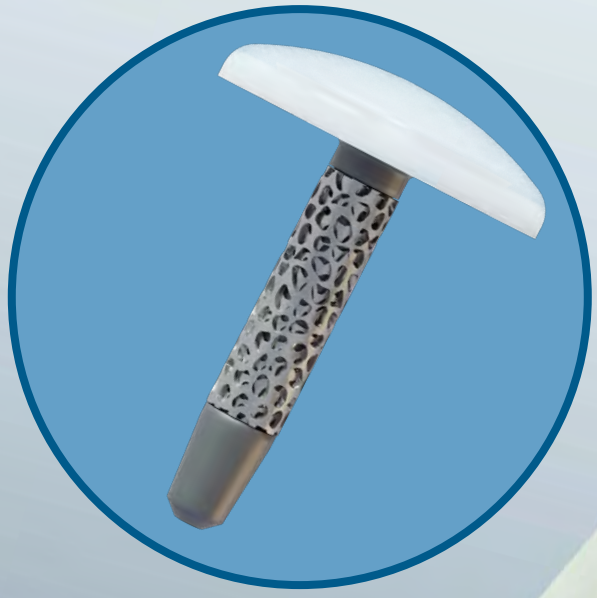
BioPoly

Lesser Toe

Hemiarthroplasty Implant



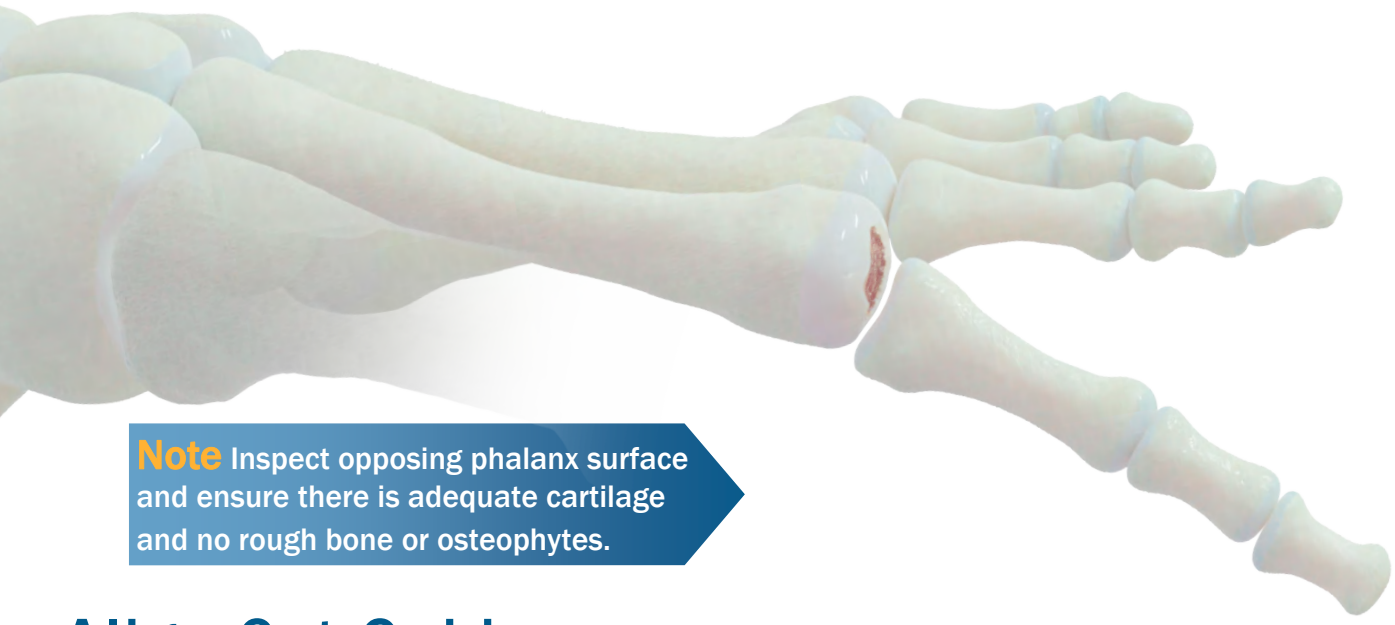
Surgical Technique

BioPoly®

BioPoly Lesser Toe Hemiarthroplasty Implant

Incision and Exposure

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

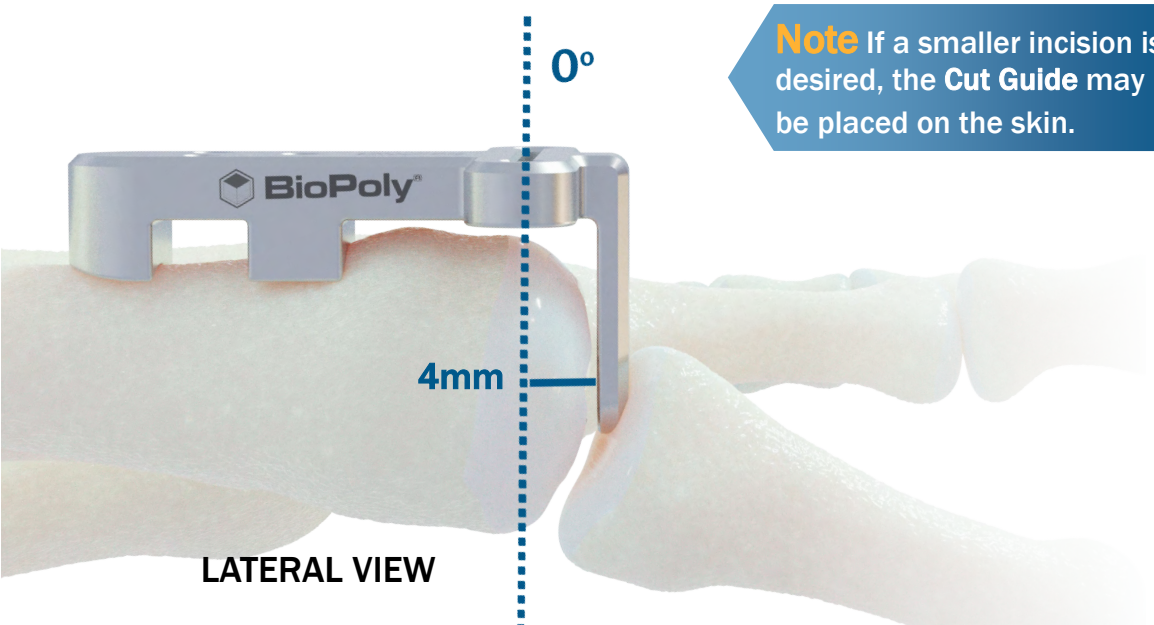


Note Inspect opposing phalanx surface and ensure there is adequate cartilage and no rough bone or osteophytes.

Align Cut Guide

Place the **Cut Guide** on the dorsal surface of the 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 If a smaller incision is desired, the **Cut Guide** may be placed on the skin.



