acumed®

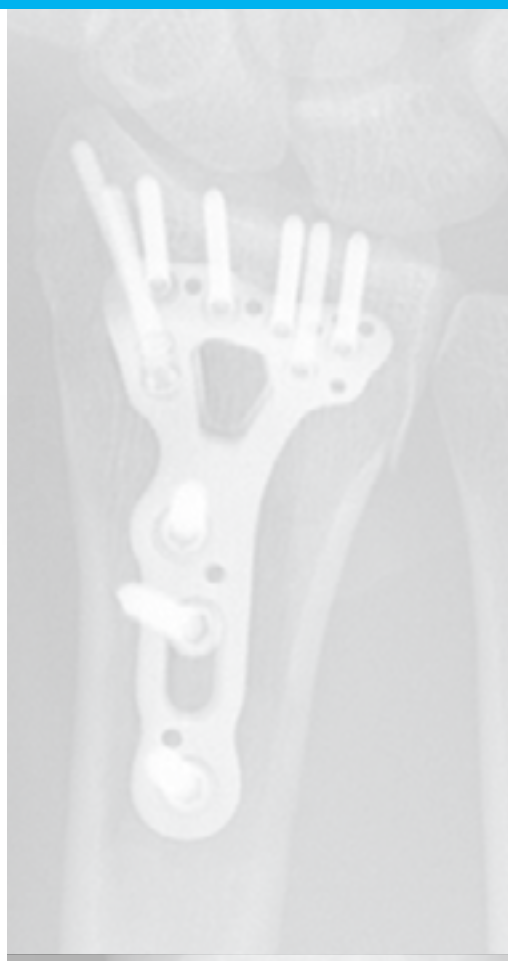
Acu-Loc® 2 Wrist Plating System

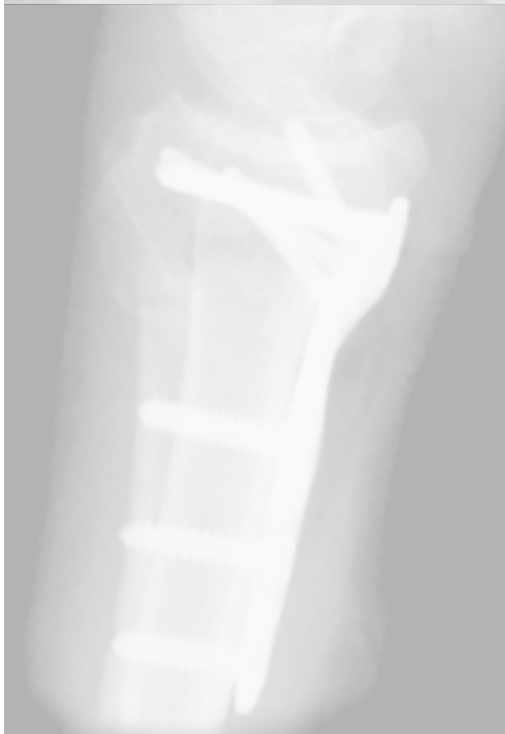
Value Analysis Committee Resource Guide

A COLSON ASSOCIATE

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-Loc 2

The original Acu-Loc Volar Distal Radius Plate has been a market leader in fracture fixation since its introduction in 2004. Acumed offered an innovative solution for repairing intra-articular fractures, malunions, and nonunions of the distal radius by designing the first anatomic volar plate.

In conjunction with our accomplished surgeon design team, Acumed developed the Acu-Loc 2 Volar Distal Radius (VDR) Plating System as the next generation in plating fixation. The system presents several new plate options, a two piece locking compression screw, instrumentation for fracture management, and new plate placement tools.

Table of Contents

Indications for Use

Acumed Acu-Loc 2 Wrist Plating System

A comprehensive system to treat fractures of the distal radius and distal ulna, the Acu-Loc 2 Wrist Plating System offers Standard, Variable Angle Locking, Fragment-Specific, and Extension Plates to address a variety of fracture patterns.

The original Acu-Loc Volar Distal Radius Plate has been a market leader in fracture fixation since its introduction in 2004. The Acu-Loc 2 Wrist Plating System introduced a patented cannulated compression screw and instruments designed to assist surgeons with plate placement and fracture reduction. The Acu-Loc and Acu-Loc 2 VDR Plates have Combined to treat over 800,000 distal radius fractures globally since 2004.

