BIOLOGICALLY ORIENTED PROSTHESES
BIOPRO

BioPro Modular Thumb Implant 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 Modular Thumb Implant is a two-piece implant consisting of a head and a press-fit plasma-sprayed stem designed to replace an arthritic carpometacarpal (CMC) joint.

Materials
Head: Cobalt Chrome (ASTM F1537) or 6-4 Eli Titanium (ASTM F136)
Stem: Cobalt Chrome (ASTM F75) or 6-4 Eli Titanium (ASTM F136)
Titanium Plasma Spray (ASTM F1580)

Indications for Use:
A painful, unstable thumb, one with limited range of motion, or subluxation of the trapeziometacarpal joint with the following indications:

1. Rheumatoid arthritis
2. Traumatic arthritis
3. Osteoarthritis
4. Post fracture deformation or bone loss

CANADA ONLY: Osteoarthritis

Contra-indications:
The age of the patient must be balanced against the severity of the disability and the need for surgery.

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. A previously infected thumb that has not been quiescent for at least six months
3. A local or systemic infection (i.e. osteomyelitis)
4. Insufficient bone stock to support the prosthesis
5. Scapho-Trapezium joint arthritis
6. Foreign body sensitivity to metals including cobalt chrome or titanium. Where material sensitivity is suspected, appropriate tests should be made prior to implantation.

Precautions and Handling

- Inspect the sterile blisters used for the implants prior to use. Sterilization cannot be assured, and implants should not be used if blister or seal is damaged.
- Implants are single use devices.
- Do not autoclave implants.
- Exercise caution while threading the impactor tip into the handle to avoid cross-threading, as this can result in damage or the failure of the impactor tip.

Potential Complications and Adverse Effects

- Allergic reactions to metal
- Delayed Healing
- Loosening or migration of the implant components
- Subluxation or dislocation of implant resulting in reduced range of motion
- Bone fracture by trauma or improper surgical technique
- Pain due to bone remodeling or reaction to implant components

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

MR Safety Information
Warning: The Modular Thumb Implant 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 head implant packaging features a color-coding system that coordinates head implant diameter.

1. Identify the CMC joint. Make an incision to expose the joint. Preserve the capsule for future closure and implant stability.
2. Resect approximately 5mm off the base of the metacarpal parallel to the varus positioned articular surface in the sagittal plane.
3. Utilizing a 5-7mm rotary burr a medialized concentric concavity is fashioned into the articulating surface of the trapezium. Care is taken to preserve the radial border of the trapezium. Gradually enlarge the recess in the trapezium to approximately 10-12mm in diameter. Trapezial socket depth should be approximately 4-5mm. Gradually enlarge the socket with the provided hemispherical burrs. Progressively increase the size of the socket as large as possible, while taking care to preserve the radial rim of the trapezium.
4. Assess the stability and freedom of motion and examine the angle of the metacarpal resection using the head sizing guide. If the thumb cannot be brought to the full range of abduction without undue force, the joint has been over spaced and must be corrected by resecting an additional amount of bone from the metacarpal or by deepening the socket. If the joint is too lax, a 2mm or 4mm neck length head is used for trial.
5. With the one-piece stem broach positioned in anatomical varus in the sagittal plane it is inserted into the medullary canal without removing cancellous bone stock. The size of the stem is increased progressively until the cancellous bone has been fully compressed to provide an optimally tight medullary interference fit.
6. Once the desired stem broach size is achieved, the one-piece broach is exchanged for the corresponding size trial stem. The trial ball matching the trapezial socket is now applied to the seated trial stem. Range of motion and stability are assessed.

7. After the desired status of articulation has been assured, the trial component is exchanged for the assembled implantable prosthesis. Use the assembly block to assemble the appropriate head and stem in-vitro. Do not assemble in-vivo. In vitro assembly allows for maximum assembly strength of the implant. The longitudinal contiguous capsule is closed tightly.

Postoperative management:
The thumb is immobilized in a position of abduction at the carpometacarpal joint and slight flexion at the metacarpal phalangeal joint for two weeks. A removable thumb spica is worn for four weeks. Hand therapy may be required to regain motion and strength. Unrestricted activity is allowed 8-12 weeks post-op. Contact surgeon if a change in performance or pain level is noticed.

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.

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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