APEX 3D™
TOTAL ANKLE REPLACEMENT

3D Printed Additive Metal Technology for Optimal Porosity

Vitamin E Cross-Linked Infusion to Reduce Oxidation, Wear Debris and Potential for Osteolysis[1,2]

Multi-Axial Articulation Mimics Natural Tibiotalar Motion

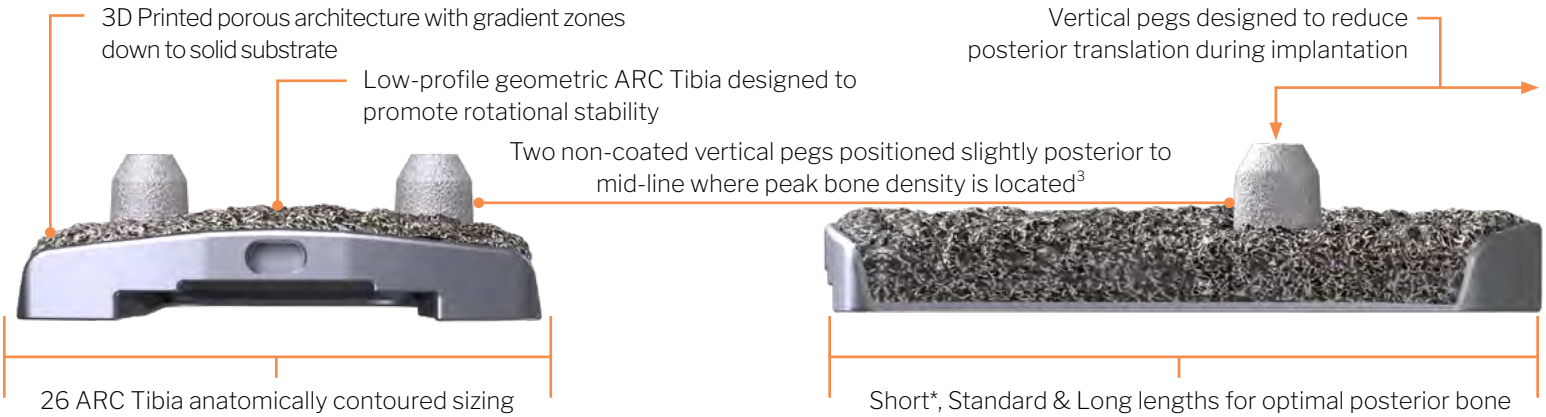
BASED ON OVER A CENTURY OF COMBINED CLINICAL EXPERIENCE...

and cutting-edge biomechanical research, the Paragon 28® APEX 3D™ Total Ankle Replacement System was designed to address end-stage ankle arthritis and current challenges within the total ankle market including: implant loosening, pathological wear, instability and persistent pain.

PARAGON 28® APEX 3D™ TOTAL ANKLE SYSTEM...

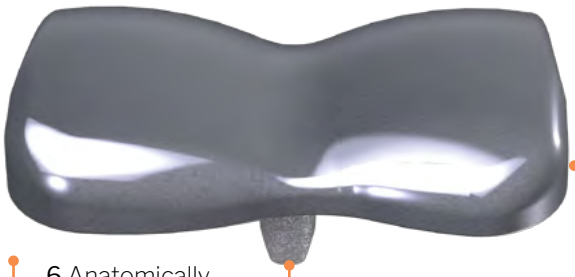
consists of cemented, fixed-bearing anatomically contoured implant components and precision instrumentation intended for use in primary or revision surgery for patients with ankle joints damaged by severe rheumatoid, post-traumatic, or degenerative arthritis. The APEX 3D™ System has been efficiently streamlined to accommodate surgeon preference, and address patient's native anatomic needs.

