# SMART28 ADVANCED TECHNOLOGIES



Case ID: HV44R

Surgeon: Surgeon, Veijo Foot Laterality: Right Image Modality: CT

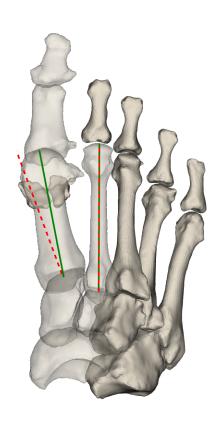
Image Type: Pre-Operative

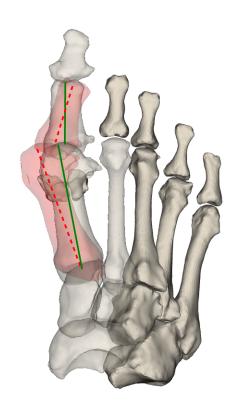


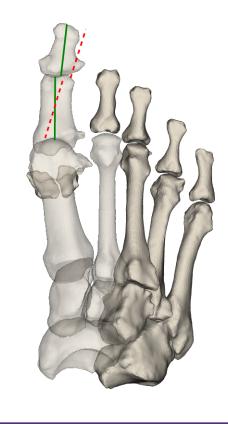




## HALLUX VALGUS CORRECTION







IMA	
1st – 2nd Intermetatarsa	al Angle

Pre-Op: 20.5°

Change: -9.4° (Valgus)

Target: 11.1°

HVA Hallux Valgus Angle	
Pre-Op: 37.2°	
Change: -25.9°	
Target: 11.3°	

IPA Interphalangeal Angle
Pre-Op: 0.5°
Change: 5.6°
Target: 6.1°

**ATTENTION:** The target IMA was limited by 1st – 2nd Metatarsal head proximity.

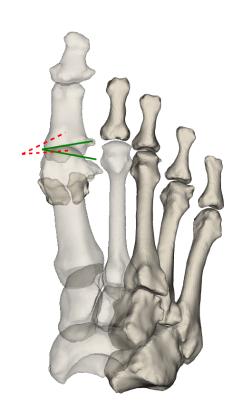
**NOTE:** Large IPA may indicate a need for an AKIN.

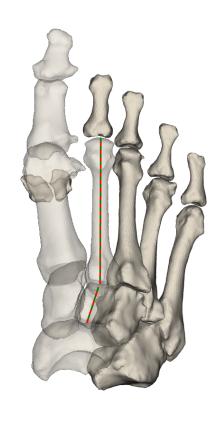


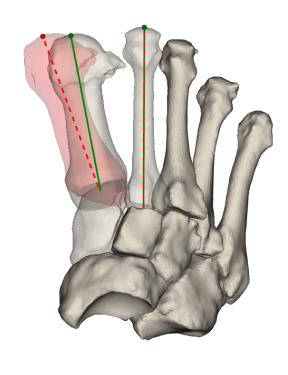
<sup>\*\*</sup>All figures throughout the report are post-op unless otherwise noted.



## HALLUX VALGUS CORRECTION







<b>DMAA</b> Distal Metatarsal Articular Angle	
Pre-Op: 22.0°	
Change: -2.3°	
Target: 19.7°	

2nd Tarsometatarsal Angle	
Pre-Op: 17.8°	
Change: 0.0°	
Target: 17.8°	

Relative Length 1st - 2nd Metatarsal	
Pre-Op: -3.8 mm	
Change: 0.3 mm	
Target: -3.5 mm	

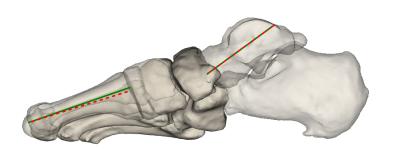
**NOTE:** Cut slots on the Medial Cuneiform Bun-Yo-Matic<sup>TM</sup> cut guide are spaced 1.45mm apart.

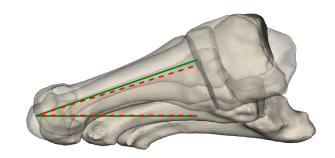


Pre-Op Measurement Post-



### SAGITTAL PLANE CORRECTION





## Meary's Angle

Pre-Op: -18.9°

Change: 1.9° (Plantarflexion)

Target: -17.0°

## 1st Metatarsal Declination Angle

Pre-Op: 17.3°

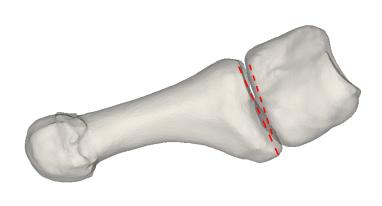
Change: 1.8° (Plantarflexion)

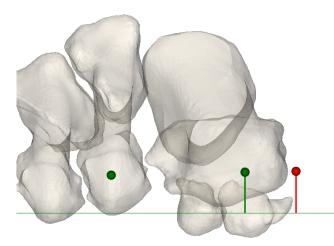
Target: 19.1°

**NOTE:** This angle may

indicate PCFD.

