

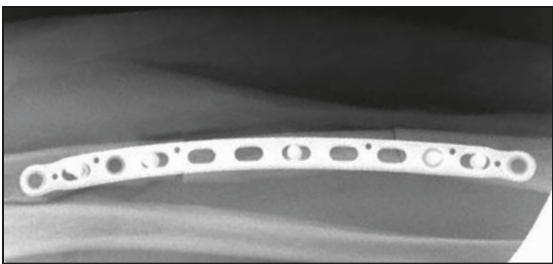
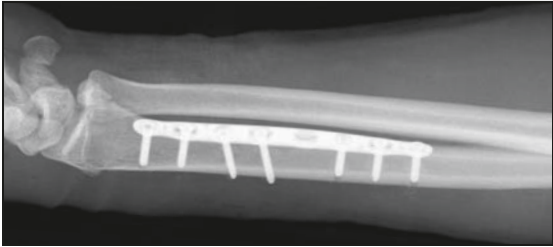
A&U MED®



**Anatomic Midshaft
Forearm Plates**

Anatomic Midshaft Forearm Plates

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



Acumed's Anatomic Midshaft Forearm Plates provide an innovative and improved method for the treatment of midshaft fractures of the radius and ulna. This system offers a comprehensive family of pre-contoured plates designed for use in the diaphyseal region of the forearm.

In line with our goal to bring to the market products that evolve and improve patient outcomes, Acumed designed this plating system to provide the surgeon with innovative features and a straightforward, time-saving surgical technique.

This versatile system may be used to treat many forearm fractures including simple to complex both-bone fractures, transverse fractures, comminuted fractures, open fractures and displaced, isolated fractures of the radius or ulna exhibiting a rotational deformity.

*X-rays courtesy of William B. Geissler, M.D.



Over recent decades surgeons have utilized plate fixation for the treatment of midshaft forearm fractures. Traditional straight plates have been reported to have a high level of success in the treatment of these fractures¹⁻⁴. Acumed looked at current treatment methods and found that hardware could be improved in the following areas:

- Anatomic contouring of plates
- Reducing stress risers above and/or below an existing plate
- Minimizing hardware prominence
- Making the procedure more surgeon-friendly

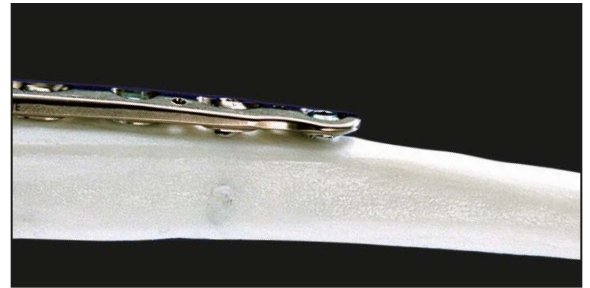
Acumed developed the Anatomic Midshaft Forearm Plates with careful consideration of these desired hardware improvements. With a pre-contoured, anatomic design and other innovative features, Acumed provides surgeons with an advancement in patient care.

Acumed's Forearm Rod System can be used in conjunction with the Anatomic Midshaft Forearm Plates for both-bone fractures when a less invasive approach is desired. Featuring an anatomic contour and bicortical interlocking capability, the radius and ulna rods are an excellent example of Acumed's ability to provide the surgeon with fracture-specific solutions.

