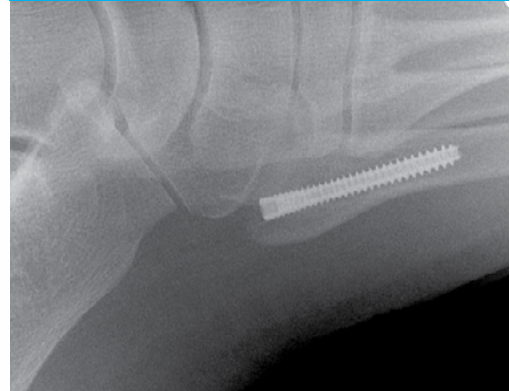


Value Analysis Committee Resource Guide



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.



About Acumed

At Acumed, we're constantly seeking to advance the field of orthopaedics. We design every product to best serve the patient, surgeon, hospital, and the collective outcome. And with everyone working together, these solutions have the power to support more than just the individual. They can transform the whole healthcare community.

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

The Acumed Advantage

ACUTRAK 2 HEADLESS SCREW SYSTEM OVERVIEW

Acumed developed Acutrak® screw technology to provide a headless compression-holding solution to fix fractures. It features the first fully threaded bone screw with a continuously variable thread pitch along the entire length of the screw.

The Acutrak 2 Headless Compression Screw System is composed of 65 unique screw size options to fit a wide variety of applications throughout the body. Backed by more than 25 years of clinical data and referenced in more than 100 studies in peer-reviewed journals, the Acutrak family of screws has demonstrated efficacy in hand, wrist, foot, and ankle applications.

THE DESIGN OF THE ACUMED ACUTRAK HEADLESS COMPRESSION SCREWS

Primary Design Objectives

1. Designed to minimize likelihood of soft tissue irritation through headless fixation
2. Achieve compression in fracture fixation with a fully threaded construct
3. Achieve compression over a wider range of insertion depths than standard AO cannulated screws and Herbert/Whipple HCS screws
4. Enable fixation in bone with cancellous-based thread design

Fully Threaded Continuously Variable Pitch

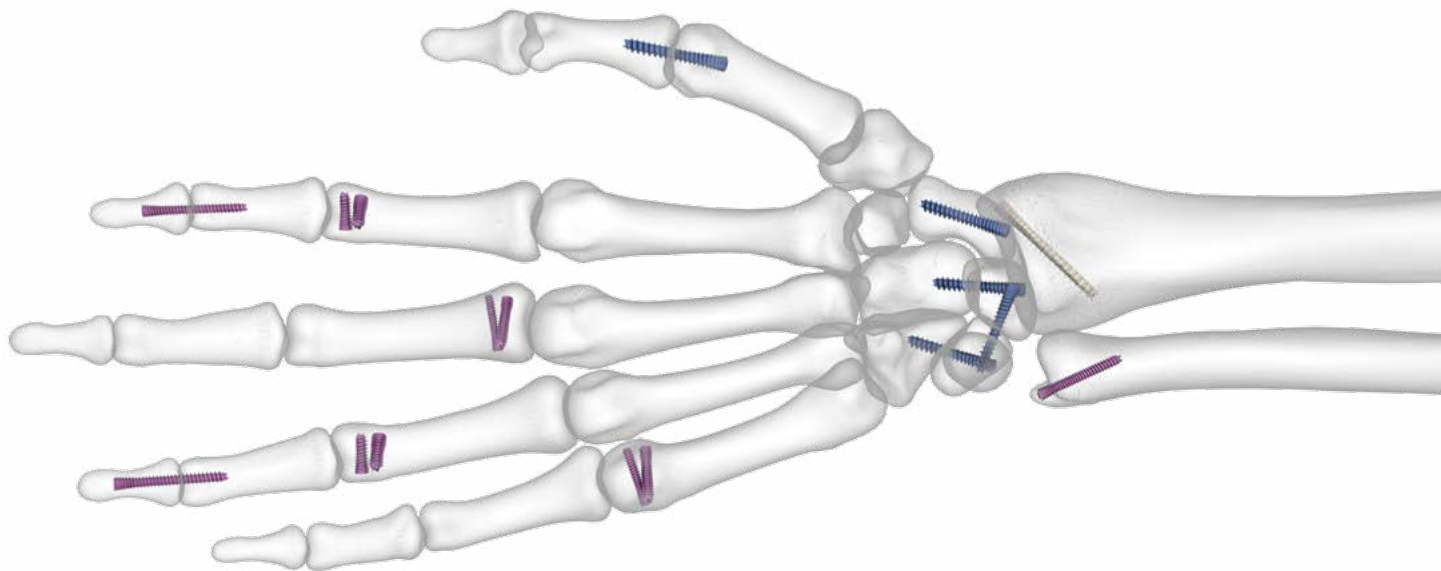
Designed to meet the above objectives, Acutrak screws deliver a new category of bone screw fixation that goes beyond headed and differential pitch screw options. It features a unique, patented thread pitch that varies continuously from tip to tail. This enables each screw rotation to engage threads into new bone along the screw's entire length. As each successive individual thread advances faster than the trailing thread counterpart, the conical shape becomes seated into bone.



