

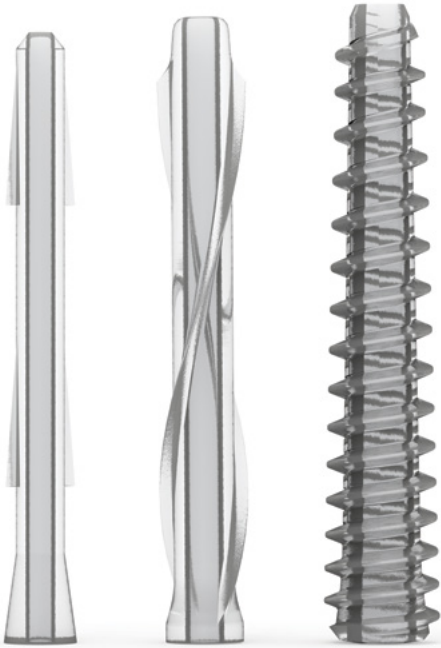
Surgical Technique





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.



Biotrak® Resorbable Fixation System

The Biotrak Resorbable Fixation System is designed to provide fixation for indications in the upper and lower extremities including fractures, fusions, and osteotomies. The Biotrak system of fixation devices is comprised of the Biotrak Helical Nail, the Biotrak Pin, and the Biotrak Screw in both Standard and Mini sizes.

Biotrak fixation devices are made from 100% poly L-lactic acid (PLLA), allowing the implant to resorb as the bone heals. The Biotrak Screw incorporates the same advanced technology as the Acumed Acutrak® family of headless compression screws including variable thread pitch, tapered profile, cannulation, and a fully-threaded length. The Biotrak Helical Nail provides compression similar to an Acutrak 2® Mini Screw (30 mm) through its helical flute design.¹ The Biotrak Pin offers surgeons a headed fixation solution with a multifaceted fin design intended to facilitate fixation, compression, and resist rotational forces.

Indications for Use:

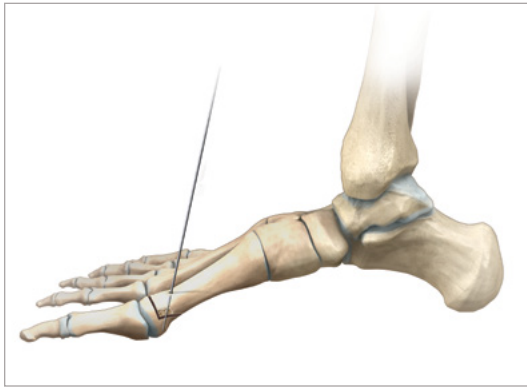
The Biotrak Screw is intended to provide fixation and/or reduction of small bone fractures, osteotomies, and arthrodeses, cancellous fragments, and osteochondral fragments in the upper and lower extremities.

The Biotrak Helical Nail and Pin are intended for use in fixation and/or alignment of fragments and fractures of non-load-bearing bones, osteotomies, arthrodesis, cancellous fragments, and osteochondral fragments in the upper and lower extremities.

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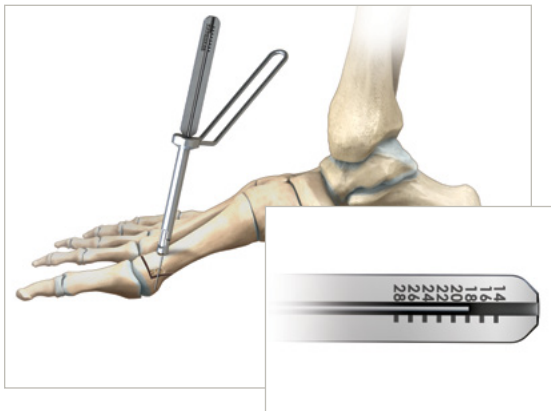
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Biotrak Mini Screw Surgical Technique



