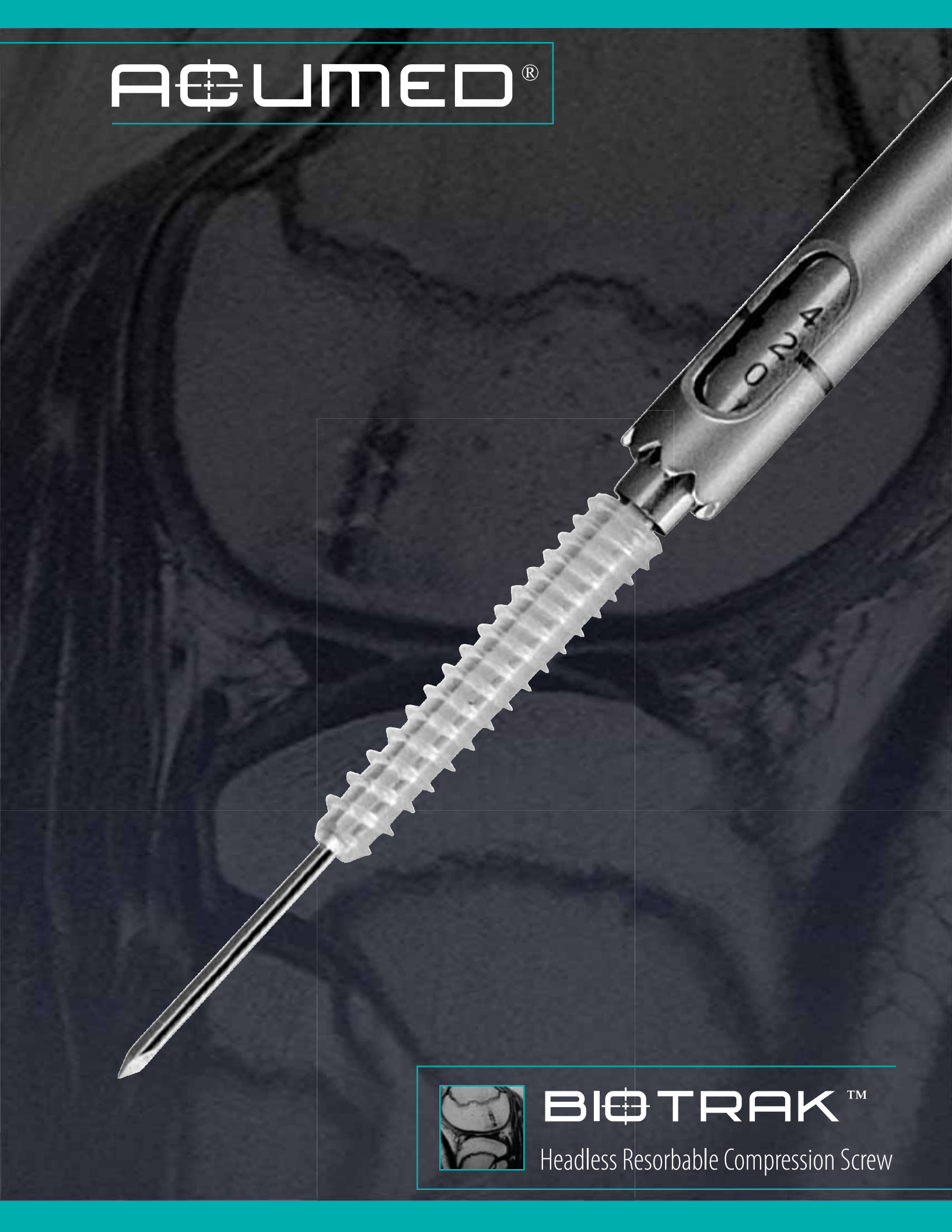
ACUMED®

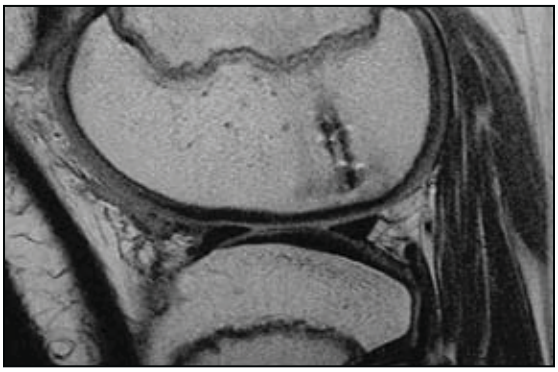


BIOTRAK™

Headless Resorbable Compression Screw

Biotrak™ Headless Resorbable Compression Screw

Since 1988, Acumed has been designing solutions to the demanding situations facing orthopaedic surgeons, hospitals and their patients. Our strategy has been to know the indication, design a solution to fit, and deliver quality products and instrumentation.



