

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



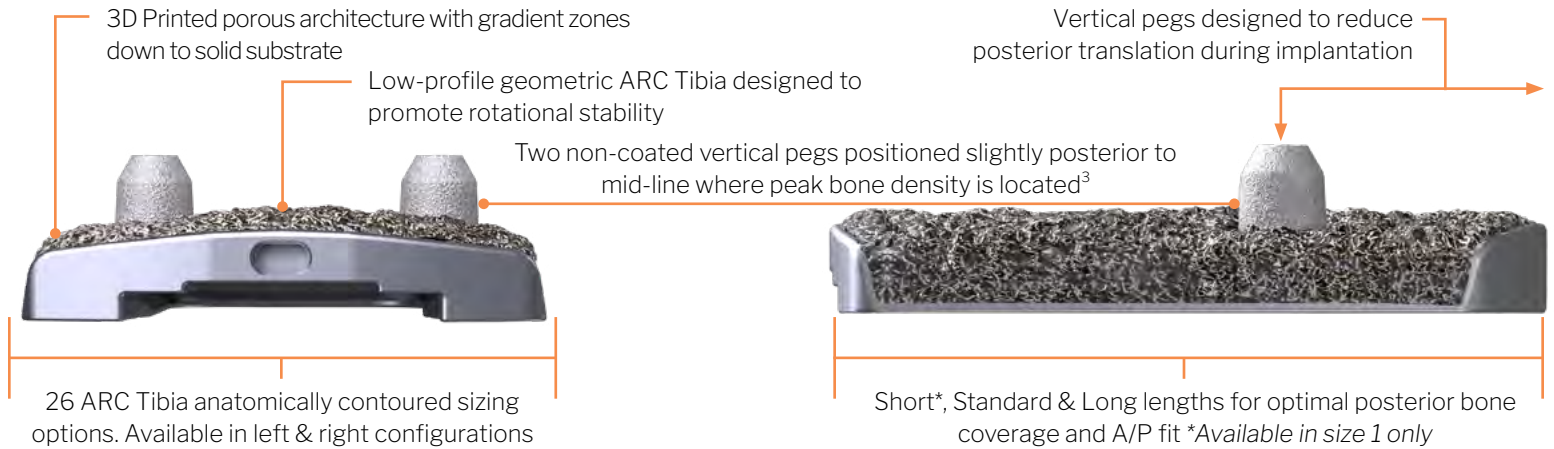
BASED ON OVER A CENTURY OF COMBINED CLINICAL EXPERIENCE...

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.

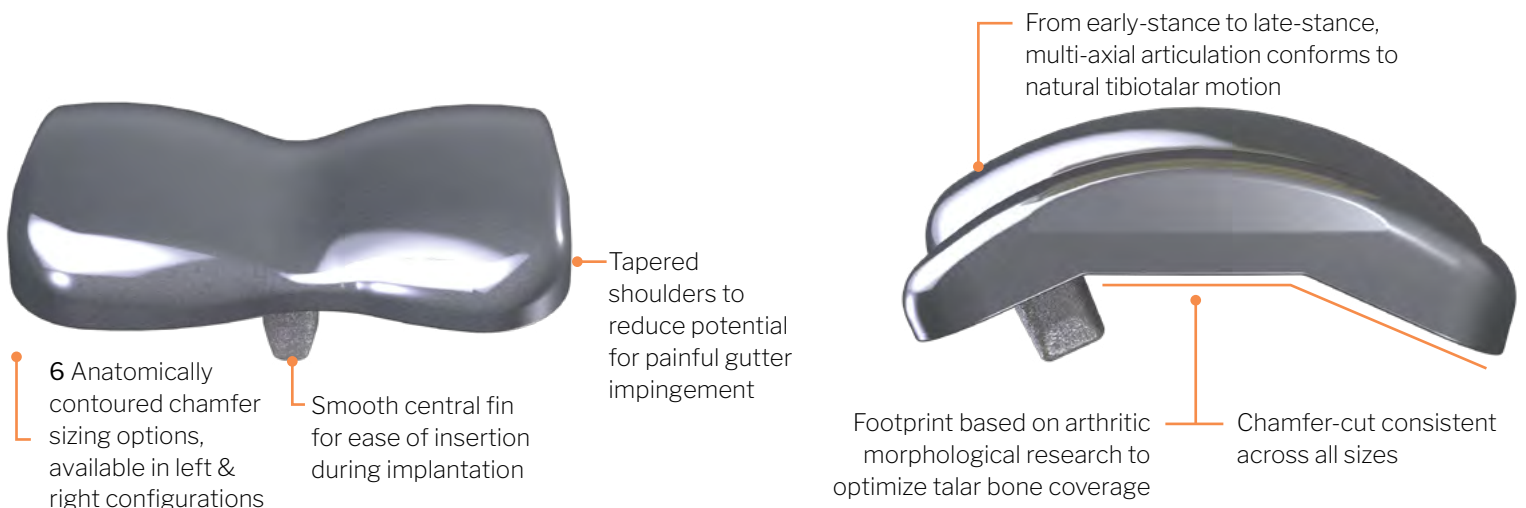
ARC TIBIAL TRAY: Designed for Rotational Stability



