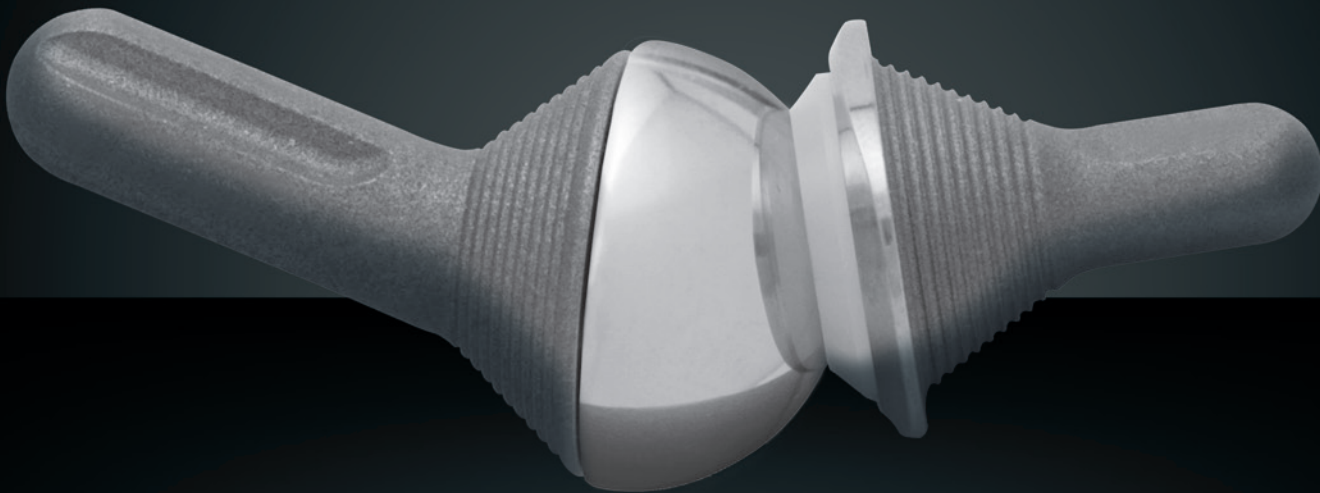


ReFlexion™

1st MTP Implant System

Surgical Technique Guide



Rethinking Possibilities, Reshaping Lives

ReFlexion™

1st MTP Implant System

SURGICAL TECHNIQUE GUIDE



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



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



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



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

INDICATIONS

The **OSTEOMED** ReFlexion Toe System (RTS) is indicated for reconstruction of the severely disabled and/or painful metatarsal-phalangeal joints resulting from osteoarthritis, rheumatoid arthritis, arthritis secondary to trauma or failure of prior arthroplasty. **Device is intended for bone cemented use only.**

CONTRAINDICATIONS

Use of the RTS is contraindicated in cases of active or suspected infection; in patients sensitive to the implant materials or in patients with bone quality or joint mechanics which would be insufficient to support an implant. Use of the implant is further contraindicated in cases of significant angular or biomechanical deformities or cases in which the implant would be subjected to excessive stresses or wear due to patient weight, activity level or in patients who may ignore the limitations of artificial joint replacement.

PRECAUTIONS

Before clinical use, the surgeon should be familiar with all aspects of the ReFlexion Toe System, its instrumentation, indications, contraindications and the surgical technique protocol. Accepted surgical practice should be followed in postoperative care. **PATIENTS SHOULD BE ADVISED OF THE LIMITATIONS OF THEIR PROSTHESIS AND SHOULD BE INSTRUCTED TO GOVERN THEIR ACTIVITIES ACCORDINGLY.**

CAUTIONS



To ensure proper implant fit, only RTS instruments and trials should be used to implant the device. Failure to correctly select, assemble and implant the prosthesis components could contribute to joint instability and lead to premature failure.

Patients should be followed closely after surgery for any signs of implant movements and/or loosening.

Dull instruments may compromise the fit of the implant.

GOALS AND OBJECTIVES

The objective of the procedure is to optimize the fit and position of the implants in the metatarsal and phalangeal bones.

FIT

When properly implanted, the implant components should fit precisely between the bone and the implant interface. The conical portion of the implant should be supported by the endosteum of the metaphyseal flare in order to allow load transfer to the bone most capable of providing long-term stability for the implant.

POSITION

While the design of the system does allow for some slight adjustment of joint alignment, the implant cannot be expected to overcome significant biomechanical problems such as hallux valgus or a long or elevated first ray. The implant components should be positioned to maximize fit and bony support. Significant biomechanical problems should be addressed by other means such as orthotics, soft tissue correction, or osteotomy.

In the sagittal plane, the metatarsal component should be positioned low within the metatarsal metaphysis to minimize any elevation of the metatarsal head. Care should be taken to avoid impingement of the sesamoids. The metatarsal component should also be positioned far enough proximally to maintain or possibly reduce metatarsal length.

The phalangeal component should be positioned centrally in the phalangeal base. The position of the articulating surface with respect to soft tissue forces will have an effect on the angle and motion of the hallux. However, since the articulating surfaces of the implant are spherical, the angular orientation of the phalangeal component will not have any effect on the resulting angle of the hallux.

WARNINGS



Do not use implant if sterile package is damaged.

DO NOT OPERATE REAMERS AT SPEEDS ABOVE 1000 RPM.

INITIAL RESECTION

1 METATARSAL HEAD

Remove 4-5mm of bone with a sagittal or oscillating saw (Figure 1). Orient the blade to remove more bone dorsally versus plantar.

The bone cuts are performed to create a relatively flat surface on which to start the guide pin and to create space to plantar flex the hallux in order to access the canals of the metatarsal and the phalanx.

Note: This cut is not critical to final implant fit, position or alignment.

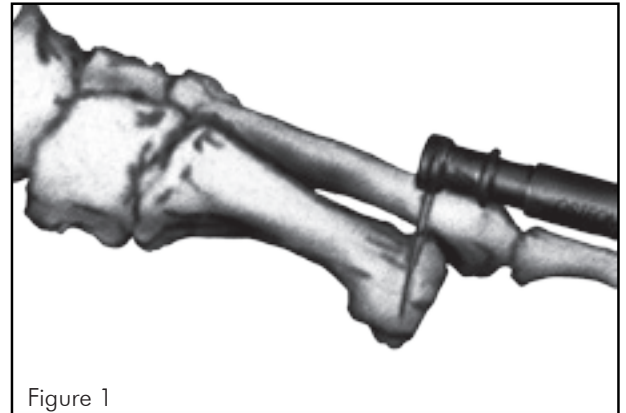


Figure 1



AVOID IMPINGEMENT OF THE SESAMOIDS

2 PHALANGEAL BASE

Remove approximately 3-4mm of bone (Figure 2).