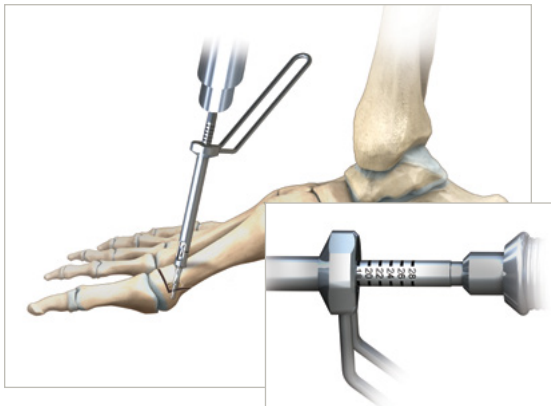
1 INSERT THE GUIDE WIRES

Insert multiple guide wires (if possible) to reduce and stabilize the fragment. Place a .035" x 6" ST Guide Wire (80100101) at the screw placement location. Advance the guide wire to the desired screw depth.



2 MEASURE THE GUIDE WIRE DEPTH

Slide the Biotrak Depth Gauge (30100109) over the guide wire until it is in full contact with the bone. Determine the depth from the back end of the guide wire. After depth is determined, advance the guide wire through the far cortex to minimize pullout when removing the drill.



3 DRILL TO THE DESIRED DEPTH

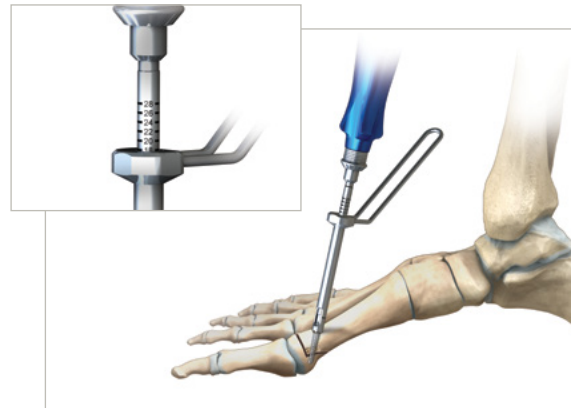
Using the Biotrak Mini Drill (30100151) inserted into the Arthroscopic Cannula (30100108), drill the bone to the depth measured. Clear the bone debris often to ease the drilling process. Measure the depth off the back end of the cannula.

Tip: The bone may be drilled using power.

4 TAP TO THE DESIRED DEPTH

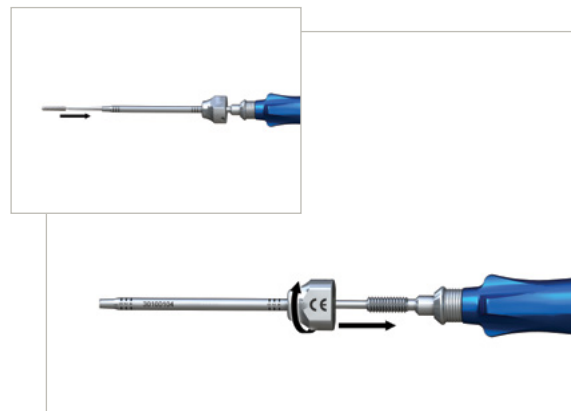
Using the Biotrak Mini Tap (30100152) inserted through the cannula, tap the bone to the same depth as drilled, to prepare a path for the screw threads. Measure the depth off the back end of the cannula.

Caution: Do not tap deeper than the drill depth as this may distract the bone fragment. Do not tap under power as this may strip the bone.