Pre-Op View





## **Plantar Gapping Angle**

Pre-Op: -6.1°

#### 1st Metatarsal Elevation

Pre-Op: 0.8 mm

Change: -0.2 mm (Plantarflexion)

Target: 0.6 mm

Pre-Op Measurement ••••••

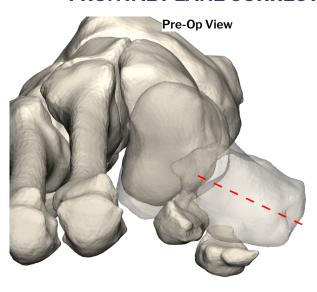
<sup>\*</sup>All measurements are simulated corrections only and are not directly controlled by instrumentation.

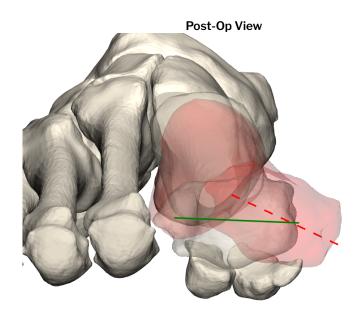
<sup>\*\*</sup>All figures throughout the report are post-op unless otherwise noted.

<sup>\*\*\*</sup>Simulated corrections do not account for soft-tissue constraints. Additional soft tissue procedures may be required.



## **FRONTAL PLANE CORRECTION**





## 1st Metatarsal Rotation

Pre-Op: 25.8°

Change: -23.5° (Supination)

Target: 2.3°

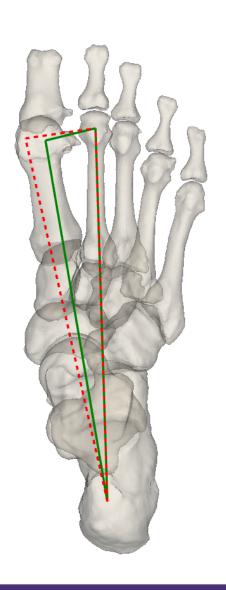


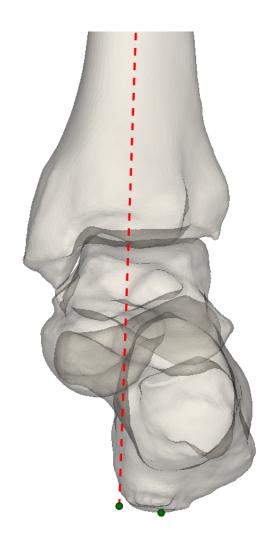


<sup>\*</sup>All measurements are simulated corrections only and are not directly controlled by instrumentation.



## **FOOT AND ANKLE RATIOS**





1st / 2nd / Calcaneus Ratio image

**Hindfoot Moment Arm (Posterior)** 

Pre-Op: 11.1 mm

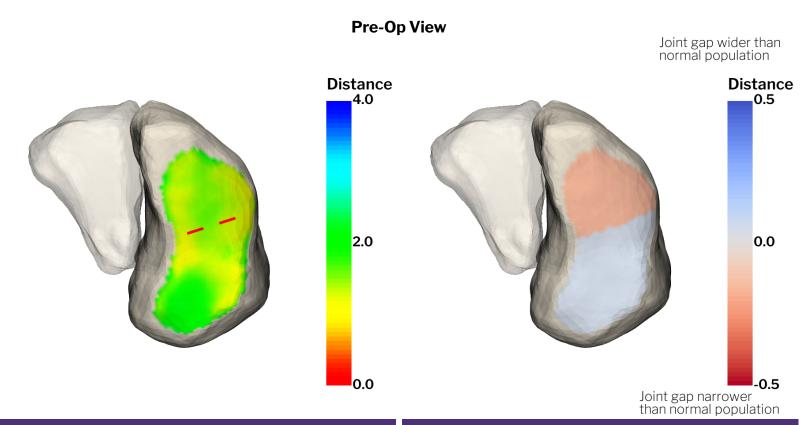




<sup>\*</sup>All measurements are simulated corrections only and are not directly controlled by instrumentation.



