ST

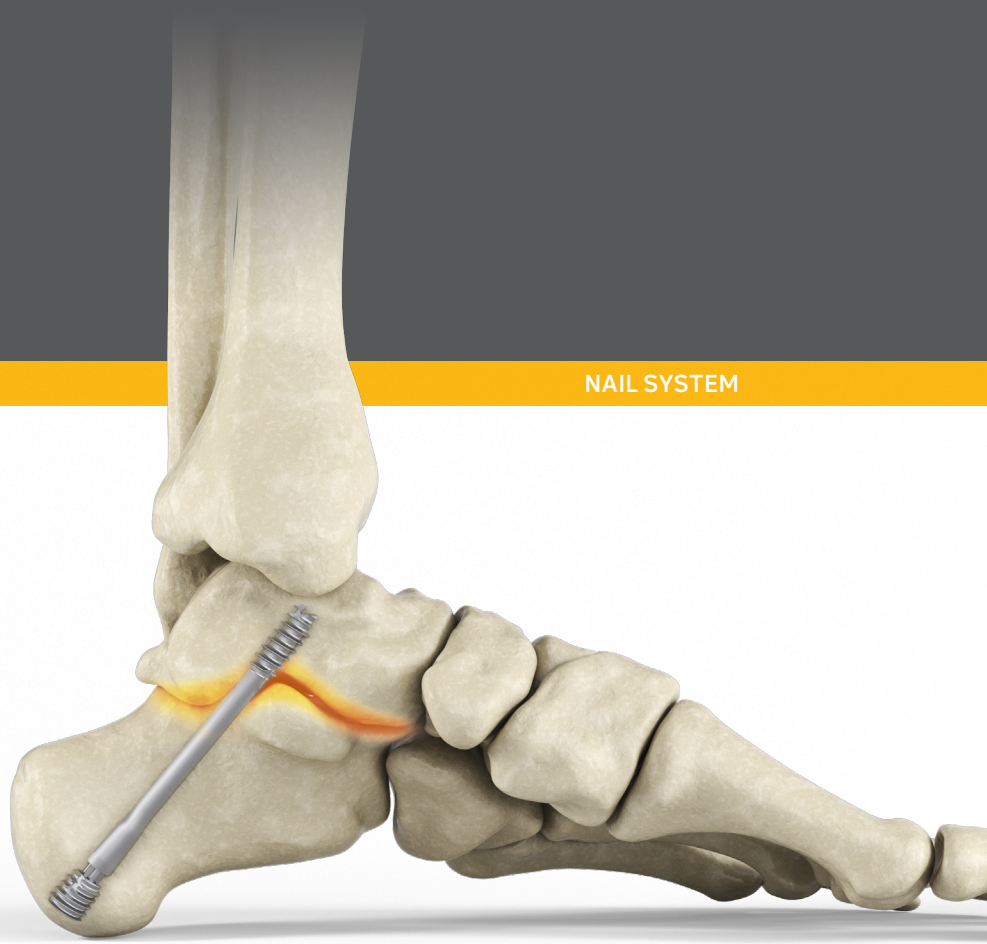
SURGICAL
TECHNIQUE

enovis™

# DYNANAIL HELIX™

ACTIVE, ADAPTIVE HEALING FOR SUBTALAR FUSION

NAIL SYSTEM



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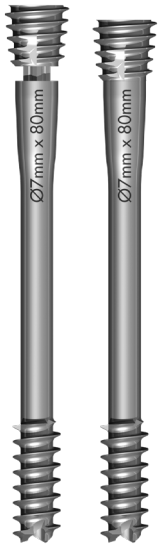





DJO® is a manufacturer of orthopedic implants and does not practice medicine. This surgical technique was prepared in conjunction with licensed health care professionals. The treating surgeon is responsible for determining the appropriate treatment, technique(s), and product(s) for each individual patient.

See package insert for complete list of potential adverse effects, contraindications, warnings and precautions.

A workshop training is recommended prior to performing your first surgery. All non-sterile devices must be cleaned and sterilized before use.

Multi-component instruments must be disassembled for cleaning. Please refer to the corresponding assembly/disassembly instructions, if applicable. Please remember that the compatibility of different product systems has not been tested unless specified otherwise in the product labeling.

The surgeon must discuss all relevant risks including the finite lifetime of the device with the patient.

## WHY DYNANAIL HELIX™ FOR SUBTALAR FUSION?

Subtalar fusion surgery is performed to relieve pain and correct severe foot deformity by achieving solid bony union. According to the Association for the Study of Internal Fixation principles, compression across a fusion site is important for promoting bone healing.

Compression also provides stability by maximizing bone-to-bone contact and limiting micro-motion. The clinical results for tibiotalocalcaneal (TTC) fusion support the biomechanical basis for applied compression at the joint site, as both external and internal fixation devices have evolved over time to better meet this need.[1]

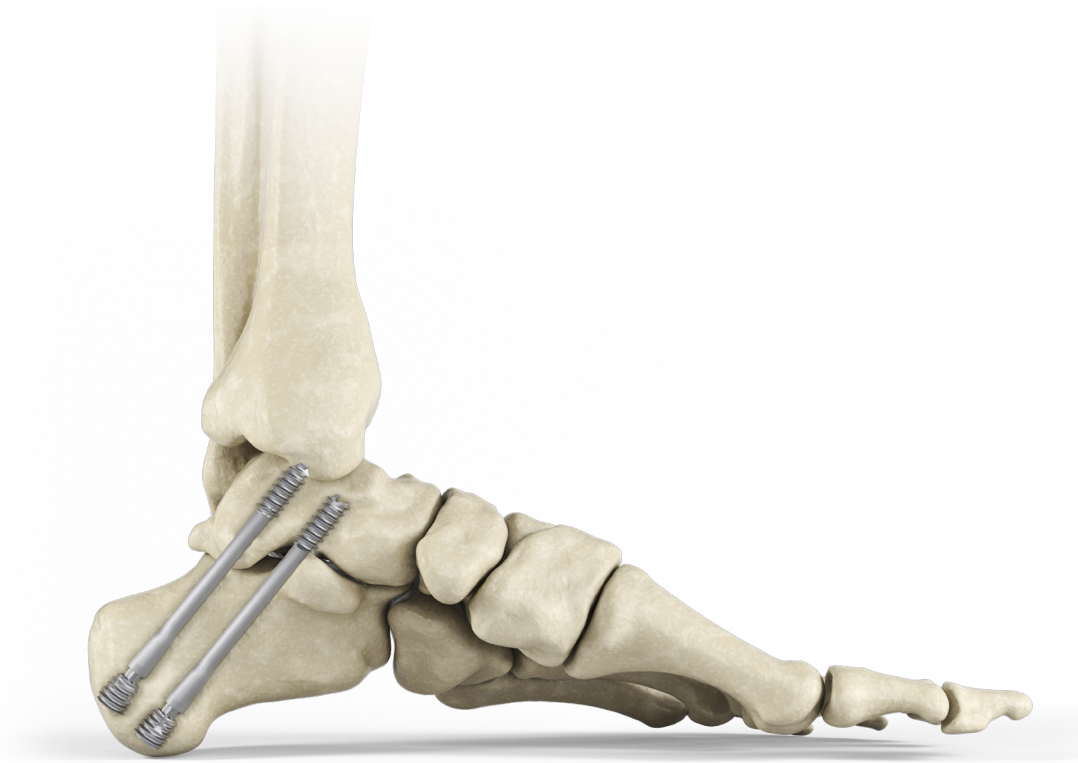
The DynaNail Helix™ Fusion System features MedShape's patented and proven superelastic NiTiNOL Compressive Element technology miniaturized for use in subtalar fusion.[2,3]

