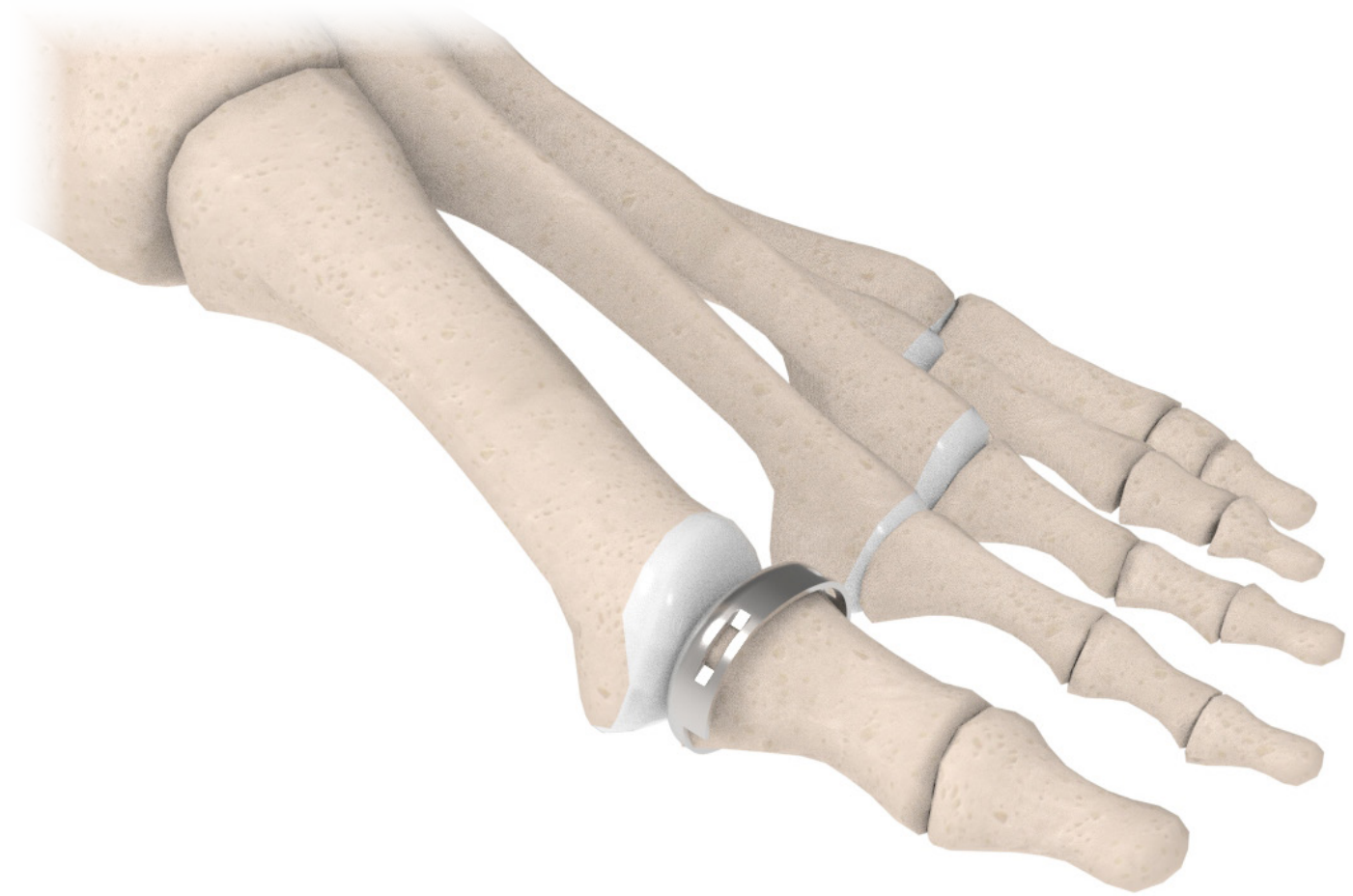


BIOLOGICALLY ORIENTED PROSTHESES

BIOPRO

HemiEDGE™

Surgical Technique



Contents

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Indications & Contraindications

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.