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...

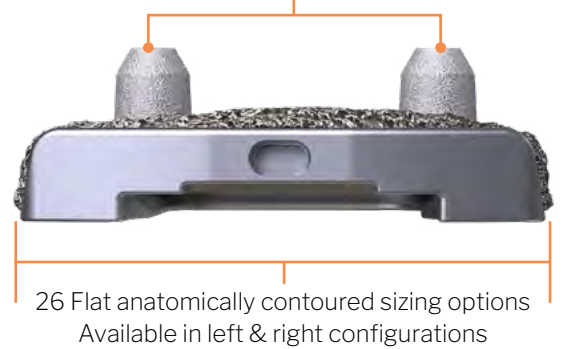
- Newer clinical evidence
- Advanced technologies
- Implant sizing & anatomic footprint based on pre-clinical arthritic tibiotalar morphological studies
- Healthy ankle kinematic weight-bearing CT research

FLAT-CUT TIBIAL TRAY:

Broad anterior surface area to optimize contact interface

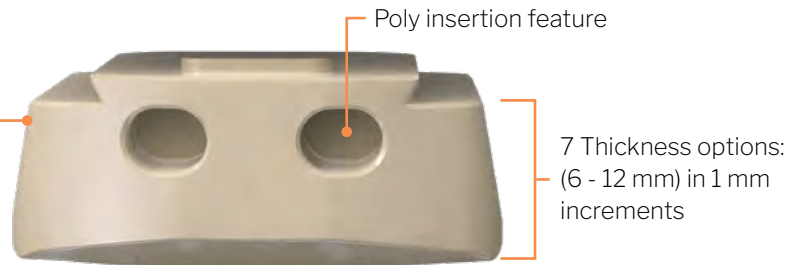


Vertical pegs positioned to target optimal tibia bone density³ for initial stabilization



VITAMIN E CROSS-LINKED TIBIAL INSERT:

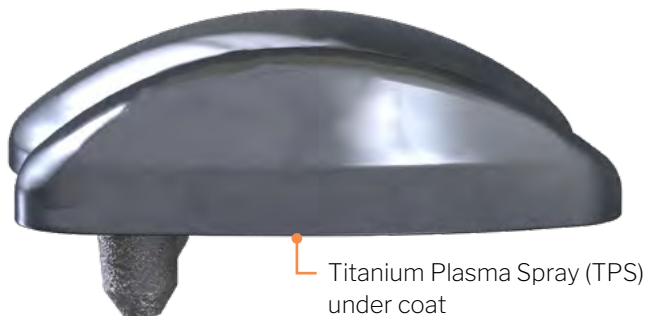
Medial / Lateral tapered to avoid protrusion and multiple thickness options for primary or revision cases



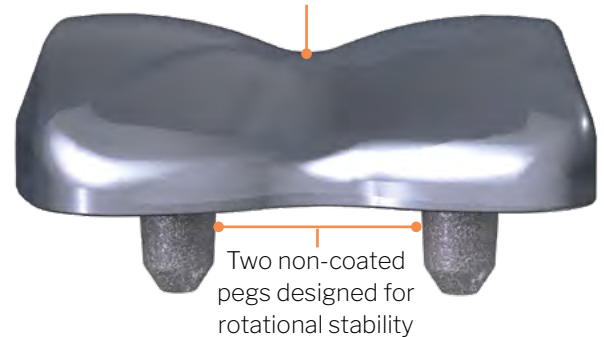
35 Sizing and thickness combinations allowing for interoperative flexibility