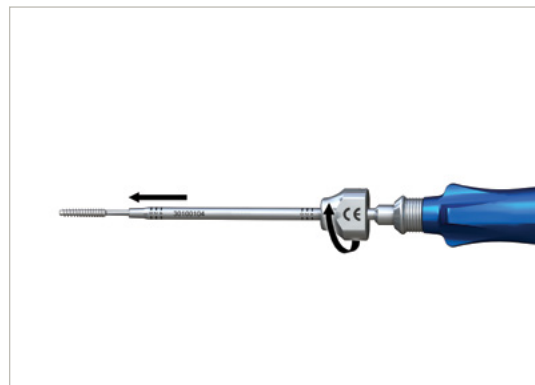
5 PREPARE THE BIOTRAK SCREW

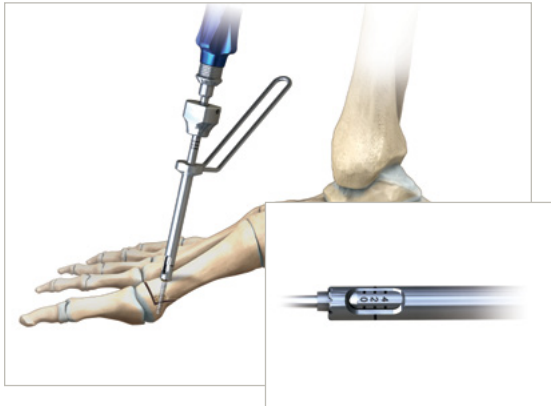
Thread the Biotrak Mini Ejector (30100154) completely onto the Biotrak Mini Driver (30100153). Select a Biotrak Mini Screw (301700XX-S) that is at least ONE SIZE SMALLER than the drill depth. Place the screw on the tip of the driver. Ensure a stiff fit between the screw and driver before proceeding.



6 PREPARE THE EJECTOR

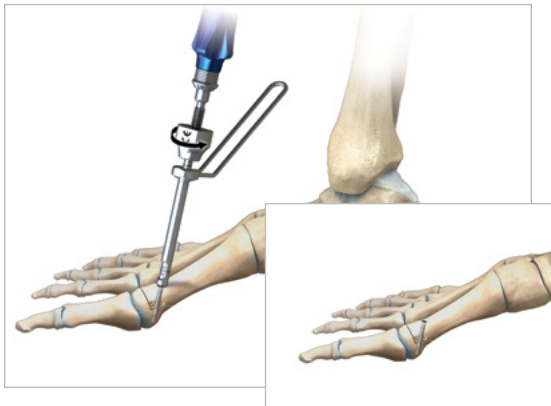
After the screw (301700XX-S) is seated on the driver, rotate the Biotrak Mini Ejector (30100154) until it just begins to touch the proximal end of the screw. Be careful not to push the screw off the driver.





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 (in millimeters) of the screw below the surface of the bone. Make sure the cannula is continually in contact 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. Insert the screw until it is buried below the cortex.



8 EJECT THE BIOTRAK SCREW

While holding the handle steady, rotate the Biotrak Mini Ejector (30100154) 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.

Biotrak Standard Screw Surgical Technique

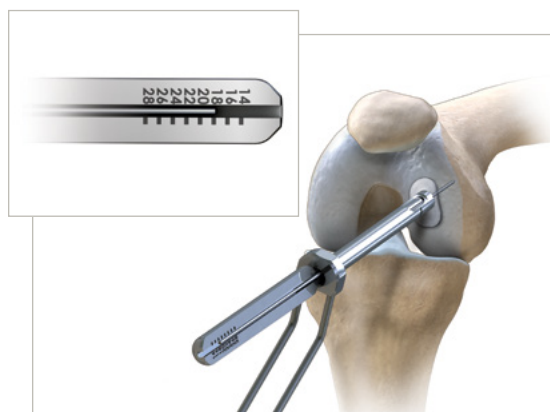
1 INSERT THE GUIDE WIRES

Insert multiple guide wires (if possible) to reduce and stabilize the fragment. Place a .045" x 6" ST Guide Wire (80100100) at the screw placement location. Advance the guide wire to the desired screw depth.



2 MEASURE THE GUIDE WIRE DEPTH

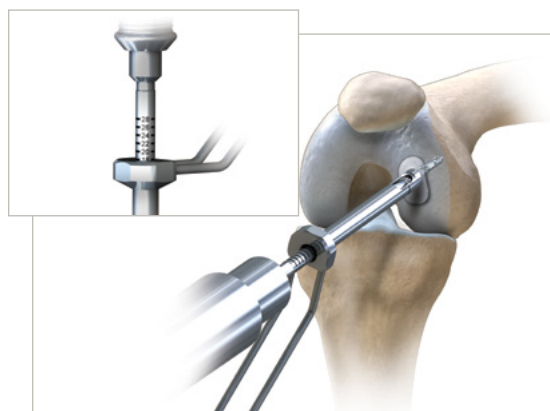
Slide the Biotrak Depth Gauge (30100109) over the guide wire until it is in full contact with the bone. Determine the depth from the back end of the guide wire. After the depth is determined, advance the guide wire through the far cortex to minimize pullout when removing the drill.

