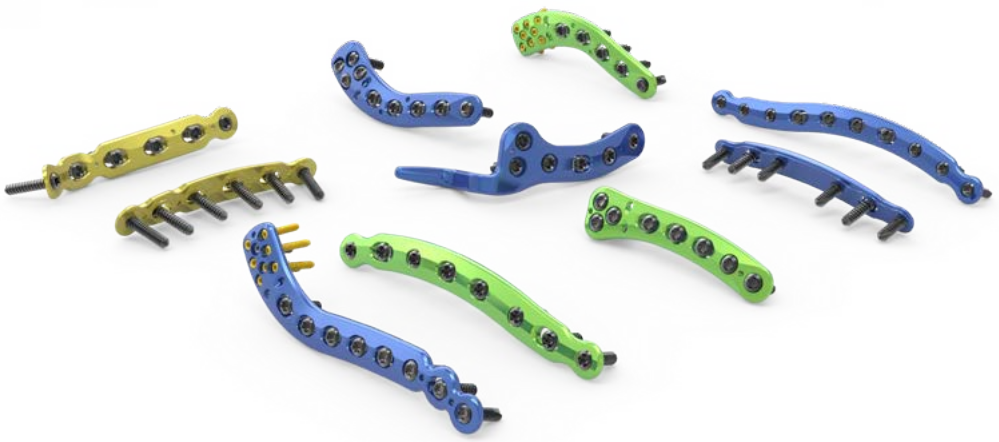
acumed®

Clavicle Fracture Solutions

Value Analysis Committee Resource Guide

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 Clavicle Plating System

The Acumed Clavicle Plating System is a market leader in fracture fixation since its introduction in 2003. Acumed offered an innovative solution for repairing intra-articular fractures, malunions, and nonunions of the clavicle by designing and producing the first precontoured clavicle plates.

In conjunction with our accomplished surgeon design team, Acumed developed the Clavicle Plating System as the next generation in plating fixation. The system includes 57 plate options and unique instrumentation designed to help streamline the surgeon's experience in the operating room.

Table of Contents

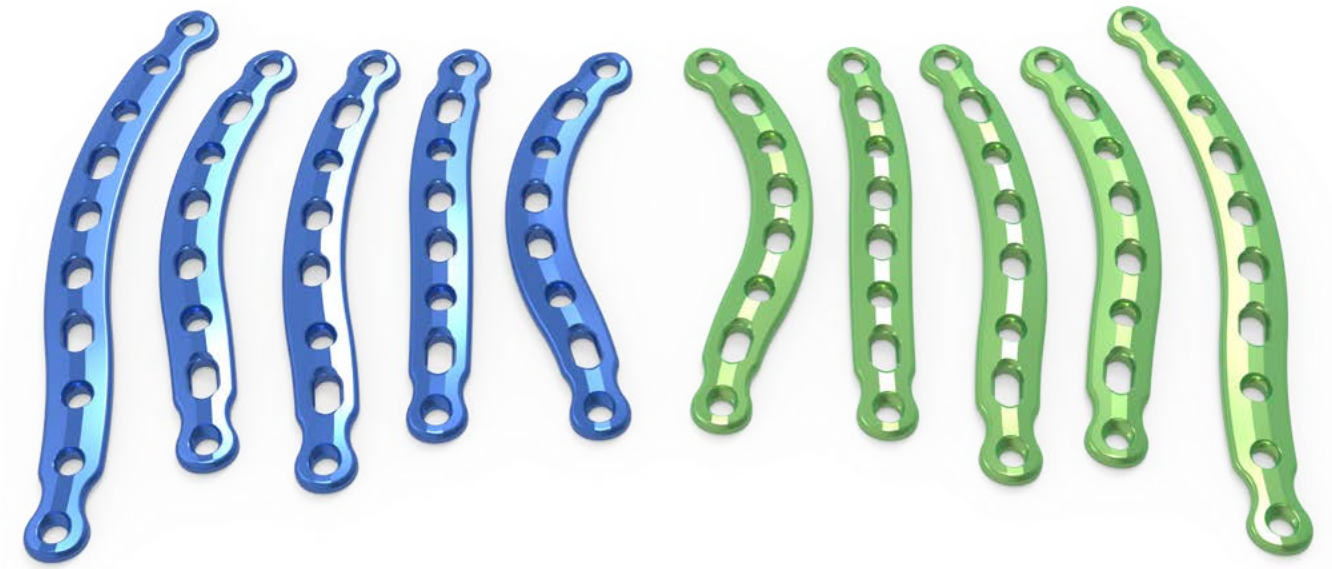
System Features

Plating System

Low-profile Superior Midshaft

Ten Low-profile Superior Midshaft Plates offered in five lengths designed to address central-third clavicle fractures.

Shortest Plate: 87 mm
Longest Plate: 121 mm



Narrow-profile Superior Midshaft

Six Narrow-profile Superior Midshaft Plates offered to accommodate patients with a small bone structure.

Shortest Plate: 74 mm
Longest Plate: 96 mm

System Features [continued]

Anterior Medial and Lateral

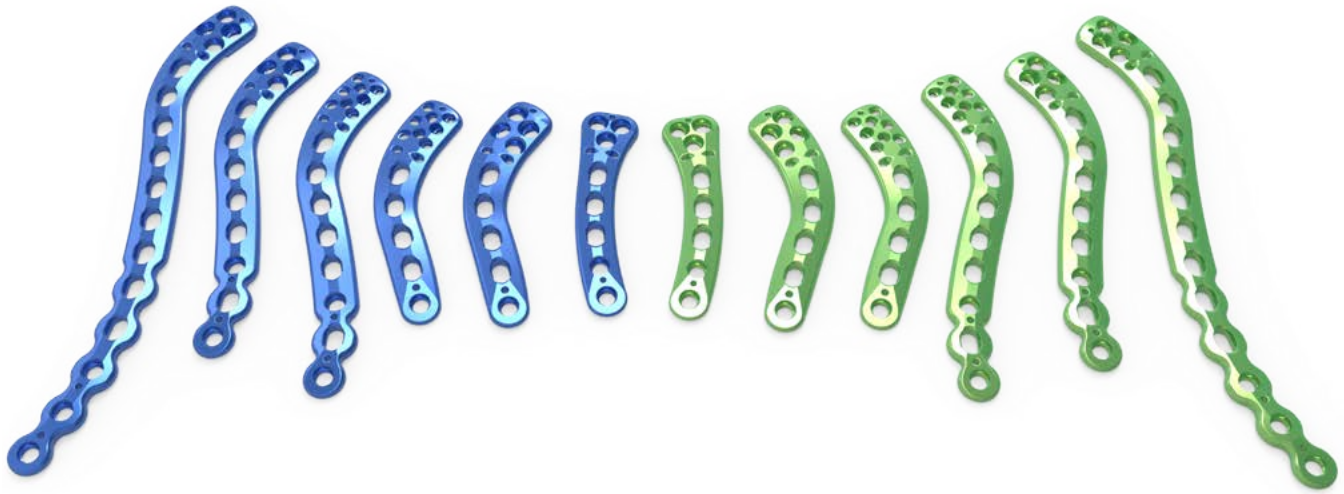
Five Anterior Plates designed for complex oblique fracture patterns as well as for surgeons who prefer an anterior approach.

