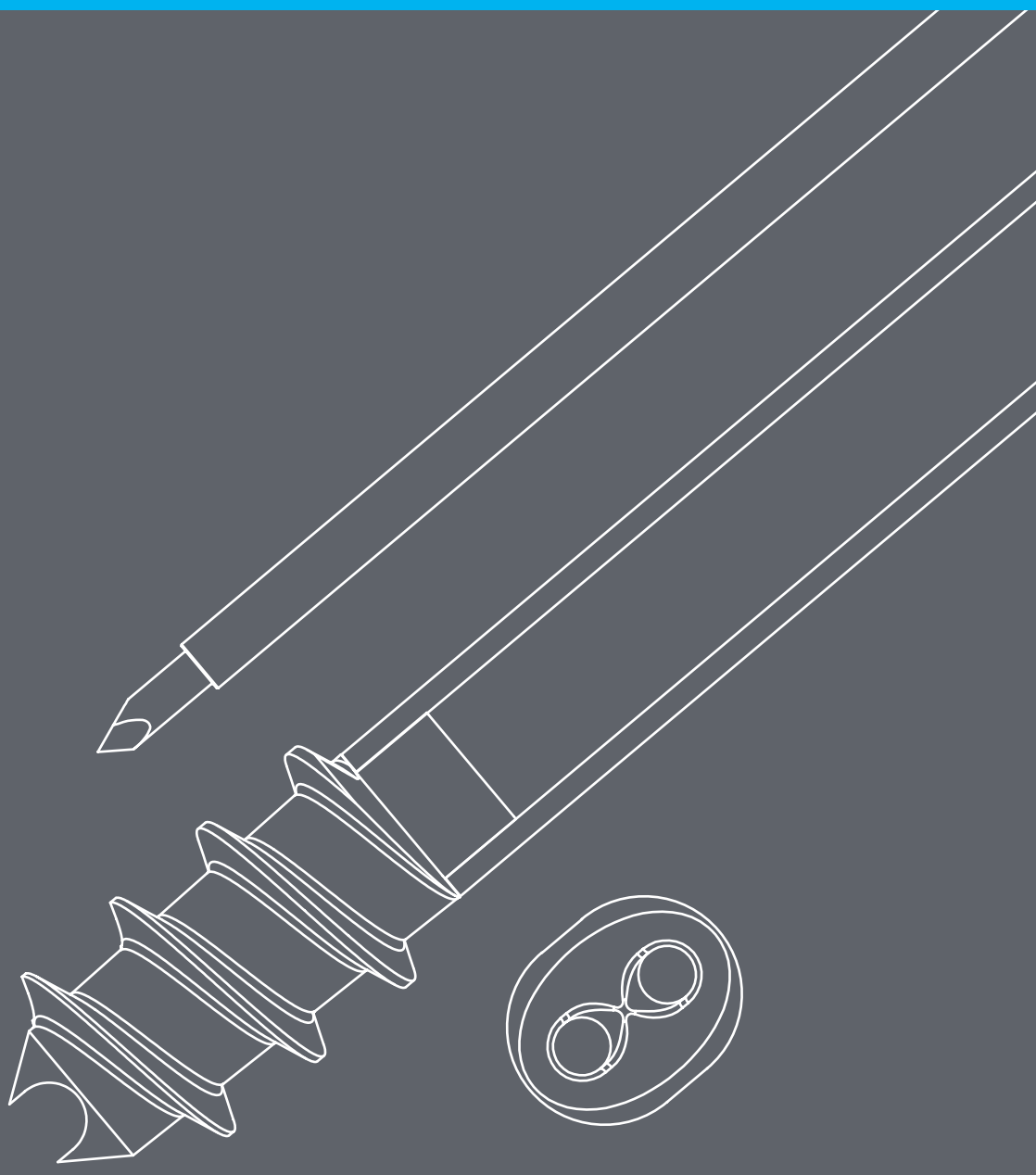
acumed

Acu-Sinch® Repair System

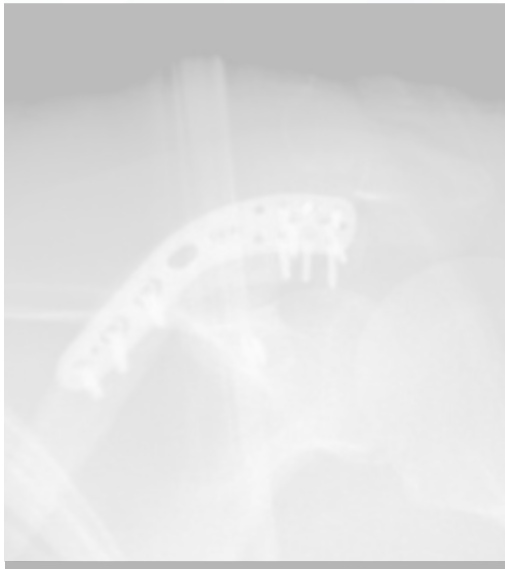
Technical Monograph



A COLSON ASSOCIATE

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

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



Acumed Acu-Sinch® Repair System

The Acumed Acu-Sinch Repair System was designed to complement the Clavicle Plating System by providing additional stability to the fracture and addressing coracoclavicular ligament injuries associated with clavicle fractures. The Acu-Sinch Repair System is used in conjunction with an Acumed Superior Midshaft or Distal Clavicle Plate to aid in the fixation of clavicle fractures.

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Introduction

Fractures of the distal clavicle make up roughly 15% to 25% of all clavicle fractures.[1] Distal clavicle fractures are classified based on their location relative to the coracoclavicular (CC) ligaments (Figure 1). The two CC ligaments, the conoid and trapezoid ligaments, connect the coracoid process of the scapula to the inferior surface of the distal clavicle. Defined using the Neer classification system, a Type IIB distal clavicle fracture consists of a fracture of the clavicle that occurs between the conoid and trapezoid ligaments and includes a disruption of the conoid ligament. This disruption of the conoid ligament untethers the proximal clavicle fragment from the shoulder girdle.

These fractures are typically displaced due to the deforming muscle forces and the weight of the arm. Gravity pulls the limb and distal clavicle fragment downward and the trapezius muscle pulls the proximal clavicle fragment upward.[2] Neer Type IIB distal clavicle fractures have the highest rate of nonunion with nonoperative treatment of all the clavicle fractures.[1,3] When treated with ORIF, adequate fixation of the distal fracture fragments can be challenging due to the comminution, size of the distal clavicle fragment, or bone quality.

Surgeons have historically approached these complex fractures by employing two main techniques to augment the fixation in the distal clavicle and maintain reduction of the fracture during the healing process.

