Acu-Sinch® Knotless Mini

Instructions for use

Acu-Sinch® Knotless Mini

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

Acu-Sinch Knotless Mini consists of two buttons, a suture strand, and instruments to aid in insertion. The buttons are manufactured from titanium alloy conforming to ASTM F136 (Ti-6AL-4V ELI). The suture is manufactured from Ultra High Molecular Weight Polyethylene (UHMWPE). The implants and instruments are provided sterile and are for single use.

INTENDED USE/ INDICATIONS FOR USE

Acumed's Acu-Sinch Knotless Mini, when used for fixation of bone-to bone or soft-tissue to bone, is intended as a fixation post, distribution bridge, or for distributing suture tension over areas of ligament or tendon repair. Specifically, Acu-Sinch Knotless Mini is indicated for Carpal Metacarpal (CMC) joint arthroplasty as an adjunct in the healing process of hematoma distraction arthroplasty by providing stabilization at the base of the first and second metacarpal when the trapezium has been excised due to osteoarthritis.

CONTRAINDICATIONS

- Active or latent infection
- Sepsis
- Insufficient quantity or quality of bone, osteoporosis, or in patients with certain metabolic diseases
- Patients with confirmed 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, because 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
  - 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.
- Devices of dissimilar material should not be used together in or near the implant site. Dissimilar metals in contact with each other can accelerate the corrosion process due to galvanic corrosion effects.
- Fractured implants should be removed from patient during surgery. If unable to remove, notify patient.
- Implants may cause distortion and/or block the view of anatomic structures on radiographic images.

- The Acumed Acu-Sinch Knotless Mini implant is not intended to be used as a ligament replacement.

Precautions

- Implants and instruments are intended only for professional use by a licensed physician.
- Use devices and instruments in accordance with the Instructions for Use.
- Do not use the sterile product past the use-by date. Refer to the device label.
- 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.
- Use of this system has not been evaluated in children or individuals that are not skeletally mature.
- Inspect all components preoperatively to ensure utility. Do not attempt a surgical procedure with faulty, damaged, or suspect instruments or implants. Alternate fixation methods should be available intraoperatively.
- Reprocessing and/or reuse of single-use devices may result in infection/cross contamination, and/or sudden failure due to previous stress.
- Use of implant components from different manufacturers has not been evaluated.
- Devices may be contaminated with biohazardous materials and/or sharp materials. Observe hospital procedures, practice guidelines, and/or government regulations for the proper handling of biohazardous material and disposal of sharp materials.

POTENTIAL ADVERSE EFFECTS

- Anesthesia-related problems, problems with positioning of the patient (e.g. nausea, vomiting, neurological impairments, etc.), thrombosis, embolism, infection or injury to other critical structures such as blood vessels, excessive bleeding, etc.
- 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.
- Swelling, abnormal scarring, impairment in musculoskeletal function, hardware prominence, migration, loosening, bending, or breakage of the implant, malunion, nonunion or delayed union due to prolonged loading or excessive forces which may lead to implant failure and reoperation.
- Metal sensitivity, histological, allergic, or adverse foreign body reaction resulting from implantation of a foreign material. Consult our "Metal Sensitivity Statement" document at http://www.acumed.net/ifu.
- Injury to user.

Important: Any adverse event that has occurred in relation to the device should be reported to Acumed through customercomplaints@acumed.net or +1.888.627.9957.

SURGICAL TECHNIQUE (including Installation and Calibration)

Acumed offers one or more Surgical Technique Guides to promote the safe and effective use of this system. Consult our Surgical Techniques at www.acumed.net. The Surgical Technique Guide also includes information about the installation and calibration of the device.

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. Consult our publication "Acumed Implants in the MR Environment" at www.acumed.net/ifu for more information.

LIFETIME

Once installed, implants are expected to provide fixation and physiological support and have an effective life during healing. The implants are biocompatible and may remain implanted at the discretion of the surgeon or patient.

STERILITY

- Products are supplied STERILE.
- **DO NOT USE IF THE STERILE PACKAGE IS DAMAGED. DO NOT USE AFTER EXPIRATION DATE.**

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 metal 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).

Consult our document "Metal Sensitivity Statement" at www.acumed.net/ifu for a detailed description of the material composition of Acumed metal implants.

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 re-process a contaminated implant.

IMPORTANT

- Physiological dimensions limit implant sizes. Select the type and size of implant that best meets the patient's requirements for close adaptation and firm seating with adequate support.
- Implants are designed to hold bones in place during bone healing at the site of trapeziectomy. Implants are not designed for excessive loadbearing. Improper selection or improper implantation of the device may increase the possibility of loosening or migration.
- Do not bend the implant except as indicated in the corresponding Surgical Technique Guide. Repeated or excessive bending may weaken the implant and cause failure at a later time.
- 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.

INSTRUMENTS

MATERIALS

The instruments are manufactured from various grades of stainless steel, medical grade adhesive, and medical grade plastic.

SINGLE USE

- Do not reuse single-use instruments. Re-use or reprocessing of devices labeled as "single use" can result in decreased mechanical and clinical performance of the devices which may result in patient harm.
- Re-use or reprocessing of single use instruments may create a risk of contamination (e.g. due to the transmission of infection material from one patient to another), which may result in patient harm.
- Dispose of single use instruments after use on a single patient, during a single procedure.

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.
- Handle and transport soiled instruments in a manner that avoids contamination of any unused implants.

STORAGE CONDITIONS

STORAGE OF PACKAGED STERILE PRODUCT

Devices should be stored in an area that provides protection from dust, pests, and temperature/ humidity extremes.

SAFE DISPOSAL

Devices may be contaminated with biohazardous materials and/or sharp materials. Observe hospital procedures, practice guidelines, and/or government regulations for the proper handling of biohazardous material and disposal of sharp materials.

Symbols Glossary

Symbol	Description	ISO 15223-1
	Consult the electronic instructions for use (eIFU) at www.acumed.net/ifu	5.4.3
	Sterilized using irradiation	5.2.4
	Sterilized using ethylene oxide	5.2.3
	Double sterile barrier system	5.2.12
	Use-by date	5.1.4
	Catalogue number	5.1.6
	Batch code	5.1.5
	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)	
	MR Conditional: An item with demonstrated safety in the MR environment within defined conditions. (ASTM F2503 7.3.2)	
	The reticle is a registered trademark of Acumed. It may appear alone or with the Acumed name.	

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