acumed®

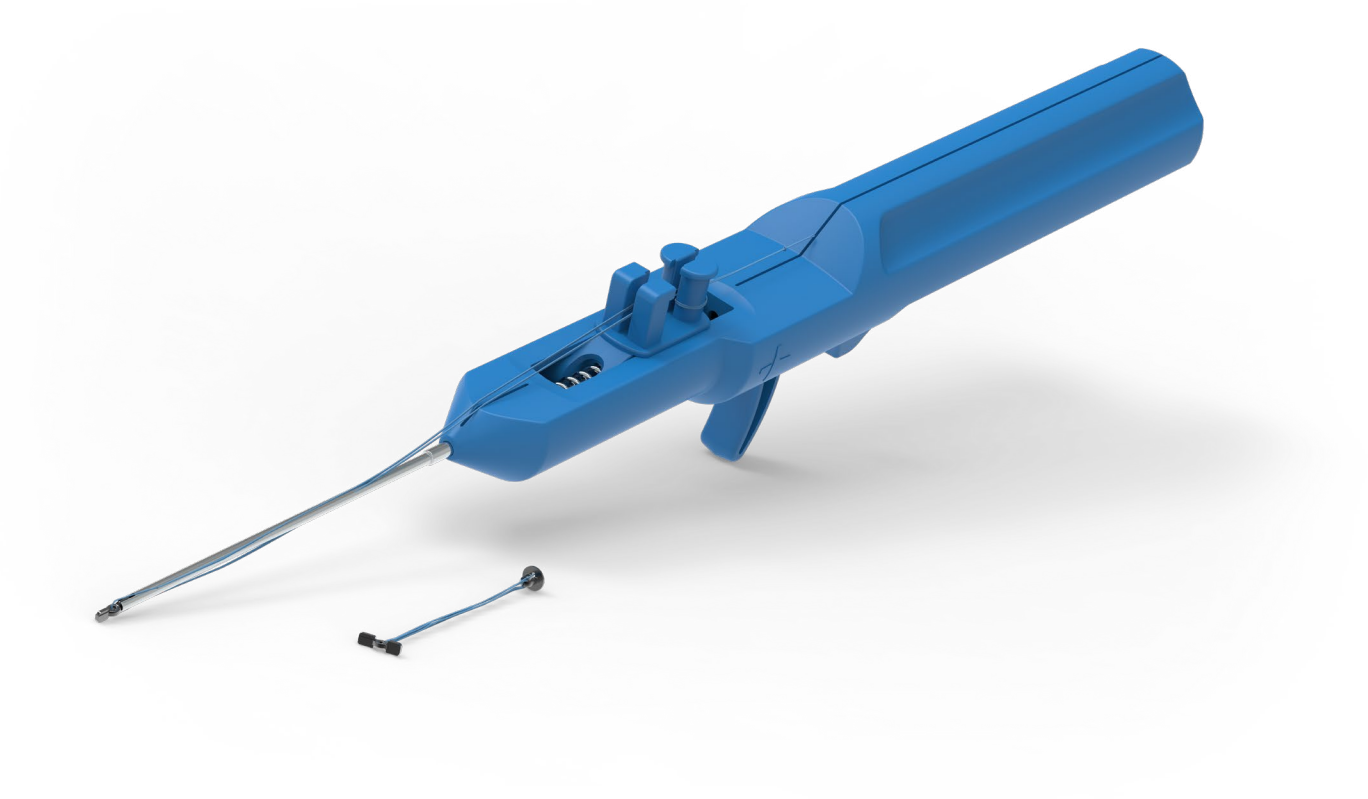
Acu-Sinch® Knotless Mini System

Value Analysis Committee Resource Guide

a Marmon Medical | Berkshire Hathaway Company

Acumed® is a global leader of innovative orthopaedic and medical solutions.

We are dedicated to developing products, service methods, and approaches that improve patient care.



Acumed Acu-Sinch® Knotless Mini System

With an aging population, the incidence of symptomatic thumb carpometacarpal joint arthritis (CMC) is on the rise. The incidence is higher in women overall, with 25% of post-menopausal women and over 40% of women aged greater than 70 years presenting with symptomatic carpometacarpal joint arthritis. The thumb CMC joint is second only to the distal interphalangeal joint as the most common arthritic joint in the hand.

