



A TRADITION OF QUALITY AND INNOVATION

ENCOMPASSTM
Metatarsal Resurfacing Implant

SURGICAL TECHNIQUE GUIDE



INDICATIONS

The OsteoMed Metatarsal Resurfacing Implant, a hemi-arthroplasty implant for the metatarsophalangeal joint (MTP), is indicated for use in the treatment of 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 limitus, hallux valgus, hallux rigidus, and an unstable or painful MTP joint. The OsteoMed Metatarsal Resurfacing Implant is intended to be used with bone cement or press fit without bone cement. The OsteoMed Metatarsal Resurfacing Implant is intended for single use only.

CONTRAINDICATIONS

Use of the OsteoMed Encompass™ Metatarsal Resurfacing Implant System is contraindicated:

- in cases of active or suspected infection or in patients who are immunocompromised;
- in patients previously sensitized to cobalt chromium or titanium
- in patients with certain metabolic diseases
- in patients exhibiting disorders which would cause the patient to ignore the limitations of artificial joint replacement

This system is further contraindicated in serious systemic diseases. The Encompass™ System should not be used in cases where the remaining bone is too diminished to provide adequate width or height to surround the implant. Implant failure may occur in cases where there is insufficient available bone or poor bone quality or in patients with blood supply limitations. Use of the implant is further contraindicated in cases of significant angular or biomechanical deformities or in cases which would subject the implant to excessive stress or wear due to patient weight and/or activity level.

DEVICE DESCRIPTION

The OsteoMed Metatarsal Resurfacing Implant is a one piece implant designed to replace the distal head of the 1st metatarsal, and provide a smooth articular surface for the adjacent phalangeal base. The implant is available in several sizes in direct proportion to the anatomic construct of the metatarsal head (implant head sizes range from 15mm to 19mm). The implant has a concave spherical inner surface that is coated with titanium plasma and hydroxyapatite coatings. The implants are characterized by a single, proximal stem which is press fit or fixated via bone cement into the intramedullary canal of the distal metatarsal.

Instructions for use

1. A dorsal incision is made from the distal third of the shaft of the first metatarsal to a point midway along the shaft of the proximal phalanx. The incision is medial to the extensor longus hallucis tendon.

1



The incision is deepened to expose the capsule of the first metatarsophalangeal joint. The capsular tissues are carefully dissected from the base of the proximal phalanx and first metatarsal head.

2. Using a sagittal saw, remove the medial bony eminence and any metatarsal dorsal lateral osteophytes from the metatarsal head. Irrigate thoroughly and check motion of the “reconstructed” joint for any impingement.

CAUTION: Avoid impingement of the sesamoids. If the sesamoids are immobile, the surgeon may elect to release them.

NOTE: Frequent and copious lavage throughout the procedure is beneficial.

2



3. Implant size selection corresponds with the drill guide size. Care should be taken to select the size which approximates the dimensions of the metatarsal and does not extend beyond the margins of the bone.

The drill guide should cover the metatarsal head from medial to lateral and dorsal to plantar. Place appropriate sized drill guide on the metatarsal head. Drill guides are sized to match the corresponding implant.

Instructions for use

4. Drive the guide pin into the center of the metatarsal shaft until the first calibration mark in the grouping point is flush with the top of the stainless steel portion of the drill guide. (Figure 1)

CAUTION: Placement of the drill guide will determine the position of the guide pin, the trial and, ultimately, the implant.