Since its introduction, the Acutrak® Headless Compression Screw has revolutionized the way surgeons gain fixation.

Incorporating the best features of the Acutrak screw as well as a number of system improvements, Acumed proudly introduces the Biotrak Headless Resorbable Compression Screw.

Biotrak screws are extremely versatile and may be used for a wide variety of indications in the upper and lower extremities including fractures, fusions and osteotomies. With greater pull-out strength than its headed competitors, the Biotrak provides a reliable means to fix everyday indications as well as the more challenging cases surgeons see in their practice with greater efficiency and effectiveness.

Key Indications Include:

- Osteochondral lesions
- Small bone fragments
- Osteotomies
- Arthrodeses
- Cancellous fragments

With the Biotrak Headless Resorbable Compression Screw, Acumed has designed an advanced orthopaedic solution for addressing bone applications where a bioresorbable implant material is desired.

Injection molded from 100% poly L-lactic acid (PLLA), the Biotrak resorbs after the bone is healed. In each application, PLLA permits natural, complete bone remodeling after surgery by allowing a gradual transfer of stress to the healing bone. This ultimately reduces the risk of stress shielding.

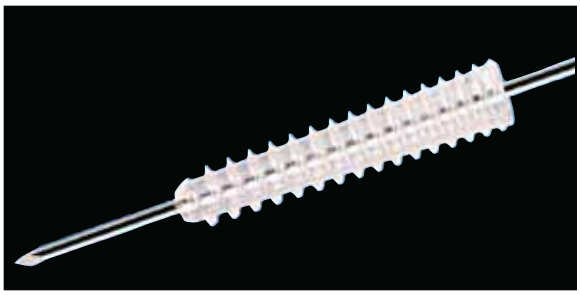
Biotrak is a true example of innovation and function combined into one versatile system. Offered in both standard and mini sizes, the Biotrak incorporates the same advanced technology as the Acutrak family of headless compression screws: variable thread pitch, tapered profile, cannulation and a fully-threaded length. Biomechanical tests have proven that the Biotrak is comparable to Acutrak in both compression and pull-out strength.[1]

These combined features make versatility a hallmark of the Biotrak screw. Biotrak is indicated for fixation of small bone fractures, osteotomies, arthrodeses, cancellous fracture fragments and osteochondral lesions in the upper and lower extremities.

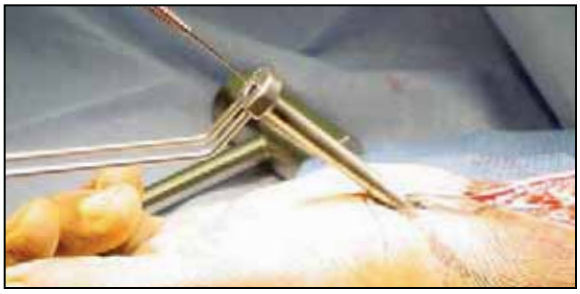
Biotrak™ Features

Acutrak® Technology
A patented variable pitch and tapered design allows the Biotrak™ to compress two bone fragments without the need for a head or overdrilling the proximal fragment to create compression. The fully-threaded length assists in generating and maintaining compression during cyclic loading.

Radiolucent
Composed of PLLA, the Biotrak Headless Resorbable Compression Screw enhances imaging abilities by reducing interference with imaging techniques; i.e. it is compatible with magnetic resonance imaging and leaves no image on an X-ray.



Minimally Invasive Instrumentation
A unique cannulated, tapered driver/ejector engages the screw along its length to maximize contact and drive it effectively into the conically reamed and tapped hole. The driver/ejector allows the surgeon to view the Biotrak's trajectory and depth under fluoroscopy. Once inserted, the ejector pushes the screw off the driver in a controlled manner to maintain fragment positioning.