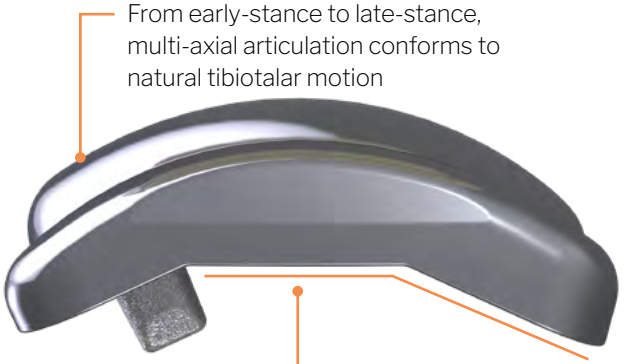
ARC TIBIAL TRAY: Designed for Rotational Stability



VITAMIN E CROSS-LINKED TIBIAL INSERT: Allows for Anatomic Conformity

CHAMFER-CUT TALAR DOME: Designed to Mimic Natural Motion





THE GOAL OF "PROJECT APEX"...

was to investigate clinically reported modes of ankle replacement failure, and conduct state-of-the-art research to better understand tibiotalar morphology and joint kinematics in order to introduce clinically relevant solutions.

IMPLANT DESIGNS WERE GUIDED BY...

- Newer clinical evidence
- Advanced technologies
- Implant sizing & anatomic footprint based on pre-clinical arthritic tibiotalar morphological studies
- Healthy ankle kinematic weight-bearing CT research

FLAT-CUT TIBIAL TRAY:

Broad anterior surface area to optimize contact interface

Poly insertion counter pressure feature

Medial / Lateral side-wall surface area designed for added fixation and rotational stability

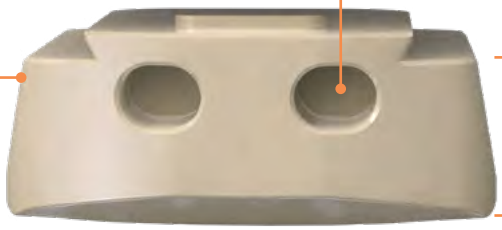
Vertical pegs positioned to target optimal tibia bone density[3] for initial stabilization

26 Flat anatomically contoured sizing options Available in left & right configurations

VITAMIN E CROSS-LINKED TIBIAL INSERT:

Poly insertion feature

Medial / Lateral tapered to avoid protrusion and multiple thickness options for primary or revision cases

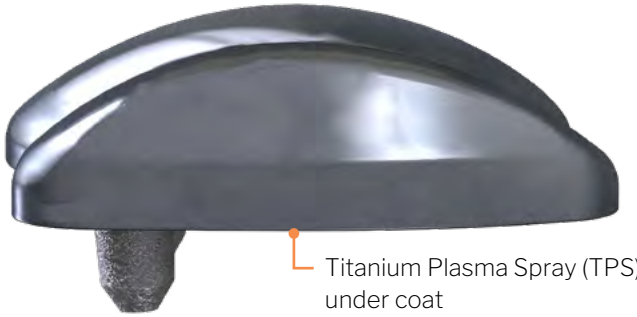


7 Thickness options: (6 - 12 mm) in 1 mm increments

35 Sizing and thickness combinations allowing for interoperative flexibility

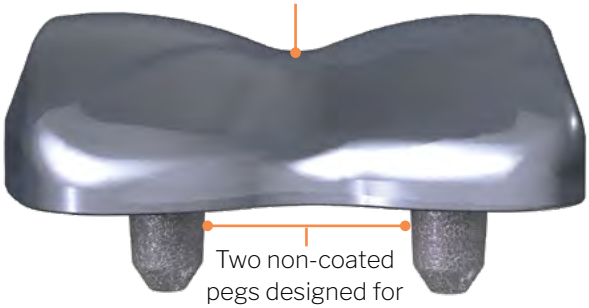
FLAT-CUT TALAR DOME:

Talar dome options provide the ability to up-size by 1, and down-size without restriction