Shortest Plate: 75 mm
Longest Plate: 115 mm

Superior Distal

Twelve Superior Distal Plates (including two optional 3.5 mm 16-Hole Superior Distal Plates) for complex clavicle fractures, featuring a cluster of 2.3 mm or 3.5 mm screws designed to provide fracture fixation and stability for comminuted fractures.

Shortest Plate: 64 mm
Longest Plate: 140 mm



Optional

Optional

Note: The optional 3.5 mm 16-Hole Superior Distal Clavicle Plates are available sterile packed only.

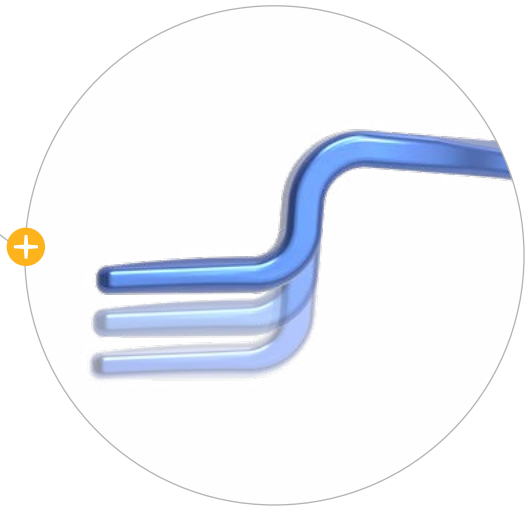
System Features [continued]

Clavicle Hook Plates

Clavicle Hook Plate lengths	
5-hole	69 mm
6-hole	80 mm
7-hole	90 mm
*9-hole	111 mm

*The 9-Hole Clavicle Hook Plate is offered sterile-packed only

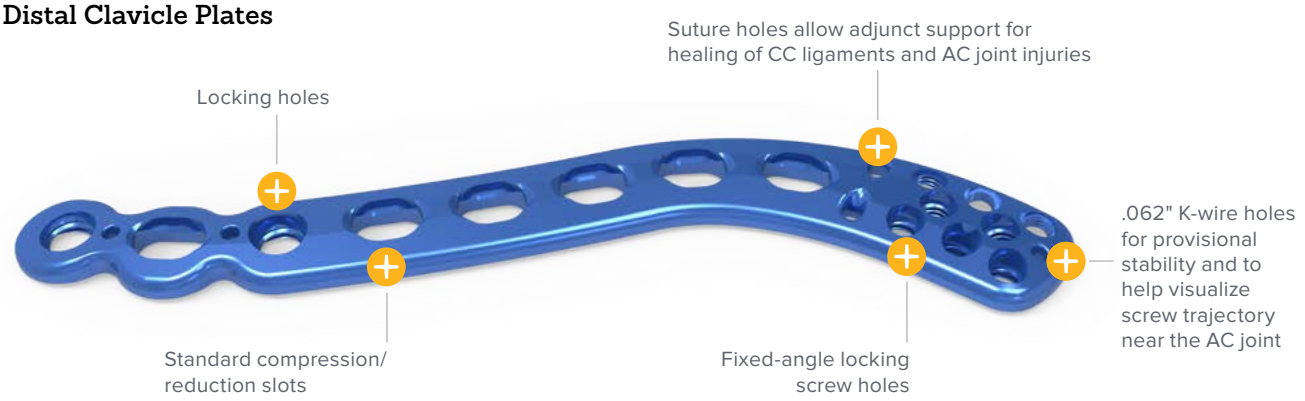
Three hook depths:
- 12 mm
- 16 mm
- 20 mm



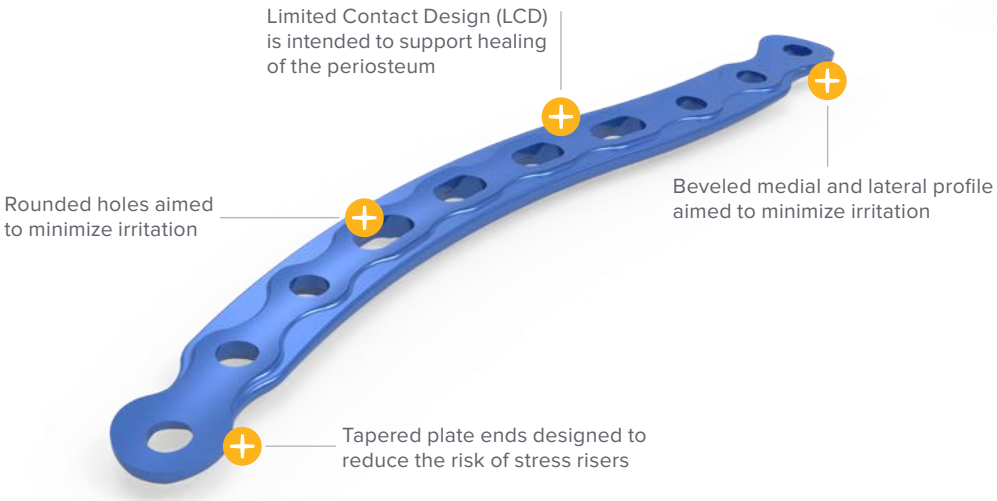
System Features [continued]

