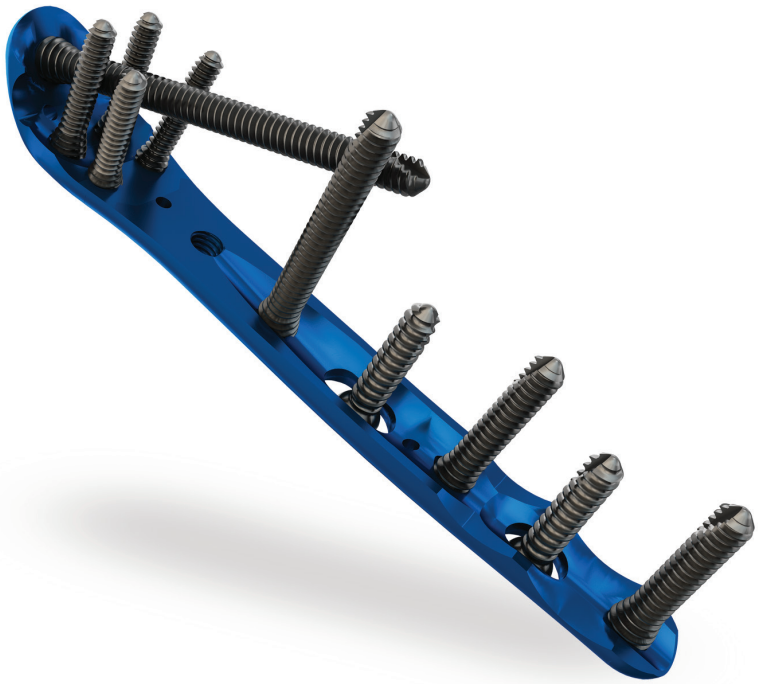
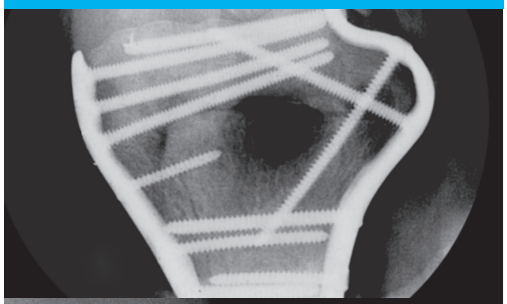
Value Analysis Committee Resource Guide

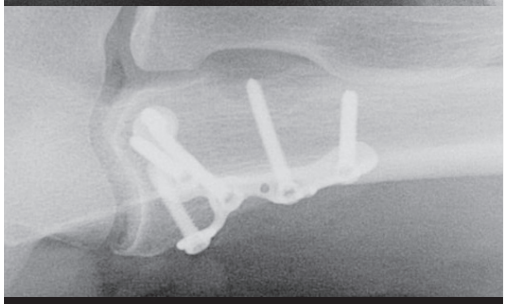
acumed® | Elbow Fracture Solutions

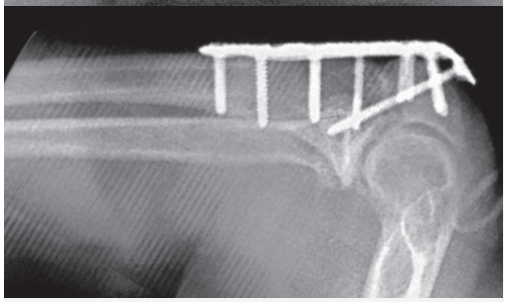
Acumed is a global leader of innovative orthopaedic and medical solutions.

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









Elbow Fracture Solutions

The Acumed Elbow Solutions feature innovative fracture fixation devices ranging from the midshaft forearm to the midshaft humerus. Our focus is to provide multiple fixation options, providing a comprehensive line of products for injuries in and around the elbow region.

The Acumed Elbow Plating System offers a comprehensive selection of precontoured plates for the distal humerus, olecranon and coronoid that utilizes a Hexalobe Screw System.

Designed in conjunction with Shawn W. O'Driscoll, Ph.D, M.D., the Anatomic Radial Head System provides anatomic implants to replace the patient's native radial head, while offering 250 head/stem combinations to accommodate different anatomies. The Locking Radial Head Plate System and the Acutrak 2® Mini and Micro instruments are included in the base of the tray as well to present a solution for a wide variety of fractures.

In addition to a wide breadth of solutions for the elbow, Acumed offers innovative solutions for diaphyseal forearm fractures: the Anatomic Midshaft Forearm Plate System and the Forearm Rod System.

Contents

Our mission is to aid the afflicted through the ingenuity of our minds, the labor of our hands, and the compassion of our hearts.

About Acumed®

Acumed began as a family business in 1988 and evolved to become a market leader in developing innovative orthopaedic and medical solutions to improve patient care around the world. Acumed strives to advance the art and science of orthopaedics for the collective good and understands that innovation cannot come at the expense of value. Acumed blends knowledge, ingenuity and skill to develop devices that solve real orthopaedic challenges to benefit the patient, surgeon and hospital.

