acumed®

ExtremiLock™ Foot Plating System

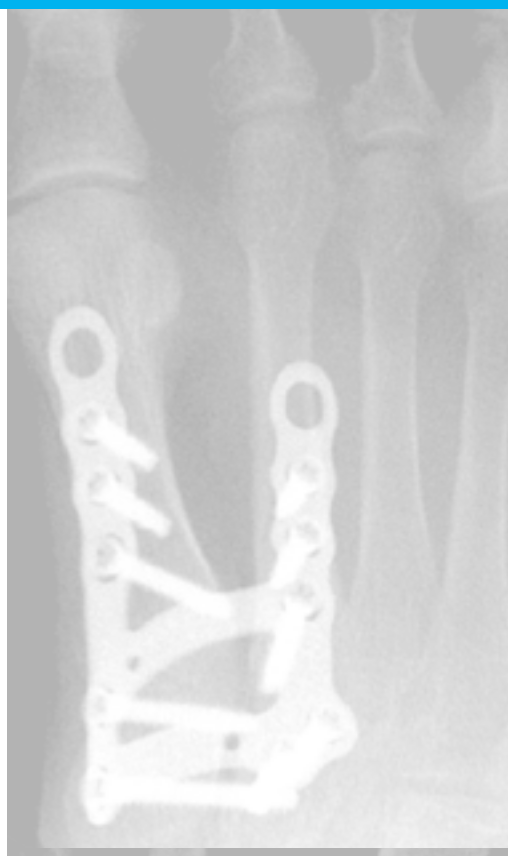
Lisfranc Plating System

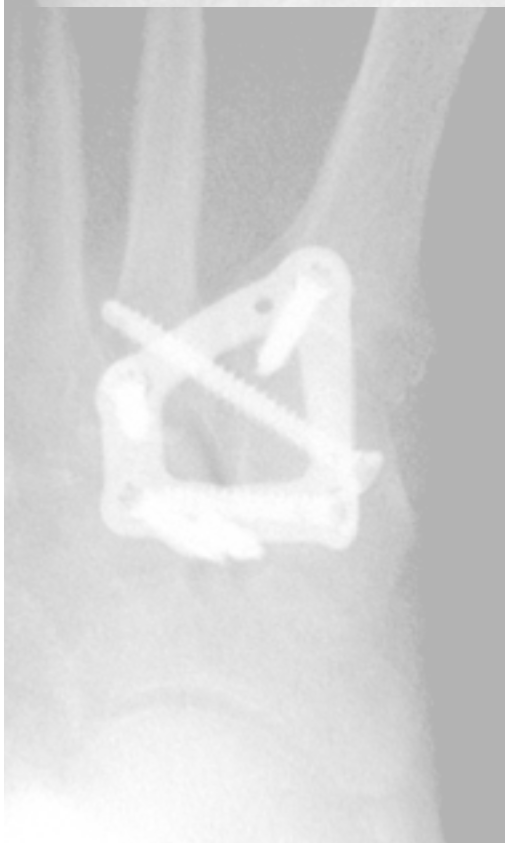
Value Analysis Committee Resource Guide

a Colson Medical | Marmon | Berkshire Hathaway Company

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.





OsteoMed® ExtremiLock Foot Plating System™

Lisfranc Plating System

Designed in conjunction with Lawrence Fallat, DPM, J. Robert Faux, MD, and Nirmal Tejwani, MD, the Lisfranc Plating System provides fixation for Lisfranc fractures-dislocations and fusions of the articulation between the first, second, and third metatarsal bones, and the cuneiform bones. This system offers the most complete selection of plates for a dorsal, dorsomedial and medial approach. The plate design allows for compression and stabilization of the TMT joint while allowing surgeons to visualize the affected area during the healing process.

The system offers a family of five plates that includes 25 left and right specific plate options in several sizes to fit various patient anatomies. The plates are low-profile and are anatomically contoured to fit the TMT joints. All plates offer universal plate holes accepting double lead 2.7 mm, 3.5 mm and/or 4.0 mm locking and nonlocking screws in any hole and up to 20° of variable angle locking in any direction (40° conical)

The system also provides a unique Lisfranc Targeting Guide that facilitates accurate Lisfranc screw fixation placement and trajectory for cases presenting with intermetatarsal instability. The guide is incredibly versatile, compatible with a wide range of screw sizes and types, making it the ideal instrument for any surgical situation.

The Lisfranc Plating System is used with the ExtremiLock Foot Plating System screws and instrumentation. The instrumentation was designed to assist with soft-tissue management, bone and plate manipulation, and screw insertion.

Indications for Use:
Refer to the provided Instructions for Use for the complete Indications, Contraindications, Warnings, and Instructions for Use, including cleaning and sterilization details.

	Definition
Warning	Indicates critical information about a potential serious outcome to the patient or the user.
Caution	Indicates instructions that must be followed in order to ensure the proper use of the device.
Note	Indicates information requiring special attention.

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Lisfranc Plating System Features

The Lisfranc Plating System is used with the ExtremiLock Foot Plating System screws and instrumentation. The instrumentation was designed to assist with soft-tissue management, bone and plate manipulation and screw insertion. All threaded holes accept 2.7 mm, 3.5 mm and/or 4.0 mm locking and nonlocking screws for patient-specific fixation.

Bridge Plating
Preserves joint surfaces

Multiple Fixation Points
Increased construct stability

Offers a reduction of intraoperative bending

Visualization Window
Allows for visualization of the TMT joint during the healing process

Multiple Distal Fixation Points
Multiple points of fixation on the metatarsal provides larger load distribution, excellent screw purchase on diaphyseal bone, and helps minimize metatarsal stress fractures

Oblong Compression Slot
Distal compression hole options providing 1—2 mm of compression across the TMT joints

