

BioPoly[®]

Great Toe

Hemiarthroplasty Implant



Surgical Technique

Incision and Exposure

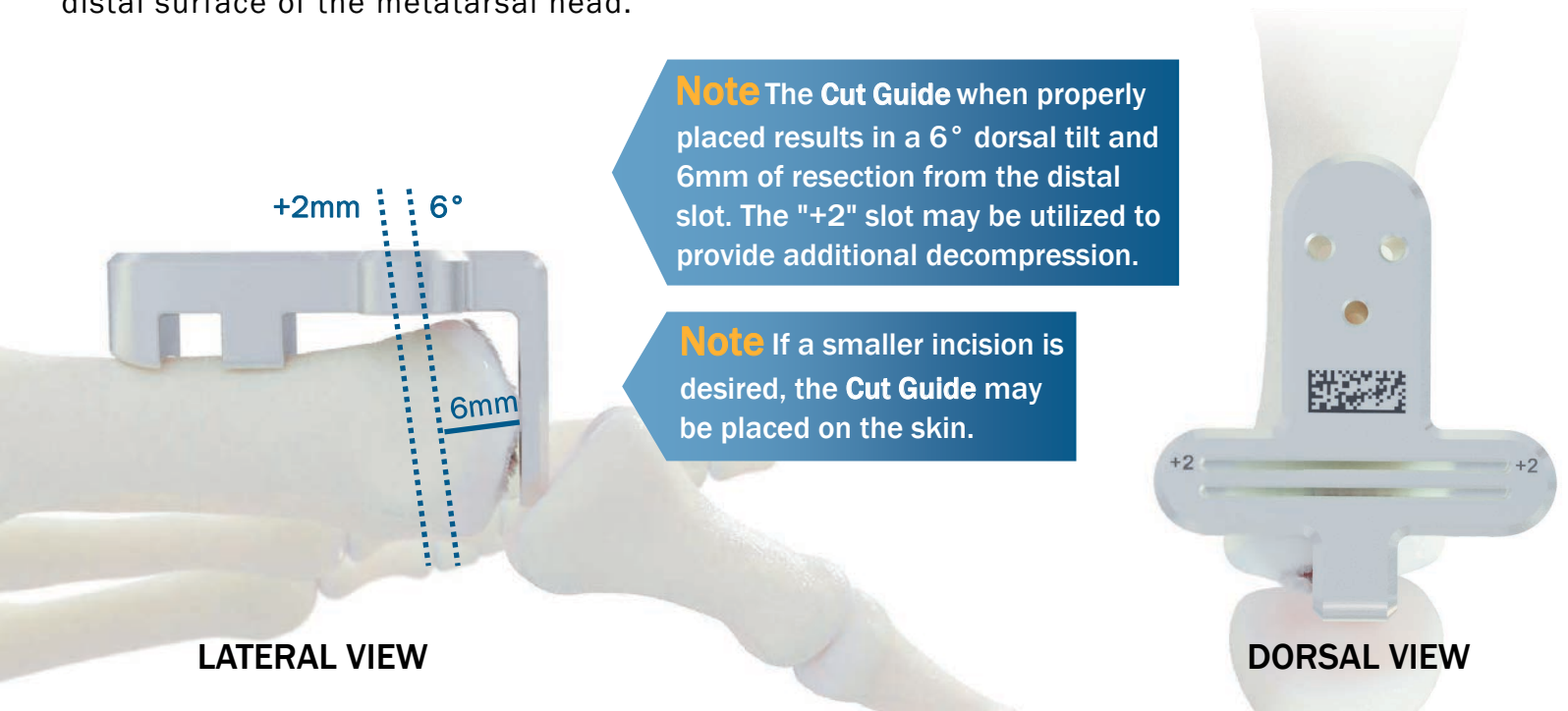
Make a small straight incision along the dorsal aspect of the first MTP joint to provide exposure of the capsule. Care should be taken to avoid nerve damage and to protect the EHL tendon. Expose the joint such that access is perpendicular to the metatarsal head. Release of the lateral and medial soft tissues or sesamoid bones may be required.



Note Implant damage and excessive wear can occur if implant articulates with anything other than cartilage (e.g., bone). Do NOT use implant in Grade IV Hallux Rigidus joint.

