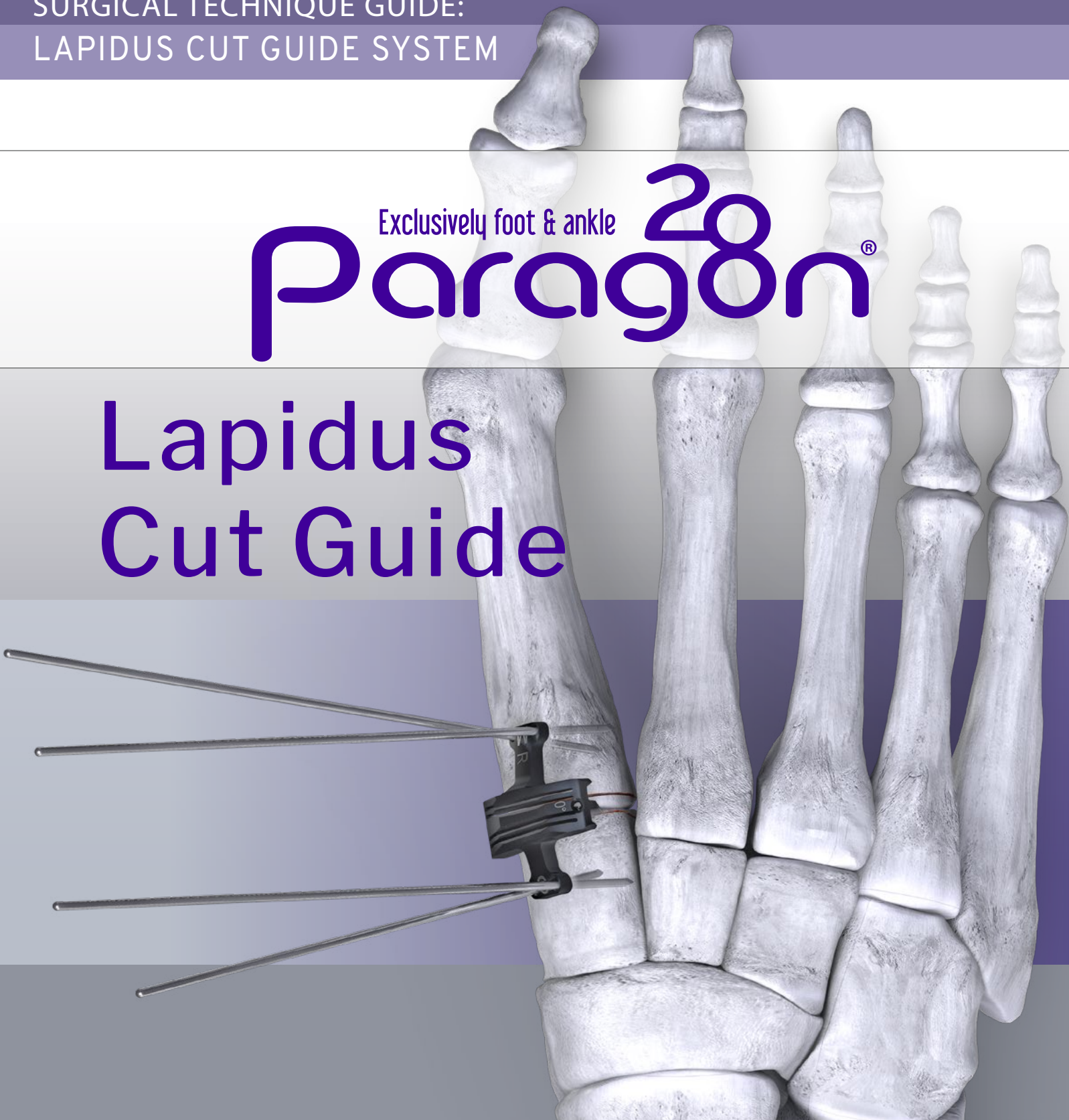


SURGICAL TECHNIQUE GUIDE:
LAPIDUS CUT GUIDE SYSTEM

Exclusively foot & ankle **20**
Paragon®

Lapidus Cut Guide



PHANTOM®
INTRAMEDULLARY NAIL

SYSTEM OVERVIEW

The Lapidus Cut Guide System was developed to allow surgeons flexibility in joint resection technique for the 1st tarsometatarsal joint while performing a Lapidus Arthrodesis procedure. The Lapidus Cut Guide System enables surgeons to make flat cuts at the distal aspect of the medial cuneiform and proximal 1st metatarsal to allow contact of congruent surfaces at the arthrodesis site. Congruent surfaces help prevent gaps present at an arthrodesis site, which presents a risk for delayed healing or nonunion.^{1,2}

