

FIRST MPJ HEMI IMPLANT

NAOS

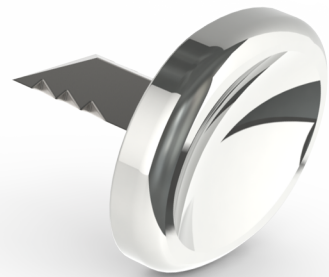


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Introduction

The HNM Medical First MPJ Hemi Implant is a simple, durable, metallic hemiarthroplasty resurfacing prosthesis for the hallux metatarsophalangeal joint capable of providing your patient with years of pain relief and restored motion. The implant is indicated for patients with osteoarthritis, rheumatoid arthritis, hallux rigidus, hallux limitus and degenerative changes of the first metatarsophalangeal joint associated with hallux abducto valgus and bunion deformity.

The First MPJ Hemi Implant has passed the test of time with positive clinical results; it has been in continuous use for over 60 years and clinical follow-up to 38 years.^[1] The implant is placed at the base of the proximal phalanx, minimizing exposure to the forces transmitted through the metatarsal head during weight bearing. Clinical research has shown successful pain relief and restored range of motion when implanting the HNM Medical First MPJ Hemi in the base of the phalanx, even if cartilage degeneration is present on all or part of the metatarsal head.^[2,3]

Features and Benefits

Minimum bone resection technique

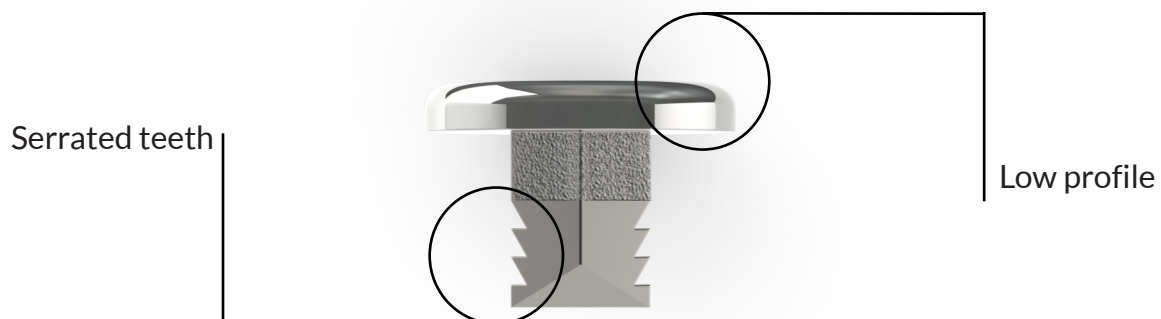
The HNM Medical First MPJ Hemi Implant is only 2mm thick and requires minimal bone resection at the base of the proximal phalanx for proper implantation. Recommended resection is double the thickness of the implant, or 4mm.

Why is this important? This is important for two reasons. First, this preserves the FHB (flexor hallucis brevis), which typically attaches 6-8mm from the base. Sacrificing the FHB can result in a lack of toe purchase post-operatively. Second, the minimal resection technique maintains bone stock within the joint. This is an extremely important point should revision surgery ever be required. Typical revision for an implant is a joint fusion. The minimal resection technique employed with the HNM Medical First MPJ Hemi Implant leaves sufficient bone stock to accommodate a fusion, should the need arise in the future.

Low profile, diamond shaped stem for intramedullary fixation

The stem of the First MPJ Hemi Implant is less than 3mm thick, and includes serrated teeth on the sides for purchase in the cancellous bone of the phalanx.

Why is this important? Similar to the minimal resection technique, the implant and instruments only compress bone within the intramedullary canal of the phalanx, not remove it. This helps preserve the natural anatomy of the phalanx and retains the maximum amount of bone.



Porous and Non-Porous versions available

The HNM Medical First MPJ Hemi Implant is available in two variations, a non-porous coated version and a porous coated version. The non-porous coated version has a smooth back and stem and relies on the teeth of the stem for biological fixation. The porous coated version has cobalt beads attached on the back and a portion of the stem, allowing for bony ingrowth. Biological fixation occurs via the bony ingrowth as well as the teeth of the stem.