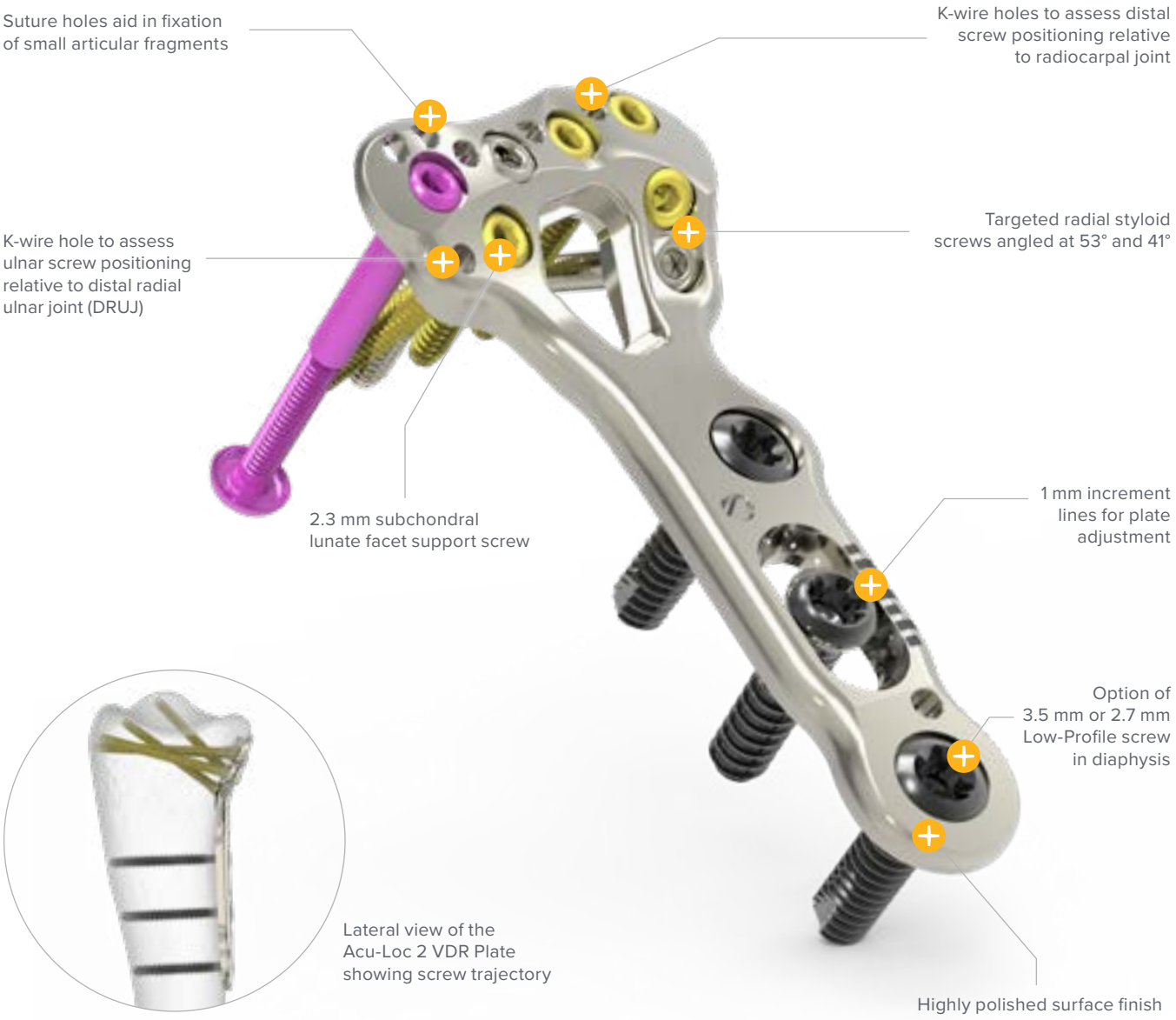
Indications for Use:

The Acumed Acu-Loc Plating System provides fixation for fractures, fusions, or osteotomies of the distal radius and ulna. The Acumed Acu-Loc 2 Plating System provides fixation for fractures, fusions, or osteotomies of the distal radius.

System Features

Acu-Loc 2 Volar Distal Radius (VDR) Plates

The standard Acu-Loc 2 Plate is designed to closely replicate the anatomical contours of the distal radius and may assist in restoring the original geometry. The 2.3 mm Locking Variable Angle Screws can be used in the distal styloid hole only for all silver-colored Acu-Loc 2 VDR Plates. Please see the 2.3 mm Locking Variable Angle Screw section for additional information.



Lateral view of the Acu-Loc 2 VDR Plate showing screw trajectory

System Features [continued]

Precontoured plates are intended to minimize the need for intraoperative plate bending to help save operating time and allow the surgeon to focus on restoring the patient's anatomy.

The implants are machined from a commercially pure titanium alloy and offer elasticity closer to that of bone while reducing the propensity for stress shielding.[11] Wolff's law states that if loading on a particular bone increases, bone will remodel itself to become stronger to resist loading and if loading on a bone decreases, bone will become weaker.[12]

The advantage to having this many plate options is the ability to address multiple different fractures with coverage of the volar/dorsal radius and ulna, as well as intra-articular fractures. Surgeons will also have the option of using an intermediate or radial column approach.

The Acu-loc 2 system contains plate families from the original Acu-Loc Volar Distal Radius Plating System.
Features and components include:

Distal Radius Fragment Specific (DRFS) Plates

Volar Lunate Suture Plate Sutures may be placed through the volar capsule and suture holes in the plate for fixation of very small bone fragments in the volar ulnar corner of the radius.

Radial Styloid Plate: Two unicortical distal screws diverge to provide subchondral bone support, with one screw targeting the dorsal rim of the sigmoid notch and the other targeting the volar rim.

Volar Distal Ulna (VDU) Plates: Designed specifically for periarticular fractures of the distal ulna, the plate features screw positioning and angulation that targets distal fragments of the ulnar head and neck.

Dorsal Rim Buttress Plates: The plate is positioned on the dorsal ulnar side of the radius and extends radially to support dorsal rim comminution and the radial styloid.

