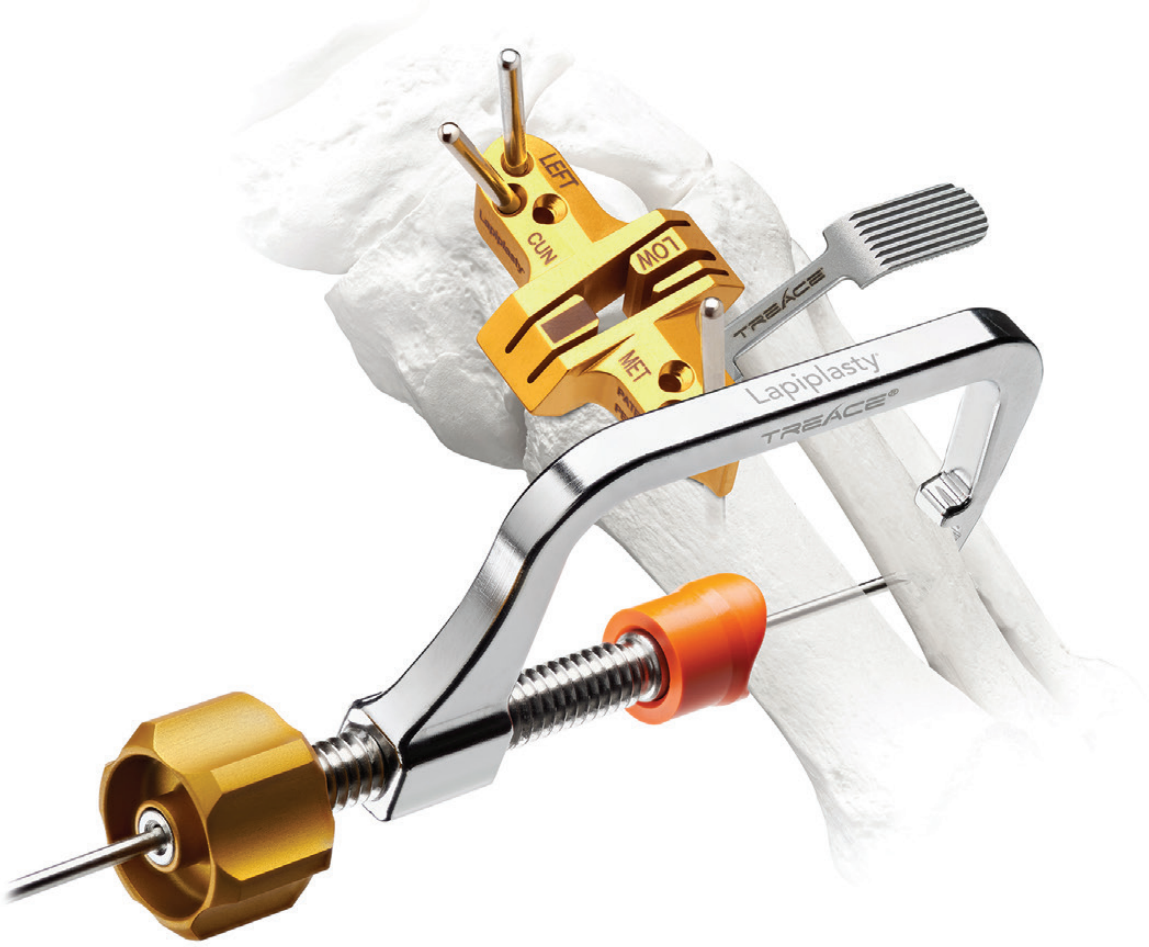
Lapiplasty®

3-Plane Correction at the CORA



Instrumented Reproducibility.

Rapid Weight-Bearing.[1]

Low Recurrence.[1]

TREACE®
Medical Concepts, Inc.
The Leader in Hallux Valgus Surgery™

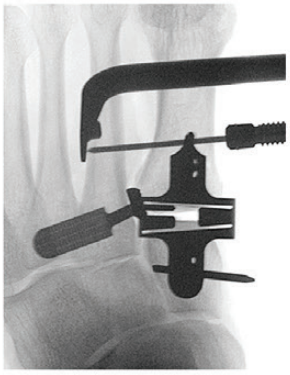
What is the Lapiplasty® Procedure?

An instrumented, reproducible approach to 3-plane correction with rapid return to weight-bearing[1]

Correct.