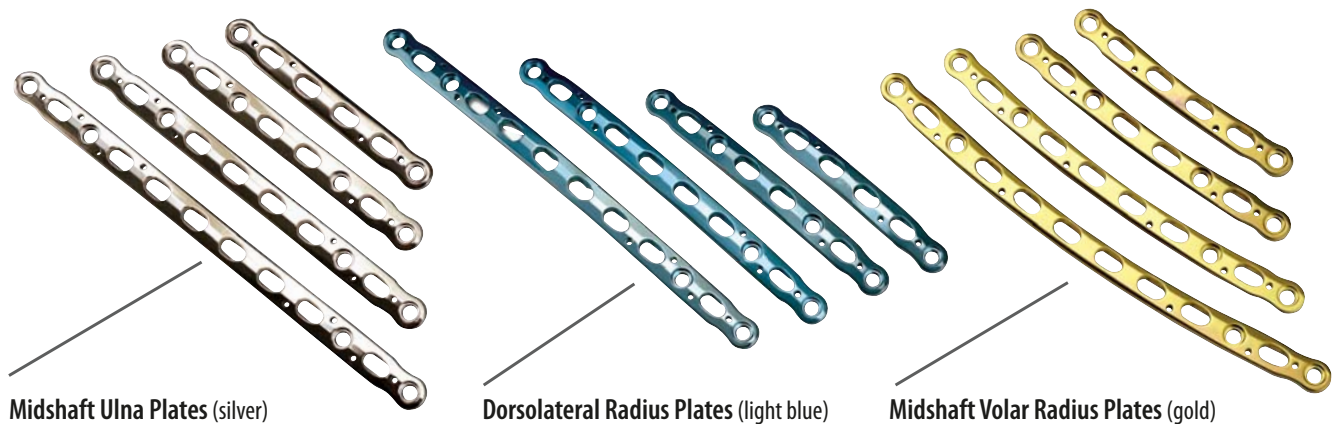
Anatomic Contouring allows the plate to fit the anatomy to properly restore forearm geometry. This maintains plate strength integrity, decreases valuable O.R. time and allows the plate to be used as a template to aid with anatomic restoration. This also facilitates with re-establishing pronation and supination since the bow of the radius is restored with the plate.



Low-Profile Plate Design minimizes the possibility of post-operative soft tissue irritation and patient discomfort. Locking and non-locking screws sit flush with the plate. Both plate ends are tapered to reduce the risk of bone refracture above or below the plate due to excess stress concentrations. The limited contact design reduces constriction of the blood supply to the periosteum.



“Approach-Specific” plates for the radius provide the surgeon with the option to choose his/her preferred surgical approach (dorsolateral or volar), providing a complete forearm plating solution with a straightforward surgical technique. Plate families are color-coded for quick distinguishing in the O.R. User-friendly, innovative instrumentation aids to further simplify the technique for the surgeon.



Biomechanical Stability

Load at Failure Comparison (Foam: 20lb/ft³)

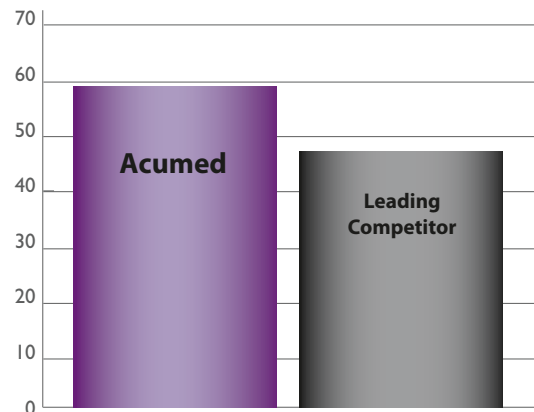


Chart 1: Load at Failure results – Acumed vs. Leading Competitor

Internal mechanical testing was performed at Acumed comparing our Anatomic Midshaft Forearm Plates (titanium alloy) to a leading competitor (316L stainless steel). The focus of our testing was the strength of the plate/bone interaction rather than testing purely the strength of the plate by itself.

Our testing involved attaching the plates to medium density foam blocks (20lb/ft³) to simulate the bone. At failure (due to foam breakage in all cases), the Acumed plate survived average loading 124% over the leading competitor's plate (Chart 1). We believe this was partially due to the strength of the material and partially due to the flexibility of the titanium to reduce stress concentrations in the plate/foam interface.