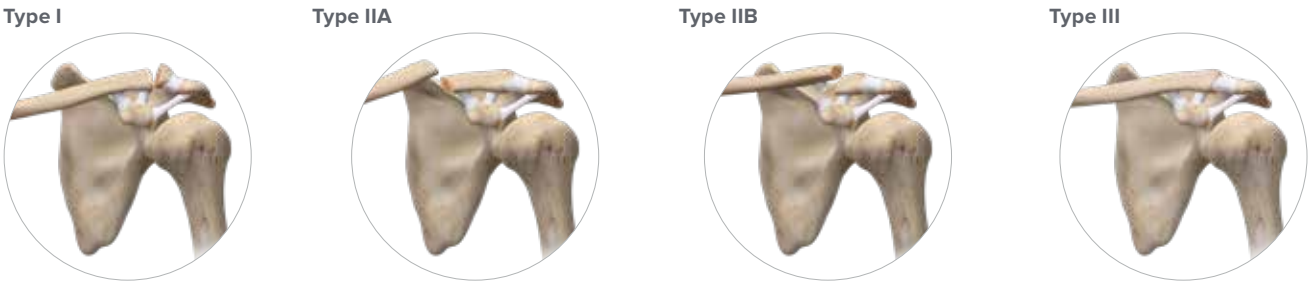


Figure 1

Hook Plate

A hook plate has screw fixation in both the proximal and distal clavicle fragments, and hooks underneath the acromion process of the scapula to augment the fixation of the distal fragments (Figure 2). A number of complications associated with hook plate usage have been reported, including hardware failure, hook migration, acromion irritation, and rotator cuff tears.[2] In addition, removal of the hook plate is generally recommended after healing to avoid damage to the acromion and restore range of motion to the shoulder.[4] Implant removal requires a second surgery under general anesthesia.

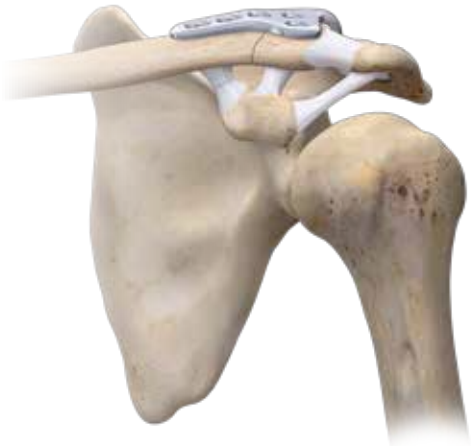


Figure 2

Coracoclavicular (CC) Fixation

Coracoclavicular fixation stabilizes the proximal clavicle fragment relative to the coracoid process. This can be accomplished by using a CC screw, suture tape passed beneath the coracoid and around the clavicle (Figure 3), or with suture button or suture anchor fixation. Each of these techniques has its own challenges and complications. Like the hook plate, CC screws often require removal after healing in order to restore proper shoulder motion and mechanics. Suture loops and coracoid button techniques require additional dissection underneath the coracoid, and have been associated with coracoid fracture.[2,5]

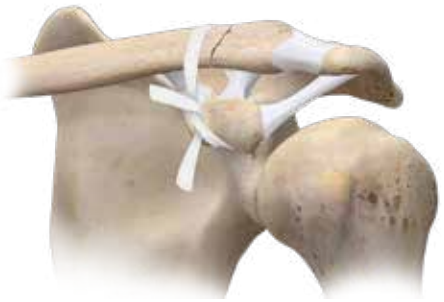
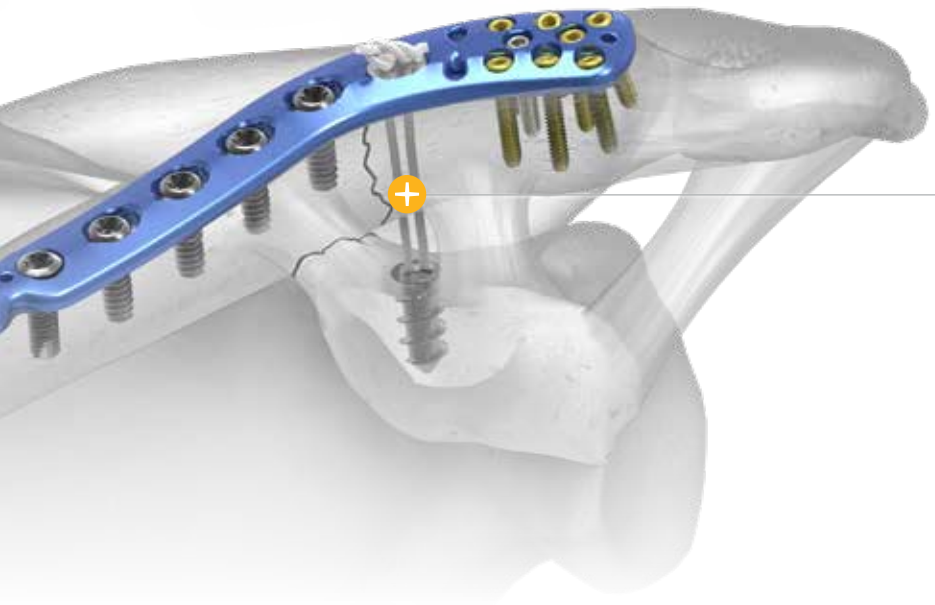


Figure 3

Design Rationale



Acu-Sinch Repair System
The Acu-Sinch Repair System anchors a high-strength suture into the base of the coracoid and is designed to integrate into Acumed's Clavicle Plates via a low-profile suture retainer.

