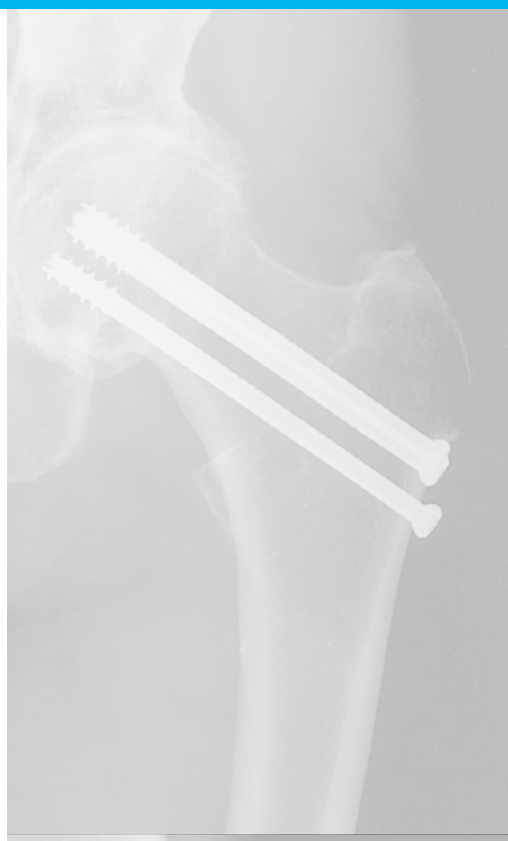
acumed®

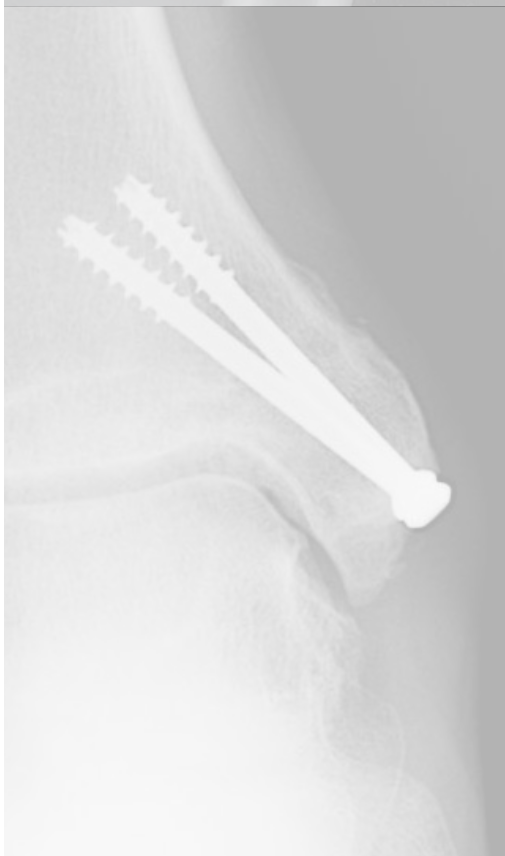
Cannulated Screw System

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® Cannulated Screw 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.

The Acumed Cannulated Screw System consists of screws, washers, and instruments designed to provide fixation for fractures, fusions, and osteotomies of large and small bones appropriate for the size of the device. The screws are available in three diameters (4.0 mm, 6.5 mm, and 7.3 mm), in lengths ranging from 10 mm to 150 mm to accommodate various indications and patient anatomies. All screws and washers are made of titanium alloy per ASTM F136. All implants are available nonsterile.

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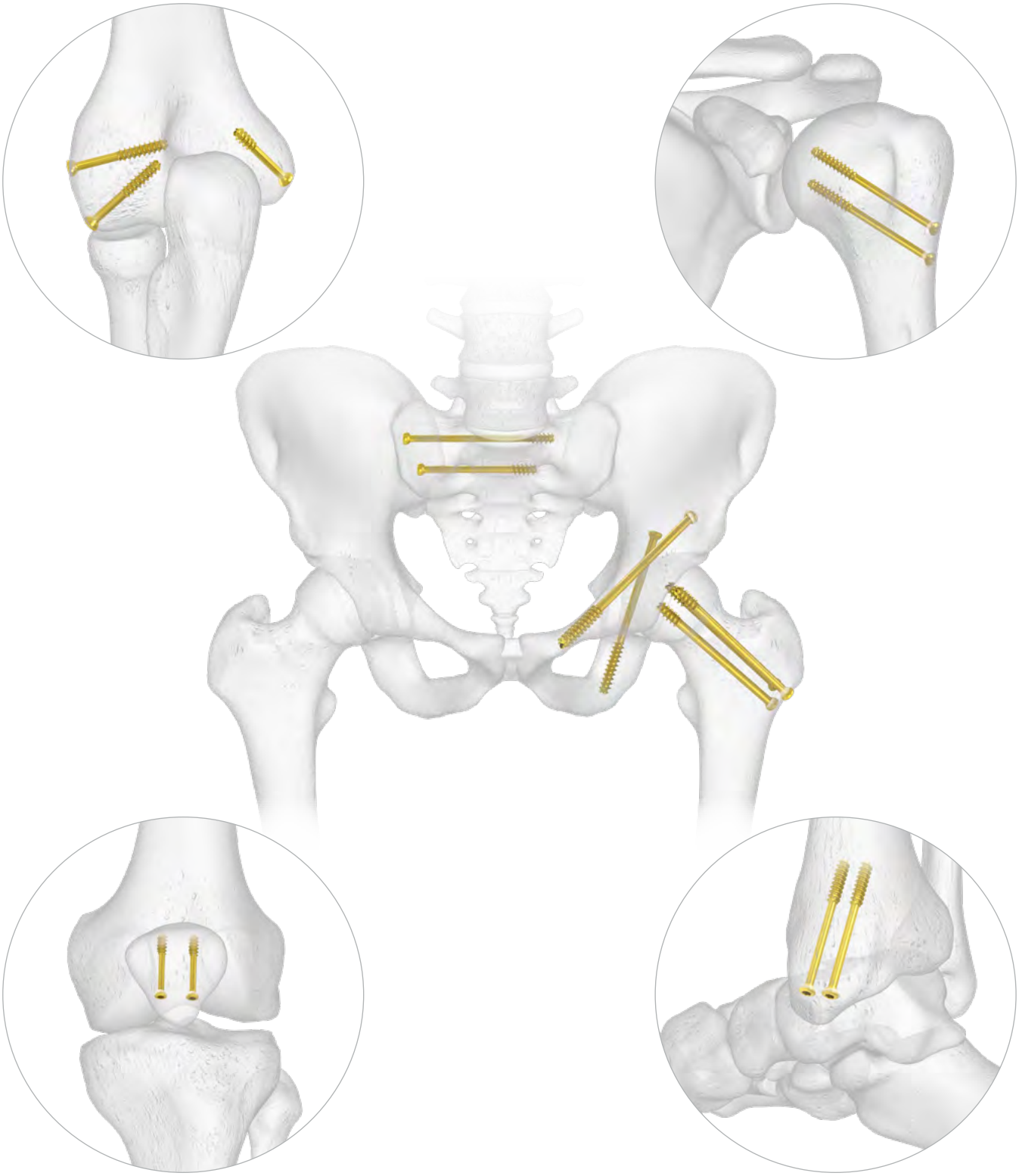
System Overview