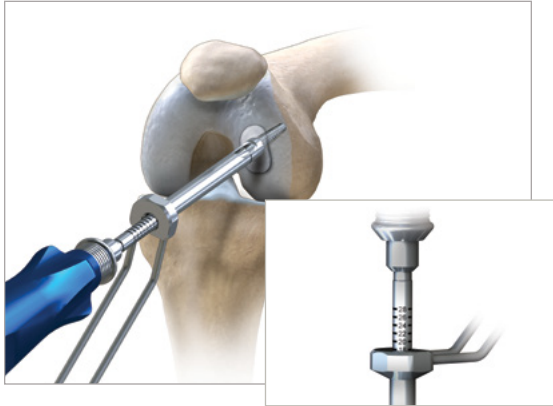


3 DRILL TO THE DESIRED DEPTH

Using the Biotrak Drill (30100101), drill the bone through the Biotrak Arthroscopic Cannula (30100108) to the depth measured. Clear the bone debris often to ease the drilling process. Measure the depth off the back end of the cannula.

Tip: The bone may be drilled using power.

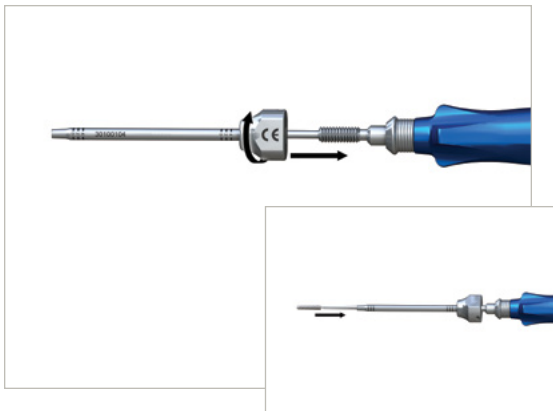




4 TAP TO THE DESIRED DEPTH

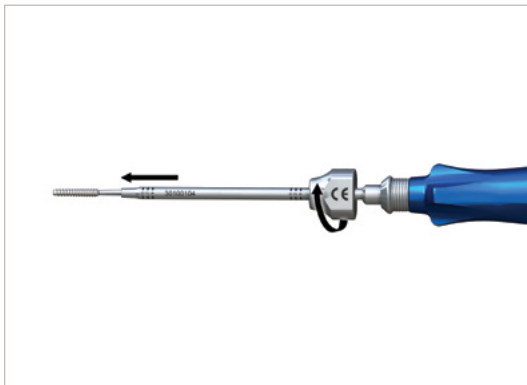
Using the Biotrak Tap (30100102), inserted through the cannula, tap the bone to the same depth as drilled to prepare a path for the screw threads. Measure the depth off the back end of the cannula.

Caution: Do not tap deeper than the drill depth as this may distract the bone fragment. Do not tap under power as this may strip the bone.



5 PREPARE THE BIOTRAK SCREW

Thread the Biotrak Ejector (30100104) completely onto the Biotrak Driver (30100103). Select a Biotrak Screw (301700XX-S) that is at least ONE SIZE SMALLER than the drill depth. Place the screw on the tip of the driver. Ensure a stiff fit between the screw and driver before proceeding.

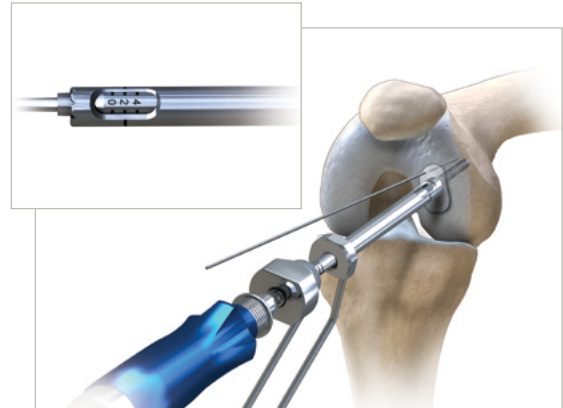


6 PREPARE THE EJECTOR

After the screw is seated on the driver, rotate the ejector until it just begins to touch the proximal end of the screw. Be careful not to push the screw off the driver.