FLAT-CUT TALAR DOME:

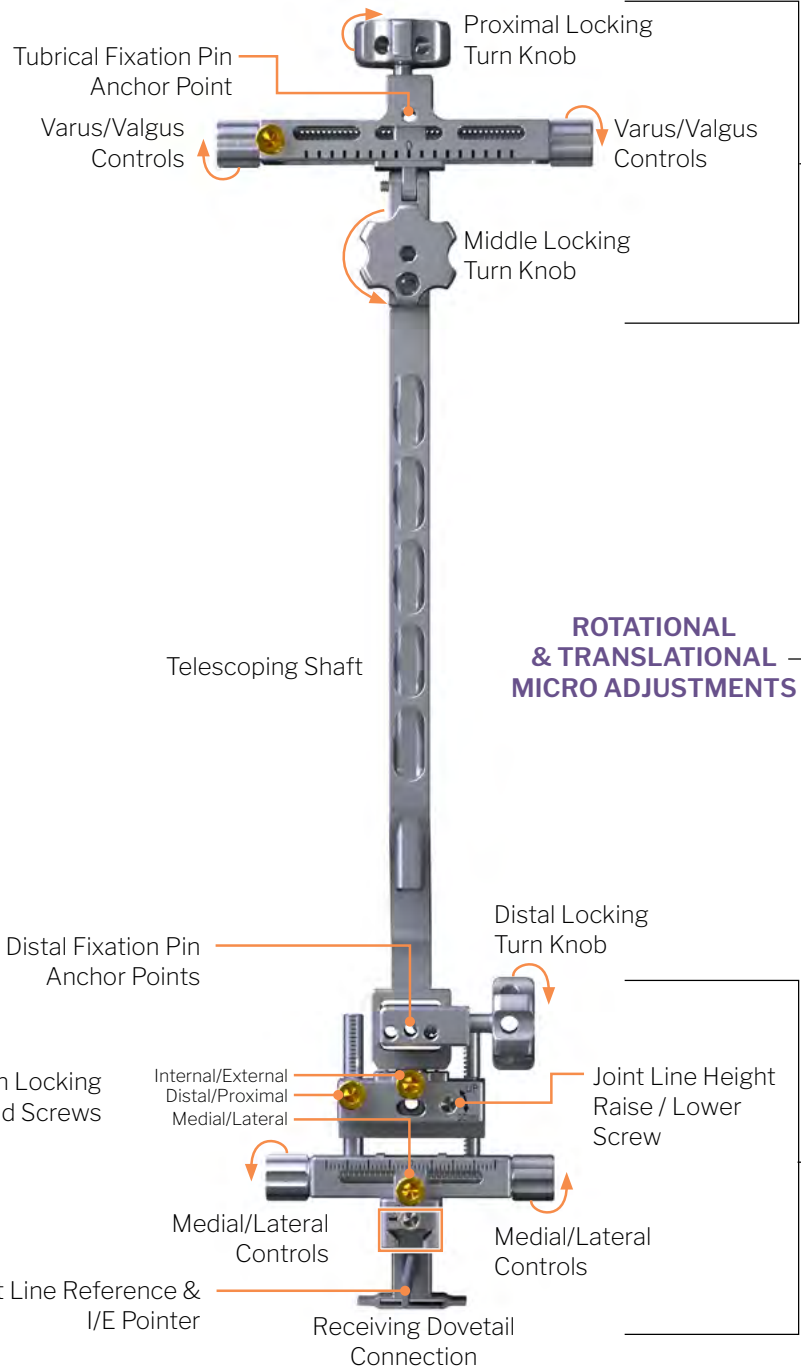
Talar dome options provide the ability to up-size by 1, and down-size without restriction



Anatomically contoured gentle sulcus resists medial/lateral translation and subluxation

