

# A&U MED<sup>®</sup>



## CONGRUENT CLAVICLE PLATES

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*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.*

The Acumed Congruent Clavicle Plate is designed to provide excellent fixation for acute fractures, malunions, and non-unions of the clavicle.

While often treated conservatively, a portion of these fractures can benefit from a low profile congruent plate that minimizes soft tissue irritation and improves patient function while returning them to their normal activities sooner.

## Closed Treatment of Displaced Middle-Third Fractures of the Clavicle Gives Poor Results.<sup>1</sup>

The results of the 52 cases studied with an average follow-up of 38 months:

- 15% nonunion rate
- 25% pain requiring NSAID's
- 36% difficulty lifting 20lb overhead
- 39% tenderness at fracture site
- 31% signs of nerve compression
- 31% were dissatisfied with the result

"We now recommend open reduction and internal fixation of severely displaced fractures of the middle third of the clavicle in adult patients"



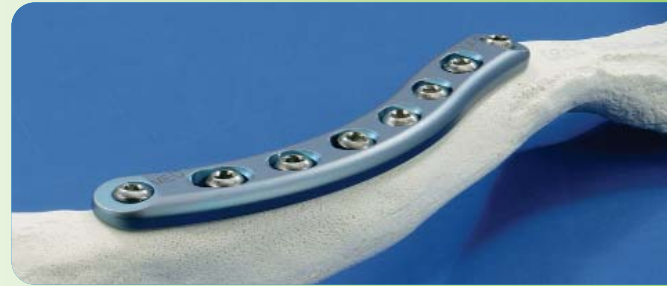
With the Congruent Clavicle Plate, Acumed has designed a comprehensive solution for repairing fractures located from the middle third to the distal third of the clavicle. Standard ORIF procedures for clavicle fractures including, pinning, reconstruction, and DC plating have historically provided less than desirable results.<sup>2</sup> Traditional hardware frequently causes soft tissue irritation and/or fails prior to union, requiring a second procedure.

Designed in conjunction with William Geissler, MD, the Congruent Clavicle Plate offers a low profile solution for superior plating of the clavicle. Pre-contoured to match the natural S-shape of the clavicle, this titanium plate offers increased strength, with a rounded profile and a low-profile screw-plate interface. This design not only reduces OR time spent in contouring a plate but also minimizes soft-tissue irritation for the patient.

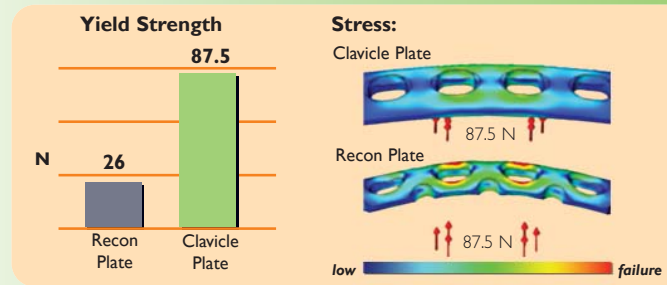


As an add-on to the existing Congruent Plate System, the Clavicle Plate requires only minimal additional instrumentation: several bone clamps, retractors and a **specialized soft tissue protector**. With these, this system efficiently utilizes the resources of the existing plate set to make for a straightforward procedure.

