

Value Analysis Committee Resource Guide



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



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



Acumed Ulna Nail 2 System

At Acumed, we support surgeons and health care providers who treat patients in their times of need. We are proud of our long-standing reputation of differentiation and our ability to consistently provide innovative solutions that benefit the whole health care community. We believe that together, we can improve patient outcomes and quality of life.

Designed in conjunction with Roy Sanders, MD, the Acumed Ulna Nail 2 is designed to address simple, transverse, and short oblique fractures as well as osteotomies of the ulna.

The system includes three nail diameters and seven length options, power reamers and carbon fiber radiolucent targeting guides to streamline the procedure, threaded holes within the nail that engage the interlocking screws, headless hexalobe screws to help minimize soft-tissue irritation, and the option to lock the nail distally, providing additional fixation within the canal.

The Ulna Nail 2 must be used in conjunction with the Acumed Fibula and Forearm Nail 2 (FFN) Base Set, which contains universal instrumentation to implant the Ulna Nail 2, Fibula Nail 2 and screws.



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System Overview

Ulna Nail 2 Overview

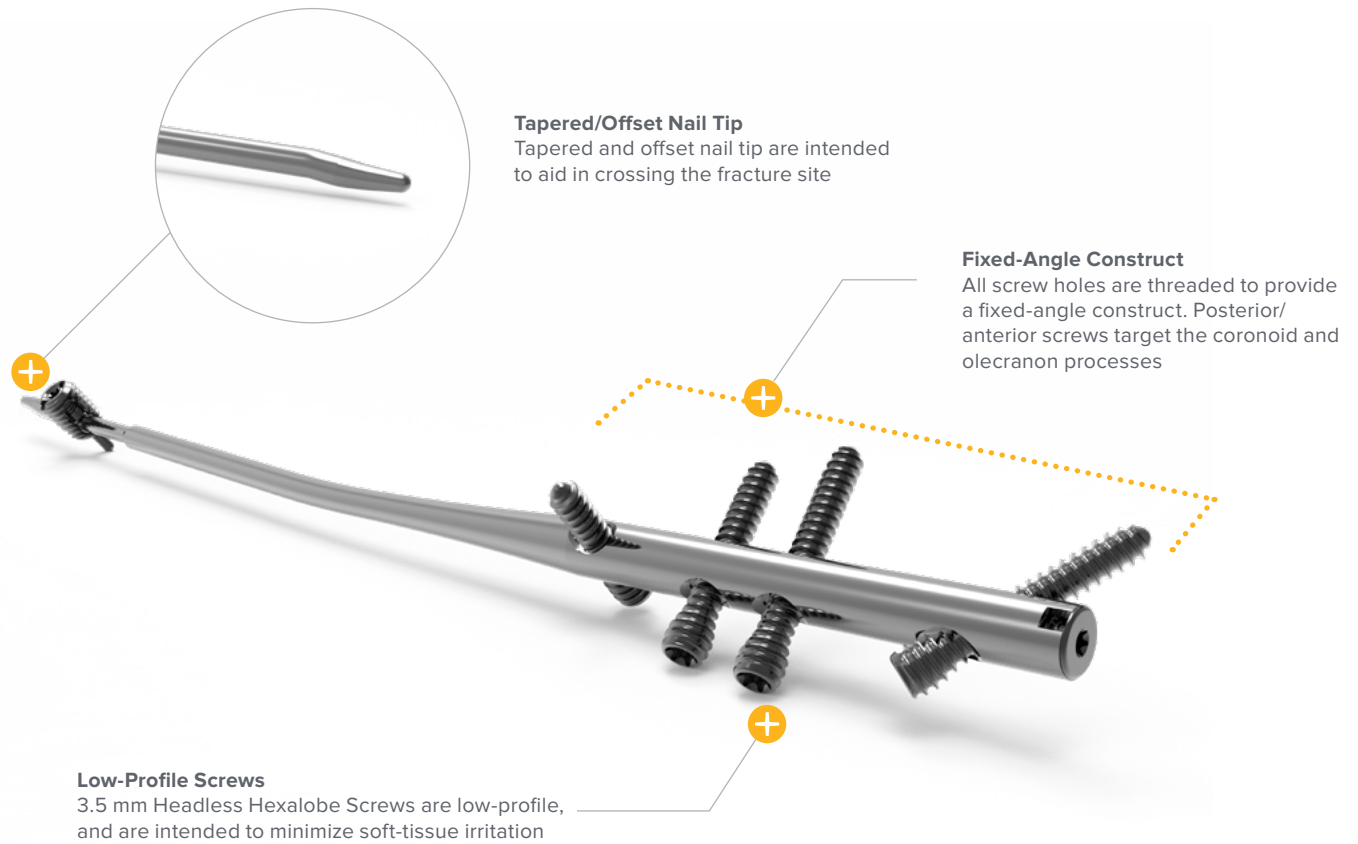
The Acumed Ulna Nail 2 offers a less invasive and less prominent alternative to open reduction internal fixation (ORIF) for adult diaphyseal forearm fractures. The Ulna Nail 2 includes a wide range of lengths, including a 120 mm Straight Ulna Nail that was designed to treat more proximal fractures. The system also includes headless hexalobe screws aimed at minimizing screw prominence and the option to lock the nail distally to provide additional points of fixation within the canal. The Ulna Nail 2 instrumentation is streamlined to include power reamers and radiolucent targeting guides.

