acumed®

Fibula Nail 2 System

with Tip-Loc™ Technology

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.

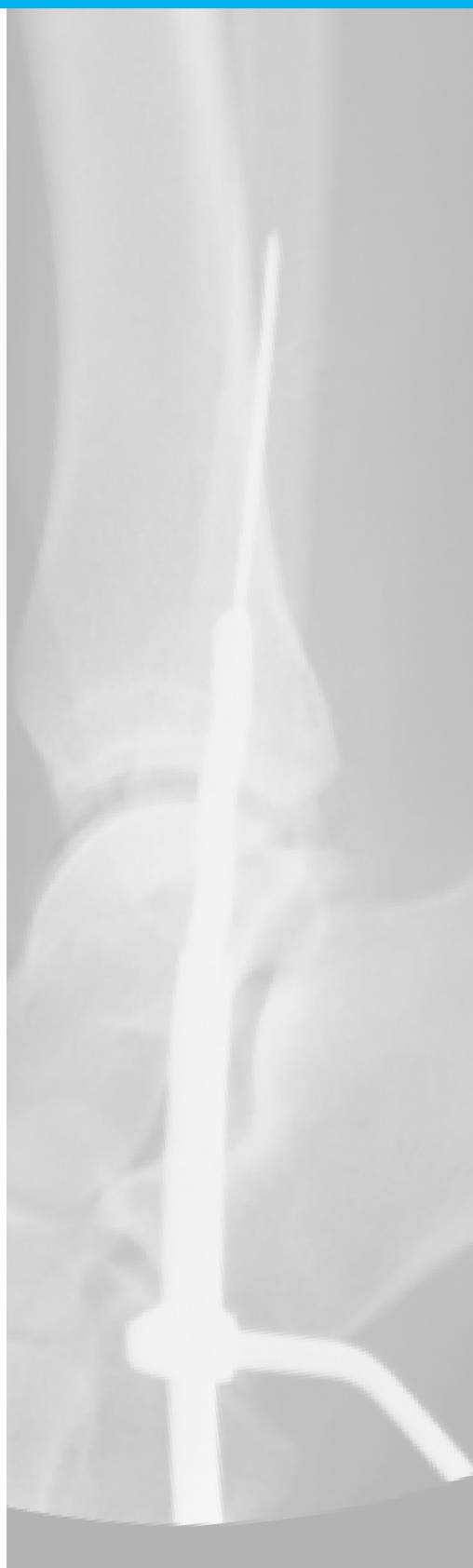
Acumed Fibula Nail 2 System

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 Fibula Nail 2 is designed to address simple, transverse, and short oblique fractures as well as osteotomies of the fibula.

The system includes three nail diameters and four length options, power reamers and carbon fiber radiolucent targeting guides to streamline the procedure, 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 proximally, providing additional fixation within the canal.

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



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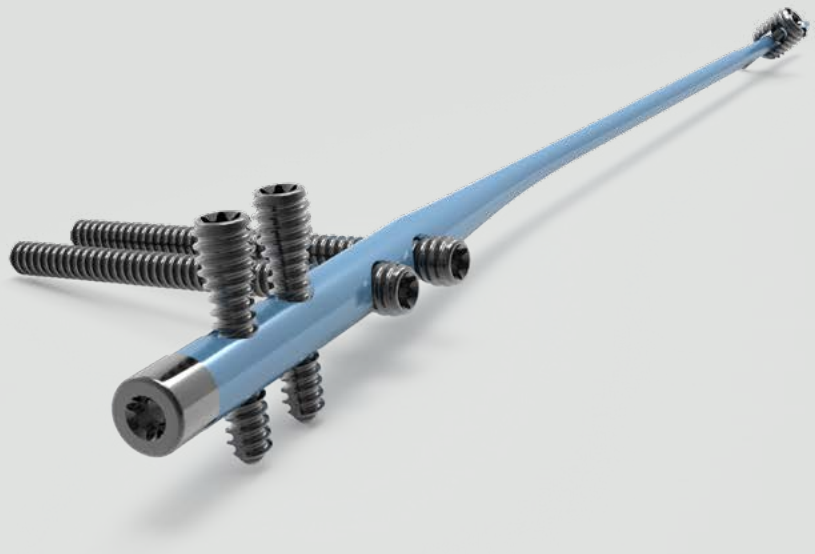


