Value Analysis Committee Resource Guide

THE AOS *Fibular* NAIL SYSTEM

AOS

ADVANCED ORTHOPAEDIC SOLUTIONS

AOS

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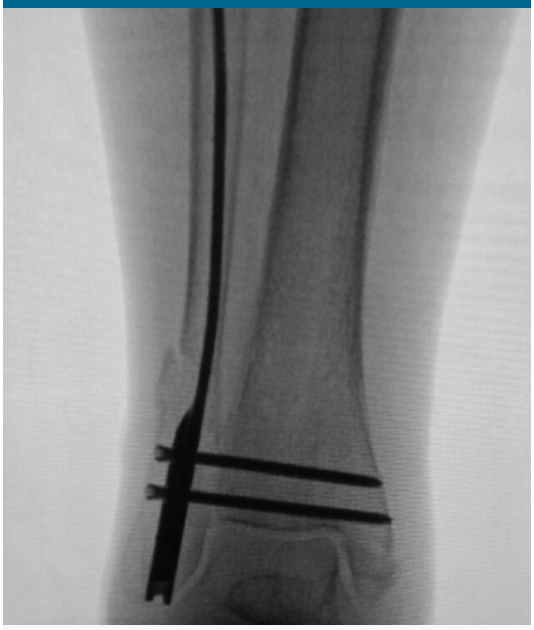
Advanced Orthopaedic Solutions designs, manufactures, and markets orthopaedic trauma products, specializing in intramedullary fixation devices for minimally invasive surgical procedures. We rely on surgeon input to create solutions which are less invasive, more cost effective, and reduce surgical OR time, without compromise to the patient.



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About Advanced Orthopaedic Solutions

AOS is entirely focused on the orthopaedic trauma industry. We base our success by relying on the expertise of the surgeon in developing new products and instruments for minimally invasive, precise and reproducible surgical procedures. Along with our surgeon champion base, AOS works with universities and research scientists to advance our knowledge and creativity in manufacturing improved product solutions. Our vertically integrated team enables the company to rapidly develop new products which are then clinically proven by experienced surgeons. AOS has a large base of manufacturing expertise within the U.S., utilizing 'state of the art' methods and practices that are compliant with US and International quality systems. Moreover, AOS's products are distributed worldwide through independent distributors and agents. By building on strong customer relationships, AOS strives to continue to improve every aspect of the way we do business.

Fibular Nail: Volume = Value Added

- Time Saving
  - ◊ Percutaneous Procedure
  - ◊ Wound Closure
- Infection Prevention
  - ◊ Fibular Technique allows for prevention of wound and infection complications
- Radiation
  - ◊ Guidewire eliminates radiation exposure through guided fracture reduction
- Cannulation: Nail vs Plate
  - ◊ 2 procedures in 1 with built-in syndesmotic capabilities
  - ◊ Intramedullary fixation reduces multiple screw techniques
  - ◊ More stable construct with fewer screws
- Reduced OR Time
  - ◊ Significantly decreases surgical procedure time
  - ◊ Percutaneous intramedullary fractures reduction versus ORIF
  - ◊ Greatly reduces sterile prep time through fewer surgical trays

Indications for Use:

The AOS Fibular Nail System is intended for fixation of fractures and osteotomies of the fibula, including fractures where the medullary canal is narrow or flexibility of the implant is paramount.

Fibular fractures are predominately fixed with plates. However, there are significant advantages, in some cases, for the nailing these same fractures. With leading champion surgeons who specialize in the area of small fractures, AOS has designed a system that has the same indications as plating but delivers anatomical advantages for reductions of fractures with consideration of patients with fragile bone structure.