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. 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

Warning: The HemiEDGE has not been evaluated for safety and compatibility in the MR environment and has not been tested for heating or migration in the MR environment. The safety of the device in the MR environment is unknown. Scanning patients who have these devices may result in patient injury.

Stages of Hallux Rigidus/Limitus

Stage I: Joint inflammation and jamming of dorsiflexion motion in propulsion are the hallmarks of Stage I. These patients will have a normal, non-weight bearing range of motion and you will not note any X-ray changes.

Stage II: In this stage, patients begin to show objective clinical signs in addition to the inflammation of Stage I. You will note a dorsal proliferative response that is palpable and evident on X-ray as well. The patient will have a limited range of motion in sagittal formation and one may see some narrowing of the joint space on X-ray.

Stage III: This is an advanced Stage II with significant objective findings. One will see changes in the contour of the joint that are secondary to compressive forces in propulsion. There will be a flattening of the metatarsal head in the sagittal and transverse plane that you can see clinically and radiographically as a widened joint dorsally and laterally. These patients will often have proliferative disease with a “Valente” spur. X-rays will also show narrowing of the joint space secondary to thinning of articular cartilage.

Stage IV: In Stage IV hallux limitus/rigidus, there is severely advanced degenerative joint disease with complete loss of articular cartilage on both sides of the joint as well as a loss of joint space. The joint is flattened and wide in all planes with severe limitation of motion in all planes and directions.

The BioPro HemiEDGE is recommended for stages II and III.

Implant Specifications

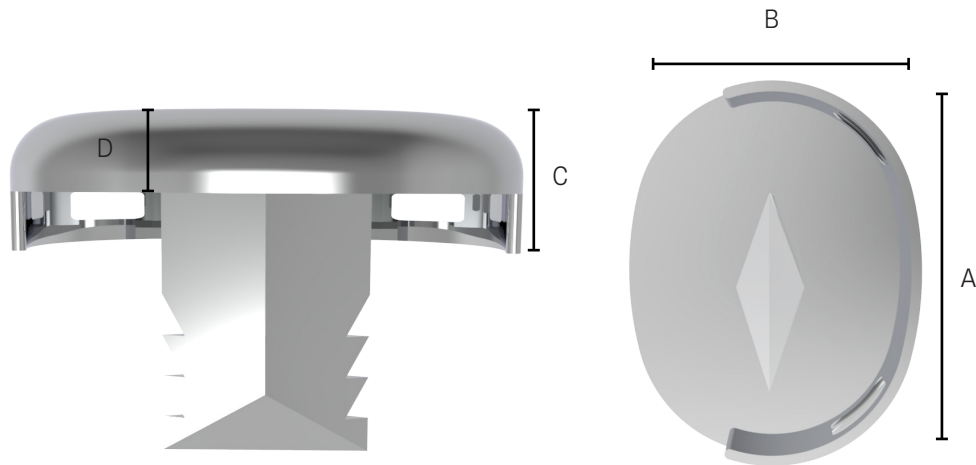
The BioPro® HemiEDGE is a simple, low-profile, press-fit implant designed to replace the articular surface of the proximal phalanx in a painful, arthritic metatarsophalangeal (MTP) joint. Based on the clinical success of our First MPJ Hemi Implant, the HemiEDGE, incorporates an overlapping edge extending around the medial, lateral and dorsal aspects of the implant. Partially encompassing the cortex of the phalanx helps ensure proper implant sizing, improve implant stability, and reduce the potential of bony overgrowth. The ultra thin profile of 2.5mm requires minimal bone resection at the base of the proximal phalanx for proper implantation.

Material

Manufactured from cobalt chrome, a highly biocompatible and durable material.

Sizing

Available in five standard sizes, the profile thickness remains the same across all sizes.

