

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.

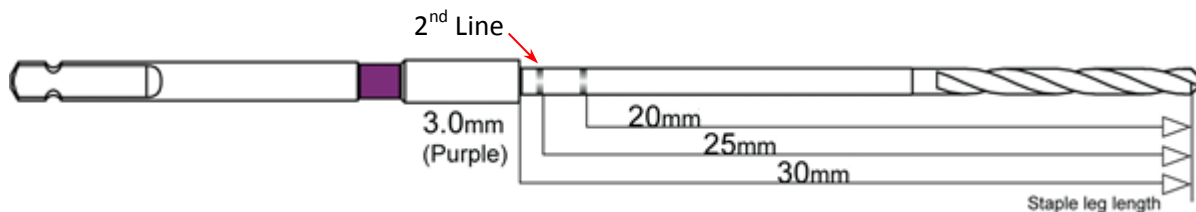
VI. Use and Storage Considerations

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

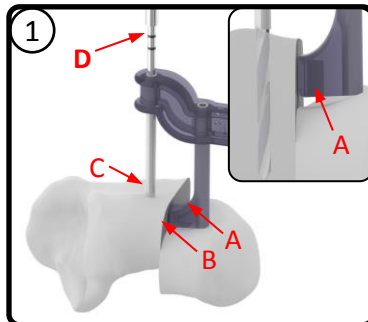
VII. Clinical Use Examples

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

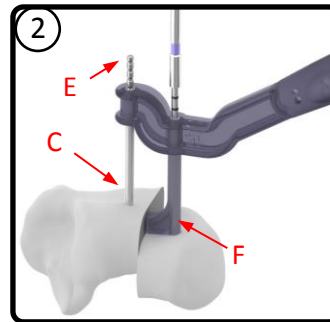
Drill Depth Mark Guide



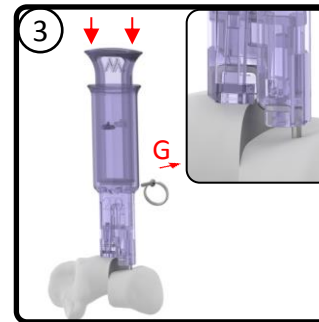
VIII. Implant Placement Instructions for Use



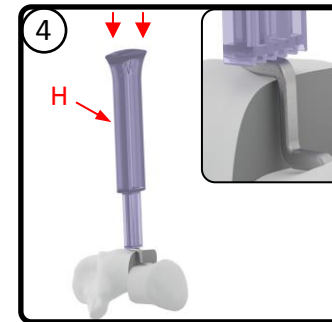
1 Cut osteotomy, place Drill Guide's offset (A) against osteotomy (B) & drill proximal hole (C) to 2nd line (D) (25mm mark. See Drill Depth Mark Guide).



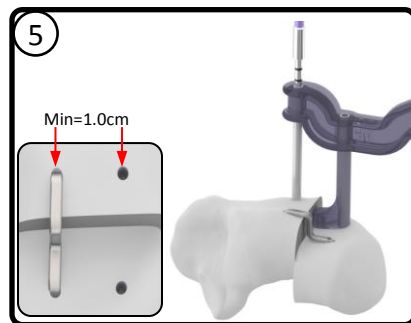
2 Place pull pin (E) in proximal hole (C) then drill distal hole (F) to 2nd line.



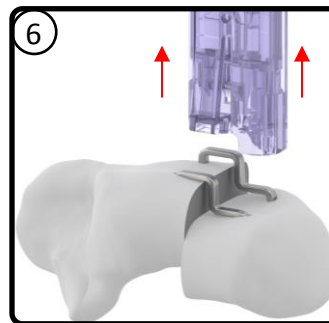
3 Insert tips of staple legs into holes, pull grenade pin (G) and push staple from instrument into bone.



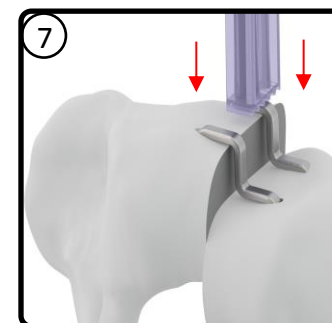
4 Using the tamp (H), fully offset the calcaneus by pushing staple flush with bone.



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 2nd staple.



7 Repeat tamp step 4 to fully seat both staples.

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.