

**I. General**

The Super Staple™ is a two-legged U-shaped staple implant with an S-back bridge that connects two legs of equal or unequal length. The Super Staple™ gives the surgeon a means of bone and soft tissue-to-bone fixation for the management of fracture and reconstructive surgery. The implants of the Super Staple™ fixation system are not intended to replace normal body structures, so when the implant's service as an aid to healing is accomplished, it should be removed (when practical and possible) at the surgeon's discretion.

**II. Basic Structure**

Super Staple™ implants are fabricated from nitinol. The Super Staple™ is retained in a cartridge, advanced into bone and released so that the elastic properties of these materials will return the staple to a closed shape. These staples pull together and compress bone as they transition from parallel legs and elongated bridge configuration to an inward leg and shortened bridge configuration. With ideal reduction and good bone quality, this shape change may not be visible as the staple is constrained by bone. Under this condition the implant applies the maximum fixation force and has the greatest potential shape change available. This potential shape change may pull the bone segments together if bone interfacial resorption occurs. This change may be visible if its use facilitates further bone reduction or if bone quality is poor.

**III. Indications for Use**

1. Hand and foot bone fragment and osteotomy fixation and joint arthrodesis,
2. Fixation of proximal tibial metaphysis osteotomy, and
3. Adjunctive fixation of small bone fragments (i.e. small fragments of bone that are not comminuted to the extent and preclude staple placement). These fragments may be located in long bones such as the femur, fibula or tibia in the lower extremities; the humerus, ulna or radius in the upper extremities; the clavicle and ribs; and in flat bone such as the pelvis, scapula and sternum.

**IV. Contraindications**

1. Comminuted bone surface, which would militate against staple placement.
2. Pathologic conditions of bone such as osteopenia, which would impair the ability to securely fix the staple.
3. Foreign body sensitivity to metals including nickel. Where material sensitivity is suspected, appropriate tests should be made prior to implantation.

**V. Warnings**

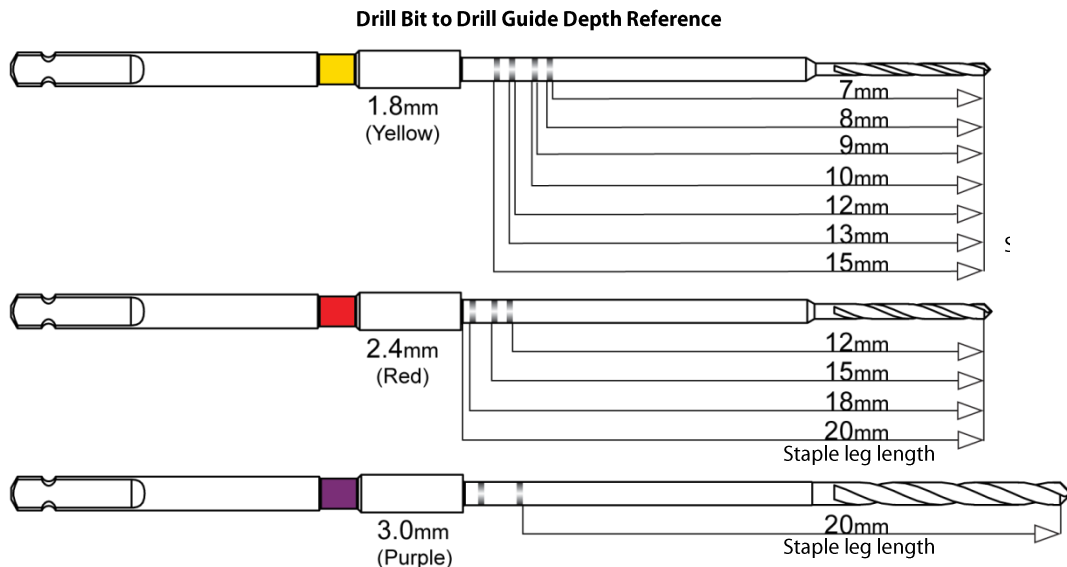
1. Immobilization, in addition to this internal fixation, until bone healing (4-6 weeks) should be achieved by routine methods (casting, splints, etc.).
2. Reduction of the site should be achieved and maintained prior to implanting the staple. The compressive force of the staple closing should not be relied upon to achieve closure or reduction of a fracture line.
3. The Super Staple™ has not been evaluated for safety and compatibility in the MR environment. It has not been tested for heating or migration in the MR environment.
4. Drill Bits – avoid excessive flexion and contact with metallic implants which can cause breakage. If breakage occurs in bone, follow appropriate orthopedic surgery protocol.