Key Features of the Acumed Acutrak 2 Screw System

- Sterile and non-sterile implants
- Compression
 - Continuously 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 than at the tail, which generates compression across the fracture site.
- Headless feature
 - Intended to reduce risk of impingement or soft tissue irritation compared to that of headed screws when implanted in or around articular regions.
- Soft tissue dissection may be minimized through percutaneous insertion, which is facilitated by cannulation of the screw.

- Refinements when compared to the original Acutrak® screw
 - Helical relief flutes at the tip of the screw are designed to aid in the removal of bone during screw insertion.
 - Available in Acutrak 2: 4.7, 5.5, and 7.5 screws only.
 - When used with the long drill, the cutting flutes at the tip of the Acutrak 2 screws feature self-cutting capabilities to aid during screw insertion.
 - The large diameter guide wires are designed to allow for provisional stabilization of the fixation site and accurate screw placement while reducing the risk of bending the wire.
 - Decreased screw depth sensitivity is achieved through pairing a cylindrical drill with a tapered profile drill. This eliminates the requirement of “downsizing” as described for the original Acutrak screw and other headless compression screws.
 - Surgical technique is consistent between screw families.
- Biomechanical performance
 - When compared to traditional (AO) and differential (Herbert) screws in cadaveric and synthetic bone material, Acutrak 2 screws were shown to have:
 - Greater push-out force¹
 - Highest amount of retained compression after cyclic loading¹
 - Highest resistance to torsional loading¹
- Broad base of patient indications addressed
 - The Acutrak 2 families of product address nearly twenty of the most common indications in the hand, wrist, foot, and ankle.
- Clinical and biomechanical data breadth
 - More than 100 published studies offer biomechanical and clinical usage analysis.



Indications for Use

The Acumed Acutrak 2 Screw System is intended as a fixation device for small bones, bone fragments, and osteotomies. It is not intended for interference or soft tissue fixation.

ACUTRAK 2 USAGE ACROSS THE ANATOMY

ACUTRAK 2: MICRO, MINI, AND STANDARD

ACUTRAK 2: 4.7, 5.5, AND 7.5



SHOULDER

- Greater Tuberoisty Fractures
- Proximal Humerus Fractures
- Shoulder Instability

ELBOW

- Radial Head
- Capitellum
- Distal Humeral Fixation
- Medial and Lateral Condyle

HAND/WRIST

- Scaphoid
- Radial Styloid
- Ulnar Styloid
- 4-corner Fusion
- DIP/PIP Fusion
- MCP Fusion
- Capitate Hamate Fusion
- Bennet's Fracture
- Radiolunate Fusion
- Phalangeal Fracture
- Metacarpal Head Fracture

KNEE

- Patellar
- OCD Lesion
- Lateral Femoral Condyle Fracture
- Medial Femoral Condyle Fracture

HINDFOOT/ANKLE

- Ankle Fusion
- Subtalar Fusion
- Triple Arthrodesis
- Calcaneal Osteotomy
- Calcaneal Fracture
- Malleolar Fracture
- Talar Navicular Fusion
- Calcaneal Cuboid Fusion

FOREFOOT/MIDFOOT

- Austin Bunionectomy
- Jones Fracture
- DIP/PIP Fusion
- Lapidus Bunionectomy
- MTP Fusion
- TMT Fusion
- Chevron Osteotomy
- SCARF Osteotomy
- Weil Osteotomy
- Hammertoe Fusion
- Akin Osteotomy

