acumed®

Ankle Syndesmosis Repair System

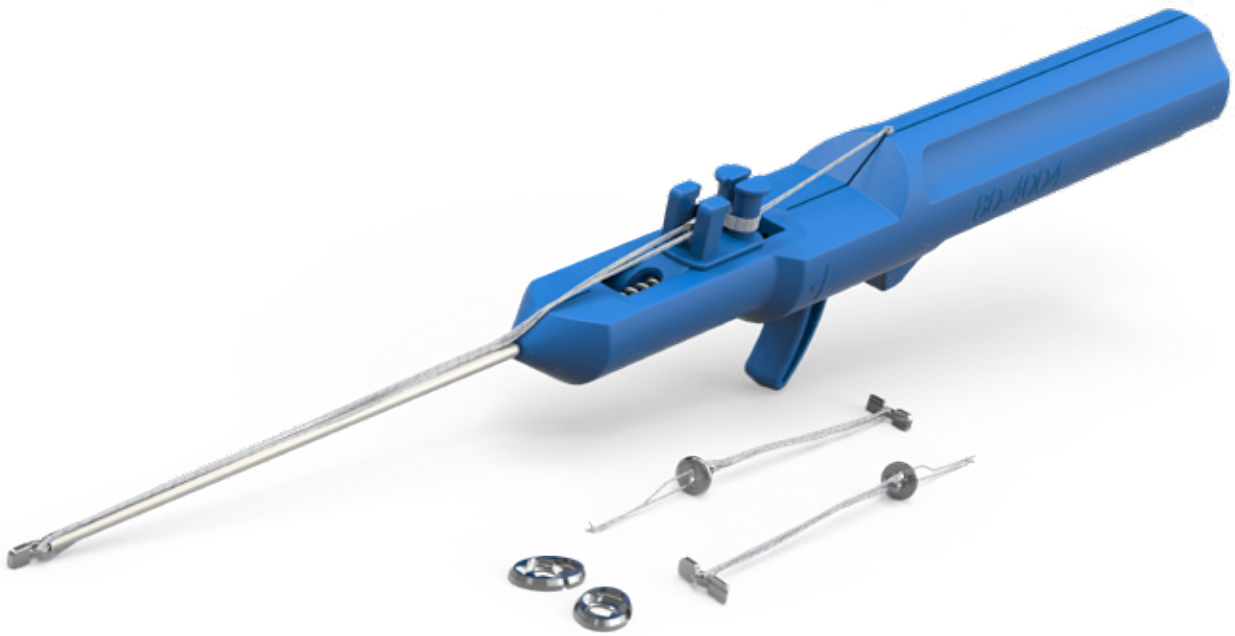
with Acu-Sinch® Knotless

Value Analysis Committee Resource Guide

a Colson Medical | Marmon | 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® Ankle Syndesmosis Repair System with Acu-Sinch® Knotless

The tibiofibular syndesmosis is disrupted in approximately 10–20% of ankle fracture cases and requires repair.[1,3] For decades, screw fixation of the syndesmosis has been the gold standard for treatment.[1] However, emerging clinical evidence has demonstrated that flexible, suture-based syndesmosis repairs have successful clinical outcomes and may reduce complications associated with malreduction of the syndesmosis when fixed with screws.[2,3,4]

Designed in conjunction with Alastair Younger, MB, Ch.B., M.Sc., Ch.M., FRCS(C); Selene Parekh, MD, MBA; and Steven Morgan, MD, the Acu-Sinch Knotless Implant enables the dynamic stabilization of laxity or syndesmotic disruptions to the tibiofibular joint.

The Acu-Sinch Knotless buttons may be augmented with a washer or may be used in conjunction with the Acumed and OsteoMed® fibula fracture fixation plates and intramedullary nails with 3.5 mm nonlocking screw holes. Our patent pending release mechanism gives the user control to place the medial button subcutaneously without the need for direct visualization.