**VI. Use and Storage Considerations**

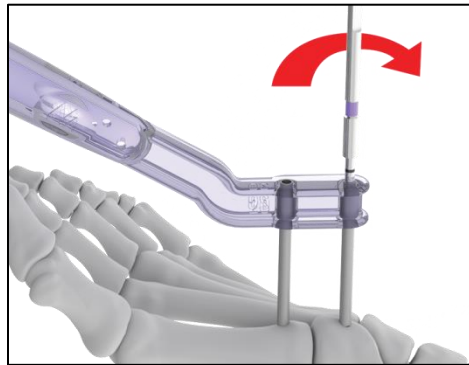
Staples and instruments should not be subjected to storage or shipping temperatures in excess of 76.7°C or 170°F.

**VII. Clinical Use Examples**

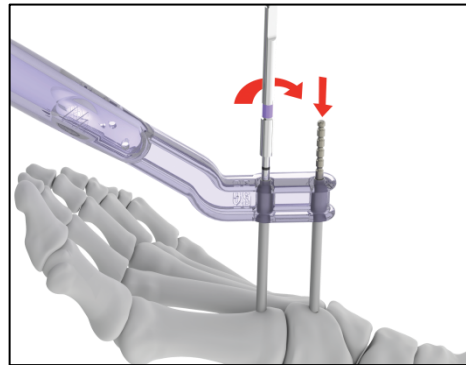
1. Hand Surgery: intracarpal and interphalangeal arthrodesis, carpal, metacarpal and phalanges fracture or osteotomy.
2. Foot Surgery: bunionectomy; tibiotarsal, Lisfranc's, calcaneocuboidal, and talonavicular arthrodesis; hind, mid, or forefoot bone fracture or osteotomy fixation.
3. General Skeletal Surgery: bone fragment retention or adjunct fracture, osteotomy or arthrodesis fixation in the femur, fibula, tibia, humerus, ulna, radius, clavicle, ribs, pelvis, scapula and sternum.



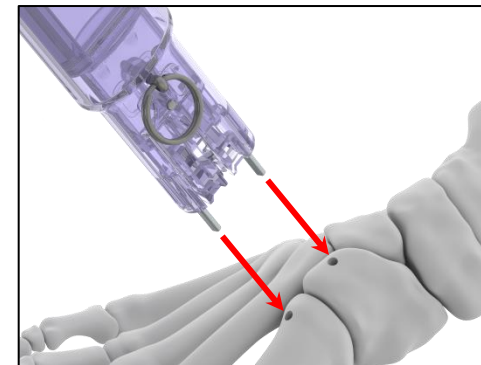
## VIII. Implant Placement Instructions for Use



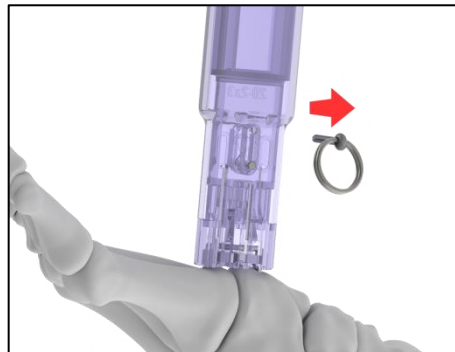
1. Place both drill tubes in firm contact with bone then drill 1<sup>st</sup> hole



