

PHANTOM[®]
HINDFOOT TTC/TC SYSTEM

PHANTOM
ACTIVCORE[™] NAIL SYSTEM

Hospital Registration Packet

_____ by _____

Exclusively foot & ankle ²⁰
Paragon[®]



THE MISSION OF PARAGON 28®

Our mission is to strategically build a company around the core principles that **drive innovation and quality**. Relentlessly working to advance the science behind foot and ankle surgery, Paragon 28 is passionate about and committed to:



Blending different surgical philosophies from various global thought leaders to develop biomechanically and clinically relevant surgical solutions.



A customer service based, dedicated, and highly-trained distribution network to the foot and ankle market.



Meeting the needs of increasing pricing pressures and reimbursement while continuing to develop cutting-edge surgical implants.



Creating complete surgeon-centric systems, specialty instruments, and next generation implants to solve real world issues faced by foot and ankle surgeons.



Improving clinical outcomes through meaningful and unbiased research. We are ready to embrace research data regardless of marketing impact.

PARAGON 28 HISTORY

In 2010, Paragon 28 was established as an orthopedic foot and ankle company. The name Paragon 28 was chosen to show that we are exclusively a foot and ankle company, with the 28 representing the number of bones in the foot. We will remain true to that vision. Paragon 28 was started as a small, family-based company and we have kept those core ideals as we have grown.

Our first product was the Monster® Screw System, followed by the Gorilla® Plating System. As we continue to add more products, we maintain a fine level of detail to every feature of every product we design. The goal is to give options to the foot and ankle surgeon, knowing there is more than one way to achieve a great result. We have listened to surgeons and will continue to do so in order to understand and address their specific needs.



Paragon 28® is pleased to announce a series of enhancements to its Phantom® TTC/TC and ActivCore™ Nails and Outrigger System intended to provide additional applications in the foot and ankle and discontinued previously available implants and Outriggers.

The newly designed nails and outrigger will provide the following benefits:

Optimized position of distal tibia pegs (i.e. pegs moved 20 mm proximally)

- ▶ Allows for use of both nail families in traumatic applications (i.e. spanning comminuted fractures of the tibia distally)
- ▶ Better accommodates varied anatomies—particularly close to the ankle joint

Enhanced radiolucency of Ghost™ Outrigger

- ▶ Improved intraoperative visualization of Nail and Peg trajectories
- ▶ Improved accuracy in determining appropriate Nail depth during insertion

Proximal Extension Arm now equipped with dynamic and static slots for positioning of proximal peg

- ▶ Allows for accurate placement of proximal peg when using a 250 or 300 mm
- ▶ Allows for flexibility in choice of static or dynamic configuration of the final construct



Phantom® ActivCore TTC/TC Nail System

The Phantom TTC/TC Nail allows for the surgeon to either lock the nail in its desired position, creating a rigid and stable construct or allow for dynamization with up to 8 mm of weight bearing compression across all joint surfaces. The Phantom ActivCore Nail has a proximal spring sheath and inner sliding core which allows for consistent active compression and up to 8 mm of bone resorption across all joint spaces.

The Phantom TTC/TC Nail and Phantom ActivCore Nail Systems leverage the same instrumentation to facilitate preparation and placement of the Nail. This instrumentation includes a comprehensive assortment of joint preparation and anatomic alignment tools. A patent pending PRECISION® Guide is offered to assist in accurate and reproducible placement of the initial K-wire setting the implant trajectory. The selected Nail is implanted utilizing the radiolucent carbon fiber Phantom® Ghost™ Outrigger which guides placement of pegs through the nail and allows for visualization of peg trajectory under fluoroscopy prior to drilling.