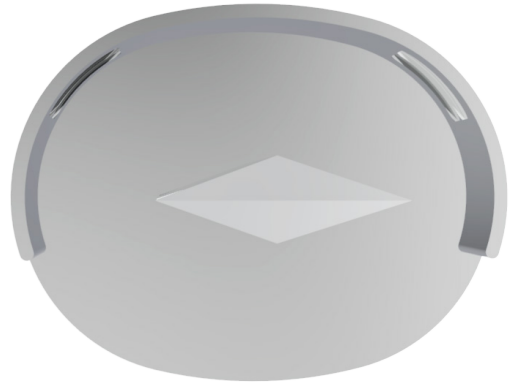


SIZE	A	B	C	D
SM - 17.0MM	17.0MM	13.0MM	4.5MM	2.5MM
M/S - 18.5MM	18.5MM	15.3MM	4.5MM	2.5MM
MD - 20.0MM	20.0MM	15.3MM	4.5MM	2.5MM
M/L - 21.5MM	21.5MM	17.5MM	4.5MM	2.5MM
LG - 23.0MM	23.0MM	17.5MM	4.5MM	2.5MM

Implant Specifications

Overlapping Edge

The overlapping edge is the main design feature differentiating the HemiEDGE from traditional phalangeal implants. This edge extends over the dorsal, medial and lateral cortices beyond the resected base of the phalanx. The plantar surface does not include the edge, preserving the flexor attachment and avoiding any implant prominence on the weight bearing surface. The edge surrounds the phalanx to help support and stabilize the implant. This improves implant stability, assists in proper placement during implantation, and reduces the potential of bone overgrowth.



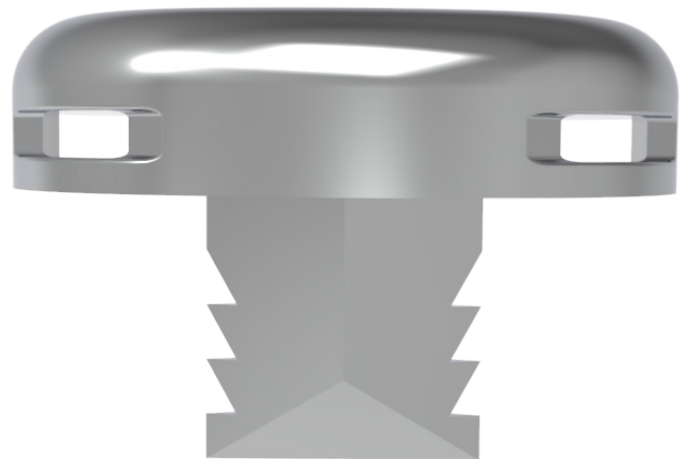
Articulating Surface

The articulating surface of the implant has a highly polished finish, allowing for unrestricted motion.



Visualization Portals

The HemiEDGE incorporates two visualization portals along the dorsal edge of the implant. These portals allow for visual confirmation that the implant is fully seated against the resected surface of the phalanx. Along with the edge design, a properly seated implant contributes to ensuring a stable implant post-operatively.

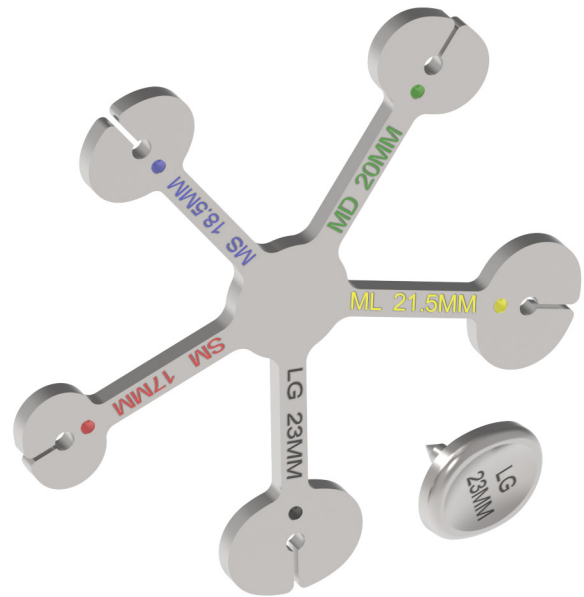


Instrument Specifications

Color Coding

The five star template, trial implants and packaging all feature a color coding system to coordinate implant size. After determining the appropriate implant size, always ensure you are using the same color code throughout the procedure.

Size	Color
SM - 17mm	Red
M/S - 18.5mm	Blue
MD - 20mm	Green
M/L - 21.5mm	Yellow
LG - 23mm	Black



Trial Implants

There are two sets of implant trials. The standard trials are used first, after insertion of the trial punch. The HemiEDGE trial implants are used after the toe punch to ensure the overlapping rim fits before opening the final implant.



