

RibLoc®

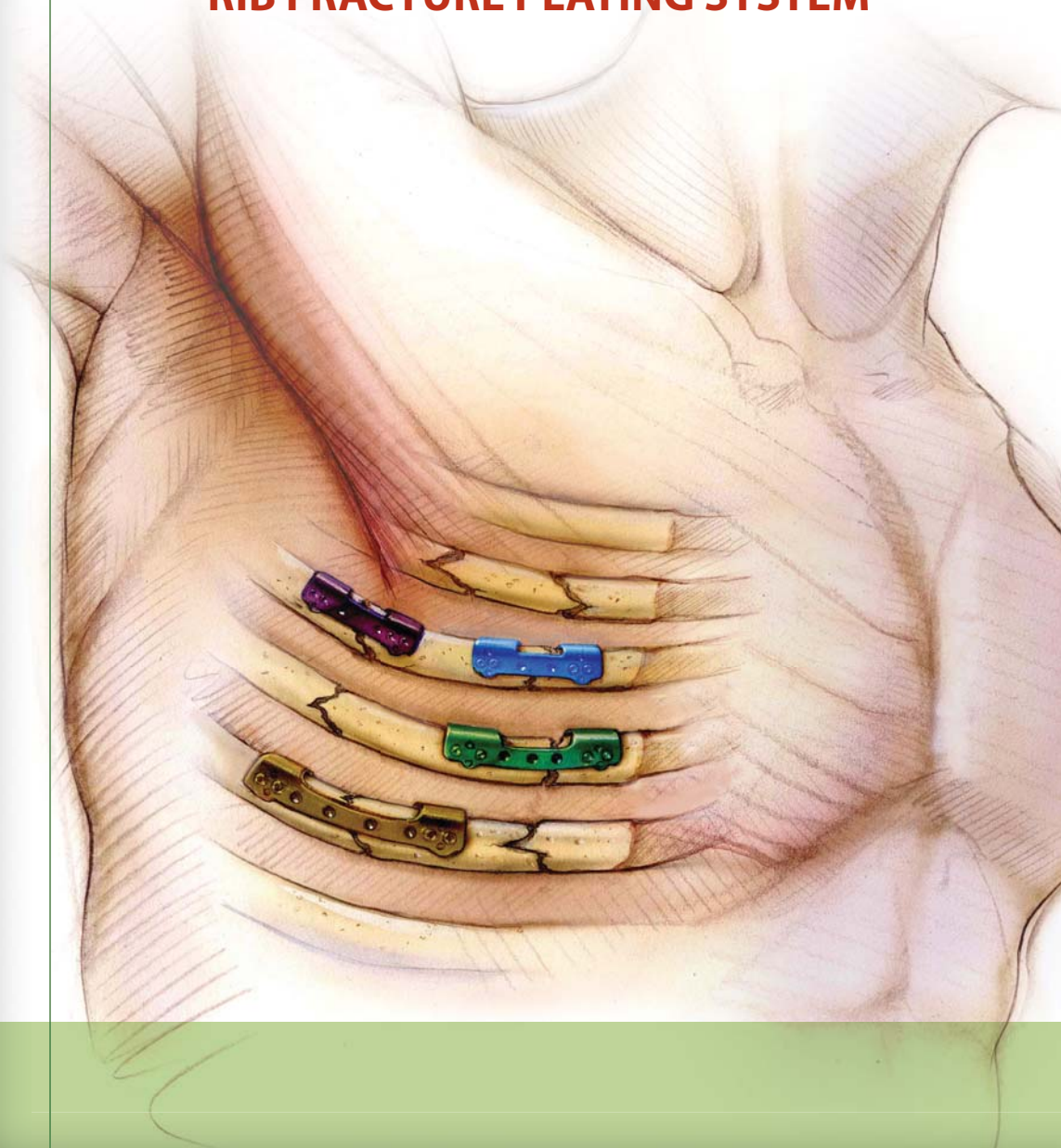
RIB FRACTURE PLATING SYSTEM

FLAIL CHEST

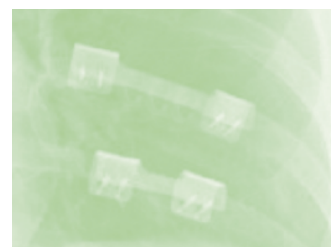
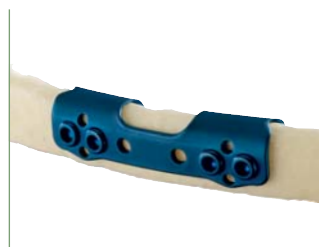
ACUTE PAIN

CHESTWALL
DEFORMITIES

FRACTURE
NON-UNION



ACUTE
Innovations®



ACUTE Innovations® is committed to providing surgeons and their patients with innovative solutions to challenging thoracic procedures.

