

The Leader in 3D Bunion Correction

Lapiplasty®

3-Plane Correction at the CORA



TREACE
Medical Concepts, Inc.

Contents

Lapiplasty® System

- What is the Lapiplasty® Procedure? 03
- Lapiplasty® Case Examples 04
- The Evidence-Based Solution 05
- Biomechanically Tested and Validated 06
- Lapiplasty® System: Anatomic Biplanar™ Implants 07

Lapiplasty® Accessory Kits

- One System for All Your Hallux Valgus Needs 08

Lapiplasty® Mini-Incision™ System

- Mini-Incision™ System Overview 09
- Mini-Incision™ Case Examples 10

Lapiplasty® Sterile-Packed Instruments

- FastGrafter®, SpeedRelease®, and TriTome™ Instruments 11

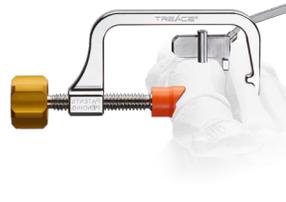
What is the Lapiplasty® Procedure?

An instrumented, reproducible¹ approach to 3-plane correction with rapid weight-bearing (in a walking boot)^{1,3} and low recurrence (0.9-3.0% in 17 and 13 months respectively)^{1,2}

Correct.

Make your correction **before** you cut

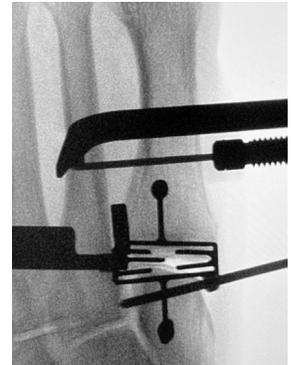
The **Lapiplasty® Positioner** is engineered to quickly and reproducibly correct the alignment in all three planes, establishing and holding true anatomic alignment of the metatarsal and sesamoids.²



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 with 2.4-3.1mm of average metatarsal shortening.⁴



Compress.

Achieve controlled compression of joint surfaces

The **Lapiplasty® Compressor** delivers controlled compression⁵ 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^{5,6} multiplanar stability for rapid return to weight-bearing (in a walking boot).^{1,3}



1. Ray J, et al. *Foot Ankle Int.* 2019 Aug;40(8):955-960. | 2. Dayton P, et al. *J Foot Ankle Surg.* 2020, 59(2): 291-297.
3. Dayton P, et al. *J Foot Ankle Surg.* 2019, 58:427-433 | 4. Hatch D, et al. *Foot & Ankle Ortho.* 2020, 5(4): 1-8.
5. Data on file. | 6. Dayton P, et al. *J Foot Ankle Surg.* 2016, 55:567-71. | 7. TMC data on file

The Reproducible Solution for Your Bunion Patients

Patented **correct before you cut** approach for reproducible¹ results



Patient Outreach Programs Driving Patient Education and Awareness

500K+

Patient website visits to
Lapiplasty.com
each month²

80K+

"Find a doctor" searches
on Lapiplasty.com
each month²

2K+

Active surgeons
performing the
Lapiplasty® Procedure

¹ Ray J, et al. Foot Ankle Int. 2019 Aug;40(8):955-960. | ² Data on file, based on trailing 6 months average, Aug 2022.

The Evidence-Based Solution for 3-Plane Correction

Backed by 21 publications and an ongoing 5-year multicenter prospective study¹, Treace Medical is recognized as the leader in advancing the scientific study of Hallux Valgus.

#1 3D Bunion Correction
most commonly used
by US Surgeons

Independent Survey, Jun 2020 | AOFAS Member Survey Aug 2021

21 Clinical publications
supporting the
Lapiplasty® Procedure

Lapiplasty® offers:

97-99% reproducible 3D correction (as demonstrated in 13 & 17 month studies) ^{2,3}	✓
<2 weeks to return to weight-bearing in a boot ^{2,6}	✓
10.4mm average reduction in osseous foot width ⁴	✓
2.4-3.1mm average shortening of first ray ⁵	✓
2-3% non-union rate (9.5 & 13.5 month follow-up) ^{2,6}	✓
3% hardware removal rate (in a 13 month study) ⁶	✓
1-3% recurrence rate (as demonstrated in 13 month studies) ^{2,3}	✓
30% increase in cycles to failure with Biplanar™ Plating ⁷ (compared to dorsomedial Lapidus plate + compression screw)	✓
>80% reduction in pain levels per VAS and MOxFQ scoring systems (interim analysis from ALIGN3D™ study of 40 patients at 24 months) ¹	✓

