acumed®

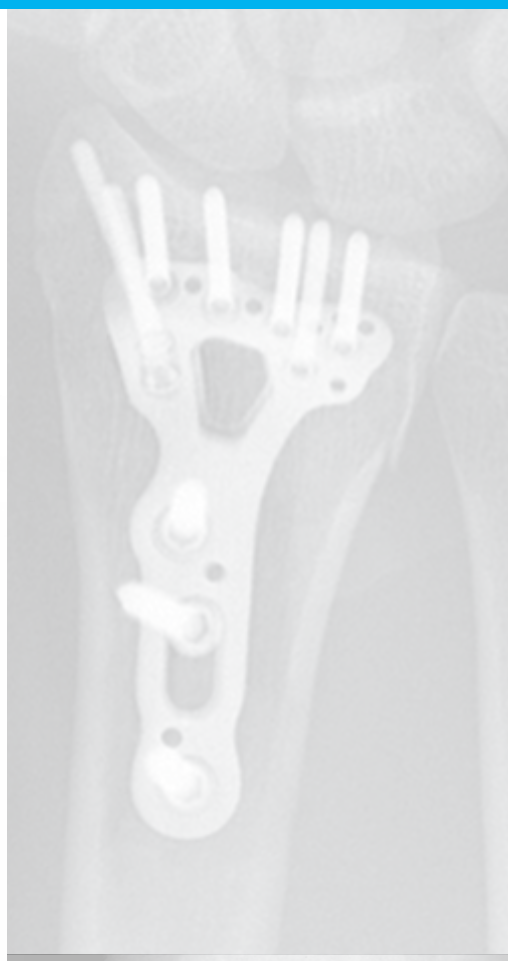
Acu-Loc® 2 Wrist Plating System

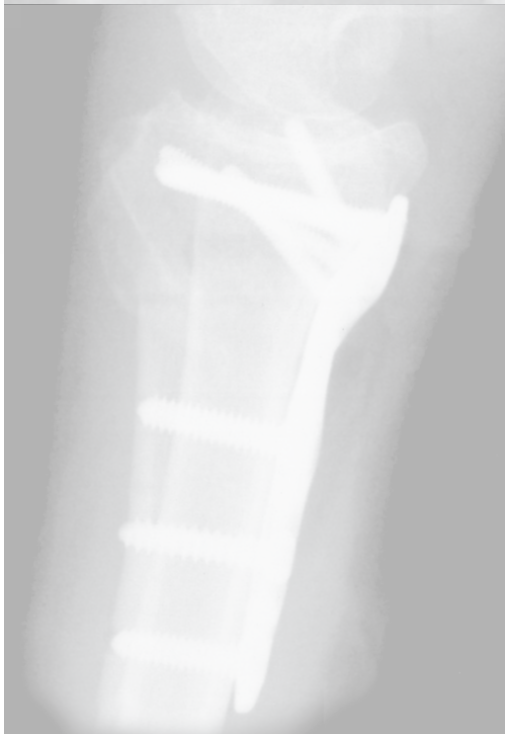
# Value Analysis Committee Resource Guide

a Colson Medical | Marmon | Berkshire Hathaway Company

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

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





## Acumed 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.

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# 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.

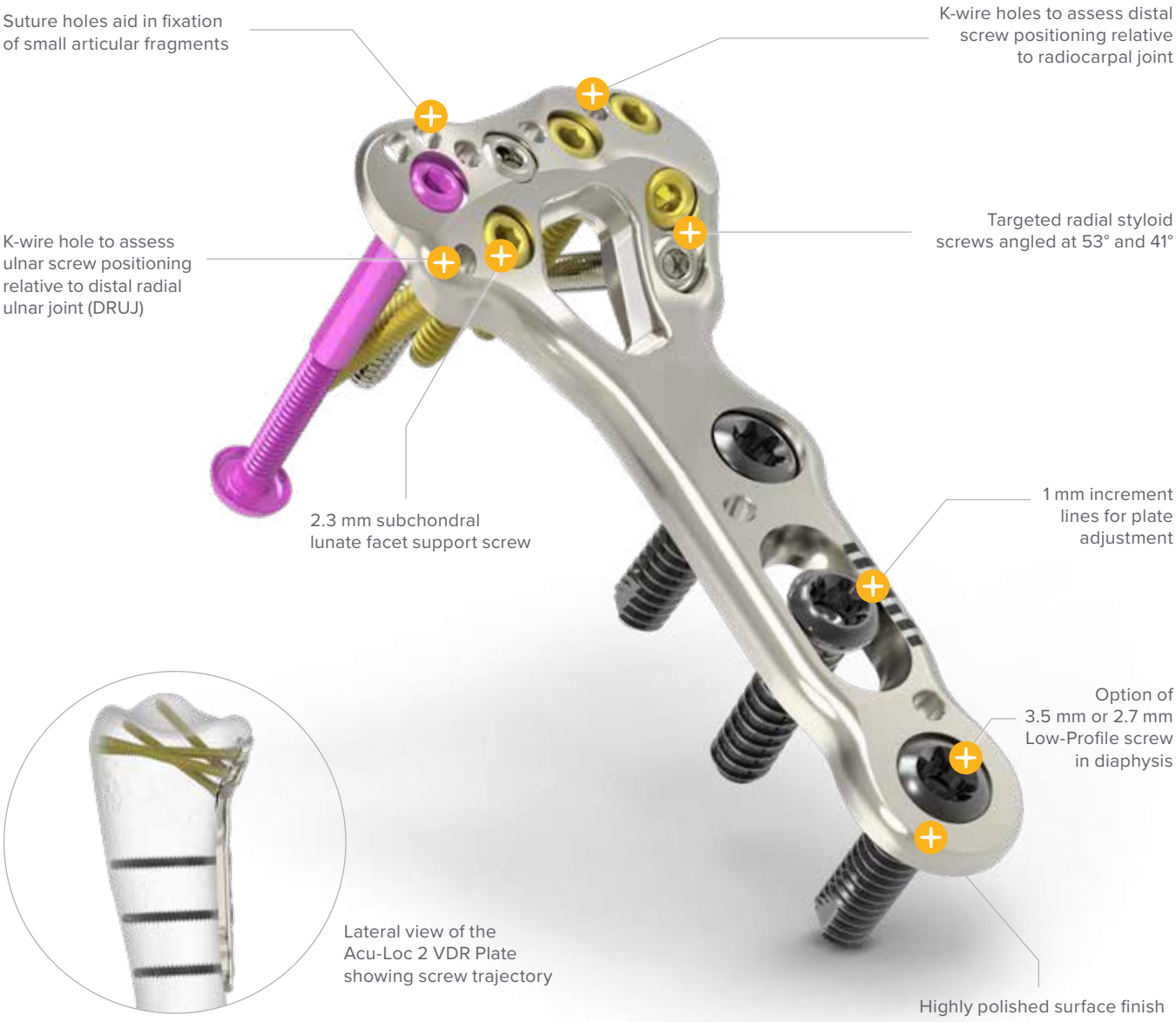
## Indications for Use:

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

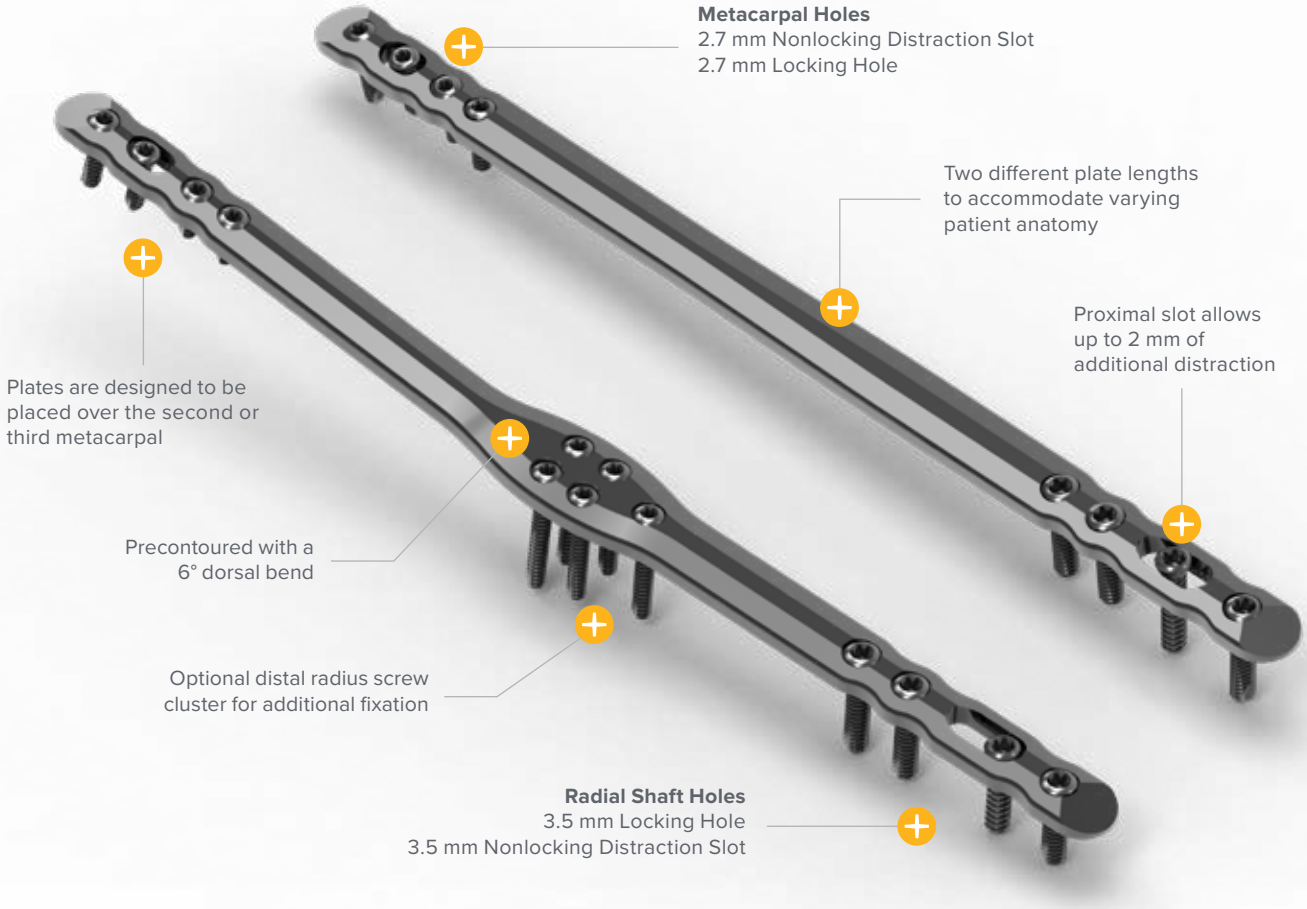
The standard Acu-Loc 2 Plate is designed to closely replicate the anatomical contours of the distal radius and may assist in restoring the original geometry. The 2.3 mm Locking Variable Angle Screws can be used in the distal styloid hole only for all silver-colored Acu-Loc 2 VDR Plates. Please see the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