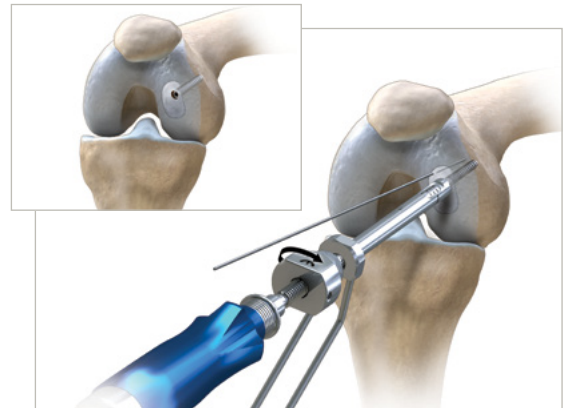
7 INSERT THE BIOTRAK SCREW

The laser marks in the window and at the proximal end of the cannula are used to indicate the depth (in millimeters) of the screw below the surface of the bone. Make sure the cannula is in full contact 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. Insert the screw until it is buried below the cortex.

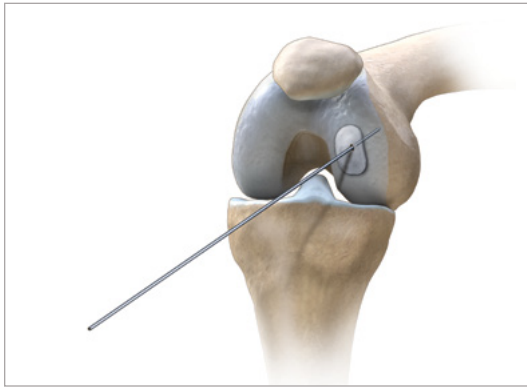


8 EJECT THE BIOTRAK SCREW

While holding the handle steady, rotate the Biotrak Ejector (30100104) 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.



Biotrak Helical Nail Surgical Technique



1 INSERT THE GUIDE WIRES

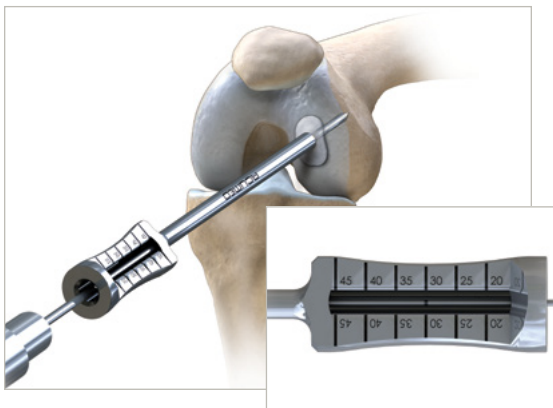
Insert guide wires to achieve sufficient fixation to reduce and stabilize the fragment. Place a Biotrak Nail Guidewire .045" x 8" ST (80-0329) at the desired implant location. Advance the guide wire to the desired implant depth.



2 DETERMINE THE NAIL LENGTH

Place the Biotrak Nail/Pin Cannula (80-0322) over the guide wire and measure the length using the laser mark on the guide wire. Choose the implant length closest to the determined depth.

If a shorter implant is desired, it may be trimmed using a wire cutter. Prior to cutting the implant, insert a guide wire through the entire cannulation of the implant to preserve the cannulation after cutting. The implant should be trimmed from the leading edge to avoid removing the head of the implant. Do not cut more than 5 mm of the implant.²



3 DRILL TO THE DESIRED DEPTH

Advance the guide wire approximately one centimeter further into the bone to avoid dislodging the wire during the drilling process. Using the Biotrak Nail Microdrill 2.5 mm (80-0327) inserted through the Biotrak Nail/Pin Cannula, drill the bone to the previously measured implant length.