The thumb CMC joint is described as a saddle joint allowing multiple arcs and planes of motion. Surgical goals have focused on providing pain relief while maintaining motion and improving grip and pinch strength. Trapeziectomy with or without ligament reconstruction and tendon interposition (LRTI) has been advocated as the surgical treatment of choice for patients with debilitating CMC joint arthritis. Newer treatment methods to suspend the thumb metacarpal via a suture button suspensionplasty (SBS) have also shown favorable clinical results with superior biomechanical strength. It is the biomechanical superiority that may allow patients to achieve a successful outcome earlier and thus reduce their overall recovery time, returning to work and sport activities sooner.

The Acumed Acu-Sinch Knotless Mini was designed in conjunction with Drs. David Ruch, Jerry Huang, and Ryan Garcia as an alternative SBS to stabilize and suspend the thumb metacarpal following trapeziectomy. Innovative drill design incorporates a recession element that maintains the suspension and allows the Acu-Sinch Knotless Mini device to pass along the drill track. Once deployed, the unique design employs a simple method to tighten and sinch the suture material without bothersome suture knots.

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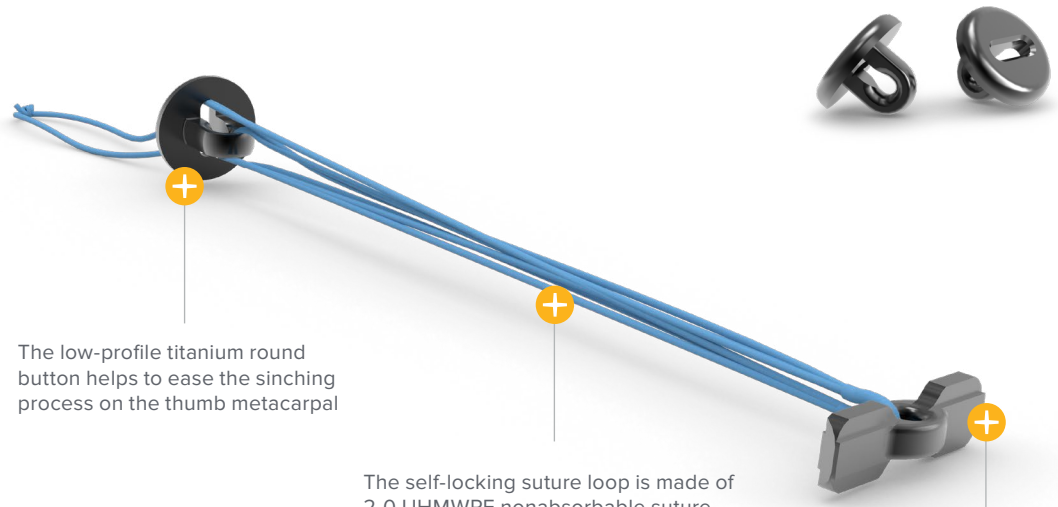
System Features

Acu-Sinch Knotless Mini System

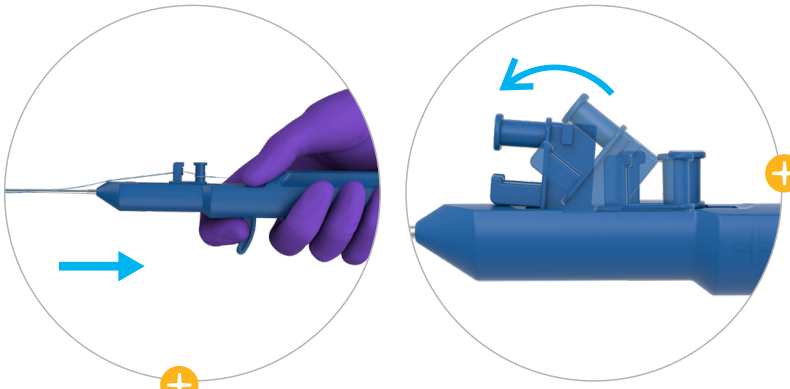
Round Buttons 4.1 mm



The low-profile titanium round button helps to ease the sinching process on the thumb metacarpal