3.0 mm Ulna Nail 2		120 mm (4011-3012N-S)	Ulna Nail 2 implants accept: ▶ 3.5 mm Headless Hexalobe Screws ▶ 3.5 mm Nonlocking Hexalobe Screws
		170 mm (4011-3017N-S)	
		190 mm (4011-3019N-S)	
		210 mm (4011-3021N-S)	
		230 mm (4011-3023N-S)	
		250 mm (4011-3025N-S)	
		270 mm (4011-3027N-S)	
3.6 mm Ulna Nail 2		120 mm (4011-3612N-S)	
		170 mm (4011-3617N-S)	
		190 mm (4011-3619N-S)	
		210 mm (4011-3621N-S)	
		230 mm (4011-3623N-S)	
		250 mm (4011-3625N-S)	
		270 mm (4011-3627N-S)	
4.0 mm Ulna Nail 2		120 mm (4011-4012N-S)	
		170 mm (4011-4017N-S)	
		190 mm (4011-4019N-S)	
		210 mm (4011-4021N-S)	
		230 mm (4011-4023N-S)	
		250 mm (4011-4025N-S)	
		270 mm (4011-4027N-S)	

Indications for Use

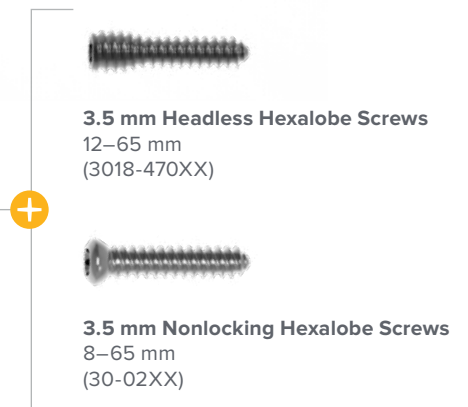
The Acumed Fibula and Forearm Nail 2 (FFN) System is intended for fixation of fractures and osteotomies of the fibula and ulna, including fractures where the medullary canal is narrow or flexibility of the implant is paramount.

Key System Features



Screws

3.5 mm Nonlocking Hexalobe (8–65 mm) and 3.5 mm Headless Hexalobe (12–65 mm) Screws are both included in the system. The 3.5 mm Headless Hexalobe Screws lock into the threaded holes within the nail and are intended to create a low-profile construct to minimize soft-tissue irritation.



Optional End Caps

End caps are offered in +0.4 mm, +5 mm, +10 mm, and +15 mm lengths and thread into the tail of the ulna nail. End caps assist in limiting ossification over the tail end of the nail, making the nail threads easier to engage if removal is desired. End caps also allow surgeons to create an intermediate nail length while adjusting for anatomic variances and screw trajectories.



Key System Features [continued]

The Ulna Nail 2 nails are delivered in sterile packaging and are designed to be used in conjunction with the Fibula and Forearm Nail 2 Base Set. This set includes shared instrumentation to implant the Ulna Nail 2, Fibula Nail 2 and screws.