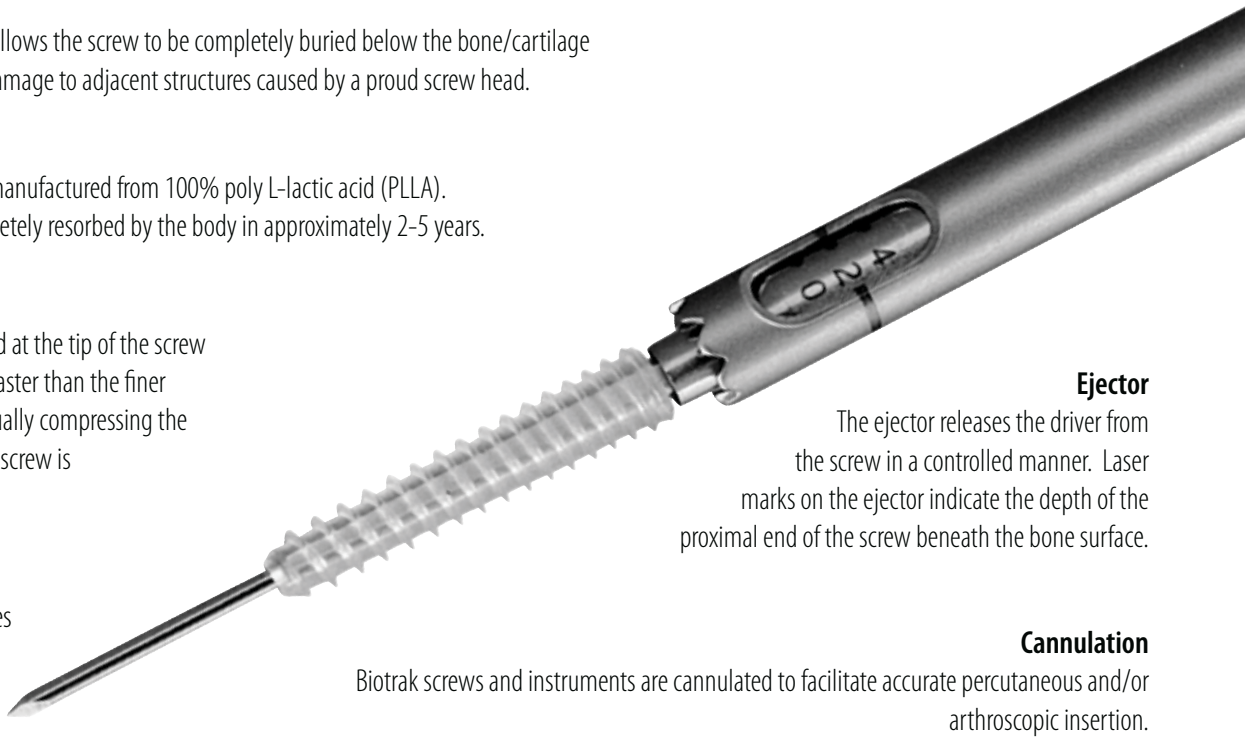


Headless
The headless design allows the screw to be completely buried below the bone/cartilage surface, preventing damage to adjacent structures caused by a proud screw head.

Resorbable
The Biotrak screw is manufactured from 100% poly L-lactic acid (PLLA). This material is completely resorbed by the body in approximately 2-5 years.

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

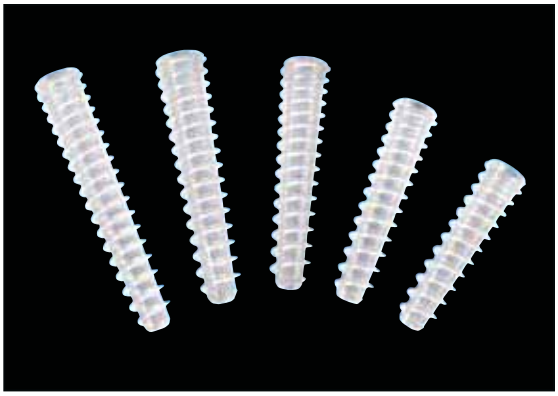
Driver
Tapered driver engages the entire length of the screw.



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 surface.

Cannulation
Biotrak screws and instruments are cannulated to facilitate accurate percutaneous and/or arthroscopic insertion.

Biotrak™ Standard



The Biotrak Screw has been recognized in particular for its success in treating OCD in the knee. The benefits of Biotrak translate equally to a wide variety of other indications that are commonly seen in the upper and lower extremities

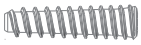
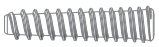
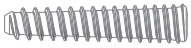
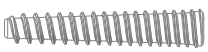
In the upper extremity, IP fusions, carpal arthodeses, radial styloid fractures, interphalangeal fractures and many other indications all benefit from the headless profile, strong compression and excellent holding power of the Biotrak Headless Resorbable Compression Screw.

Biotrak Screws can also be utilized in the lower extremity. Whether used for bunions, MTP fusions or a wide variety of other indications in the lower extremity, the benefits of the screw consistently contribute to great postoperative results.

Available in lengths ranging from 16mm to 24mm, the Biotrak Standard screws are inserted with a cannulated instrument set over a .045" guide wire.