Competitive Matrix

Where used to treat the indications described Indications for Use section, it may be possible to use an Acutrak 2 screw of similar size instead of the competitors' screws listed below:

VENDOR	PRODUCT	AVAILABLE LENGTHS	MATERIAL
Acumed	Acutrak 2: Micro Acutrak 2: Mini Acutrak 2: Standard Acutrak 2: 4.7 Acutrak 2: 5.5 Acutrak 2: 7.5	8–30 mm 16–30 mm 16–34 mm 20–50 mm 25–60 mm 40–120 mm	Titanium
Arthrex	2.5 Micro 3.5 Mini 4.0 Standard Compression FT	8–30 mm 12–34 mm 16–50 mm	Titanium
Biomet	BioDrive Micro Screw	10–28 mm 10–32 mm	Titanium
DePuy Synthes	2.5 FRS Screw 3.0 FRS Screw	10–22 mm 24–34 mm	Titanium
Integra	2.8 Mini KMI Kompressor 4.0 Standard KMI Kompressor	10–26 mm 14–34 mm	Titanium
Integra	3.0 mm QWIX Screw 4.3 mm QWIX Screw 5.5 mm QWIX Screw 7.5 mm QWIX Screw	12–24 mm 24–60 mm 30–80 mm 40–120 mm	Titanium
Medartis	2.2 Speed Tip CCS 3.0 Speed Tip CCS	10–40 mm 10–40 mm	Titanium
Orthomedical	HBS, Cannulated Headless Bone Screw	12–30 mm	Titanium
Small Bone Innovations (SBI)	2.0 AutoFIX 2.5 AutoFIX 3.0 AutoFIX 4.0 AutoFIX	10–30 mm 10–30 mm 12–40 mm 20–50 mm	Stainless Steel
Smith and Nephew	3.0 Headless Compression Screw	8–40 mm	Stainless Steel
Strkyer	2.5 mm Fixos Compression Screw 3.5 mm Fixos Compression Screw	10–30 mm 14–24 mm	Titanium
Strkyer	4.1 mm Twinfix	14–34 mm	Titanium
Synthes	2.4 Headless Compression Screw 3.0 Headless Compression Screw 4.5 Headless Compression Screw 6.5 Headless Compression Screw	10–40 mm 16–40 mm 30–80 mm 30–120 mm	Stainless Steel and Titanium
Trimed	2.3 Small Headless Screw 3.0 Small Headless Screw 3.5 Small Headless Screw	10–28 mm 10–36 mm 20–45 mm	Titanium
Wright Medical	3.0 Charolette MUC Screw 4.3 Charolette MUC Screw 7.0 Charolette MUC Screw	10–34 mm 14–60 mm 40–110 mm	Stainless Steel
Zimmer	Herbert/Whipple Screw Herbert Mini Screw	12–30 mm 10–24 mm	Titanium

The Facts on 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.¹ Later studies presented evidence that fully threaded, headed screws were able to maintain more interfragmentary compression than partially threaded, headless screws. However, interest remained in partially threaded, headless screws due to the elimination of exposed hardware.^{1,2}

Acumed recognized the market need and designed the Acumed Acutrak Headless Compression Screw, the first fully threaded headless compression screw with continuously varying thread. It was generally accepted that in order for a fracture to heal, there needed to be adequate compression between the two fractured fragments. Designers hypothesized that enhanced compression could be achieved with continuous variable threads that would create compression forces across the fracture site. When this fully threaded, headless screw was introduced to the market, several biomechanical studies were conducted to assess the impact of the continuous variable thread feature on push-out and compression.

“In foam, the Acutrak screw showed significantly greater push-out force than did the AO or Herbert screw. The Acutrak and AO screws had significantly greater push-out 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.”¹

INTERFRAGMENTARY COMPRESSION AND DURABILITY OF INTERFRAGMENTARY COMPRESSION

At least one animal study suggests that fractures may fail to heal because of micro-motion at the fracture site causing shearing and subsequent fibrous tissue formation.⁷ Cadaveric studies have demonstrated that carpal and metacarpal fractures may also fail to heal due to bending, rotational, and translational forces that strain the fracture site and cause shearing.⁹⁻¹² These studies indicate that internal fixation should be as rigid as possible. A previous study by Wheeler et al. demonstrated that the Acutrak screw enabled fracture fragment stability in terms of compression achieved, pullout, and resistance to torque.¹ In comparison to Herbert screws, the Acutrak screws achieved greater compression, maintained compression over a greater depth, and had a greater push-out force.¹ The Acutrak screw also required greater torque to break fragment contact and maintained compression after cyclic loading better than either AO or Herbert screws.¹