Standard Trial Implant



HemiEDGE Trial Implant

Instrument Specifications



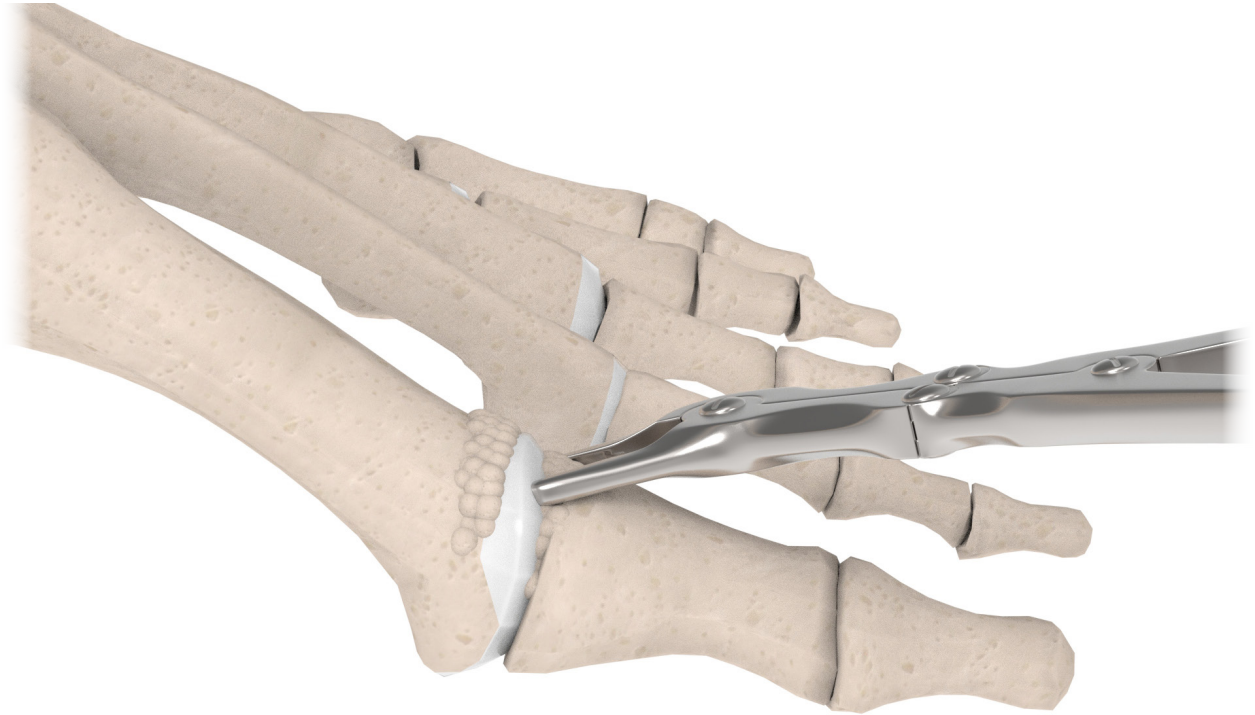
Broaching

The instrument kit includes both a trial punch and toe punch for compression broaching. It is imperative to the success of the implant that these are inserted parallel to the long axis of the proximal phalanx.



Fluoroscopy may be used to ensure proper insertion angle prior to final placement.