Along with the other implants within the DynaNail product line, the DynaNail Helix is the only device that maintains active compression post-surgery in response to bone resorption or settling. The DynaNail Helix is inserted like a screw but allows for sustained compression and stability to prevent device migration.

*1. Dupont KM, Shibuya N, Bariteau JT. Tibiotalocalcaneal Arthrodesis with Intramedullary Nails – Mechanobiological Background and Evolution of Compressive Technology. Global J Orthopedic Research, 2019. 1(5).*

*2. Yakacki CM, Gall K, Dirschl DR, Pacaccio DJ. Pseudoelastic intramedullary nailing for tibio-talo-calcaneal arthrodesis. Expert Rev Med Devices, 2011; 8(2): 159-66.*

*3. Ford SE, Kwon JY, Ellington K. Tibiotalocalcaneal Arthrodesis Utilizing a Titanium Intramedullary Nail With an Internal Pseudoelastic Nitinol Compression Element: A Retrospective Case Series of 33 Patients. J Foot Ankle Surg, 2019. 58(2):266-272.*



# INDICATIONS AND CONTRAINDICATIONS



## INDICATIONS

### DYNANAIL HELIX™ FUSION SYSTEM

The DynaNail Helix™ Fixation System is indicated for use in:

- Bone reconstruction
- Osteotomy
- Arthrodesis
- Joint fusion
- Fracture repair
- Fracture fixation

These indications apply to bones appropriate for the size of the device.

## CONTRAINDICATIONS

### DYNANAIL HELIX FUSION SYSTEM

The DynaNail Helix Fusion System is contraindicated for:

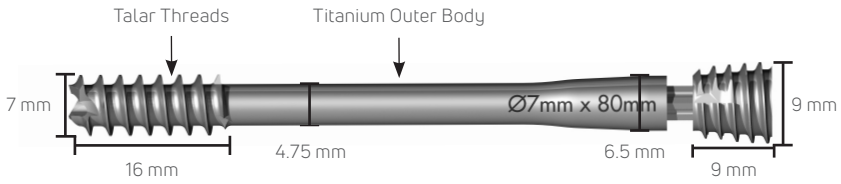
- Patients with an active local or systemic infection.
- Patients with an active soft tissue infection or osteomyelitis of foot and ankle.
- Patients with severe peripheral vascular disease.
- Patients with an obliterated medullary canal or other conditions that tend to retard healing such as blood supply limitations or previous infections.
- Patients with a dysvascular limb.
- Patients with an insufficient quantity or quality of bone to permit fusion of the joints or stabilization of the arthrodesis.
- Patients with conditions that restrict his or her ability or willingness to follow postoperative instructions during the healing process.
- Patients with suspected foreign body sensitivity or documented metal allergy or intolerance. Where material sensitivity is suspected, appropriate tests should be conducted and sensitivity ruled out prior to implantation.

# TECHNICAL SPECIFICATIONS



## HEADLESS NAIL IMPLANT

Available in 7 mm diameter and 50-100 mm lengths in 5 mm increments.




*7 X 50 MM*


*7 X 55 MM*


*7 X 60 MM*


*7 X 65 MM*


*7 X 70 MM*


*7 X 75 MM*


### AMOUNT OF POST-OPERATIVE COMPRESSION BY IMPLANT LENGTH

| NAIL LENGTH | COMPRESSION |
|---|---|
| 50 MM | 1.3 MM |
| 60 MM | 1.9 MM |
| 70 MM | 2.4 MM |
| 80 MM | 3.0 MM |
| 90 MM | 3.5 MM |
| 100 MM | 4.1 MM |

*7 X 80 MM*


*7 X 85 MM*


*7 X 90 MM*


*7 X 95 MM*


*7 X 100 MM*

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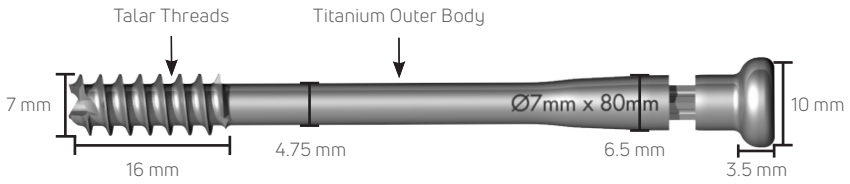


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*7 X 90 MM*


*7 X 95 MM*


*7 X 100 MM*

# DESIGN FEATURES



## OUT OF THE PACKAGE

The DynaNail Helix™ is provided with the NiTiNOL Compressive Element pre-stretched and pre-loaded on the disposable inserter assembly.

## IMMEDIATE POST-SURGERY

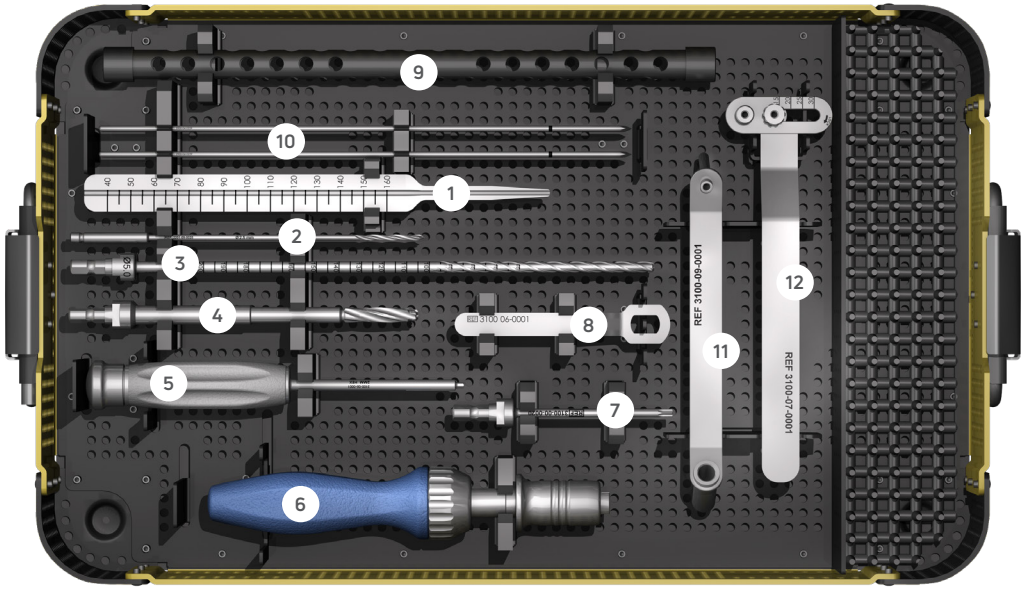
The Compressive Element will already be in its stretched, activated position with the Sliding Head extending plantarly from the implant body.