The company was founded as Accurate Machine and Design (Acumed) in an 1100-square-foot space in Butler, New Jersey, with a single machinist as the first employee. Accurate Machine and Design started out engineering prototypes for companies like Howmedica, Kirschner and Exactech®, in addition to designing test machines and creating prototypes of hip stems, acetabular cups, and knee implants.

In 1991 the company relocated to Oregon as Acumed and launched the Oregon Fixation Screw. Intended for repair of ACL ligaments in the knee, the Oregon Fixation Screw was the first line of arthroscopy screws created by Acumed. The success of the product allowed Acumed to expand from the arthroscopy market into trauma. Acumed has continued to research, design, and manufacture products to improve patient care while adding new product lines each year, including Acutrak 2® Screws, Acu-Loc® 2, Clavicle Plating System, Elbow Plating System, and the Fibula Rod System.

In 1999, The Marmon Group purchased Acumed. This allowed for investments in equipment and the purchase of a new building for additional onsite design and manufacturing. In 2002, after five decades of leading The Marmon Group as CEO, Robert Pritzker stepped down and created Colson Associates. This move allowed more time and attention to be focused on Colson businesses, including Acumed.

Today, Acumed is a multi-award-winning company dedicated to delivering innovative and quality medical device solutions. Committed to the highest standards of manufacturing, Acumed is proud to produce over 90% of our implants in the U.S.A.

Throughout our history, Acumed has stayed true to our founders' vision of addressing the challenges facing orthopaedic surgeons and their patients. Acumed will continue to fulfill this vision by designing and developing innovative products and instruments to meet even the most complex indications and demanding procedural needs.

Acumed is headquartered in Hillsboro, Oregon, with a global distribution network and offices worldwide.

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 elbow fixation in 1999. Since then, Acumed has grown to become one of the technology leaders in options for operative treatment of displaced elbow 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.

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

In 2012, the company began preparing to track and report 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.

Green Initiatives

Acumed has formed a cross-functional group dedicated to preserving the environment and educating Acumed employees on the benefits of being "green". The Green Team's purpose statement is:

We empower Acumed and the global community through education, encouragement, and execution of sustainable business practices. By doing this, we engage our sphere of influence to deliver innovative products that respect the community's natural systems, support ethical equity, and drive customer loyalty.

The Acumed vision includes being respectful stewards of our local community and global environment, and a large part of this is our commitment to "green" initiatives.

No Bottled Water Pledge

In 2012, the Green Team sponsored a "no bottled water" pledge program to reduce the consumption of bottled water by Acumed. To date, over 200 employees have pledged to avoid drinking bottled water while on site or traveling domestically on behalf of Acumed. In addition, during on site sales rep trainings, attendees are provided with reusable water bottles.

Papercut

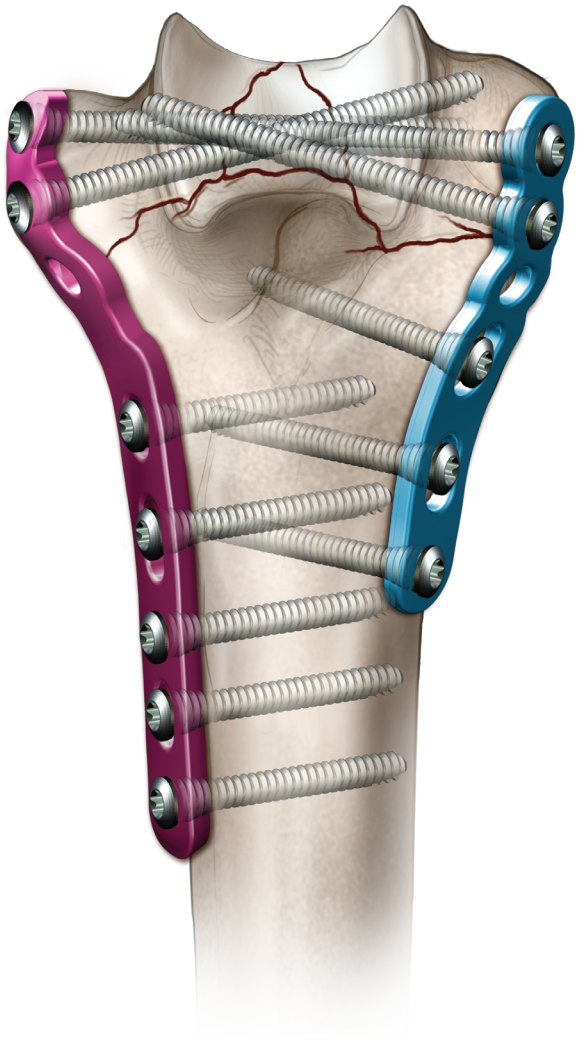
Acumed is committed to reducing paper consumption in our daily business operations. In 2012, the Green Team drove projects to reduce paper consumption and will expand this to reduce overall landfill waste by 10% in 2013. Activities include eliminating paper stubs, defaulting to double-sided printing, copying, and providing compostable lunchroom supplies.