1st—2nd Dorsal Plates, Left & Right Specific

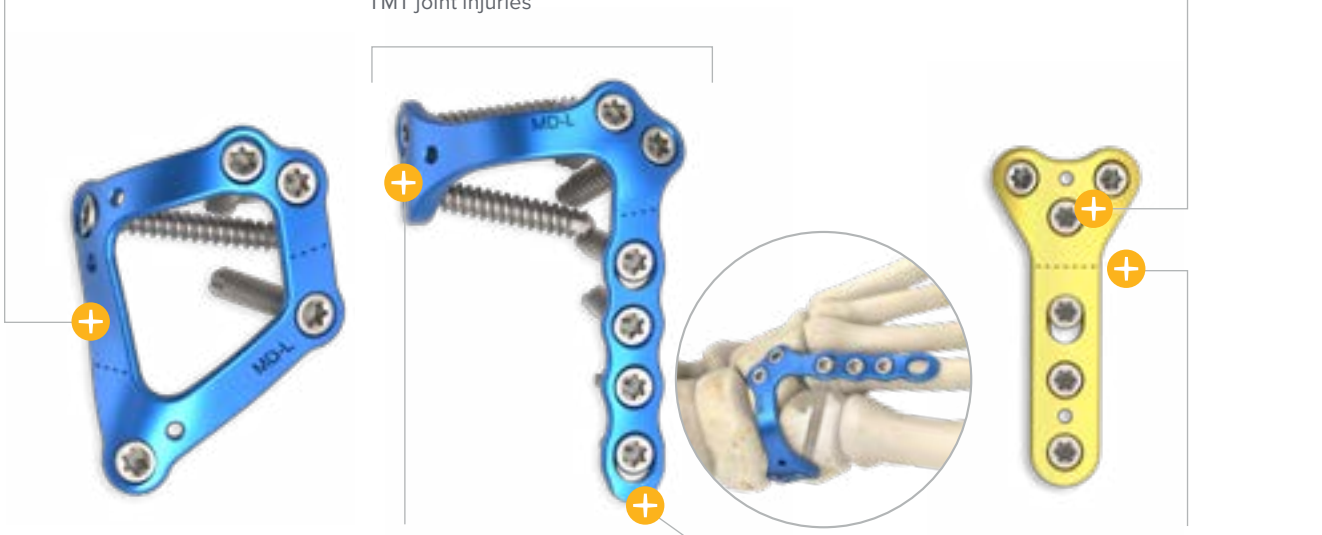
2nd—3rd Dorsal Plates, Left & Right Specific

Lisfranc Plating System Features [continued]

1st TMT Bridge
Allows room for interfragmentary screw placement and/or flexible fixation implant

Dorsal Bridge
Provides stable fixation between the middle and medial column for isolated TMT joint injuries

Lisfranc Screw Fixation
Distal hole trajectory allows the use of interfragmentary screws and/or flexible fixation implant for intermetatarsal instability fixation



Medial Fixation
Distal hole trajectory allows the use of interfragmentary screws and/or flexible fixation implant for intermetatarsal instability fixation

Low Profile
Tapered distal tip and anatomic low-profile design eases percutaneous insertion and minimizes soft-tissue irritation

Joint Alignment Laser Mark
Facilitates plate positioning

Stabilization Plates, Left & Right Specific

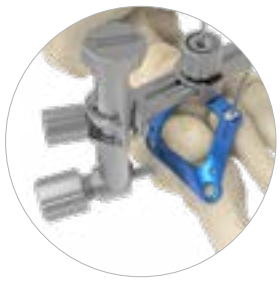
Dorsomedial Plates, Left & Right Specific

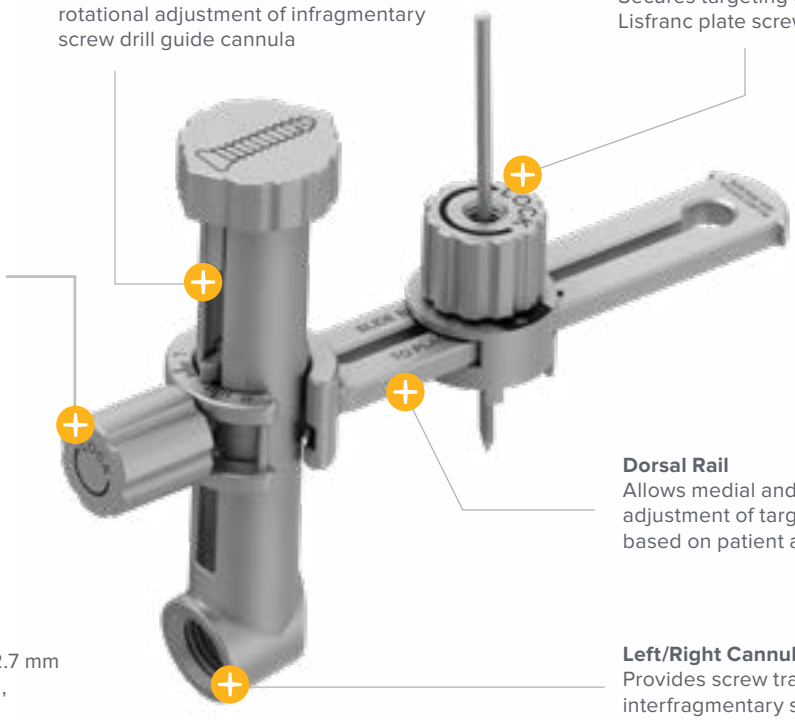
Universal Medial Plate

Lisfranc Plating System Features [continued]

Targeting Guide

The system provides a unique Lisfranc Targeting Guide that facilitates accurate Lisfranc screw fixation placement and trajectory for cases presenting with intermetatarsal instability. The guide is incredibly versatile, compatible with a wide range of screw sizes and types, making it the ideal instrument for any surgical situation.





Medial Arm
Allows for dorsal and plantar, and rotational adjustment of infragmentary screw drill guide cannula

Threaded TAK & Knob
Secures targeting guide to Lisfranc plate screw hole

Angle Locking Knob
Secures medial arm in place for interfragmentary screw placement

Dorsal Rail
Allows medial and lateral adjustment of targeting guide based on patient anatomy

Threaded Drill Guide & Guide Wire Insert
Allows interfragmentary screw placement of 2.7 mm and/or 3.5 mm solid cortical screws or 3.0 mm, 4.0 mm partially threaded cannulated screws

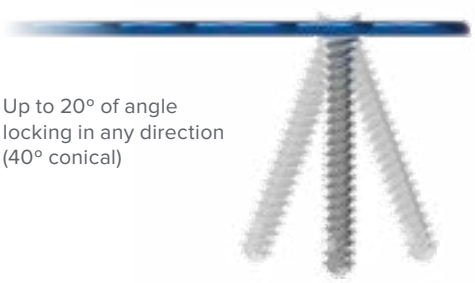
Left/Right Cannula
Provides screw trajectory for interfragmentary screw

Screw Features

Variable Angle Locking & Nonlocking Screw

The ExtremiLock Foot Plating System features double lead screw technology and provides surgeons with a broad range of screw fixation options. All screws are made from titanium alloy, and includes 2.7 mm, 3.5 mm and 4.0 mm cortical locking and nonlocking screws.