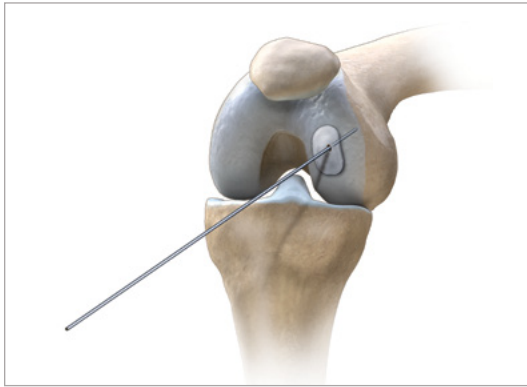
If the implant is to be countersunk beneath the surface of the tissue, add that length to the drilling depth. The depth of the drill can be determined by using the laser mark on the drill measured on the cannula.

4 INSERT THE HELICAL NAIL

Place the implant on the guide wire. Distract the proximal portion of the handle on the Biotrak Nail/Pin Plunger (80-0323) to set the plunger to the desired countersink depth (0, 2, or 4 mm). Slide the plunger over the guide wire and through the cannula to the head of the nail. Use a mallet to tap the implant into the bone until the plunger makes contact with the collar of the cannula.

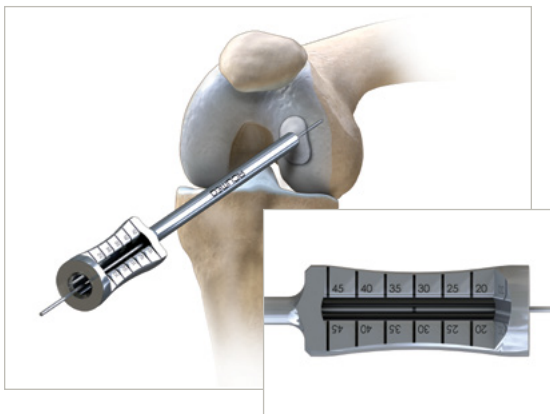


Biotrak Pin Surgical Technique



1 INSERT THE GUIDE WIRES

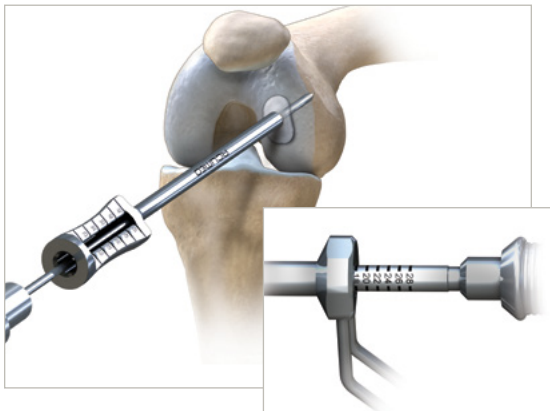
Insert guide wires to achieve sufficient fixation to reduce and stabilize the fragment. Place a .035" x 7" ST Guide Wire (80100102) at the desired implant location. Advance the guide wire to the desired implant depth.



2 DETERMINE THE PIN LENGTH

Place the Biotrak Pin Cannula (30100352) over the guide wire and measure the length using the laser mark on the guide wire. Select the implant length closest to determined depth.

If a shorter implant is desired, it may be trimmed using a wire cutter. Prior to cutting the implant, insert a guide wire through the entire cannulation of the implant to preserve the cannulation after cutting. It should be trimmed from the leading edge to avoid removing the head of the implant. Do not cut more than 5 mm of the implant.²



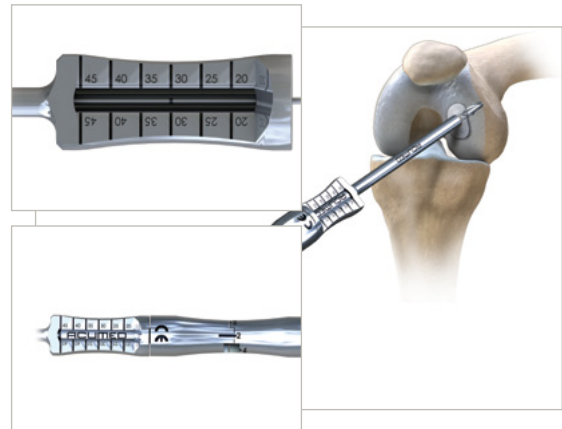
3 DRILL TO THE DESIRED DEPTH

Advance the guide wire approximately one centimeter further into the bone to avoid dislodging the guide wire during the drilling process. Using the Biotrak Pin Microdrill, 2 mm (30100351) inserted through the cannula, drill to the previously measured implant length.