## WEEKS TO MONTHS POST-SURGERY

The Compressive Element unloads (i.e. recovers its stretched length) in response to bone resorption or settling.

# INSTRUMENT TRAY






| # | DESCRIPTION | PART # | QTY |
|---|---|---|---|
| 1 | DEPTH GAUGE | 2900-17-001 | 1 |
| 2 | Ø2.5 MM DRILL | 2201-09-0025 | 1 |
| 3 | Ø5.0 MM DRILL | 3100-01-0005 | 1 |
| 4 | PROFILE DRILL, 6.5 MM | 3100-01-0007 | 1 |
| 5 | NITINOL RELEASE TOOL HEX DRIVER, 2.0 MM | 3100-08-0001 | 1 |
| 6 | RATCHETING HANDLE | 3100-10-0001 | 1 |
| 7 | REMOVAL DRIVER | 3100-00-0020 | 1 |
| 8 | NITINOL RELEASE COUNTER TORQUE WRENCH | 3100-06-0001 | 1 |
| 9* | TRAJECTORY WIRE, 1.0 x 260 MM | 3100-04-0001 | 8 |
| 10 | GUIDEWIRE, 2.4 x 229 MM | 2900-04-0229 | 10 |
| 11 | TISSUE PROTECTOR | 3100-09-0001 | 1 |
| 12 | PARALLEL PIN GUIDE | 3100-07-0001 | 1 |

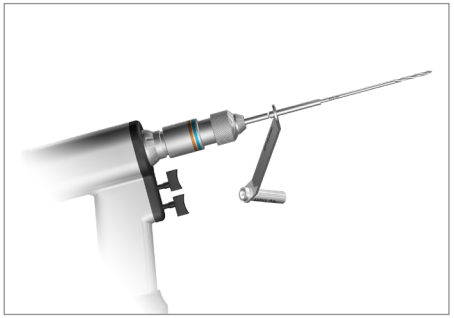
**Note: Trajectory Wire is only utilized for potential assistance in removal of implant.*

# QUICK REFERENCE GUIDE

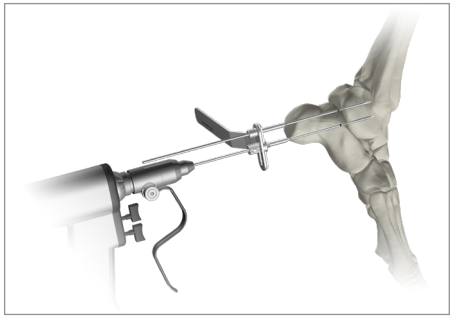


The following is a general overview of the DynaNail Helix™ Surgical Technique intended to be used as an easy reference. A more detailed surgical technique including technical tips and pearls is available in the following pages.

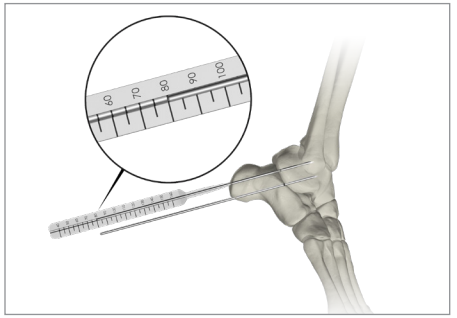
## STEP 1: JOINT PREPARATION



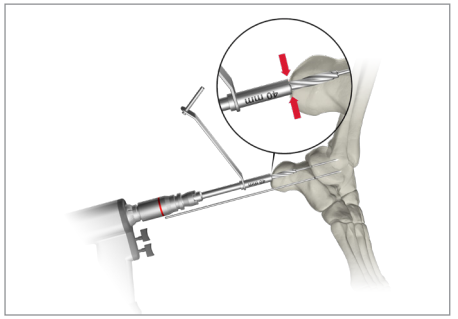
## STEP 2: PLACE GUIDEWIRES



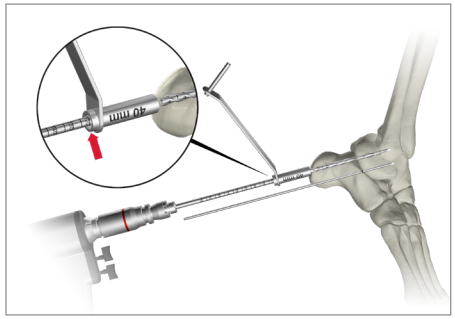
## STEP 3: DETERMINE IMPLANT LENGTH



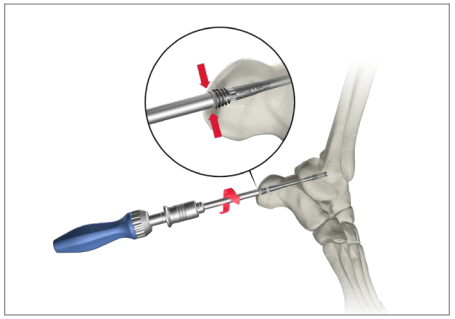

## STEP 4: DRILLING FOR IMPLANT



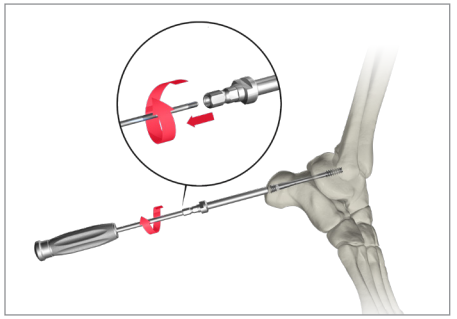
## STEP 5: REAM ENTRY CANAL



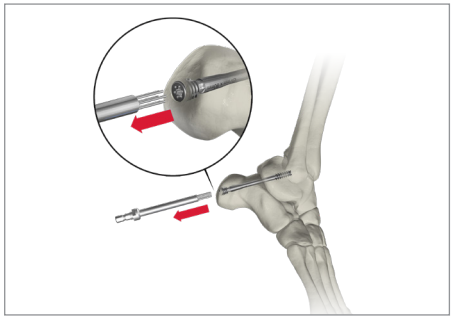
## STEP 6: INSERT IMPLANT



## STEP 7: REMOVE CONNECTION BOLT



## STEP 8: REMOVE INSERTER ASSEMBLY



## 1. JOINT PREPARATION

Instruments Used:

1. Fenestration Drill, 2.5 mm x 6" (24)

2. Soft Tissue Protector (23)

Using a lateral approach, reduce the joint to the correct position by first exposing the subtalar joint. Distract the joint using a lamina spreader. Prepare the joint by completely removing middle facets using a sharp osteotome, a curette, and a rongeur until there is exposed bleeding subchondral bone. Leave the overall contours of the bones intact. Once all cartilage is removed, use a sharp osteotome to "fish-scale" the posterior and middle facets. The 2.5 mm Fenestration Drill with the 2.5 mm Drill Guide on the Soft Tissue Protector (FIGURE 1) can be used to aid in creating bleeding bone and feathering the joint surface. Ensure that the bleeding bone surfaces are in apposition before proceeding. Place any graft material if desired.

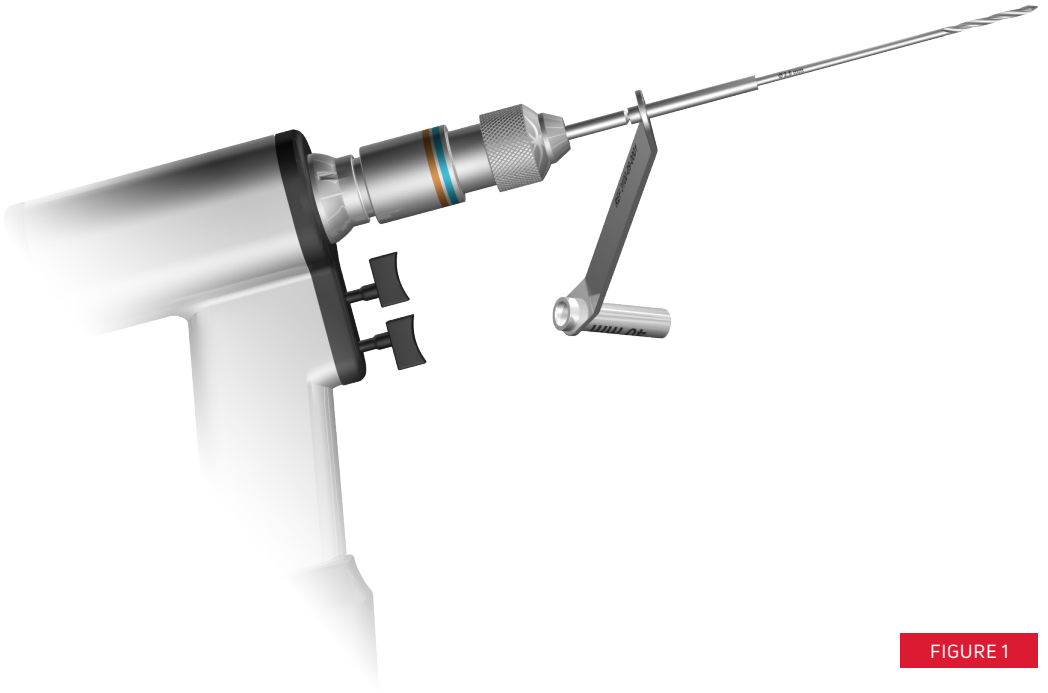


FIGURE 1

## 2. GUIDEWIRE PLACEMENT

Instruments used:

**1.** Guidewire, 2.4 mm x 229 mm (10)

Make a 2 cm incision down to the bone at the posterior-plantar junction of the calcaneal tuberosity.

Compress the joint before placing the Guidewire (FIGURE 2). Keep joint in proper orientation and under compression throughout procedure. Additional guidewires may be used to fixate the subtalar joint if desired. FIGURE 3 shows the Parallel Pin Guide being used to place additional wires.

**TIP:** Verify Guidewire placement under fluoroscopy in at least two planes. Additional oblique views may be helpful to visualize the wire trajectory. Ensure there is sufficient Guidewire length in the talus to allow for the threaded tip of the Implant to cross the joint entirely.

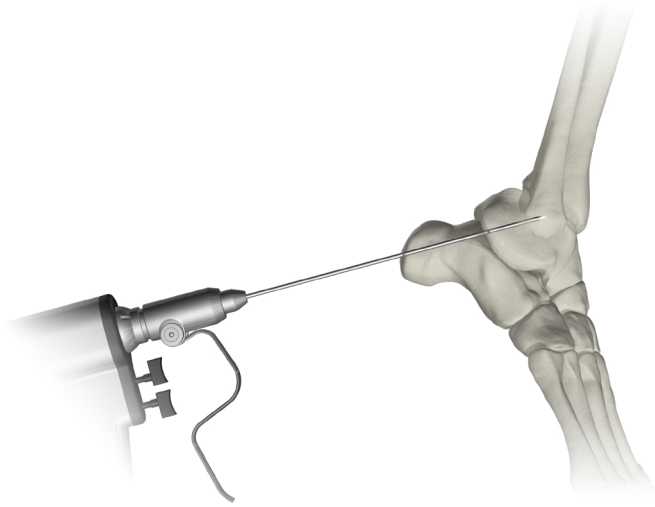


FIGURE 2

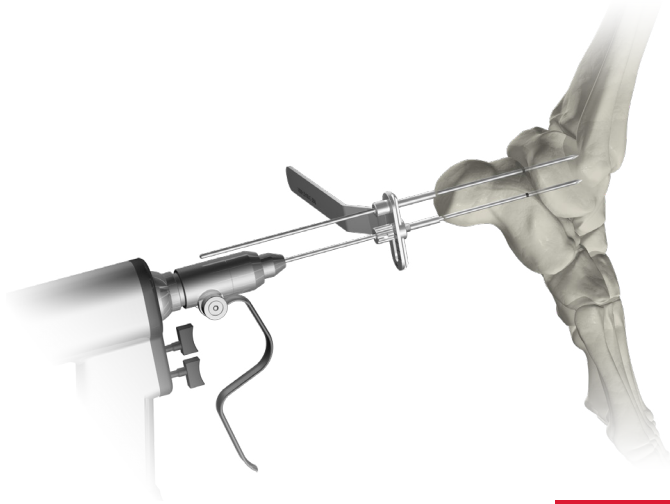


FIGURE 3

## 3. DETERMINE IMPLANT LENGTH

Instruments used:

**1.** Guidewire Depth Gauge (28)

Place the Guidewire Depth Gauge onto the Guidewire and rest firmly against the calcaneus (FIGURE 4). Read the length from end of the Guidewire.

