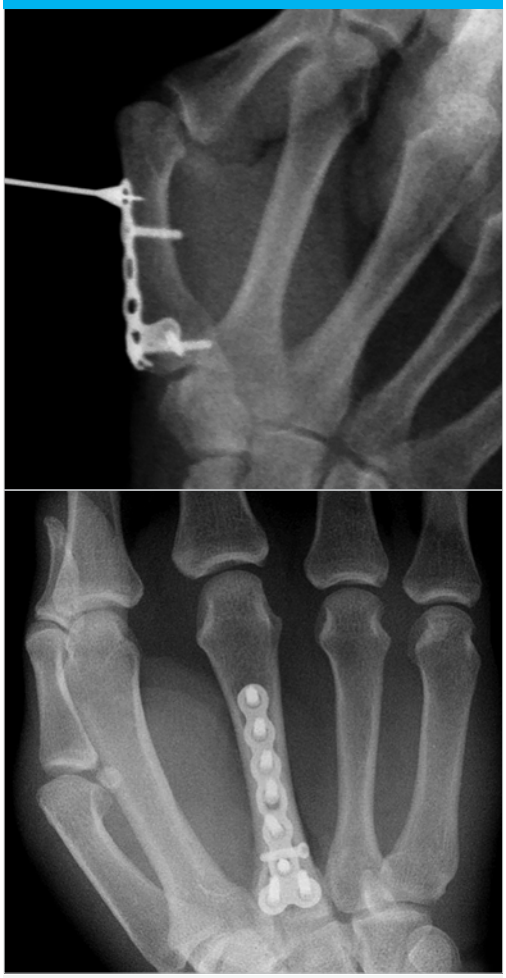
Value Analysis Committee Resource Guide

acumed® | Hand Fracture System

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.

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.

Product Overview

Acumed offers the all-in-one Hand Fracture System for management of fractures, fusions, and osteotomies for distal, middle, and proximal phalanges and metacarpals. This low-profile, multi-plate system features precontoured standard and specialty plates, Hexalobe MultiScrews, Hexalobe Lag Screws, pins, and external fixation devices, which are all included to streamline the surgical experience. Acumed's Hexalobe MultiScrew technology allows for the same screw to act as a nonlocking and locking variable angle screw, eliminating the need for traditional locking and nonlocking screws. Innovative instrumentation is provided for provisional fixation, along with a rounded-edge plate cutter designed to minimize soft tissue irritation. This comprehensive system contains multiple surgical treatment options for the hand in one convenient tray.

Acumed Hand Fracture System Key Features

Plates
Designed to address the most common fractures of the hand, difficult to treat fractures of the metacarpal neck, base of the first metacarpal, and avulsion fractures, as well as rotational malunions, Acumed's Hand Fracture System offers plates in 0.8 mm and 1.3 mm thicknesses. These plates feature divots that aid in provisional fixation when used with the system's forceps and clamps. Plates can be cut to length and bent to fit to better treat a wide variety of fracture patterns.

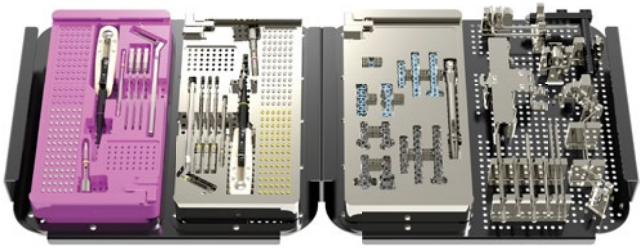
Hexalobe MultiScrews
Designed to be used with any plate in Acumed's Hand Fracture System, 1.5 mm and 2.3 mm Hexalobe MultiScrews act as both nonlocking and variable angle locking screws in one. The Hexalobe MultiScrew design allows for variable angle screw insertion of up to 15° in any direction for a total of 30°. Cutting flutes on the screw are intended to limit the need for a bone tap.