- T15 Hexalobe drive
- Double lead threads
- Self-tapping
- Blunt tip



Up to 20° of angle locking in any direction (40° conical)

Low-profile head

Double Lead Screw
2.50 mm per turn

Single Lead Screw
1.25 mm per turn

ExtremiLock Foot Plating System Features

The ExtremiLock Foot System tray features a modular design. Offering eight plate modules, three screw caddies and general instrumentation. The Lisfranc Plating System modules are housed within the ExtremiLock Foot plating system tray. One module contains the 1st-2nd, 2nd-3rd ray plates and dorsomedial plates. The second module contains the stabilization plates, medial plates, *2.7 mm locking and nonlocking screws, *3.5 mm nonlocking screws (32 mm—60 mm) and targeting guide. Instrumentation and the 3.5 mm and 4.0 mm screws required to implant the Lisfranc plates are housed within the ExtremiLock Foot Plating System tray.

*The 2.7 mm Screws and 3.5 mm screws (32 mm—60 mm) used with the Lisfranc plating system are included in the in the Lisfranc Screw Module. The 2.7 mm screws within the ExtremiLock Foot Plating System have a smaller head diameter and will not work with the Lisfranc Plating System.

Clinical Evidence

Lisfranc Fixation Techniques and Postoperative Functional Outcomes: A Systematic Review

Philpott A, Epstein DJ, Lau SC, Mnatzaganian G, Pang J. Lisfranc Fixation Techniques and Postoperative Functional Outcomes: A Systematic Review. *J Foot Ankle Surg.* 2021 Jan-Feb;60(1):102-108. doi: 10.1053/j.jfas.2020.04.005. Epub 2020 Oct 8. PMID: 33039319.

go.acumed.net/Lisfranc-Fixation-Techniques

Dorsal Bridge Plating vs. Transarticular Screw Fixation for Lisfranc Injuries: A Systematic Review and Metaanalysis

Boksh K, Sharma A, Grindlay D, Divall P, Mangwani J. Dorsal bridge plating versus. Transarticular screw fixation for lisfranc injuries: A systematic review and meta-analysis. *J Clin Orthop Trauma.* 2020 May-Jun;11(3):508-513. doi: 10.1016/j.jcot.2020.03.019. Epub 2020 Apr 3. PMID: 32581491; PMCID: PMC7303533.

go.acumed.net/Lisfranc-Dorsal-Bridge-vs-Screw-Fixation

Dorsal Bridge Plating or Transarticular Screws for Lisfranc Fracture Dislocations: A Retrospective Study Comparing Functional and Radiological Outcomes

Kirzner N, Zotov P, Goldbloom D, Curry H, Bedi H. Dorsal bridge plating or transarticular screws for Lisfranc fracture dislocations: a retrospective study comparing functional and radiological outcomes. *Bone Joint J.* 2018 Apr 1;100-B(4):468-474. doi: 10.1302/0301-620X.100B4. BJJ-2017-0899.R2. PMID: 29629578; PMCID: PMC6503757.

go.acumed.net/Lisfranc-Fracture-Dislocation

Additional Acumed Solutions

ExtremiLock™ Foot Plating System

go.acumed.net/ELock-FPS

ExtremiFix™ Cannulated Screw System-Mini & Small

go.acumed.net/Cann-Mini-Small

Related Documents

ExtremiLock™ Foot Lisfranc Plating System

go.acumed.net/Lisfranc-Bro
FNA10-04

go.acumed.net/Lisfranc-ST
FNA10-05

Competitive Comparison

Lisfranc–1st-2nd Dorsal Plate

	Acumed® 1st-2nd Dorsal Plate	Paragon28 Dual Ray 1st and 2nd	Arthrex Dorsal Midfoot Fusion Plate	Medline UNITE Recon Plate
Material	CTPi Grade 4	Ti 6Al-4V ELI	Titanium	Titanium
Sizes	**Small** (Length: 59 mm, Width: 30 mm) **Medium** (Length: 65 mm, Width: 36 mm) **Large** (Length: 68 mm, Width: 39 mm)	Small, Medium, Large	Small, Medium, Large	One Size
Left/Right Anatomic	Yes	Yes	No	Yes
Thickness	1.4 mm	1.4 mm	1.5 mm	Not Available
Hole Count	8 Screw Holes 4 Compression Slots	4 Screw Holes 2 Compression Slots	14 Screw Holes 2 Compression Slots	6 Screw Holes 1 Compression Slot
Angle Locking	+/- 20	+/- 15	+/- 15	+/- 15
Screw Hole	2.7 mm, 3.5 mm, 4.0 mm	2.7 mm, 3.5 mm, 4.2 mm	3.0 mm	2.7 mm, 3.5 mm, 4.0 mm
Screw Lengths	2.7 mm (10—32 mm) 3.5 mm (10—60 mm) 4.0 mm (20—60 mm)	2.7 mm (8—40 mm) 3.5 mm (10—50 mm) 4.2 mm (10—70 mm)	3.0 mm (10—40 mm)	2.7 mm (10—30 mm) 3.5 mm (10—60 mm) 4.0 mm(14—60 mm)
Double Lead Screws	Yes	Yes	No	No
Lisfranc Screw Targeting Guide	Yes	No	No	No

***1st-2nd Dorsal Plate** options not available through *Stryker, Novastep, Enovis, Zimmer Biomet*

Competitive Comparison [continued]