Dorsal Lunate Plates: Used for stabilizing fracture patterns that involve the dorsal lunate facet of the distal radius and the sigmoid notch, the plates provide support to the lunate facet.

System Features [continued]

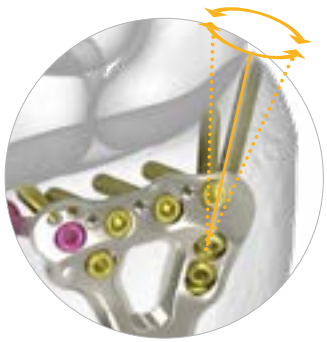
Modular Extension Plate: Attachments Offer surgeons the option to extend any of the long and wide Volar Distal Radius Proximal Plates up to 176 mm

Acu-Loc Dorsal Plates: The locking Acu-Loc Dorsal Plates offer a solution to treat distal radius fractures that need to be addressed from the dorsal side.

Acu-Loc Extra-articular (EX) Plates: 2.3 mm locking variable angle screws may be used in the distal row of the Acu-Loc EX Plates. These screws are provided to aid in the capture of specific fragments or to accommodate variations in patient anatomy.

The 2.3 mm Locking Variable Angle Screws can be used in any distal hole of the gold-colored Acu-Loc 2 VDR Proximal and Acu-Loc EX Plates as well as the distal styloid hole only for all silver-colored Acu-Loc 2 VDR Plates.

- The screw allows a total variance of 15 degrees
- Orange color-coded instrumentation allows for quick identification of the proper drill, drill guide, and driver handle in the system.



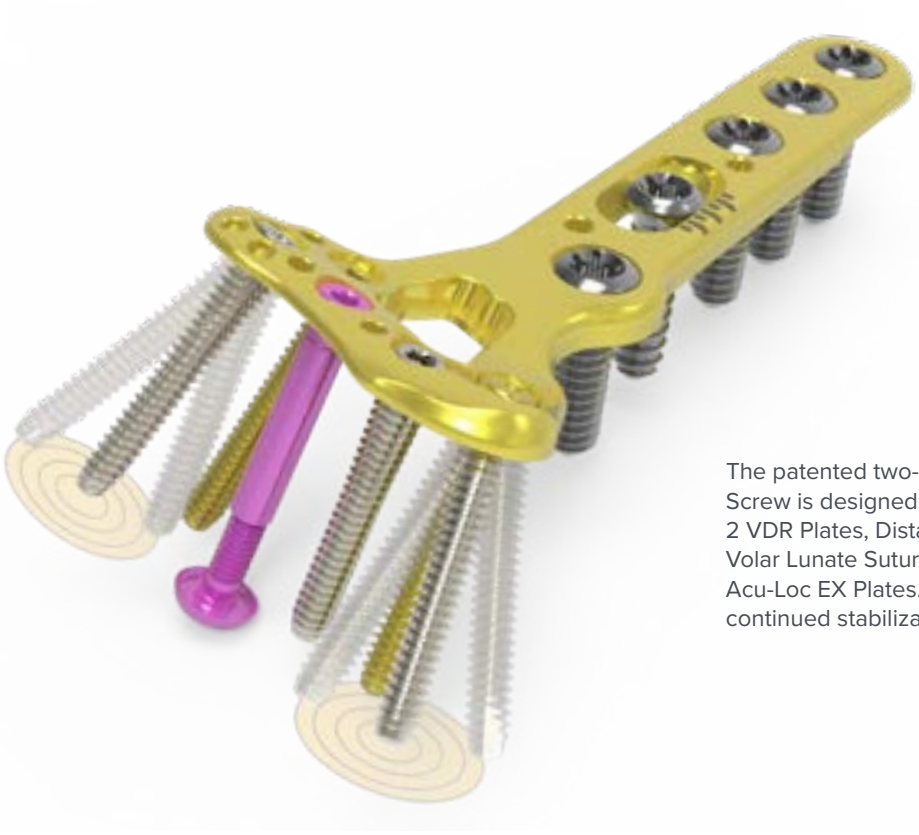
Standard VDR Plate with VAL Screw in distal styloid hole

System Features [continued]

The Acumed Acu-Loc 2 VDR Plating System offers advanced instrumentation designed to help with plate placement and fracture reduction.

- Patented radiolucent targeting guides with radiopaque markings and the Plate Positioning Handle aid in the flouroscopic visualization of anticipated screw trajectories and plate placement.
- For support with the distal first reduction technique and corrective osteotomies, Kickstand Posts aid in plate angulation relative to the dorsally displaced distal radius.

System Features [continued]



The patented two-part, cannulated Frag-Loc® Compression Screw is designed to reduce dorsal fragments to the Acu-Loc 2 VDR Plates, Distal Radius Fragment Specific (DRFS) Plates, Volar Lunate Suture Plate, Acu-Loc VDR Plates, and Acu-Loc EX Plates. liturature has shown its benefit in continued stabilization of interarticular fractures.[13, 14]

The Acumed Acu-Loc 2 VDR Plating System offers a variety of screw types to accommodate the surgeon's preference for fracture fixation.

