Exclusively foot & ankle

Paragon 28®

TITAN 3-D™ Wedge 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 TITAN 3-D™ Wedge 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.

DESCRIPTION

The TITAN 3-D™ Wedge System contains a series of titanium alloy implants used for the correction of small bones in the foot. It is offered in varying shapes and sizes to accommodate a variety of small bone applications. Implants are made from medical grade titanium alloy (Ti6Al4V) per ASTM F2924.

IMPLANT MATERIALS

The TITAN 3-D™ Wedge System implants are made from Titanium Alloy (ASTM F2924). The instrumentation is made from medical grades of stainless steel, silicone and/or anodized aluminum.

INDICATIONS FOR USE

The TITAN 3-D™ Wedge System implants are intended to be used for internal bone fixation for lateral column lengthening (Evans) osteotomies and medial cuneiform opening wedge (Cotton) osteotomies in the foot and ankle. The TITAN 3-D™ Wedge System implants are intended for use with ancillary fixation. The TITAN 3-D™ Wedge System implants are not intended for use in the spine.

CONTRAINDICATIONS

Use of the TITAN 3-D™ Wedge 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 metal
- 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 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 and 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.
- Instruments, guide wires and screws are to be treated as sharps.
- **Do not use other manufacturer's instruments or implants in conjunction with the TITAN 3-D™ Wedge System.**
- **Do not resterilize the TITAN 3-D™ Wedge System implants**.

MR (MAGNETIC RESONANCE) SAFETY INFORMATION

Non-clinical testing has demonstrated the TITAN 3-D™ Wedge implants are MR conditional. A patient with these devices can be safely scanned in an MR system meeting the following conditions:

- Static magnetic field of 3 T or 1.5 T
- Maximum spatial field gradient of 1900 gauss/cm (19 T/m)
- Maximum MR system reported, whole body averaged specific absorption rate (SAR) of 2 W/kg (Normal Operating Mode)

Under the scan conditions defined above, non-clinical testing results indicate the TITAN 3-D™ Wedge is expected to produce a maximum temperature rise of less than 2.8°C after 15 minutes of continuous scanning.

In non-clinical testing, the image artifact caused by the device extends approximately 26 mm from the TITAN 3-D™ Wedge when imaged with a gradient echo pulse sequence and a 3 T MR system.

MAINTAINING 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 TITAN 3-D™ Wedge System is not intended to endure excessive abnormal functional stresses.
- Failure to use dedicated, unique TITAN 3-D™ Wedge 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.
- **The surface coating of anodized aluminum devices may degrade due to exposure to highly alkaline cleaning processes and/or inappropriate handling and/or normal use. Such devices may require replacement if they no longer perform as designed.**
- **If an instrument is damaged, contact Paragon 28® immediately to arrange replacement and/or disposal.**
- Paragon 28® Inc. recommends the use of Paragon 28® Inc. products in a sterile environment.

HANDLING AND STERILIZATION

Implants:

The TITAN 3-D™ Wedge System implants in this system are provided sterile by exposure to a minimum dose of 25kGy of gamma radiation. 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.

Implants in sterile packaging should be inspected to ensure that the packaging 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 implant should only be opened after the correct size has been determined. The implants should be opened using an aseptic technique. The box will contain a double pouch. An unsterile member of the operating room team should open the box to retrieve the double pouch containing the TITAN 3-D™ implant. The unsterile team member should present the sterile inner pouch to a sterile team member using aseptic technique who then can remove the implant from the sterile inner package.

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

Reusable Instruments:

Instruments that are presented in a tray are provided non-sterile. All non-sterile instruments should be cleaned using established hospital methods before sterilization and introduction into a sterile surgical field. Compliance is required with the manufacturer's user instructions and recommendations for chemical detergents. Refer to the Paragon 28® ***Instrument Reprocessing Instructions for Reusable Instruments*** document P99-CLN-0001. This is also available by calling +1 (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	Minimum Temperature	Minimum 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 TITAN 3-D™ Wedge System. Refer to the TITAN 3-D™ Wedge System Surgical Technique (P03-STG-0001 (*US*) and P03-STG-1001 (*OUS*)) for complete instructions for use. For product information or to obtain a copy of the surgical technique manual, please contact Paragon 28® by phone, +1 (855)786-2828.

IMPLANT REMOVAL

- Instrumentation can be provided for implant removal.
- Removal instructions are provided in the TITAN 3-D™ Wedge System Surgical Technique: P03-STG-0001 (*US*) and P03-STG- 1001 (*OUS*)

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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