

## 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® Biotrak® Resorbable Fixation System

The Biotrak resorbable fixation system is designed to provide fixation for small bones and bone fragments in the upper and lower extremities, including fractures, fusions, and osteotomies. The Biotrak system of fixation devices is composed of the Biotrak Helical Nail, the Biotrak Pin, and the Biotrak Standard and Mini Screw.

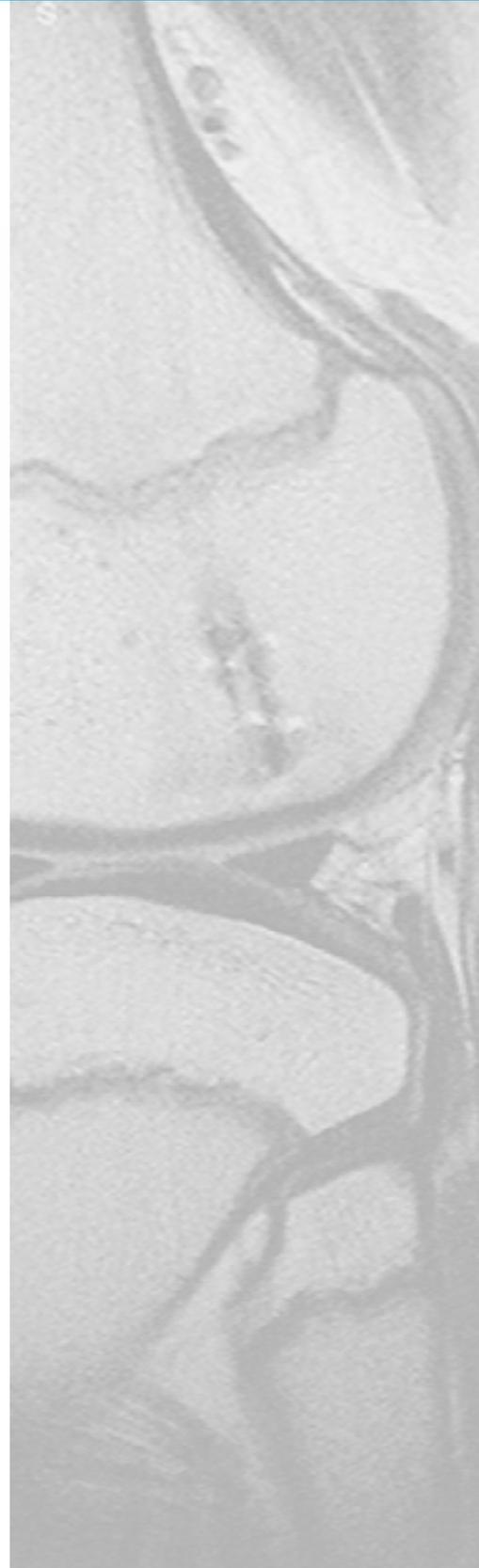
Biotrak fixation devices are made from 100% poly L-lactic acid (PLLA), allowing the implant to resorb over five years as the bone heals.<sup>1</sup> The Biotrak Screw incorporates the same advanced technology as the Acumed Acutrak® family of headless compression screws including continuously variable thread pitch, tapered profile, cannulation, and a fully threaded length. The Biotrak Helical Nail provides compression similar to an Acutrak screw with the insertion ease of a pin.<sup>2</sup> The Biotrak Pin offers surgeons a headed fixation solution with a multifaceted fin design intended to facilitate fixation and compression and protect against rotational forces.

### Patient Needs Addressed by Biotrak Resorbable Fixation System

- ▶ Broad base of patient indications addressed:
  - The Biotrak family of products addresses more than 20 of the most common indications of the hand and wrist, foot, and ankle

### When Compared to Similar Metal Fixation Devices, the Biotrak Resorbable Implants Offer:

- ▶ Predictable degradation to provide progressive bone loading
  - May prevent stress shielding, thereby aiding in bone healing
- ▶ Compatible with magnetic resonance imaging (MRI)
  - May improve postoperative imaging
- ▶ Reduced radiographic scatter/obstruction
  - May clarify postoperative viewing of affected region