These testing results demonstrate our rationale for choosing to manufacture the Anatomic Midshaft Forearm Plates from titanium alloy rather than 316L stainless steel. The flexibility provided by titanium performed well in preventing key complications with the traditional stainless steel option: stress shielding and stress concentrations are reduced, and callus formation at the fracture site is increased when a small amount of micromotion is permitted by the flexing of the plate.

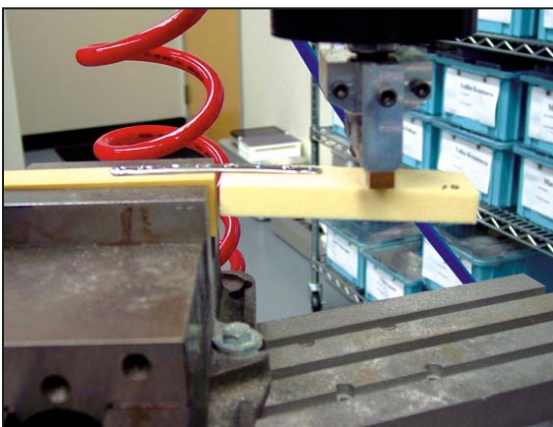
We also conducted low-load cyclic loading in a slightly lower density foam (15lb/ft³), for 5,000 cycles. Two of the three Acumed samples survived the test; foam breakage was the failure in the third. All three samples from the leading competitor failed due to screw pull-out (Chart 2). Again, we believe strength and flexibility were the contributing factors.

The combination of locking holes and compression slots were carefully considered when designing the plates. Because the longer 10- and 12-hole plates are used primarily for comminuted fractures, we wanted to ensure the surgeon was provided multiple options to angle screws to capture fracture fragments. We chose the number of locking holes and compression slots based on mechanical testing of our plates and rationale for locking and non-locking screw usage in diaphyseal regions published in the literature. Careful balance of locking and non-locking hole options is considered to avoid a plate/bone construct that is too stiff and could result in hardware failure.

Cyclic Loading for 5,000 Cycles (Foam: 15lb/ft³)

Sample Tested	Cycle at Failure	Mode of Failure
Acumed Plate 1	n/a	n/a- sample survived
Acumed Plate 2	4,587 cycles	foam breakage
Acumed Plate 3	n/a	n/a- sample survived
Competitor Plate 1	108 cycles	screw pull-out
Competitor Plate 2	158 cycles	screw pull-out
Competitor Plate 3	258 cycles	screw pull-out

Chart 2: Cyclic Loading results – Acumed vs. Leading Competitor



Screw configuration testing in a cantilever set-up.

*All data presented on this page is on file at Acumed.

Innovative Instrumentation

Several innovative instruments have been designed specifically for the Anatomic Midshaft Forearm Plate System to make the surgery quicker and more user-friendly.

A customized Plate Clamp has one end shaped to fit and grasp over the plate. The opposing end has serrated teeth to grip the bone to maintain plate placement and reduction. The clamp's precise fit helps to accurately position the plate on the bone and prevents scratching of the plate caused when a traditional clamp's serrated jaw closes down on the plate.

An Angled Drill Guide is included to allow the surgeon to angle the drill at three pre-determined angles: 15, 30 and 45 degrees. Surgeons may lag across the fracture site through the plate or prior to plate application. The Angled Drill Guide also contains K-wire holes for visualization of the screw's trajectory and placement in the bone.

A unique Soft Tissue Spreader attaches to the locking holes in the plate and then holds the soft tissues away from the surgical site. This allows fewer retractors and instruments in the surgical site. K-wire holes are provided to secure the spreader to the plate for alignment if the locking bolt is not used. The Soft Tissue Spreader provides an additional set of hands for the operating surgeon.



