

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

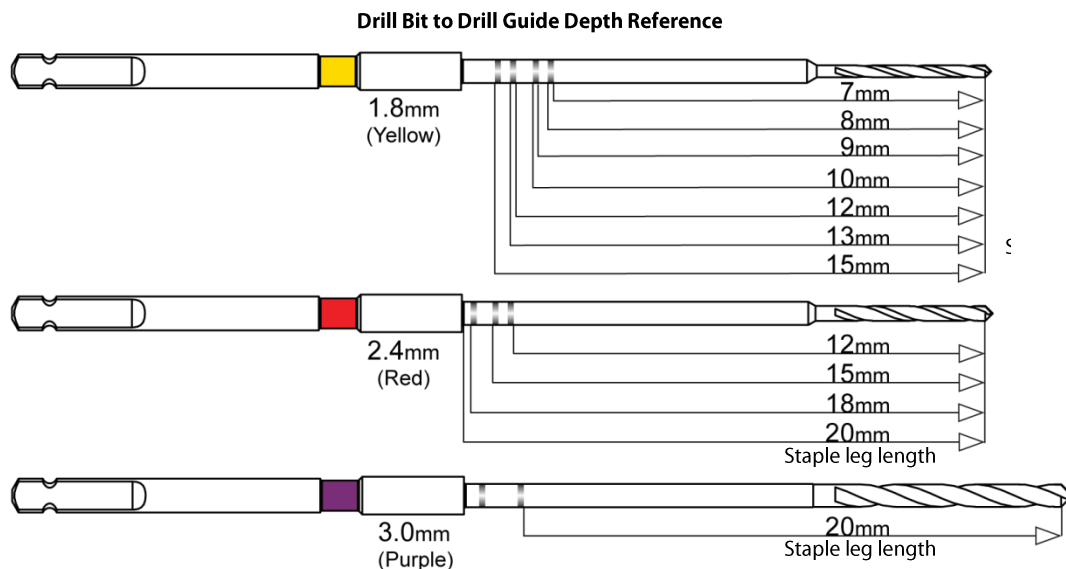
1. Immobilization, in addition to this internal fixation, until bone healing (4-6 weeks) should be achieved by routine methods (casting, splints, etc.).
2. Reduction of the site should be achieved and maintained prior to implanting the staple. The compressive force of the staple closing should not be 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

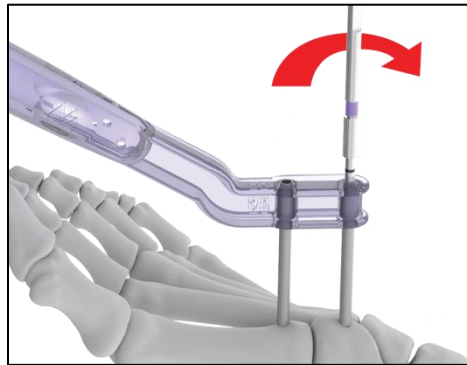
Staples and instruments should not be subjected to storage or shipping temperatures in excess of 76.7°C or 170°F.

VII. Clinical Use Examples

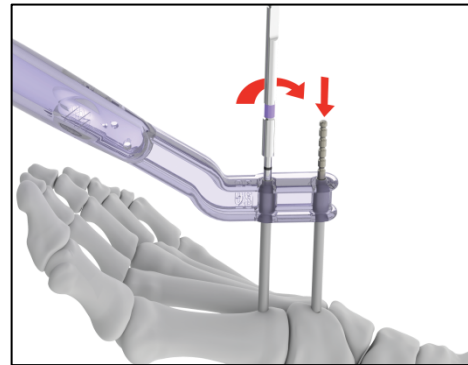
1. Hand Surgery: intracarpal and interphalangeal arthrodesis, carpal, metacarpal and phalanges fracture or osteotomy.
2. Foot Surgery: bunionectomy; tibiotarsal, Lisfranc's, calcaneocuboidal, and talonavicular arthrodesis; hind, mid, or forefoot bone fracture or osteotomy fixation.
3. General Skeletal 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.



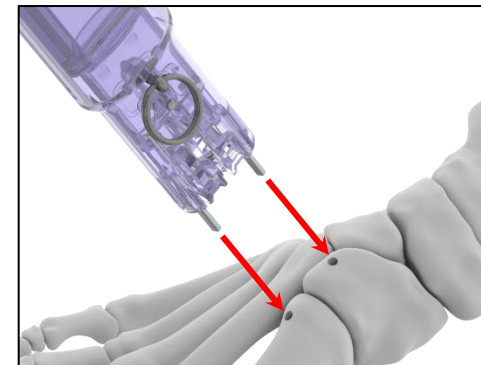
VIII. Implant Placement Instructions for Use



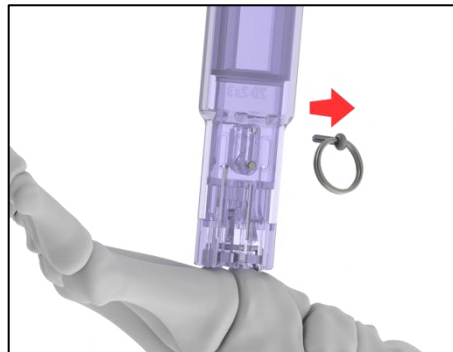
1. Place both drill tubes in firm contact with bone then drill 1st hole



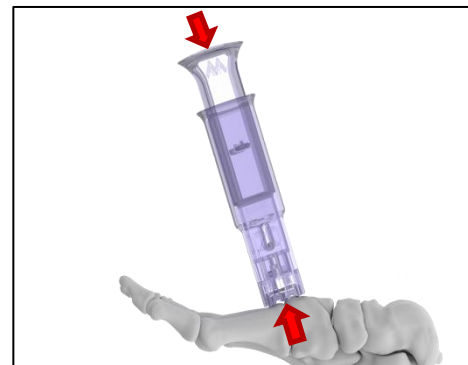
2. Place pull pin in 1st hole then drill second hole



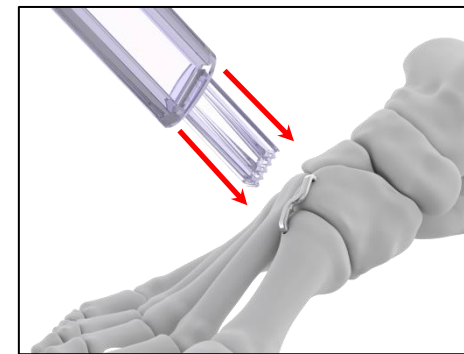
3. Insert staple legs completely



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.