IMPROVED COMPRESSION IN SECOND GENERATION HEADLESS SCREWS

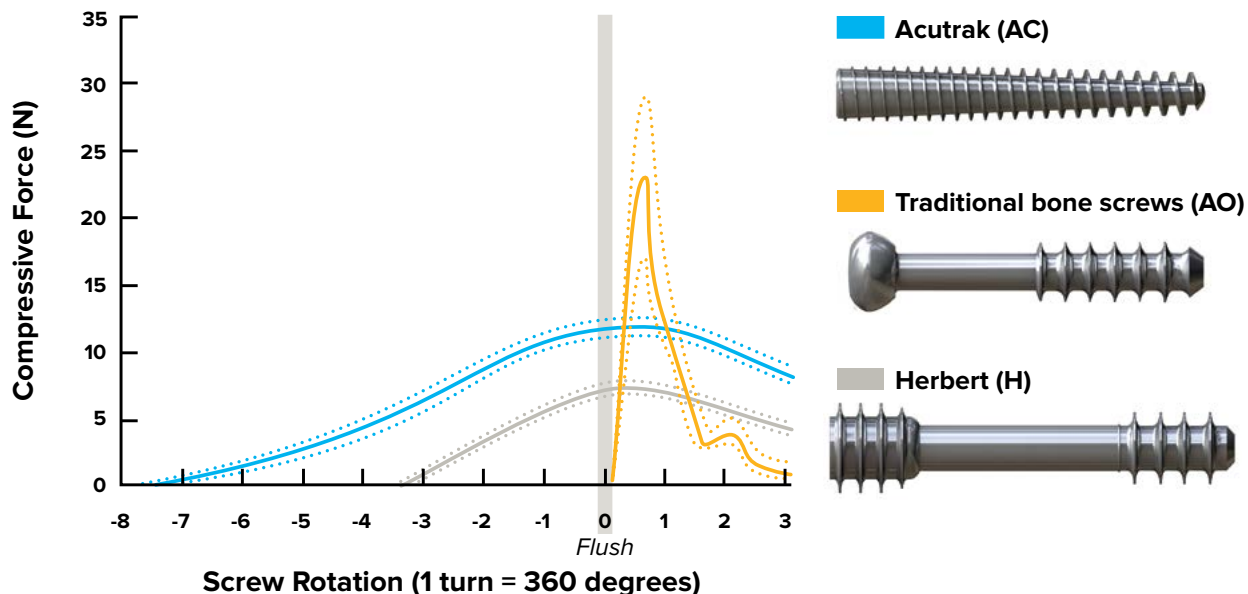
Prior to the headless compression screw, internal fixation options included open or percutaneous guide wire fixation or open reduction with headed lag screws. Guide wire fixation had a propensity for fracture distraction, fracture instability, and secondary loss of reduction.¹³ Open lag screw fixation could result in either poor compression or joint arthrosis, as the head of the screw could reside on the articular surface and therefore cause secondary joint injury.¹³ During the 1990s, cannulated headless compression screws were popular, when used with an open or percutaneously placed guide wire, from the volar and dorsal approach. Soroush et al. assessed the biomechanical characteristics of the first generation Herbert/Whipple screw versus various next generation headless compression technologies.¹³ The Acutrak 2 Mini was cited as generating the maximum compressive force when compared with these other second generation technologies.¹³ In the same study, the Acutrak 2 Mini was shown to have no reduction in compression due to over-fastening, unlike some of the other screws studied.¹³

ACUTRAK TECHNOLOGY’S LARGER “WINDOW OF COMPRESSION”

All bone screw technologies have a “window of compression” that determines the number of screw rotations needed to reach a maximum compressive force (beyond which further rotations decrease this value). Traditional bone screws have a narrow window of compression as compared to differential pitched screws. This narrow window results in a

fixation construct that is more sensitive to loss of compression due to over rotation and the stripping of thread purchase. Conversely, Acutrak technology has a wide window of compression, which is less sensitive to stripping the bone and is more flexible in its placement depth enabling a maximum amount of compression.¹