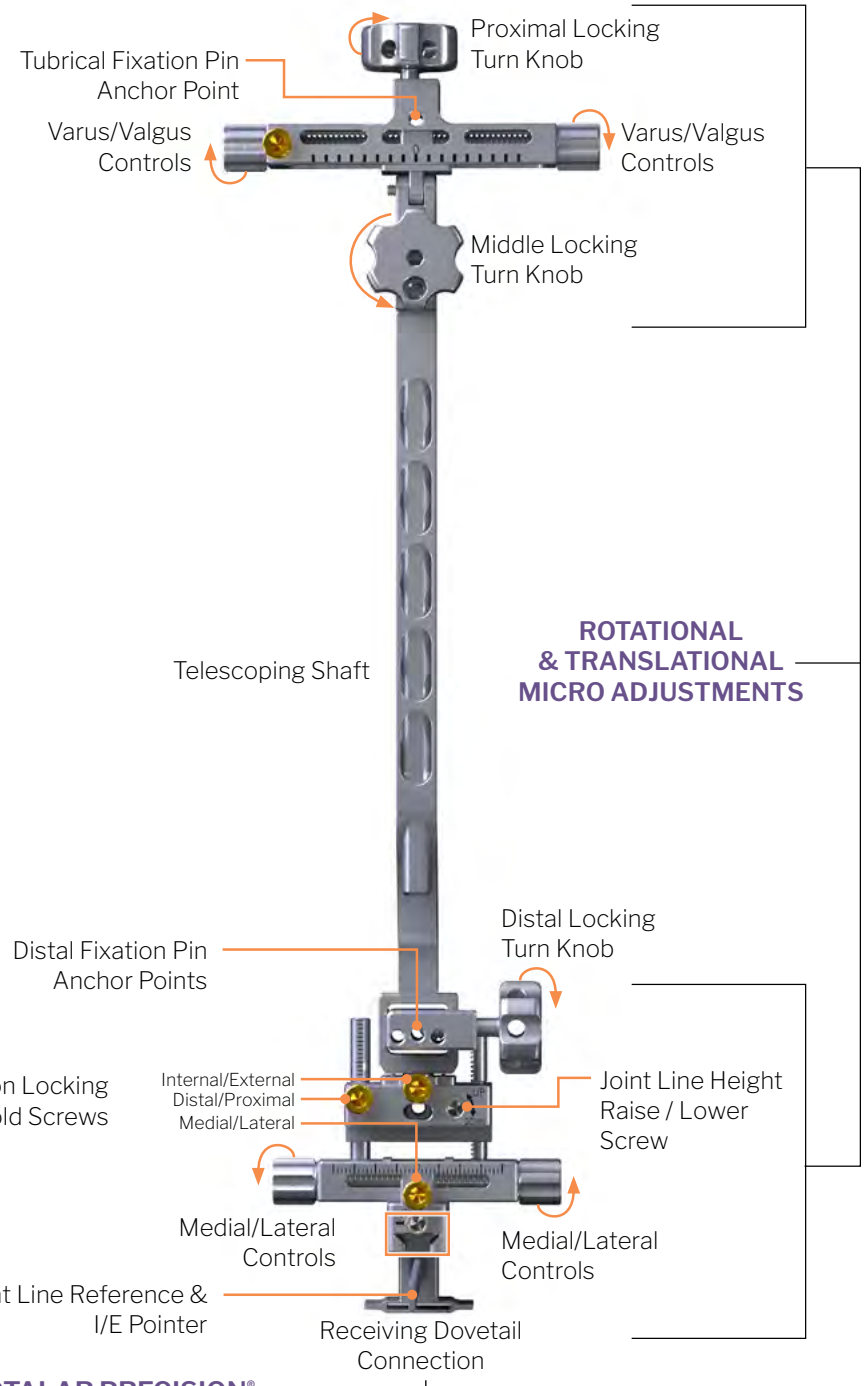
Titanium Plasma Spray (TPS) under coat

Anatomically contoured gentle sulcus resists medial/ lateral translation and subluxation



