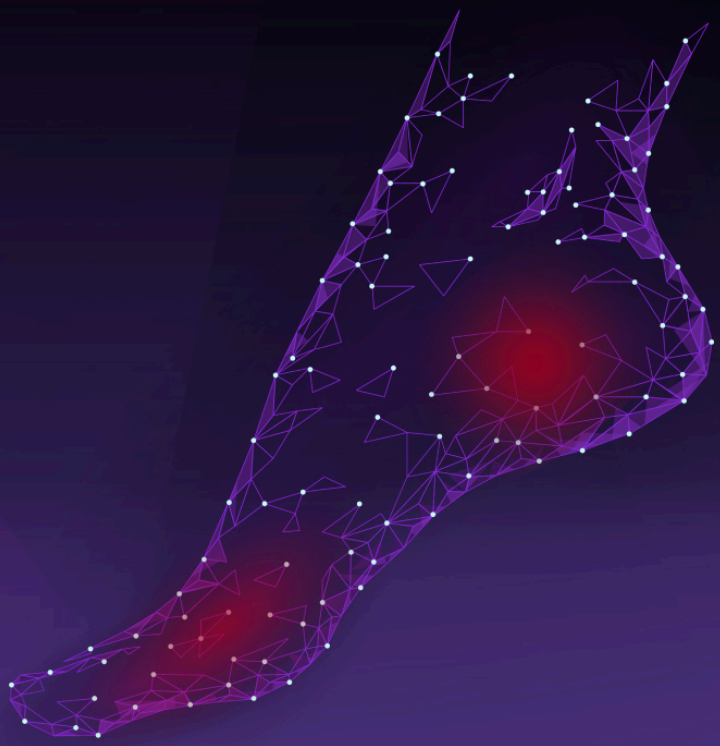
SMART28®
ADVANCED TECHNOLOGIES

SMART28® PCFD

Case ID: 6DEGR
Surgeon: Kuhlefelt, Kira
Foot Laterality: Right
Image Modality: CT
Image Type: Pre-Operative



