

SURGICAL TECHNIQUE



kgtiTM

Kinetik Great Toe Implant System

kmi
KINETIKOS MEDICAL INC.

"Elegant Solutions for Extremity Challenges"

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DESCRIPTION

The Kinetik Great Toe Implant System is a two-piece, non-constrained implant for the total replacement of the 1st MPJ. This two-component system offers an alternative to fusion for the non-salvageable 1st MPJ.

FEATURES

- Two component system offers an alternative to fusion for the non-salvageable 1st MPJ.
 - Non-constrained implant allows for a full anatomic range of motion.
 - Dorsal flange on metatarsal component extends dorsal range of motion.
 - Biocompatible materials may cause less tissue reaction than non-metal implants.
 - Optimal stem design improves implant stability.
 - Interchangeable components and complete range of sizes provide a precise fit.
 - Simple instrumentation allows for reproducible results.
-

INDICATIONS:

The Kinetik Great Toe Implant is indicated for use in cases with painful loss of motion due to:

- Osteoarthritis of the first MPJ
 - Rheumatoid arthritis
 - Trauma
 - Hallux rigidus/limitus
 - Hallux valgus with degenerative joint disease
 - Prior surgery (including replacement of previously failed implants)
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CONTRAINDICATIONS:

Any condition that would contraindicate the use of a joint replacements in general, including:

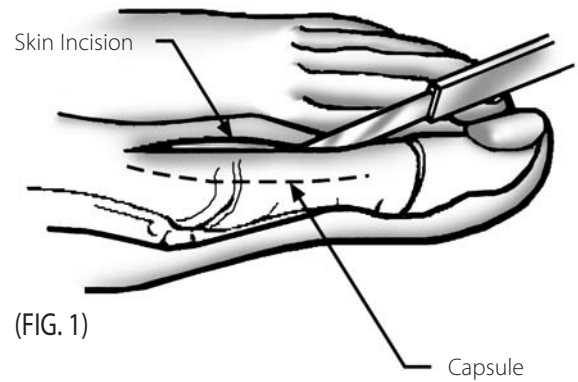
- Infection
- Poor bone quality
- Severe tendon, neurological or vascular deficiencies, or any concomitant disease



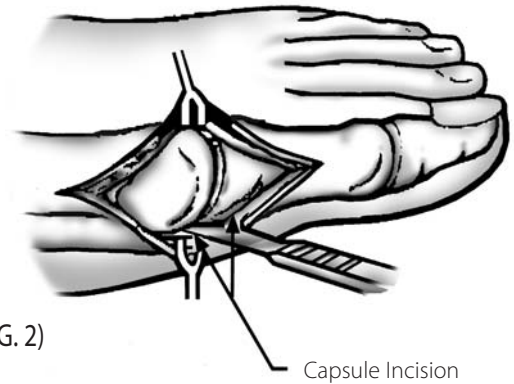
STEP
1

EXPOSURE

- Make a **linear incision over the medial aspect of the first MPJ** parallel to the EHL tendon to expose the metatarsal head and base (**Figure 1**).
- Obtain optimal exposure by completely releasing the capsular structures around the joint (**Figure 2**).



(FIG. 1)

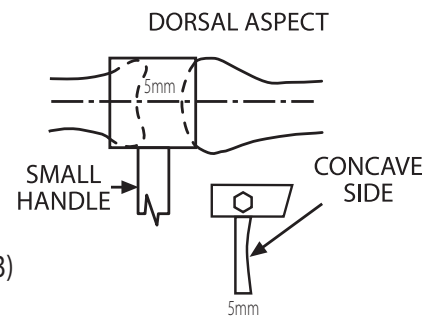


(FIG. 2)

