OSTEOMED®

A TRADITION OF QUALITY AND INNOVATION

HEMI™

SURGICAL TECHNIQUE GUIDE

Great Toe Implant

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SURGICAL TECHNIQUE GUIDE

DANGER DANGER indicates an imminently hazardous situation which, if not avoided, will result in death or serious injury.

WARNING WARNING indicates a potentially hazardous situation which, if not avoided, could result in death or serious injury.

CAUTION CAUTION indicates a potentially hazardous situation which, if not avoided, may result in minor or moderate injury.

CAUTION CAUTION used without the safety alert symbol indicates a potentially hazardous situation which, if not avoided, may result in property damage.

INDICATIONS

The **OSTEOMED** 1st MPJ Hemi Implant System is intended for use in the treatment of patients with inflammatory arthritis in the first metatarsal joint in the presence of good bone stock and integrity of the first metatarsal head, along with the following clinical conditions: hallux valgus, hallux rigidus and an unstable or painful metatarsophalangeal joint. **OSTEOMED** 1st MPJ Hemi Implant System implants are intended for single patient use only.

CONTRAINDICATIONS

Use of the **OSTEOMED** 1st MPJ Hemi Implant System is contraindicated in cases of active or suspected infection or in patients who are immunocompromised; in patients previously sensitized to the implant material; in patients with certain metabolic diseases; or 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 **OSTEOMED** 1st MPJ Hemi Implant 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 implants to excessive stress or wear due to patient weight and/or activity level.

WARNINGS

WARNING

The **OSTEOMED** 1st MPJ Hemi Implant System implants are not intended to endure excessive functional stresses. Such stresses may lead to accelerated implant wear and/or failure.

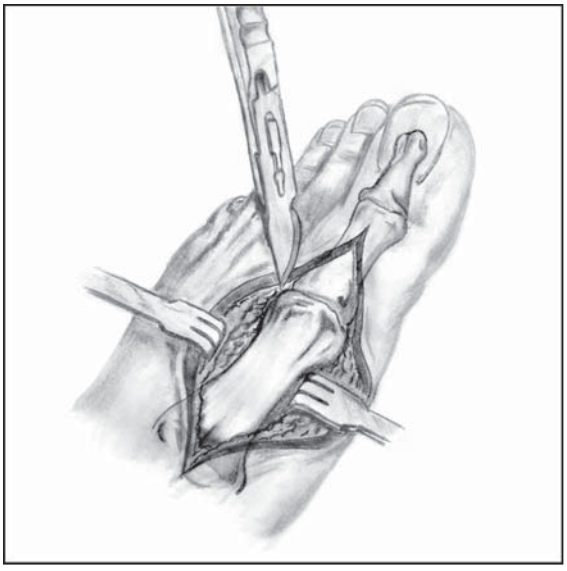
WARNING

Protect Implant surfaces from scratching or other surface damage. Such damage may lead to accelerated implant failure. Avoid direct impact on implants with hammers or other instruments.

Instructions for Use

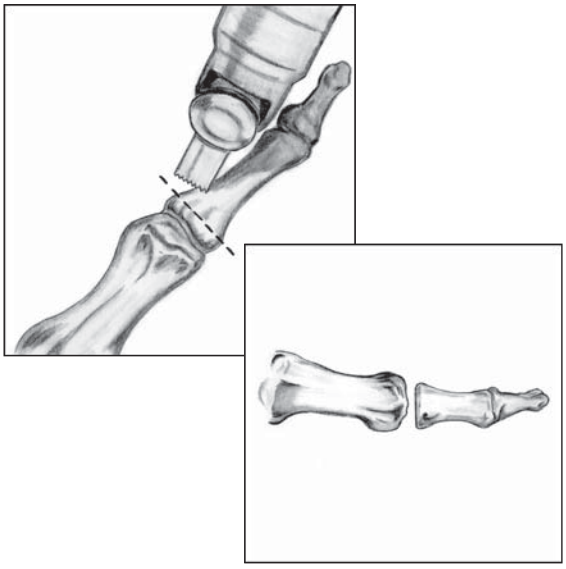
1 The 1st Metatarsal Phalangeal Joint is exposed through a 4cm to 5cm dorsal medial incision with appropriate dissection to expose the joint capsule.

2 The skin is retracted and an incision is made to the bone, in-line with the skin incision. The capsular tissues are carefully dissected from the base of the proximal phalanx and first metatarsal head, on the medial, dorsal, and anterolateral aspect.

