Scapholunate Repair System

Instructions for use

Scapholunate Repair System

US **These instructions are intended for the Operating Surgeon and supporting Healthcare Professionals. The US instructions are intended for users in the United States and its territories.** **Rx only**

DESCRIPTION

The Scapholunate Repair System is an implant and instrument system designed to treat scapholunate interosseous ligament (“SLIL”) ruptures.

INDICATIONS FOR USE

The Scapholunate Repair System is intended to provide fixation and anatomically reduce two bones or bone portions. Specifically, these indications include acute or chronic, static or dynamic scapholunate instability in the absence of significant capitolunate osteoarthritis, scapholunate ligament repair, scapholunate reduction, lunotriquetral ligament repair, lunotriquetral reduction, and carpal instability.

CONTRAINDICATIONS

This device is contraindicated in the presence of active or latent infection, sepsis, osteoporosis, insufficient quantity and/or quality of bone, presence of cartilage degeneration on the bones, absence of potential for soft tissue healing or soft tissue reconstruction spanning the bones, or with patients who are unwilling or unable to follow post-operative care instructions.

WARNINGS & PRECAUTIONS

Implant Warning:

For safe and effective use of the implant, the surgeon must be thoroughly familiar with the implant, the methods of application, instruments, and the recommended surgical technique for the device. 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. The implants may cause distortion and/or block the view of anatomic structures on radiographic images.

Surgical Instrument Warning:

For safe and effective use of any Acumed instrument, the surgeon must be familiar with the instrument, the method of application, and the recommended surgical technique. Instrument breakage or damage, as well as tissue damage, can occur when an instrument is subjected to excessive loads, dense bone, improper use or unintended use. The patient must be cautioned, preferably in writing as to the risks associated with these types of instruments.

Implant Precautions:

An implant shall never be reused. Previous stresses may have created imperfections, which can lead to a device failure. Protect implants against scratching and nicking. Such stress concentrations can lead to failure. Mixing implant components from different manufacturers is not recommended for metallurgical, mechanical and functional reasons. The benefits from implant surgery may not meet the patient's expectations or may deteriorate with time, necessitating revision surgery to replace the implant or to carry out alternative procedures. Revision surgeries with implants are not uncommon.

Surgical Instrument Precautions:

Single use surgical instruments shall never be reused. Previous stresses may have created imperfections, which can lead to a device failure. Protect instruments against scratching and nicking, such stress concentrations can lead to failure.

ADVERSE EFFECTS

Possible adverse effects include:

Possible adverse effects are pain, discomfort, or abnormal sensations and nerve or soft tissue damage due to the presence of an implant or due to surgical trauma. Implant migration and/or loosening may occur. Fracture of the implant may occur due to excessive activity, prolonged loading upon the device, incomplete healing, or excessive force exerted on the implant during insertion. Metal sensitivity, histological, allergic or adverse foreign body reaction resulting from implantation of a foreign material may occur. 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.

SURGICAL TECHNIQUE

Acumed offers one or more Surgical Techniques to promote the safe and effective use of this system. Consult our Surgical Techniques at www.acumed.net.

Important: Surgical techniques may contain important safety information.

> **Important:** The instruments and implants in this system are intended to be used by suitably trained and qualified surgeons in a hospital operating room setting. Before treatment, the surgeon is advised to read and fully understand all instructions and communicate to the patient any relevant medical information provided therein, including the use, limitations, risks (safety communications), and possible adverse effects of the proposed treatment.
>
> Consult the most recent versions of the Instructions for Use and Surgical Techniques as they are subject to change. Contact Acumed or an authorized agent to request any additional information.

MRI SAFETY INFORMATION

The implants have undergone testing for safety in the MRI environment. Consult our publication "Acumed Implants in the MRI Environment" at www.acumed.net/ifu for more information.

IMPLANTS

MATERIALS

The implants are made of titanium alloy, Ti-6Al-4V ELI, per ASTM F136.

IMPLANT INFORMATION FOR USE:

The surgeon must select the type and size implant that best meets the patient's surgical needs.

INSTRUMENTS

MATERIALS

The instruments are made of surgical grade stainless steel according to ASTM F899.