The RibLoc® Rib Fracture Plating System is designed to provide stable fixation that is less invasive for fractures, non-unions and rib repair post thoracotomy.

Most rib fractures are treated conservatively using pain management. Some patients with severe fractures, non-unions or post thoracotomy pain benefit from open reduction internal fixation. ACUTE has developed a system, that provides stable fixation and a quick and straightforward technique.

Plating, intramedullary pins, wiring, suture, struts and staples have all been used with mixed results and no clear standard of care. Stabilizing rib fractures has been challenging for the following reasons:

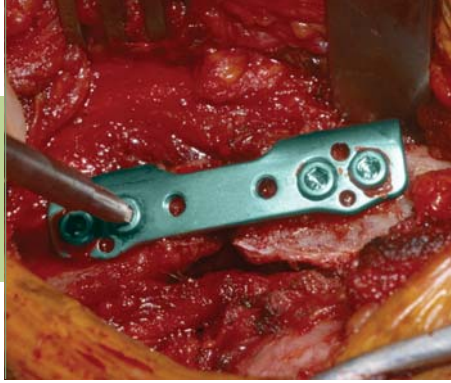
- Large incisions are needed to accommodate fixation, which leads to a more morbid procedure
- Ribs are narrow with a thin cortex that surrounds soft marrow, making reliable fixation problematic
- Fixation must endure upwards of 25,000 breathing cycles per day, including coughing
- Risk of damage to the neurovascular bundle

RibLoc®

RIB FRACTURE PLATING SYSTEM

With the RibLoc Rib Fracture Plating System, ACUTE Innovations has designed a comprehensive system of implants and instruments specifically for repairing rib fractures. The plate's unique U-shape with locking screw technology provides excellent fixation and allows for a less invasive approach. The precise targeting and instrumentation provide straightforward insertion that reduces OR time.





LESS INVASIVE

The plates in the system range from 46mm to 76mm in length. The 46mm plate requires only four screws for fixation. A 10cm incision allows multiple levels of fractures to be fixed. 61mm & 76mm plates requiring slightly larger incisions, can address oblique or complicated fracture patterns. The system provides for preservation of the neurovascular bundle.

