

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

<b>DESCRIPTION</b>	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.
<b>INFORMATION FOR USE</b>	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.
<b>INDICATIONS</b>	The Acute Innovations RibLoc Rib Fracture Plating System, including plates, screws and accessories, is designed for rib fractures, fusions or osteotomies.
<b>CONTRAINDICATIONS</b>	<ul style="list-style-type: none"> <li>• 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.</li> <li>• 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.</li> </ul>
<b>WARNINGS</b>	<ul style="list-style-type: none"> <li>• 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.</li> <li>• The device is not designed to withstand the stress of continuous weight bearing, continuous load bearing, or excessive activity.</li> <li>• 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.</li> <li>• 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.</li> <li>• Improper insertion of the device during implantation can increase the possibility of loosening or migration.</li> <li>• 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 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.</li> </ul>
<b>PRECAUTIONS</b>	<ul style="list-style-type: none"> <li>• An implant shall never be reused. Previous stresses may have created imperfections which can lead to a device failure.</li> <li>• 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.</li> <li>• During use of a drill, while cutting or installing plates and inserting screws, take necessary precautions when in close proximity to sharp edges and points, and be aware that metal debris/fragments can be generated. Remove any observed debris/fragments from the surgical field with suction or manually and dispose of appropriately.</li> <li>• 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.</li> <li>• Over tightening of screws can lead to the screws or hex driver being stripped.</li> </ul>
<b>ADVERSE EFFECTS</b>	<ul style="list-style-type: none"> <li>• Possible adverse affects are pain, discomfort, or abnormal sensations due to the presence of an implant.</li> <li>• 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.</li> <li>• 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.</li> </ul>

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<b>REPROCESSING INFORMATION</b>	
<b>PRECAUTIONS</b>	<ul style="list-style-type: none"> <li>• ACUTE Innovations products are provided non-sterile and require cleaning and sterilization prior to use.</li> <li>• Any device contaminated with blood, tissue or other bodily fluids should be handled according to hospital protocol. Personal protective equipment should be utilized when working with contaminated or potentially contaminated devices.</li> <li>• In accordance with AORN and AAMI guidelines, ACUTE Innovations does not recommend or support immediate use steam sterilization (also known as flash sterilization) of implants.</li> <li>• Lumens, channels, crevices, joints, mating surfaces and threads require particular attention during cleaning. Flood with copious amounts of cleaning solutions using a syringe to flush out soil.</li> <li>• Caution should be exercised when handling instruments with sharp points or cutting edges.</li> <li>• Do not use metal brushes or scouring pads during manual cleaning process.</li> <li>• The use of neutral pH enzymatic and cleaning agents is recommended. If alkaline cleaning agents are used, neutralize and thoroughly rinse from device.</li> </ul>
<b>LIMITATIONS ON REPROCESSING</b>	<ul style="list-style-type: none"> <li>• Instruments are designed to withstand multiple cleaning and sterilization cycles.</li> <li>• Instrument end of life is normally determined by damage and wear due to use. Instruments and implants should be inspected after cleaning for damage such as corrosion, scratches and wear.</li> <li>• Damaged instruments should be returned to ACUTE Innovations for replacement.</li> </ul>
<b>INSTRUCTIONS</b>	
<b>Point of use:</b>	<ul style="list-style-type: none"> <li>• Remove biological material from the instruments with a lint-free disposable wipe.</li> <li>• Do not allow contamination to dry on the device prior to cleaning/reprocessing.</li> <li>• It is recommended that instruments are decontaminated as soon as possible following use.</li> </ul>
<b>Preparation for decontamination:</b>	<ul style="list-style-type: none"> <li>• Disassembly of devices is not required.</li> <li>• Rinse instruments in warm (not hot) running water to remove blood, body fluids and tissue remaining. Transport devices (instruments and implants) in the tray provided.</li> </ul>
<b>Cleaning: Manual</b>	<p><u>Equipment:</u> Nylon soft bristle scrub brush (M16), pipe cleaner (2.7mm), lint-free cloth, irrigation syringe, warm running tap water and reverse osmosis or deionized (RO/DI) water, bath ultrasonic cleaner.</p> <p><u>Solutions:</u> Neutral pH (&lt;8.5) low foaming enzymatic detergent solution (e.g., EnzoI®).</p> <ol style="list-style-type: none"> <li>1. Rinse soil from devices with warm running tap water.</li> <li>2. Prepare enzymatic detergents solution at the dilution recommended by the manufacturer in warm tap water. Fresh solutions should be prepared when existing solutions become contaminated.</li> <li>3. Submerge the devices in enzymatic solution and soak for a minimum of 3 minutes but no more than 5 minutes.</li> <li>4. Scrub with a soft bristle brush to remove all visible soil from the surfaces, crevices and channels. Rotate the devices while scrubbing paying particular attention to lumens, crevices, channels and hard to reach areas. Ensure that hinged, articulating and threaded instruments are cleaned in both open and closed positions.</li> <li>5. Remove the devices from the enzymatic solution and place in RO/DI water in an ultrasonic unit and sonicate for five (5) minutes.</li> <li>6. Rinse each device with ambient tap water and holding devices under water for 30 seconds to ensure lumens, crevices and channels are flushed with water. Use an irrigation syringe to flush water into lumens, crevices and mating surfaces.</li> </ol>
<b>Drying</b>	<ul style="list-style-type: none"> <li>• Remove devices from water and wipe devices dry with a clean, lint-free cloth then allow to air dry.</li> <li>• Load devices into the provided tray according to the diagram on the tray bottom. For automated processing, transfer the trays to the washer/disinfector.</li> </ul>