Lisfranc–Stabilization Plate

	Acumed® Stabilization Plate	Arthrex Dorsal Midfoot Fusion Plate
Material	CTPi Grade 4	Titanium (Not specified)
Sizes	**Small** (Length: 35 mm, Width: 29 mm) **Medium** (Length: 43 mm, Width: 33 mm) **Large** (Length: 47 mm, Width: 35 mm)	Small, Medium, Large
Left/Right Anatomic	Yes	Yes
Thickness	1.4 mm	1.4 mm
Hole Count	5 Screw Holes	3 Screw Holes 1 Compression Slot
Angle Locking	+/- 20	+/- 15
Screw Hole	2.7 mm, 3.5 mm, 4.0 mm	3.5 mm, 4.0 mm
Screw Lengths	2.7 mm (10—32 mm) 3.5 mm (10—60 mm) 4.0 mm (20—60 mm)	3.5 mm (14—60 mm) 4.0 mm (14—60 mm)
Double Lead Screws	Yes	No
Lisfranc Screw Targeting Guide	Yes	No

***Stabilization Plate** options not available through *Paragon28, Stryker, Novastep/ Enovis, Medline UNITE, Zimmer Biomet*

Competitive Comparison [continued]

Lisfranc–2nd-3rd Dorsal Plate

	Acumed® 2nd-3rd Dorsal Plate	Paragon28 Dual Ray 2nd and 3rd	Stryker Anchorage Plate System-Lisfranc Plates	Wright Medical Ortholoc 3Di-0U-Plate sdufhwsrhbisgv
Material	CTPi Grade 4	Ti 6Al-4V ELI	Ti 6Al-4V ELI	Ti 6Al-4V ELI
Sizes	**Small** (Length: 49 mm, Width: 29 mm) **Medium** (Length: 56 mm, Width: 35 mm) **Large** (Length: 61 mm, Width: 37 mm)	Small, Medium, Large	Small, Medium, Large	Small, Medium, Large
Left/Right Anatomic	Yes	Yes	Yes	Yes
Thickness	1.4 mm	1.4 mm	1.5 mm	Not Available
Hole Count	7 Screw Holes 2 Compression Slots	4 and 8 Screw Holes 2 Compression Slots	7 Screw Holes 2 Compression Slots	6 Screw Holes 2 Compression Slots
Angle Locking	+/- 20	+/- 15	+/- 15	+/- 15
Screw Hole	2.7 mm, 3.5 mm, 4.0 mm	2.7 mm, 3.5 mm, 4.2 mm	3.0 mm, 3.5 mm, 3.0 mm Compression Slot Only	2.7 mm, 3.5 mm
Screw Lengths	2.7 mm (10—32 mm) 3.5 mm (10—60 mm) 4.0 mm (20—60 mm)	2.7 mm (8—40 mm) 3.5 mm (10—50 mm) 4.2 mm (10—70 mm)	3.0 mm (10—40 mm)	2.7 mm (10—30 mm) 3.5 mm (10—60 mm)
Double Lead Screws	Yes	Yes	No	No
Lisfranc Screw Targeting Guide	Yes, Available for 2.7 mm 3.5 mm Solid Fully Threaded Screws 3.0 mm and 4.0 mm Partially Threaded Screws	No	No	Not Available for Ortholoc 3Di System Available for Lisfranc Charlotte Ssytem 3.7 mm and 4.5 mm Fully Threaded Screws Only

Competitive Comparison [continued]

Lisfranc–2nd-3rd Dorsal Plate

	Arthrex Dorsal Midfoot Fusion Plate	Novastep/ Enovis	Medline UNITE Recon Plate-Lisfranc Plates	Zimmer Biomet A.L.P.S.–Dorsal Midfoot Fusion Plates
Material	Titanium	TA6V Ti Alloy-Type II Anodized	Titanium	Ti 6Al-4V ELI
Sizes	Small, Medium, Large	**Small** (Length: 37 mm, Width: 24 mm) **Medium** (Length: 37 mm, Width: 27 mm) **Large** (Length: 37 mm, Width: 30 mm)	One Size	**Small** (Length: 37 mm, Width: 27 mm) **Large** (Length: 54 mm, Width: 24 mm)
Left/Right Anatomic	No	No	Yes	No
Thickness	1.5 mm	1.5 mm	Not Available	2.0 mm
Hole Count	14 Screw Holes 2 Compression Slots	6 Screw Holes 2 Compression Slots	5 Screw Holes 2 Compression Slots	4 and 6 Screw Holes 2 and 4 Compression Slots
Angle Locking	+/- 15	+/- 15	+/- 15	+/- 15
Screw Hole	3.0 mm	3.0 mm, 3.5 mm, 3.0 mm Compression Slot Only	2.7 mm, 3.5 mm, 4.0 mm	2.7 mm, 3.5 mm, 4.0 mm 3.5 mm Variable Angle Locking/Nonlocking
Screw Lengths	3.0 mm (10—40 mm)	3.0 mm (10—30 mm) 3.5 mm (10—40 mm)	2.7 mm (10—30 mm) 3.5 mm (10—60 mm) 4.0 mm (14—60 mm)	2.7 mm (10—50 mm) 3.5 mm (10—50 mm) 4.0 mm (10—50 mm)
Double Lead Screws	No	No	No	No
Lisfranc Screw Targeting Guide	No	No	No	No

Competitive Comparison [continued]

Lisfranc-Dorsomedial Plate and Medial Plate

	Acumed® Dorsomedial Plate	Medline UNITE Recon Plate-Lisfranc Plates	Acumed® Medial Plate
Material	CTPi Grade 4	Titanium	CTPi Grade 4
Sizes	**Small** (Length: 51 mm, Width: 25 mm) **Medium** (Length: 53 mm, Width: 33 mm) **Large** (Length: 56 mm, Width: 35 mm)	One Size	**One Size** (Length: 51 mm, Width: 25 mm)
Left/Right Anatomic	Yes	Yes	Universal
Thickness	1.4 mm	Not Available	1.4 mm
Hole Count	5 Screw Holes	5 Screw Holes 2 Compression Slots	5 Screw Holes 1 Compression Slot
Angle Locking	+/- 20	+/- 15	+/- 20
Screw Hole	2.7 mm, 3.5 mm, 4.0 mm	2.7 mm, 3.5 mm, 4.0 mm	2.7 mm, 3.5 mm, 4.0 mm
Screw Lengths	2.7 mm (10—32 mm) 3.5 mm (10—60 mm) 4.0 mm (20—60 mm)	2.7 mm (10—30 mm) 3.5 mm (10—60 mm) 4.0 mm (14—60 mm)	2.7 mm (10—32 mm) 3.5 mm (10—60 mm) 4.0 mm (20—60 mm)
Double Lead Screws	Yes	No	Yes
Lisfranc Screw Targeting Guide	Yes	No	Yes