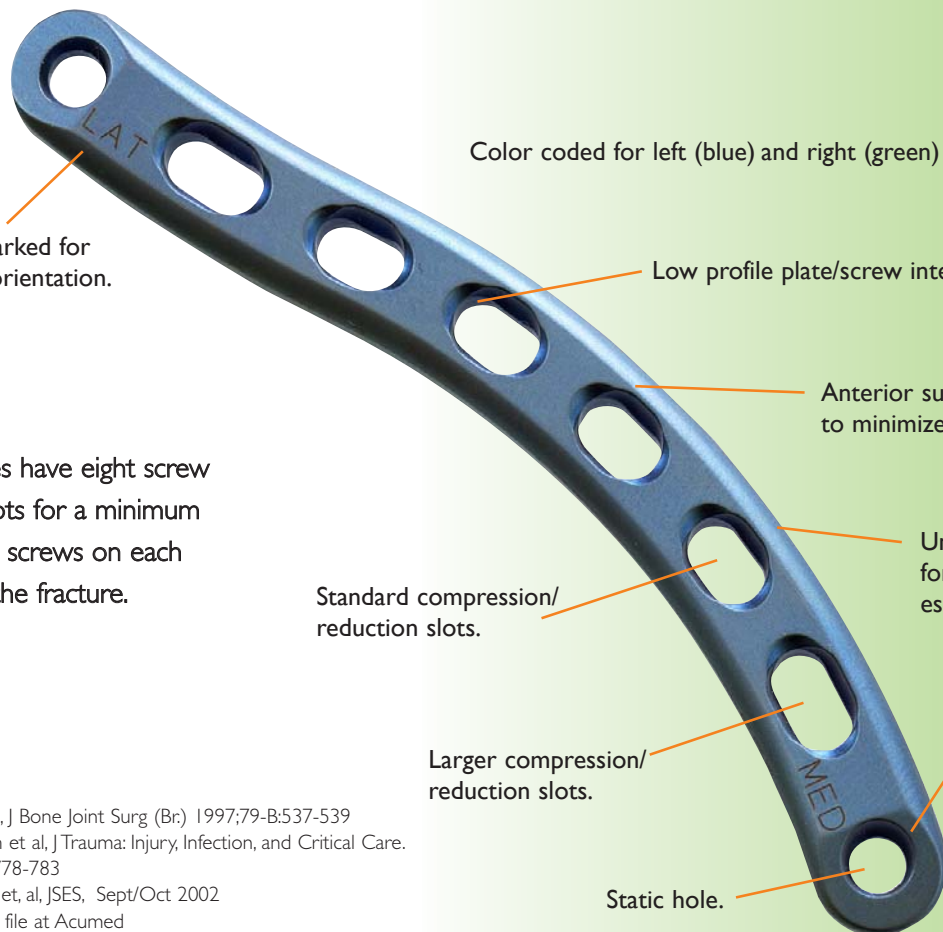
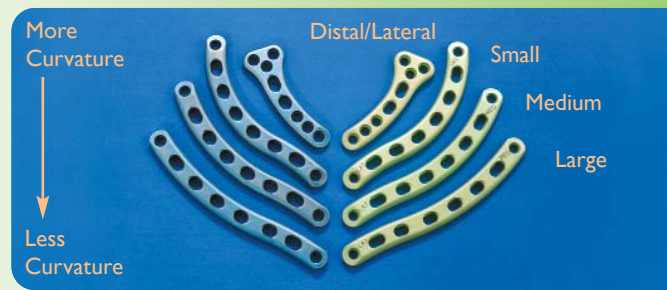
**Precontoured Plate Geometry** matches the anatomy of the patient with little or no bending. The Congruent Clavicle Plate may also act as guide or template for restoring the patient's original anatomy when reconstructing a malunion, nonunion, or a highly comminuted fracture, unlike intramedullary rods/pins or straight plates.



**Superior Biomechanical Stability** is engineered into both the design of the plates and their orientation on the clavicle. Plating the superior aspect of the clavicle has been found to be biomechanically the most stable<sup>3</sup>. Acumed in house analysis showed that when subjected to equal force, a 3.5mm SS reconstruction plate broke in multiple locations while the Congruent Clavicle Plate suffered no permanent deformation<sup>4</sup>.



**Multiple Plate Options** are available to fit a wide variety of clavicle curvatures. For central one-third applications, there are three different curvatures in both left (blue) and right (green), and for distal/lateral fractures a specialized "J" plate is available.



Color coded for left (blue) and right (green) application.

Laser marked for proper orientation.

Low profile plate/screw interface.

Anterior surface is rounded to minimize irritation.

Undersurface is tubularized for additional stability, especially in torsion.

All plates have eight screw holes/slots for a minimum of three screws on each side of the fracture.

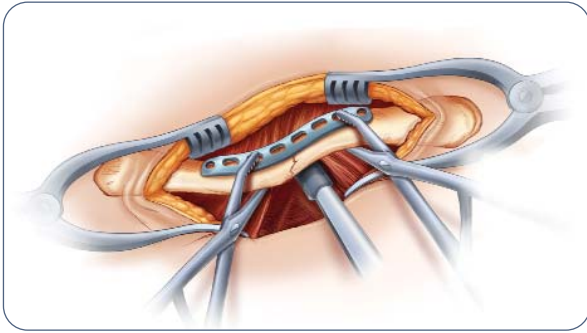
Standard compression/reduction slots.

Larger compression/reduction slots.

