acumed®

Polarus® 3 Solution

Plates and Nails

Value Analysis Committee Resource Guide

A COLSON ASSOCIATE

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

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.

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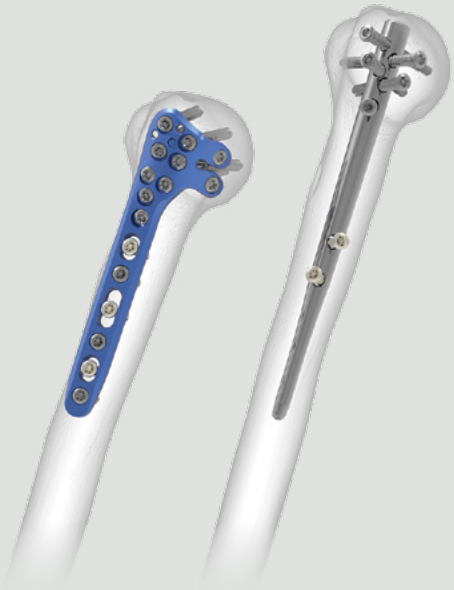
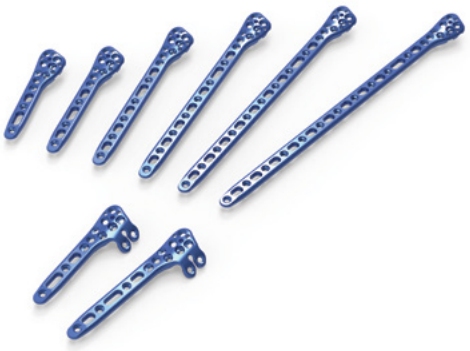


System Overview

Designed to provide multiple solutions for fractures, fusions, and osteotomies of the proximal and midshaft humerus, the Polarus 3 Solution provides plate and nail options in one comprehensive system. While many proximal humerus fractures can be treated nonoperatively, the goal of surgery with a plate or nail is to obtain anatomic reduction and stable primary fixation in order for the fracture to heal rapidly and provide immediate postoperative functional therapy.

Polarus® 3 Solution Plates

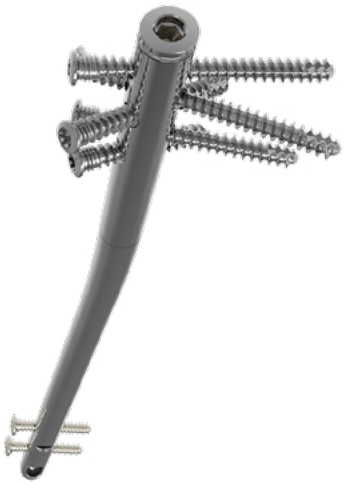
The Polarus 3 Solution contains anatomically precontoured plates, including Standard and Posterior Plates, ranging from 94 mm to 275 mm (Standard only) to accommodate a wide variety of fracture patterns. Polarus 3 Plates are designed as locking plates, functioning as an internal fixator on the bone.[3]



- More distal plate placement than the previous generation PHP (8–10 mm below the greater tuberosity) is designed to avoid impingement on the acromion
- Posterior plates include wrap-around bendable tabs designed to capture posterior fragments
- Low-profile plate design allows the plate to be as thin as possible while maintaining strength and allowing screw heads to sit flush with the surface of the plate
- Three dedicated medial calcar support screws are intended to help provide stable medial column support and maintain fracture reduction[1]
- Suture undercuts are provided for ease of passing suture needles underneath the plate

Polarus® 3 Solution Nails

The Polarus 3 Solution also offers two intramedullary nail options—Proximal and Long—to treat a variety of fracture patterns. Polarus 3 nails are anatomically precontoured and designed to avoid the axillary nerve.



- Nails are available in a variety of lengths: 150 mm, 200 mm, 220 mm, 240 mm, 260 mm, and 280 mm
- The nails are designed to have a 4° lateral bend and the Proximal Nails are left and right specific to accommodate patient anatomy
- Pre-assembled polyether ether ketone (PEEK) inserts are intended to create proximal locking screw friction
- Polarus 3 Nail screw patterns are designed to avoid the axillary nerve
- Fully cannulated nails and instrumentation allow use of a guide wire to ease insertion
- Nail insertion point is designed to minimize rotator cuff disruption
- Instrumentation is included for removal and an end cap is included to help prevent bony in-growth
- Nail is designed to be retrievable for removal or revision if needed
- Radiolucent targeting guides are provided to facilitate insertion of proximal locking screws
- Ratcheting cannulas are designed to lock and unlock for stability within the targeting guide

Indications for Use

The Acumed Polarus 3 Solution includes plates, nails, screws, and accessories designed to address fractures, fusions, and osteotomies of the humerus.