**TIP:**

**For headless options**: Match the reading from the gauge and round down to accomodate compression. This ensures the head can sit flush with the bone.

**For headed options**: Add 3 mm to the gauge reading to accomodate the head of the implant, which will sit approximately 3 mm proud. If using a washer, add 5 mm to the gauge reading. Round down to accommodate compression.

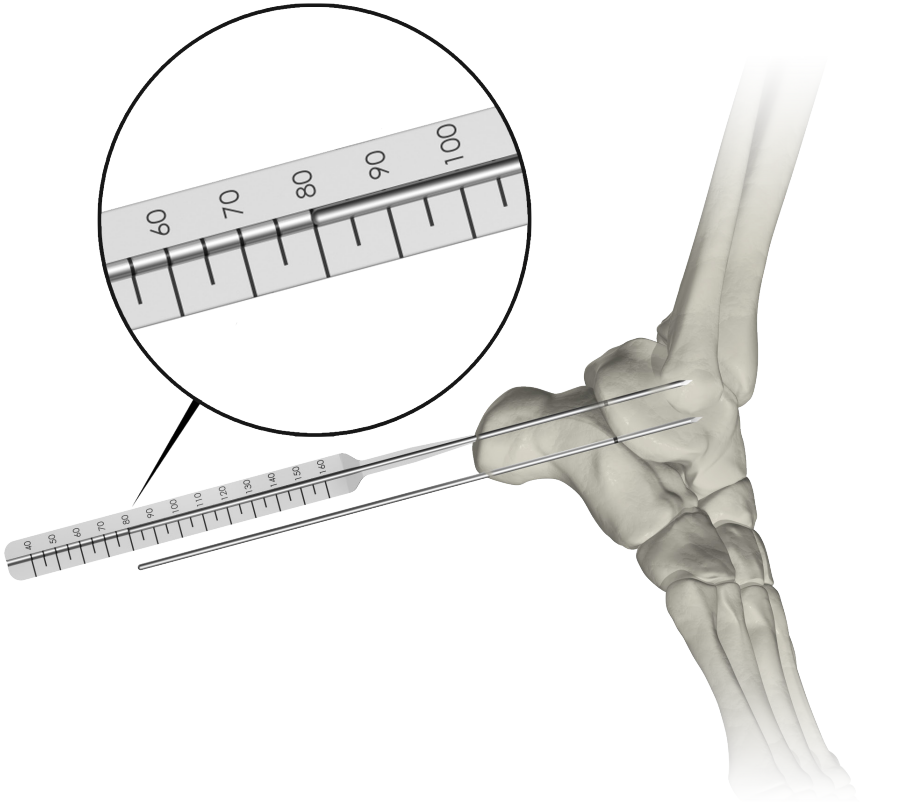



FIGURE 4

## 4. DRILL FOR IMPLANT

Instruments used:

**1.** Soft Tissue Protector (23)

**2.** Profile Drill, 6.5 mm (33)

Place the Profile Drill over the Guidewire and drill until notch is flush with bone. The Tissue Protector may be used when drilling with the Profile Drill. Using the Tissue Protector will ensure the correct depth as long as it is placed flush against the bone.

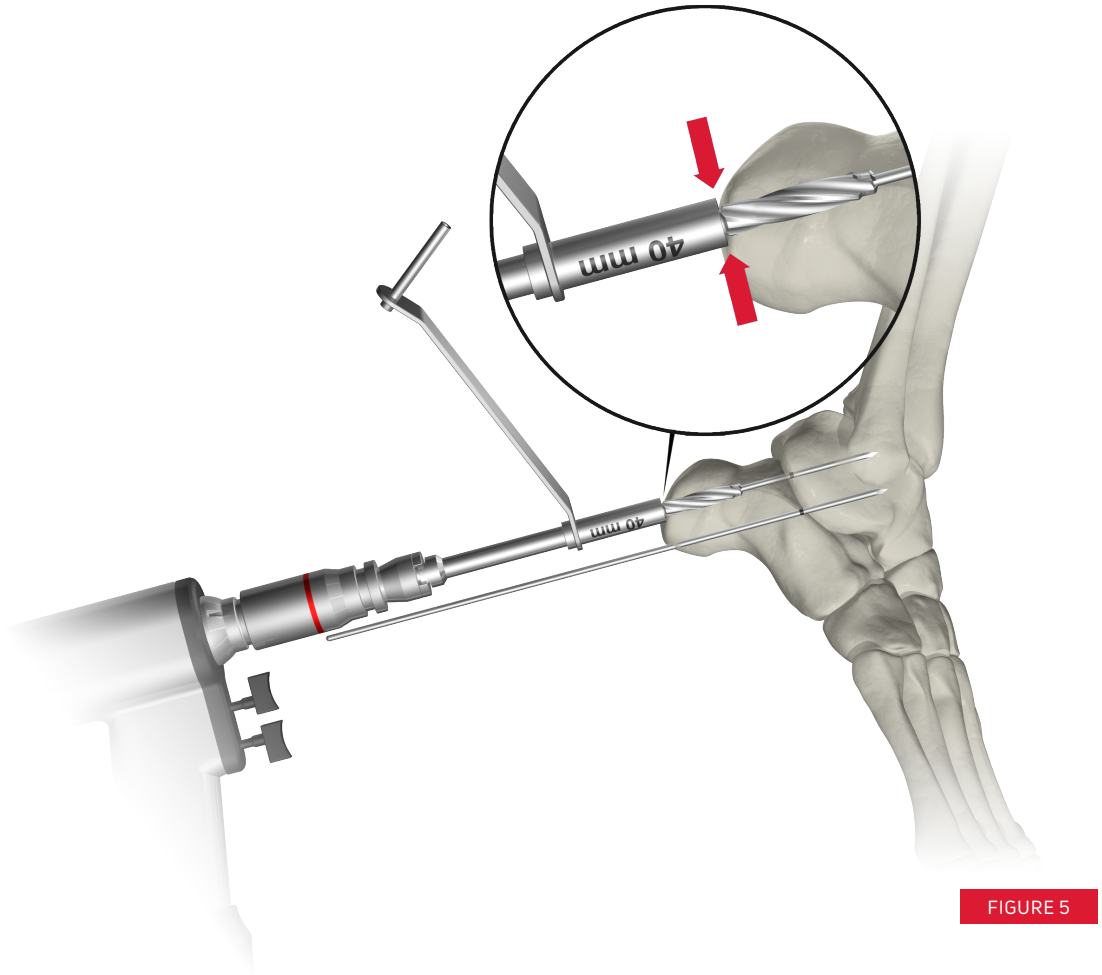



FIGURE 5

## 5. REAM ENTRY CANAL

Instruments used:

**1.** Drill, 5 mm

**2.** Tissue Protector

Place the 5 mm Drill over the 2.4 mm Guidewire and drill until the full implant depth is reached (FIGURE 6). The Tissue Protector may be used when drilling with the 5 mm Drill. If using the Tissue Protector while reading laser marks, there will be a 40 mm offset.