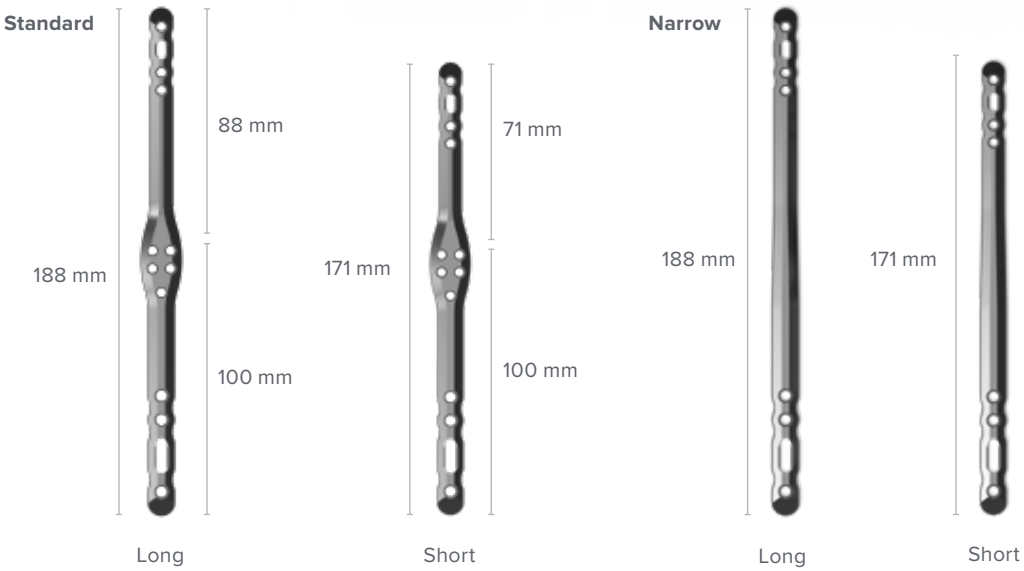
# System Features

## Wrist Spanning Plates

Designed to address complex distal radius fractures, these temporary fixators hold the wrist in distraction and provide ligamentotaxis while the distal radius heals.




## Acu-Loc 2 Wrist Spanning Plate System




Caution: 2.7 mm Locking and Nonlocking Hexalobe Screws (30-03XX-S) 8 mm to 22 mm are intended to be used in the distal and central screw cluster holes. 2.7 mm Locking (COL-2XXX) and Nonlocking (CO-27XX) Cortical Screws have larger heads and are not intended to be used in these holes.

# 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]

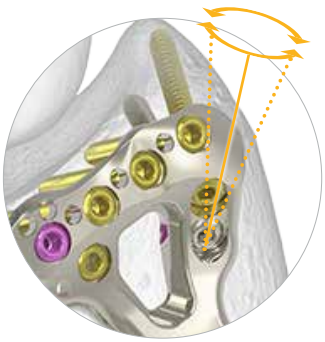
**Modular Extension Plate:** Attachments Offer surgeons the option to extend any of the long and wide Volar Distal Radius Proximal Plates up to 176 mm

**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
- Variable Angle Screws are compatible with the Avulsion Hook Plate



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]

## 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, Volar, Dorsal Fragment Specific Distal Radius Plates, and optional Avulsion Hook Plate.

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.

## Acu-Loc 2 Wrist Spanning Plate Systems

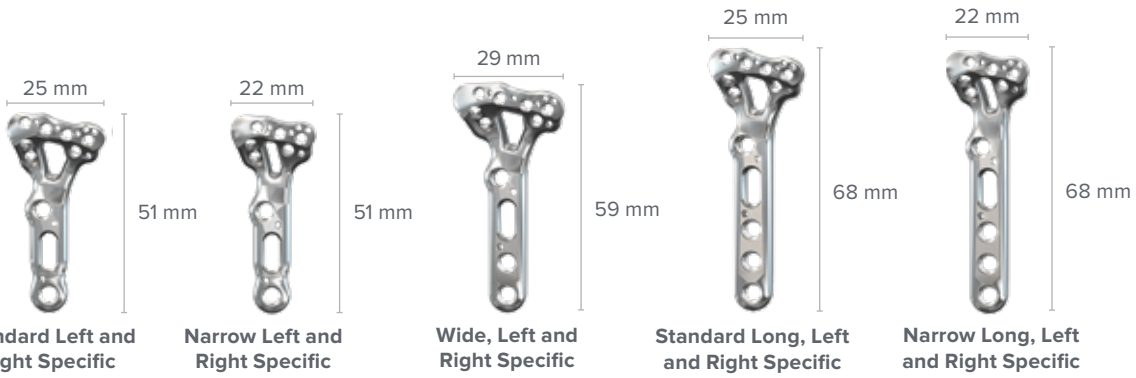
Acumed offers various plate families for Wrist Spanning Plates for complex distal radius fractures. The plating families are designed to hold the wrist in distraction and to provide ligamentotaxis to the wrist on a temporary basis while the distal radius heals.

# Distal Radius Fracture Treatment Options [continued]

## Acumed Product Solutions

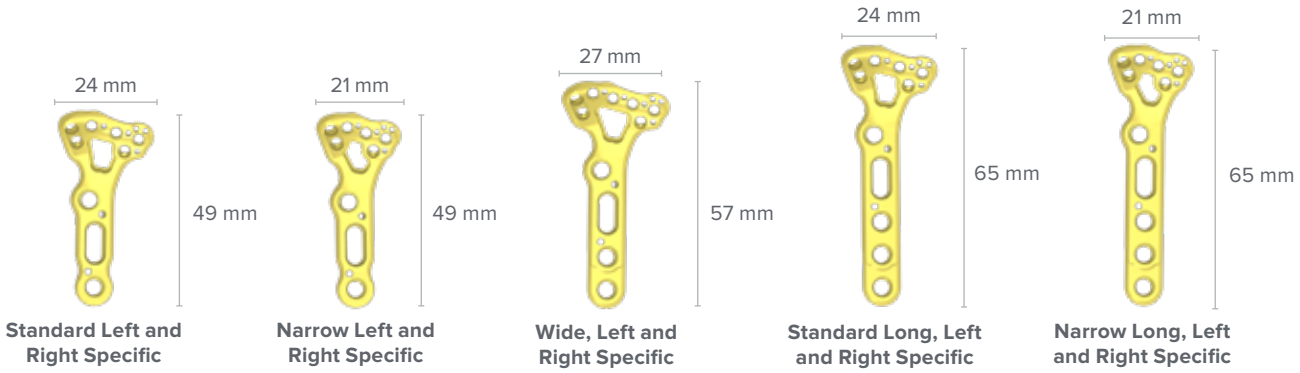
### Acu-Loc 2 VDR Plate Options

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]

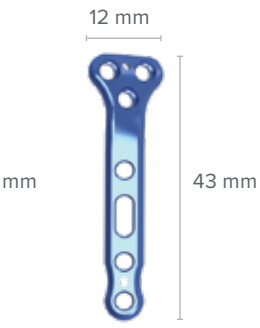
- The standard Acu-Loc 2 Plate is designed to closely replicate the anatomical contours of the distal radius and may assist in restoring the original geometry.
- Optimized plate design allows for support of the radial and intermediate distal radius columns. Converging ulnar screws, suture holes, and 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
- Optional Avulsion Hook Plate to address volar and dorsal marginal rim fragments
- 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

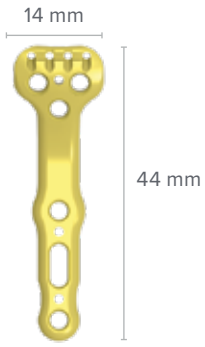
Six fragment specific plates are designed to independently address fractures of the intermediate and radial columns.