System Overview

Fibula Nail 2 Overview

The Acumed Fibula Nail 2 offers a less invasive and less prominent alternative to open reduction internal fixation (ORIF) for unstable fibula fractures. Intramedullary nailing of the fibula may serve as an attractive option vs. traditional plating, particularly in the elderly or those patients with overlying skin conditions or comorbidities, such as diabetes.[1] Hardware under the lateral malleolar incision is also a common source of skin and soft-tissue irritation, and the resulting discomfort that require costly revision surgery to remove prominent metal work.[1]

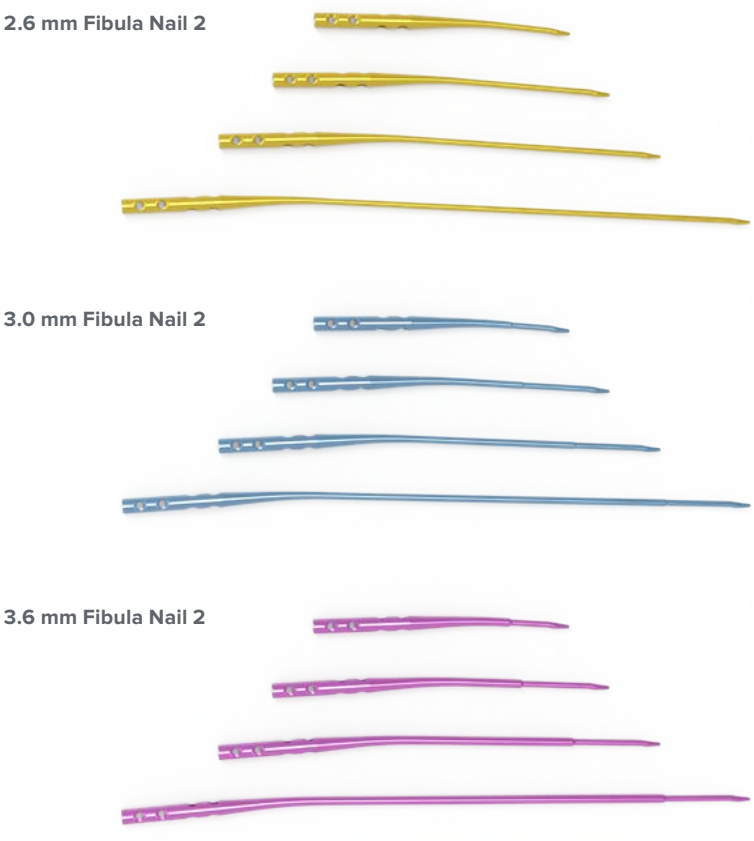
The Acumed Fibula Nail 2 is designed to address simple, transverse, and short oblique fractures as well as osteotomies of the fibula.

The Fibula Nail 2 includes:

- 12 nails offered in three diameters and four lengths including a small 2.6 mm diameter
- 5° bend in the nail designed to accommodate the shape of the intramedullary canal
- Power reamers and carbon fiber radiolucent targeting guides to streamline the procedure
- Threaded holes within the nail that engage the interlocking screws
- Two A/P and two L/M hole options
- L/M holes angled 8° superior to avoid the joint space and allow for syndesmotic reduction
- Headless hexalobe screws aimed to minimize soft-tissue irritation
- Option to lock the nail proximally, providing additional fixation within the canal

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

Note: All nail tail diameters are 6.35 mm



Fibula Nail 2 implants accept:

- 3.5 mm Headless Hexalobe Screws
- 3.5 mm Nonlocking Hexalobe Screws

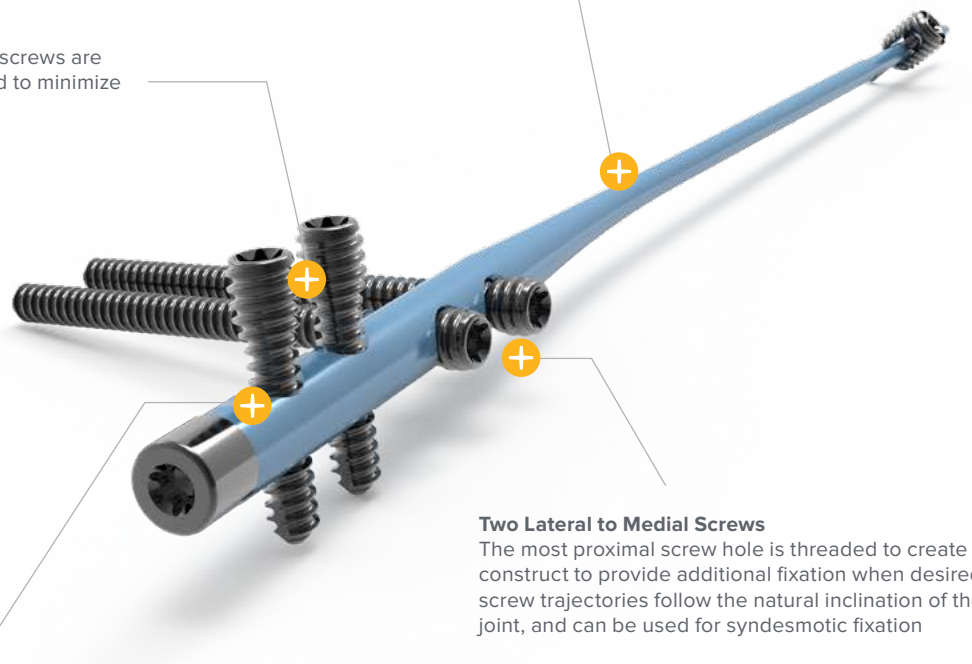
Indications for Use

The Acumed Fibula and Forearm Nail 2 Base Set 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

Nail Bend
The nail's 5° bend is designed to accommodate the shape of the intramedullary canal

Low-Profile Screws
3.5 mm headless hexalobe screws are low-profile and are intended to minimize soft-tissue irritation



Two Lateral to Medial Screws
The most proximal screw hole is threaded to create a locking construct to provide additional fixation when desired. Both screw trajectories follow the natural inclination of the tibio talar joint, and can be used for syndesmotic fixation

Fixed-Angle Screw Holes
Two threaded anterior to posterior fixed-angle screw holes

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.

3.5 mm Headless Hexalobe Screws
12–65 mm
(3018-470XX)

3.5 mm Nonlocking Hexalobe Screws
8–65 mm
(30-02XX)

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 fibula nail. End caps assist in limiting ossification over the 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]

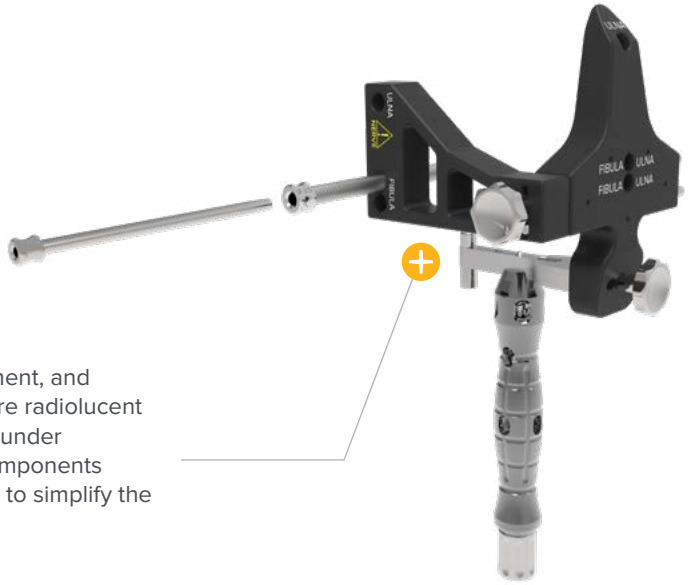
The Fibula Nail 2 nails are delivered in sterile packaging and are designed to be used in conjunction with the Fibula and Forearm Nail 2 Base Set. This set includes shared instrumentation to implant the Fibula Nail 2, Ulna Nail 2, and screws.

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 2.7 mm Reamer (80-2459)	2.6 mm Fibula Nail 2 (4010-26XXN-S)
FFN 3.1 mm Reamer (80-2460)	3.0 mm Fibula Nail 2 (4010-30XXN-S)
FFN 3.7 mm Reamer (80-2461)	3.6 mm Fibula Nail 2 (4010-36XXN-S)



Radiolucent Carbon Fiber Targeting Guides

Both the primary targeting guide, which aids in L/M screw placement, and secondary targeting guide, which aids in A/P screw placement, are radiolucent to allow for uninhibited viewing of the nail and screw positioning under fluoroscopy to ensure correct placement. The targeting guide components were designed to only allow assembly in one orientation in order to simplify the process for the scrub tech.