Indications for Standard:

- Osteochondral Defects (OCDs)
- Femoral Condyle
- Patella
- Humeral Condyle Fractures
- Radial Styloid Fractures
- Chevron Osteotomies (Bunions)
- Allograft Procedures
- Navicular Fractures

Biotrak™ Standard Screws	Length	Tip Diameter	Back End Diameter	Guide Wire (in)	Part Number
	16mm	3.6mm	4.3mm	.045"	30170007-S
	18mm	3.6mm	4.4mm	.045"	30170008-S
	20mm	3.6mm	4.5mm	.045"	30170009-S
	22mm	3.6mm	4.6mm	.045"	30170010-S
	24mm	3.6mm	4.7mm	.045"	30170011-S

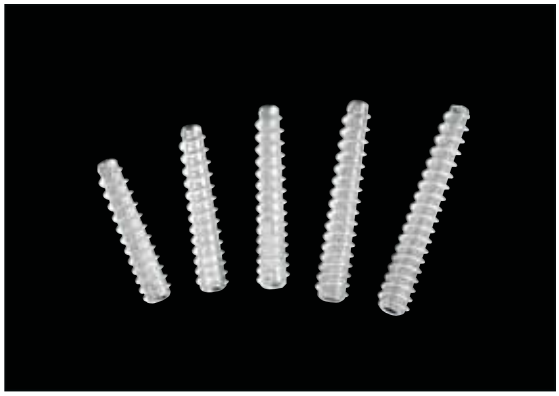
Biotrak™ Mini

The Biotrak Mini uses the same design principles and lengths as the Biotrak Standard but has a smaller diameter. It can be used in smaller bones or in cases where less hardware is required.

For smaller bones of the hand, wrist, foot and ankle, the Biotrak Mini provides an excellent means of fixation for both fractures and fusions.

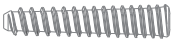
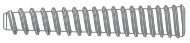
The Biotrak Mini screws can be used for a wide variety of indications, including radial head fractures, radial head fractures, avulsion fractures, IP fusions, OCD repair and phalangeal fractures.

Available in lengths ranging from 16mm to 24mm, the Biotrak Mini screws are inserted with a cannulated instrument set over a .035" guide wire.

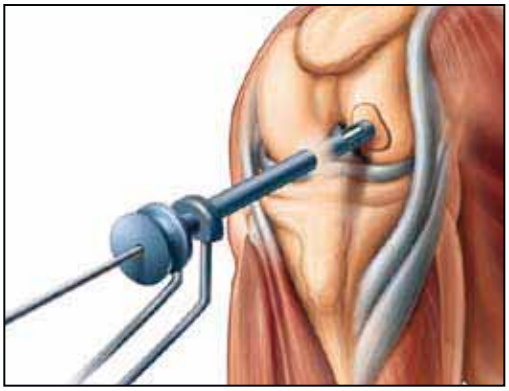


Indications for Mini:

- Osteochondral Defects (OCDs)
- Femoral Condyle
- Patella
- Radial Head Fractures
- PIP Fusions
- DIP Fusions
- Hammertoes
- Chevron Osteotomies (Bunions)
- Humeral Condyle Fractures

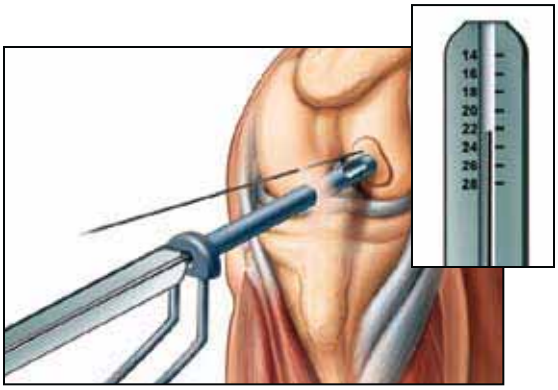
Biotrak™ Mini Screws	Length	Tip Diameter	Back End Diameter	Guide Wire (in)	Part Number
	16mm	3.2mm	3.5mm	.035"	30170057-S
	18mm	3.2mm	3.6mm	.035"	30170058-S
	20mm	3.2mm	3.6mm	.035"	30170059-S
	22mm	3.2mm	3.7mm	.035"	30170060-S
	24mm	3.2mm	3.7mm	.035"	30170061-S

Biotrak™ Standard



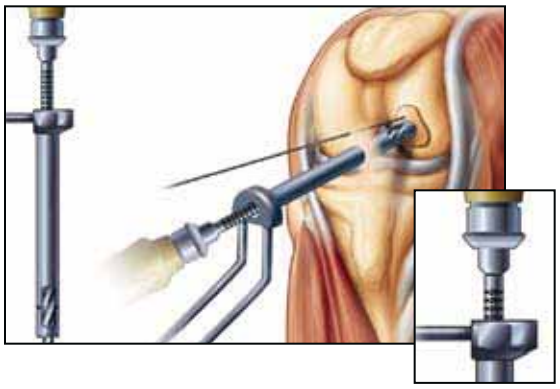
STEP 1: Insert Guide Wires

Insert multiple guide wires (if possible) to reduce and stabilize the fragment. Place a guide wire at the screw placement location. Advance the guide wire to the desired screw depth.



