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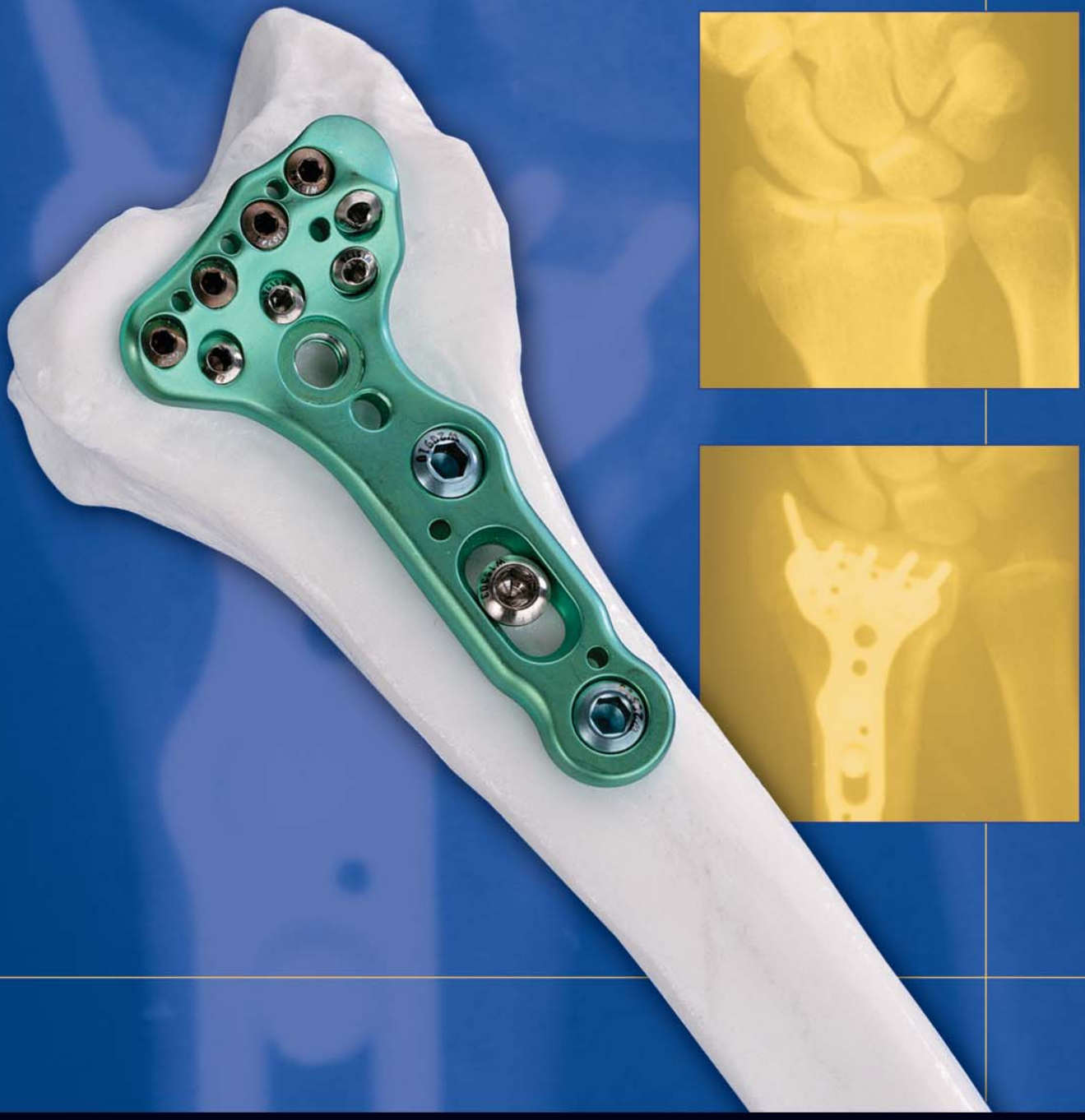


ACU-LOC®

Targeted Distal Radius System

ACU-LOC®
Targeted Distal Radius System

Since 1988 Acumed has been designing solutions to the demanding situations facing orthopedic surgeons, hospitals and their patients. Our strategy has been to know the indication, design a solution to fit, and deliver quality products and instruments.