INSTRUMENTATION

Met-Cuneiform Cut Guides

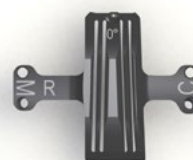
Straight Cut Guide
Left

0°



Straight Cut Guide
Right

0°



- A 0° cut will result in the least amount of bone loss, while intending to achieve transverse and frontal plane correction of the deformity via rotational correction of the 1st metatarsal.

Angled Cut Guides
Left

8°



10°



12°



14°



16°



18°



20°



Angled Cut Guides
Right

8°



10°



12°



14°



16°



18°



20°



- The angled cuneiform cuts allow for 1st metatarsal correction to be achieved in the transverse plane using the cut geometry with optional rotation.

Cleanup Guide

- Allows for approximately 1.5 mm of additional cartilage/subchondral bone resection following the initial bone cuts
- Designed for use in an uneven joint when additional cartilage remains, or when additional bone resection is desired via a parallel cut
- Guide aligns parallel to the previous cut for consistent orientation
- Can be used on the metatarsal or cuneiform
- Universal for right and left



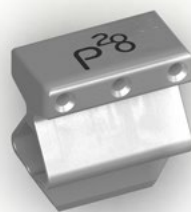
4° Cut Guide: Right and Left

- Creates a 4° dorsal to plantar taper on the 1st metatarsal to allow additional plantarflexion of the 1st metatarsal to be built into the cut
- Used for 1st metatarsal resection only



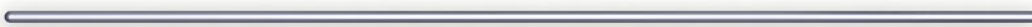
Alignment Tool

- Shows anticipated alignment of the 1st metatarsal in the transverse plane to determine if selected Angled Cut Guide is appropriate for desired correction
- Double blunt tip K-wire is placed into one of the 3 holes
- Inserts into the cuneiform slots of the Angled Cut Guide



K-Wires

1.6 x 100 mm Double Blunt
Tip K-wire



1.6 x 100 mm K-Wire



INCISION / EXPOSURE

The procedure may be combined with a lateral release for hallux valgus correction, if desired. A medial or dorsomedial incision is made over the 1st tarsometatarsal (TMT) joint. Dissection is carried down to the 1st TMT joint.



CUT GUIDE SELECTION AND POSITIONING

In this example, a 12° Met-Cuneiform Guide is selected. The Cut Guide is inserted by pointing the “M” laser mark distally and the “C” laser mark proximally and placing the paddle into the 1st TMT joint. The orientation of the cut guide should be checked by placing a 1.6 mm double blunt K-wire into the dorsal hole on the cut guide. Align this K-wire with the long axis of the tibia to yield a 45° dorsomedial position of the cut guide.