4

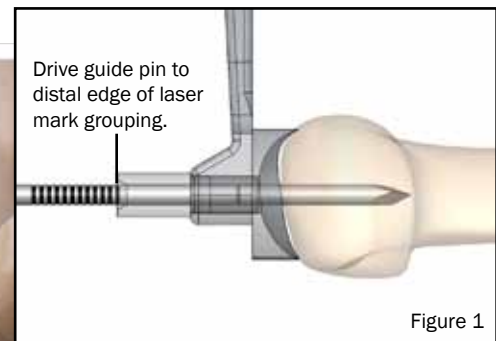


Figure 1

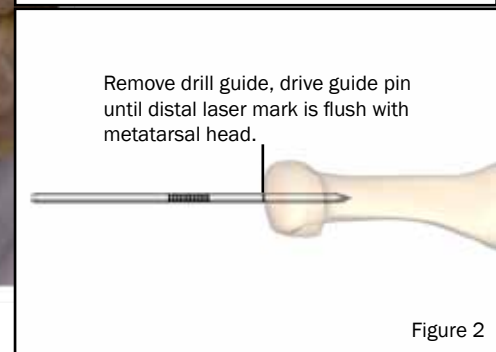


Figure 2

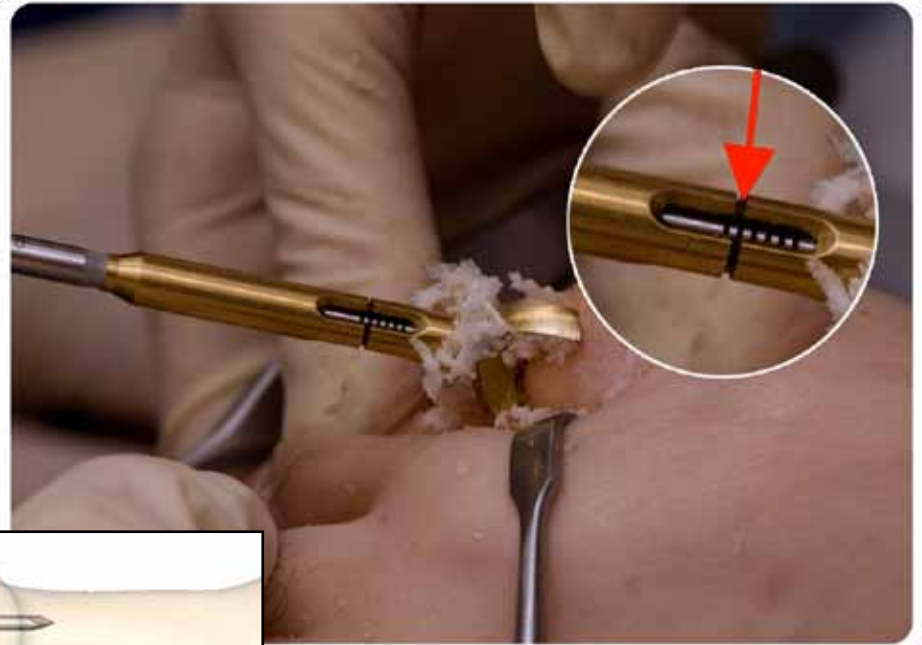
NOTE: The resulting orientation of the guide pin should be at the midpoint of the metatarsal head. The guide pin should be within and parallel to the cortical surfaces.

NOTE: Intraoperative fluoroscopy should be used to visualize the metatarsal shaft and confirm positioning of the guide pin.

Remove the drill guide and drive guide pin until distal laser mark is flush with the metatarsal head. (Figure 2)

Irrigate the site.

5. Select the spherical reamer which matches the corresponding drill guide. Once the reamer is fully seated against the metatarsal head, the zero calibration mark on the guide pin will be visible (Figure 4). Ream the metatarsal bone an additional 2-3mm until all articular cartilage is removed and bleeding bone is present. (Figure 5)



5

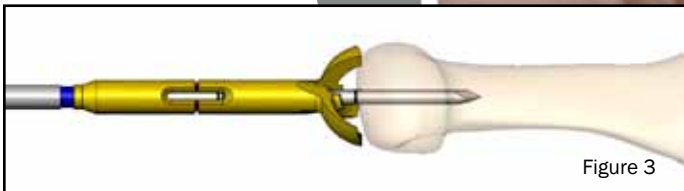


Figure 3

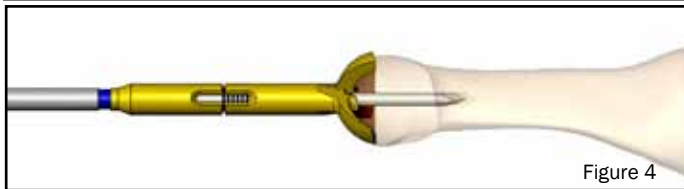


Figure 4

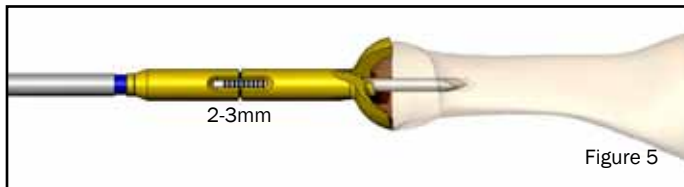


Figure 5

NOTE: The zero calibration mark on the guide pin may not be visible until the reamer is fully seated against the metatarsal head.