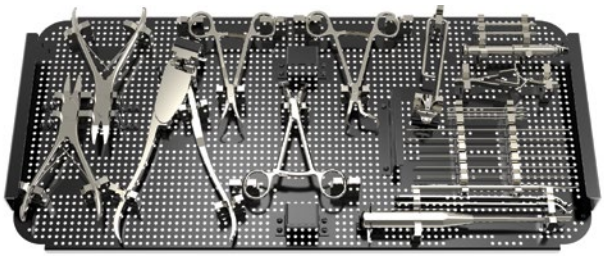
Hexalobe Lag Screws
Designed to be used as an adjunct to plate fixation or for fractures which can be treated with lag screws alone, Acumed's 1.5 mm and 2.3 mm Hexalobe Lag Screws do not require overdrilling of the near cortex. Hexalobe Lag Screws are intended to be used independently of plates or through slotted plate holes only.

Threaded Titanium K-wires
Designed to surgically treat less complex metacarpal and phalangeal fractures which can be fixed with pinning alone.

Small Bone Fixator
Designed for temporary stabilization of the metacarpals and phalanges, Acumed's Small Bone Fixator aids in reduction and compression to help correct fragment alignment for various fractures and osteotomies.

Small Bone Distractor
Designed to aid with temporary stabilization, Acumed's Small Bone Distractor is used in conjunction with guide pins to maintain distraction forces during fracture healing.





