



Acumed Small Fragment  
Base Set Required



Acumed Variable Angle  
Screw Compatible

## Value Analysis Committee Resource Guide

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



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





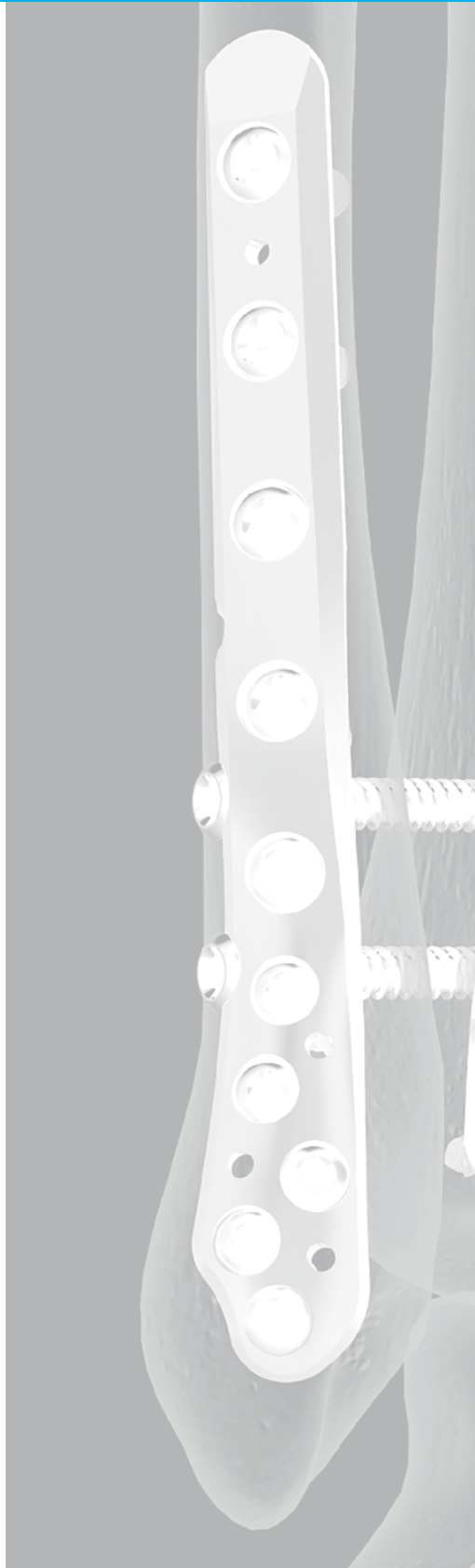
### Acumed® Ankle Plating System 3

The Acumed Ankle Plating System 3 is indicated for fixation of fractures, osteotomies, and nonunions of the distal tibia and fibula, particularly in osteopenic bone.

Designed in conjunction with Anish Kadakia, MD and Bruce Ziran, MD, the Ankle Plating System 3 is composed of seven plate families designed specifically for the treatment of ankle fractures. The indication-specific plates address fracture patterns of the medial, lateral, and posterior malleoli. Specialized plate features and unique instrumentation address disruption of the syndesmosis. 4.0 mm cannulated screws in lengths of 36 mm, 42 mm, and 48 mm are also included in the tray for the treatment of medial malleolar fractures. In addition, both short thread and long thread 4.0 mm cannulated screws ranging in length from 10 mm to 72 mm are available. These screws are housed in a standalone tray and use the 4.0 mm cannulated screw instruments within the Ankle Plating System 3.

The Ankle Plating System 3 is used in combination with the Acumed Small Fragment Base Set. The Small Fragment Base Set includes One-Third Tubular Plates, as well as cut-to-length and bend-to-fit 2.7 mm L-shaped, T-shaped, and straight Fragment Plates that can also be used to address ankle fractures. The 2.7 mm and 3.5 mm nonlocking, locking, and variable angle hexalobe screws, 4.0 mm fully threaded and partially threaded cancellous hexalobe screws, and universal instrumentation are all housed in the Small Fragment Base Set. A selection of Tension Band Pins and AcuTwist® Compression Screws are also included. Together, these systems provide multiple options for ankle fracture fixation, osteotomies, and nonunions.

	Definition
	Products with this symbol require use of the Acumed Small Fragment Base Set in order to complete surgery following the recommended surgical technique.
	Products with this symbol are compatible with Acumed 2.7 mm and 3.5 mm Variable Angle Screws for use in completing surgery following the recommended surgical technique.



# Table of Contents

System Overview .....	<b>2</b>
System Features .....	<b>4</b>
Indications for Use .....	<b>16</b>
Associated Acumed Products.....	<b>16</b>
Clinical Data Influence .....	<b>17</b>
Competitive Matrix .....	<b>18</b>
510(k) Information .....	<b>19</b>
Dedicated to Excellence .....	<b>44</b>
References .....	<b>46</b>

# System Overview

## Ankle Plating System 3

The Acumed Ankle Plating System 3 is designed to provide a variety of fixation options for simple fractures of the distal tibia and fibula. Seven indication-specific plate families address fracture patterns of the medial, lateral, and posterior malleoli.

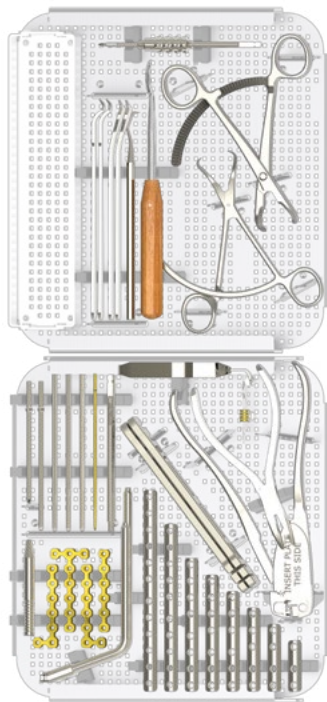
Two of these plate families specifically address posterior malleolus fractures, as recent literature suggests an increase in open reduction and internal fixation of posterior malleolus fractures.<sup>1</sup> Additionally, One-Third Tubular Plates, as well as 2.7 mm L-shaped, T-shaped, and straight Fragment Plates are included within the Acumed Small Fragment Base Set, which is paired with the Ankle Plating System 3 to provide comprehensive solutions for ankle fractures. Coupled together, these systems not only provide nine plate family options, but also multiple screw and pin options including 2.7 mm and 3.5 mm locking, nonlocking, and variable angle hexalobe screws, 4.0 mm fully threaded and partially threaded cancellous hexalobe screws, Tension Band Pins, and AcuTwist® Compression Screws and 4.0 mm cannulated screws. This wide array of fracture-fixation devices provides a variety of surgical treatment options for ankle fractures, streamlining the surgical experience.

### This System Includes:

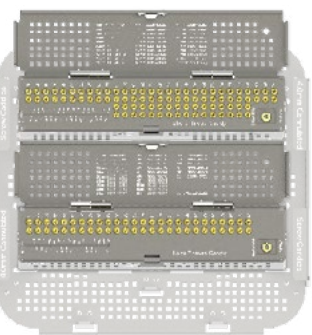
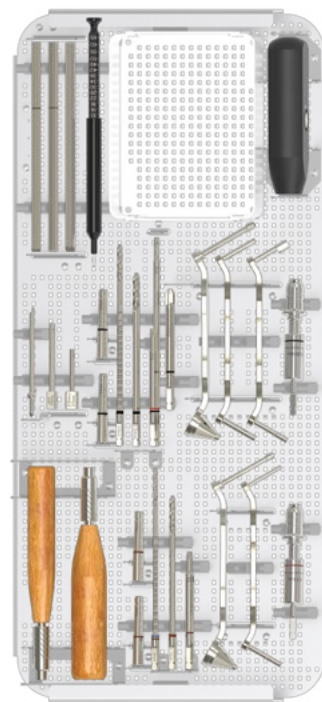
- ▶ Seven indication-specific plate families that address fracture patterns of the medial, lateral, and posterior malleoli, with the addition of two standard plate families in the Small Fragment Base Set.
- ▶ Specialized features incorporated within the plates:
  - Plates have a thin distal taper designed to limit screw head prominence in areas of limited soft tissue coverage.
  - The plates are anatomically precontoured, intended to act as a template and to aid in anatomic fracture reduction.
- ▶ All ankle-specific plates include 2.7 mm screws to capture small distal fragments and offer 3.5 mm or 4.0 mm screw options along the shaft of the plates.