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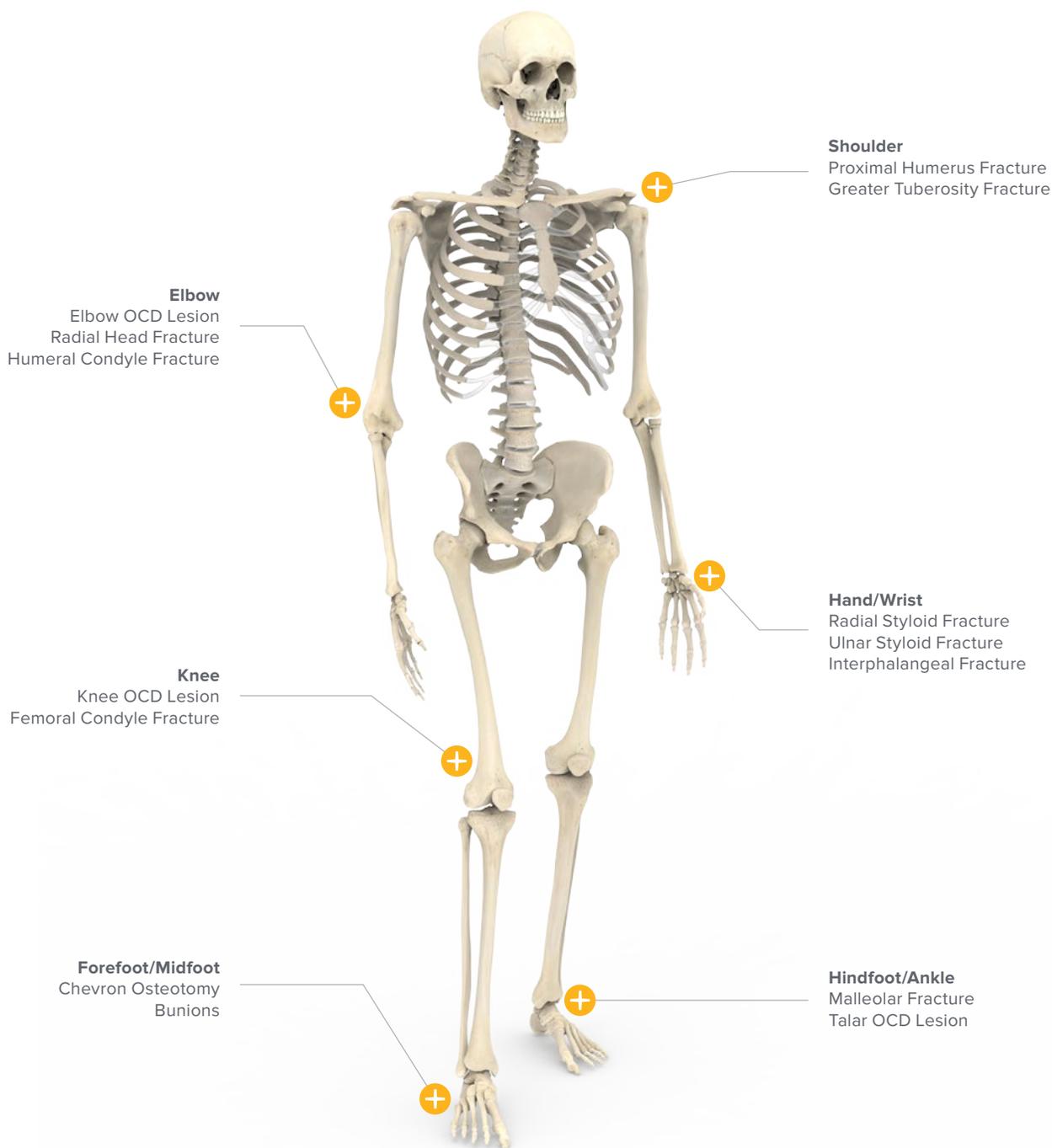
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# Indications for Use

## Acumed Biotrak® Resorbable Fixation System

The Biotrak Resorbable Compression Screw and Helical Nail are intended to provide fixation and/or reduction of small bone fractures, osteotomies, arthrodeses, cancellous fragments, and osteochondral fragments in the upper and lower extremities. Specifically, these indications include osteochondral defects (OCDs), patella rim fractures, tarsal fractures, metatarsal fusions and fractures, metatarsal osteotomies, hallux valgus corrections, humeral condyle fractures, metacarpal fusions and fractures, carpal fusions and fractures, radial head fractures, and distal radius fractures. The Biotrak Pin is intended for use in fixation and/or alignment of fragments and fractures of non-load-bearing bones, osteotomies, arthrodeses, cancellous fragments, and osteochondral fragments in the upper and lower extremities.

## Biotrak Usage Across the Anatomy



# System Features

## Biotrak Screw

The Biotrak Resorbable Compression Screw incorporates the same advanced technology as the Acutrak® family of headless compression screws: continuously variable thread pitch, tapered profile, cannulation, and a fully threaded length. Acumed's Biotrak Standard and Mini headless resorbable compression screws are an orthopaedic solution for bone applications where a resorbable implant is desired.

### Strength and Durability

Biomechanical tests demonstrate the Biotrak screw is comparable to Acutrak in the compression achieved in foam bone [Acumed Test Report: TR00695].

**Headless**  
Designed to allow the screws to be implanted in and around articular regions with minimal risk of impingement or soft tissue irritation

**Fully Threaded Length**  
Biomechanical studies have shown that, in comparison to partially threaded headed screws, fully threaded screws better handle the cyclic loading that may occur during healing.<sup>2</sup> In addition, this feature allows the length of the screw to lie almost anywhere along the fracture or osteotomy site

**Cannulated**  
Designed to facilitate accurate percutaneous insertion with minimal soft tissue dissection

**Resorbable**  
Manufactured from 100% PLLA, Biotrak screws resorb completely over five years.<sup>3</sup> PLLA permits natural bone remodeling through a gradual transfer of stress to the healing bone, which may reduce the risk of stress shielding

**Continuously Variable Thread Pitch**  
The wider thread pitch at the tip of the screw penetrates the bone faster than the finer trailing threads, compressing the two fragments gradually as the screw is advanced

**Ejector**  
The ejector releases the driver from the screw in a controlled manner. Laser marks on the ejector indicate the depth of the proximal end of the screw beneath the bone's surface

Description	Tip Size	Guide Wire
<b>Biotrak Standard</b> 16–22 mm	3.6 mm	.045" x 6"
<b>Biotrak Mini</b> 16–24 mm	3.2 mm	.035" x 6"