Align Cut Guide

Place the **Cut Guide** on the dorsal surface of the first metatarsal, aligning the guide such that the slot aligns with the intended articular surface. This may create a slight mismatch with the long axis of the metatarsal, more commonly valgus than varus. Some large dorsal osteophytes may need to be removed. In the lateral view, press the long foot of the **Cut Guide** against the distal surface of the metatarsal head.



Note The Cut Guide when properly placed results in a 6° dorsal tilt and 6mm of resection from the distal slot. The "+2" slot may be utilized to provide additional decompression.

Note If a smaller incision is desired, the Cut Guide may be placed on the skin.

Surgical Technique

Secure Cut Guide

Once the Cut Guide is aligned, (1) drill a 1.6mm **Kirschner wire (K-Wire)** through the centermost, distal hole in the guide. Slight adjustments in the articular angle can be made after this wire is placed. Then, (2) drill another two **K-Wires** through both of the remaining angled proximal holes.



Resect Metatarsal Head

Resect the distal head of the metatarsal bone by taking a sagittal sawblade up to 0.38mm thick, and cutting through the chosen slot in the cut guide, from the dorsal surface until resection is complete. This resection should avoid any tendon or critical tissue. Remove the K-Wires, and then remove the Cut Guide.



Determine Implant Size

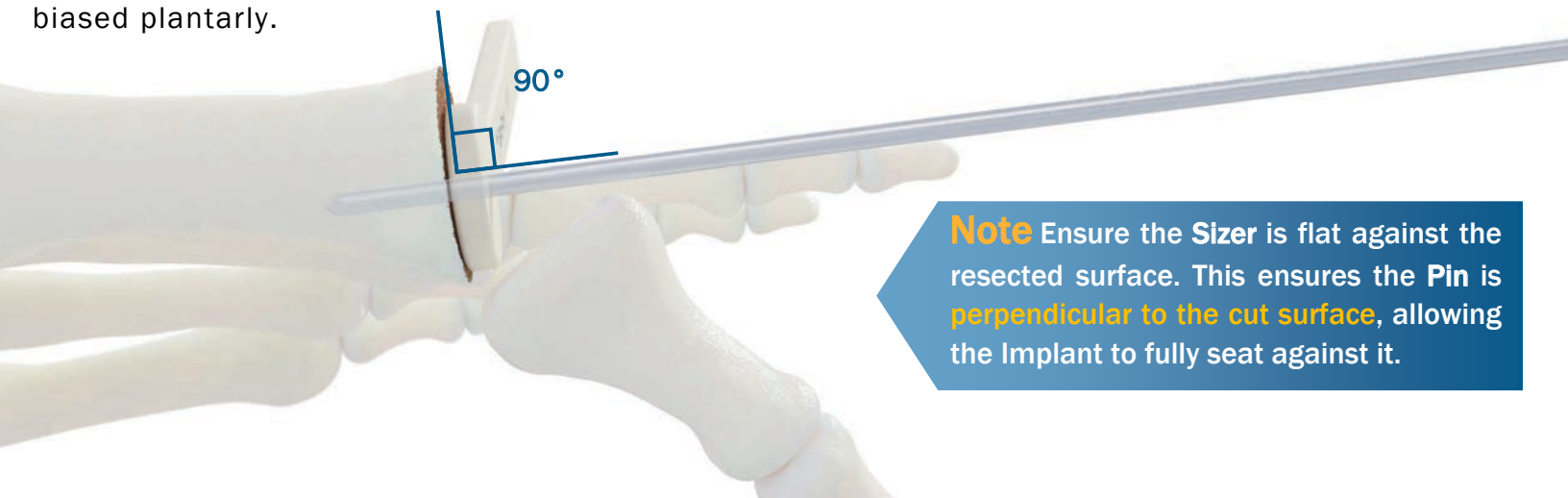
After resection of the metatarsal head, place the various **Sizers** (14mm, 16mm, 18mm, 20mm, and 22mm) over the resection and trial until adequate coverage is determined. To size the implant, align the plantar edge of the Sizer with plantar edge of resected surface (in line with the crista), ensuring no overhang of Sizer to avoid sesamoid impingement. Select the Sizer that is 1-2mm shorter than the dorsal/plantar length of the cut bone surface. Excess bone will be removed during the Trialing step.

Note Pay special attention to plantar overhang to prevent proud edges dorsally or interference with sesamoid bones on the plantar side.