## **DISTANCE MAPPING**



## 1st TMT Distance Mapping

Average gap: 1.5 mm

Average gap superior: 1.4 mm

Average gap inferior: 1.5 mm

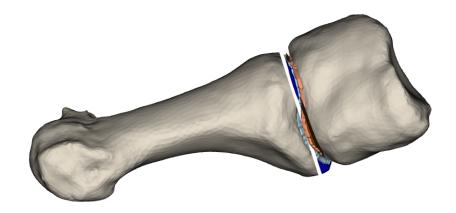
**Average Gap Difference From Normal Population** 





## **Intra-Op Plan:**

### **PLANNED RESECTIONS**

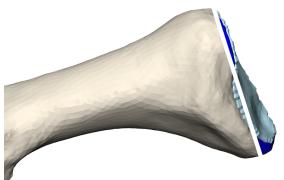


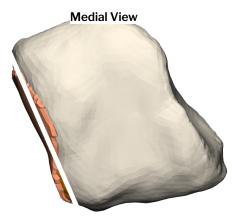
**NOTE:** Measurements may vary based on actual cartilage thickness.

**ATTENTION:** 2nd cut slot on Medial Cuneiform Bun-Yo-Matic cut guide may be needed.

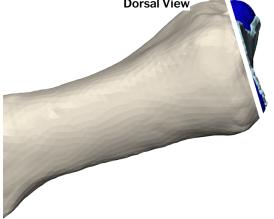
**ATTENTION:** Removal of cartilage by scraping with hand tools may be need







**Dorsal View** 



**Dorsal View** 



**MEDIAL** 

#### 1st Metatarsal

Average Bone Resection Thickness: 0.5 mm

## **Medial Cuneiform**

Average Bone Resection Thickness: 0.1 mm

**Medial Cuneiform Cartilage Estimate** 

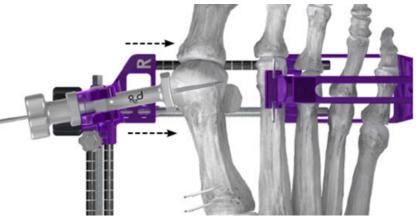
**MEDIAL** 

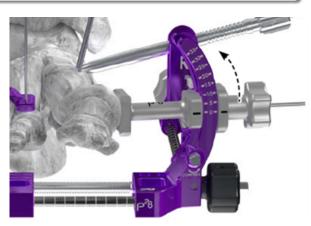


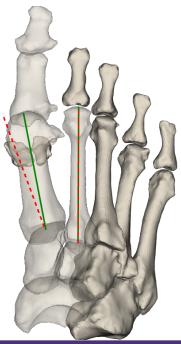
## **Intra-Op Plan:**

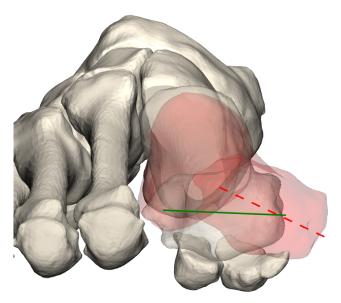
## **Bun-Yo-Matic<sup>™</sup> Correction**

**NOTE:** Completing correction with the Bun-Yo-Matic<sup>TM</sup> settings listed below is a recommendation only. Final correction settings are up to surgeon discretion.









## 1-2 IMA Adjustment 1st – 2nd Intermetatarsal Angle

Pre-Op: 20.5°

Target: 11.1°

Bun-Yo-Matic™ Translation: 10 mm

## 1st Metatarsal Rotation Adjustment

Pre-Op: 25.8°

Target: 2.3°

Bun-Yo-Matic™ Rotation: 22.5° (Supination)

**NOTE:** The translation adjustment allowable by the Bun-Yo-Matic™ system ranges from 0mm to 33mm.

**NOTE:** The rotation adjustment allowable by the Bun-Yo-Matic<sup>TM</sup> system ranges from  $0^{\circ}$  to  $35^{\circ}$ .



<sup>\*</sup>All measurements are simulated corrections only and are not directly controlled by instrumentation.

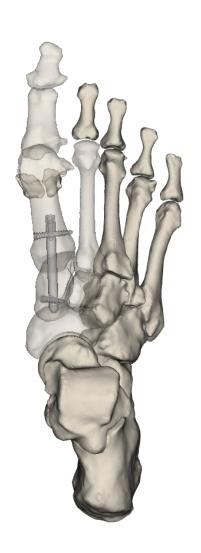
<sup>\*\*</sup>All figures throughout the report are post-op unless otherwise noted.

<sup>\*\*\*</sup>Simulated corrections do not account for soft-tissue constraints. Additional soft tissue procedures may be required.