Distal Screw Options:

- 2.3 mm Locking Cortical Pegs (8 mm–28 mm)
- 2.3 mm Locking Cortical Screws (8 mm–46 mm)
- 2.3 mm Nontoggling Cortical Screws (8 mm–46 mm)
- 2.3 mm Locking Variable Angle Screws (14 mm–28 mm)
- Frag-Loc Compression Screws (16 mm–28 mm range)

Proximal Screw Options:

- 2.7 mm Locking Low-Profile Hexalobe Screws (8 mm–19 mm)
- 2.7 mm Nonlocking Low-Profile Hexalobe Screws (9 mm–19 mm)
- 3.5 mm Locking Hexalobe Screws (8 mm–18 mm)
- 3.5 mm Nonlocking Hexalobe Screws (10 mm–18 mm)

Facts About Distal Radius Fractures

According to the study "Plating of the Distal Radius" that appeared in the *Journal of the American Academy of Orthopaedic Surgeons*, distal radius fractures make up as much as 15% of all extremity fractures.[2] Surgical fixation of unstable distal radius fractures continues to evolve in an effort to provide rigid stabilization, permit motion early, and reduce soft tissue morbidity.[1] Distal radius plates are the standard of care for these fractures, which are among the most common forms of skeletal injuries in the adult population.[3] Distal radius fractures tend to be more common in the elderly because the bone becomes osteoporotic over time. Patients not only include elderly individuals, but also younger persons involved in high-energy trauma.

Historically, distal radius fractures have been treated by a variety of methods. Literature states that treatment options can range from closed reduction and immobilization to open reduction with plates and screws. The study also mentions that plating allows direct restoration of the anatomy, stable internal fixation, a decreased period of immobilization, and early return of wrist function.[2]

2018 Hand and Wrist Data

According to the 2020 SmartTRAK US Upper Extremities Internal Fixation Revenues Report, in 2018, the wrist internal fixation market exceeded $459 million growing at a rate of 5.0% with a combined hand and wrist market of $495 million including distal radius, wrist fusion, and finger/hand internal fixation. Within the hand and wrist internal fixation market, distal radius plates accounted for 92.9% of the total treatments.

Classification of Distal Radius Fractures

The "Plating of the Distal Radius" study also states that conceptually, the distal radius and ulna may be divided into three columns based on the anatomy. This columnar classification can be used to guide treatment plans. The distal radius is divided into the lateral and medial columns, which anatomically correlate with the scaphoid facet and lunate facet, respectively. The medial column of the distal radius is further subdivided into dorsal medial and volar medial columns. The lateral, dorsal medial, and volar medial columns correspond with Melone's system for classifying intra-articular distal radius fractures. The ulnar column represents the ulnar styloid and the TFCC.[2]

There are multiple classifications for wrist fractures. The Universal classification system is descriptive but does not direct treatment. Universal codes include:[4]

- Type I: extra-articular, undisplaced,
- Type II: extra-articular, displaced,
- Type III intra-articular, undisplaced
- Type IV: intra-articular, displaced

Studies show that the system that comes closest to directing treatment has been devised by Melone.[4] This includes: I Stable fracture, II Unstable "die-punch", III "Spike" fracture, IV Split fracture, and V Explosion injuries. An anatomic description of the fracture may be the easiest way to describe the fracture, decide on treatment, and make an assessment of stability.[4]

Examples:

- Articular incongruity
- Radial shortening
- Radial angulation
- Comminution of the fracture (the amount of crumbling at the fracture site)
- Open (compound fracture) or closed injury
- Associated ulnar styloid fracture
- Associated soft tissue injuries

Distal Radius Fracture Treatment Options

Surgical Versus Nonsurgical Intervention

A 2011 study, "Distal radius fractures treated with non-surgical treatment", concluded that the treatment of distal radius fractures should consider individualized treatment plans for every patient and for each type of fracture. Specific indications for surgical and non-surgical treatment should be taken into account to develop reasonable and viable treatment options.[5]

According to a published report in the Journal of Bone and Joint Surgery, the operative treatment of distal radius fractures has become increasingly common compared with nonoperative treatment.[6]

> "Over the last fifteen years, there has been a trend toward internal plate-and-screw fixation for the treatment of these fractures"[6]

Surgical Intervention with Plate Fixation

History

In addition to splinting and casting, external fixators and pins were among the first methods used for distal radius fracture fixation. By the mid to late 1980's and early 1990's internal fixation with the use of more modern classification systems became increasingly common. Melone classification was first described in 1984 with the AO classification first being used in 1986.[7]