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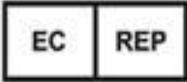
<p><b>Cleaning: Automated</b></p> <p><u>Equipment:</u> An automated washer or washer /disinfector that has been installed and qualified to ISO 15883-1 and ISO 15883-2.</p> <p><u>Solutions:</u> Prepare solutions per manufacturer's instructions. Use Neutral pH (&lt;8.5) low foaming, enzymatic wash solution (e.g., Enzo<sup>®</sup>), neutral pH, low foaming wash solution (e.g., Prolystica Neutral 2x), instrument lubricant (e.g., Ultra Clean Surgical Milk) if W/D is capable.</p> <p><b>NOTE:</b> Explicitly follow washer/disinfector manufacturer's instructions for loading.</p> <p><b>Motor Speed:</b> High</p>								
		<b>Phase</b>	<b>Recirculation Time</b>	<b>Temperature</b>	<b>Detergent Type and Concentration</b> *or equivalent			
		Pre-wash	2:00 minutes	Cold tap water	N/A			
		Enzyme Wash	4:00 minutes	Hot tap water	*Enzol <sup>®</sup> 1 oz./gal			
		Wash	2:00 minutes	65.5°C (150°F)	*Prolystica 2x Neutral 1/8 oz./gal			
		Rinse	15 seconds	Hot tap water	N/A			
		Drying	6:00 minutes	98.9°C (210°F)	N/A			
		<ul style="list-style-type: none"> <li>Inspect device under normal lighting to ensure soil has been removed. If any visible soil is seen, repeat cleaning process.</li> <li>Whenever possible, using a washer/disinfector with a dedicated disinfection cycle is preferable.</li> </ul> <p><b>NOTE:</b> Surgical instruments made from stainless steel can corrode and must be dried to prevent rust formation.</p>						
<p><b>Maintenance, Inspection, and Testing:</b></p>		<ul style="list-style-type: none"> <li>Inspect the clean and dried devices for wear or damage prior to sterilization. If any damage or corrosion is observed, contact ACUTE Innovations for a replacement.</li> <li>Some instruments with articulations, joints, mating surfaces and screws require lubrication following cleaning. Only water soluble, non-silicone, steam permeable lubricants (e.g., Ultra Clean Spray Lube or Surgical Milk) intended for surgical instruments should be used. Some automated washer/disinfectors have a cycle that includes a lubricant. If a washer/disinfector includes a lubricant, manual application of a lubricant is not necessary.</li> <li>Manually spray a small amount of lubricant onto the instruments at articulation areas, where mated surfaces make contact, on exposed screw threads and at hinges. Fully submerging instruments in lubricant is never advised. Actuate devices to ensure lubricant is distributed over the surfaces. If the instruments are difficult to actuate, threads bind or components do not move smoothly over mating surfaces, contact ACUTE Innovations for a replacement.</li> <li>Allow lubricated instruments to air dry prior to sterilization.</li> </ul>						
<p><b>Packaging:</b></p>		<ul style="list-style-type: none"> <li>The instruments should be replaced in appropriate locations in the accompanying surgical tray.</li> <li>Wrap the tray in two layers of 1 ply polypropylene wrap (e.g., Kinguard KC600) and place in a steam sterilizer.</li> </ul>						
<p><b>Sterilization:</b></p>		<ul style="list-style-type: none"> <li>Sterilization may be performed using one of the following methods outlined below. Explicitly follow your sterilization equipment manufacturer's written instructions for the specific sterilizer and load configuration used.</li> </ul>						
System Tray Part Number	System Tray Description	Pre-Vacuum Autoclave			Gravity Displacement Autoclave			
		Temp	Time	Dry Time	Temp	Time	Dry Time	
RBP4000	18 x 28 x 4 cm (7 x 11 x 1.5 inch) Plastic tray	132°C (270°F)	15 min	30 min	132°C (270°F)	30 min	30 min	
RBP4010	25 x 56 x 8 cm (10 x 22 x 3 inch) Metal tray	132°C (270°F)	4 min	20 min	132°C (270°F)	20 min	70 min	
		135°C (275°F)	3 min	16 min				

