Great Toe Hemiarthroplasty Implant

Instructions for Use

DEVICE DESCRIPTION

The BioPoly Great Toe Hemiarthroplasty Implant is a hemiarthroplasty device specifically designed to restore the articular surface of the head of the first metatarsal bone in patients with degenerative and post-traumatic arthritis. The implant is supplied in porous and non-porous designs with diameters of 14mm, 16mm, 18mm, 20mm, and 22mm for selection by the physician. One implant is provided in the sterile packaging.

MATERIALS

The BioPoly Great Toe Hemiarthroplasty Implant is made of BioPoly material (ultra-high molecular weight polyethylene and crosslinked hyaluronan), Ti-6Al-4V, and commercially pure titanium (porous version only).

INTENDED USE

The BioPoly Great Toe Hemiarthroplasty Implant is intended to restore the articular surface of the first metatarsal bone. BioPoly medical devices are intended to be surgically implanted in a sterile environment by a surgeon.

INDICATIONS FOR USE

The BioPoly Great Toe Hemiarthroplasty Implant is intended to be implanted to replace the distal metatarsal surface of the great toe of patients over 21 years of age with degenerative and post-traumatic arthritis in the first metatarsal joint in the presence of good bone stock along with the following clinical conditions: hallux valgus or hallux limitus, hallux rigidus, and an unstable or painful metatarsal/phalangeal (MTP) joint. The device is a single use implant intended to be used with bone cement.

CONTRAINDICATIONS

- Inadequate bone stock
- Inflammatory or rheumatoid arthritis, infection, sepsis, and osteomyelitis
- Osteoporosis
- Metabolic disorders which may impair the formation or healing of bone
- Infections at remote sites which may spread to the implant site
- Chronic instability or deficient soft tissues and other support structures
- Vascular or muscular insufficiency
- Allergy to titanium, ultra-high molecular weight polyethylene (UHMWPE), or hyaluronan
- Use with opposing articulating phalangeal components

DIRECTIONS FOR USE

The BioPoly Great Toe Hemiarthroplasty instrumentation must be used to ensure proper fit and alignment of the implant. Refer to the surgical technique manual for specific instructions on the use of the instruments and implantation of the prosthesis.

WARNINGS AND PRECAUTIONS

- Prior to use, the surgeon should thoroughly read and understand all aspects of the surgical technique.
- This device is provided STERILE as a single use product. If sterile barrier is broken or the packaging otherwise damaged, the device may not be administered. Re-sterilization of the device is not permitted.
- During removal of the device from the packaging, special care should be taken to preserve the articulating surface finish.
- In case of damage to the implant, including scratches or indentations on the articulating surface, bending of the fixation stem, or any other disfigurement, the device may not be administered.
- Any alteration or modification to the device prior to the surgical implantation is prohibited.
- Excessive insertion force can damage the articulating surface of the implant.
- Implant articulation with non cartilage or abnormal anatomic surface can damage the implant.
- Do not reuse device. Risks of reuse include damage to implant, loss of performance, and infection.
- Improper implant selection, placement, positioning, or depth can lead to migration or loss of fixation.
- The implant is intended to be used with the corresponding BioPoly instrument set. Use of other instruments may result in improper fixation resulting in implant failure.
- MR image quality may be compromised if the area of interest is in the same area or relatively close to the position of the device.

MRI SAFETY INFORMATION

The BioPoly Great Toe Hemiarthroplasty Implant has not been evaluated for safety and compatibility in the MR environment. It has not been tested for heating, migration, or image artifact in the MR environment. The safety of the BioPoly Great Toe Hemiarthroplasty Implant in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

POSSIBLE ADVERSE EFFECTS

- Infections
- Allergies or other reactions to implant materials
- Subsidence, migration, or loss of fixation
- Pain or discomfort
- Wear and damage to the implant articulating surface
- Wear and damage to the adjacent and opposed articular cartilage surfaces or soft tissue support structures
- Intraoperative or postoperative bone fracture
- Incomplete range of motion due to improper selection or positioning of the implant
- Embolism

STORAGE AND HANDLING
Store in a cool, dry place and in a manner that protects the integrity of the packaging of the implant. Prior to use, inspect product packaging for signs of damage and/or tampering.

PACKAGING AND STERILIZATION
The BioPoly Great Toe Hemiarthroplasty Implant is sterilized using ethylene oxide. The implant is provided sterile and for single use.

- Do not use if the sterile packaging has been breached or damaged
- Do not attempt to re-sterilize the implant
- Do not use if the expiration date has elapsed

CAUTION
Federal (USA) law restricts this device to sale by or on the order of a physician.

DISPOSAL
After use, this product may be a potential biohazard. Handle and dispose in accordance with accepted medical practice and applicable local, state, and federal laws and regulations.

SYMBOLS GLOSSARY

Symbol	Standard Reference	Symbol Title	Symbol Description
	ISO 15223-1; 5.1.1	Manufacturer	Indicates the medical device manufacturer.
	ISO 15223-1; 5.1.4	Use by date	Indicates the date after which the medical device is not to be used.
	ISO 15223-1; 5.1.5	Batch code	Indicates the manufacturer's batch code so that the batch or lot can be identified.
	ISO 15223-1; 5.1.6	Catalogue number	Indicates the manufacturer's catalogue number so that the medical device can be identified.
	ISO 15223-1; 5.2.3	Sterilized by ethylene oxide treatment	Indicates a medical device that has been sterilized using ethylene oxide.
	ISO 15223-1; 5.2.8	Do not use if package is damaged	Indicates a medical device that should not be used if the package has been damaged or opened.

SYMBOLS GLOSSARY (CONTINUED)

Symbol	Standard Reference	Symbol Title	Symbol Description
	ISO 15223-1; 5.4.2	Do not reuse	Indicates a medical device that is intended for one use, or for use on a single patient during a single procedure.
	ISO 15223-1; 5.4.3	Consult instructions for use	Indicates the need for the user to consult the instructions for use.
	ISO 15223-1; 5.4.4	Caution: Read all warnings and precautions in instructions for use	Indicates the need for the user to consult the instructions for use for important cautionary information such as warnings and precautions that cannot, for a variety of reasons, be presented on the medical device itself.
	21 CFR; 801.109(b)	Prescription only	CAUTION: Federal (USA) law restricts this device to sale by or on the order of a physician.

REFERENCES

- ISO 15223-1: Medical devices – Symbols to be used with medical device labels, labelling, and information to be supplied – Part 1: General requirements
- 21 CFR 801: Labeling

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