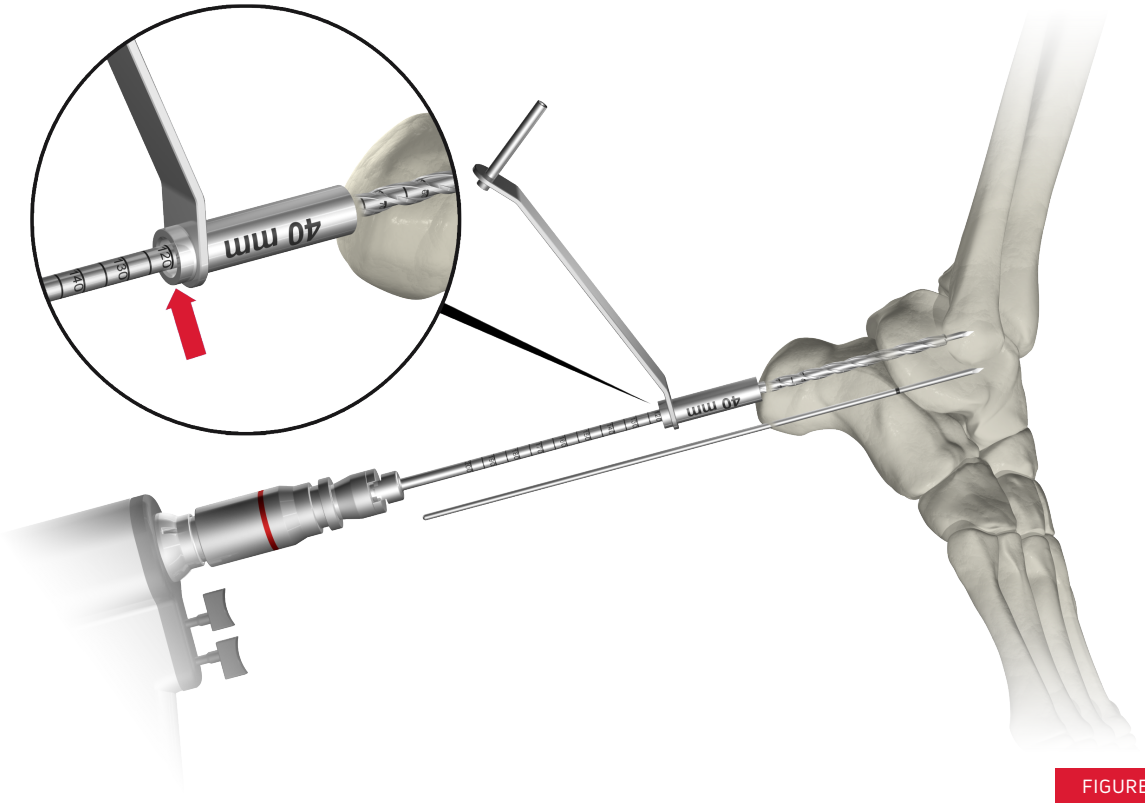



FIGURE 6

## 6. INSERT IMPLANT

Instruments used:

**1.** Blue-Handle Ratchet Driver (4)

Confirm the 2.4 guidewire is fully removed. Attach the Helix Implant to the Blue Handle Ratchet Driver.

Insert the Implant into the reamed canal and advance the threads of the Helix Implant assembly by using the Ratchet Driver (FIGURE 7). The Implant is inserted into the bone tunnel to full depth. If using the headless option, avoid sinking the head deeper than the surface of the bone.

Use fluoroscopy to determine that proper depth has been reached.

**TIP:** Do not push or pull on the driver in an attempt to alter the trajectory of the nail. Doing so could potentially cause the nail guide to break. Keep the driver axially aligned with the nail during insertion. Exercise care while implanting, and use fluoroscopy to confirm implant trajectory during placement.

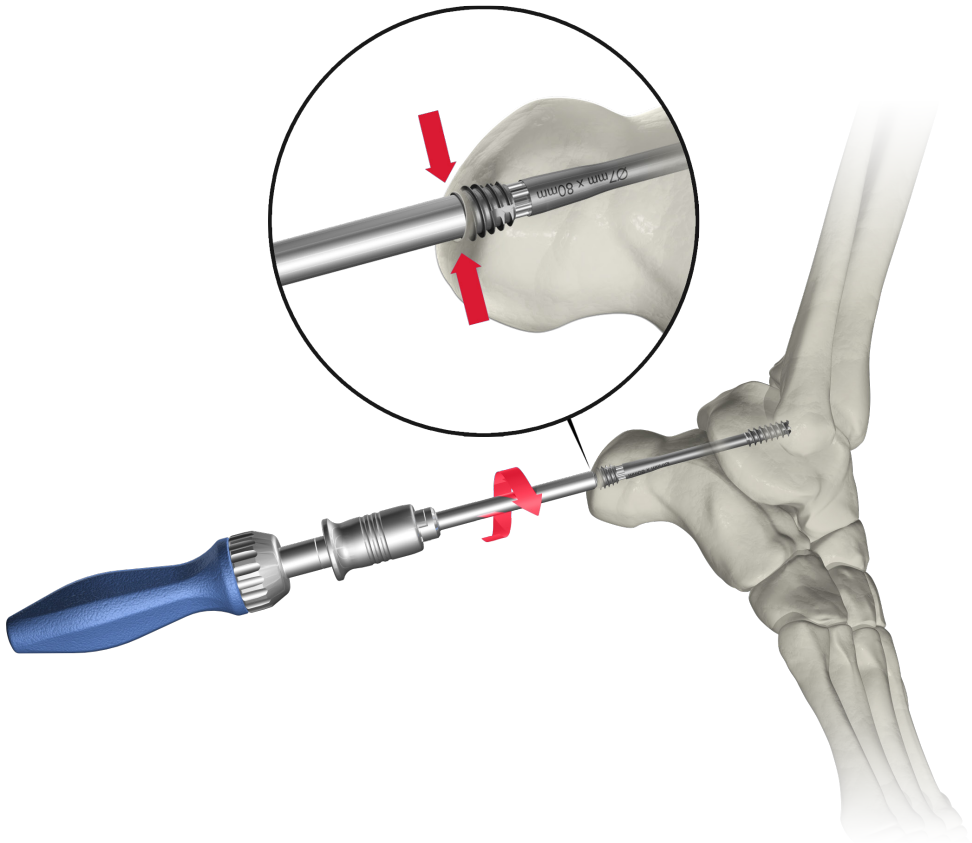


FIGURE 7

## 7. REMOVE CONNECTION BOLT

Instruments used:

**1.** Hex Driver, 2.0 mm

Remove the Ratcheting Handle and utilize the Hex Driver to remove the Connection Bolt from the DynaNail Helix implant (FIGURE 8).