Plate Design

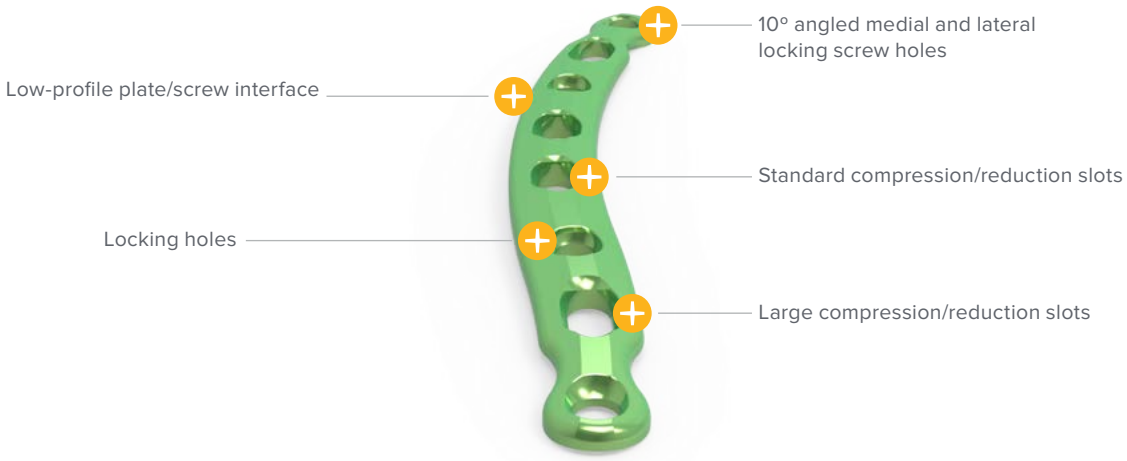
Superior Distal Clavicle Plates



Low-profile Superior Midshaft Plates

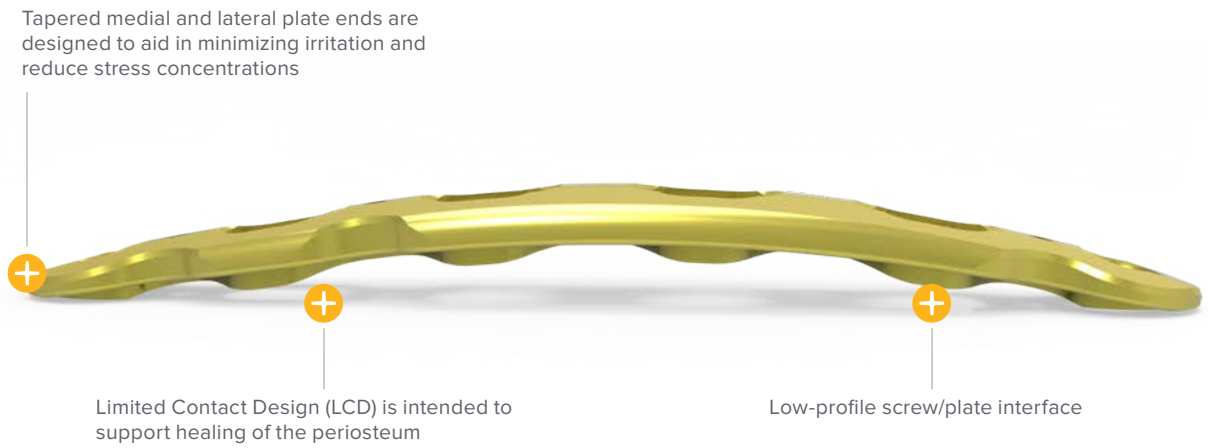


Narrow-profile Superior Midshaft Plates

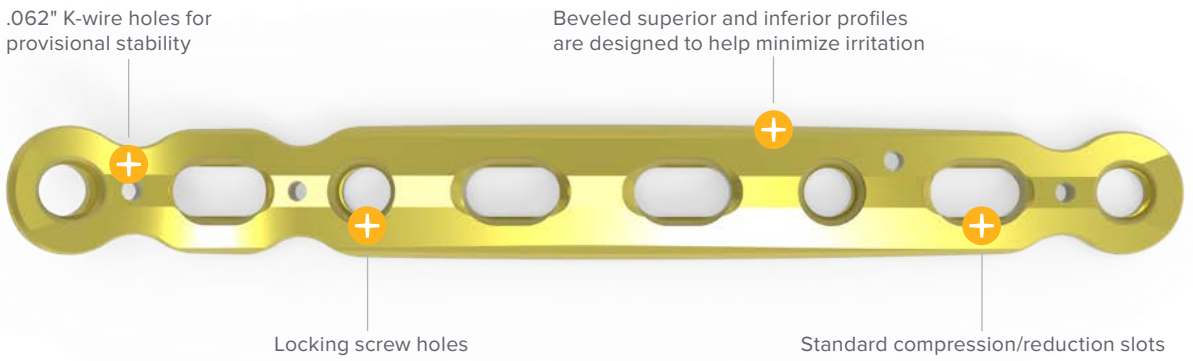


System Features [continued]

