

RibLoc® RIB FRACTURE PLATING SYSTEM
FOR THE PERSONAL ATTENTION OF THE OPERATING SURGEON

		 MediMark® Europe Sarl. 11 rue Emile ZOLA. BP 2332 38033 GRENOBLE CEDEX 2 FRANCE +33 4 76 86 43 22	 ACUTE Innovations LLC 21421 NW Jacobson Road Suite 700 Hillsboro, OR 97124 USA +1 (503) 686-7200 www.acuteinnovations.com	
				

DESCRIPTION	The Acute Innovations® RibLoc® Rib Fracture Plating System of bone plates, screws and accessories are designed to provide fixation for fractures, fusions or osteotomies of the rib.
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 Acute Innovations RibLoc Rib Fracture Plating System, including plates, screws and accessories, is designed for rib fractures, fusions or osteotomies.
CONTRAINDICATIONS	<ul style="list-style-type: none"> • Contraindications for this system are costal cartilage repair, active or latent infection, sepsis, osteoporosis, insufficient quantity or quality of bone/soft tissue, and material sensitivity. If sensitivity is suspected, tests are performed prior to implantation. • Patients who are unwilling or incapable of following postoperative care instructions are contraindicated for this device. This device is not intended for screw attachment or fixation to the posterior elements (pedicles) of the cervical or lumbar spine.
WARNINGS	<ul style="list-style-type: none"> • For safe effective use of this implant, the surgeon must be thoroughly familiar with the implant, the methods of application, instruments, and the recommended surgical technique for this device. • The device is not designed to withstand the stress of continuous weight bearing, continuous load bearing, or excessive activity. • Device breakage or damage can occur when the implant is subjected to increased loading associated with trauma, delayed union, nonunion, or incomplete healing. This type of device breakage could lead to additional surgery and device removal. • Surgeons must carefully consider the likelihood of bone union being achieved when plating a non-union since this system is only designed to withstand loading during a reasonable healing time period, and is not designed for permanent replacement of a rib. • Improper insertion of the device during implantation can increase the possibility of loosening or migration. The patient must be cautioned, preferably in writing, about the use, limitations, and possible adverse effects of this implant. These cautions include the possibility of the device or treatment failing as a result of loose fixation and/or loosening, stress, excessive activity, or continuous weight bearing or continuous load bearing, particularly if the implant experiences increased loads due to delayed union, nonunion, or incomplete healing, and the possibility of nerve or soft tissue damage related to either surgical trauma or the presence of the implant. The patient must be warned that failure to follow postoperative care instructions can cause the implant and/or treatment to fail
PRECAUTIONS	<ul style="list-style-type: none"> • An implant shall never be reused. Previous stresses may have created imperfections, which can lead to a device failure. • The drill bit shall be discarded after each surgery since after normal use the drill bit can become too dull to perform as intended. Instruments should be inspected for wear or damage prior to usage. • Protect implants against scratching and nicking, as such stress concentrations can lead to failure. Particular care should be paid to hex drivers, drill bits and instruments used for implant insertion.
ADVERSE EFFECTS	<ul style="list-style-type: none"> • Possible adverse affects are pain, discomfort, or abnormal sensations due to the presence of an implant. • Implant fracture, migration and/or loosening may occur due to excessive activity, prolonged loading upon the device, incomplete healing, or excessive force exerted on the implant during insertion. • Metal sensitivity or histological or allergic reaction resulting from implantation of a foreign material may occur. Nerve or soft tissue damage, necrosis of bone or bone resorption, necrosis of the tissue or inadequate healing may result from the presence of an implant or due to surgical trauma.
STORAGE INSTRUCTIONS	Store in a cool dry place and keep away from direct sunlight. Prior to use, inspect instruments and tray for signs of tampering.

CAUTION: For professional use ONLY!

CLEANING

Acute Innovations surgical trays must be thoroughly cleaned before reuse. Decontamination should occur immediately after completion of the surgical procedure. Excess blood or debris should be wiped off to prevent it from drying to the surface. Using an enzymatic cleaning product, prepare the cleaning solution according to the manufacturer's instructions. Avoid prolonged soaking, greater than 5 minutes, and use a soft bristle brush to remove any detergent residue. Instruments with lumens should be held under water ensuring the lumen is flushed with water. Use an ultrasonic cleaner with deionized water for 5 minutes and then rinse in water. Gently wipe down with a dry clean cloth then air dry. Note: Even surgical instruments from high grade stainless steel must be dried to prevent rust formation, and all devices in the tray must be inspected for cleanliness and wear before sterilization.