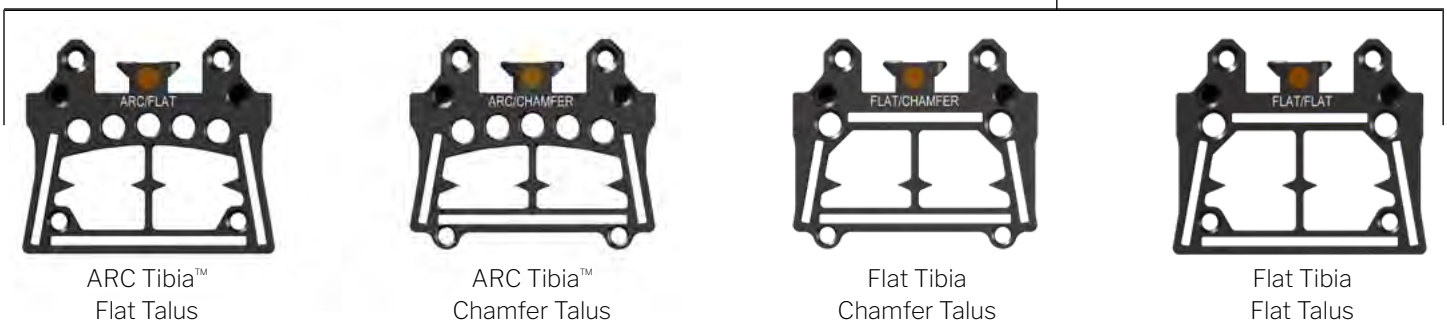


TRADITIONAL ALIGNMENT GUIDE: Alignment Accuracy & Intuitive Controls



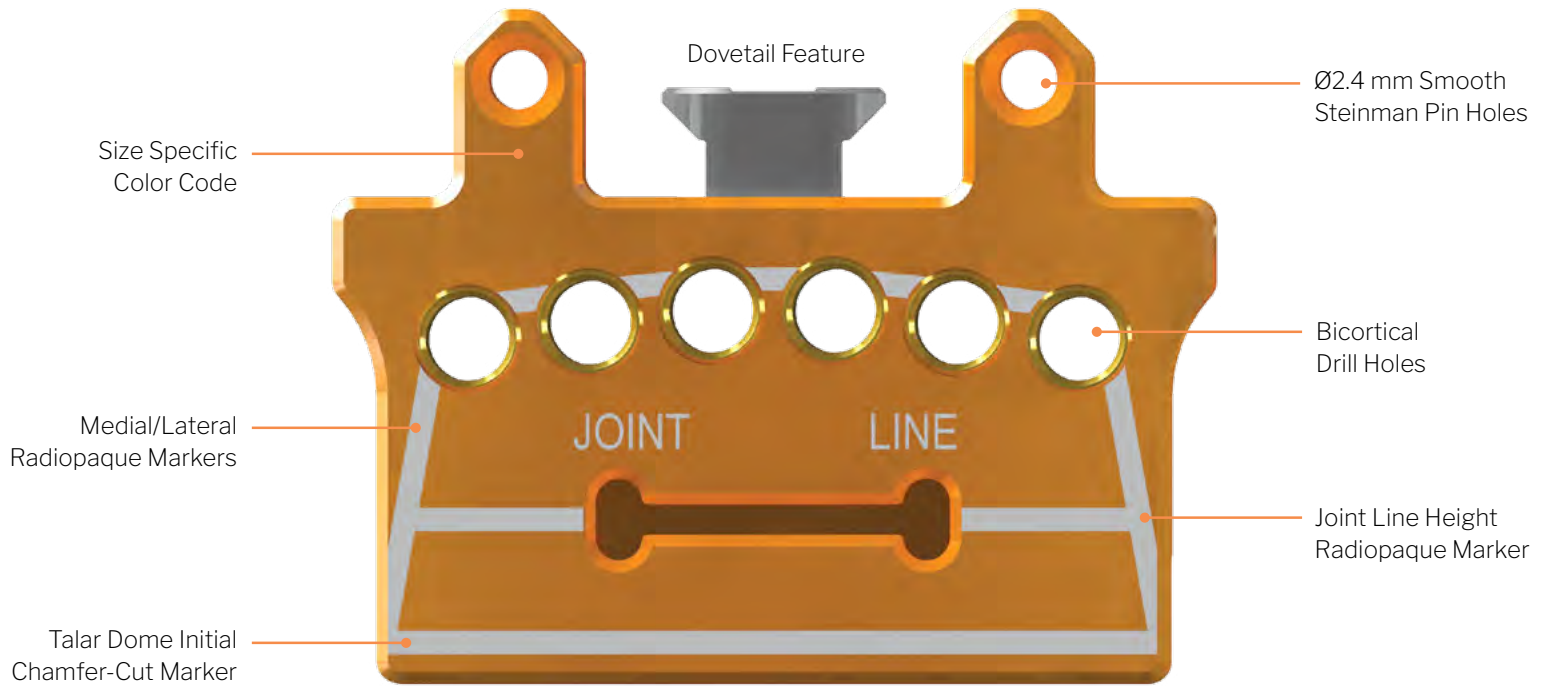
ROTATIONAL & TRANSLATIONAL MICRO ADJUSTMENTS