Anterior Clavicle Plates—Side

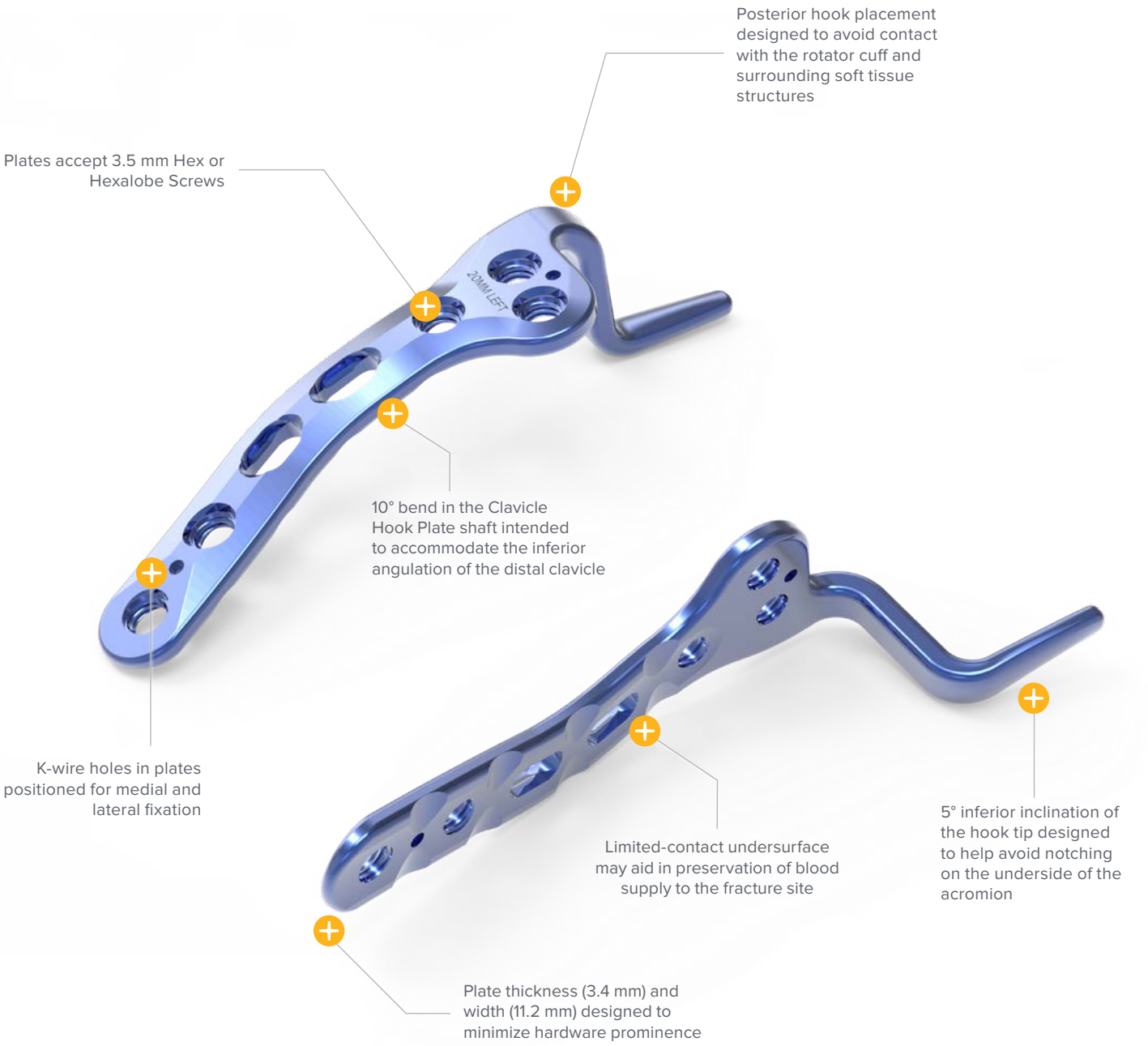


Anterior Clavicle Plates—Top



System Features [continued]

Clavicle Hook Plates



System Features [continued]

Instrumentation

The Clavicle Hook Plating System must be used in conjunction with the Acumed Clavicle Plating System, which contains the instruments and screws necessary to implant the Clavicle Hook Plates.

Clavicle Hook Plate Depth Sizer

The Clavicle Hook Plate Depth Sizer provides the hook depth selection within a single instrument. The hook is inserted under the acromion and the hook depth is chosen by rotating the knob on the depth sizer to trial each of the three hook depth options.

Plate Tacks can be used to temporarily fixate the Clavicle Hook Plate Depth Sizer to the bone while the hook depth measurement is being trialed and/or while the confirmatory fluoroscopic image is being taken.

Clavicle Hook Plate Length Sizer

The Clavicle Hook Plate Length Sizer helps to select plate length for both left- and right-sided plates. The Clavicle Hook Plate Length Sizer can be positioned on top of the depth sizer for length and depth measurements. All plate length options can be seen within a single fluoroscopic image.

A 3.5 mm Locking Drill Guide may be threaded into the Clavicle Hook Plate Length Sizer and used as a handle to maneuver the template.

System Features [continued]

Screw Options

Superior Midshaft, Anterior, and Superior Distal Clavicle Plates

Hexalobe Screws

3.0 mm Locking Hexalobe Screw
8 mm–26 mm
(30-02XX)

3.0 mm Nonlocking Hexalobe Screw
8 mm–26 mm
(30-03XX)

3.5 mm Locking Hexalobe Screw
8 mm–26 mm
(30-02XX)

3.5 mm Nonlocking Hexalobe Screw
8 mm–26 mm
(30-02XX)

Optional Cortical (Hex) Screws*

2.7 mm Locking Cortical (Hex) Screw 8 mm–65 mm
(COL-2XX0)

2.7 mm (Nonlocking) Cortical (Hex) Screw 8 mm–65 mm
(CO-27XX)

4.0 mm Cancellous Screw
12 mm–60 mm
(CA-4XX0)

3.5 mm Locking Cortical (Hex) Screw 6 mm–65 mm
(COL-3XX0)

3.5 mm (Nonlocking) Cortical (Hex) Screw 6 mm–65 mm
(CO-3XX0)

*The 2.7 mm Cortical Screw and 3.5 mm Cortical Screw lengths of 28–65 mm are intended for use with the Scapula Plating System.

Clavicle Hook Plates

Hexalobe Screws

3.5 mm Locking Hexalobe Screw
8 mm–26 mm
(30-02XX)

3.5 mm Nonlocking Hexalobe Screw
8 mm–26 mm
(30-02XX)

Cortical (Hex) Screws

3.5 mm Locking Cortical (Hex) Screw
8 mm–26 mm
(COL-3XX0)

3.5 mm (Nonlocking) Cortical (Hex) Screw
8 mm–26 mm
(CO-3XX0)

Superior Distal Clavicle Plates Only

Cortical (Hex) Screws

2.3 mm Locking Cortical (Hex) Screw
8 mm–26 mm
(CO-T23XX)

2.3 mm Nontoggling (Nonlocking) Cortical (Hex) Screw
8 mm–26 mm
(CO-N23XX)

System Features [continued]

Indications for use

The Acumed Clavicle Plating System is intended to provide fixation for fractures, malunions, and nonunions of the clavicle.

The Acumed Clavicle Hook Plating System is intended to be used in conjunction with the Clavicle Plating System to provide fixation of lateral clavicle fractures, osteotomies, malunions, nonunions and dislocations of the acromioclavicular joint.

The Acu-Sinch® Repair System is intended to be used in conjunction with the Clavicle Plating System to provide fixation during the healing of clavicle fractures.