**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

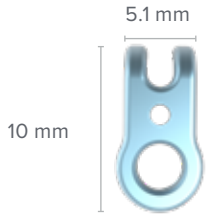
The Acu-Loc VDU Plates are designed specifically for periarticular fractures of the distal ulna. The screw positioning and angulation targets distal fragments of the ulnar head and neck.


**Standard, Left and Right Specific**


**Long, Left and Right Specific**

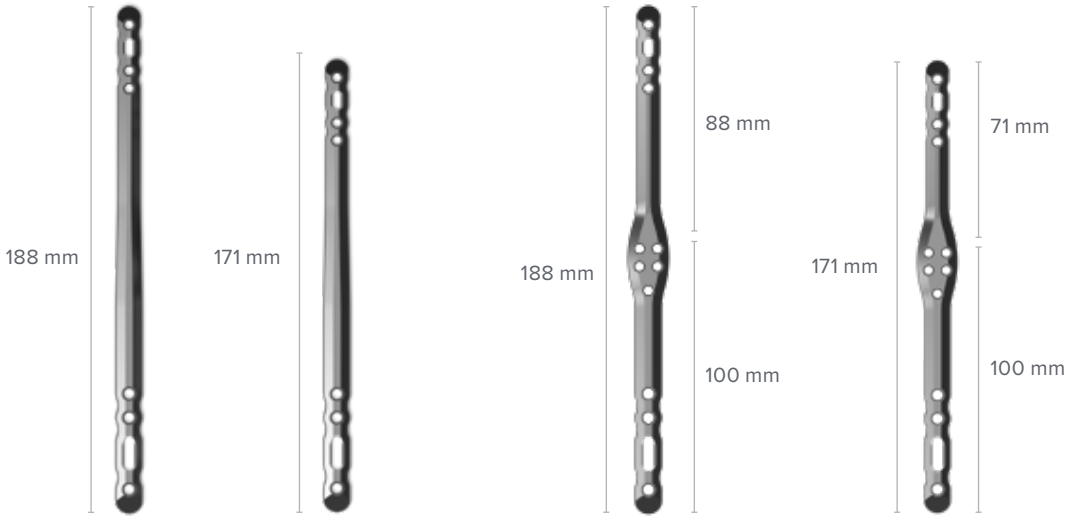
# Distal Radius Fracture Treatment Options [continued]

### Optional Avulsion Hook Plate
Provides extended fixation for volar and dorsal marginal rim fragments.




**Universal**

Acumed offers various plate families for Wrist Spanning for complex distal radius fractures. The plates are designed to hold the wrist in distraction and provide ligamentotaxis the wrist on a temporary basis while the distal radius heals.




**Narrow, Long** **Narrow, Short,** **Standard, Long** **Standard, Short**

## Acu-Loc 2 Wrist Spanning Plates Key Features

- Designed for second or third metacarpal placement
- Two plating options, 171 mm and 188 mm lengths, enable treatment of a wide range of patient anatomies
- 2.7 mm and 3.5 mm screw options (TI or CoCr, Locking or Nonlocking)
- 2 mm of additional wrist distraction

### Narrow Wrist Spanning Plate Key Features
- Streamlined Design: 34% narrower*, smooth surface with chamfered edges to facilitate soft tissue navigation
- Customizable: The low profile, straight, neutral shape can be adjusted to accommodate various surgical needs
- Versatile: Two plating lengths and fixation options of either titanium (TI) and cobalt chrome (CoCr) screws enable treatment of a wide range of patient anatomies
- Improved Dynamic Strength: Built 74% stronger† to withstand increased loads and provide better performance and durability

### Standard Wrist Spanning Plate Key Features:
- Optional distal radius screw cluster for additional subcondylar support
- Precontoured with a 6 degree bend

*Than previous generation
†Data on file vs leading competitor

# 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<br>▸ Offers the Frag-Loc® two-piece locking fixation device for small dorsal fragments<br>▸ Patented radiopaque positioning posts within the targeting guides show screw trajectory<br>▸ Offers 2 volar position for proximal and distal fitting<br>▸ Optional Avulsion Hook Plate for volar and dorsal lip fragments | ▸ Offers volar radius, small frag, styloid radius and corrective osteotomy plates<br>▸ PEEK mono-block guide allows drilling, measuring, and screw insertion without requiring removal<br>▸ 2.5 mm screws for entire plate<br>▸ FPL radius plates have distal gap<br>▸ 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 with Radiopaque Positioning Posts | PEEK Monoblock |
| Screws and Pegs | | |
| **Options** | 2.3 mm Locking Peg<br>2.3 mm Locking Screw<br>2.3 mm Locking Variable Angle screw<br>2.3 mm Nonlocking Screw<br>3.5 mm Locking Screw (shaft)<br>3.5 mm Nonlocking Screw (shaft)<br>2.7 mm Low-profile Locking Screw (shaft)<br>2.7 mm Low-profile Nonlocking Screw (shaft) | 2.5 mm Cortical Screw<br>2.5 mm TriLock Screw<br>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 | TriMed |
|---|---|---|
| DVR Anatomic Volar Plating System | Titanium Wrist Plating System | Volar Bearing Plate |
| ▸ F.A.S.T. Guides prethreaded drill guides<br>▸ Precontoured titanium plates for the volar distal radius<br>▸ Plate sits proximally and comes in a lengths from 51 mm to 175 mm | ▸ Graft window for fragment manipulation and bone grafting<br>▸ Two styloid screws<br>▸ PEEK monoblock guide and attached drill sleeves | ▸ Screws that lock into threaded bearings inside the plate allow for polyaxial angulation |
| Titanium Alloy | Titanium Alloy | Stainless Steel |
| 14 Total | 18 Total | 4 Total |
| No | No | Fragment-specific Only |
| No | 1 Total | Fragment-specific Only |
| No | 2 Total | 8 Total |
| F.A.S.T. Guides | Block or Preloaded Guides | Individual Threaded Drill Guide |
| 2.0 mm Smooth Locking Peg<br>2.5 mm Multidirectional Threaded Peg<br>2.5 mm Nonlocking Screw<br>3.5 mm Nonlocking Cortical Screw | 3.5 mm Cortical Locking Screw<br>3.5 mm Cortical Nonlocking Screw<br>2.4 mm Locking Compression Screws<br>2.4 mm VAL & Near Cortex Screw<br>2.4 mm Cortex Screw Nonlocking | 3.2 mm Cortical Screw<br>2.3 mm Cortical Screw, Threaded and Smooth Peg |
| CoCr (multidirectional)/Titanium Alloy | CoCr (polyaxial)/ Titanium Alloy | Stainless Steel |
| 2.0 mm Square Tip<br>2.5 mm Hex | 2.0 mm Square Tip /T10 | Torx Driver T8 |
| 2.0 mm | 2.0 mm | 1.75 mm |
| 2.5 mm | 2.5 mm | NA |