Clinical Publication Excerpts

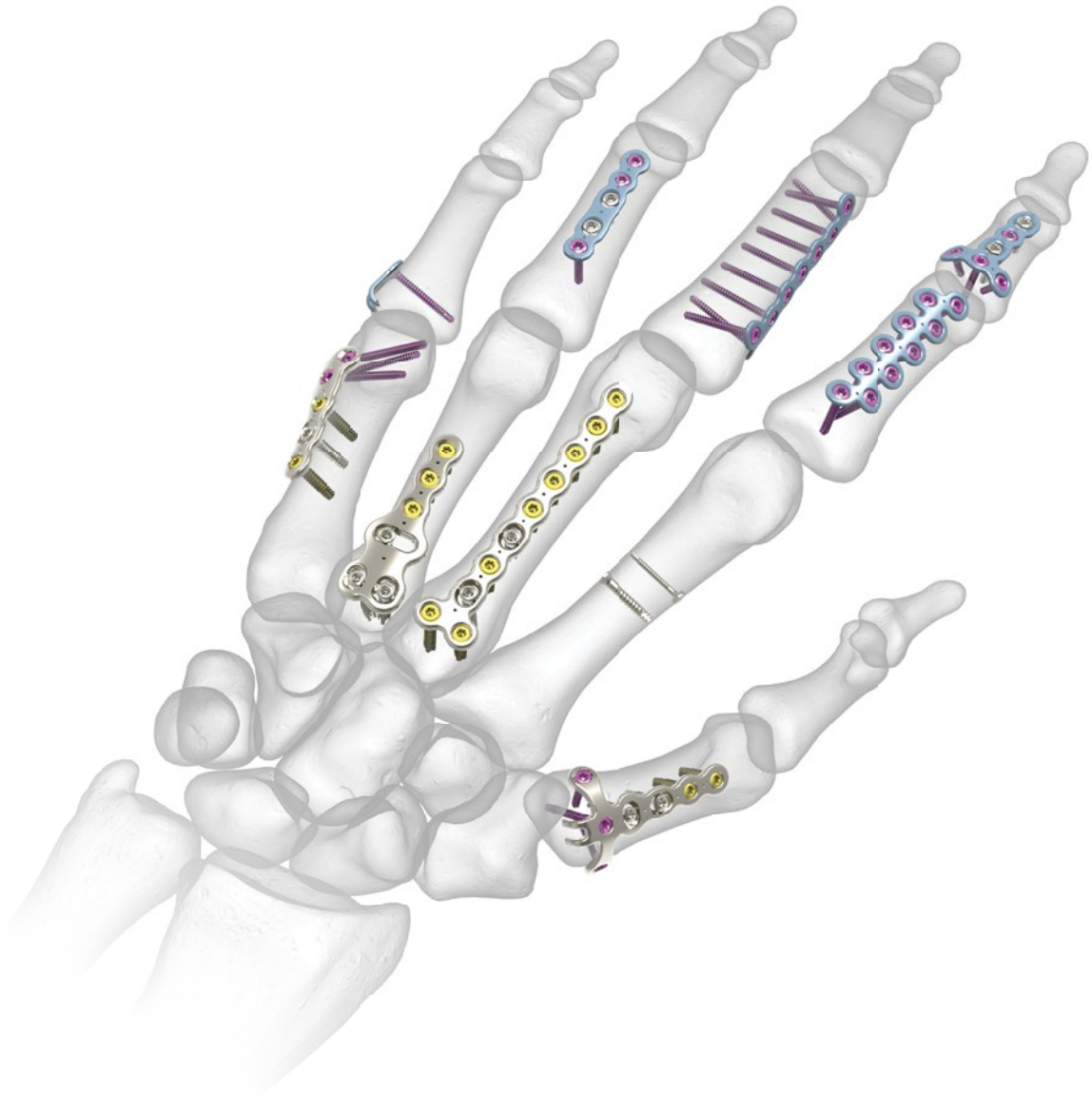
Metacarpal and phalangeal fractures comprise 10% of all fractures; greater than 50% of these are work related. These fractures constitute anywhere from 1.5% to 28% of all emergency department visits, depending on survey methods.[1] Hand metacarpal and phalangeal fracture, fusion, and osteotomy plating procedures have a very high rate of union healing.[2,3] The high rate of unions corresponds with good published clinical outcomes. Although the grip strength of the operated hand is typically reduced compared with the contralateral side[4,5] and function is impaired for some specific activities,[6] the majority of patients report a marked improvement in the function of their operated hand following surgery.[2,7,8,9,10] In terms of function, plate and screw fixation has significantly superior outcomes than minimal fixation options.[11] Whenever injury permits, plate fixation is recommended over K-wire fixation due to precise, intraoperative correction, and rigid stabilization. Shortened immobilization time and early motion are significant benefits of plate fixation, which allows for faster recovery times.[12] Studies suggest that external fixation devices can be considered for all hand fractures requiring surgical treatment, with emphasis on intra-articular and comminuted fractures.[13] A prospective study by Gupta, *et al* in the Indian Journal of Orthopaedics was undertaken to evaluate the functional outcome after surgical stabilization of metacarpal and phalangeal fractures. Overall results were excellent to good in 87% of these cases. Patients observed better outcomes and total active range of motion with plate and screw fixation techniques compared to closed reduction and percutaneous K-wire fixation. Because of improved function, and better alignment, some published studies report a high patient satisfaction rate associated with repairs of phalangeal and metacarpal fractures using surgical treatment options.[2,9] "Rotational metacarpal malunion treated by metacarpal osteotomy and AO plate fixation can be performed with confidence of achieving a good or excellent result."[14] Post-operative clinical data reports that the use of low profile plating procedures requires the use of a splint for 75% less time than K-wire procedures.[15]

