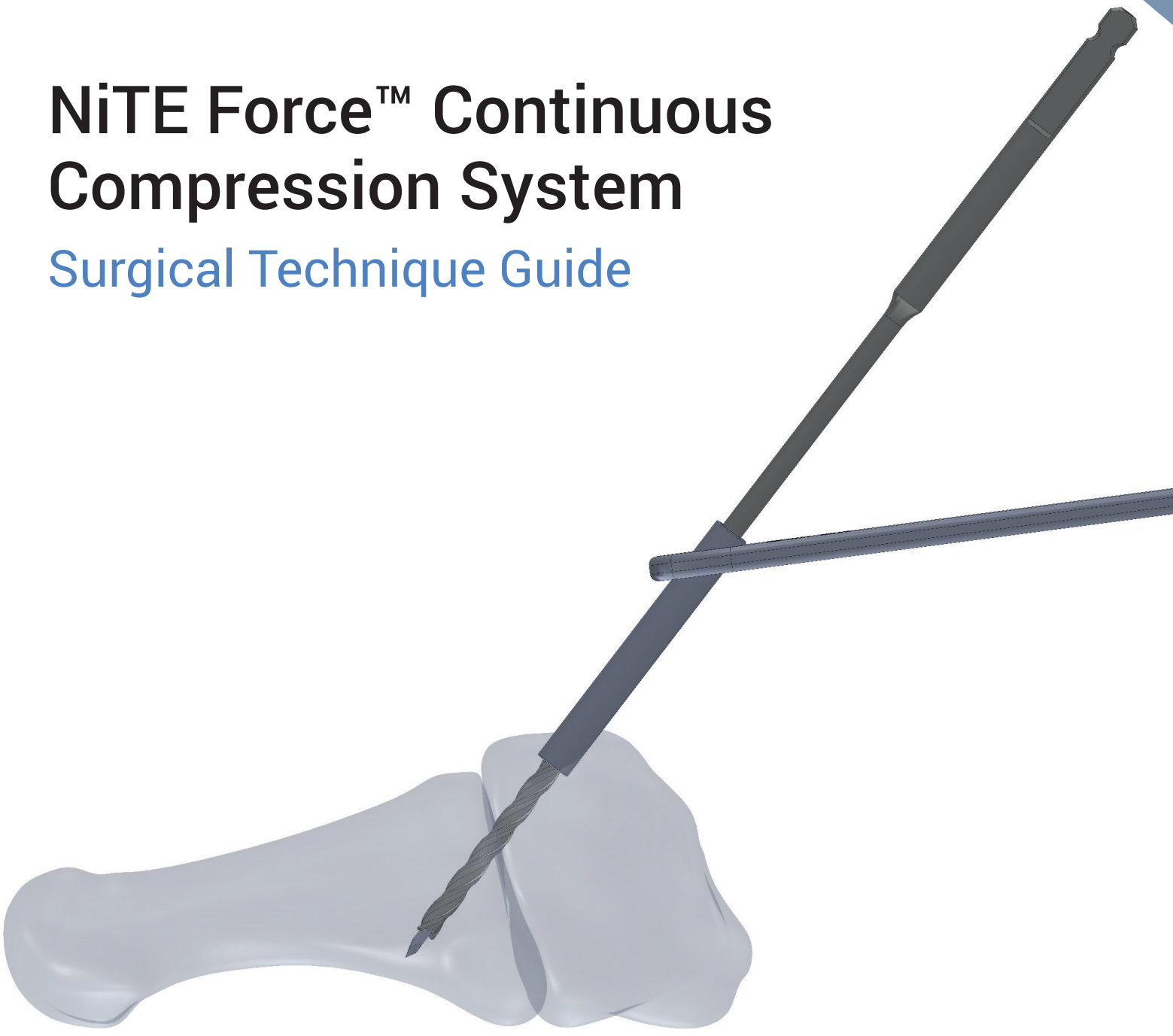
NITE FORCE

conventus FLOWER ORTHOPEDICS

NiTE Force™ Continuous Compression System

Surgical Technique Guide



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SYSTEM OVERVIEW

1 Indications for Use

The NiTE Force™ Continuous Compression System is indicated for use in bone reconstruction, osteotomy, arthrodesis, joint fusion, fracture repair and fracture fixation of small bones and small bone fragments.

Caution: Federal Law (USA) restricts this device to sale by or on the order of a physician.