Two non-coated pegs designed for rotational stability

TRADITIONAL ALIGNMENT GUIDE: Alignment Accuracy & Intuitive Controls



TIBIOTALAR PRECISION® BONE PREPARATION OPTIONS

ARC Tibia™ Flat Talus

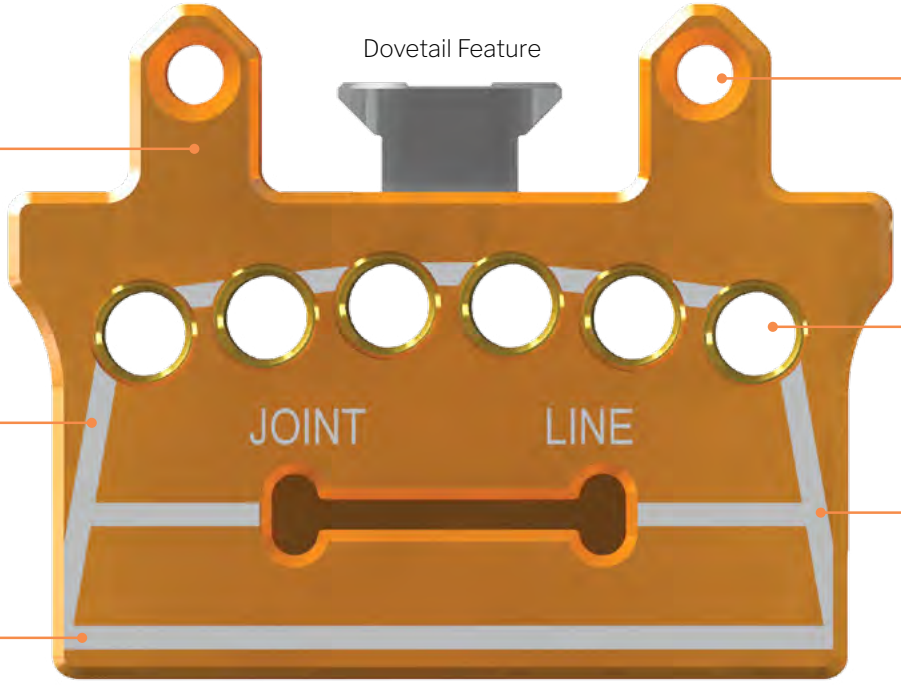
ARC Tibia™ Chamfer Talus

Flat Tibia Chamfer Talus

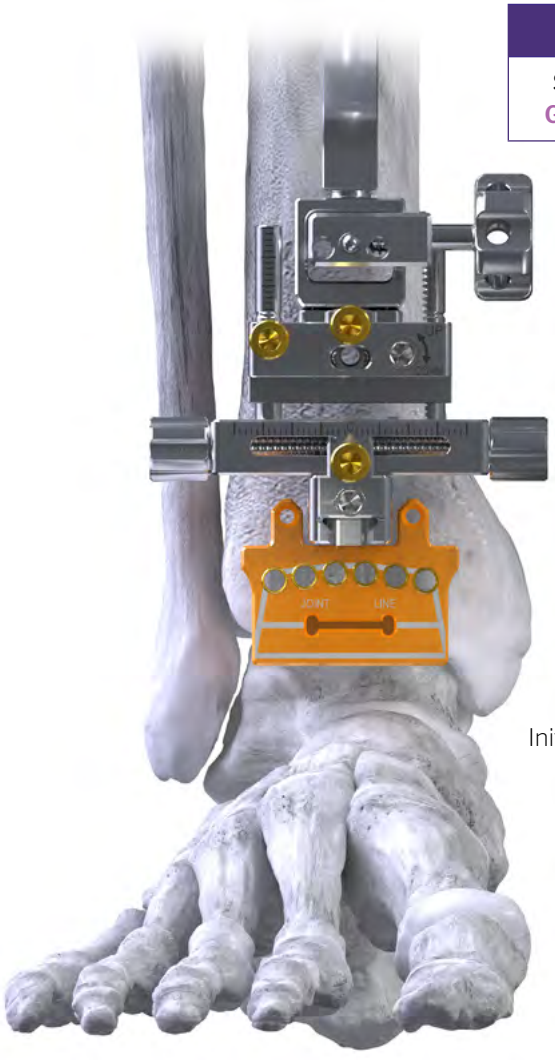
