AcuTie® II Sternal Closure System

FOR THE PERSONAL ATTENTION OF THE OPERATING SURGEON

INSTRUCTIONS FOR USE

DESCRIPTION	The ACUTE Innovations® AcuTie® II Sternal Closure System consists of plates and accessories that provide a cerclage-based fixation following sternotomies and sternal fractures.
INFORMATION FOR USE	The effective use of AcuTie II plates depends upon the surgeon's knowledge of the patient's anatomy and bone physiology. The surgeon must determine the wire tension and optimum plate position that best meets the patient's requirements for close sternal approximation and firm seating with adequate support.
INDICATIONS	The ACUTE Innovations® AcuTie II Sternal Fixation System is intended for use in the stabilization and fixation of fractures of the anterior chest wall, including sternal fixation following sternotomy and sternal reconstructive surgical procedures.
CONTRAINDICATIONS	• Costal cartilage repair, active or latent infection, sepsis, osteoporosis, insufficient quantity or quality of bone/soft tissue, and material sensitivity. • If metal sensitivity is suspected, perform testing prior to implantation. • Patients who are unwilling or incapable of following postoperative care instructions are contraindicated for this device.
WARNINGS	• For safe and effective use of this device, the surgeon must be thoroughly familiar with the implant, the methods of application, the instruments, and the recommended surgical technique for this device. • Surgeons must carefully consider the likelihood of tissue healing being achieved when plating sternotomies. This system is only designed to withstand loading during a reasonable healing time period and is not designed for permanent tissue replacement. • The patient must be cautioned, preferably in writing, about the use, limitations, and potential adverse effects of this implant. These include the possibility of the device or treatment failing as a result of loosening due to abnormal stresses, excessive physical activity, or continuous load bearing past the normal healing time. • Implant failure can occur when the device experiences increased loads due to delayed union, nonunion, or incomplete bone healing. Implant failure could lead to additional surgery and device removal. • Improper insertion of the device during implantation can increase the possibility of tear through, loosening or migration. • Reentry after device implantation may take longer compared to twisted wire. To ensure efficient reentry, follow the instructions contained in the attached Technique. • As with any surgical implantation there is a possibility of nerve or soft tissue damage related to either surgical trauma or the presence of the implant. • The ACUTE Innovations AcuTie II System has not been evaluated for safety and compatibility in the Magnetic Resonance Imaging (MRI) environment including heating or migration.
PRECAUTIONS	• An implant is a single use device and must never be reused. • Instruments should be inspected for wear or damage prior to usage. • Over-lubrication of the wire tensioning instrument may result in equalizer shuttle back travel during use. • Caution should be taken to not over tension the surgical wire as this can cause damage to the sternum. • Use caution when holding the tensioning instrument on or near the equalizer shuttle (see Figure 1) while wire is under tension. Spring back of the equalizer arm can occur suddenly due to wire breakage or incorrect wire being cut. • Stainless Steel surgical wire ends and AcuTie II cleats are potentially sharp and caution should be taken to avoid puncture injuries and glove tears. It is recommended that forceps or needle drivers are used to hold the plate and thread the surgical wire. • The AcuTie II plate can only be used with USP #5-7 stainless steel wire.
ADVERSE EFFECTS	• Possible adverse effects include 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. These types of adverse effects could lead to additional surgery and device removal. • 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. • A histological or allergic reaction resulting from the implantation of a foreign material in the body may occur. • The implant contains metal that may induce an allergic reaction in patients with a known nickel allergy, or with an allergy or sensitivity to other plate metallic components.

ACUTIE II REPROCESSING INFORMATION

PRECAUTIONS	• ACUTE Innovations products are provided non-sterile and require cleaning and sterilization prior to use. • 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. • In accordance with AORN and AAMI guidelines, ACUTE Innovations does not recommend or support the use of immediate use steam sterilization (also known as flash sterilization) of implants. • 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 and use a nylon brush to remove gross soil. • Caution should be exercised when handling instruments or implants with sharp points or cutting edges. • Do not use metal brushes or scouring pads during manual cleaning process. • For exposed springs and lead screw threads (**Figure 1**), flood the crevices with copious amounts of cleaning solutions to flush out soil. Scrub the instruments with a scrub brush to remove all visible soil from surface and crevices. • The use of neutral pH enzymatic and cleaning agents is recommended. If alkaline cleaning agents are used, neutralize and thoroughly rinse from device.
LIMITATIONS ON REPROCESSING	• The instruments are designed to withstand multiple cleaning and sterilization cycles. • 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. • Damaged instruments should be returned to ACUTE Innovations for replacement.