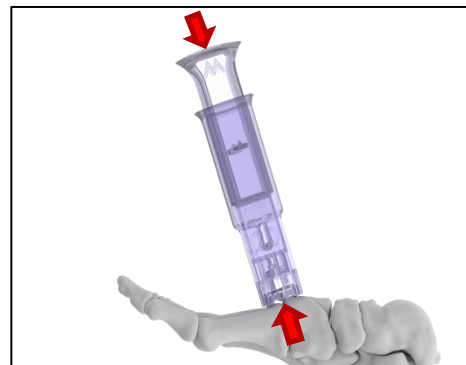
2. Place pull pin in 1<sup>st</sup> hole then drill second hole



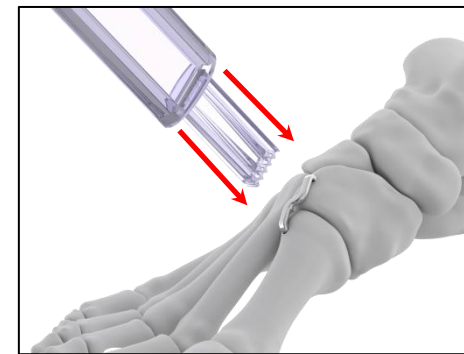
3. Insert staple legs completely



4. Pull grenade pin to unlock plunger.



5. Press plunger down while applying firm counter pressure to implant and release staple



6. If needed seat the staple bridge with tamp

## IX. Care and Caution

1. Implants and instruments are provided pre-sterilized in a single-use kit.
2. Pre-sterilized implants and instrument packages should be inspected prior to use.
3. Sterility cannot be assured and implants and accessories should not be used if package or seal is damaged.

## **I. General**

The Super Scaffold™ (Intramedullary Fixation Scaffold System) is a hollow fenestrated cylinder implant fabricated from nitinol alloy with a section that increases its diameter while shortening its length. Features on the cylinder's surface lock in to bone. The Super Scaffold™ implant has distal and proximal segments which vary in length and extent of contraction. The Super Scaffold™ gives the surgeon a means of end-to-end bone fixation for the long bones of the foot and hand (inter-phalangeal or phalangeal-metatarsal/metacarpal).

## **II. Basic Structure**

The Super Scaffold™ is retained in an instrument, advanced into bone and released so that the elastic properties of nitinol will cause the Super Scaffold™ to expand its diameter and shorten its length. The Super Scaffold™ is designed to expand and lock into the intramedullary space and pull together and compress bone as the Super Scaffold™ shortens. This shape change may not occur when the Super Scaffold™ is constrained by bone. In this condition the implant applies the maximum fixation force and has the greatest potential shape change. This potential shape change may pull the bone segments together if bone interfacial resorption occurs.

## **III. Indications for Use**

1. The Super Scaffold™ is indicated for small bone fixation, reconstruction and fusion such as inter-digital fusion of the fingers and toes.

## **IV. Contraindications**

1. Comminuted bone surface, which would militate against Super Scaffold™ placement.
2. Pathologic conditions of bone such as osteopenia, which would impair the ability to securely fix the Super Scaffold™.
3. Foreign body sensitivity to metals including nickel. Where material sensitivity is suspected, appropriate tests should be made prior to implantation.

## **V. Warnings**

1. Immobilization, in addition to this internal fixation, until bone healing (4-6 weeks) should be achieved by routine methods (casting, splints, etc.).
2. Reduction of the site should be achieved and maintained prior to removal of the Lock Plate. The compressive force of the Super Scaffold™ should not be relied upon to achieve closure of reduction of bone.
3. Implant removal is recommended to avoid implant breakage in the event of a malunion or nonunion of the fusion site.
4. The Super Scaffold™ has not been evaluated for safety, compatibility, heating or migration in the Magnetic Resonance environment.

## **VI. Use and Storage Considerations**

Super Scaffold™ and instruments should not be subjected to storage or shipping temperatures in excess of 76.7°C (170°F).