2 Contraindications

Prior to using the NiTE Force Continuous Compression System, ensure that none of the following patient conditions are present:

- active or latent infection
- sepsis
- osteoporosis
- insufficient quantity or quality of bone and/or soft tissue
- material sensitivity (if sensitivity is suspected, tests are performed prior to implantation}
- patients who are unwilling or incapable of following post-operative care instructions
- any condition not included in the Indications for Use

3 Warnings

- The patient must be cautioned about the use, limitations, and potential adverse effects of this device including the possibility of delayed union, non-union, device or treatment failure as a result of loose fixation and/or loosening, stress, excessive activity, or weight bearing or load bearing, and the possibility of nerve or soft tissue damage related to either the original trauma, surgical trauma or the presence of the device.
- The patient should be informed about the importance of following the prescribed post-operative rehabilitation protocol and to understand the possible limitations in activities of daily living. The patient must be warned that failure to follow postoperative care instructions may cause the implant or treatment to fail.
- For safe, effective use of the implant, the surgeon must be thoroughly familiar with the surgical technique for the device, implant, and associated instruments. Potential failures of the NiTE Force Continuous Compression System may include delayed union, non-union, loosening of fixation, stress fractures of the bones, or incomplete healing as a result of excessive activity, overloading or noncompliance to postoperative rehabilitation.
- The device is not designed to withstand the stress of weight bearing, load bearing, or excessive physical activity. Device breakage may occur when the implant is subjected to excessive loading associated with delayed union or nonunion. Improper insertion of the device during implantation may also increase the possibility of loosening or migration.
- The NiTE Force Compression System implants are single-use only devices. DO NOT reuse any of the NiTE Force Compression System implantable components. Reuse may compromise the structural integrity of the implant and/or lead to failure, which may result in patient injury.

4 Precautions

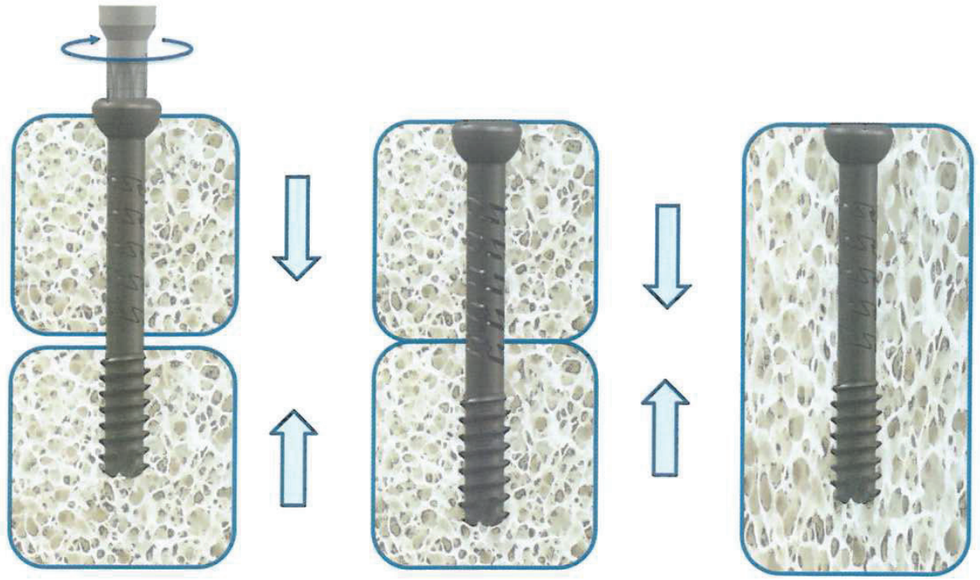
- Protect the NiTE Force Continuous Compression System implantable components against scratching or nicking. Such stress concentration can lead to implant failure.
- Before using the NiTE Force Continuous Compression System, inspect all implants and instruments for wear, disfiguration and physical damage. If evidence of wear, disfiguration or physical damage is found, DO NOT use and contact your local representative or Conventus Flower Orthopedics directly.
- DO NOT mix implant components from different manufacturers for metallurgical, biomechanical and functional reasons.
- DO NOT use implant lengths that will excessively protrude through the far cortex as it may result in soft tissue irritation.
- The benefits from implant surgery may not meet the patient's expectations or may deteriorate over time, requiring revision surgery to replace the implant or to carry out alternative procedures. Note: To maintain traceability of the implanted NiTE Force Compression System device, record each of the respective component's LOT numbers in the patient record post implantation.