Why is this important? Having two options offers more flexibility to the surgeon. The non-porous coated version is great for patients with good bone stock and is actually thinner (approximately 0.5mm) and may be easier to insert into hard bone stock due to the lack of beads on the stem. The porous coated version offers extra security for patients with softer bone stock as it allows bony ingrowth on multiple surfaces for additional implant stability.

Standard Cobalt Chrome with the option of Titanium for metal allergies

The standard First MPJ Hemi implant is manufactured from Cobalt Chrome, an extremely hard alloy that polishes incredibly smoothly to provide an excellent articulating interface against bone. The implant is also available in Titanium, known as a highly biocompatible alloy.

Why is this important? Cobalt Chrome has a small amount of Nickel in it and there are a small percentage of patients with a nickel allergy. For those patients, use of the titanium version is recommended as titanium does not contain any nickel. If no metal allergies are present, the Cobalt Chrome implant is recommended due to its superiority as an articulating surface.

Porous Coated



Non-Porous Coated



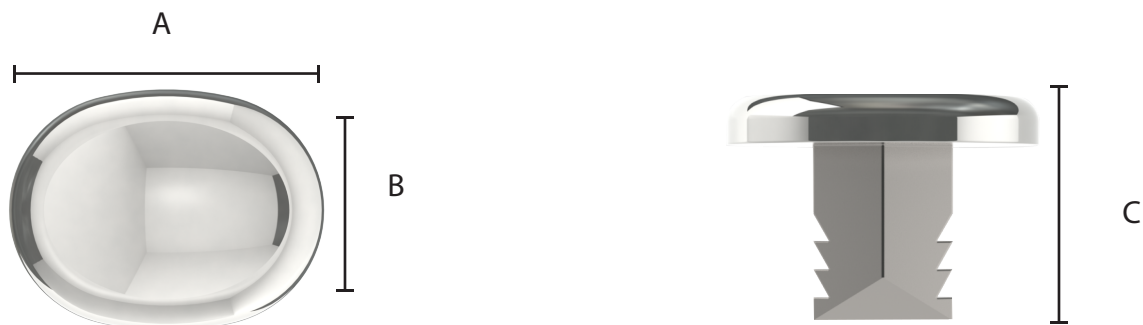
Ordering Information

The HNM Medical First MPJ Hemi Implant is manufactured from cobalt chrome and is available in porous coated (PC) and non-porous coated (NPC). The First MPJ Hemi Implant is also available in titanium for patients with a metal sensitivity.

Item #	Description	Size
HTR-01-040212	COBALT CHROME POROUS COATED	17MM
HTR-01-700334	COBALT CHROME POROUS COATED	18.5MM
HTR-01-040413	COBALT CHROME POROUS COATED	20MM
HTR-01-040460	COBALT CHROME POROUS COATED	21.5MM
HTR-01-040414	COBALT CHROME POROUS COATED	23MM
HTR-01-000760	COBALT CHROME NON-POROUS COATED	17MM
HTR-01-000733	COBALT CHROME NON-POROUS COATED	18.5MM
HTR-01-000761	COBALT CHROME NON-POROUS COATED	20MM
HTR-01-000758	COBALT CHROME NON-POROUS COATED	21.5MM
HTR-01-000762	COBALT CHROME NON-POROUS COATED	23MM
HTR-01-704735	TITANIUM POROUS COATED	17MM
HTR-01-704797	TITANIUM POROUS COATED	18.5MM
HTR-01-704736	TITANIUM POROUS COATED	20MM
HTR-01-704737	TITANIUM POROUS COATED	21.5MM
HTR-01-704738	TITANIUM POROUS COATED	23MM
HTR-01-684213	TITANIUM NON-POROUS COATED	17MM
HTR-01-684298	TITANIUM NON-POROUS COATED	18.5MM
HTR-01-684214	TITANIUM NON-POROUS COATED	20MM
HTR-01-684215	TITANIUM NON-POROUS COATED	21.5MM
HTR-01-684216	TITANIUM NON-POROUS COATED	23MM
HTR-01-730768	FIRST MPJ HEMI INSTRUMENT KIT	