Ankle Plating System 3 Trays



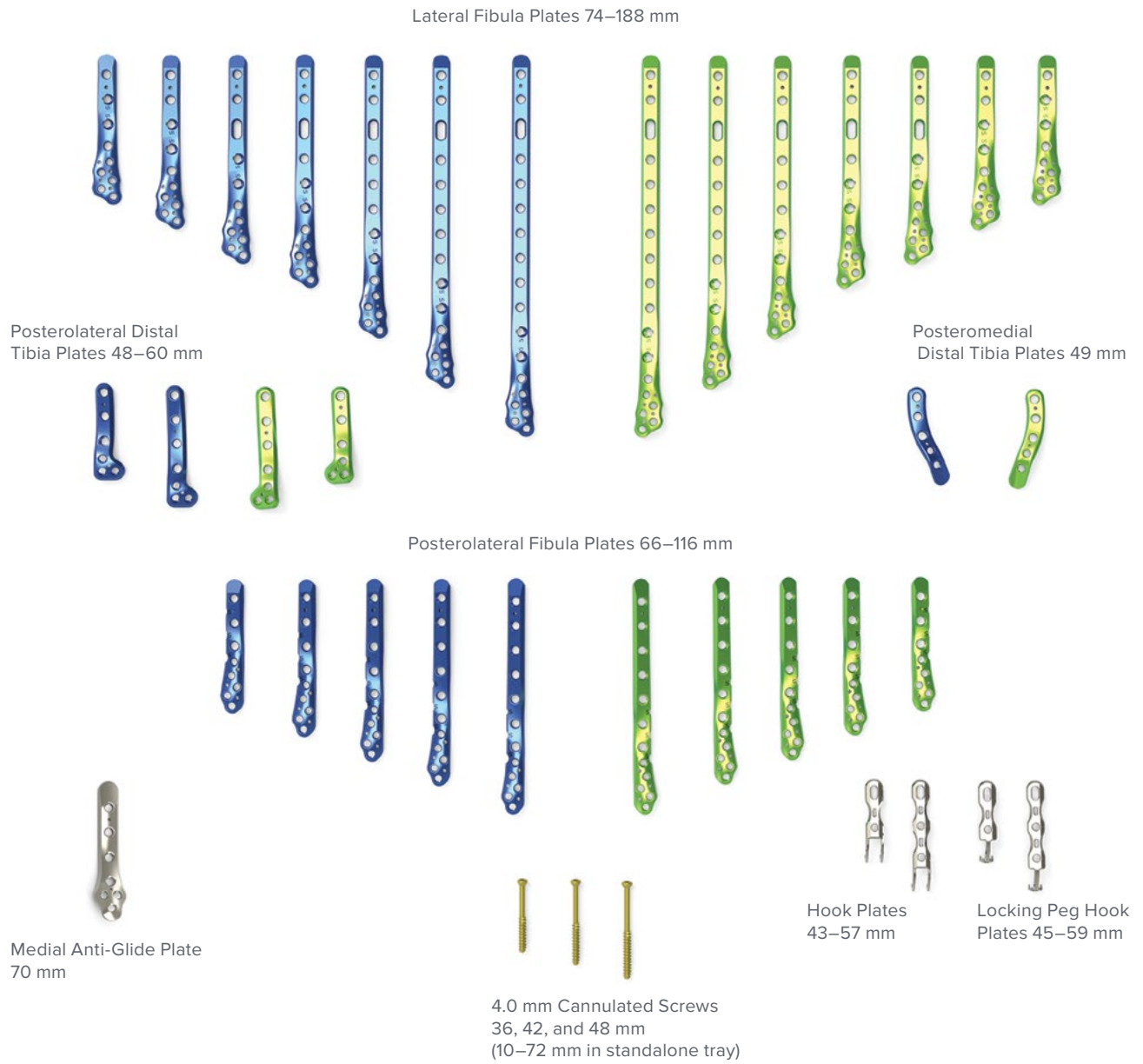
Small Fragment Base Set Trays



4.0 mm Cannulated Screw Caddy

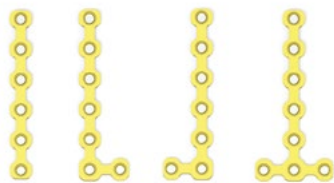
# System Overview [continued]

## Acumed Ankle Plating System 3 Implants



## Small Fragment Base Set Implants

2.7 mm Fragment Plates 61 mm



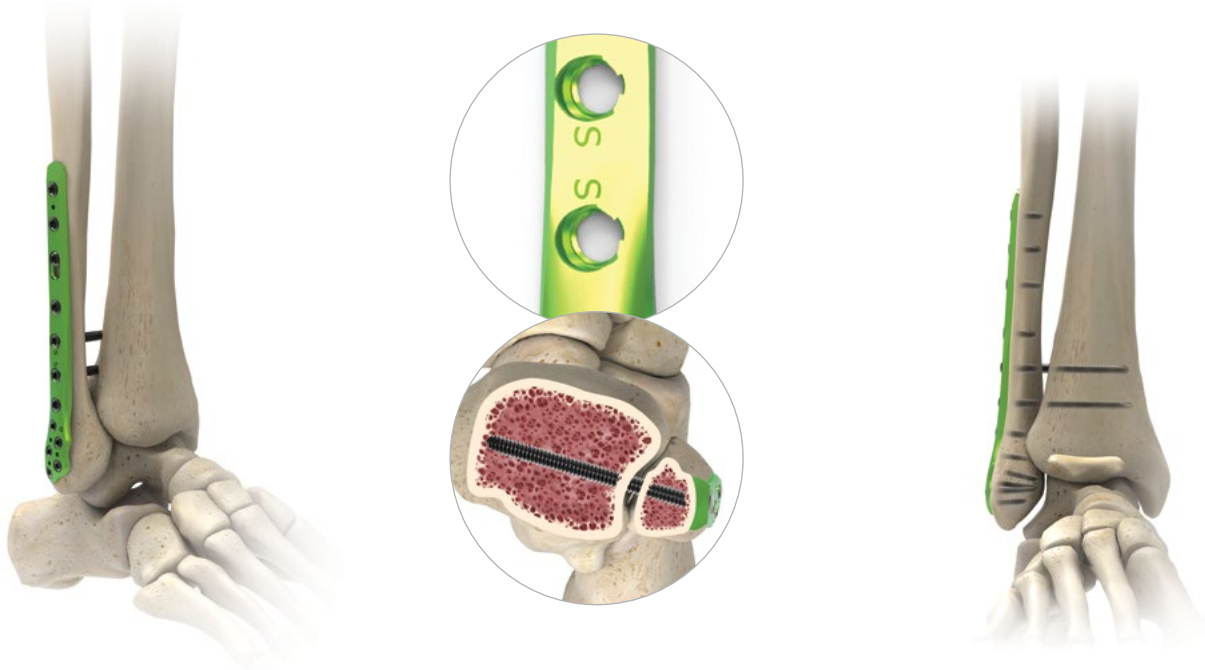
One-Third Tubular Plates 37–145 mm



## System Features

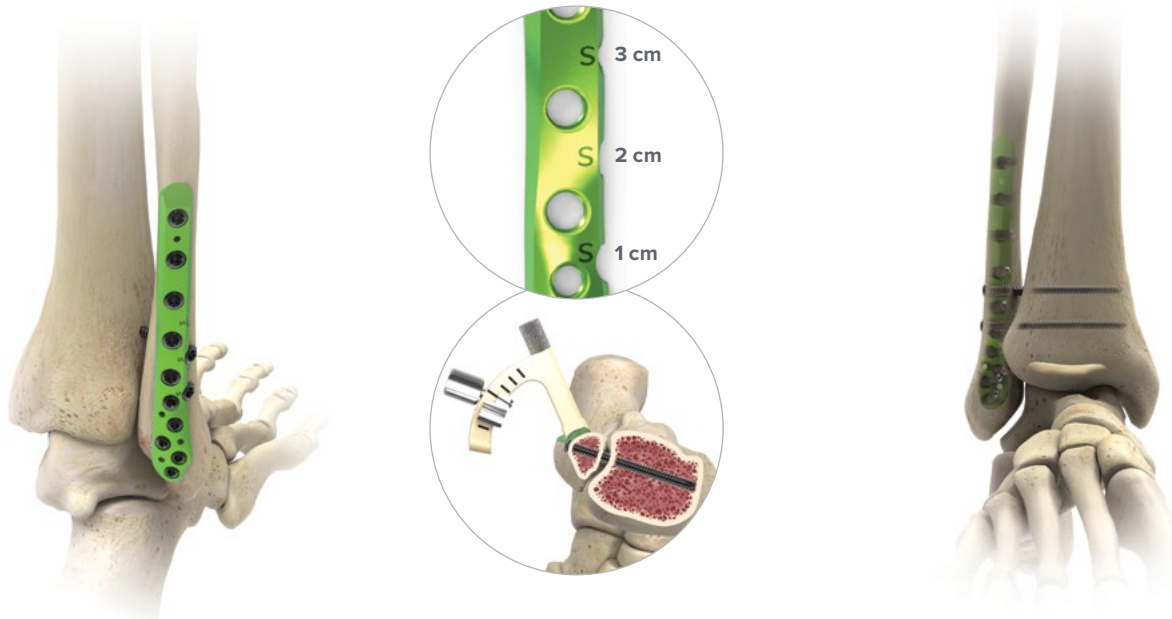
### Lateral Fibula Plates

- ▶ Each Lateral Fibula Plate includes two plate holes labeled with an “S” which have a fixed 30° anterior angle to target the center of the tibia to help optimize syndesmosis screw positioning.<sup>2</sup>



### Posterolateral Fibula Plates

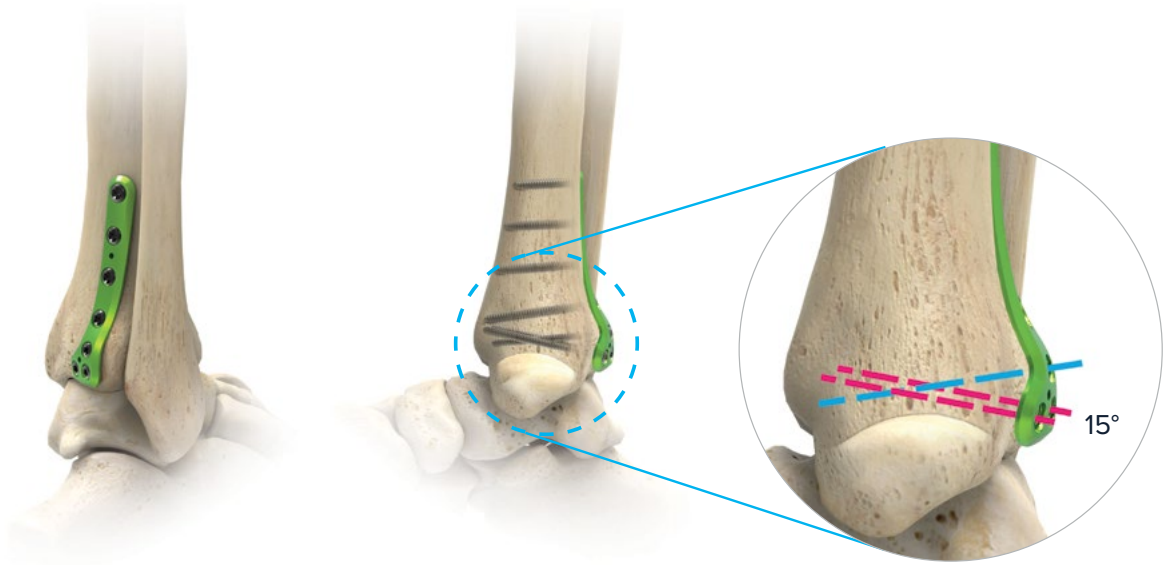
- ▶ Each Posterolateral Fibula Plate contains three scallops along the lateral edge of the plate labeled with an “S” for syndesmosis fixation. The plate scallops indicate where the surgeon can target syndesmosis screw fixation adjacent to the plate at approximately 1, 2, and 3 cm above the tibial plafond (see figure below). The scallops were also designed to allow the head of the 3.5 mm nonlocking hexalobe screws to sit flush with the plate.
- ▶ Published literature suggests that the target location for syndesmosis screw fixation is at the center of the tibia, through the fibula, 1 to 3 centimeters above the tibial plafond.<sup>3</sup> Acumed has designed a unique instrument called the Syndesmosis Targeting Guide which is used to target syndesmotic screw fixation adjacent to the Posterolateral Fibula Plates. This instrument is intended to aid the surgeon in capturing syndesmosis screw fixation with ease at the desired angle.



