restore the natural anatomic geometry of the distal humerus and proximal ulna.

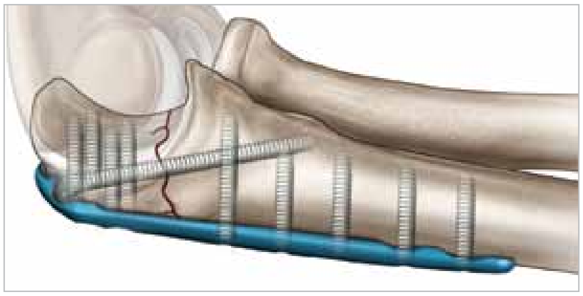
Parallel Plate Placement provides a more stable construct than plates placed at a 90° orientation[2]. Biomechanical data shows that parallel plate placement has greater strength and stability, especially when the elbow is subjected to A/P and torsional forces[3].

Hexalobe Screw System was designed specifically for fractures of the elbow. Variable Angle Tap-Loc® Technology allows up to 20° screw angulation, providing flexibility when capturing fracture fragments while maintaining the benefits of a traditional locking screw.



Locking Olecranon Plates





The Locking Olecranon Plates provide excellent fixation in the proximal ulna for both fractures and osteotomies. The plates feature an advanced anatomic design with contours proximally and along the shaft to provide a precise anatomic fit as well as a lower profile than previous generation plates.

Left and Right-specific plates greatly improve anatomic fit proximally and distally along the ulnar shaft. An improved locking screw trajectory allows screws to capture fracture fragments without interference with other locking screws. Increased plate length range makes this Olecranon Plate System the most comprehensive plate offering on the market.

Prongs on the proximal tip of the Standard Plates provide provisional fixation into the triceps tendon, assisting with reduction and improving final stability. The plate is placed directly over the triceps tendon, eliminating the need for a triceps split. A 3-hole plate is included for osteotomies and more proximal olecranon fractures that do not require a longer plate length. A radiolucent targeting guide for the proximal 2.7mm screw cluster eases the surgical technique and may help to save valuable operating room time. K-wire holes facilitate provisional plate fixation.

The Extended Plate family does not have prongs and is offered for the treatment of fractures that extend proximally. The proximal three holes are threaded to allow locking screws to be utilized. With the Extended Plates, the surgeon may choose several proximal locking screw options depending on the fixation needed for the particular fracture pattern. An angled "home run" screw in hole #3 or a long intramedullary screw in hole #2 may be utilized along with smaller fragment screws in the other proximal holes.

Optional Narrow Plates were designed specifically for smaller patients under 120lbs (54 kg) to fit smaller bone geometry. An optional 15-hole plate is available for the treatment of segmental fractures or where comminution extends distally along the ulnar shaft.

Olecranon Plate lengths range from 65mm to 190mm.

Technical Objectives for Locking Olecranon Plates:

1. Each screw should be as long as possible.
2. Locking screws should interlock to provide a stable "fixed angle" structure inside the bone fragment.
3. Plate should buttress against anterior pull of elbow flexors.
4. Plate should provide stable fixation of the ulnar shaft.
5. Plate should be applied with compression across the fracture.
6. Plate must be strong and stiff enough to resist bending before union occurs.

Coronoid Plates

The Coronoid Plates are designed specifically for fractures of the anteromedial facet of the coronoid. The plate acts as a buttress to the coronoid and counteracts the tendency of the elbow to subluxate. Threaded .035" and .045" titanium wires are included for supplementary fixation of the small coronoid fragments if necessary.

Distal Humerus Plates

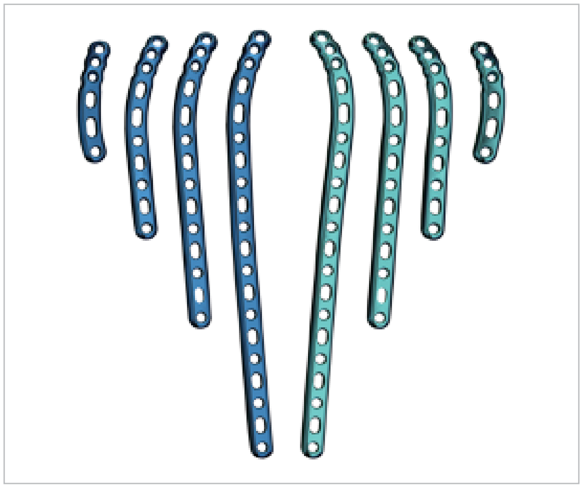
Precontoured in three planes, the Locking Distal Humerus Plates offer multiple lengths and sizes to treat a wide variety of fractures.

Lateral Column Plates

These plates improve upon posterior plating biomechanically by enabling the use of longer screws that interdigitate with screws coming from the medial side. The Lateral Plates are offered in both Left (blue) and Right (green) and are 11mm in width and 2.0mm at the thickest point. Lengths range from 58mm to 206mm.

Medial Column Plates

Distally these plates extend down to, or wrap around the medial epicondyle or even extend down onto the medial trochlea. Extending up the condylar ridge, these locking plates offer solid fixation and compression. This fixation is maximized when the screws in the articular fragments can interdigitate with those coming from the lateral side. The Medial Plates are 11mm wide and 2.0mm at the thickest point and offer 2-4 screw holes for fixation of the articular fragments. Lengths range from 84mm to 175mm.



Technical Objectives for Locking Distal Humerus Plates:

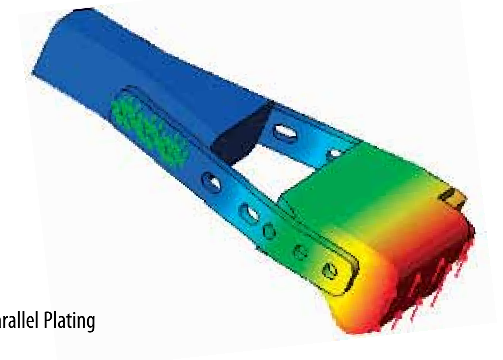
1. Every screw should pass through a plate.
2. Each screw engages a fragment on the opposite side that is also attached to a plate.
3. Each screw should be as long as possible.
4. Each screw should engage as many fragments as possible.
5. The screws in the distal fragments should lock together by interdigitation, creating a "fixed angle" structure.
6. Plates should be applied such that compression is achieved at the supracondylar level for both columns.
7. Plates must be strong and stiff enough to resist breaking or bending before union occurs.

Parallel Plate Placement

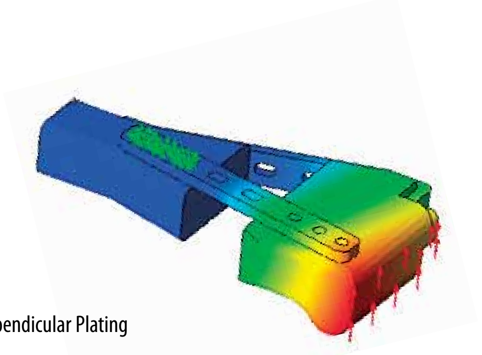
The parallel placement of the Locking Distal Humerus Plates provides a strong, stable construct which may reduce the need for immobilization of the elbow for an extended postoperative period. The strength of the plates, along with the parallel application and locking technology, greatly reduces the chance of hardware failure. The patient may be able to begin rehabilitation and range of motion exercises immediately after surgery.

Because screws come from opposing sides of the condyles, long screws are able to interdigitate in the distal fragments, creating an "arch" construct. The interdigitating screws provide the keystone to the arch, creating a stable construct to facilitate with immediate, aggressive rehabilitation.

Biomechanical Testing



Parallel Plating



Perpendicular Plating

90° plate orientation was supported early on in a study that compared 90° plating to a Y-plate and crossed screws, but did not compare "perpendicular" to "parallel" plating[4]. A second comprehensive study found "parallel" plating to be the best construct for reconstruction of a comminuted distal humerus[5]. This study proved that plates placed in parallel configuration on the medial and lateral columns were stronger than 90° plating when a gap was present between the articular fragments and the shaft, as when the humerus is severely fractured. Both studies were written before the introduction of the Elbow Plating System which optimizes the biomechanics even further with locking capability, plate placement and plate strength.

Finite element analysis testing at Acumed® indicated significant advantages of parallel plating versus 90° plating[6]. For this study, a computer modeled a distal humerus fracture and assumed equivalent plate fixation and strength (two areas in which the Acumed® Locking Elbow Plates are significantly better than 90° plating with reconstruction or tubular plates). The program simulated a load of 50lbs in three different planes: A/P, M/L, and Torsion. The results supported parallel plating, especially in torsional loads.

