Phantom® Hindfoot TTC Trauma Nail System

BEFORE USING PRODUCT, READ THE FOLLOWING IMPORTANT INFORMATION

A FULL SYMBOLS GLOSSARY CAN BE FOUND AT: www.paragon28.com/resources

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

This booklet is designed to assist in using the Phantom® Hindfoot TTC Trauma Nail System. It is not a reference for surgical techniques.

CAUTION

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

GENERAL DESCRIPTION

The Paragon 28® Phantom® Hindfoot TTC/TC Nail System is comprised of the Phantom® TTC Nail, Phantom® ActivCore Nail and the Phantom® TTC Trauma Nail. These devices include intramedullary nails, screws and accessory components. The Phantom® nails are offered in a variety of lengths to accommodate variations in patient anatomy. The Phantom® screws insert through the intramedullary nail to secure the construct. These are offered in varying lengths to accommodate the anatomical fixation required. End caps are provided as accessories to the nails.

The system instruments include, but are not limited to, guide wires, drills/reamers, guides, jigs, gauges and drivers. The instruments are used to place and/or remove the implants.

MATERIALS

The implants of the Paragon 28® Phantom® Hindfoot TTC Trauma Nail System are made from Titanium Alloy (ASTM F136). The instrumentation is manufactured from medical grades of titanium alloy, stainless steel, anodized aluminum and polymer.

INDICATIONS FOR USE

The Phantom® Hindfoot TTC Trauma Nail System is indicated for tibiotalocalcaneal arthrodesis (fusion) and to provide stabilization of the hindfoot and ankle including the transverse tarsal joints coupling the mid-foot to the hindfoot. Examples of specific indications include:

- Post-traumatic or degenerative arthritis
- Previously infected arthrosis
- Revision of failed ankle arthrodesis
- Revision of failed total ankle arthroplasty
- Talar deficiency conditions such as avascular necrosis of the talus (requiring tibiocalcaneal arthrodesis)
- Neuromuscular deformity or other neuromuscular disease with severe deformity or instability of the ankle
- Rheumatoid arthritis
- Osteoarthritis
- Nonunions or pseudarthrosis of hindfoot and distal tibia
- Trauma (severe or malunited tibial pilon fracture)
- Charcot foot (neuroarthropathy)
- Severe end-stage degenerative arthritis
- Instability and skeletal defects after tumor resection
- Pantalar arthrodesis
- Severe foot/ankle deformity

CONTRAINDICATIONS

The Paragon 28® Phantom® Hindfoot TTC Trauma Nail System implants are not designed or sold for any use except as indicated. Use of the Phantom® Hindfoot TTC Trauma Nail System is contraindicated in the following situations:

- Active, suspected or latent infection in the affected area
- Patients who are physiologically or psychologically inadequate
- Corpulence; an overweight or corpulent patient can strain the implant to such a degree that stabilization or implant failure can occur
- Patients previously sensitized to titanium
- Longitudinal splits, fractures, or deformities
- Insufficient quantity or quality of bone to permit stabilization, conditions that retard healing (not including pathological fractures) and conditions causing poor blood supply
- Open epiphyseal plates
- Patients with an insufficient plantar fat pad
- Patients with an intact asymptomatic subtalar joint
- Patients with significant tibial malalignment (>10 degrees in either sagittal or coronal plane)
- In patients where there is a possibility for conservative treatment
- Indications not included in the **INDICATIONS FOR USE**

POTENTIAL COMPLICATIONS AND ADVERSE REACTIONS

In any surgical procedure, the potential for complications and adverse reactions exist. The risks and complications with these implants include:

- Loosening, deformation or fracture of the implant
- Acute post-operative infections and late infections with possible sepsis
- Migration, subluxation of the implant with resulting reduction in range of movement
- Fractures resulting from unilateral joint loading
- Thrombosis and embolism
- Wound hematoma and delayed wound healing
- Temporary and protracted functional neurological perturbation
- Tissue reactions as a result of allergy or foreign body reaction to dislodged particles
- Corrosion with localized reaction and pain
- Pain, a feeling of malaise or abnormal sensations due to the implant used
- Bone loss due to stress shielding
- Loss of fixation in bone attributable to nonunion, osteoporosis and/or markedly unstable comminuted fractures
- Nonunion or malunion with rotation or angulation resulting in limb shortening or loss of anatomic positioning
- Irritation of soft tissues, including impingement syndrome

All possible complications listed here are not typical of Paragon 28®, Inc. products but are in principle observed with any implant. Promptly inform Paragon 28®, Inc. as soon as complications occur in connection with the implants or surgical instruments used. In the event of premature failure of an implant in which a causal relationship with its geometry, surface quality or mechanical stability is suspected, please provide Paragon 28®, Inc. with the explant(s) in a cleaned, disinfected and sterile condition. Paragon 28®, Inc. cannot accept any other returns of used implants. The surgeon is held liable for complications associated with inadequate asepsis, inadequate preparation of the osseous implant bed in the case of implants, incorrect indication or surgical technique or incorrect patient information and consequent incorrect patient behavior.

WARNINGS AND PRECAUTIONS

- Re-operation to remove or replace implants may be required at any time due to medical reasons or device failure. If corrective action is not taken, complications may occur.
- Use of an undersized implant in areas of high functional stresses may lead to implant fracture and failure.
- Implants, wires, or other appliances of dissimilar metals should not be used together in or near the implant site.
- The implants and guide wires are intended for single use only.
- Instruments, guide wires and screws are to be treated as sharps.
- **Do not use other manufacturer's instruments or implants in conjunction with the Phantom® Hindfoot TTC Trauma Nail System**
- **Do not resterilize the Phantom® Hindfoot TTC Trauma Nail**

MR SAFETY INFORMATION

MRI Safety Information 

A patient with the Paragon 28 Phantom® Hindfoot TTC Trauma Nail System may be safely scanned under the following conditions. Failure to follow these conditions may result in injury to the patient.

Name/Identification of device	Paragon 28 Phantom® Hindfoot TTC Trauma Nail System
Nominal value(s) of Static Magnetic Field [T]	1.5 T or 3 T
Maximum Spatial Field Gradient [T/m and gauss/cm]	30 T/m (3000 gauss/cm)
RF Excitation	Circularly Polarized (CP)
RF Transmit Coil Type	**Body Coil**: See scan limitations below. **Local Coils**: No restrictions on local transmit-receive coils that the device is not within.
Operating Mode	Normal Operating Mode
Maximum Head SAR [W/kg]	3.2 W/kg (Normal Operating Mode)
Maximum Whole Body SAR [W/kg]	See details below
RF Conditions	Whole body average SAR ≤ 1.0 W/kg
Limits on Scan Duration	10 minutes of continuous RF (a sequence or back-to-back series/scan without breaks) followed by a 20 minute cooling period, repeated for an hour-long scanning session
MR Image Artifact	The presence of this implant may produce an image artifact.
Additional instructions or information essential for safe use in the MR environment	Scanning should remain within either of the following SAR limits. A patient with the implant should not enter the MR environment or be scanned if all the conditions cannot be met.
If information about a specific parameter is not included, there are no conditions associated with that parameter.	

MAINTANING DEVICE EFFECTIVENESS

- The surgeon should have specific training, experience, and thorough familiarity with the use of fixation devices.
- The surgeon must exercise reasonable judgment when deciding which implant type to use for specific indications.
- The Phantom® Hindfoot TTC Trauma Nail System implants are not intended to endure excessive abnormal functional stresses.
- The Phantom® Hindfoot TTC Trauma Nail System implants are intended for temporary fixation only until osteogenesis occurs.
- Failure to use dedicated, unique Phantom® Hindfoot TTC Trauma Nail System instruments for every step of the implantation technique may compromise the integrity of the implanted device, leading to premature device failure and subsequent patient injury. Failed devices may require re-operation and removal.
- Carefully inspect the implants prior to use. Do not modify the implants. Inspect the instruments before and after each procedure to assure they are in proper operational condition. Instruments which are faulty, damaged or suspect should not be used.
- Paragon 28®, Inc. recommends the use of Paragon 28®, Inc. products in a sterile environment.