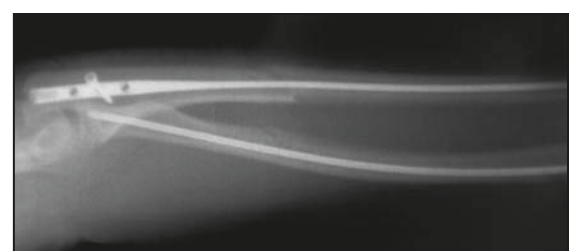
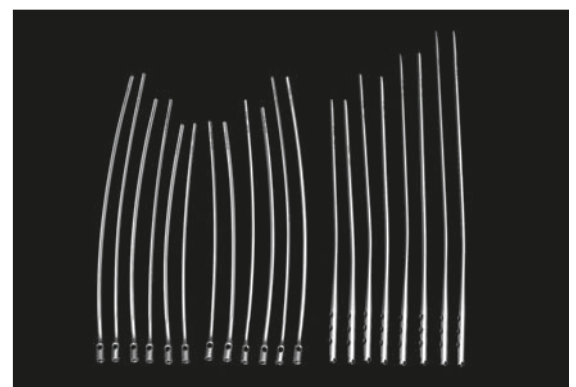
Forearm Fracture Solutions

Acumed's goal is to provide surgeons with fixation options that treat various indications and ultimately improve patient outcome. Our unique, innovative products for the forearm are an excellent example of Acumed's ability to provide the surgeon with fracture-specific solutions.

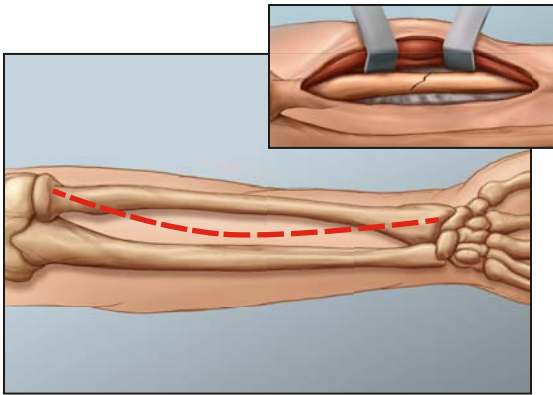
Acumed's Forearm Rod System offers the surgeon a unique array of features designed to rotationally stabilize and provide fixation for a variety of diaphyseal forearm fractures. Each fluted rod is designed to be flexible enough to insert through a small incision with minimal canal reaming. A targeted interlocking screw, combined with a paddle blade tip design, locks and rotationally secures the bone segments to promote fracture union. The radius and ulna rods are offered in two diameters and a wide range of lengths.

Radius Rods: Length Range: 190-230mm; Dia.: 3.0 & 3.6mm; R/L Specific.

Ulna Rods: Length Range: 210-270mm; Dia.: 3.0 & 3.6mm.



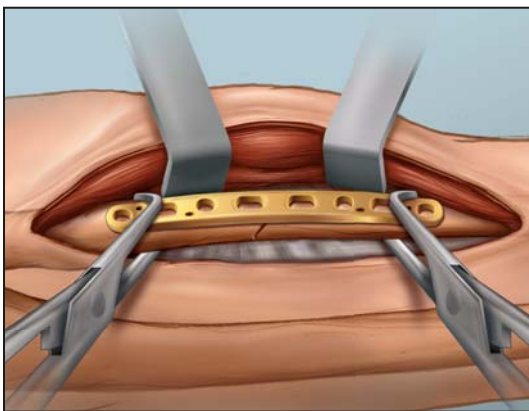
Surgical Technique



Step 1: Exposure & Fracture Reduction

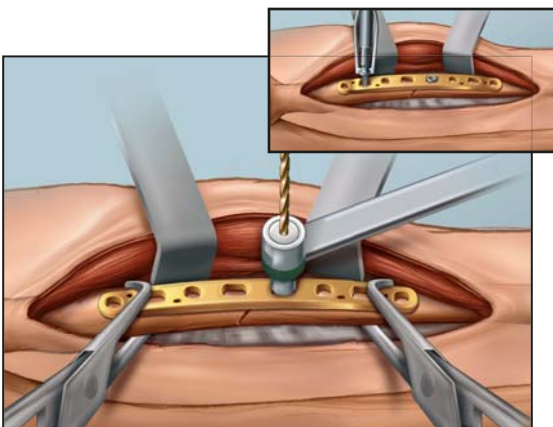
The surgeon's preferred approach is used to expose the surgical site. If both the radius and ulna are fractured, the bone with the simplest fracture should be reduced first.