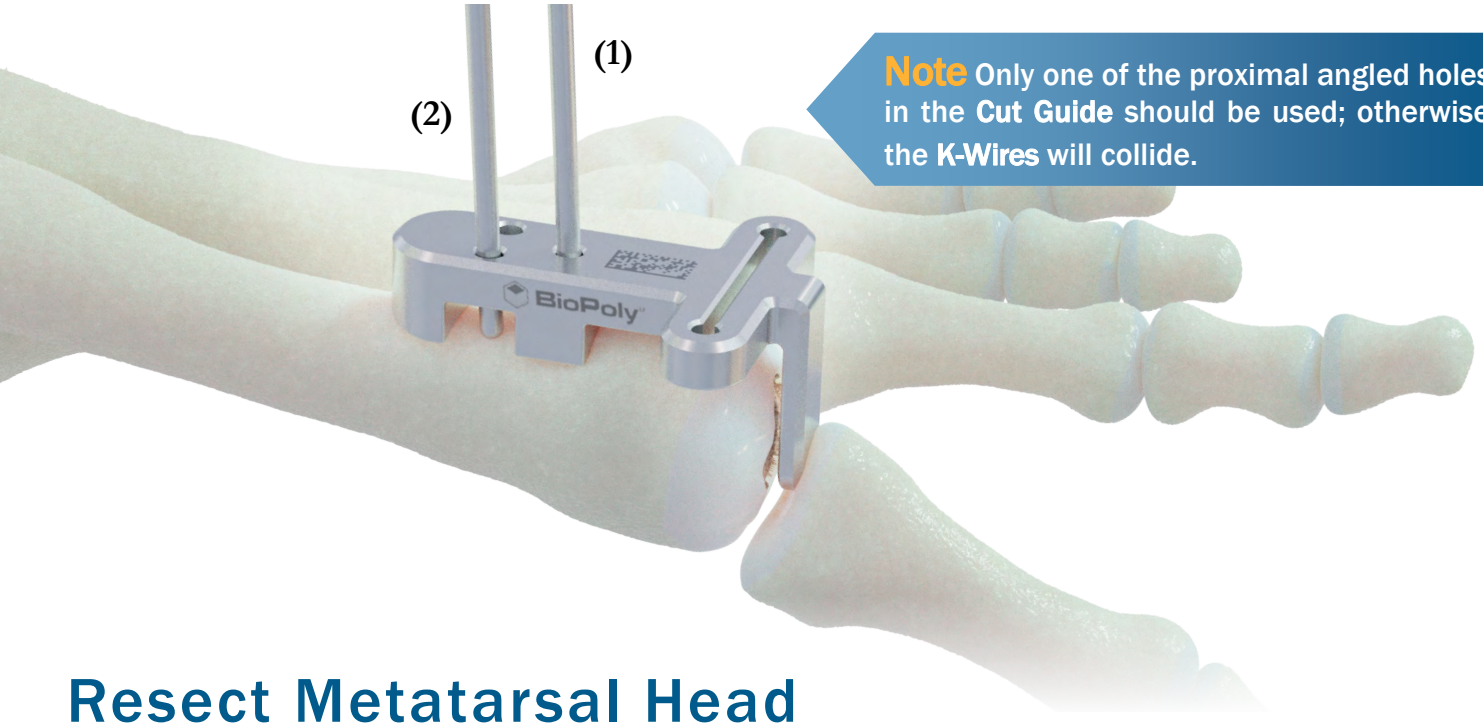
LATERAL VIEW

DORSAL VIEW

Surgical Technique

Secure Cut Guide

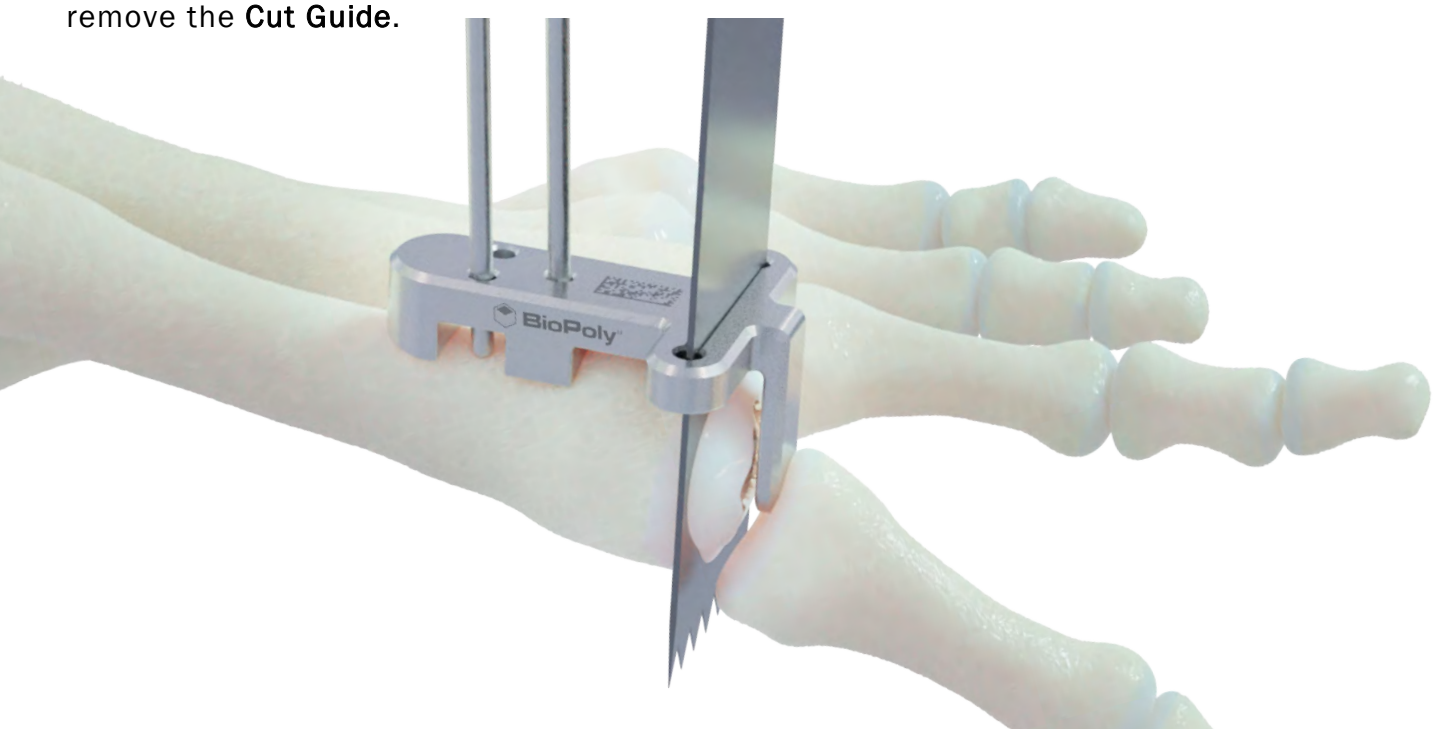
Once the **Cut Guide** is aligned, **(1)** drill a 1.6mm **Kirschner wire (K-Wire)** through the centermost, distal hole in the guide. Slight adjustments in the articular angle can be made after this pin is placed. Then, **(2)** drill another **K-Wire** through *one* of the remaining angled proximal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