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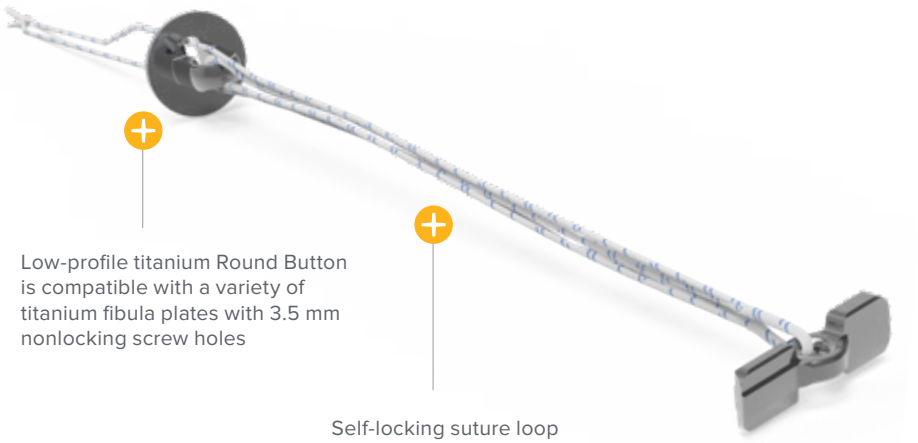
System Features

Acu-Sinch® Knotless System 3.5 mm



Low-profile titanium Round Button is compatible with a variety of titanium fibula plates with 3.5 mm nonlocking screw holes

Self-locking suture loop made from #2 UHMWPE nonabsorbable HS Fiber enables an adjustable knotless repair

Titanium Flip Button is designed to pass through a 3.5 mm bone tunnel, plates, or intramedullary nails with a nonlocking 3.5 mm hole

Acu-Sinch Washer 3.5 mm

Slotted titanium washer is designed for assembly over the suture after the Acu-Sinch Knotless has been deployed, for increased surface area on the bone

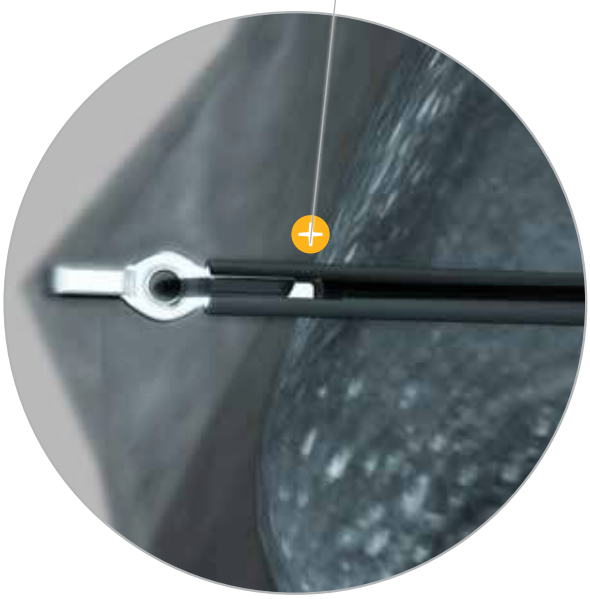
Suture carriage automatically ejects from the handle during deployment

Spring-loaded trigger for one-step Flip Button delivery

The Acu-Sinch Knotless System is provided on a disposable inserter handle preassembled and sterile packaged

Patent pending Flip Button design obviates the need for a medial incision

System Features [continued]



Indications for Use:

The Ankle Syndesmosis Kit is intended to be used as an adjunct in fracture repair involving metaphyseal and periarticular small bone fragments where screws are not indicated. It is also intended to be used as an adjunct in external and intramedullary fixation systems involving plates and rods, with fracture braces and casting.

Specifically, the Ankle Syndesmosis Kit is intended to provide fixation during the healing process following a syndesmotic trauma, such as fixation of syndesmosis disruption in connection with Weber B and C ankle fractures.

The Acu-Sinch Knotless is compatible with implants from with Acumed and OsteoMed® fibula fracture fixation products:

- Acumed Ankle 3 Lateral Fibula Plates
- Acumed 1/3 Tubular Plates
- Acumed Locking Ankle System (LPL) Fibula Plates
- Acumed Fibula Rods
- Acumed Fibula Nail 2
- OsteoMed® ExtremiLock Ankle Lateral Fibula Plate
- OsteoMed® 1/3 Tubular Plates

The Acu-Sinch Knotless devices may be used alone, or in conjunction with titanium plates and nails designed to accept 3.5 mm nonlocking screws.