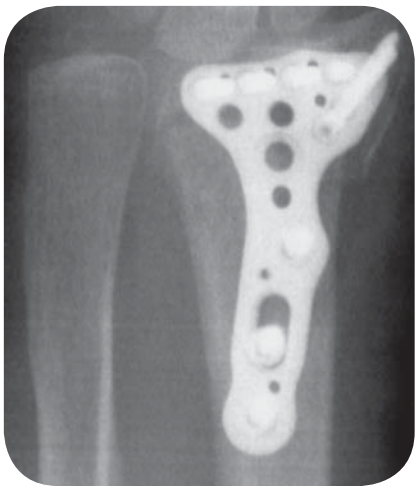
In a continuing effort to advance orthopedics, Acumed introduces the Acu-Loc Targeted Distal Radius Plate. The plate has several key features that contribute to an overall stable construct, ultimately benefiting the patient.

Our goal was to design a plate that incorporated both a locking construct and a screw trajectory that maximized purchase in the distal fragments. The Acu-Loc instrumentation includes a low profile, radiolucent targeting guide to maximize visualization and improve the surgical technique.

The Acu-Loc plate family and its comprehensive, unique instrumentation system brings to orthopedics an advancement in the treatment of distal radius fractures. The implants and instruments are an extension of Acumed's philosophy to bring to the market an innovative product that addresses the issues with current treatment methods for a specific indication.

With the Acu-Loc Targeted Distal Radius Plate, Acumed has designed an innovative solution for repairing fractures of the distal radius. Both the Acu-Loc plate and the instrumentation system contain several key features that address the issues faced with other plating techniques. Acumed recognized these issues and designed a solution that attends to these difficulties while also embracing innovation.

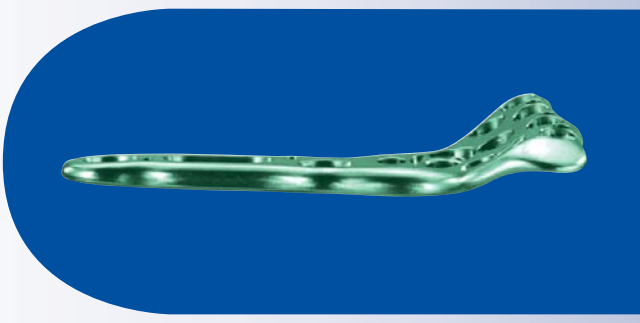
When designing the Acu-Loc plates, Acumed's goal was to design a better implant for the patient while improving the overall procedure for the surgeon. The anatomic design of the titanium plate, in conjunction with precise screw positioning and locking capabilities, creates an extremely stable construct with minimal soft tissue irritation. The low profile radiolucent targeting device minimizes O.R. time and improves the surgical technique.



Acumed's precise screw positioning and angulation targets the distal fragments and provides secure, stable fracture fixation. Two of the distal screws aggressively target the radial styloid to provide fixation along the entire distal radius. The screw positioning ensures that most fragments can be captured by a locking or non-locking screw.

Precise Screw Placement enables the surgeon to maximize purchase in the distal radius and the radial styloid. Unicortical locking proximal screws provide stability while eliminating soft tissue impingement on the dorsal surface of the distal radius.

Anatomic Plate Design assists in restoring the original geometry of the patient's anatomy. Extensive cadaveric research aided in the development of an anatomically contoured plate design. Left and Right specific plate options are available in the system that precisely match the anatomical curvature of the distal radius.



Advanced Radiolucent Targeting Guide is low profile and allows the surgeon to visualize and target each of the distal screws. This saves valuable O.R. time and frustration associated with individual targeting guides. The targeting guide set screw threads into the guide to maintain a strong interface during insertion.

Color coded for application.
(Blue) Left (Green) Right

Targeted Radial Styloid Screws

K-wire holes for provisional stability and to ensure screws do not pass through the radial-carpal joint