***Dorsomedial Plate** options not available through *Paragon28®, Stryker, Arthrex®, Novastep®/ Enovis™, Zimmer Biomet™**

***Medial Plate** options not available through *Paragon28®, Stryker, Arthrex®, Novastep®/ Enovis™, Medline UNITE®, Zimmer Biomet™*

510(k) Clearance Information

JUN 18 2013

Special 510(k) Summary

Name of Submitter: OsteoMed

3885 Arapaho Road
Addison, Texas 7500
Phone: (972) 677-4600
Fax: (972) 677-4601

Contact Person: [illegible] Abraham

Date Prepared: May 17, 2013

Device Proprietary Name: OsteoMed Extrem LOCK Foot Plate and Screw Rigid Fixation System

Device Common Name: OsteoMed ExtremiLOCK Foot Plating System

Classification Name: 21 CFR 888.3030: Single/multiple component metallic bone fixation appliances and accessories

Product Code: HRS

Predicate Devices

OsteoMed Foot Plating Systems, K091614
Classification Name: Single/multiple component metallic bone fixation appliances and accessories (21CFR 888.3030, Product Code HRS)
Device Class: II

OsteoMed Calcaneal Plate and Screw Fixation, K071105
Classification Name: Single/multiple component metallic bone fixation appliances and accessories (21CFR 888.3030, Product Code HRS)
Device Class: II

Summary

Device Description:

The OsteoMed ExtremiLOCK Foot Plating System consists of plates of various shapes and sizes featuring compression, locking, elongated or compression elongated holes, angulated locking, non-locking and cannulated screws, implantable K-Wires, washers, and appropriate instrumentation. Modifications to plates of the subject system include increasing/decreasing the thickness of the plates, material changes, and addition of features.

The implants of the OsteoMed ExtremiLOCK Foot Plating System are made from Titanium (ASTM F-67) or Titanium alloy (ASTM F 136). Surgical instrumentation is provided to facilitate

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510(k) Clearance Information [continued]

modification, insertion, and removal of implants. The instrumentation is made from various grades of stainless steel, anodized aluminum, and/medical grade polymer.

Intended Use:
The OsteoMed ExtremiLOCK Foot Plating System is indicated for use in trauma, general surgery, and reconstructive procedures of the foot, ankle or other bones appropriate for the size of the device.

The OsteoMed ExtremiLOCK Foot Plating System implants are intended for single use only.

Technological Characteristics:
The OsteoMed ExtremiLOCK Foot Plating System is recommended for fixation/reconstruction of small fragment bones, forefoot, mid-foot, rear-foot, ankle or other bones appropriate for the size of the device.

ExtremiLOCK implants are manufactured from Titanium (ASTM F-67) or Titanium alloy (ASTM F-136), the same materials used in the manufacture of the predicate devices. These materials are biocompatible.

Performance/Clinical Data:
The OsteoMed ExtremiLOCK Foot Plating System was compared to the OsteoMed Foot Plating System, K091614, and the OsteoMed Calcaneal Foot and Screw Fixation System, K071105. The ExtremiLOCK implants underwent verification evaluation to ensure that the design features met the required mechanical strength criteria for their intended use. The intended use of the OsteoMed ExtremiLOCK implants is the same as the OsteoMed Foot Plating System and the OsteoMed Calcaneal Foot and Screw Fixation System.

Performance equivalence was shown through the verification comparison to the predicate devices.

Clinical Testing is not required to support substantial equivalence.

Substantial Equivalence:

A design, dimensional, and performance comparison was performed to establish substantial equivalence to the legally marketed predicate devices listed in this summary. The basis of substantial equivalence for this device is based on similarities in intended use, material, function, performance, design, technology and operational principles to the OsteoMed Foot Plating System (K091614), and similarities in material, function, design, technology and operational principles to the OsteoMed Calcaneal Plate and Screw Fixation (K071105).

The basis of substantial equivalence of the OsteoMed ExtremiLOCK Foot Plating System to the OsteoMed Foot Plating System, K091614, and the OsteoMed Calcaneal Foot and Screw Fixation System, K071105, is based on the similarities in design, technology, material, function, sterilization, and intended use. OsteoMed believes that the non-clinical tests demonstrate that the device is as safe, and effective as the predicate devices.

510(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

June 18, 2013

OsteoMed
% Mr. Blesson Abraham
3885 Arapaho Road
Addison, Texas 75001

Re: K131445
Trade/Device Name: OsteoMed ExtremiLOCK Foot Plating 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
Dated: May 17, 2013
Received: May 20, 2013

Dear Mr. Abraham:

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

510(k) Clearance Information [continued]

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

Enclosure

510(k) Clearance Information [continued]

Indications for Use

510(k) Number (if known): K131445

Device Name: OsteoMed ExtremiLOCK Foot Plating System

Indications for Use:

The OsteoMed ExtremiLOCK Foot Plating System is indicated for use in trauma, general surgery, and reconstructive procedures of the foot, ankle or other bones appropriate for the size of the device.

The OsteoMed ExtremiLOCK Foot Plating System implants are intended for single use only.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Elizabeth L. Frank -S

Division of Orthopedic Devices

Certification of Insurance

ACORD

CERTIFICATE OF LIABILITY INSURANCE

DATE (MM/DD/YYYY) 12/30/2022

THIS CERTIFICATE IS ISSUED AS A MATTER OF INFORMATION ONLY AND CONFERS NO RIGHTS UPON THE CERTIFICATE HOLDER. THIS CERTIFICATE DOES NOT AFFIRMATIVELY OR NEGATIVELY AMEND, EXTEND OR ALTER THE COVERAGE AFFORDED BY THE POLICIES BELOW. THIS CERTIFICATE OF INSURANCE DOES NOT CONSTITUTE A CONTRACT BETWEEN THE ISSUING INSURER(S), AUTHORIZED REPRESENTATIVE OR PRODUCER, AND THE CERTIFICATE HOLDER.