References

1. Egol, Kenneth A., Kenneth J. Koval and Joseph D. Zuckerman. *Handbook of Fractures.* 4th ed. Philadelphia: Lippincott, Williams & Wilkins, 2010. Print.
2. Bindra R, Burke F. "Metacarpal Osteomy for correction of acquired phalangeal rotational deformity." *J Hand Surg Am.* Jul./Aug. 2009, 34A: 1895–1899.
3. Bansky R, Racz N. "The use of titanium miniplates in arthrodesis of the interphalangeal joints and a metacarpal neck fracture." *Bratisi Lek Listy.* 2005, 106(8-9): 287–290.
4. Jupiter JB, Koniuch MP, Smith RJ. "The management of delayed union and nonunion of the metacarpals and phalanges." *J Hand Surg Am.* Jul. 1985, 10(4): 457–466.
5. Ikeda M, Kobayashi Y, Saito I, Ishii T, Shimizu A, Oka Y. "Open reduction and internal fixation for dorsal fracture dislocations of the proximal interphalangeal joint using a miniplate." *Tech Hand Up Extrem Surg.* Dec. 2011, 15(4): 219–224.
6. Soyer AD. "Fractures of the base of the first metacarpal;current treatment options." *J AM Acad Orthop Surg* Nov./Dec. 2011, 7(6): 403–412.
7. Soni A, Gulati A, Bassi JL Singh D, Saini UC. "Outcome of closed ipsilateral metacarpal fractures treated with mini fragment plates and screws, a prospective study." *J Orthop Traumatol.* Mar. 2012, 13(1): 29–33.
8. Souer JS, Mudgal CS. "Plate fixation in closed ipsilateral multiple metacarpal fractures." *J Hand Surg Eur.* 11 Aug. 2008, 33(6): 740–744.
9. Gupta R, Singh R, Siwach R, Sangwan S, Magu NK, Diwan R. "Evaluation of surgical stabilization of metacarpal and phalangeal fractures of the hand." *Indian J Orthop.* Jul. 2007, 4(3): 224–229.
10. Kang GC, Yam A, Phoon ES, Lee JY, Teoh LC. "The hook plate technique for fixation of phalangeal avulsion fractures." *J Bone Joint Surg Am.* 6 Jun. 2012, 94(11): e72.
11. Komurcu M, Alemdaroglu B, Kurklu M, Ozkan H, Basbozkurt M. "Handgun injuries with metacarpal and proximal phalangeal fractures; early definitive treatment." *Int Orthop.* 2008 Apr;32(2): 257–262.
12. Sanders RA, Frederick HA. "Metacarpal and phalangeal osteotomy with miniplate fixation." *Orthop Rev.* May 1991, 20(5): 449–456.
13. Dailiana Z, Agorastakis D., Varitimidis S., Bargiotas K., Roidis N., Malizos KN. "Use of mini-external fixator for the treatment of hand fractures." *J Hand Surg Am.* Apr. 2009, 34(4): 630–636.
14. "Corrective Osteotomy for Metacarpal and Phalangeal Malunions." *OrthopaedicsOne Articles.* In: OrthopaedicsOne—The Orthopaedic Knowledge Network. Created Jun 04, 2010 20:56. Last modified Jul 24, 2012 22:32 ver.HYPERLINK "http://www.orthopaedicsone.com/pages/viewpage.action?pageId=33687314" 3. Retrieved 2014-08-20, from http://www.orthopaedicsone.com/x/EgcCAg.
15. Takigami H, Sakano H, Saito T. "Internal fixation with the low profile plate system compared with Kirschner wire fixation: clinical results of treatment for metacarpal and phalangeal fractures." *Hand Surg.* 2010, 15(1): 1–6.

Indications for Use

The Acumed Hand Fracture System is designed for the management of fractures, fusions, and osteotomies of the distal, middle, and proximal phalanges and metacarpals and other bones of appropriate size for the devices.



