BIOLOGICALLY ORIENTED PROSTHESES
BIOPRO

BioPro Memory 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 Memory Staple 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 Memory Staple is manufactured from Nitinol, a memory metal. Patient body heat causes the legs of the staple to bend toward each other resulting in compression.

Material:
Nickel Titanium Alloy (Nitinol) to ASTM F2063

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

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) for a minimum of two hours will return staples to their original position.
- The staples are a single use device.
- Do not autoclave staples.
- Always handle the staple with the provided clamps, never by hand, as this may result in premature activation.

Potential Complications and Adverse Effects:
- Allergic reactions to metal (titanium or nickel)
- Delayed or Non-union of bone
- Delayed Healing
- Staples may break
- Staples 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 Memory 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:

Please note that the staple packaging features a color-coding system that coordinates staple leg size with drill diameter. Always ensure the drill diameter chosen matches the color code on the staples packaging.

1. Appropriately dissect and expose the entire site releasing all ligamentous and soft tissue structures as needed.
2. For joint arthrodesis, remove the articular surfaces with the power equipment of choice.
3. Coaptate both bone segments, assuring congruity, and temporarily fixate with either K-wires or a compression clamp.
4. Select the appropriate staple by using the template overlay on the corresponding x-ray or intra-operatively using one of the provided drill guides. Choose the appropriate width and staple leg length. (Note: Choose the staple leg which extends closest to the plantar cortex.)
5. Using the adjustable drill guide, select the correct width on the engraving window and drill a perpendicular hole using the appropriate staple drill size.
6. Insert the anchor pin for stability and drill a perpendicular hole on the proximal side of the adjustable drill guide.
7. Insert the BioPro Memory Staple using the appropriate staple clamp and push flush to the dorsal cortex with the appropriate staple punch.
8. 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.
9. Remove temporary K-wires and or the compression clamp.
10. 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: None of the instruments in the instrument tray require disassembly for 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.

Unique Device Identification (UDI)

All BioPro components can be identified by M209XXXXX, where "XXXXX= Item #". For a complete listing of BioPro item numbers visit www.bioproimplants.com/udi

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