Place Central Pin

Holding the **Sizer** flat against the cut surface, drill a **2mm Steinmann Pin** through the central hole of the **Sizer**. C-Arm X-Ray can be used to ensure the **Pin** is perpendicular to the cut surface. The Pin will NOT be parallel to the long axis of the metatarsal bone when viewed laterally. Given that the implant is undersized and aligned with the plantar edge of the bone, the central hole will be biased plantarly.

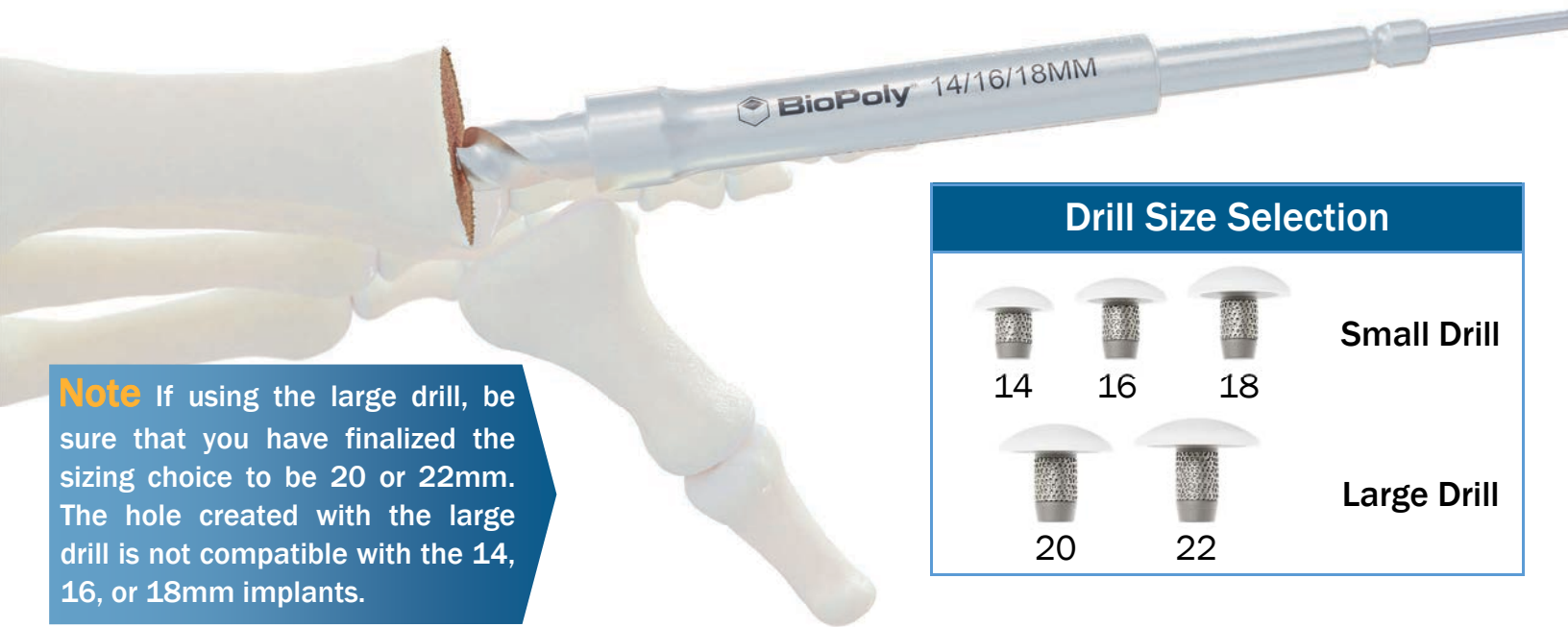







Note Ensure the **Sizer** is flat against the resected surface. This ensures the **Pin** is **perpendicular to the cut surface**, allowing the Implant to fully seat against it.

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Drill Implant Site

Remove the Sizer by sliding it over the top of the **Central Pin**. Place the cannulated **Drill** (See Drill Size Selection Table for appropriate size) over the **Central Pin**. Drill until the **Drill** collar contacts the resected planar bone surface. After drilling is complete, remove the **Pin**.



Drill Size Selection				
			Small Drill	
14	16	18		
		Large Drill		
20	22			

Insert Trial and Assess Implant

To verify implant size is acceptable, insert the Trial that is 1-2mm shorter than the dorsal/plantar length of the cut surface, ensuring that it does not protrude beyond any cut surface, especially plantarly.