Beveled medial and lateral profile to minimize irritation.

Static hole.

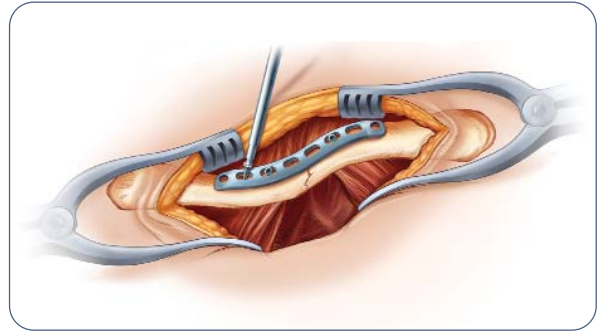
- 1) Hill et al, J Bone Joint Surg (Br) 1997;79-B:537-539
- 2) Bostman et al, J Trauma: Injury, Infection, and Critical Care. 1997; 5:778-783
- 3) Iannotti, et, al, JSES, Sept/Oct 2002
- 4) Data on file at Acumed



**Step 5: Plate Placement**

Once the ideal position of the plate has been selected, it is provisionally stabilized to the clavicle with bone clamps. The clavicle plate screws may be placed either unicortical or bicortical. If bicortical screws are used, it is important to not over-penetrate the distal cortex and potentially risk neurovascular injury. A curved retractor may be placed under the inferior surface of the clavicle to protect the neurovascular structures from over-penetration of the drill bit.

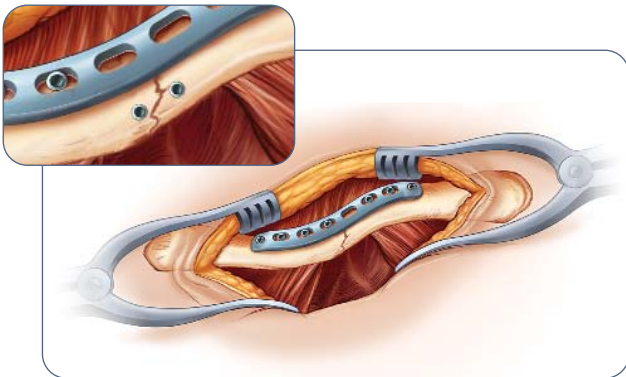
**NOTE:** The drill may need to be replaced if it comes in contact with the retractor.



**Step 6: Screw Insertion**

Initially, one screw should be placed medial and one screw lateral to the fracture site for early stability (typically the third and sixth holes). Once these two screws are placed, the provisional bone clamps holding the plate to the clavicle may be removed. The second and seventh holes of the plate are compression slots enabling screw placement to further compress the fracture site. The medial and lateral screws may now be placed so that there are three screws on each side of the fracture.

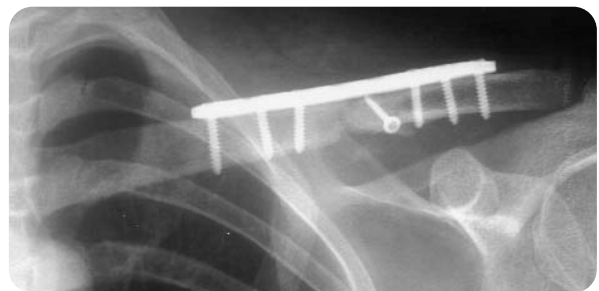
**NOTE:** The bolster supporting the patient's head may be temporarily removed if the head is in the way during drilling of the medial screws. Once the medial screws are placed, the bolster supporting the head may be replaced.



**Step 7: Final Plate and Screw Position**

The remaining two center screws may be placed, depending on the amount of comminution. Lag screw fixation across the major fracture fragment may be performed prior to placement of the plate. The 3.5/2.0mm drill sleeve (PL-CL07) from the Acumed set may be used for lagging. After the near cortex is drilled with the 3.5mm drill, the 3.5/2.0mm drill sleeve (PL-CL07) from the Acumed instrument set is inserted and the far cortex is drilled with a 2.0mm drill.

An intraoperative radiograph is recommended to check the position of the screws and the final reduction of the fracture. The musculature is then re-approximated directly over the plate. The skin is then closed in layers with a subcuticular stitch for the remaining skin layer.