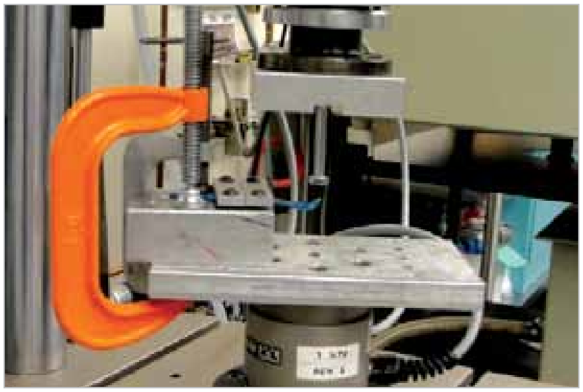
90° Plating Displaced:
Anterior/Posterior: 53% more
Medial/Lateral: 5% less
Torsion: 80% more

Results of a biomechanical study tested perpendicular 3.5mm LCP Distal Humerus Plates (316L) versus parallel Locking Distal Humerus Plates (titanium) for stiffness in compression and internal/external rotation, plastic deformation and failure in torsion[7]. Both systems were utilized for fixation of a distal intra-articular humerus fracture with a metaphyseal comminution in osteoporotic bone. Results showed that the Acumed® "parallel locking system showed improved stability compared with the perpendicular locking system, and therefore may be more indicated."

Locking Distal Humerus Plates provided a significantly higher stability in compression and external rotation, and a greater ability to resist axial plastic deformation.

- Axial compressive stiffness of our plates was 2.3 times GREATER than the perpendicular locking system.
- The perpendicular locking plates experienced an average of 2.9 times GREATER axial plastic deformation than the Acumed® plates.

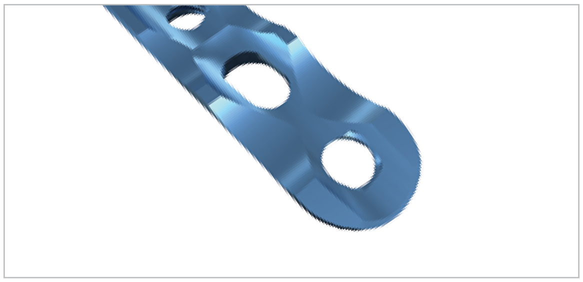
The Acumed® Locking Olecranon Plates are Grade 4 unalloyed titanium. Our previous generation Olecranon Plates are Grade 2 unalloyed titanium. Because Grade 4 unalloyed titanium has higher yield strength, the plates are able to be lower profile than our previous generation of plates without compromising strength.



Mechanical testing of our Locking Olecranon Plates versus previous generation Olecranon Plates was performed utilizing two separate loading scenarios for metaphyseal and diaphyseal plate strength. Both scenarios investigated direct load to failure of the plate. Failure of the plate was considered to have occurred when permanent plastic deformation of the plate occurred.

The Acumed® Grade 4 unalloyed titanium Olecranon Plates have a 6% lower profile than our Grade 2 unalloyed titanium Olecranon Plates. Testing results showed mean failure load of the Grade 4 unalloyed titanium plate is statistically equal to the mean failure load of the existing the Grade 2 unalloyed titanium plate in proximal cantilever bending. Results of the second loading scenario showed mean failure load of the Grade 4 unalloyed titanium plate is statistically greater by 16% than the mean failure load of the existing Grade 2 unalloyed titanium plate in diaphyseal four-point bending[8].

Precontoured Plates



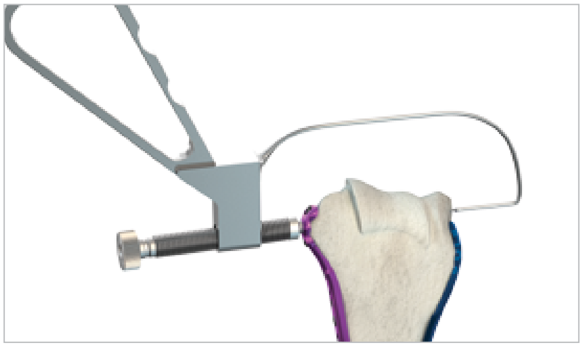
The Elbow Plating System offers a comprehensive range of precontoured plates that maximize fixation in the articular fragments, contributing to the stability of the entire reconstruction. Plates are precontoured to match the natural anatomy of the elbow, minimizing the need for surgeons to bend the plates prior to application. For complex fractures, the plates are able to act as a template for anatomic restoration of the elbow.

Traditional straight plates weaken with repeated bending. Our precontoured plates offer a stronger alternative[9] while maintaining a low-profile. This precontoured design also allows for maximum fixation and stability in the distal humerus and proximal ulna.

Plates should maximize stability of peri-articular fragments to facilitate rehabilitation. Clustered screw holes in the articular region increase stability and strength of the reconstruction. This improved stability allows the plates to compress these articular fragments with the shaft to achieve union of the fracture fragments. Plate profile and screw/plate interface were designed with the soft tissues in mind. The plates thin down in the peri-articular region and the screw heads are recessed within the low-profile plates.

Plate thickness should be optimized for each region of the bone. Continuous change in thickness provides strength along the metaphysis/diaphysis where it is needed, while maintaining a low-profile in the peri-articular areas with limited soft tissue coverage.

Instrumentation



In addition to the innovative features of the implants, Acumed® designed the instrumentation system for ease of use by including everything needed for surgery in a well organized tray.

The Osteotomy Cutting Jig is an instrument unique to the Acumed® Elbow Plating System. The Cutting Jig provides four location options to start the chevron osteotomy of the olecranon and also provides pre-drilling capability for future Olecranon Plate application.

Color-coded instrumentation is provided to allow for quick identification of proper drills, taps, driver tips and drill guides in the system for each screw diameter. An improved screw caddy design provides a durable all metal design, a removable caddy lid and user friendly handles for quick removal from the system tray. All screw diameters are bordered by colors that correspond with the color bands on the appropriate instrumentation. The Elbow Plating System features a user friendly depth gauge design as well as "Tri-Flat" Locking Drill Guides that allow one-step drilling and depth measurement.

The Targeted Drill Guide allows surgeons to drill and position the distal screws in the Distal Humerus Plates with confidence and accuracy. The drill guide cannula is placed in the appropriate plate hole and the tip of the guide is positioned in the desirable location of the screws' ending point.

Comparison of Acumed® Hex and Hexalobe Screws

The Elbow Plating System features the Hexalobe Screw System. The Hexalobe Screws were designed specifically with elbow fractures in mind. These screws have maximized strength and a Hexalobe drive interface to optimize performance in dense bone, especially when longer length screws are necessary.

Sleeveless "Stick Fit" Screw/Driver Interface

The addition of Santoprene®, a rubber-like material on the driver, allows the driver to stick in the screw, obviating the need for a screw sleeve and reducing OR time.

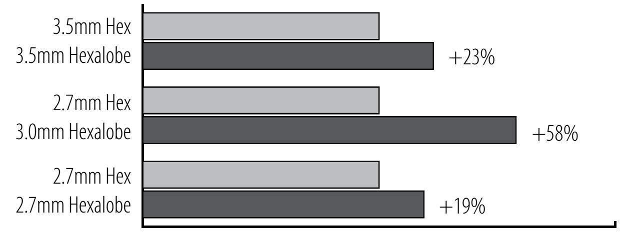
Modified Screw Root and Taper

Additional material on the screw root diameter and a larger wall thickness around the screw head gives the modified driver/screw interface additional strength to reduce breakage.

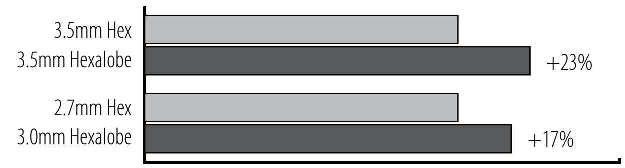
Additional Cutting Flutes

Acumed® Hex Screws only have one cutting flute to aid insertion. The Hexalobe System provides three cutting flutes on our longer screws (34mm and up) to help ease screw insertion.