**TIBIOTALAR PRECISION®
BONE PREPARATION OPTIONS**

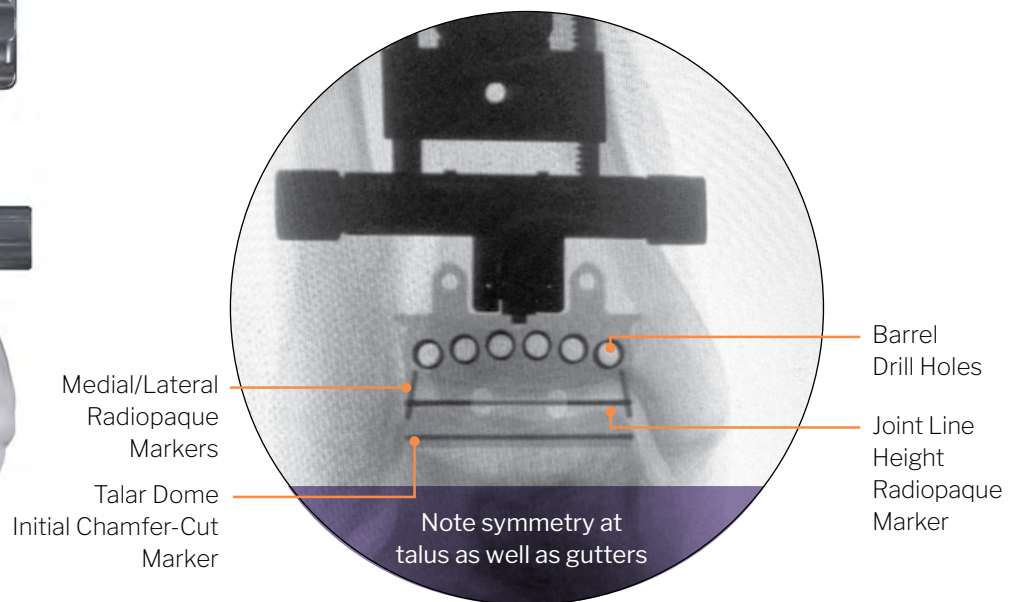
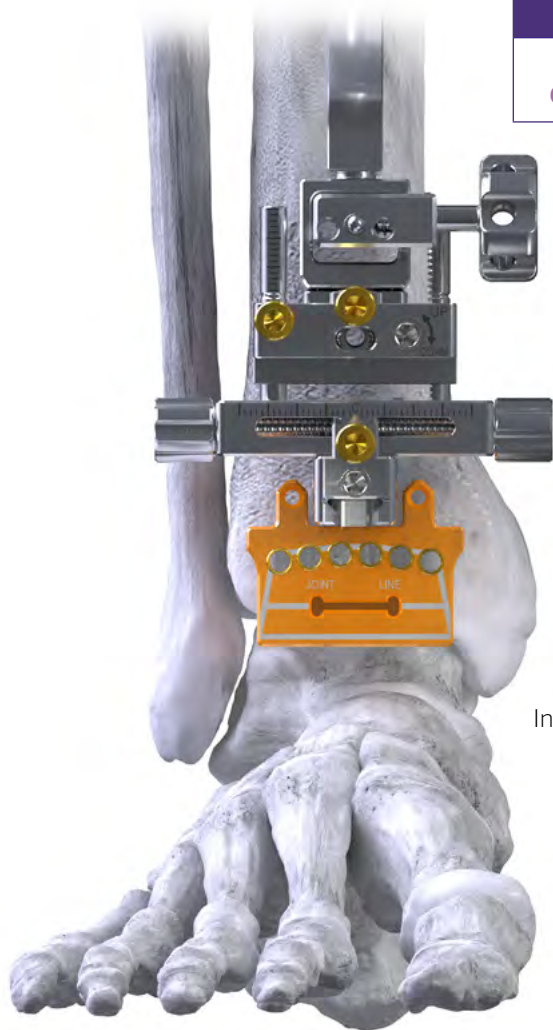