Instrumentation

Reamers

Reamers are included in the system to provide a single step in which to measure for both nail length and diameter. The reamers may be used by hand or under power to optimize operative time.



Reamer	Nail
FFN 3.1 mm Reamer (80-2460)	3.0 mm Ulna Nail 2 (4011-30XXN-S)
FFN 3.7 mm Reamer (80-2461)	3.6 mm Ulna Nail 2 (4011-36XXN-S)
FFN 4.1 mm Reamer (80-2462)	4.0 mm Ulna Nail 2 (4011-40XXN-S)



Radiolucent Carbon Fiber Targeting Guides

The radiolucent carbon fiber FFN Primary and Secondary Targeting Guides allow for unobstructed viewing of the nail and screw positioning under fluoroscopy to ensure correct placement. Five guide wire holes have been included in the design of the FFN Primary Targeting Guide. The center-most proximal guide wire hole allows for precise viewing of nail depth relative to the FFN Locking Bolt under fluoroscopy, while the four converging guide wire holes allow for initial fracture fixation when needed.



FFN Bolt
(80-3886)



2.0 mm Easyout, QR
(80-0599)



3.0 mm Easyout, QR
(80-0601)

Removal Instruments

A variety of instruments to aid in both implant and screw removal are included in the system. The FFN Bolt (80-3886), 2.0 mm Easyout, QR (80-0599), and 3.0 mm Easyout, QR (80-0601) provide multiple options to remove the screws or ulna nail 2 if necessary.

Key System Features [continued]

Optional Tip-Loc™ Bushing & Set Screw

The Ulna Nail 2 offers the option to lock the nail distally, providing additional axial and rotational fracture fixation.

The Tip-Loc Bushing and Tip-Loc Set Screw sit centrally within the most distal 1.5" of the nail. These sterile packed implants are offered in 1 mm increments ranging from 6 mm through 16 mm in length and are selected according to the ulnar canal size.

Note: The 120 mm length ulna nails in all three diameters do not accept the Tip-Loc Bushing & Set Screw as these short nails were designed for more-proximal ulna fractures in which distal locking is not necessary.



Tip-Loc Bushing (3017-650XX)

- ▶ Titanium
- ▶ 6.35 mm in diameter



Tip-Loc Set Screw (3017-250XX)

- ▶ Cobalt Chrome
- ▶ 3.4 mm in diameter
- ▶ Implanted using FFN T8 Driver
- ▶ Sterile-packed with corresponding bushing size

Tip-Loc Bushing & Set Screw Kit	Part number
Tip-Loc Bushing & Set Screw , 6 mm	47-0006-S
Tip-Loc Bushing & Set Screw , 7 mm	47-0007-S
Tip-Loc Bushing & Set Screw , 8 mm	47-0008-S
Tip-Loc Bushing & Set Screw , 9 mm	47-0009-S
Tip-Loc Bushing & Set Screw , 10mm	47-0010-S
Tip-Loc Bushing & Set Screw , 11 mm	47-0011-S
Tip-Loc Bushing & Set Screw , 12 mm	47-0012-S
Tip-Loc Bushing & Set Screw , 13 mm	47-0013-S
Tip-Loc Bushing & Set Screw , 14 mm	47-0014-S
Tip-Loc Bushing & Set Screw , 15 mm	47-0015-S
Tip-Loc Bushing & Set Screw , 16 mm	47-0016-S



Tip-Loc Clamp
(80-3891)

The Tip-Loc Bushing is implanted using the Tip-Loc Clamp, a Near Cortex Drill, and a Far Cortex Drill. The Tip-Loc Clamp is entirely radiolucent to aid in visualization under fluoroscopy and includes a central cannula that allows for +/- 2 mm of adjustment to center and align the bushing with the nail tail.