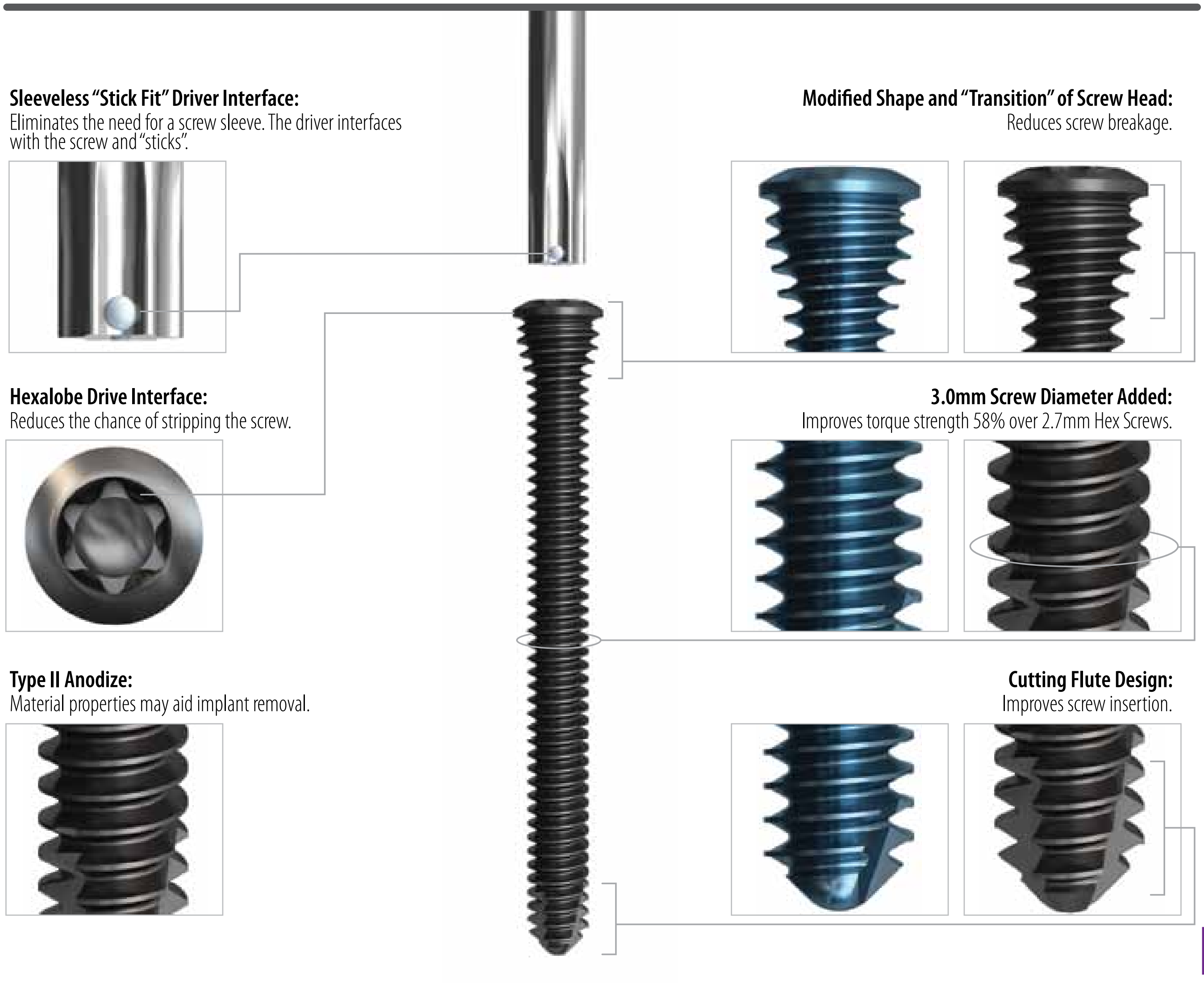
Increased Torque Strength*

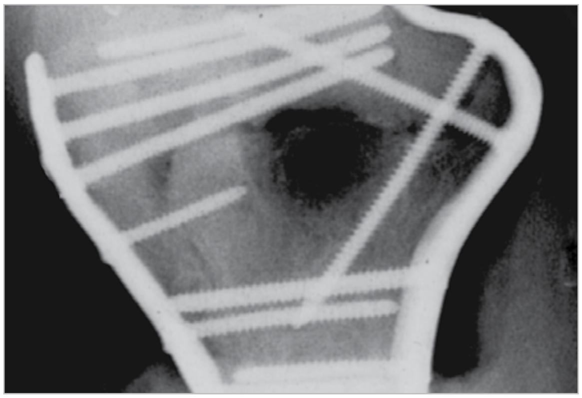


Increased Root Diameter of Screws



*Testing on file



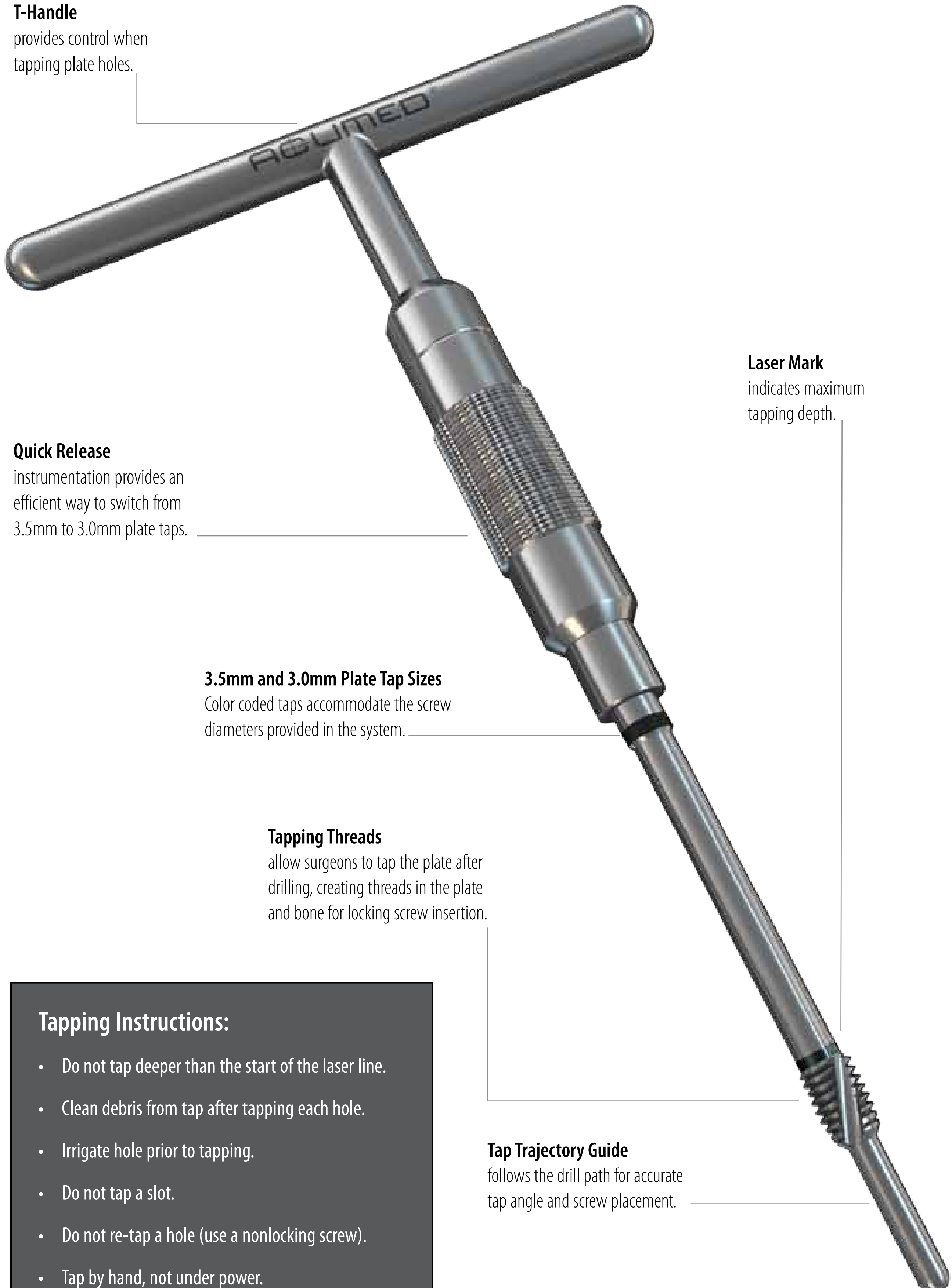


Acumed® believes that surgeons should have the ability to determine the trajectory of the locking screws in the distal humerus. This freedom offers them a means to maximize fixation in the distal fragments, providing the best possible fixation of the fracture. Our Distal Humerus Plates offer patented Tap-Loc® Technology, allowing surgeons to choose the optimal locking screw trajectory in the distal fragments.