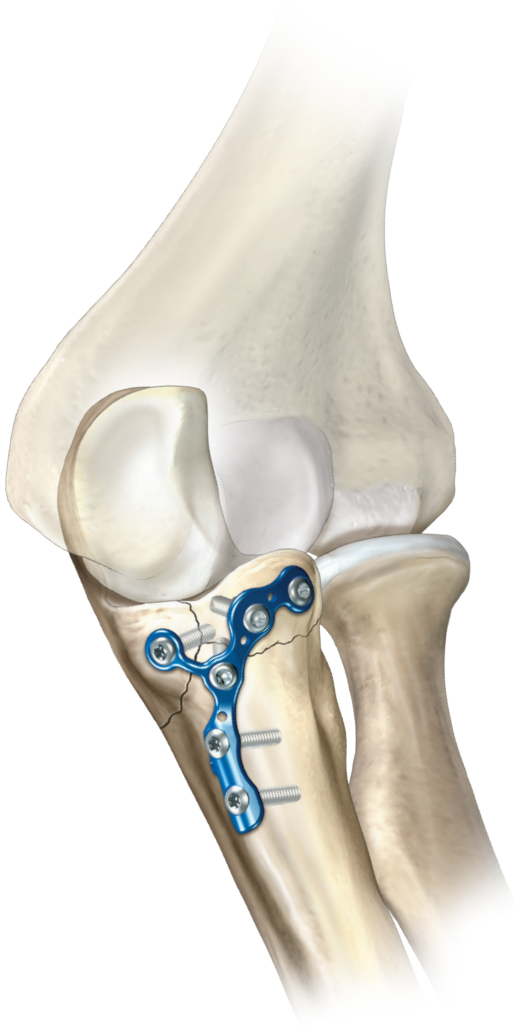
The Facts on Elbow Fractures

Incidence and Patient Demographics

According to recent clinical literature on the incidence of upper extremity fractures, up to 30% of all adult fractures involve the elbow.[2] Of these, approximately 0.5% to 7% involve the distal humerus and 10% involve the olecranon, the latter being among the most commonly seen orthopaedic procedures in the elbow.[3-5] Conversely, capitellum fractures were shown to be rare, accounting for only 1% of all elbow fractures and 6% of all distal humerus fractures.[6]

In addition, an analysis by Robinson et al. in the Journal of Orthopaedic Trauma details the projected incidence rate of elbow fracture as 5.7 cases per 100,000 in the population per year with an almost equal male to female ratio for distal humerus fractures.[7]





Classification of Elbow Fractures

There are several classification systems for fractures of the distal humerus, capitellum, trochlea, olecranon, and coronoid. Certain fracture patterns can be medically managed without surgical intervention while others require some type of fixation in order to heal properly.

Fracture Type	Classification System	Detail
Distal Humerus Fractures	AO/ASIF Muller's	The AO/ASIF Muller's classification system divides distal humerus fractures into three types: • Type A for extra-articular fractures; • Type B for fractures that extend into the articular surface; • Type C for fractures that cause a separation between the articular surface and shaft.[8]
Capitellum Fractures	Bryan & Morrey and McKee et. al.	The Bryan & Morrey and McKee et. al. classification systems divide capitellum fractures into four types: • Type I for the entire capitellum and lateral trochlear ridge; • Type II for the entire articular surface of capitellum; • Type III for comminuted fractures of the capitellum; • Type IV for coronal shear fracture that extends into the trochlea.[9,10]
Olecranon Fractures	AO	The AO classification system divides olecranon fractures into three types: • Type A for extra-articular of the radius or ulna; • Type B for intra-articular of the radius or ulna; • Type C for intra-articular of both the olecranon and radial head.[11]
	Mayo	The Mayo classification system divides the olecranon into six types: • Type 1A, undisplaced, noncomminuted; • Type 1B, undisplaced, comminuted; • Type 2A, displaced, stable, non-comminuted; • Type 2B, stable, displaced, comminuted; • Type 3A, displaced, unstable, non-comminuted; • Type 3B unstable, displaced, comminuted.[12]
	Schatzker-Schmeling	The Schatzker-Schmeling classification system divides olecranon fractures into six types: • Type A, transverse; • Type B, transverse-impacted; • Type C, oblique; • Type D, comminuted; • Type E oblique-distal; • Type F, fracture-dislocation.[13]
Coronoid Fractures	Regan & Morrey	The Regan & Morrey classification system divides these fractures into three types: • Type I for fractures involving the tip; • Type II for a single or comminuted fragment involving <50% of the coronoid process; • Type III for a single or comminuted fragment involving >50% of coronoid process.[14]