SURGICAL INSTRUMENT INFORMATION FOR USE:

Instruments provided with this system may be single use or reusable.

- The user must refer to the instrument's label to determine whether the instrument is single use or reusable. Single use instruments are labeled with a "do not re-use" symbol as described in the Symbol Legend section, below.
- Single use instruments must be discarded after a single use.
- Reusable instruments have a limited lifespan. Prior to and after each use, reusable instruments must be inspected where applicable for sharpness, wear, damage, proper cleaning, corrosion and integrity of the connecting mechanisms. Particular care should be paid to hex drivers, drill bits and instruments used for cutting or implant insertion.

PROCESSING

Important: Processing personnel must be qualified with suitable training and experience. Use proper personal protective equipment (PPE) when working with contaminated devices.

IMPLANT CLEANING:

Implants provided non-sterile that have not been used, but have become soiled, should be processed according to the following:

Warnings & Precautions

- Resterilization of the implants should not be performed if the implant comes into contact with contamination (e.g. biological tissue contact, such as bodily fluids/blood) unless the single use device

(SUD) has been reprocessed by an authorized facility who has received appropriate regulatory clearance for such. In the United States, cleaning a SUD after it comes into contact with human blood or tissue constitutes reprocessing.

- Do not use an implant if the surface has been damaged. Damaged implants should be discarded.
- Users should wear appropriate personal protective equipment (PPE).
- All users should be qualified personnel with documented evidence of training and competency. Training should be inclusive of current applicable guidelines, standards and hospital policies.

Manual Processing

Equipment: Soft bristled brush, neutral enzymatic cleaner or neutral detergent with a pH ≤ 8.5.

1. Prepare a solution using warm tap water and detergent or cleaner. Follow the enzymatic cleaner or detergent manufacturer's recommendations for use paying close attention to the correct exposure time, temperature, water quality, and concentration.
2. Carefully wash the implant manually. Do not use steel wool or abrasive cleaners on implants.
3. Rinse implant thoroughly with DI or purified water. Use DI or purified water for final rinse.
4. Dry the implant using a clean, soft, lint-free cloth to avoid scratching the surface.

Ultrasonic Processing

Equipment: Ultrasonic cleaner, neutral enzymatic cleaner or neutral detergent with a pH ≤ 8.5. Note: Ultrasonic cleaning may cause additional damage to implants that have surface damage.

1. Prepare a solution using warm tap water and detergent or cleaner. Follow the enzymatic cleaner or detergent manufacturer's recommendations for use paying close attention to the correct exposure time, temperature, water quality, and concentration.
2. Clean implants ultrasonically for a minimum of 15 minutes.
3. Rinse implant thoroughly with DI or purified water. Use DI or purified water for final rinse.
4. Dry the implant using a clean soft, lint-free cloth to avoid scratching the surface.

INSTRUMENT CLEANING:

Acumed Instruments and Accessories must be thoroughly cleaned before reuse, following the guidelines below:

Warnings & Precautions

- Decontamination of reusable instruments or accessories should occur immediately after completion of the surgical procedure. Do not allow contaminated instruments to dry prior to cleaning/ reprocessing. Excess blood or debris should be wiped off to prevent it from drying onto the surface.
- All users should be qualified personnel with documented evidence of training and competency. Training should be inclusive of current applicable guidelines and standards and hospital policies.
- Do not use metal brushes or scouring pads during manual cleaning process.
- Use cleaning agents with low foaming surfactants for manual cleaning in order to see instruments in the cleaning solution. Cleaning agents must be easily rinsed from instruments to prevent residue.
- Mineral oil or silicone lubricants should not be used on Acumed instruments.
- Neutral pH enzymatic and cleaning agents are recommended for cleaning reusable instruments. It is very important that alkaline cleaning agents are thoroughly neutralized and rinsed from instruments.
- Surgical instruments must be dried thoroughly to prevent rust formation, even if manufactured from high grade stainless steel.
- All instruments must be inspected for cleanliness of surfaces, joints, and lumens, proper function, and wear and tear prior to sterilization.
- Anodized aluminum must not come in contact with certain cleaning or disinfectant solutions. Avoid strong alkaline cleaners and disinfectants or solutions containing iodine, chlorine or certain metal salts. Also, in solutions with pH values above 11, the anodization layer may dissolve.