Note Only one of the proximal angled holes in the **Cut Guide** should be used; otherwise, the **K-Wires** will collide.

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 provided 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**.



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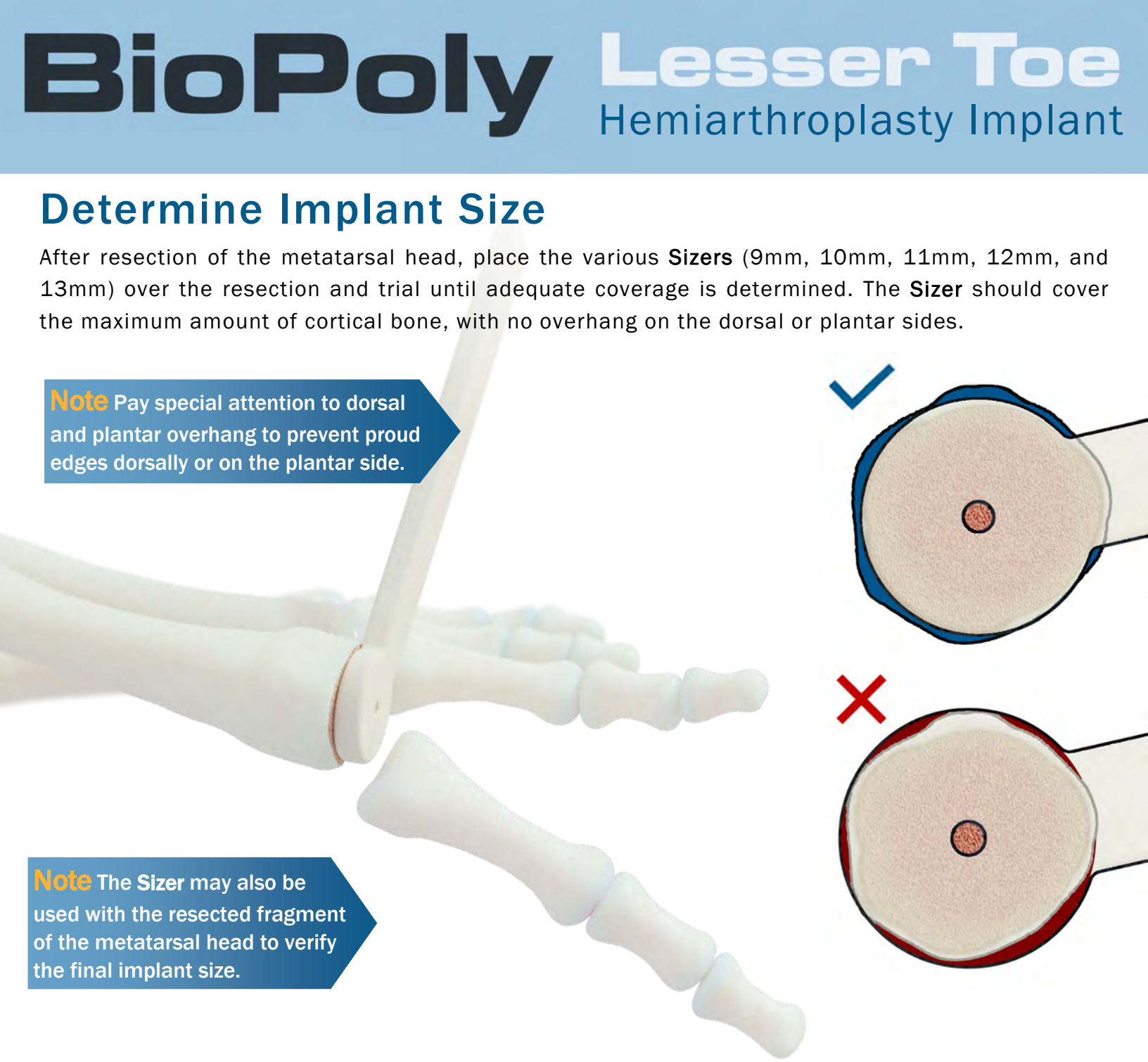
Determine Implant Size