STEP 2: Measure Guide Wire Depth

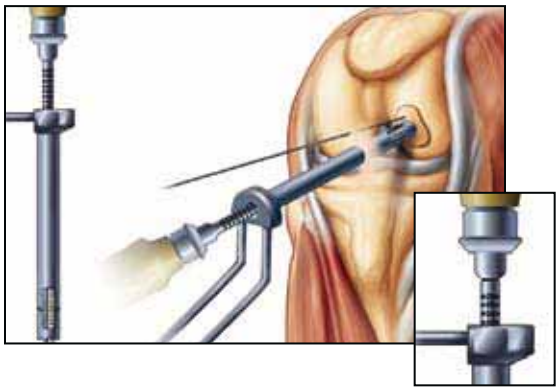
Slide the depth gauge over the guide wire until flush with the bone. Determine the depth from the back end of the guide wire. Advance the guide wire through the far cortex to minimize pull-out when removing the drill.



STEP 3: Drill to Depth

Drill the bone through the cannula to the depth determined in Step 2. Clear the bone debris often to ease the drilling process. Measure the depth off the back end of the cannula.

NOTE: The bone may be drilled under power.



STEP 4: Tap to Depth

Tap the bone through the cannula to the same depth as drilled in Step 3 to prepare a path for the screw threads. Measure the depth off the back end of the cannula.

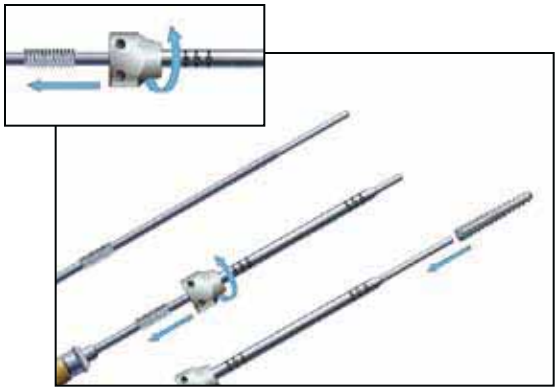
NOTE: <u>DO NOT</u> tap deeper than the drill depth as this may distract the bone fragment. <u>DO NOT</u> tap under power as this may strip the bone.

STEP 5: Prepare the Biotrak™ Screw

Thread the ejector completely onto the driver.

Choose a Biotrak screw that is at least ONE SIZE SMALLER than the drill depth.

Place the screw on the tip of the driver. Ensure that the screw is fully seated (the distal end of the driver and screw will be nearly flush).



STEP 6: Prepare the Ejector

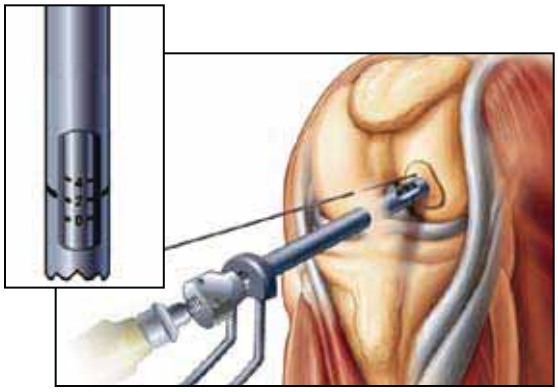
After the screw is seated on the driver, rotate the ejector until it just begins to touch the proximal end of the screw.

NOTE: DO NOT push the screw off the driver.

STEP 7: Insert the Biotrak Screw

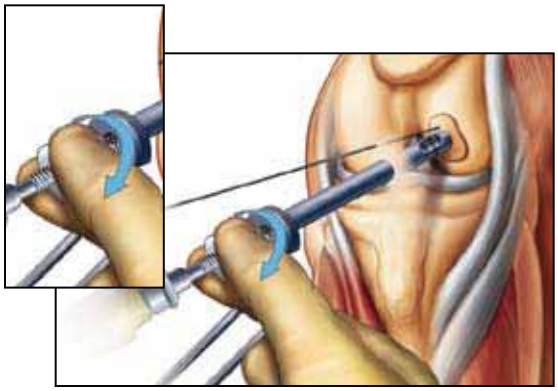
The laser marks in the window and at the proximal end of the cannula are used to indicate the depth (mm) of the screw below the surface of the bone. Make sure the cannula is flush with the bone during this step.

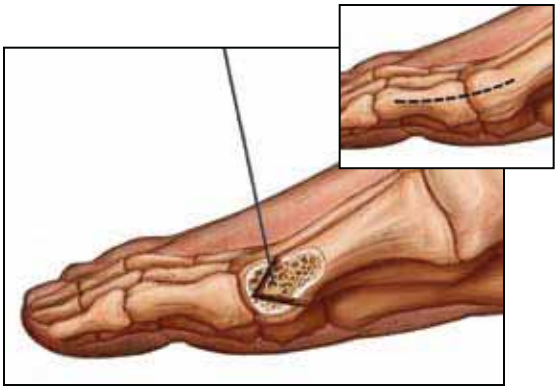
NOTE: Insert the screw until it is buried below the cartilage to ensure it will resorb.