NOTE: The NiTiNOL Release Counter Torque tool can also be utilized for anti-rotation when removing the Connection Bolt.

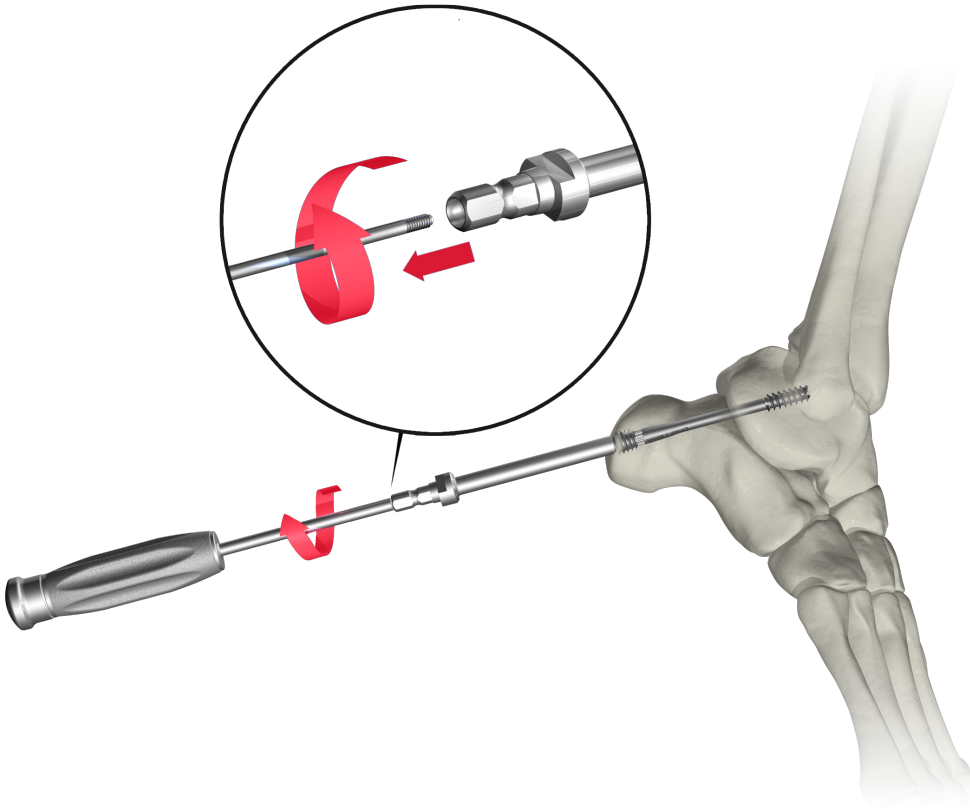


FIGURE 8

## 8. REMOVE INSERTER ASSEMBLY

Once the Connection Bolt is removed, remove the Inserter Assembly from the DynaNail Helix Implant (FIGURE 9).

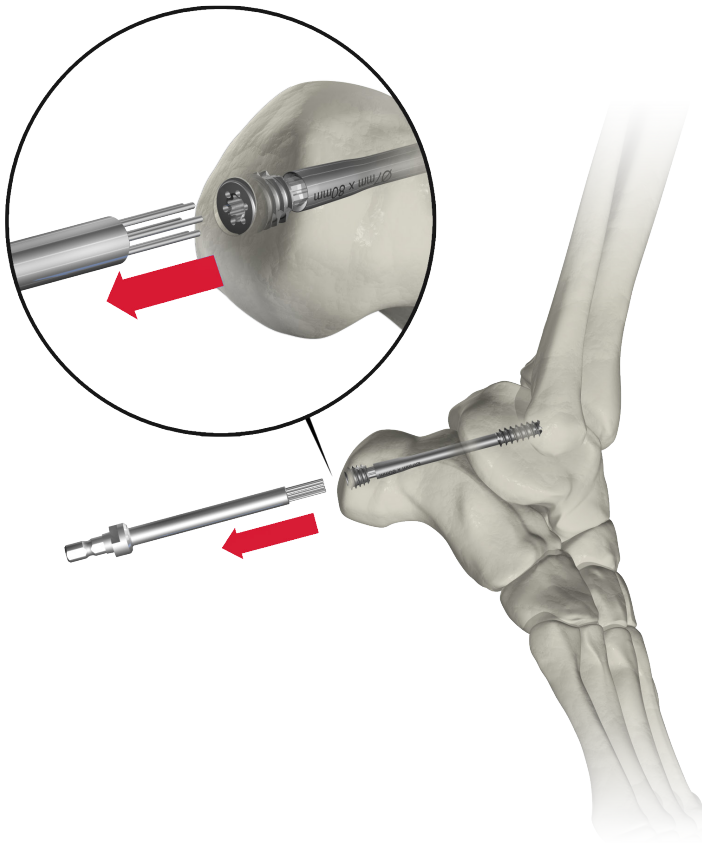


FIGURE 9

## 9. FINAL PLACEMENT

The device is now implanted and the NiTiNOL is applying sustained compression.

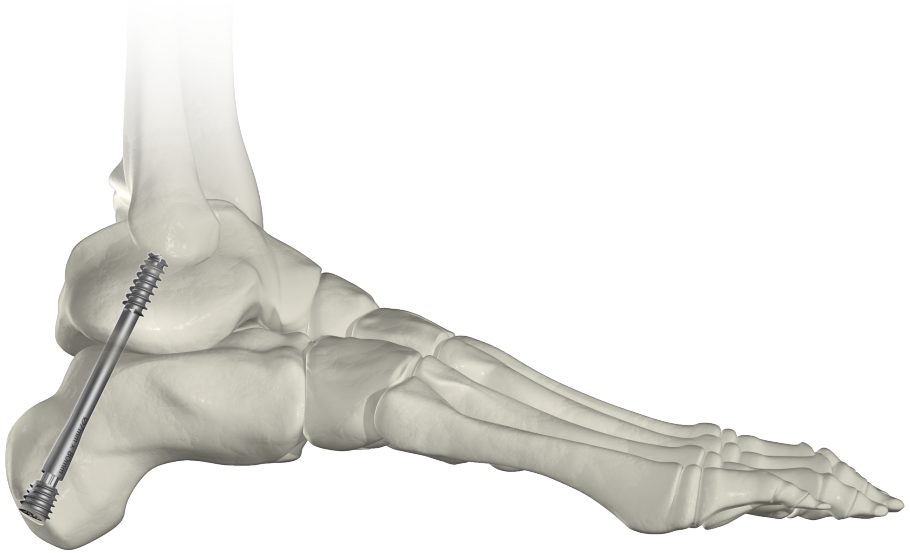


FIGURE 10

## REMOVAL TECHNIQUE

Instruments used:

**1.** Blue-Handle Ratchet Driver (4)

If removing the DynaNail Helix™ Implant, use the Ratcheting Handle in conjunction with the Removal Driver to remove the device (FIGURE 2).