System Features [continued]

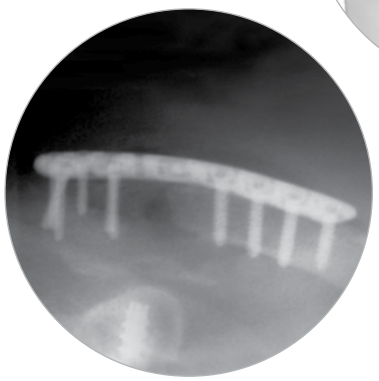
Acu-Sinch® Repair System

Coracoclavicular (CC) Ligament Support

Disruption of the CC ligaments is a common incident associated with displaced distal clavicle fractures.

The Acu-Sinch Repair System is designed to support healing of the CC ligaments and is used in conjunction with an Acumed Superior Midshaft or Distal Clavicle Plate to provide fixation during the healing of clavicle fractures. This suture-and-anchor soft tissue repair system offers the surgeon the ability to penetrate only the superior cortex of the coracoid, preserving the integrity of the inferior cortex, and protecting the neurovascular structures below.

The Acu-Sinch Repair System is supplied in a sterile procedure pack which includes an Acu-Sinch Drill, an Acu-Sinch Driver with a preassembled Anchor and Acumed FlexBraid® Suture, and two Acu-Sinch Suture Retainers. The Acumed FlexBraid Suture is a #5, non-absorbable, UHMWPE (Ultra high molecular weight polyethylene) suture.



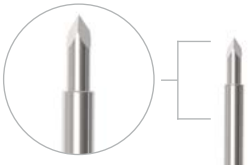
Anchor
Preassembled onto the Acu-Sinch Driver with the suture strands running through the driver handle

3.5 mm minor diameter

5.5 mm major diameter

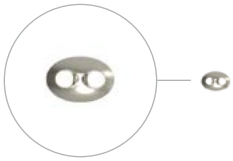
12 mm in length

Drill
3.5 mm Acu-Sinch Drill with a shoulder to help ensure drilling only through the superior cortex of the coracoid



Suture Retainer
Fits into any slot in the Acumed Midshaft Superior or Distal Clavicle Plates

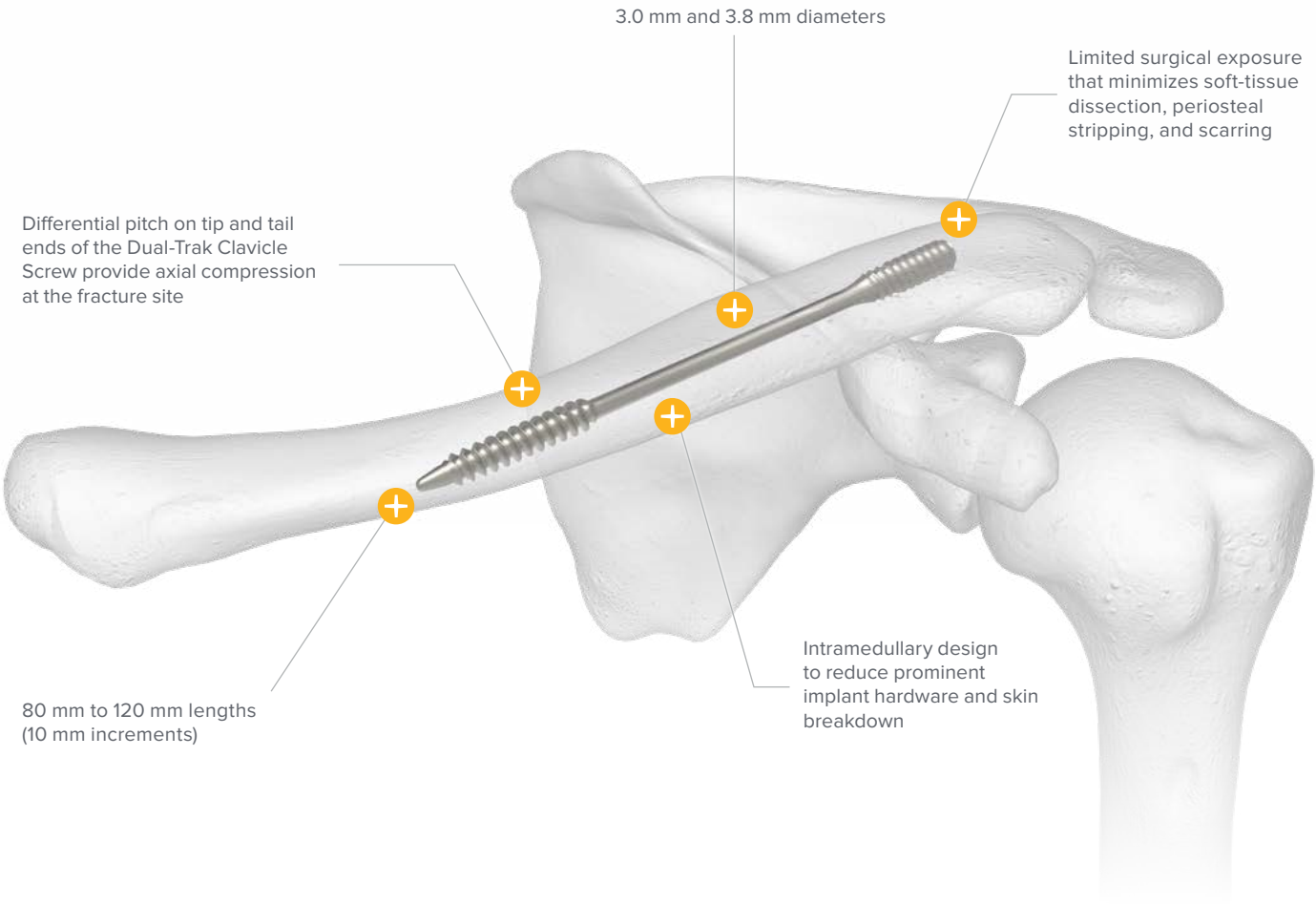
Concave design may minimize the potential for soft tissue irritation



FlexBraid Suture
The FlexBraid Suture is a #5, non-absorbable, UHMWPE suture

System Features [continued]