One- and Two-Year Analysis of a Five-Year Prospective Multicenter Study Assessing Radiographic and Patient-Reported Outcomes Following Triplanar First Tarsometatarsal Arthrodesis With Early Weightbearing for Symptomatic Hallux Valgus

Liu, G., Chhabra, A., Dayton, M.J., Dayton, P., Duke, W., Farber, D., Hatch, D., Kile, D., Koay, J., McAleer, J.P., Raissi, A., Raspovic, K.M., Santrock, R.D., Taylor, R.P., VanPelt, M., Wukich, D., JFAS. 2022 APR 26. [https://www.jfas.org/article/S1067-2516\(22\)00118-1/fulltext](https://www.jfas.org/article/S1067-2516(22)00118-1/fulltext)

Summary: Interim analysis from the Lapiplasty® ALIGN3D™ multicenter, prospective clinical study of 117 patients with at least 12 months of follow-up, of whom 40 patients have at least 24 months of follow-up (out of 173 total study patients).

- Early return to weight bearing in a walking boot within 7.8 days on average.
- Significant improvement in radiographic measures of 3-dimensional bunion correction from pre-surgery to 6 weeks and maintained at 12 months (n=108) and 24 months (n=38) post-surgery; with 1 recurrence reported at 12 months post-surgery (0.9% recurrence rate).
- Return to work within 4 weeks (25.2 days) and to full, unrestricted activity within 4 months post-surgery on average.
- Significant improvement in patient-reported pain reduction on VAS (n=112) and quality of life measurements on MOxFQ (n=113) and PROMIS (n=108) scores at 12 months and at 24 months (n=40).

1. Liu, G.T. et al. J Foot Ankle Surg. 2022 Apr 26 | 2. Ray J, et al. Foot Ankle Int. 2019;40(8):955-960. | 3. Dayton P, et al. J Foot Ankle Surg. 2020, 59(2): 291-297.

4. Vaida J, et al. Foot & Ankle Othopaedics. 2020. Vol. 5(3) 1-5. | 5. Hatch D, et al. Foot & Ankle Ortho. 2020, 5(4): 1-8. | 6. Dayton P, et al. J Foot Ankle Surg. 2019; 58(3):427-433.

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

Biomechanically Tested and Validated

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.

Biplanar™ Plating Gen 1



VS

Anatomic Dorsal Locking Plate w/ 4.0 Interfrag Screw



130%

Increase in Ultimate Failure Load¹

30%

Increase in Cycles to Failures^{1,2}

S1 Biplanar™ Plating



VS

Biplanar™ Plating Gen 1



50%

Increase in Ultimate Failure Load²

100%+

Increase in Cycles to Failures²

S2 Biplanar™ Plating



VS

Biplanar™ Plating Gen 1



78%

Increase in Ultimate Failure Load²

179%

Increase in Cycles to Failures²

¹ Dayton P, et al. J Foot Ankle Surg. 2016. 55:567-71. | ² TMC, Data on File (ER 1405-2031)

Lapiplasty® System

Anatomic Biplanar™ Implants

Biplanar configuration for multiplanar stability and low-profile, anatomic shape contoured to fit the 1st TMT joint

S1

Lapiplasty® System 1



Sterile-packed Biplanar™ Plating kit for versatility to fit each patient's anatomy, while delivering multiplanar strength.¹

- 2.7mm standard-sized locking screws eliminates intra-operative measuring
- 1.6mm thickness, with anatomic contour for low-profile fit

SK12 Plate Width | 3.6mm | Locking Screws | 2.7x12mm (5) | 2.7x14mm (4)

S2

Lapiplasty® System 2



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

- 10% increased cross-sectional width allows for designed for (compared to Lapiplasty® System 1)
- Low-profile thickness and anatomic contour maintained

SK14 Plate Width | 3.9mm | Locking Screws | 2.7x12mm (5) | 2.7x14mm (4)

S3^R

Lapiplasty® System 3R



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

- Increased center span (+5mm) to accommodate grafts and challenging anatomy
- Most cross-sectional width for robust stabilization; while maintaining the low-profile thickness

SK23 Plate Width | 4.3mm | Locking Screws | 3.0x12mm (4) | 3.0x16mm (8)

S4^A

Lapiplasty® System 4A



Next-generation Multiplanar™ Plating option with an advanced, three-dimensional proximal contour design accommodates the anatomy placement along the tarsometatarsal joint.