Paragon28®
a ZIMMER BIOMET company

Pre-Op Plan

PRE-OPERATIVE STATE

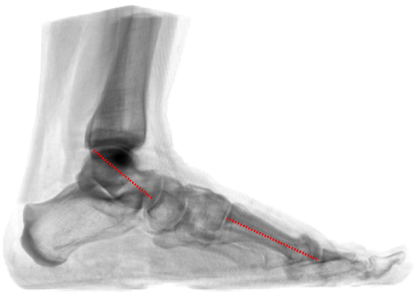
Foot alignment



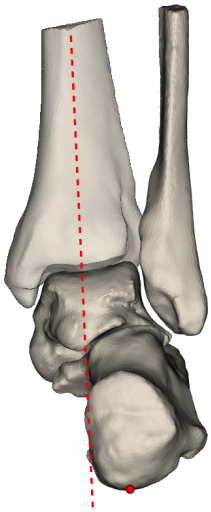
POSTERIOR

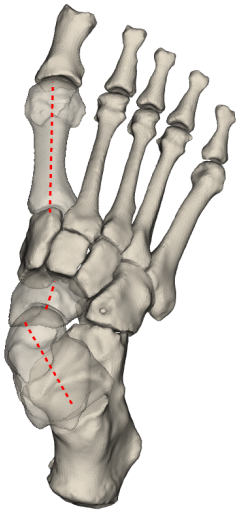


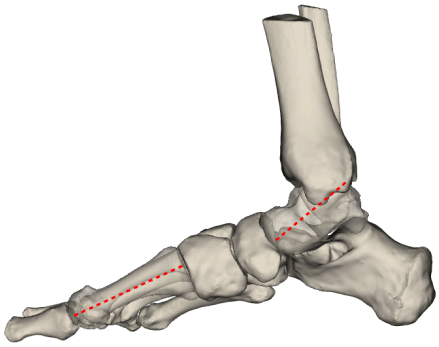
AXIAL



SAGITTAL







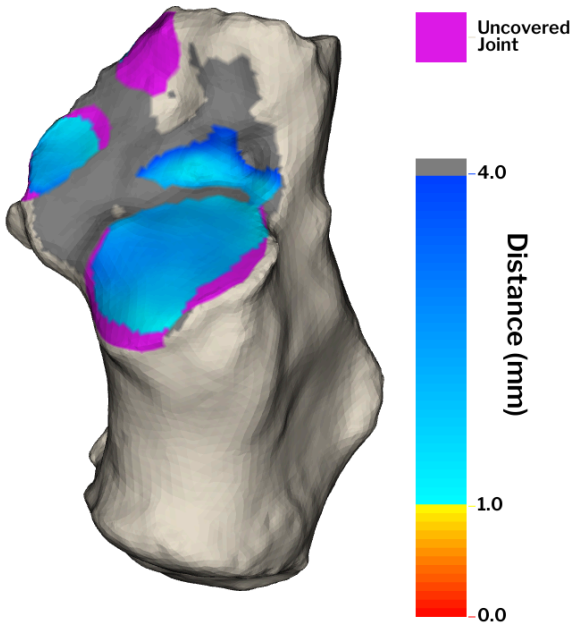
Pre-Op ------

	HINDFOOT VALGUS	FOREFOOT ABDUCTION		ARCH COLLAPSE
	Hindfoot Moment Arm	Meary's Angle (Axial)	Talonavicular Angle (Axial)	Meary's Angle (Sagittal)
Pre-Op	12.3 mm	31.3°	48.1°	-14.9°

Pre-Op Plan

PRE-OPERATIVE STATE

Peritalar distances and coverages



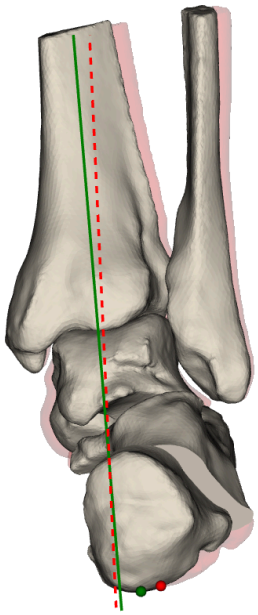
Covered Area Distance Mapping
Covered Anterior Facet Average Distance: 2.3 mm
Covered Middle Facet Average Distance: 2.0 mm
Covered Posterior Facet Average Distance: 2.2 mm
Covered Sinus Tarsi Average Distance: 2.4 mm

NOTE: *Visualized facet areas are based on general foot model. Individual facet regions may differ.*