CUT GUIDE PLACEMENT

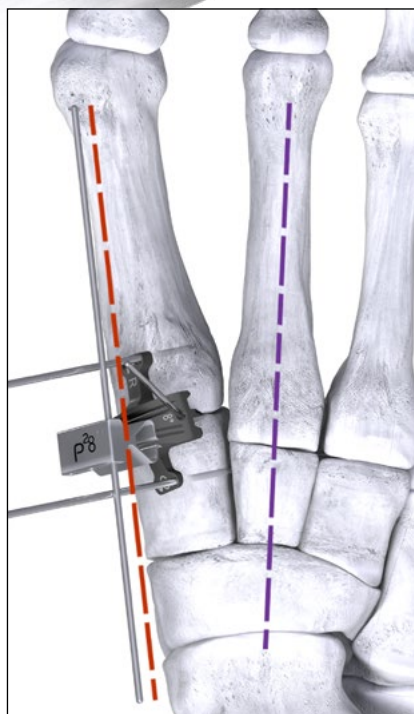
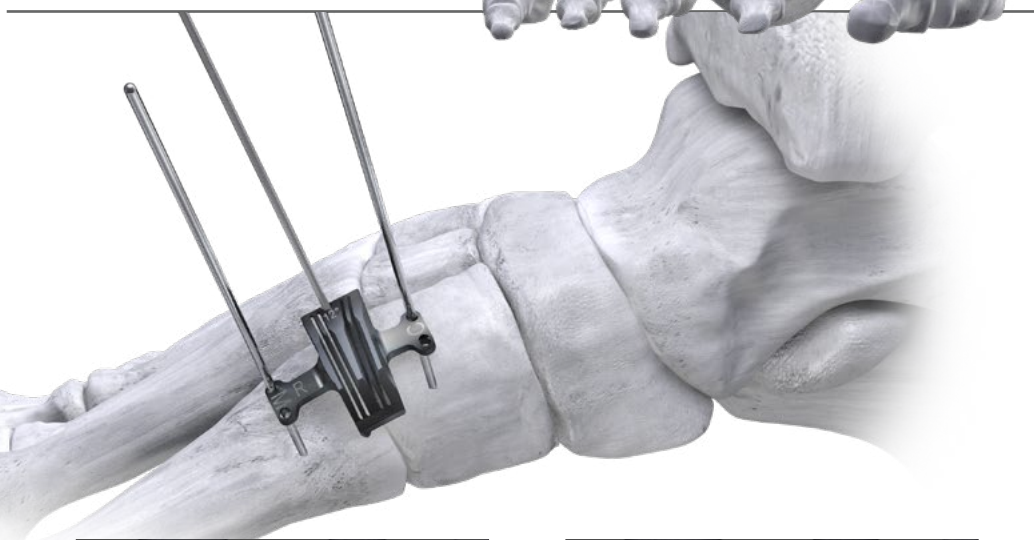
Place a 1.6 mm K-wire into the dorsal Cut Guide hole on the medial cuneiform.

Place a 1.6 mm K-wire into the dorsal Cut Guide hole on the metatarsal.

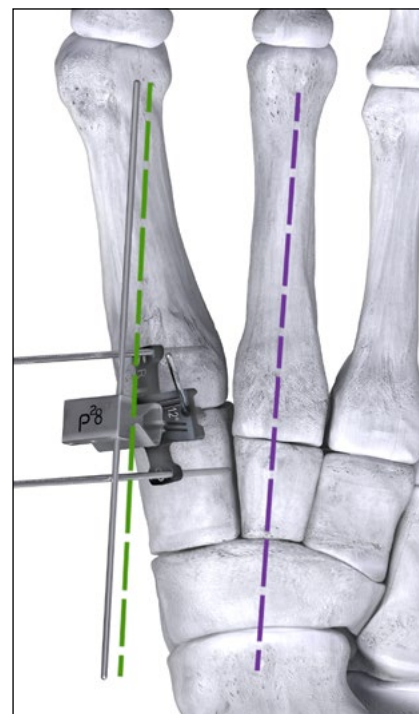
Remove the 1.6 mm double blunt K-wire.

If using an Angled Cut Guide, insert the alignment tool into the Cut Guide slots in the medial cuneiform. Place the 1.6 mm double blunt K-wire into any one of the three holes on the top portion of the alignment tool. The wire trajectory indicates anticipated position of the 1st metatarsal following bone cuts and deformity correction. If the angle is not the correction amount that is desired, go up or down a Cut Guide angle.

NOTE: The two dorsal wires are parallel to allow the Cut Guide to be slid off if a different angulation is desired. Interchangeability of the Cut Guide is possible when choosing between 8°, 10°, 12° and 14° or between 16°, 18° and 20°.