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 fibula nail 2 if necessary.

Key System Features [continued]

Optional Tip-Loc™ Bushing & Set Screw

The Fibula Nail 2 offers the option to lock the nail proximally, providing additional fixation within the canal.

The Tip-Loc Bushing and Tip-Loc Set Screw sit centrally within the last 1.5" of the nail. The bushings are available in 1 mm size increments ranging from 6 mm through 16 mm in length and are selected according to the fibular canal size.

Tip-Loc Bushing (47-00XX-S)
- Titanium
- 6.35 mm in diameter

Tip-Loc Set Screw (47-00XX-S)
- 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 tip.

FFN Near Cortex Drill
(80-3696)

FFN Far Cortex Drill
(80-3697)

Fibula Nail 2 System Associated Acumed Products

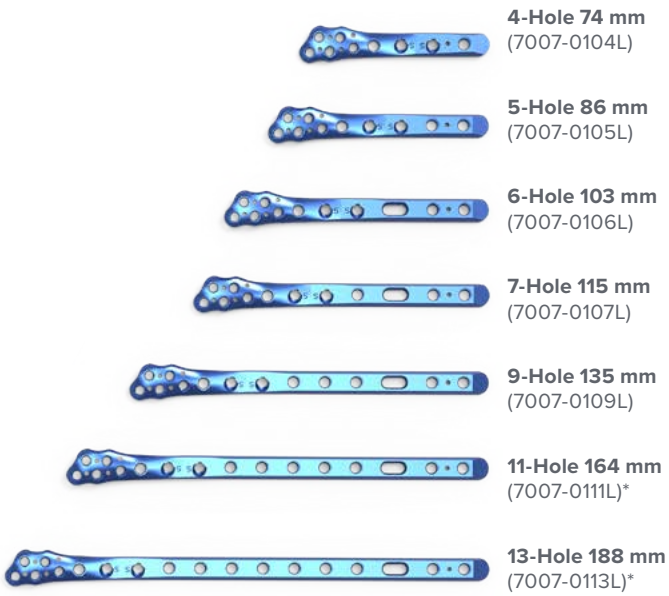
Acutrak 2® Headless Compression Screw System

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	

Fibula Nail 2 System Associated Acumed Products [continued]

Ankle Plating System 3

Lateral Fibula Plates



4-Hole 74 mm
(7007-0104L)

5-Hole 86 mm
(7007-0105L)

6-Hole 103 mm
(7007-0106L)

7-Hole 115 mm
(7007-0107L)

9-Hole 135 mm
(7007-0109L)

11-Hole 164 mm
(7007-0111L)*

13-Hole 188 mm
(7007-0113L)*

13-Hole 188 mm
(7007-0113R)*

11-Hole 164 mm
(7007-0111R)*

9-Hole 135 mm
(7007-0109R)

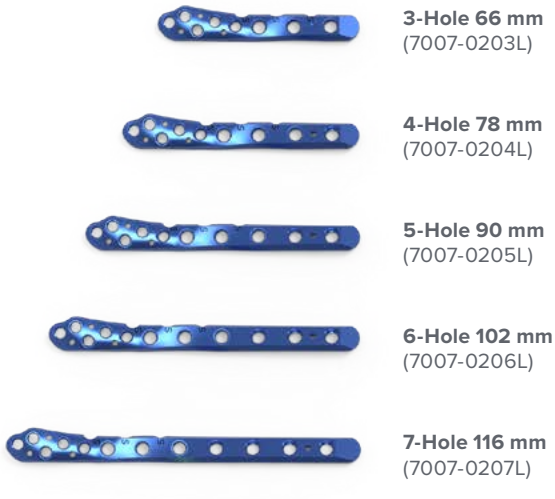
7-Hole 115 mm
(7007-0107R)

6-Hole 103 mm
(7007-0106R)

5-Hole 86 mm
(7007-0105R)

4-Hole 74 mm
(7007-0104R)

Posterolateral Fibula Plates



3-Hole 66 mm
(7007-0203L)

4-Hole 78 mm
(7007-0204L)

5-Hole 90 mm
(7007-0205L)

6-Hole 102 mm
(7007-0206L)

7-Hole 116 mm
(7007-0207L)