Features & Benefits:

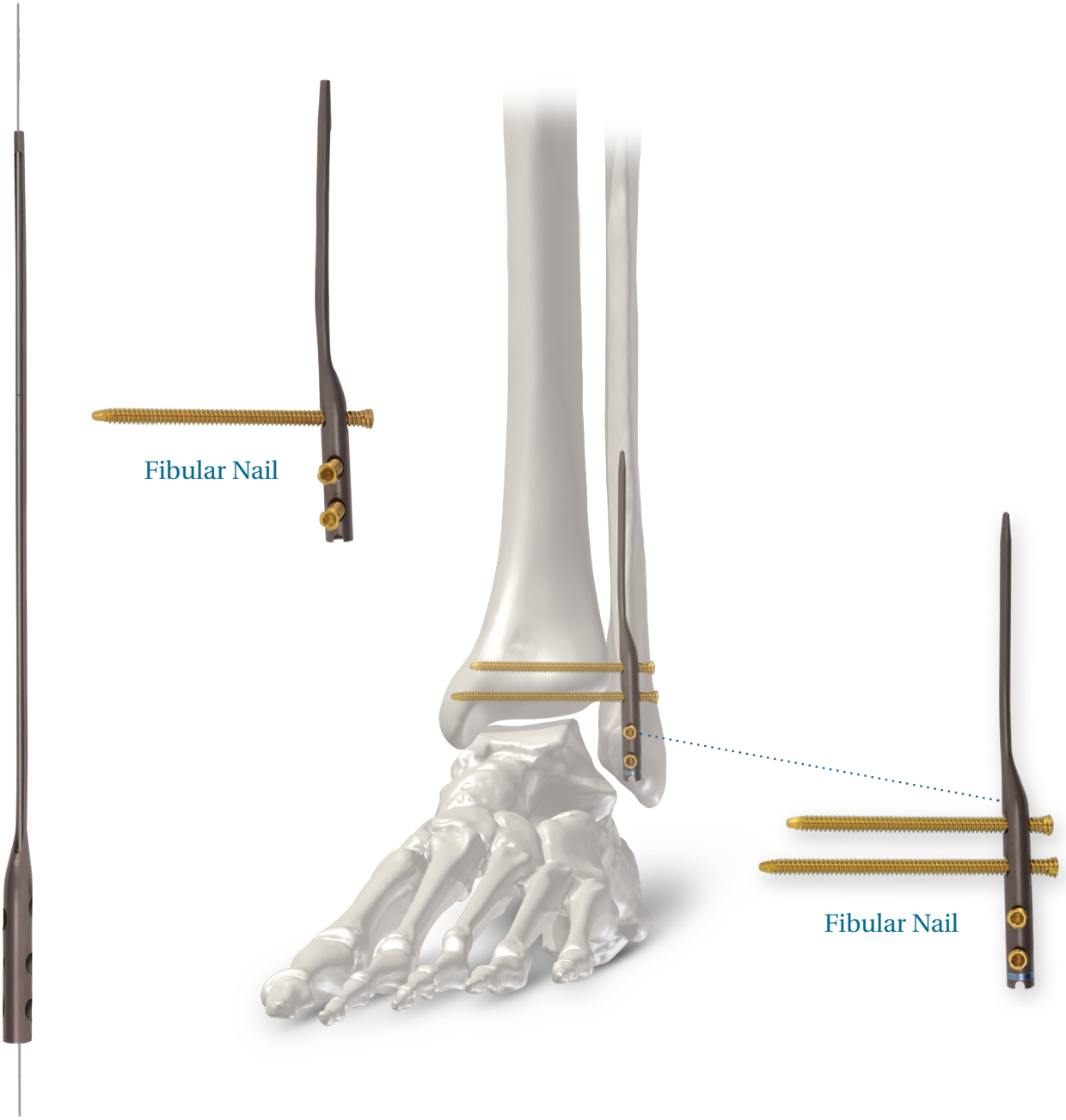
- Smaller shaft diameters and shorter proximal body options than the competition.
- **The Fibular Nail** has 2 Diameters, 2.5mm Solid Nail and 3.0mm Cannulated Nail.
- 3 Screw Configurations.
- 4 Lengths - 1 more than the competition 225mm.
- Side Specific to right and left anatomy for all three nail options.
- All Nails can be used in conjunction with the Fibonacci Lower Extremity Plates.
- **Significantly fewer wound complications** with nails.
- **Skin and Soft tissue trauma** is decreased because of less tissue dissection.
- **Nails lessen load bearing** throughout the healing process and as a result accelerate patient rehabilitation.
- **Proprietary Verbrugge Forceps**, 60° offset of Jaw.
- Variations in height of Proximal body to accommodate smaller anatomy.
- 48 different nail options to accommodate variations in patient anatomy and fracture types.
- **Countersink 3.5mm and 2.7mm Screws** eliminates soft tissue irritation from screw head prominence
- **Superior tilted and built-in Anteversion** of the syndesmotic screws for the fibular nail provide enhanced anatomical screw trajectories through the syndesmosis.