All screws are cannulated in order to be used over a guide wire, and each screw is either partially or fully threaded using a cancellous thread form. Partially threaded screws may be used to lag one bone fragment to another, where the far bone fragment is captured by the threads of the screw and pulled toward the near cortex fragment on the head side of the screw. Fully threaded screws are intended to be used to stabilize fractures with little to no compression across the fracture.



System Overview [continued]

6.5 mm/7.3 mm Cannulated Screws

Driver Size	4.0 mm Cannulated LQR Hex Driver Tip (80-1874)
Drill Size	5.0 mm Cannulated Drill (80-1871)
Guide Wire Size	2.8 mm (.110") x 300 mm Threaded (80-1878) 2.8 mm (.110") x 300 mm Fluted (80-2535) 2.8 mm (.110") x 450 mm Threaded (80-2533)
Washer Size	13.0 mm Outer Diameter (OD) x 6.7 mm Inner Diameter (ID) (7003-13067)

Short Thread 16 mm

(3005-XXXXX)
30–150 mm

Long Thread 32 mm

(3006-XXXXX)
45–150 mm

Full Thread

(3007-XXXXX)
30–150 mm

Cannulated Screw Washer

(7003-13067)
13.0 mm OD x 6.7 mm ID

4.0 mm Cannulated Screws

Driver Size	2.5 mm Short Cannulated Hex Driver (80-3956)
Drill Size	2.7 mm Cannulated Drill, Quick Connect (80-2075)
Guide Wire Size	1.3 mm Threaded Guide Wire, 150 mm (80-2038) 1.3 mm Smooth Guide Wire, 150 mm (80-2039)
Washer Size	7.0 mm Outer Diameter (OD) x 3.6 mm Inner Diameter (ID) (7003-07036)

Partially Threaded Short – 1/3 Thread
4.0 mm x 10–72 mm

(3005-400XX)

10–60 mm – 2 mm increments
60–72 mm – 4 mm increments

Partially Threaded Long – 1/2 Thread
4.0 mm x 16–72 mm

(3006-400XX)

16–60 mm – 2 mm increments
60–72 mm – 4 mm increments

Cannulated Screw Washer

(7003-07036)
7.0 mm OD x 3.6 mm ID

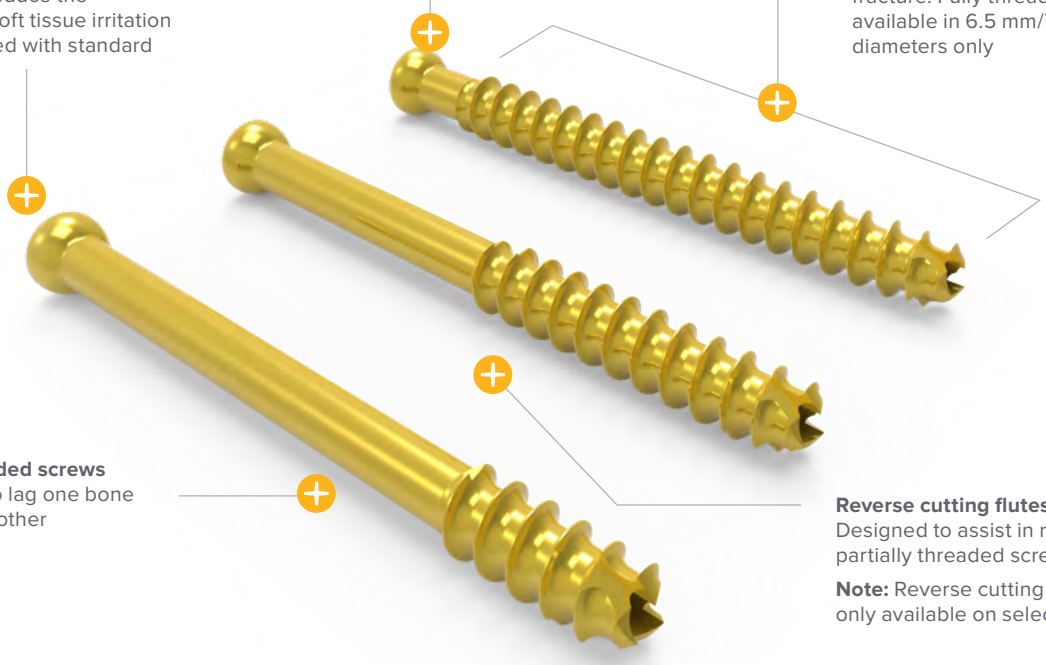
Cannulated Screw System Features

6.5 mm/7.3 mm screws

Cancellous thread form
Designed to maximize purchase in cancellous bone

Low-profile head
Designed to reduce the possibility of soft tissue irritation when compared with standard screw heads

Fully threaded screw
Provides stability across the fracture. Fully threaded screws available in 6.5 mm/7.3 mm diameters only



