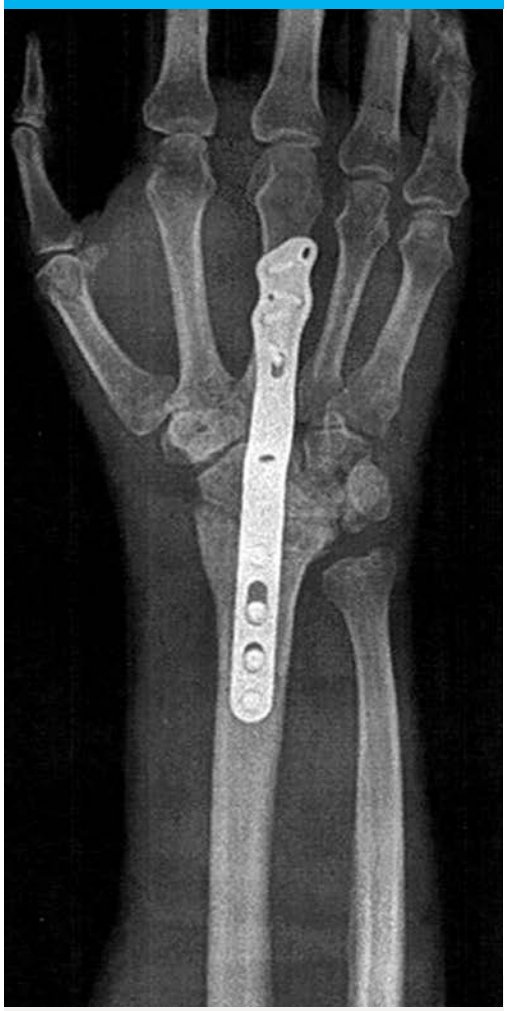
Value Analysis Committee Resource Guide

acumed® | Total Wrist Fusion Plating 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.



Contents

About Acumed®

Headquartered in Hillsboro, Oregon, with a global distribution network, Acumed provides medical solutions designed to advance orthopaedic care. Whether it's creating greater efficiencies for a hospital administrator or adding an extra five degrees of flexibility to a patient's range of motion, Acumed blends ingenuity, experience, and resources to create solutions that benefit the medical community as a whole.

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 Total Wrist Fusion Plating System for wrist arthrodesis due to deformities associated with degenerative arthritis, brachial plexus palsies, and spastic disorders. This five plate system features both innovative and traditional designs. Specifically, four of the five plates are positioned on the second metacarpal. These left and right specific designs are positioned on the second metacarpal which may reduce extensor tendon irritation. Additionally, the fifth plate is a neutral option that is placed on the third metacarpal and developed for use with a proximal row carpectomy. All plates have a 15° dorsal bend, established as a balance between anatomic resting position, hand function, and grip strength. Our Hexalobe MultiScrew technology allows for the same screw to be placed in both a locking hole and a nonlocking slot, eliminating the need for traditional locking and nonlocking screws. This, combined with a range of instrumentation designed to assist the surgery, creates a comprehensive standalone system for total wrist fusions.

The Acumed Total Wrist Fusion Plating System key features:

- Four of the five plates are left and right specific with two size variations to accommodate different patient anatomies in the carpal regions. They are placed on the second metacarpal and designed to avoid extensor tendon irritation.
- The fifth plate is a neutral option that is placed on the third metacarpal and developed for use with a proximal row carpectomy.
- Plates place wrist in 15° dorsiflexion and 0°-10° of ulnar deviation.
- Convergent distal screw construct is designed to increase resistance to pullout.
- The carpal cross-screw is intended to offer additional implant stability.
- Precontoured plates are designed to avoid intraoperative bending.
- The Hexalobe MultiScrews act as nonlocking screws when inserted into unthreaded slots and locking screws when inserted into threaded holes.
- The SaveLock Compression Sleeve engages screw head threads, reducing the plate to the bone by preventing the screw from locking into the plate until the SaveLock Compression Sleeve is disengaged.
- Nonlocking drill guides fit into the plate counterbore.
- Guide wires and plate tacks are included for provisional plate fixation.