HANDLING AND STERILIZATION

Sterile Product:

Paragon 28® Phantom® Hindfoot TTC Trauma Nails are provided sterile using gamma irradiation. Several instruments are also provided sterile via gamma irradiation. Do not re-sterilize. SINGLE USE ONLY. The risk of re-use of device includes potential for patient to develop infection. Do not use sterile product after expiration date. Packages for sterile product should be intact upon receipt.

The sterile packaging should be inspected to ensure that the package has not been damaged or previously opened. If the inner package integrity has been compromised, DO NOT USE THE PRODUCT. Contact the manufacturer for further instructions. The packages should be opened using aseptic technique. Once the seal of the product is broken, the product should not be re-sterilized.

All sterile product should be stored in a clean, dry environment.

Non-Sterile Product:

Product that is presented in a caddy is provided non-sterile. All non-sterile instruments must first be cleaned using the Paragon 28 validated methods (P31-CLN-0001) before sterilization and introduction into a sterile surgical field. Compliance is required with the manufacturer's user instructions and recommendations for chemical detergents. Refer to the Paragon 28®, Inc. ***Instrument Reprocessing Instructions for Reusable PHANTOM® Hindfoot TTC/TC System Instruments*** document P31-CLN-0001. This is also available by calling 855-786-2828.

Unless specifically labeled sterile, the implants and instruments are supplied NONSTERILE and MUST be sterilized prior to use. Recommended sterilization methods include steam autoclaving after removal of all protective packaging and labeling. Prior to sterilization, verify that all instruments are in their open and unlocked position within the instrument tray(s). The use of an FDA cleared sterilization wrap is recommended. The following validated steam autoclave cycle is recommended:

Method	Cycle	Temperature	Exposure Time	Dry Time
Steam	Pre-vacuum	270°F (132°C)	4 Minutes	30 Minutes

INSTRUCTIONS FOR USE

Only surgeons who are fully experienced in the use of such implants and the required specialized surgical techniques should implant the Paragon 28® Phantom® Hindfoot TTC Trauma Nail System. Refer to the product-specific Phantom® Hindfoot TTC Nail System Surgical Technique Guide (P31-STG-0001), Phantom® ActivCore Surgical Technique Guide (P31-STG-0002), for complete instructions for use. For product information or to obtain a copy of the product-specific surgical technique guide, please contact Paragon 28®, Inc. by phone, (855) 786-2828.

PHANTOM® HINDFOOT TTC TRAUMA NAIL IMPLANT REMOVAL (IF NECESSARY)

- Locate the implant with intra-operative imaging
- Attach jig to the implant construct
- Remove all screws from the construct and pass from the operative field
- Use provided instrumentation to back the nail out of the foot until completely removed.
- See the product-specific surgical technique for detailed removal instructions.

PRODUCT COMPLAINTS

The customer or health care provider should report any dissatisfaction with the product quality, labeling, or performance to Paragon 28®, Inc. immediately. Paragon 28®, Inc. should be notified immediately of any product malfunction by telephone or written correspondence. When filing a complaint, the name, part number and lot number of the part should be provided along with the name and address of the person filing the complaint.

Please contact company for product inquiries, cleaning instructions and surgical techniques, or to report any adverse event.

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Patient implant card

Print information

Print true to size (100% scale) with minimal margins

Step 1

Cut along solid line

Step 2

Fold paper vertically

Step 3

Fold paper horizontally