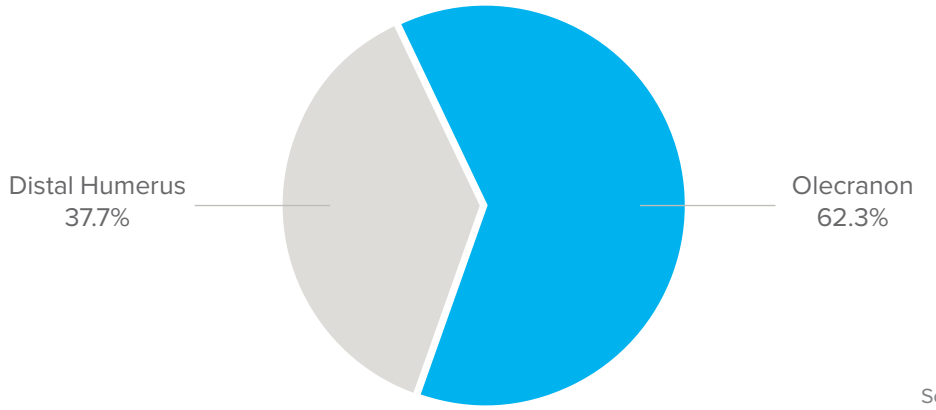
Elbow Fracture Treatment Options

Distal humerus and olecranon fractures have been treated with open reduction internal fixation (ORIF), external fixation, pins, as well as conservative treatment. Alternatively, the literature presents that capitellum fractures have only recently been treated with ORIF due to the complexity of these types of fractures.[15] Furthermore, coronoid fractures have generally been treated non-operatively because they have high rates of complications, are uncommon, and often occur with associated injuries resulting in complex elbow instability.[16,17]

Depending on the degree of displacement and the location of the fracture, surgeons may use plate fixation or other methods of fracture treatment. The Acumed Elbow Plating System is an option for fixation when ORIF is preferred and consists of medial, lateral, posterolateral, olecranon, and coronoid plates.

Surgical Versus Non-Surgical Intervention

According to the 2013 US Market for Small Bone & Joint iData report, distal humerus and olecranon cases with plates and screws account for 37.7% and 62.3% respectively.[18]



Source: iData Research Inc.

Distal Humerus

Recent studies have shown that surgical intervention is the preferred treatment option for most displaced distal humerus fractures.[19, 20] According to the literature, if a displaced elbow is treated non-surgically, there is a possibility that posttraumatic osteoarthritis can occur.[21] Surgical treatment varies depending on the fracture pattern but some options include plates or screws.

Capitellum

Over the last few decades, the literature has recognized the importance of surgical intervention for fractures of the capitellum despite these being rare fractures at 1% of all elbow fractures.[22] The complexity of the fractures has led to publication of new classification systems as fracture patterns are discovered.[23] The first capitellum fracture was described in 1853 by Hahn based on findings during an autopsy of a palpable prominence at the elbow and many methods of treatment have since been described.[24] Current literature supports ORIF treatment of the capitellum in order to restore the lateral buttress of the elbow.[25]

Olecranon

The olecranon is an important component of the elbow. As it is the second most common fracture of the elbow, surgical intervention has been explored in various literature.[26] Surgical treatment varies depending on the fracture pattern but some options are plates, nails/rods, tension band pins, and screws. The literature discusses that plate fixation has become an important method of treating displaced olecranon fractures including comminuted fractures, Monteggia fracture dislocations, oblique fractures distal to the midpoint of the trochlear notch, and fractures that involve the coronoid process.[27,28]

Coronoid

Traditionally, non-surgical intervention has been a preferred treatment option for coronoid fractures. As more literature is being published, there is a shift to surgical intervention for coronoid repair. The literature shows the importance of ORIF treatment of the coronoid process and how improved management of coronoid fractures is leading to better recovery from elbow injury.[29] Today the choice for surgical fixation includes lag screws, sutures, suture anchors, threaded pins, and plates.[30]

Surgical Intervention with Plate Fixation

Dynamic Compression/Reconstruction Plates

A variety of straight or uniformly curved plating systems have been used to repair elbow fractures. Among the earliest utilized, dynamic compression and reconstruction plates are straight and generally require bending prior to use in order to accommodate a patient's elbow anatomy. In addition to being a time-consuming activity, bending a compression plate can cause it to weaken and it still may not fit the patient properly, as the plates are non-elbow specific. A poorly fitting plate can cause soft tissue irritation and possibly skin erosion at the site of implant.[31]

Precontoured Elbow Plates

A precontoured plating system is designed to assist in restoring the original structure of the patient's anatomy with little or no intraoperative bending by the surgeon. This can save valuable time during the procedure.

"The plates are precontoured to fit the natural anatomy of the elbow and in the case of complex fractures they provide a guide for the anatomic restoration of the distal humerus." [32]

The Acumed Elbow Plating is a comprehensive system of plates that match the anatomical contours of the elbow including the medial and lateral epicondyles, posterolateral column, coronoid, and olecranon. The plates act as a template for support and reduction of the fracture.