# Competitive Comparison

| | Acumed | Medartis |
|---|---|---|
| **Product Name** | Acu-Loc® 2 Wrist Spanning Plate | APTUS Wrist 2.5 |
| **Special Features** | ▸ Offering 2 plate designs, featuring a straight lower profile design to aid in insertion and curved cluster option with a 6 degree dorsal bend for additional fixation options | ▸ Offers 2 plating options with a straight and curved design with their Tri-Lock with 15+VAL capabilities with a single screw and drill size. Left and Right specific sizing |
| Plates | | |
| **Material** | Titanium Alloy | Titanium Alloy |
| **Plate Types** | Straight, Narrow, and Curved Cluster Universal | Straight and Curved |
| **Plate Options** | 4 total | 4 Total |
| **Lengths** | 171 mm and 188 mm | 195 mm Straight and 196 mm Curved |
| Screws and Pegs | | |
| **Options** | 2.7 mm Locking and Nonlocking Hexalobe<br>3.5 mm Locking and Nonlocking Hexalobe | 2.5 mm |
| **Material** | Titanium Alloy and Cobalt Chrome | Titanium Alloy |
| **Drive** | T15 Hexalobe | HexaDrive 7 |
| **Drill (distal)** | 2.0 mm | 2.0 mm |
| **Drill (proximal)** | 2.0, 2.8 mm | 2.0 mm |

# Competitive Comparison [continued]

| Zimmer Biomet (Hand Innovations) | Arthrex | TriMed |
|---|---|---|
| DVR Anatomic Volar Plating System | Titanium Wrist Plating System | Volar Bearing Plate |
| ▸ DVR is designed with an increased central width and concave contouring for added strength at the midsection. Crosslocking screws provide fixation angulation of 20 degrees for flexibility of locking screws | | ▸ Designed to be tapered at the distal portion of the plate, and central holes for subcondylar support |
| | | |
| Titanium Alloy | Materials Stainless Steel | Titanium Alloy |
| | | Straight Plate |
| 1 Total | 1 Total | 1 Total |
| 180 mm | 180 mm | 180 mm |
| | | |
| 2.7 mm Locking, Nonlocking and Multidirectional | 2.7 mm Nonlocking and Locking Distally<br>3.2 mm Nonlocking and Locking Proximal | 2.4 mm Nonlocking and Variable Angle Locking Distal<br>3.5 mm Nonlocking and Locking Proximal |
| CoCr (Multidirectional/Titanium Alloy) | | Titanium |
| 1.7 mm Square Driver | 2.0 distal Hex<br>2.5 mm Hex Proximal | T8 and T15 Hexalobe |
| 2.2 mm | 2.0 mm | 1.7 mm |
| 2.2 mm | 2.3 mm | 2.5 mm |

# 501(k) Clearance Information

acumed



| | |
|---|---|
| **Title:** 510(k) Letter to File_Narrow Wrist Spanning Plates | **Number:** LFT-014243 |
| **Owning Department:** Regulatory | **Version:** 1.2 |
| **State:** Released as of 2024-09-02 | |

## 510(k) Letter-to-File

**(Assessment of change to an existing device)**

This assessment determines if the addition or modification made to a legally marketed device (system) will require submission of a new 510(k).

**I. Subject device:**

| **Currently cleared** | **Date cleared** | **510(k) no.** |
|---|---|---|
| Acumed Wrist Spanning Plate | 05SEP2013 | K131764 |
| **Previously cleared** | **Date cleared** | **510(k) no.** |
| N/A | N/A | N/A |
| **Additional proprietary name(s)** | | |
| Narrow Wrist Spanning Plate (nWSP), Acu-Loc® Narrow Wrist Spanning Plate | | |
| | | |

**II. Device description:**

The Wrist Spanning Plate system (WSP) currently consists of two anatomically designed dorsal fixation plates, part numbers 7006-1170N-S and 7006-1190N-S for distal radius fracture repair. The WSP is a single use, temporary fixation implantable device. The two bone plates are functionally identical and differ only in the length of the distal section to better accommodate anatomical size differences among the patient population. The plate is secured using previously developed screws and instrumentation to the radius and the second or third metacarpal bone, and thus, spans the radiocarpal joint to provide temporary internal fixation for fractures of the radius. The Acu-Loc® Wrist Spanning Plates were cleared by the FDA on 05SEP2013 with 510(k) K131764. All instrumentation and screw implants used with the WSP are included in the previously cleared Acumed Congruent Plate System (K012655). As such, risk assessment in this report is limited to the associated interface of the screw to the plate. The WSP is manufactured from titanium alloy Ti-6AL-4V ELI per ASTM F136 and provided in sterile packaging.