Mounting holes for targeting guide

Proximal locking screws

Low profile plate/screw interface

K-wire holes for povisional stability

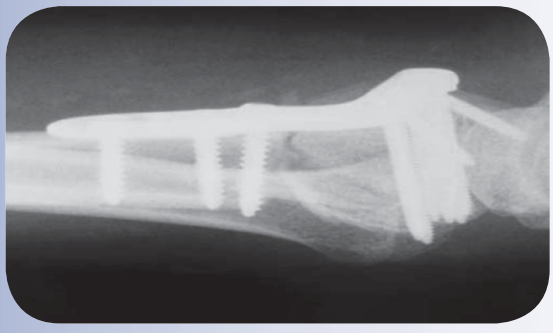
Beveled plate edges minimize irritation

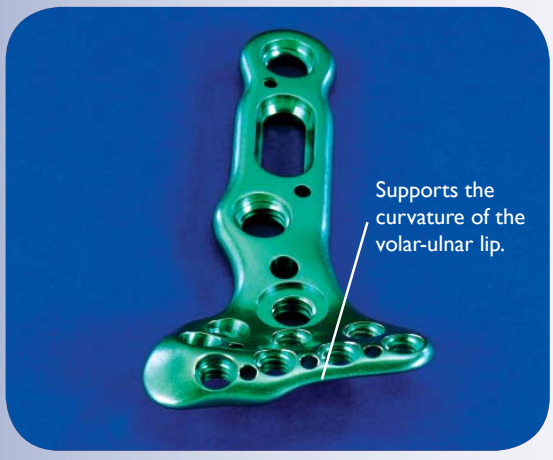
SCREW PLACEMENT

The Acu-Loc® plate is designed to be placed more distal than many other volar plates. The distal screws, angled forward six degrees from the plate, maximize purchase in the subchondral bone. The unique distal screw placement maximizes stability and aggressivly captures the radial styloid for a complete fixation solution.

In order to improve fixation and pull-out strength and minimize soft tissue irritation, Acumed chose to give the surgeon options for proximal screw placement. The proximal holes in the plate are threaded to accept 3.5mm unicortical locking screws or traditional 3.5mm bicortical screw fixation. The screw holes are angled to maximize pull-out strength, improving overall plate stability. When combined with the Acu-Loc's distal screw placement, the plate provides maximum fixation to promote fracture union.

ANATOMIC DESIGN



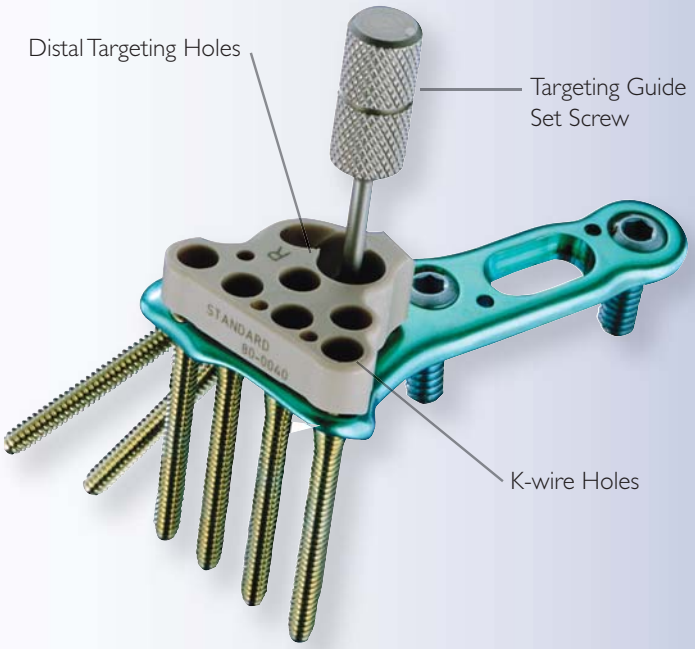


The Acu-Loc plate is pre-contoured to match the anatomy of the patient. Acumed's goal was to design a plate that most closely replicated the anatomical contours of the distal radius in order to maximize support and accurately reduce the fracture.

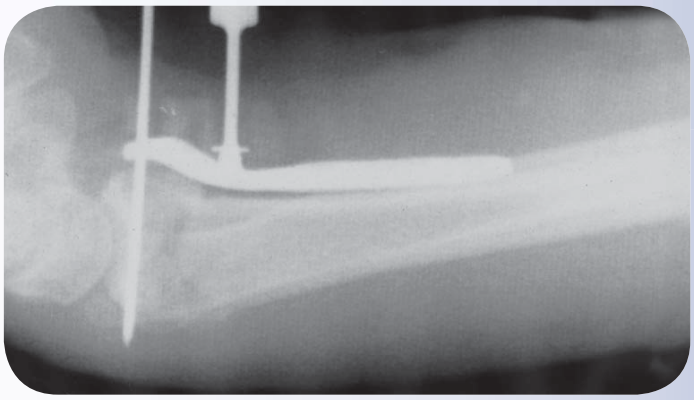
When compared to traditional T-shaped plates, the Acu-Loc addresses the key anatomical structures of the distal radius. The shape of the plate allows it to sit more distal than many other volar plates, allowing the screws to capture and support the subchondral bone. The distal portion of the plate has surface variations to accommodate for the contours of the radius.