This cut should pass through the subchondral bone distal to the concave surface of the phalangeal base. Leave the intrinsic plantar flexors and the sesamoid apparatus attachments intact, if possible.

Note: This cut is not critical to final implant fit, position or alignment.

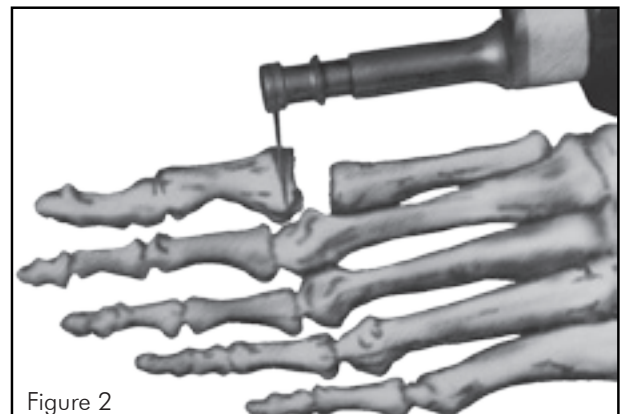
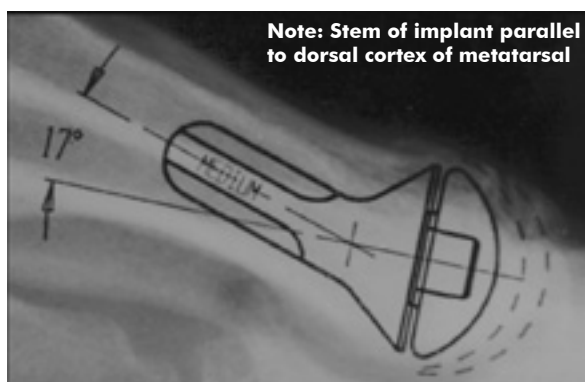


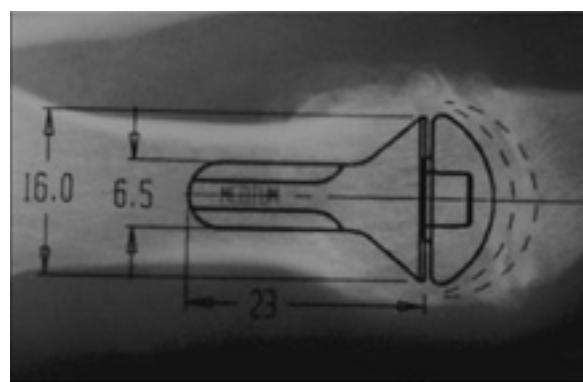
Figure 2

3 SESAMOIDS

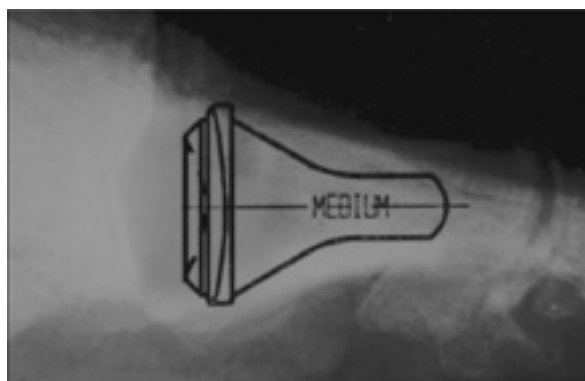
If the sesamoids are immobile, the surgeon may elect to release them with a McGlamery type elevator.



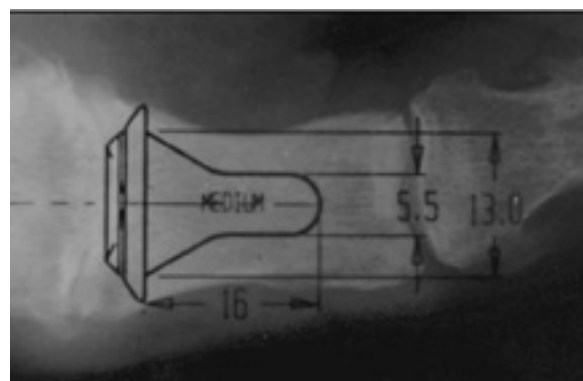
Template of metatarsal stem and head positioned over pre-operative lateral radiograph of 1st metatarsal.



Template of metatarsal stem and head positioned over pre-operative dorsal-plantar radiograph of 1st metatarsal.



Template of phalangeal component positioned over pre-operative lateral radiograph of proximal phalanx.

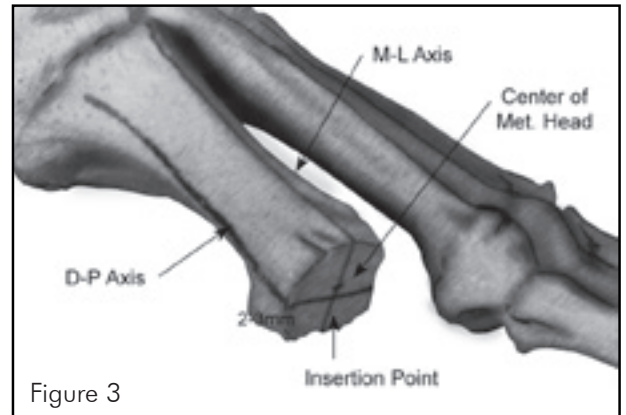


Template of phalangeal component positioned over pre-operative dorsal-plantar radiograph of proximal phalanx.

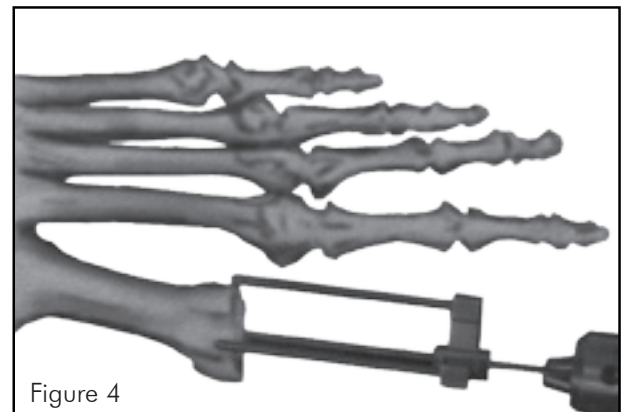
METATARSAL PREPARATION

1 INSERTION OF GUIDE PIN

Locate the Metatarsal Guide Pin insertion point on the metatarsal head (Figure 3). This point is generally centered M-L and 2-3 mm more plantar than dorsal on the metatarsal head.