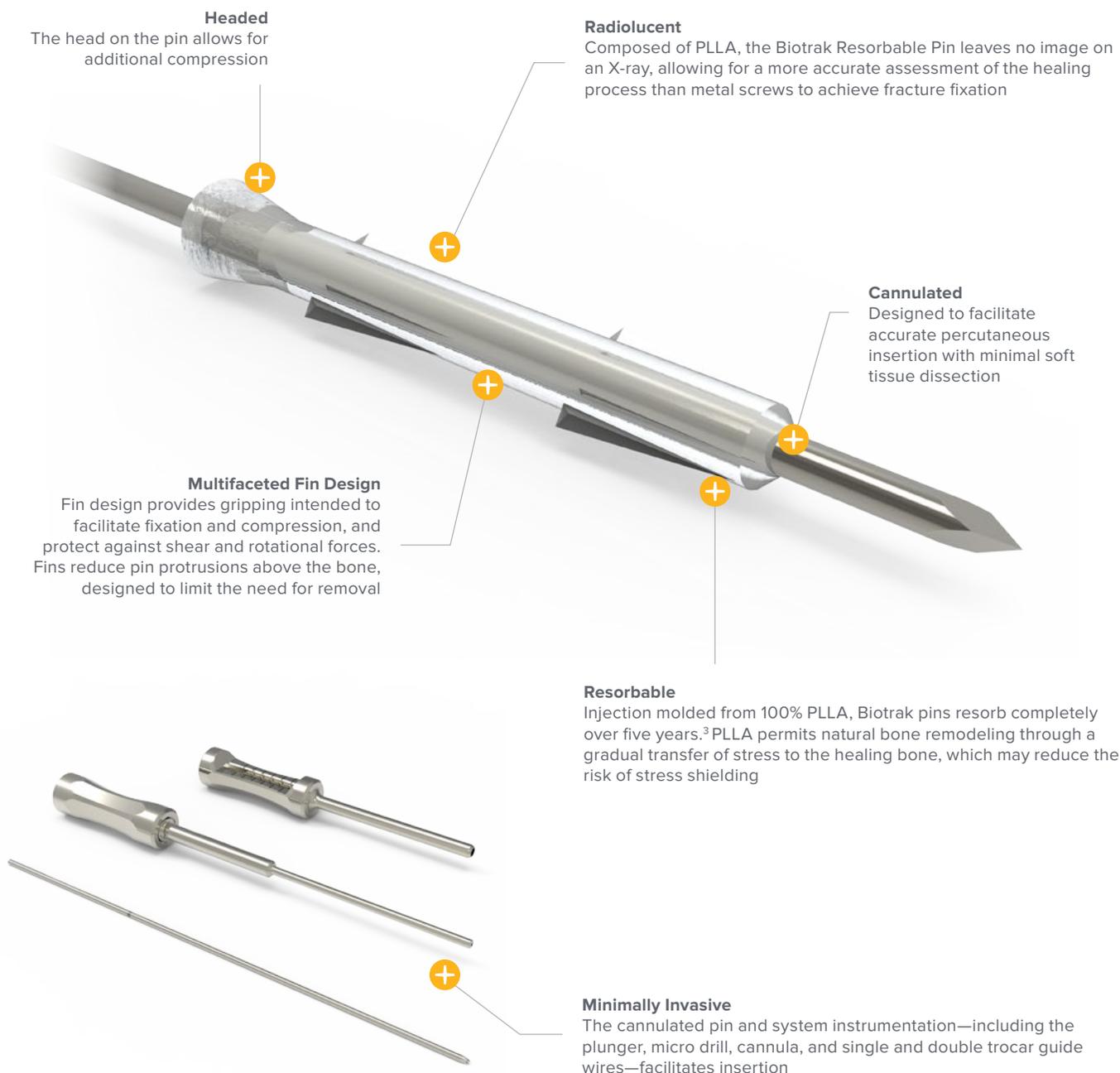
## Potential Applications

- ▶ Osteochondral Defects
- ▶ Patellar Rim Fractures
- ▶ Tarsal Fractures
- ▶ Metatarsal Fractures
- ▶ Metatarsal Osteotomies
- ▶ Humeral Condyle Fractures
- ▶ Metacarpal Fractures
- ▶ Radial Head Fractures
- ▶ Distal Radius Fractures

## System Features [continued]

### Biotrak Resorbable Pin

Combining advanced implant technology with straightforward cannulated instrumentation, the Acumed Biotrak Resorbable Pin is an excellent alternative to metal fixation for fractures, fusions, and osteotomies in non-load-bearing bone in the upper and lower extremities.