5 Device Description

The NiTE Force Continuous Compression System consists of continuous compression style implants. The implants are headed, cannulated, partially threaded and offered in a 4.0mm diameter with lengths ranging from 28 to 60mm. The NiTE Force Continuous Compression System incorporates a helical expansion section in the smooth shaft of the implant.

Facilitated by the superelastic Nitinol material, the continuous compression feature works like a spring. As the distal thread engages bone, the active section of the implant is elongated. This places the implant in tension which then produces a persistent, continuous compression force across the intervening fracture site. This persistent compressive force continues even as the bone fragments move closer together during the healing phase.

6 Technique Details



Large Diameter Guide Wire 1.4mm

NiTE Force Guide Wires have large diameter to allow for optimal bending stiffness and reduce deflection.

Cannulated Depth Gauge

Measure for the desired implant length by using the Cannulated Depth Gauge. Slide the Cannulated Depth Gauge over the Guide Wire and position directly against the bone.

To ensure accurate measurement, appropriately subtract any shortening due interfragmentary or inter-segmentary compression, and implant center section self-limiting elongation during implant insertion of 2mm. Choose a implant length 2mm less than measured length.

Cannulated Depth Gauge must always be placed perpendicular to the bone surface. If perpendicular to the bone surface is not feasible, subtract appropriately to ensure proper implant head placement.

Countersink (optional)

Countersink must always be done manually. The Cannulated Countersink is inserted into the bone until the notches are flush with the bone surface, or a desired depth is attained.

Cortical Tap/Depth Gauge

Tapping is highly recommended. Slide the Cortical Tap over the Guide Wire and tap to the depth of the desired final implant placement.

Verify the implant length using the marking on the Tap's shaft. Subtract 2mm from the measured length to account for elongation of the continuous compression section.

SURGICAL TECHNIQUE

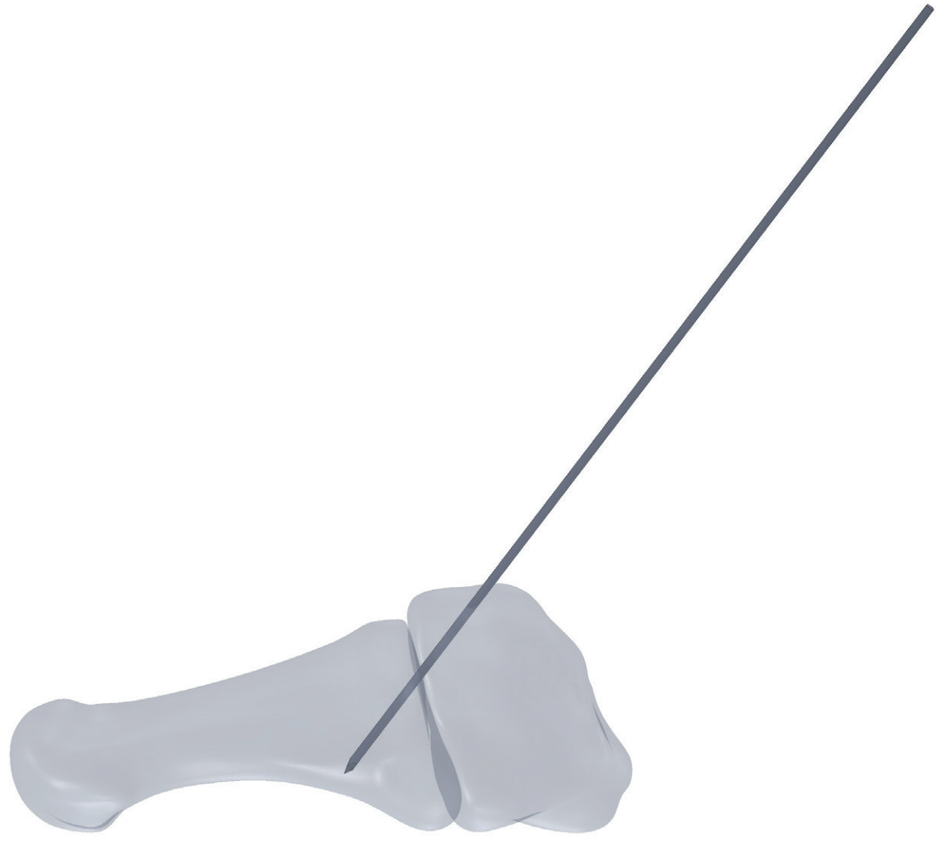
7 Step 1: Stabilize

Instruments:

617-1	Guide Wire 1.4mm x 150mm

Position Drill Guide and insert a Guide Wire (1.4mm) into the bone until the appropriate depth.