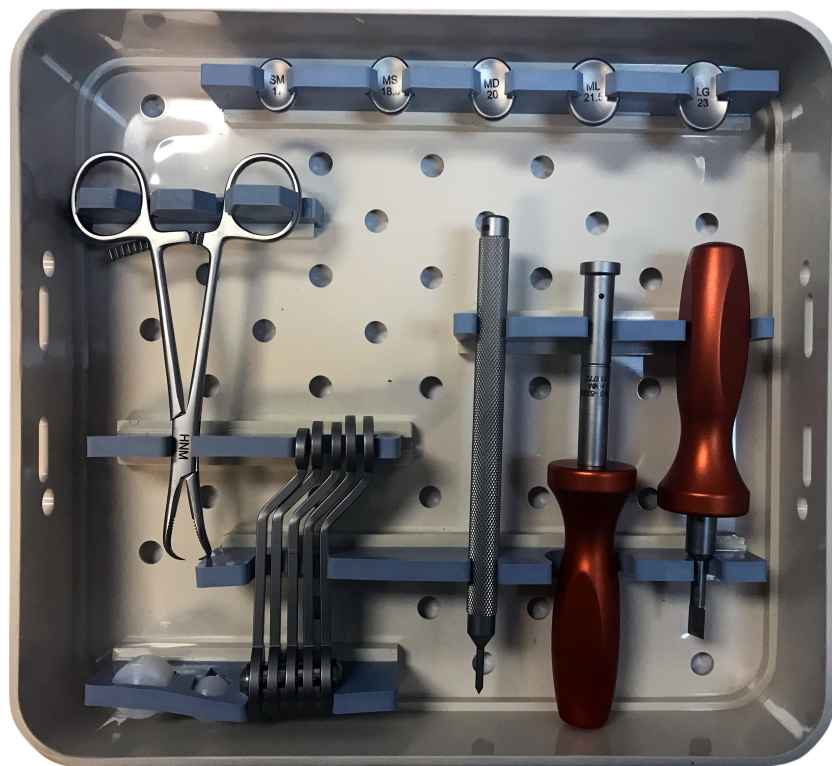
First MPJ Hemi Implant Dimensions

	A	B	C
Small	17.0mm	13.0mm	12.0mm
Medium/Small	18.5mm	15.3mm	12.9mm
Medium	20.0mm	15.3mm	13.6mm
Medium/Large	21.5mm	17.5mm	14.4mm
Large	23.0mm	17.5mm	15.3mm



First MPJ Hemi Instrument Kit

Item #	Description
HTR-01-770186	NAOS Punch
HTR-01-510812	NAOS Chisel
HTR-01-520359	Impactor Handle w/Shaft
HTR-01-520256	Impactor Tip SM
HTR-01-520957	Impactor Tip LG
HTR-01-821000	Towel Clamp
HTR-01-730209	NAOS Template 5 prong
HTR-01-220335	NAOS Trial SM
HTR-01-710480	NAOS Trial MS
HTR-01-220536	NAOS Trial MD
HTR-01-490659	NAOS Trial ML
HTR-01-220737	NAOS Trial LG



First MPJ Instrument Kit- 17368



Indications

Specific examples of implant applications:

- Hallux Limitus/Hallux Rigidus
- Osteoarthritis
- Post-traumatic arthritis
- Rheumatoid arthritis
- Causes
- Degenerative arthritis – wear and tear
- Injury or trauma
- Inflammatory diseases
- Rheumatoid arthritis
- Gout

Stages of Hallux Limitus

There are four stages of Hallux Limitus.

Stage I. Joint inflammation and jamming of dorsiflexion motion in propulsion are the hallmarks of Stage I. These patients will have a normal, nonweightbearing range of motion and you will not note any X-ray changes.^[4]

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 dorsiflexion due to exostosis formation and one may see some narrowing of the joint space on X-ray.^[4]

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.^[4]

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.^[4]

The HNM Medical First MPJ Hemi Implant is recommended for stages II, III.