Key System Features

Proximal Humerus Plates

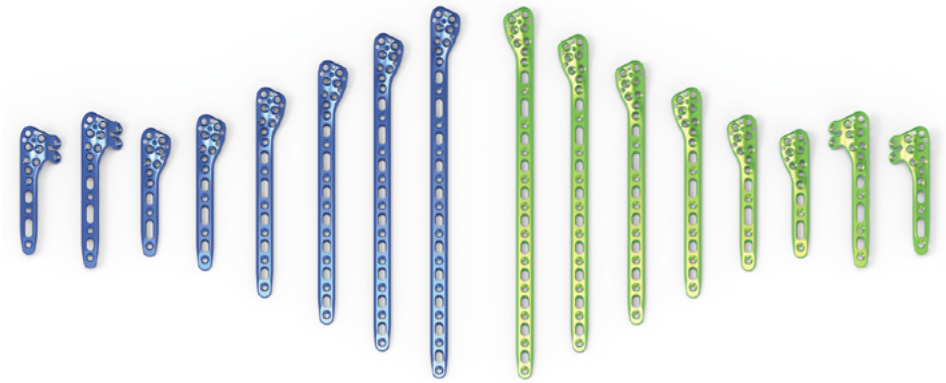
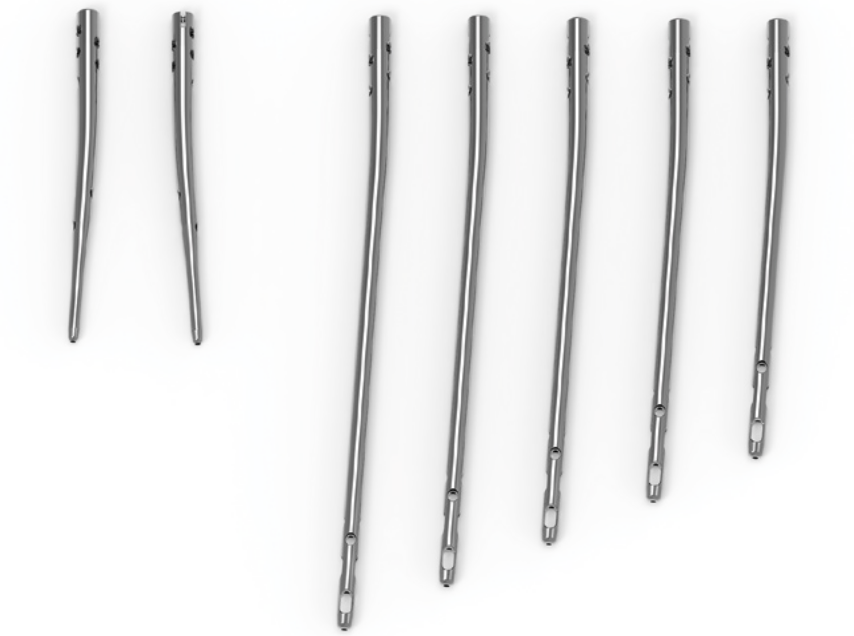


Plate Lengths	
Standard	
4-hole	94 mm
6-hole	115 mm
10-hole	155 mm
14-hole*	195 mm
18-hole*	235 mm
22-hole*	275 mm
Posterior	
4-hole	94 mm
6-hole	115 mm

Standard and Posterior Plates are left/right specific to better suit patient anatomy
*Special-order, sterile-packed only

Proximal and Long Nails



Nail Lengths	
Proximal Nail	150 mm
Long Nail	200 mm
Long Nail	220 mm
Long Nail	240 mm
Long Nail	260 mm
Long Nail	280 mm

Versatile Screws

4.3 mm low-profile hexalobe screws, which function as locking screws, may be used in any hole of the Polarus 3 plate and the proximal portion of the nail

3.5 mm nonlocking low-profile hexalobe screws may be used in any hole of the Polarus 3 plate, as well as the distal portion of the nail

