# Lapiplasty®

## 3D Bunion Correction®


TREACE®

*A Step Ahead.™*

# Contents

## Lapiplasty® System



## Lapiplasty® Accessory Kits



## Lapiplasty® Sterile-Packed Instruments

## What is the Lapiplasty® Procedure?

An instrumented, reproducible[1] approach to 3-plane correction with rapid return to weight-bearing (in a walking boot)[1,3] and low recurrence (0.9% and 3.2% in studies at 17 and 13 months follow-up, respectively)[1,2]

# Correct.

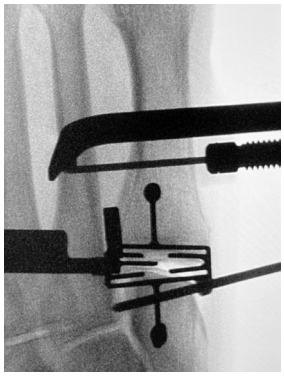
### Make your correction **before** you cut

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** is designed to deliver precise cuts with the metatarsal held in the corrected position, helping to facilitate optimal cut trajectory with minimal metatarsal shortening.[4]*



# Compress.

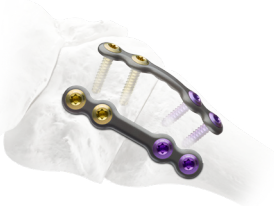
### Achieve controlled compression of joint surfaces

The **Lapiplasty® Compressor** is designed to deliver controlled compression[5] 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]