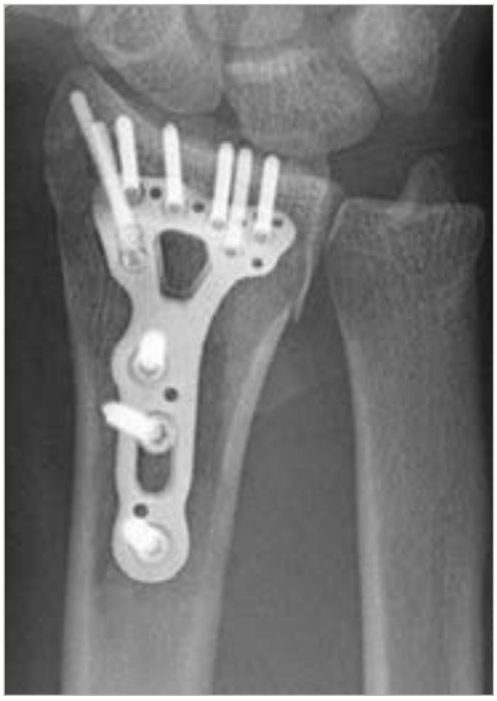
Recent studies have shown that internal fixation of unstable distal radius fractures with a volar locking plate system provides excellent outcomes. These results are associated with the prevention of radial shortening, malunion, and articular incongruity based on the stable fixation of Volar Locking Plate System.[8] Acumed launched the first anotomical volar distal radius plate on the market. the original Acu-Loc Volar Distal Radius (VDR) Plating System featured 2.3 mm distal locking screws that targeted the radial styloid to provide fixation of radial styloid fragments.[8] In 2010, the Acu-Loc 2 VDR was released as the next generation and included a design enhancement to add an additional support screw to the lunate facet.

Precontoured Distal Radius Plates

The design of the precontoured distal radius plates is intended to avoid the need to bend a plate intraoperatively, which could streamline the operative procedure. The Acumed Acu-Loc 2 is a comprehensive plating system for repairing intra-articular fractures, malunions, and nonunions of the distal radius.

Plate Construct

Another important consideration when choosing a plating system is its construct material. The elasticity of the plate material can impact the strength of the healing fracture. In order for the distal radius to heal properly, the bone must be under constant load, thereby strengthening the newly formed bone during the healing process. Therefore, the plate must have enough elasticity to create stress on the healing distal radius while maintaining enough support and stabilization during the healing process.[9]



Each unique plate material has a distinct measure of elasticity. While surgical steel has traditionally been used due to its high strength, it has since been surpassed by titanium as the preferred option. Titanium offers strength characteristics and elasticity closer to that of natural bone. Titanium implants also have tissue tolerance due to the fact that the material is highly inert and insoluble in body fluids. In addition, there is a lower incidence of hypersensitivity compared to other biometals.[10]

Acumed® Acu-Loc® 2 Wrist Plating System

The Acu-Loc 2 Wrist Plating System offers various plate families and screw technologies to treat multiple fracture patterns of the distal radius and distal ulna regions. Included are the Volar Distal Ulna Plates and the Volar, Dorsal, and Fragment Specific Distal Radius Plates.

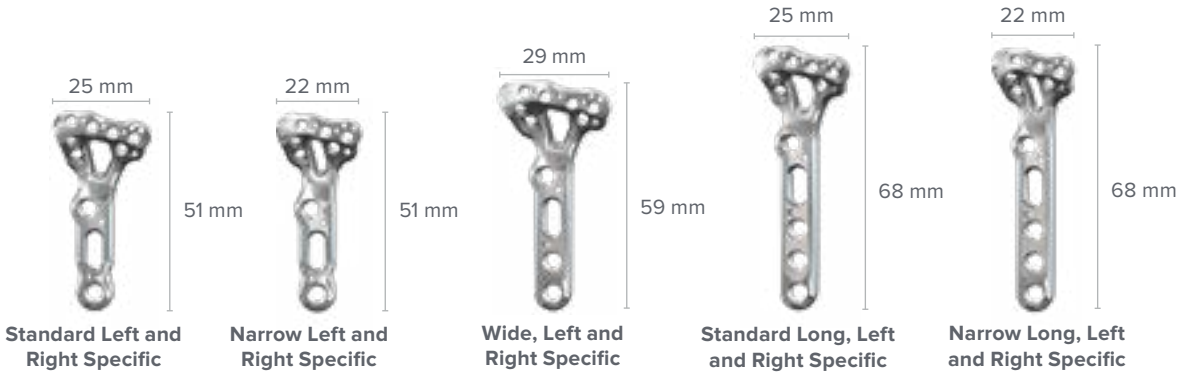
Acumed has introduced the Acu-Loc 2 Volar Distal Radius (VDR) Plating System as the next generation in plating fixation. The system presents several new plate options, a unique two-piece locking compression screw, innovative instrumentation for fracture management, and new plate placement tools.

Distal Radius Fracture Treatment Options [continued]

