acumed®

Ankle Syndesmosis Repair System

with Acu-Sinch® Knotless

Instructions for use

Ankle Syndesmosis Repair System with Acu-Sinch® Knotless

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 Acumed Ankle Syndesmosis Repair System is intended as an adjunct in fracture repair involving metaphyseal and periarticular small bone fragments where screws are not indicated, and as an adjunct in external and intramedullary fixation systems involving plates and rods, with fracture braces and casting.

INDICATIONS FOR USE

The Acumed Ankle Syndesmosis Repair System is intended as an adjunct in fracture repair involving metaphyseal and periarticular small bone fragments where screws are not indicated, and as an adjunct in external and intramedullary fixation systems involving plates and rods, with fracture braces and casting.

Specifically, the Acumed Ankle Syndesmosis Repair System is intended to provide fixation during the healing process following a syndesmotic trauma, such as fixation of syndesmosis (syndesmosis disruptions) in connection with Weber B and C ankle fractures.

CONTRAINDICATIONS

- Active or latent infection
- Sepsis
- Insufficient quantity or quality of bone, osteoporosis
- Soft tissue or material sensitivity
- Patients who are unwilling or incapable of following post-operative care instructions

WARNINGS & PRECAUTIONS

Warning:

- The treatment or implant may fail, including sudden failure, as a result of:
  - Loose fixation and/or loosening
  - Stress, including stress from inappropriate bending of the implant during surgery
  - Stress concentrations
  - Stress of weight bearing, load bearing, or excessive activity
- Failure is more likely if the implant experiences increased loads due to delayed union, nonunion, or incomplete healing. Failure is more likely if the patient does not follow post-operative care instructions.
- Nerve or soft tissue damage may result from surgical trauma or the presence of an implant.
- Instrument breakage or damage, as well as tissue damage, may occur when an instrument is subjected to excessive loads, excessive speeds, dense bone, improper use or unintended use.
- Implants may cause distortion and/or block the view of anatomic structures on radiographic images.
- The Acumed Ankle Syndemosis implant is not intended to be used as a ligament replacement

Caution:

- The implants and instruments are intended only for professional use by a licensed physician.
- Do not use or re-sterilize an implant provided in sterile packaging if the package has been damaged. The sterility may be compromised and the cleanliness of the implant may be uncertain. Report damaged packaging to your distributor or Acumed.
- Mixing implant components from different manufacturers is not recommended for metallurgical, mechanical and functional reasons.
- Do not use the sterile product past the use-by date. Refer to the device label.
- Do not reuse single use surgical instruments. The instrument may suddenly fail as a result of previous stresses.
- Do not resharpen drill bits or reamers as these devices have critical dimensions and geometries that cannot be restored once the instrument has been consumed.
- Screws, tacks, Kirschner wires, guidewires, cutting instruments, and similar devices may be sharp. Observe hospital procedures, practice guidelines, and/or government regulations for the proper handling and disposal of sharps.

ADVERSE EFFECTS

Possible adverse effects include:

- Pain, discomfort, or abnormal sensations, nerve or soft tissue damage, necrosis of bone or tissue, bone resorption, or inadequate healing from the presence of an implant or due to surgical trauma.
- Implant fracture due to excessive activity, prolonged loading upon the device, incomplete healing, or excessive force exerted on the implant during insertion. Implant migration and/or loosening may occur.
- Metal sensitivity, histological, allergic or adverse foreign body reaction resulting from implantation of a foreign material. Consult our document "Metal Sensitivity Statement" at www.acumed.net/ifu.

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

Many Acumed implants have been evaluated for safety in the MR environment and have deemed to be MR Conditional. Consult our publication "Acumed Implants in the MR Environment" at www.acumed.net/ifu for more information.

LIFETIME

- Sterile parts may be implanted up to the date of expiration indicated on the label.

STERILITY

- Implants and instruments are provided sterile as indicated on the label.
- Devices purchased and received sterile were exposed to a minimum dose of 25.0 kGy gamma radiation or to an ethylene oxide gas sterilization method to obtain a minimum Sterility Assurance Level (SAL) of 10^{-6}.

"In accordance with the State of California Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65):

> WARNING: This product can expose you to chemicals including ethylene oxide, which is known to the State of California to cause cancer and birth defects or other reproductive harm. For more information go to www.P65Warnings.ca.gov."

IMPLANTS

MATERIALS

- The implants are manufactured from wrought annealed titanium-6aluminum-4vanadium ELI (extra low interstitial) alloy (UNS R56401) per ASTM F136.
- The sutures are manufactured from Ultra High Molecular Weight Polyethylene (UHMWPE) per ASTM F2848-17.

SINGLE USE

- Implants are intended for single use only, as indicated on the label.
- Do not reuse single use implants as this may increase the risks of failure and cross-contamination.
- Dispose of any unused implant that is contaminated with human blood or tissue. Do not process a contaminated implant.

IMPORTANT

- For safe and effective use, the surgeon must be thoroughly familiar with the implant, the methods of application, instruments, and the recommended surgical technique.
- Implants are not designed to withstand the stresses of full weight or load bearing, or excessive activity.
- Improper selection or improper implantation of the device may increase the possibility of loosening or migration.
- Only combine implants when they are intended for that purpose.

- Protect implants against scratching and nicking to prevent stress concentrations, which can result in failure.
- Prevent unused implants from becoming soiled.
- 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.

INSTRUMENTS

MATERIALS

The instruments are manufactured from various grades of stainless steel, plastic, and Loctite.

MULTIPLE USE and SINGLE USE

- Instruments are intended for single use only.
- Single use instruments are intended to be disposed after use on a single patient during a single procedure.
- Do not reuse single use instruments as this may increase the risks of failure and cross-contamination.

IMPORTANT

- Protect instruments against scratching and nicking to prevent stress concentrations, which can lead to instrument failure.
- Avoid prolonged instrument contact with iodine and saline.

PROCESSING

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

IMPORTANT

- This product is provided sterile for single-use only, and should not be re-processed.
- Any general use instruments should be sterilized according to manufacturer recommendations.

STERILIZATION

- Resterilization of sterile-packaged devices is not recommended.
- If sterile packaging is damaged, the product must not be used

STORAGE CONDITIONS

STORAGE OF PACKAGED STERILE PRODUCT

- Final packaged product should be stored at room temperature (59-77 °F or 15-25 °C) and protected from direct sunlight, pests, and high humidity.

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
	Sterilized using ethylene oxide	5.2.3
	MR Conditional	ASTM F2503-20
	Double sterile barrier system	5.2.12
	Use-by date	5.1.4
	Catalogue number	5.1.6
	Batch code	5.1.5
	Authorized representative in the European Community / European Union	5.1.2
	Medical device	5.7.7
	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.	
CE	CE marking of conformity, Article 17 of EU Directive 93/42/EEC or Article 20 of Regulation (EU) 2017/745. CE marking may be accompanied by the identification number of the notified body responsible for conformity assessment.	

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