Contra-indications

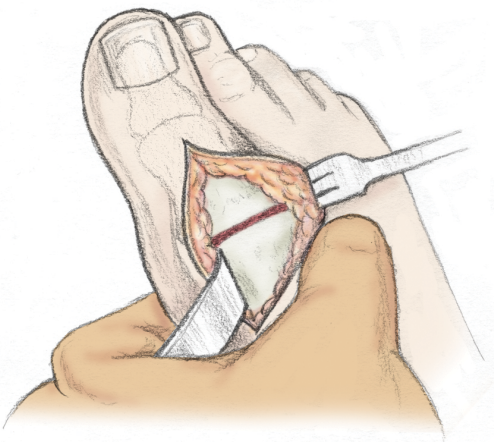
- A general health problem that might pose a significant threat to the life of the patient if subjected to a major surgical procedure
- An active infection or a previous infection of the lower extremity that has not been quiescent for at least six months
- A local or systemic infection
- Significant deficiency in the vascular supply to the extremity
- Severe structural deficiency of the sub-chondral bone that may result in insufficient support for the prosthesis
- A condition of the toe which may lend itself to a more conservation procedure
- Severe compromise of the supporting muscles or ligaments about the toe

Surgical Technique

Important Notes:

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 HNM Medical First MPJ Implant can be implanted in conjunction with distal metatarsal osteotomies.

Fig. 1

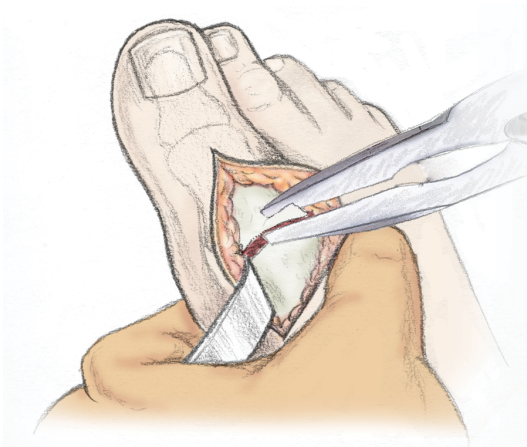


Step One:

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. (Fig. 1)

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.

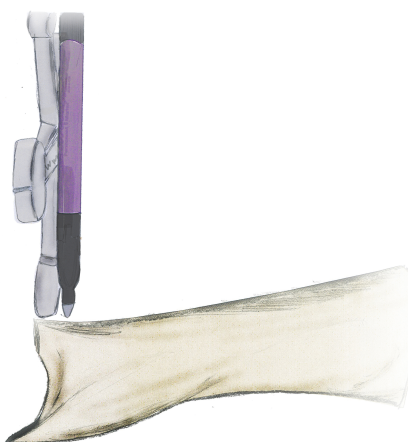
Fig. 2A



Step Two:

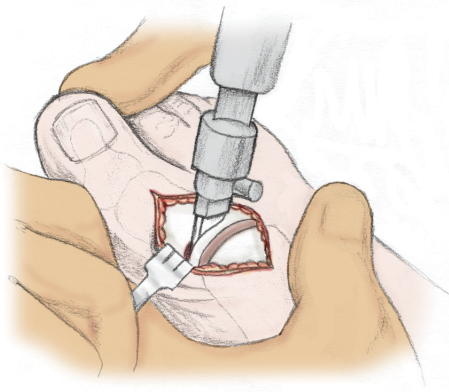
Remove a small segment of dorsal bone overgrowth or cupping on the base of the proximal phalanx with a rongeur to identify the "zone of articular cartilage". (Fig. 2A) Using the 5-sided implant template as a guide, placed vertically on the dorsal aspect of the cartilage line and using a marking pen, mark the osteotomy site on the distal side of the 5-sided implant template. The appropriate amount of base removal is typically between 4 and 5 mm. (Fig. 2b)

Fig. 2B



Note: Anything greater than 6 mm may detach the insertion of the flexor hallucis brevis tendon.