## System Features [continued]

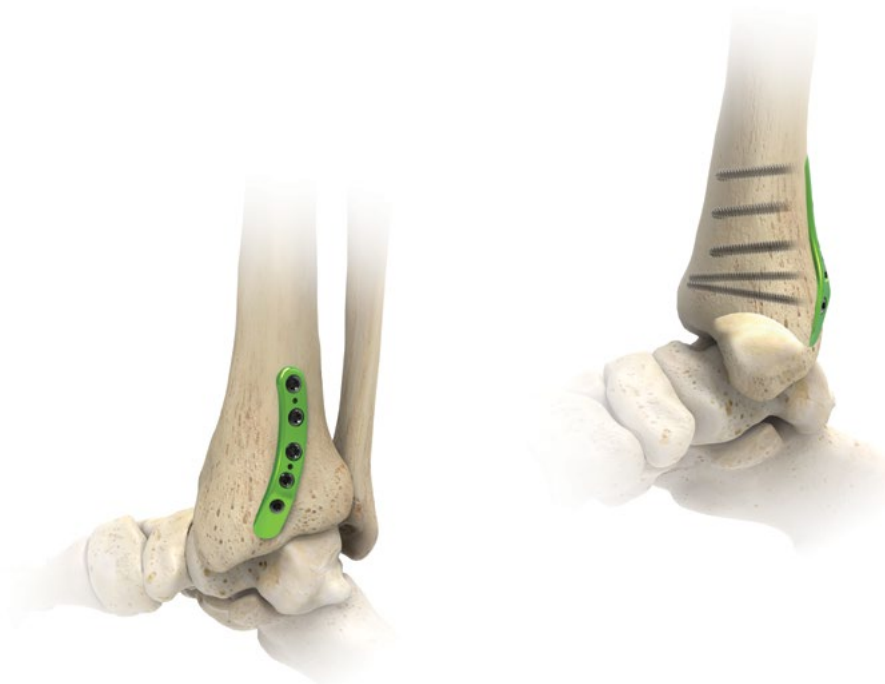
### Posterolateral Distal Tibia Plates

- ▶ The two most distal 2.7 mm hexalobe screws of each Posterolateral Distal Tibia Plate are angled approximately 15° anterior with the intention to avoid the joint space.



### Posteromedial Distal Tibia Plate

- ▶ The Posteromedial Distal Tibia Plates incorporate two distal 2.7 mm hexalobe screws that are angled away from the joint space.



## System Features [continued]

### Hook Plates

- ▶ The prongs in the Hook Plate are used to support an avulsion fragment when the fragment may be too small for a lag screw.



### Locking Peg Hook Plates

- ▶ The Locking Peg Hook Plate is also designed to support an avulsion fragment. It utilizes a 2.3 mm Cortical Peg through the distal end of the plate for additional support.





## System Features [continued]

### Medial Anti-Glide Plate

- ▶ The Medial Anti-Glide Plate is designed to address vertical shear fractures of the medial malleolus. This plate functions similarly to a one-third tubular plate but is more contoured and includes a distal cluster of 2.7 mm hexalobe screws to capture fragments in cases with distal comminution.



### 4.0 mm Cannulated Screws

- ▶ Three common lengths of 4.0 mm cannulated screws for medial malleolus fractures (36 mm, 42 mm, and 48 mm) are included in the Ankle Plating System 3 tray.
- ▶ In addition, both short thread and long thread 4.0 mm cannulated screws ranging in length from 10 mm to 72 mm are also available. These screws are housed in a standalone tray and use the 4.0 mm cannulated screw instruments within the Ankle Plating System 3.



# System Features [continued]

## Small Fragment Base Set Features

The Acumed Small Fragment Base Set contains One-Third Tubular Plates in a variety of lengths as well as 2.7 mm L-shaped, T-shaped, and straight Fragment Plates to treat small bone fractures and malunions. Plates are designed to minimize soft tissue irritation.

### One-Third Tubular Plates



**One-Third Tubular Plate 3-Hole 37 mm**  
(7008-0103)



**One-Third Tubular Plate 7-Hole 85 mm**  
(7008-0107)



**One-Third Tubular Plate 4-Hole 49 mm**  
(7008-0104)



**One-Third Tubular Plate 8-Hole 97 mm**  
(7008-0108)



**One-Third Tubular Plate 5-Hole 61 mm**  
(7008-0105)



**One-Third Tubular Plate 10-Hole 121 mm**  
(7008-0110)



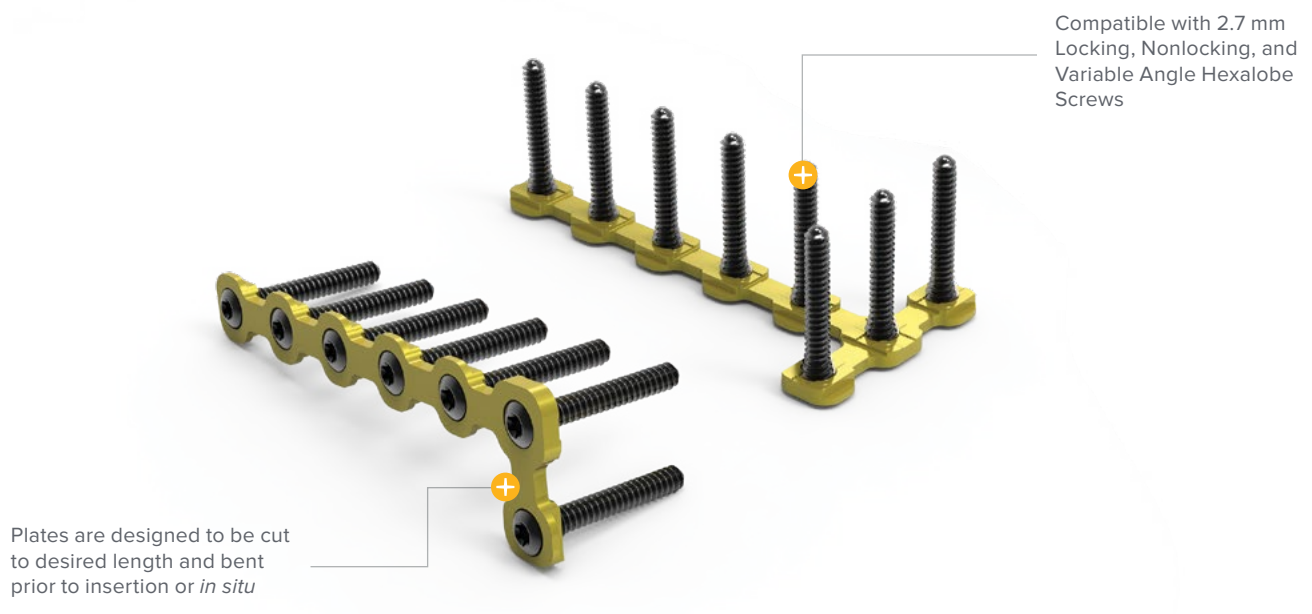
**One-Third Tubular Plate 6-Hole 73 mm**  
(7008-0106)



**One-Third Tubular Plate 12-Hole 145 mm**  
(7008-0112)

# System Features [continued]

## 2.7 mm Fragment Plates



**Fragment Plate 2.7 mm, 60 mm**  
(7010-0106N)



**L Fragment Plate 2.7 mm Right, 61 mm**  
(7010-0107R)



**L Fragment Plate 2.7 mm Left, 61 mm**  
(7010-0107L)



**T Fragment Plate 2.7 mm, 61 mm**  
(7010-0108N)

## Washers



**Cannulated Screw Washers 7.0 mm OD x 3.6 mm ID**  
(7003-07036)

# System Features [continued]

## Screw Options

Acumed plating systems supported by the Small Fragment Base Set accept the following screws. These screws feature a hexalobe recess and are designed to have greater torsional strength in comparison to similar size hex screws.

### 2.7 mm and 3.5 mm Variable Angle Hexalobe Screws

For use in locking holes (except the "S" holes in Locking Fibula Plates)

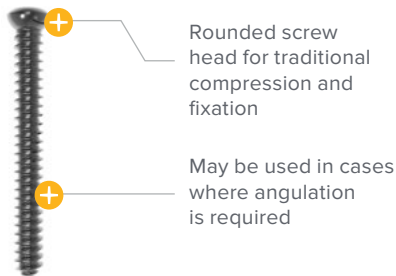
Head shape facilitates angling of the screw up to 15 degrees off axis in any direction



### 2.7 mm and 3.5 mm Nonlocking Hexalobe Screws

Designed for fixation in cortical bone

For use in locking and nonlocking plate holes

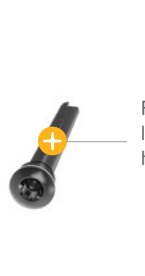


### 2.7 mm and 3.5 mm Locking Hexalobe Screws

Threaded conical screw head

For use in all locking holes

Follow predefined locking plate hole angle



### 4.0 mm Partially Threaded Cancellous Hexalobe Screws

For use in all 3.5 mm plate holes

Partially threaded for metaphyseal bone and lag techniques

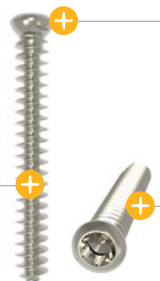


### 4.0 mm Fully Threaded Cancellous Hexalobe Screws

For use in all 3.5 mm plate holes

Rounded screw head for traditional compression and fixation

Fully threaded for metaphyseal bone and lag techniques



Screw Type	Material	Available Lengths	
		(2 mm increments)	(5 mm increments)
2.7 mm Variable Angle Hexalobe Screws	Cobalt Chrome	10–50 mm	50–60 mm
3.5 mm Variable Angle Hexalobe Screws		10–50 mm	50–65 mm
2.7 mm Locking Hexalobe Screws	Titanium	8–50 mm	50–60 mm
3.5 mm Locking Hexalobe Screws		8–50 mm	50–65 mm
2.7 mm Nonlocking Hexalobe Screws		8–50 mm	50–60 mm
3.5 mm Nonlocking Hexalobe Screws		8–50 mm	50–65 mm
4.0 mm Partially Threaded Cancellous Hexalobe Screws		12–30 mm	30–60 mm
4.0 mm Fully Threaded Cancellous Hexalobe Screws		10–30 mm	30–60 mm

## System Features [continued]

### AcuTwist® Acutrak® Compression Screw

The AcuTwist Acutrak Compression Screw is designed to provide compressive fixation for use in fractures, fusions, and osteotomies. It is not intended for interference or soft tissue fixation.

