Paratrooper™ Plantar Plate Repair 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 Paratrooper™ Plantar Plate Repair 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® Paratrooper™ Plantar Plate Repair System is comprised of an all-suture anchor device that is intended for soft tissue reattachment.

MATERIALS
The implants of the Paratrooper™ Plantar Plate Repair System are made from ultra-high-molecular-weight-polyethylene (UHMWPE) co-braid suture and polyester suture. The suture anchors meet or exceed USP standards for non-absorbable sutures. The co-braid suture is manufactured with the following:

- White/Blue Co-Braid: white UHMWPE and blue polypropylene (PP) monofilament strands
  - Dye: [phthalocyaninato (2-)] copper <0.5% by weight per 21 CFR §74.3045
- White/Black Co-Braid: white UHMWPE and black Nylon monofilament strands
  - Dye: logwood extract <1.0% by weight per 21 CFR §73.1410
- White/Green Co-Braid: white UHMWPE fibers and green polyester (PET) fibers
  - Dye: D&C Green #6 < 0.75% by weight per 21 CFR §74.3206

The instrumentation is manufactured from medical grades of stainless steel, nitinol, and polymer.

INDICATIONS FOR USE
The Paratrooper™ Plantar Plate Repair System is intended for fixation of tissue to bone and tissue to tissue. Specific indications:

Foot/ankle:

- Lateral Stabilization
- Medial Stabilization
- Achilles Tendon Repair
- Metatarsal Ligament and Tendon Repair
- Hallux Valgus Reconstruction
- Digital Tendon Transfers
- Mid-foot Reconstruction
- Plantar Plate Repair

CONTRAINDICATIONS
The Paragon 28® Paratrooper™ Plantar Plate Repair System implants are not designed or sold for any use except as indicated. Use of the Paratrooper™ Plantar Plate Repair System is contraindicated in the following situations:

- Active, suspected or latent infection in the affected area
- Patients who are physiologically or psychologically inadequate
- Patients with a known allergy to the implant material(s)
- Insufficient quantity or quality of bone or soft tissue to permit stabilization, conditions that retard healing (not including pathological fractures) and conditions causing poor blood supply
- In patients where there is a possibility for conservative treatment
- Use in cardiac indications
- Indications not included in the INDICATIONS FOR USE

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

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 failure of the implant
- Acute post-operative infections and late infections with possible sepsis
- Migration, subluxation of the implant with resulting altered range of motion
- 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
- Implant degradation with localized reaction and pain
- Pain, a feeling of malaise or abnormal sensations due to the implant used
- Bone resorption or over-production

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 implant in areas of high functional stresses may lead to implant failure.
- The implants are intended for single use only.
- Instruments and implants are to be treated as sharps.
- Avoid K-wires and sutures through the implant.
- Avoid flawing implant surfaces to minimize the potential for early fatigue failure.
- **Do not use other manufacturer's instruments or implants in conjunction with the Paratrooper™ Plantar Plate Repair System.**
- **Do not resterilize the Paratrooper™ Plantar Plate Repair System Implants and Instruments.**

MR SAFETY INFORMATION
The Paratrooper™ Plantar Plate Repair 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 Paratrooper™ Plantar Plate Repair 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 Paratrooper™ Plantar Plate Repair System implants are not intended to endure excessive abnormal functional stresses.
- Failure to use dedicated, unique Paratrooper™ Plantar Plate Repair 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.

HANDLING AND STERILIZATION
Sterile Product:
Paragon 28® Paratrooper™ Plantar Plate Repair System implants and some instruments are provided sterile using Ethylene Oxide processing (EO). Do not re-sterilize. SINGLE USE ONLY. The risk of re-use of the device includes potential for patient to develop infection. Do not use devices after expiration date. Packages 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 IMPLANT OR INSTRUMENT. Contact the manufacturer for further instructions. The implants and instruments 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 should be cleaned using established hospital methods before sterilization and introduction into the 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*** (P99-CLN-0001). This is also available by calling (855) 786-2828.

Unless specifically labeled sterile, the 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® Paratrooper™ Plantar Plate Repair System. Refer to the Paratrooper™ Plantar Plate Repair System Surgical Technique (P13-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.

IMPLANT REMOVAL (IF NECESSARY)

- Instrumentation can be provided for implant removal.
- Removal instructions are provided in the Paratrooper™ Plantar Plate Repair System Surgical Technique (P13-STG-0001).

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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