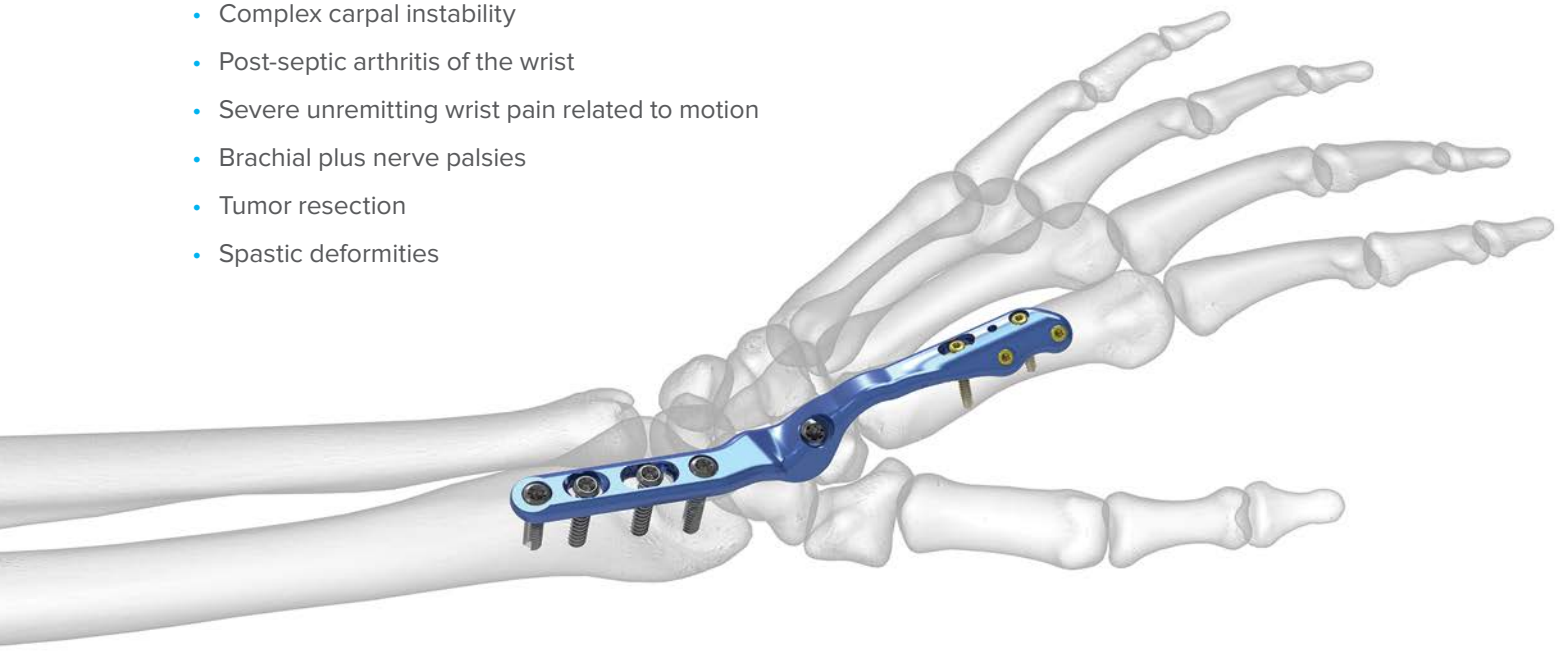
Clinical Publication Excerpts

Total wrist fusion procedures using a plate have a very high rate of fusion, with some studies reporting up to a 100% fusion rate.[1, 2, 3, 5, 6, 7, 8] The high rate of fusion corresponds with good published clinical outcomes. For example, although the grip strength of the operated hand is typically reduced compared with the contralateral side[8, 9] and function is impaired for some specific activities, the majority of patients report an improvement in the function of their operated hand following surgery.[4, 10, 11, 12] The plated fusions result in improved hygiene and cosmesis.[1, 13] The primary clinical benefit for many patients, however, is pain reduction.[2, 4, 7, 11, 13] Because of the reduced pain, improved function, and better aesthetics, most published studies report a high (> 75%) patient satisfaction rate associated with plated wrist arthrodeses. Most patients indicate post-operatively that they would have the procedure again.[1, 2, 3, 7, 12, 13]

Indications for Use

The Acumed Total Wrist Fusion Plating System is designed for management of:

- Post-traumatic arthritis of the joints of the wrist
- Rheumatoid wrist deformities requiring restoration
- Complex carpal instability
- Post-septic arthritis of the wrist
- Severe unremitting wrist pain related to motion
- Brachial plus nerve palsies
- Tumor resection
- Spastic deformities



Associated Acumed® Products

- Acu-Loc® Volar Distal Radius Plating System
- Acu-Loc® 2 Volar Distal Radius 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
- Hand Fracture System
- Modular Hand System
- SLIC Screw® System
- Small Bone External Fixation System
- Stableloc External Fixation System
- Ulna Shortening Plating System