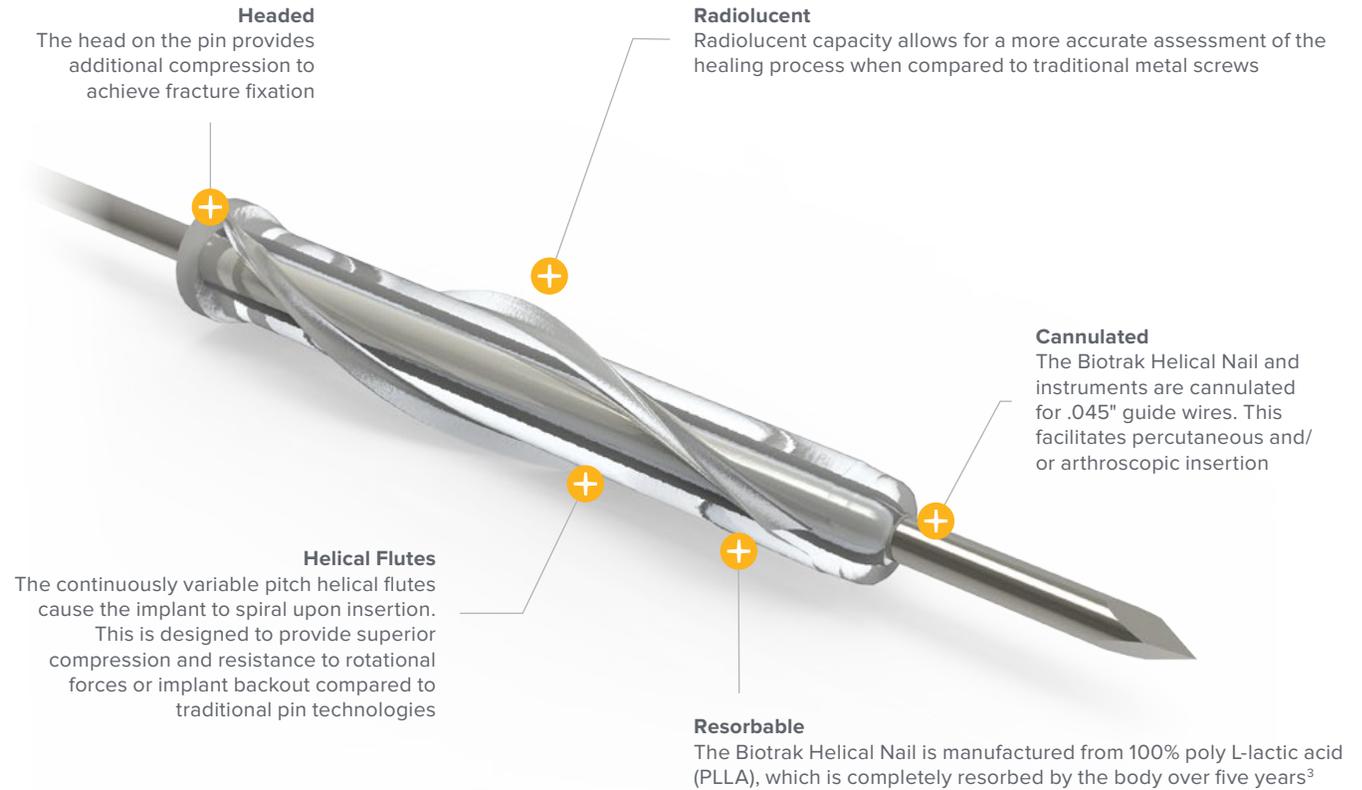
### Potential Applications

- ▶ Fixation and alignment of fragments and fractures in non-load-bearing bones of the upper and lower extremities
- ▶ Osteotomies
- ▶ Arthrodesis
- ▶ Cancellous Fragments
- ▶ Osteochondral Fragments

## System Features [continued]

### Biotrak Helical Nail

The Biotrak Helical Nail provides compression and pullout strength with the insertion ease of a pin.



### Potential Applications

- ▶ Osteochondral Defects
- ▶ Patellar Rim Fractures
- ▶ Tarsal Fractures
- ▶ Metatarsal Fusions and Fractures
- ▶ Metatarsal Osteotomies
- ▶ Hallux Valgus Corrections
- ▶ Humeral Condyle Fractures
- ▶ Metacarpal Fusions and Fractures
- ▶ Carpal Fusions and Fractures
- ▶ Radial Head Fractures
- ▶ Distal Radius Fractures

## System Technology



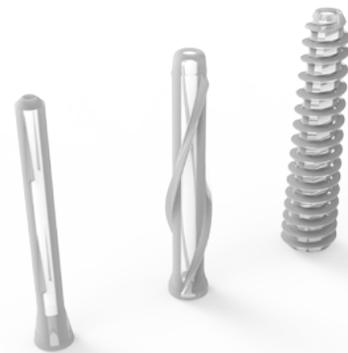
### Continuously Variable Thread Pitch (Biotrak Standard and Mini)

Biotrak Standard and Mini design features include a unique, patented thread pitch that varies continuously from tip to tail. This ensures each screw rotation engages threads into new bone along the screw's entire length. As each successive individual thread advances faster than the trailing thread counterpart, the conical shape becomes seated into bone. This radial expansion of the screw threads, combined with their axial advancement, creates the ability to reduce and compress bone fragments in a headless construct.

### PLLA Resorbable Technology

Traditionally, metallic screws have usually been used to provide initial graft fixation. However, possible long-term adverse effects of permanently implanted metallic devices have been suggested.<sup>1</sup> Resorbable implants were developed to avoid potential metal sensitivity and stress concentrations associated with permanently implanted metal screws, to allow undistorted postoperative radiological follow-up studies, and to limit the necessity for a possible second operation for metal removal.<sup>1</sup>

Bioresorbable implants may offer advantages over traditional metal implants. The purpose of bioresorbable implants is to provide initial fixation strength comparable to commercially available metallic interference screws while allowing eventual resorption and replacement with host bone. Clinical and biomechanical studies demonstrated that metal screws used in cruciate ligament surgery can be successfully replaced by bioresorbable screws. Biocompatibility and complete degradation of these screws, as well as their substitution by new bone, have been confirmed by clinical experience over many years. These implants are designed to retain their strength long enough to support a healing bone, then gradually disintegrate in the patient's body.<sup>1</sup>



### PGA Resorbable Polymers vs PLLA

The two most common orthopaedic polymers, poly L-lactic acid (PLLA) and polyglycolic acid (PGA), exhibit distinctly different degradation behavior.<sup>1</sup> PGA is hydrophilic and degrades very quickly, losing virtually all strength within one month and all mass within 6–12 months.<sup>1</sup> During this phase of rapid degradation, large quantities of the glycolide monomer are released.<sup>1</sup>

PLLA has a much slower rate of absorption.<sup>1</sup> This homopolymer of L-lactide is highly crystalline due to the ordered pattern of the monomers and has been documented to take more than five years to absorb.<sup>1</sup>

The incidence of adverse tissue reactions to implants made of PGA (faster degradation) has been reported from 2.0 to 46.7%.<sup>1</sup> Adverse reactions can occur if the rate of degradation exceeds the limit of tissue tolerance, as can be the case with PGA.<sup>1</sup> The pH of tissue near the implant may decrease as a result of accumulation of released monomers as the implant degrades.<sup>1</sup> This drop in the local pH in turn can lead to increased osmotic pressure, which may lead to a temporary expansion of the implant cavity or to a local sterile fluid accumulation. The patient would notice this reaction as swelling and pain, and would typically be prescribed anti-inflammatory drugs and rest.<sup>1</sup>

Conversely, in studies investigating PLA-based implants (slower degradation), the incidence of adverse tissue reaction is much lower, from 0% to 1%.<sup>1</sup>

## System Technology [continued]

### Metal vs PLLA Implants

Titanium is currently the most widely used metal for fracture fixation. Other metals commonly used include stainless steel and cobalt chrome. While metal has the high strength and rigidity to allow the healing process to begin, it can also have negative effects. Metal implants have the potential to cause:

- ▶ Stress shielding<sup>1</sup>
- ▶ Accumulation of metals in tissues<sup>1</sup>
- ▶ Metal sensitivity<sup>1</sup>
- ▶ Growth restriction<sup>1</sup>
- ▶ Pain<sup>1</sup>
- ▶ Corrosion<sup>1</sup>
- ▶ Implant migration<sup>1</sup>
- ▶ Imaging and radiotherapy interference<sup>1</sup>

Additionally, metal implants may require an operation to remove the implant once the healing process is complete or due to any of the complications above.