Competitive Comparison

Proximal Humerus Plates

Synthes 3.5 mm LCP Proximal Humerus Plates Source: Synthes Philos + Philos Long Surgical Technique (036.000.166)	Acumed Polarus 3 Plate
Both titanium and stainless steel available	Titanium alloy, Ti-6Al-4V
90 mm–290 mm plate lengths	94 mm–275 mm plate lengths
Not left and right specific	Left and right specific
Nine proximal screw holes	Eight or ten proximal screw holes
Ten suture holes	Two or four suture holes
Uses locking and “combi” holes	Uses locking holes and compression slots
Three screw options—3.5 mm locking, 3.5 mm cortex, 4.0 mm cortex and 4.0 mm cancellous bone screws	4.3 mm low-profile hexalobe screws and 3.5 mm nonlocking low-profile hexalobe screws can be used in any hole of the plate. The 4.3 mm low-profile hexalobe screws function as locking screws.
	Posterior plate option

Synthes 3.5 mm LCP Periarticular Proximal Humerus Plate Source: Synthes LCP Periarticular Proximal Humerus Plate Surgical Technique (036.001.136)	Acumed Polarus 3 Plate
Both titanium and stainless steel available	Titanium alloy, Ti-6Al-4V
91 mm–307 mm plate lengths	94 mm–275 mm plate lengths
Eight proximal screw holes	Eight or ten proximal screw holes
Left and right specific	Left and right specific
Two dedicated medial calcar support screws	Three dedicated medial calcar support screws
Uses locking and “combi” holes	Uses locking holes and compression slots
3.5 mm locking and nonlocking screws, 4.0 mm cancellous bone screws, 3.5 mm conical screws, 3.5 mm locking screws, 3.5 mm cortex screws	4.3 mm low-profile hexalobe screws and 3.5 mm nonlocking low-profile hexalobe screws can be used in any hole of the plate. The 4.3 mm low-profile hexalobe screws function as locking screws.
	Posterior plate option

Stryker AxSOS Locking Plating System Source: Stryker Proximal Humeral Locking Plate Surgical Technique (982275)	Acumed Polarus 3 Plate
Titanium	Titanium alloy, Ti-6Al-4V
Seven proximal screw holes	Eight or ten proximal screw holes
Unthreaded “freedom hole” proximally for freehand placement or lagging	Locking proximal screws with option of bendable posterior tabs
Uses 3.5 mm cortical nonlocking and 4.0 mm cancellous and locking screws	4.3 mm low-profile hexalobe screws and 3.5 mm nonlocking low-profile hexalobe screws can be used in any hole of the plate. The 4.3 mm low-profile hexalobe screws function as locking screws.
	Posterior plate option

Competitive Comparison [continued]

Proximal Humerus Nails

Stryker T2 Humerus Nailing System Source: Stryker T2 Proximal Humeral Nailing System Surgical Technique (B1000009)	Acumed Polarus 3 Nail
Titanium alloy, Ti-6Al-4V	Titanium alloy, Ti-6Al-4V
140 mm–320 mm nail lengths	150 mm–280 mm nail lengths
7 mm–9 mm diameters available	Proximal nail 10 mm–5.5 mm diameters Long nail 10 mm–8 mm diameters
6° proximal bend, 4° distal bend	4° bend for more medial entry point
Left and right specific screw arrays	Left and right specific proximal screw arrays
Antegrade and retrograde options available	Antegrade only option
Four proximal static locking screw holes, one proximal dynamic screw slot	Five locking proximal screw holes
Three distal hole options	Four distal hole options
Threaded proximal holes with nylon bushing	Threaded proximal holes with PEEK insert
4.0 mm partially and fully threaded screws ranging from 20 mm–60 mm	4.3 mm low-profile hexalobe screws may be used in the proximal portion of the nail. 3.5 mm nonlocking low-profile hexalobe screws may be used in the distal portion of the nail. Screw length ranges from 18 mm—64 mm (in 2 mm increments).

