BIOLOGICALLY ORIENTED PROSTHESES
BIOPRO

BioPro Clover™ Staple Instructions for Use

For the most current instructions for use and symbol glossary visit www.bioproimplants.com/ifu. Instructions for Use should always be reviewed before using or implanting a device. To receive a printed IFU within 5 business days, please contact orders@bioproimplants.com

Federal Law (USA) restricts this device to sale and use by, or on the order of, a physician.

Description

The BioPro Clover Staple allows for 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 manufactured from Nitinol, a memory metal. The staple activates at patient body temperature causing the legs of the staple to bend toward each other resulting in compression.

Materials

Nickel Titanium Alloy (Nitinol) to ASTM 2063

Indications for use:

1. Hand and foot bone fragment and osteotomy fixation and joint arthrodesis.

Contra-indications:

1. A debilitating general health problem that might pose a significant threat to the life of the patient if subjected to a major surgical procedure.
2. Comminuted bone surface which would militate against staple placement.
3. Pathologic conditions of bone such as osteopenia which would impair the ability to securely fix the staple.
4. Foreign body sensitivity to metals including nickel or titanium. 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.

Precautions and Handling

- Inspect the sterile blisters used for the implants prior to use. Sterilization cannot be assured, and staples should not be used if blister or seal is damaged.
- Staples should be stored at 24°C (75º F) or less. Staples should be cooled to 24°C (75º F) prior to removing from the shipping block. placing staples at -20°C (-5ºF) will return staples to original position.
- Staples are a single use device
- Do not autoclave staples

Potential Complications and Adverse Effects

- Allergic reactions to metal (titanium or nickel)
- Delayed or Non-union of bone
- Delayed Healing
- Staple may break
- Staple may extrude or back out of the surgical site

Contact surgeon if a change in performance or pain level is noticed.

MR Safety Information

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.

Sterile:

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.

Sterilization Guidelines for Instrument Trays

These guidelines are intended to provide a better understanding of the care and handling of BioPro surgical instruments. These guidelines are not intended for use with electrical, pneumatic or other powered surgical instruments. All instruments are shipped in a NON-STERILE condition and must be cleaned and sterilized prior to use.

General Care and Handling
Use instruments only for their intended purpose, such as cutting, holding, retracting, torquing, etc. Avoid undue stress or strain when handling or cleaning. Always transport contaminated or soiled items in or on a cart. Tap water can contain many minerals that may discolor and stain surgical instruments; therefore, it is recommended that deionized water be used for the final rinsing to prevent spotting. For instruments contaminated with protein material, prevention of drying prior to cleaning will facilitate cleaning. Placing instruments in water until cleaning can prevent drying.

NOTE: Ensure that the impactor tips included in the tray are disassembled from the impactor handle prior to cleaning.

Cleaning: Follow these steps to thoroughly clean all instruments

1. Submerge instruments in an enzymatic detergent. Prepare detergent according to the manufacturer's recommendations. Soak the instruments for ten (10) minutes in the protein solubilizing detergent.
2. Scrub the submerged instruments with a soft sponge and agitate.
3. Use a pipe cleaner or brush in any lumens and crevices.
4. Rinse in warm (38-49 degree C) tap water for one (1) minute.
5. Thoroughly flush all lumens and other difficult to reach areas.
6. Ultrasonically clean the instruments for ten (10) minutes in a neutral pH detergent (Neutrad or acceptable alternative). Prepare the detergent according to the manufacturer's recommendations.
7. Rinse the instruments with clean tap water for at least one (1) minute, repeat twice.
8. Dry the instruments thoroughly with a clean, lint free cloth.
9. Visually Inspect instruments for any damage or remaining contaminates instruments should be visually clean.
10. Repeat cleaning procedure if necessary if contamination remains. The instrument must be thoroughly clean.
11. Contact BioPro if any instruments are damaged.

Sterilization
Following the cleaning process, place a sterilization indicator in each instrument tray along with the instruments. Instrument tray is to be wrapped in a double layer of CSR wrap. Steam sterilization is required with the following parameters:

For pre-vacuum cycle:
Wrapped items: 4 minutes exposure at a minimum temperature of 132° C (270° F), maximum temperature of 143° C (290°F), 4 pulses, 30 minutes dry time

Examination Prior to Use
All instruments should be carefully examined for wear or damage by surgeons and staff in operating centers prior to surgery. The examination shall include a visual and functional inspection. It should also include verifying the cleanliness of the device, as well as the absence of any cracks, distortion, wear, corrosion, or other change. Like any precision surgical device, all instruments should undergo regular checks by knowledgeable personnel to ensure that they remain in good condition and continue to act as intended. Do not use any instrument or device that is damaged, incomplete, showing signs of excessive wear and tear, or that has been repaired outside the control of the manufacturer.

Warnings and Precautions

- Devices must only be used by surgeons who have been trained in the surgical technique and are familiar with the instruments provided.
- Use care in handling and storage. Some instruments are sharp and incorrect use or handling may result in puncture wounds.
- Improper use may result in breakage of the instrumentation during operation.
- Remove all broken instrument fragments. As a result of mechanical features required, the device is made of medical grade but not implant grade materials. Failure to remove broken instruments from the patient could result in patient complications and further intervention.
- Incorrect maintenance, cleaning or handling may render the instrument unsuitable for its intended use, cause corrosion, dismantling, distortion and/or instrument breakage or injury to the patient or operating staff. Potential complications include device breakage, leaching of debris, lack of component engagement, infection, and damage to tissue.

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