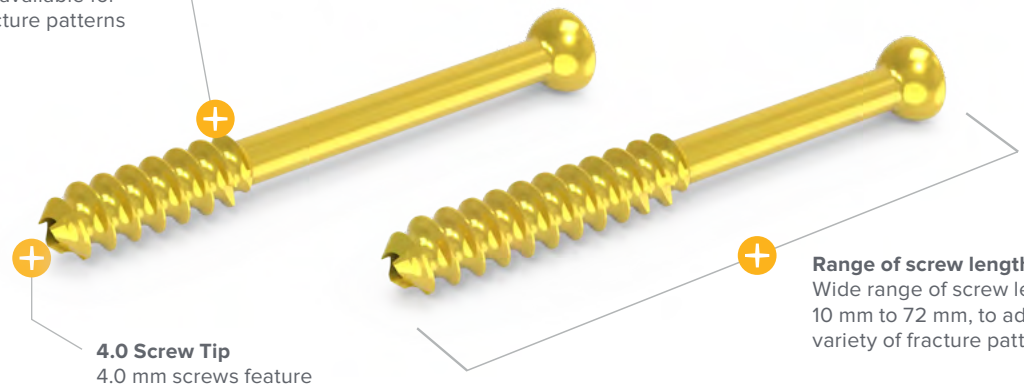
Partially threaded screws
May be used to lag one bone fragment to another

Reverse cutting flutes
Designed to assist in removal of partially threaded screws.

Note: Reverse cutting flutes only available on select screws

Short and long threads
Short- and long-threaded screws are available for various fracture patterns

4.0 mm screws



Range of screw lengths
Wide range of screw lengths, from 10 mm to 72 mm, to address a large variety of fracture patterns

4.0 Screw Tip
4.0 mm screws feature cutting flutes for self-drilling and self-tapping

- Wide range of screw lengths address a variety of fracture patterns
- Reverse cutting flutes are designed to assist in the removal of partially threaded screws (not included on some short thread 4.0 mm screws)
- Both threaded and fluted guide wires may assist the surgeon in targeting and establishing provisional fixation
- Both partially and fully threaded screws with a cancellous thread form are intended to treat a variety of fracture patterns
- Fully threaded screws are designed to maintain the compression generated during provisional fixation

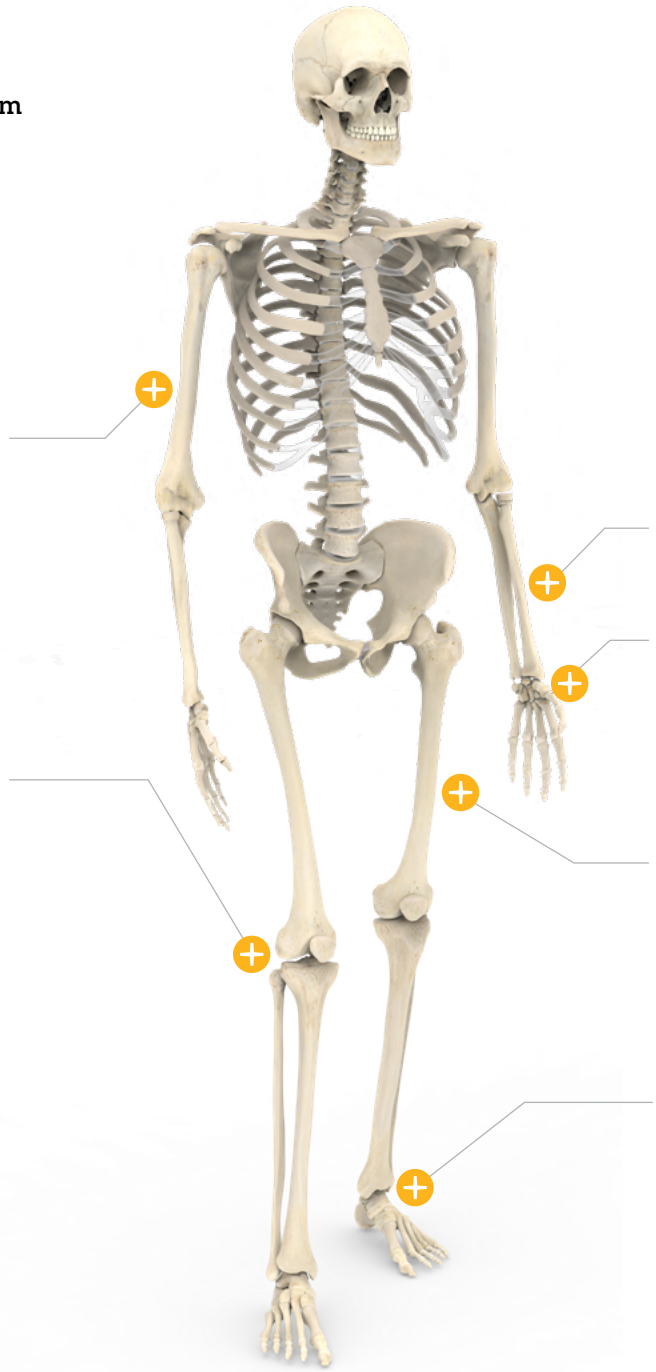
Indications for Use

The Acumed Cannulated Screw System consists of screws, washers, and instruments and is generally intended for fixation of fractures, fusions, and osteotomies of large and small bones appropriate for the size of the device.

Examples of Common 6.5 mm and 7.3 mm Fusions and Fractures

- Minimally invasive reconstruction of fractures and joints
- Adjuvant for osteosynthesis in complex joint fractures
- Simple metaphyseal fractures
- Condylar fractures
- Osteochondral fractures
- Fractures of the olecranon and distal humerus
- Humeral head fractures
- Tarsal fusions
- Fractures of the femoral head and neck
- An adjunct to DHS in basilar neck fractures
- Sacroiliac joint disruptions
- Acetabular fractures and other fractures of the pelvic ring
- Intracapsular fractures of the hip

Examples of Common 4.0 mm Fusions and Fractures



Shoulder and Elbow
Fractures of the olecranon and distal humerus
Radial head fractures
Humeral head fractures
Glenoid fractures

Forearm
Fractures of the ulna and radius

Hand and Wrist
Fragments of the wrist

Knee
Fractures of the distal femur and proximal tibia
Patellar fractures
Tibial plateau fractures

Femur
Intercondylar femur fractures
Supracondylar femoral fractures

Foot and Ankle
Metatarsal osteotomies
Avulsion fractures
Subtalar and ankle arthrodesis
Distal tibia and pilon fractures
Fractures of the fibula, malleoli, and calcaneus
Fractures of the tarsals and metatarsals
Calcaneal and talar fractures
Tarsometatarsal and metatarsophalangeal arthrodesis

6.5 mm/7.3 mm Cannulated Screw System Features

6.5 mm/7.3 mm Cannulated Countersink

The 6.5 mm/7.3 mm systems include a countersink that is designed to allow the screw to sink deeper into the bone, thus reducing the prominence of the head of the screw. Countersinking may reduce contact stress and the risk of local microfracture beneath the screw head, especially if the screw is highly angled.

