Phantom™ Small Bone Intramedullary Nail System

BEFORE USING PRODUCT, READ THE FOLLOWING IMPORTANT INFORMATION.

This booklet is designed to assist in using the Phantom™ Small Bone Intramedullary 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™ Small Bone Intramedullary System is comprised of small bone intramedullary nails, locking screws and threaded pegs. The Phantom™ Nails are offered in a variety of lengths to accommodate variations in patient anatomy. The Phantom™ threaded pegs and locking screws insert through the intramedullary nail to secure the construct. These are offered in varying lengths to accommodate the anatomical fixation required.

The system instruments include sphere wires, K-wires, combination tissue protector/drill guide/obturator, drill guides, drill bits, polyaxial targeting guides, outriggers, outrigger sliders, depth gauges, screw drivers and driver handles. The instruments are used to place the small bone intramedullary nail, threaded pegs and locking screws.

IMPLANT MATERIALS

The implants of the Paragon 28® Phantom™ Small Bone Intramedullary Nail System including the small bone intramedullary nails, threaded pegs and locking screws are made from Titanium Alloy (ASTM F136). The instrumentation is manufactured from medical grades of stainless steel, anodized aluminum and polymer.

INDICATIONS FOR USE

The Phantom™ Small Bone Intramedullary Nail System is indicated for use in stabilization and fixation of the small bones of the feet and ankle for the treatment of fractures, osteotomies, arthrodesis, nonunions, pseudoarthroses and malunions caused by revision, joint fusion or reconstruction procedures.

CONTRAINDICATIONS

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

- Active, suspected or latent infection in the affected area
- Patients who are physiologically or psychologically inadequate
- Patients previously sensitized to titanium
- Longitudinal splits or longitudinal fractures
- 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 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

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.
- Plates and screws, 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 and K-wires are to be treated as sharps.
- **Do not use other manufacturer's instruments or implants in conjunction with the Phantom™ Small Bone Intramedullary Nail System**

MR SAFETY INFORMATION

The Phantom™ System has been evaluated for MR 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™ Small Bone Intramedullary System in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

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™ Small Bone Intramedullary Nail System implants are not intended to endure excessive abnormal functional stresses.
- The Phantom™ Small Bone Intramedullary Nail System implants are intended for temporary fixation only until osteogenesis occurs.
- Failure to use dedicated, unique Phantom™ Small Bone Intramedullary 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, 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, Inc. ***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 is recommended. The following validated steam autoclave cycle is recommended:

	Option 1	**Option 2**
Sterilizer Type	Pre-Vacuum	Pre-Vacuum
Temperature	270°F (132°C)	273°F (134°C)
Time	4 minutes	3 minutes
Dry Time	30 minutes	30 minutes

INSTRUCTIONS FOR USE

Surgeons, who are fully experienced in the use of such implants and the required specialized surgical techniques, should only implant the Paragon 28 Phantom™ Small Bone Intramedullary Nail System. Refer to the Phantom™ Small Bone Intramedullary Nail System Surgical Technique P30-STG-0001 for complete instructions for use. For product information or to obtain a copy of the surgical technique manual, please contact Paragon 28, Inc. by phone, (855) 786-2828.

PHANTOM™ SMALL BONE INTRAMEDULLARY NAIL IMPLANT REMOVAL (IF NECESSARY)

- Locate the implant with intra-operative imaging
- Remove locking screw using the appropriate driver
- Attach the outrigger and appropriately sized outrigger slider to the small bone intramedullary nail. Insert the tissue protector into one of the holes on the outrigger or outrigger slider.
- Use the driver through the tissue protector to engage the threaded peg. Rotate the driver counterclockwise until the threaded peg is retrieved. Pass from the operative field.
- Repeat the above step for the remaining two threaded pegs.
- Attach the Slaphammer to the thumb screw on the outrigger by rotating it clockwise. Use the Slaphammer to back the small bone intramedullary nail out of the foot until completely removed.

Paragon 28, Inc
4B Inverness Ct. E,
Suite 280
Englewood, CO 80112
(888) 728-1888

EC REP

Emergo Europe
Prinsessegracht 20
2514 AP, The Hague
Netherlands

Australian Sponsor

Emergo Australia
201 Sussex Street
Level 20, Tower II, Darling Park
Sydney, NSW 2000 Australia

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

SYMBOL EXPLAINATIONS

EC REP	Authorized EU Representative			Manufacturer
LOT	Lot Number			Non-sterile
REF	Item Number			Do Not Reuse
	Consult IFU		Rx Only	For prescription use only
	Keep Dry			Caution, consult accompanying documents

CE 0086

P30-IFU-1001 Rev. A