Insert Trial and Assess Implant

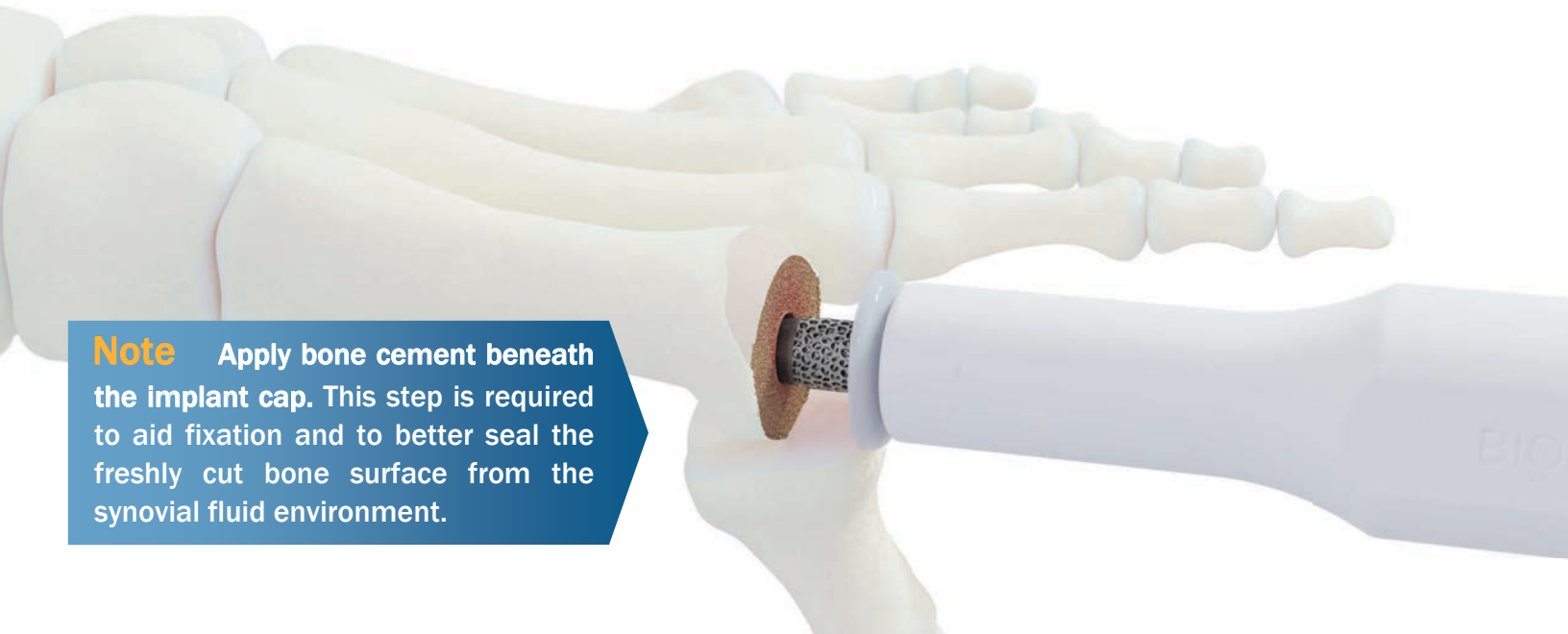
Using the Trial as a guide, remove the excess bone dorsally by performing a thorough cheilectomy. Assess the motion of the toe during full range of motion. If necessary, release the sesamoid bones in this step, before final implantation.



Note Ensure again during this step that the Trial is located properly with no overhang on the plantar surface or interaction with the sesmoids.