Manual Cleaning/Disinfection Instructions

1. Prepare enzymatic and cleaning agents at the use-dilution and temperature recommended by the manufacturer. Fresh solutions should be prepared when existing solutions become grossly contaminated.
2. Place instruments in enzymatic solution until completely submerged. Actuate all moveable parts to allow detergent to contact all surfaces. Soak for a minimum of twenty (20) minutes. Use a nylon soft bristled brush to gently scrub instruments until all visible debris is removed. Pay special attention to hard to reach areas. Pay special attention to any cannulated instruments and clean with an appropriate bottle brush. For exposed springs, coils, or flexible features: Flood the crevices with copious amounts of cleaning solution to flush out any soil. Scrub the surface with a scrub brush to remove all visible soil from the surface and crevices. Bend the flexible area and scrub the surface with a scrub brush. Rotate the part while scrubbing to ensure that all crevices are cleaned.
3. Remove the instruments and rinse thoroughly under running water for a minimum three (3) minutes. Pay special attention to cannulations, and use a syringe to flush any hard to reach areas.
4. Place the instruments, fully submerged, in an ultrasonic unit with cleaning solution. Actuate all moveable parts to allow detergent to contact all surfaces. Sonicate the instruments for a minimum of ten (10) minutes.
5. Remove the instruments and rinse in deionized water for a minimum of three (3) minutes or until all signs of blood or soil are absent in the rinse stream. Pay special attention to cannulations, and use a syringe to flush any hard to reach areas.
6. Inspect instruments under normal lighting for the removal of visible soil.
7. If visible soil is seen, repeat the sonication and rinse steps above.
8. Remove excess moisture from the instruments with a clean, absorbent, nonshedding wipe.

STERILITY:

System components are provided non-sterile.

Non-Sterile Product*:*

Unless clearly labeled as sterile and provided in an unopened sterile package provided by Acumed, all implants and instruments must be considered non-sterile, and sterilized by the hospital prior to use. Sterilization of non-sterile devices has been validated using the sterilization parameters listed below, where devices are provided in fully-loaded trays with all parts placed appropriately.

Sterilization Methods

- Consult your equipment manufacturer's written instructions for specific sterilizer and load configuration instructions.
- Follow current AORN "Recommended Practices for Sterilization in Perioperative Practice Settings" and ANSI/AAMI ST79: 2010 – Comprehensive guide to steam sterilization and sterility assurance in health care facilities.
- Flash sterilization is not recommended, but if used, should only be performed according to requirements of ANSI/AAMI ST79: 2010 – Comprehensive guide to steam sterilization and sterility assurance in health care facilities.

Scapholunate Repair System:

Prevacuum Steam Sterilizer Parameters	
Storage Case Part Numbers:	55-0044; 55-0045
Condition:	Wrapped
Exposure Temperature:	270°F (132°C)
Exposure Time:	4 minutes
Dry Time:	30 minutes

STORAGE INSTRUCTIONS:
Store in a cool dry place and keep away from direct sunlight. Prior to use, inspect product package for signs of tampering, or water contamination. Use oldest lots first.

Symbols Glossary

Symbol	Description	ISO 15223-1
	Consult the electronic instructions for use (eIFU) at www.acumed.net/ifu	5.4.3
	Caution	5.4.4
	Sterilized using irradiation	5.2.4
	Non-sterile	5.2.7
	Use-by date	5.1.4
	Catalogue number	5.1.6
	Batch code	5.1.5
	Manufacturer	5.1.1
	Date of manufacture	5.1.3
	Do not resterilize	5.2.6
	Do not re-use	5.4.2
	Do not use if package is damaged and consult instructions for use / do not use if the product sterile barrier system or its packaging is compromised	5.2.8
Rx Only	Caution: U.S. federal law restricts this device to sale by or on the order of a physician.	U.S. 21 CFR 801.109
	The reticle is a registered trademark of Acumed. It may appear alone or with the Acumed name.	

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PKGI-011317-A | Effective 07-2020 |