Acumed Product Solutions

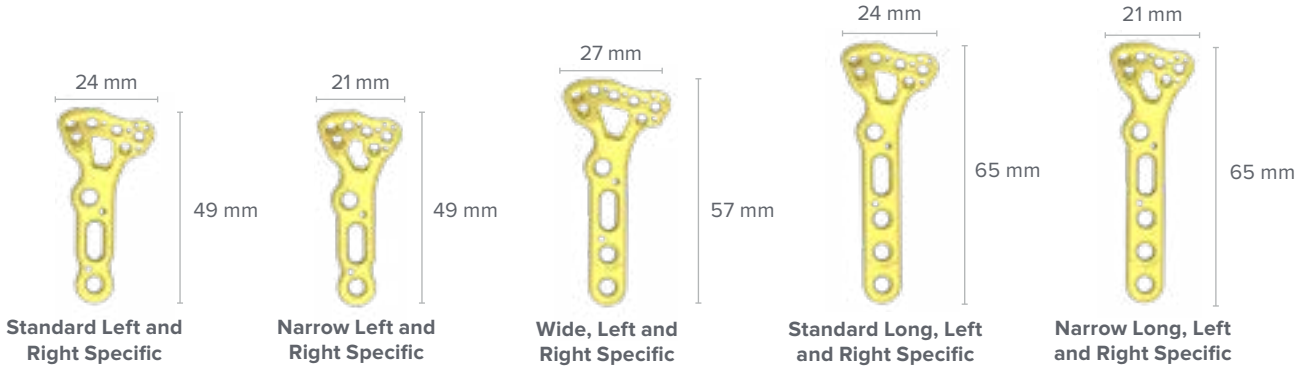
Acu-Loc 2 VDR Plate Options

Comprised of 10 plates, these distally fitting silver plates offer coverage for complex intra-articular fractures.



Acu-Loc 2 VDR Proximal Plate Options

This gold plate family includes 10 plates and is designed for surgeons who prefer a more proximal plate placement. The Acu-Loc 2 Extension Plates can also be used with the proximal sitting plates. The Variable Angle Plating System, which can be used with all 10 of the gold Proximal VDR Plates, includes two additional EX Plates from the original system. The Variable Angle Locking Screws allow for a variance of 5 mm dorsally.



Acumed VDR Plates Key Features:[9]

- The standard Acu-Loc 2 Plate is designed to closely replicate the anatomical contours of the distal radius and may assist in restoring the original geometry.
- Optimized plate design allows for support of the radial and intermediate distal radius columns. Converging ulnar screws, suture holes, and additional K-wire holes provide improved support of the volar ulnar lip and lunate facet.
- Two diverging styloid screws. Plate window offers fracture visualization as well as access to metaphyseal comminution, using the Fragment Reduction Tool for articular reconstruction.
- Plate adjustment markers on shaft of plate
- Smooth and rounded plate edges may reduce patient soft tissue irritation
- Optimal plate strength aids in:
  - Maintaining thread position when screws are torqued into the plate
  - Bending
  - Compression loading

Distal Radius Fracture Treatment Options [continued]

Distal Radius Fragment Specific (DRFS) Plates Options

Six fragment specific plates are designed to independently address fractures of the intermediate and radial columns.

Dorsal Rim Buttress, Left and Right Specific

Dorsal Lunate, Left and Right Specific

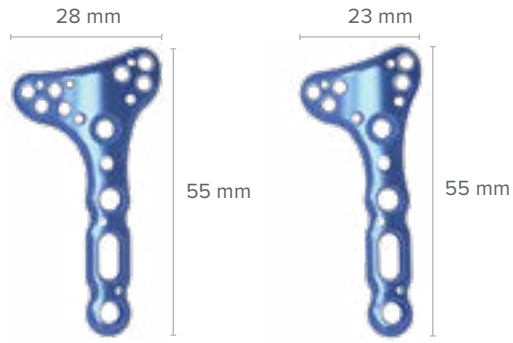
Radial Styloid

Volar Lunate Suture

DRFS Plate Reference Chart	
Gold	Neutral
Blue	Left-specific
Green	Right-specific

Acu-Loc Dorsal Plates

The locking Acu-Loc Dorsal Plates offer a solution to treat distal radius fractures that need to be addressed from the dorsal side.

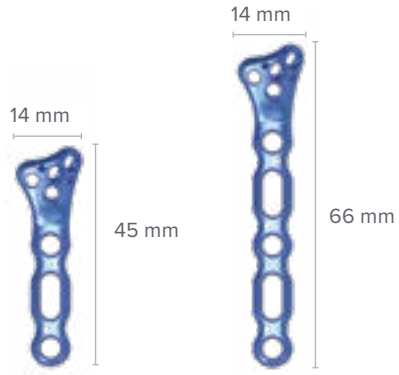


Standard, Left and Right Specific

Narrow, Left and Right Specific

Acu-Loc Volar Distal Ulna (VDU) Plates

The Acu-Loc VDU Plates are designed specifically for periarticular fractures of the distal ulna. The screw positioning and angulation targets distal fragments of the ulnar head and neck.



Standard, Left and Right Specific

Long, Left and Right Specific

Competitive Comparison

	Acumed	Medartis
Product Name	Acu-Loc® 2 Wrist Plating System	APTUS Wrist 2.5
Special Features	▸ Offers specialized instrumentation including the plate positioning handle, fragment reduction tool, and kickstand posts ▸ Offers the Frag-Loc® two-piece locking fixation device for small dorsal fragments ▸ Patented radiopaque positioning posts within the targeting guides show screw trajectory	▸ Offers volar radius, small frag, styloid radius and corrective osteotomy plates ▸ PEEK mono-block guide allows drilling, measuring, and screw insertion without requiring removal ▸ 2.5 mm screws for entire plate ▸ FPL radius plates have distal gap ▸ Radius hook plates use 1.5 mm screws to address small volar lip fragments
Plates		
Material	Titanium Alloy	Titanium Grade 4
Volar Option	22 (34 plating options with Extension Plates)	46 (5 plate families; see below for details)
Dorsal Option	4 total	2 total
Ulna Option	4 total	2 total
Fragment-specific Option	6 total	9 total
Distal Targeting Method	PEEK monoblock w/radiopaque positioning posts	PEEK monoblock
Screws and Pegs		
Options	2.3 mm locking peg 2.3 mm locking screw 2.3 mm locking variable angle screw 2.3 mm nonlocking screw 3.5 mm locking screw (shaft) 3.5 mm nonlocking screw (shaft) 2.7 mm low-profile locking screw (shaft) 2.7 mm low-profile nonlocking screw (shaft)	2.5 mm cortical screw 2.5 mm TriLock screw 2.5 mm TriLock Express screw
Material	Titanium Alloy	Titanium Alloy
Drive	1.5 mm/T15 Hexalobe	HexaDrive 7
Drill (distal)	2.0 mm	2.0 mm
Drill (proximal)	2.8 mm	2.0 mm