7-Hole 116 mm
(7007-0207R)

6-Hole 102 mm
(7007-0206R)

5-Hole 90 mm
(7007-0205R)

4-Hole 78 mm
(7007-0204R)

3-Hole 66 mm
(7007-0203R)

4.0 mm Cannulated Screws

System	Specifications
Ankle Plating System 3	36 mm Long Thread (1/2 Threaded) 42 mm Long Thread (1/2 Threaded) 48 mm Long Thread (1/2 Threaded)
Standalone 4.0 mm Cannulated Screw Caddies	10–72 mm Short Thread (1/3 threaded) 16–72 mm Long Thread (1/2 threaded) 10–60 mm (2 mm increments) 60–72 mm (4 mm increments)

Fibula Nail 2 System Associated Acumed Products [continued]

Ankle Plating System 3

Posterolateral Distal Tibia Plates

3-Hole 48 mm
(7007-0303L)

4-Hole 60 mm
(7007-0304L)

4-Hole 60 mm
(7007-0304R)

3-Hole 48 mm
(7007-0303R)

Posteromedial Distal Tibia Plates

3-Hole 49 mm
(7007-0403L)

3-Hole 49 mm
(7007-0403R)

Hook Plates

2 Hole 43 mm
(7007-0602)

3-Hole 57 mm
(7007-0603)

Locking Peg Hook Plates

2-Hole 45 mm
(7007-0702)

3-Hole 59 mm
(7007-0703)

One-Third Tubular Plates

One-Third Tubular Plate 3-Hole 37 mm
(7008-0103)

One-Third Tubular Plate 4-Hole 49 mm
(7008-0104)

One-Third Tubular Plate 5-Hole 61 mm
(7008-0105)

One-Third Tubular Plate 6-Hole 73 mm
(7008-0106)

One-Third Tubular Plate 7-Hole 85 mm
(7007-0107)

One-Third Tubular Plate 8-Hole 97 mm
(7008-0108)

One-Third Tubular Plate 10-Hole 121 mm
(7008-0110)

One-Third Tubular Plate 12-Hole 145 mm
(7008-0112)

Medial Anti-Glide Plate

4-Hole 70 mm
(7007-0504)

Fibula Nail 2 System Associated Acumed Products [continued]

Ankle Plating System 3

2.7 mm Fragment Plates

Fragment Plate 2.7 mm, 60 mm
(7010-0106N)

L Fragment Plate 2.7 mm Left, 61 mm
(7010-0107L)

L Fragment Plate 2.7 mm Right, 61 mm
(7010-0107R)

T Fragment Plate 2.7 mm, 61 mm
(7010-0108N)

Locking Ankle Plating System

7-Hole LPL Anterior Tibia Plate
(70-0247)

5-Hole LPL Anterior Tibia Plate
(70-0245)

7-Hole LPL Medial Tibia Plate
(70-0227)

9-Hole LPL Medial Tibia Plate
(70-0229)

9-Hole Locking Lateral Fibula Plate
(70-0169)

11-Hole Locking Lateral Fibula Plate
(70-0171)

13-Hole Locking Lateral Fibula Plate
(70-0173)

13-Hole LPL Lateral Fibula Plate
(70-0153)

11-Hole LPL Lateral Fibula Plate
(70-0151)

9-Hole LPL Lateral Fibula Plate
(70-0149)

7-Hole LPL Lateral Fibula Plate
(70-0147)

5-Hole LPL Lateral Fibula Plate
(70-0145)