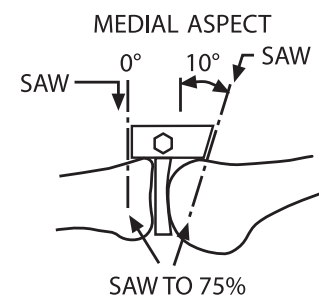
STEP
2

RESECTIONS OF THE PHALANX & METATARSAL

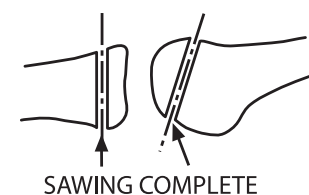
- Remove minimal bone from the dorsal surface of the metatarsal head to provide an even surface for the **0mm or 5mm Primary Resection Guide (Instrument #1)** to rest upon.
- Evaluate the soft tissue and bony anatomy of the proximal phalanx to determine which Primary Resection Guide to use.
- The **0mm Guide** removes only the amount of bone replaced by the implant.
- The **5mm Guide** removes an additional 5mm from the phalanx only. The **5mm Guide is recommended for a tight joint (Figure 3)**.
- The Small Handle or the 90° Handle fit with the primary resection guides to facilitate insertion of the guides and provide stability while resecting.
- Place the Stem of the Primary Resection Guide between the proximal phalanx and the distal metatarsal. Slide it plantarly until it rests on the dorsal surfaces of the metatarsal head and the proximal phalanx. The **concave surface of the Guide should always be placed toward the metatarsal**.
- Holding the Guide in the position that the hallux should articulate with the metatarsal, place the saw blade against the side of the Cutting Guide and **cut approximately 75%** of the way through each resection (**Figure 4**).
- Remove the Guide and complete the resections.



(FIG. 3)



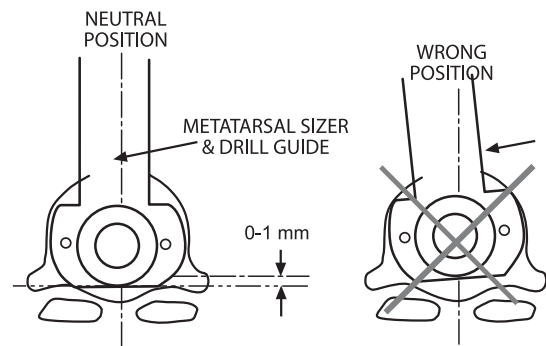
(FIG. 4)



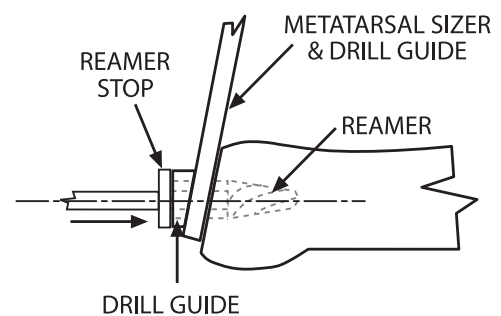
STEP 3

SIZE METATARSAL AND CREATE PILOT HOLE

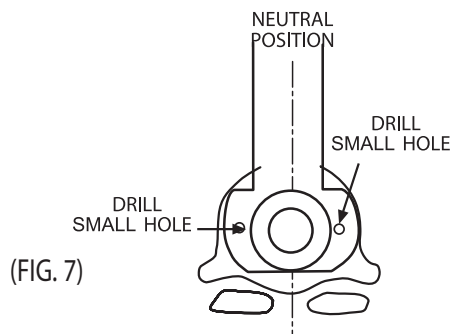
- Place the **Metatarsal Sizer & Drill Guide** (**Instrument #2**) over the profile of the resected Metatarsal Head to estimate the metatarsal size (**Figure 5**).
- The plantar aspect of the sizer corresponds with the plantar aspect of the implant.
- The plantar aspect of the Sizer should be positioned **0-1 mm above the most dorsal aspect of the sesamoidal grooves**.
- Start drilling a pilot hole through the Drill Guide with the **M/P Reamer (Instrument #3)**. Check to see that the hole is located in the center of the metatarsal before completing the pilot hole (**Figure 6**).
- With the Metatarsal Sizer & Drill Guide in place, use a **.045" k-Wire** or a **Drill Bit less than 1.5mm** in diameter to make holes on either side of the pilot hole to facilitate placement of the **dorsal flange Resection Guide (Instrument #4)** (**Figure 7**).



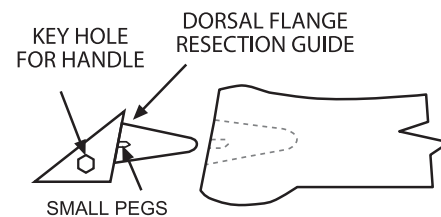
(FIG. 5)



(FIG. 6)



(FIG. 7)

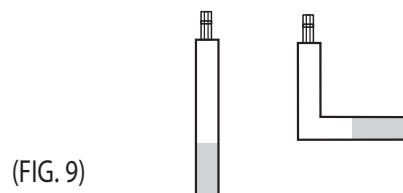


(FIG. 8)

STEP 4

DORSAL FLANGE RESECTION

- Position the **Dorsal Flange Resection Guide** so that the central peg is placed in the previously formed pilot hole and the small pegs fit within the pre-drilled smaller holes (**Figure 8**).
- The small handle or the 90° handle fit with the Dorsal Flange Resection Guide to facilitate the insertion of the Guide and provide stability while resecting (**Figure 9**).
- Make sure the alignment is correct.
- Using the angled surface as a guide for the saw, **make the dorsal cut (Figure 10)**.