Multiple Parallel Wire Targeting Guide

The Multiple Parallel Wire Targeting Guide allows for targeting in six locations at an 8 mm radius relative to the central hole in the guide. The surgeon places the guide wire into the center of the bone (either through the guide or without). The guide can then be slipped over the wire and rotated to allow for accurate placement of corresponding wires. This may be particularly useful in femoral neck fixation.

6.5 mm/7.3 mm Cannulated Tap

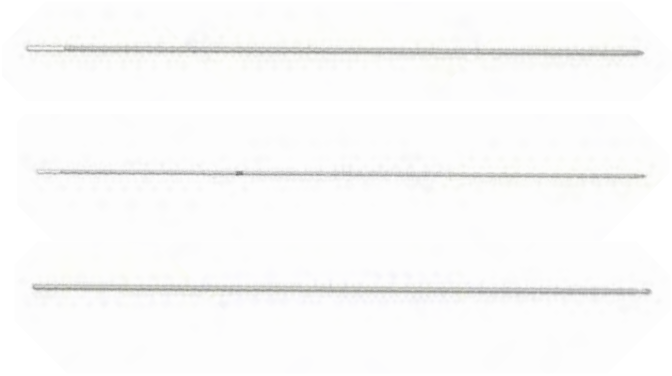
The 6.5 mm/7.3 mm systems both include a tap that may be used to create threads in a hole drilled in bone. The tap is recommended for use in particularly hard bone (cortical bone). The tap should be used after first drilling a pilot hole with the appropriately sized drill. The 6.5 mm/7.3 mm Cannulated Screws were designed with self-drilling and self-tapping features that may limit the need for use of the tap.

6.5 mm/7.3 mm Cannulated Screw System Features [continued]

6.5 mm/7.3 mm Screw Holding Sleeve

The 6.5 mm/7.3 mm System includes a Screw Holding Sleeve that is intended to slide over the 4.0 mm Driver and is recommended for use with all screws in the system to assist in maintaining contact between the driver interface and screw head. To use, slip the 4.0 mm Driver into the back of the Screw Holding Sleeve, engage the driver with the screw, and slip the Screw Holding Sleeve over the head of the screw. To remove, push on the back of the Screw Holding Sleeve with thumb while pulling back on the smooth portion of the sleeve.

Push forward with thumb and slide the Screw Holding Sleeve off the driver.



Guide Wires

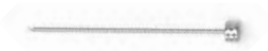
Acumed has included threaded and fluted guide wires in this system. To minimize the chance of a guide wire backing out during drilling, it is recommended that the surgeon run the drill on reverse when backing out of bone over the guide wire. Additionally, the surgeon may place a guide wire or plunger through the cannulated portion of the drill to hold the wire in place. Finally, the use of threaded and fluted guide wires should reduce the likelihood of the guide wire backing out during drilling.

2.8 mm Parallel Wire Guide

The Parallel Wire Guide allows for placement of one wire relative to the primary wire within a radius of 14 mm to 28 mm. The surgeon will place the guide wire through the fixed sleeve and then tighten the nut on the adjustable sleeve to set the parallel distance.

6.5 mm/7.3 mm Cannulated Screw Instrument Overview

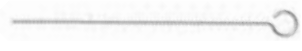
- System includes both threaded and fluted guide wires, designed to assist the surgeon with provisional fixation and screw placement
- Instrumentation is designed to aid in percutaneous insertion
- Easyout removal tool may aid in screw removal



2.8 mm Trocar
(80-1882)

7.3 mm/6.5 mm Screw Sizer
(80-1879)

4.0 mm Long Easyout, Quick Release
(80-2537)



2.8 mm Cleaning Stylet
(80-1887)

2.8 mm Wire Protection Sleeve
(80-1880)

2.8 mm (.110") x 300 mm Threaded Guide Wire
(80-1878)

2.8 mm (.110") x 300 mm Fluted Guide Wire
(80-2535)

2.8 mm (.110") x 450 mm Threaded Guide Wire
(80-2533)

Coupling Large Quick Release to Quick Release
(80-1884)

7.3 mm/6.5 mm Cannula
(80-1883)

2.8 mm Parallel Wire Guide
(80-1886)

7.3 mm/6.5 mm Screw Holding Sleeve
(80-1885)

13 mm Washer Sleeve
(80-1881)

5.0 mm Cannulated Drill
(80-1871)

7.3 mm/6.5 mm Cannulated Countersink
(80-1872)

7.3 mm/6.5 mm Cannulated Tap
(80-1873)

4.0 mm Cannulated Large Quick Release Hex Driver Tip
(80-1874)

4.0 mm Solid Large Quick Release Hex Driver Tip
(80-1875)

Handle, Large AO Type, Quick Release
(80-2216)

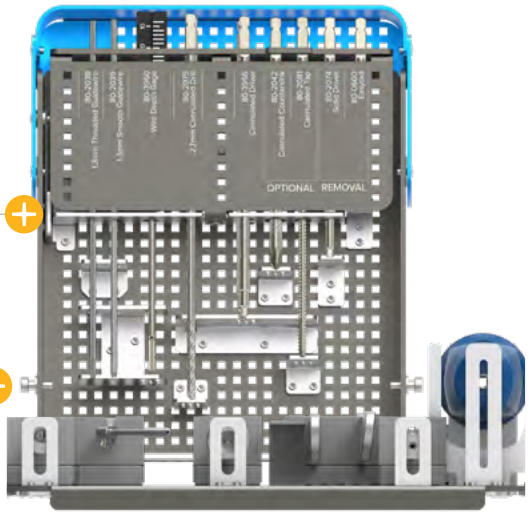
Additional

Multiple Parallel Wire Targeting Guide
(80-2534)

4.0 mm Cannulated Screw System Features

Locking Flip-Up Caddy

Contains core implantation instruments in an upright orientation with integrated locking feature, designed for maximum stability on the back table.