## **Intra-Op Plan:**

## **EXAMPLE FINAL FIXATION SIZING**



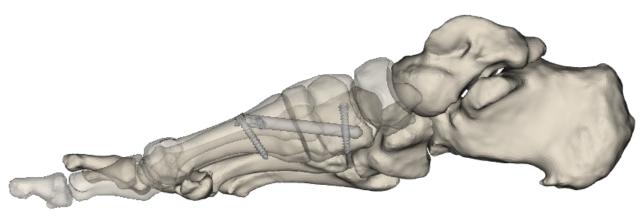
Hardware Component	Size Shown
Phantom® Nail Length¹	Ø5.5 x 54 mm
Phantom® Nail Threaded Peg Length <sup>2</sup> (Proximal Medial Cuneiform)	Ø3.5 x 24 mm
Phantom® Nail Threaded Peg Length <sup>2</sup> (Metatarsal)	Ø3.5 x 22 mm
Phantom® Nail Locking Screw Length <sup>2</sup>	Ø3.5 x 22 mm

<sup>1</sup>Phantom® Nail sizes available: Ø5.5 x 38-60 mm (2 mm increments) <sup>2</sup>Screw sizes available: Ø3.5 x 10-46 mm (2 mm increments)

ATTENTION: The Phantom® Nail and screws are provided for visualization purposes only.

Proper execution of the Phantom® Nail technique guide is required to determine final implant placement and sizing.

**NOTE:** Final fixation type may vary by surgeon preference.



<sup>\*</sup>All measurements are simulated corrections only and are not directly controlled by instrumentation.

<sup>\*\*\*</sup>Simulated corrections do not account for soft-tissue constraints. Additional soft tissue procedures may be required.

\*\*\*For the contraindications, potential complications and adverse reactions, warnings and precautions associated with the Phantom Small Bone Intramedullary Nail System, please refer to the instructions for use at http://www.paragon28.com/ifu.



<sup>\*\*</sup>All figures throughout the report are post-op unless otherwise noted.



#### **INFORMATION**



Due to the automated report generation, minor segmentation errors may exist.

## **ANALYSIS RESULTS - ERRORS AND WARNINGS**



No errors or warnings.

#### **NORMATIVE REFERENCE VALUES**

The target correction values of SMART Bun-Yo-Matic<sup>SM</sup> are dictated by the normative reference values unless alternative target values are set by the user. For more information, see the SMART Bun-Yo-Matic<sup>SM</sup> Instructions for Use (PRO IFU MAN 231 SMART Bun-Yo-Matic (CT)).

Measurement	Average
1st - 2nd Intermetatarsal Angle (Axial)	9.4°
Meary's Angle (Sagittal)	-7.5°
1st Metatarsal Rotation	2.3°
Hallux Valgus Angle (Axial)	11.3°
Hallux Valgus Angle (Sagittal)	10.6°
2nd Tarsometatarsal Angle (Axial)	19.6°
3rd Tarsometatarsal Angle (Axial)	19.2°





Please check the website, www.paragon28.com/ifus, for the most current instructions for use document.

#### Prescription use only statement

CAUTION: Federal Law (USA) restricts this device to sale and use by, or on the order of, a physician.

#### Indications for use

Smart Bun-Yo-Matic software is to be used by orthopaedic healthcare professionals for diagnosis and surgical planning in a hospital or clinic environment. The medical imaging type intended to be used as the input of the software is Computed Tomography (CT).

Smart Bun-Yo-Matic software provides:

- Visualization report of the three-dimensional mathematical models of the anatomical structures of foot and ankle and three-dimensional models of orthopaedic fixation devices,
- Measurement templates containing radiographic measures of foot and ankle,
- Surgical planning application for visualization of foot and ankle anatomical three-dimensional structures, radiographic measures, and surgical instrument parameters.

The visualization report containing the measurements can be used for the diagnosis of orthopaedic healthcare conditions. The surgical planning application containing the visualizations of the three-dimensional structural models, orthopaedic fixation device models and surgical instrument parameters combined with the measurements can be used for the planning of treatments and operations to correct orthopaedic healthcare conditions of foot and ankle.

#### **Contraindications**

Smart Bun-Yo-Matic software is not intended for other anatomies than foot and ankle. Using unvalidated medical imaging modality, such as magnetic resonance imaging (MRI), or using medical imaging of non-weight-bearing condition as an input for the software is not allowed. The software output alone cannot be used for diagnostic of the orthopaedic healthcare condition and planning of the surgical operation without careful professional assessment. Any physical model generated from the output of the software is not validated for diagnostic or surgical planning purposes.



# SMARTZ8 ADVANCED TECHNOLOGIES





www.Paragon28.com

Paragon 28, Inc. 14445 Grassland

14445 Grasslands Dr Englewood, CO 80112 USA (855) 786-2828

PRO SMARTB TEM 031 Revision 1.0 SMART Bun-Yo-Matic<sup>SM</sup> version : 0.1.2 (2023-05)