Acumed conducted extensive cadaveric research to determine how to best match the complex anatomy of the distal radius. The plate surface is angled upward to accommodate and support the radial styloid. The plate surface is angled back to accommodate the anatomical fluctuations of the volar-ulnar lip, which differs from patient to patient.

The Acu-Loc® Targeted Distal Radius System features a unique targeting system for precise drilling and screw placement. All distal screws can be targeted using a single targeting guide, eliminating the time and frustration with traditional drilling and screw placement techniques. The guide allows the surgeon to accurately and consistently target and insert all distal screws.



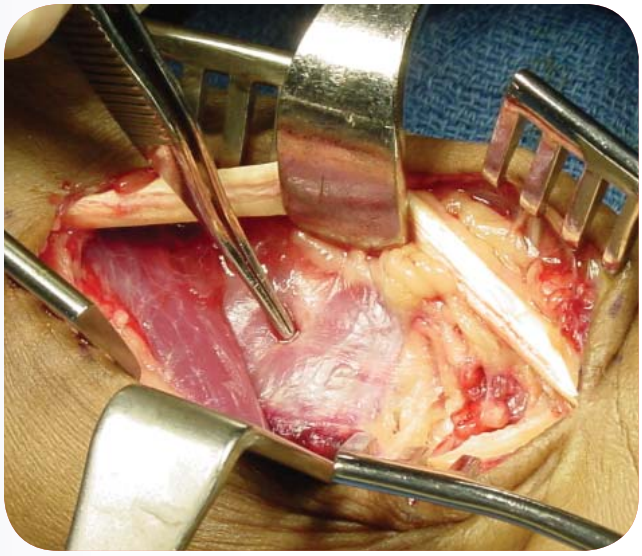
The low profile radiolucent targeting guide has several features that contribute to an improved surgical technique for the surgeon. The distal K-wire holes in both the targeting guide and the plate allow placement of one or more K-wires for provisional stability and verify plate positioning. The K-wire holes are in line with the distal screws, allowing the surgeon to verify screw placement. The targeting guide also features a dual hole, allowing accurate placement of the two radial styloid screws. The targeting guides are left and right specific, with one guide to accommodate for the standard, long and extra-long plates, a second guide to accommodate the wide plate. A third guide accommodates the narrow plate. The targeting guides are housed next to the appropriate plates in the base of the tray for ease of use.



The Acu-Loc instrumentation system gives the surgeon a comprehensive, complete set of instruments to implant the plate. The system features a number of clamps, retractors and soft tissue protectors in addition to the drivers, drills and targeting device. Acumed's goal is to have one self-contained kit with everything needed for a case, eliminating the hassle of opening other instrumentation sets for additional components.

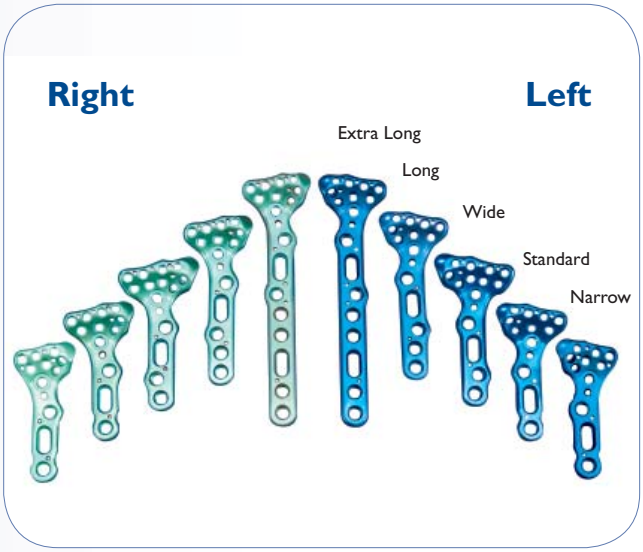
Acu-Loc® Targeted Distal Radius System

Step 1: The patient's forearm is supinated to expose the surgical site. To maximize exposure, a towel is placed under the wrist placing it in extension. A longitudinal incision is made approximately six centimeters in length just radial to the FCR tendon to protect against potential injury to the palmar cutaneous branch of the median nerve.