Use fluoroscopy to control reduction and Guide Wire placement. Place additional Guide Wires if necessary.



8 Step 2: Measure

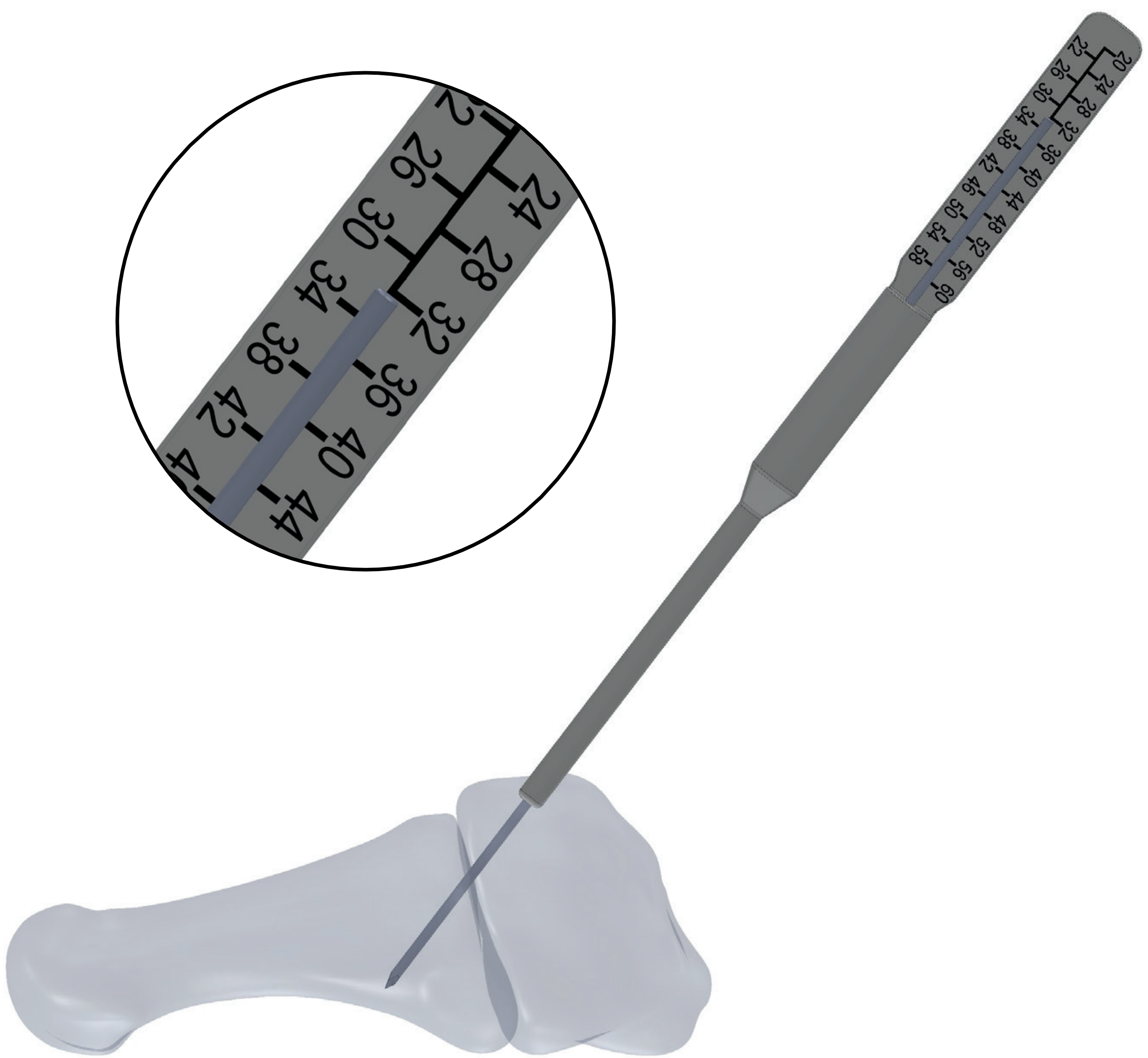
Instruments:

611-1	Cannulated Depth Gauge

Slide the Cannulated Depth Gauge over the Guide Wire.