Dr. O'Driscoll's goal is to combine his principles for distal humeral fracture fixation with variable angle locking technology. Because anatomy and fracture patterns in the distal humerus vary from patient to patient, he saw the importance of allowing the surgeon to choose the angle of the distal locking screws. In addition, the locking threads of each locking screw should accurately coincide with the threads in the plate to ensure maximum locking strength and stability and avoid cross-threading screws into plates like other variable angle locking methods.

The Locking Distal Humerus Plates features patented Tap-Loc® Technology, offer multidirectional screw angles to give surgeons the freedom to angle the distal locking screws up to 20° in each direction. This provides flexibility when capturing fracture fragments while maintaining the benefits of a traditional locking screw.

Mechanical testing was performed to provide a comparative strength analysis of Acumed® Locking Hexalobe Screws used in pre-threaded holes, holes tapped at 0° from the centerline of the hole using Tap-Loc® Technology, and holes tapped at 20° from the centerline of the hole using Tap-Loc® Technology. Results showed that a Hexalobe Screw installed using Tap-Loc® Technology at 20° can sustain a load up to 90% of the failure load of a screw installed in a pre-threaded hole and Hexalobe Screws installed using Tap-Loc® Technology at 0° were equal in strength to the pre-threaded holes [10].

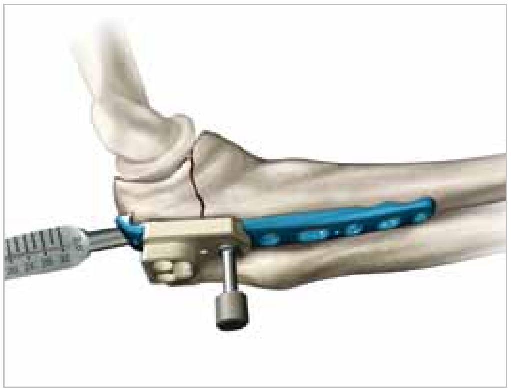


Tapping Instructions:

- Do not tap deeper than the start of the laser line.
- Clean debris from tap after tapping each hole.
- Irrigate hole prior to tapping.
- Do not tap a slot.
- Do not re-tap a hole (use a nonlocking screw).
- Tap by hand, not under power.
- Angle of tapped hole must not exceed 20°.

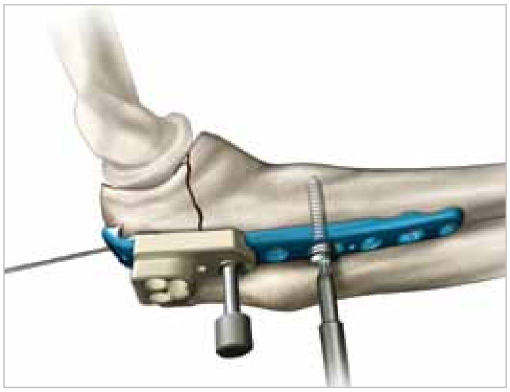
1 Fracture Reduction and Plate Placement:

Attach the proximal targeting guide (80-0654) to the plate with the locking bolt (80-0652). Flex the elbow 90°, reduce the fracture and apply the plate. The prongs in the proximal end of the plate should penetrate the triceps tendon and provide provisional fixation. These prongs do not compress the tendon and a gap between the plate and the bone should be visible on X-ray.



2 Provisional Wire Placement:

If a locking screw is to be utilized in the most proximal hole of the plate, thread the 2.3mm locking drill guide (80-0622) into the plate hole. A 2.0mm wire (WS-2009ST) is drilled through the locking drill guide and across the fracture site, penetrating the anterior metaphyseal cortex. Do not remove this wire until Step 6. Alternatively, two .062" wires (WS-1607ST) can be placed across the fracture, one on each side of the plate.



3 Nonlocking Distal Screw Placement:

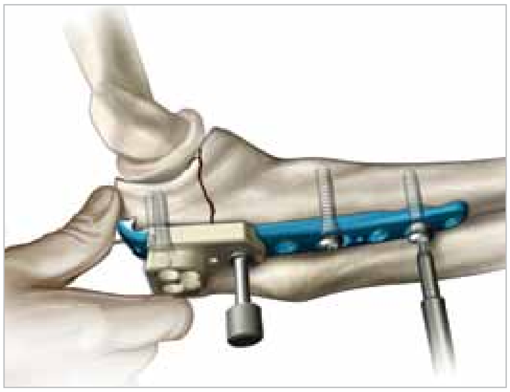
With provisional reduction confirmed, drill with the 2.8mm drill (80-0387), measure depth (80-0623) and insert a 3.5mm nonlocking screw through the slotted hole distal to the fracture site and into the ulnar shaft. Connect the T15 Hexalobe Driver (80-0760) to the ratcheting driver handle (80-0663) and tighten the screw partially to allow for later compression. Bone taps are provided and recommended for patients with dense bone.

4 Proximal Locking Screw Placement:

Insert two 2.7mm locking screws into the proximal holes on either side of the 2.0mm wire, using the 2.0mm locking drill guide (80-0621). When drilling with the 2.0mm drill (80-0318), be careful not to exit the bone. Drill depth may be read directly off of the laser line on the drill or with the 2.0mm depth probe (80-0643). The T8 Hexalobe Driver (80-0759) is used to insert the 2.7mm screws. When using the T8 Driver, care should be taken to not "overtighten" the screw or apply more torque than necessary to seat the locking screw into the plate. Screws should be tightened by hand and not under power. The fixed angle locking screw trajectory is meant to create maximum fixation in the small proximal fragments.

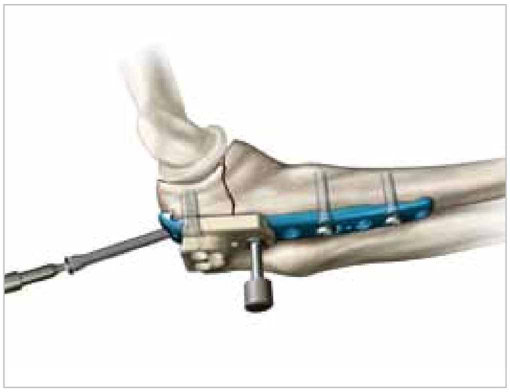
5 Fracture Site Compression:

If the plate length selected has two or more compression slots, the fracture site is compressed in the following manner. Insert a 3.5mm nonlocking screw in dynamic compression mode into a distal slot along the ulnar shaft using the offset drill guide (PL-2095). The proximal shaft screw must be slightly loosened to allow for compression. If a longer plate is used and further compression is required, partially insert another nonlocking screw into a distal slot in dynamic compression mode and then loosen the first two screws to allow for plate movement.



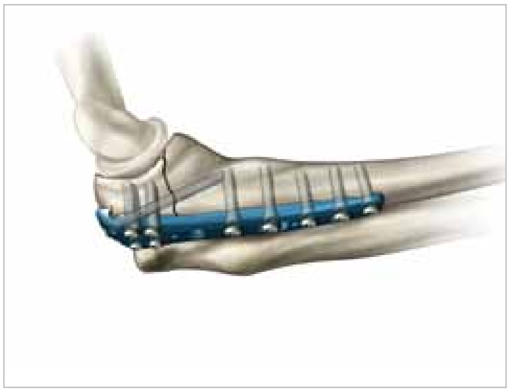
6 Final Screw Placement:

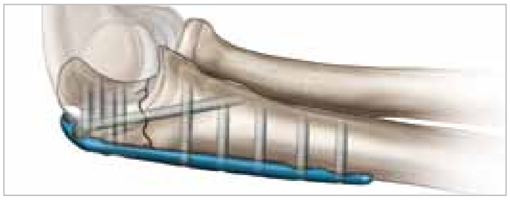
Remove the 2.0mm wire from the most proximal plate hole and insert a locking 3.5mm screw: attach the 2.8mm locking drill guide (80-0668) and use the 2.8mm drill (80-0387) in the path of the wire. Measure depth and insert the screw. If a 3.0mm "home run" screw is desired, the 2.3mm locking drill guide (80-0622) and drill (80-0627) are utilized. The proximal targeting guide may be removed at this time. The remaining locking screws are then inserted at the surgeon's discretion.