Note: A lag screw may be placed across the fracture prior to plate application, or through the plate in a later step. A 3.5mm drill (MS-DC35) and drill guide (80-0204 or PL-2196) are included in the system to lag a 3.5mm screw.



Step 2: Plate Selection & Placement

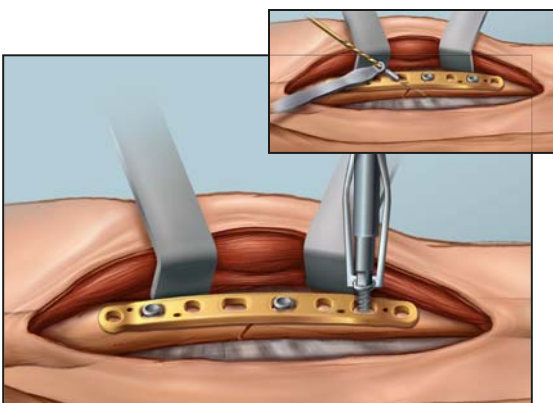
Fracture assessment and/or pre-operative x-ray templating may be utilized to determine appropriate plate length. Place selected plate onto the bone with the middle of the plate positioned over the fracture site to optimize compression. Plate Tacks (PL-PTACK), reduction clamps (80-0223 or PL-CL04) or .062" K-wires may be used to aid with provisional plate fixation. The Soft Tissue Spreader (80-0251) may be threaded into one of the locking holes in the plate with the locking bolt (80-0252) to aid with visibility of the surgical site.



Step 3: Non-Locking Screw Insertion

Non-locking bicortical screws are inserted first to ensure compression in the axial plane. Bicortical 3.5mm screws are recommended for optimal fixation. The offset drill guide (PL-2095) may be utilized for both neutral and dynamic compression drilling with the 2.8mm drill (MS-DC28). Screws should be inserted by alternating from one side of the fracture to the other. Forearm rotation should be checked regularly during the procedure.

Note: 2.7mm cortical and 4.0mm cancellous screws are available in the system. Bone taps (MS-LTT27/35) are highly recommended for patients with dense bone.



Step 4: Fracture Site Compression

To provide compression at the fracture site, use the gold end of the offset drill guide (PL-2095) to drill in dynamic compression mode. Insert 3.5mm non-locking screws on both sides of the fracture, engaging at least 6 cortices on each side.

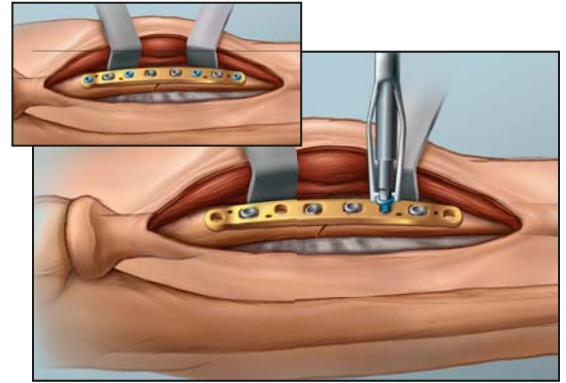
Note: The plates have static locking holes if the surgeon chooses to utilize locking screw fixation. Results of Acumed's biomechanical testing show that greater pull-out strength is achieved when using all non-locking 3.5mm bicortical screws⁵. If locking screw fixation is desired, proceed to Step 5.