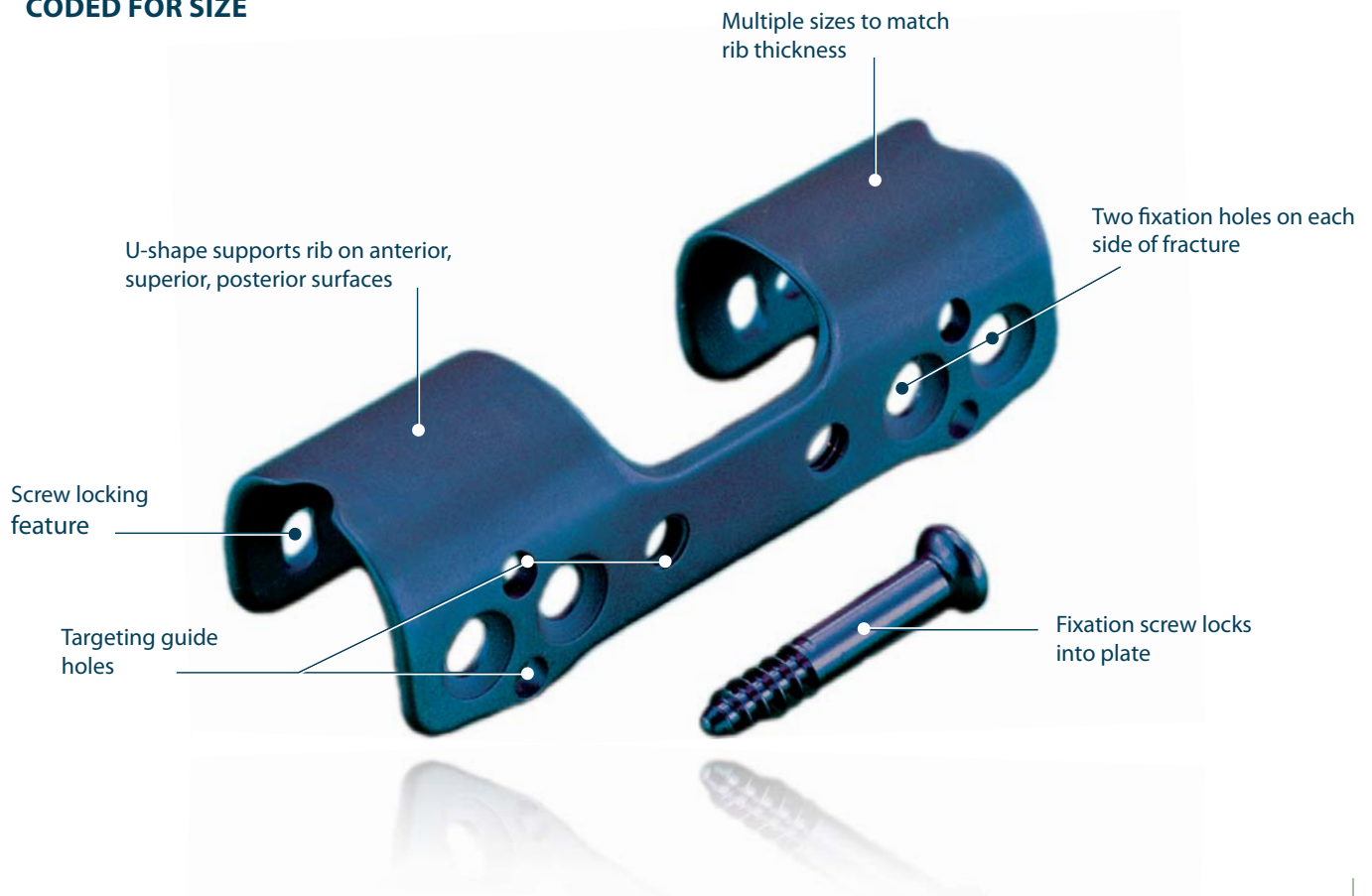
STRAIGHTFORWARD TECHNIQUE

The plates are available in four sizes to match the anterior/posterior thickness of the rib. Color coding of the plates, screws and instrumentation ensures that the correct length of screw is used for the rib. The innovative targeting guides aid the surgeon installing the plates in a straightforward, precise and repeatable manner. All of these features were carefully developed to save OR time.

STABLE FIXATION

The plate's innovative U-shape and locking screws allows fixation to be independent of bone quality and/or screw purchase in the bone. The plate supports the fracture on three surfaces and avoids the neurovascular bundle on the inferior margin. This shorter U-shape construct has been shown to be biomechanically more stable compared to a longer anterior plate¹.

PLATES AND SCREWS ARE MADE FROM TITANIUM AND COLOR CODED FOR SIZE



INDICATIONS FOR RIB FRACTURE REPAIR

FLAIL CHEST:

Studies have shown significant patient benefit by repair and stabilization through internal fixation of Rib Fractures, Flail Chest, and Chest Crushing injuries.² Stabilization of the chest wall can also help improve tidal volume, increase blood oxygenation and reduce ventilation days.

ACUTE PAIN:

Internal stabilization of selected patients has been shown to provide a decrease in pain. Patients with minimal or no extra-thoracic injuries that are experiencing pain due to rib fracture movement may be good candidates for internal stabilization.³

CHEST WALL DEFORMITIES:

Patients with significant chest wall deformities or defects have been recommended for defect repair, because of the severity of the deformity, regardless of their pulmonary status.

FRACTURE NON-UNION:

If a patient is still experiencing significant pain and movement to the associated rib fracture after the typical healing period of 6-8 weeks, they may be a strong candidate for surgical stabilization or intervention.



46mm RibLoc® Plate



61mm RibLoc® Plate



76mm RibLoc® Plate



COMMINUTED FRACTURE

DEFINITION:

A comminuted rib fracture is one in which the bone is broken, splintered or crushed into at least three separate pieces. This type of fracture can be challenging to treat due to the complexity of the break.

RECOMMENDATION:

The RibLoc's 61mm RibLoc Plates & 76mm RibLoc Plates offer intermediate locking screws that will help to provide stabilization to those additional bone fragments.



OBLIQUE FRACTURE

DEFINITION:

An oblique fracture is a slanted or angled fracture of the shaft along the bone's long axis, typically resulting in a sharp angle to the fracture.

