TenoTac® Soft Tissue Fixation 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 TenoTac® Soft Tissue Fixation 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® TenoTac® Soft Tissue Fixation System is comprised of specialized threaded tacks and sleeves. The TenoTac® Soft Tissue Fixation System components are offered in various sizes to accommodate patient anatomy.

MATERIALS
The implants of the TenoTac® Soft Tissue Fixation System are made from Titanium Alloy (ASTM F136). The instrumentation is manufactured from medical grades of stainless steel, silicone, anodized aluminum, nitinol and polymers.

INDICATIONS FOR USE
The TenoTac® Soft Tissue Fixation System is intended to be used for soft tissue to bone fixation.

Specific indications for the TenoTac® include:
- Foot & Ankle: Medial/lateral repair and reconstruction, mid and forefoot repair, hallux valgus repair, hallux malleus repair and reconstruction, metatarsal ligament/tendon repair and reconstruction including plantar plate attenuation and tear, and the correction of hammer toe, claw toe, mallet toe, crossover toe, floating toe, and any other lesser toe deformities, correction of metatarsophalangeal joint instability due to shortening from interphalangeal fusion, correction of metatarsophalangeal joint instability due to shortening from Weil osteotomy, Achilles tendon repair.
- Hand & Wrist: Collateral ligament repair, Scapholunate ligament reconstruction, tendon transfers in phalanx, Volar plate reconstruction.

CONTRAINDICATIONS
The Paragon 28® TenoTac® Soft Tissue Fixation System implants are not designed or sold for any use except as indicated. Use of the TenoTac® Soft Tissue Fixation 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 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
- 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.
- Implants, wires, or other appliances of dissimilar metals should not be used together in or near the implant site.
- The implants and K-wires 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 TenoTac® Soft Tissue Fixation System.**
- **Do not resterilize the sterile packaged TenoTac® Soft Tissue Fixation System implants and instruments. The sterile packaged implants and instruments are intended for single use only.**

MR SAFETY INFORMATION
The TenoTac® Soft Tissue Fixation 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 TenoTac® Soft Tissue Fixation 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 TenoTac® Soft Tissue Fixation System implants are not intended to endure excessive abnormal functional stresses.
- Failure to use dedicated, unique TenoTac® Soft Tissue Fixation 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® TenoTac® Soft Tissue Fixation System implants and instruments 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 and instruments after expiration date. Packages for implants 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 INSTRUMENTS. Contact the manufacturer for further instructions. The implants 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 implants and 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 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 caddy. 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® TenoTac® Soft Tissue Fixation System. Refer to the TenoTac® Soft Tissue Fixation System Surgical Technique P42-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 TenoTac® Soft Tissue Fixation System Surgical Technique (P42-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.

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

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