The screw design includes a variable thread pitch, a tapered profile, a break-off groove, and threads along the entire length of the screw. The fully threaded screw length allows for greater resistance to pull-out force than partially threaded headed and headless screws.<sup>4</sup>

Visit [www.acumed.net](http://www.acumed.net) for the complete AcuTwist Acutrak Compression Screw surgical technique (SPFOO-07).

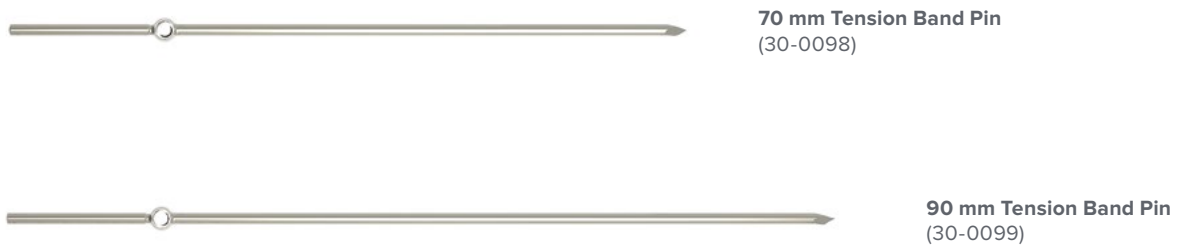


### Acumed Tension Band Pin System

The Acumed Tension Band Pin System is the first interlocking solution designed to provide low-profile, secure fixation for patella, olecranon, and malleolus fractures to minimize soft tissue irritation and postoperative pin migration. This innovative solution is intended to minimize post-surgical complications associated with traditional tension band pinning with K-wires.

The Acumed Tension Band Pin System features an innovative method intended to minimize pin migration. An eyelet is located on the proximal end of the stainless steel pin. The pin is secured by passing the cerclage wire through the eyelet, minimizing migration of the pins postoperatively. The capturing of the pin allows compression to be maintained across the fracture or osteotomy site.

Visit [www.acumed.net](http://www.acumed.net) for the full Tension Band Pin System surgical technique (SPFOO-04).



## System Features [continued]

### Variable Angle Screws



The 2.7 mm and 3.5 mm Variable Angle Screws are included as part of the Small Fragment Base Set. These screws can be used in locking plate holes\* within the Small Fragment Base Set as well as any systems dependent upon the Small Fragment Base Set. The variable angle hexalobe screw has a spherical head to accommodate insertion at various angles and may be angled up to 15 degrees off axis in any direction. Variable angle screws are provided to aid in the capture of specific fragments and to accommodate variations in patient anatomy.

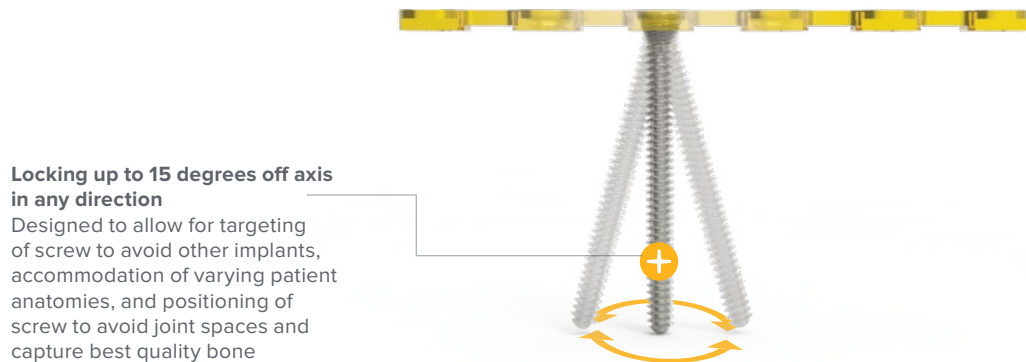
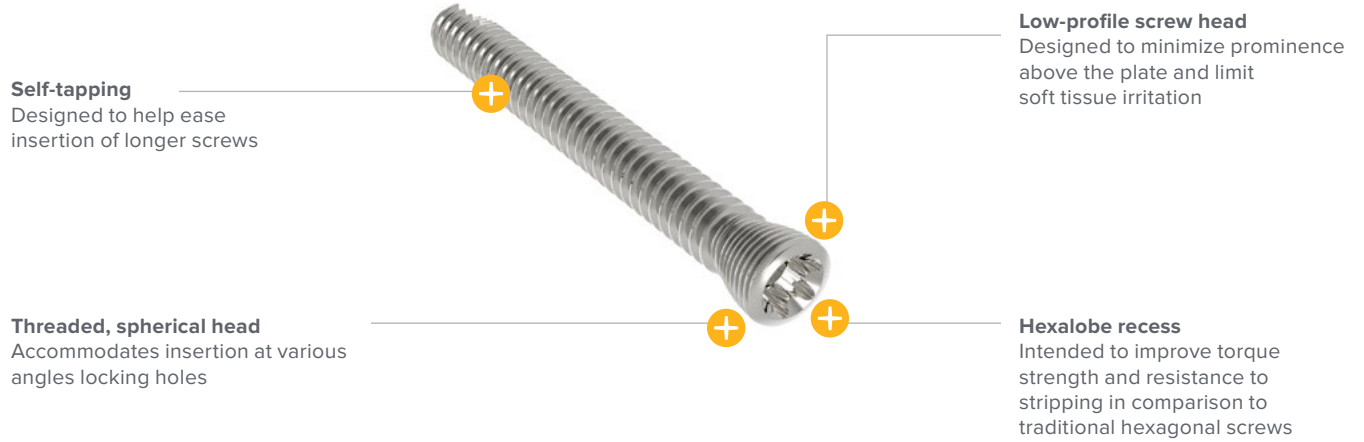
Variable angle screws are designed to facilitate screw placement and allow the surgeon to:

- ▶ Target and capture best quality bone
- ▶ Angle screw to avoid joint penetration
- ▶ Tailor screw position to accommodate differences in patient anatomy and fracture fragment location
- ▶ Avoid existing implants

\*Refer to Acumed Ankle Plating System 3 Surgical Technique (LEX00-06) to determine which screws are appropriate for the holes and slots in each plate type.

# System Features [continued]

## Variable Angle Screw Features

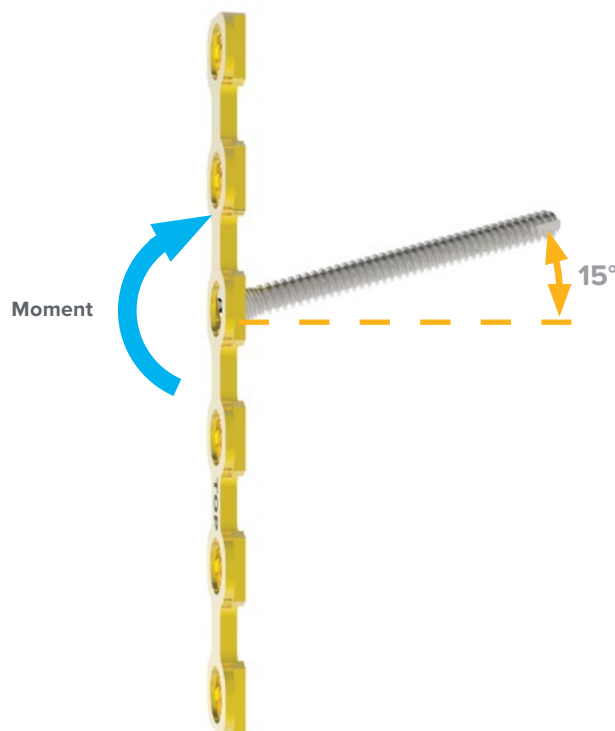
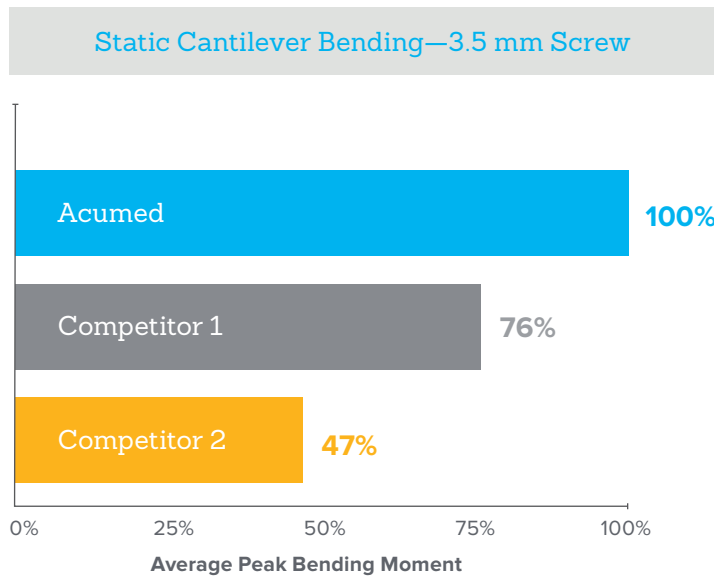
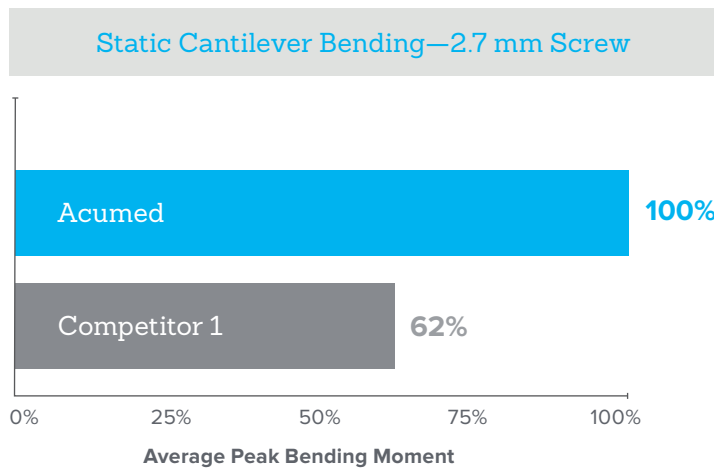


## System Features [continued]

### Mechanical Testing: Variable Angle Screws

#### Cantilever Bending

Mechanical testing was performed to evaluate the strength of the screw-to-plate interface for Acumed’s variable angle screws. Similar testing was performed for two competitive variable angle screw systems. Screws were inserted into plates at angulations of 0, 5, 10, and 15 degrees from the axis of the hole. A load was applied to each screw at a uniform distance from the bottom of the plate to generate a bending moment at the screw-to-plate interface. The peak bending moment at failure was recorded for each screw. The table below represents a summary of this testing as an average of all loads at 15° angulation.