The Acu-Sinch Repair System is specifically designed for distal clavicle fractures with coracoclavicular ligament involvement. The suture anchor is sized for the coracoid and the anchor profile has been optimized to fit inside the coracoid process without violating the inferior cortex. A 3.5 mm hole is drilled centrally in the coracoid base (Figure 4), and the suture anchor is placed into the superior aspect of the coracoid under direct visualization. Suture anchor fixation in the coracoid avoids the need for extensive subcoracoid dissection. The unicortical fixation feature is a key advantage of the Acu-Sinch system, since drilling through both cortices is associated with the risk of coracoid fracture and places the neurovascular structures that pass beneath the coracoid at risk[5,6] (Figure 5). In addition, the Acu-Sinch suture anchor provides comparable pullout strength to bicortical fixation, such as a button underneath the coracoid.

Figure 4

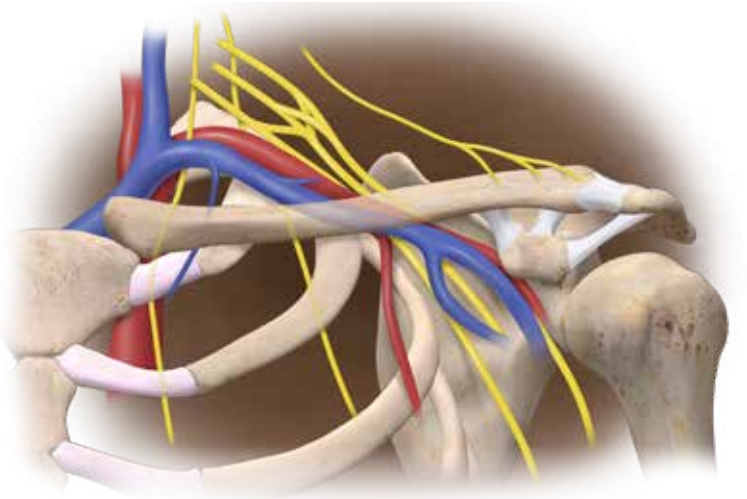


Figure 5

Design Rationale [continued]

The surgical technique begins with direct visualization of the coracoid (Figure 6), which is accessible through the clavicle fracture, followed by insertion of the suture anchor into the coracoid (Figure 7, 8). The instrumentation is designed so that the driver automatically disengages from the suture anchor, ensuring that the anchor is fully seated in the coracoid.
The connection between the coracoid and the clavicle uses FlexBraid #5 high-strength (UHMWPE) suture, which minimizes elongation under load. This suture contributes to the strength of the overall construct, but is designed to fail before pullout of the anchor in order to prevent migration of the implant.
In contrast, button fixation on the underside of the coracoid does risk hardware migration in the case of suture rupture.[5]
The suture construct allows relative motion and rotation between the coracoid and clavicle, because the shoulder girdle naturally allows motion between these two bones.