Step 2: The tendon sheath is opened and the tendon is retracted radially to protect the radial artery. The flexor pollicus longus is identified by passive flexion/extension of the thumb interphalangeal joint and is retracted ulnarly to protect the median nerve. Next, the pronator quadratus is identified by its transverse fibers and is released radial to ulnar to expose the fracture site.

Step 3: The fracture is reduced and evaluated under fluoroscopy. The brachioradialis may need to be released from its insertion on the radial styloid to facilitate reduction and visualization.

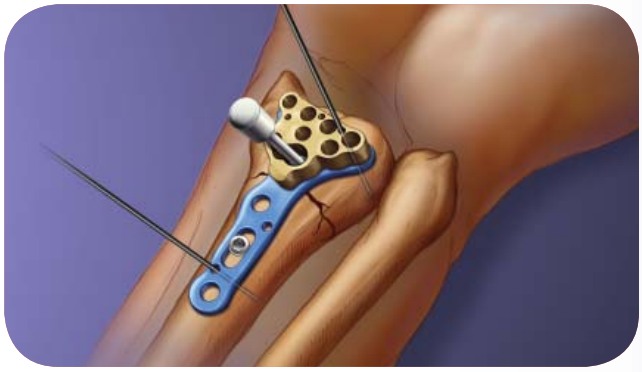


Step 4: There are five different plates in the set, each with a left and right option. Left plates are Blue, Right plates are Green. The standard plate (PL-DR50 L/R) is most commonly used. However, if the fracture extends proximally, the long plate (PL-DR60 L/R) may be needed. If the distal radius is wider or narrower than normal, the wide plate (PL-DR70 L/R) or the narrow plate (PL-DR30 L/R) may be selected.

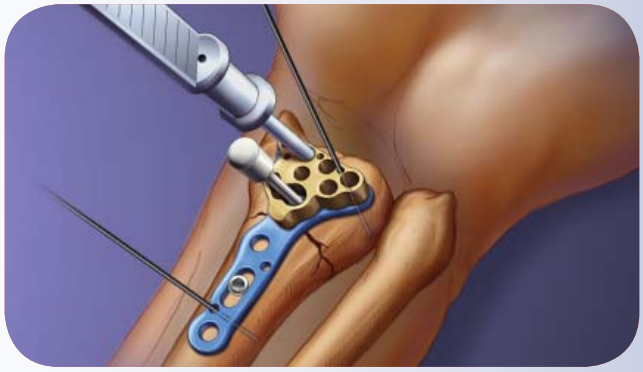
Step 5: Once the plate is selected, the appropriate size targeting guide is attached using the targeting guide set screw (80-0038). The targeting guide may be attached to the plate on the back table prior to insertion and then placed on the bone. The plate's position is then secured proximally and distally with K-wires. An alternate method is to secure the plate to the bone with a cortical screw proximally and then attach the targeting guide. A third method is to secure the plate to the bone with a 0.045" K-wire proximally and a 0.054" K-wire distally. The guide then slides over the distal K-wire and into position. Care should be taken not to angle the distal K-wires.

Step 6: The plate is made to sit along the distal aspect of the radius to support the volar articular fracture fragments. To temporarily hold the plate in place, a 0.045" K-wire may be placed through one of the small holes in the proximal part of the plate.

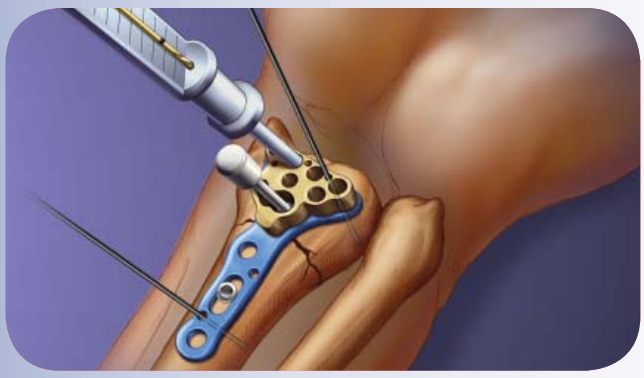
To assess the position of the distal locking screws relative to the articular surface, a 0.054" K-wire may be placed through the distal holes on the plate. The fracture reduction, position of the plate, and the location of the distal K-wire relative to the joint is assessed under fluoroscopy. If the distal K-wire does not penetrate the joint, the subsequent distal locking screws will not as well. Care should be taken that there is no soft tissue in the targeting guide.



