Phantom® Metatarsal Shortening 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® Metatarsal Shortening 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 Phantom® Metatarsal Shortening System includes a series of titanium (Ti-6Al-4V ELI per ASTM F136) intramedullary implants used for the correction of small bones in the foot. The implants are designed to provide stability and fixation of bone fragments to ultimately achieve fusion. The Phantom® Metatarsal Shortening implant utilizes a slot that accepts a Ø2.0mm Baby Gorilla crossing screw.

MATERIALS
All Phantom® Metatarsal Shortening implants are made from Titanium Alloy (ASTM F136). The instrumentation is made from medical grades of stainless steel, nylon coated stainless steel, silicone, titanium, polypropylene, radel and anodized aluminum.

INDICATIONS
The Phantom® Metatarsal Shortening System is indicated for use in bone reconstruction, osteotomy, arthrodesis, joint fusion, fracture repair and fracture fixation, appropriate for the size of the device. Specific examples include:

- Metatarsal and phalangeal osteotomies
- Metatarsal deformity correction
- Hammertoe
- Revision hammertoe
- Claw toe
- Mallet toe
- Proximal Interphalangeal Joint Arthrodesis
- Distal Interphalangeal Joint Arthrodesis

CONTRAINDICATIONS
Use of the Phantom® Metatarsal Shortening System is contraindicated in cases of inflammation, cases of active or suspected sepsis / infection and osteomyelitis; or in patients with certain metabolic diseases.

All applications that are not defined by the indications are contraindicated. In addition, surgical success can be adversely affected by:

- Acute or chronic infections, local or systemic
- Vascular, muscular or neurological pathologies that compromise the concerned extremity
- All concomitant pathologies that could affect the function of the implant
- Osteopathies with reduced bone substance that could affect the function of the implant
- Any mental or neuromuscular disorder that could result in an unacceptable risk of failure at the time of fixation or complications in post-operative treatment
- Known or suspected sensitivity to metal
- Corpulence; an overweight or corpulent patient can strain the implant to such a degree that stabilization or implant failure can occur
- Whenever the use of the implant comes into conflict with the anatomical structures of physiological status

Other medical or surgical pre-conditions that could compromise the potentially beneficial procedure, such as:

- The presence of tumors
- Congenital abnormalities
- Immunosuppressive pathologies
- Increased sedimentation rates that cannot be explained by other pathologies
- Increased leukocyte (WBC) count
- Pronounced left shift in the differential leukocyte count

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 wound 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 the result of allergy or foreign body reaction to dislodged particles.
- Corrosion with localized tissue reaction and pain
- Pain, a feeling of malaise or abnormal sensations due to the implant used
- Bone loss due to stress shielding

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® 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® with the explant(s) in a cleaned, disinfected and sterile condition. Paragon 28® 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 screw in areas of high functional stresses may lead to implant fracture and failure.
- Plates and screws, wires, or other appliances of dissimilar metals should not be used together in or near the implant site.
- The implants, sawblades and wires are intended for single use only. Re-use may cause product failure and could lead to disease transmission.
- Instruments, wires and screws are to be treated as sharps.
- **Do not use other manufacturer's instruments or implants in conjunction with the Phantom® Metatarsal Shortening System.**

MR SAFETY INFORMATION
The Phantom® Metatarsal Shortening System has not been evaluated for safety and compatibility in the MR environment. It has not been tested for heating, migration, or image artifact in the MR environment. The safety of the Phantom® Metatarsal Shortening System in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

MAINTAINING DEVICE EFFECTIVENESS

- The surgeon should have specific training, experience, and thorough familiarity with the use of screws.
- The surgeon must exercise reasonable judgment when deciding which screw type to use for specific indications.
- The Phantom® Metatarsal Shortening System implants are not intended to endure excessive abnormal functional stresses.
- The Phantom® Metatarsal Shortening System implants are intended for temporary fixation only until osteogenesis occurs.
- Failure to use dedicated, unique Phantom® Metatarsal Shortening 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, 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.

CLEANING AND DECONTAMINATION
All implants and instruments must first be cleaned using established hospital methods 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® Phantom® Metatarsal Shortening System - Instrument Reprocessing Instructions for Reusable Instruments document P99-CLN-0001. This is also available by calling (855) 786-2828.

STERILIZATION
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, such as the KimGuard® 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 Min.	30 Min.

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 Metatarsal Shortening System. Refer to the Phantom® Metatarsal Shortening System Surgical Technique, P35-STG-0001 for complete instructions for use. For product information or to obtain a copy of the surgical technique manual, please contact Paragon 28® by phone, (855) 786-2828.

IMPLANT REMOVAL (IF NECESSARY)

- Attach the HX7 Solid Driver to the AO Handle. Identify the head of the screw at the dorsal-proximal end of the implant.
- Insert the HX7 Solid Driver into the screw head and rotate counterclockwise until the screw is removed.
- Distract the existing osteotomy or create an osteotomy around the central aspect of the implant if bone healing has occurred to expose the proximal implant.
- Assemble the AO handle to the appropriately sized Implant Inserter.
- Connect the exposed (proximal) end of the implant to the Implant Inserter and rotate counterclockwise until the implant is removed.
- Confirm complete implant removal using fluoroscopy.

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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