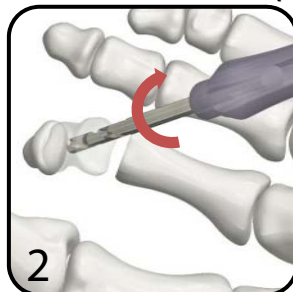
## **VII. Clinical Use Examples**

1. Foot Surgery: metatarsal to phalangeal and interphalangeal arthrodesis.
2. Hand Surgery: metacarpal to phalangeal and interphalangeal arthrodesis.

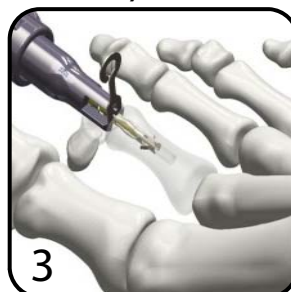
**VIII. Implant Placement Instructions for Use (foot shown)**



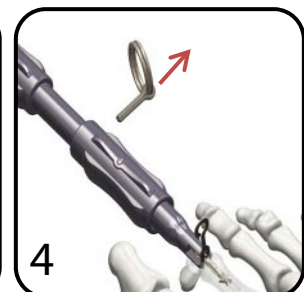
1 Drill the proximal phalanx to the drill bit 2<sup>nd</sup> line<sup>2</sup>



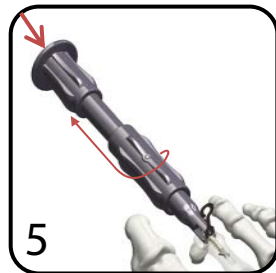
2 Drill the distal phalanx to the drill bit 1<sup>st</sup> line<sup>1</sup>



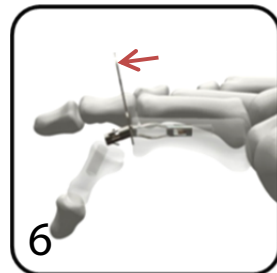
3 Insert Super Scaffold™ into the proximal phalanx



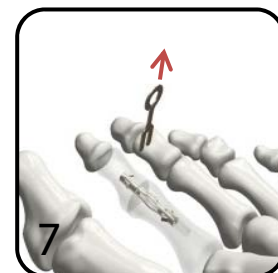
4 Remove the grenade pin



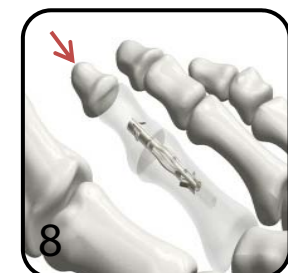
5 Turn knob clockwise and slide knob back *\*If resistance is encountered during retraction, rotate Lock Plate back and forth around implant while continuing to pull back on the knob*



6 Reduce distal phalanx while applying gentle forward pressure to Lock Plate



7 Remove the Lock Plate by pulling it from the Super Scaffold™



8 Push bones together

**IX. Implant Removal Instructions**

1. Prior to Super Scaffold™ release from the instrument in the proximal bone:
  - a. During implantation removal of the Super Scaffold™ from the proximal bone prior to release of the implant from the Super Scaffold™ instrument (Step 5) can be achieved by counter clockwise rotation of the implant and instrument while pulling the instrument and Super Scaffold™ from bone. The bone anchors on the Super Scaffold™ are angled so they deflect inwards when the Super Scaffold™ is turned counter clockwise.
2. If Super Scaffold™ loosening occurs:
  - a. Stabilization of a loose implant until fusion occurs can be accomplished by placement of a K-wire through the fixated bones and lumen of the Super Scaffold™.
  - b. Distract the phalanx to open the joint and expose the implant. Clear tissue from the lumen of the implant with a pick, drill or burr. Turn the protruding portion of the Super Scaffold™ counter clockwise 1 turn while pulling gently to collapse the fixation features, then turn while pulling to remove the implant from bone.
3. If Super Scaffold™ breakage occurs:
  - a. Open the joint. Hold the visible ends of the implant with a needle driver and twist counter clockwise 1 turn, then pull gently while turning counter clock-wise to remove each the distal and proximal portions of the implant.
4. If removal is required and the joint is fused or tissue cannot be fully removed from the Super Scaffold™ lumen, removal of the implant may require soft tissue and bone dissection to fully expose the implant to allow its removal through a slot in the bone.