RECOMMENDATION:

Oblique fractures of the rib can range from semi-simple or lateral fractures, to severely angular. The diversity in lengths of the 46mm, 61mm & 76mm RibLoc Plates was designed to offer significant benefit and superior stability to almost all lengths of oblique rib fractures.



SEGMENTAL FRACTURE

DEFINITION:

A segmental fracture in a bone is one in which several large bone fragments separate from the main body of a fractured bone. The ends of the fragments may pierce into the chest cavity.

RECOMMENDATION:

In situations where the segmental fractures are not in relative proximity to each other, the 46MM RibLoc Plates can easily stabilize those fractures. When there are segmental fractures located 46MM or less from one another, the 61MM & 76MM RibLoc Plates can stabilize both fractures simultaneously.



SPIRAL FRACTURE

DEFINITION:

A spiral rib fracture is helical and is a type of bone fracture which is caused by a twisting force. You may also hear spiral fractures referred to as torsion fractures, in reference to the forces involved. In a spiral fracture, the bone has been twisted apart along the bones long axis.

RECOMMENDATION:

The 61MM & 76MM RibLoc Plates can provide stabilization to these long sections of fractured rib while the intermediate screws of these plates are ideal for securing the bones chunks or fragments.

FRACTURE PATTERNS

BIOMECHANICAL TESTING

A novel rib fracture repair plating system was developed to provide durable fixation with a shorter length than standard systems and thus facilitate minimally invasive repair. We hypothesized that U-plate (RibLoc®) fixation would be at least equivalent in durability to standard anterior fixation.

STUDY DESIGN:

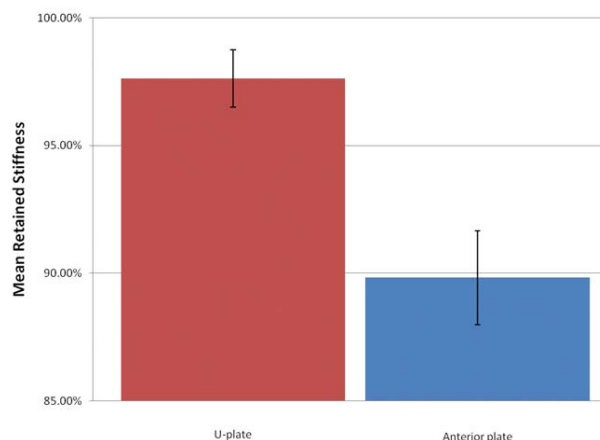
Twenty fresh frozen human cadaver ribs were first tested for intact stiffness (force/deformation). A fracture was created in the middle of each rib and was reconstructed with either the U-plate (RibLoc®) (4.6cm length) with 4 screws or an anterior locking plate (9.5cm length) with 6 screws. The reconstructed ribs were cycled 50,000 times with a load of $\pm 2N$ at 1 Hz in a simulation of the repetitive loading of deep breathing. The stiffness of the construct was measured throughout the test.

RESULTS:

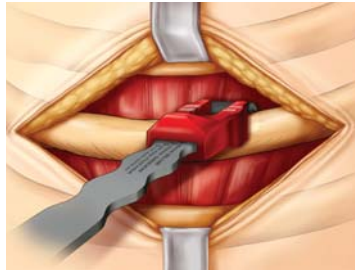
After 50,000 cycles the U-plated ribs lost a mean 3% of stiffness, while the anterior-plated ribs lost a mean 10% of stiffness ($p=0.001$).

CONCLUSIONS:

The U-plate (RibLoc®) construct retained more stiffness after repetitive loading than a standard anterior plating system with twice as much length. This is relevant because a loss of stiffness correlates with motion at the screw/bone interface, which ultimately leads to loss of fixation. If durable fixation can be achieved with a shorter plate, minimally invasive repair may be facilitated.



STEP 1: MEASURE RIB

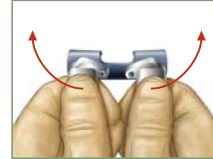


- A | Measure the anterior/posterior rib thickness near fracture using the thickness gauge. Read the size from back or top center of red sleeve. If between sizes select the larger size.
- B | Select plate size based on rib thickness.

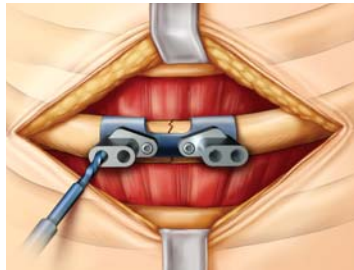
STEP 2: PREPARE THE PLATE



- A | Assemble both targeting guides to plate.
- B | Contour the plate, if necessary, by leveraging off the target guides. If more than minor adjustment is needed for a long plate (61mm or 76mm) then insert the intermediate screws into the threaded holes of the plate prior to bending.