CAUTION: Only ream 2-3mm to avoid impingement of the sesamoid bones.

Remove the spherical reamer and guide pin.

Instructions for use

6. Select and place the trial corresponding to the size of the spherical reamer and drill guide previously used. Assess amount of reamed bone and trial placement. The trial should sit flush on the reamed bone surface.

With trial implant in place, use a bone marking pen to outline the excess bone around the trial component, reducing the potential for damaging the final implant once it is in place. After removing the trial use a saw, rasp, bur or rongeur to remove the excess bone outlined.

6



Confirm that the metatarsal length has been adjusted properly, and then check the joint for range of motion and stability.

NOTE: If desired, greater dorsiflexion may be accomplished by reaming more of the metatarsal bone.

NOTE: If trial size is not desired, insert guide pin back into its previous location and repeat steps 5 and 6 using the next smaller sized spherical reamer and trial.

7. After confirming trial size and orientation via step 6, mark the location of the trial alignment groove on the dorsal aspect of the metatarsal head with a marking pen.



7

Remove the trial.

8. When broaching the bone, align the groove on the broach with the pen mark line made on the dorsal aspect of the metatarsal bone in step 7. To insert the broach, the slaphammer or mallet technique may be used. Place the broach into the reamed canal until the broach bottoms out on the metatarsal head. Ensure the broach stem is in the intramedullary canal and does not violate cortical bone.

CAUTION: Ensure that the broach alignment groove remains positioned with the bone pen marking made on the dorsal aspect of the metatarsal head while driving the broach to prevent undesirable final implant orientation.

NOTE: If difficulty occurs while inserting the broach, remove and clean, and then re-insert the broach.



8

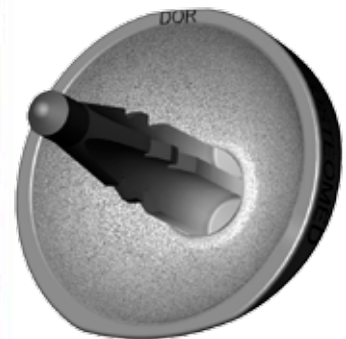
Instructions for use

9. Final implant is selected and visually inspected for any defects or scratches due to mishandling. The EnCompass™ implant is partially inserted into the metatarsal and rotated to the proper orientation. The implant is marked to indicate the dorsal side. Use the impactor to fully seat the implant against the metatarsal bone.

9



NOTE: DOR (Dorsal)



10. Once fully implanted, check alignment, range of motion and carefully check soft tissue balance. Perform any adjustments if the alignment, range of motion, component fixation, or soft tissue balance is suspect.



NOTE: Intraoperative fluoroscopy should be used to visualize the metatarsal shaft and confirm positioning of the final implant.

11. Remove any debris from the joint space or implant, irrigate, and then close using standard closure techniques.

Reamers

- 386-1215 EnCompass™ 15mm Reamer
- 386-1216 EnCompass™ 16mm Reamer
- 386-1217 EnCompass™ 17mm Reamer
- 386-1218 EnCompass™ 18mm Reamer
- 386-1219 EnCompass™ 19mm Reamer



Drill Guides

- 386-1015 EnCompass™ 15mm Drill Guide
- 386-1016 EnCompass™ 16mm Drill Guide
- 386-1017 EnCompass™ 17mm Drill Guide
- 386-1018 EnCompass™ 18mm Drill Guide
- 386-1019 EnCompass™ 19mm Drill Guide



Trials



- 386-1315 EnCompass™ 15mm Trial
- 386-1316 EnCompass™ 16mm Trial
- 386-1317 EnCompass™ 17mm Trial
- 386-1318 EnCompass™ 18mm Trial
- 386-1319 EnCompass™ 19mm Trial

Other Instruments



386-1551 EnCompass™ Shaft

386-1500 EnCompass™ Broach



320-0417 Quick Release Adapter



386-1560-01 EnCompass™ Slaphammer



386-1100 EnCompass™ Guide Pin



386-1600 EnCompass™ Impactor



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