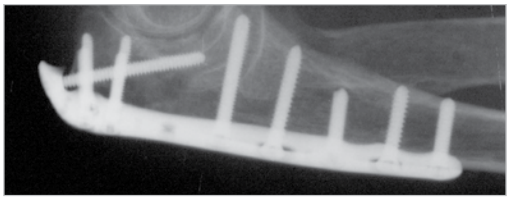


7 Postoperative Protocol by Shawn W. O'Driscoll Ph.D., M.D.:

Immediately after closure, the elbow is placed in a bulky non-compressive Jones dressing with an anterior plaster slab to maintain the elbow in extension. The initial rehabilitation is planned according to the extent of soft-tissue damage. When the fracture is associated with severe soft-tissue damage, the extremity is kept immobilized with the elbow in extension for three to seven days postoperatively. If the fracture is closed and there is no severe swelling or fracture blisters, the Jones dressing is removed after two days and an elastic non-constrictive sleeve is applied over an absorbent dressing placed on the wound. A physical therapy program including active and passive motion is then initiated.



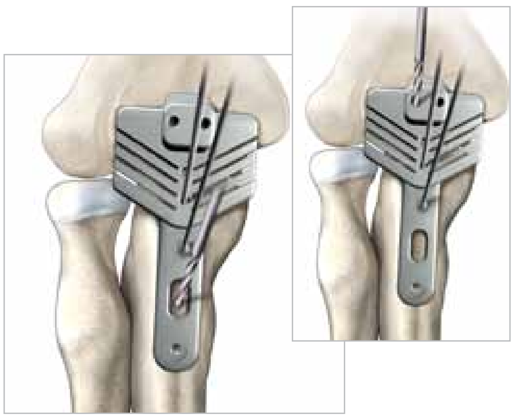




Olecranon Osteotomy Cutting Jig

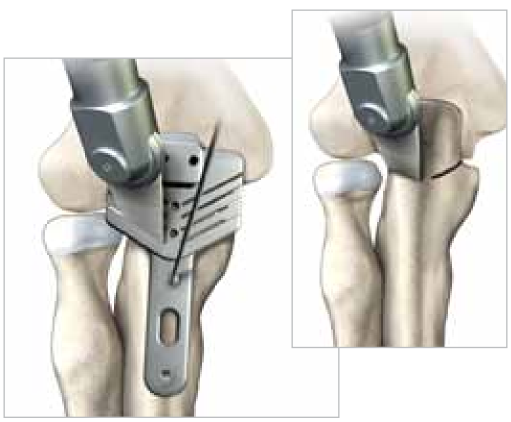
1 Provisional Fixation:

Place the Olecranon Osteotomy Cutting Jig (80-0653) onto the proximal portion of the olecranon with the elbow flexed at 90°. The jig is designed to sit on top of the triceps tendon. Secure the jig provisionally by placing a plate tack (PL-PTACK) into the plate tack holes in the jig. A .062" K-wire (WS-1607ST) may also be placed in the small K-wire hole between the cutting slots.



2 Pre-Drill Screw Holes:

The Olecranon Osteotomy Cutting Jig allows pre-drilling of the screw holes that will be used with future placement of the Olecranon Plate. Use a 2.8mm drill (80-0387) to drill the slot for future placement of a 3.5mm screw. The 2.0mm drill (80-0318) is utilized to drill the two smaller, proximal holes for future placement of the 2.7mm screws.

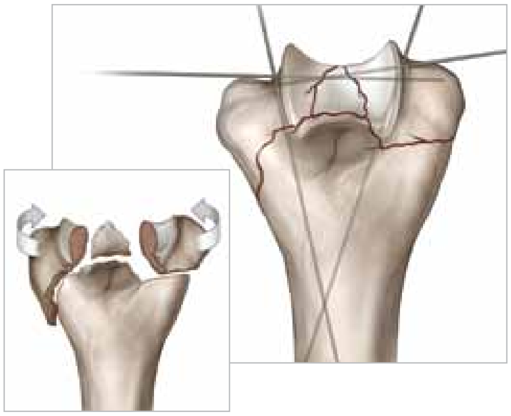


3 Create Osteotomy:

Select the cutting slot that provides the most optimal position for the chevron osteotomy. Using a thin-bladed oscillating saw (.025" in thickness), create an osteotomy about 1/3 of the way through the olecranon.Remove the Osteotomy Cutting Jig. Use the oscillating saw to join the two sides of the provisional cut. A thin-bladed osteotome is used to complete the osteotomy.

1 **Articular Fragment Reduction:**

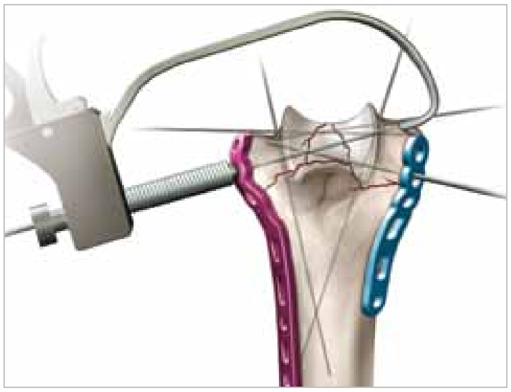
The articular fragments, which tend to be rotated toward each other in the axial plane, are reduced anatomically and provisionally held with .045" smooth K-wires (WS-1106ST). It is essential that these wires be placed close to the subchondral level to avoid interference with later screw placement, and away from where the plates will be placed on the lateral and medial columns (see Step 2). One or two strategically placed wires can then be used to provisionally hold the distal fragments in alignment with the humeral shaft.



2 **Plate Placement and Provisional Fixation:**

The selected Medial and Lateral Plates are placed and held apposed to the distal humerus, while one smooth 2.0mm K-wire (WS-2009ST) is inserted through hole #2 (numbered from distal to proximal) of each plate through the epicondyles and across the distal fragments to maintain provisional fixation. These 2.0mm wires are left in place until Step 7 to simplify placing the locking screws in the distal fragments.

Note: The Medial and Lateral Distal Humerus Plates are designed to accept 3.0mm and 3.5mm Hexalobe Screws. The 2.7mm Hexalobe Screws have a smaller head diameter and should **NOT** be used with the Medial and Lateral Distal Humerus Plates.

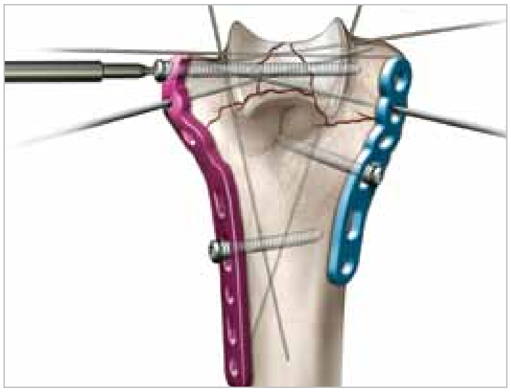


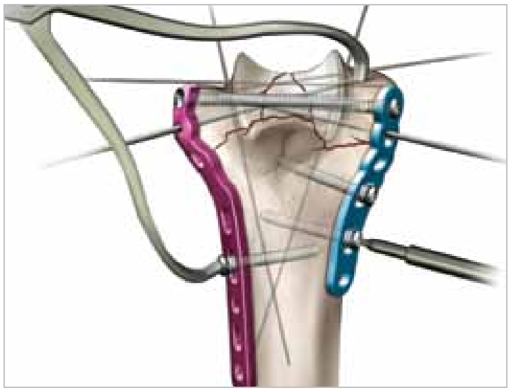
3 **Initial Proximal Screw Placement:**

With provisional reduction confirmed, drill with the 2.8mm drill (80-0387), measure depth (80-0623) and insert a 3.5mm nonlocking screw into a slotted hole of each plate proximal to the fracture site. Connect the T15 Hexalobe Driver (80-0760) to the ratcheting driver handle (80-0663) and tighten the screw partially, allowing some freedom for the plate to move proximally during compression later. (Because the undersurface of each plate is tubular in the metaphyseal and diaphyseal regions, the screw in the slotted hole only needs to be tightened slightly to provide excellent provisional fixation of the entire distal humerus.) Bone taps are recommended for patients with dense bone.