Flat Tibia Flat Talus

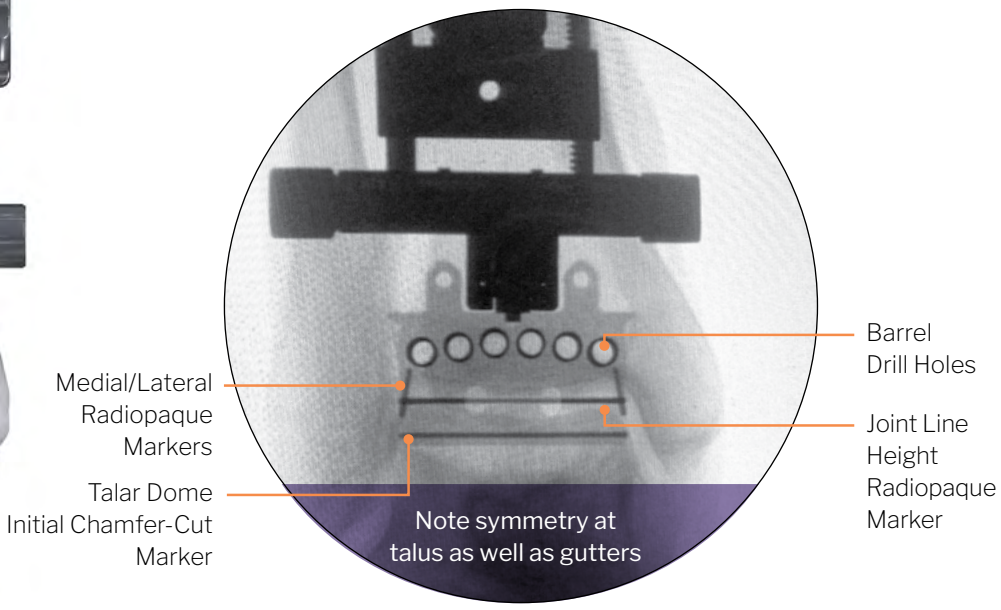
SIZING EVALUATION: Precision Bone Preparation

SIZING RESECTION BLOCK



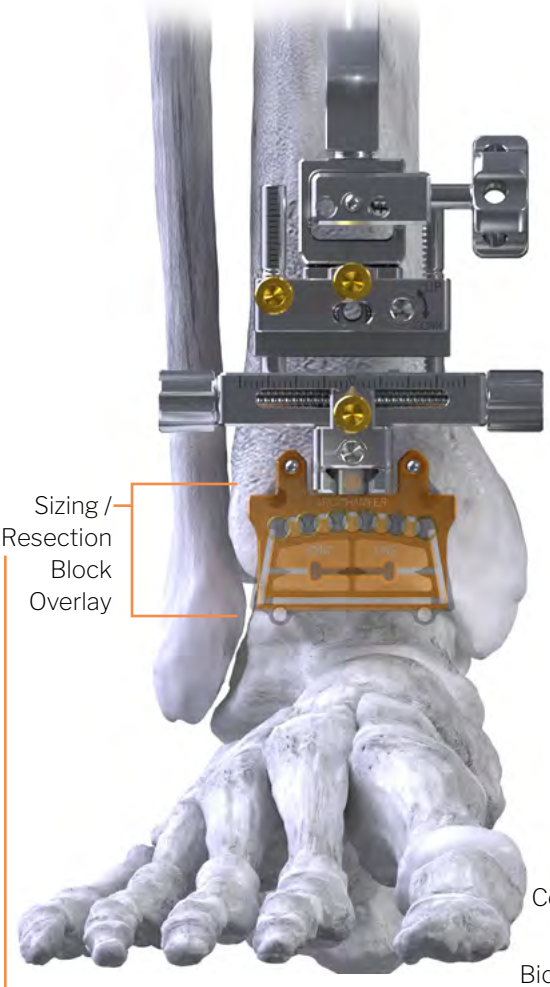
APEX 3D™ COLOR CODES					
Size 1 - Green	**Size 2 -** Yellow	**Size 3 -** Purple	**Size 4 -** Orange	**Size 5 -** Dark Blue	**Size 6 -** Bronze

