Grappler™ Interference Screw 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 Grappler™ Interference Screw 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® Grappler™ Interference Screw System is comprised of PEEK screws that are intended for soft tissue reattachment. The Grappler™ Interference Screw System implant is offered in various sizes to accommodate patient anatomy.

IMPLANT MATERIALS
The implants of the Grappler™ Interference Screw System are made from polyetheretherketone (PEEK) per ASTM F2026. The instrumentation is manufactured from medical grades of stainless steel, nitinol, anodized aluminum, and silicone.

INDICATIONS FOR USE
The Grappler™ Interference Screw System is intended for soft tissue reattachment, i.e. fixation of ligament and tendon graft tissue and tendon transfers in surgeries of the shoulder, elbow, knee, foot/ankle, and hand/wrist. Specifically:

Shoulder:
- Rotator Cuff Repairs
- Bankart Repair
- SLAP Lesion Repair
- Biceps Tenodesis
- Acromio-Clavicular Separation Repair
- Deltoid Repair
- Capsular Shift or Capsulolabral Reconstruction.

Foot/Ankle:
- Lateral Stabilization
- Medial Stabilization
- Achilles Tendon Repair
- Hallux Valgus Reconstruction
- Midfoot Reconstruction
- Metatarsal Ligament Repair
- Flexor Hallucis Longus Transfer for Achilles Tendon Reconstruction, and
- Flexor Digitorum Longus Transfer for Posterior Tibial Tendon Reconstruction.

Knee:
- Anterior Cruciate Ligament Repair
- Medial Collateral Ligament Repair
- Lateral Collateral Ligament Repair
- Patellar Tendon Repair
- Posterior Oblique Ligament Repair
- Illiotibial Band Tenodesis

Elbow:
- Biceps Tendon Reattachment
- Ulnar or Radial Collateral Ligament Reconstruction

Hand/Wrist:
- Scapholunate Ligament Reconstruction
- Ulnar Collateral Ligament Reconstruction
- Radial Collateral Ligament Reconstruction
- Carpometacarpal joint arthroplasty (basal thumb joint arthroplasty)
- Carpal Ligament Reconstructions and repairs
- Ligament Reconstruction and Tendon Interposition.

CONTRAINDICATIONS
The Paragon 28® Grappler™ Interference Screw System implants are not designed or sold for any use except as indicated. Use of the Grappler™ Interference Screw 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
- Insufficient quantity or quality of bone 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
- 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
- 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 or implant material
- Pain, a feeling of malaise or abnormal sensations due to the implant used
- Bone resorption or over-production
- Nonunion or delayed union

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 are intended for single use only.
- Instruments and implants are to be treated as sharps.
- **Do not use other manufacturer's instruments or implants in conjunction with the Grappler™ Interference Screw System.**
- **Do not resterilize the Grappler™ Interference Screw System Implants.**

MR SAFETY INFORMATION
The Grappler™ Interference Screw 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 Grappler™ Interference Screw 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 Grappler™ Interference Screw System implants are not intended to endure excessive abnormal functional stresses.
- Failure to use dedicated, unique Grappler™ Interference Screw 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® Grappler™ Interference Screw System implants are provided sterile using 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 implants after expiration date. Packages for implants should be intact upon receipt.

Implants in 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. Contact the manufacturer for further instructions. The implants should be opened using aseptic technique. The implant should only be opened after the correct size has been determined. Once the seal of the product is broken, the product should not be re-sterilized.

All implants should be stored in a clean, dry environment.

Non-Sterile Product:
Instruments that are presented in a case are 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® Grappler™ Interference Screw System. Refer to the Grappler™ Interference Screw System Surgical Technique P41-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 Grappler™ Interference Screw System Surgical Technique (P41-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.

Australian Sponsor
Emergo Australia
Level 20, Tower II, Darling Park
201 Sussex St., Sydney, NSW 2000
Australia

Paragon 28®, Inc.
14445 Grasslands Dr.,
Englewood, CO 80112
USA
(855) 786-2828