REPROCESSING INSTRUCTIONS

Point of use:	• Remove biological material from the instruments with a lint-free disposable wipe. • Do not allow contamination to dry on the device prior to cleaning/reprocessing. • It is recommended that instruments are decontaminated as soon as possible following use.
Preparation for decontamination:	• Disassembly of the instrumentation is not required. • It is recommended that instruments are decontaminated as soon as practical following use. • 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.
Cleaning: Manual	Equipment: 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. Solutions: Neutral pH (<8.5) low foaming enzymatic detergent solution (e.g., Enzol®). 1. Rinse soil from devices with warm running tap water and irrigation syringe. 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. 3. Submerge the devices in enzymatic solution and soak for a minimum of 3 minutes but no more than 5 minutes. 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. 5. Remove the devices from the enzymatic solution and place in RO/DI water in an ultrasonic unit and sonicate for five (5) minutes. 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.
Drying	• Remove devices from water and wipe devices dry with a clean, lint-free cloth then allow to air dry. • Load devices into the provided tray according to the diagram on the tray bottom. • For automated processing, transfer the trays to the washer/disinfector.
Cleaning: Automated	Equipment: An automated washer-disinfector that has been installed and qualified to ISO 15883-1 and ISO 15883-2. Solutions: Prepare solutions per manufacturer's instructions. Use Neutral pH (<8.5) low foaming, enzymatic wash solution (e.g., Enzol®), neutral pH, low foaming wash solution (e.g., Prolystica Neutral 2x), instrument lubricant (e.g., Ultra Clean Surgical Milk) if capable. **NOTE**: Explicitly follow washer/disinfector manufacturer's instructions for loading. **Motor Speed: High**

Cleaning: Automated Washer/Disinfector Cycle Parameters

Phase	*Recirculation Time*	*Temperature*	*Detergent Type and Concentration* *or equivalent
Pre-wash	2:00 minutes	Cold tap water	N/A
Enzyme Wash	4:00 minutes	Hot tap water	*Enzol® 1 oz/gal
Wash	2:00 minutes	65.5ºC (150ºF)	*Prolystica 2x Neutral 1/8 oz/gal
Rinse	15 seconds	Hot tap water	N/A
Drying	6:00 minutes	98.9ºC (210ºF)	N/A

- Inspect device under normal lighting to ensure soil has been removed. If any visible soil is seen, repeat cleaning process.

  NOTE: Surgical instruments made from stainless steel can corrode and must be dried to prevent rust formation.

Maintenance, Inspection, and Testing:

- 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.
- 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. If a washer/ disinfector includes a lubrication cycle, manual application of a lubricant may not be necessary.
- If the instruments are difficult to actuate, threads bind or components do not move smoothly over mating surfaces, contact ACUTE Innovations for replacement.
- Allow lubricated instruments to air dry prior to sterilization.

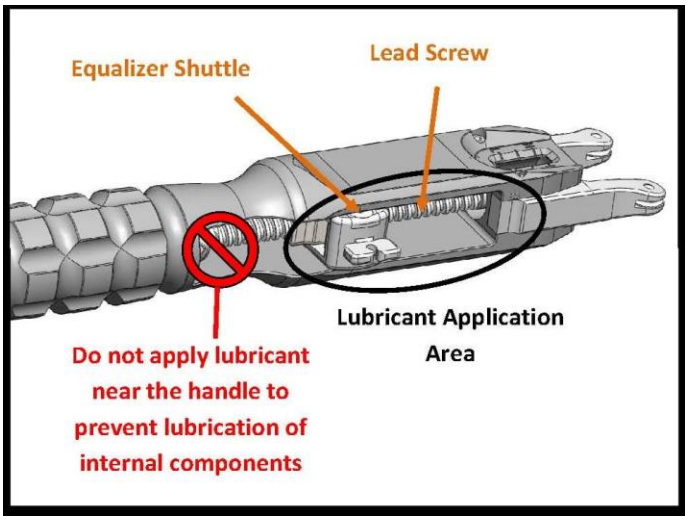


Figure 1: Tensioner Lubricant Application

Packaging:

- The instruments should be placed in their appropriate locations in the accompanying surgical tray.
- Wrap the tray in two layers of 1 ply polypropylene wrap (e.g., Kimguard KC600) and prior to placing in a steam sterilizer.

