



Radial Head Implant

Instructions for Use

DEVICE DESCRIPTION

The BioPoly Radial Head Implant is a hemiarthroplasty device specifically designed to restore the articular surface and spacing of the proximal head of the radius in patients following fracture, resection, and/or degenerative disability. The implant is supplied with head diameters of 20mm, 23mm, and 26mm; and stem diameters of 6mm, 7mm, 8mm, and 9mm with +0mm, +3mm, and +6mm height offsets for selection by the physician.

MATERIALS

The BioPoly Radial Head Implant is made of BioPoly material (ultra-high molecular weight polyethylene and crosslinked hyaluronan) and Ti-6Al-4V.

INTENDED USE

The BioPoly Radial Head Implant is intended to restore the articular surface of the proximal radial head. BioPoly medical devices are intended to be surgically implanted in a sterile environment by a surgeon.

INDICATIONS FOR USE

The BioPoly Radial Head Implant is indicated for:

- Replacement of the radial head for degenerative or post-traumatic disabilities presenting pain, crepitation, and decreased motion at the radio-humeral and or proximal radio-ulnar joint with:
 - joint destruction and/or subluxation visible on x-ray; and/or
 - resistance to conservative treatment.
- Primary replacement after fracture of the radial head.
- Symptomatic sequelae after radial head resection.
- Revision following failed radial head arthroplasty.

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 capitellar components
- Patients who are unwilling or incapable of following post-operative care instructions

DIRECTIONS FOR USE

The BioPoly Radial Head 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 spacers and 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 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.
- 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 constraint.
- The implant is intended to be used with the corresponding BioPoly instrument set. Use of other instruments may result 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.
- Use of an implant size larger than the native radial head is not allowed.

MRI SAFETY INFORMATION

The BioPoly Radial Head 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 Radial Head Implant in the MR environment is unknown. Performing an MR exam on a person with this medical device may result in injury or device malfunction.

POSSIBLE ADVERSE EFFECTS

- Infections
- Allergies or other reactions to implant materials
- Subsidence, migration, or loss of constraint
- 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
- Soft tissue damage/impingement

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 Radial Head 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.
R_x Only	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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160-3004-01 Rev. B
February 2024