ACUTE Innovations® LLC 21421 NW Jacobson Road, Suite 700, Hillsboro, OR 97124
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RibLoc® RIB FRACTURE PLATING SYSTEM

FOR THE PERSONAL ATTENTION OF THE OPERATING SURGEON

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: 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: 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 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 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 weight bearing or 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.

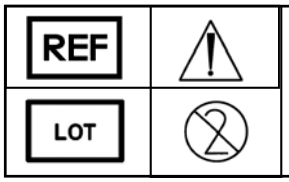
PRECAUTIONS: An implant shall never be reused. Previous stresses may have created imperfections, which can lead to a device failure. The drill bit shall be discarded after each surgery. Instruments should be inspected for wear or damage prior to usage. Protect implants against scratching and nicking, 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: 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.

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 ST46: 2002 – 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)	15 min	30 min	270°F (132°C)	30 min	50 min

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.



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RibLoc® Surgical Technique

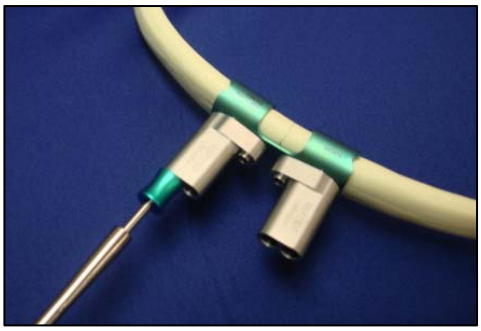
Step 1: Measure Rib Thickness

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

Step 2: Prepare the Plate

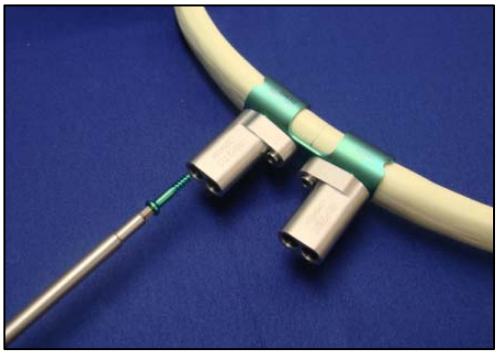
A. Assemble both targeting guides to plate
B. Contour the plate, if necessary, by leveraging off the target guides. If more than minor adjustment is needed for a long plate (61mm or 76mm) then insert the intermediate screws into the threaded holes of the plate prior to bending (see page 3)

Step 3: Drill



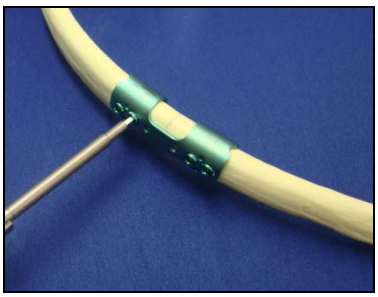
A. Place plate onto rib, centered over fracture
B. Use drill guide that matches plate color
C. Insert drill guide into targeting guide barrel
D. Insert drill thru drill guide, advance until drill bottoms out on the guide
E. Use one drill bit per case and discard when finished

Step 4: Insert Screws



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

Step 5: Tighten Screws



A. Remove targeting guides
B. Sequentially tighten each set of screws until snug, don't 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 guide and screw size by matching colors
D. Tighten screws in pairs until snug, over tightening may cause stripping
E. Use one drill per case

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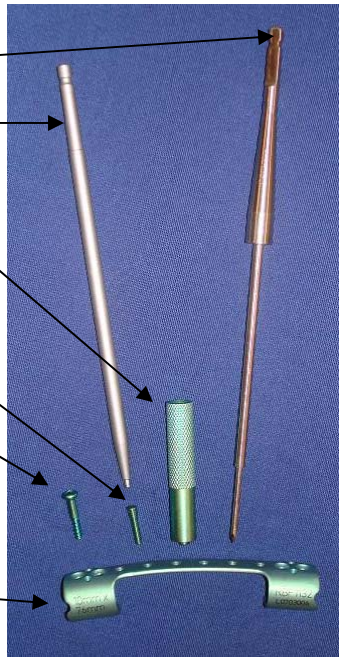
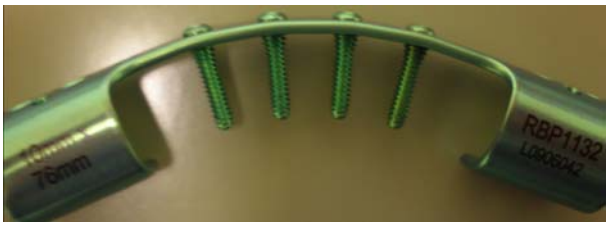
Long Plate Components



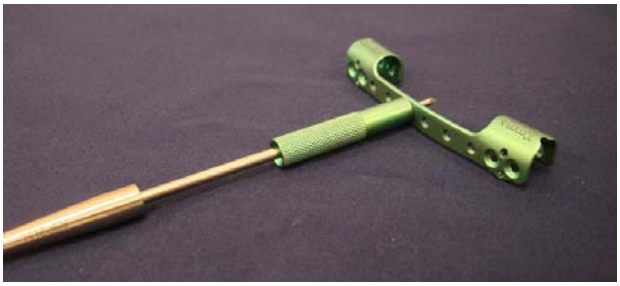
Contouring Long Plates



A. If more than minor contouring of the long plate is needed then insert the screws into the threaded holes prior to bending to preserve the integrity of the threads in the plate

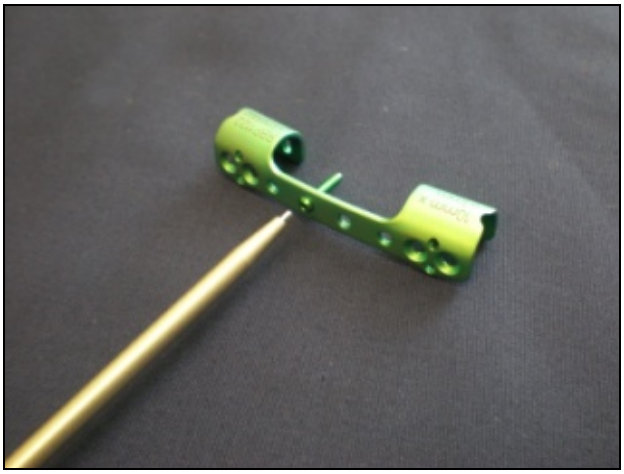
B. Remove the screws after bending, install the plate onto the rib and follow the remaining steps

Step 6: Drilling for 2.3mm screws



A. Thread corresponding colored drill guide into one of the central holes
B. Using 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

Step 7: Insert Screws



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