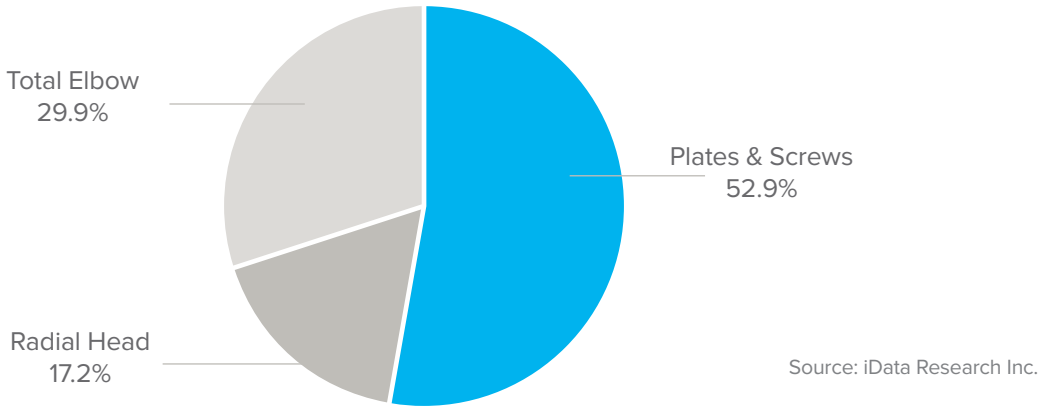
Plate Construction

Another important consideration when choosing a plating system is its construction material. The elasticity of the plate material can impact the strength of the healing fracture. In order for the elbow to heal properly the bone must be under constant load, thereby strengthening the newly formed bone during the healing process. Therefore, the plate material must have enough elasticity to create stress on the healing elbow while maintaining enough support and stabilization during the healing process.[33]

Each unique plate material has a distinct measure of elasticity. While surgical steel has traditionally been used due to its high strength, titanium is an alternative option. Titanium offers strength characteristics and elasticity closer to that of natural bone, and it is more often used for elbow plates for this reason as well as its biocompatibility.[34] Soft tissue has tolerance to titanium implants 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.[35] The Acumed Elbow Plating System is comprised of commercially pure titanium plates. Coupled with its low-profile design, the plates are designed to minimize the possibility of soft-tissue disruption and provide a plate contoured to match patient anatomy.

Perpendicular versus Parallel Plating of the Distal Humerus

According to the 2012 US Market for Small Bone & Joint iData report, cases with plates and screws account for 52.9% of the surgical elbow repair market while prostheses account for the remaining 47.1% of the treatment market.[36]



Source: iData Research Inc.

Within the plate and screw market, studies have shown that there are two common plating practices for treating distal humerus fractures: parallel and perpendicular (90/90) plating techniques. Parallel plating is a combination of two plates that support the medial and lateral epicondyles. 90/90 plating is a combination of two plates that support the posterolateral column and the medial epicondyle.

Research demonstrates that both fixation methods provide support due to the two plates creating compression across a fracture site. 90/90 plating is considered an acceptable standard of treatment for distal humerus fractures and has been advocated for several years.[37-53] Parallel plating is a newer plating method that satisfies a number of technical objectives to help create a stable construct to promote healing and full rehabilitation. There have been a number of biomechanical studies comparing parallel to 90/90 plating.[54-56] Some claim parallel plating is biomechanically superior to 90/90 plating. Other studies have shown there is no biomechanical advantage to one plating method over another.[57-73]

The Acumed Elbow Plating System includes both lateral and medial epicondyle plates as well as posterolateral plates that can be used based on the operating surgeon's preference for parallel or 90/90 plate fixation methods.

Several Key Features of the Acumed Elbow Plates:

- Machined from commercially pure titanium, the elbow plates offer elasticity closer to that of bone and reduces the propensity for stress shielding.[74] 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.[75]
- Prongs on the distal end of the standard olecranon plates are designed to preserve the triceps tendon by allowing the plate to sit on the top of the tendon rather than requiring the tendon to be split.
- Tapered plate ends of the posterolateral and olecranon plates are designed to minimize the possibility of bone re-fracture above or below the plate due to excess stress concentration.

Surgical Intervention with Screw Fixation

Partially Threaded versus Fully Threaded Compression Screws

Historically, studies supported the belief that screw threads across the fracture site would prevent compression across the fracture. Therefore, the industry standard was to use a screw with partial threading for proper surgical intervention.[76] Later studies presented evidence that fully threaded, headed screws were able to maintain more interfragmentary compression than a partially threaded, headless screws but the interest remained towards using a partially threaded, headless screw due to the elimination of exposed hardware.[77, 78] Acumed recognized the market need and designed a unique, fully threaded, headless compression screw.