### Performance Data of PLLA Implants

Numerous studies have demonstrated similar performance outcomes between metal and PLLA bioresorbable screws, pins, and nails in osteochondral lesions and tibial inlays. Bioresorbable screw fixation as part of a tibial inlay technique for posterior cruciate ligament reconstruction in one study was shown to not compromise the strength and stiffness characteristically afforded by metal fixation.<sup>4</sup> Another study examined the results of osteochondral lesions involving the femoral condyle that were repaired with a PLLA bioresorbable nail. Reviewed 33 months postoperatively, results showed a mean postoperative Lysholm score (cumulative assessment of patient response to various criteria including limp, pain, locking, swelling, etc.) of 94—a similar result to that found with metallic fixation.<sup>3</sup> Another study compared the clinical results of 745 patients undergoing ACL reconstruction (including 378 patients managed with bioresorbable screws and 367 patients managed with metal screws).<sup>5</sup> The clinical results associated with bioresorbable screws and metal screws were statistically similar in response to IKDC, Lysholm, and Tegner activity scores. Additionally, Laxity evaluation demonstrated no significant difference between bioresorbable screws and metal screws.<sup>5</sup> A final study assessed whether the use of bioresorbable pins made from PLLA with prolonged degradation periods for fracture fixation may lead to adverse soft tissue reactions, including seromas, discharging sinuses, or osteolytic change. A total of 21 patients with varying levels of Mason classification radial head fractures were clinically and radiographically evaluated, and no material-related adverse effects were observed during or beyond that degradation period.<sup>6</sup>

### Patient Response to Bioresorbable Implants

Results of a patient perspective study published in the February 2005 Journal of Injury by Mittal et al cited that 91% of patients referred to the removal operation as the most negative aspect of a metal implant distal radius repair.<sup>7</sup> An additional surgery increases treatment and rehabilitation time, which can have a significant impact on the quality of patients' lives. Some patients may experience temperature sensitivity with metal implants and may be uncomfortable being able to see and feel the metal under the skin. They may also be apprehensive of metal-detecting security systems.<sup>1</sup>

The Mittal et al study also mentioned that 95% of patients appreciated the features of bioresorbable implants and responded that they would prefer to have their fracture stabilized with a bioresorbable implant.<sup>1</sup>

### Overall Potential Benefits of Bioresorbable Implants

#### Patient Benefits

- ▶ No permanent implant in the body
- ▶ Biocompatible material, designed to limit the risk of metal allergic reactions
- ▶ No long-term implant palpability
- ▶ No implant temperature sensitivity

#### Additional Benefits

- ▶ Predictable degradation to provide progressive bone loading, designed to prevent stress shielding to aid better bone healing
- ▶ Provided sterile, reducing risk of cross-infection

#### Surgical Benefits

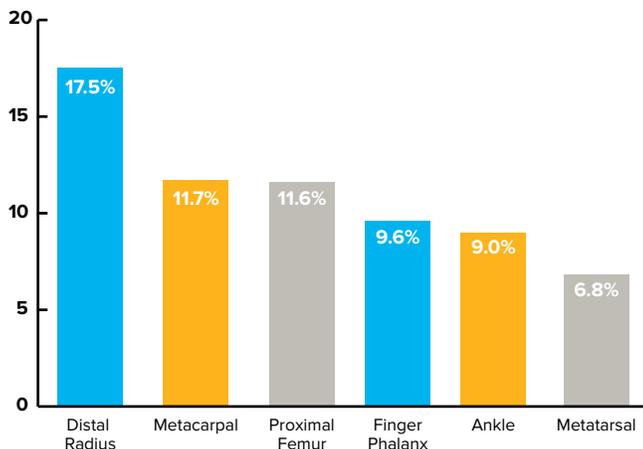
- ▶ Compatible with magnetic resonance imaging (MRI) for post-operative diagnosis
- ▶ Reduced radiographic scatter/obstruction
- ▶ Minimized risk of obstruction during any follow-up surgery

# Clinical Data Influence

## Small Bone Fracture Incidence and Operative Rates

It is estimated that nearly 17.6 million fractures occurred in the United States in 2013. This figure was determined by multiplying the rate of fractures treated in 2000 in Edinburgh (5,593 fractures per 100,000 people)<sup>8</sup> by the 2013 US population (315.1M people).<sup>9</sup>

2000 Common Fractures in Edinburgh<sup>8</sup>



Common methods of repair for these procedures are:

- ▶ Open and closed reduction with and without fixation
- ▶ Internal fixation without reduction
- ▶ Application of external fixator<sup>4</sup>

## Hand and Wrist Incidence and Operative Rates

The tables below estimate the number of fractures occurring as well as operative rates identified in the literature. Children and the elderly are the most affected populations, with the most common mechanism of injury being falls at nearly 50%.<sup>9</sup> These numbers have been used to estimate the number of operations expected to occur in the US for each fracture type.<sup>8,9</sup>

Average Incidence Rates <sup>8</sup>	Per 100,000
Carpal Fractures	29.7
Metacarpal Fractures	130.3
Phalangeal Fractures	107.3