TripleTwist™ Cannula System

This modular cannula system is designed to protect the soft tissues and support a minimally invasive procedure. The cannulas feature an intuitive locking mechanism and are stacking and interchangeable to streamline the procedure. The cannulas can be used singularly or sequentially for flexibility and to accommodate procedural variations over nonstacking cannulas.

Parallel Wire Guide

Allows placement of two parallel wires. The drop-in cannula can be assembled after initial wire placement, then adjusted to select the optimal distance between wires and ultimately screw fixation.

Wire Depth Gauge

Includes large, high-contrast markings designed for accuracy and ease of use.

4.0 mm Cannulated Screw System Features [continued]

4.0 mm Cannulated Screw Instrument Specifications

	1.3 mm Threaded Guide Wire, 150 mm (80-2038)	Offered for provisional fixation and over-the-wire screw placement
	1.3 mm Smooth Guide Wire, 150 mm (80-2039)	Offered for provisional fixation and over-the-wire screw placement
	2.5 mm Short Cannulated Hex Driver (80-3956)	Laser marked for use with the modular cannula system
	4.0 mm Cannulated Tap (80-2081)	Provided for patients with hard bone and can be used according to surgeon preference
	5.3 mm Cannulated Countersink (80-2042)	The shorter length countersink is designed to improve control compared with competitors' longer devices, and features a textured portion for improved grip over competitive smooth-shaft countersinks when used by hand.
	2.5 mm Screw Driver Sleeve (80-3957)	Designed for retrieval of 4.0 mm screw, and retention on screw driver, from caddy to over-the-wire placement

4.0 mm Cannulated Screw Instrument Overview

Flip-up Caddy Instruments

1.3 mm Threaded Guide Wire, 150 mm
(80-2038)

1.3 mm Smooth Guide Wire, 150 mm
(80-2039)

1.3 mm Wire Depth Gauge
(80-3960)

2.7 mm Cannulated Drill, Quick Connect
(80-2075)

Cannula Handle
(80-3961)

1.3 mm Wire Cannula
(80-3962)

2.7 mm Drill Cannula
(80-3963)

4.0 mm Screw Cannula
(80-3964)

2.5 mm Short Cannulated Hex Driver
(80-3956)

5.3 mm Cannulated Countersink
(80-2042)

4.0 mm Cannulated Tap
(80-2081)

1.25 mm Cleaning Stylet
(80-2246)

Large Screw Holding Forceps
(MS-45210)

2.5 mm Screw Driver Sleeve
(80-3957)

1.3/2.7 mm Double Drill Sleeve
(80-2079)

1.3 mm Parallel Guide Base
(80-3778)

1.3 mm Parallel Guide Drop-in Cannula
(80-3781)

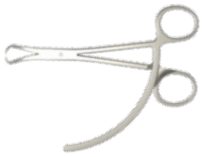
Small Ratchet Handle with Quick Release Connection
(80-0398)

2.5 mm Solid Hex Driver, Quick Connect
(80-2074)

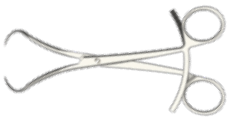
2.5 mm Easyout, Quick Release
(80-0600)

4.0 mm Cannulated Screw Instrument Overview [continued]

Reduction Instruments



Pointed Forceps w/Ratchet, Narrow Long
(80-2376)



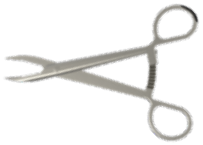
8" Bone Reduction Forceps
(MS-1280)

Periosteal Elevator
(MS-46212)

15 mm Hohmann Retractor
(MS-46827)

Freer Elevator 7.5
(MS-57614)

Bone Reduction Forceps, 5.25
(MS-45300)



Reduction Forceps w/ Serrated Jaw
(PL-CL04)

8 mm Hohmann Retractor
(PL-CL05)

Sharp Hook
(PL-CL06)

Note: Instrumentation in the system is not available in all markets or configurations.

Clinical Data Influence

Clinical Outcome of Arthroscopic Fixation of Anterior Tibial Eminence Avulsion Fractures in Skeletally Mature Patients: A Comparison of Suture and Screw Fixation Technique

Abstract

Background
Extreme tensile force to the anterior cruciate ligament results in an avulsion of the tibial eminence and it was believed to be more common in skeletally immature adolescent than adult. The purpose of this study is to compare the clinical results of both screw and suture fixation for surgical treatment of anterior tibial eminence fractures in skeletally mature patients.

Methods
A retrospective review was conducted on patients from 2002 to 2009 who sustained fractures of the anterior tibial eminence and were treated with arthroscopic-assisted fixation using either cannulated screws (25 patients) or Ethibond sutures (23 patients). Follow-up assessment included function evaluation, ligament laxity, and range of motion.

Results
Seventy-five percent of the anterior tibial eminence fractures resulted from traffic-related injuries in this study. Median operating time was 75 minutes in screw fixation group and 92 minutes in suture fixation group ($p = 0.006$). The objective International Knee Documentation Committee (IKDC) results for patients were 23 A, 2 B, and no C or D in screw fixation group and 16 A, 4 B, 3 C, and no D ($p = 0.040$) in suture fixation group. The KT-1000 side-to-side difference was greater than 5 mm in two patients (8%) in the screw fixation group and in three patients (13%) in the suture fixation group ($p = 0.058$). Among patients in screw fixation group, two (8%) patients had grade 1 pivot shift and 2 (8%) patients had grade 2 pivot shift. Among patients in suture fixation group, five (22%) patients had grade 1 pivot shift, three (13%) patients had grade 2 pivot shift, and 1 (9%) patient had grade 3 pivot shift ($p = 0.037$).

Conclusions
Significant better IKDC objective evaluation, lower glide pivot shift phenomenon, and shorter operating time requirement in screw fixation group with respect to suture fixation group were shown in our study although the other functional knee scores (Lysholm score, Tegner activity level, and the IKDC subjective score) and KT-1000 manual side-to-side difference only revealed a trend with better clinical results in screw fixation group than in suture fixation group rather than significant difference.[1]

Clinical Data Influence [continued]

Closed Reduction and Percutaneous Screw Fixation for Tibial Plateau Fractures

Abstract

Purpose

To evaluate treatment outcomes of closed reduction and percutaneous screw fixation for tibial plateau fractures.