The plate implants are comprised of a long (part number: 7006-1170N-S) and short size (part number: 7006-1190N-S), with the length of the distal section as the only difference between the plates. The plates have a combination of distal and proximal holes with utilize 2.7mm and 3.5mm screws to attach the plate to the metacarpal and distal radius, respectively. The 2.7mm and 3.5mm screws are available in both a locking and non-locking design, as two slots are also present in each plate. In addition, each plate provides a set of holes at the midsection for anatomical reduction and securing of bone segments to repair distal radius fractures. The proximal section allows for three 3.5mm screws to be placed into each of three screw holes. The midsection has five screws holes that accept 2.7mm screws. The distal section has three 2.7mm screw holes. Distal to the midsection, the plate possesses a slight dorsal bend, which places the wrist in an anatomically natural position compared to that of a straight plate. In addition, the plate is Type II anodized and laser marked for identification.

The new plates (7006-3370N-S and 7006-3390N-S) are the same design as the existing plates but with the removal of the expanded width, set of holes at the midsection, and 6° dorsal bend.

# 501(k) Clearance Information [continued]

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| **Title:** 510(k) Letter to File_Narrow Wrist Spanning Plates | **Number:** LFT-014243 |
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**III. Previous changes (If Applicable):**

| Date | Summary |
|---|---|
| N/A | N/A |
| | |

**IV. Reason for the modification:**

Per the Clinical Evaluation Report for the Wrist Spanning Plate (file name: TEC-0283_CER_Wrist Spanning Plate_5_final), the biggest drawbacks associated with dorsal spanning plate fixation are as follows:

1. the additional surgical procedure for removal of the spanning plate after fracture consolidation, where implant removal (plate and screws) is typically carried out after ~3 months, once the fracture has healed

2. the possibility of extensor tendon irritation or rupture and scar adhesions due to close interaction with plate placement

3. potential for wrist and finger stiffness due to the long period of immobilization (avoiding over distraction of the radiocarpal space by more than 5mm reduces the likelihood of digital stiffness).

The midsection design for the previous plates in the Acu-Loc 2 system provided several fixation holes, which were designed to secure fractured bone fragments in the distal radius. As per surgeon feedback from field use of the Acu-Loc 2 plates in indicated distal radius fracture repair procedures, there were concerns about the larger cluster of holes in the midsection of the plates. In cases where there was no need to secure bone segments in the midsection, the holes would remain open, which allowed tissue migration and caused the soft tissue to get entangled. This could cause difficulty in removal of the plates following fracture consolidation. Additionally, user feedback has also determined a desire for flat plates that do not have the angled dorsal bend.

Per user request, the new plates (7006-3370N-S and 7006-3390N-S) are the same design as the existing plates but are to be updated with the removal of the expanded width, removal of set of midsection holes at the midsection to provide an alternative option for plates that will not interfere with existing tissue or enable scar adhesions, and removal of the 6° dorsal bend.

The following implants and/or instruments are being added or modified:

| Part no. | Description Use Material Description as it appears in SAP/Product Label | Add | Mod |
|---|---|---|---|
| **7006-3370N-S** | **Acu-Loc® Narrow Wrist Spanning Plate, Short** | ☒ | ☐ |
| **7006-3390N-S** | **Acu-Loc® Narrow Wrist Spanning Plate, Long** | ☒ | ☐ |
| | | ☐ | ☐ |
| | | ☐ | ☐ |
| | | ☐ | ☐ |
| | | ☐ | ☐ |

# 501(k) Clearance Information [continuted]

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**V. Comparison to the last cleared version:**

The center screw cluster and widened plate diameter in the midsection will be removed, and the dorsally angled 6° bend in the distal section will be removed so as to provide straight, flat plate options for the Acu-Loc 2 line.

**VI. List of all labeling changes, including new or expanded intended use or indications for use:**

There are no changes to intended use or indications for use statement for the cleared system.

The Surgical Technique (HNW10-05) will be updated with new nWSP part numbers

The Instructions for Use (PKGI-70) will be maintained

New labels shall be created for new part numbers using existing templates

MRI information brochures (GEN70-56) will be updated with new nWSP part numbers

**VII. Decision making process for Letter-To-File justification:**

FDA Guidance "Deciding when to submit a 510(k) for a change to an existing device" was used to create the following table. Answer each level 1 question and higher levels when indicated.

| No. | Question | Yes | No | Justification, comments |
|---|---|---|---|---|
| **General** | | | | |
| 1 | Is the change made with intent to significantly improve the safety or effectiveness of the device? | ☐ 510(k) | ☒ | There are no significant changes that will impact safety or effectiveness |
| 2 | Is it a change in labeling? | ☐ A. Lab. | ☒ | The indications for use statement and intended use are the same<br>There are no significant changes in labeling |
| 3 | Is it a change in technology, engineering, or performance? | ☒ B. Tech. | ☐ | |
| 4 | Is it a change in materials? | ☐ C. Mat. | ☒ | There are no changes in materials |
| | | | LTF if questions 1 - 4 are No | |
| **A. Labeling Changes** | | | | |
| A1 | Is it a change in the indications for use statement? | ☐ A1.1 | ☒ A2 | The indications for use statement and intended use are the same |
| A1.1 | Is it a change from a device labeled for single use only to a device labeled as reusable? | ☐ 510(k) | ☒ A1.2 | There will be no change in single-use for the system to reusable |
| A1.2 | Is it a change from Rx to over the counter use? | ☐ 510(k) | ☒ A1.3 | The device will still be prescription use |
| A1.3 | Is it a change to the device name or to solely improve readability or clarity? | ☐ LTF | ☒ A1.4 | There will be no change to the device name |
| A1.4 | Does the new change describe a new disease, condition, or patient populations that the device | ☐ | ☒ | There are no changes in disease conditions or patient populations |