4 **Nonlocking Distal Screw Placement:**

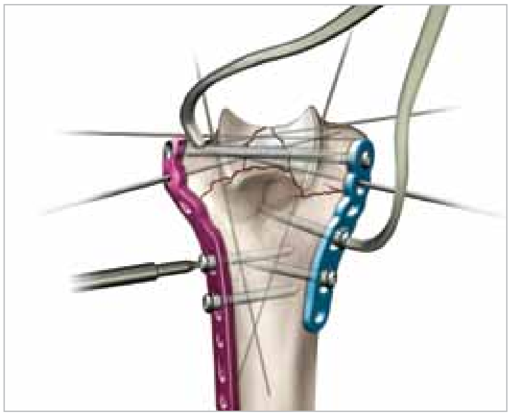
Drill and insert screws through hole #1 on both the medial and lateral side. The targeted drill guide cannot be used in hole #1 of the Medial Plate if the angle of the nonlocking screw exceeds 20°. After drilling, measure depth and insert the appropriate size 3.5mm nonlocking screw. The 3.0mm screws may be used in osteoporotic bone to enable more screws to be placed in the distal fragments to maximize stability.





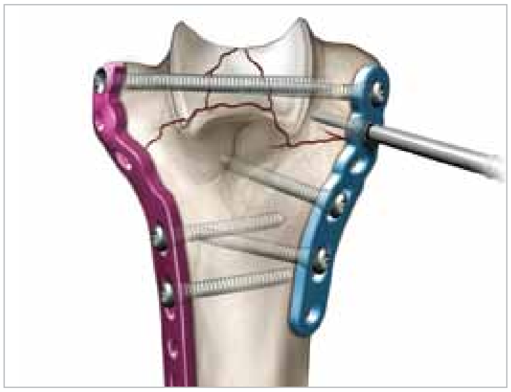
5 Compress Lateral Column:

Using a large tenaculum (MS-1280) to provide interfragmentary compression across the fracture at the supracondylar level, the lateral column is first fixed. A screw is inserted in the Lateral Plate in dynamic compression mode in a slotted hole proximal to the fracture site using the offset drill guide (PL-2095). Tightening this screw further enhances interfragmentary compression at the supracondylar level to the point of causing some distraction at the medial supracondylar ridge. The .045" wires used for provisional fixation may be removed at this point.



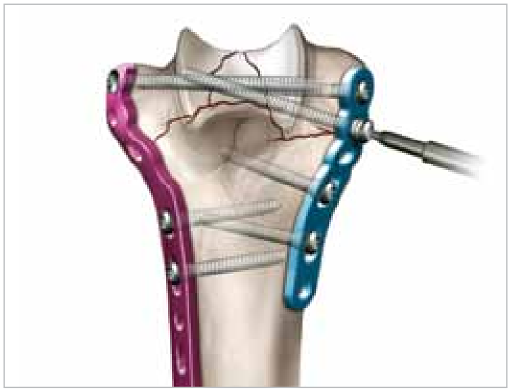
6 Compress Medial Column:

The medial column is then compressed in a similar manner using the large tenaculum (MS-1280), and a 3.5mm nonlocking screw is inserted in the Medial Plate in dynamic compression mode in a slotted hole proximal to the fracture site, using the offset drill guide (PL-2095). If the plates are slightly under contoured, they can be compressed against the metaphysis with a large bone clamp, giving further supracondylar compression. Remove the 2.0mm wires that were inserted in Step 2.



7 Tap Distal Plate Holes:

If using a 3.5mm screw, use the 2.8mm drill in the path of the wire. If using a 3.0mm screw (osteoporotic bone), the 2.3mm drill is utilized. Measure drill depth (80-0623) to determine screw size. Connect the plate tap (80-0661 or 80-0659) to the T-Handle (MS-T1212) and tap the plate. The front end of the tap will act as a guide to ensure that the locking screw follows the correct trajectory. Turning the tap one-half turn at a time, tap the plate taking care not to insert the tap further than the start of the laser line on the tap threads (See Tapping Instructions). The T-Handle should only be used with the plate taps and not for locking or nonlocking screw insertion. The proximal slotted holes are NOT to be tapped.



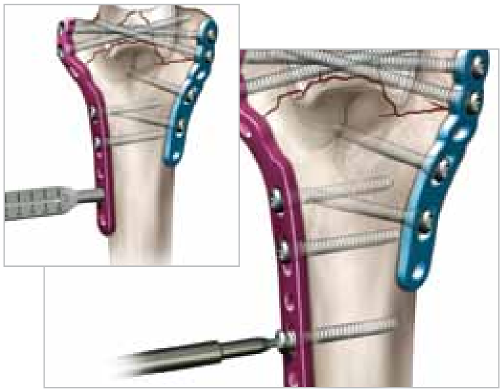
8 Insert Distal Locking Screws:

Insert the appropriate size locking screws. Care should be taken to not overtighten the screw.

The #3 holes on both the medial and lateral columns are optional. If these holes are used, be sure to use locking screws if locking screws have already been inserted in previous steps.

9 Insert Proximal Locking Screws:

The remaining locking shaft screws may be inserted at the surgeon's discretion. Note that the plate holes in the humeral shaft are pre-threaded, fixed angle screws. To insert the 3.5mm or 3.0mm locking screws, thread the appropriate size locking drill guide (80-0668 or 80-0622) into the locking hole in the plate. Drill with the appropriate size drill (80-0387 or 80-0627). Drill depth may be read directly off of the laser line on the drill or with the 2.3mm depth probe (80-0664). Insert the appropriate size locking screws.



10 Postoperative Protocol by Shawn W. O'Driscoll Ph.D., M.D.:

Immediately after closure, the elbow is placed in a bulky non-compressive Jones dressing with an anterior plaster slab to maintain the elbow in extension. The initial rehabilitation is planned according to the extent of soft-tissue damage. When the fracture is associated with severe soft-tissue damage, the extremity is kept immobilized with the elbow in extension for three to seven days postoperatively. If the fracture is closed and there is no severe swelling or fracture blisters, the Jones dressing is removed after two days and an elastic non-constrictive sleeve is applied over an absorbent dressing placed on the wound. A physical therapy program including active and passive motion is then initiated.

Acumed® Single Use Tapping Instrument Precautions:

Tapping a plate using a plate tap will cause titanium debris to be generated, which should be removed. Failure to remove the plate debris can cause, among other complications, inflammation, cartilage damage and patient discomfort. The taps are single surgery use and should be discarded after each surgery or if the tap becomes dull or damaged. If the resistance increases while using a tap, discard the tap immediately. Breakage to the tap can occur due to excessive torque or levering and care should be taken to avoid such conditions. Should breakage occur, carefully remove all tap pieces.

Tapping Instructions:

- Do not tap deeper than the start of the laser line.
- Clean debris from tap after tapping each hole.
- Irrigate hole prior to tapping.
- Do not tap a slot.
- Do not re-tap a hole (use a nonlocking screw).
- Tap by hand, not under power.
- Angle of tapped hole must not exceed 20°.

Technical Objectives Checklist:

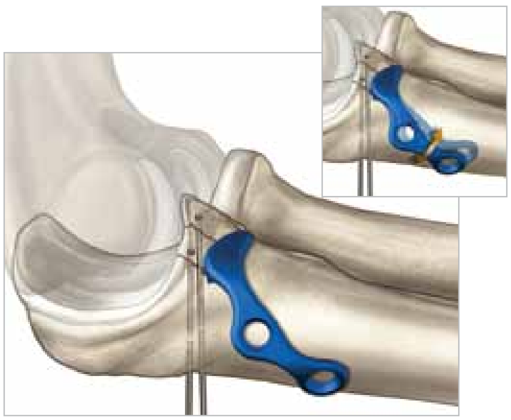
1. Every screw should pass through a plate.
2. Each screw engages a fragment on the opposite side that is also attached to a plate.
3. Each screw should be as long as possible.
4. Each screw should engage as many fragments as possible.
5. The screws in the distal fragments should lock together by interdigitation, creating a "fixed angle" structure.
6. Plates should be applied such that compression is achieved at the supracondylar level for both columns.
7. Plates must be strong and stiff enough to resist breaking or bending before union occurs.

Screw Diameter	Drill Diameter
3.0mm	2.3mm
3.5mm	2.8mm

Coronoid Plate

1 **Fracture Fragment Fixation:**

Expose the coronoid through an anteromedial approach. Reduce and provisionally hold the fragments with threaded titanium wires (WT-xx0xSTT) drilled from posterior to anterior. These are best placed when retracting the coronoid fragments so that you can see the wires emerge into the fracture surface. They are then backed past the fracture site to allow for reduction. Once proper reduction is achieved, re-advance the wires past the fracture site and into the fragments.