THERE ARE INHERENT CHALLENGES IN ADDRESSING TTC AND TC ARTHRODESIS

TTC and TC Arthrodesis Challenges	Phantom® Hindfoot System Benefits
Difficulty in achieving consistent compression across the entire ankle and TTC joints, allowing for bone resorption on joint surfaces.	The Phantom® TTC/TC Nail (1) allows for up to 8 mm of weight bearing compression, or (2) locks in at its desired position and holds the external compression forces applied. The Phantom ActivCore™ Nail has a proximal spring sheath and inner sliding core which allows for up to 8 mm of active compression during non-weight bearing across the TTC joint.
Precise and reproducible placement of the initial drill-pin to determine implant trajectory.	PRECISION® Guide technology allows for reproducibility when placing a Ø3.0 mm drill-pin from distal to proximal, through the center of the calcaneus and up to the tibia. (See Figure 1)
Stress risers in the proximal tibia due to final insertion of a rigid implant.	The proximal end of the Phantom® Nails were engineered with a flex coil design to provide flexibility as the implant finds its way through the contouring of the tibial canal and allow for stress sharing. (See Figure 2)
Fibular take down due to the location and insertion point of a talar peg into and through the implant.	All pegs are inserted from posterior to anterior and medial to lateral eliminating the need to take down the fibula.
Diversity in nail offerings (lengths/widths) to address varied anatomies and deformities.	47 different nail options across all diameters (Ø10, Ø11.5, Ø13) and lengths (150, 175, 200, 250, and 300 mm) with multiple points of fixation throughout the calcaneus and tibia.
Ability to access all joint surfaces and ensure adequate preparation.	A robust offering of procedural instrumentation addresses joint preparation and restoration of anatomic alignment.



Figure 1: PRECISION® Guide Technology

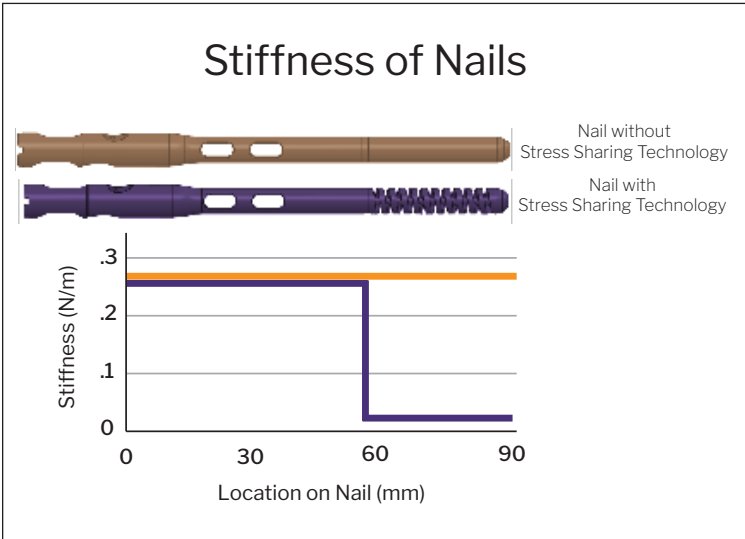


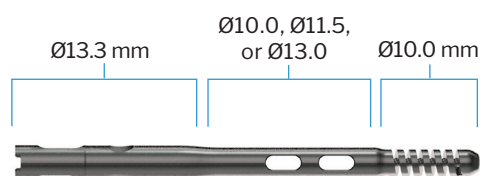
Figure 2: Flex Coil Design Promotes Stress Sharing

PHANTOM® HINDFOOT NAIL OFFERINGS

The Phantom Hindfoot Nails are constructed from Type II Anodized Titanium Alloy and will be offered in 47 size options with three diameters and five lengths. All distal diameters of the nails are Ø13.3 mm with a transition to either; Ø10, Ø11.5 or Ø13 mm proximally. The distal diameter was increased at the joint spaces to add strength to the implant where it's needed most.

PHANTOM® HINDFOOT TTC/TC SYSTEM	Phantom® TTC/TC Nail Phantom ActivCore™ Nail	Length Options (mm)			
		175	200	250	300
Diameter Options (mm)	Ø10	●	● ●	● ●	● ●
	Ø11.5	●	● ●	● ●	● ●
	Ø13	●	● ●	● ●	

Phantom® TTC Nail



PHANTOM® TTC/TC NAILS

The TTC Nail allows for up to 8 mm of weight bearing compression or can be locked in at its desired position and hold the external compression forces applied. To allow for weight bearing compression the tibial pegs are placed proximally in the oblong holes (see image 1). To lock the nail in its desired position the proximal tibia peg is placed most proximal and the distal tibia peg is placed most distal in the oblong holes (see image 2).