Surgical Technique



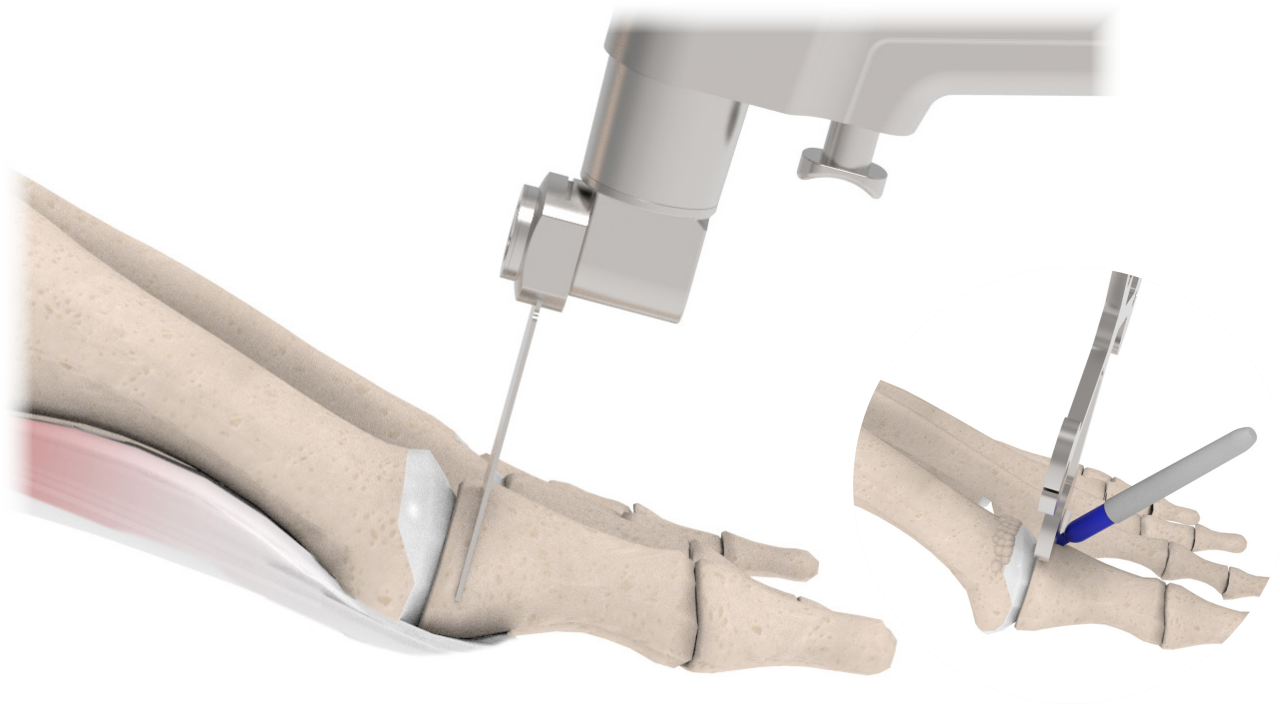
Always be sure to treat all pathologies involved with a case. Joint replacement of the first MP joint treats hallux limitus/rigidus only. Typical accompanying pathologies such as elevatus, hallux valgus, or hallux varus need to be treated with the appropriate osteotomy, or the surgeon's preferred method. The HemiEDGE Implant can be implanted in conjunction with distal metatarsal osteotomies.

Step One:

Begin by exposing the MPJ by either a dorsal medial or medial incision. In the majority of cases, the pathology presents itself as a rectus joint and therefore requires minimal medial/lateral subcutaneous dissection. Continue with a capsular incision which extends the full length of the skin incision with placement at least one centimeter medial to the long extensor tendon. This will prevent capsular under roll and provide easier closure at the end of the procedure. Perform precise capsular dissection about the head of the first metatarsal and approximately 1/2 of the proximal phalanx. Follow proximal phalanx dissection along the entire medial and lateral segments. This will help facilitate easy removal of the osteotomized base.

Step Two:

Remove a small segment of dorsal bone overgrowth or cupping on the base of the proximal phalanx with a rongeur to identify the "zone of articular cartilage".



Step Three:

Resect approximately 4 to 6mm off the base of the proximal phalanx. The saw blade is placed parallel to the articular surface and perpendicular to the long axis of the proximal phalanx.

Important Note

Care is taken not to cut the flexor hallucis brevis on the plantar surface. Anything greater than 6mm may detach the insertion of the flexor hallucis brevis.

Important Note

Failure to cut at 90° can result in the implant stem impacting or breaking through the plantar cortex.

Surgical Pearl (Optional)

Place the five star implant template vertically on the dorsal aspect of the cartilage line. Using a marking pen, utilize the distal side of the template as a guide to mark the osteotomy site. The appropriate amount of base removal is typically between 4mm and 6mm. The Template is approximately 3mm thick.