SIZING EVALUATION: Precision Bone Preparation

SIZING RESECTION BLOCK

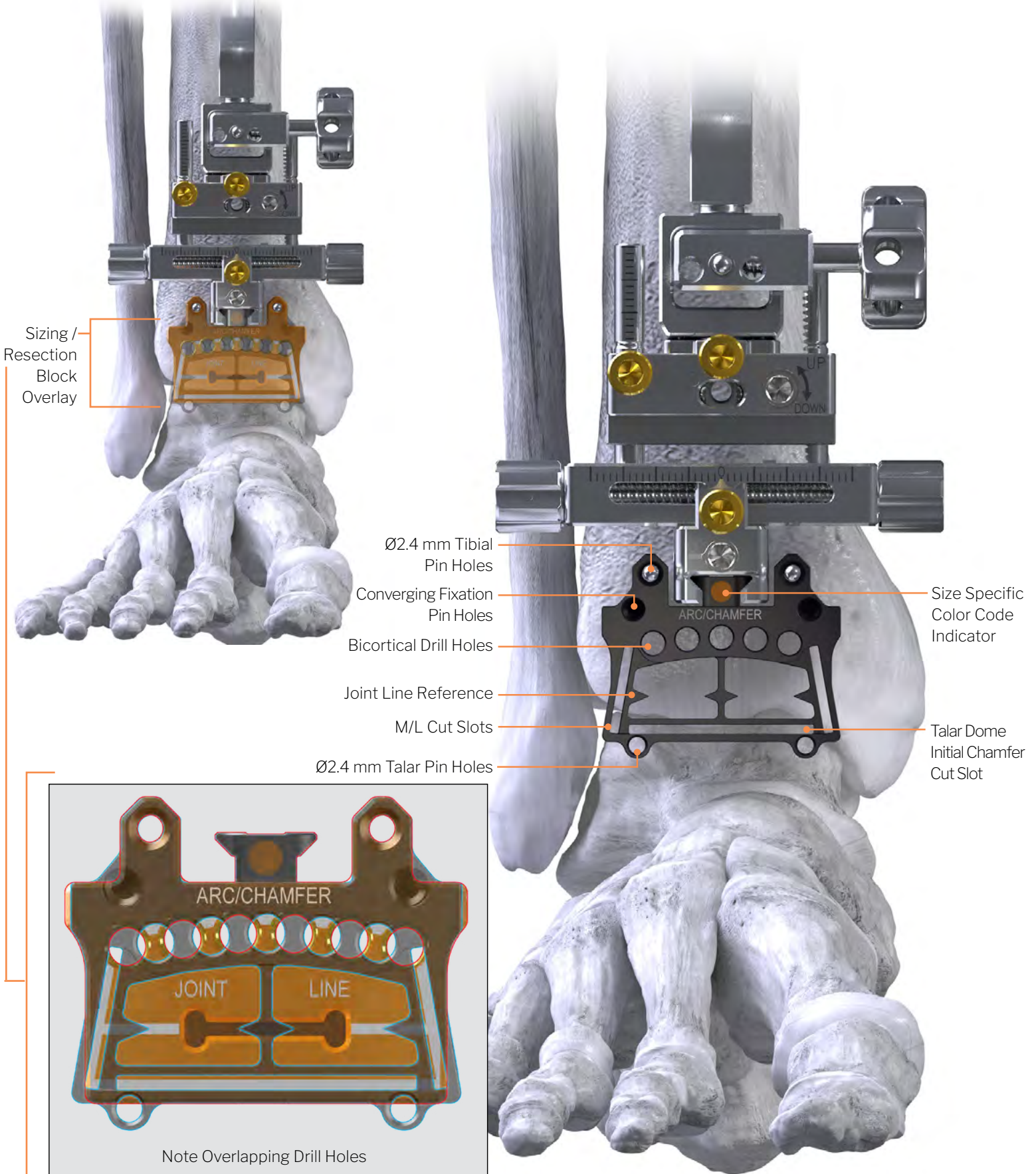


APEX 3D™ COLOR CODES					
Size 1 - Green ●	Size 2 - Yellow ●	Size 3 - Purple ●	Size 4 - Orange ●	Size 5 - Dark Blue ●	Size 6 - Bronze ●