STERILITY

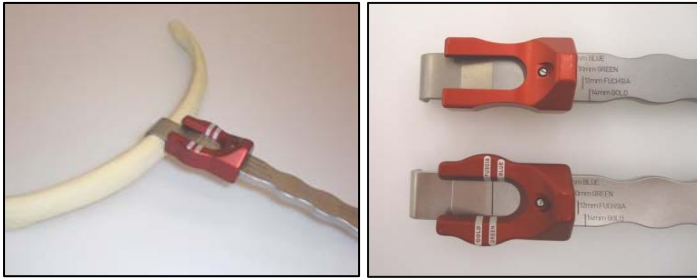
This product is provided non-sterile. Sterilization may be performed using one of the following methods outlined below. Please consider your sterilization equipment manufacturer's written instructions for the specific sterilizer and load configuration used. Recommendations found in current AORN "Recommended Practices for Sterilization in Perioperative Practice Settings" and ANSI/AAMI ST79: 2010 – Comprehensive Guide to Steam Sterilization and Sterility Assurance in Healthcare Facilities should be followed.

System tray part #	System tray description	Pre-Vacuum Autoclave			Gravity Displacement Autoclave		
		Temp	Time	Dry Time	Temp	Time	Dry Time
RBP4000	7 x 11 x 1.5 inch plastic (18 x 28 x 4 cm)	270°F (132°C)	15 min	30 min	270°F (132°C)	30 min	30 min
RBP4010	10 x 22 x 3 inch metal (25 x 56 x 8 cm)	270°F (132°C)	4 min	20 min	270°F (132°C)	30 min	50 min
		275°F (135°C)	3 min	16 min			

CAUTION: For professional use ONLY!

RibLoc® Surgical Technique

Step 1: Measure Rib



- A. Measure the anterior/posterior rib thickness near the fracture using the thickness gauge. Read the size from either the back or top center of red sleeve (gauges vary by tray – see above). If in-between sizes select the larger size.
- B. Select plate size/color based on rib thickness.

Step 2: Prepare the Plate



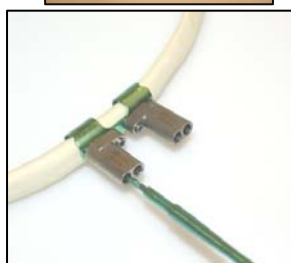
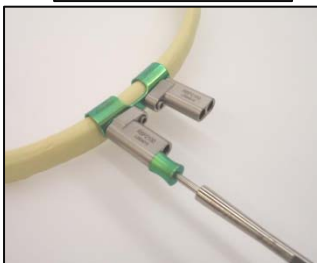
- A. Assemble both targeting guides to the plate.
- B. Contour the plate, if necessary, by leveraging off the targeting guides. If more than minor adjustment is needed for a long plate (61mm or 76mm) then insert the intermediate screws into the threaded holes of the plate prior to bending. (See page 5)

Step 3: Drill

2.7mm Drill & Guide



One-Piece 2.7mm Drill

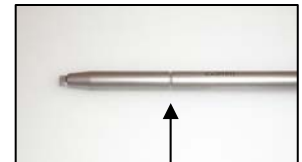
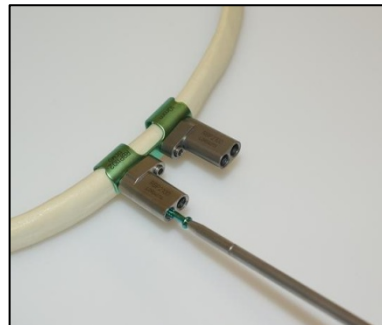


- A. Place plate onto the rib, centered over the fracture.
- B. Use drill or guide that matches the plate color.
- C. Insert drill bit into targeting guide barrel and advance until drill bottoms out on the guide.
- D. Use one drill bit per case and discard when finished.