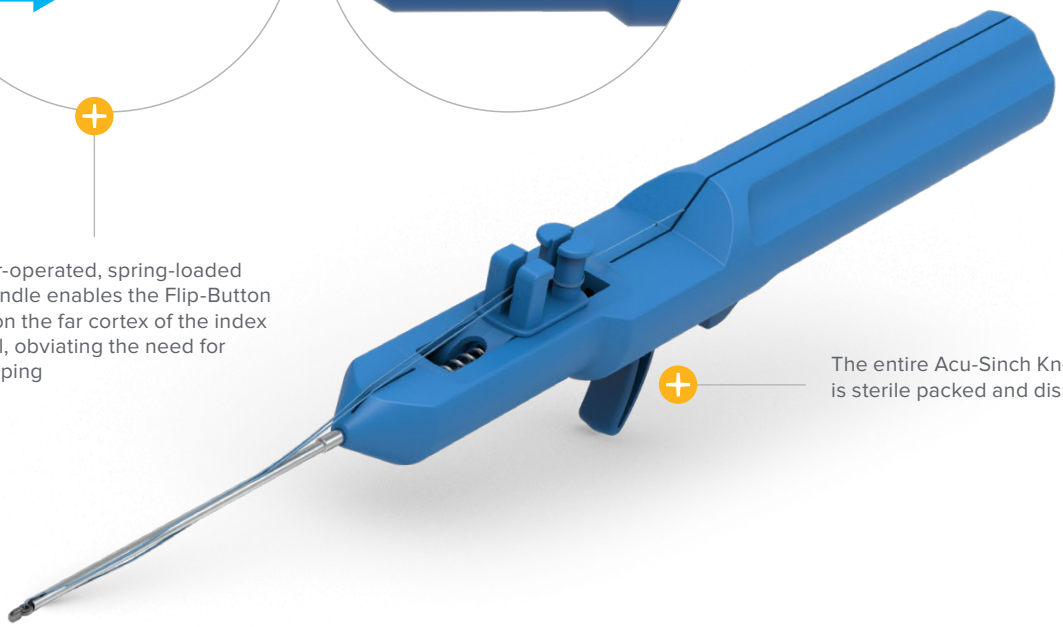
The self-locking suture loop is made of 2-0 UHMWPE nonabsorbable suture

The titanium Flip-Button is designed to pass through the 2.3 mm bone tunnel and is engaged by simply pulling the trigger on the inserter handle



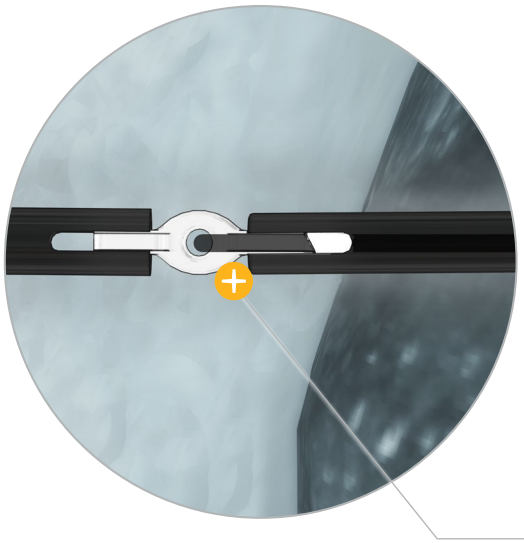
Suture carriage automatically deploys the Flip-Button and unfurls the suture as the user pulls the inserter handle

The trigger-operated, spring-loaded inserter handle enables the Flip-Button to deploy on the far cortex of the index metacarpal, obviating the need for manual flipping



The entire Acu-Sinch Knotless Mini System is sterile packed and disposable

System Features [continued]



A central ejector shaft facilitates button flipping

Fluoroscopy can be used to visualize the “indicating window” on the suture button prior to engaging the flip mechanism

The Acu-Sinch Knotless Mini System provides a slotted distal end design that allows for the maintenance of the drill tunnel alignment while passing the button and the suture

Indications for Use:

Acu-Sinch Knotless Mini System, when used for fixation of bone to bone or soft tissue to bone, is intended as a fixation post, a distribution bridge, or for distributing suture tension over areas of ligament or tendon repair. Specifically, the Acu-Sinch Knotless Mini System is indicated for Carpometacarpal (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.

Competitive Comparison

	Acumed Acu-Sinch Knotless Mini System	Arthrex Tightrope Mini for CMC
Button Material	Titanium	Stainless Steel
Suture Material/Suture	2-0 UHMWPE Suture	#2 FiberWire Suture
1st Metacarpal Incision	Yes	Yes
Knotless	Yes	No
Drill Size	2.3 mm	1.1 mm Guidewire

Competitive Comparison [continued]

Arthrex Fiberlock Suspension	Arthrex Internal Brace
UHMWPE Fibertack Anchor	PEEK
SutureTape Suture	2-0 FiberLoop Suture and APL Graft
Yes	No
Yes	Yes, as there are no knots being tied with the suture or APL graft
1.6 mm	3.0 mm

510(k) Clearance Information

January 23, 2025

Acumed LLC
Marina Bull
Regulatory Affairs Specialist
5885 NE Cornelious Pass
Hillsboro, Oregon 97124

Re: K243624
Trade/Device Name: Acu-Sinch Knotless Mini
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/Multiple Component Metallic Bone Fixation Appliances And Accessories
Regulatory Class: Class II
Product Code: HTN
Dated: November 22, 2024
Received: November 25, 2024

Dear Marina Bull:

We have reviewed your section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (the Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

510(k) Clearance Information [continued]

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-

510(k) Clearance Information [continued]

assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

RYAN TROMBETTA -S

For: Limin Sun, Ph.D.
Assistant Director
DHT6A: Division of Joint
Arthroplasty Devices
OHT6: Office of Orthopedic Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Our mission is to aid the afflicted through the ingenuity of our minds, the labor of our hands, and the compassion of our hearts.

