BIOLOGICALLY ORIENTED PROSTHESES

BIOPRO

BioPro Memory Staple

General
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.

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.
- This staple system 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.

Care and Caution:
- Inspect the sterile blisters used for the implants prior to use. Sterilization cannot be assured and staple 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.
- The staples are a single use device.
- Do not autoclave staples

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. This 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. 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.

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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