Competitive Comparison [continued]

Zimmer Biomet (Hand Innovations)	Arthrex	OsteoMed	TriMed
DVR Anatomic Volar Plating System	Titanium Wrist Plating System	Extremilock Wrist Plating System	Volar Bearing Plate
▸ F.A.S.T. Guides prethreaded drill guides ▸ Precontoured titanium plates for the volar distal radius ▸ Plate sits proximally and comes in a lengths from 51 mm to 175 mm	▸ Graft window for fragment manipulation and bone grafting ▸ Two styloid screws ▸ PEEK monoblock guide and attached drill sleeves	▸ Offers a short volar plate for fractures at the epiphyseal/ metaphyseal junction using a smaller incision, and provides more points of fixation ▸ Plates can use either 2.4 or 2.7 mm screws in all holes	▸ Screws that lock into threaded bearings inside the plate allow for polyaxial angulation
Titanium Alloy	Titanium Alloy	Titanium Grade 2	Stainless Steel
14 total	18 total	43 total	4 total
No	No	8 plates	Fragment-specific only
No	1	No	Fragment-specific only
No	2	6 plates	8 total
F.A.S.T. guides	Block or preloaded guides	Block	Individual threaded drill guide
2.0 mm smooth locking peg 2.5 mm multidirectional threaded peg 2.5 mm nonlocking screw 3.5 mm nonlocking cortical screw	3.5 mm cortical locking screw 3.5 cortical nonlocking screw 2.3 mm/2.7 mm threaded locking peg 2.7 mm threaded nonlocking peg 2.7 mm high compression locking peg 2.0 mm smooth locking peg 2.5 mm polyaxial locking screw	2.0 mm smooth locking peg 2.3 mm locking screw 2.7 mm locking screw 2.7 mm partial thread locking screw 2.3 mm nonlocking screw 2.7 mm nonlocking screw 2.7 mm partial thread nonlocking screw	3.2 mm cortical screw 2.3 mm cortical screw, threaded and smooth peg
CoCr (multidirectional)/ Titanium Alloy	CoCr (polyaxial)/ Titanium Alloy	Titanium Alloy	Stainless Steel
2.0 mm Square Tip 2.5 mm Hex	2.0 mm Square Tip /T10	Torx Driver T7	Torx Driver T8
2.0 mm	2.0 mm	1.9 mm	1.75 mm
2.5 mm	2.5 mm	2.0 mm	NA

501(k) Clearance Information

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

501(k) Clearance Information [continued]

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

501(k) Clearance Information [continuted]

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

501(k) Clearance Information [continuted]

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)

501(k) Clearance Information [continuted]

510(k) Summary

Device Trade Name:	Congruent Bone Plate System	JAN - 4 2011
Manufacturer:	Acumed, LLC 5885 NW Cornelius Pass Road Hillsboro, OR 97124	
Contact:	Mr. Ed Boehmer Global Regulatory and Quality Director Chief Compliance Officer Phone: (503) 627-9957	
Prepared by:	Musculoskeletal Clinical Regulatory Advisers, LLC 1331 H Street NW, 12th Floor Washington, DC 20005 Phone: (202) 552-5800 Fax: (202) 552-5798	
Date Prepared:	December 14, 2010	
Classification:	21 CFR 888.3030, Single/multiple component metallic bone fixation appliances and accessories	
Class:	II	
Product Code:	HRS	

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.

Device Description:
The predicate Congruent Bone Plate System (K012655) consists of bone plates and screws which provide fixation for fractures, fusions, and osteotomies of the clavicle, humerus, radius, ulna, metacarpal, metatarsal, malleolus, tibia, and fibula.

The purpose of this 510(k) is to modify two components of the Congruent Bone Plate System and to add one component to this predicate system. These modifications are intended to allow the operating surgeon to better accommodate various patient anatomies when treating distal and midshaft fractures of the radius. All components are made of titanium alloy conforming to ASTM F136.

501(k) Clearance Information [continuted]

Predicate Device:
The modified Congruent Bone Plate System is substantially equivalent to the predicate Congruent Bone Plate System previously cleared in K012655 with respect to indications, design, function, and materials.

Preclinical Testing:
The new components were subjected to static and dynamic 4-point bend testing in accordance with ASTM F382, Standard Specification and Test Method for Metallic Bone Plates. The results demonstrate that the modified components are substantially equivalent to the predicate.