FFN Near Cortex Drill
(80-3696)



FFN Far Cortex Drill
(80-3697)

Ulna Nail 2 System Associated Acumed Products

Acutrak 2® Headless Compression Screw System



Acutrak 2 Screws	Diameter	Length	
Micro	Tip: 2.5 mm Tail: 2.8 mm	1 mm increments 8–14 mm	2 mm increments 14–30 mm
Mini	Tip: 3.5 mm Tail: 3.6 mm	2 mm increments 16–30 mm	
Standard	Tip: 4mm Tail: 4.1mm	2 mm increments 16–34 mm	
4.7	Tip: 4.5 mm Tail: 4.7 mm	2 mm increments 20–30 mm	5 mm increments 30–50 mm
5.5	Tip: 5.2 mm Tail: 5.5 mm	5 mm increments 25–60 mm	
7.5	Tip: 7.0 mm Tail: 7.5 mm	5 mm increments 40–120 mm	

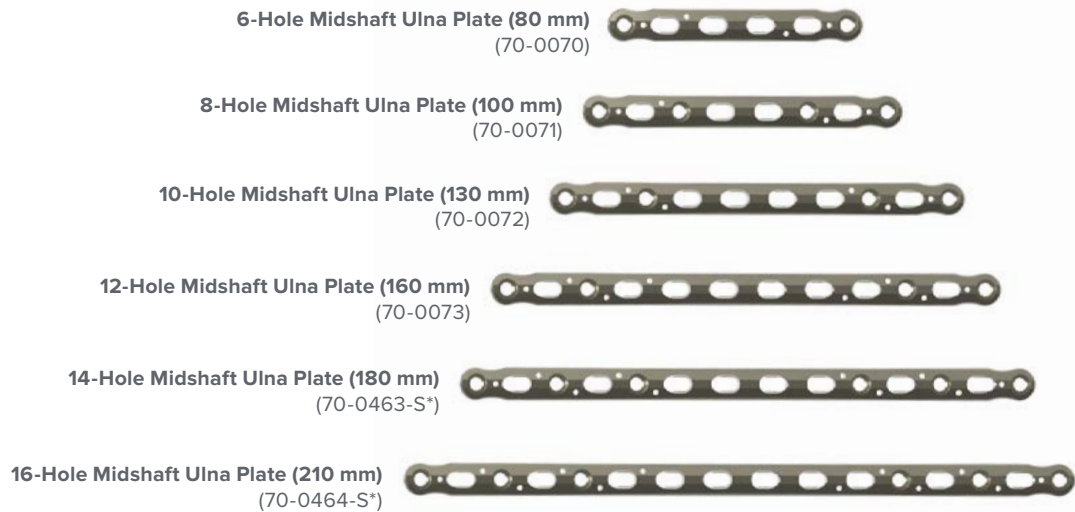
Ulna Nail 2 System Associated Acumed Products [continued]

Anatomic Midshaft Forearm Plating System

Dorsolateral Midshaft Radius Plates



Midshaft Ulna Plates



Volar Midshaft Radius Plates



*Optional, sterile-packed only

Competitive Comparison

	Acumed Ulna Nail 2 System	DePuy Synthes Titanium Elastic Nail (TEN) System
Material	Titanium	Titanium
Distal Locking Option	Tip-Loc™ Bushing & Set Screw (Optional)	No
Nail Size (Diameter)	3.0 mm, 3.6 mm, 4.0 mm	1.5, 2.0, 2.5, 3.0, 3.5, 4.0 mm
Nail Size (Length)	120, 170, 190, 210, 230, 250, 270 mm	Cut to Length (1.5 mm: max 300 mm, 2.0–4.0 mm: max 440 mm)
Screws	3.5 mm Nonlocking Hexalobe Screws (8–65 mm) 3.5 mm Headless Hexalobe Screws (12–65 mm)	No screws in system
Features	3.5 mm Headless Hexalobe Screws Straight nail for proximal olecranon fractures Threaded locking holes Distal locking option available with Tip-Loc	“Elastic” nail is designed to conform to anatomy of bone
Benefits	3.5 mm Headless Hexalobe Screws are designed to minimize soft-tissue irritation Straight nail designed to address more-proximal olecranon fractures Threaded locking holes provide a fixed angle construct Optional Tip-Loc Bushing & Set Screw allows the nail to achieve two points of fixation, both proximal and distal, of rigid fixation throughout the entire nail within the canal	The elastic flexible nails are bent and inserted into the medullary canal. This elastic deformation within the medullary canal creates a bending moment within the long bone that is not rigid, but that is stable enough to reduce and fix the fracture
Product Notes	The Ulna Nail 2 includes three nail diameters and seven length options, streamlined instrumentation to assist in the operative room, multiple threaded holes within the nail that engage the interlocking screws, headless hexalobe screws to minimize soft-tissue irritation, and the option to lock the nail distally to provide two points of rigid fixation throughout the entire nail within the canal	A nonanatomic solution for intramedullary fixation, the Synthes TENS nail is indicated primarily for pediatrics but is also used for osteosynthesis of the clavicle, forearm, and humerus fractures in adults. The simple design is amenable to several indications and features a distal “hook” that facilitates nail insertion and sliding along the medullary canal. This product is designed with developmental growth plates in mind and therefore cannot offer the stability or reduction that other products are able to.