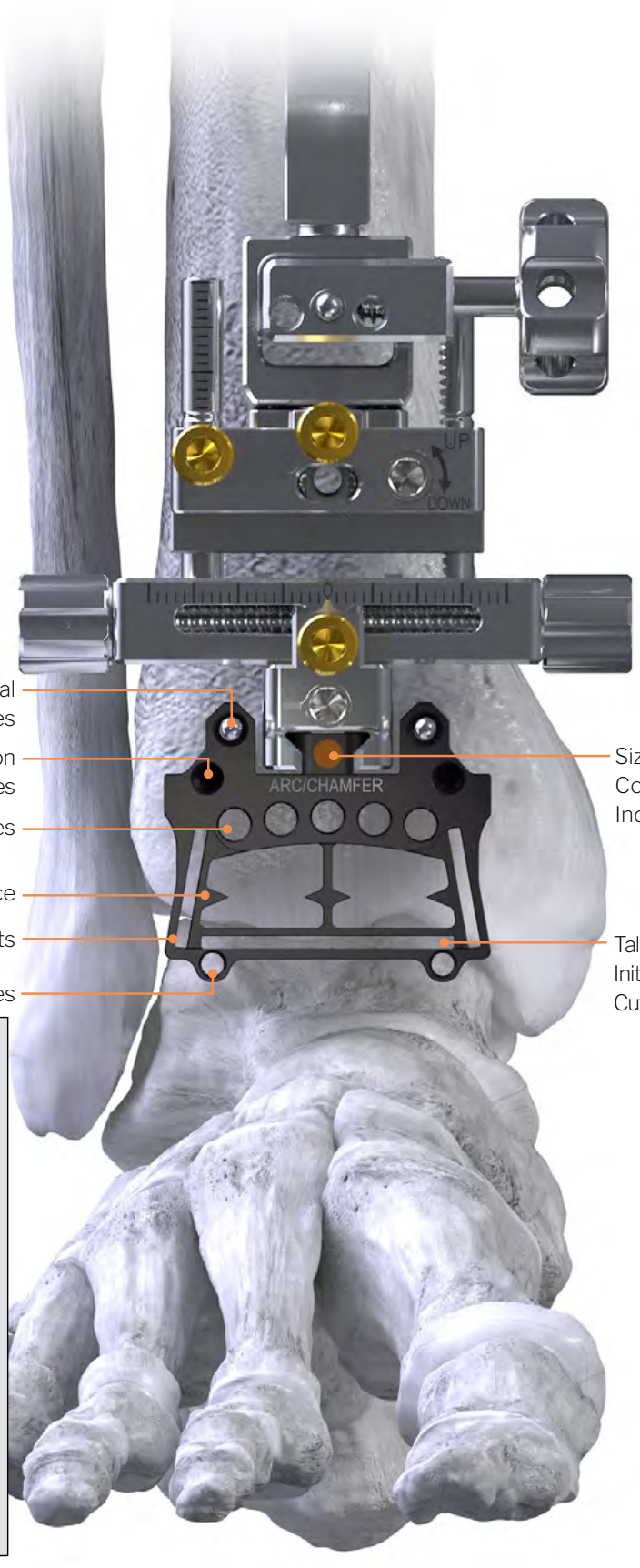


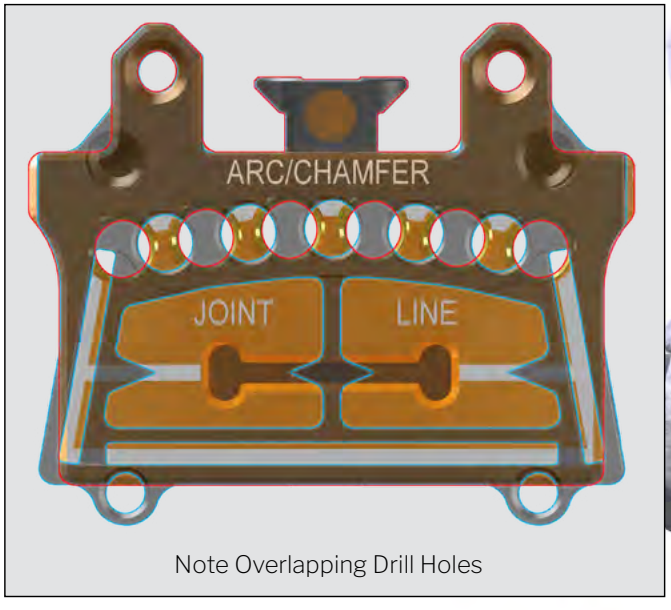


ARC TIBIA™ & CHAMFER TALUS: Precision Bone Preparation

RESECTION BLOCK



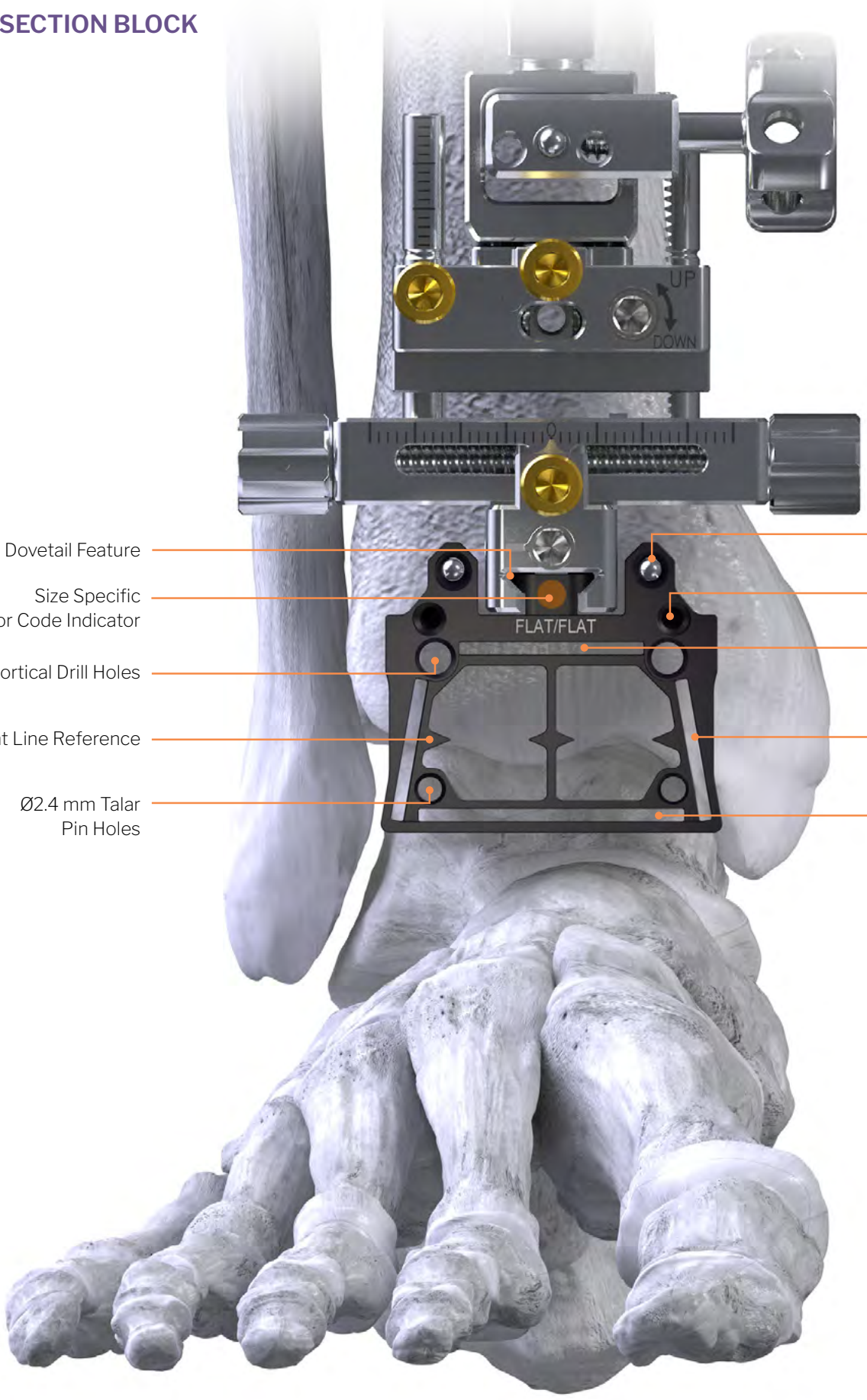




Note Overlapping Drill Holes

FLAT TIBIA & FLAT TALUS: Precision Bone Preparation

RESECTION BLOCK



Dovetail Feature

Size Specific Color Code Indicator

Bicortical Drill Holes

Joint Line Reference

Ø2.4 mm Talar Pin Holes

Ø2.4 mm Tibia Pin Holes

Converging Fixation Pin Holes

Tibial Flat-Cut Slot

M/L Cut Slots

Talar Dome Flat-Cut Slot

Type	Talar Dome Options						
Tibial Tray Options	Style	Chamfer-Cut / Flat-Cut					