501(k) Clearance Information [continuted]

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
% Mr. Ed. Boehmer
5885 Northwest Cornelius Pass Road
Hillsboro, Oregon 97124

JAN - 4 2011

Re: K102998
Trade/Device Name: Congruent Bone Plate System
Regulation Number: 21 CRF 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: Class II
Product Code: HRS
Dated: October 6, 2010
Received: October 8, 2010

Dear Mr. Boehmer:

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

501(k) Clearance Information [continuted]

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

501(k) Clearance Information [continuted]

K102998

4. Indications for Use

JAN – 4 2011

510(k) Number (if known): K102998

Device Name: Congruent Bone Plate System

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.

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)

for M. Melkerson

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

510(k) Number K102998

Page 1 of 1

501(k) Clearance Information [continuted]

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. Brittany Cunningham
Regulatory Specialist
5885 Northwest Cornelius Pass Road
Hillsboro, Oregon 97124-9432

JUL 13 2012

Re: K120903
Trade/Device Name: Acumed Congruent Bone Plate System: 2.3 mm Variable Angle Locking Screw for Use with Acu-Loc2 Plate
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, 2012
Received: June 15, 2012

Dear Ms. Cunningham:

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 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

501(k) Clearance Information [continuted]

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

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 began developing products for distal radius fractures in 1999. Since then, Acumed has grown to become one of the technology leaders in options for operative treatment of distal radius fractures. [1] Acumed will continue to devote resources to the development of implants that aid in improving patient outcomes and advancing the field of orthopaedic surgery.

Acumed Maintains Ethical Behaviors with Respect to Compliance Standards and Laws.

1. Buzzell, Jonathan, Douglas R. Weikert, et al. "Precontoured Fixed-Angle Volar Distal Radius Plates: A Comparison of Anatomic Fit." *JHS/ASSH Scientific Article 33A*. (2008) : 1144–1152. Print.

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

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2. Nana, Arvind D., et al. “Plating of the Distal Radius.” *Journal of the American Academy of Orthopaedic Surgeons* 13.3. May/June (2005) : 159–171. Print.
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4. “Distal Radius Fracture.” *Wikipedia, the free encyclopedia*. (2013): n. page. Web. 4 Apr. 2013. <http://en.wikipedia.org/wiki/Distal_radius_fracture>.
5. “Distal radius fractures treated with non-surgical treatment.” *Third Affiliated Hospital of Southern Medical University* (Guangzhou, China 510630). (2011) : n. page. Web. 4 Apr. 2013.
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7. Kural, Cemal, Sungur Ibrahim et al. “Evaluation of the Reliability of Classification Systems Used for Distal Radius Fractures.” *Orthopedics* 33.11 November (2010). Print.
8. Iba, Kousuke, Yasuhiro Ozasa, et al. “Efficacy of radial styloid targeting screws in volar plate fixation of intra-articular distal radial fractures: a biomechanical study in a cadaver fracture model.” *Journal of Orthopaedic Surgery and Research* 5.90 (2010): 1 of 8. Print. <http://www.josr-online.com/content/5/1/90>.
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11. Mazzocca, A.D. et. al. “Principles of Internal Fixation.” Browner B.D. et. al. *Skeletal Trauma, Fractures, Dislocations, Ligamentous Injuries*. Philadelphia: WB Saunders, 1998: 293. Print.
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13. Takaaki Kanazawa, MD Kazunari Tomita, MD, PhD Keikichi Kawasaki, MD, PhD Toshio Yagi, MD Yuji Tanabe, PhD Katsunori Inagaki, MD, PhD Comparison of Locking and Frag-Loc Screws for Fixation of Die-Punch Fragments. *Journal of Wrist Surgery* 2018;7:205–210.
14. David S. Ruch, MD,* Francesca L. Tocci, MS, MA,* A. Jordan Grier, MD,* Jeremy J. Miles, MD,* Preet S. Patel, BS,† Suhail K. Mithani, MD,‡ Marc J. Richard, MD* Integrated Compression Screw Stabilization of the Dorsal Lunate Facet in Intra-Articular Distal Radius Fractures, *J Hand Surg Am*. 2019

Additional Published Literature Supporting Acumed Treatment Principles

Reece, M.D., M.S., Edward. “Case Series: Acu-Loc VDR Plate and Frag-Loc Compression Screw.” *Case Study. HNW70-01-B*. (2011) : n. page. Print.

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Mab, Kheng, Byung Sung Kim, et al. “Distal Radius Fractures Using Acu-Loc Volar Plate.” *Soonchungyang Medical Science 17.1* (2011): 1–4. Print.

Rampoldi, Michele, Dante Palombi, et al. “Distal radius fractures with diaphyseal involvement: fixation with fixed angle volar plate.” *Journal of Orthopaedics and Traumatology* 12.3 (2011): 137–143. Print.

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“Characterization of titanium and stainless steel medical implants surfaces” *RMZ-Materials and Geoenvironment, 54.2* (2007) : 151–164. Print.

A Seth Greenwald, D. Phil. (Oxon), Paul D. Postak, B.Sc., et al. “Biomechanical Properties of Fixed-Angle Volar Distal Radius Plates Under Dynamic Loading” *Orthopaedic Research Laboratories, Cleveland, Ohio.* AAOS 2007. Print.

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Notes:

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