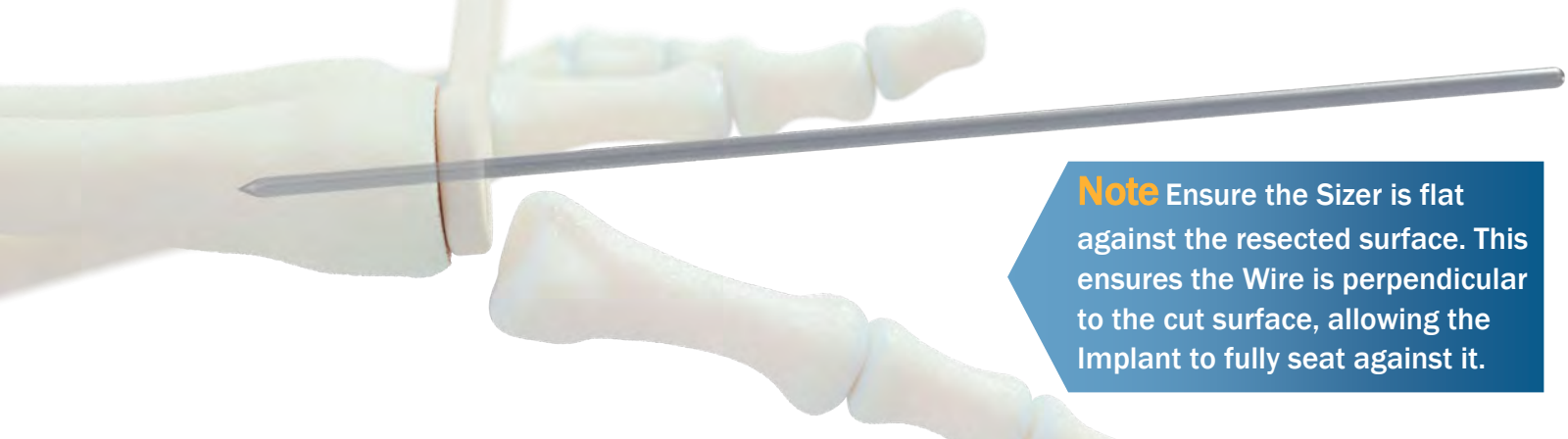
After resection of the metatarsal head, place the various **Sizers** (9mm, 10mm, 11mm, 12mm, and 13mm) over the resection and trial until adequate coverage is determined. The **Sizer** should cover the maximum amount of cortical bone, with no overhang on the dorsal or plantar sides.

Note Pay special attention to dorsal and plantar overhang to prevent proud edges dorsally or on the plantar side.



Note The **Sizer** may also be used with the resected fragment of the metatarsal head to verify the final implant size.

Holding the Sizer in place, drill a **1.6mm K-Wire** through the central hole of the Sizer. C-Arm X-Ray can be used to ensure the **K-Wire** is perpendicular to the cut surface.