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Willis Towers Watson Midwest, Inc. c/o 26 Century Blvd P.O. Box 305191 Nashville, TN 372305191 USA	PHONE (A/C, No, Ext): 1-877-945-7378 FAX (A/C, No): 1-888-467-2378 E-MAIL ADDRESS: certificates@willis.com

INSURER(S) AFFORDING COVERAGE	NAIC #
INSURER A : Travelers Property Casualty Company of Ame	25674
INSURER B : Continental Casualty Company	20443
INSURER C : Columbia Casualty Company	31127
INSURER D :	
INSURER E :	
INSURER F :	

INSURED
Acumed LLC
5885 NE Cornelius Pass Road
Hillsboro, OR 97124

COVERAGES **CERTIFICATE NUMBER:** W27572276 **REVISION NUMBER:**

THIS IS TO CERTIFY THAT THE POLICIES OF INSURANCE LISTED BELOW HAVE BEEN ISSUED TO THE INSURED NAMED ABOVE FOR THE POLICY PERIOD INDICATED. NOTWITHSTANDING ANY REQUIREMENT, TERM OR CONDITION OF ANY CONTRACT OR OTHER DOCUMENT WITH RESPECT TO WHICH THIS CERTIFICATE MAY BE ISSUED OR MAY PERTAIN, THE INSURANCE AFFORDED BY THE POLICIES DESCRIBED HEREIN IS SUBJECT TO ALL THE TERMS, EXCLUSIONS AND CONDITIONS OF SUCH POLICIES. LIMITS SHOWN MAY HAVE BEEN REDUCED BY PAID CLAIMS.

INSR LTR	TYPE OF INSURANCE	ADDL INSD	SUBR WVD	POLICY NUMBER	POLICY EFF (MM/DD/YYYY)	POLICY EXP (MM/DD/YYYY)	LIMITS	
A	X COMMERCIAL GENERAL LIABILITY CLAIMS-MADE X OCCUR GEN'L AGGREGATE LIMIT APPLIES PER: X POLICY PRO-JECT LOC OTHER:			TJEXGL-1100L019-TIL-22	12/31/2022	12/31/2023	EACH OCCURRENCE DAMAGE TO RENTED PREMISES (Ea occurrence) MED EXP (Any one person) PERSONAL & ADV INJURY GENERAL AGGREGATE PRODUCTS - COMP/OP AGG	$ 1,000,000 $ 1,000,000 $ 0 $ 1,000,000 $ 10,000,000 $ Excluded
	AUTOMOBILE LIABILITY ANY AUTO OWNED AUTOS ONLY HIRED AUTOS ONLY SCHEDULED AUTOS NON-OWNED AUTOS ONLY						COMBINED SINGLE LIMIT (Ea accident) BODILY INJURY (Per person) BODILY INJURY (Per accident) PROPERTY DAMAGE (Per accident)	$ $ $ $
	UMBRELLA LIAB OCCUR EXCESS LIAB CLAIMS-MADE DED RETENTION $						EACH OCCURRENCE AGGREGATE	$ $
	WORKERS COMPENSATION AND EMPLOYERS' LIABILITY ANYPROPRIETOR/PARTNER/EXECUTIVE OFFICER/MEMBER EXCLUDED? (Mandatory in NH) Y / N If yes, describe under DESCRIPTION OF OPERATIONS below	N / A					PER STATUTE OTH-ER E.L. EACH ACCIDENT E.L. DISEASE - EA EMPLOYEE E.L. DISEASE - POLICY LIMIT	$ $ $
B	Products Liability			ADT 4031919959	12/31/2022	12/31/2023	Each Occurrence	$5,000,000

DESCRIPTION OF OPERATIONS / LOCATIONS / VEHICLES (ACORD 101, Additional Remarks Schedule, may be attached if more space is required)

SEE ATTACHED

CERTIFICATE HOLDER

Acumed LLC
5885 NE Cornelius Pass Road
Hillsboro, OR 97124

CANCELLATION

SHOULD ANY OF THE ABOVE DESCRIBED POLICIES BE CANCELLED BEFORE THE EXPIRATION DATE THEREOF, NOTICE WILL BE DELIVERED IN ACCORDANCE WITH THE POLICY PROVISIONS.

AUTHORIZED REPRESENTATIVE

ACORD 25 (2016/03) The ACORD name and logo are registered marks of ACORD

SR ID: 23530022 BATCH: 2788983

Certification of Insurance [continued]

Page 1 of 1

ACORD

CERTIFICATE OF LIABILITY INSURANCE

DATE (MM/DD/YYYY): 12/30/2022

THIS CERTIFICATE IS ISSUED AS A MATTER OF INFORMATION ONLY AND CONFERS NO RIGHTS UPON THE CERTIFICATE HOLDER. THIS CERTIFICATE DOES NOT AFFIRMATIVELY OR NEGATIVELY AMEND, EXTEND OR ALTER THE COVERAGE AFFORDED BY THE POLICIES BELOW. THIS CERTIFICATE OF INSURANCE DOES NOT CONSTITUTE A CONTRACT BETWEEN THE ISSUING INSURER(S), AUTHORIZED REPRESENTATIVE OR PRODUCER, AND THE CERTIFICATE HOLDER.

IMPORTANT: If the certificate holder is an ADDITIONAL INSURED, the policy(ies) must have ADDITIONAL INSURED provisions or be endorsed. If SUBROGATION IS WAIVED, subject to the terms and conditions of the policy, certain policies may require an endorsement. A statement on this certificate does not confer rights to the certificate holder in lieu of such endorsement(s).