STEP 8: Eject the Screw

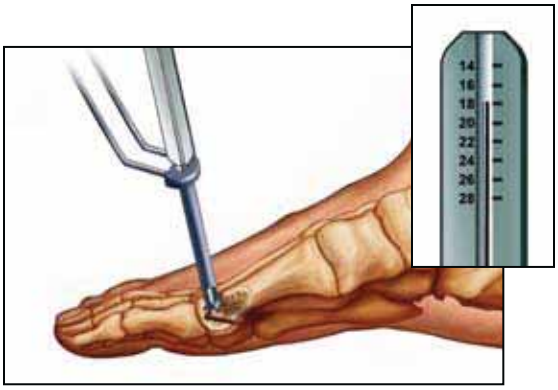
While holding the handle steady, rotate the ejector clockwise several turns to eject the screw off the driver. If there is resistance while pulling out the driver, rotate the ejector several more times and then disengage the driver from the screw.





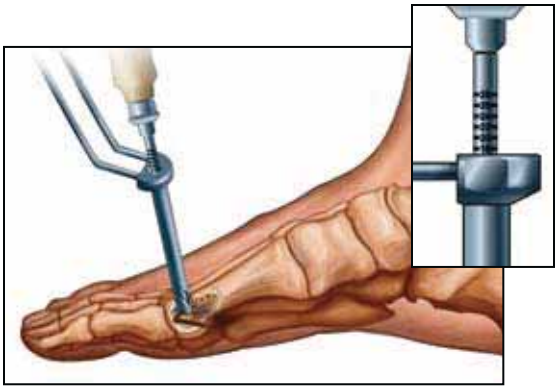
STEP 1: Insert Guide Wire

Insert multiple guide wires (if possible) to reduce and stabilize the fragment. Place a guide wire at the screw placement location. Advance the guide wire to the desired screw depth.



STEP 2: Measure Guide Wire Depth

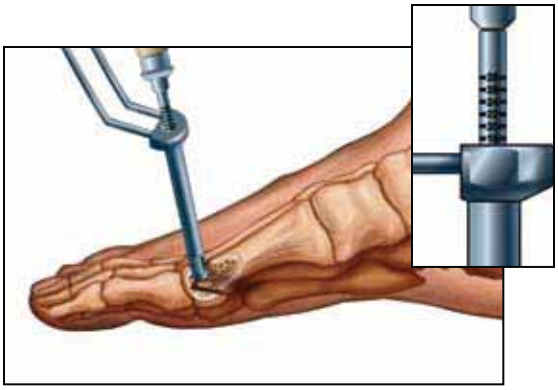
Slide the depth gauge over the guide wire until flush with the bone. Determine the depth from the back end of the guide wire. Advance the guide wire through the far cortex to minimize pull-out when removing the drill.



STEP 3: Drill to Depth

Drill the bone through the cannula to the depth determined in Step 2. Clear the bone debris often to ease the drilling process. Measure the depth off the back end of the cannula.

NOTE: The bone may be drilled under power.



STEP 4: Tap to Depth

Tap the bone through the cannula to the same depth as drilled in Step 3 to prepare a path for the screw threads. Measure the depth off the back end of the cannula.

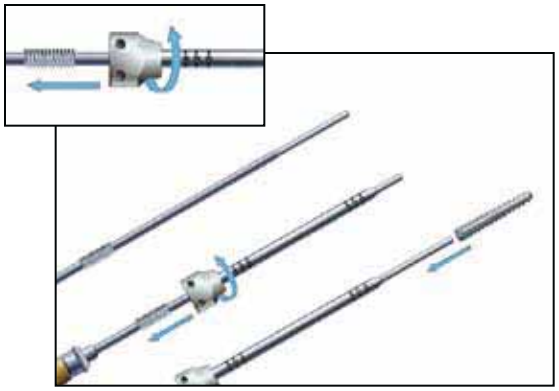
NOTE: <u>DO NOT</u> tap deeper than the drill depth as this may distract the bone fragment. <u>DO NOT</u> tap under power as this may strip the bone.

STEP 5: Prepare the Biotrak™ Screw

Thread the ejector completely onto the driver.

Choose a Biotrak screw that is at least ONE SIZE SMALLER than the drill depth.

