Phantom® Fibula 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® Fibula 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® Fibula Nail System includes 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® Fibula Nail System are made from Titanium Alloy and Cobalt-Chromium-Molybdenum
Alloy, which conform to ASTM or ISO standards. The instrumentation is manufactured from medical grades of stainless steel, anodized aluminum and polymer.

INDICATIONS FOR USE

The Phantom® Fibula Nail System is intended for use in the fixation of fibular fractures and osteotomies.

CONTRAINDICATIONS

The Paragon 28® Phantom® Fibula Nail System implants are not designed or sold for any use except as indicated. Use of the Phantom® Fibula 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 or cobalt chromium molybdenum alloy
- 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
- 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 exists. 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 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® Fibula Nail System**
- **Do not resterilize the Phantom® Fibula Nail**

MR SAFETY INFORMATION

The Phantom® Fibula Nail System has not been evaluated for safety in the MR environment. It has not been tested for heating or unwanted movement in the MR environment. The safety of the Phantom® Fibula Nail System in the MR environment is unknown. Performing an MR exam on a person who has this medical device may result in injury or device malfunction.

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® Fibula Nail System implants are not intended to endure excessive abnormal functional stresses.
- The Phantom® Fibula Nail System implants are intended for temporary fixation only until osteogenesis occurs.
- Failure to use dedicated, unique Phantom® Fibula 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® Fibula Nail System is 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 products 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 products 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 (P99-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 Instruments*** document P99-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® Fibula Nail System. Refer to the product-specific Phantom® Fibula Nail System Surgical Technique Guide (P36-STG-0001), 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® FIBULA NAIL IMPLANT REMOVAL (IF NECESSARY)

- Locate the implant with intra-operative imaging.
- Remove all screws from the construct and pass from the operative field.
- De-actuate the proximal fixation mechanism using the provided instrumentation.
- Attach jig to the implant construct.
- 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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