Synthes MultiLoc Source: Synthes MultiLoc Humeral Nail Surgical Technique (J9981-B)	Acumed Polarus 3 Nail
Titanium–6% aluminium–7% niobium alloy (TAN)	Titanium alloy, Ti-6Al-4V
Short nails 160 mm in length	Proximal nails 150 mm in length
Long nails 180 mm–315 mm in length	Long nails 200 mm–280 mm in length
Short nails 8 mm–9.5 mm diameter	Proximal nail 10 mm–5.5 mm diameter
Long nails 7 mm–8.5 mm diameter	Long nail 10 mm–8 mm diameter
Straight-nail design	4° lateral bend
Short nails left and right specific Long nails left and right specific	Proximal nails left and right specific
Three proximal screw holes and optional A/P hole and an ascending screw	Five proximal locking holes
Three distal screw options in the long nails	Four distal screw options in the long nails
Polyethylene inlay for proximal screws	Threaded proximal holes with PEEK insert
4.5 mm MultiLoc and 3.5 mm locking screws ranging from 26 mm–52 mm lengths 4.0 mm locking screws (18 mm–70 mm lengths in 2 mm increments), ASLS screws	4.3 mm locking low-profile hexalobe screws may be used in the proximal portion of the nail. 3.5 mm nonlocking hexalobe screws may be used in the distal portion of the nail. Screw length ranges from 18 mm to 64 mm (in 2 mm increments).
Ascending screw design puts the screw entry point directly in the axial nerve zone	Avoids axillary nerve zone

Clinical Data Influence

Original Polarus Nails

A study by Georgousis et al of 24 patients with displaced proximal humerus fractures found that “the Polarus nail offers specific advantages especially for multi-fragment or displaced fractures where open reduction would require an extensive surgical approach.”[4] Other advantages identified include the preservation of periosteal blood supply and biomechanical stability of the fracture site. “The Polarus nail appeared in this study as an effective device to treat proximal humeral fractures, with good overall functional results and a low complication rate.”[4]