Sterilization:

- This product is provided non-sterile. The steam sterilization methods identified below have been validated to the requirements of ISO 17665. Please consider your sterilization equipment manufacturer's written instructions for the specific sterilizer and load configuration used.

System Tray Part Number	System Tray Description	Pre-Vacuum Autoclave			Gravity Displacement Autoclave		
		Temp	Time	Dry Time	Temp	Time	Dry Time
STW4001	21 x 10 x 2 1/4 in (53.3 x 25.4 x 5.7 cm)	270°F (132°C)	10 min	30 min	270°F (132°C)	20 min	70 min

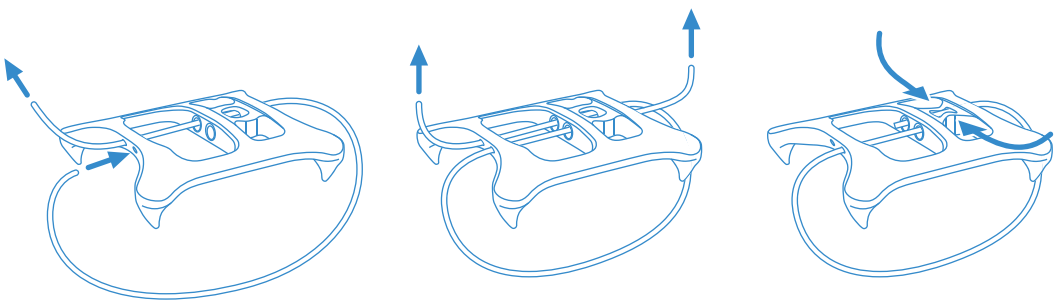
Storage: Store in a cool dry place and keep away from direct sunlight. Prior to use, inspect instruments and tray for signs of tampering.

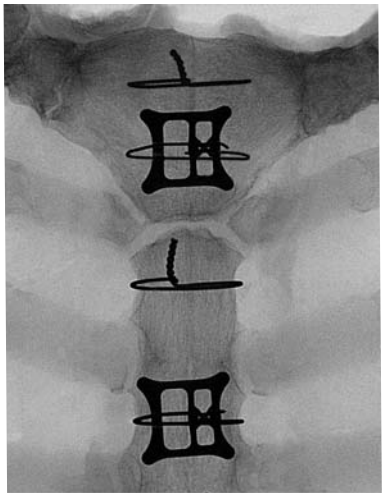
Manufacturer Contact: ACUTE Innovations Customer Service
866-623-4137 Toll Free or 503-686-7200

REF	Part Number	⚠	Caution, consult instructions for use.		**ACUTE Innovations® LLC** 2141 NW Jacobson Road, Suite 700 Hillsboro, OR 97124 USA +1 (503) 686-7200 **www.acuteinnovations.com**
LOT	Lot Number		Do not re-use		