## Clinical Data Influence [continued]

### Foot and Ankle Incidence and Operative Rates

2010–2017 Global Foot and Ankle Internal Fixation Devices Market Volume by Product (No. of Units) <sup>10</sup>						Average Incidence Rates <sup>8</sup>	Per 100,000
	2010	2011	2012	2017	CAGR% (2012–2017)		
<b>Plates</b>	635,513	690,157	749,595	1,135,372	8.7	Tarsal/ Metatarsal	75.4
<b>Screws</b>	1,779,733	1,915,482	2,061,604	2,977,902	7.6		
<b>Wires &amp; Pins</b>	1,509,869	1,650,698	1,804,594	2,816,847	9.3	Ankle	100.8
<b>Fusion Nails</b>	81,485	89,379	98,052	156,157	9.8	Calcaneus	13.7
<b>Total</b>	4,006,600	4,347,727	4,713,845	7,088,295	7.6		

### OCD Incidence and Operative Rates

Osteochondritis dissecans (OCD) is a pathological condition that results in destruction of subchondral bone with secondary damage to overlying articular cartilage.<sup>11</sup> Factors such as inflammation, ossification, and repetitive trauma contribute to the pathogenesis of OCD. Left untreated, OCD can lead to the development of osteoarthritis at an early age, resulting in progressive pain and disability.<sup>11</sup> OCD is classified as a juvenile or adult form based on the skeletal maturity of the patients.

2012 Average Incidence Rates United States	Per 100,000
Ankle	4.70
Elbow	2.20
Foot	0.05
Shoulder	0.11
Knee	27.90



# Competitive Comparison

## Biotrak Screw

	Acumed	ConMed Linvatec	Zimmer Biomet	Zimmer Biomet
<b>Product</b>	Biotrak Standard Screw  Biotrak Mini Screw	SmartScrew II Implants <sup>1</sup>	Weil-Carver Hammertoe Implant <sup>2</sup>	ReUnite Orthopedic Screw System <sup>3</sup>
<b>Available Diameters &amp; Lengths</b>	3.6 mm: 16–24 mm 3.2 mm: 16–24 mm	2.0 mm: 10–20 mm 2.7 mm: 10–24 mm 3.5 mm: 14–40 mm 4.5 mm: 24–70 mm	2.0 mm: 16 mm 2.3 mm: 22 mm 2.5 mm: 22 mm	2.0 mm: 5–17 mm 2.5 mm: 5–27 mm 2.8 mm: 11–33 mm
<b>Cannulated</b>	Yes	3.5 and 4.5 mm only	Yes	No
<b>Material</b>	PLLA	96L/4D PLA	PLLA/PGA	PLLA

	Acumed	Arthrex	Arthrex
<b>Product</b>	Biotrak Standard Screw  Biotrak Mini Screw	Bio-Compression Screws <sup>4</sup>	Trim-It Screws <sup>5</sup>
<b>Available Diameters &amp; Lengths</b>	3.6 mm: 16–24 mm 3.2 mm: 16–24 mm	3.0 mm: 16–26 mm 3.5 mm: 16–32 mm	2.7 mm: 30 mm 3.5 mm: 40 mm 4.0 mm: 50 mm 4.5 mm: 60 mm
<b>Cannulated</b>	Yes	Yes	Yes
<b>Material</b>	PLLA	PLLA	PLLA

## Competitive Comparison [continued]

### Biotrak Screw

	Acumed	Bioretec	Tornier
<b>Product</b>	Biotrak Standard Screw Biotrak Mini Screw	ActivaScrew <sup>6</sup>	RFS Screws <sup>7</sup>
<b>Available Diameters &amp; Lengths</b>	3.6 mm: 16–24 mm 3.2 mm: 16–24 mm	3.5 mm: 20–40 mm 4.0 mm: 40–90 mm 4.5 mm: 40–90 mm	2.7 mm: 14–24 mm 3.5 mm: 14–45 mm 4.5 mm: 35–90 mm
<b>Cannulated</b>	Yes	Yes	No
<b>Material</b>	PLLA	PLGA	PLGA

## Competitive Comparison [continued]

### Biotrak Pin

	Acumed	Arthrex	ConMed Linvatec	Bioretec
<b>Product</b>	Biotrak Pin	Trim-It Spin Pin <sup>8</sup>	SmartPin Implants <sup>9</sup>	ActivaPin <sup>10</sup>
<b>Available Diameters &amp; Lengths</b>	2.0 mm: 20 mm, 30 mm, 40 mm	1.5 mm: 100 mm 2.0 mm: 100 mm 2.0 mm: 100 mm	1.1 mm: 10–40 mm 1.5 mm: 10–70 mm 2.0 mm: 20–70 mm 3.2 mm: 30–70 mm 4.5 mm: 40–70 mm	1.5 mm: 20–70 mm 2.0 mm: 20–70 mm 2.7 mm: 50–70 mm 3.2 mm: 70 mm
<b>Cannulated</b>	Yes	No	No	No
<b>Material</b>	PLLA	PLLA	PLLA	PLGA

	Acumed	Tornier	Zimmer Biomet	Zimmer Biomet
<b>Product</b>	Biotrak Pin	RFS Pins <sup>11</sup>	OrthoSorb LS Resorbable Pins <sup>12</sup>	ReUnite Orthopedic Pin System <sup>13</sup>
<b>Available Diameters &amp; Lengths</b>	2.0 mm: 20 mm, 30 mm, 40 mm	1.5 mm: 20 mm 2.0 mm: 20 mm 2.7 mm: 20 mm	1.3 mm 2.0 mm Cut to length	1.5 mm: 40 mm 2.0 mm: 40 mm
<b>Cannulated</b>	Yes	Yes	No	No
<b>Material</b>	PLLA	PLGA	PLLA/PGA	PLLA

## Competitive Comparison [continued]

### Biotrak Helical Nail

	Acumed	Arthrex	ConMed Linvatec	Zimmer Biomet
<b>Product</b>	Biotrak Helical Nail	Chondral Dart <sup>14</sup>	SmartNail Implants <sup>15</sup>	LactoNail Bone Fixation <sup>16</sup>
<b>Available Diameters &amp; Lengths</b>	2.0 mm: 20 mm, 30 mm, 40 mm	1.3 mm: 18 mm	1.5 mm: 16–25 mm 2.4 mm: 16–45 mm	1.6 mm: 14–26 mm 2.0 mm: 14–26 mm
<b>Cannulated</b>	Yes	No	No	Yes
<b>Material</b>	PLLA	PLLA	96L/4D PLA	PLLA PGA



## 501(k) Clearance Information



ARC Surgical, LLC 21300 NW Jacobson Rd, Hillsboro, OR 97124  
phone: (503) 645-9300 / fax: (503) 645-9304 / web: www.arcsurgical.com

### 510(k) Summary

SEP 19 2006

This summary regarding 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR 807.92.