Surgical Pearl (Optional)

When performing the osteotomy, progress from dorsal to plantar approximately 3/4 through the bone. Remove the saw and insert a small chisel. Bend slightly to create a greenstick fracture. Remove this dorsal bone component leaving the plantar edge intact. Grasp the center of the proximal phalanx with the enclosed bone clamp to easily distract the joint. Carefully dissect free the tendon fibers of the short flexor tendon attached to the bone shelf. Once freed completely, remove the shelf with a power saw. This will ensure the insertion of the short flexor tendon is maintained.

Surgical Pearl

In the event the flexor hallucis brevis is inadvertently cut, drill a small hole on an angle from approximately 3-4mm above the plantar surface on the base of the proximal phalanx and out the plantar surface of the phalanx. Pass a small suture through this hole and secure it to the flexor hallucis longus.



Step Four:

Remodel the metatarsal head and remove all abnormal or irregular bone with a power saw, burr or rasp, taking care to maintain as much dorsal cartilage as possible.

Surgical Pearl

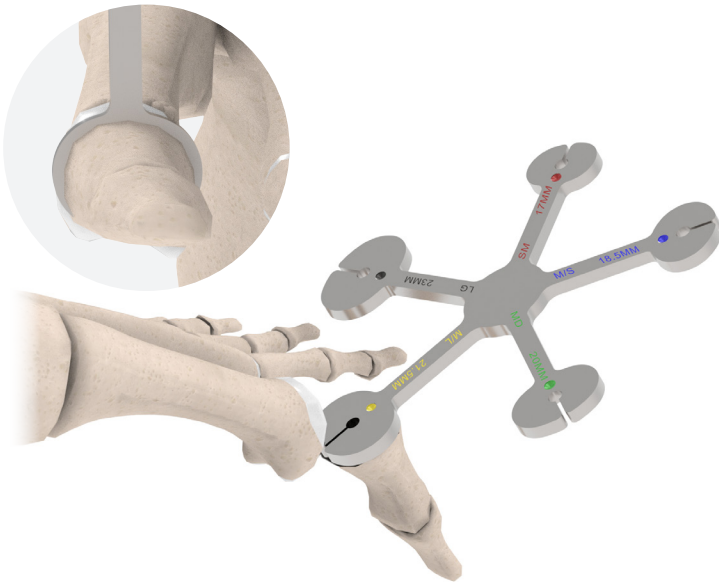
It is advisable to frequently irrigate the surgical site. It is at this point of the surgical procedure that metatarsal head osteotomies may be performed, if warranted.

Surgical Pearl

When remodeling the head of the first metatarsal, ensure there is sufficient taper for the implant to glide dorsally. The implant will not easily move dorsally on a flat head.

Important Note

Release the sesamoid complex with an elevator instrument. Failure to release the sesamoids can result in limited postoperative range of motion.



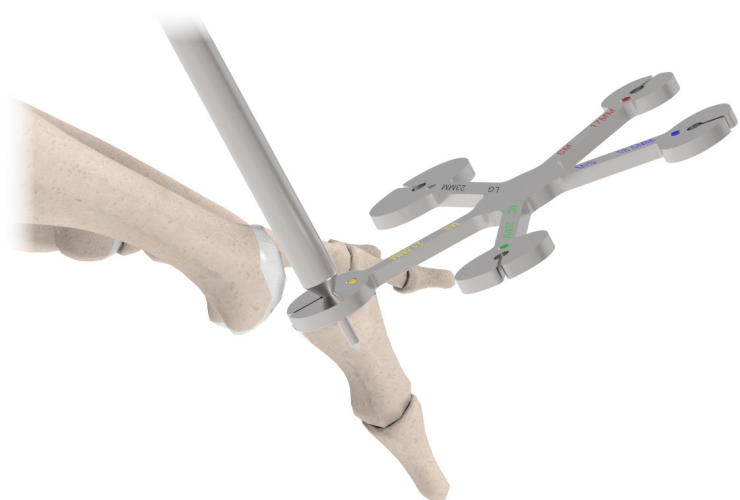
Step Five:

Implant selection is made using the 5-star template. Plantarflex the proximal phalanx and abut the template to the phalanx. Select the appropriate size (17mm, 18.5mm, 20mm, 21.5mm, 23mm) so the implant is slightly larger than the circumference of the base.