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<b>Storage:</b>	Remove surgical tray from the autoclave and store at ambient temperature and humidity, keep away from direct sunlight. Prior to use, inspect tray and contents for wear, damage or tampering.
<b>Manufacturer Contact:</b>	ACUTE Innovations® Customer Service (866) 623-4137 Toll Free (USA) +1 (503) 686-7200 International www.acuteinnovations.com customerservice@acuteinnovations.com

*The instructions provided above have been validated by ACUTE Innovations for the listed devices as CAPABLE of being prepared for reuse. It is the responsibility of the healthcare facility to ensure the reprocessing as actually performed using the equipment, materials and personnel in the reprocessing facility achieve the desired result. This normally requires validation and routine monitoring of the processes.*

	Part Number		Caution, consult instructions for use.		ACUTE Innovations® LLC 21421 NW Jacobson Road Suite 700 Hillsboro, OR 97124 USA +1 (503) 686-7200 International (866) 623-4137 Toll Free USA www.acuteinnovations.com
	Lot Number		Do not re-use		
<b>Patents:</b> US – 7,635,365; 7,695,501; 8,632,573 UK – GB2423935; GB2435429 JP – JP 4808621; JP 5314074 EU – EP 1667590 Other patents pending		 0473		 MediMark Europe Sarl. 11 rue Emile Zola. BP 2332 F- 38033 Grenoble Cedex 2 France Tel: +33 476 86 43 22 www.medimark-europe.com	

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# RibLoc® Surgical Technique

## Step 1: Measure Rib



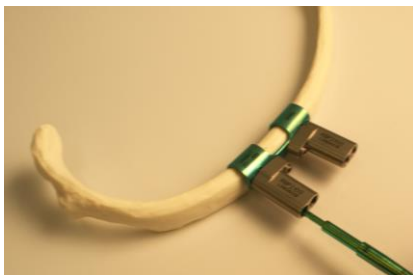
- A. Measure the anterior/posterior rib thickness near the fracture using the thickness gauge. Read the size from either the back or top center of red sleeve. If in-between sizes select the larger size.
- B. Select plate size/color based on rib thickness.

## 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 7)

## Step 3: Drill

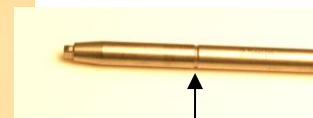
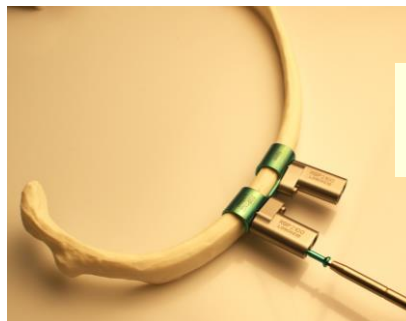


- A. Place plate onto the rib, centered over the fracture.
- B. Use drill that matches the plate color.
- C. Insert drill bit into targeting guide barrel and advance until drill bottoms out on the guide.
- D. Use one drill bit per case and discard when finished.

**Note:**

- 7 x 11 x 1.5 inch (18 x 28 x 4 cm) Plastic RibLoc® Tray (PN: RPB4000) includes separate 2.7mm Drills & Guides
- 10 x 22 x 3 inch (25 x 56 x 8 cm) Metal RibLoc® Tray (PN: RBP4010) 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 near flush with entrance of targeting guide barrel until screws are snug.
- C. Repeat drilling and screw insertion for all four holes.

**Caution: Do not over tighten screws.**

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**Step 5: Tighten Screws**



- A. Remove the targeting guides and confirm screws are fully seated and flush with the front of the plate.
- 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.

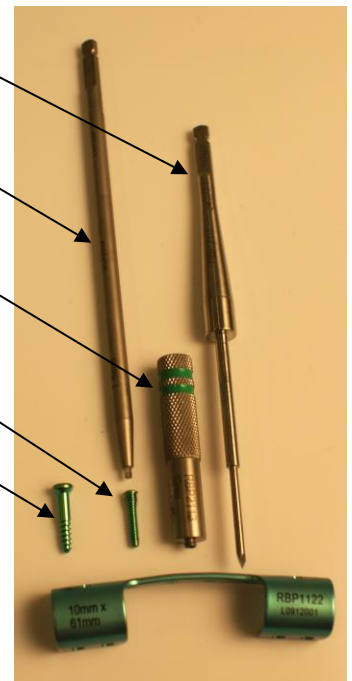
**Step 7: Insert Screws  
Long plate application**

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



**Long Plate Components**

- A. 2.0mm Intermediate drill bit
- B. 1.5mm hex driver
- C. Drill guide for Intermediate Screw hole drilling
- D. Intermediate 2.3mm screw
- E. Primary locking screw



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**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.



Caution: Avoid repeated bending as this weakens the plate.

**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.

A screw removal set is also available upon request.

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

**+1 (503) 686-7200 International**  
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