Product Comparisons

ACUMED®	SYNTHES®
Titanium Alloy, Ti-6Al-4V	Both Titanium and Stainless Steel available
105 mm and 108 mm plate lengths	112 mm and 118 mm plate lengths
Left/right specific plates	n/a
Not left/right specific plate (Neutral)	Not left/right specific plates
Small bend plates	Short bend plates
Standard bend plates	Standard bend plates
n/a	Straight plate
15 degrees dorsiflexion of plates	10 degrees dorsiflexion of plates
0-10 degrees ulnar deviation of left/right specific plates	n/a
4 converging dorsal distal screw construct	3 straight dorsal distal screws
4 proximal screws	4 proximal screws
Carpal Cross-screw for unicortical fixation in the hamate or capitate	Combi hole for fixation in the capitate
Uses locking holes and compression slots	Uses Combi hole technology–locking and compression slots
One 2.3 mm Hexalobe MultiScrew for distal screws acting as locking in holes and nonlocking in compression slots	2.4 mm or 2.7 mm locking and nonlocking distal screws
3.5 mm locking and nonlocking proximal screws	3.5 mm locking and nonlocking proximal screws
Third metacarpal plate fixation in conjunction with Proximal Row Carpectomy (PRC)	Third metacarpal plate fixation in conjunction with Proximal Row Carpectomy (PRC)
Second metacarpal plate fixation	n/a

ACUMED®	TRIMED®
Titanium Alloy, Ti-6Al-4V	Both Titanium and Stainless Steel available
105 mm and 108 mm plate lengths	*Information Not Available*
Left/right specific plates	n/a
Not left/right specific plate (Neutral)	Not left/right specific plates
Small bend plates	*Information Not Available*
Standard bend plates	*Information Not Available*
n/a	Straight plates
15 degrees dorsiflexion of plates	*Information Not Available*
0-10 degrees ulnar deviation of left/right specific plates	*Information Not Available*
4 converging dorsal distal screw construct	4 straight dorsal distal screws
4 proximal screws	5 proximal screws
Carpal Cross-screw for unicortical fixation in the hamate or capitate	n/a
Uses locking holes and compression slots	Uses locking holes and compression slots
One 2.3 mm Hexalobe MultiScrew for distal screws acting as locking in holes and nonlocking in compression slots	2.7 mm locking and nonlocking distal screws
3.5 mm locking and nonlocking proximal screws	3.2 mm locking and nonlocking proximal screws
Third metacarpal plate fixation in conjunction with Proximal Row Carpectomy (PRC)	Third metacarpal plate fixation
Second metacarpal plate fixation	n/a

Product Comparisons

ACUMED®	INTEGRA®
Titanium Alloy, Ti-6Al-4V	*Information Not Available*
105 mm and 108 mm plate lengths	*Information Not Available*
Left/right specific plates	n/a
Not left/right specific plate (Neutral)	Not left/right specific plates
Small bend plates	Short bend plate
Standard bend plates	Standard bend plate
n/a	Straight plate
15 degrees dorsiflexion of plates	0 degrees to 35 degrees dorsiflexion of plates; surgical technique recommends to bend the straight plate up to 35 degrees
0-10 degrees ulnar deviation of left/right specific plates	n/a
4 converging dorsal distal screw construct	4 straight dorsal distal screws
4 proximal screws	4 proximal screws
Carpal Cross-screw for unicortical fixation in the hamate or capitate	Hole for fixation in the carpals in straight plate only
Uses locking holes and compression slots	Uses locking holes and compression slots
One 2.3 mm Hexalobe MultiScrew for distal screws acting as locking in holes and nonlocking in compression slots	2.7 mm locking and nonlocking distal screws
3.5 mm locking and nonlocking proximal screws	3.5 mm locking and nonlocking proximal screws
Third metacarpal plate fixation in conjunction with Proximal Row Carpectomy (PRC)	Third metacarpal plate fixation
Second metacarpal plate fixation	n/a

ACUMED®	SKELETAL DYNAMICS®
Titanium Alloy, Ti-6Al-4V	Titanium Alloy Nails and Cobalt Chrome Setscrews
105 mm and 108 mm plate lengths	107 mm to 142 mm nail lengths
Left/right specific plates	n/a
Not left/right specific plate (Neutral)	Not left/right specific intramedullary nails
Small bend plates	Small bend nail options
Standard bend plates	Standard bend nail options
n/a	Straight nail options
15 degrees dorsiflexion of plates	0 degrees to 22.5 degrees dorsiflexion of nails
0-10 degrees ulnar deviation of left/right specific plates	Setscrews allow for ulnar deviation
4 converging dorsal distal screw construct	1 straight dorsal distal screws
4 proximal screws	3 proximal screws
Carpal Cross-screw for unicortical fixation in the hamate or capitate	n/a
Uses locking holes and compression slots	Uses locking holes and compression slots
One 2.3 mm Hexalobe MultiScrew for distal screws acting as locking in holes and nonlocking in compression slots	2.8 mm nonlocking distal screws
3.5 mm locking and nonlocking proximal screws	2.8 mm nonlocking distal screws
Third metacarpal plate fixation in conjunction with Proximal Row Carpectomy (PRC)	Third metacarpal intramedullary nail fixation
Second metacarpal plate fixation	n/a