OVERVIEW

FEED WIRE. **TENSION.** **CRIMP.**





DETAILED TECHNIQUE

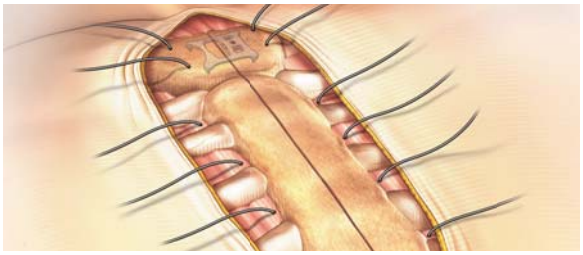
1: INSTALL WIRE

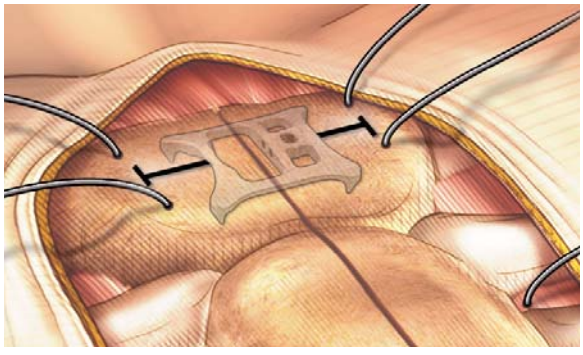
A. Feed #5, 6, or 7 wire through or around the sternum using a standard technique.

B. Ensure the distance between wire penetration is sufficient to allow room for the plate.

CAUTION: For each wire, the distance between penetrations must be greater than the width of the plate (~2cm) when the sternum is approximated, or adequate closure may not be achieved.

C. When removing needles and applying needle drivers, leave wires as long and straight as possible.





2: APPROXIMATE

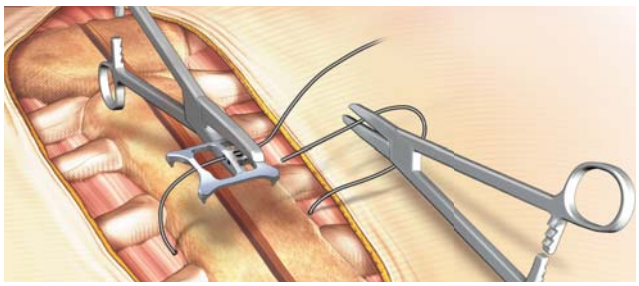
A. Approximate the sternum halves by twisting wire where plates will not be used.

ACUTE Innovations®

3: FEED WIRE

A. Use needle drivers to handle and feed wire through the plate. If necessary, trim kinked wire ends, leaving wire as long as possible to facilitate smooth wire passage.

CAUTION: Avoid sharp wire ends.



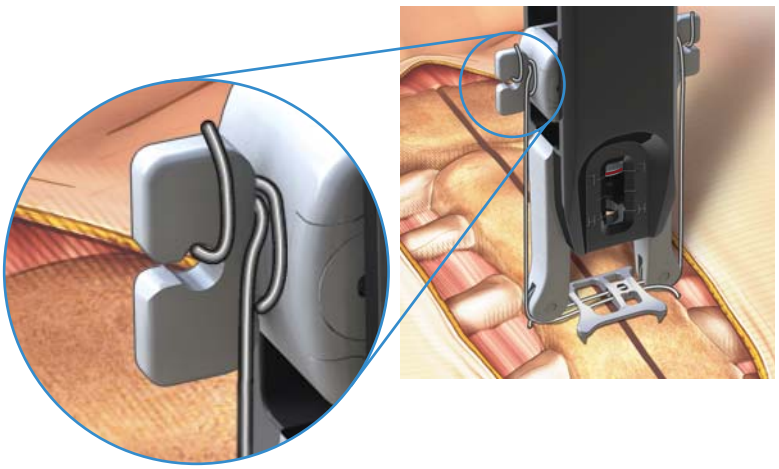
B. Use needle drivers to pull the wire ends laterally, centering the plate over the sternotomy.

TIP: Avoid pulling wires anteriorly, which can cause kinks in the wire and make the plate difficult to seat.