Anatomic Midshaft Forearm Plates

Step 5: Locking Screw Insertion

To insert the 3.5mm locking screws, thread the locking drill guide (MS-LDG35) into a locking hole in the plate. Drill with the 2.8mm drill, measure for depth and insert the appropriate size 3.5mm locking cortical screw.

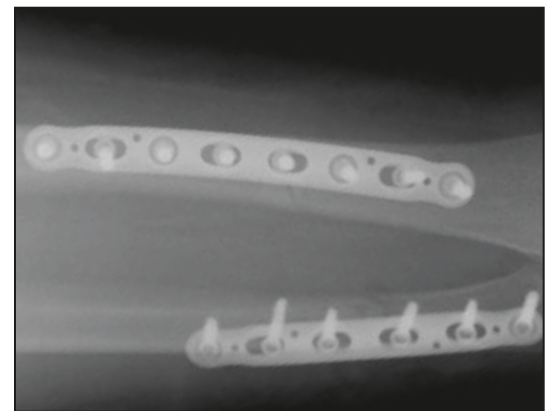
Note: 2.7mm locking cortical screws are available with corresponding instrumentation to use if desired.



Post-op Protocol

Postoperative treatment with the Anatomic Midshaft Forearm Plating System follows suit with other diaphyseal forearm plating procedures.

This section offers Acumed's suggested method for implanting the Anatomic Midshaft Forearm Plates. For specific questions not addressed here, please contact your local Acumed representative or Acumed at (888) 627-9957 or on the web at www.acumed.net.



Ordering Information

Note: The Anatomic Midshaft Forearm Plates can be used with the following Acumed systems: Locking Clavicle Plate, Congruent Locking Elbow Plate, Locking Forefoot/Midfoot Plate and the Universal Congruent Plate System.

Midshaft Ulna Plates	
6-hole Midshaft Ulna Plate (80mm)	70-0070
8-hole Midshaft Ulna Plate (100mm)	70-0071
10-hole Midshaft Ulna Plate (130mm)	70-0072
12-hole Midshaft Ulna Plate (160mm)	70-0073

Midshaft Volar Radius Plates	
6-hole Midshaft Volar Radius Plate (80mm)	70-0066
8-hole Midshaft Volar Radius Plate (100mm)	70-0067
10-hole Midshaft Volar Radius Plate (130mm)	70-0068
12-hole Midshaft Volar Radius Plate (160mm)	70-0069

Midshaft Dorsolateral Radius Plates	
6-hole Dorsolateral Radius Plate (80mm)	70-0074
8-hole Dorsolateral Radius Plate (100mm)	70-0075
10-hole Dorsolateral Radius Plate (130mm)	70-0076
12-hole Dorsolateral Radius Plate (160mm)	70-0077

Midshaft Forearm Plate Instrumentation	
Plate Clamp	80-0223
Angled Drill Guide	80-0204
Soft Tissue Spreader	80-0251
Soft Tissue Spreader Locking Bolt	80-0252
Midshaft Forearm Plate Tray Insert Assembly	80-0182



1. Anderson LD, Sisk TD, Tooms RE, et. al. Compression plate fixation in acute diaphyseal fracture of the radius and ulna. *J Bone Joint Surg Am.* 1975;57:287-97.
2. Hadden WA, Reschaver R, Seggl W. Results of AO plate fixation of forearm shaft fractures in adults. *Injury.* 1982;15:448.
3. Chapman MW, Gordon JE, Zissimos AG. Compression-plate fixation of acute fractures of the diaphyses of the radius and ulna. *J Bone Joint Surg Am.* 1989;71:159-69.
4. Hertel R, Pisan M, Lambert S, et. al. Plate osteosynthesis of diaphyseal fractures of the radius and ulna. *Injury.* 1996;27:545-48.
5. Data on file at Acumed.

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