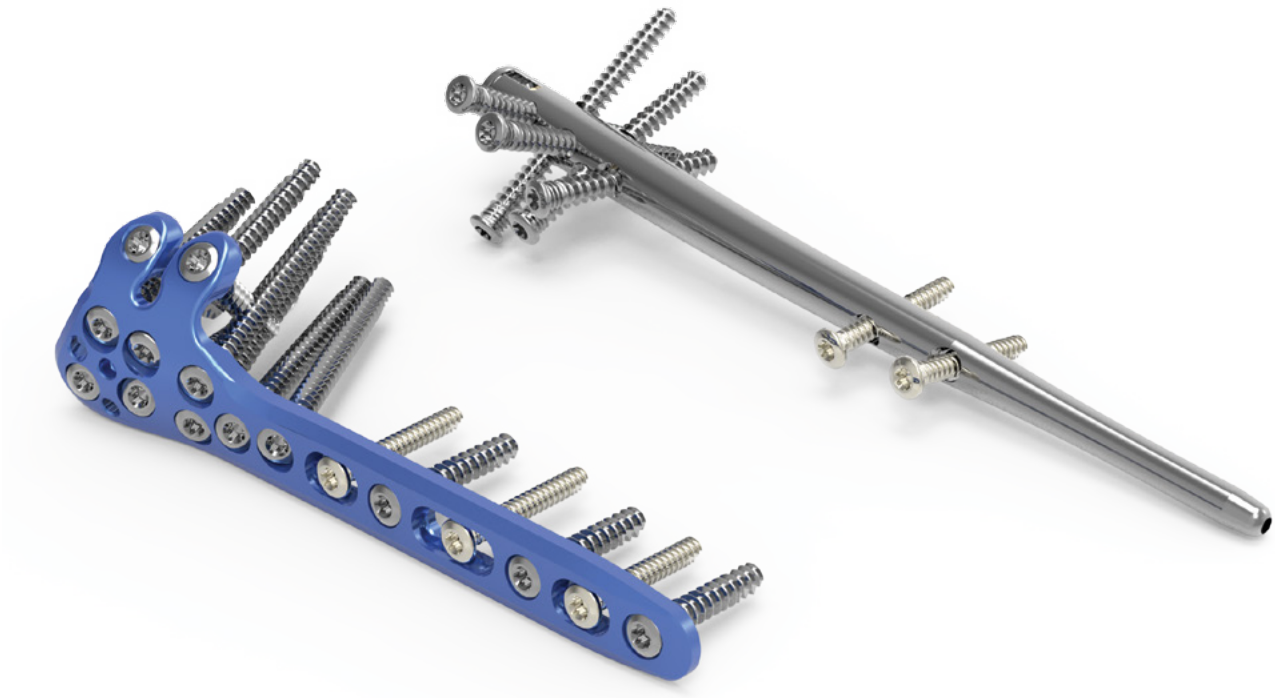
Locking Proximal Humerus Plates

An article printed in the Journal of Shoulder and Elbow Surgery (Feb. 2014) by Ockert et al, regarding long-term results obtained from a group of 43 patients with proximal humerus fractures, found that early results of using locking plates in the management of displaced proximal humerus fractures have shown that this technology compares favorably with hemiarthroplasty and older fixation techniques.[5] In conclusion, they stated that, “Ten years after locked plating of displaced proximal humeral fractures, patients show good to excellent outcomes in the majority of cases with no relevant decline compared with the shoulder function 1 year after surgery. However, poor long-term outcome is seen in 16% of patients and relates to a low Constant Score (CS) 1 year after surgery. Thus, patients developing poor long-term outcomes may be identified at an earlier stage.”[5]

In their study of open reduction and internal fixation of proximal humerus fractures with the use of a locking proximal humerus plate, Südkamp et al found that surgical treatment of displaced proximal humerus fractures with use of a locking proximal humeral plate can lead to a good functional outcome provided that the correct surgical technique is used.[6]

Comparison of Plate and Nail

An investigation by Zhu et al compared the outcomes of treating two-part proximal humeral fractures with locking intramedullary nails vs. locking plates in a total of 51 patients. In conclusion, they stated that “Satisfactory results can be achieved by treating two-part proximal humeral surgical neck fractures with either a locking plate or a locking nail. There is no significant difference regarding the final American Shoulder and Elbow Surgeons (ASES) scores between these two implants at three years postoperatively. The complication rate was lower in the locking intramedullary nail group, while fixation with a locking plate had the advantage of a better one-year outcome.”[7]



Polarus 3 Nail

Polarus 3 Plate

510(k) Clearance Information

DEPARTMENT OFI IEA LTtl & H UMA ' SERVICES

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Food and Dmc Administr.uion
10903 New 1 lnmp;hirc Avenue Documcn1
Corurol Center -W066.(;609 Srlver Spnng.
MD 20993-0002

October 10, 2013

Acumed, LLC
Ms. Brittany Cunningham
Regulatory Specialist 2
5885 North West Cornelius Pass Road
Hillsboro, Oregon 97124

Re: Kl31636
Trade/Device Name: Polarus[10] Conneet
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: Class II Product
Code: LXT, HRS, HSB
Dated: September 26, 2013
Received: September 30, 2013

Dear Ms. Cunningham:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH docs 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 Ill (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 docs 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 80 I); medical device report ing (reporting of medical

510(k) Clearance Information [continued]

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll- free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fdagov/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/MedicaiDevices/Safety/ReportaProblern/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/Medical Devices/Resources forYou/Industry/default.htm.

Sincerely yours,

for **Erin I. 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]

K131636 Pagel o£2

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved : OMB No. 0910-0120 Expira on Date: Deoember 31, 2013 See PRA Statement on /ostpage.

510(k) Number *(if known)*
Kl31636

Device Name
Polarus® Connect

Indications tor Use *(Ducri)*
The Acumed Polarus® Connect System includes plates, nails, screws and accessories designed to address flllctures, fusions, and osteotomies oflhe humerus.

Type o1 Use *(&feet one orbolh. as applicable)*

Prescription Use {Part 21 CFR S01 Subpart 0) O Over· The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CORH) *(Signature)*

Elizabeth L. Frank-S

FORM FDA 38111 (9/13) Page 1of2 PSC Publishing Services (301) 443-6740 EF

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 proximal humerus fracture treatment in 1999. Since then, Acumed has grown to become one of the technology leaders in options for operative treatment of proximal humerus fractures. Acumed will continue to devote resources to the development of implants that aid in improving patient outcomes and advancing 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 anti-corruption training for employees interacting with healthcare professionals or government officials (foreign or domestic). In addition, Acumed sales representatives in the United States as well as international distribution partners must complete anti-corruption training programs.

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

Transparency in Business Practice

In 2012, the company began preparing to track and report spending in accordance with the Physician Payment Sunshine Act. In order to become an Acumed partner, all distributors must go through a due diligence analysis and a robust training and education program to ensure they share Acumed's values with respect to anti-corruption and compliance. Acumed maintains ethical behaviors with respect to compliance standards and laws.

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, 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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Notes:

Notes:

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