axIOLink PCFD Tether 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 axIOLink PCFD Tether System. It is not a reference for surgical techniques.

GENERAL DESCRIPTION

The Paragon 28® axIOLink PCFD Tether System is comprised of suture anchors and suture tape that are intended for soft tissue repair. The implant construct for the axIOLink PCFD Tether System includes two PEEK suture anchors connected by UHMWPE suture. The suture tape is a doubled-over USP 2 equivalent tape. The implant construct comes pre-loaded on two inserter handles.

MATERIALS

The implants of the axIOLink PCFD Tether System are made from polyetheretherketone (PEEK), ultra-high molecular weight polyethylene (UHMWPE) and polylactic glycolic acid polymer (PGLA). The instrumentation is manufactured from medical grades of stainless steel, and polymer.

INTENDED USE/INDICATIONS FOR USE

The axIOLink PCFD Tether System is intended for the fixation of soft tissue to bone including:

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Foot/Ankle: Medial Stabilization (Deltoid and Spring Ligament Repair for addressing Progressive Collapsing Foot Deformity), Hindfoot Repair (Correction of Peritalar Subluxation/Dislocation, Hindfoot Valgus Deformity and Subfibular Impingement for Addressing Progressive Collapsing Foot Deformity), Interosseous Talocalcaneal Ligament Repair to address Progressive Collapsing Foot Deformity

CONTRAINDICATIONS

The Paragon 28® axIOLink PCFD Tether System implants are not designed or sold for any use except as indicated. Use of the axIOLink PCFD Tether 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 with a known allergy to the implant material(s)
- Patients previously sensitized to titanium
- 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 fracture of the implant
- Acute post-operative infections and late infections with possible sepsis
- Migration, subluxation of the implant
- 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
- 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.

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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 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.
- Avoid K-wires 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 axIOLink PCFD Tether System.**
- **Do not resterilize the axIOLink PCFD Tether System Implants and Instruments.**

MR SAFETY INFORMATION

The axIOLink PCFD Tether 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® Suture Anchor 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.
- Surgeons should consider the *in vivo* performance when selecting a suture
- The surgeon must exercise reasonable judgment when deciding which implant type to use for specific indications.
- Consideration should be taken in the use of absorbable sutures in tissues with poor blood supply as suture extrusion and delayed absorption may occur.
- The axIOLink PCFD Tether System implants are not intended to endure excessive abnormal functional stresses.
- Failure to use dedicated, unique axIOLink PCFD Tether 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® axIOLink PCFD Tether System products are provided sterile using ethylene oxide. Do not re-sterilize. SINGLE USE ONLY. The risk of re-use of device includes potential for patient to develop infection. Do not use product after expiration date. Packages for product should be intact upon receipt.

Product 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 DEVICE. Contact the manufacturer for further instructions. The product should be opened using aseptic technique. Once the seal of the product is broken, the product should not be re-sterilized.

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

DEVICE REMOVAL

- Instrumentation can be provided for device removal.
- Removal instructions are provided in the axIOLink PCFD Tether System Surgical Technique (P62-STG-0001).

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® axIOLink PCFD Tether System. Refer to the axIOLink PCFD Tether System Surgical Technique P62-IFU-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.

PRODUCT COMPLAINTS

The customer or health care provider should report any dissatisfaction with the product quality, labeling, or performance to Paragon 28® immediately. Paragon 28® 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 Paragon 28® for product inquiries, cleaning instructions and surgical techniques, or to report any adverse event.

CAUTION: Federal Law (USA) restricts this device to sale and use by, or on the order of, a physician.

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