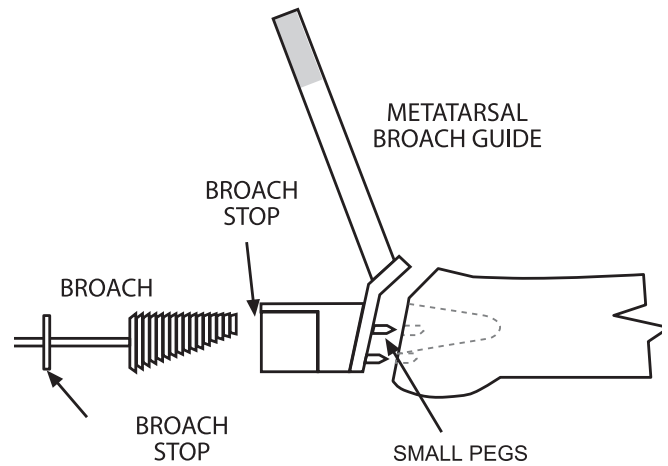
(FIG. 9)



(FIG. 10)

BROACH METATARSAL STEM HOLE

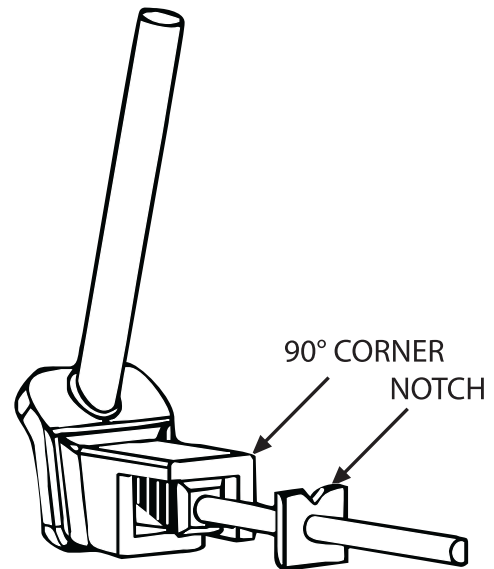
- Position the right or left **Metatarsal Broach Guide (Instrument #5)** over the metatarsal cuts with the top pins placed in the previously drilled small holes. A mallet can be used to seat the Broach Guide flush with the bone (**Figure 11**).



(FIG. 11)

- Broaching may be done with a **reciprocator** (power) or through the use of a **mallet** (manual).

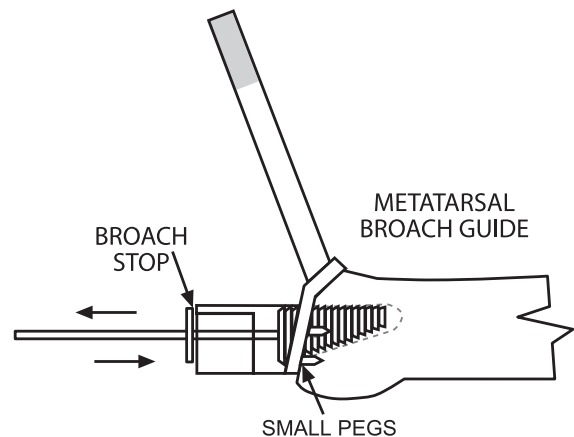
- Place the correct **Metatarsal Broach (Instrument #6)** through the **square hole** with the **notch** in the stop pointing dorsal and the **90° corner** of the Broach aligned with the 90° corner of the guide (**Figure 12**).



(FIG. 12)

- Broach the stem hole with an in-and-out motion until the stop on the broach **abuts the outer most edge of the Guide (Figure 13)**.

- For cemented application, remove the broach guide and broach the hole deeper. This will enlarge the hole equally on all sides to provide an even cement mantle.