The Acumed Acutrak® Headless Compression Screw was the first fully threaded headless compression screw with continuously varying thread to enter the market. It was determined that in order for a fracture to heal, there needed to be adequate compression holding two fragments together. One way this was achieved was with continuous variable threads designed to create compression forces across the fracture site. As this fully threaded, headless screw was introduced to the market, several studies were conducted to determine the importance of the continuous variable threads and compression, as well as to compare headless versus headed screws.

"In foam, the Acutrak screw showed significantly greater pushout force than did the AO or Herbert screw. The Acutrak and AO screws had significantly greater pushout force than did the Herbert screw in cancellous bone. The Acutrak screw maintained an average of 91.3% of its pretest compression in fresh scaphoid bone, whereas the AO and Herbert screw maintained averages of 65.4% and 72.2% of initial compression, respectively. The torque required to break fragment contact was significantly greater for the Acutrak screw than the torques required for the AO or Herbert screws." [79]

As fully threaded, headless screws achieve greater compression, pushout force, and torque strength, the Acumed Acutrak Headless Compression Screw provides additional support in areas of external loading compared to partially threaded or headed screws.[80]

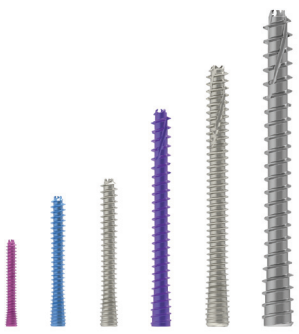
Acutrak® Headless Compression Screws in the Elbow

It is generally accepted that surgical intervention for displaced elbow fractures may result in better patient outcomes for a variety of fracture patterns. Headless screws are an alternative option to plate fixation, external fixation, tension band pins, nails/rods, or lag screws if surgical intervention is preferred.

The literature discusses how, depending upon fracture patterns, anatomic complexity, and patient health, a screw may be an alternative method to other surgical intervention as it is a recognized method of treatment.

"Open reduction and internal fixation using headless screw compression via a lateral approach is a reliable treatment for large coronal shear fractures of capitellum and lateral trochlea, and results in stable fixation and restoration of a functional arc of motion." [81]

The Acumed Acutrak Headless Compression Screws can be used in the elbow based on surgeon preference for surgical intervention.



Several Key Features of the Acumed® Acutrak® Headless Compression Screws:

- Biomechanical studies have shown that fully-threaded, headless screws maintain compression for a greater number of cycles in comparison to a partially threaded screw that may occur during healing as well as allow a fracture or osteotomy site to lie almost anywhere along the length of the screw.[82]
- Headless feature allows the titanium screws to be implanted in and around articular regions with lessened risk of impingement or soft tissue irritation as compared to headed screws.
- Variable pitch is created by having a wider thread pitch at the tip of the screw followed by finer trailing threads. This allows the screw to penetrate the bone faster at the tip as compared to the tail which compresses the two fragments as the screw is advanced.
- Percutaneous insertion is facilitated with cannulation of the screw to minimize the soft tissue dissection.
- Helical Relief Flutes on the tip of the screw aid in bone removal for screw insertion.
- Self-tapping design on the tip of the Acutrak® Mini and Standard screws aids in screw insertion.
- Cutting flutes on the tip of the Acutrak 2® Micro, Mini, and Standard screws, when used with the long drill, provide self-cutting capabilities to aid in screw insertion.