**Source:** Acumed Internal Test Reports TR01402, TR01558, and TR01607



## System Features [continued]

### Galvanic Corrosion Testing: Variable Angle Screws

The 2.7 mm and 3.5 mm variable angle hexalobe screws included in Acumed's Small Fragment Base Set are composed of cobalt-chromium-molybdenum (CCM) alloy and are used with Acumed plates composed of titanium alloy and commercially pure titanium.

Dissimilar metals in contact in an electrolyte solution may initiate an electrochemical process known as galvanic corrosion, where one metal corrodes another as a result of an electropotential difference between the metals.<sup>5</sup> Galvanic corrosion manifests as accelerated corrosion of the more active, corroding metal (anode) and slower corrosion of the more noble metal, if it corrodes at all.<sup>6</sup>

There is significant history on the safe use of CCM and titanium in the body. Both CCM and titanium are self-passivating, indicating that these materials would tend not to have galvanic interactions over time.<sup>6</sup> Kummer et al previously demonstrated that CCM-titanium couples result in low, stable galvanic currents that gradually decrease over time.<sup>6</sup> A number of orthopaedic device manufacturers are currently utilizing CCM screws and titanium plates in the same combination as Acumed.

In order to quantify the potential impact of galvanic corrosion on Acumed's CCM variable angle screws, third-party testing was completed. The corrosion rate and mass loss for each sample couple was determined and used to calculate material release.

### Summary of Galvanic Couple Current Data for Variable Angle Screw Platform Materials (CCM, Titanium Alloy, Commercially Pure Titanium)

Average results of testing each titanium material (cathode) in presence of CCM material (anode)

Corrosion Rate (CR) Mils Per Year (mpy) <sup>7</sup>	Mass Loss (MR) ( $\mu\text{g}/\text{cm}^2/\text{day}$ )	Calculated Material Release ( $\mu\text{g}/\text{day}$ )
0.001	0.04	0.07

**Source:** Acumed Internal Test Report TR01671

The calculated corrosion rate (CR) was less than 0.001 mpy. The MR was less than 0.04  $\mu\text{g}/\text{cm}^2/\text{day}$ . For these cobalt chromium screws, with a surface area of 1.63  $\text{cm}^2$ , this translates to less than 0.07  $\mu\text{g}/\text{day}$  of cobalt chromium material released.

In addition to the corrosion rate, mass loss, and calculated material release, the cobalt chrome screws were examined pre- and post-testing at up to 40X magnification to assess their general condition. This examination revealed no pitting or indication of corrosion.

Acumed's findings are consistent with those in the research literature which have indicated that CCM and titanium alloys generate a finite current ultimately resulting in a stable passive film, limiting material loss to nearly undetectable levels.<sup>6</sup>

## Indications for Use

The Acumed Ankle Plating System 3 includes plates with the following indications:

- ▶ Lateral Fibula Plates, Posterolateral Fibula Plates, Posteromedial Distal Tibia Plates, Posterolateral Distal Tibia Plates, and Medial Anti-Glide Plates are intended for use for fixation of fractures, osteotomies, and nonunions of the distal tibia and fibula. 2.7 mm and 3.5 mm nonlocking hexalobe screws are also intended to be used independently as lag screws.
- ▶ Hook Plates and Locking Peg Hook Plates are intended for fixation of fractures, osteotomies, and nonunions of small bones including the tibia and fibula.

The Ankle Plating System 3 is intended to be used with certain components of the Acumed Cannulated Screw System.

- ▶ The Acumed Cannulated Screw System is generally intended for fixation of fractures, fusions, and osteotomies of large and small bones appropriate for the size of the device.

The Acumed Ankle Plating System 3 is intended to be used with the Acumed Small Fragment Base set with the following indications:

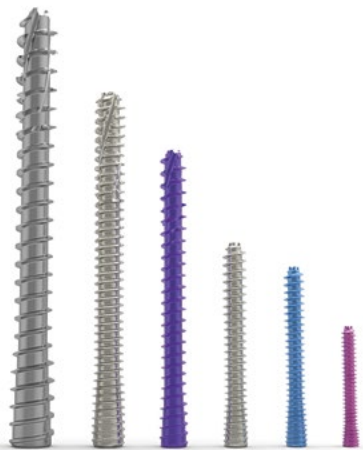
- ▶ Acumed 2.7 mm Fragment Plates and 4.0 mm cancellous screws are intended for fractures, osteotomies, nonunions, replantations, and fusions of small bones and small bone fragments.
- ▶ Acumed One-Third Tubular Plates are intended for fixation of fractures, osteotomies, and nonunions of the distal tibia and fibula.

The Small Fragment Base Set tray includes accompanying AcuTwist® screws and Tension Band Pins.

- ▶ Tension Band Pins are intended to be used in conjunction with orthopedic wire to address malleolar, patella, and olecranon fractures in tension band wiring procedures.
- ▶ AcuTwist® Acutrak® Compression Screws are intended as a fixation device for small bones, bone fragments, and osteotomies. They are not intended for interference or soft tissue fixation.

## Associated Acumed Products

Acutrak 2® Headless Compression Screw System, Fibula Rod System



Acutrak 2® Screws



Fibula Rod with Targeting Guide

## Clinical Data Influence

Ankle fractures represent 9% of all adult fractures.<sup>7</sup> With an estimated fracture rate of 187 per 100,000 people per year, “ankle fractures are the fourth most common fracture to require operative repair.”<sup>8</sup> Ankle fractures involve the distal end of the tibia and fibula, particularly the bony protuberances on each side of the ankle that are referred to as malleoli. The lateral, medial, and posterior malleoli can all be addressed utilizing the nine different plate family options offered within the Acumed Ankle Plating System 3 and Acumed Small Fragment Base Set.

### Posterior Malleolus Fractures

Published literature has placed attention on fractures of the posterior malleolus.<sup>2,9,10</sup> Most ankle fractures are generally considered to fall into one of two categories: malleolar (rotational force) or pilon (axial load). “The posterior malleolus plays an important role in load transfer between the distal tibia and the talar dome, as well as in posterior stability.”<sup>11</sup> Studies suggest that ankle fractures with involvement of the posterior malleolus lead to poorer outcomes even when the fragment is small, with outcomes that may be worse with larger fragments.<sup>11</sup> One paper reports that posterior malleolus fractures can occur in 7–44% of ankle fractures<sup>12</sup> and another study reports these fractures as high as 50%.<sup>9</sup>

The preferred treatment for posterior malleolus fractures involving the articular surface has not been fully established, but recent literature suggests that there is an increasing trend towards open reduction and fixation of these fractures.<sup>1</sup> Switaj et al notes that “increased recognition of posterior malleolar fractures may alter the surgeon’s selection of operative approach, reduction strategies, and implant selection.”<sup>9</sup> Unlike traditional fixation methods, the Acumed Ankle Plating System 3 incorporates anatomically precontoured plating options for both the posteromedial and posterolateral aspect of the distal tibia to specifically address these difficult fracture patterns. These plates were designed to ease implantation and plate placement so focus can be placed on anatomic reduction of these fractures. In addition to precontoured plates for the posterior malleolus, Acumed offers one-third tubular plates, a variety of fragment plates, and 4.0 mm cancellous and cannulated screws that may also be used to treat this fracture pattern, offering surgeons many different treatment options within one compact system.

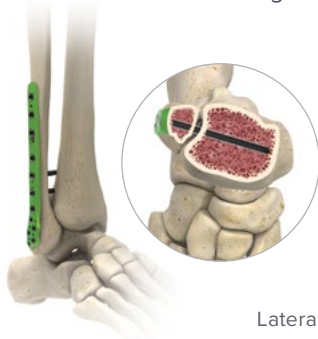


Posteromedial and  
Posterolateral  
Distal Tibia Plates

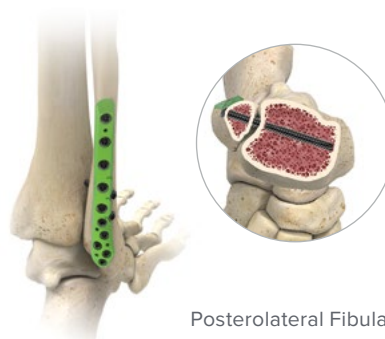
### Syndesmotic Fixation

The syndesmosis is a joint between the distal tibia and fibula, constrained by multiple ligaments and an interosseous membrane between the tibia and fibula. Often the syndesmosis is partially or completely ruptured in conjunction with a rotational ankle fracture. “It has been demonstrated that 13% of all ankle fractures and 20% of all operative ankle fractures have a disrupted syndesmosis.”<sup>10</sup>

Published literature has shown that the target location for syndesmosis screw fixation is at the center of the tibia, through the fibula,<sup>2</sup> 1 to 3 centimeters above the tibial plafond.<sup>3</sup> Both the Lateral Fibula Plate and the Posterolateral Fibula Plate within the Ankle Plating System 3 have built-in features to aid the surgeon in achieving syndesmosis fixation. The Lateral Fibula Plate features two holes that are angled 30° anterior to target the center of the tibia. The Posterolateral Fibula Plate features three plate scallops adjacent to the plate that indicate where the surgeon can target syndesmosis fixation, while allowing the head of the screw to sit flush with the plate. These screws can either be targeted freehand or with the Syndesmosis Targeting Guide that attaches to the Posterolateral Fibula Plate. The surgeon can then adjust the angle of the guide to capture syndesmotic screw fixation at the desired angle.