To select the appropriate implant length, **subtract 2mm from the measured Depth Gauge length to account for the continuous compression section elongation**.

Note: Based on Guide Wires location associated with the far cortex, adjust implant length appropriately and cautiously.

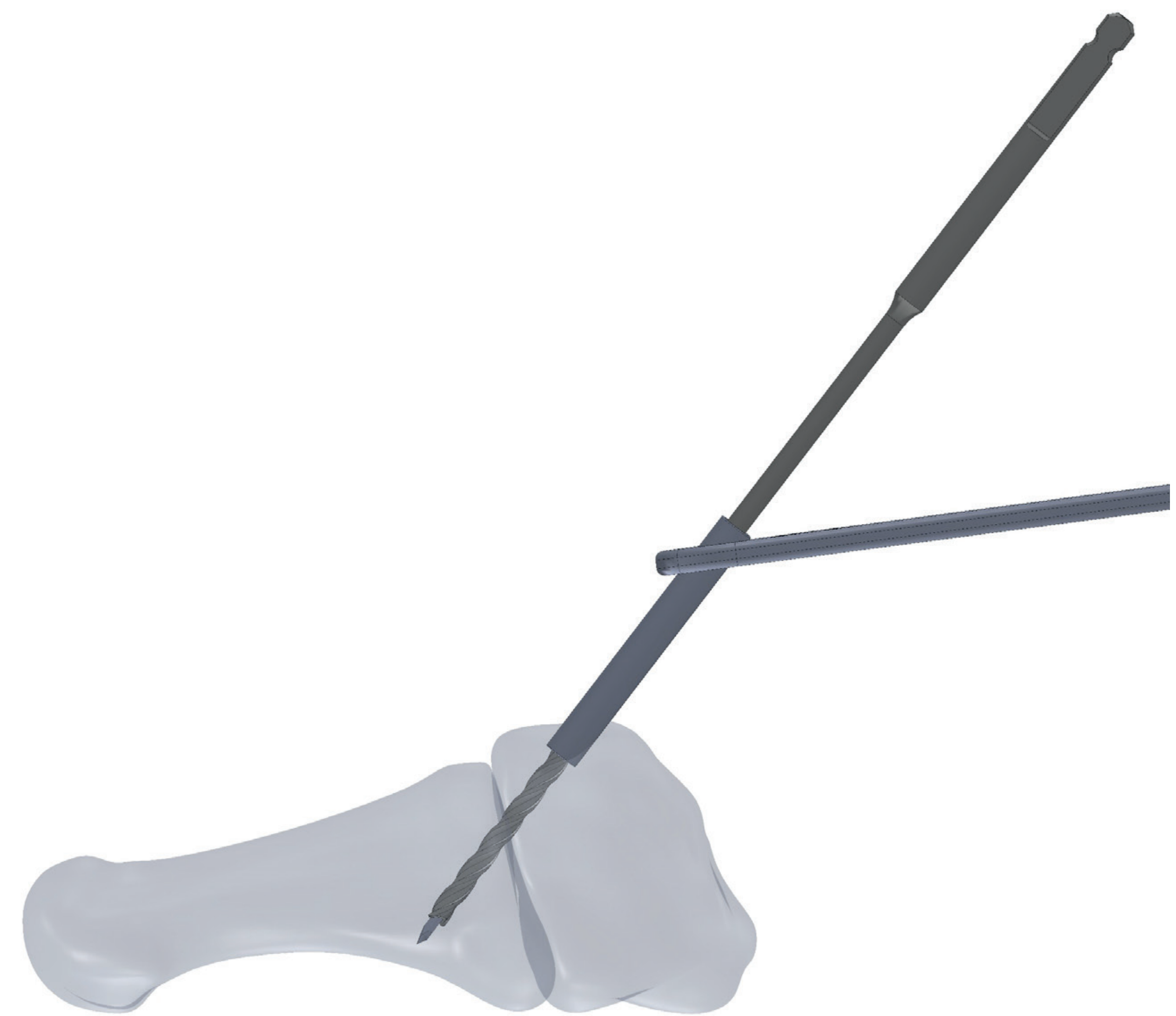


9 Step 3: Pre-Drilling

Instruments:

618-30	3.0mm Cannulated Drill Bit
612-1	Tissue Protector

Slide the 3.0mm Cannulated Drill Bit over the Guide Wire and through the Tissue Protector. Drill to the appropriate depth.