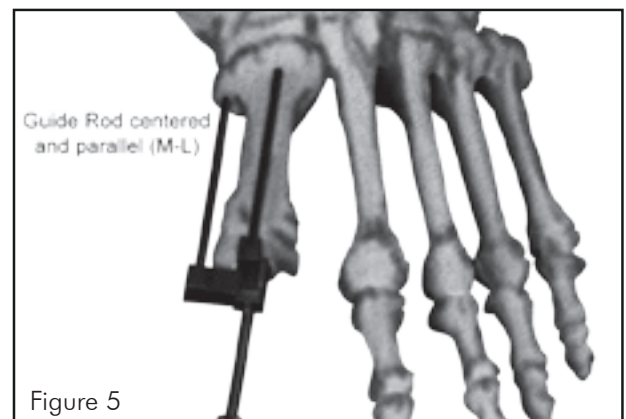
With the Metatarsal Guide Pin chucked in a drill or wire driver, slide the pin through the Alignment Guide and push the point of the pin slightly into the bone at the insertion point (Figure 4).



2 ALIGNMENT

With one of the Alignment Guide Rods over the dorsal aspect of the metatarsal and the other over the medial aspect, tilt the drill and Guide Pin until the Guide Rods are parallel and centered on the metatarsal (Figures 5 & 6).

Reposition the insertion point if the Alignment Rods are not centered on the metatarsal in either the M-L or D-P plane.



NOTE: Make sure the Metatarsal Guide Pin is properly placed because the position and angle of the Metatarsal Guide Pin determine the final position of the metatarsal component.

As an alternative or adjunct to the use of the alignment device, a “mini-C-arm” can be used to visualize the metatarsal shaft and aid in positioning the Guide Pin.

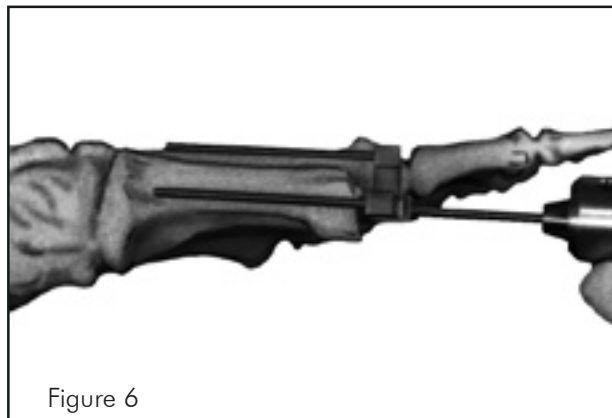


Figure 6

3 INSERTION OF THE GUIDE PIN

Drive the Metatarsal Guide Pin into the metatarsal canal to a point beyond the isthmus of the metatarsal but short of the metatarsal base.



Do not drive the Metatarsal Guide Pin into or beyond the metatarsal-cuneiform joint.

NOTE: Once the Metatarsal Guide Pin has penetrated the dense bone of the metatarsal head, it should advance freely through the intramedullary canal. If continuous resistance is encountered, it is likely that the pin is misdirected and is engaging the cortical wall of the metatarsal diaphysis. If this is the case, check alignment and insertion point and redirect the pin. Resistance should be encountered as the tip of the pin meets the cortical bone of the metatarsal base. At that point, remove the pin and replace it with the blunt Guide Pin.

Inserting the Blunt Guide Pin

To reduce the potential of penetrating the metatarsal-cuneiform joint during reaming, replace the Metatarsal Guide Pin with the blunt Guide Pin. Seat the pin into the base of the metatarsal by tapping it gently with a mallet.

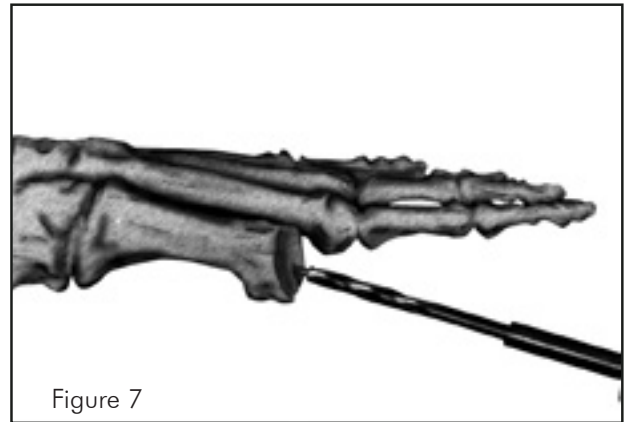
NOTE: A final check of the Guide Pin alignment is advised.

4 CYLINDRICAL REAMING

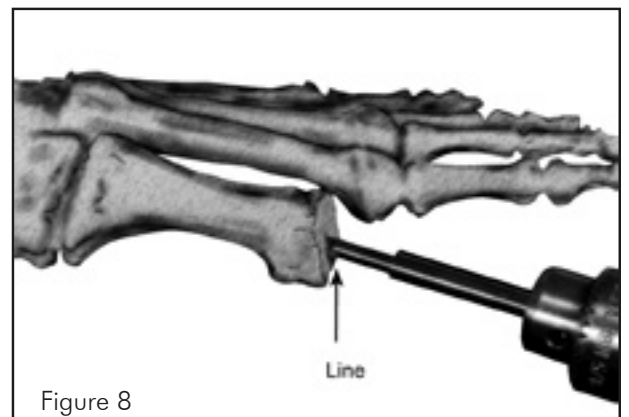
The diameter of all the reamer shafts is 0.25" (6.35 mm).

A. Starter Reamer (4.5mm)

With the power off, place the Starter Reamer into a Jacobs Chuck and slide it over the blunt Guide Pin (Figure 7).



Drive the Starter Reamer over the blunt Guide Pin into the metatarsal canal approximately 45mm (1.75 inches). This point is about 6mm proximal to the flutes of the reamer, as indicated by the line etched around the reamer shaft (Figure 8).