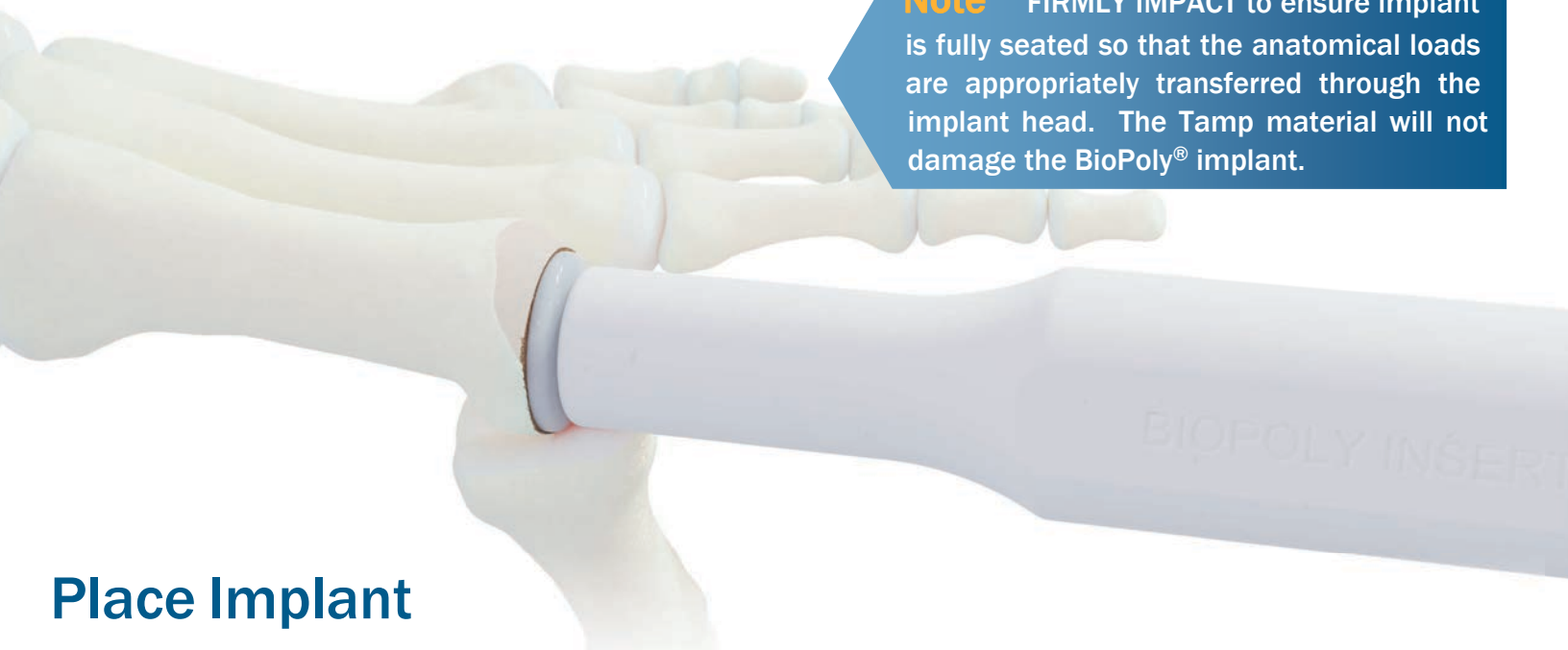
Place Implant

After bone cement has been applied, place the tapered end of the implant into the drilled hole. Place the concave surface of the **Insertion Tamp** against the articular surface of the implant with a mallet and Insertion Tamp, **FIRMLY IMPACT** to fully seat the BioPoly[®] Implant.



Note Apply bone cement beneath the implant cap. This step is required to aid fixation and to better seal the freshly cut bone surface from the synovial fluid environment.

Surgical Technique



Note FIRMLY IMPACT to ensure implant is fully seated so that the anatomical loads are appropriately transferred through the implant head. The Tamp material will not damage the BioPoly® implant.

Place Implant

Carefully remove any extruded cement with a curette, taking care not to scratch or scrape the implant articular surface. A C-Arm can be used to confirm that the implant is fully seated against the resected bone. Assess final range of motion and ensure no impingement plantarly (i.e. sesmoids) or dorsally (i.e. ensure dorsal cheilectomy is thorough).



Extraction

In the event of a revision or necessary removal of the implant, an osteotome or sagittal saw may be utilized. Work the instrument blade between the implant head and resected metatarsal surface to provide leverage for removal. Use the osteotome to gradually pry the implant from the defect.

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 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.

Intended Use

The BioPoly[®] Great Toe Hemiarthroplasty Implant is intended to restore the articular surface of the first metatarsal bone.

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 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, 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
- Gout

Caution

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

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 packaging for signs of damage and/or tampering.

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.