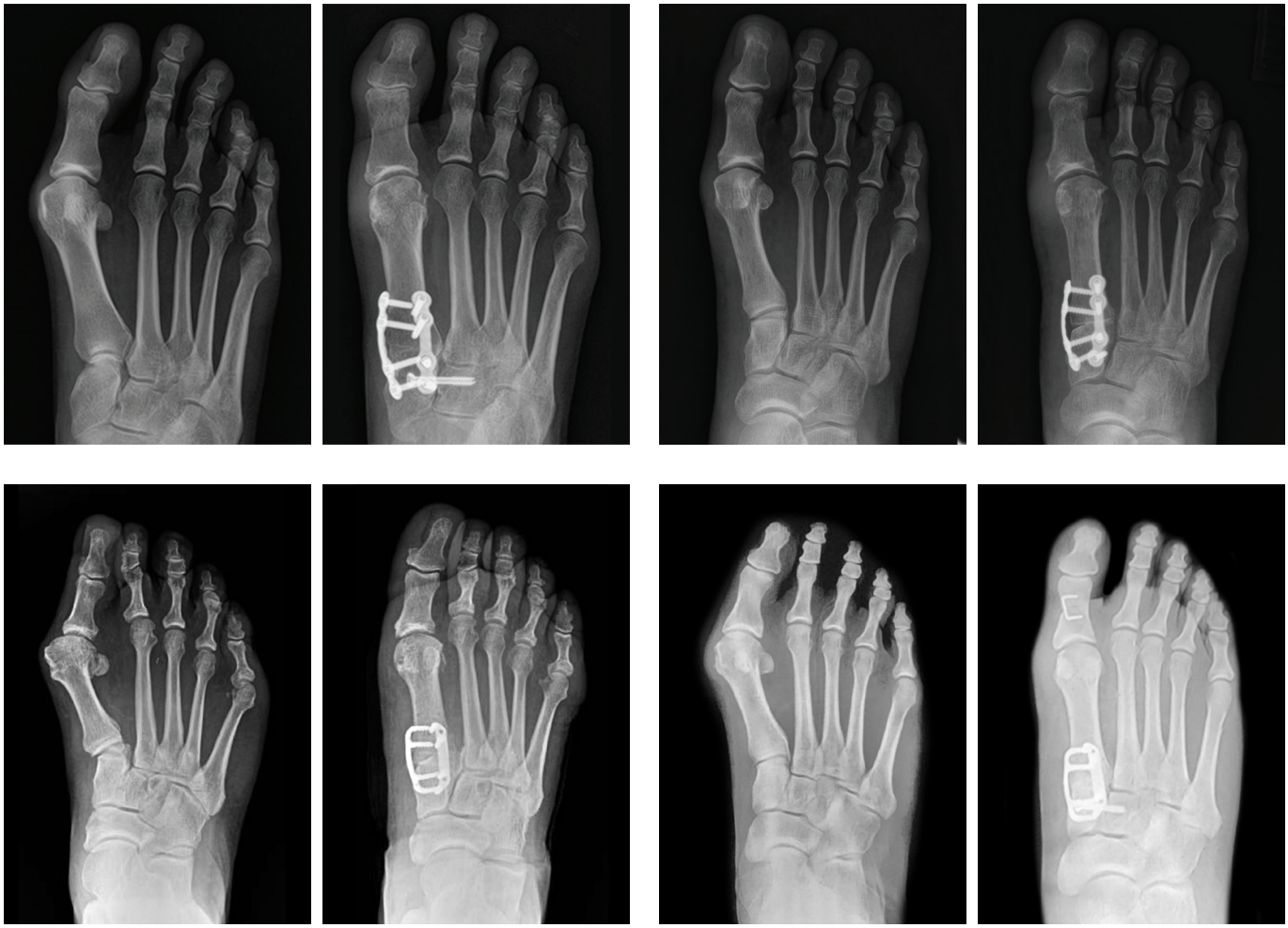


*2.4 and 3.1 in lateral and AP radiographs, respectively

1. Ray J, et al. Foot Ankle Int. 2019;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(3):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(3):567-571.

## The Reproducible Solution for Your Bunion Patients

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



## Growing Awareness Across the US

**500K+**

**Monthly web visits**
to Lapiplasty.com[1]

**3K+**

**Surgeons**
performing the
Lapiplasty® Procedure[1]

**100K+**

**Patients treated**
with the
Lapiplasty® Procedure[1]

1. Data on file.

# The Evidence-Based Solution for 3-Plane Correction

Backed by 24 publications and an ongoing 5-year multicenter prospective study, Treace Medical is recognized as the leader in advancing the scientific study of Hallux Valgus.[1]

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

AOFAS Member Survey Aug 2023

**24** **Clinical publications** supporting the Lapiplasty® Procedure

| | Lapiplasty® offers: |
|---|---|
| **97 and 99% successful maintenance of 3D correction** (as demonstrated in 13 &17 months follow-up, respectively)[3,2] | ✓ |
| **<2 weeks to return to weight-bearing in a boot**[3,6] | ✓ |
| **10.4mm average reduction in osseous foot width**[4] | ✓ |
| **2.4 and 3.1mm average shortening of first ray**[5] **(in lateral and AP radiographs, respectively)** | ✓ |
| **2-3% non-union rate** (13.5 & 9.5 month follow-up)[3,6] | ✓ |
| **3% hardware removal rate** (in a 13 month study)[6] | ✓ |
| **0.9% and 3.2% recurrence rate** (as demonstrated in studies at 17 & 13 months follow-up, respectively)[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 GT, Chhabra A, Dayton MJ, Dayton P, Duke W, Farber D, Hatch D, Kile D, Koay J, McAleer JP, Raissi A, Raspovic KM, Santrock RD, Taylor RP, VanPelt M, Wukich D. J Foot Ankle Surg. 2022; 61:1308-1316. https://doi.org/10.1053/j.jfas.2022.04.008.

**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 (n=117).
- 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 (n=117).
- 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 GT, et al. J Foot Ankle Surg. 2022. 61:1308-1316. | 2. Dayton P, et al. J Foot Ankle Surg. 2020;59(2):291-297. | 3. Ray J, et al. Foot Ankle Int. 2019;40(8):955-960.
4. Vaida J, et al. Foot & Ankle Ortho. 2020;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(3):567-571.

# 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 Load[1]

**30%**

Increase in Cycles to Failures[1,2]

**S1 Biplanar™ Plating**

**VS**

**Biplanar™ Plating Gen 1**

**50%**

Increase in Ultimate Failure Load[2]

**100%+**

Increase in Cycles to Failures[2]

**S2 Biplanar™ Plating**

**VS**

**Biplanar™ Plating Gen 1**

**78%**

Increase in Ultimate Failure Load[2]

**179%**

Increase in Cycles to Failures[2]

1. Dayton P, et al. J Foot Ankle Surg. 2016;55(3):567-571. | 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 eliminate 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)

---

### S3R

**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)

---

### S4A

**Lapiplasty® System 4A**

Next-generation Multiplanar™ Plating option with an advanced, three-dimensional proximal contour designed to conform to the anatomy of 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

See Instructions for Use LBL 1405-9005. 1. TMC, Data on File (ER 1405-0289).