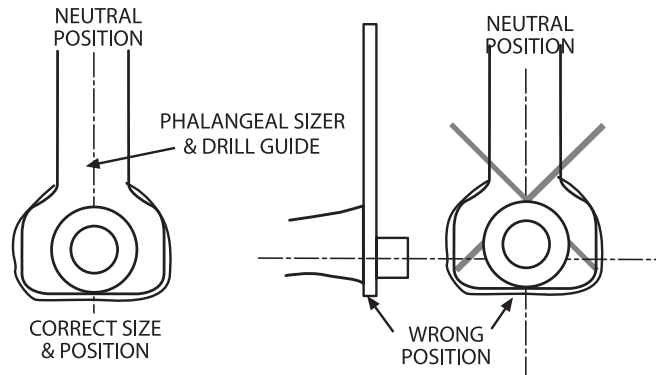


(FIG. 13)

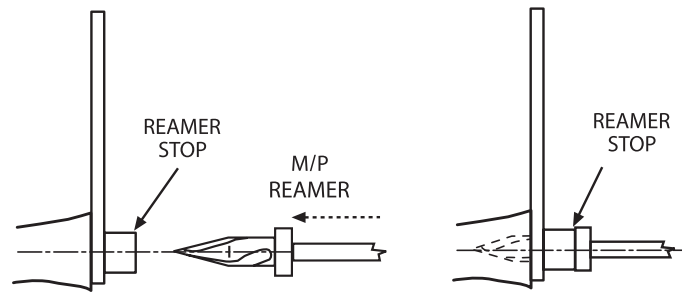
STEP 6

SIZE PHALANX AND CREATE PILOT HOLE

- Use the **Phalangeal Sizer and Drill Guide (Instrument #7)** to size the proximal phalanx.
- Make sure the profile of the sizer provides **adequate coverage** of the resected surface (**Figure 14**).
- With the **Phalangeal Sizer and Drill Guide** held in place over the proximal phalanx, drill a few millimeters with the **M/P Reamer (Instrument #3)** and check to see that the hole is evenly placed medial to lateral and just dorsal to the medullary canal.
- Continue to drill the central hole with the **M/P Reamer** until the Reamer abuts the stop on the guide (**Figure 15**).



(FIG. 14)

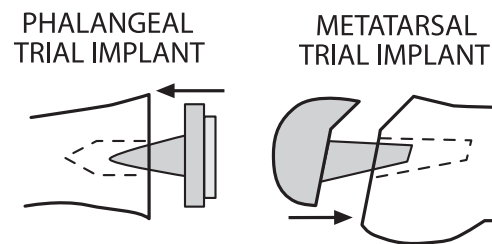


(FIG. 15)

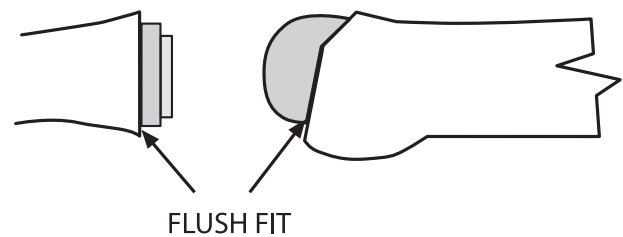
STEP 7

TRIAL IMPLANTATION

- Place the **Trial Phalangeal Stem** of the pre-determined size into the reamed hole of the proximal phalanx (**Figure 16**). Make sure the Trial Implant is **slightly larger** than the resected base of the phalanx.
- Align the **Metatarsal Stem** of the correctly sized Metatarsal Trial into the broached hole of the Metatarsal Head (**Figure 17**). Remodel the Metatarsal Head to contour the bone to the Implant.
- Reduce the joint and check for range of motion.
 - If the joint is **too tight**, resect additional bone from the proximal phalanx parallel to the previous resection.
 - If the joint is **too lax**, test a larger metatarsal component.
- For optimal range of motion, **free up the plantar sesamoids**.



(FIG. 16)