Dedicated to Excellence

From manufacturing to business practices to product innovation, Acumed has an unwavering commitment to excellence. It is reflected in the honors received from industry peers and in the performance of our suite of surgical fixation solutions.

The AME Manufacturing Excellence Award

In 2011, Acumed received the AME Manufacturing Excellence Award, an honor recognizing North American manufacturing sites that have demonstrated operational excellence through continuous improvement, best practices, creativity, and innovation. This award supports AME's vision, mission and values of inspiring commitment to enterprise excellence through shared learning and access to best practices.

The Association for Manufacturing Excellence is North America's premier organization for the exchange of knowledge in Organizational Excellence through the implementation of techniques such as Lean Tools, Leadership, Lean Product Development, Lean Supply Chain, and Lean Accounting.

The Frost & Sullivan Manufacturing Leadership 100 Operational Excellence Award

In 2013, Acumed received the Frost & Sullivan Manufacturing Leadership 100 award for Operational Excellence, an honor recognizing the top 100 global manufacturing companies who are shaping the future through projects that deliver outstanding value, innovation, and return on investment.

Frost & Sullivan Manufacturing Leadership 100 is the world's first member-driven leadership network with knowledge in manufacturing leadership. It was created through a global community of executives working within the manufacturing industry.

A Leader in Product Development and Innovation

Acumed is proud to expand its industry-leading portfolio of hand and upper extremity solutions with the launch of the Acu-Sinch Knotless Mini System—our first product designed specifically for the treatment of CMC arthritis. This innovative solution marks Acumed's entry into a new area of care, reinforcing our ongoing commitment to surgical excellence and thoughtful design.

With the addition of the Acu-Sinch Knotless Mini System, we continue to deliver on our promise to provide comprehensive, high-quality solutions for surgeons and their patients—now including advanced options for CMC arthritis.

Acumed will continue to devote resources to the development of implants that aid in improving patient outcomes and advance the field of orthopaedic surgery.

Dedicated to Excellence [continued]

Industry Compliance

As a longstanding member of the Advanced Medical Technology Association (AdvaMed), Acumed endorses the AdvaMed Code of Ethics. Adherence to this Code ensures ethical interaction with healthcare professionals. Acumed requires anti-corruption training for employees interacting with healthcare professionals or government officials (foreign or domestic). In addition, Acumed sales representatives in the United States as well as international distribution partners must complete anti-corruption training programs.

Acumed also supports the United Nations Global Compact and Boston College Center for Corporate Citizenship organizations.

Transparency in Business Practice

Acumed tracks and reports spending in accordance with the Physician Payment Sunshine Act. In order to become an Acumed partner, all distributors must go through a due diligence analysis and a robust training and education program to ensure they share Acumed's values with respect to anti-corruption and compliance. Acumed maintains ethical behaviors with respect to compliance standards and laws.

A Commitment to Social Responsibility

At Acumed we understand that being an outstanding orthopaedic company is about more than creating top quality products: it's about being aware of the contributions we as an organization make to the world around us. Our company culture puts a great amount of emphasis on responsible business practices, the mindful stewardship of resources, and support for local and global humanitarian efforts.

The Charitable Giving Committee supports Acumed's commitment to helping those in need through educational initiatives, community action, and volunteerism. Beneficiaries include the Oregon Food Bank, STEM (Science, Technology, Engineering, Math) Connect, and SIGN Fracture Care International.

The Green Team educates and engages employees in sustainable practices that make a difference both at Acumed and at home. Eco-friendly landscaping, recycling events, weather-smart irrigation controls, and dedicated efforts to reduce power consumption are just a few of our green initiatives. In 2015, Acumed received special recognition for Excellence in Employee Engagement from the Energy Trust of Oregon. This recognition was the result of the work of the Acumed Green Team and the strategies they developed and enacted in order to bring more awareness to issues related to energy savings and environmental stewardship.

Notes:

Notes:

www.acumed.net

www.acumed.net/patents

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