Step 7: Place the first 3.5mm non-locking cortical screw through the slot in the plate. The position of the plate relative to the articular surface can then be fine tuned by sliding the plate proximal or distal under fluoroscopy. Using the 2.8mm drill (MS-DC28) and the drill guide (PL-2018), drill through the far cortex. Drill depth is measured with the depth gauge (MS-9020). Note that if provisional K-wires are in place, they may interfere with drilling and screw insertion. Insert the appropriate silver 3.5mm non-locking screw (CO-3xx0), taking care that the screw is the proper length.



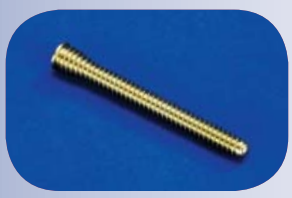
Step 8: Select one of the four screws closest to the joint to target first. There are three types of screws that can be used in any of the eight distal holes: Fully-Threaded Locking Screws, Smooth Locking Pegs and Non-Toggling Screws. Insert the drill guide (MS-DG23) into one of the holes, followed by the 2.0mm drill (MS-DCR20).



Step 9: The depth of the screw is measured using the laser mark on the shaft of the drill and the scale on the drill guide. An alternative way to measure the screw length is by using the Depth Probe (MS-DRPB). The probe is inserted through the drill guide, hooking the far cortex. The screw length measurement is read from the laser mark on the probe. Both the probe and the drill guide are removed together prior to screw insertion.

Step 10: A Gold Threaded Locking Screw (CO-T23xx) is inserted using the 1.5mm driver tip (HPC-0015), sleeve (MS-SS23) and driver handle (MS-2210). A Bronze Smooth Locking Peg (CO-S23xx), or a Silver Non-Locking Screw (CO-N23xx) may also be used.

An alternative method to drilling the distal screws is available with the Acu-Loc plate. An Individual Locking Drill Guide (MS-LDG23) is available in the system that threads into each of the eight distal locking holes. Screw length can be read using the Depth Gauge (MS-9020).



2.3mm gold fully threaded locking screws have the same pitch from tip to tail and are tapered under the head to facilitate insertion.

2.3mm silver non-locking screw with enlarged tail end to minimize the toggle effect.

2.3mm bronze smooth locking peg for optional distal fragment fixation. Pegs are tapered under the head to facilitate insertion.

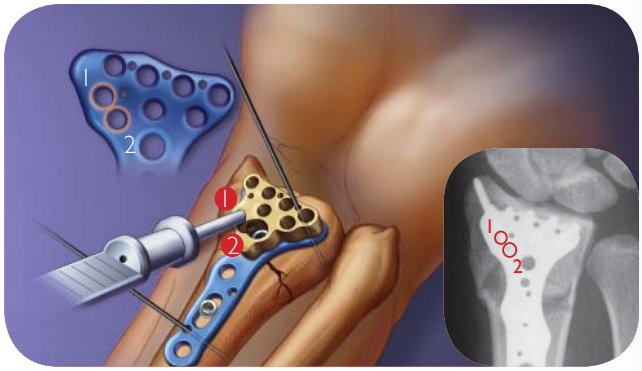
3.5mm light blue proximal locking screws have the same pitch from tip to tail and are tapered under the head to facilitate insertion.

3.5mm silver non-locking cortical screws for bi-cortical proximal fixation.

Step 11: It is at the discretion of the surgeon when to use the Threaded Locking Screws, the Smooth Locking Pegs, and the Non-Toggling (non-locking) Screws. The thread pitch on the Threaded Locking Screw is the same from the tip to the head minimizing the "differential pitch effect" as the screw is tightened into the plate. All eight distal holes accept the three different screw designs.

The radial styloid screws are designed specifically to target and support the radial styloid fragment at angles of 41 and 53 degrees from the plate. A C-Arm overlay is available in the system to determine the trajectory of the distal/radial screw prior to screw insertion. The overlay is used with an A/P view of the distal radius.

Note: A minimum of 6 distal screws should be used.



Step 12: The two radial styloid screws are approached from the back of the targeting guide. Using the dual slot on the back of the guide, the distal/radial screw is targeted by inserting the drill guide to the radial side (1) of the dual slot. The more proximal/ulnar screw is targeted by inserting the drill guide to the ulnar side of the dual slot (2). Both radial styloid screws should be drilled through the targeting guide. Remove the guide to measure and insert the screws. The guide is removed to increase visualization of the drill holes when inserting the screws. With the targeting guide in place, it may be difficult to remove the radial styloid screws if a different size screw is needed. If resizing is necessary, remove the guide and the screw, measure with the depth gauge and insert the proper screw.