PRODUCER	CONTACT NAME: Willis Towers Watson Certificate Center	
Willis Towers Watson Midwest, Inc. c/o 26 Century Blvd P.O. Box 305191 Nashville, TN 372305191 USA	PHONE (A/C, No, Ext): 1-877-945-7378	FAX (A/C, No): 1-888-467-2378
	E-MAIL ADDRESS: certificates@willis.com	

INSURER(S) AFFORDING COVERAGE	NAIC #
INSURER A : Travelers Property Casualty Company of Ame	25674
INSURER B : Continental Casualty Company	20443
INSURER C :	
INSURER D :	
INSURER E :	
INSURER F :	

INSURED
Acumed LLC
4860 NE Brookwood Parkway
Hillsboro, OR 97124

COVERAGES **CERTIFICATE NUMBER:** W27572277 **REVISION NUMBER:**

THIS IS TO CERTIFY THAT THE POLICIES OF INSURANCE LISTED BELOW HAVE BEEN ISSUED TO THE INSURED NAMED ABOVE FOR THE POLICY PERIOD INDICATED. NOTWITHSTANDING ANY REQUIREMENT, TERM OR CONDITION OF ANY CONTRACT OR OTHER DOCUMENT WITH RESPECT TO WHICH THIS CERTIFICATE MAY BE ISSUED OR MAY PERTAIN, THE INSURANCE AFFORDED BY THE POLICIES DESCRIBED HEREIN IS SUBJECT TO ALL THE TERMS, EXCLUSIONS AND CONDITIONS OF SUCH POLICIES. LIMITS SHOWN MAY HAVE BEEN REDUCED BY PAID CLAIMS.

INSR LTR	TYPE OF INSURANCE	ADDL INSD	SUBR WVD	POLICY NUMBER	POLICY EFF (MM/DD/YYYY)	POLICY EXP (MM/DD/YYYY)	LIMITS	
A	X COMMERCIAL GENERAL LIABILITY CLAIMS-MADE X OCCUR GEN'L AGGREGATE LIMIT APPLIES PER: X POLICY PRO-JECT LOC OTHER:			TJEXGL-1100L019-TIL-22	12/31/2022	12/31/2023	EACH OCCURRENCE DAMAGE TO RENTED PREMISES (Ea occurrence) MED EXP (Any one person) PERSONAL & ADV INJURY GENERAL AGGREGATE PRODUCTS - COMP/OP AGG $	$ 1,000,000 $ 1,000,000 $ 0 $ 1,000,000 $ 10,000,000 $ Excluded $
	AUTOMOBILE LIABILITY ANY AUTO OWNED AUTOS ONLY SCHEDULED AUTOS HIRED AUTOS ONLY NON-OWNED AUTOS ONLY						COMBINED SINGLE LIMIT (Ea accident) BODILY INJURY (Per person) BODILY INJURY (Per accident) PROPERTY DAMAGE (Per accident) $	$ $ $ $ $
	UMBRELLA LIAB OCCUR EXCESS LIAB CLAIMS-MADE DED RETENTION $						EACH OCCURRENCE AGGREGATE $	$ $ $
	WORKERS COMPENSATION AND EMPLOYERS' LIABILITY ANYPROPRIETOR/PARTNER/EXECUTIVE OFFICER/MEMBER EXCLUDED? Y / N (Mandatory in NH) If yes, describe under DESCRIPTION OF OPERATIONS below	N / A					PER STATUTE OTH-ER E.L. EACH ACCIDENT E.L. DISEASE - EA EMPLOYEE E.L. DISEASE - POLICY LIMIT	$ $ $
B	Products Liability			ADT 4031919959	12/31/2022	12/31/2023	Each Occurrence	$5,000,000

DESCRIPTION OF OPERATIONS / LOCATIONS / VEHICLES (ACORD 101, Additional Remarks Schedule, may be attached if more space is required)

CERTIFICATE HOLDER

Acumed LLC
4860 NE Brookwood Parkway
Hillsboro, OR 97116

CANCELLATION

SHOULD ANY OF THE ABOVE DESCRIBED POLICIES BE CANCELLED BEFORE THE EXPIRATION DATE THEREOF, NOTICE WILL BE DELIVERED IN ACCORDANCE WITH THE POLICY PROVISIONS.

AUTHORIZED REPRESENTATIVE

ACORD 25 (2016/03) **The ACORD name and logo are registered marks of ACORD**

SR ID: 23530022 BATCH: 2788983

Certification of Insurance [continued]

Page 1 of 2

ACORD

CERTIFICATE OF LIABILITY INSURANCE

DATE (MM/DD/YYYY) 12/30/2022

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PRODUCER	CONTACT NAME: Willis Towers Watson Certificate Center
Willis Towers Watson Midwest, Inc. c/o 26 Century Blvd P.O. Box 305191 Nashville, TN 372305191 USA	PHONE (A/C, No, Ext): 1-877-945-7378 FAX (A/C, No): 1-888-467-2378 E-MAIL ADDRESS: certificates@willis.com

INSURER(S) AFFORDING COVERAGE	NAIC #
INSURER A : Travelers Property Casualty Company of Ame	25674
INSURER B : Travelers Indemnity Company of CT	25682
INSURER C : Farmers Casualty Insurance Company	40169
INSURER D : Continental Casualty Company	20443
INSURER E : Columbia Casualty Company	31127
INSURER F :	

INSURED
Acumed LLC
5885 NE Cornelius Pass Road
Hillsboro, OR 97124

COVERAGES **CERTIFICATE NUMBER:** W27572278 **REVISION NUMBER:**

THIS IS TO CERTIFY THAT THE POLICIES OF INSURANCE LISTED BELOW HAVE BEEN ISSUED TO THE INSURED NAMED ABOVE FOR THE POLICY PERIOD INDICATED. NOTWITHSTANDING ANY REQUIREMENT, TERM OR CONDITION OF ANY CONTRACT OR OTHER DOCUMENT WITH RESPECT TO WHICH THIS CERTIFICATE MAY BE ISSUED OR MAY PERTAIN, THE INSURANCE AFFORDED BY THE POLICIES DESCRIBED HEREIN IS SUBJECT TO ALL THE TERMS, EXCLUSIONS AND CONDITIONS OF SUCH POLICIES. LIMITS SHOWN MAY HAVE BEEN REDUCED BY PAID CLAIMS.