Note:

- 7 x 11 x 1.5 inch (18 x 28 x 4 cm) Plastic RibLoc® Tray includes separate 2.7mm Drills & Guides
- 10 x 22 x 3 inch (25 x 56 x 8 cm) Metal RibLoc® Tray includes one-piece 2.7mm Drills

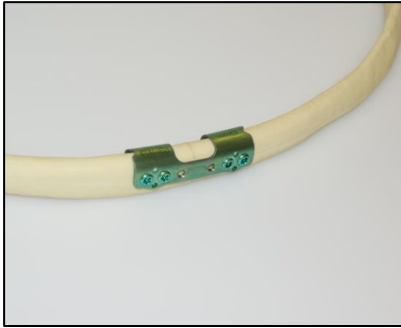
Step 4: Insert Screws



- A. Remove drill.
- B. Insert screw through targeting 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.

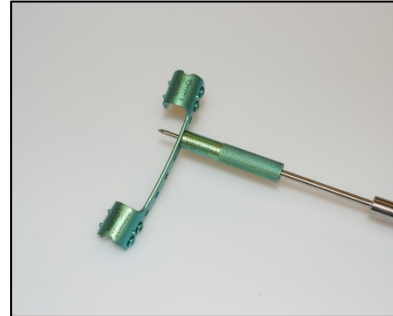
CAUTION: For professional use ONLY!

Step 5: Tighten Screws



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

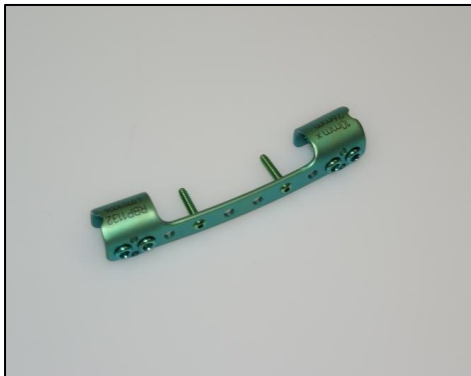
**Step 6: Drilling 2.3mm screws
Long plate application**



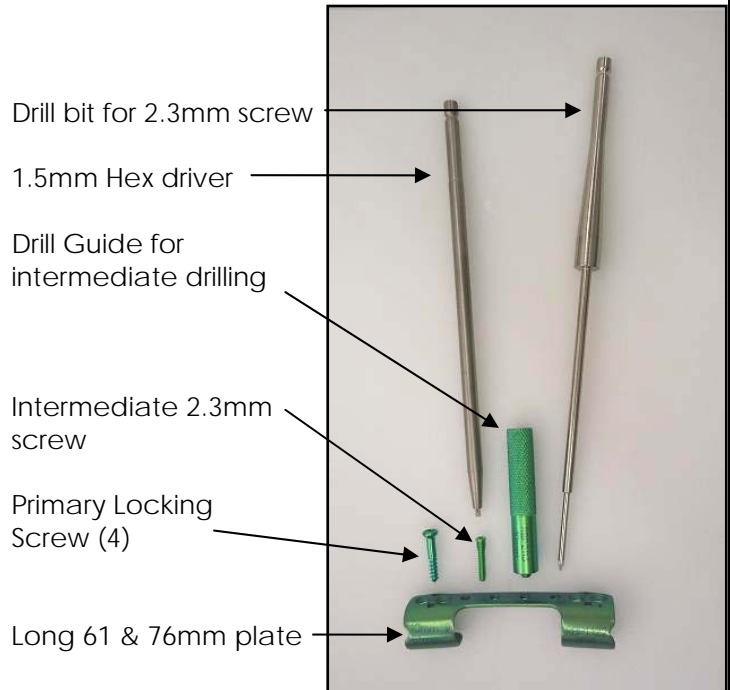
- A. Thread corresponding colored drill guide into one of the center holes.
- B. Using the 2.0 mm drill bit, drill through drill guide, and advance until drill bottoms out on the guide.
- C. Use one drill bit per case.

**Step 7: Insert Screws
Long plate application**

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



Long Plate Components



CAUTION: For professional use ONLY!

Keys to Success:

- A. Select the correct size/color of plate for the rib thickness.
- 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.

Long Plate Extreme Bending:



- A. If more than minor contouring of a 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.



Plate Removal

Once bone healing has occurred the plates can be removed using the RibLoc Surgical Set. Remove the screws using the hex driver tips and then remove the plate.

Please contact your local sales representative or the company directly to arrange for returning any removed product for evaluation.

1-866-623-4137
WWW.ACUTEINNOVATIONS.COM