**CAUTION: Removal of the Super Scaffold™ from osteopenic bone may result in bone damage or fracture.**

**Note<sup>1</sup>:** Drill to 1<sup>st</sup> edge of 1<sup>st</sup> line for Super Scaffold™ with 6.5mm distal length; drill to 2<sup>nd</sup> edge of 1<sup>st</sup> line for 8.5mm distal length.

**Note<sup>2</sup>:** Drill to 1<sup>st</sup> edge of 2<sup>nd</sup> line for Super Scaffold™ with short proximal length; drill to 2<sup>nd</sup> edge of 2<sup>nd</sup> line for long proximal length.

**I. General**

The SuperSTEP™ is a two-legged U-shaped staple implant with a bridge containing a vertical drop of a specified length that connects two legs of equal or unequal length. The SuperSTEP™ gives the surgeon a means to off-set and fixate bone. The implants of the SuperSTEP™ fixation system are not intended to replace normal body structures, so when the implant's service as an aid to healing is accomplished, it should be removed (when practical and possible) at the surgeon's discretion.

**II. Basic Structure**

SuperSTEP™ implants are fabricated from nitinol. The SuperSTEP™ is retained in a cartridge, advanced into bone and released so that elastic properties will return the staple to a closed shape. These staples pull together and compress bone as they transition from parallel legs and elongated bridge configuration to an inward leg and shortened bridge configuration. With ideal reduction and good bone quality, this shape change may not be visible as the staple is constrained by bone. Under this condition the implant applies the maximum fixation force and has the greatest potential shape change available. This potential shape change may pull the bone segments together if bone interfacial resorption occurs. This change may be visible if its use facilitates further bone reduction or if bone quality is poor.

**III. Indications for Use**

1. Hand and foot bone fragment and osteotomy fixation and joint arthrodesis,
2. Fixation of proximal tibial metaphysis osteotomy, and
3. Adjunctive fixation of small bone fragments (i.e. small fragments of bone that are not comminuted to the extent and preclude staple placement). These fragments may be located in long bones such as the femur, fibula or tibia in the lower extremities; the humerus, ulna or radius in the upper extremities; the clavicle and ribs; and in flat bone such as the pelvis, scapula and sternum.

**IV. Contraindications**

1. Comminuted bone surface, which would militate against staple placement.
2. Pathologic conditions of bone such as osteopenia, which would impair the ability to securely fix the staple.
3. Foreign body sensitivity to metals including nickel. Where material sensitivity is suspected, appropriate tests should be made prior to implantation.

**V. Warnings**

1. Immobilization, in addition to this internal fixation, until bone healing should be achieved by routine methods (casting, splints, etc.).
2. Reduction of the site should be achieved and maintained prior to implanting the staple. The compressive force of the staple closing should not be relied upon to achieve closure or reduction of a fracture line.
3. The SuperSTEP™ has not been evaluated for safety and compatibility in the MR environment. It has not been tested for heating or migration in the MR environment.
4. Drill Bits – avoid excessive flexion and contact with metallic implants which can cause breakage. If breakage occurs in bone, follow appropriate orthopedic surgery protocol.

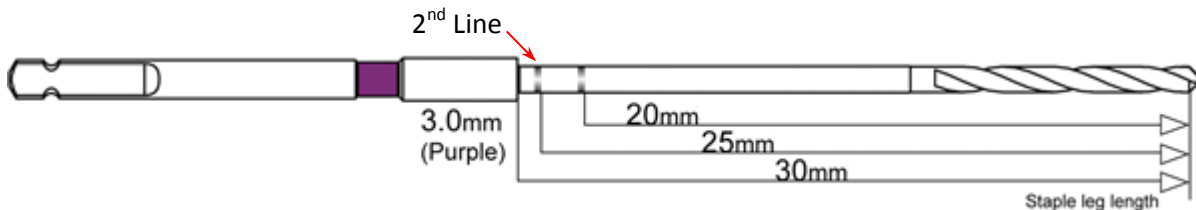
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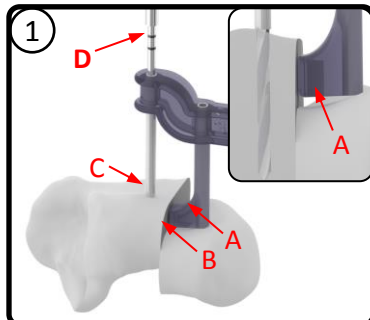
**VII. Clinical Use Examples**