Submitter Information: Arc Surgical LLC  
21300 NW Jacobson Rd  
Hillsboro, OR 97124  
USA  
Phone: (503) 645-9300  
FAX: (503) 645-9304  
Contact: Ed Boehmer, Regulatory Supervisor

Classification Name: Smooth or threaded metallic bone fixation fastener  
Common Name: Screw, Fixation, Bone  
Proprietary Name: Arc Surgical Biotrak™ Screw System  
Proposed Regulatory Class: Class II, 21 CFR 888.3040  
Device Product Code: HWC  
Legally Marketed Equivalent Device(s): Arthrex Bio-Compression Screw K032098  
Bionx Smart Screw K003077  
Biomet ReUnite Bone Screw K992301

**Device Description:** The ARC Surgical Biotrak™ Screw System is composed of screws injection molded from poly-L-lactic acid (PLLA) with diameter (4.3mm to 4.8mm) and length (16mm to 24mm). Headless screw compression is obtained from the variable pitch of the threads. The screws are provided sterile.

**Intended Use:** The Biotrak™ resorbable compression screw is intended to provide fixation and/or reduction of small bone fractures, osteotomies, and arthrodeses, cancellous fragments, and osteochondral fragments in the upper and lower extremities. Specifically, these indications include osteochondral defects (OCDs), patella rim fractures, tarsal fractures, metatarsal fusions and fractures, metatarsal osteotomies, hallux valgus corrections, humeral condyle fractures, metacarpal fusions and fractures, carpal fusions and fractures, radial head fractures, and distal radius fractures.

These are similar to the intended use of predicate devices and do not raise new issues of safety and effectiveness.

**Technological Characteristics:** The screws are being injection molded from PLLA pellets (Boehringer-Ingelheim Resomer 210S). The PLLA pellets are polymerized from L-lactide monomers through the process of ring-opening polymerization. Stannous (tin) octoate is utilized as the catalyst. The predicate devices listed use either PLLA or LactoSorb (82% PLLA/18%PGA).

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*Arthroscopy and Related Concepts*

## 501(k) Clearance Information [continued]



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phone: (503) 645-9300 / fax: (503) 645-9304 / web: [www.arcsurgical.com](http://www.arcsurgical.com)

*Performance data is included in Section 10.*

*A discussion of clinical and non-clinical tests is not applicable.*

Based upon the similarities of the ARC Surgical biotrak™ Screw System and the predicate devices studied, the safety and effectiveness of the ARC Surgical biotrak™ Screw System is substantially equivalent to the predicate devices referenced.

## 501(k) Clearance Information [continued]



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

SEP 19 2006

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Arc Surgical LLC  
% Mr. Ed Boehmer  
Regulatory Supervisor  
21300 NW Jacobson Road  
Hillsboro, Oregon 97124

Re: K061763

Trade/Device Name: Arc Surgical BIOTRAK™ Screw System  
Regulation Number: 21 CFR 888.3040  
Regulation Name: Smooth or threaded metallic bone fixation fastener  
Regulatory Class: Class II  
Product Code: HWC  
Dated: August 10, 2006  
Received: August 14, 2006

Dear Mr. Boehmer:

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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such 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); 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.

## 501(k) Clearance Information [continued]

Page 2 – Mr. Ed Boehmer

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). 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 240-276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Mark N. Melkerson". The signature is written in a cursive style and is positioned above the typed name.

Mark N. Melkerson  
Director  
Division of General, Restorative  
and Neurological Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

# 501(k) Clearance Information [continued]

Page 1 of 1

510(k) Number (if known): K061763

Device Name: Arc Surgical biotrak™ Screw System

**Indications For Use:**

The Biotrak™ resorbable compression screw is intended to provide fixation and/or reduction of small bone fractures, osteotomies, and arthrodeses, cancellous fragments, and osteochondral fragments in the upper and lower extremities. Specifically, these indications include osteochondral defects (OCDs), patella rim fractures, tarsal fractures, metatarsal fusions and fractures, metatarsal osteotomies, hallux valgus corrections, humeral condyle fractures, metacarpal fusions and fractures, carpal fusions and fractures, radial head fractures, and distal radius fractures.

Prescription Use X  
(Part 21 CFR 801 Subpart D)

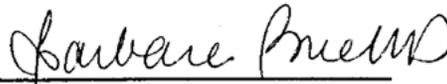
AND/OR

Over-The-Counter Use No  
(Part 21 CFR 807 Subpart C)

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

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Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)  
Division of General, Restorative,  
and Neurological Devices

510(k) Number K061763

## 501(k) Clearance Information [continued]



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phone: (503) 645-9300 / fax: (503) 645-9304 / web: www.arcsurgical.com

K071616 p1 of 2

### 510(k) Summary

This summary regarding 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR 807.92.