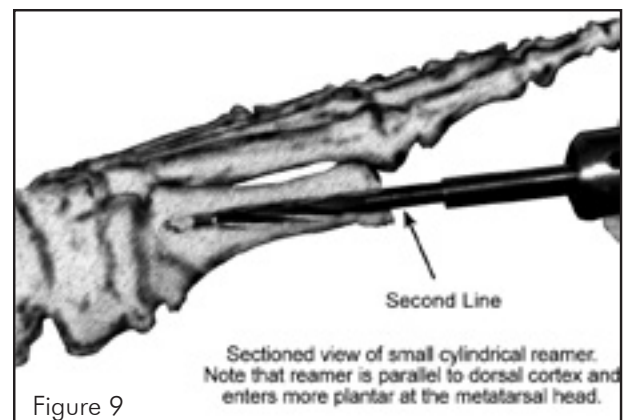


NOTE: The Starter Reamer has end cutting flutes to facilitate cutting through the dense bone of the metatarsal head. Once this bone has been penetrated, the reamer should advance with little resistance. If continuous resistance is encountered, reamer position and alignment should be checked.

NOTE: Cylindrical reaming extends beyond the length of the actual implant stem in order to allow clearance for the Cone Reamer Guide and avoid the potential for impingement of the stem tip.

B. Small Reamer (5.5mm)

Drive the small Straight Reamer over the blunt Guide Pin to the line etched around the reamer shaft (Figure 9).



5 PLACEMENT OF THE CONE REAMER GUIDE

The Cone Reamer Guide maintains a 17 degree angle between the axis of the reamed cylinder in the metatarsal and the cone to be reamed into the metaphysis. This guide orients the position of the articulating head.

A. Inserting the Small Cone Reamer Guide (5.5mm)

Insert the small Cone Reamer Guide into the reamed cylindrical canal (Figure 10) until the serrations come in contact with the resected surface of the bone (Figure 11). Make sure the stem points dorsally.

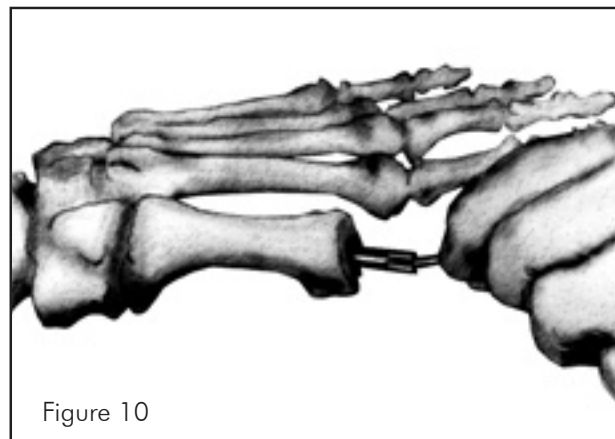


Figure 10

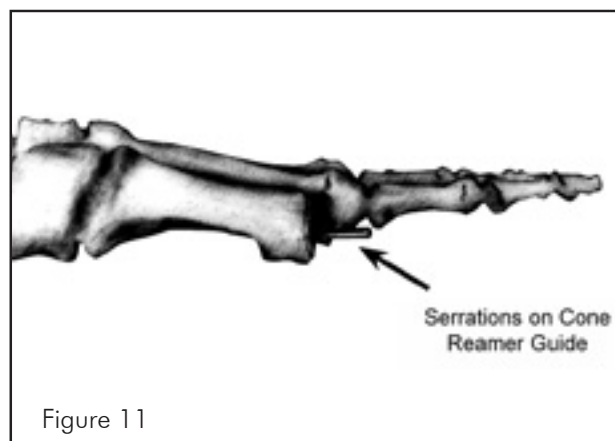


Figure 11

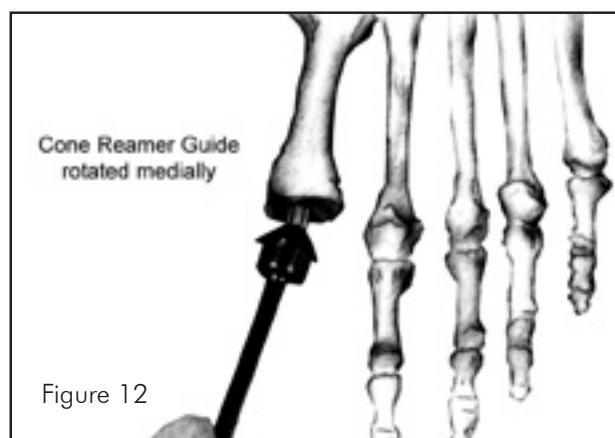
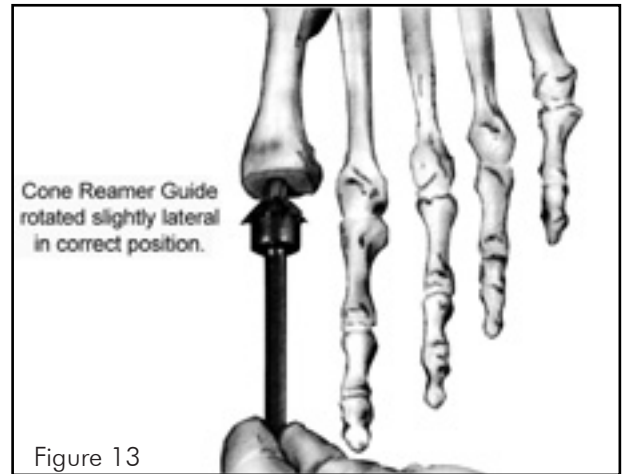


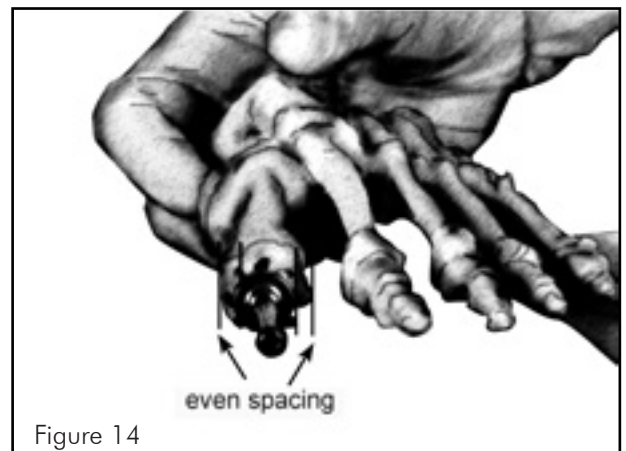
Figure 12

B. Setting the Cone Axis

Place one of the Cone Reamers on the guide and note the direction of the reamer stem (Figure 12).