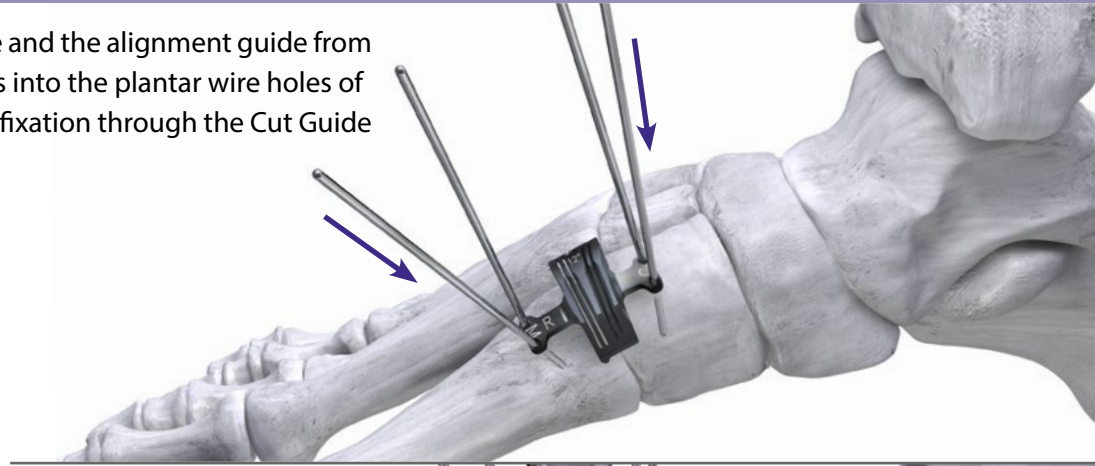
MISALIGNED



ALIGNED

SURGICAL TECHNIQUE GUIDE: LAPIDUS CUT GUIDE SYSTEM

Remove the 1.6 mm double blunt K-wire and the alignment guide from the Cut Guide. Place two 1.6 mm K-wires into the plantar wire holes of the Cut Guide to allow for two points of fixation through the Cut Guide in each bone.

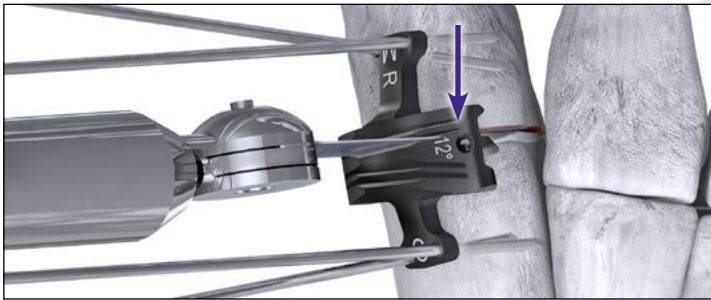


1ST METATARSAL CUT

Retrieve the provided saw blade, and insert the saw blade in the metatarsal slot closest to the 1st TMT joint.

NOTE: The slot furthest from the 1st TMT joint is only used if intentional shortening of the 1st ray is required or if there is a need to remove additional bone, such as an uneven joint surface.

While using irrigation, perform the first metatarsal cut using a sweeping method to ensure appropriate cutting of the metatarsal dorsally, laterally and plantarly.

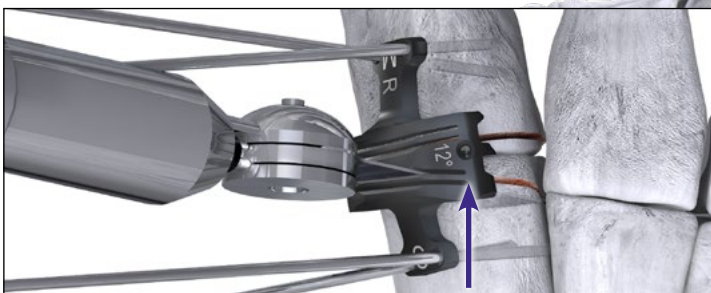
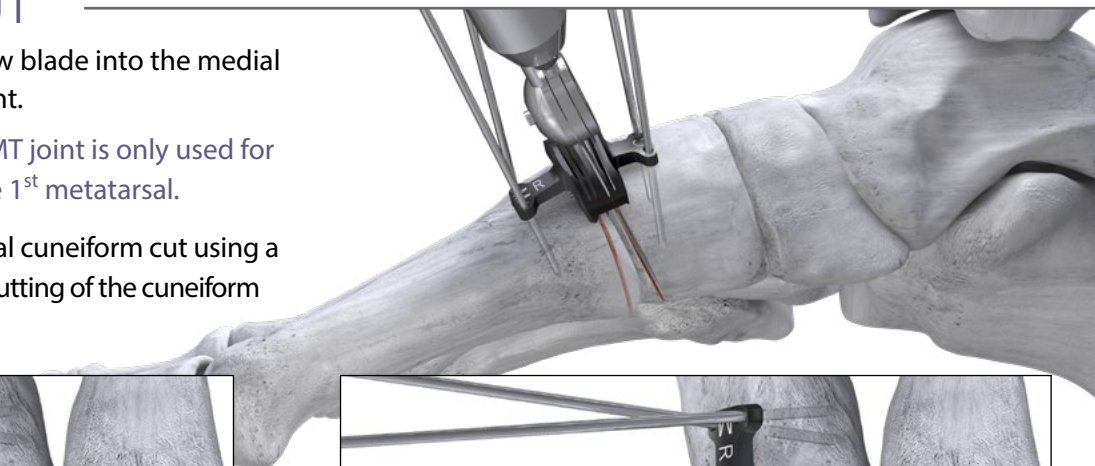