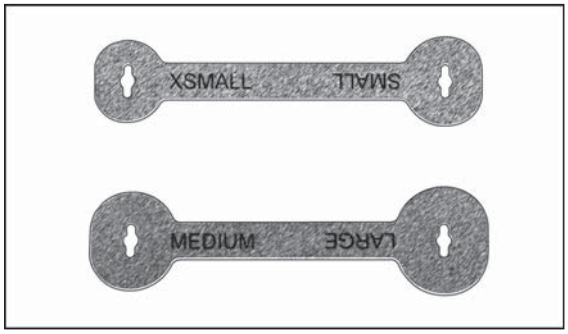


3 Osteophytes are resected completely from the lateral, dorsal, and medial aspects of the metatarsal head to allow normal range of motion. Check motion of the "new" joint for any impingement.

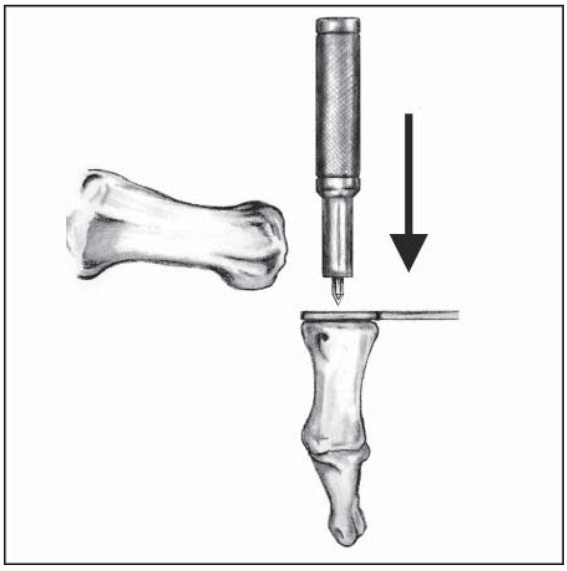
4 Resect 2mm to 8mm of the articular surface of the phalanx, removing only sufficient bone to avoid prosthetic overspacing and excessive joint tension and to accommodate the thickness of the articulating plate of the implant. The plane of the resection should be parallel to the plane of the concavity of the phalangeal articular surface.



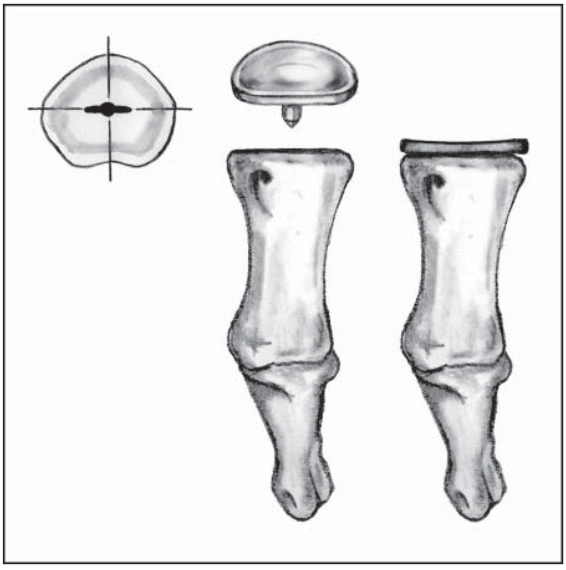
5 Implant size selection is made using the sizers. Care should be taken to select the size which approximates the dimensions of the osteotomized phalanx and does not extend beyond the margins of the cut surface. Sizers feature a center hole/slot which is used as a guide for the punch instrument.



6 Using the sizer as a guide, use the punch instrument and a mallet to create a small hole in the center of the bone. This hole will serve to center the instrumentation to assist in placing the implant.