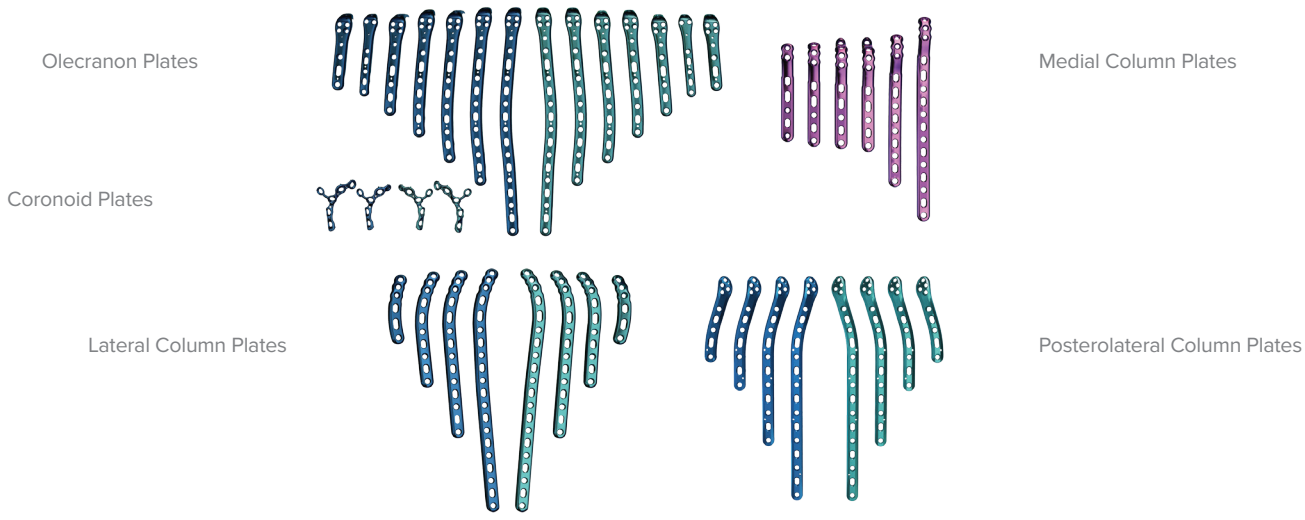
Anatomic Complexity

Several studies have shown the variety and complexity of fracture patterns in the distal humerus, capitellum, olecranon, and coronoid. These differences and difficulties make it advantageous to have a variety of plate options available to the surgeon, allowing for a better fit for the particular patient as well as the ability to treat a greater variety of fracture patterns.

"A review of the surgical time required to repair these complex fractures indicates that these are relatively lengthy procedures that use significant operating room resources. Further these open injures may also have sustained bone loss, adding to the difficulty and time required for ORIF." [83]

The Acumed® Advantage

Precontoured anatomic plate designs assist in restoring the original structure of the patient's anatomy with little to no bending of the plate. The Acumed Elbow Plating System is a comprehensive system of plates that match the anatomic contours of the elbow and can act as a template when reconstructing a malunion, nonunion or a highly comminuted fracture to provide support and reduce the fracture. The precontoured, approach-specific plates may aid in reduced surgery time.

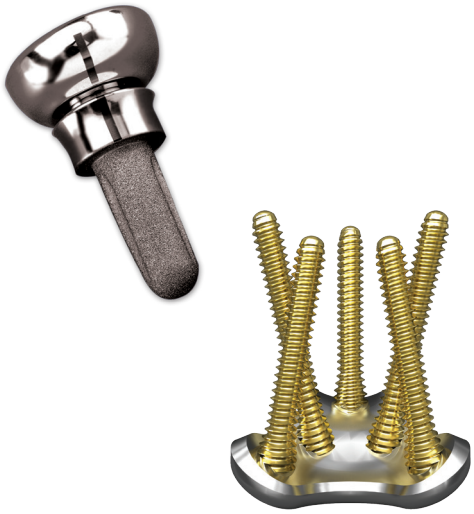


The Acumed Elbow Plating System in relation to Patient Outcomes:

- The Acumed Elbow Plating System contains anatomically precontoured plates including fourteen distal humerus plates (six medial and eight lateral), eight posterolateral plates, four coronoid plates, and fourteen olecranon plates. When the medial and lateral plates are used together, a parallel plating construct is created for additional fixation across the fracture site.
- Compression slots, reduction slots, and locking holes provide for screw fixation.
- Tubulerized undersurface may support healing of the periosteum and enables a better fit to the bone.
- The Acumed Distal Humerus plates provide structural support for both medial and lateral epicondyle fragments through the interdigitation of longer screws.
- The Acumed Distal Humerus plates are designed to utilize the hexalobe screw technology.
- The Acumed Tap-Loc® technology is designed to be used with the Distal Humeral Medial or Lateral plates to capture additional fragments with up to twenty degrees of angulation.
- The Acumed Posterolateral plates provide fixation of isolated capitellar fragments and have a precontoured bend in both the diaphyseal region of the plate and the lateral tip to support the anatomy. When used with a medial distal humerus plate, a 90/90 plating construct is created for additional fixation of distal humerus fractures.
- The Acumed Olecranon plates feature prongs on the proximal end designed to avoid splitting the triceps tendon by penetrating the tendon without creating compression of the tendon. The only exception is the extended plate, which provides more proximal fixation but requires splitting of the triceps tendon. The most proximal “homerun” screw provides additional compression across the fracture site.
- The Acumed Olecranon plates include a medial/lateral tilt in the proximal tip, a distal bow, and 6° proximal dorsal angulation in order to fit patient anatomy.
- The Acumed Olecranon Osteotomy Cutting Jig sits directly on the bone, provides four different cutting slots for chevron osteotomy location, and allows for pre-drilling of the screw holes for plate placement after the osteotomy has been performed.
- Tension Band Pins are an additional treatment option for transverse olecranon fractures or osteotomies. The gauge wire is inserted through the eyelet feature of the Tension Band Pin to create compression and fixation of the fracture or osteotomy.
- The Acumed Coronoid plates are designed with prongs intended to grasp and buttress the anteromedial facet of the coronoid as well as an offset screw hole to target fractures of the sublime tubercle.

Associated Products

- Anatomic Radial Head Prosthesis
- Locking Radial Head Plate
- Acutrak® Headless Compression Screw—Mini and Standard
- Acutrak 2® Headless Compression Screw—Micro, Mini, and Standard
- Acutrak® AcuTwist®
- Tension Band Pins



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Additional Published Literature Supporting Acumed® Treatment Principles

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OCT 5 - 2004

K 041858

ACUMED®,LLC

5885 N.W. Cornelius Pass Road, Hillsboro, Oregon 97124-9432 Tel (503) 627-9957

510(k) Summary

This summary regarding 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR 807.92.