Clinical Data Influence

Acumed Intramedullary Nail for the Treatment of Adult Diaphyseal Both-Bone Forearm Fractures

The following clinical study represents Acumed's first-generation intramedullary ulna nail.

Abstract

Objective:

To evaluate the results of Acumed intramedullary nail for the treatment of adult diaphyseal fractures of both-bone forearm fractures.

Methods:

From January 2009 to December 2016, 86 adult patients with both forearm fractures were treated by intramedullary nail including 54 males and 32 females with an average age of 36.8 years old ranging from 18 to 72 years old; There were 50 cases on the right and 36 cases on the left. The operation time, blood loss and X-ray expose time intra-operation, time of fracture union, complications, DASH (Disabilities of the Arm, Shoulder and Hand questionnaire), Grace-Eversman criteria were recorded to evaluate the clinical outcomes of intramedullary nail for the treatment of forearm fractures.

Results:

All patients were followed up from 48 to 144 weeks with an average of 86.8 weeks; the blood loss intraoperation was 30 to 80 ml with an average of 52 ml; the the X-ray expose time was 1 to 6 min with an average of 2.5 min; the operation time was 31 to 55 min with an average of 46 min; Among them, 85 cases healed successfully, the union time was 10 to 16 weeks with an average of 13.3 weeks. There were 1 case of hypertrophic nonunion, 1 case of Ulnar radial bone bridge formation, and 1 case of extensor hallucis longus tendon injury. The DASH score was 4 to 37 (means 15.6); according to Grace-Eversman criteria, the results were excellent in 65 cases, good in 15, acceptable in 5, poor in 1.

Conclusions:

Intramedullary fixation method in treating both-bone forearm fractures has advantages of closed application, short operation time, little complication, and clinical outcomes is satisfied.

Reference

He HY, Zhang JZ, Wang XW, Liu Z. Zhongguo Gu Shang, China Journal of Orthopedics and Traumatology. 2018;31(9):803-807. doi:10.3969/j.issn.1003-0034.2018.09.005

501(k) Clearance Information



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

February 5, 2015

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

Re: K143276
Trade/Device Name: Acumed Small Bone IM Nail System
Regulation Number: 21 CFR 888.3020
Regulation Name: Intramedullary fixation rod
Regulatory Class: Class II
Product Code: HSB
Dated: November 12, 2014
Received: November 14, 2014

Dear Mr. Wolf:

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

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

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

501(k) Clearance Information [continued]

Page 2 – Mr. Nathan Wolf

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

Lori A. Wiggins -S

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

Enclosure

501(k) Clearance Information [continued]

Acumed Small Bone IM Nail System 510(k)

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)

K143276

Device Name

Acumed Small Bone IM Nail System

Indications for Use (Describe)

The Acumed Small Bone IM Nail System is intended for fixation of fractures and osteotomies of the fibula, radius, and ulna, including fractures where the medullary canal is narrow or flexibility of the implant is paramount.