The diagram below illustrates the window of compression for Acutrak technology, traditional bone screws (AO) and differential pitch screws (Herbert).¹

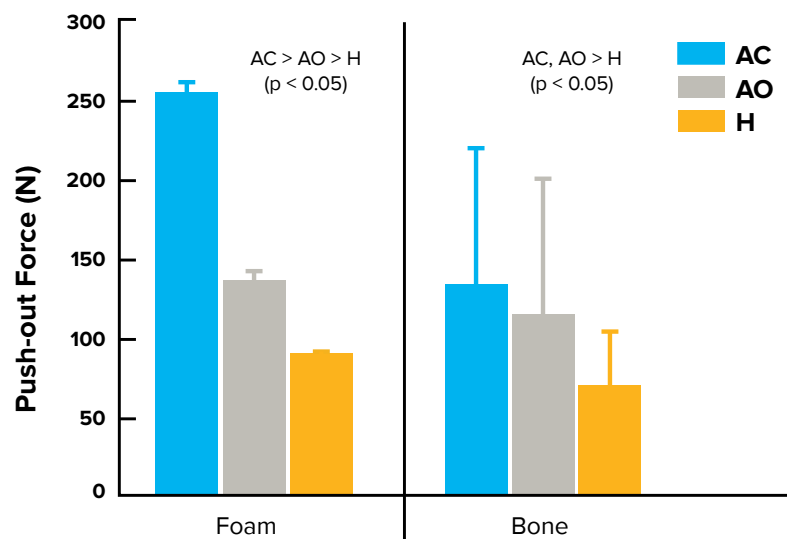


The above graph illustrates the window of screw rotations during which each screw delivers maximum compressive force. The Acutrak screw has the largest window of compression, which is attributed to the additive property of each variable thread pitch providing compression on the fully threaded screw.

ENHANCED FRACTURE FIXATION BIOMECHANICS

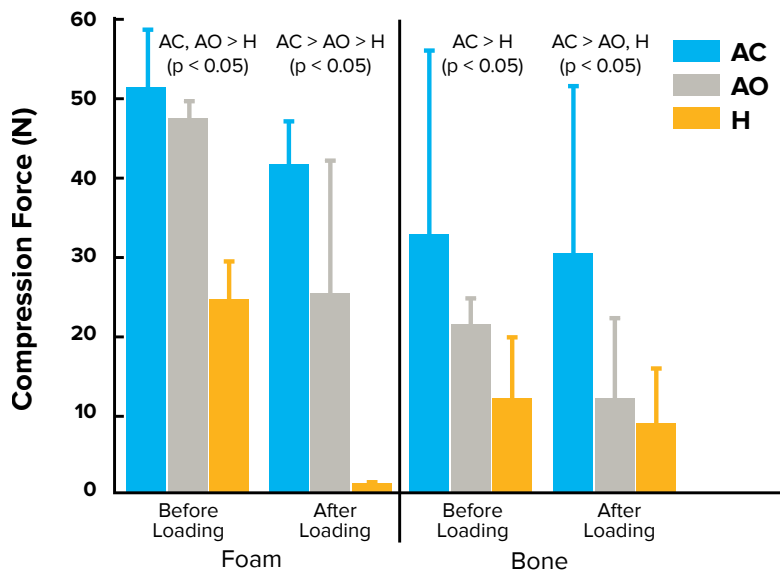
Pullout strength and resistance to cyclic and torsional loading are key measurable elements of bone screw fixation performance. The performance of Acutrak (AC) in each of these elements was compared to traditional (AO) and differential (Herbert/H) bone screws. A summary of the results is shown in the figures below:

