AcuTie® II Sternal Closure System

FOR THE PERSONAL ATTENTION OF THE OPERATING SURGEON

INSTRUCTIONS FOR USE

DESCRIPTION	The 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 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 components of this system have not been tested for safety, heating, or migration in the MRI environment. Similar products have been tested and described in terms of how they may be safely used in post-operative clinical evaluation using MRI equipment1. Acumed recommends contacting the manufacturer of the MRI equipment or the surgeon to determine MRI compatibility of our implants. [1] *Shellock, F.G. Reference Manual for magnetic Resonance Safety, Implants, and Devices: 2011 Edition. Biomedical Research Publishing Group, 2011.*
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.

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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	• Acumed 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, Acumed 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 Acumed 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 & Decontamination: 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.

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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.
- Continue with automated cleaning, 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 Acumed 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 Acumed for replacement.
- Allow lubricated instruments to air dry prior to sterilization.

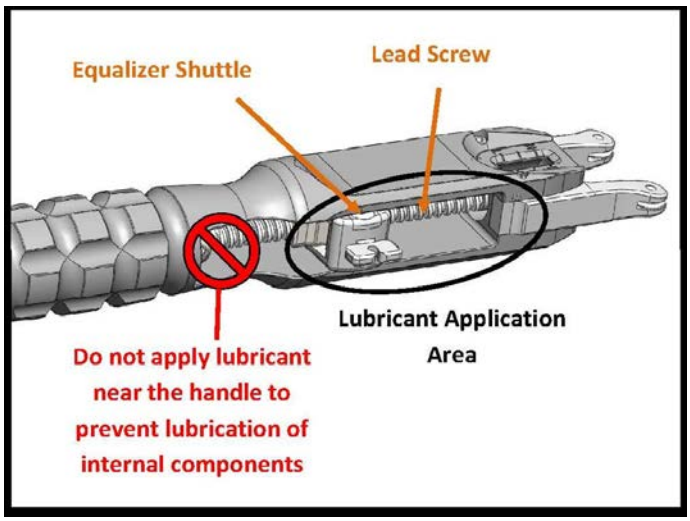

Figure 1: Tensioner Lubricant Application

Packaging:

For sterilization in polypropylene wrap	For sterilization in rigid container
Wrap the tray in two layers of 1 ply polypropylene wrap (e.g., Kimguard KC600).	**ONLY FOR TRAY LOT NUMBERS STARTING L1710XX AND ABOVE** Prepare a rigid container (#JN44) with Single Use Filters (#US751), place system tray in the container, cover and secure lid (#J489) to rigid container.

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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 and Packaging	System Tray Description	Gravity Displacement Autoclave		
		Temp	**Time**	**Dry Time**
STW4001 polypropylene wrap	21 x 10 x 2 1/4 in (53.3 x 25.4 x 5.7 cm)	270°F (132°C)	20 min	70 min

System Tray Part Number and Packaging	System Tray Description	Pre-Vacuum Autoclave		
		Temp	**Time**	**Dry Time**
STW4001 polypropylene wrap	21 x 10 x 2 1/4 in (53.3 x 25.4 x 5.7 cm)	270°F (132°C)	4 min	30 min
		273°F (134°C)	3 min	30 min
STW4001 rigid container **TRAY LOT NUMBER STARTING L1710XX AND ABOVE ONLY**	21 x 10 x 2 1/4 in (53.3 x 25.4 x 5.7 cm)	270°F (132°C)	4 min	30 min
		273°F (134°C)	3 min	30 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.

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REF	Part Number		Caution, consult instructions for use.		MANUFACTURER
LOT	Lot Number		Do not re-use	NON STERILE	Non-Sterile
	Consult the electronic instructions for use (eIFU) at www.acumed.net/ifu		Do not use if package is damaged	**Rx Only**	Caution: U.S. federal law restricts this device to sale by or on the order of a physician.
	The reticle is a registered trademark of Acumed. It may appear alone or with the Acumed name.				

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