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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 surface or soft tissue support structures
- Intraoperative or postoperative bone fracture
- Incomplete range of motion due to improper selection or positioning of the implant
- Embolism

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

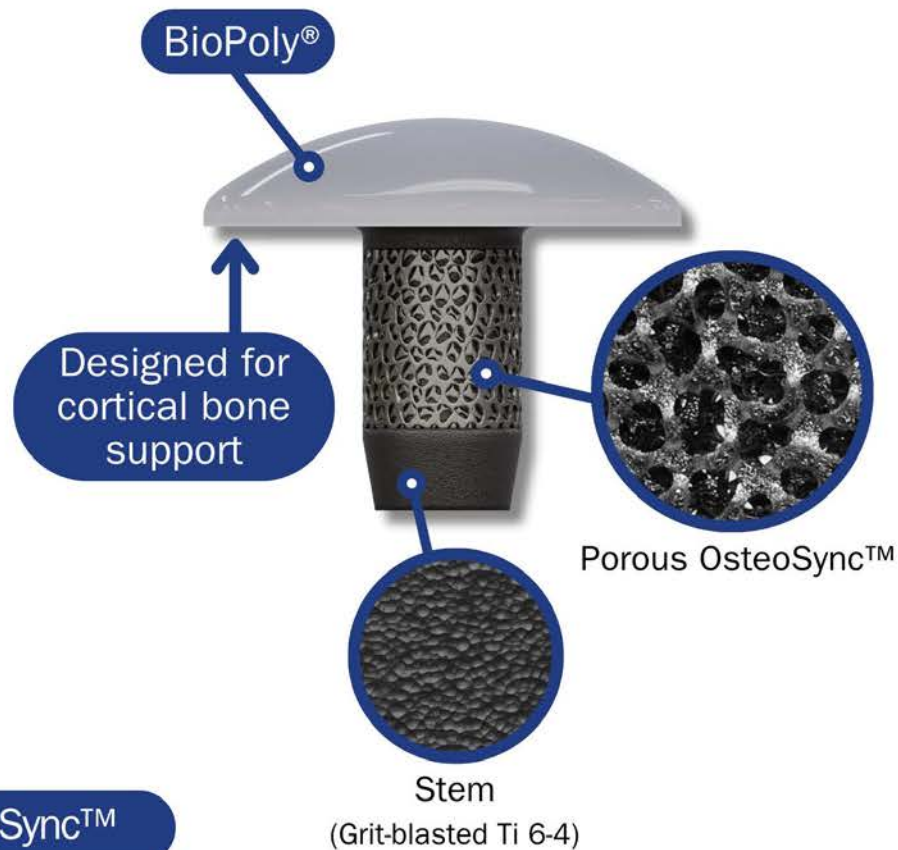
MRI Safety Information

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.

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 the 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.

Design Features



Porous OsteoSync™

Stem Outer Surface

Clinically proven porous material along fixation shaft to resist subsidence and loosening

BioPoly® Synthetic Cartilage

Articulating Surface

- Ultra-High Molecular Weight Polyethylene (UHMWPE) and Hyaluronic Acid
- “Self-lubricates” in the joint due to its hydrophilic properties
- Cartilage-friendly articulation while supporting physiological loads
- 85% lower Coefficient of Friction than Cobalt Chrome when articulating with cartilage
- 40% less cartilage wear than Cobalt Chrome when articulating with cartilage
- Proven material in knee resurfacing since 2012¹

Implants

Description	Reference
Great Toe Hemiarthroplasty Implant - 14mm	135-5114
Great Toe Hemiarthroplasty Implant - 16mm	135-5116
Great Toe Hemiarthroplasty Implant - 18mm	135-5118
Great Toe Hemiarthroplasty Implant - 20mm	135-5120
Great Toe Hemiarthroplasty Implant - 22mm	135-5122

Instruments

Description	Reference
Instrument Set	135-5500
Drill - Small	135-2100-01
Drill - Large	135-2100-02
Insertion Tamp	135-2100-03
1.6mm Wire	135-2100-05
2.0mm Pin	135-2100-06
Cut Guide	135-2100-07
Sagittal Blade (Stryker replacement)	135-2100-08
Sagittal Blade (Conmed replacement)	135-2100-09
Sizer - 14mm	135-2114-01
Trial - 14mm	135-2114-02
Sizer - 16mm	135-2116-01
Trial - 16mm	135-2116-02
Sizer - 18mm	135-2118-01
Trial - 18mm	135-2118-02
Sizer - 20mm	135-2120-01
Trial - 20mm	135-2120-02
Sizer - 22mm	135-2122-01
Trial - 22mm	135-2122-02



Advancing Materials. Advancing Outcomes.™



Manufactured By:
BioPoly LLC, a Schwartz Biomedical Company
7136 Gettysburg Pike, Fort Wayne, IN 46804, USA
Phone 260.999.6135 | www.BioPolyortho.com

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