1. Greater Push-out Strength



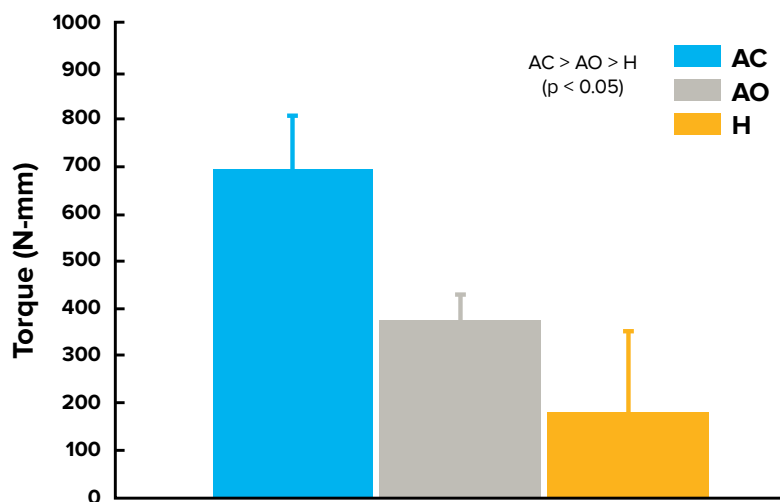
Acutrak® screws have the highest push-out force when compared to AO & Herbert bone screws (AC).¹

2. Greater Resistance to Cyclic Loading



Acutrak® screws have the highest amount of retained compression after cyclic loading when compared to AO & Herbert bone screws (AC).¹

3. Greater Resistance to Torsional Loading



Acutrak® screws have the highest resistance to torsional loading when compared to AO & Herbert bone screws (AC).¹

SMALL BONE FRACTURE INCIDENCE AND OPERATIVE RATES

It is estimated that nearly 17.6 million fractures occurred in the United States in 2013. This figure was determined by multiplying the rate of fractures treated in 2000 in Edinburgh (5,593 fractures per 100,000 people)³ by the 2013 U.S. population (315.1M people).⁸ The most common fractures identified in Edinburgh in 2000 were:

- Distal Radius - 17.5%
- Metacarpal - 11.7%
- Proximal Femur - 11.6%
- Finger Phalanx - 9.6%
- Ankle - 9.0%
- Metatarsal - 6.8%

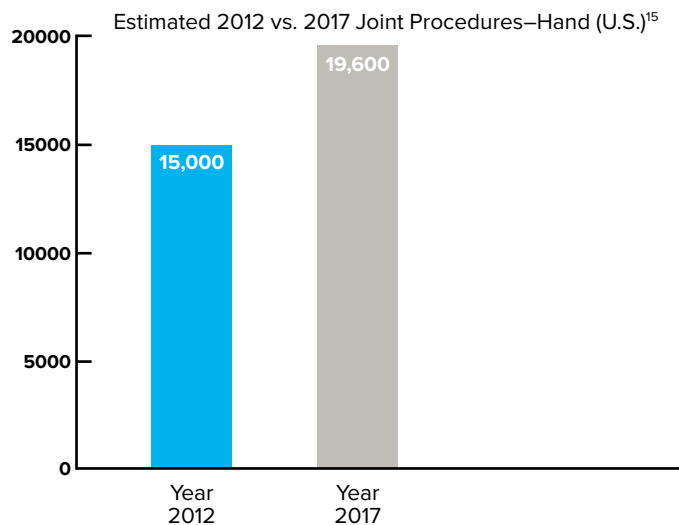
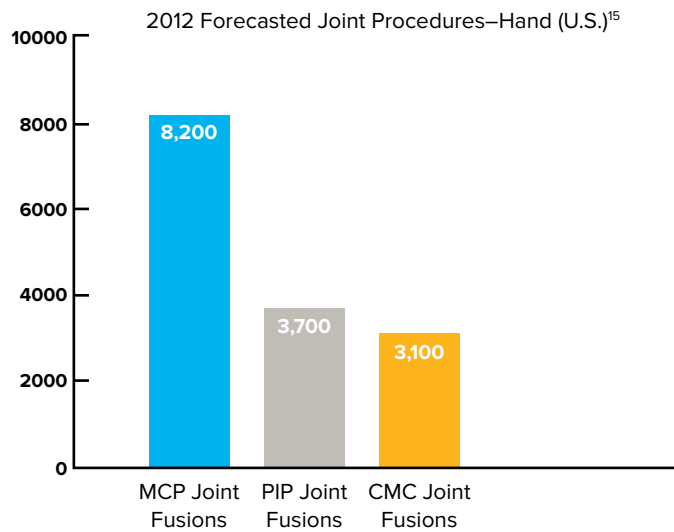
The most common methods of repair for these procedures are:

- Open and closed reduction with and without fixation
- Internal fixation without reduction
- Application of external fixator⁴