**Post-op Protocol**

The patient is placed in an arm sling and starts pendulum range of motion exercises. Passive motion exercises are initiated from the first four weeks, active assisted from four to six weeks, active strengthening is initiated at six weeks post operatively, once healing is seen radiographically.

## CONGRUENT BONE PLATE SYSTEM FOR THE PERSONAL ATTENTION OF THE OPERATING SURGEON

**DESCRIPTION:** Acumed Bone plates, screws, and accessories are designed to provide fixation for fractures, fusions or osteotomies.

**INFORMATION FOR USE:** Physiological dimensions limit the sizes of implant appliances. The surgeon must select the type and size that best meets the patient's requirements for close adaptation and firm seating with adequate support.

**INDICATIONS:** The Acumed bone plate system includes plates and screws designed specifically for clavicle, humerus, radius, ulna, metacarpal, metatarsal, malleolus, tibia, and fibula. The wrist fusion plates and accessories are designed specifically for fusion of the small bones of the hand including: hamate, capitate, lunate, triquetrum.

**CONTRAINDICATIONS:** Active or latent infection. Osteoporosis, insufficient quantity or quality of bone/soft tissue. Material sensitivity. If suspected, tests are to be performed prior to implantation. Sepsis. Patients who are unwilling or incapable of following postoperative care instructions. This device is not intended for screw attachment or fixation to the posterior elements (pedicles) of the cervical, thoracic, or lumbar spine.

**WARNINGS:** For safe and effective use of this implant, the surgeon must be thoroughly familiar with the implant, the method of application, instruments, and the recommended surgical technique for this device. The device is not designed to withstand the stress of weight bearing, load bearing, or excessive activity. Device breakage or damage can occur when the implant is subjected to increased loading associated with delayed union, nonunion, or incomplete healing. Improper insertion of the device during implantation can increase the possibility of loosening and migration. The patient must be cautioned, preferably in writing, about the use, limitations, and possible adverse effects of this implant including the possibility of the device failing as a result of loose fixation and/or loosening, stress, excessive activity, or weight bearing or load bearing, particularly if the implant experiences increased loads due to delayed union, nonunion, or incomplete healing. The patient must be warned that failure to follow postoperative care instructions can cause the implant and/or treatment to fail.

**PRECAUTIONS:** An implant shall never be reused. Previous stresses may have created imperfections which can lead to device failure. Instruments shall be inspected for wear or damage prior to usage. Protect implant appliances against scratching and nicking. Such stress concentrations can lead to failure.

**ADVERSE EFFECTS:** Fracture of the implant due to excessive activity, prolonged loading upon the device, incomplete healing, or excessive force exerted on the implant during insertion. Implant migration and/or loosening. Metal sensitivity or histological or allergic reaction resulting from implantation of a foreign material. Pain, discomfort, or abnormal sensations due to the presence of an implant. Nerve damage resulting from surgical trauma. Necrosis of bone or bone resorption. Necrosis of tissue or inadequate healing.

**STERILITY:** This product is provided nonsterile. Sterilization may be performed using one of the following methods. For a gravity displacement autoclave, set at 250° F (121°C) for 30 minutes. For a prevacuum autoclave, set at 270° F (132°C) for 4 minutes, or at 273°F-279°F (134°C to 137°C) for 3 minutes. Please consider your equipment manufacturer's written instructions for the specific sterilizer and load configuration being used, and current AORN standards and recommended practices.

**STORAGE INSTRUCTIONS:** Store in a cool dry place, and keep away from direct sunlight. Prior to use, inspect product package for signs of tampering, damage, or water contamination.

**CAUTION:** Federal Law (USA) restricts this product to sale by or on the order of a physician or hospital.



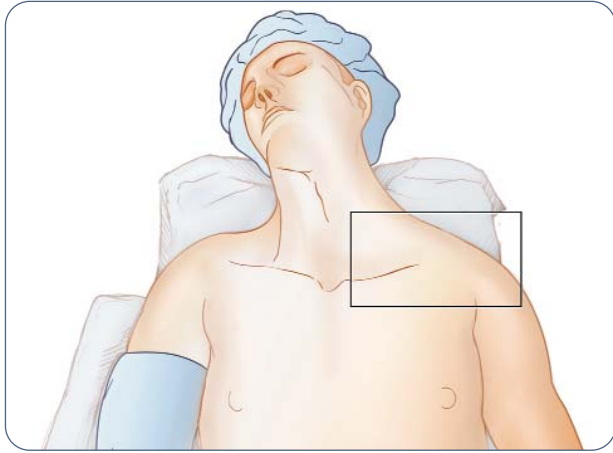
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CPS00-00-01  
Effective: 10/2003