1. Foot Surgery: calcaneal slide, flat foot correction, plantar displacement of 1<sup>st</sup> metatarsal head, and epiphysiodesis. Drill to front edge of 25mm mark.

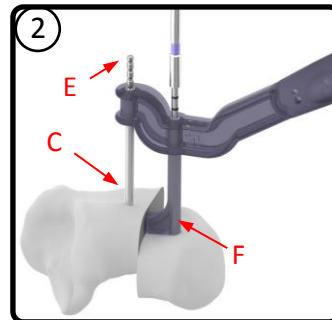
**Drill Depth Mark Guide**



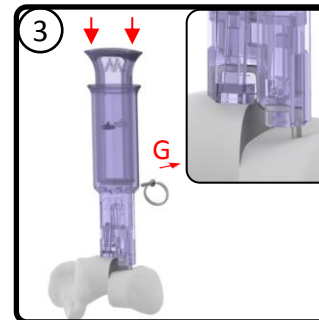
## VIII. Implant Placement Instructions for Use



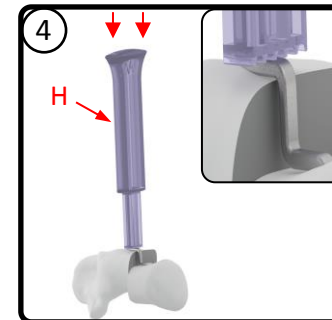
1 Cut osteotomy, place Drill Guide's offset (A) against osteotomy (B) & drill proximal hole (C) to 2<sup>nd</sup> line (D) (25mm mark. See Drill Depth Mark Guide).



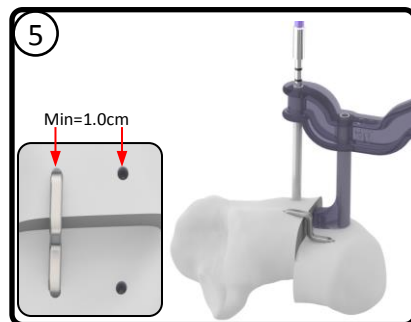
2 Place pull pin (E) in proximal hole (C) then drill distal hole (F) to 2<sup>nd</sup> line.



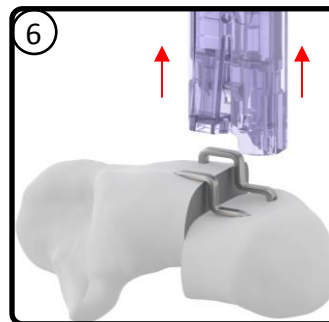
3 Insert tips of staple legs into holes, pull grenade pin (G) and push staple from instrument into bone.



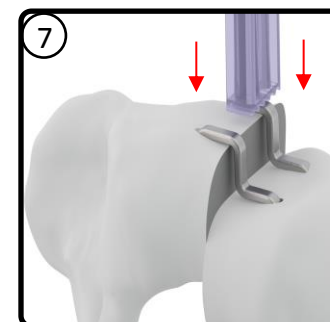
4 Using the tamp (H), fully offset the calcaneus by pushing staple flush with bone.



5 For the second staple, repeat Drill Guide steps 1 & 2 while insuring staples have minimum 1.0cm separation from each other.



6 Repeat step 3 to insert 2<sup>nd</sup> staple.



7 Repeat tamp step 4 to fully seat both staples.

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