4: LOAD TENSIONER

A. Lower the tensioner shuttle to the distal end by turning the knob. Center the tensioner over the plate.

B. While keeping the wires contained within the pulleys, wrap the wires fully around the wings.

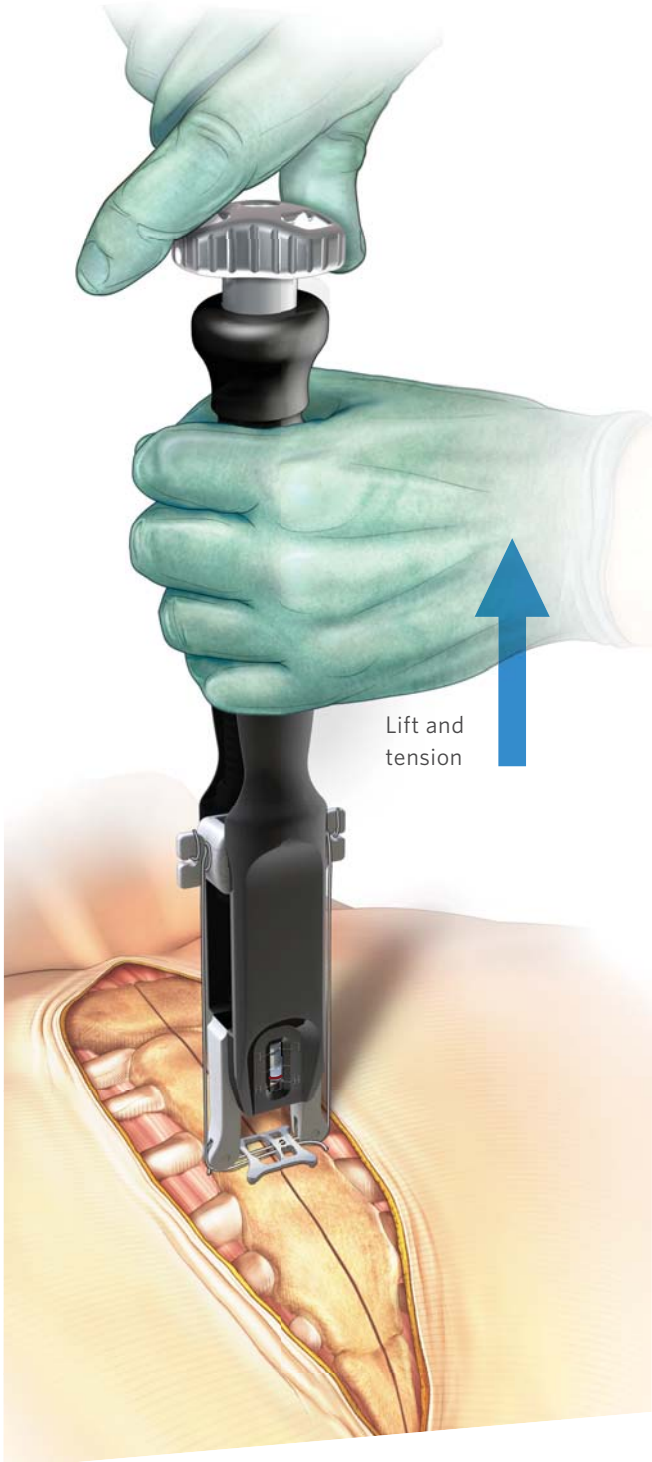


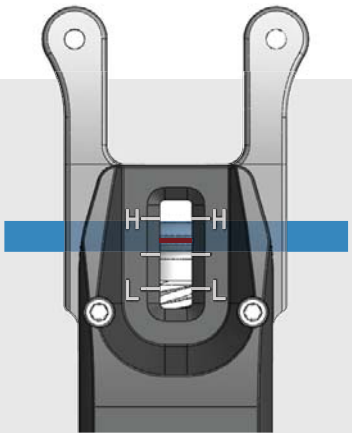
5: TENSION

A. Lift up on the tensioner grip while tensioning by turning the knob.

B. Tension until cleats seat into the sternum.

TIP: Optimal tension is typically between **Medium** and **High**.





Tension indicator

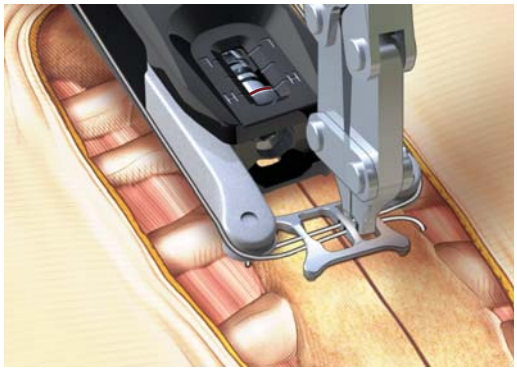
OPTIMAL TENSION LEVEL

CAUTION: The torque necessary to turn knob is not an indicator of tension. Wire forces on the sternum can exceed 45lbs when tensioned above High.