MEDIAL CUNEIFORM CUT

Using the same saw blade, insert the saw blade into the medial cuneiform slot closest to the 1st TMT joint.

NOTE: The slot furthest from the 1st TMT joint is only used for the reasons previously described for the 1st metatarsal.

While using irrigation, perform the medial cuneiform cut using a sweeping method to ensure appropriate cutting of the cuneiform dorsally, laterally and plantarly.

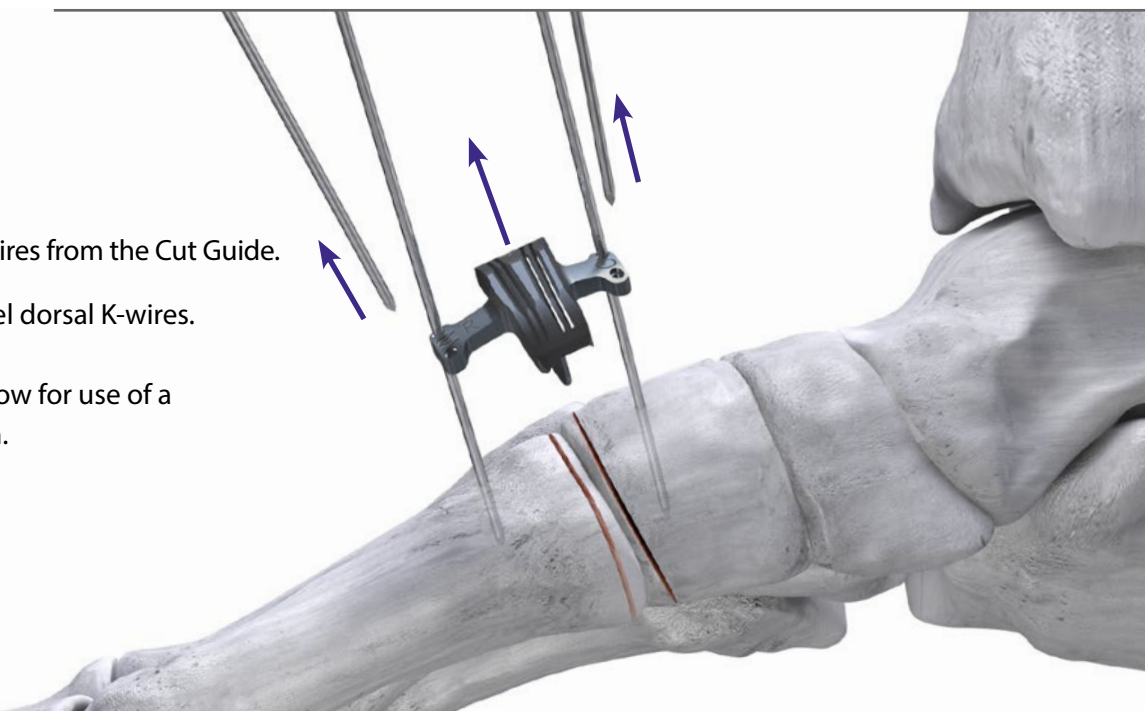


CUT GUIDE REMOVAL

Remove the two plantar 1.6 mm K-wires from the Cut Guide.