# 501(k) Clearance Information [continuted]

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| No. | Question | Yes | No | Justification, comments |
|---|---|---|---|---|
| | is intended in diagnosing, treating, preventing, curing, or mitigating? | 510(k) | A1.5 | |
| A1.5 | Does a risk-based assessment identify any new risks or significantly modified existing risks? | ☐ 510(k) | ☒ LTF | There are no significantly modified existing risks or new risks identified |
| A2 | Does the change add or delete a contraindication? | ☐ 510(k)* | ☒ A3 | There are no added or deleted contraindications |
| ** If only adding a contraindication, submit a change being effected (CBE) 510(k)* | | | | |
| A3 | Is it a change in the warnings or precautions? | ☐ A1.1 | ☒ A4 | There are no changes in warnings or precautions |
| A4 | Could the change affect the directions for use of the device? | ☐ A1.1 | ☒ LTF | There is no impact on directions for use |
| **B. Technology, Engineering, and Performance Changes** | | | | |
| B1 | Is the device an IVD? | ☐ N/A | ☒ B2 | |
| B2 | Is it a control mechanism, operating principle, or energy type change? | ☐ 510(k) | ☒ B3 | There are no changes in control mechanism, operating principle, or energy type change |
| B3 | Is it a change in sterilization, cleaning, or disinfection? | ☐ B3.1 | ☒ B4 | There are no changes in sterilization, cleaning, or disinfection |
| B3.1 | Is it a change to a novel method, does it lower the SAL, or is it a change to how the device is provided? | ☐ 510(k) | ☒ B3.2 | There is no change in how the device is provided |
| B3.2 | Could the change significantly affect the performance or biocompatibility of the device? | ☐ 510(k) | ☒ LTF | There is no change in materials that would affect biocompatibility of the device, and verification/validation testing has demonstrated that design changes do not impact performance. |
| B4 | Is there a change in packaging or expiration dating? | ☐ B4.1 | ☒ B5 | There is no change in packaging or expiration dating |
| B4.1 | Is the same method or protocol, described in a previously cleared 510(k), used to support the change? | ☒ LTF | ☐ 510(k) | The same methods and protocols for the previously cleared 510(k) support the change |
| B5 | Is it any other change in design (e.g., dimensions, performance, specifications, wireless communications, components or accessories, patient/user interface) | ☒ B5.1 | ☐ LTF | Verification/validation testing has demonstrated that design changes do not impact performance |
| B5.1 | Does the change significantly affect the use of the device? | ☐ 510(k) | ☒ B5.2 | There is no significant impact on use of the device |
| B5.2 | Does a risk-based assessment of the changed device identify any new risks or significantly modified existing risks? | ☐ 510(k) | ☒ B5.3 | No new significant risks have been identified |
| B5.3 | Are clinical data necessary to evaluate safety or effectiveness for purposes of design validation? | ☐ 510(k) | ☒ B5.4 | Clinical data is not necessary to evaluated safety or effectiveness |

# 501(k) Clearance Information [continuted]

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| No. | Question | Yes | No | Justification, comments |
|---|---|---|---|---|
| B5.4 | Do design verification and/or validation activities produce any unexpected issues of safety or effectiveness? | ☐ 510(k) | ☒ LTF | Verification/validation testing has demonstrated that design changes do not impact safety or effectiveness |
| **C. Material changes** | | | | |
| C1 | Is the device an IVD? | ☐ N/A | ☒ C2 | |
| C2 | Is this a change in material type, material formulation, chemical composition, or the material's processing?? | ☐ C3 | ☒ LTF | There is no change in material or processing |
| C3 | Will the changed material directly or indirectly contact body tissues or fluids? | ☐ C4 | ☒ C5 | There is no change in material or processing |
| C4 | Does a risk assessment identify any new or increased biocompatibility concerns? | ☐ C4.1 | ☒ C5 | There is no change in material or processing that would impact biocompatibility |
| C4.1 | Has the manufacturer used the same material in a similar legally marketed device? | ☒ C5 | ☐ 510(k) | |
| C5 | Could the change affect the device's performance specifications? | ☐ B5 | ☒ LTF | Verification/validation testing has demonstrated that design changes do not impact device performance specifications |

**VIII. Supporting documents:**

Project Registration Plan: Form-0215_Narrow Wrist Spanning Plate Product Registration Plan

DCTM-012412_RevE-FORM-0083_V20_4

Risk Management Review: TEC-0282 Risk Management Report Wrist Spanning Plate Family_Rev8

TR-011272_Biological Evaluation Report: Velocity, Formerly Known as AMT_RevC

TR-011398 - Biological Evaluation Report Hand and Wrist Plating System_RevC

TR-011920 - nWSP Mechanical Testing Verification Report: ASTM F382 Static Bending and Dynamic Fatigue Strength Testing of Narrow Wrist Spanning Plate, RevA

TR-011919 – Aculoc nWSP Design Validation Report: Design Validation of the Narrow Wrist Spanning Plates, RevA

**IX. Conclusion:**

This assessment has considered the individual changes along with their combined effect on the entire system. Additionally, the change has been assessed in comparison to the most recently cleared system and accounts for any previous changes as described in Section II.

An analysis of the elements in Section VII has been performed in accordance with current FDA Guidance. The conclusion of this analysis, in consideration of all likely and unlikely determinations of 510(k), is that the addition or modification to the subject device, as described in Section I through Section VI,

☐ requires a new 510(k).

☒ does not require a new 510(k) and the change is documented via this assessment (LTF).

# 501(k) Clearance Information [continuted]

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References

FDA-Guidance *Deciding when to Submit a 510(k) for a Change to an Existing Device* (10/25/2017)

21 CFR 807.81 (a)(3)(i) Establishment Registration and Device Listing, Subpart E - Premarket Notification Procedures, *When a premarket notification submission is required*

21 CFR 888.9 Orthopedic Devices, Subpart A - General Provisions, *Limitations of exemptions from section 510(k) of the Federal Food, Drug, and Cosmetic Act (the act)*

21 CFR 888.4540 Orthopedic Devices, Subpart E - Surgical Devices, *Orthopedic manual surgical instrument*

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**This document was approved by:**

Melissa Traylor, ORG_ApproverRegulatoryMgr, 2024-09-02 12:52 PDT

# 501(k) Clearance Information [continuted]

April 22, 2024

Acumed LLC
Anusha Gedala
Regulatory Affairs Specialist
5885 NE Cornelius Pass Road
Hillsboro, Oregon 97124

Re: K233311
Trade/Device Name: Acumed Wrist 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: March 19, 2024
Received: March 20, 2024

Dear Anusha Gedala:

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

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

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

# 501(k) Clearance Information [continuted]



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

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

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

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

Shumaya Ali -S

Shumaya Ali, MPH
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

# 501(k) Clearance Information [continuted]

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.*

510(k) Number *(if known)*

Device Name
Acumed Wrist Plating System

Indications for Use *(Describe)*
Acumed Wrist Plating System provides fixation for fractures, fusions, or osteotomies of the distal radius and ulna.