Step 13: Select one of the two remaining proximal holes and insert the Threaded Drill Guide (MS-LDG35) if a locking screw is desired, or the Standard Drill Guide (PL-2018) if a non-locking screw is needed. Drill with the 2.8mm drill (MS-DC28) for either proximal screw.

Step 14: Drill depth is measured with the depth gauge (MS-9020). Insert the appropriate Light Blue 3.5mm Locking Screw (COL-3xx0), taking care that the screw does not exit the bone dorsally. Insert the locking screw using the 2.5mm driver tip (HPC-0025), sleeve (MS-SS35) and driver handle (MS-3200). Using the same process, drill and place the final locking screw.

Step 15: Following thorough radiographic evaluation, the wound is closed. Start immediate finger range of motion and forearm rotation post-op. Allow early functional use of the hand for light ADLs. Support the wrist according to bone quality and stability.

ORDERING INFORMATION

Acu-Loc® Distal Radius Plates	
Standard Distal Radius Plate - Left	PL-DR50L
Standard DIstal Radius Plate - Right	PL-DR50R
Long Distal Radius Plate - Left	PL-DR60L
Long Distal Radius Plate - Right	PL-DR60R
Extra Long Distal Radius Plate - Left	PL-DR65L
Extra Long Distal Radius Plate - Right	PL-DR65R
Wide DIstal Radius Plate - Left	PL-DR70L
Wide Distal Radius Plate - Right	PL-DR70R
Narrow Distal Radius Plate - Left	PL-DR30L
Narrow DIstal Radius Plate - Right	PL-DR30R

Drill Bits	
2.8mm Drill Bit	MS-DC28
2.0mm Drill Blt	MS-DCR20

K-Wires & Drill Guides	
.045 K-Wire	WS-1106ST
.054 K-Wire	WS-1406ST
Locking Drill Guide - Distal	MS-LDG23
Locking Drill Guide - Proximal	MS-LDG35

3.5mm Cortical Screws	
3.5mm Cortical Screw 10mm Long	CO-3100
3.5mm Cortical Screw 12mm Long	CO-3120
3.5mm Cortical Screw 14mm Long	CO-3140
3.5mm Cortical Screw 16mm Long	CO-3160
3.5mm Cortical Screw 18mm Long	CO-3180

3.5mm Locking Cortical Screws	
3.5mm Locking Cortical Screw 8mm Long	COL-3080
3.5mm Locking Cortical Screw 10mm Long	COL-3100
3.5mm Locking Cortical Screw 12mm Long	COL-3120
3.5mm Locking Cortical Screw 14mm Long	COL-3140
3.5mm Locking Cortical Screw 16mm Long	COL-3160
3.5mm Locking Cortical Screw 18mm Long	COL-3180

2.3mm Smooth Peg	
2.3mm Peg 14mm Long	CO-S2314
2.3mm Peg 16mm Long	CO-S2316
2.3mm Peg 18mm Long	CO-S2318
2.3mm Peg 20mm Long	CO-S2320
2.3mm Peg 22mm Long	CO-S2322
2.3mm Peg 24mm Long	CO-S2324
2.3mm Peg 26mm Long	CO-S2326
2.3mm Peg 28mm Long	CO-S2328

2.3mm Threaded Locking Screw	
2.3mm Threaded Locking Screw 14mm Long	CO-T2314
2.3mm Threaded Locking Screw 16mm Long	CO-T2316
2.3mm Threaded Locking Screw 18mm Long	CO-T2318
2.3mm Threaded Locking Screw 20mm Long	CO-T2320
2.3mm Threaded Locking Screw 22mm Long	CO-T2322
2.3mm Threaded Locking Screw 24mm Long	CO-T2324
2.3mm Threaded Locking Screw 26mm Long	CO-T2326
2.3mm Threaded Locking Screw 28mm Long	CO-T2328