Make your correction ***before*** you cut

The **Lapiplasty® Positioner** is engineered to quickly and reproducibly correct the alignment in all three planes, establishing and holding true anatomic alignment of the metatarsal and sesamoids.[1]



Cut.

Perform precision cuts with confidence

The **Lapiplasty® Cut Guide** delivers precise cuts with the metatarsal held in the corrected position, ensuring optimal cut trajectory while virtually eliminating the risk of metatarsal shortening.

Compress.

Achieve controlled compression of joint surfaces

The **Lapiplasty® Compressor** delivers over 150N of controlled compression[2] to the precision-cut joint surfaces, while maintaining the 3-plane correction.

Fixate.

Apply multiplanar fixation for robust stability

Low-profile **Biplanar™ Plating** provides biomechanically-tested[3,4] multiplanar stability for rapid return to weight-bearing.[1]

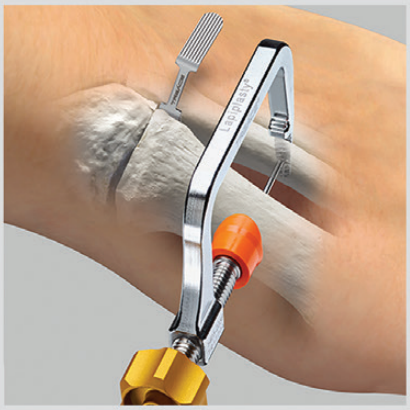
[1]Ray J, et al. Foot Ankle Int. 2019 Aug;40(8):955-960.
[2]Data on file.
[3]Dayton P, et al. J Foot Ankle Surg. 2016. 55:567-71.
[4]Data on file.

How does the Lapiplasty® Procedure work?

Key surgical steps*

1.
Joint Release

Run sagittal saw congruously down the 1st TMT joint to mobilize and plane the joint surfaces.

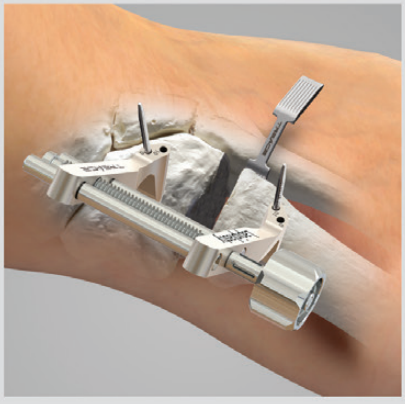


2.
Anatomic Correction

Apply the **Lapiplasty® Positioner,** simultaneously securing the IM angle, frontal-plane rotation, and sagittal alignment in corrected position.

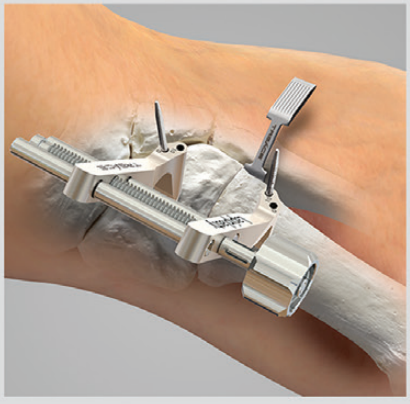
3.
Precision Cuts

Secure the **Lapiplasty® Cut Guide** and make precise joint cuts with the triplanar correction held in place.



4.
Joint Distraction

Apply the **Lapiplasty® Compressor** over the **Cut Guide Pins** to distract the joint for removal of bone slices and fenestration of the joint surfaces.



5.
Joint Compression

Using the **Lapiplasty® Compressor,** bring the precision-cut joint surfaces together for controlled apposition and compression of the arthrodesis site.

6.
Multiplanar Fixation

Apply low-profile **Biplanar™ Plates** dorsally and medially, providing multiplanar fixation for rapid weight-bearing.[1]

*Treace Medical Concepts, Inc. Surgical Technique LBL 1405-9001

Lapiplasty® System

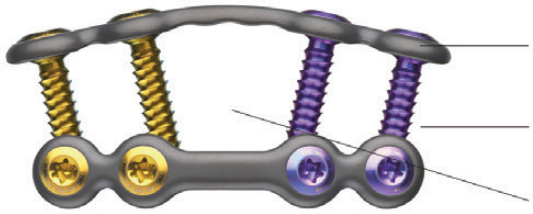
Anatomic Biplanar™ Implants

Lapiplasty® System 1

S1

Sterile-packed Biplanar™ Plating kit for versatility to fit each patient's anatomy, while delivering superior multiplanar strength.[3]

SK12



- Low-profile, anatomic shape contoured to fit the 1st TMT joint
- 2.7mm standard-sized locking screws eliminates intra-operative measuring
- Biplanar™ configuration for multiplanar stability

Plate Width	**3.6mm**	Locking Screws	**2.7x12mm** (5) | **2.7x14mm** (4)

Lapiplasty® System 2

S2

An evolution of Biplanar™ Plating with increased cross-sectional width for additional construct strength.