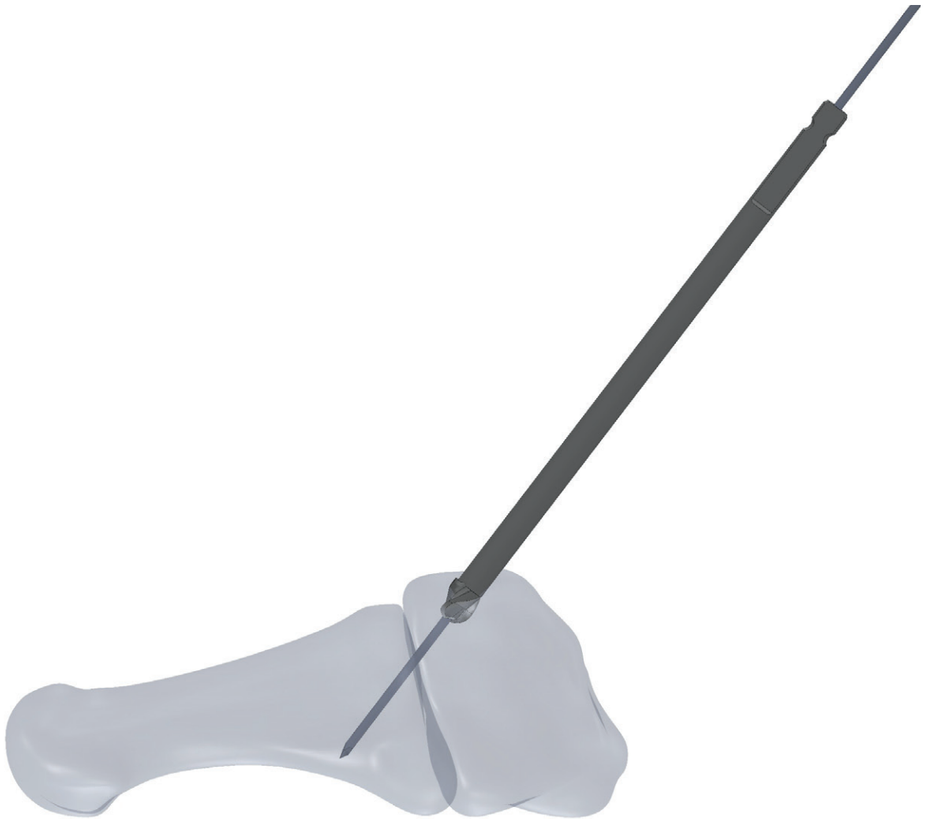
10 Step 4: Countersink (optional)

Instruments:

616-1	5.5mm Cannulated Countersink

Where the bone is surrounded by only a thin layer of soft tissue, the implant head may be countersunk using the 5.5 mm Cannulated Countersink to prevent projection of the implant head.

Note: Countersinking must always be done manually and over the Guide Wire.



11 Step 5: Tapping & Final Implant Measurement

Instruments:

614-1	Cortical Tap/Depth Gauge

Slide the Cortical Tap/Depth Gauge over the Guide Wire and tap to the depth of the desired final implant position.

Verify the implant length using the marking along the Cortical Tap's shaft. Again, to select the appropriate implant length, **subtract 2mm from the measured length to account for the continuous compression section elongation**.

Note: Based on the Cortical Tap's location associated with the far cortex, adjust implant length appropriately and cautiously.