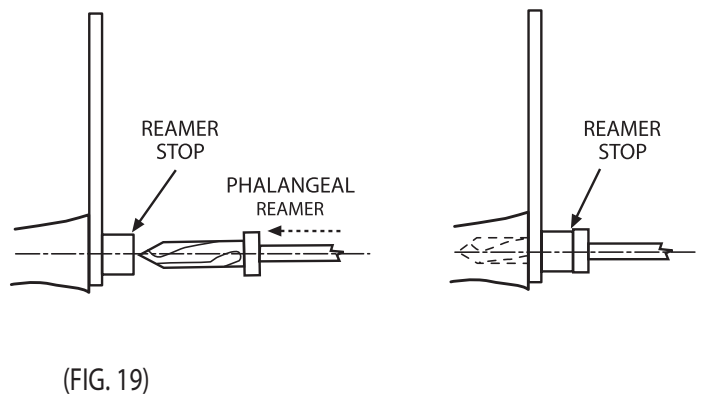
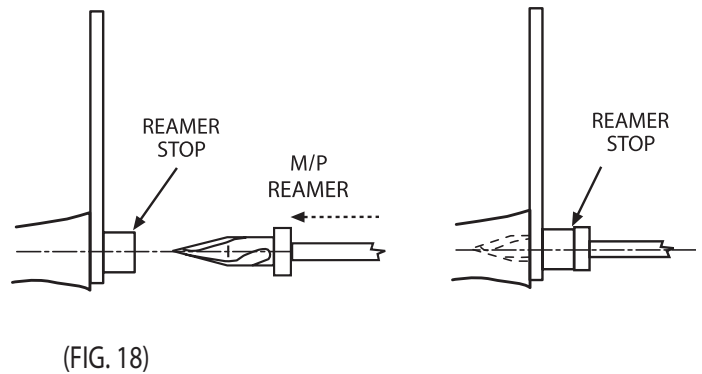


(FIG. 17)

STEP
8

REAM PHALANGEAL STEM HOLE

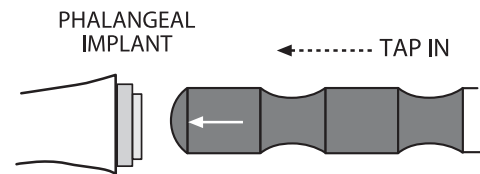
- The **M/P Reamer** provides a small hole for the Phalangeal Trial Implant (**Figure 18**).
- After trial implantation, place the **phalangeal Sizer and Drill guide** over the resected surface of the proximal phalanx and use the **Phalangeal Reamer (Instrument #8)** to **enlarge the pilot hole** to accept the Stem of the actual Phalangeal Implant (**Figure 19**).
- For cement application, remove the Phalangeal Sizer and Drill Guide and ream the hole deeper.



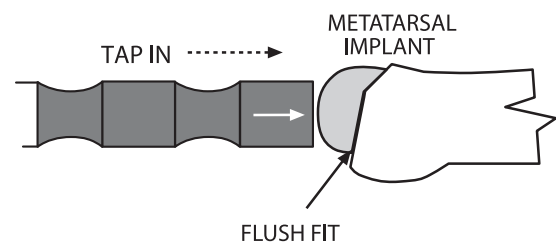
STEP
9

IMPLANTATION AND CLOSURE

- Flush the area with copious amounts of irrigating solution.
- Place the **stem of the Phalangeal Implant into the reamed cavity of the proximal phalanx** and tap into place with the Phalangeal Impactor and a mallet (**Figure 20**).
- Align the **stem of the metatarsal implant in the prepared cavity of the metatarsal** and tap into place with the Metatarsal Impactor and a mallet (**Figure 21**).
- Reduce the joint and re-check the range of motion.
- Close the incision.



(FIG. 20)



(FIG. 21)

POST-OP/FOLLOW-UP

The foot is kept elevated for 72 hours. Ambulation is in a post-operative shoe and may be increased to tolerance after 72 hours. Passive range of motion begins several days post-op, with active motion on the 1st MPJ beginning in two weeks.



Kinetik Great Toe Implant System



FEATURES

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- Biocompatible materials may cause less tissue reaction than non-metal implants.
- Optimal stem design improves implant stability.
- Interchangeable components and complete range of sizes provide a precise fit.
- Simple instrumentation allows for reproducible results.

Pain relief with range of motion: the total solution

INSTRUMENT SET



PART NO.	DESCRIPTION	SIZE
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Implants

01-2002	Metatarsal Component	Size 1, Right
01-2003	Metatarsal Component	Size 1, Left
01-2004	Metatarsal Component	Size 2, Right
01-2005	Metatarsal Component	Size 2, Left
01-2006	Metatarsal Component	Size 3, Right
01-2007	Metatarsal Component	Size 3, Left

01-2010	Phalangeal Component	Size 0
01-2012	Phalangeal Component	Size 1
01-2014	Phalangeal Component	Size 2
01-2016	Phalangeal Component	Size 3

COMPONENT MATERIALS

- Metatarsal Component: Cobalt Chrome
- Phalangeal Component: Titanium Alloy and Polyethylene (UHMWPE)

Single Use Instruments

01-5080	M/P Reamer
01-5090	Phalangeal Reamer

01-5000	Instrument Set
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