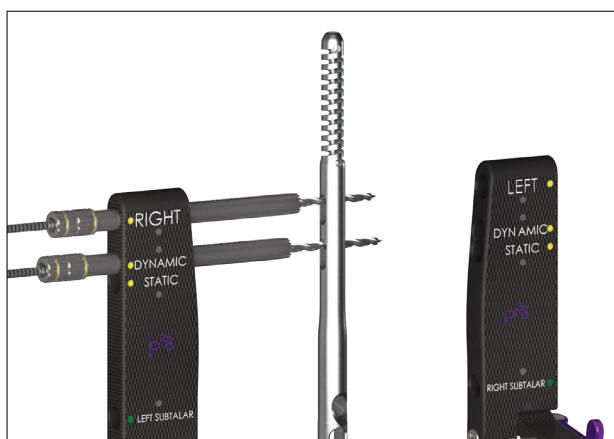


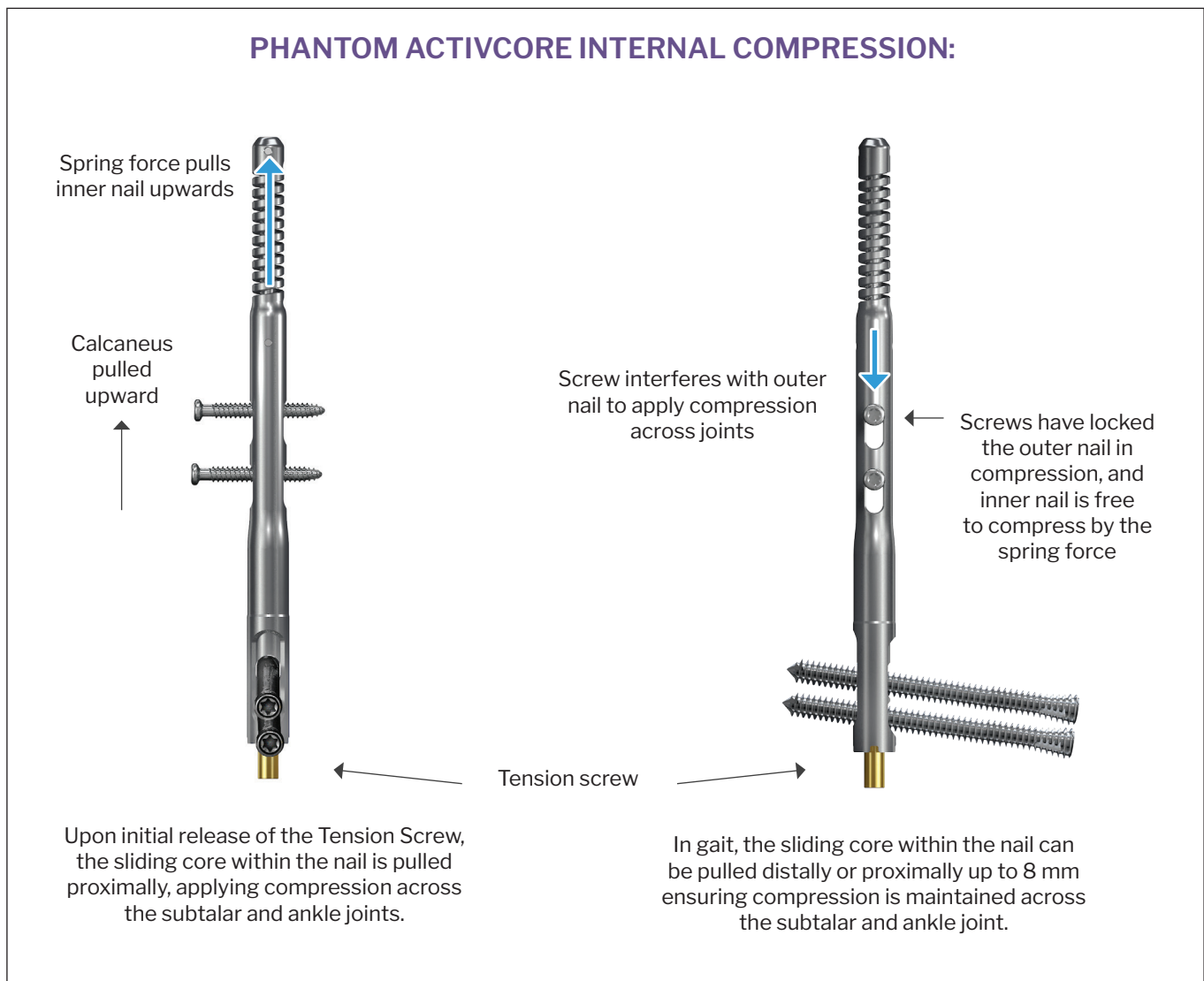
Image 1: Weight Bearing Compression



Image 2: Locked

PHANTOM ACTIVCORE™ NAIL

The ActivCore Nail addresses TTC arthrodesis and has a proximal spring sheath and inner sliding core which allows for consistent active compression and up to 8 mm of bone resorption across all joint spaces. This nail has two calcaneal pegs that are inserted from posterior to anterior at a variable (0-18°) angle. These pegs provide adequate fixation distally and work with the inner core feature and tibial pegs to allow for active compression to pass through all joint surfaces.