Methods

48 men and 8 women aged 19 to 61 (mean, 36) years underwent closed reduction and percutaneous screw fixation for closed tibial plateau fractures with <5 mm depression. According to the Schatzker classification, patients were classified into type I (n=9), type II (n=22), type IV (n=5), and type V (n=20). Closed reduction was achieved using manual ligamentotaxis with traction in extension under image intensifier control. Reduction was fixed percutaneously with cancellous screws (6.5 mm) and washers. Functional outcome (pain, walking capacity, extension lag, range of motion, and stability) was evaluated using the Rasmussen score. A total score of 28 to 36 was considered as excellent, 20 to 27 as good, 10 to 20 as fair, and <10 as poor.

Results

Patients were followed up for a mean of 2.8 (range, 1-4) years. The mean length of hospital stay was 5 (range, 2-15) days. All the fracture united radiographically after a mean of 3 (range, 2.5-4.2) months. Respectively in Schatzker types-I, -II, -IV, and -V fractures, outcomes were excellent in 6, 10, 2, and 2 patients, good in 2, 9, 3, and 14 patients, fair in 1, 3, 0, and 2 patients, and poor in 0, 0, 0, and 2 patients. Outcome was satisfactory (good-to-excellent) in 89%, 86%, 100%, and 80% of the respective fracture types of patients. The mean Rasmussen score was 25.7 for all patients; it was 27.7 for type I, 26.3 for type II, 28.6 for type IV, and 23.4 for type V fractures. The mean Rasmussen score was significantly lower in 12 patients with ligament injury than in 44 patients without ligament injury (19.8 vs. 27.3, p<0.001). No patient had any complication (infection, wound dehiscence or hardware problem).

Conclusion

Closed reduction and percutaneous screw fixation for tibial plateau fractures is minimally invasive. It reduces the length of hospital stay and costs, enables early mobilisation with minimal instrumentation, and achieves satisfactory outcomes.[2]

Clinical Data Influence [continued]

Cannulated Screw Fixation for Femoral Neck Fractures: A 5-year Experience in a Single Institution

Abstract

Cannulated screw fixation is a widely accepted surgical method for management of fractures of the neck of femur especially in patients with poor premorbid conditions, minimally displaced fractures and those from a younger age group. A five year retrospective study was carried out in 53 consecutive patients between 2006 to 2010 to determine the pattern of injuries, management, outcomes and the associated predictive factors. All the patients underwent cannulated screw fixation, with 37 (69.8%) having had surgery within 24 hours and the remaining 16 (30.2%) 24 hours after the initial injury. All patients were followed up to union of fractures and complications thereafter if any. Good outcome was observed in 43 (81.1%) patients leaving only 10 (18.9%) patients with a poor outcome, of whom nine developed avascular necrosis (90%) and one non-union (10%). We found no significant relationship between the incidence of avascular necrosis and age of patient, fracture displacement, numbers of cannulated screws used, fracture reduction acceptability and anatomical location of the fracture. The time interval from injury to surgery and the presence of posterior comminution did seem to influence the rate of avascular necrosis but due to the small number of patients, was not statistically significant. We conclude that cannulated screw fixation is a viable option of treatment for fractures of the neck of femur.[3]

Clinical Data Influence [continued]

Comparison of Reconstruction Plate Screw Fixation and Percutaneous Cannulated Screw Fixation in Treatment of Tile B1 Type Pubic Symphysis Diastasis: A Finite Element Analysis and 10-year Clinical Experience

Abstract

Objective

The objective of this study is to compare the biomechanical properties and clinical outcomes of Tile B1 type pubic symphysis diastasis (PSD) treated by percutaneous cannulated screw fixation (PCSF) and reconstruction plate screw fixation (RPSF).

Materials and Methods

Finite element analysis (FEA) was used to compare the biomechanical properties between PCSF and RPSF. CT scan data of one PSD patient were used for three-dimensional reconstructions. After a validated pelvic finite element model was established, both PCSF and RPSF were simulated, and a vertical downward load of 600 N was loaded. The distance of pubic symphysis and stress were tested. Then, 51 Tile type B1 PSD patients (24 in the PCSF group; 27 in the RPSF group) were reviewed. Intra-operative blood loss, operative time, and the length of the skin scar were recorded. The distance of pubic symphysis was measured, and complications of infection, implant failure, and revision surgery were recorded. The Majeed scoring system was also evaluated.

Results

The maximum displacement of the pubic symphysis was 0.408 and 0.643 mm in the RPSF and PCSF models, respectively. The maximum stress of the plate in RPSF was 1846 MPa and that of the cannulated screw in PCSF was 30.92 MPa. All 51 patients received follow-up at least 18 months post-surgery (range 18–54 months). Intra-operative blood loss, operative time, and the length of the skin scar in the PCSF group were significantly different than those in the RPSF group. No significant differences were found in wound infection, implant failure, rate of revision surgery, distance of pubic symphysis, and Majeed score.

Conclusion

PCSF can provide comparable biomechanical properties to RPSF in the treatment of Tile B1 type PSD. Meanwhile, PCSF and RPSF have similar clinical and radiographic outcomes. Furthermore, PCSF also has the advantages of being minimally invasive, has less blood loss, and has shorter operative time and skin scar.[4]

Clinical Data Influence [continued]

Comparison of Rates of Union and Hardware Removal Between Large and Small Cannulated Screws for Calcaneal Osteotomy

Abstract

Background

The calcaneal osteotomy is a common procedure to correct hindfoot malalignment. Reported union rates are high, utilizing fixation methods including staples, plates, and most commonly cannulated screws. We began our practice using 6.5 mm and 7.3 mm cannulated screws, but complaints of postoperative posterior heel pain led to hardware removal in many patients. A switch to smaller 4.5 mm cannulated screws resulted in fewer symptoms, thus we hypothesized that using a smaller screw would decrease screw removal while maintaining an equally high union rate.

Methods

The records of patients who underwent a calcaneal osteotomy by 2 surgeons between January 1996 and April 2012 were retrospectively reviewed. The rates of hardware removal and union were compared between osteotomies held with two 7.3 mm, 6.5 mm, and 4.5 mm cannulated screws.