# SURGICAL TECHNIQUE

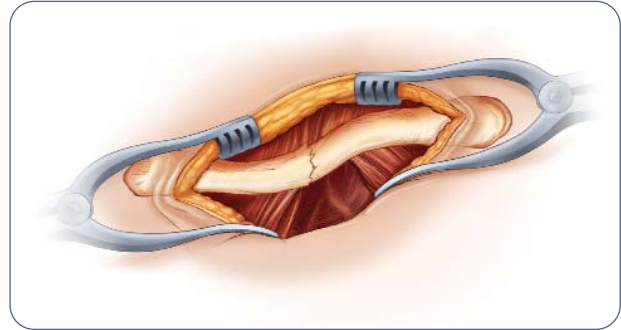
By William Geissler, M.D.

This section offers Acumed's suggested method for implanting the Congruent Clavicle Plate. For specific questions not addressed here, please contact your local Acumed representative or Acumed at 888 627-9957.



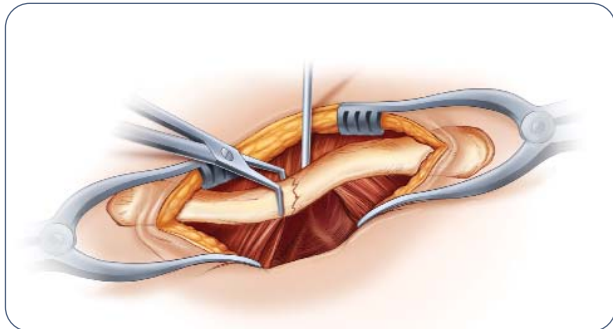
## Step 1: Patient Positioning

The patient is initially placed in the beach chair position. A bolster is placed between the shoulder blades to help facilitate reduction of the fracture during the case. The patient's involved upper extremity is prepped and draped in a sterile fashion allowing the arm to be manipulated to help further reduce the fracture if required.



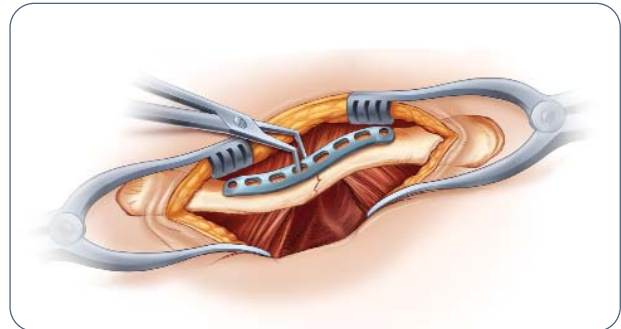
## Step 2: Exposure

Approximately a six cm transverse (medial to lateral) incision is made over the palpable fracture of the clavicle, usually in the middle third. The medial fragment is usually proximal in relation to the distal fragment. The incision is usually placed midway between the proximal/distal migration of the fascia and the skin flaps are elevated. The cutaneous nerves are protected. The musculature is then subperiosteally elevated off the bone fragments. It is important to keep soft tissue attachments to the butterfly fragments in an attempt to maintain vascularity.



## Step 3: Fracture Reduction

Once the fracture fragments are exposed, the fracture is anatomically reduced and provisionally stabilized with bone clamps.



## Step 4: Plate Selection

The appropriately sized left or right clavicle plate is then selected from the three different curvatures (small, medium and large). Usually, the large plate is ideal for most males, the medium plate for smaller males and most females, and the small plate for smallest patients. The two middle holes may be placed over the fracture, ideally leaving three holes both proximal and distal to the fracture fragments; however, the plate can be slid medially or laterally for the most ideal location. In cases of non-union or malunion, the curve of the plate can assist in anatomic reduction of the clavicle, reducing strain on the sternoclavicular and acromioclavicular joints.

**NOTE:** The plate may be rotated 180° for a more anatomical fit on fractures that are more lateral than the central 1/3.

The "J" plate is indicated for displaced Type II clavicle fractures where the lateral fragment is usually quite small but wide. The distal 3 screw holes were designed to be placed in the lateral fragment, the two oval holes for possible lag screw placement, and the three remaining medial holes for stabilization of the medial fragment.



J Plate