- Anatomic, 3D contour accommodates the intercuneiform joint and tibialis anterior insertion
- Centerline helps align with tarsometatarsal joint

SK39 Plate Width | 3.9mm | Locking Screws | Not Included

One System for All Your Hallux Valgus Needs

Sterile-packed kits for operational efficiency

Lapiplasty® Accessory Kits

Headless Screws¹

SK20

2.5x20mm

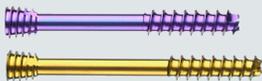
2.5x28mm



SK26

4.0x36mm

4.0x40mm



Headed Interfrag Screws¹

SK18

3.0x36mm

3.0x40mm



SK25

4.0x36mm

4.0x40mm



Transverse Screws¹

SK19

3.5x23mm

3.5x26mm



Snap-Off Screws²

SK21

2.0x12mm

2.0x14mm

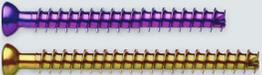


Fully Threaded Screws¹

SK37

4.0x32mm

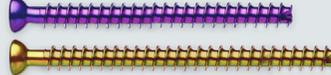
4.0x36mm



SK38

4.0x38mm

4.0x42mm

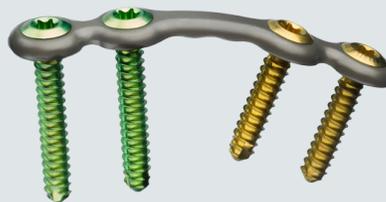


Lesser TMT Fixation Pack³

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

SK28

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



Lapiplasty® FastPitch³ 2.7mm High Pitch Locking Screws

- **Plate Compression** High pitch compression ratio compresses plate to the bone as screws lock in⁵
- **Faster Insertion** Increased thread pitch results in 33% faster screw insertion⁶
- **Lapiplasty Compatibility** Locking screws compatible with all Lapiplasty plating systems*

SD21

2.7x16mm (4)



SD22

2.7x12mm (2)

2.7x14mm (2)



Lapiplasty® Long Locking Screws³

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 1. LBL 1405-9056 | 2. LBL 1405-9110 | 3. LBL 1405-9005 | 4. LBL 1507-9005 | 5. TMC Data on file (ER 1405-0289) | 6. TMC Data on File (ER 1405-0313)
*Excludes Lapiplasty System Gen 1 and Plantar Python 1 plates.

Lapiplasty® Mini-Incision™ System

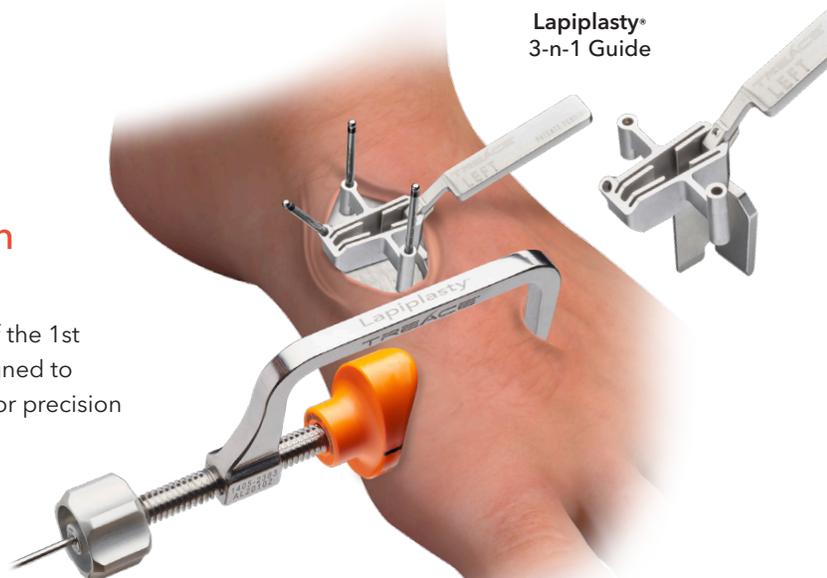
The Power of Lapiplasty® **Now Through a 3.5cm Incision**

Mini-Incision™

Precision Instrumentation Set

Mini Incision + Triplanar Correction Minus the Compromise

By applying the Mini-Incision™ Positioner over the skin of the 1st metatarsal, the Lapiplasty® Mini-Incision™ System is designed to deliver the patented **Correct Before You Cut** approach for precision 3-plane correction through a 3.5cm dorsal incision.