Lateral Fibula Plate



Posterolateral Fibula Plate



Syndesmosis Targeting Guide

# Competitive Matrix

	Acumed	Synthes	Arthrex	Stryker
	Source: Acumed Ankle Plating System 3 (LEX00-06) Acumed Small Fragment Base Set (TMA10-01)	Source: Synthes VA LCP Ankle Trauma Surgical Technique (J11515-B) Synthes Small Fragment LCP System (J6088-C)	Source: Arthrex Ankle Fracture Management System (LB1-0439-EN)	Source: VariAx Fibula Locking Plate System (90-07810) SPS Small Fragment Set (982181)
<b>Product</b>	Ankle Plating System 3 Small Fragment Base Set	VA LCP Ankle Trauma System  Small Fragment Locking Compression Plate (LCP) System	Ankle Fracture Management System	VariAx Fibula Locking Plate System  SPS Small Fragment Set
<b>Plate Material</b>	Titanium	Stainless Steel and Titanium	Stainless Steel	Stainless Steel and Titanium
<b>Screw Options</b>	<ul style="list-style-type: none"> <li>▶ 2.7 mm Nonlocking Hexalobe Screws</li> <li>▶ 2.7 mm Locking Hexalobe Screws</li> <li>▶ 2.7 mm Variable Angle Hexalobe Screws</li> <li>▶ 3.5 mm Nonlocking Hexalobe Screws</li> <li>▶ 3.5 mm Locking Hexalobe Screws</li> <li>▶ 3.5 mm Variable Angle Hexalobe Screws</li> <li>▶ 4.0 mm Partially Threaded Cancellous Screws</li> <li>▶ 4.0 mm Fully Threaded Cancellous Screws</li> <li>▶ 4.0 mm Cannulated Screws</li> <li>▶ AcuTwist® Compression Screws</li> <li>▶ Tension Band Pins</li> </ul>	<ul style="list-style-type: none"> <li>▶ 2.7 mm Cortex Screws</li> <li>▶ 2.7 mm Low-Profile Metaphyseal Compression Screws</li> <li>▶ 2.7 mm Variable Angle Locking Screws</li> <li>▶ 3.5 mm Cortex Screws</li> <li>▶ 3.5 mm Variable Angle Locking Screws</li> <li>▶ 4.0 mm Cancellous Bone Screws</li> <li>▶ 4.0 mm Cortex Screws</li> </ul>	<ul style="list-style-type: none"> <li>▶ 2.7 mm Locking Screws</li> <li>▶ 3.0 mm Nonlocking Cancellous Screw</li> <li>▶ 3.5 mm Nonlocking Cortical Screws</li> <li>▶ 3.5 mm Locking Screws</li> <li>▶ 4.0 mm Nonlocking Cancellous Screws</li> <li>▶ 4.0 mm Short-Thread Cannulated Screws</li> <li>▶ 4.0 mm Long-Thread Cannulated Screws</li> <li>▶ 4.0 mm Short-Thread Screws</li> <li>▶ 4.0 mm Long-Thread Screws</li> </ul>	<ul style="list-style-type: none"> <li>▶ 3.5 mm Locking Screws</li> <li>▶ 3.5 mm Nonlocking Screws</li> <li>▶ 4.0 mm Locking Screws</li> <li>▶ 4.0 mm Cancellous Screws, Partial Thread</li> <li>▶ 4.0 mm Cancellous Screws, Full Thread</li> </ul>
<b>Plate Options</b>	<ul style="list-style-type: none"> <li>▶ Lateral Fibula Plate</li> <li>▶ Posterolateral Fibula Plate</li> <li>▶ Hook Plate</li> <li>▶ Locking Peg Hook Plate</li> <li>▶ Posterolateral Distal Tibia Plate</li> <li>▶ Posteromedial Distal Tibia Plate</li> <li>▶ Medial Anti-Glide Plate</li> <li>▶ One-Third Tubular Plate</li> <li>▶ 2.7 mm L-Fragment Plate</li> <li>▶ 2.7 mm T-Fragment Plate</li> <li>▶ 2.7 mm Straight Fragment Plate</li> </ul>	<ul style="list-style-type: none"> <li>▶ Lateral Distal Fibula Plate</li> <li>▶ Posterolateral L-Plate</li> <li>▶ Posterolateral T-Plate</li> <li>▶ Posterolateral Distal Fibula Plate</li> <li>▶ One-Third Tubular Plate</li> <li>▶ Hook Plate</li> </ul>	<ul style="list-style-type: none"> <li>▶ Locking Distal Fibular Plate</li> <li>▶ Locking Straight Plate</li> <li>▶ Locking Third Tubular Plate</li> <li>▶ Reconstruction Plate</li> <li>▶ Locking Medial Hook Plate</li> <li>▶ Locking Lateral Hook Plate</li> </ul>	<ul style="list-style-type: none"> <li>▶ VariAx Distal Lateral Fibula Plate</li> <li>▶ VariAx Fibula Straight Plate</li> <li>▶ One-Third Tubular Plate</li> </ul>

510(k) Information



DEPARTMENT OF HEALTH &amp; HUMAN SERVICES

Public Health Service

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

Acumed, LLC  
 Mr. Nathan Wolf  
 Regulatory Specialist  
 5885 North West Cornelius Pass Road  
 Hillsboro, Oregon 97124

April 6, 2015

Re: K143385  
 Trade/Device Name: Acumed Ankle 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 4, 2015  
 Received: March 6, 2015

Dear Mr. Wolf:

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

Page 2 – Mr. Nathan Wolf

(21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical 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 contact the Division of Industry and Consumer Education 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>. 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 Industry and Consumer Education 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 -S**

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

Enclosure

**Acumed Ankle Plating System 510(k)**

DEPARTMENT OF HEALTH AND HUMAN SERVICES  
Food and Drug Administration

Form Approved: OMB No. 0910-0120  
Expiration Date: January 31, 2017  
See PRA Statement below.

**Indications for Use**

510(k) Number (if known)

Device Name

Acumed Ankle Plating System

Indications for Use (Describe)

The Acumed Ankle Plating System is intended for fixation of fractures, osteotomies, and non-unions of the distal tibia and fibula, particularly in osteopenic bone.

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

Prescription Use (Part 21 CFR 801 Subpart D)

Over-The-Counter Use (21 CFR 801 Subpart C)

**CONTINUE ON A SEPARATE PAGE IF NEEDED.**

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

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

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

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

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

Acumed Ankle Plating System  
510(k) Notification K143385

## **510(k) Summary**

---

### **Contact Details**

Applicant Name: Acumed LLC  
5885 NW Cornelius Pass Road, Hillsboro, OR 97124-9432

Nathan Wolf, Regulatory Specialist  
503-726-6622 (Cell)  
503-207-1502 (Desk)  
503-520-9618 (Fax)

Date Prepared: 24 November 2014

### **Device Name**

Trade Name: Acumed Ankle Plating System

Common Name: Ankle Plating System

Classification: 21 CFR 888.3030 Single/multiple component metallic bone fixation appliances and accessories

Class: Class II

Product Code: HRS, HWC

### **Legally Marketed Predicate Device(s)**

The Synthes Third Tubular Plate (pre-amendment per K011335), Synthes VA LCP Ankle Trauma System cleared in 2012 (K120854), and the Synthes 2.7 mm/3.5 mm LCP Distal Fibula Plates cleared in 2008 (K083213) serve as the predicate devices.

### **Device Description**

The Acumed Ankle Plating System consists of plates and accompanying screws implanted in the distal fibula and tibia. The plates are available in a variety of sizes and use a variety of screw sizes to accommodate varying patient anatomies and fracture patterns. All plates are anatomically pre-contoured, and are provided in left and right limb-specific options where applicable. All implants are manufactured from Ti-6Al-4V per ASTM F136 and provided both sterile and non-sterile. The system contains pre-contoured plates, 2.7, 3.5, and 4.0mm screws, syndesmosis targeting instrumentation, and other typical instrumentation for ankle plating cases.



Acumed Ankle Plating System  
510(k) Notification K143385

Page 2 of 2

### **Intended Use/Indications for Use**

The Acumed Ankle Plating System is intended for fixation of fractures, osteotomies, and non-unions of the distal tibia and fibula, particularly in osteopenic bone.

### **Substantial Equivalence Comparison**

In consideration of the comparisons given herein, the Acumed Ankle Plating System has been determined to be substantially equivalent to its predicate devices, the Synthes Third Tubular Plates (pre-amendment), Synthes VA LCP Ankle Trauma System (K120854), and Synthes 2.7 mm/3.5 mm LCP Distal Fibula Plates (K083213). Substantial equivalence was determined due to similarities in materials, technology, function, and dimensions.

### **Non-clinical Testing**

Comparative testing between the Acumed Ankle Plating System and a predicate device was conducted per ASTM F382-99. The test data showed the Acumed Ankle Plating System was substantially equivalent to the predicate device in both static four-point bend and bending fatigue tests as described herein.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

Acumed, LCC  
Nathan Wolf  
Regulatory Specialist  
5885 NW Cornelius Pass Road  
Hillsboro, Oregon 97124

January 23, 2015

Re: K143394  
Trade/Device Name: Acumed Small Fragment Base Set  
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: December 9, 2014  
Received: December 12, 2014

Dear Mr. Nathan Wolf:

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 device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

Page 2 – Mr. Nathan Wolf

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 contact the Division of Industry and Consumer Education 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>. 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 Industry and Consumer Education 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 -S**

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

Enclosure

Acumed Small Fragment Base Set 510(k)

K143394 page 1 of 1

DEPARTMENT OF HEALTH AND HUMAN SERVICES  
Food and Drug Administration

Form Approved: OMB No. 0910-0120  
Expiration Date: January 31, 2017  
See PRA Statement below.

