BIOLOGICALLY ORIENTED PROSTHESES
BIOPRO

BioPro Clover Staple™

General
The BioPro implant gives the surgeon a means of bone fixation and helps in the management of fracture and reconstructive surgery; it is not intended to replace normal body structures. The Biopro Clover Staple is made of Nitinol. Body heat causes the prongs to deflect toward each other resulting in compression.

Indications for Use:
• Hand and foot bone fragment and osteotomy fixation and joint arthrodesis of the hand and foot bones.

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

Warning:
• Immobilization in addition to this internal fixation until bone healing should be achieved by routine methods (casting, splints, etc.)
• 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 the fracture line.

Care and Caution:
• Staples should be stored at 24°C (75ºF) or less. Staples should be cooled to 24°C (75º F) prior to removing from the shipping block. Placing staples at -20°C (-5°F) while still in the polyethylene retainer, will return staples to original position.

Warning: The Clover Staple has not been evaluated for safety and compatibility in the MR environment and has not been tested for heating or migration in the MR environment. The safety of the device in the MR environment is unknown. Scanning patients who have these devices may result in patient injury.

Adverse Effects:
• Allergic reactions to metal (titanium or nickel)
• Delayed or Non-union of bone
• Delayed Healing
• Staples may break
• Staples may extruded or back out of the surgical site
• Contact surgeon if a change in performance or pain level is noticed.

Sterile: STERILE | EO Rx Only

Sterilized with ethylene oxide gas. Caution: For one procedure only. Do not re-sterilize. Do not use if package is open or damaged. This is a single use device. Re-use of this device can result in the transfer of materials not limited to bone, tissue, blood, or infectious disease. The device is provided sterile and re-sterilization of the device has not been validated.

Instructions for Use:
1. Appropriately dissect and expose the entire site releasing all ligamentous and soft tissue structures as needed.
2. Remove the articular cartilage on all bone surfaces to be fused and fenestrate or decorticate all subchondral bone with the surgeon's preferred method.
3. Coaptate all bone segments, assuring congruity, and temporarily fixate with K-wires.
4. Assess appropriate staple size by using the Staple Pushers or Burr Guides.
5. Fixate the Burr Guide chosen in step four to the dorsal surface of the carpals using three to four 0.045 k-wires. Bend the k-wires outward to allow easier access to the Burr Guide.
6. Utilize the Burr Cutter in a low speed rotary power equipment to plane around the inside of the Burr Guide to create a recess for the Clover Staple.
7. Place the appropriately sized Drill Guide into the Burr Guide and drill the corresponding holes for the staple legs. Note: 1.5mm drill bits are included sterile packaged along with the sterile packaged Clover Staples, they are NOT included in the instrument kit.
8. Prior to removing the Burr Guide, be sure to mark the drill holes, either with a marking pen or the electro-cautery device. Now, remove the Burr Guide and all corresponding k-wires.
9. Utilize the depth gage to determine the depth of the holes. Select the longest leg length possible, without going bi-cortical.
10. Select the appropriate staple and remove the steel band from the carrying block.
11. Insert the Staple Pusher into the bottom of the block to push the staple partially out of the block.
12. Utilize the Staple Positioner. Slide it under the staple and remove the staple from the block.
13. Insert the staple into the bone in the corresponding holes drilled in step 7 and impact the staple flush with the dorsal surface of the carpal bones.
14. Staple compression will occur by body temperature, however, compression time may be hastened by irrigating the staple with saline 36.5°C to 37.5° C (98°F to 100°F). Mean Closing time at 37°C is 2.57 Seconds with a range of 1-4 Seconds.
15. Remove the temporary k-wire fixation.
16. Complete the surgical procedure using established surgical techniques.

For a complete glossary of symbols, please visit www.bioproimplants.com/IFU. To receive a printed version within 5 business days, please contact orders@bioproimplants.com

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