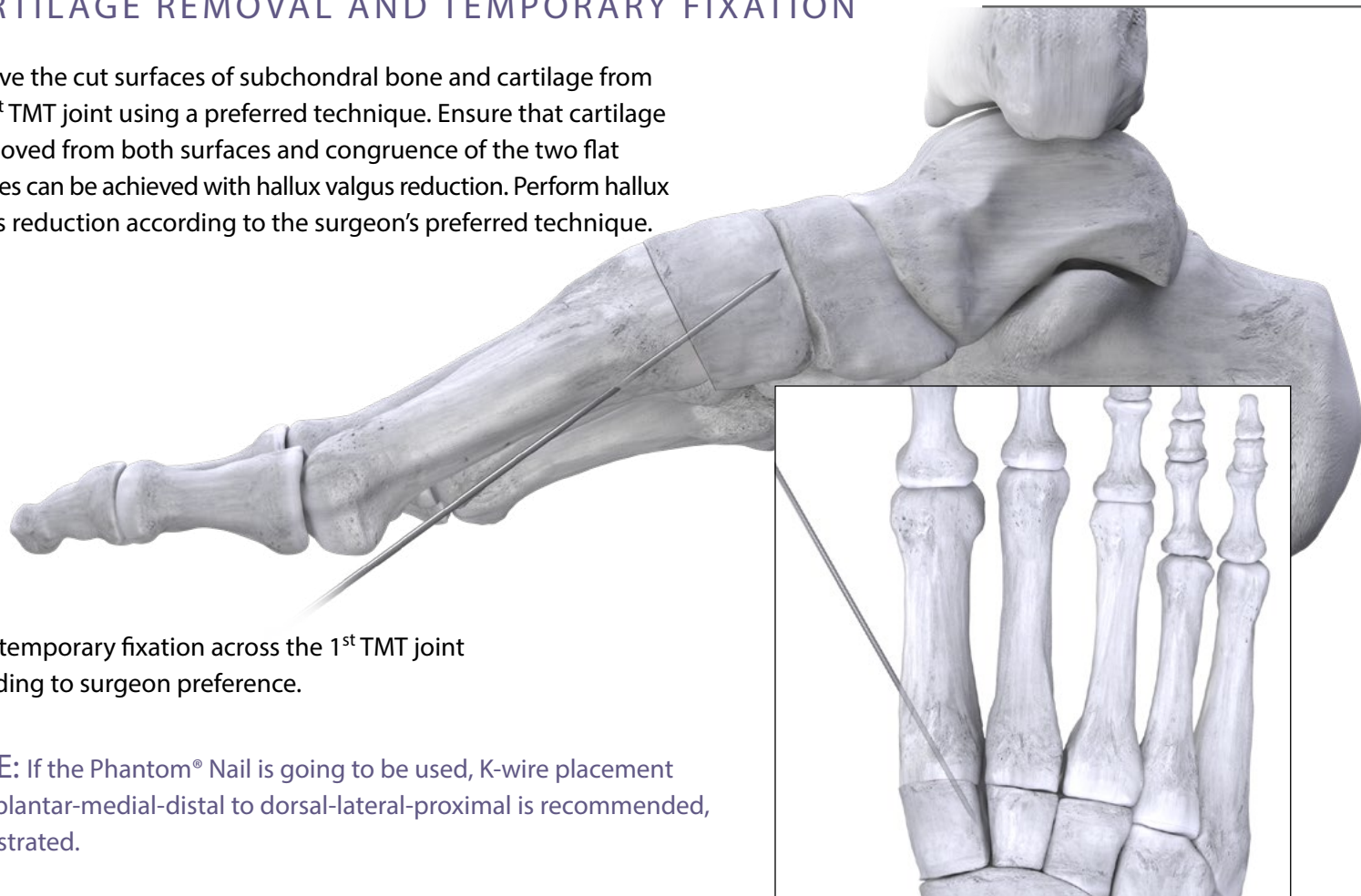
Slide the Cut Guide off of the parallel dorsal K-wires.

The dorsal K-wires can remain to allow for use of a pin distractor, or to assist in rotation.



CARTILAGE REMOVAL AND TEMPORARY FIXATION

Remove the cut surfaces of subchondral bone and cartilage from the 1st TMT joint using a preferred technique. Ensure that cartilage is removed from both surfaces and congruence of the two flat surfaces can be achieved with hallux valgus reduction. Perform hallux valgus reduction according to the surgeon's preferred technique.



Place temporary fixation across the 1st TMT joint according to surgeon preference.

NOTE: If the Phantom® Nail is going to be used, K-wire placement from plantar-medial-distal to dorsal-lateral-proximal is recommended, as illustrated.