Product Overview:

AOS Fibular Nail System

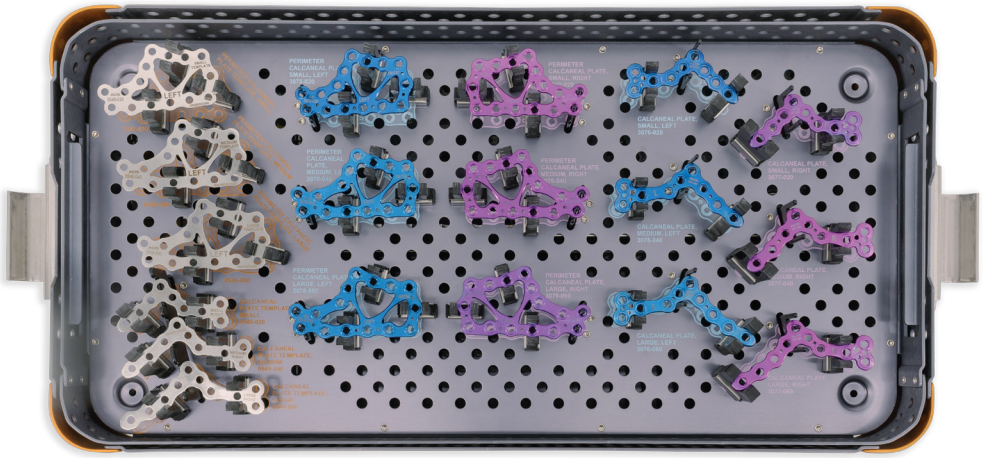
The AOS fibular nail facilitates the maintenance of length, proper alignment, and rotation while being minimally invasive.

- Side specific intramedullary nails for the fibula.
- The distal diameters of all nails range from 2.5mm / 3.0mm. Lengths range from 110mm – 225mm.
- The intramedullary nails (excluding the 2.5mm nail) features a proprietary cannulation that facilitates implantation over a 1.3mm Stainless Steel Guide Wire.
- All the intramedullary nails have a 6.0mm proximal diameter with holes that allow for 3.5mm and 2.7mm locking screws that provide additional fixation to the proximal section of nail.