# SpeedPlate™

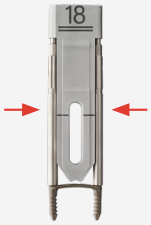
**Dynamic Compression**
offers continuous compression across the fusion site

**Titanium Alloy**
implant does not contain nickel2

**Anatomic Contour**
implant shape accommodates intercuneiform joint and tibialis anterior insertion

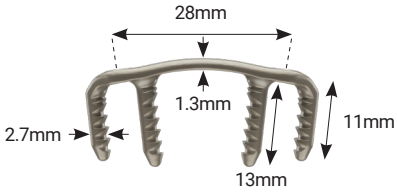
**Step 1**
Position & Drill


**Step 2**
Preload & Insert

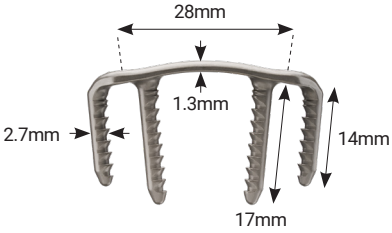


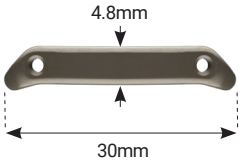

**Step 3**
Release & Compress

**Anatomic Quad - SK50** 28x13x11mm

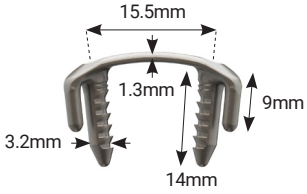



**Long Tine Anatomic Quad - SK53** 28x17x14mm

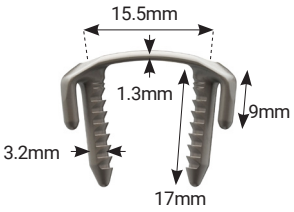


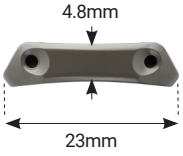




**Micro-Quad™ - SK61** 14mm

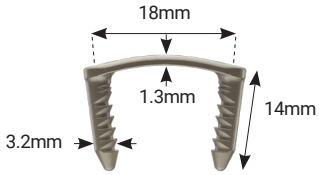



**Micro-Quad™ - SK61** 17mm

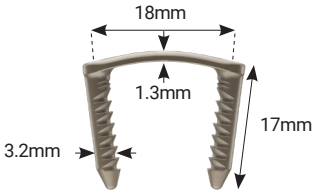


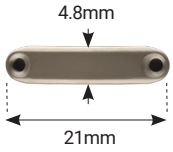




**SpeedPlate™ Dual - SK51** 18x14mm

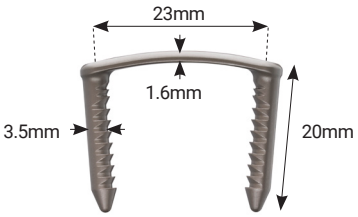


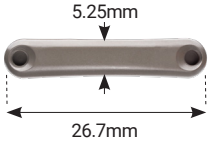

**SpeedPlate™ Dual - SK52** 18x17mm




**SpeedPlate™ Dual - SK54** 23x20mm




Refer to Treace Medical Concepts 09-00005L for full Instructions for Use 1. For complete information see ASTM F136-13, Standard Specification for Wrought Titanium-6Aluminum-4Vanadium ELI (Extra Low Interstitial) Alloy for Surgical Implant Applications (UNS R56401)

# Systems for all your Fixation Needs

Sterile-packed kits for operational efficiency

## Headless Screws[1]

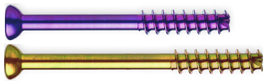
**SK20**
2.5x20mm
2.5x28mm

**SK26**
4.0x36mm
4.0x40mm

## Headed Interfrag Screws[1]

**SK18**
3.0x36mm
3.0x40mm

**SK25**
4.0x36mm
4.0x40mm



## Transverse Screws[1]

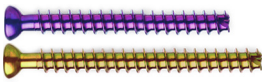
**SK19**
3.5x23mm
3.5x26mm

## Snap-Off Screws[2]

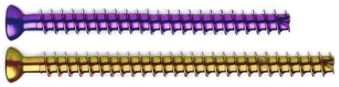
**SK21**
2.0x12mm
2.0x14mm

## Fully Threaded Screws[1]

**SK37**
4.0x32mm
4.0x36mm



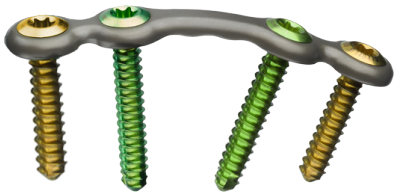
**SK38**
4.0x38mm
4.0x42mm



## Lesser TMT Fixation Pack[3]

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

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



## Lapiplasty® Locking Screws[3]

**2.7mm Locking Screw Pack**
**SD28**
2.7x12mm (2)
2.7x14mm (2)

## Hammertoe PEEK Fixation System[7]

**Small SK31**


**Medium SK32**


**Large SK33**


## Lapiplasty® FastPitch® Locking Screws[3]

- **Plate Compression** Screw thread design compresses plate to the bone during insertion[5]
- **Faster Insertion** Increased thread pitch results in 33% faster screw insertion[6]
- **Lapiplasty® Compatibility** Locking screws compatible with all Lapiplasty® plating systems*

**2.7mm High Pitch Locking Screw Pack**
**SD21**
2.7x16mm (4)

**2.7mm High Pitch Locking Screw Pack**
**SD22**
2.7x12mm (2)
2.7x14mm (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). | 7. LBL 1405-9203.
Sawbones® is a registered trademark of Pacific Research Laboratories, Inc. *Excludes Lapiplasty System Gen 1 and Plantar Python 1 plates.