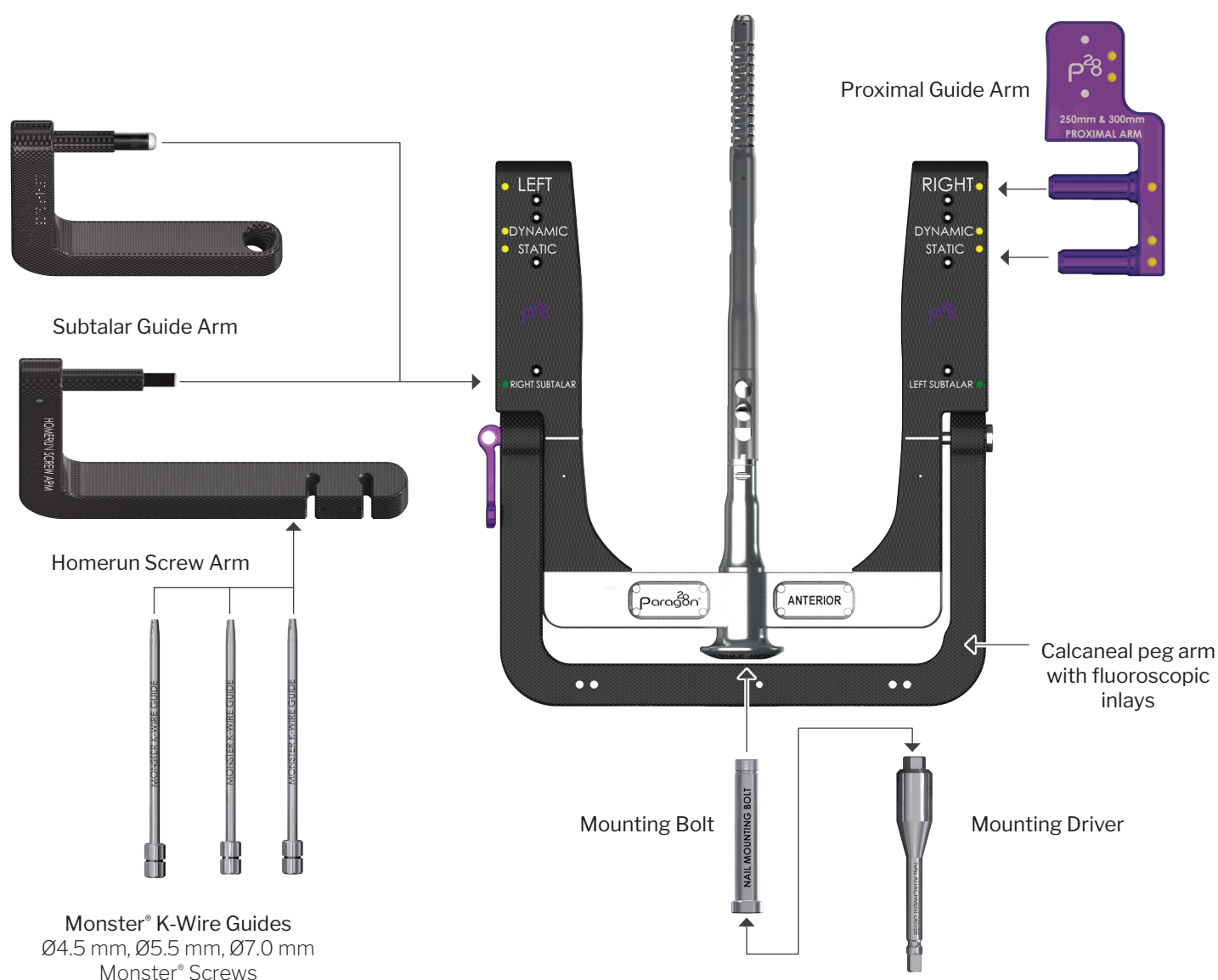


PHANTOM[®] GHOST[™] OUTRIGGER

The Phantom[®] TTC/TC and Phantom ActivCore Nails are implanted utilizing the carbon fiber Phantom[®] Ghost[™] Outrigger. The radiolucent and inlay features of the Outrigger allow for visualization of peg trajectory under fluoroscopy prior to drilling.



PHANTOM GHOST OUTRIGGER FEATURE SUMMARY

- ▶ Rigid and stout guide with Cam lock technology allows for more accurate placement of pegs
- ▶ Variable (0-18°) angle placement of the posterior to anterior peg in the calcaneus allows for maximum boney purchase based on individual patient anatomy
- ▶ A subtalar joint peg can be placed in the TTC Nail with the guided system from posterior to anterior at a 30-degree angulation and 16.4-degree variance to gain maximum purchase in the calcaneus and talus
- ▶ Proximal peg extension arm attaches to the guide allowing the surgeon to accurately place a peg into the 250 mm and 300 mm length nails



