BIOLOGICALLY ORIENTED PROSTHESES
BIOPRO

BioPro Toe Joint Instructions for Use

First MPJ Hemi Implant, Lesser MPJ Hemi Implant and HemiEDGE

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 First MPJ Hemi Implant, Lesser MPJ Hemi Implant and HemiEDGE are low-profile press-fit implants designed to resurface the proximal phalanx in the metatarsophalangeal joint.

Material
Cobalt Chrome (ASTM F1537) or 6-4 Eli Titanium (ASTM F136)

Indications for Use:

1. Arthritic degradation of the metatarsophalangeal joint that has resulted in disabling pain, limited motion, and loss of the normal ambulatory function of the forefoot.
2. Degenerative arthritis
3. Rheumatoid arthritis
4. Bunion deformity associated with arthritis of the metatarsophalangeal joint.
5. The titanium version is available for use only in patients susceptible to nickel chromium allergies.

Contra-indications:

1. A general health problem that might pose a significant threat to the life of the patient if subjected to a major surgical procedure.
2. An active infection or a previous infection of the lower extremity that has not been quiescent for at least six months.
3. A local or systemic infection.
4. Significant deficiency in the vascular supply to the extremity.
5. Severe structural deficiency of the sub-chondral bone that may result in insufficient support for the prosthesis.
6. A condition of the toe which may lend itself to a more conservative procedure.
7. Severe compromise of the supporting muscles or ligaments about the toe.
8. 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
- 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
Cobalt Chrome devices have been evaluated for safety and compatibility in the MR environment and are MR conditional. Contact BioPro for MR parameters. **Warning:** HemiEDGE and Titanium devices have not been evaluated for safety and compatibility in the MR environment and have not been tested for heating or migration in the MR environment. The safety of HemiEDGE and titanium devices 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 implant packaging features a color-coding system that coordinates implant size.

1. Extreme care is to be taken to preserve all the capsular structures and to maintain attachment of the intrinsic musculature. The joint capsule is released subperiosteally from the base of the proximal phalanx at the medial, plantar and lateral aspects of the bone.
2. Using a narrow oscillating blade remove a section of bone sufficient to avoid prosthetic over spacing and excessive joint tension and to accommodate the thickness of the articulating plate of the implant.
3. Next, the intramedullary canal is prepared with a punch, the implant is sized with the most appropriately approximated dimension of the osteotomized phalanx, which does not extend beyond the margins, and is inserted into the remaining base of the proximal phalanx making sure that the implant is completely seated. Extra care is taken not to impinge any capsular structures.
4. At this time the metatarsal head is remodeled, and all marginal osteophytes are completely resected. Range of motion of the joint should be smooth and without evidence of crepitation or binding.

Postoperative Management:
The patient is allowed to ambulate with weightbearing to tolerance on the operated foot within limits imposed by postoperative discomfort, utilizing modified footgear. The progression to normal ambulation and the use of standard footgear is limited only by the persistence of postoperative swelling and discomfort. 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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