Fig. 3



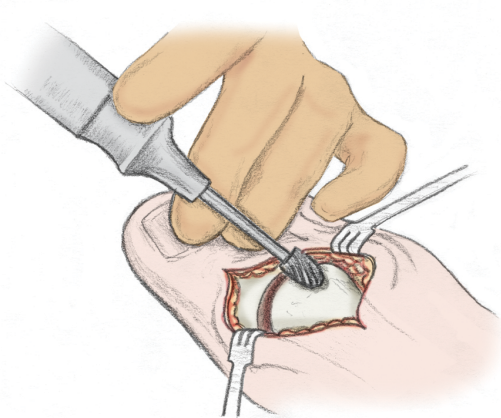
The saw blade is placed parallel to the articular surface and perpendicular to the long axis of the proximal phalanx. (Fig. 3)

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

Surgical Pearl: 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.

Fig. 4

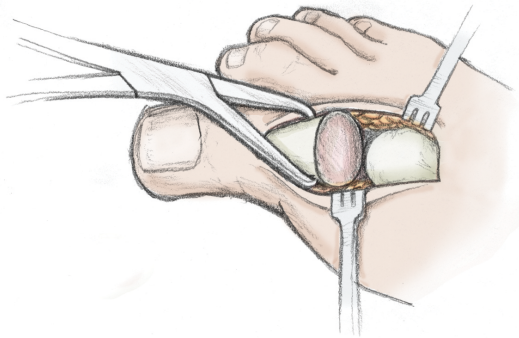


Step Three:

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. (Fig. 4) Release the sesamoid complex with an elevator instrument, similar to a McGlamry Elevator.

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.

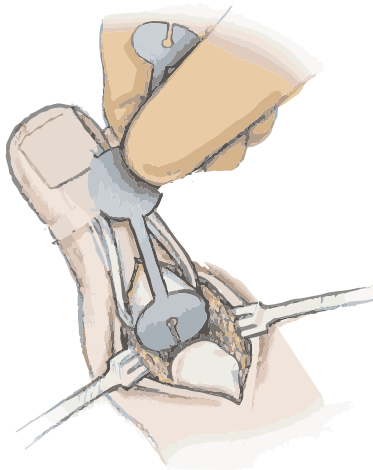
Fig. 5



Step Four:

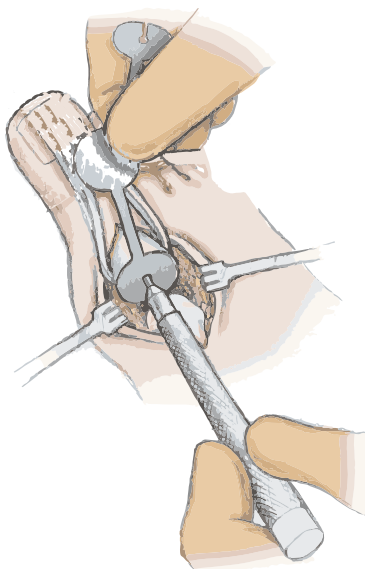
Grasp the proximal phalanx with the enclosed bone clamp and distract to reveal the base. (Fig.5)
Implant selection is made using the HNM Medical 5-sided Implant Template.

Fig. 6



Select the appropriate size (small, medium small, medium, medium large, large) so the implant is slightly larger than the circumference of the base. (Fig. 6) This allows the cortex to maintain stability of the implant and prevents the possibility of implant telescoping or bone overgrowth.

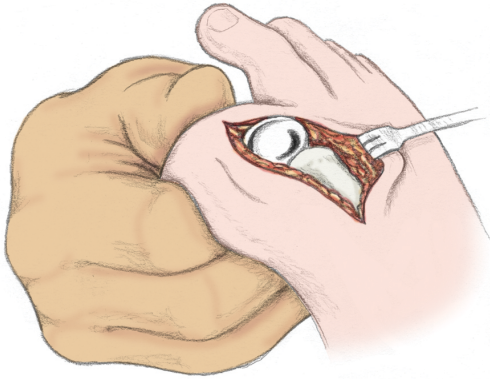
Fig. 7



Step Five:

Using the Sizer key Implant 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. (Fig 7).