**Indications for Use**

510(k) Number (if known)

K143394

Device Name

Acumed Small Fragment Base Set

Indications for Use (Describe)

The Acumed Small Fragment Base Set contains orthopedic plates and screws with the following indications: Acumed Hook Plates and Locking Peg Hook Plates are intended for fixation of fractures, osteotomies, and non-unions of small bones including the ulna, radius, tibia, and fibula. Acumed Fragment Plates and 4.0mm Cancellous Screws are intended for fixation of fractures, osteotomies, non-unions, replantations, and fusions of small bones and small bone fragments. Acumed One-Third Tubular Plates are intended for fixation of fractures, osteotomies, and non-unions of the clavicle, scapula, olecranon, humerus, radius, ulna, pelvis, distal tibia, and fibula.

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

Prescription Use (Part 21 CFR 801 Subpart D)

Over-The-Counter Use (21 CFR 801 Subpart C)

**CONTINUE ON A SEPARATE PAGE IF NEEDED.**

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

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

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

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

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

Acumed Small Fragment Base Set  
510(k) Notification

K143394 page 1 of 2

## **510(k) Summary**

---

### **Contact Details**

Applicant Name: Acumed LLC  
5885 NW Cornelius Pass Road, Hillsboro, OR 97124-9432

Nathan Wolf, Regulatory Specialist  
503-726-6622 (Cell)  
503-207-1502 (Desk)  
503-520-9618 (Fax)

Date Prepared: 05 January 2015

### **Device Name**

Trade Name: Acumed Small Fragment System

Common Name: Bone Plates and Screws

Classification: 21 CFR 888.3030 Single/multiple component metallic bone fixation appliances and accessories

Class: Class II

Product Code: HRS, HWC

### **Legally Marketed Predicate Device(s)**

The Synthes (USA) Modular Mini Fragment LCP System cleared in 2006 (K063049), Synthes (USA) 3.5mm LCP Hook Plate cleared in 2008 (K082072), Synthes One-Third Tubular DCL Plate cleared in 2001 (K011335), and Synthes Sterile 3.5mm and 4.0mm Cannulated Screws cleared in 1996 (K963192) serve as predicate devices.

### **Device Description**

The Acumed Small Fragment Base Set contains orthopedic plates and screws indicated for general fragment fixation as described below. Plates and screws are manufactured from titanium alloy Ti-6Al-4V ELI per ASTM F136, or from commercially pure titanium per ASTM F67. All implants are provided both sterile and non-sterile. The set also contains typical instrumentation for general orthopedic fracture fixation cases.

## Acumed Small Fragment Base Set 510(k) Notification

### **Intended Use/Indications for Use**

The Acumed Small Fragment Base Set contains orthopedic plates and screws with the following indications: Acumed Hook Plates and Locking Peg Hook Plates are intended for fixation of fractures, osteotomies, and non-unions of small bones including the ulna, radius, tibia, and fibula. Acumed Fragment Plates and 4.0mm Cancellous Screws are intended for fixation of fractures, osteotomies, non-unions, replantations, and fusions of small bones and small bone fragments. Acumed One-Third Tubular Plates are intended for fixation of fractures, osteotomies, and non-unions of the clavicle, scapula, olecranon, humerus, radius, ulna, pelvis, distal tibia, and fibula.

### **Substantial Equivalence Comparison**

In consideration of the comparisons given herein, the Acumed Small Fragment Base Set has been determined to be substantially equivalent to its predicate devices, the Synthes (USA) Modular Mini Fragment LCP System (K063049), Synthes (USA) 3.5mm LCP Hook Plate (K082072), Synthes One-Third Tubular DCL Plate (K011335), and Synthes Sterile 3.5mm and 4.0mm Cannulated Screws (K963192). Substantial equivalence was determined due to similarities in materials, technology, function, and dimensions.

### **Non-clinical Testing**

Comparative testing between the Acumed Small Fragment Base Set implants and similar devices was conducted as follows:

- Fragment Plate static bending strength and cyclic fatigue testing was performed per ASTM F382.
- One-Third Tubular Plate static bending strength and cyclic fatigue testing was performed per ASTM F382.
- Hook Plate static bending strength and cyclic fatigue testing was performed per ASTM F384
- Locking Peg Hook Plate static bending strength and cyclic fatigue testing was performed per ASTM F384
- 4.0 Cancellous Screw pullout and torque testing was performed per ASTM F543.

The results provided in Section 20 demonstrate the substantial equivalence of the Acumed Small Fragment Base Set.



## DEPARTMENT OF HEALTH &amp; HUMAN SERVICES

Public Health Service

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

Acumed, LCC  
% Mr. Nathan Wolf  
Regulatory Consultant  
Wolf Regulatory Consulting LLC  
P.O. Box 796  
Loma Linda, California 92354

Re: K151886  
Trade/Device Name: Acumed Ankle and Small Fragment Base Set Update  
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: September 28, 2015  
Received: October 1, 2015

Dear Mr. Nathan Wolf:

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

Page 2 - Mr. Nathan Wolf

Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical 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 contact the Division of Industry and Consumer Education 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>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to

<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 Industry and Consumer Education 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 -S**

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

Enclosure



**Acumed Ankle and Small Fragment Base Set Update 510(k)**

DEPARTMENT OF HEALTH AND HUMAN SERVICES  
Food and Drug Administration

Form Approved: OMB No. 0910-0120  
Expiration Date: January 31, 2017  
See PRA Statement below.

**Indications for Use**

510(k) Number (if known)

Device Name

Acumed Ankle and Small Fragment Base Set Update

Indications for Use (Describe)

The Acumed Ankle Plating System contains orthopedic plates and lag screws intended for fixation of fractures, osteotomies, and non-unions of the distal tibia and fibula, particularly in osteopenic bone.

The Acumed Small Fragment Base Set contains orthopedic plates and screws with the following indications: Acumed Hook Plates and Locking Peg Hook Plates are intended for fixation of fractures, osteotomies, and non-unions of small bones including the ulna, radius, tibia, and fibula. Acumed Fragment Plates and 4.0mm Cancellous Screws are intended for fixation of fractures, osteotomies, non-unions, replantations, and fusions of small bones and small bone fragments. Acumed One-Third Tubular Plates are intended for fixation of fractures, osteotomies, and non-unions of the clavicle, scapula, olecranon, humerus, radius, ulna, pelvis, distal tibia, and fibula.

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

Prescription Use (Part 21 CFR 801 Subpart D)

Over-The-Counter Use (21 CFR 801 Subpart C)

**CONTINUE ON A SEPARATE PAGE IF NEEDED.**

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

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

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

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

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

Acumed Ankle and Small Fragment Base Set Update  
510(k) Notification

510(k) Summary

---

Contact Details

Applicant Name: Acumed LLC  
5885 NW Cornelius Pass Road  
Hillsboro, OR 97124-9432

Applicant Contact: Ms. Kara Budor, Regulatory Manager  
503-207-1413  
503-520-9618 (Fax)

Correspondent: Mr. Nathan Wolf, Regulatory Consultant  
858-263-0605  
nathan@wolfregulatory.com

Date Prepared: July 7, 2015

Device Name

Trade Name: Acumed Ankle and Small Fragment Base Set Update

Common Name: Bone Plates and Bone Screws

Classification: 21 CFR 888.3030 Single / Multiple component metallic bone fixation appliances and accessories

Class: Class II

Product Code: HRS, HWC

Legally Marketed Predicate Device(s)

The Acumed Ankle Plating System cleared in 2015 (K143385), Acumed Small Fragment Base Set cleared in 2015 (K143394), Howmedica Osteonics Stryker® Foot Plating System cleared in 2007 (K063875), Howmedica Osteonics VariAx™ Distal Fibula Plate cleared in 2008 (K081284), and Smith & Nephew Peri-Loc™ Periarticular Locked Plating System cleared in 2007 (K071563) serve as the predicate devices for this system.

Device Description

The Acumed Ankle and Small Fragment Base Set Update introduces new 2.7mm and 3.5mm variable angle screws for use with previously cleared plates from the Acumed Ankle Plating System (K143385) and Acumed Small Fragment Base Set (K143394).

## Acumed Ankle and Small Fragment Base Set Update 510(k) Notification

Additionally, this submission expands the Ankle Plating System to include use of existing 2.7mm and 3.5mm non-locking screws in independent bone fixation, for the K143385 indications.

### Intended Use/Indications for Use

The Acumed Ankle Plating System contains orthopedic plates and lag screws intended for fixation of fractures, osteotomies, and non-unions of the distal tibia and fibula, particularly in osteopenic bone.

The Acumed Small Fragment Base Set contains orthopedic plates and screws with the following indications: Acumed Hook Plates and Locking Peg Hook Plates are intended for fixation of fractures, osteotomies, and non-unions of small bones including the ulna, radius, tibia, and fibula. Acumed Fragment Plates and 4.0mm Cancellous Screws are intended for fixation of fractures, osteotomies, non-unions, replantations, and fusions of small bones and small bone fragments. Acumed One-Third Tubular Plates are intended for fixation of fractures, osteotomies, and non-unions of the clavicle, scapula, olecranon, humerus, radius, ulna, pelvis, distal tibia, and fibula.

### Substantial Equivalence Comparison

In consideration of the comparisons given herein, the Acumed Ankle and Small Fragment Base Set Update has been determined to be substantially equivalent to its predicate devices. Substantial equivalence was determined due to similarities in materials, technology, function, and dimensions.