Rotate the Cone Reamer Guide slightly from medial to lateral and note the orientation of the reamer stem. A general rule of thumb is that the reamer stem should be parallel with the second toe (provided there are no deformities of the second toe) (Figure 13).



NOTE: Rotating the guide laterally will position the center of the metatarsal head laterally and will reduce the effective IM angle. Conversely, rotating the guide medially will position the center of the head medially and will increase the effective IM angle.

Verify that the Cone Reamer is evenly spaced relative to the metatarsal head (Figure 14).

C. Locking the Orientation of the Cone Reamer Guide

Once the orientation has been determined, the Cone Reamer Guide can be pushed into the canal to the point where the serrations prevent further rotation of the guide.

6 CONE REAMING

The Cone Reamer shafts are 0.25" (6.35mm) in diameter.

A. Reaming to Depth

Slide the small Cone Reamer over the stem of the Cone Reamer Guide (Figure 15). Do not turn power on until the reamer is fully seated over the post of the Cone Reamer Guide.

Before turning power on, advance the guide and reamer as a unit until the cutting surfaces of the reamer are fully engaged into the bone (Figure 16). If the Cone Reamer Guide does not advance, it may be necessary to tap with a mallet.

Advance the reamer to the desired position taking into consideration how much bone was resected and how much metatarsal length is to be removed.

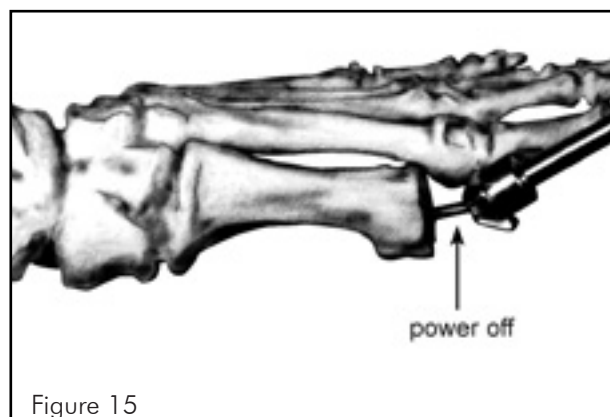


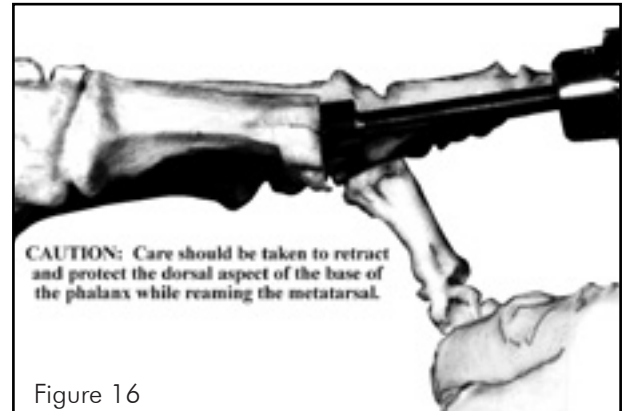
Figure 15

ReFlexion

Reaming should be done at a speed less than 1000 rpm. Irrigation will minimize the potential for bone necrosis and heating of the reamer/guide interface. As the reamer teeth become filled with bone, it may be necessary to clean the reamer to maintain cutting efficiency.

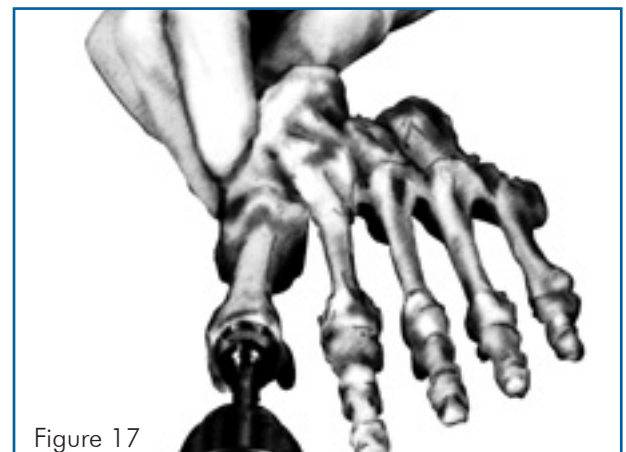


It is important that the Cone Reamer be advanced far enough into the metatarsal metaphysis to allow for satisfactory dorsiflexion without requiring excessive shortening of the phalangeal base.



B. Reaming to Diameter

Once the appropriate reaming depth has been established, the diameter can be expanded if desired by using a larger straight reamer, corresponding larger cone reamer guide and finally the corresponding larger cone reamer, until the desired size is achieved. (Total of three sizes available.) (Figure 17)





It is important to check the position of the reamer teeth with respect to the plantar cortex. Final implant position should not impinge the sesamoid apparatus and the cortex should be left sufficiently thick to support weight bearing through a solid shelf of plantar bone. The outer edge of the reamer should just reach the external cortical surface of the metatarsal metaphysis medially, laterally and dorsally (Figure 18).

Additionally, you may use the metatarsal cone head trial to check the position of the reamed out area by placing it over the cone reamer guide.

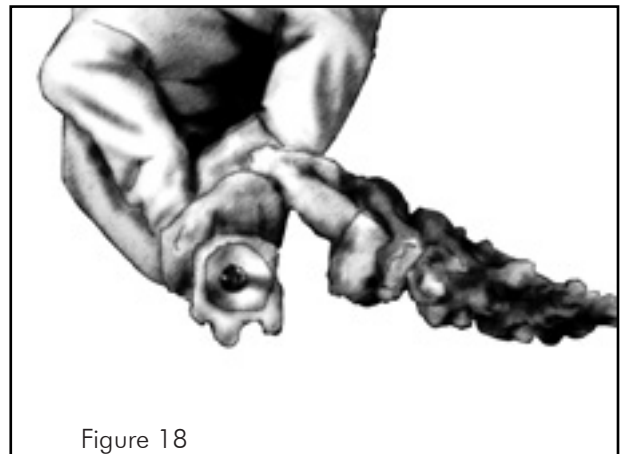


Figure 18

PHALANGEAL PREPARATION

The proximal metaphysis of the phalanx typically flares more plantarly than dorsally. This plantar flare accommodates the attachment of the intrinsic plantar flexors via the sesamoid apparatus. The phalangeal component should be placed centrally, with the stem slightly inclined from proximal central to distal dorsal (Figure 19). This will allow for optimal fit of the base while avoiding potentially breaking through the dorsal cortex proximally or plantar cortex distally.