Fig. 8

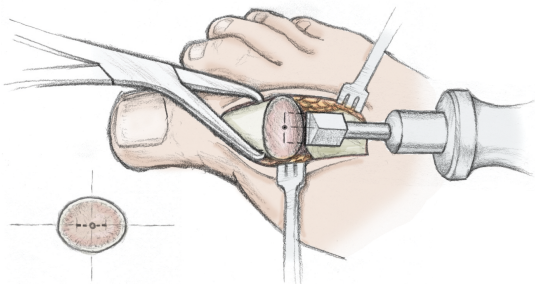


Step Six:

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. (Fig 8) 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 along with the absence of clicking. Abnormalities are corrected by fine burring technique.

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.

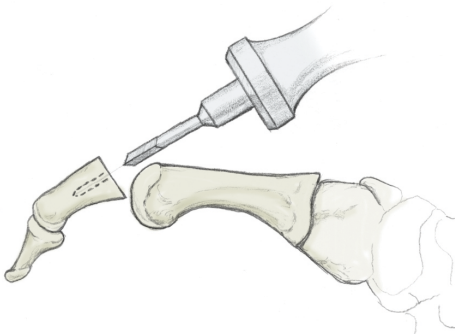
Fig. 9



Step Seven:

Distraction of the joint is once again performed using the bone clamp to accommodate the HNM Medical Chisel. The central line of the reaming device is centered at the punch hole (Fig 9) 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 reaming device to the stop mechanism. A mallet may be used if hard bone prevents insertion of the Chisel with hand pressure only.

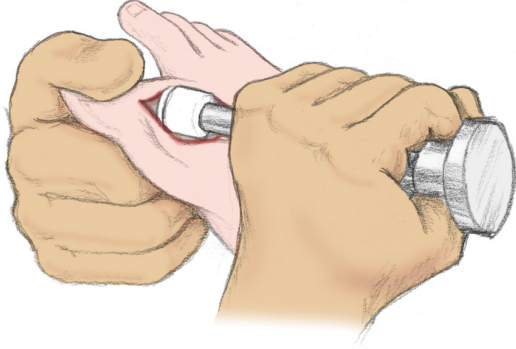
Fig. 10



Important Note:

It is imperative that the Chisel be perfectly parallel with the long axis of the proximal phalanx. (Fig 10)

Fig. 11

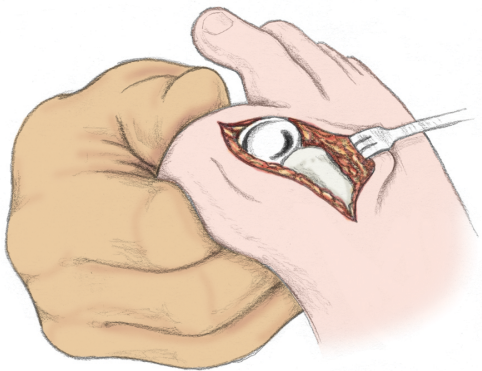


Step Eight:

Insert the appropriate size implant into the canal. (Fig 11) Final seating is performed using the HNM Medical Impactor fitted with the appropriately sized Impactor Tip until the implant is flush with the bone.

Surgical Pearl: It is advisable to have only instrument contact with the implant. This may be accomplished by grabbing the stem of the implant close to its base with a Kocher, inserting the stem into the canal, partially impact the implant, remove the Kocher and complete final impaction until the implant is flush with the bone. It is also suggested to insert the implant with the serial number dorsally.

Fig. 12



Once again, perform joint range of motion followed by closure of all layers with sutures of choice. (Fig 12)

Post-operative Protocol

The following recommendations are suggestions only. Each doctor must evaluate his or her own patient and how Physical Therapy Protocol applies to them. One must also consider any adjunct procedures to hemiarthroplasty that may prohibit or modify these recommendations. Physical therapy post-operative care should be done by Certified Physical Therapists or trained office podiatric assistants. These recommendations apply to the following:

- a) Hemiarthroplasty without first metatarsal osteotomy (may include other adjunct procedures which will accommodate full weight bearing and motion exercises.)
- b) Hemiarthroplasty with first metatarsal osteotomy (May include other adjunct procedures which will accommodate full weight bearing and motion exercises. Rigid forms of fixation required for distal osteotomies to accommodate motion and normal function.)