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.***

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*"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."*

# 501(k) Clearance Information [continuted]

K233111

## 510(k) Summary

**Date prepared**: April 15, 2024

### I. Contact Details

Applicant Name: Acumed LLC
Applicant Address: 5885 NE Cornelius Pass Rd. Hillsboro OR 97124 United States
Applicant Contact Name: Ms. Anusha Gedala
Applicant Telephone: 503-207-1638
Applicant Contact Email: anusha.gedala@acumed.net

### II. Device Name

Device Trade Name: Acumed Wrist Plating System
Common Name: Plate, Fixation, Bone
Classification Name: Single/multiple component metallic bone fixation appliances and Accessories
Smooth or threaded metallic bone fixation fastener
Regulation Number: 21 CFR 888.3030
21 CFR 888.3040
Product Code: HRS, HWC

### III. Legally Marketed Primary Predicate Devices

Primary Predicate Device: Congruent Bone Plate System, K012655
Common Name: Plate, Fixation, Bone
Classification Name: Single/multiple component metallic bone fixation appliances and Accessories
Regulation Number: 21 CFR 888.3030
Product Code: HRS

Predicate Device: Congruent Bone Plate System – Acu-Loc 2 Plate, K120903 / K102998
Common Name: Plate, Fixation, Bone
Classification Name: Single/multiple component metallic bone fixation appliances and Accessories
Smooth or threaded metallic bone fixation fastener
Regulation Number: 21 CFR 888.3030
21 CFR 888.3040
Product Code: HRS, HWC

Reference Device: Acumed Hand Plating System, K132769
Common Name: Plate, Fixation, Bone
Classification Name: Single/multiple component metallic bone fixation appliances and Accessories
Regulation Number: 21 CFR 888.3030

# 501(k) Clearance Information [continuted]

K233111

Product Code: HRS, HWC

Reference Device: Frag-Loc System, K130986
Common Name: Washer, Bolt, Nut
Classification Name: Single/multiple component metallic bone fixation appliances and Accessories
Regulation Number: 21 CFR 888.3030
Product Code: HTN, HWC

## IV. Device Description Summary

Acumed Wrist Plating System is a set of plates, screws and instruments that are provided in case and tray configurations when distributed non-sterile as well as sterile packaged product. The system is an extension of the core technology cleared for Acumed's Congruent Bone Plate Systems, per K012655, K120903 and K102998.

Acumed Wrist Plating System plates and screws are designed to provide fixation for fractures, fusions, or osteotomies of the distal radius and ulna. The system provides plates and screws in different diameters and lengths to suit different anatomical locations, patient size, and fracture patterns. All the plates and screws are manufactured from titanium alloy per ASTM F136 and pure titanium per ASTM F67, are single use and are provided both sterile and non-sterile.

The Acumed Wrist Plating System plates and screws are an extension of the Congruent Bone Plate family with new lengths and the addition of new size plates and screws. Plates and screws are intended for single patient use only.

Instruments supplied with the Acumed Wrist Plating System are intended to aid in the screw insertion and removal. Instruments are supplied sterile and non-sterile, to be sterilized by the end users. System cases consisting of screw trays, instrument trays, caddies and lids are also provided to house non-sterile implants and instruments.

## V. Intended Use/ Indications for Use

The Acumed Wrist Plating System provides fixation for fractures, fusions, or osteotomies of the distal radius and ulna.

## VI. Indications for Use Comparison

The subject device system, Acumed Wrist Plating System includes a subset of the indications for use of the primary predicate device, Congruent Bone Plate System (K012665).

## VII. Technological Comparison

The operating principles and anatomical site for implantation of the subject device are identical to the predicate devices. Both subject and predicate devices are bone plates and screws intended to provide fixation for fractures, fusions and osteotomies. There are some differences in basic shape, design, and size between the subject and predicate.

# 501(k) Clearance Information [continuted]

K233111

### VIII. Non-Clinical and/or Clinical Tests Summary & Conclusions

Non-Clinical testing to support performance was conducted per FDA's Guidance:

*Orthopedic Fracture Fixation Plates – Performance Criteria for Safety and Performance Based Pathway Guidance for Industry and Food and Drug Administration Staff, April 11, 2022*

*Orthopedic Non-Spinal Metallic Bone Screws and Washers – Performance Criteria for Safety and Performance Based Pathway Guidance for Industry and Food and Drug Administration Staff,* December 11, 2020

*Testing and Labeling Medical Devices for Safety in the Magnetic Resonance (MR) Environment- Guidance for Industry and Food and Drug Administration Staff*, May 20, 2021.

Safety and Performance evaluation conducted for the subject devices:

- Safety and Performance evaluation conducted for the subject devices (ASTM F382-17)
- Torsional Yield Strength (ASTM F543 Annex A1)
- Driving Torque (ASTM F543 Annex 2)
- Axial Pullout Force (ASTM F543 Annex 3)
- Self-Tapping Performance (ASTM F543-17 Annex 4)
- Sterilization (ISO 17665-1)
- Sterilization (ISO 11137-1)
- Packaging (ISO 11607-1)
- Biocompatibility (ISO 10993-1)
- Screw Lifetime Verification Testing
- Self-Drilling Verification Testing
- Magnetically Induced Displacement Force (ASTM F2052)
- Magnetically Induced Torque (ASTM F2213)
- MR Image Artifact (ASTM F2119)
- MRI Safety Labelling (ASTM F2503)

Performance data demonstrates that the Acumed Wrist Plating System plates and screws are equivalent to the designated predicate devices when used as intended.

Clinical testing was not necessary.

Based on the results of the non-clinical testing described above, it was concluded that the subject and predicate devices are substantially equivalent when used as intended.

**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.

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