Results

There were 272 feet that met the inclusion criteria. The hardware removal rate for 130 osteotomies held with two 7.3 mm screws was 29.2% and the removal rate for 115 osteotomies held with 4.5 mm screws was 13.0%, which was significantly different ($P < .05$). The removal rate for 27 osteotomies with 6.5 mm screws was 33.3%. The union rate for all groups was 100%.

Conclusion

Fixation of calcaneal osteotomies with two 4.5 mm screws is advantageous over larger screws with respect to future hardware removal. There was no loss of position from the smaller screws and we feel that the 4.5mm cannulated screw provides sufficient compression and achieves a high rate of union equal to that of the larger screws.[5]

Clinical Data Influence [continued]

Functional Outcome of Capitellar Fracture Fixation with Cannulated Cancellous Screws

Abstract

Introduction

Management of capitellar fractures is a challenge to the orthopaedic surgeons considering the complications they pose. They are rare injuries and fewer studies have been published, in view of this the present study was done over a span of 9 years in order to obtain and study adequate number of cases. The purpose of this study was to evaluate the functional outcome of capitellar fracture fixation with cannulated cancellous screws.

Materials and Methods

Eighteen patients with capitellum fractures were studied between March 2002 and October 2010 (15 men and 3 women). Sixteen cases were operated within 9 days of injury. Patients were treated with open reduction and internal fixation using cannulated cancellous screws. All patients were followed up for a mean period of 49 months. Functional outcome was measured using Mayo elbow performance index and by radiology.

Results

The mean Mayo elbow performance index score was 95. All patients except one had excellent functional ratings according to this evaluation. The mean range of movements at elbow in flexion\extension was 124° (114°-134°) while range of movements in pronation\supination was 172° (124°-180°). Radiologically no evidence of avascular necrosis was noted in any of the patients at 1 year of follow up. One patient had secondary arthritis.

Conclusion

Cannulated cancellous screws fixation of capitellar fractures have very good functional outcome.[6]

Clinical Data Influence [continued]

Ankle Arthrodesis: A Systematic Approach and Review of the Literature

Abstract

Ankle arthrodesis is a common treatment used for patients with end-stage ankle arthritis (ESAA). The surgical goal of ankle arthrodesis is to obtain bony union between the tibia and talus with adequate alignment [slight valgus (0°-5°)], neutral dorsiflexion, and slight external rotation positions) in order to provide a pain-free plantigrade foot for weightbearing activities. There are many variations in operative technique including deferring approaches (open or arthroscopic) and differing fixation methods (internal or external fixation). Each technique has its advantage and disadvantages. Success of ankle arthrodesis can be dependent on several factors, including patient selection, surgeons' skills, patient comorbidities, operative care, etc. However, from our experience, the majority of ESAA patients obtain successful clinical outcomes. This review aims to outline the indications and goals of arthrodesis for treatment of ESAA and discuss both open and arthroscopic ankle arthrodesis. A systematic step by step operative technique guide is presented for both the arthroscopic and open approaches including a postoperative protocol. We review the current evidence supporting each approach. The review finishes with a report of the most recent evidence of outcomes after both approaches and concerns regarding the development of hindfoot arthritis.[7]

Competitive Comparison

6.5 mm/7.3 mm Cannulated Screws

	Acumed	Arthrex	Zimmer Biomet	DePuy Synthes
Product	Cannulated Screw System 6.5 mm/7.3 mm	4.5 mm/6.7 mm Low-Profile Screw	Biomet 6.5 mm/8.0 mm Cannulated Screw System	6.5 mm and 7.3 mm Cannulated Screws
Available Diameters & Lengths	6.5 mm x 30–150 mm, 16 mm Thread 6.5 mm x 45–150 mm, 32 mm Thread 6.5 mm x 30–150 mm, Full Thread 7.3 mm x 30–150 mm, 16 mm Thread 7.3 mm x 45–150 mm, 32 mm Thread 7.3 mm x 30–150 mm, Full Thread	6.7 mm x 40–120 mm, 18 mm Thread 6.7 mm x 40–120 mm, 28 mm Thread 6.7 mm x 40–120 mm, Full Thread	6.5 mm x 30–180 mm, 16 mm Thread 6.5 mm x 70–180 mm, 40 mm Thread 6.5 mm x 30–180 mm, Full Thread 8.0 mm x 30–180 mm, 16 mm Thread 8.0 mm x 70–180 mm, 40 mm Thread 8.0 mm x 30–180 mm, Full Thread	6.5 mm x 30–180 mm, 16 mm Thread 6.5 mm x 45–180 mm, 32 mm Thread 6.5 mm x 20–180 mm, Full Thread 7.3 mm x 30–180 mm, 16 mm Thread 7.3 mm x 45–180 mm, 32 mm Thread 7.3 mm x 20–180 mm, Full Thread
Material	Titanium	Titanium	Titanium	Stainless Steel and Titanium

Competitive Comparison [continued]

6.5 mm/7.3 mm Cannulated Screws

	Acumed	Smith & Nephew	Stryker	Wright Medical
Product	Cannulated Screw System 6.5 mm/7.3 mm	Large Cannulated Screw System 6.5 mm, 7.0 mm	Asnis III Cannulated Screw System	DARCO Headed Cannulated Screw System
Available Diameters & Lengths	6.5 mm x 30–150 mm, 16 mm Thread 6.5 mm x 45–150 mm, 32 mm Thread 6.5 mm x 30–150 mm, Full Thread 7.3 mm x 30–150 mm, 16 mm Thread 7.3 mm x 45–150 mm, 32 mm Thread 7.3 mm x 30–150 mm, Full Thread	6.5 mm x 30–180 mm, 22 mm Thread 6.5 mm x 55–180 mm, 46 mm Thread 6.5 mm x 30–180 mm, Full Thread 7.0 mm x 30–150 mm, 16 mm Thread 7.0 mm x 45–150 mm, 32 mm Thread 7.0 mm x 30–130 mm, Full Thread	6.5 mm x 40–120 mm, 20 mm Thread 6.5 mm x 40–130 mm, 40 mm Thread 6.5 mm x 30–150 mm, Full Thread 8.0 mm x 40–180 mm, 25 mm Thread (135-180 Stainless Steel only) 8.0 mm x 40–150 mm, Full Thread	6.5 mm x 35–120 mm, Short Thread 6.5 mm x 70–120 mm, Long Thread 7.5 mm x 35–120 mm, Short Thread 7.5 mm x 70–120 mm, Long Thread
Material	Titanium	Stainless Steel and Titanium	Stainless Steel and Titanium	Titanium