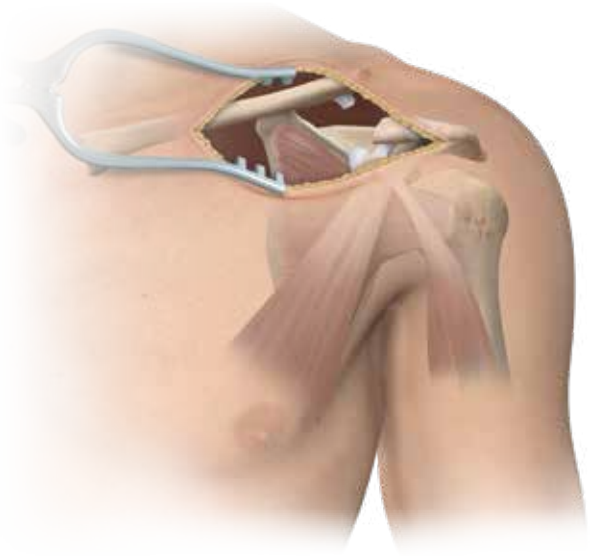


Figure 6

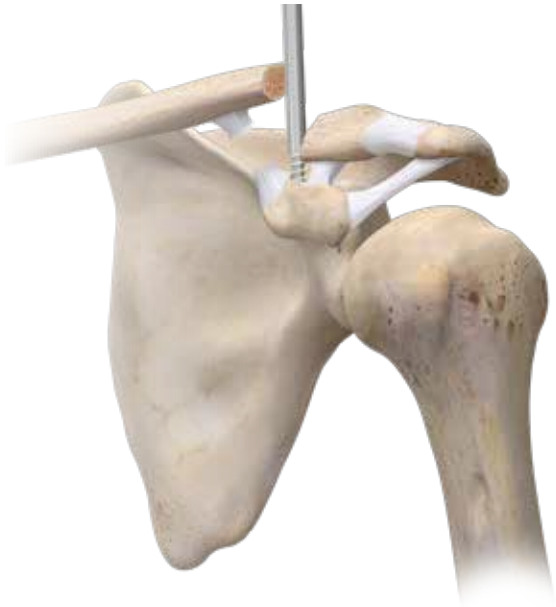


Figure 7

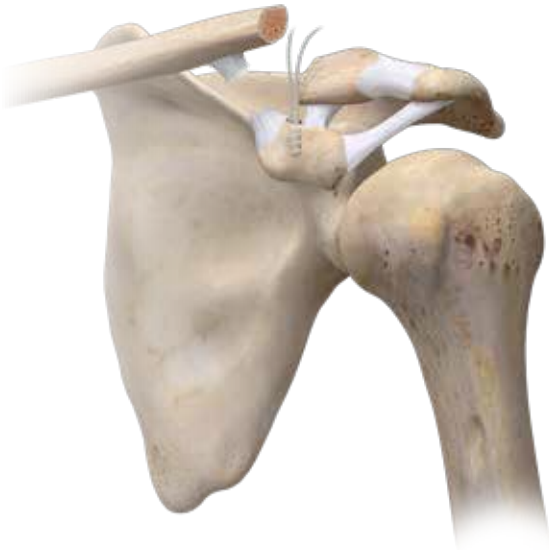


Figure 8

Design Rationale [continued]

Acumed designed a clavicle plate suture retainer that sits below the level of the plate surface within a clavicle plate slot (Figure 9). A low profile is important on the distal clavicle due to the lack of soft tissue coverage in this area. The retainer has a concave surface that allows the knot to sit deeper into the plate, minimizing the profile (Figure 10). In addition, the Acu-Sinch system allows for an alternative subclavian knot-tying technique if the surgeon wishes to have no profile on top of the plate (Figure 11).

The Acu-Sinch repair system augments plate fixation of Neer Type IIB displaced distal clavicle fractures because it helps maintain the reduction of the proximal clavicle and distal clavicle fragments by restoring the CC ligament complex and neutralizing the associated superoinferior forces. In cadaveric testing, addition of the Acu-Sinch repair system almost doubled the load-to-failure of the fixation construct.[3] There is also clinical data that concludes an anatomical locking plate combined with additional suture anchor fixation has better functional and radiographic outcomes than a plate without additional suture anchor fixation.[7] Biomechanically, the Acu-Sinch Repair System provides flexible fixation between the coracoid and the clavicle, allowing motion that naturally occurs between these two independent structures. The hook plate, on the other hand, may compromise natural shoulder motion due to the hardware hooking underneath the acromion. Hook plates generally require removal and can lead to additional complications such as hardware failure, acromion irritation, and rotator cuff tears.[2,3,4]