Dual-Trak Clavicle Screw System



Facts About Clavicle Fractures

Current clinical literature estimates that approximately 2% to 5% of all fractures in adults and 10% to 15% of all fractures in children involve a fracture of the clavicle.[1] The literature continues with the projected incidence rate of a clavicle fracture in the adolescent and adult population to be between 29 and 64 per 100,000 persons annually. There tends to be a higher incidence rate for younger male patients, aged under 30 years, and elderly patients aged over 70 years appear to be at higher risk for clavicle fractures.[1]

Historically, many clavicle fractures have been treated utilizing non-surgical techniques. The most common method has been to use a sling or figure-8 brace to immobilize the shoulder and allow the patient to heal. Recent studies have begun to show that certain types of clavicle fractures either fail to heal properly or, possibly not at all, resulting in nonunion, shoulder dysfunction, or residual pain after use of non-surgical management techniques. Studies now indicate that certain clavicle fractures require surgical intervention in order to heal properly.[1,2,3,4]

Allman Classification	Description[7]	Neer Classification	Description[7]
Group I	Fracture in middle third of clavicle	Nondisplaced	Fracture with less than 100% displacement
		Displaced	Fracture with more than 100% displacement
Group II	Fracture in distal third of clavicle	Type I	Fracture lateral to CC ligaments, conoid and trapezoid ligaments intact
		Type IIA	Fracture medial to CC ligaments, conoid and trapezoid ligaments intact
		Type IIB	Fracture lateral to or between CC ligaments, conoid ligament torn, trapezoid ligament intact
		Type III	Intraarticular fracture extending into the AC joint, conoid and trapezoid ligaments intact
		Type IV	Physeal fracture, periosteal sleeve avulsed, conoid and trapezoid ligaments intact
		Type V	Comminuted fracture, conoid and trapezoid ligaments intact
Group III	Fracture in medial third of clavicle		

Allman type I and type III fractures are typically treated conservatively unless excessive shortening or displacement necessitates fixation.[1] Treatment of Allman type I fractures can be controversial, options for these fractures may include intramedullary fixation or plating.[1,2,3,4,5]

Competitive Comparison

Feature	Acumed Clavicle Plating System	Arthrex Clavicle Plate and Screw System	Stryker VariAx Clavicle Locking Plate System	DePuy Synthes Modular Clavicle Plate System
Clavicle Plating Options	57	21	43	36
Longest Plate Option	140 mm	126 mm	144 mm	135 mm
Distal Screw Sizes	3.5 mm, 3.0 mm*, or 2.3 mm	2.7 mm, 3.5 mm	2.7 mm, 3.5 mm	2.7 mm or 2.4 mm
Coracoclavicular Ligament Injury Solutions	Acu-Sinch® Repair System, Hook Plate	TightRope®, Dog Bone Button	Hook Plate	Hook Plate
Distal Screw Hole Cluster	3-, 4-, or 8-hole cluster	5-hole cluster	6-hole cluster	6-hole cluster
Solution-Based System	Yes	No	No	No
J-Plate	Yes	No	No	No

*2.7 mm for hex screw configurations

Competitive Comparison [continued]

Discussion
In addition to Arthrex's clavicle plating options, Acumed offers multiple anterior plates, hook plates, a J-plate, and two additional distal screw cluster configurations. Stryker does not offer multiple distal screw cluster configurations or a J-plate option. Synthes has only one plate shape per family and its selection is based on length. Our selection is based on curvature, which may provide more anatomic options.
The Acumed 16-hole clavicle plate spans 140 mm, intended for larger-statured patients. The Acumed 16-hole clavicle plate is longer than Synthes's longest plating equivalent, which may be advantageous for larger-statured patients.
Acumed Superior Plates offer three distal screw sizes, which gives surgeons an additional screw option compared with Arthrex, Stryke or Synthes. This may prove advantageous in treating a range of fracture patterns.
The Acu-Sinch® provides unicortical fixation, which does not require drilling of the inferior cortex of the coracoid. The Dog Bone Button requires bicortical drilling. Arthrex offers an AC guide for use underneath the coracoid to prevent the risk of injury to the neurovascular structures. Acumed also offers a Clavicle Hook Plate option to stabilize the AC joint by placing the hook beneath the acromion. Hook plates are typically removed to avoid limited range of motion, pain, and other shoulder complications.[6] The Acu-Sinch® addresses CC ligament disruptions associated with clavicle fractures using a suture anchor in the coracoid tethered by suture to the clavicle plate. The Stryker lateral hook plate and Acumed Clavicle Hook Plate stabilize the AC joint by placing the hook beneath the acromion. Hook plates are typically removed to avoid limited range of motion, pain, and other shoulder complications.[6] The Acu-Sinch® addresses CC ligament disruptions associated with clavicle fractures using a suture anchor in the coracoid tethered by suture to the clavicle plate. The Synthes 3.5 mm LCP hook plate and Acumed Clavicle Hook Plate stabilize the AC joint by placing the hook beneath the acromion. Hook plates are typically removed to avoid limited range of motion, pain, and other shoulder complications.[6]
The Acumed clavicle system offers three distal screw hole cluster options compared to Arthrex's one. Acumed provides three distal cluster options along with an additional screw size to address simple to complex distal clavicle fractures. Acumed Superior Plates offer three distal screw sizes, which gives surgeons an additional screw option compared with Stryker. This may prove advantageous in treating a range of fracture patterns. The Acumed clavicle system offers three distal screw hole cluster options compared to Synthes's one. Acumed provides three distal cluster options along with an additional screw size to address simple-to-complex distal clavicle fractures.
▸ The Acu-Sinch Repair System and Clavicle Hook Plates can address CC ligament disruptions associated with clavicle fractures. ▸ The Dual-Trak Clavicle System provides intramedullary clavicle fixation. ▸ The Scapula Plating System offers the first anatomically precontoured plating solution for scapula fractures.
Acumed offers a J-plate that can be used for medial fractures with a 3-hole cluster that is designed to maximize screw purchase.

510(k) Clearance Information

Clavicle Plating System

K012655

NOV 0 7 2001

Appendix V - 510(k) Summary

This summary regarding 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.93.