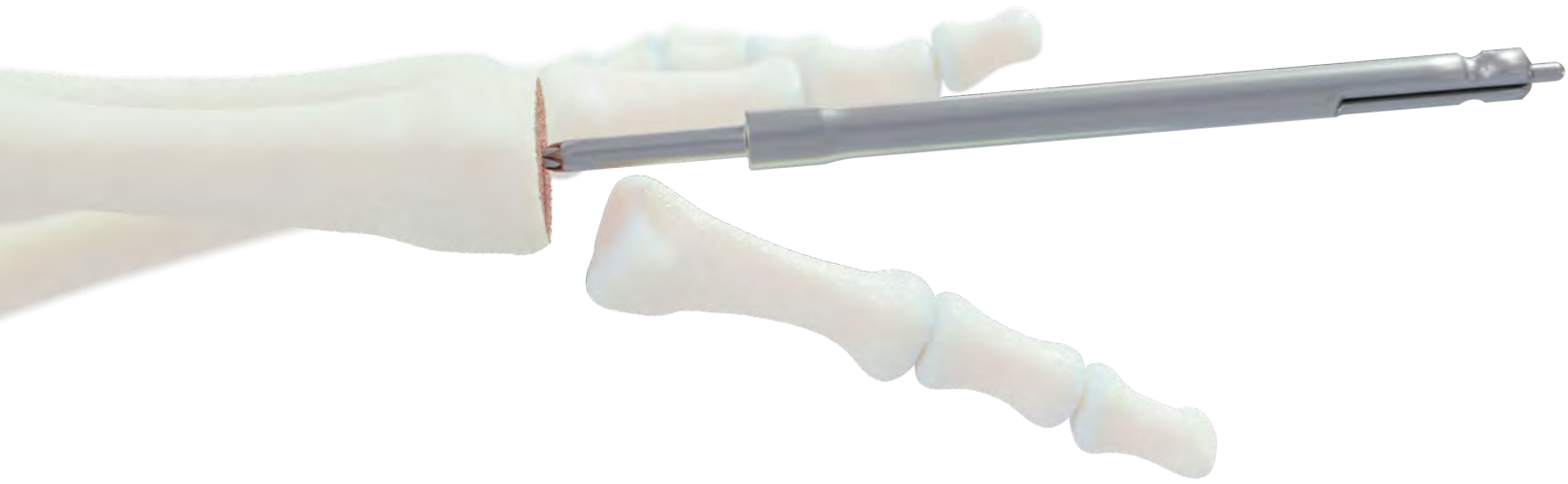


Note Ensure the Sizer is flat against the resected surface. This ensures the Wire is perpendicular to the cut surface, allowing the Implant to fully seat against it.