2 **Plate Placement:**

Apply the Coronoid Plate so that the two prongs grasp and buttress the section of the coronoid between its tip and its sublime tubercle on which the anterior bundle of the MCL inserts. The plate should wrap around the brachialis tendon insertion onto the medial side of the ulna distally.

Note: The Coronoid Plates are designed to accept 3.0mm and 3.5mm Hexalobe Screws. The 2.7mm Hexalobe Screws have a smaller head diameter and should NOT be used with the Coronoid Plates.

3 **Initial Screw Placement:**

While holding the plate reduced, drill the middle hole with the 2.3mm drill (80-0627) and insert a 3.0mm nonlocking screw . Connect the T15 Hexalobe Driver (80-0760) to the ratcheting driver handle (80-0663) and insert the screw. Do not tighten the screw.

Note: Tapping the bone prior to screw insertion with the bone tap (80-0626) is recommended for patients with dense bone.

4 **Buttress Fragments with Plate:**

Push the distal tip of the plate anteriorly, applying a lever force against the coronoid fragments, and insert a 3.0mm screw through the distal hole. Do not tighten the screw.

5 Tighten Screws and Cut Threaded Wires:

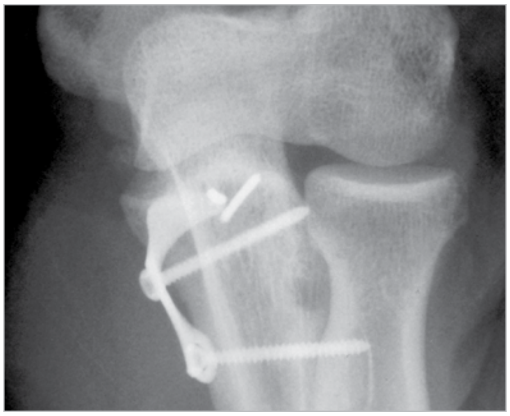
Tighten the proximal screw to bring the midsection of the plate to the bone and fully secure the buttress against the coronoid fragments. Tighten the distal screw. The plate will flex and contour to follow the line of the bone as this final screw is tightened.

Cut the threaded titanium wires flush with the ulna, eliminating soft tissue irritation. If buttressing is excellent, the wires can be removed. If they are to be left in they must be titanium and threaded (WT-xx0xSTT), not smooth.

6 Postoperative Protocol by Shawn W. O'Driscoll Ph.D., M.D.:

Immediately after closure, the elbow is placed in a bulky non-compressive Jones dressing with an anterior plaster slab to maintain the elbow in extension. The initial rehabilitation is planned according to the extent of soft tissue damage. When the fracture is associated with severe soft tissue damage, the extremity is kept immobilized with the elbow in extension for 3-7 days postoperatively. If the fracture is closed and there is no severe swelling or fracture blisters, the Jones dressing is removed after two days and an elastic non-constrictive sleeve is applied over an absorbent dressing placed on the wound.

In cases in which fracture stability is not a concern, a program of continuous passive motion begins within the limits of motion determined by soft tissue compliance, which itself is diminished due to fluid accumulation at the elbow region. Edema control is important postoperatively, as swelling limits elbow motion. It is essential that gravitational varus stresses are avoided, as these will result in displacement of the medial coronoid fracture fragment. Therefore, the arm is maintained in a vertical plane when the elbow is being moved and supporting the wrist whenever the arm is moved away from the body and loads the weight of the forearm. Both active and passive motion is permissible in most coronoid fractures treated with the described technique.



If by 4-6 weeks motion is not returning satisfactorily, a program of patient-adjusted static flexion and extension splinting should be commenced to assist with regaining motion. If heterotopic ossification is forming, the splinting program should still be used. The forces generated are small and not a risk of worsening the heterotopic ossification.

Ordering Information

Olecranon Plates

Olecranon Plate, Std, 3-hole, LT (65mm)	70-0302
Olecranon Plate, Std, 3-hole, RT (65mm)	70-0303
Olecranon Plate, Std, 5-hole, LT (90mm)	70-0304
Olecranon Plate, Std, 5-hole, RT (90mm)	70-0305
Olecranon Plate, Std, 7-hole, LT (110mm)	70-0306
Olecranon Plate, Std, 7-hole, RT (110mm)	70-0307
Olecranon Plate, Std, 11-hole, LT (150mm)	70-0308
Olecranon Plate, Std, 11-hole, RT (150mm)	70-0309
Olecranon Plate, Ext, 5-hole, LT (90mm)	70-0312
Olecranon Plate, Ext, 5-hole, RT (90mm)	70-0313
Olecranon Plate, Ext, 9-hole, LT (130mm)	70-0314
Olecranon Plate, Ext, 9-hole, RT (130mm)	70-0315

Optional Olecranon Plates

Olecranon Plate, Std, 15-hole, LT (190mm)	70-0310
Olecranon Plate, Std, 15-hole, RT (190mm)	70-0311
Olecranon Plate, Nrw, 5-hole, LT (85mm)	70-0316
Olecranon Plate, Nrw, 5-hole, RT (85mm)	70-0317

Distal Humerus Plates

7 Hole Locking Medial Plate (84mm)	PL-LEM7
8 Hole Locking Medial Plate (88mm)	PL-LEM8
Long 9 Hole Locking Medial Plate (96mm)	PL-LEM9L
Short 9 Hole Locking Medial Plate (95mm)	PL-LEM9S
12 Hole Locking Medial Plate (130mm)	PL-LEM12
16 Hole Locking Medial Plate (175mm)	PL-LEM16
Left 6 Hole Locking Lateral Plate (58mm)	PL-LEL6L
Right 6 Hole Locking Lateral Plate (58mm)	PL-LEL6R
Left 10 Hole Locking Lateral Plate (100mm)	PL-LEL10L
Right 10 Hole Locking Lateral Plate (100mm)	PL-LEL10R
Left 14 Hole Locking Lateral Plate (142mm)	PL-LEL14L
Right 14 Hole Locking Lateral Plate (142mm)	PL-LEL14R
Left 20 Hole Locking Lateral Plate (206mm)	PL-LEL20L
Right 20 Hole Locking Lateral Plate (206mm)	PL-LEL20R

Coronoid Plates

Coronoid Plate, Left	PL-ELCOL
Coronoid Plate, Right	PL-ELCOR

3.5mm Locking Hexalobe Screws

3.5mm x 8mm Locking Hexalobe Screw	30-0232
3.5mm x 10mm Locking Hexalobe Screw	30-0233
3.5mm x 12mm Locking Hexalobe Screw	30-0234
3.5mm x 14mm Locking Hexalobe Screw	30-0235
3.5mm x 16mm Locking Hexalobe Screw	30-0236
3.5mm x 18mm Locking Hexalobe Screw	30-0237
3.5mm x 20mm Locking Hexalobe Screw	30-0238
3.5mm x 22mm Locking Hexalobe Screw	30-0239
3.5mm x 24mm Locking Hexalobe Screw	30-0240
3.5mm x 26mm Locking Hexalobe Screw	30-0241
3.5mm x 28mm Locking Hexalobe Screw	30-0242
3.5mm x 30mm Locking Hexalobe Screw	30-0243
3.5mm x 32mm Locking Hexalobe Screw	30-0244
3.5mm x 34mm Locking Hexalobe Screw	30-0245
3.5mm x 36mm Locking Hexalobe Screw	30-0246
3.5mm x 38mm Locking Hexalobe Screw	30-0247
3.5mm x 40mm Locking Hexalobe Screw	30-0248
3.5mm x 45mm Locking Hexalobe Screw	30-0249
3.5mm x 50mm Locking Hexalobe Screw	30-0250
3.5mm x 55mm Locking Hexalobe Screw	30-0251
3.5mm x 60mm Locking Hexalobe Screw	30-0252

3.5mm Nonlocking Hexalobe Screws

3.5mm x 8mm Nonlocking Hexalobe Screw	30-0255
3.5mm x 10mm Nonlocking Hexalobe Screw	30-0256
3.5mm x 12mm Nonlocking Hexalobe Screw	30-0257
3.5mm x 14mm Nonlocking Hexalobe Screw	30-0258
3.5mm x 16mm Nonlocking Hexalobe Screw	30-0259
3.5mm x 18mm Nonlocking Hexalobe Screw	30-0260
3.5mm x 20mm Nonlocking Hexalobe Screw	30-0261
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3.5mm x 24mm Nonlocking Hexalobe Screw	30-0263
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3.5mm x 30mm Nonlocking Hexalobe Screw	30-0266
3.5mm x 32mm Nonlocking Hexalobe Screw	30-0267
3.5mm x 34mm Nonlocking Hexalobe Screw	30-0268

3.5mm Nonlocking Hexalobe Screws (cont.)

