R3ACT™ Stabilization 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 R3ACT™ Stabilization 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® R3ACT™ Stabilization System is a fixation device that is implanted as a rigid screw-type anchor and transitions to engage the internal UHMWPE suture loop and bumper to allow for dynamic diastatic motion and fibular rotation in a semi-constrained fashion. It is offered in varying sizes to accommodate a variety of applications and variation in anatomy. The suture loop is non-absorbable and meets all applicable requirements established by the USP for non-absorbable surgical sutures.

MATERIALS

The implants of the R3ACT™ Stabilization System are made from Titanium Alloy, UHMWPE suture, and thermoplastic polyurethane. The instrumentation is manufactured from medical grades of stainless steel, polymers, aluminum and titanium.

INDICATIONS FOR USE

The R3ACT™ Stabilization System is intended as an adjunct in fracture repair and ligamentous injuries of small bones of the feet and ankles including the distal tibia, distal fibula, talus, and calcaneus, and as an adjunct in external and intramedullary fixation systems involving plates and rods. Specifically, the R3ACT™ Stabilization System is intended to provide fixation during the healing process following a syndesmotic trauma, such as fixation of syndesmosis (syndesmosis disruptions) in connection with Weber B and C ankle fractures.

CONTRAINDICATIONS

Use of the R3ACT™ Stabilization System is contraindicated in cases of inflammation, cases of active or suspected sepsis/infection and osteomyelitis; or in patients with certain metabolic diseases.

All applications that are not defined by the indications are contraindicated. In addition, surgical success can be adversely affected by:

- Acute or chronic infections, local or systemic
- Vascular, muscular or neurological pathologies that compromise the concerned extremity
- All concomitant pathologies that could affect the function of the implant
- Osteopathies with reduced bone substance that could affect the function of the implant
- Any mental or neuromuscular disorder that could result in an unacceptable risk of failure at the time of fixation or complications in post-operative treatment.
- Known or suspected sensitivity to implant materials
- Corpulence; an overweight or corpulent patient can strain the implant to such a degree that stabilization or implant failure can occur
- Whenever the use of the implant comes into conflict with the anatomical structures of physiological status

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
- Pronounced left shift in the differential leukocyte 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, migration, subluxation, or fracture of the implant
- Acute post-operative wound 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 or embolism
- Wound hematoma and delayed wound healing
- Temporary and protracted functional neurological perturbation
- Tissue reactions as the result of allergy or foreign body reaction to dislodged particles
- Corrosion with localized tissue 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® in the event that 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® with the explant(s) in a cleaned, disinfected and sterile condition. Paragon 28® 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 non-compliant 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.
- The implants and guide wires are intended for single use only.
- Guide wires and screws are to be treated as sharps.
- **Do not use other manufacturer's instruments or implants in conjunction with the R3ACT™ Stabilization System.**
- **Do not re-sterilize the R3ACT™ Stabilization System Implants or Instruments.**

MR SAFETY INFORMATION

The R3ACT™ Stabilization 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 R3ACT™ Stabilization System in the MR environment is unknown. MR scanning of 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 device.
- The surgeon must exercise reasonable judgment when deciding to use the device.
- The R3ACT™ Stabilization System implant is not intended to endure excessive abnormal functional stresses.
- The R3ACT™ Stabilization System implant is intended for temporary fixation only until ligament healing occurs.
- Failure to use dedicated, unique R3ACT™ Stabilization 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 and 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® R3ACT™ Stabilization System product provided sterile are sterilized using ethylene oxide. 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 sterile devices after expiration date. Packages for devices must 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 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 product 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 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® R3ACT™ Stabilization System. Refer to the R3ACT™ Stabilization System Surgical Technique P80-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 R3ACT™ Stabilization System Surgical Technique (P80-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
(855) 786-2828