Surgical Technique

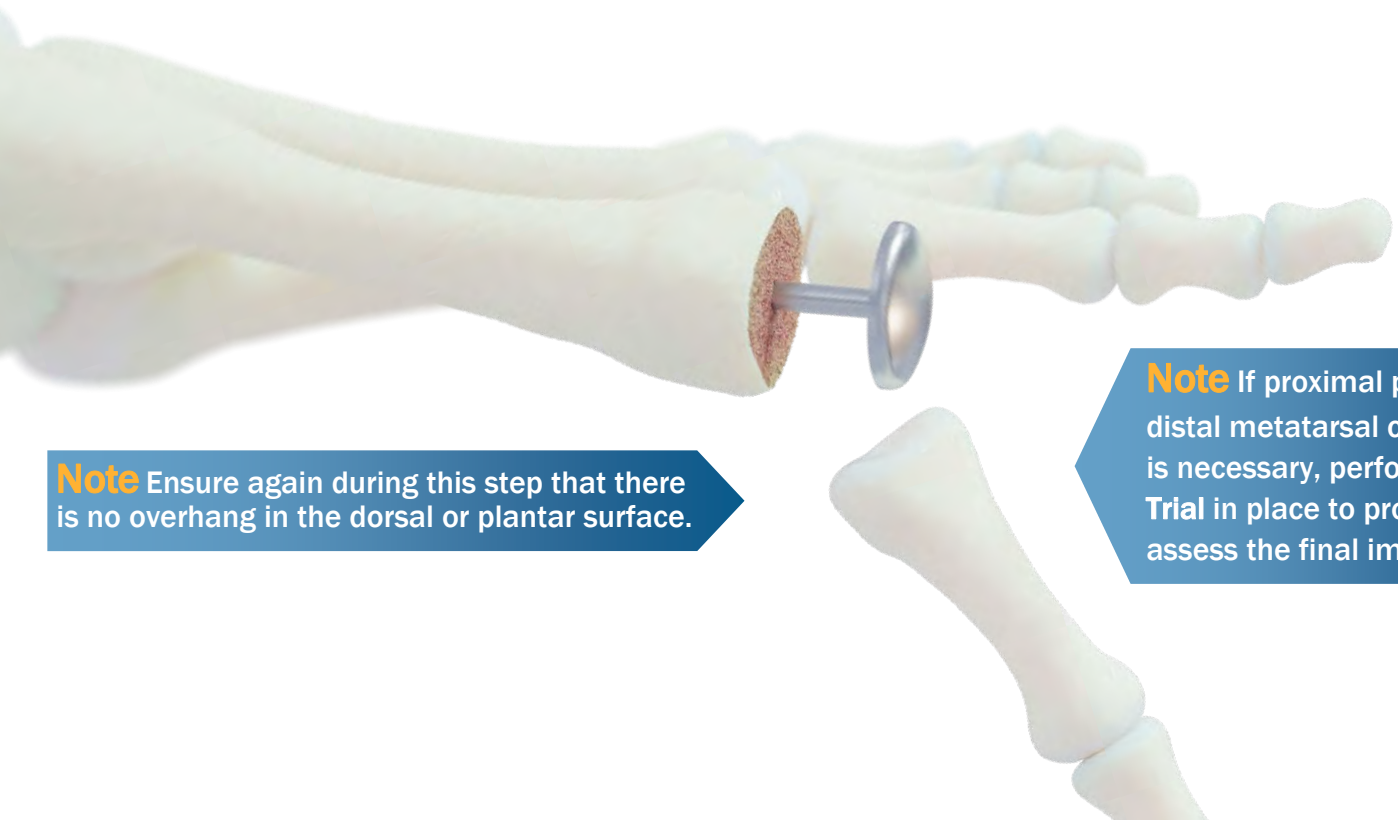
Drill Implant Site

Remove the **Sizer** by sliding it over the top of the **Central K-Wire**. Place the cannulated Drill over the **Central K-Wire**. Drill until the Drill collar contacts the resected planar bone surface. After drilling is complete, remove the **K-Wire**.



Insert Trial and Assess Implant

To verify implant size is acceptable, insert the **Trial** that matches the desired implant size. Assess the motion of the toe during full range of motion.



Note Ensure again during this step that there is no overhang in the dorsal or plantar surface.

Note If proximal phalanx or distal metatarsal cheilectomy is necessary, perform with **Trial** in place to protect and assess the final implant.