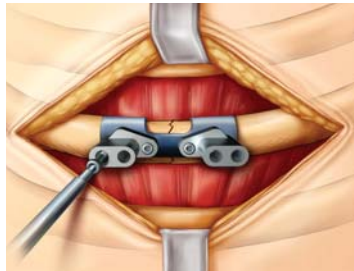
STEP 3: DRILL BONE FOR SCREW INSERTION



- A | Place plate onto rib, centered over fracture.
- B | Use drill or drill guide that matches the color of the plate.
- C | Insert drill bit into targeting guide barrel and advance until drill bottoms out on the guide.
- D | Use one drill bit per case and discard when finished.



STEP 4: INSERT SCREWS



- A | Remove drill.
- B | Insert screw through guide & tighten until groove on driver shaft is flush with entrance of targeting guide barrel.
- C | Repeat drilling and screw insertion for all four holes.



STEP 5: TIGHTEN SCREWS



- A | Remove targeting guides.
- B | Sequentially tighten each set of screws until snug, do not over tighten.

KEYS TO SUCCESS

- A | Select the correct thickness of plate for the rib
- B | Firmly attach both targeting guides to plate
- C | Use the correct drill and screw size by matching colors
- D | Tighten screws in pairs until snug, over tightening may cause stripping
- E | Use one drill per case

SURGICAL TECHNIQUE

LONG PLATE APPLICATION

DRILLING FOR 2.3mm SCREWS



- A | Thread corresponding colored drill guide into one of the center holes.
- B | Use the 2.0 mm drill bit. Insert drill through drill guide, advance until drill bottoms out on the guide.
- C | Use one drill bit per case.

INSERT SCREWS



- A | Remove drill guide.
- B | Insert screws using the 1.5mm hex driver for the 2.3mm screws.
- C | Tighten screw until snug. Caution not to over tighten.

LONG PLATE COMPONENTS



- 1 | Intermediate 2.3mm screw
- 2 | Primary locking screw(4)
- 3 | Drill guide for intermediate screw hole drilling
- 4 | 2.3mm hex driver
- 5 | Drill bit for 2.3mm screw

LONG PLATE EXTREME BENDING



- A | If more than minor contouring of long plate (61mm or 76mm) is needed then insert the screws into the threaded holes prior to bending to preserve the integrity of the threads in the plate.
- B | Remove the screws after bending. Install the plate onto the rib and follow steps above.

CLOSURE AND POST-OP PROTOCOL

A chest tube is placed through the thoroscopic port site and secured. If possible the retromuscular fatty tissue is then closed over the plate. The musculature is closed with suture. A closed suction drain is placed in the retromuscular space prior to muscle closure to prevent seroma formation. The subcutaneous tissues are closed and the skin is then closed with subcuticular stitch.

Daily chest radiographs are taken for two to three days post-operatively to confirm plate fixation stability. Intravenous antibiotics are given until the drains are removed. Patients are counseled to avoid vigorous physical activity such as lifting and sports for at least one month and follow-up chest radiographs are obtained in the outpatient setting at two weeks post-op and as needed thereafter.



21421 NW Jacobson Road
Suite 700
Hillsboro, OR 97124
866.623.4137
www.acuteinnovations.com



Distributed by:

¹ J. Rafe Sales, MD1, Thomas J. Ellis, MD1, Joel Gillard, BS, Qi Liu, MS, Joyce Chen, MD, Bruce Ham, MD, FACS, & John C. Mayberry, MD, FACS. **Biomechanical Testing of a Novel, Minimally Invasive Rib Fracture Plating System.** Journal of Trauma 2008; 64(5) 1270-1274

² H. Tanaka, T. Yukioka, Y. Yamaguti, S. Shimizu, H. Goto, H. Matsuda, S. Shimazaki. **"Surgical stabilization of internal pneumatic stabilization. A prospective randomized study of management of severe flail chest patients."** J trauma. 2002; (4):727-32; discussion 32

³ R. Nirula, J. Diaz Jr., D. Trunkey, J. Mayberry. **"Rib Fracture Repair: Technical issues, and Future Directions"** World Journal of Surgery 2009:33:14-22

Patents: 7,695,501; 7,635,365; GB2435429; GB2423935
Other Patents Pending
RBP7000G | Effective 04/2011

An **ACUMED** Company