The tables and charts below estimate the number of fractures occurring as well as operative rates identified in the literature. Children and the elderly are the most affected populations, with the most common mechanism of injury being falls at nearly 50%.⁵ These numbers have been used to estimate the number of operations expected to occur in the U.S. for each fracture type.^{3,14}

Hand and Wrist Incidence and Operative Rates

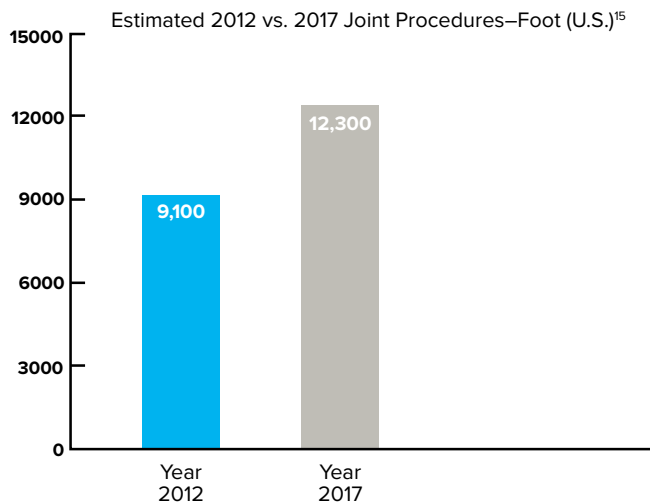
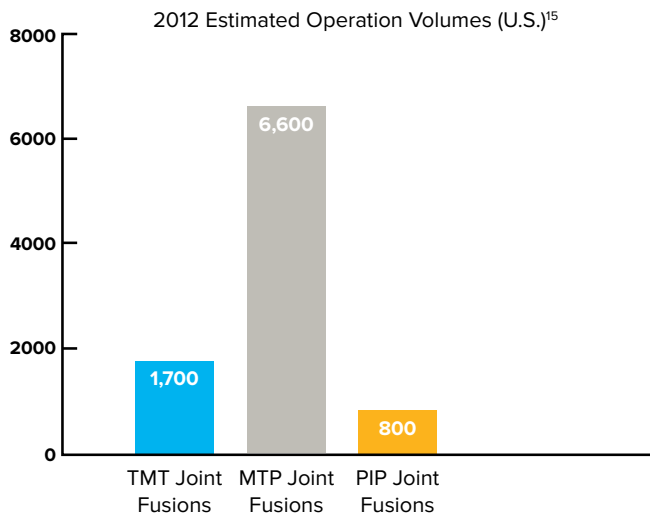
AVERAGE INCIDENCE RATES ¹⁴	
Carpal Fractures	29.7/100,000
Metacarpal Fractures	130.3/100,000
Phalangeal Fractures	107.3/100,000



Foot and Ankle Incidence and Operative Rates

AVERAGE INCIDENCE RATES ¹⁴	
Tarsal/Metatarsal	75.4/100,000
Ankle	100.8/100,000
Calcaneus	13.7/100,000

Foot and Ankle Joint Forecast



GLOBAL FOOT AND ANKLE INTERNAL FIXATION DEVICES MARKET VOLUME BY PRODUCT, 2010–2017 (NO. OF UNITS)⁶

	2010	2011	2012	2017	CAGR% (2012–2017)
Plates	635,513	690,157	749,595	1,135,372	8.7
Screws	1,779,733	1,915,482	2,061,604	2,977,902	7.6
Wires & Pins	1,509,869	1,650,698	1,804,594	2,816,847	9.3
Fusion Nails	81,485	89,379	98,052	156,157	9.8
Total	4,006,600	4,347,727	4,713,845	7,088,295	7.6

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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

Since its introduction in 1994, the Acutrak® headless compression screw has revolutionized the way surgeons gain fixation. The Acumed Acutrak Screw System was designed to eliminate the need to countersink a head, drill a glide hole or, in many cases, make large incisions. With the Acutrak headless compression screw, Acumed designed a solution for repairing fractures, performing joint fusions, and fixing osteotomies throughout the upper and lower extremities unlike any other product in the marketplace.

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

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. The Green Team drove projects to reduce paper consumption and will expand this to reduce overall landfill waste. Activities include eliminating paper stubs, defaulting to double-sided printing and copying, and providing compostable lunchroom supplies.



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