# Lapiplasty® Sterile-Packed Instruments

## 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**

## FastGrafter®

Autograft Harvesting System

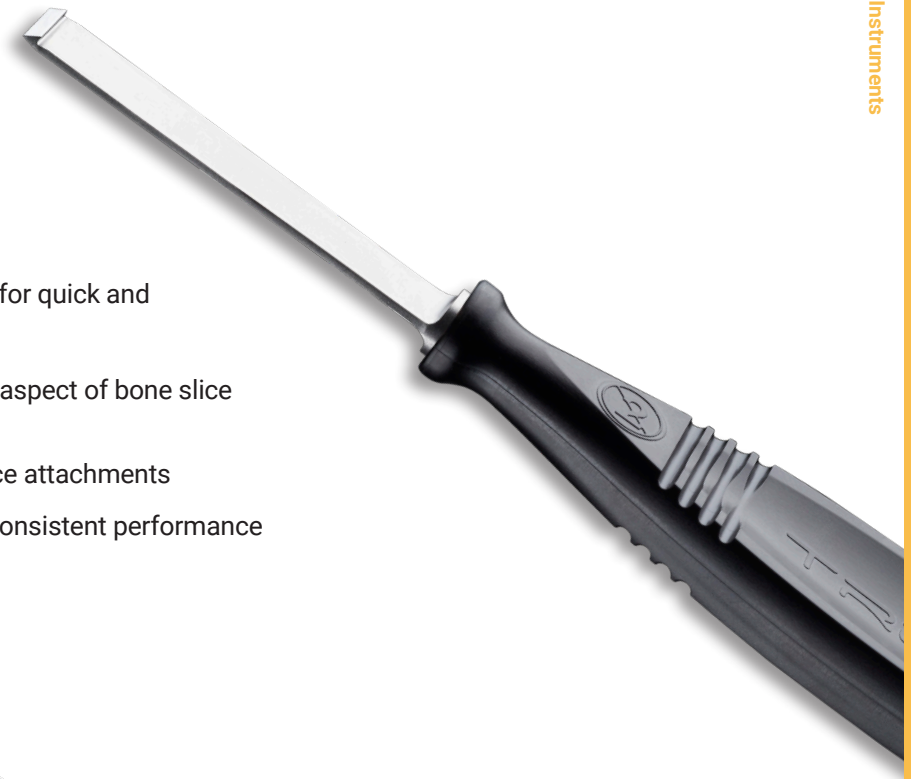

Sterile-packed, single-use device designed for quick and efficient harvest of cancellous autogenous bone from the calcaneus, distal tibia, and other harvest sites through a minimal incision approach.

- **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**

Refer to Treace Medical Concepts 09-00001L Sterile Instruments Instructions for Use, LBL 1507-9005 FastGrafter Instructions for Use

# Lapiplasty® Sterile-Packed Instruments



## LapiTome™

Hooked Bone Removal Osteotome

Sterile-packed, single-use instrument designed for quick and complete removal of osteotomy bone slices.

- **Hooked feature** designed to engage plantar aspect of bone slice for efficient removal
- **Sharp tip** to aid in releasing plantar bone slice attachments
- **Sterile-packed** for convenient delivery and consistent performance

**SN25**

## RazorTome™

7mm Precision Osteotome

Sterile-packed, single-use instrument designed to release plantar soft tissue attachments following TMT bone cuts.

- **Narrow design** for precision usage
- **Thin 1.2mm cutting end** to access tight anatomy
- **Sterile-packed** for convenient delivery and consistent sharpness

**SN24**

Before use of the system, the surgeon should refer to the appropriate instructions for use and surgical technique for complete warnings, precautions, indications, contraindications, and adverse events. Risks include, but are not limited to: infection, discomfort from the presence of the implant, loosening of the implant, and loss of correction with nonunion or malunion. If any of these occur, additional treatments may be needed. Additional information about risks, warnings, and instructions is available at Lapiplasty.com/surgeons/labeling.

**To learn more, visit Lapiplasty.com**

TREACE®
Medical Concepts, Inc.
*A Step Ahead.*