If the implant is to be countersunk beneath the surface of the tissue, add that length to the drilling depth. The depth of the drill can be determined by using the laser mark on the drill measured on the cannula.

4 INSERT THE PIN

Place the implant on the guide wire. Distract the proximal portion of the handle on the Biotrak Nail/Pin Plunger (80-0323) to set the plunger to the desired countersink depth (0, 2, or 4 mm). Slide the Biotrak Pin Plunger (30100353) over the guide wire and through the cannula to the head of the pin. Use a mallet to tap the pin into the bone until the plunger makes contact with the collar of the cannula.



Ordering Information

Biotrak® Mini Screws

Biotrak Mini 16 mm Screw	30170057-S
Biotrak Mini 18 mm Screw	30170058-S
Biotrak Mini 20 mm Screw	30170059-S
Biotrak Mini 22 mm Screw	30170060-S
Biotrak Mini 24 mm Screw	30170061-S

Biotrak® Mini Screw Instrumentation

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 Depth Gauge	30100109
Biotrak Arthroscopic Cannula	30100108
Arthroscopic Probe	30100105

Biotrak® Standard Screws

Biotrak 16 mm Screw	30170007-S
Biotrak 18 mm Screw	30170008-S
Biotrak 20 mm Screw	30170009-S
Biotrak 22 mm Screw	30170010-S
Biotrak 24 mm Screw	30170011-S

Biotrak® Standard Screw Instrumentation

Biotrak Drill	30100101
Guide Wire .045" x 6" ST	80100100
Biotrak Tap	30100102
Biotrak Driver	30100103
Biotrak Ejector	30100104
Biotrak Depth Gauge	30100109
Biotrak Arthroscopic Cannula	30100108
Arthroscopic Probe	30100105
Quick Release Handle	80100125
Biotrak Screw System Tray Assembly	80-0516

Biotrak® Pin

Biotrak 2.0 mm x 20 mm Pin	30170320-S
Biotrak 2.0 mm x 30 mm Pin	30170330-S
Biotrak 2.0 mm x 40 mm Pin	30170340-S

Biotrak® Pin Instrumentation

Biotrak Pin Plunger	30100353
Biotrak Pin Cannula	30100352
Biotrak Pin Microdrill, 2 mm	30100351
.035" x 7" ST Guide Wire	80100102
.035" x 7" DT Guide Wire	80100103

Biotrak® Helical Nail

Biotrak 20 mm Helical Nail	55-0001-S
Biotrak 30 mm Helical Nail	55-0002-S
Biotrak 40 mm Helical Nail	55-0003-S

Biotrak® Helical Nail Instrumentation

Biotrak Nail/Pin Cannula	80-0322
Biotrak Nail/Pin Plunger	80-0323
Biotrak Nail Microdrill 2.5 mm	80-0327
Biotrak Nail Guidewire .045" x 8" DT	80-0328
Biotrak Nail Guidewire .045" x 8" ST	80-0329
Arthroscopic Probe	30100105
Biotrak Pin Microdrill, 2.0 mm	80-0469
Guide Wire .035" x 8" ST	80-0471
Guide Wire .035" x 8" DT	80-0470
Biotrak Arthroscopic Cannula	30100108
Biotrak Pin/Helical Nail Tray Assembly	80-0484

To learn more about the full line of Acumed® innovative surgical solutions, please contact your local Acumed sales representative, call 888.627.9957, or visit acumed.net.

REFERENCES

1. Acumed Internal Test Report No. TR00695.
2. Acumed Internal Test Report No. TR00717.

The devices described herein are covered by one or more of the following patents: 5,562,672; 5,871,486; 8,092,505. Other U.S. and international patents pending.



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