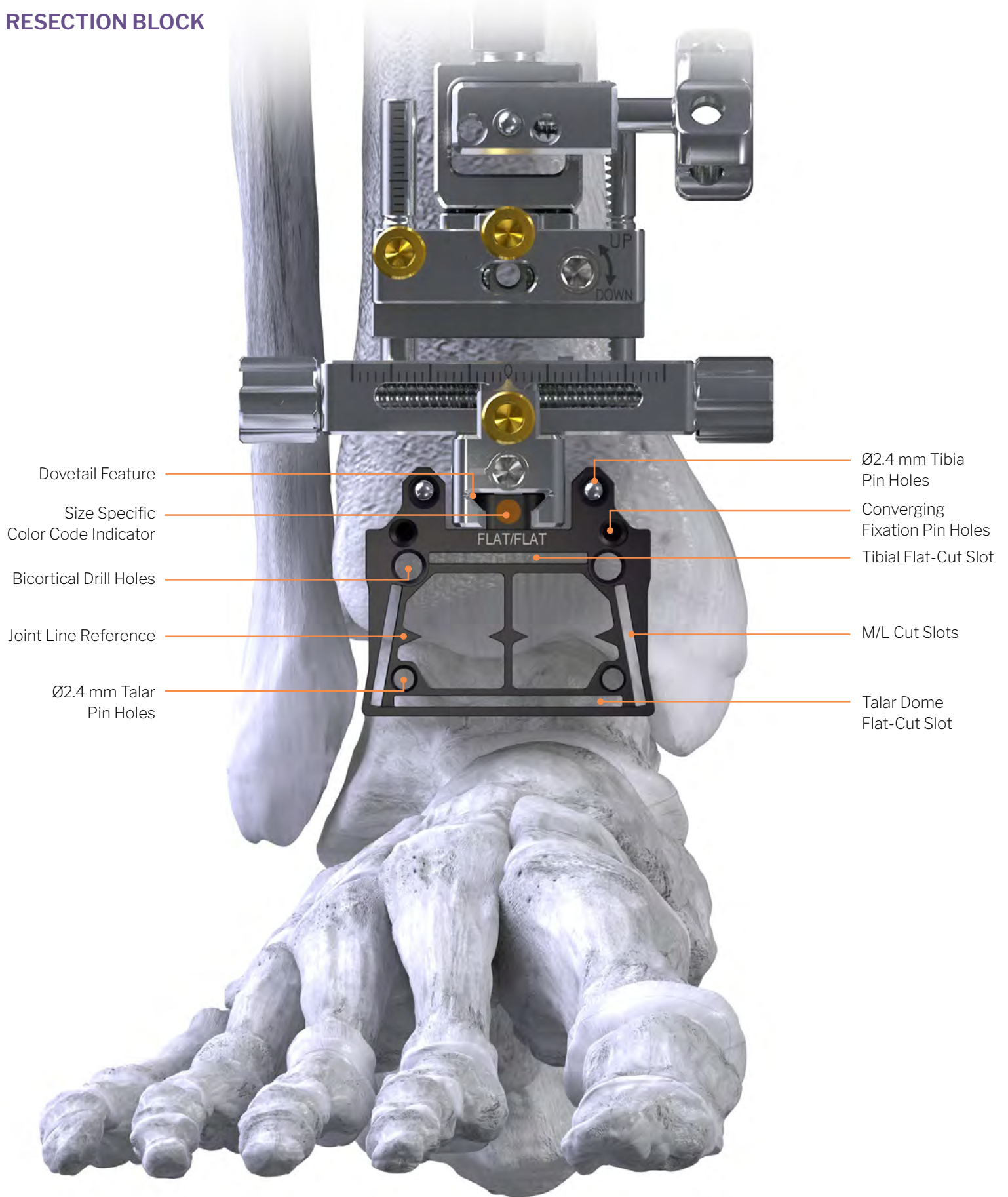
ARC TIBIA™ & CHAMFER TALUS: Precision Bone Preparation

RESECTION BLOCK



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

FLAT/FLAT

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

P10-STM-0001 Rev. A

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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>