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.

Cleaning and Sterilization

WARNING: Please note that a single use device (SUD) which comes in contact with human blood or tissue should not be re-used and should be returned to the manufacturer or properly disposed of. The instrument tray must be wrapped in FDA cleared wraps or containers for the steam sterilization process.

Pre-Cleaning Procedure

Disassemble all multi-component instruments prior to cleaning.

- Prepare an ENZOL® (or equivalent) solution according to the manufacturer's directions.
- Rinse each instrument under cool running tap water (< 35°C) for one (1) minute. Use a nylon bristled brush to remove gross soil.
- Immerse each instrument in the ENZOL® (or equivalent) cleaning solution for two (2) minutes. While immersed, use a nylon bristled brush to remove soil from all areas of the instrument, paying attention to all crevices and cannulations.
- Rinse each instrument under cool running tap water (<35°C) for one (1) minute.
- Prepare an ENZOL® (or equivalent) in a sonicator according to the manufacturer's directions.
- Sonicate each instrument for ten (10) minutes.
- Rinse each instrument by submerging the components into DI water for two (2) minutes, taking care to rinse any lumens.
- Place each instrument back into its specific location.

Automated Cleaning Process

Treatment Step	Time (mm:ss)	Water Temperature	Cleaning Agent (if applicable)
Pre-Wash	2:00	Unheated Tap Water	N/A
Enzyme Wash	Stage 1: 1:00	122°F (50°C)	Enzymatic Detergent Solution
	Stage 2: 2:00	150°F (65.6°C)	
Wash	1:00	185°F (85°C)	Steris® Prolystica Detergent Solution (or equivalent)
PURW Thermal Rinse	2:00	185°F (85°C)	N/A
Dry	5:30	N/A	N/A
Inspect	As Needed	N/A	N/A

Sterilization:
The BioPro Modular Thumb Implant components are separately packed and are provided sterile. For the provided instrument kit, moist heat sterilization is recommended using the Association for the Advancement of Medical Instrumentation (AAMI) guideline Good Hospital Practice: "steam sterilization and sterility assurance. "The recommended steam sterilization parameters for non-sterile devices are as follows. This is in accordance with ANSI/AAMI ST79:2006 in meeting a Sterility Assurance Level (SAL) of 10^{-6}.

METHOD	TIME	TEMPERATURE	DRY TIME
Pulsed Pre-vacuum	4 minutes	270° F (132° C)	30 Minutes

Unique Device Identification (UDI)

All components in the BioPro Modular Thumb Implant 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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