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

Prescription Use (Part 21 CFR 801 Subpart D)

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

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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501(k) Clearance Information [continued]

Acumed Small Bone IM Nail System
510(k) Notification

510(k) Summary

Contact Details

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

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

Date Prepared: 12 November 2014

Device Name

Trade Name: Acumed Small Bone IM Nail System

Common Name: Intramedullary Fixation Rod/Pin

Classification: 21 CFR 888.3020, Intramedullary Fixation Rod

Class: Class II

Product Code: HSB

Legally Marketed Predicate Device(s)

The Synthes Elastic Intramedullary Nail (EIN), cleared in 1997 (K971783), the Synthes EIN End Cap, cleared in 2008 (K082148), and the Acumed Small Bone Locking Rod System II, cleared in 2003 (K031438) serve as the predicate devices.

Device Description

The Acumed Small Bone IM Nail is a titanium alloy (Ti-6Al-4V) intramedullary rod/nail manufactured in multiple lengths (110mm to 270mm) and diameters (2.6mm to 4.0mm). The nails have openings used in conjunction with titanium alloy cortical screws, which lock them in place. The nails are compatible with an optional far-end locking (FEL) bushing and set screw that provide a locking option at the distal end of the nail. The nails are also compatible with optional end caps that thread into the proximal portion of the nail to provide additional length if desired. All implants are provided both sterile and non-sterile.

501(k) Clearance Information [continued]

Acumed Small Bone IM Nail System
510(k) Notification

Intended Use/Indications for Use

The Acumed Small Bone IM Nail System is intended for fixation of fractures and osteotomies of the fibula, radius, and ulna, including fractures where the medullary canal is narrow or flexibility of the implant is paramount.

Substantial Equivalence Comparison

In consideration of the comparisons given herein, the Acumed Small Bone IM Nail System has been determined to be substantially equivalent to its predicate devices, the Synthes EIN (K971783), Synthes EIN End Cap (K082148), and Acumed Small Bone Locking Rod System II (K031438). Substantial equivalence was determined due to similarities in materials, technology, function, and dimensions.

Non-clinical Testing

Comparative testing between the Acumed Small Bone IM Nailing system and a predicate device was conducted as per ASTM F1264-03. The test data showed the Acumed Small Bone IM Nail was substantially equivalent to the predicate device in a static four-point bend test, static torsion test, and bending fatigue test as described herein.



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

Dedicated to Excellence

From manufacturing to business practices to product innovation, Acumed has an unwavering commitment to excellence. It is reflected in the honors received from industry peers and in the performance of our suite of surgical fixation solutions.



The AME Manufacturing Excellence Award

In 2011, Acumed received the AME Manufacturing Excellence Award, an honor recognizing North American manufacturing sites that have demonstrated operational excellence through continuous improvement, best practices, creativity, and innovation. This award supports AME's vision, mission and values of inspiring commitment to enterprise excellence through shared learning and access to best practices.

The Association for Manufacturing Excellence is North America's premier organization for the exchange of knowledge in Organizational Excellence through the implementation of techniques such as Lean Tools, Leadership, Lean Product Development, Lean Supply Chain, and Lean Accounting.



The Frost & Sullivan Manufacturing Leadership 100 Operational Excellence Award

In 2013, Acumed received the Frost & Sullivan Manufacturing Leadership 100 award for Operational Excellence, an honor recognizing the top 100 global manufacturing companies who are shaping the future through projects that deliver outstanding value, innovation, and return on investment.

Frost & Sullivan Manufacturing Leadership 100 is the world's first member-driven leadership network with knowledge in manufacturing leadership. It was created through a global community of executives working within the manufacturing industry.

A Leader in Product Development and Innovation

Acumed began developing products for elbow and forearm fixation in 1999. Since then, Acumed has grown to become one of the technology leaders in solutions for the operative treatment of displaced elbows and forearm fractures.¹ We will continue to devote resources to the development of implants that aid in improving patient outcomes and advance the field of upper extremity orthopaedic surgery.

1. iData Research Inc. 2012. U.S. Market for Small Bone & Joint Orthopedic Devices. Retrieved March 26, 2013 from www.idataresearch.net

Dedicated to Excellence [continued]

Industry Compliance

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

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



Transparency in Business Practice

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

A Commitment to Social Responsibility

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

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

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





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GEN10-17-A | Effective: 2020/10 | © 2020 Acumed® LLC

Competitive Comparison Source

DePuy Synthes Titanium Elastic Nail (TEN) System Surgical Technique DSUS/TRM/0916/1030; 2017