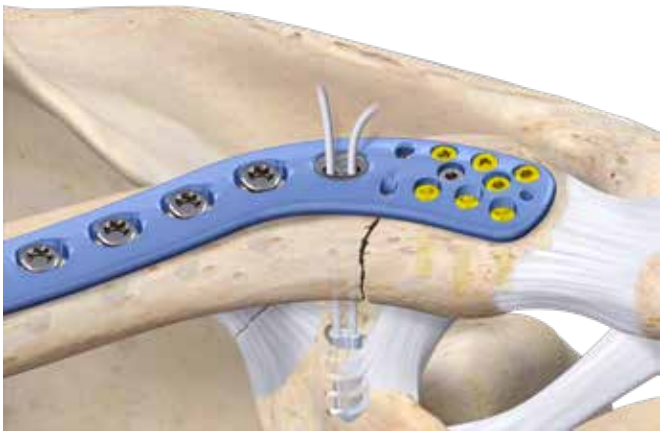


Figure 9

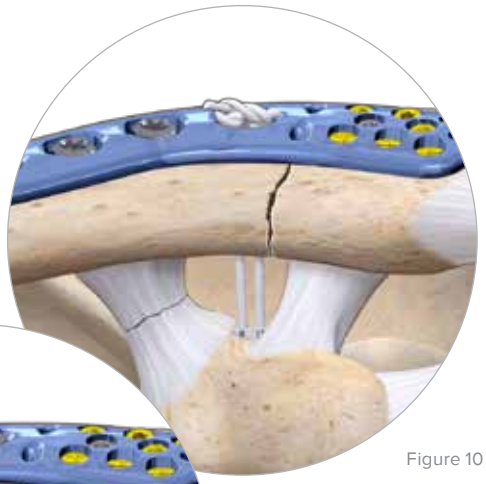


Figure 10

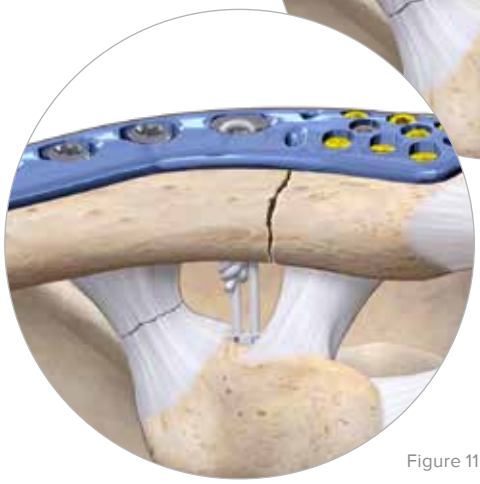


Figure 11

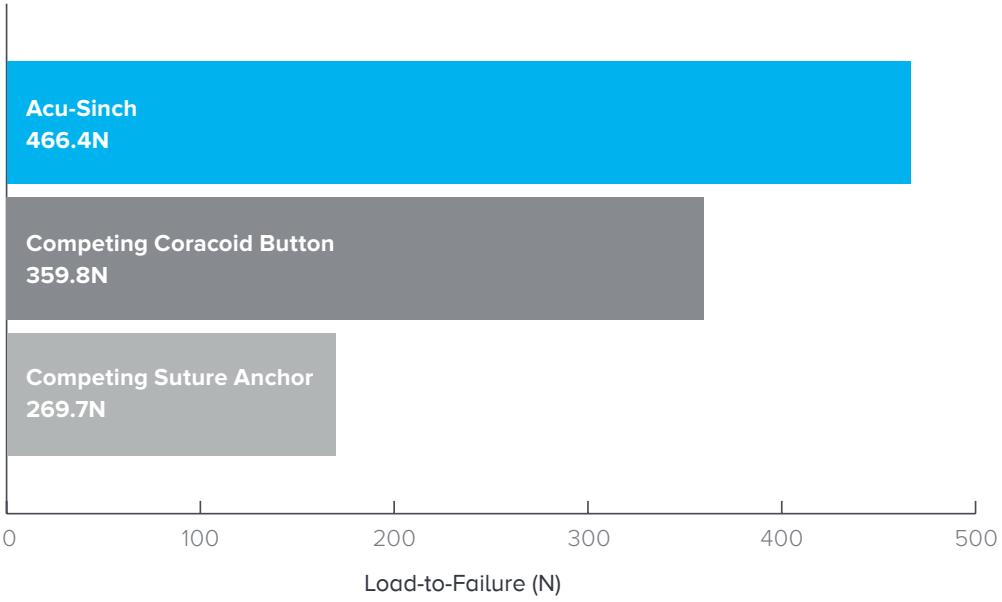
Testing/Evidence

Internal testing has shown that the Acu-Sinch Repair System is statistically comparable to competing coracoclavicular (CC) ligament repair systems.

Acu-Sinch Ultimate Strength Comparison (TR00956)[8]

- *In vitro* testing has shown the failure load of the Acu-Sinch Repair System to be at least comparable to a competing coracoid button device and higher than a leading suture anchor.
  (See graph below; comparisons were made at the 99% assurance level.)
- Furthermore, the Acu-Sinch Repair System has been designed so that in the event of excessive loading, the suture would break before the other components pull out, pull through, or cause any fracturing of the bone, which may occur in coracoid button devices. This superior mode of failure was consistent throughout testing.

Load-to-Failure – 99% Assurance Level



Acu-Sinch System Cyclic Testing (TR00816)[9]

- Acu-Sinch Repair System successfully completed fatigue testing that simulated six months of motion following a surgical procedure. The cycles tested simulated arm movement, weight, and rotation.
- Average elongation of suture construct was only 2.4 mm at the end of the cyclic testing.
- The average load-to-failure after cyclic testing remained at 88% of the construct's original load-to-failure.

Acu-Sinch Cadaveric Testing

- Acu-Sinch Repair System successfully completed cyclic testing simulating the weight of the arm swinging.[3]
- Cadaveric testing of Acu-Sinch with an Acumed locking clavicle plate showed no failures during cyclic testing.[3]