Figure 19

1 INSERTION OF THE PHALANGEAL GUIDE PIN

A. Insertion Position

The Phalangeal Guide Pin should be centered M-L on the phalangeal shaft and D-P on the base of the proximal phalanx (Figure 20).

NOTE: Adequate exposure is important for proper visualization and access to the phalangeal base. The hallux should be plantar flexed to about 90 degrees and the plantar edge of the base should be visible.

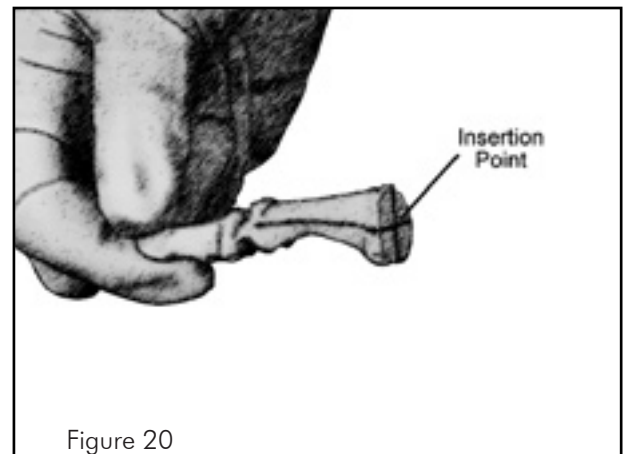


Figure 20

B. Alignment

Align the Phalangeal Guide Pin parallel with the shaft of the proximal phalanx M-L (Figure 21) and direct toward the dorsal aspect of the IP joint in the D-P plane (Figure 22).

C. Inserting the Phalangeal Guide Pin

Drive the Phalangeal Guide Pin into the shaft of the proximal phalanx, taking care not to penetrate the IP joint. Once the pin has penetrated the subchondral bone of the base, it should advance easily through the phalangeal canal. Resistance should be encountered again as the tip of the pin approaches the distal end of the proximal phalanx. Remove the Phalangeal Guide Pin when this resistance is encountered.



Figure 21

D. Inserting the blunt Guide Pin

Replace the Phalangeal Guide Pin with the Blunt Guide Pin. Gently tap the pin with a mallet to seat it in the cortical bone.

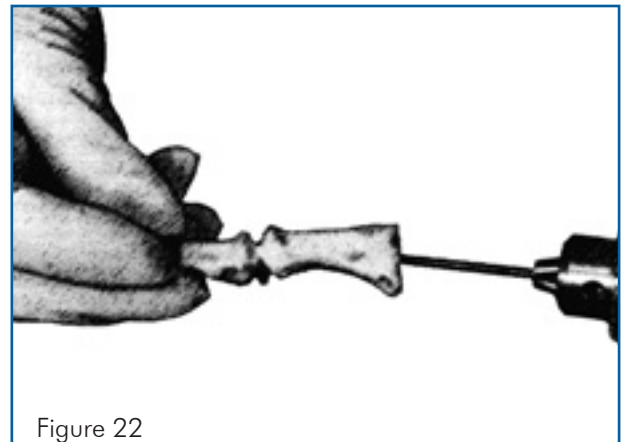


Figure 22

2 PHALANGEAL REAMING

A. Reaming the Proximal Phalanx

Place the Starter Reamer over the blunt Guide Pin and advance it to the first laser marked line, or just enough to break through the dense subchondral bone of the base (Figure 23).

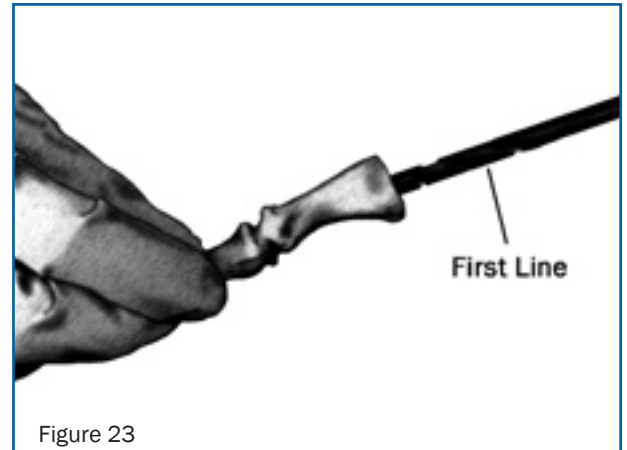


Figure 23

B. Phalangeal Reamer

Place the small Phalangeal Reamer over the blunt Guide Pin and ream into the base of the proximal phalanx to the desired depth (when the back of the cutting flutes are flush to the bone) (Figure 24).

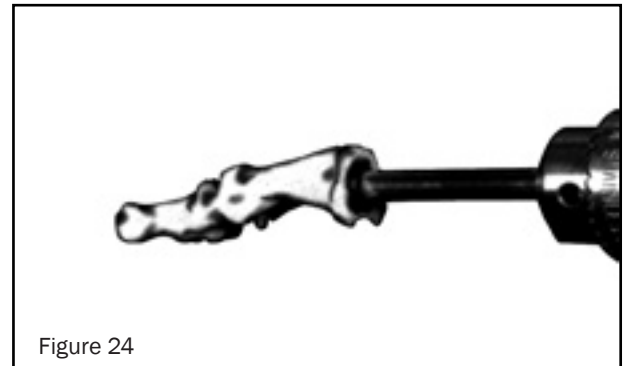


Figure 24

C. Desired Phalangeal Size

Insert the small (green) plastic phalangeal trial into the reamed phalangeal base (Figure 25). Check the range of motion with the metatarsal stem and metatarsal head trials previously selected (Figure 26).



Figure 25

If more motion is desired, more bone can be removed by reaming the proximal phalanx deeper one millimeter at a time (Figure 27). Keep in mind that as you ream deeper, it is necessary to use the Base Planer to remove the excess bone around the cortex to keep the same shape of the Phalangeal Base.

NOTE: The depth and position of the cone determine the final position of the Phalangeal Base and the amount of dorsiflexion that can be achieved immediately following the surgery.