This allows the cortex to maintain stability of the implant and prevents the possibility of implant telescoping or bone overgrowth.

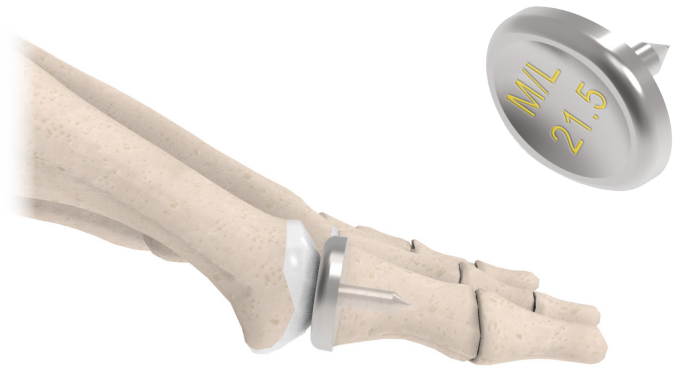
Surgical Pearl

Place the BioPro 5-sided implant template so that the etched line is facing distally. This will enable you to visualize and place the line at least 1mm above the dorsal cortex.



Step Six:

Using the 5-star template center hole, insert the trial punch and tap to stop point. Ensure the trial punch is inserted parallel to the long axis of the phalanx and is positioned perpendicular to the implant template. Remove the punch and template.

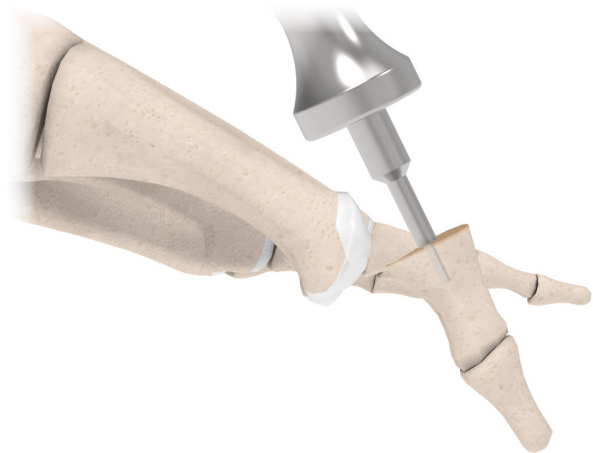


Step Seven:

The appropriately sized trial implant is now inserted into the hole created by the trial punch. Verification of the correct size is made and the hallux put through the normal range of motion. It is at this time that final remodeling of the metatarsal head is made if required. The trial implant should move freely about the metatarsal head with no evidence of medial or lateral deviation and no clicking. Abnormalities are corrected by fine burring technique. The trial implant is now removed after verification.

Important Note

Evaluate joint tension while the trial implant is in place to ensure appropriate resection has been made. When fully distracting the proximal phalanx from the metatarsal head, approximately 5mm of joint space should be observed. If less than 5mm is possible, there is insufficient resection and the final joint may be tight and lack motion. Additional resection of the phalanx may be necessary.



Step Eight:

The final impression is created with the toe punch. The toe punch is centered at the trial punch hole and forward hand pressure is applied with slight medial lateral movement using the corners of the reamer to assist in bone penetration. Continue penetration of the toe punch to the stop mechanism. A mallet may be used if hard bone prevents insertion of the toe punch with hand pressure only.

Important Note

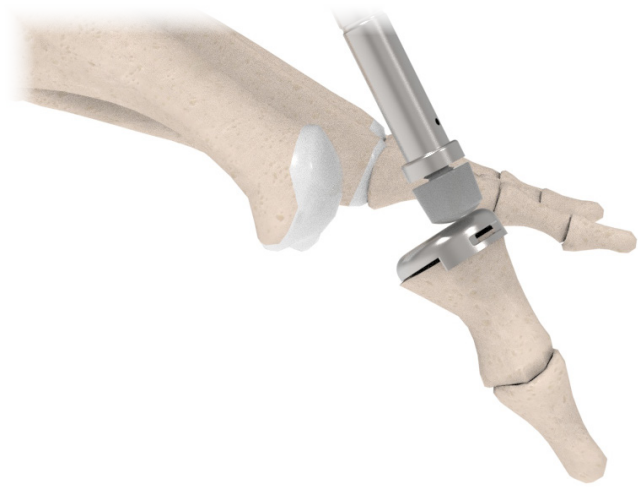
It is imperative that the toe punch be perfectly parallel with the long axis of the proximal phalanx.