Submitter Information: Acumed LLC
5885 N.W. Cornelius Pass Road
Hillsboro, OR 97124-9432
USA
Phone: (503) 627-9957
FAX: (503) 716-1001
Contact: Ed Boehmer, Regulatory & Documentation Supervisor

Classification Name:	Prosthesis, Elbow, Hemi-, Radial, Polymer
Common Name:	Elbow Hemi-, Prosthesis
Proprietary Name:	Acumed Anatomic Radial Head System
Proposed Regulatory Class:	Class II, 21 CFR 888.3170
Device Product Code:	KWI
Legally Marketed Equivalent Device(s):	Avanta Radial Head Implant K002644 Wright Medical Inc. Modular Radial Head K991915

Device Description: The Acumed Anatomic Radial Head System includes modular heads and stems with accessories to anatomically replace the proximal potion of the radius and restore the natural articulation of the radial head with the radial notch of the ulna and capitulum of the distal humerus.

Intended Use: The Acumed Anatomic Radial Head System is indicated for use in:

1. Replacement of the radial head for degenerative or post-traumatic disabilities presenting pain, crepitation, and decreased motion at the radio-humeral and/or proximal radio-ulnar joint with: joint destruction and/or subluxation, resistance to conservative treatment.
2. Primary replacement after fracture of the radial head.
3. Symptomatic sequelae after radial head resection.
4. Revision following failed radial head arthroplasty

These are similar to intended use of predicate devices and do not raise new issues of safety and effectiveness.

Technological Characteristics: The Acumed Anatomic Radial Head System uses an elliptically shaped, highly polished cobalt alloy head (ASTM F1537) with a titanium alloy stem (ASTM F136). Both cobalt alloy and titanium alloy have been successfully used in numerous implant prostheses. There are no technological characteristics that raise new issues of safety or effectiveness.

An assessment of performance data is not applicable.
A discussion of clinical and non-clinical tests is not applicable.

Based upon the similarities of the Acumed Anatomic Radial Head System and the predicate devices studied, the safety and effectiveness of the Acumed Anatomic Radial Head System is substantially equivalent to the predicate devices referenced.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 5 - 2004

Mr. Ed Boehmer
Regulatory and Documentation Supervisor
Acumed, LLC
5885 N.W. Cornelius Pass Road
Hillsboro, Oregon 97124-9432

Re: K041858
Trade/Device Name: Acumed Anatomic Radial Head System
Regulation Number: 21 CFR 888.3170
Regulation Name: Elbow joint radial (hemi-elbow) polymer prosthesis
Regulatory Class: II
Product Code: KWI
Dated: July 8, 2004
Received: July 9, 2004

Dear Mr. Boehmer:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

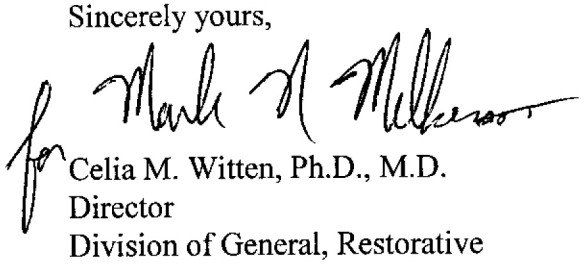
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish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

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



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

Enclosure

510(k) Number (if known): K041858

Device Name: Acumed Anatomic Radial Head System

Indications For Use:

The Acumed Anatomic Radial Head System and accessories are designed specifically for:

1. Replacement of the radial head for degenerative or post-traumatic disabilities presenting pain, crepitation, and decreased motion at the radio-humeral and/or proximal radio-ulnar joint with: joint destruction and/or subluxation, resistance to conservative treatment.
2. Primary replacement after fracture of the radial head.
3. Symptomatic sequelae after radial head resection.
4. Revision following failed radial head arthroplasty

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

for Mark N Millner

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

510(k) Number K041858

K012655

NOV 0 7 2001

Appendix V - 510(k) Summary

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

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

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

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

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

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 0 7 2001

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

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

Dear Ms. Jeffers:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

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

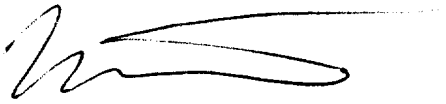
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing

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

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

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

Sincerely yours,



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

Enclosure

NOV 0 7 2001

510(k) Number (if known): K012655

Device Name: Congruent Bone Plate System

Indications For Use:

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

510(k) Number K012655

Prescription Use X OR Over-The-Counter Use
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
1390 Piccard Drive
Rockville, MD 20850

JUL 26 1993

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.

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 oleacranon 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.

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,

for 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)

GEN10-02-A
Effective: **10/2013**

Acumed®
5885 NW Cornelius Pass Road
Hillsboro, OR 97124

Office: 888.627.9957
Fax: 503.520.9618
acumed.net