Associated Acumed® Products

- Acu-Loc® Volar Distal Radius Plating System
- Acu-Loc® 2 Wrist Plating System
- Acu-Loc® Wrist Spanning Plate
- Acutrak® Headless Compression Screw Mini and Standard
- Acutrak 2® Headless Compression Screw Micro, Mini, and Standard
- Acutrak® Acutwist
- ARC Wrist Tower System
- Forearm Fracture Solutions
- Modular Hand System
- SLIC Screw® System
- Small Bone External Fixation System
- Stableloc External Fixation System
- Total Wrist Fusion Plating System
- Ulna Shortening Plating Osteotomy System

Product Comparisons

COMPANY	ACUMED	STRYKER	DEPUY SYNTHES
Product Name	Hand Fracture System	VariAX/ Profyle	LCP Compact Hand
Plate Material	Titanium	Titanium	Titanium Stainless Steel
Plate Thickness	0.8, 1.3 mm	0.55, 1.0, 1.3, 1.5 mm	Unknown
Screw Size: Nonlocking	NA	1.2, 1.7, 2.3 mm	1.0, 1.3, 1.5, 2.0, 2.4 mm
Screw Size: Locking	NA	NA	1.5, 2.0, 2.4 mm
Screw Size: Variable Angle	1.5, 2.3 mm (±15°)	1.7, 2.3 mm (±10°)	NA
Screw Size: Lag	1.5, 2.3 mm	NA	NA
Screw Size: Rescue	NA	1.4, 1.9, 2.5 mm	NA
Specialty Plates	Avulsion Plate Curved Medial/Lateral Plate Metacarpal Neck Plate Rolando Plate Offset Plate Rotational Correction Plate	Avulsion Plate H-Plate Metacarpal Neck Plate Replantation Plate (Offset Plate) Rotation Plate	H-Plate Rotation Correction Plate Strut Plate (Offset Plate)

COMPANY	MEDARTIS	BIOMET	OSTEOMED
Product Name	APTUS Hand	A.L.P.S. Hand Fracture System	hps Hand Plating System
Plate Material	Titanium	Titanium	Titanium
Plate Thickness	0.6, 0.8, 1.0, 1.3 mm	1.0, 1.1, 1.65 mm	Unknown
Screw Size: Nonlocking	1.2, 1.5, 2.0, 2.3 mm	1.3, 1.5, 2.5 mm	1.2, 1.6, 2.0, 2.4 mm
Screw Size: Locking	NA	2.5 mm	NA
Screw Size: Variable Angle	1.5, 2.0 mm (±15°)	1.5, 2.5 mm (±10°)	1.6, 2.0, 2.4 mm (± 17° to 22°)
Screw Size: Lag	NA	NA	1.2, 1.6, 2.0, 2.4 mm
Screw Size: Rescue	1.8, 2.5 mm	NA	NA
Specialty Plates	Avulsion Plate Double Row T-Plate Grid Plate (Offset Plate) H-Plate Rotation Correction Plate Scaphoid Plate	Web Plate T-/Y-Plate	Fusion Plate Offset Grid Plate

510(k) Clearance Letter

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

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

June 13, 2014

Acumed, LLC
Ms. Mariah Knight
Regulatory Specialist
5885 NW Cornelius Pass Road
Hillsboro, Oregon 97124

Re: K141383
Trade/Device Name: Acumed Hand Fracture 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: May 22, 2014
Received: May 27, 2014

Dear Ms. Knight:

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

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,

Lori A. Wiggins

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

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

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

510(k) Number *(if known)*
K141383

Device Name
Acumed Hand Fracture System

Indications for Use *(Describe)*
The Acumed Hand Fracture System is intended for the management of fractures, fusions, and osteotomies of the distal, middle and proximal phalanges and metacarpals and other bones of appropriate size for the devices

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Elizabeth L. Frank -S

Division of Orthopedic Devices

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."

FORM FDA 3881 (1/14) Page 1 of 1 PSC Publishing Services (301) 443-6740 EF

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 phalangeal and metacarpal fractures in 2000. Since then, Acumed has grown to become one of the technology leaders in options for operative treatment of the hand. 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.

Notes:

Notes:

Notes:

GEN10-07-B
Effective: 1/2015

Acumed® Headquarters
5885 NW Cornelius Pass Road
Hillsboro, OR 97124

Office: 888.627.9957
Fax: 503.520.9618
acumed.net