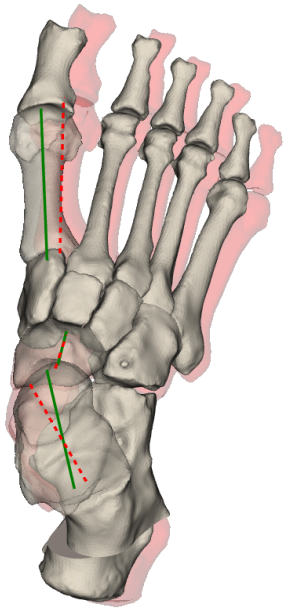
Intra-Op Plan

ESTIMATED POST-OPERATIVE STATE

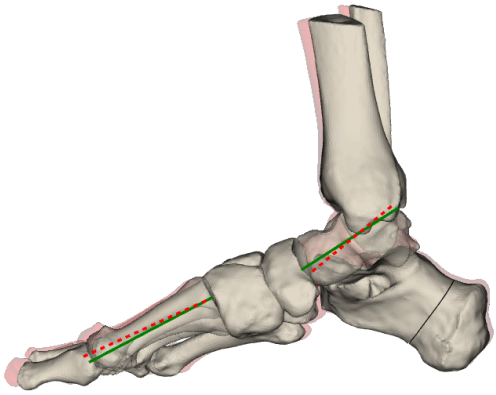
POSTERIOR



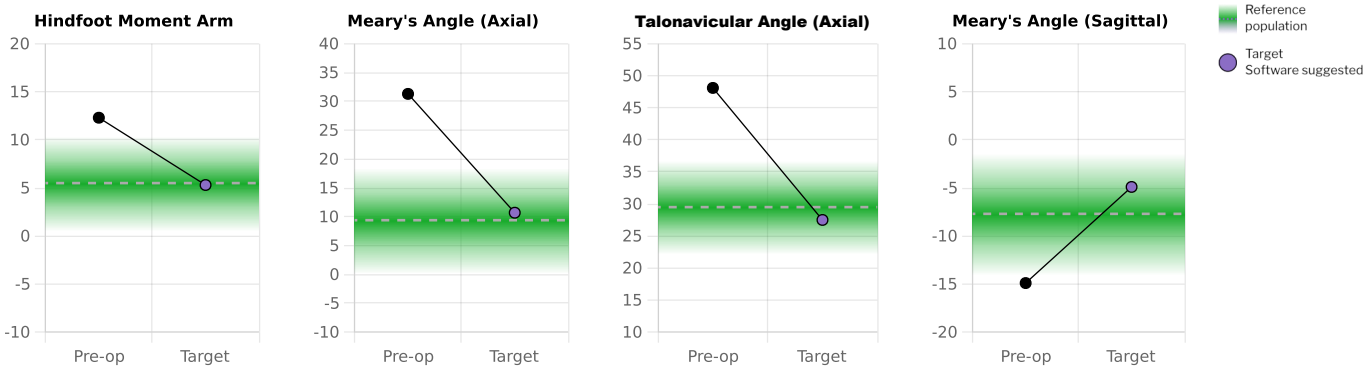
AXIAL



SAGITTAL



Pre-Op ------ **Target** ——



	HINDFOOT VALGUS	FOREFOOT ABDUCTION		ARCH COLLAPSE
	Hindfoot Moment Arm	Meary's Angle (Axial)	Talonavicular Angle (Axial)	Meary's Angle (Sagittal)
Pre-Op	12.3 mm	31.3°	48.1°	-14.9°
Change	-7.0 mm	-20.6°	-20.6°	10.0°
Target	5.3 mm	10.7°	27.5°	-4.9°

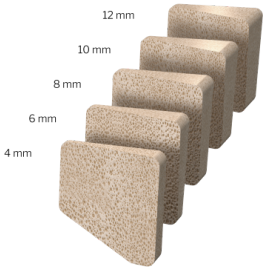
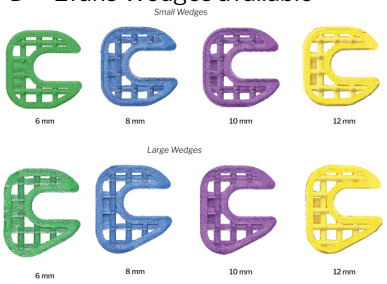
NOTE: *Anatomical post-operative visualizations for reference only. Patient-specific mechanics of soft tissue interactions are not simulated. Additional soft tissue procedures may be required to achieve planned correction.*

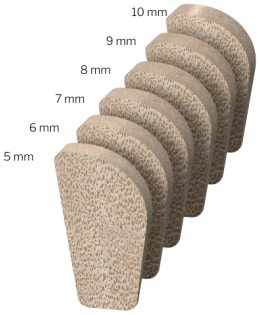
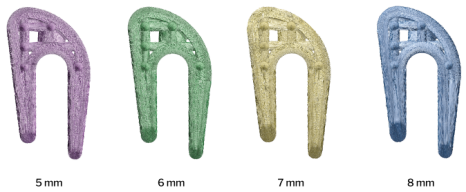
Intra-Op Plan

PCFD CORRECTION

Selected operation combination

Medial Displacement Calcaneal Osteotomy	
Selected size	7 mm

Lateral Column Lengthening	
Selected size	7 mm
PRESERVE™ Evans Grafts available 	Titan 3-D™ Evans Wedges available 

Cotton Osteotomy	
Selected size	5 mm
PRESERVE™ Cotton Grafts available 	Titan 3-D™ Cotton Wedges available 

OPERATION COMBINATION SELECTION		
Software suggested	**User-adjusted (Assisted mode)**	**User-adjusted (Manual mode)**
X		

NOTE: *For LCL procedures, if the operation sizes exceed or fall below the available graft or wedge sizes, refer to the instructions in the corresponding surgical technique guide.*