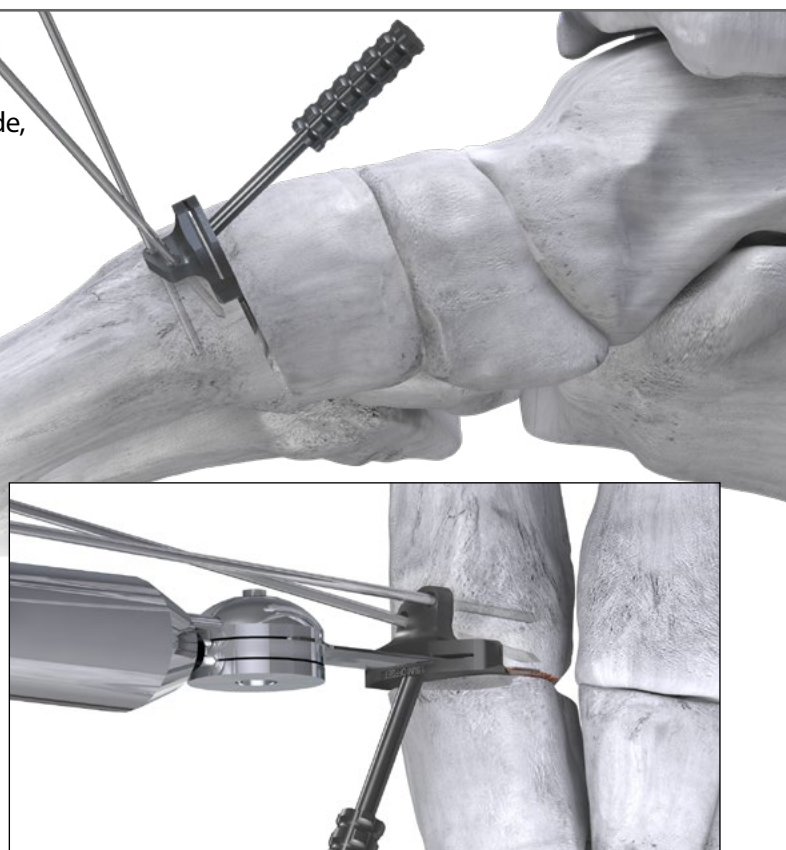
PERMANENT FIXATION/CLOSURE

Permanent fixation can be achieved using the Phantom® Nail or per surgeon preference. Proceed with incision closure or concomitant procedures at this time.

CLEANUP GUIDE

Following initial cartilage removal using the Met-Cuneiform Cut Guide, additional cartilage/subchondral bone (1.5 mm) removal can be performed using the Cleanup Guide, if necessary.

The Cleanup Guide is attached to either the 1st metatarsal (shown) or medial cuneiform by inserting the paddle in the joint space with the cut slot directed at the bone requiring additional joint resection. Attach the Cleanup Guide to bone using two 1.6 mm K-wires. Using the saw and while irrigating, perform the cut using a sweeping method to ensure appropriate cutting of the bone dorsally, laterally and plantarly. Remove the Cleanup Guide, and resected cartilage/subchondral bone, and proceed with temporary fixation, as previously described.