PlantarPower™

Anatomic Tension-Side Plate

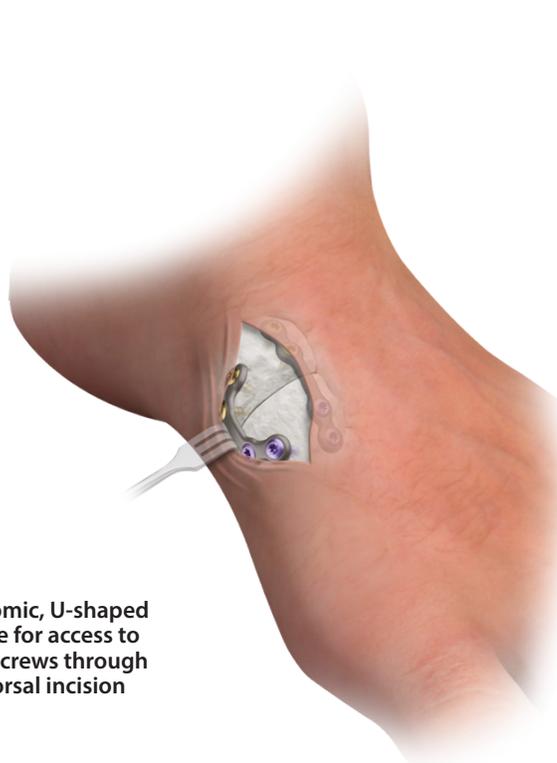
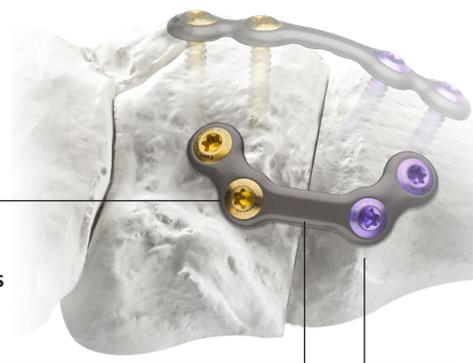
Powerful Tension-Side Fixation Designed for a Mini Incision

The PlantarPower™ Plate is uniquely contoured to span plantarly across the tension-side of the 1st TMT joint, while providing easy access to each locking screw without the need for extensive retraction of the mini dorsal incision.

Anatomic contour accommodates tibialis anterior tendon insertion

Center span extends plantarly across tension-side of 1st TMT joint

3D anatomic, U-shaped curvature for access to locking screws through a mini dorsal incision



Mini-Incision™ Case Examples



Individual results may vary. These results are specific to these patients only as actual patient case examples are being presented.*

Laplasty®

Sterile-Packed Instruments

FastGrafter®

Autograft Harvesting System (7mm)

The FastGrafter® Autograft Harvesting System is a sterile-packed, single-use device designed for quick and efficient harvest of cancellous autogenous bone from the calcaneus, distal tibia, and other harvest sites through a minimal incision approach.

- **Single-piece** harvester designed to reduce instrumentation and system complexity
- **Morselizing cutting** tip penetrates cortex and morselizes bone during harvest
- **Sterile-packed system** designed for quick and efficient harvest of autograft bone

SK27



SpeedRelease™

Guided Release Instrument

Sterile-packed, single-use instrument designed for quick and controlled release of the sesamoidal suspensory ligament and other soft tissues.

- **Guided tip** to direct insertion within the lateral joint capsule
- **Cutting edge** for quick and controlled release of the contracted soft tissue
- **Sterile-packed** for convenient delivery and consistent sharpness

SN20



TriTome™

Triple-Edge Release Instrument

Sterile-packed, single-use instrument designed to release between the metatarsal bases for the Adductoplasty™ Procedure and other applications.

- **Three cutting** edges for quick and controlled soft-tissue release
- **Thin 1.5mm cutting end** to access challenging anatomy
- **Sterile-packed** for convenient delivery and consistent sharpness

SN21



To learn more about benefit and risks, visit Lapiplasty.com