Competitive Comparison

	Acumed® Ankle Syndesmosis Repair System	Arthrex Syndesmosis TightRope XP Implant System
Button Material	Titanium Alloy	Stainless Steel and Titanium
Suture Material/Suture	UHMWPE HS Suture	UHMWPE/Polyester FiberWire Suture
Medial Incision Required	No	No
Knotless	Yes	Yes
Drill Size	3.5 mm	3.7 mm
Compatibility with Fibula Plates and Nails	Lateral Fibula Plates, Posterolateral Fibula Plates, 1/3 Tubular Plates, Fibula Rod, titanium implants with non-threaded holes designed to accomodate a 3.5 mm drill	Lateral Fibula Plates, Syndesmosis Plates

Competitive Comparison [continued]

	Zimmer-Biomet ZipTight Implant System	Wright Medical GRAVITY SYNCHFIX Implant	Smith & Nephew INVISIKNOT Implant System
	Stainless Steel and Titanium	Titanium	Titanium
	UHMWPE MaxBraid Suture	UHMWPE ForceFiber Suture	UHMWPE ULTRATAPE Suture
	Needles through Skin	Yes	Yes
	Yes	No, single square knot recommended	No, two surgical knots required
	3.2 mm	2.8 mm	3.5 mm
	Lateral Fibula Plates, 1/3 Tubular Plates	Lateral Fibula Plates, Syndesmosis Plates	Lateral Fibula Plates, Posterolateral Fibula Plates, 1/3 Tubular Plates

501(k) Clearance Information

January 7, 2022

Acumed LLC
Janki Bhatt
Regulatory Affairs Lead
5885 NE Cornelius Pass Road
Hillsboro, Oregon 97124

Re: K212990
Trade/Device Name: Acumed Ankle Syndesmosis Repair System
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: Class II
Product Code: HTN, HTW, LXH
Dated: December 8, 2021
Received: December 9, 2021

Dear Janki Bhatt:

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 (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 located 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.

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

U.S. Food & Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
www.fda.gov

501(k) Clearance Information [continued]

801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 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-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,

Limin Sun, Ph.D.
Acting 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

501(k) Clearance Information [continued]

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

Submission Number *(if known)*

K212990

Device Name

Acumed Ankle Syndesmosis Repair System

Indications for Use *(Describe)*

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.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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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 developed and launched the first-to-market Fibula Nailing system and added the Ankle 3 Plating System with posterior malleolus plates, making Acumed a global leader in ankle fracture fixation. The Ankle Syndesmosis Repair System represents another innovative offering in Acumed's comprehensive ankle fracture portfolio.

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 logo 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 orthopaedics 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.

References

Citations

1. Schepers T. Acute distal tibiofibular syndesmosis injury: a systematic review of suture-button versus syndesmotic screw repair. *Int Orthop.* 2012;36(6):1199-1206. doi:10.1007/s00264-012-1500-2
2. Raeder B, Figved W, Madsen J, Frihagen F, Jacobsen S, Andersen M. Better outcome for suture button compared with single syndesmotic screw for syndesmosis injury: five-year results of a randomized controlled trial. *Bone Joint J.* 2020;102-B(2):212-219. doi:10.1302/0301-620X.102B2.BJJ-2019-0692.R2.
3. Shimozono Y, Hurley E, Myerson C, Murawski C, Kennedy J. Suture Button Versus Syndesmotic Screw for Syndesmosis Injuries A Meta-analysis of Randomized Controlled Trials. *Am J Sports Med.* 2019 Sep;47(11):2764-2771. doi:10.1177/0363546518804804
4. Laflamme M, Belzile E., Bédard L, van den Bekerom M, Glazebrook M, Pelet S. A prospective randomized multicenter trial comparing clinical outcomes of patients treated surgically with a static or dynamic implant for acute ankle syndesmosis rupture. *J Orthop Trauma* 2015; 29(5): 216-223.

Competitor Content Sources

Arthrex Syndesmosis TightRope XP Implant System Surgical Technique, LT1-00082-EN_D, 2019.

Zimmer-Biomet ZipTight Syndesmosis Surgical Technique, 2265.1-GLBL-en-REV0419

Wright Medical GRAVITY SYNCHFIX Syndesmotic Fixation Device Surgical Technique, 015664B_22-Feb-2018

Smith & Nephew INVISIKNOT Ankle Syndesmosis Repair Kit Surgical Technique, 06082-US V4 06/18

Notes:

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