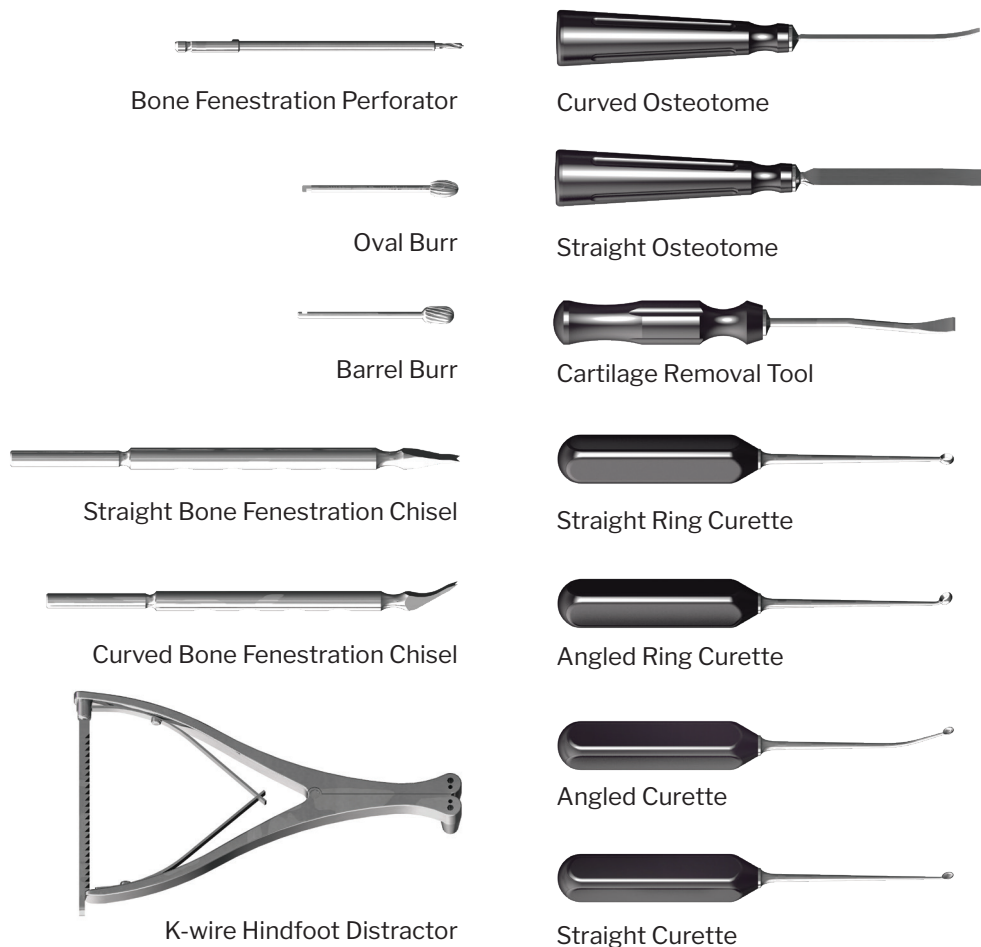
PHANTOM® PEG OFFERINGS

The Phantom® pegs are constructed from Type II Anodized Titanium Alloy and offered in two fully thread diameters (Ø5.0 and Ø7.2 mm) with headed and headless options. The Ø5.0 mm pegs are offered in lengths 20 – 70 mm in 2 mm increments. The Ø7.2 mm pegs are offered in lengths 45 – 120 mm in 5 mm increments.

		
Diameters	Ø5.0 mm	Ø7.2 mm
Lengths	20 – 70 mm	45 – 120 mm
Increments	2 mm	5 mm
Placements	Tibia	Calcaneus and Subtalar Joint

PHANTOM® JOINT PREPARATION INSTRUMENTATION

The Phantom® Hindfoot TTC/TC System includes a robust offering of joint preparation instrumentation for TTC and TC arthrodesis. These items include:



Phantom® TTC Nails

Part #	Description
P31-600-175L-S	Phantom® TTC Nail, 10.0 X 175 mm, LEFT
P31-600-175R-S	Phantom® TTC Nail, 10.0 X 175 mm, RIGHT
P31-600-200L-S	Phantom® TTC Nail, 10.0 X 200 mm, LEFT
P31-600-200R-S	Phantom® TTC Nail, 10.0 X 200 mm, RIGHT
P31-600-250L-S	Phantom® TTC Nail, 10.0 X 250 mm, LEFT
P31-600-250R-S	Phantom® TTC Nail, 10.0 X 250 mm, RIGHT
P31-600-300L-S	Phantom® TTC Nail, 10.0 X 300 mm, LEFT
P31-600-300R-S	Phantom® TTC Nail, 10.0 X 300 mm, RIGHT