Place the screw on the tip of the driver. **The screw is fully seated when it is approximately 3mm from the tip of the driver.**



STEP 6: Prepare the Ejector

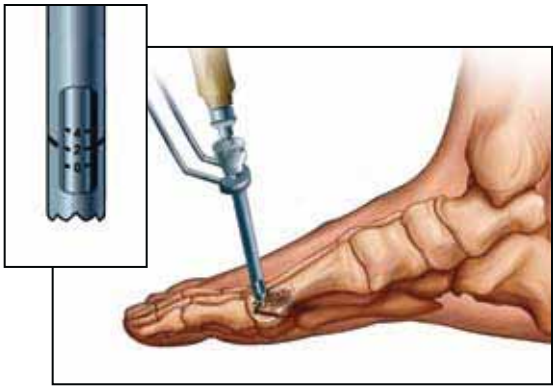
After the screw is seated on the driver, rotate the ejector until it just begins to touch the proximal end of the screw.

NOTE: DO NOT push the screw off the driver.

STEP 7: Insert the Biotrak Screw

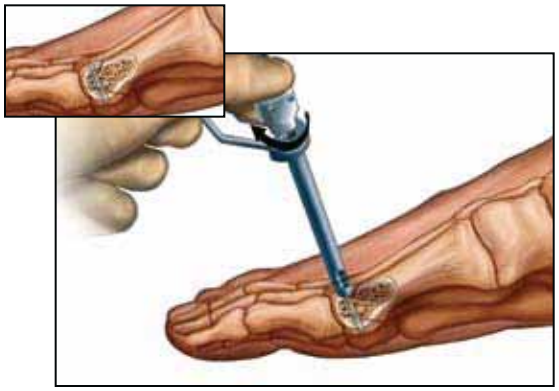
The laser marks in the window and at the proximal end of the cannula are used to indicate the depth (mm) of the screw below the surface of the bone. Make sure the cannula is flush with the bone during this step. After the screw is seated on the driver, rotate the ejector until it just begins to touch the proximal end of the screw.

NOTE: Insert the screw until it is buried below the cartilage to ensure it will resorb.



STEP 8: Eject the Screw

While holding the handle steady, rotate the ejector clockwise several turns to eject the screw off the driver. If there is resistance while pulling out the driver, rotate the ejector several more times and then disengage the driver from the screw.



Biomechanical Studies

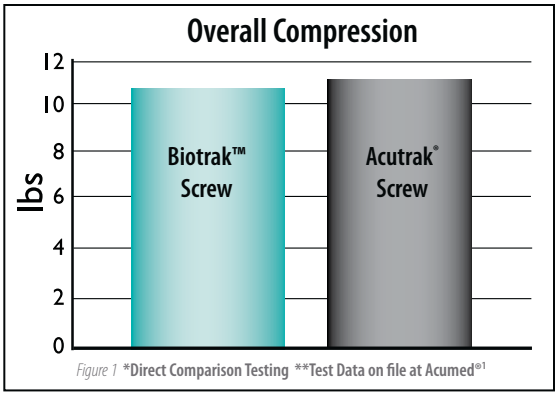


Figure 1 **Direct Comparison Testing **Test Data on file at Acumed®[1]

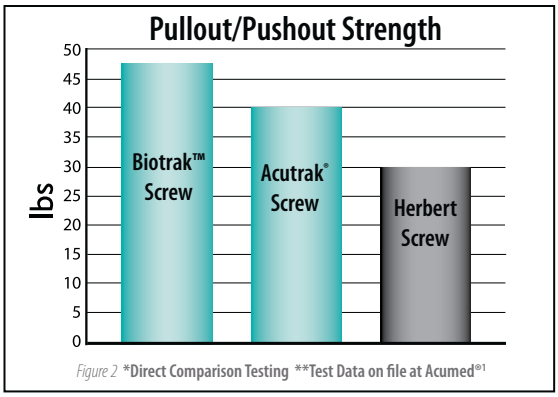
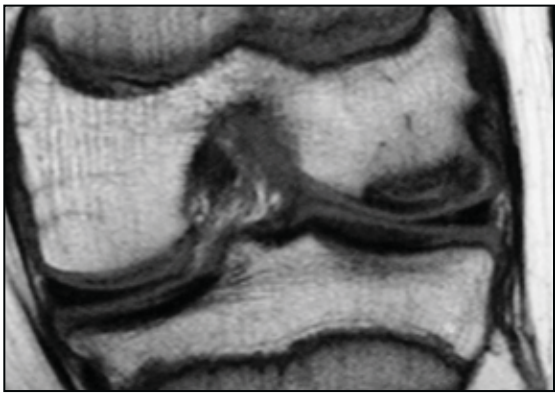
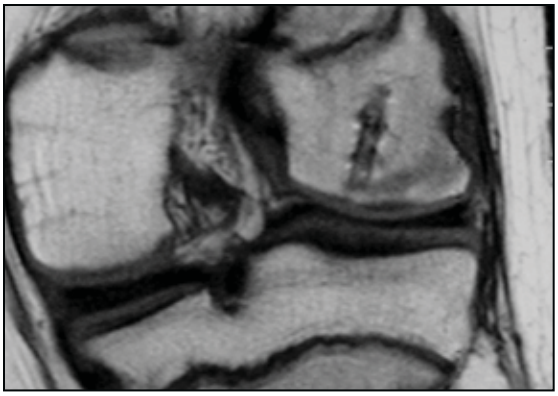