	ARC Tibia™/ Flat	Direction	Left/Right				
		Left/Right	Size Options	Size 1 N	Size 1	Size 2	Size 3	Size 4	Size 5
			Size 1 Short/Standard/Long	D	S	U			
			Size 2 Standard/Long	D	D	S	U		
			Size 3 Standard/Long	D	D	D	S	U	
			Size 4 Standard/Long	D	D	D	D	S	U
			Size 5 Standard/Long	D	D	D	D	D	S
			Size 6 Standard/Long	D	D	D	D	D	D

References:

1. Kurtz, S.M., Bracco, P., Costa, L., Oral, E., Muratoglu, O.K. (2016) Vitamin E-Blended UHMWPE Biomaterials. UHMWPE Biomaterials Handbook, 293-325.

2. G. Rochcongar, MD, G. Buia, MD, E. Bourroux, J. Dunet, MD, V. Chapus, MD, and C. Hulet, MD, PhD. (2018) Creep and Wear in Vitamin E-Infused Highly Cross-Linked Polyethylene Cups for Total Hip Arthroplasty A Prospective Randomized Controlled Trial. Journal of Bone and Joint Surgery, Incorperated.

3. Hvid, I. et. al. (1985) Trabecular Bone Strength Profiles at the Ankle Joint. Clinical Orthopaedics and Related Research, 306-312.

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For the contraindications, potential complications and adverse reactions, warnings and precautions associated with this device, please refer to the device specific instructions for use at http://www.paragon28.com/ifus