WARNING: Recommended settings are meant to assist the surgeon in optimizing the performance of the system, not to replace the surgeon's judgment. Ideal tension may vary with bone quality or geometry. Reduced bone quality may warrant a lower tension.

6: CRIMP

A. Align the crimper perpendicular to the plate and push down to ensure that the crimper tips fully engage the crimp feature.

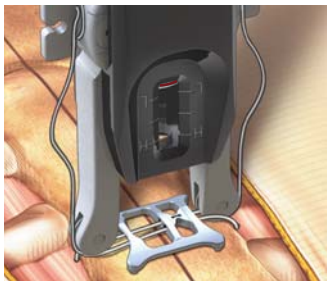


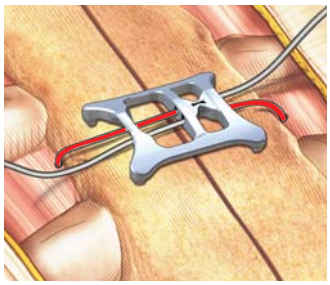
B. Crimp the plate to lock the wire tension by fully compressing the crimper until the "stops" make contact.

Full crimp achieved when "stops" make contact.

7: TRIM WIRE

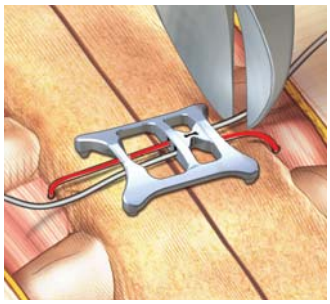
A. Prior to cutting the wire, fully lower the shuttle to release the wire tension. This resets the tensioner for the next use and prevents snap-back caused by sudden release of tension.

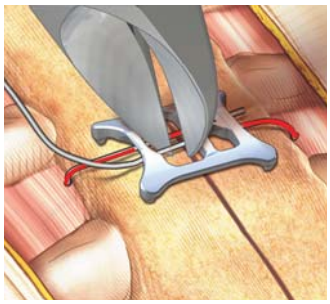




B. Cut the free ends of the wire with the supplied wire cutters, as pictured. Take care not to cut the tensioned wire loop encircling the sternum (illustrated as red).

NOTE: Cutting wire end within window, eases plate removal if reentry is required.

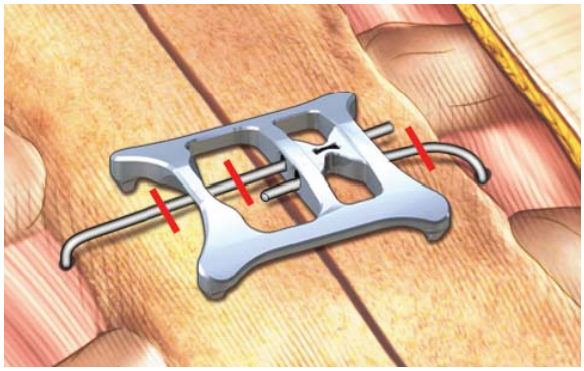


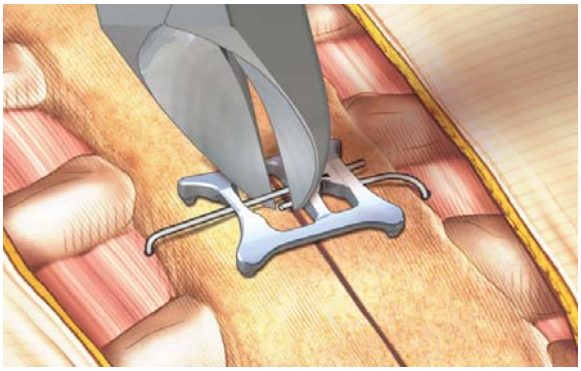


C. Confirm closure is secure. Re-twist wires as needed after all plates are installed.

REENTRY

A. Cut encircling wire within the window or at the lateral edge of the plate.





B. If two wires are present in the cutting window, cutting one wire at a time may be easier than cutting both simultaneously.

CAUTION: If cutting both wires, retrieve any wire fragments.

(866) 623-4137

customerservice@acuteinnovations.com

21421 NW Jacobson Rd.
Suite 700
Hillsboro, OR 97124