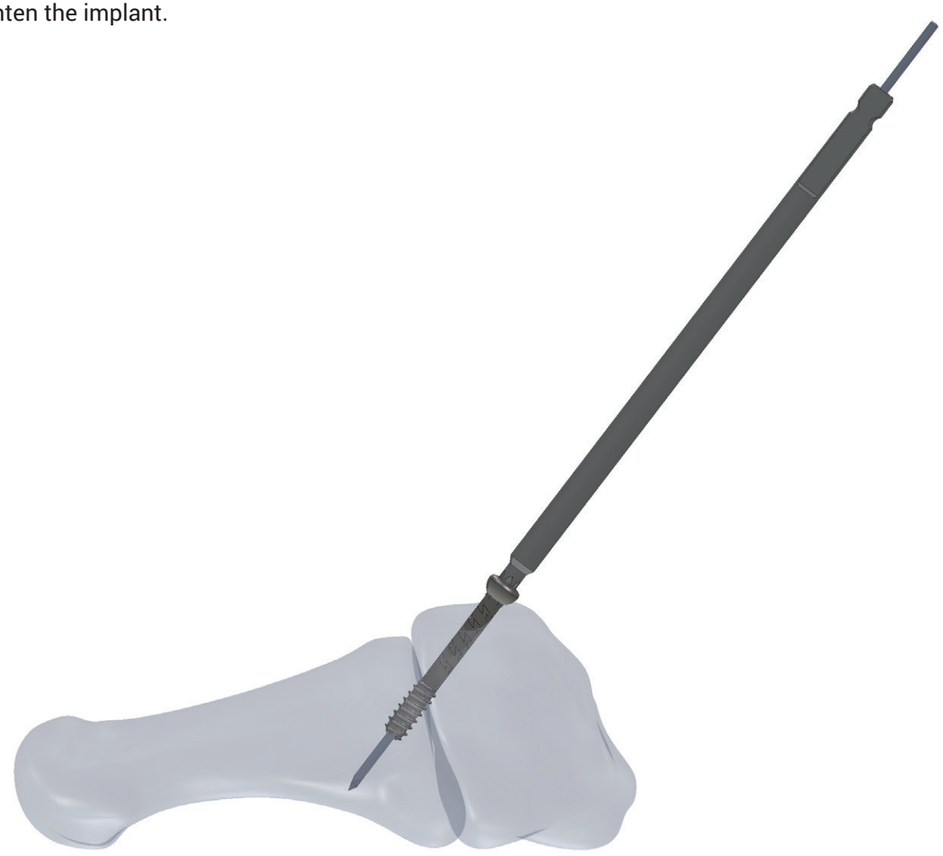
12 Step 6: Implant Placement

Instruments:

615-1	H15 Cannulated Driver

Insert the appropriate length NiTE Force Implant using the H15 Cannulated Driver until the implant head is flush with the cortex.

Once the fragments are lagged together and the implant head is flush with the cortex, turn the implant an additional 2 full turns to elongate the center section and provide continuous compression. To prevent over-compression or stripping of the bony fragments, be cautious not to over-tighten the implant.

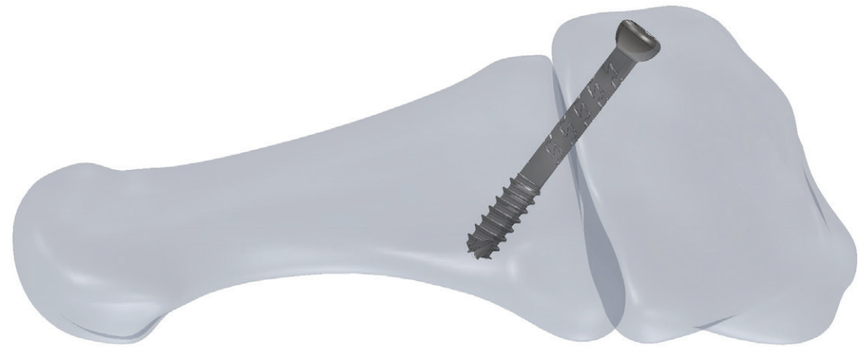


13 Step 7: Continuous Compression

Implants:

505-XX	Continuous Compression Implant

A correctly placed implant provides a persistent, continuous compressive force across the intervening fracture site. This persistent compressive force continues even as the bone fragments move closer together during the healing phase.



PRODUCT INFORMATION

14 Implants & Instruments

NiTE Force Continuous Compression Implants
28mm - 60mm Lengths (2mm increments)
505-XX

H15 Cannulated Driver
615-1

5.5mm Cannulated Countersink
616-1

Cortical Tap/Depth Gauge
614-1

Guide Wire
1.4mm x 150mm
617-1

Cannulated Depth Gauge
611-1

3.0mm Cannulated Drill Bit
618-30

AO Quick Connect Handle
619-1

Tissue Protector
612-1

15 Notes

Caution: Federal law restricts these devices to sale by or on the order of a licensed physician.

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