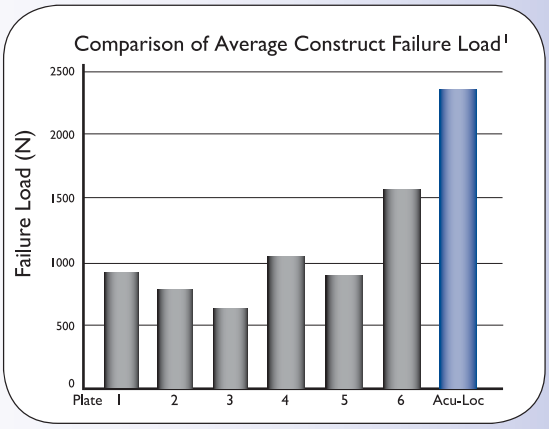
2.3mm Threaded Non-Toggling Screw	
2.3mm Non-Toggling Screw 14mm Long	CO-N2314
2.3mm Non-Toggling Screw 16mm Long	CO-N2316
2.3mm Non-Toggling Screw 18mm Long	CO-N2318
2.3mm Non-Toggling Screw 20mm Long	CO-N2320
2.3mm Non-Toggling Screw 22mm Long	CO-N2322
2.3mm Non-Toggling Screw 24mm Long	CO-N2324
2.3mm Non-Toggling Screw 26mm Long	CO-N2326
2.3mm Non-Toggling Screw 28mm Long	CO-N2328
2.3mm Non-Toggling Screw 30mm Long	CO-N2330
2.3mm Non-Toggling Screw 32mm Long	CO-N2332

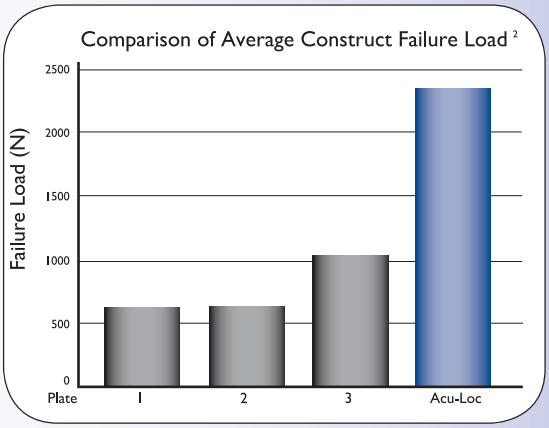
The ability of locked screws to resist the loads in the distal radius has been shown in several studies comparing the average construct failure load of several plates on the market. Acumed simulated the testing methods used in these studies to determine the failure load of the Acu-Loc® plate.

The failure load of the Acu-Loc plate was compared with the results of two recent biomechanical studies.

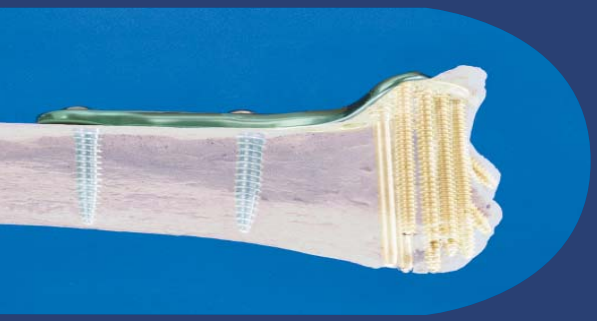
In the first study[1], the biomechanical properties of six dorsal and volar plate designs were compared. Average construct failure load of the six plates was measured. The study stated that an estimated 250 N of force is applied to the wrist joint in the flexed digit position. Testing conducted on the Acu-Loc plate resulted in a construct load of 2400 N without failure, showing that the Acu-Loc can withstand nearly 9X the force that is applied to the wrist during patient rehabilitation. All plates, including the Acu-Loc, exceeded this 250 N benchmark. The six plates in the study failed in a similar fashion. Bending of the plates occurred without screw loosening.

The Acu-Loc's biomechanical results were also compared to the results of a second biomechanical study[2]. In this study, the average construct failure load of three volar plate designs were compared. Screw loosening and bending occurred at the point of failure for the three plates studied.





Summary: Biomechanical tests show that the Acu-Loc plate can withstand a force far beyond the loads that are seen in the radius during patient rehabilitation.



1. Osada, et. al. "Comparison of Different Distal Radius Dorsal and Volar Fracture Fixation Plates: A Biomechanical Study". The Journal of Hand Surgery, Vol. 28A No. 1 January 2003.

2. Osada, et. al. "Biomechanics in Uniaxial Compression of Three Distal Radius Volar Plates". The Journal of Hand Surgery, Vol. 29A No. 3 May 2004.

The charts from the two studies were reproduced by Acumed with the Acu-Loc information added for clarity.

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