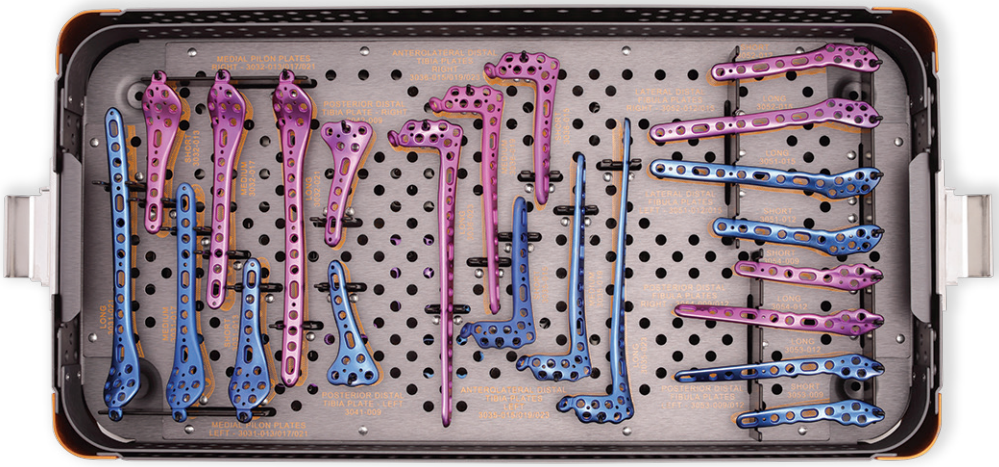


Associated AOS Products

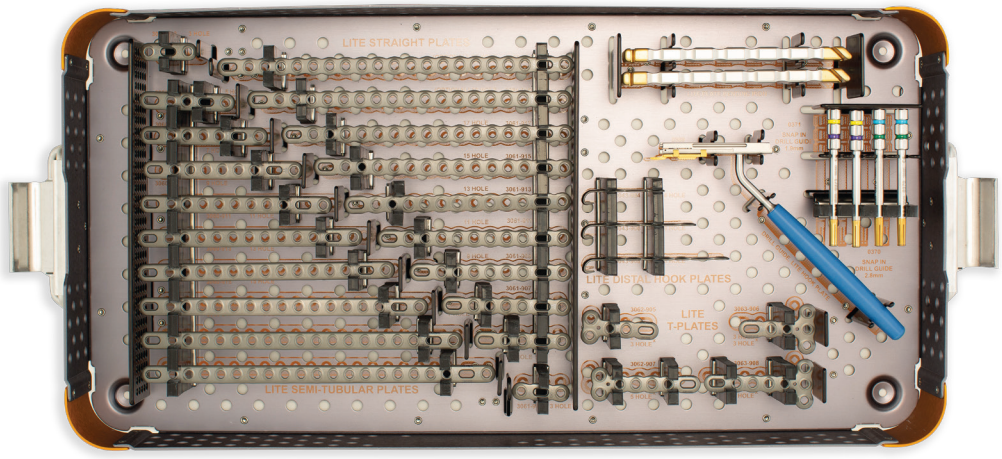
Fibonacci Calcaneal Plating System



Fibonacci Lower Extremity System



Fibonacci Lite System



Product Comparisons

	AOS Fibular Nail System	*Acumed® Fibular Rod System*
Screws		
Screw Diameter	2.7mm Countersink	Product Not Available
Screw Length	8-40mm	Product Not Available
Driver	Star T10 Driver	Product Not Available
Material	Titanium Alloy	Product Not Available

Screws		
Screw Diameter	3.5mm Countersink	3.5mm Locking
Screw Length	8-70mm	8-65mm
Driver	Star T10 Driver	2.5 mm Quick Release Solid Hex Driver
Material	Titanium Alloy	Titanium Alloy

Screw Fixation Patterns

	2 AP Screws and 1 Syndesmotic Screw	2 AP Screws and 1 Syndesmotic Screw
Length	110, 145, 185, 225mm	Product Not Available
Proximal Diameter	2.5mm, 3.0mm	Product Not Available
Cannulated Nail	3.0mm Cannulated Nail	Product Not Available
Distal Diameter	6.0mm	Product Not Available
Valgus Bend	3.5°	Product Not Available
Side Specific	Right & Left	Product Not Available
Material	Titanium Alloy	Product Not Available

Nails (Other)		
Nail Proximal Shaft Length	1.1"	Product Not Available
Nail Degree Anteversion	20°	Product Not Available

Screw Fixation Patterns

	2 AP Screws and 2 Syndesmotic Screw	2 AP Screws and 2 Syndesmotic Screw
Length	110, 145, 185, 225mm	110, 145, 180mm
Proximal Diameter	2.5mm, 3.0mm	3.0mm/3.6mm
Cannulated Nail	3.0mm Cannulated Nail	No
Distal Diameter	6.0mm	6.0mm
Valgus Bend	3.5°	5°
Side Specific	Right & Left	Product Not Available
Material	Titanium Alloy	Titanium Alloy

	AOS Fibular Nail System	Acumed® Fibular Rod System
Nails (Other)		
Nail Proximal Shaft Length	1.2”	Product Not Available
Nail Degree Anteversion	20°	25°

Screw Fixation Patterns

	2 AP Screws & 1 Oblique Screw	2 AP Screws & 1 Oblique Screw
Length	110, 145, 185, 225mm	Product Not Available
Proximal Diameter	2.5mm, 3.0mm	Product Not Available
Cannulated Nail	3.0mm Cannulated Nail	Product Not Available
Distal Diameter	6.0mm	Product Not Available
Valgus Bend	3.5°	Product Not Available
Side Specific	Right & Left	Product Not Available
Material	Titanium Alloy	Product Not Available

Nails (Other)		
Nail Proximal Shaft Length	1.5”	2.6”
Nail Degree Anteversion	20°	0°

	AOS Fibular Nail System	Arthrex FibuLock® Fibular Nail
Screws		
Screw Diameter	2.7mm Countersink	2.7mm Locking
Screw Length	8-40mm	12-24mm
Driver	Star T10 Driver	FibuLock Hexalobe Driver T10
Material	Titanium Alloy	Stainless Steel