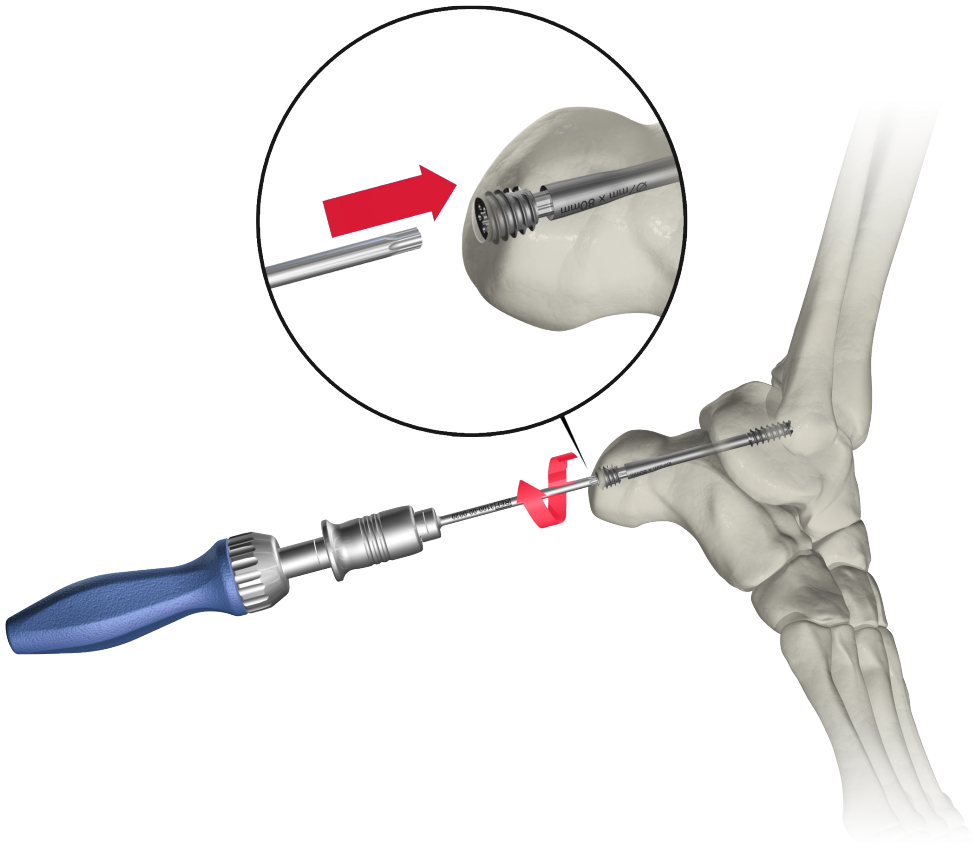


FIGURE 10

# ORDERING INFORMATION



## DYNANAIL HELIX™ IMPLANTS

| PART # | DESCRIPTION |
|---|---|
| 3200-00-7050 | Ø7 MM x 50 MM, DYNANAIL HELIX HEADED FUSION NAIL |
| 3200-00-7055 | Ø7 MM x 55 MM, DYNANAIL HELIX HEADED FUSION NAIL |
| 3200-00-7060 | Ø7 MM x 60 MM, DYNANAIL HELIX HEADED FUSION NAIL |
| 3200-00-7065 | Ø7 MM x 65 MM, DYNANAIL HELIX HEADED FUSION NAIL |
| 3200-00-7070 | Ø7 MM x 70 MM, DYNANAIL HELIX HEADED FUSION NAIL |
| 3200-00-7075 | Ø7 MM x 75 MM, DYNANAIL HELIX HEADED FUSION NAIL |
| 3200-00-7080 | Ø7 MM x 80 MM, DYNANAIL HELIX HEADED FUSION NAIL |
| 3200-00-7085 | Ø7 MM x 85 MM, DYNANAIL HELIX HEADED FUSION NAIL |
| 3200-00-7090 | Ø7 MM x 90 MM, DYNANAIL HELIX HEADED FUSION NAIL |
| 3200-00-7095 | Ø7 MM x 95 MM, DYNANAIL HELIX HEADED FUSION NAIL |
| 3200-00-7100 | Ø7 MM x 100 MM, DYNANAIL HELIX HEADED FUSION NAIL |
| 3200-01-7050 | Ø7 MM x 50 MM, DYNANAIL HELIX HEADLESS FUSION NAIL |
| 3200-01-7055 | Ø7 MM x 55 MM, DYNANAIL HELIX HEADLESS FUSION NAIL |
| 3200-01-7060 | Ø7 MM x 60 MM, DYNANAIL HELIX HEADLESS FUSION NAIL |
| 3200-01-7065 | Ø7 MM x 65 MM, DYNANAIL HELIX HEADLESS FUSION NAIL |
| 3200-01-7070 | Ø7 MM x 70 MM, DYNANAIL HELIX HEADLESS FUSION NAIL |
| 3200-01-7075 | Ø7 MM x 75 MM, DYNANAIL HELIX HEADLESS FUSION NAIL |
| 3200-01-7080 | Ø7 MM x 80 MM, DYNANAIL HELIX HEADLESS FUSION NAIL |
| 3200-01-7085 | Ø7 MM x 85 MM, DYNANAIL HELIX HEADLESS FUSION NAIL |
| 3200-01-7090 | Ø7 MM x 90 MM, DYNANAIL HELIX HEADLESS FUSION NAIL |
| 3200-01-7095 | Ø7 MM x 95 MM, DYNANAIL HELIX HEADLESS FUSION NAIL |
| 3200-01-7100 | Ø7 MM x 100 MM, DYNANAIL HELIX HEADLESS FUSION NAIL |

## DYNANAIL HELIX™ SINGLE USE INSTRUMENTS

| PART # | DESCRIPTION |
|---|---|
| 2900-04-0229 | GUIDEWIRE, 2.4 MM x 229 MM |
| 3100-01-0005 | 5.0 MM DRILL |
| 3100-01-0007 | PROFILE DRILL, 6.5 MM |
| 3100-04-0001 | TRAJECTORY WIRE, 1.0 x 260 MM |
| 2201-09-0025 | 2.5 MM DRILL |

# NOTES

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enovis

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MK-10221 Rev 02