Post-Op Physical Therapy Protocol falls into two categories, doctors who believe in early and active return to natural motion (early return to normal shoe gear e.g. sneakers) vs. doctors who believe in more reserved and limited motion through the prolonged use of an approved post-op surgical shoe. Elements of post-op protocol may be applied to both schools of thought.

Protocol I: Begin 10-14 days post surgery with or without distal osteotomy
Length: 2-4 weeks

Criteria to initiate protocol:

- Wound closure without infection, strength of incision
- Proper implant fixation & alignment confirmed on x-ray
- Physician clearance

Goals:

- Breakup scar/wound adhesions
- Decrease edema
- Promote flexor hallucis brevis muscle activity and sesamoid complex
- Reduce pain
- Increase first MTP AROM & PROM
- Patient will be independent with an initial ROM/Ex program

Activities:

- Whirlpool @ 65-70o F with AROM
- AROM activities (toe wiggles, towel curls, alphabet exercise)
- Joint ROM exercises as instructed by physician
- At doctors' discretion, use of a mechanically assisted ROM device
- E-stim (in water bath)
- Myofascial/soft tissue mobilization massage
- Light compression tubular stockinette , 10mmhg pressure
- Icing after exercise: 20 min. on, one hour off.
- Sneaker wear

Protocol II: Begin 5th week

Length: 4-8 weeks

Goals:

- Further increase AROM & PROM
- Continue to reduce edema
- Normalize gait pattern and proprioception
- Increase foot & ankle strength

Activities:

- General ankle & lower extremity ROM/Strengthening
- Static & dynamic balance/proprioception activities
- Continued modalities (E-stim, WP, Ice/Heat, Compression)
- Continue specific first MTP range of motion

Precautions:

- No ultrasound
- Monitor standard soft tissue healing times for non-smoking patients only
- Osteoporosis patient may progress slower
- Take periodic x-rays to monitor implant position and fixative devices
- Post-op swelling may last 6-8 months in certain cases.

Clinical Results



Clinically Successful Performance Since 1952

The x-ray featured to the left is a 35 year post-op with an implanted First MPJ Hemi Implant. The First MPJ Hemi has been used for over 60 years with numerous studies supporting the design. (Listed below)

If you would like a copy of a First MPJ Hemi study, please contact the HNM Medical customer service department.

First MPJ Hemi Implant Studies

- Voskuijl, Timothy et al. Operative Treatment for Osteoarthritis of the First Metatarsophalangeal Joint: Arthrodesis Versus Hemiarthroplasty. *The Journal of Foot and Ankle Surgery* , Volume 54 , Issue 6 , 1085 - 1088
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- Warren S. Taranow, DO, Michael J. Moutsatson, DO, Jonathan M. Cooper, DO. Contemporary Approaches to Stage II and III Hallux Rigidus: The Role of Metallic Hemiarthroplasty of the Proximal Phalanx. *Foot Ankle Clin N Am.* 2005;10: 713– 728
- Thomas S. Roukis, DPM, AACFAS, and Charles O. Townley, MD. (2003) HNM Medical Resurfacing Endoprosthesis Versus Periarticular Osteotomy for Hallux Rigidus: Short-Term Follow-Up and Analysis. *The Journal of Foot & Ankle Surgery* 2003;42: 350-358.
- Eric Giza, MD and Martin R. Sullivan, MD. (2005) First Metatarsophalangeal Hemiarthroplasty for Grade III and IV Hallux Rigidus. *Techniques in Foot and Ankle Surgery* 2005;4: 10-17
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- Warren S. Taranow, DO and Judson R. Moore, PA-C, JD. Hallux Rigidus: A Treatment Algorithm. *Tech Foot & Ankle* 2012;11: 65–73

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3. Kissel CG, Husain ZS, Et Al. A Prospective Investigation of the HNM Medical Hemi-Arthroplasty for the First Metatarsophalangeal Joint. *Journal of Foot and Ankle Surgery.* 2008, 47: 505-509
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TOTAL RECON