Competitive Comparison

	Acumed® Fibula Nail 2 System	Arthrex FibuLock Fibular Nail System	Advanced Orthopaedic Solutions Fibular Nail System
Material	Titanium	Stainless Steel	Titanium
Proximal Locking Option	Yes - Tip-Loc™ Bushing & Set Screw	Yes - Deployable talons	No
Nail Size (Diameter)	2.6, 3.0, 3.6 mm	3.0, 3.8 mm	2.5 mm solid nail 3.0 mm cannulated nail
Nail Size (Length)	110, 145, 190, 270 mm	130, 180 mm	110, 145, 185, 225 mm
Screws	3.5 mm Nonlocking Hexalobe Screws (8–65 mm) 3.5 mm Headless Hexalobe Screws (12–65 mm)	2.7 mm Non-locking Cortical Screws (12–24 mm) 3.5 mm Non-locking Cortical Screws (14–80 mm)	2.5 mm solid nail Right and left specific
Features	3.5 mm Headless Hexalobe Screws Two A/P and Two L/M screw hole options Threaded locking holes Proximal locking option available with Tip-Loc™	Self-tapping screws Deployable talons for proximal locking	2.7 and 3.5 mm screws
Benefits	3.5 mm Headless Hexalobe Screws are designed to minimize the risk of soft-tissue irritation Two L/M syndesmotic screws have a 8° superior tilt 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	Proximal talons are designed to “hug” the triangular fibula canal and offer rotational stability[1]	2.5 mm solid nail offers an option for petite fibular canals Two syndesmotic screws have 5° superior tilt and 20° anterversion Oblique A/P screw creates additional point of fixation
Product Notes	The Fibula Nail 2 includes three nail diameters and four 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 proximally to provide two points of rigid fixation within the canal.	The FibuLock Fibular Nail offers the ability to achieve both proximal and distal fixation along with syndesmotic. Multiplanar distal fixation allows for treatment of almost any ankle fracture. The nail insertion outrigger can provide compression if needed and ensure syndesmosis fixation is parallel to the mortise with 3.5 mm screws.	The AOS fibular nail facilitates the maintenance of length, proper alignment, and rotation while being minimally invasive

Clinical Data Influence

Ankle fractures are the fourth most common fracture to require operative repair[6] with an estimated fracture rate of 187 per 100,000 people per year[6] and an increase of incidence in the elderly[1]. Additionally, ankle fractures may be further complicated by instances of poor bone quality, overlaying skin conditions, and other comorbidities. Fibula nailing, including the Fibula Nail 2 Set, provides a minimally invasive alternative to traditional open reduction and internal fixation (ORIF).

Ankle fractures involve the distal end of the tibia and fibula, as well as associated soft-tissues, and typically arise from rotational forces during daily activity and sports. Approximately 82% of all ankle fractures involve the fibula[3] and surgical complication rates are reported to be as high as 40%, including a 23% incidence rate of implant removal due to prominent hardware related pain.[1,7] Appleton, et al. stated that "given the difficulties encountered with operating on (the) elderly, including osteoporotic fractures, the higher incidence of wound complications, loss of fixation, and prominent, painful metal work, the use of a fibula nail is appealing as it affords stable fixation with minimal surgical exposure and less prominent metal work."[1] Bugler, et al. mirrors this idea stating that the use of a fibula nail "has the potential to reduce the incidence of complications."[4]

Additional patient populations, such as diabetics, may benefit from a minimally invasive approach provided with the use of fibula nailing with reduced risk of complications vs. plating with ORIF.[4] Comorbidities associated with systemic diseases such as diabetes and neuropathy provide challenges to surgeons when considering the risk of complications and infection in a patient's overall treatment plan. In a study by Ashman, et al., which examined fibular nailing in diabetic patients, it was noted that "patients with diabetes…had significantly increased in-hospital mortality, high rates of post-operative complications including infection and amputation, longer average hospital length-of-stay, higher rates of 'non-routine' discharges and higher overall average cost of care."[5] In the same study of diabetic fibular fractures, Ashman, et al. found that "…following fibular nail fixation for unstable ankle fractures in high-risk patients with diabetes, there was a low re-operation rate for wound complications, low overall complication rates, and in addition, favorable functional outcomes."[5] In a study by Bugler et al, treating unstable factures of the ankle with a technique utilizing a smaller incision size than traditional plating with ORIF, the risk of complications was reduced while maintaining fibular length rotation, which may allow for early weight bearing.[4]

The Fibula Nail 2 Set was built upon the foundation of 10+ years of success and surgeon feedback on the first generation Acumed Fibula Rod System. Improvements in the system include a greater range of implant sizes for varying patient anatomies and optimized surgical instrumentation to aid in streamlining the minimally invasive technique. The longevity of the first-generation Fibula Rod System has also led to multiple published clinical studies on the implant and minimally invasive technique.

501(k) Clearance Information [continued]

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

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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

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 managing foot and ankle fractures in 2000, followed by the introduction of the first-generation Fibula Rod System. Acumed has grown to become one of the technology leaders in solutions for foot and ankle fractures. We will continue to devote resources to the development of implants that aid in improving patient outcomes and advance the field of lower extremity orthopaedic surgery.

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.

The 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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Competitive Comparison Sources

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