NOTE: *Final correction and fixation options are up to surgeon discretion. Fixation options may vary by surgeon preference.*

NOTE: *Cut guides may be used to aid locating a suitable cut position and to avoid possible structures at risk.*

FIXATION HARDWARE LISTING

MDCO fixation

Hardware Component	Sizes Available
Gorilla® Calc Slide Plate	One size
Gorilla® R3CON Plating Screws	• Ø2.7 x 8-20 mm (1 mm increments) and 22-40 mm (2 mm increments) • Ø3.5 x 10-50 mm (2 mm increments) • Ø4.2 x 10-50 mm (2 mm increments) and 55-70 mm (5 mm increments)
Monster® Hindfoot Screws	• Ø4.5 x 18-50 mm (2 mm increments) and 55-70 mm (5 mm increments) • Ø5.5 x 26-60 mm (2 mm increments) and 65-90 mm (5 mm increments) • Ø7.0 x 36-50 mm and 72-90 mm(2 mm increments) and 55-70 mm and 95-130 mm (5 mm increments)

LCL fixation

Hardware Component	Sizes Available
Gorilla® Universal HEvans® Plate	Several sizes
Gorilla® R3CON Plating Screws	• Ø2.7 x 8-20 mm (1 mm increments) and 22-40 mm (2 mm increments) • Ø3.5 x 10-50 mm (2 mm increments) • Ø4.2 x 10-50 mm (2 mm increments) and 55-70 mm (5 mm increments)
Monster® Screws	• Ø3.5 x 10-50 mm (2 mm increments) • Ø4.0 x 10-50 mm (2 mm increments) and 55-60 mm (5 mm increments)

Cotton fixation

Hardware Component	Sizes Available
Gorilla® Universal 28 Plates	Several sizes
Gorilla® R3CON Plating Screws	• Ø2.7 x 8-20 mm (1 mm increments) and 22-40 mm (2 mm increments) • Ø3.5 x 10-50 mm (2 mm increments) • Ø4.2 x 10-50 mm (2 mm increments) and 55-70 mm (5 mm increments)
Monster® Screws	• Ø3.5 x 10-50 mm (2 mm increments) • Ø4.0 x 10-50 mm (2 mm increments) and 55-60 mm (5 mm increments)

NOTE: *Final correction and fixation options are up to surgeon discretion. Fixation options may vary by surgeon preference.*

INFORMATION

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

ANALYSIS RESULTS - WARNINGS

No warnings.

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

SMART28® PCFD software is to be used by orthopedic healthcare professionals for diagnosis and surgical planning of Progressive Collapsing Foot Deformity (PCFD) in a hospital or clinic environment. The medical image modality intended to be used in the software is weight-bearing CT(WBCT).

SMART28® PCFD software provides for the user:
• Visualization report of the three-dimensional (3D) mathematical models and measurements of the anatomical structures of foot and ankle and three-dimensional models of orthopedic fixation devices,
• Measurement templates containing radiographic measures of foot and ankle, and
• Surgical planning application for visualization of foot and ankle anatomical three-dimensional structures, radiographic measures, and surgical instrument parameters supporting the following common flatfoot procedures: Medializing Displacement Calcaneal Osteotomy (MDCO), Lateral Column Lengthening (LCL), and Cotton Osteotomy (CO).

The visualization report containing the measurements can be used for the diagnosis of PCFD. The surgical planning application containing the visualizations of the three-dimensional structural models, orthopedic fixation device models and surgical instrument parameters combined with the measurements can be used for treatment planning of PCFD.

Contraindications

SMART28® PCFD software is not intended for other anatomies than the 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 orthopedic healthcare condition and planning of the surgical operation without careful professional assessment. The software output should not be used for planning purposes if the CT scan date is greater than 6 months from the patient's surgery date, or significant changes to the patient's anatomy have occurred since the medical scan was obtained.

SMART28®
ADVANCED TECHNOLOGIES

SMART28® PCFD

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a ZIMMER BIOMET company

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SMART28® PCFD
UDI: (01) 06429810209054 (10) 1.1.1
Manufacturing date: 2026-09

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