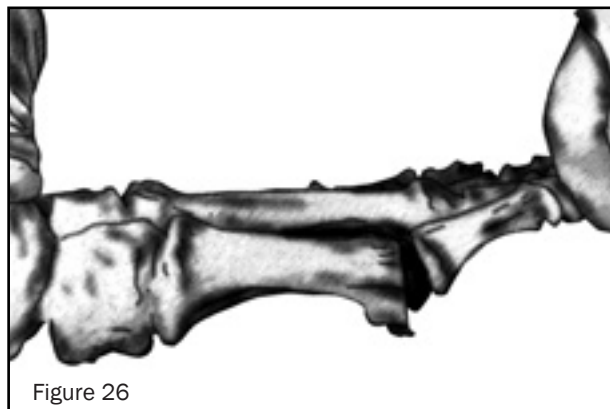


Figure 26

Once the desired depth has been established with the small Phalangeal Reamer, the diameter of the cone can be increased using the medium or large Phalangeal Reamers as needed if a larger phalangeal implant is necessary (Figure 28).

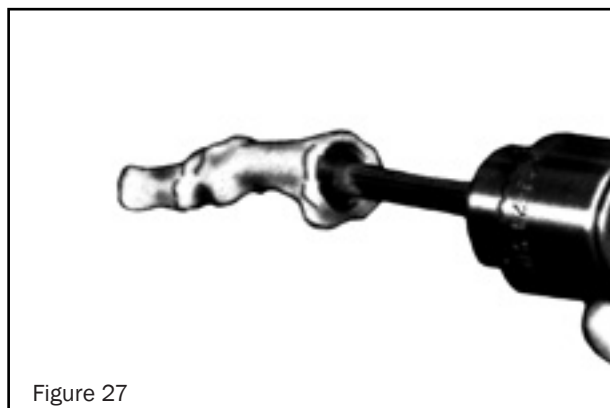


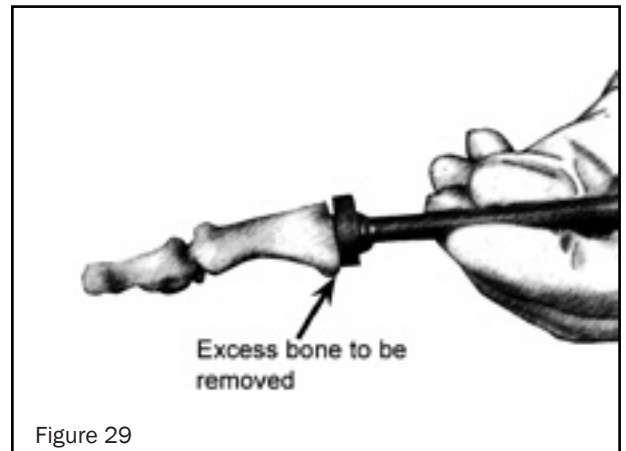
Figure 27



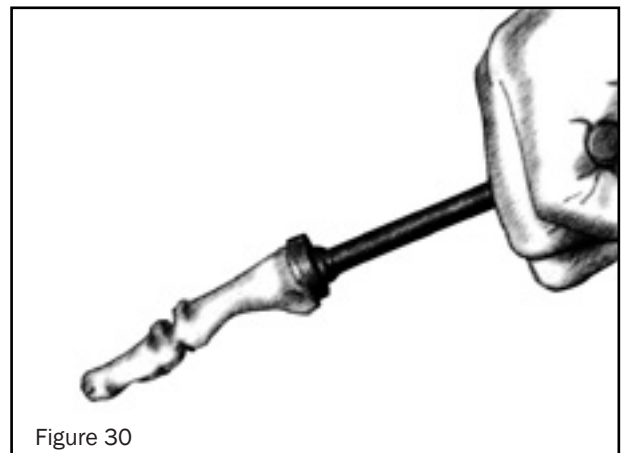
Figure 28

3 FINAL BASE PLANING

After depth and cone diameter have been determined, use the Base Planer (size corresponds to size implant to be used, small, medium or large) to remove excess bone from around the opening of the cone (Figure 29). Removal of excess bone will allow the Phalangeal Component to seat fully in the cone without hanging up on the flange.



When the bone is completely planed, the Base Planer should turn freely on the smooth pilot without any resistance (Figure 30).



4 FINAL TRIAL REDUCTION

- A. Insert the Metatarsal Stem Trial.**
- B. Insert the Phalangeal Trial.**
- C. Insert the Metatarsal Head Trial.**

Check the joint for range of motion and stability. If desired, greater dorsiflexion may be accomplished by reaming deeper either on the metatarsal or phalangeal side of the joint as previously described.

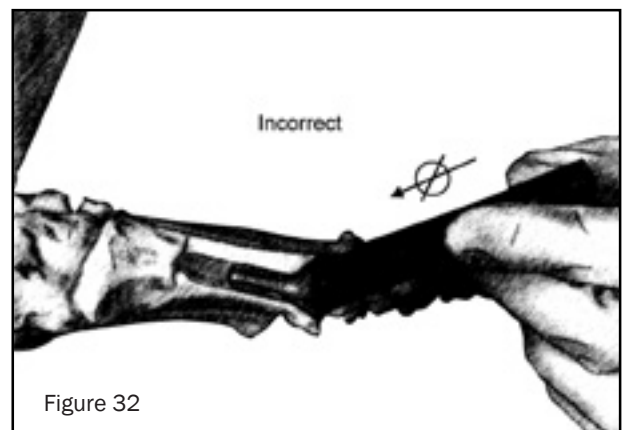
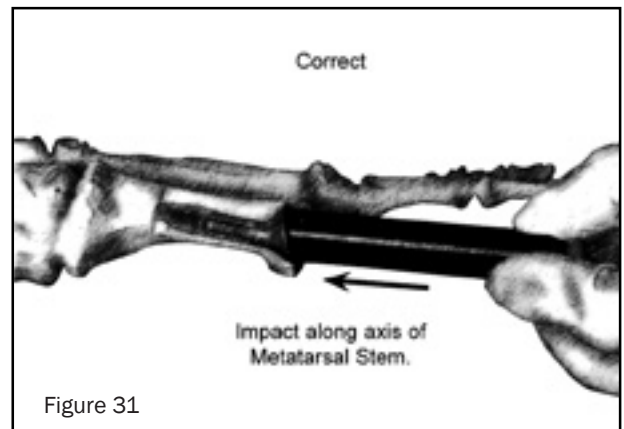
With trial implants in place, use a saw, rasp, bur or rongeurs to remove excess bone around the trial components to reduce the potential for damaging the actual implants once they are in place.