SK14

- Anatomic contour and low-profile thickness maintained
- 2.7mm star-drive screws for excellent screw driver engagement; compatible across systems
- Increased cross-sectional width for improved stability

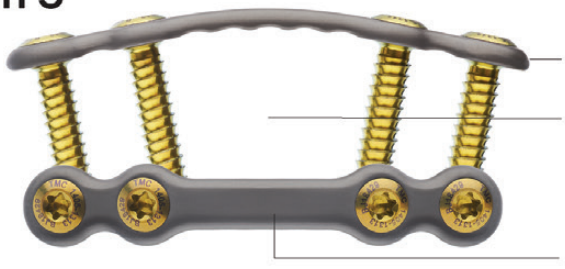
Plate Width	**3.9mm**	Locking Screws	**2.7x12mm** (5) | **2.7x14mm** (4)

Lapiplasty® System 3R

S3R

Versatile Biplanar™ Plating option with widest cross-section, 3.0mm screws, and increased span to address revision cases and challenging anatomy.

SK23



- Low-profile thickness maintained
- Increased center span (+5mm) to accommodate grafts and challenging anatomy
- Most cross-sectional width for robust stabilization

Plate Width	**4.3mm**	Locking Screws	**3.0x12mm** (4) | **3.0x16mm** (8)

Plantar Python® 2 Plate

Sterile-packed, pre-contoured, easy-to-apply tenside-side fixation.

SD14/15 (L/R)

Lapiplasty® Long Locking Screws

2.7mm Long Screw Pack SD16
2.7x16mm (2) + 2.7x18mm (2)

3.0mm Long Screw Pack SD17
3.0x18mm (2) + 3.0x20mm (2)

See Instructions for Use LBL1405-9005

One System for All Your Hallux Valgus Needs

Sterile-packed kits for operational efficiency

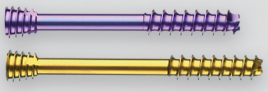
Lapiplasty® Accessory Kits

Headless Screws*

Headless titanium compression screws for Akin osteotomies, tarsal-metatarsal fusions, & other applications

SK20
2.5x20mm
2.5x28mm

SK26
4.0x36mm
4.0x40mm

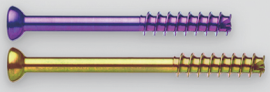


Headed Interfrag Screws*

Low-profile headed, titanium cannulated compression screws for tarsal-metatarsal fusions & other applications

SK18
3.0x36mm
3.0x40mm

SK25
4.0x36mm
4.0x40mm



Transverse Screws*

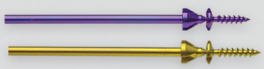
Low-profile headed, titanium cannulated compression screws for tarsal fusion & other applications

SK19
3.5x23mm
3.5x26mm

Snap-Off Screws**

Titanium snap-off screws for Weil osteotomies & other applications

SK21
2.0x12mm
2.0x14mm



Lesser TMT Fixation Pack

Single low-profile S1 plate w/ locking screws for lesser TMT fusions (metatarsus adductus) & other applications

SK28
S1 Plate | 2.7x14mm (2) | 2.7x18mm (3)

FastGrafter® Autograft Harvesting System (7mm)

Sterile-packed, single-use device for quick and efficient harvest of cancellous autogenous bone from the calcaneus, distal tibia, and other harvest sites through a minimal incision approach.

SK27

See Instructions for Use LBL1405–9056 or LBL1405-9110***

Biomechanically Proven for Rapid Weight-Bearing

Biomechanical test specimens were constructed using Sawbones® surrogate bone models (Pacific Research Laboratories Inc, Vashon, WA) and tested in cantilever bending to simulate functional 1st TMT joint loading. The testing included both static ultimate failure and cyclic load to failure. Three different studies were performed under this test protocol, which are detailed below.