Classification Name: Plate, Fixation, Bone
Common Name: Bone Plate
Proprietary Name: Congruent Bone Plate System
Proposed Regulatory Class: II
Device Product Code: HRS
Manufacturing Facility: Acumed, Inc.
10950 SW 5th Street, Suite 170
Beaverton, OR 97005 U.S.A.
Establishment Registration No.: 3025141
Contact: Shari Jeffers
Labeling/Promotional Materials: See Appendix III
Substantial Equivalence:
The Acumed Congruent Bone Plate System is similar in indication, intended use, material, design, and size to Howmedica's Distal Humeral Plate (K890939) and Luhr Fixation System (K951415), to Synthes' Curved Reconstruction Plate (K011334), the Modular Foot System (K001941), and the One-Third Tubular Plate (K011335), and to Link's May Tibia Bone Plates (K912936). Literature on these predicate devices is included in Appendix IV.

The Congruent Bone Plate System consists of bone plates and screws for fractures, fusions, and osteotomies. The bone plates are pre-bent to minimize bending which is done intraoperatively. Instruments are supplied with the implants to aid in the insertion of the plates and screws. Each of the plate styles utilizes the same screw types and screw instruments for insertion. All of the plates and screws are manufactured from titanium and are provided non-sterile. The screws were cleared for marketing and distribution under K942340 and K942341.

Congruent Bone plates are provided non-sterile and are individually packaged in a plastic bag. On file at Acumed is data which shows that the instrumentation and implants can be successfully steam sterilized under specific process parameters which will obtain a resulting SAL of 10^{-6}. Information regarding labeling has been provided.

Predicate devices that are substantially equivalent to Acumed's Congruent Bone Plate System are Howmedica's Distal Humeral Plate and Luhr Fixation System; Synthes' Curved Reconstruction Plate, the Modular Foot System, and the One-Third Tubular Plate; and Link's May Tibia Bone Plates. All the devices mentioned above are manufactured from similar material, and have the same indication/intended use and similar design and size characteristics.
Based on the similarities between the Acumed Congruent Bone Plate System and the predicate devices studied, the safety and effectiveness of the Acumed Congruent Bone Plate System is expected to be similar to the predicate devices mentioned above.

10950 SW 5th Street, Suite 170, Beaverton, OR 97005 U.S.A. ♦ (503) 627-9957 ♦ Fax: (503) 520-9618

510(k) Clearance Information [continued]

Clavicle Plating System

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 0 7 2001

Ms. Shari Jeffers
Manager of Regulatory Affairs
Acumed, Inc.
10950 SW 5th Street, Suite 170
Beaverton, Oregon 97005

Re: K012655
Trade/Device Name: Acumed Congruent Bone Plate System
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/Multiple Component Metallic Bone Fixation Appliances and Accessories
Regulatory Class: Class II
Product Code: HRS
Dated: August 6, 2001
Received: August 13, 2001

Dear Ms. Jeffers:

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. 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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such 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

510(k) Clearance Information

Clavicle Plating System

Page 2 – Ms. Shari Jeffers

(21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Celia M. Witten, Ph.D., M.D.
Director
Divison of General, Restorative and
Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Clearance Information [continued]

Clavicle Plating System

Page 1 of 1

NOV 0 7 2001

510(k) Number (if known): K012655

Device Name: Congruent Bone Plate System

Indications For Use:

The Acumed Congruent Bone Plate System provides fixation for fractures, fusions, or osteotomies for the clavicle, humerus, radius, ulna, metacarpal, metatarsal, malleolus, tibia, and fibula.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative and Neurological Devices

510(k) Number K012655

Prescription Use X OR Over-The-Counter Use

(Per 21 CFR 801.109)

(Optional Format 1-2-96)

510(k) Clearance Information [continued]

Clavicle Hook Plating System

July 15, 2021

Acumed LLC
Janki Bhatt
Regulatory Specialist 3
5885 NE Cornelius Pass Road
Hillsboro, Oregon 97124

Re: K210750
Trade/Device Name: Acumed Clavicle Hook Plating System
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/Multiple Component Metallic Bone Fixation Appliances And Accessories
Regulatory Class: Class II
Product Code: HRS, HWC
Dated: June 14, 2021
Received: June 16, 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

510(k) Clearance Information [continued]

Clavicle Hook Plating System

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,

For: Shumaya Ali, M.P.H.
Assistant Director
DHT6C: Division of Restorative, Repair,
and Trauma Devices
OHT6: Office of Orthopedic Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

510(k) Clearance Information [continued]

Clavicle Hook Plating System

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)*

K210750

Device Name

Acumed Clavicle Hook Plating System

Indications for Use *(Describe)*

The Acumed Clavicle Hook Plating System is intenced for fixation of lateral clavicle fractures, osteotomies, mal-unions, non-unions and dislocations of the acromioclavicular joint.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Clearance Information [continued]

Dual-Trak Clavicle Screw System

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY - 5 1995

Ms. Shari L. Jeffers
Quality Regulatory Coordinator
Acumed, Inc.
10950 Southwest 5th, Suite 170
Beaverton, Oregon 97005

Re: K944330
Acutrak Plus Fixation System
Regulatory Class: II
Product Code: HWC
Dated: April 19, 1995
Received: April 21, 1995

Dear Ms. Jeffers:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent to devices marketed in interstate commerce prior to May 28, 1976 or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). This decision is based on your device being found equivalent only to similar devices labeled and intended for fusion, fracture fixation and osteotomy fixation in the clavicle, humerus, radius, ulna, ilium, femur, patella, fibula, tibia, talus, malleolus and calcaneus. You may, therefore, market your device subject to the general controls provisions of the Act.

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. Note that labeling or otherwise promoting a device for pedicular screw fixation/attachment would cause the device to be adulterated under 501(f)(1) of the Act. This device, if intended for use in pedicular screw fixation/attachment, would be found not substantially equivalent and would be a class III device under Section 513(f) of the Act. Class III devices are required to have an approved premarket approval (PMA) application prior to marketing. Accordingly:

1. All labeling for this device, including the package label, must state that there are labeling limitations. The package insert must prominently state that the device is intended for fusion, fracture fixation and osteotomy fixation in the clavicle, humerus, radius, ulna, ilium, femur, patella, fibula, tibia, talus, malleolus and calcaneus only; and

510(k) Clearance Information [continued]

Dual-Trak Clavicle Screw System

Page 2 - Ms. Shari L. Jeffers

2. You may not label or in any way promote this device for pedicular screw attachment to, or fixation of the cervical, thoracic or lumbar vertebral column. If this device is a screw with outer diameters of 3 mm - 10 mm and overall lengths of 10 mm - 75 mm inclusively, the labeling must include the following statement, **"WARNING:** This device is not approved for screw attachment or fixation to the posterior elements (pedicles) of the cervical, thoracic, or lumbar spine." Any pedicular screw fixation/attachment to the cervical, thoracic or lumbar vertebral column of this device is considered investigational and may only be investigated as a significant risk device in accordance with the investigational device exemption (IDE) regulations under 21 CFR, Part 812. All users of the device for pedicular screw fixation/attachment must receive approval from their respective institutional review boards (IRBs) and the Food and Drug Administration (FDA) prior to conduct of the investigation.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval) it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations (CFR), Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practices (GMP) for Medical Devices: General GMP regulation (21 CFR Part 820) and that, through periodic GMP inspections, the Food and Drug Administration (FDA) will verify such assumptions. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal Laws or Regulations.