510(k) Clearance Letter

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

June 10, 2013

Acumed, LLC
% Ms. Brittany Cunningham
Regulatory Specialist II
5885 Northwest Cornelius Pass Road
Hillsboro, Oregon 97124

Re: K131380
Trade/Device Name: Acumed Wrist Arthrodesis 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, HWC
Dated: May 10, 2013
Received: May 14, 2013

Dear Ms. Cunningham:

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 Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

For Erin D. Keith

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

Enclosure

510(k) Clearance Letter

Section 3: INDICATIONS FOR USE

510(k) Number (if known): K131380

Device Name: Acumed Wrist Arthrodesis Plate System

Indications for Use:

The Acumed Wrist Arthrodesis Plate System is intended for wrist arthrodesis and fractures of other small bones. Specific indications include post traumatic arthritis of the joints of the wrist, rheumatoid wrist deformities requiring restoration, complex carpal instability, post-septic arthritis of the wrist, severe unremitting wrist pain related to motion, brachial plexus nerve palsies, tumor resection, and spastic deformities.

Prescription Use X AND/OR Over-the-Counter Use

(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

Elizabeth L. Frank -S

Division of Orthopedic Devices

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 wrist arthrodesis treatment in 2002. Since then, Acumed has grown to become one of the technology leaders in options for operative treatment of wrist arthrodesis. 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, copying, and providing compostable lunchroom supplies.

References

1. Giuffre JL, Bishop AT, Spinner RJ, Kircher MF, Shin AY. "Wrist, first carpometacarpal joint, and thumb interphalangeal joint arthrodesis in patients with brachial plexus injuries." *J Hand Surg Am.* 2012 Dec;37(12):2557-63.e1. PubMed PMID: 23174070.
2. Murray PM. "Radioscapholunate arthrodesis." *Hand Clin*. 2005 Nov;21(4):561-6. PubMed PMID: 16274866.
3. Meads BM, Scougall PJ, Hargreaves IC. "Wrist arthrodesis using a Synthes wrist fusion plate." *J Hand Surg Br.* 2003 Dec;28(6):571-4. PubMed PMID: 14599830.
4. Pech J, Sosna A, Rybka V, Pokorný D. "Wrist arthrodesis in rheumatoid arthritis: A new technique using internal fixation." *J Bone Joint Surg Br.* 1996 Sep;78(5):783-6. PubMed PMID: 8836071.
5. Hastings H 2nd, Weiss AP, Quenzer D, Wiedeman GP, Hanington KR, Strickland JW. "Arthrodesis of the wrist for posttraumatic disorders." *J Bone Joint Surg Am.* 1996 Jun;78(6):897-902. PubMed PMID: 8666608.
6. O'Bierne J, Boyer MI, Axelrod TS. "Wrist arthrodesis using a dynamic compression plate." *J Bone Joint Surg Br.* 1995 Sep;77(5):700-4. PubMed PMID: 7559693.
7. Weiss AP, Hastings H 2nd. "Wrist arthrodesis for traumatic conditions: a study of plate and local bone graft application." *J Hand Surg Am.* 1995 Jan;20(1):50-6. PubMed PMID: 7722266.
8. Richards RS, Roth JH. "Simultaneous proximal row carpectomy and radius to distal carpal row arthrodesis." *J Hand Surg Am.* 1994 Sep;19(5):728-32. PubMed PMID: 7806792.
9. Bolano LE, Green DP. "Wrist arthrodesis in post-traumatic arthritis: a comparison of two methods." *J Hand Surg Am.* 1993 Sep;18(5):786-91. PubMed PMID: 8228047.
10. Houshian S, Schrøder HA. "Wrist arthrodesis with the AO titanium wrist fusion plate: a consecutive series of 42 cases." *J Hand Surg Br.* 2001 Aug;26(4):355-9. PubMed PMID: 11469839.
11. Hartigan BJ, Nagle DJ, Foley MJ. "Wrist arthrodesis with excision of the proximal carpal bones using the AO/ASIF wrist fusion plate and local bone graft." *J Hand Surg Br.* 2001 Jun;26(3):247-51. PubMed PMID: 11386777.
12. Sagerman SD, Palmer AK. "Wrist arthrodesis using a dynamic compression plate." *J Hand Surg Br.* 1996 Aug;21(4):437-41. PubMed PMID: 8856529.
13. Jebson PJ, Adams BD. "Wrist arthrodesis: review of current techniques." *J Am Acad Orthop Surg*. 2001 Jan-Feb;9(1):53-60. PubMed PMID: 11174163.

GEN10-06-A
Effective: 5/2014

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

Office: 888.627.9957
Fax: 503.520.9618
acumed.net

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