5 FINAL SEATING OF THE IMPLANTS

A. Remove selected implants from the double pouched, sterile packages. Care should be taken to avoid damaging the morse taper on the Metatarsal Component.

B. First insert the Metatarsal Stem by hand. Gently guide the cone to the proper rotational orientation. Use the Metatarsal Stem Impactor with a mallet to seat the component (Figures 31 & 32).

C. Insert the Phalangeal Base, orienting the flat edge towards the plantar surface of the proximal phalanx (Figure 33).



ReFlexion

Use the Phalangeal Impactor with a mallet to seat the Phalangeal Base (Figure 34).

The Metatarsal Head Component is placed on the morse taper of the Metatarsal Stem. The taper should be wiped clean and the head should be seated using the Metatarsal Head Impactor with a mallet.

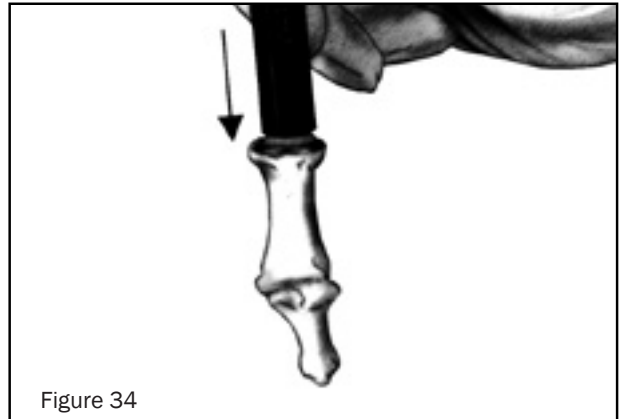


Figure 34

6 CLOSURE

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.

Implants



- 370-0203 Metatarsal Head, Standard
- 370-0205 Metatarsal Head, Long
- 370-0207 Metatarsal Head, Extra Long



- 370-0223 Metatarsal Stem, Small
- 370-0225 Metatarsal Stem, Medium
- 370-0227 Metatarsal Stem, Large



- 370-0423 Phalangeal Base, Small
- 370-0425 Phalangeal Base, Medium
- 370-0427 Phalangeal Base, Large

Trials



- 371-0203 Metatarsal Head Trial, Standard
- 371-0205 Metatarsal Head Trial, Long
- 371-0207 Metatarsal Head Trial, Extra Long



- 371-0223 Metatarsal Stem Trial, Small
- 371-0225 Metatarsal Stem Trial, Medium
- 371-0227 Metatarsal Stem Trial, Large



- 371-0423 Phalangeal Base Trial, Small
- 371-0425 Phalangeal Base Trial, Medium
- 371-0427 Phalangeal Base Trial, Large

Reamers



- 372-0403 Small Phalangeal Reamer
- 372-0405 Medium Phalangeal Reamer
- 372-0407 Large Phalangeal Reamer



- 372-0203 Small Cone Reamer
- 372-0205 Medium Cone Reamer
- 372-0207 Large Cone Reamer



- 372-0045 4.5mm Straight Reamer
- 372-0055 5.5mm Straight Reamer
- 372-0065 6.5mm Straight Reamer
- 372-0075 7.5mm Straight Reamer

Guide Pin Devices



- 373-0224 Metatarsal Guide Pin



- 373-0324 Metatarsal Guide Pin



- 373-0424 Metatarsal Guide Pin



- 373-0002 Metatarsal Wire Alignment Guide

Impactors



- 374-0202 Small Cone Reamer Guide



- 374-0200 Metatarsal Stem Impactor

Base Planners



- 372-0413 Small Base Planer
- 372-0415 Medium Base Planer
- 372-0417 Large Base Planer

Cone Reamer Guides



- 373-0203 Small Cone Reamer Guide
- 373-0205 Medium Cone Reamer Guide
- 373-0207 Large Cone Reamer Guide



Part Number

Description

Implants

370-0203	Metatarsal Head, Standard
370-0205	Metatarsal Head, Long
370-0207	Metatarsal Head, Extra Long
370-0223	Metatarsal Stem, Small
370-0225	Metatarsal Stem, Medium
370-0227	Metatarsal Stem, Large
370-0423	Phalangeal Base, Small
370-0425	Phalangeal Base, Medium
370-0427	Phalangeal Base, Large

Part Number

Description

Trials

371-0203	Metatarsal Head Trial, Standard
371-0205	Metatarsal Head Trial, Long
371-0207	Metatarsal Head Trial, Extra Long
371-0223	Metatarsal Stem Trial, Small
371-0225	Metatarsal Stem Trial, Medium
371-0227	Metatarsal Stem Trial, Large
371-0233	Metatarsal Cone-Head Trial, Small
371-0235	Metatarsal Cone-Head Trial, Medium
371-0237	Metatarsal Cone-Head Trial, Large
371-0423	Phalangeal Base Trial, Small
371-0425	Phalangeal Base Trial, Medium
371-0427	Phalangeal Base Trial, Large
379-0001	ReFlexion™ Autoclave Tray

Part Number

Description

Instruments for Metatarsal System

372-0045	4.5mm Straight Reamer
372-0055	5.5mm Straight Reamer
372-0065	6.5mm Straight Reamer
372-0075	7.5mm Straight Reamer
372-0203	Small Cone Reamer
372-0205	Medium Cone Reamer
372-0207	Large Cone Reamer
373-0002	Metatarsal Wire Alignment Guide
373-0203	Small Cone Reamer Guide
373-0205	Medium Cone Reamer Guide
373-0207	Large Cone Reamer Guide
373-0224	Metatarsal Guide Pin
373-0324	Metatarsal Guide Pin, Blunt
374-0200	Metatarsal Stem Impactor
374-0202	Metatarsal Head Impactor

Part Number

Description

Instruments for Phalangeal System

372-0403	Small Phalangeal Reamer
372-0405	Medium Phalangeal Reamer
372-0407	Large Phalangeal Reamer
372-0413	Small Base Planer
372-0415	Medium Base Planer
372-0417	Large Base Planer
373-0002	Metatarsal Wire Alignment Guide
373-0203	Small Cone Reamer Guide
373-0205	Medium Cone Reamer Guide
373-0207	Large Cone Reamer Guide
373-0224	Metatarsal Guide Pin
373-0324	Metatarsal Guide Pin, Blunt
373-0424	Phalangeal Guide Pin



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