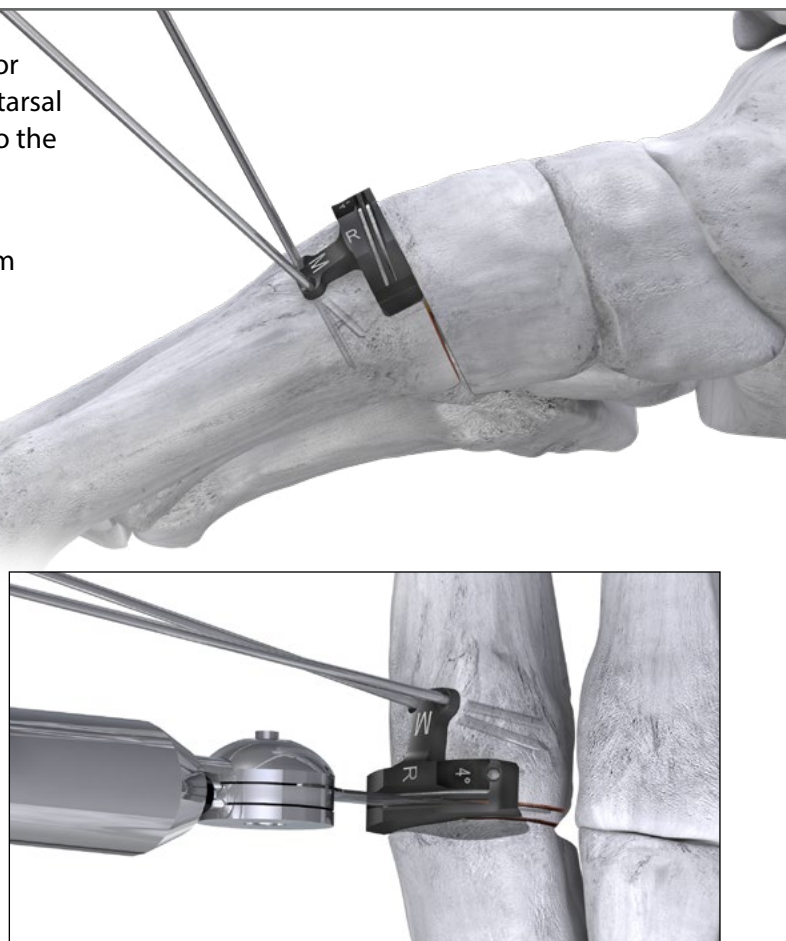
4° CUT GUIDE

If more than 2° of plantarflexion of the 1st metatarsal is required for sagittal plane correction, the 4° Cut Guide is used for the 1st metatarsal prior to making any other cuts. Insert the 4° Cut Guide paddle into the 1st TMT joint with the cut slot distal over the 1st metatarsal.

The orientation of the 4° Cut Guide is checked by placing a 1.6 mm double blunt K-wire into the dorsal hole on the 4° Cut Guide. Align this K-wire with the long axis of the tibia to yield a 45° dorsomedial position of the cut guide.

After aligning, secure the 4° Cut Guide using two 1.6 mm K-wires. Using the saw and while irrigating, perform the cut in the 1st metatarsal using a sweeping method to ensure appropriate cutting of bone dorsally, laterally and plantarly.

Proceed to inserting the Met-Cuneiform Cut Guide into the 1st TMT joint. Follow the steps above for aligning and securing the Cut Guide. Use the Met-Cuneiform Cut Guide for the medial cuneiform cut. Complete Cut Guide removal, cartilage/subchondral bone removal and temporary fixation as previously described.



LAPIDUS CUT GUIDE SYSTEM CADDY: _____

Part #	Description	Use
P30-942-G101	Metatarsal Alignment Guide	Reusable
P30-940-C101	Cleanup Guide	Reusable
P30-940-R1[04-20]	Metatarsal Cut Guide, Right, 4-20°	Reusable
P30-940-L1[04-20]	Metatarsal Cut Guide, Left, 4-20°	Reusable
P99-192-1610	K-Wire, Single Ended Trocar Tip, Smooth 1.6 X 100mm	Single-use
P30-192-1615	1.6, Double-Blunt K-wire, 150 mm	Single-use
P99-151-P30M	Sawblade 9x31x.051mm MicroAire Con.	Single-use
P99-151-P30S	Sawblade 9x31x.051mm Stryker Con.	Single-use

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LapidusCutGuide

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For Instructions for Use, please visit:

www.paragon28.com/ifus

References

1. Claes, L., Eckert-Hübner, K., & Augat, P. (2003). The fracture gap size influences the local vascularization and tissue differentiation in callus healing. *Langenbeck's archives of surgery*, 388(5), 316-322.
2. Lim, S. J., So, S. Y., Yoon, Y. C., Cho, W. T., & Oh, J. K. (2015). A forward-striking technique for reducing fracture gaps during intramedullary nailing: A technical note with clinical results. *Injury*, 46(12), 2507-2511.

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DISCLAIMER

The purpose of the Lapidus Cut Guide Surgical Technique Guide is to demonstrate the optionality and functionality of the Lapidus Cut Guide System instrumentation. Although various methods can be employed for these procedures, the procedure demonstrated was chosen for simplicity of explanation and demonstration of the unique features of our device. Federal law (U.S.A.) restricts this device to sale and use by, or on order of, a physician.