### Non-clinical Testing

Non-clinical included:

- ASTM F543 comparative testing
- Cantilever bend comparative testing
- Galvanic corrosion analysis

Test data showed the variable angle screws introduced in this 510(k) submission are substantially equivalent to predicate devices.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

March 18, 2013

Acumed LLC  
% Ms. Kara Budor  
Regulatory Specialist  
5885 Northwest Cornelius Pass Road  
Hillsboro, Oregon 97124

Re: K123890

Trade/Device Name: Acumed Cannulated Screw System  
Regulation Number: 21 CFR 888.3040  
Regulation Name: Smooth or threaded metallic bone fixation fastener  
Regulatory Class: Class II  
Product Code: HWC, OUR  
Dated: December 17, 2012  
Received: December 18, 2012

Dear Ms. Budor:

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 device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

Page 2 – Ms. Kara Budor

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,

**Erin I. Keith**

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

Enclosure

Acumed Cannulated Screw System  
510(k) Notification

### Indications for Use

510(k) Number (if known): K123890 (pg 1/1)

Device Name: Acumed Cannulated Screw System

Indications for Use:

The Acumed Cannulated Screw System consists of screws, washers, and accessories and is generally intended for fixation of fracture, fusion and osteotomies of large and small bones appropriate for size of device, which may include the following: Minimally invasive reconstruction of fractures and joints; Adjuvant for osteosynthesis in complex joint fractures; Multifragment joint fractures; Simple metaphyseal fractures; Fractures of the wrist, ankle, elbow, and shoulder; Condylar fractures; Epiphyseal and metaphyseal fractures in children; Osteochondritis dissecans; Osteo-Chondral Fractures; Ligament avulsion injuries; Ligament fixation; Other small fragment, cancellous bone fractures; Small joint fusion; Areas where accurate screw placement is vital; Metatarsal and phalangeal osteotomies; Fractures of the tarsals, metatarsals and other fractures of the foot; Avulsion fractures and fractures of metatarsal V; Tarso-metatarsal and metatarso-phalangeal arthrodesis; Tarsal Fusions; Calcaneal and talar fractures; Subtalar arthrodesis; Ankle arthrodesis; Fractures of small joints, such as: Ankle fractures, Navicular fractures; Fractures of the fibula, malleolus, and calcaneus; Distal tibia and pilon fractures; Acetabular fractures; Other fractures of the pelvic ring; Sacroiliac joint disruptions; Fractures of the femoral head and neck; Supracondylar femoral fractures; Slipped capital femoral epiphyses; An adjunct to DHS in basilar neck fractures; Pediatric femoral neck fractures; Intercondylar femur fractures; Intracapsular fractures of the hip; Fractures of the distal femur and proximal tibia; Patellar fractures; Tibial plateau fractures; Small fragments of the hand and wrist; Fractures of the carpals and metacarpals; Carpal and metacarpal arthrodesis; Scaphoid fracture and other fractures of the hand; Phalangeal and interphalangeal fractures; Fractures of the ulna and radius; Radial head fractures; Fractures of the olecranon and distal humerus; Humeral head fractures; Ligament fixation at the proximal humerus; and Glenoid fractures. Washers may be used with the screws in certain applications.

Prescription Use   X    
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use \_\_\_\_\_  
(Part 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)

Elizabeth L. Frank -S

Division of Orthopedic Devices



## DEPARTMENT OF HEALTH &amp; HUMAN SERVICES

Public Health Service

JUL 26 1993

Food and Drug Administration  
1390 Piccard Drive  
Rockville, MD 20850

Mr. Gene Conrad  
Product Development Engineer  
Acumed, Inc.  
10950 S.W. 5th Street  
Suite 170  
Beaverton, OR 97005

Re: K930834  
Acutrak  
Regulatory Class: II  
Dated: May 11, 1993  
Received: May 12, 1993

Dear Mr. Conrad:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent to devices marketed in interstate commerce prior to May 28, 1976. This decision is based on your device being found equivalent only to similar devices labeled and intended for small bone fracture and osteotomy fixation. You may, therefore, market your device subject to the general controls provisions of the Federal Food, Drug, and Cosmetic Act (Act).

The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, and labeling, and prohibitions against misbranding and adulteration. Note that labeling or otherwise promoting this device for pedicle screw fixation/attachment would cause the device to be adulterated under 501(f)(1) of the Act.

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

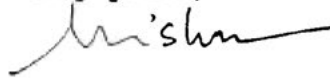
1. You may not label or in any way promote this device for pedicular screw attachment to, or fixation of the cervical, thoracic or lumbar vertebral column;
2. All labeling for this device, including package label and labeling included within the package, must prominently state that the device is intended for small bone fracture and osteotomy fixation.
3. Any pedicle screw fixation/attachment to the cervical, thoracic or lumbar vertebral column of this device is considered investigational and may only be investigated as significant risk device in accordance with the investigational device exemption (IDE) regulation under 21 CFR, Part 812. All users of the device for pedicle screw fixation/attachment must receive approval from their respective institutional review boards (IRBs) and the Food and Drug Administration (FDA) prior to conduct of the investigation.

Page 2 - Mr. Gene Conrad

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval) it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under the Radiation Control for Health and Safety Act of 1968, or other Federal Laws or Regulations.

This letter immediately will allow you to begin marketing your device intended for small bone fracture and osteotomy fixation. An FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and permits your device to proceed to the market, but it does not mean that FDA approves your device system. Therefore, you may not promote or in any way represent your device or its labeling as being approved by FDA. If you desire specific advice on the labeling for your device please contact the Division of Compliance Operations, Regulatory Guidance Branch (HFZ-323) at (301) 427-1116. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at their toll free number (800) 638-2041 or at (301) 443-6597.

Sincerely yours,

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



**ACUMED™**

K964500

*Quality Orthopaedic Instruments and Implants*

DEC 9 1996

**Enclosure D - 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.

The Acumed Tension Band Pin is used in conjunction with orthopedic wire to address malleolar, patella, and olecranon fracture fixation in tension band wiring procedures. This device is not intended for usage in the spine. This device has a diameter of .0625" and is available in lengths of 35mm, 45mm, and 55mm. The Acumed Tension Band Pin is manufactured from 316L stainless steel and is provided pre-sterile. Sterility is achieved by a minimum dose of 2.5 megarads of gamma radiation. Validation of sterility is maintained on site. Sterility level is  $10^{-6}$ . Information regarding packaging and labeling have been provided.

The Acumed Tension Band Pin is similar to the Acumed Fixation Pin and the Howmedica Kirschner Wire in material and design. Like Howmedica's Kirschner Wire, the Acumed Tension Band Pin is intended to be used in tension band wiring procedures addressing malleolar, patella, and olecranon fractures.

Based on the similarities between the Acumed Tension Band Pin and both the Acumed Fixation Pin and Howmedica Kirschner Wire, the safety and effectiveness is expected to be similar to the Acumed Fixation Pin and Howmedica Kirschner Wire.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

DEC 9 1996

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

Re: K964500  
Acumed Tension Band Pin  
Regulatory Class: II  
Product Code: HTY  
Dated: November 5, 1996  
Received: November 8, 1996

Dear Ms. Jeffers:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to 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). 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.

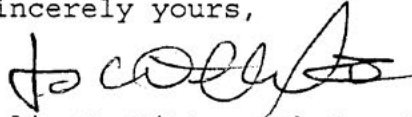
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially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


Page 2 - Ms. Shari L. Jeffers

This letter will allow you to begin marketing your device as described in your 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 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" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address "dsmo@fdadr.cdrh.fda.gov".

Sincerely yours,



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

Enclosure

510(k) Number (if known): K964500

Device Name: Acumed Tension Band Pin

Indications For Use:

This device is intended to be used in conjunction with orthopedic wire to address malleolar, patella, and olecranon fractures in tension band wiring procedures.

(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 Devices

510(k) Number K964500

Prescription Use X  
(Per 21 CFR 801.109)

OR

Over-The-Counter Use \_\_\_\_\_

(Optional Format 1-2-96)



**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 managing foot and ankle fractures in 2000. Since then, Acumed has grown to become one of the technology leaders in options for fractures of the foot and ankle. Acumed will continue to devote resources to the development of implants that aid in improving patient outcomes and advancing the field of orthopaedic surgery.

## Dedicated to Excellence [continued]

### Industry Compliance

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

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



### Transparency in Business Practice

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

### A Commitment to Social Responsibility

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

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

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



## References

1. Gardner M, Streubel P, McCormick J, Klein S, Johnson J, Ricci W. Surgeon practices regarding operative treatment of posterior malleolus fractures. *Foot Ankle Int.* 2011;32:385.
2. Needleman, RL. Accurate reduction of an ankle syndesmosis with the “glide path” technique. *Foot Ankle Int.* 2013;34:1308–1311.
3. Wheelless C. Technique of syndesmotic fixation. Wheelless Textbook of Orthopaedics website. [http://www.wheelessonline.com/ortho/technique\\_of\\_syndesmotic\\_fixation](http://www.wheelessonline.com/ortho/technique_of_syndesmotic_fixation). Published December 11, 2014.
4. Wheeler DL, McLoughlin SW. Biomechanical assessment of compression screws. *Clin Orthop Relat Res.* 1998;350:237–245.
5. Urish K, Anderson P, Mihalko W and the AAOS Biomedical Engineering Committee. The challenge of corrosion in orthopaedic implants. *AAOS Now.* April 2013.
6. Kummer F, Rose R. Corrosion of titanium/cobalt-chromium alloy couples. *J Bone Joint Surg.* October 1983.
7. Court-Brown C, Caesar B. Epidemiology of adult fractures: a review. *Injury.* 2006;37:691–697.
8. Daly PJ, Fitzgerald RH Jr, Melton LJ, Ilstrup DM. Epidemiology of ankle fractures in Rochester, Minnesota. *Acta Ortho Scand.* 1987;58:539–544.
9. Switaj P, Weatherford B, Fuchs D, Rosenthal B, Pang E, Kadakia AR. Evaluation of posterior malleolar fractures and the posterior pilon variant in operatively treated ankle fractures. *Foot Ankle Int.* Published online June 18, 2014.
10. Van Staa T. Epidemiology of fractures in England and Wales. *Bone.* 2001;29:517–522.
11. Duan X, Kadakia AR. (2017). Operative treatment of posterior malleolar fractures. *Open Orthop J.* 2017;11:732 -742.
12. Klammer G, Kadakia AR, Joos DA, Seybold JD, Espinosa N. Posterior pilon fractures: a retrospective case series and proposed classification system. *Foot Ankle Int.* 2013;34:189–199.









Acumed Headquarters  
5885 NE Cornelius Pass Road  
Hillsboro, OR 97124  
Office: +1.888.627.9957  
Office: +1.503.627.9957  
Fax: +1.503.520.9618  
www.acumed.net

These materials contain information about products that may or may not be available in any particular country or may be available under different trademarks in different countries. The products may be approved or cleared by governmental regulatory organizations for sale or use with different indications or restrictions in different countries. Products may not be approved for use in all countries. Nothing contained on these materials should be construed as a promotion or solicitation for any product or for the use of any product in a particular way which is not authorized under the laws and regulations of the country where the reader is located. Specific questions physicians may have about the availability and use of the products described on these materials should be directed to their particular local sales representative. Specific questions patients may have about the use of the products described in these materials or the appropriateness for their own conditions should be directed to their own physician.

**GEN10-11-D** | Effective: 2018/06 | © 2018 Acumed® LLC