Competitive Comparison [continued]

4.0 mm Cannulated Screws

	Acumed	DePuy Synthes	Stryker	Arthrex
Product	Cannulated Screw System 4.0 mm	4.0 mm Cannulated Screw	Asnis III Cannulated Screw System	QuickFix Cannulated Screw Set
Overall Length Range (mm)	10–72 mm	10–72 mm	10–70 mm	14–60 mm
Size Increment (mm)	**1/3 thread:** 10–60 mm in 2 mm increments 64–72 mm in 4 mm increments (10–28 mm, 2 ea 30–60 mm, 4 ea 64–72 mm, 2 ea) **1/2 thread:** 16–60 mm in 2 mm increments 64–72 mm in 4 mm increments (2 ea)	**1/3 thread:** 10–60 mm in 2 mm increments 64–72 mm in 4 mm increments (set only, 10–50 mm, 3 ea) **1/2 thread:** 16–60 mm in 2 mm increments 64–72 mm in 4 mm increments	**Partially threaded (1/3 thread):** 14 mm–70 mm 14 mm–50 mm in 2 mm increments 55 mm–70 mm in 5 mm increments **Fully threaded:** 10 mm–50 mm in 2 mm increments	**Partially threaded:** 14–60 mm in 2 mm increments, 4 ea
Low-profile Head	Yes	Yes	Yes	Yes
Threads	1/3 thread and 1/2 thread	4.5 available in fully threaded	1/3 thread and full thread	Partially threaded
Material	Titanium	Titanium or stainless	Titanium and/or stainless	Titanium
Anodization/ Color	Anodized gold	Titanium only, gold color	Titanium screws, dark grey	Type II, light grey

Competitive Comparison [continued]

Implantation Instruments

	Acumed	DePuy Synthes	Stryker	Arthrex
Guide Wire Type	Threaded and smooth	Threaded and smooth	Threaded (smooth only offered in Asnis JFX System)	Threaded and smooth
Screw/Driver Interface	2.5 mm Hex	2.5 mm Hex	2.5 mm Hex (Hexalobe Asnis JFX only)	Hexalobe
Self-drilling/Self-tapping	Yes	Yes	Yes	Yes
Reverse Cutting Flutes	Yes	Yes	Yes	No
Driver with Elastosil Handle	Yes	No	Yes	No

Novel Instruments

	Acumed	DePuy Synthes	Stryker	Arthrex
Modular, Interlocking, Soft Tissue Protection, Cannula System	Yes	No	No	No
Parallel Wire Guide with Removable Cannula	Yes	No	No	No
Shorter Countersink with Textured Portion for Grip	Yes	No	No	No

510(k) Clearance Information

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

March 18, 2013

Acumed LLC
% Ms. Kara Budor
Regulatory Specialist
5885 Northwest Cornelius Pass Road
Hillsboro, Oregon 97124

Re: K123890
Trade/Device Name: Acumed Cannulated Screw System
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: Class II
Product Code: HWC, OUR
Dated: December 17, 2012
Received: December 18, 2012

Dear Ms. Budor:

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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,

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]

Acumed Cannulated Screw System
510(k) Notification

Indications for Use

510(k) Number (if known): K123890 (pg 1/1)

Device Name: Acumed Cannulated Screw System

Indications for Use:

The Acumed Cannulated Screw System consists of screws, washers, and accessories and is generally intended for fixation of fracture, fusion and osteotomies of large and small bones appropriate for size of device, which may include the following: Minimally invasive reconstruction of fractures and joints; Adjuvant for osteosynthesis in complex joint fractures; Multifragment joint fractures; Simple metaphyseal fractures; Fractures of the wrist, ankle, elbow, and shoulder; Condylar fractures; Epiphyseal and metaphyseal fractures in children; Osteochrondritis dissecans; Ostero-Chondral Fractures; Ligament avulsion injuries; Ligament fixation; Other small fragment, cancellous bone fractures; Small joint fusion; Areas where accurate screw placement is vital; Metatarsal and phalangeal osteotomies; Fractures of the tarsals, metatarsals and other fractures of the foot; Avulsion fractures and fractures of metatarsal V; Tarso-metatarsal and metatarso-phalangeal arthrodesis; Tarsal Fusions; Calcaneal and talar fractures; Subtalar arthrodesis; Ankle arthrodesis; Fractures of small joints, such as: Ankle fractures, Navicular fractures; Fractures of the fibula, malleolus, and calcaneus; Distal tibia and pilon fractures; Acetabular fractures; Other fractures of the pelvic ring; Sacroiliac joint disruptions; Fractures of the femoral head and neck; Supracondylar femoral fractures; Slipped capital femoral epiphyses; An adjunct to DHS in basilar neck fractures; Pediatric femoral neck fractures; Intercondylar femur fractures; Intracapsular fractures of the hip; Fractures of the distal femur and proximal tibia; Patellar fractures; Tibial plateau fractures; Small fragments of the hand and wrist; Fractures of the carpals and metacarpals; Carpal and metacarpal arthrodesis; Scaphoid fracture and other fractures of the hand; Phalangeal and interphalangeal fractures; Fractures of the ulna and radius; Radial head fractures; Fractures of the olecranon and distal humerus; Humeral head fractures; Ligament fixation at the proximal humerus; and Glenoid fractures. Washers may be used with the screws in certain applications.

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Elizabeth L. Frank -S

Division of Orthopedic Devices

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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 Trauma Solutions

Acumed has pioneered trauma solutions for indications across the upper and lower extremities for more than 30 years. In order to address the needs of long-bone trauma surgeons, Acumed developed the Cannulated Screw System for fixation of fractures of the pelvis and lower extremities.

Acumed's other trauma solutions include:

- Acutrak® 1 & 2 Screw System
- Clavicle Plating System
- Polarus® 3 Plate and Nail System
- Elbow Plating System
- Anatomic Radial Head Solutions 2
- Acu-Loc® 2 Wrist Plating System
- Pelvic Plating System
- Fibula Rod System
- Ankle Plating System 3

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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