Step Nine:

Insert the HemiEDGE trial implant of the appropriate size into the canal. The overlapping edges of the sizer should have at least a 1mm space between the dorsal cortex and the implant edge. (Fig 8) The edge should not be in contact with bone dorsally, medially or laterally. Remove any impingement or areas of bone preventing proper trial seating with a rongeur.

Again, the hallux is put through normal range of motion, ensuring the trial moves freely around the metatarsal head. Now remove the HemiEDGE trial sizer.



Step Ten:

Insert the appropriately sized implant into the canal. Final seating is performed using the impactor fitted with the appropriately sized impactor tip until the implant is flush with the bone. Verify the implant seats flush against the resected base of the phalanx through the visualization portals.

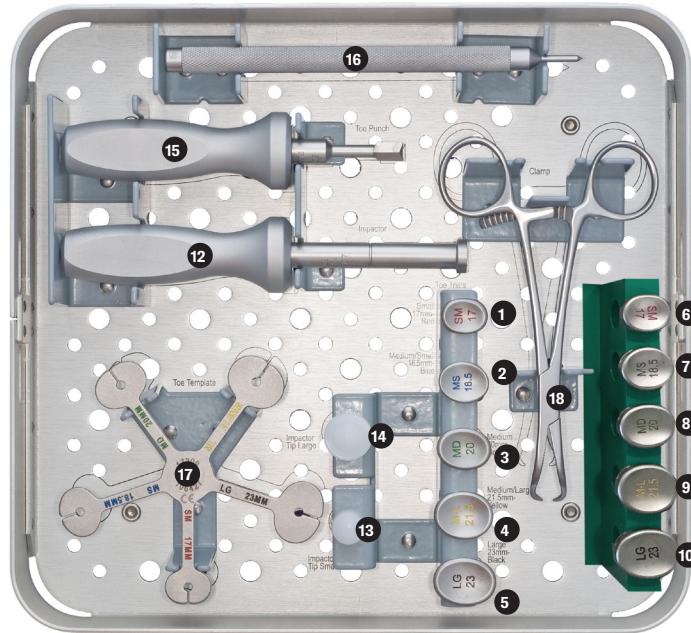


Once again, perform joint range of motion followed by closure of all layers with sutures of choice.

Implant Ordering

ITEM #	DESCRIPTION	SIZE
19538	HEMIEDGE IMPLANT	SM - 17MM
19539	HEMIEDGE IMPLANT	M/S - 18.5MM
19540	HEMIEDGE IMPLANT	MD - 20MM
19541	HEMIEDGE IMPLANT	M/L - 21.5MM
19542	HEMIEDGE IMPLANT	LG - 23MM

Instrument Overview



HemiEDGE Complete Kit-20287

Location	Item #	Description
2	12235	MPJ Trial 17mm (SM)
3	17180	MPJ Trial 18.5mm (MS)
4	12236	MPJ Trial 20mm (MD)
5	14959	MPJ Trial 21.5mm (ML)
6	12237	MPJ Trial 23mm (LG)
7	19673	HemiEDGE Trial 17mm (SM)
8	19674	HemiEDGE Trial 18.5mm (MS)
9	19675	HemiEDGE Trial 20mm (MD)
10	19676	HemiEDGE Trial 21.5mm (ML)
11	19677	HemiEDGE Trial 23mm (LG)
12	15259	Impactor Handle
13	15256	Impactor Tip Sm
14	15257	Impactor Tip Lg
15	17786	Punch
16	15112	Chisel
17	17309	5-Sided Implant
18	18100	Towel Clamp

BIOLOGICALLY ORIENTED PROSTHESES

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Call us at 1-810-982-7777 to schedule a case today.

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BioPro, Inc.
2929 Lapeer Road, Port Huron, MI 48060, USA
info@bioproimplants.com | 1-810-982-7777
www.bioproimplants.com



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