Screws		
Screw Diameter	3.5mm Countersink	3.5mm Locking
Screw Length	8-70mm	14-60mm (then 5mm increments from 65-80mm)
Driver	Star T10 Driver	FibuLock Hexalobe Driver T10
Material	Titanium Alloy	Stainless Steel

Screw Fixation Patterns

	2 AP Screws and 1 Syndesmotic Screw	2 AP Screws and 1 Syndesmotic Screw
Length	110, 145, 185, 225mm	Product Not Available
Proximal Diameter	2.5mm, 3.0mm	Product Not Available
Cannulated Nail	3.0mm Cannulated Nail	Product Not Available

	AOS Fibular Nail System	*Arthrex FibuLock® Fibular Nail*
Distal Diameter	6.0mm	Product Not Available
Valgus Bend	3.5°	Product Not Available
Side Specific	Right & Left	Product Not Available
Material	Titanium Alloy	Product Not Available
Nails (Other)		
Nail Proximal Shaft Length	1.1"	Product Not Available
Nail Degree Anteversion	20°	Product Not Available

Screw Fixation Patterns

	2 AP Screws and 2 Syndesmotic Screw	2 LM Screws, 1 AP Screw, and 1 Syndesmotic Screw
Length	110, 145, 185, 225mm	130mm
Proximal Diameter	2.5mm, 3.0mm	3.0mm
Cannulated Nail	3.0mm Cannulated Nail	No
Distal Diameter	6.0mm	5.0mm
Valgus Bend	3.5°	6°
Side Specific	Right & Left	Right & Left
Material	Titanium Alloy	Stainless Steel
Nails (Other)		
Nail Proximal Shaft Length	1.2"	30mm (1.18")
Nail Degree Anteversion	20°	25.15°

Screw Fixation Patterns

	2 AP Screws and 2 Syndesmotic Screw	2 LM Screws, 1 AP Screw, and 1 Syndesmotic Screw
Length	110, 145, 185, 225mm	180mm
Proximal Diameter	2.5mm, 3.0mm	3.8mm
Cannulated Nail	3.0mm Cannulated Nail	No
Distal Diameter	6.0mm	6.0mm
Valgus Bend	3.5°	6°
Side Specific	Right & Left	Right & Left
Material	Titanium Alloy	Stainless Steel
Nails (Other)		
Nail Proximal Shaft Length	1.2"	40mm (1.575")
Nail Degree Anteversion	20°	25.15°

	AOS Fibular Nail System	*Arthrex FibuLock® Fibular Nail*
	Screw Fixation Patterns	
	2 AP Screws & 1 Oblique Screw	2 AP Screws & 1 Oblique Screw
Length	110, 145, 185, 225mm	Product Not Available
Proximal Diameter	2.5mm, 3.0mm	Product Not Available
Cannulated Nail	3.0mm Cannulated Nail	Product Not Available
Distal Diameter	6.0mm	Product Not Available
Valgus Bend	3.5°	Product Not Available
Side Specific	Right & Left	Product Not Available
Material	Titanium Alloy	Product Not Available
Nails (Other)		
Nail Proximal Shaft Length	1.5”	Product Not Available
Nail Degree Anteversion	20°	Product Not Available

DEPARTMENT OF HEALTH & HUMAN RESOURCES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue

Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

Advanced Orthopaedic Solutions, Inc. (AOS)
Alex Bhaskarla
Regulatory Affairs Manager
3203 Kashiwa St.
Torrance, California 90505

January 24, 2017

Re: K163014

Trade/Device Name: AOS Small Bone Nailing System
Regulation Number: 21 CFR 888.3020
Regulation Name: Intramedullary Fixation Rod
Regulatory Class: Class II
Product Code: HSB
Dated: October 7, 2016
Received: October 28, 2016

Dear Alex Bhaskarla:

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" (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 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,

Mark N. Mel

FDA

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

Enclosure

References

1. (https://www.acumed.net/products/foot-ankle/fibula-rod-system/) through their “Related Documents” Section and through this supportive document
2. (https://www.orthoaktiv.de/images/ortho/anleitungen/Fu%C3%9F-Sprungelenk_Fibulanagel.pdf)