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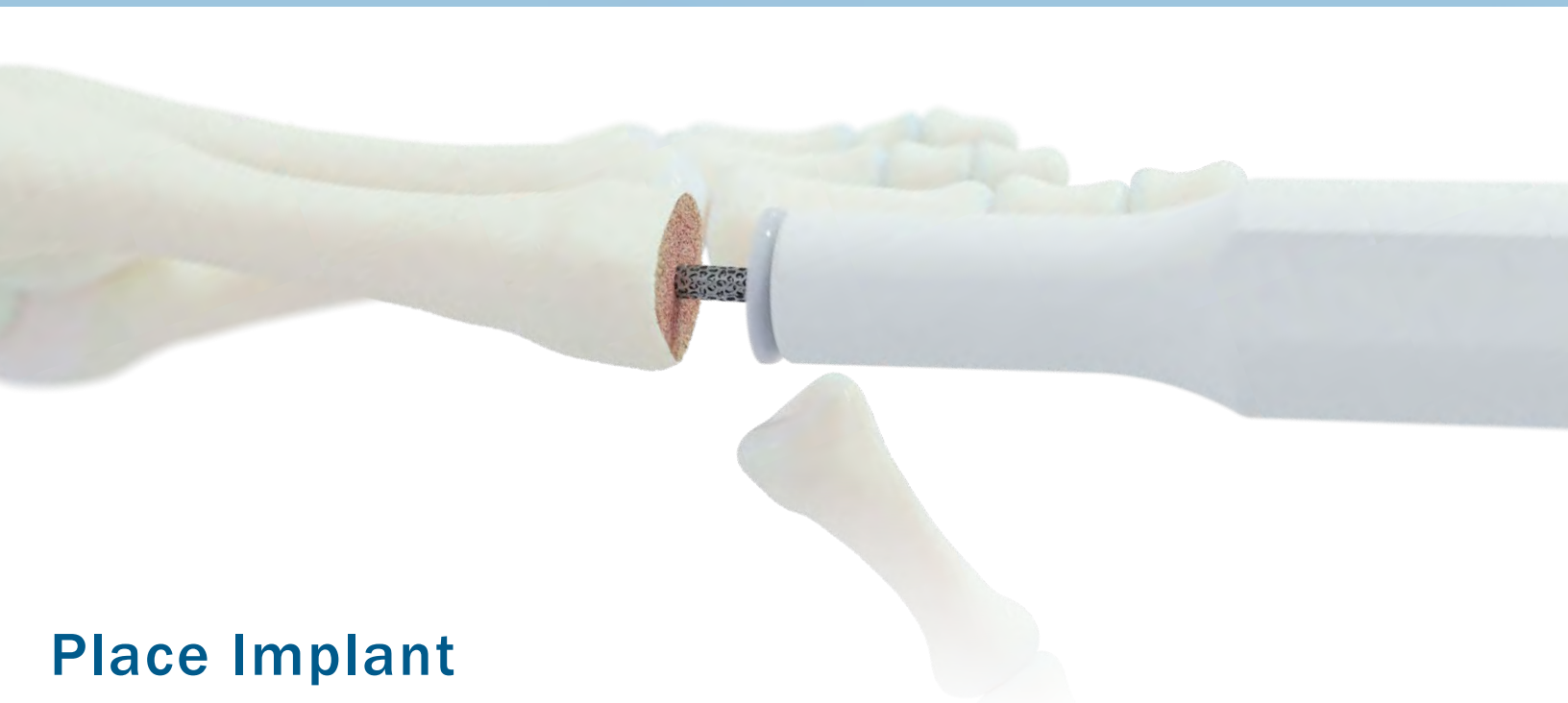

Place Implant

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 and progressively tap with a mallet until the implant is firmly seated in the prepared site. Carefully remove any extruded cement with a curette, taking care not to scratch or scrape the implant articular surface. Confirm that the implant is fully seated against the resected bone.

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.

Surgical Technique

Device Description
The BioPoly Lesser Toe Hemiarthroplasty Implant is a hemiarthroplasty device specifically designed to restore the articular surface of the metatarsal bone in patients with degenerative and post-traumatic arthritis. The implant is supplied in porous and non-porous designs with diameters of 9mm, 10mm, 11mm, 12mm, and 13mm for selection by the physician. One implant is provided in the sterile packaging.

Materials
The BioPoly Lesser 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 Lesser 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 Lesser Toe Hemiarthroplasty Implant is intended to be implanted to replace the distal metatarsal surface in patients with degenerative and post-traumatic arthritis in the MTP joint in the presence of good bone stock and integrity of the phalangeal base, 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

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 product 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.

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
- Improper implant selection, placement, positioning, or depth can lead to migration or loss of fixation.
- Embolism

Packaging and Sterilization
The BioPoly Lesser 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 Lesser 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 Lesser 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 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.

Implants

Description	Reference
Lesser Toe Hemiarthroplasty Implant – 9mm	130-5109
Lesser Toe Hemiarthroplasty Implant – 10mm	130-5110
Lesser Toe Hemiarthroplasty Implant – 11mm	130-5111
Lesser Toe Hemiarthroplasty Implant – 12mm	130-5112
Lesser Toe Hemiarthroplasty Implant – 13mm	130-5113

Instruments

Description	Reference
Instrument Set	130-5500
1.6mm Wire	135-2100-06
Sagittal Blade (Stryker replacement)	135-2100-08
Sagittal Blade (Conmed replacement)	135-2100-09
Cut Guide	130-2100-01
Drill	130-2100-02
Sizer – 9mm	130-2109-01
Trial – 9mm	130-2109-02
Sizer – 10mm	130-2110-01
Trial – 10mm	130-2110-02
Sizer – 11mm	130-2111-01
Trial – 11mm	130-2111-02
Sizer – 12mm	130-2112-01
Trial – 12mm	130-2112-02
Sizer – 13mm	130-2113-01
Trial – 13mm	130-2113-02
Insertion Tamp	135-2100-03

BioPoly®

Advancing Materials. Advancing Outcomes.™

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