INSR LTR	TYPE OF INSURANCE	ADDL INSD	SUBR WVD	POLICY NUMBER	POLICY EFF (MM/DD/YYYY)	POLICY EXP (MM/DD/YYYY)	LIMITS	
A	X COMMERCIAL GENERAL LIABILITY CLAIMS-MADE X OCCUR GEN'L AGGREGATE LIMIT APPLIES PER: X POLICY PRO-JECT LOC OTHER:			TJEXGL-1100L019-TIL-22	12/31/2022	12/31/2023	EACH OCCURRENCE DAMAGE TO RENTED PREMISES (Ea occurrence) MED EXP (Any one person) PERSONAL & ADV INJURY GENERAL AGGREGATE PRODUCTS - COMP/OP AGG	$ 1,000,000 $ 1,000,000 $ 0 $ 1,000,000 $ 10,000,000 $ Excluded
	AUTOMOBILE LIABILITY ANY AUTO OWNED AUTOS ONLY HIRED AUTOS ONLY SCHEDULED AUTOS NON-OWNED AUTOS ONLY						COMBINED SINGLE LIMIT (Ea accident) BODILY INJURY (Per person) BODILY INJURY (Per accident) PROPERTY DAMAGE (Per accident)	$ $ $ $
	UMBRELLA LIAB OCCUR EXCESS LIAB CLAIMS-MADE DED RETENTION $						EACH OCCURRENCE AGGREGATE	$ $
B	WORKERS COMPENSATION AND EMPLOYERS' LIABILITY ANYPROPRIETOR/PARTNER/EXECUTIVE OFFICER/MEMBER EXCLUDED? (Mandatory in NH) Y / N: No If yes, describe under DESCRIPTION OF OPERATIONS below	N / A		UB-7N728811-22-51-K	12/31/2022	12/31/2023	X PER STATUTE OTH-ER E.L. EACH ACCIDENT E.L. DISEASE - EA EMPLOYEE E.L. DISEASE - POLICY LIMIT	 $ 1,000,000 $ 1,000,000 $ 1,000,000
C	Workers Compensation and Employers Liability Per Statute			UB-7N677449-22-51-R	12/31/2022	12/31/2023	E.L. Each Accident E.L. Disease-EA Empl E.L. Disease-Pol Lmt	$1,000,000 $1,000,000 $1,000,000

DESCRIPTION OF OPERATIONS / LOCATIONS / VEHICLES (ACORD 101, Additional Remarks Schedule, may be attached if more space is required)

SEE ATTACHED

CERTIFICATE HOLDER

Acumed LLC
5885 NE Cornelius Pass Road
Hillsboro, OR 97124

CANCELLATION

SHOULD ANY OF THE ABOVE DESCRIBED POLICIES BE CANCELLED BEFORE THE EXPIRATION DATE THEREOF, NOTICE WILL BE DELIVERED IN ACCORDANCE WITH THE POLICY PROVISIONS.

AUTHORIZED REPRESENTATIVE

ACORD 25 (2016/03) **The ACORD name and logo are registered marks of ACORD**

SR ID: 23530022 BATCH: 2788983

Who We Are

For more than 35 years, Acumed has developed innovative orthopaedic solutions designed to serve the needs of the entire health care community. Our mission is to aid the afflicted through the ingenuity of our minds, the labor of our hands, and the compassion of our hearts.

As a global market leader, our products are rooted in evidence-based design, and show positive patient outcomes and superior biomechanical performance.

We are 100% compliant with the rules and regulations that guide our industry.

Our Foundations of Excellence

Education

At Acumed, education is not just a cool buzzword, but something we take great pride in. It is at the heart of who we are. We believe surgeon education and training are essential to elevating patient standard of care and improving outcomes. That is why we are committed to supporting surgeons throughout their entire educational journey from residency to advanced medical professional.

Choose from a myriad of learning options, everything from participating in one of our Surgical Skills courses, diving deep into an ELiTE Resident and Fellow Program, gleaning expertise with a virtual PRO Series, or getting hands-on experience in our Acumed Mobile Cadaver Labs circulating the United States.

Evidence

We educate and conduct ongoing clinical and biomechanical research, using this information for validation and continuous improvement to deliver the greatest value to our customers.

Innovation

Innovation has been a cornerstone of Acumed's success for the past 35 years.

For Acumed to continue to earn the goodwill brand of innovation, we must continue to launch new "industry first" and market-leading products that address unmet clinical needs. In addition to advances in plate and screw design, Acumed strives to simplify procedures through the innovation of novel instruments and technologies that improve surgical efficiency and approaches.

Quality

Acumed is recognized by our surgeon customers for our commitment to quality.

Our Quality Management System is embedded in our everyday activities and it drives our quality-first culture. In the spirit of continuous improvement, we monitor and act upon data related to manufacturing, suppliers, and customer feedback. We use this data to enhance the quality of our design, product realization, medical education, and customer experiences to deliver optimal patient outcomes.

Dedicated to Excellence

From manufacturing 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, Association for 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.

AME 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

We are proud to lead the way in product development and innovation with our new Lisfranc Plating System, an exciting addition to our ExtremiLock Foot Plating System. Developed in partnership with leading experts, including Lawrence Fallat, DPM, J. Robert Faux, MD, and Nirmal Tejwani, MD, we have expanded our technology to address Lisfranc fractures-dislocations and fusions, delivering a comprehensive solution that addresses the intricate needs of Lisfranc injuries. Our Lisfranc Plating System stands out for its versatility, offering a wide selection of plates for dorsal, dorsomedial, and medial approaches. This system seamlessly integrates with the ExtremiLock Foot Plating System, using the same screws and instrumentation.

Innovative and comprehensive, the Lisfranc Plating System represents a significant step forward in foot and ankle surgery. Acumed will continue to devote resources to developing implants that help improve patient outcomes and advances the field of 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 anticorruption training for employees interacting with health care professionals or government officials (foreign or domestic). In addition, Acumed sales representatives in the United States and international distribution partners must complete anticorruption 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 anticorruption 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 at Acumed and at home. Ecofriendly 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, which developed and implemented strategies to bring more awareness to issues related to energy savings and environmental stewardship.

Notes:

Notes:

www.acumed.net

Acumed USA Campus
5885 NE Cornelius Pass Road
Hillsboro, OR 97124
+1.888.627.9957

OsteoMed USA Campus
3885 Arapaho Road
Addison, TX 75001
+1.800.456.7779

Acumed Iberica Campus
C. Proción, 1
Edificio Oficor
28023 Madrid, Spain
+34.913.51.63.57

FNA70-17-A | Effective: 2023/11 |