3.5mm x 36mm Nonlocking Hexalobe Screw	30-0269
3.5mm x 38mm Nonlocking Hexalobe Screw	30-0270
3.5mm x 40mm Nonlocking Hexalobe Screw	30-0271
3.5mm x 45mm Nonlocking Hexalobe Screw	30-0272
3.5mm x 50mm Nonlocking Hexalobe Screw	30-0273
3.5mm x 55mm Nonlocking Hexalobe Screw	30-0274
3.5mm x 60mm Nonlocking Hexalobe Screw	30-0275
3.5mm x 65mm Nonlocking Hexalobe Screw	30-0276

3.0mm Locking Hexalobe Screws

3.0mm x 8mm Locking Hexalobe Screw	30-0278
3.0mm x 10mm Locking Hexalobe Screw	30-0279
3.0mm x 12mm Locking Hexalobe Screw	30-0280
3.0mm x 14mm Locking Hexalobe Screw	30-0281
3.0mm x 16mm Locking Hexalobe Screw	30-0282
3.0mm x 18mm Locking Hexalobe Screw	30-0283
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3.0mm x 24mm Locking Hexalobe Screw	30-0286
3.0mm x 26mm Locking Hexalobe Screw	30-0287
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3.0mm x 32mm Locking Hexalobe Screw	30-0290
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3.0mm x 38mm Locking Hexalobe Screw	30-0293
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3.0mm x 45mm Locking Hexalobe Screw	30-0295
3.0mm x 50mm Locking Hexalobe Screw	30-0296
3.0mm x 55mm Locking Hexalobe Screw	30-0297
3.0mm x 60mm Locking Hexalobe Screw	30-0298

3.0mm Nonlocking Hexalobe Screws

3.0mm x 8mm Nonlocking Hexalobe Screw	30-0301
3.0mm x 10mm Nonlocking Hexalobe Screw	30-0302
3.0mm x 12mm Nonlocking Hexalobe Screw	30-0303
3.0mm x 14mm Nonlocking Hexalobe Screw	30-0304
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3.0mm x 36mm Nonlocking Hexalobe Screw	30-0315
3.0mm x 38mm Nonlocking Hexalobe Screw	30-0316
3.0mm x 40mm Nonlocking Hexalobe Screw	30-0317
3.0mm x 45mm Nonlocking Hexalobe Screw	30-0318
3.0mm x 50mm Nonlocking Hexalobe Screw	30-0319
3.0mm x 55mm Nonlocking Hexalobe Screw	30-0320
3.0mm x 60mm Nonlocking Hexalobe Screw	30-0321
3.0mm x 65mm Nonlocking Hexalobe Screw	30-0322

2.7 Locking Hexalobe Screws

2.7mm x 8mm Locking Hexalobe Screw	30-0324
2.7mm x 10mm Locking Hexalobe Screw	30-0325
2.7mm x 12mm Locking Hexalobe Screw	30-0326
2.7mm x 14mm Locking Hexalobe Screw	30-0327
2.7mm x 16mm Locking Hexalobe Screw	30-0328
2.7mm x 18mm Locking Hexalobe Screw	30-0329
2.7mm x 20mm Locking Hexalobe Screw	30-0330
2.7mm x 22mm Locking Hexalobe Screw	30-0331
2.7mm x 24mm Locking Hexalobe Screw	30-0332
2.7mm x 26mm Locking Hexalobe Screw	30-0333
2.7mm x 28mm Locking Hexalobe Screw	30-0334
2.7mm x 30mm Locking Hexalobe Screw	30-0335
2.7mm x 32mm Locking Hexalobe Screw	30-0336

Ordering Information

2.7 Nonlocking Hexalobe Screws

2.7mm x 8mm Nonlocking Hexalobe Screw	30-0343
2.7mm x 10mm Nonlocking Hexalobe Screw	30-0344
2.7mm x 12mm Nonlocking Hexalobe Screw	30-0345
2.7mm x 14mm Nonlocking Hexalobe Screw	30-0346
2.7mm x 16mm Nonlocking Hexalobe Screw	30-0347
2.7mm x 18mm Nonlocking Hexalobe Screw	30-0348
2.7mm x 20mm Nonlocking Hexalobe Screw	30-0349
2.7mm x 22mm Nonlocking Hexalobe Screw	30-0350
2.7mm x 24mm Nonlocking Hexalobe Screw	30-0351
2.7mm x 26mm Nonlocking Hexalobe Screw	30-0352
2.7mm x 28mm Nonlocking Hexalobe Screw	30-0353
2.7mm x 30mm Nonlocking Hexalobe Screw	30-0354
2.7mm x 32mm Nonlocking Hexalobe Screw	30-0355

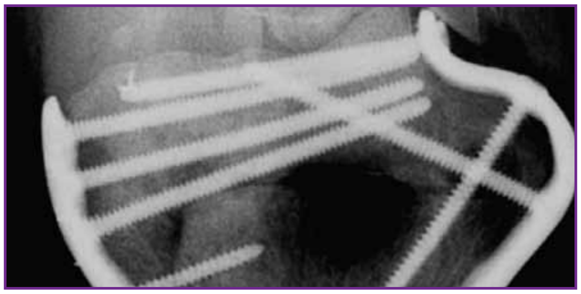
Tension Band Pins

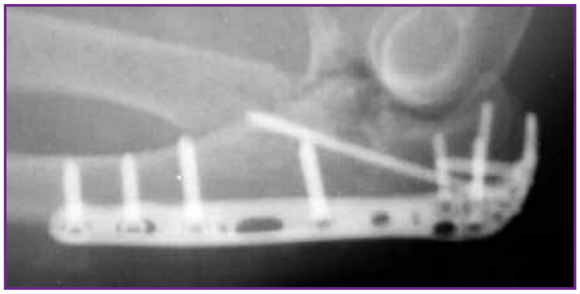
70mm Non-Sterile Tension Band Pin	30-0098
90mm Non-Sterile Tension Band Pin	30-0099

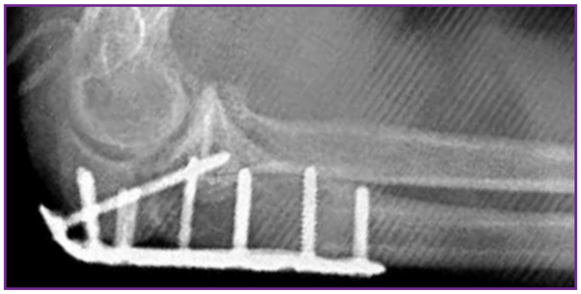
Instrumentation

T8 Stick-Fit Hexalobe Driver	80-0759
T15 Stick-Fit Hexalobe Driver	80-0760
2.0mm Quick Release Drill	80-0318
2.3mm Quick Release Drill	80-0627
2.8mm Quick Release Drill	80-0387
3.5mm Quick Release Drill	MS-DC35
Bone Tap for 2.7mm Hexalobe Screws	80-0625
Bone Tap for 3.0mm Nonlocking Screws	80-0626
3.5mm Long Tap Tip	MS-LTT35
Plate Tap for 3.0mm Screw	80-0659
Plate Tap for 3.5mm Screw	80-0661
2.0mm x 9" Guide Wire, Single Trocar	WS-2009ST
.045" x 6" SS Guide Wire	WS-1106ST
.062" x 6" SS Guide Wire	WS-1607ST
.062" x 6" Titanium Guide Wire (threaded)	WT-1606STT
.035" x 6" Titanium Guide Wire (threaded)	WT-0906STT
Plate Tack	PL-PTACK

These implants are available nonsterile or sterile-packed. Add -S to product number for sterile products. To order, contact your local Acumed Representative.







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7. "Comparative Stability of Perpendicular Versus Parallel Double-Locking Plating Systems in Osteoporotic Comminuted Distal Humerus Fractures," Stoffel, et. al., Journal of Orthopaedic Research, 2008.
8. Data on file at Acumed.
9. Data on file at Acumed.
10. Data on file at Acumed.

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