Gen1 vs. Conventional Plating

Biplanar™ Plating Gen 1

vs

Anatomic Dorsal Locking Plate w/ 4.0 Interfrag Screw

130%
Increase in Ultimate Failure Load

30%
Increase in Cycles to Failure

Dayton et al, J Foot Ankle Surg. 2016, 55:567-71.

S1 vs. Gen1

S1 Biplanar™ Plating

vs

Biplanar™ Plating Gen 1

50%
Increase in Ultimate Failure Load

100%+
Increase in Cycles to Failure

TMC Data on file.

S2 vs. Gen1

S2 Biplanar™ Plating

vs

Biplanar™ Plating Gen 1

78%
Increase in Ultimate Failure Load

179%
Increase in Cycles to Failure

TMC Data on file. (M171A)

The Evidence-Based Solution for 3-Plane Correction

Treace Medical Concepts is dedicated to advancing the understanding of the Lapiplasty® Procedure and its benefits to patients, surgeons, and the healthcare system through research studies and publications in the peer-reviewed literature.

Multicenter Early Radiographic Outcomes of Triplanar Tarsometatarsal Arthrodesis With Early Weightbearing

Multicenter, retrospective study of 57 hallux valgus (62 feet) patients treated with the Lapiplasty® Procedure and early return to weight-bearing at mean follow-up of 13.5 months.

	Pre-Op	6 Week	4 Month	12 Month/Final	P-value
IMA	13.6° ± 2.7°	6.1° ± 2.1°	6.1° ± 2.3°	6.6° ± 1.9°	< 0.001
HVA	24.2° ± 9.3°	11.6° ± 5.1°	10.2° ± 5.9°	9.7° ± 5.1°	< 0.001
TSP	5.0 ± 1.3	1.6 ± 0.7	1.8 ± 0.9	1.9 ± 0.9	< 0.001

Ray J, et al. Foot Ankle Int. 2019 Aug;40(8):955-960.

Highlights of the study:

- Mean return to weight-bearing at 10.9 days in a walking boot
- 96.8% of study patients maintained their 3-plane bunion correction as assessed by Intermetatarsal Angle (IMA), Hallux Valgus Angle (HVA) and Tibial Sesamoid Position (TSP)
- Symptomatic non-union rate of 1.6% (1 foot)

Progression of Healing on Serial Radiographs Following First Ray Arthrodesis in the Foot Using a Biplanar Plating Technique Without Compression

Multicenter, retrospective study of bone healing with accelerated weightbearing protocol in 195 patients undergoing TMT or MTP fusions with Lapiplasty® biplanar plating at mean follow up of 9.5 months.

Highlights of the study:

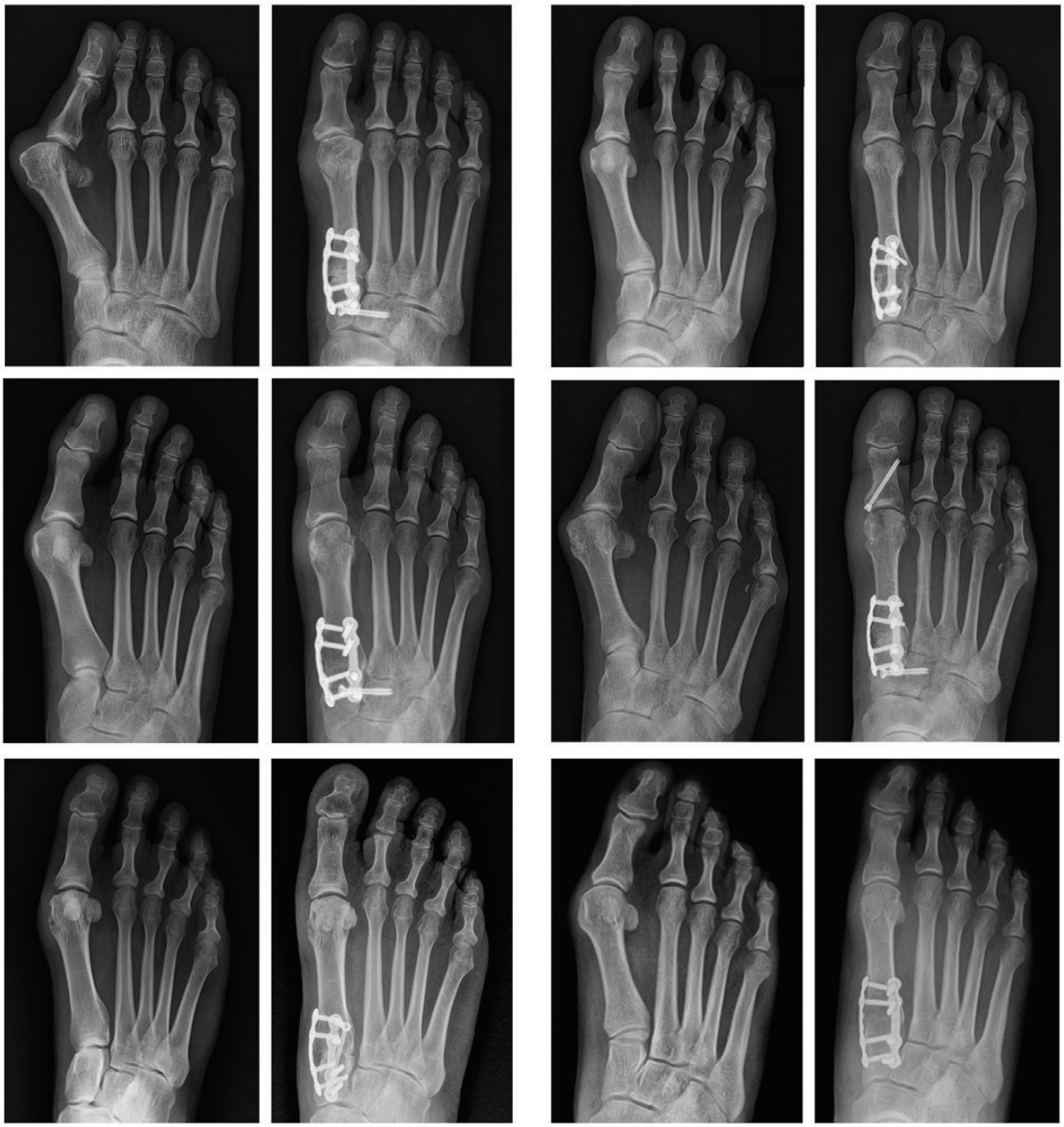
- Patients began weight-bearing at 5 days post-op in a walking boot
- 97.4% of the patients demonstrated a successful bony fusion and 98.9% of the patients maintained a stable joint position
- 3.1% overall implant removal rate for irritation and hardware failure

Dayton P, et al. J Foot Ankle Surg. 2019. 58:427-433.

Lapiplasty® Publications

1. Ray JJ, et al. Multicenter Early Radiographic Outcomes of Triplanar Tarsometatarsal Arthrodesis With Early Weightbearing. *Foot Ankle Int*. 2019, Aug;40(8):955-960.
2. Dayton P, et al. Progression of Healing on Serial Radiographs Following First Ray Arthrodesis in the Foot Using a Biplanar Plating Technique Without Compression. *Foot Ankle Surg*. 2019, 58:427-433.
3. Hatch et al. Triplane Hallux Abducto Valgus Classification. *J Foot Ankle Surg*. 2018, 57:972–981.
4. Dayton et al. Biomechanical Characteristics of Biplane Multiplanar Tension-Side Fixation for Lapidus Fusion. *J Foot Ankle Surg*. 2018, 57:766-770.
5. Dayton (Ed.) *Evidence-Based Bunion Surgery: A Critical Examination of Current and Emerging Concepts and Techniques*. Springer International Publishing [Textbook]. 2018.
6. Santrock et al. Hallux Valgus Deformity and Treatment. A Three-Dimensional Approach: Modified Technique for Lapidus Procedure. *Foot Ankle Clin*. 2018, 23:281-295.
7. Smith et al. Understanding Frontal Plane Correction in Hallux Valgus Repair. *Clin Podiatr Med Surg*. 2018, 35:27-36.
8. Dayton et al. Comparison of Tibial Sesamoid Position on Anteroposterior and Axial Radiographs Before and After Triplane Tarsal Metatarsal Joint Arthrodesis. *J Foot Ankle Surg*. 2017, 56:1041-1046.
9. Smith et al. Intraoperative Multiplanar Alignment System to Guide Triplanar Correction of Hallux Valgus Deformity. *Techniques in Foot & Ankle Surgery*. 2017, 16:175-82.
10. Dayton et al. Comparison of the Mechanical Characteristics of a Universal Small Biplane Plating Technique Without Compression Screw and Single Anatomic Plate with Compression Screw. *J Foot Ankle Surg*. 2016, 55:567-71.

The Beauty of *Reproducibility*



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