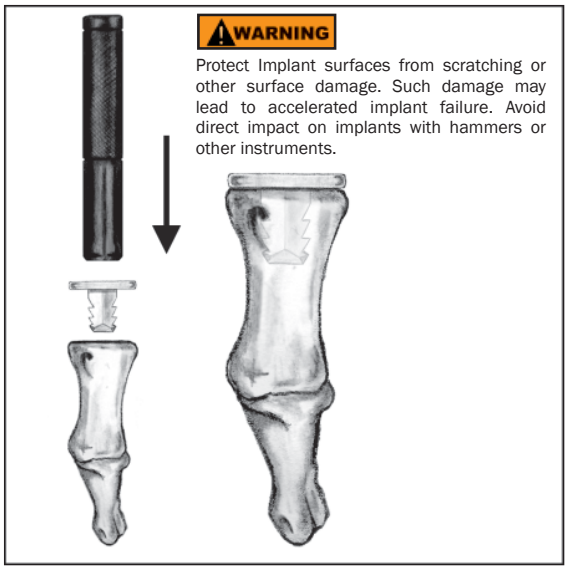


7 The trial, corresponding to the selected size implant, is then inserted into the phalangeal medullary canal using the impactor and a mallet. The joint is then reduced and is examined for tension and motion. If the joint is too tight, remove the trial and resect an appropriate amount of additional bone from the proximal phalanx. **An overly tight joint may result in limited motion and contraction hallux deformity post surgery.**



8 Reinsert the trial and reassess range of motion. A normal range of concentric, unimpinged motion, particularly in dorsiflexion, should be demonstrated. Final remodeling is performed to assure that the entire bone is covered by the implant; the trial is removed.

9 Once the appropriate size implant is determined and the first metatarsal head remodeled, the implant is fitted into place. Using the impactor, impact the implant until it is flush with the bone.



10 With all the components implanted, check alignment, range of motion and carefully inspect soft tissue balance. Perform any adjustments if the alignment, range of motion, component fixation, or soft tissue balance is suspect. Remove any debris from the joint space or implant, irrigate, then close using standard closure techniques.

11 The patient is allowed to ambulate with weight bearing to tolerance on the operated foot within limits imposed by postoperative discomfort, utilizing modified foot gear (a soft bedroom slipper, a postoperative type shoe, or a cutout in a standard shoe). The progression to normal ambulation and the use of standard foot gear is limited only by the persistence of postoperative swelling and discomfort.

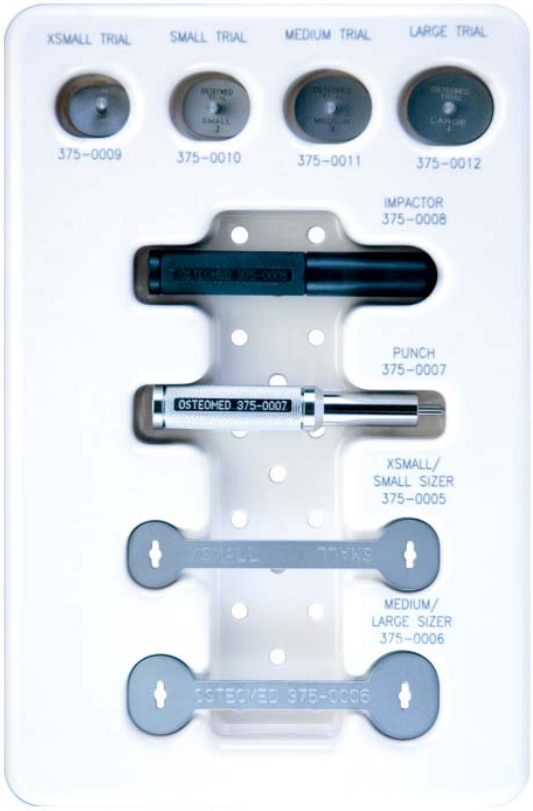
INSTRUMENTS

375-0009

375-0010

375-0011

375-0012



375-0000

375-0008

375-0007

375-0005

375-0006

375-0001

375-0002

375-0003

375-0004

Part Number	Description
375-0000	Hemi Great Toe Implant Instrument Kit
375-0001	Hemi Great Toe Implant, Extra Small
375-0002	Hemi Great Toe Implant, Small
375-0003	Hemi Great Toe Implant, Medium
375-0004	Hemi Great Toe Implant, Large
375-0005	Hemi Great Toe Implant Sizer, Extra Small/Small
375-0006	Hemi Great Toe Implant Sizer, Medium/Large
375-0007	Hemi Great Toe Implant Punch
375-0008	Hemi Great Toe Implant Impactor
375-0009	Hemi Great Toe Implant Trial, Extra Small
375-0010	Hemi Great Toe Implant Trial, Small
375-0011	Hemi Great Toe Implant Trial, Medium
375-0012	Hemi Great Toe Implant Trial, Large
375-0013	Hemi Great Toe Implant Autoclave Tray

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