P31-615-175L-S	Phantom® TTC Nail, 11.5 X 175 mm, LEFT
P31-615-175R-S	Phantom® TTC Nail, 11.5 X 175 mm, RIGHT
P31-615-200L-S	Phantom® TTC Nail, 11.5 X 200 mm, LEFT
P31-615-200R-S	Phantom® TTC Nail, 11.5 X 200 mm, RIGHT
P31-615-250L-S	Phantom® TTC Nail, 11.5 X 250 mm, LEFT
P31-615-250R-S	Phantom® TTC Nail, 11.5 X 250 mm, RIGHT
P31-615-300L-S	Phantom® TTC Nail, 300 mm, LEFT
P31-615-300R-S	Phantom® TTC Nail, 300 mm, RIGHT
P31-630-175L-S	Phantom® TTC Nail, 13.0 X 175 mm, LEFT
P31-630-175R-S	Phantom® TTC Nail, 13.0 X 175 mm, RIGHT
P31-630-200L-S	Phantom® TTC Nail, 13.0 X 200 mm, LEFT
P31-630-200R-S	Phantom® TTC Nail, 13.0 X 200 mm, RIGHT
P31-630-250L-S	Phantom® TTC Nail, 13.0 X 250 mm, LEFT
P31-630-250R-S	Phantom® TTC Nail, 13.0 X 250 mm, RIGHT

Phantom® ActivCore Nails

Part #	Description
P31-202-2000-S	Phantom® ActivCore Nail, 10.0 X 200 mm
P31-202-2500-S	Phantom® ActivCore Nail, 10.0 X 250 mm
P31-202-3000-S	Phantom® ActivCore Nail, 10.0 X 300 mm
P31-215-2000-S	Phantom® ActivCore Nail, 11.5 X 200 mm
P31-215-2500-S	Phantom® ActivCore Nail, 11.5 X 250 mm
P31-215-3000-S	Phantom® ActivCore Nail, 11.5 X 300 mm
P31-230-2000-S	Phantom® ActivCore Nail, 13.0 X 200 mm
P31-230-2500-S	Phantom® ActivCore Nail, 13.0 X 250 mm