Submitter Information: ARC Surgical LLC  
21300 NW Jacobson Rd  
Hillsboro, OR 97124  
USA  
Phone: (503) 645-9300  
Fax: (503) 645-9304  
Contact: Ed Boehmer, Regulatory Supervisor

DEC 19 2007

Classification Name:	Bone Fixation Pin
Common Name:	Bioabsorbable Bone Fixation Pin
Proprietary Name:	ARC Surgical BIOTRAK™ Pin System
Proposed Regulatory Class:	Class II, 21 CFR 888.3040
Device Product Code:	HTY
Legally Marketed Equivalent Device(s):	Linvatec Biomaterials Ltd. SmartPin (K041288) Biomet, Inc. Resorbable Bone Pins (K011522) Arthrex, Inc. Bio-Pin (K050259) Arthrex, Inc. Chondral Dart (K991971)

**Device Description:** The ARC Surgical BIOTRAK™ Pin System is composed of pins injection molded from poly-L-lactic acid (PLLA) with diameter 1.5mm to 2.0mm and length 20mm to 40mm. External features on the pin provide increased resistance to loosening of bone fragments. The screws are provided sterile.

**Intended Use:** The BIOTRAK™ Pin is intended for use in fixation and/or alignment of fragments and fractures of non-load bearing bones, osteotomies, arthrodeses, cancellous fragments, and osteochondral fragments in the upper and lower extremities.

These are similar to the intended use of predicate devices and do not raise new issues of safety and effectiveness.

**Technological Characteristics:** The pins are being injection molded from PLLA pellets (Boehringer-Ingelheim Resomer 210S). The PLLA pellets are polymerized from L-lactide monomers through the process of ring-opening polymerization. Stannous (tin) octoate is utilized as the catalyst. The predicate devices listed use either PLLA, PLA/PGA mix.

*A discussion of clinical and non-clinical tests is not applicable.*

## 501(k) Clearance Information [continued]



*ARC Surgical, LLC 21300 NW Jacobson Rd, Hillsboro, OR 97124*  
*phone: (503) 645-9300 / fax: (503) 645-9304 / web: [www.arcsurgical.com](http://www.arcsurgical.com)*

Based upon the similarities of the ARC Surgical BIOTRAK™ Pin System and the predicate devices studied, the safety and effectiveness of the BIOTRAK™ Pin is substantially equivalent to the predicate devices referenced.

## 501(k) Clearance Information [continued]



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

ARC Surgical, LLC  
% Mr. Ed Boehmer  
21300 NW Jacobson Road  
Hillsboro, OR 97124

DEC 19 2007

Re: K071616  
Trade/Device Name: ARC Surgical BIOTRAK PIN System  
Regulation Number: 21 CFR 888.3040  
Regulation Name: Smooth or threaded metallic bone fixation fastener  
Regulatory Class: II  
Product Code: HTY  
Dated: December 5, 2007  
Received: December 6, 2007

Dear Mr. Boehmer:

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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such 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); 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.

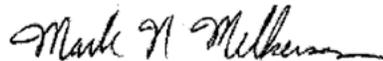
## 501(k) Clearance Information [continued]

Page 2 - Mr. Ed Boehmer

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. 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 (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Mark N. Melkerson  
Director  
Division of General, Restorative  
and Neurological Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

## 501(k) Clearance Information [continued]

### Indications For Use

510(k) Number (if known):

Device Name: ARC Surgical BIOTRAK™ Pin System

Indications For Use:

The BIOTRAK™ Pin is intended for use in fixation and/or alignment of fragments and fractures of non-load bearing bones, osteotomies, arthrodeses, cancellous fragments, and osteochondral fragments in the upper and lower extremities.

Prescription Use X  
(Part 21 CFR 801 Subpart D)

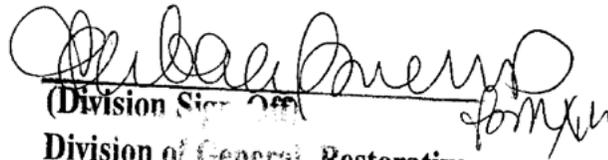
AND/OR

Over-The-Counter Use       
(Part 21 CFR 807 Subpart C)

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

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Concurrence of CDRH, Office of Device Evaluation (ODE)

  
(Division Sign Off)  
Division of General, Restorative,  
and Neurological Devices

510(k) Number K071616

Page 1 of 1



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

## Dedicated to Excellence

From manufacturing to business practices to product innovation, Acumed has an unwavering commitment to excellence. It is reflected in the honors received from industry peers and in the performance of our suite of surgical fixation solutions.



### The AME Manufacturing Excellence Award

In 2011, Acumed received the AME Manufacturing Excellence Award, an honor recognizing North American manufacturing sites that have demonstrated operational excellence through continuous improvement, best practices, creativity, and innovation. This award supports AME's vision, mission and values of inspiring commitment to enterprise excellence through shared learning and access to best practices.

The Association for Manufacturing Excellence is North America's premier organization for the exchange of knowledge in Organizational Excellence through the implementation of techniques such as Lean Tools, Leadership, Lean Product Development, Lean Supply Chain, and Lean Accounting.



### The Frost & Sullivan Manufacturing Leadership 100 Operational Excellence Award

In 2013, Acumed received the Frost & Sullivan Manufacturing Leadership 100 award for Operational Excellence, an honor recognizing the top 100 global manufacturing companies who are shaping the future through projects that deliver outstanding value, innovation, and return on investment.

Frost & Sullivan Manufacturing Leadership 100 is the world's first member-driven leadership network with knowledge in manufacturing leadership. It was created through a global community of executives working within the manufacturing industry.

### A Leader in Product Development and Innovation

Acumed began developing poly-L-lactide acid (PLLA) resorbable implants in 2006. Acumed was able to incorporate a number of the Acutrak design features into the design of the Biotrak Standard and Mini Resorbable implants. These were the first resorbable implants to utilize a continuously variable fully threaded headless construct. In 2007, Acumed released the Biotrak Pin and Biotrak Helical Nail to provide a more versatile portfolio of resorbable devices capable of addressing fixation of even smaller bony fragments. 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, recycling events, 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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