This letter immediately will allow you to begin marketing your device for fracture fixation of the clavicle, humerus, radius, ulna, ilium, femur, patella, fibula, tibia, talus, malleolus and calcaneus only as described in your 510(k) premarket notification. An FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and permits your device to proceed to the market, but it does not mean that FDA approves your device. Therefore, you may not promote or in any way represent your device or its labeling as being approved by FDA. If you desire specific advice regarding labeling for your device in accordance with 21 CFR Part 801, promotion, or advertising please contact the Office of Compliance, Promotion and Advertising Policy Staff (HFZ-302) at (301) 594-4639.

510(k) Clearance Information [continued]

Dual-Trak Clavicle Screw System

Page 3 - Ms. Shari L. Jeffers

Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at their toll free number (800) 638-2041 or at (301) 443-6597.

Sincerely yours,

Paul R. Beninger, M.D.
Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

510(k) Clearance Information [continued]

Acu-Sinch® Repair System

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Acumed LLC
% Ms. Lino Tsai
Regulatory Specialist
5885 NW Cornelius Pass Road
Hillsboro, Oregon 97124-9432

NOV 14 2011

Re: K112111
Trade/Device Name: Acu-Sinch 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, HWC, MBI, HRS
Dated: October 10, 2011
Received: October 11, 2011

Dear Ms. Tsai:

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. 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 801); medical device reporting (reporting of medical

510(k) Clearance Information [continued]

Acu-Sinch® Repair System

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Clearance Information [continued]

Acu-Sinch® Repair System

4. Indications for Use

510(k) Number (if known): ~~K112111~~ K112111

Device Name: Acu-Sinch Repair System

The Acu-Sinch Repair System is intended to be used in conjunction with a clavicle plate of the Congruent Bone Plate System to provide fixation during the healing of clavicle fractures.

The Acu-Sinch Repair System also may be used as a stand-alone system for treatment of acromioclavicular and/or coracoclavicular ligament disruption.

Prescription Use ___√___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Page 1 of 2

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K112111

510(k) Clearance Information [continued]

Acu-Sinch® Repair System

K112111

The Acumed Suture Anchor is intended for fixation of suture to bone in the shoulder, foot/ankle, knee, hand/wrist, and elbow in the following procedures:

- Shoulder: Rotator Cuff Repairs, Bankart Repair, SLAP Lesion Repair, Biceps Tenodesis, Acromio-Clavicular Separation Repair, Deltoid Repair, Capsular Shift or Capsulolabral Reconstruction
- Foot/Ankle: Lateral Stabilization, Medial Stabilization, Achilles Tendon Repair, Hallux Valgus Reconstruction, Midfoot Reconstruction, Metatarsal Ligament Repair
- Knee: Anterior Cruciate Ligament Repair, Medial Collateral Ligament Repair, Lateral Collateral Ligament Repair, Patellar Tendon Repair, Posterior Oblique Ligament Repair, and Iliotibial Band Tenodesis
- Hand/Wrist: Scapholunate Ligament Reconstruction, Ulnar Collateral Ligament Reconstruction, Radial Collateral Ligament Reconstruction
- Elbow: Biceps Tendon Reattachment, Ulnar or Radial Collateral Ligament Reconstruction

Acumed's Locking Clavicle Plating System is designed to provide fixation during fractures, fusions, or osteotomies of the clavicle.

Prescription Use ___√___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic, and Restorative Devices

510(k) Number K112111

Page 2 of 2

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 launched the industry-first precontoured clavicle plating system in 2003. Since then, the Acumed Clavicle Plating System has been used for successful treatment of over 300,000 clavicle fractures. Acumed will continue to devote resources to the development of implants that aid in improving patient outcomes and advance the field of orthopedic surgery. As a partner, Acumed provides a pipeline of leading-edge products.

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.

Acumed's 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

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3. McKee MD, et al. Midshaft malunions of the clavicle. *J Bone Joint Surg AM* 2003;May;85(5):790-797.
4. Wijdicks FJ, et al. Systematic review of complications after intramedullary fixation for displaced midshaft clavicle fractures. *Can J Surg*. 2013; Feb;56(1):58-64.
5. Zlowodzki M, et al. Treatment of acute midshaft clavicle fractures: systematic review of 2144 fractures: on behalf of the Evidence-Based Orthopaedic Trauma Working Group. *J Orthop Trauma*. 2005;19:504-507.
6. Chen C, et al. Effects of hook plate on shoulder function after treatment of acromioclavicular joint dislocation. *Int J Clin Exp Med.* 2014;7(9):2564-2570.
7. Eugene S. Jang,* MD, et al. A current concepts review of clavicle injuries in ice hockey from sternoclavicular to acromioclavicular joint. *Orthop J Sports Med.* Volume 8, Issue 9, September 2020:1-8

Competitor Content Sources

DePuy Synthes Modular Clavicle Plate System Surgical Technique (DSUS/TRM/1014/0270); 2015.

DePuy Synthes 3.5 mm LCP Clavicle Hook Plate Surgical Technique (DSUS/TRM/1016/1127); 2017.

Stryker VariAx Clavicle Locking Plate System Operative Technique (VAX-ST-8 Rev.3, 09-2015); 2015.

Stryker VariAx Clavicle System Components Guide (VAX-SCS-3 Rev 1, 11-2015); 2015.

Arthrex Clavicle Plate and Screw System Surgical Technique (LT1-0255-EN_C): 2019

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