Ø7.2 mm Threaded Pegs

Part #	Description
P31-772-045F	Phantom® Hindfoot Nail, Threaded Peg, 7.2 mm x 45 mm
P31-772-050F	Phantom® Hindfoot Nail, Threaded Peg, 7.2 mm x 50 mm
P31-772-055F	Phantom® Hindfoot Nail, Threaded Peg, 7.2 mm x 55 mm
P31-772-060F	Phantom® Hindfoot Nail, Threaded Peg, .2 mm x 60 mm
P31-772-065F	Phantom® Hindfoot Nail, Threaded Peg, 7.2 mm x 65 mm
P31-772-070F	Phantom® Hindfoot Nail, Threaded Peg, 7.2 mm x 70 mm
P31-772-075F	Phantom® Hindfoot Nail, Threaded Peg, 7.2 mm x 75 mm
P31-772-080F	Phantom® Hindfoot Nail, Threaded Peg, 7.2 mm x 80 mm
P31-772-085F	Phantom® Hindfoot Nail, Threaded Peg, 7.2 mm x 85 mm
P31-772-090F	Phantom® Hindfoot Nail, Threaded Peg, 7.2 mm x 90 mm
P31-772-095F	Phantom® Hindfoot Nail, Threaded Peg, 7.2 mm x 95mm
P31-772-100F	Phantom® Hindfoot Nail, Threaded Peg, 7.2 mm x 100 mm
P31-772-105F	Phantom® Hindfoot Nail, Threaded Peg, 7.2 mm x 105 mm
P31-772-110F	Phantom® Hindfoot Nail, Threaded Peg, 7.2 mm x 110 mm
P31-772-115F	Phantom® Hindfoot Nail, Threaded Peg, 7.2 mm x 115 mm
P31-772-120F	Phantom® Hindfoot Nail, Threaded Peg, 7.2 mm x 120 mm

Phantom® ActivCore TTC/TC Nail System

Ø5.0 mm Threaded Pegs	
Part #	Description
P32-450-020F	Phantom® Hindfoot Nail, Threaded Peg, 5.0 mm x 20 mm
P32-450-022F	Phantom® Hindfoot Nail, Threaded Peg, 5.0 mm x 22 mm
P32-450-024F	Phantom® Hindfoot Nail, Threaded Peg, 5.0 mm x 24 mm
P32-450-026F	Phantom® Hindfoot Nail, Threaded Peg, 5.0 mm x 26mm
P32-450-028F	Phantom® Hindfoot Nail, Threaded Peg, 5.0 mm x 28 mm
P32-450-030F	Phantom® Hindfoot Nail, Threaded Peg,
P32-450-032F	Phantom® Hindfoot Nail, Threaded Peg, 5.0 mm x 32 mm
P32-450-034F	Phantom® Hindfoot Nail, Threaded Peg, 5.0 mm x 34 mm
P32-450-036F	Phantom® Hindfoot Nail, Threaded Peg, 5.0 mm x 36 mm
P32-450-038F	Phantom® Hindfoot Nail, Threaded Peg, 5.0 mm x 38 mm
P32-450-040F	Phantom® Hindfoot Nail, Threaded Peg, 5.0 mm x 40 mm
P32-450-042F	Phantom® Hindfoot Nail, Threaded Peg, 5.0 mm x 42 mm
P32-450-044F	Phantom® Hindfoot Nail, Threaded Peg, 5.0 mm x 44 mm

P32-450-046F	Phantom® Hindfoot Nail, Threaded Peg, 5.0 mm x 46 mm
P32-450-048F	Phantom® Hindfoot Nail, Threaded Peg, 5.0 mm x 48 mm
P32-450-050F	Phantom® Hindfoot Nail, Threaded Peg, 5.0 mm x 50 mm
P32-450-052F	Phantom® Hindfoot Nail, Threaded Peg, 5.0 mm x 52 mm
P32-450-054F	Phantom® Hindfoot Nail, Threaded Peg, 5.0 mm x 54 mm
P32-450-056F	Phantom® Hindfoot Nail, Threaded Peg, 5.0 mm x 56 mm
P32-450-058F	Phantom® Hindfoot Nail, Threaded Peg, 5.0 mm x 58 mm
P32-450-060F	Phantom® Hindfoot Nail, Threaded Peg, 5.0 mm x 60 mm
P32-450-062F	Phantom® Hindfoot Nail, Threaded Peg, 5.0 mm x 62 mm
P32-450-064F	Phantom® Hindfoot Nail, Threaded Peg, 5.0 mm x 64 mm
P32-450-066F	Phantom® Hindfoot Nail, Threaded Peg, 5.0 mm x 66 mm
P32-450-068F	Phantom® Hindfoot Nail, Threaded Peg, 5.0 mm x 68 mm