- Acu-Sinch with an Acumed locking clavicle plate retained a significantly higher load to failure following cyclic testing than the locking plate alone.[3]

System Components

Acu-Sinch Repair System

The Acu-Sinch Repair System is provided as a sterile procedure pack containing the implant and the instrumentation required to implant the device.

Anchor
Preassembled onto the Acu-Sinch Driver with the suture strands running through the driver handle

3.5 mm minor diameter

5.5 mm major diameter

12 mm in length

Drill
3.5 mm Acu-Sinch Drill with a shoulder to help ensure drilling only through the superior cortex of the coracoid

Suture Retainer
Fits into any slot in the Acumed Midshaft Superior or Distal Clavicle Plates

Concave design may minimize the potential for soft tissue irritation

FlexBraid Suture
The FlexBraid Suture is a #5, nonabsorbable, UHMWPE suture

Summary

The Acu-Sinch Repair System is an important adjunct for the treatment of Neer Type IIB distal clavicle fractures, augmenting the construct strength of Acumed's clavicle plates. It has advantages over the other common methods of fracture fixation and augmentation. The Acu-Sinch repair system does not require hardware removal like the hook plate and coracoclavicular screw techniques. In addition, it provides comparable fixation strength to bicortical fixation without drilling through both cortices of the coracoid.[4] The low-profile suture retainer is designed to integrate with the Acumed Clavicle Plating System, reducing the risk of soft tissue irritation due to knot prominence.

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Notes:

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