Figure 2 **Direct Comparison Testing **Test Data on file at Acumed®[1]





Testing Summary

Compression between bone fragments is an important factor in fracture healing. Wheeler and McLoughlin[2] studied the compression profiles of the Acutrak® screw and found it provided adequate compression while reducing the risk of overtightening versus a an AO Lag Screw.

The purpose of the test shown in Figure 1 was to compare the compression generated by the Biotrak screw with that of the standard Acutrak screw. It was concluded that the Biotrak screw provides similar overall compression when used in the fixation of small bones and fragments.

Furthermore, it is important to have high pullout/pushout resistance to maintain compression, bony allignment, and prevent the screw from backing out into articulating surfaces. Wheeler and McLoughlin[2] also studied the pullout and pushout resistance of both the Acutrak and Herbert screw.

Figure 2 shows the Biotrak provides similar pushout and pullout resistance to that of the Acutrak, and superior performace to the Herbert screw.

Ordering Information

BIOTRAK™ Standard Resorbable Headless Compression Screws	
Biotrak Standard16mm	30170007-S
Biotrak Standard18mm	30170008-S
Biotrak Standard 20mm	30170009-S
Biotrak Standard 22mm	30170010-S
Biotrak Standard 24mm	30170011-S

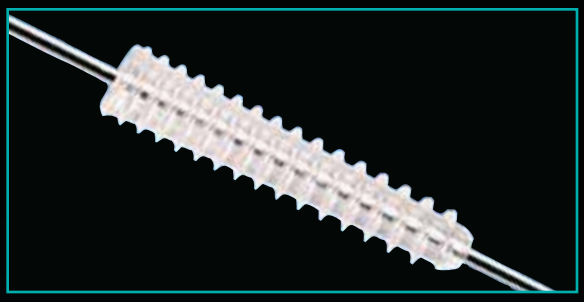
BIOTRAK™ Mini Resorbable Headless Compression Screws	
Biotrak Mini16mm	30170057-S
Biotrak Mini18mm	30170058-S
Biotrak Mini 20mm	30170059-S
Biotrak Mini 22mm	30170060-S
Biotrak Mini 24mm	30170061-S

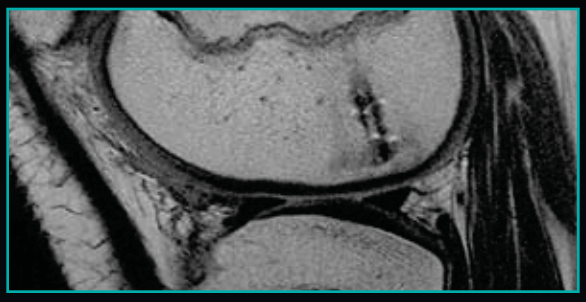
BIOTRAK™ Individual Instruments	
Cannulated Drill 16mm-24mm	30100101
.045" Guide Wire	80100100
Cannulated Tap 16mm-24mm	30100102
Cannulated Driver 16mm-24mm	30100103
Screw Ejector 16mm-24mm	30100104
Depth Gauge	30100109
Arthroscopic Probe	30100105
Quick Release Handle	80100125
Arthroscopic Cannula	30100108
Biotrak Standard Instrument Tray	30100120

BIOTRAK™ Mini Individual Instrument Set	
Biotrak Mini Drill	30100151
Biotrak Mini Tap	30100152
Biotrak Mini Driver	30100153
Biotrak Mini Ejector	30100154
.035" x 6" ST Guide Wire	80100101
Quick Release Handle	80100125
Biotrak Mini Depth Gauge	30100109
Arthroscopic Probe	30100105
Arthroscopic Cannula	30100108
Biotrak Mini Instrument Tray	30100170

BIOTRAK™ Complete Instrument Set	
Biotrak Standard Instrument Set and Tray (includes one of each instrument and tray)	30100100

BIOTRAK™ Mini Complete Instrument Set	
Biotrak Mini Instrument Set and Tray (includes one of each instrument and tray)	30100150





1. Data on file at Acumed.
2. Wheeler, D. McLoughlin, S. (1998). "Clinical Orthopaedics and Related Research," Vol. 350 Pg. 237-245.

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SPF00-00-A
Effective: 3/2009