Disposables	
Part #	Description
P99-100-2010	Bone Fenestration Perforator
P99-192-2020	K-Wire, Single Ended Trocar Tip, SMOOTH, 2.0 x 200 mm
P99-192-2330	K-Wire, Single Ended Trocar Tip, SMOOTH, 2.3 x 300 mm
P31-951-3032	PRECISION® Guide Drill Pin, 3.0 X 320 mm
P31-951-0199	PRECISION® Guide Sphere Wire
P99-110-7019	7.0 x 20 cm Drill
P99-110-0813	Stepped Reamer
P31-955-1550	Phantom® Hindfoot Ball Tipped Guide Rod, 3.0 x 550 mm
P31-955-0080	Phantom® Hindfoot Reamer, 8.0 mm
P31-955-0085	Phantom® Hindfoot Reamer, 8.5 mm
P31-955-0090	Phantom® Hindfoot Reamer, 9.0 mm
P31-955-0095	Phantom® Hindfoot Reamer, 9.5 mm
P31-955-0100	Phantom® Hindfoot Reamer, 10.0 mm
P31-955-0105	Phantom® Hindfoot Reamer, 10.5 mm
P31-955-0110	Phantom® Hindfoot Reamer, 11.0 mm
P31-955-0115	Phantom® Hindfoot Reamer, 11.5 mm
P31-955-0120	Phantom® Hindfoot Reamer, 12.0 mm
P31-955-0125	Phantom® Hindfoot Reamer, 12.5 mm
P31-955-0130	Phantom® Hindfoot Reamer, 13.0 mm
P31-955-0135	Phantom® Hindfoot Reamer, 13.5 mm
P31-955-0140	Phantom® Hindfoot Reamer, 14.0 mm
P99-110-4630	Drill, 4.6 x 300mm, Cannulated, 3/16 Sq. Connection
P99-100-4630	Drill, 4.6 X 300mm, Solid, Trocar Tip, 3/16 Sq. Connection
P99-100-3825	Drill, 3.8 X 250mm Drill, Solid, Trocar Tip, 3/16 Sq. Connection
P31-955-1800-S	Phantom® Hindfoot Ball Tipped Guide Rod, 3.0 x 800 mm
P99-106-6005-S	Barrel Burr, 6.0, 55 mm OAL, J-Notch
P99-107-6005-S	Oval Burr, 6.0, 55 mm OAL, J-Notch

Reusables — Usage Codes	
Part #	Description
P7770-955	Phantom® Hindfoot Flexible Reamer Shaft,
P7770-954	Phantom® Hindfoot Flexible Reamer Shaft,
P7770-0813	Phantom® Stepped Reamer, Cannulated, 8.0 mm to 13.0 mm
P2220-PHTM	Phantom® Outrigger Guide

Internal Compression Screw and End Caps	
Part #	Description
P31-101-0000-03	Phantom® Hindfoot Nail, Internal Compression Screw
P31-102-0001	Phantom® Hindfoot Nail, Shouldered End Cap, Short
P31-102-0005	Phantom® Hindfoot Nail, Shouldered End Cap, Long
P31-111-0000-03	Phantom® Hindfoot Nail, Compression End Cap, Short
P31-111-0000-07	Phantom® Hindfoot Nail, Compression End Cap, Long

PHANTOM[®]

HINDFOOT TTC/TC SYSTEM

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ACTIVCORE[™] NAIL SYSTEM

Thank you for your consideration of approval for the Phantom Hindfoot TTC/TC System at your facility.
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The following materials are available at www.paragon28.com and provide additional information on this novel solution

- ▶ 510k
- ▶ Abbreviated Surgical Technique
- ▶ Part List

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Exclusively foot & ankle
Paragon²⁸[®]

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