Exclusively foot & ankle Paragon 28®

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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.

GENERAL 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.

INTENDED/ EXPECTED CLINICAL BENEFITS

Intended/Expected Clinical Benefits of the TITAN 3-D™ Wedge System include:

- Successful Implantation of TITAN 3-D™ Wedge System Devices
- Bone Healing
- Deformity Correction

The Summary of Safety and Clinical Performance (SSCP) can be found at:

https://ec. europa.eu/tools/eudamed by searching for Manufacturer: Paragon 28 (upon Eudamed activation). Until Eudamed is activated, to request a copy of the SSCP, please contact Paragon 28®, Inc. by phone, (+1) (855) 786-2828.

Residual Risks identified within the SSCP are included as warnings and precautions.

IMPLANT MATERIALS

The TITAN 3-D™ Wedge System implants are made from Titanium Alloy (ASTM F2924). The maximum possible composition of each element is as follows:

Element	Maximum Composition, % (Mass/Mass)
Nitrogen	0.05
Carbon	0.08
Hydrogen	0.015
Iron	0.30
Oxygen	0.20
Aluminium	6.75
Vanadium	4.5
Yttrium	0.005
Other (each)	0.10
Other (Total)	0.40
Titanium	89.95

INSTRUMENT MATERIALS

The instrumentation is made from medical grades of stainless steel, silicone and/or plastics.

CMR, EDP, PHTHALATES

The TITAN 3-D™ Wedge System Implants & Surgically Invasive Instruments do not contain substances ≥0.1% (w/w) which are classified as carcinogenic, mutagenic or toxic to reproduction (CMR), substances ≥0.1% (w/w) which have endocrine disrupting properties (EDP) and do not contain phthalates.

INTENDED USE/ INTENDED PURPOSE / 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
- 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
- Pronounced left shift in the differential leukocyte count

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. Any single use device which has been used may have come in contact with tissue, bone, blood or other bodily fluids. This is considered contaminated and must be discarded for the safety of the patient and other users.
- 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 re-sterilize the TITAN 3-D™ Wedge System implants**.
- In any surgical procedure, the potential for complications and adverse reactions exists. The residual risks, potential complications and adverse reactions 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

- Adverse events include but are not limited to those described in this document

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.

MR SAFETY INFORMATION

MR

MRI Safety Information
A person with the TITAN 3-D™ Wedge System Implant may be safely scanned under the following conditions. Failure to follow these conditions may result in injury to the patient.

Name/Identification of device	TITAN 3-D™ Wedge System Implant
Nominal value(s) of Static Magnetic Field (T)	1.5 T or 3.0 T
Maximum Spatial Field Gradient [T/m and gauss/cm]	19 T/m (1900 gauss/cm)
RF Excitation	Circularly Polarized (CP)
RF Transmit Coil Type	Whole body transmit coil, Head RF transmit-receive coil
Maximum Whole-Body SAR [W/kg]	2.0 W/kg (Normal Operating Mode)
Limits on Scan Duration	2.0 W/kg whole-body average SAR for 60 minutes of continuous RF (a sequence or back-to-back series/ scan without breaks)
MR Image Artifact	The presence of this implant may produce an image artifact of 26mm .
If information about a specific parameter is not included, there are no conditions associated with that parameter.	

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 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.
- If an instrument is damaged, contact Paragon 28® immediately to arrange replacement and/or disposal.
- Paragon28 non-sterile devices are precision medical devices and must be used and handled with care. Inspect the devices for damage prior to use, and at all stages of handling thereafter. If damage is detected, do not use the device prior to consulting the manufacturer for guidance.
- Devices with cutting functions or sharp points become dull with continuous use. This condition does not indicate a defective device and may indicate normal wear. Any sign of a dull or wearing devices may require replacement if they no longer perform as designed. Inspection prior to use should include verifying the cutting ability and sharpness of these points and edges.
- Paragon 28® Inc. recommends the use of Paragon 28® Inc. products in a sterile environment.

HANDLING AND STERILIZATION

Sterile Product:

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. Any device labeled as Single Use only must never be reused or reprocessed. Any device opened from its packaging is considered used and may have come in contact with tissue, bone, blood or other bodily fluids. This is considered contaminated and must be discarded for the safety of the patient and other users. Do not use implants or instruments after expiration date. Packages for implants and instruments should be intact upon receipt.

Implants and instruments in sterile packaging should be inspected to ensure that the packaging has not been damaged or previously opened. If the package integrity has been compromised, potential for patient harm could occur, DO NOT USE THE IMPLANT or INSTRUMENT. 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 and instruments must be stored in a clean, dry environment.

Non-Sterile Product:

Instruments or 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 (Manual Method P99-CLN-0001). For product information or to obtain a copy of the surgical technique manual and/ or the Summary of Safety and Clinical Performance, please contact Paragon 28®, Inc. by phone, +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 2 layers of 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

INTENDED USERS

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-1001 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 (IF NECESSARY)

- Instrumentation can be provided for implant removal.
- Removal instructions are provided in the TITAN 3-D™ Wedge System Surgical Technique: P03-STG-1001

TARGETED POPULATION

TITAN 3-D™ Wedge System is intended for members of the adult general population requiring internal bone fixation for lateral column lengthening (Evans) osteotomies and medial cuneiform opening wedge (Cotton) osteotomies in the foot and ankle. The population does not include patients that are pregnant nor any others with conditions listed in the contraindications.

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., or it's EC Representative, 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.

DISPOSAL OF IMPLANT OR INSTRUMENT

The implant and associated instrumentation will be used in a surgical suite, and thus, any disposal of the implant(s), instrument(s), and/or packaging will occur in the surgical suite by the user.

- The sterile packaged implant will be opened in the surgical suite with the packaging disposed of by the user. The outside packaging is not passed onto the operative field and should not be contaminated by human tissue or blood. The outside packaging is disposed of in a standard waste receptacle. If the inner packaging is in contact with human tissue or blood, the inner packaging must be disposed of in a standard biowaste container. If the inner packaging does not come in contact with human tissue or blood, the inner packaging can be disposed of in a standard waste receptacle.
- In the case of an implant removal, or if an implant must be disposed of during surgery, the disposal will occur in the surgical suite by the user. Because the implant has been in contact with human tissue or blood and may have a sharp physical hazard, the implant must be disposed of in a biohazard waste container intended for sharps.
- In the case of instrument disposal, the disposal will occur in the surgical suite by the user. Because the instrument has been in contact with human tissue or blood and may have a sharp physical hazard, the instrument must be disposed of in a biohazard container intended for sharps.

Please contact Paragon 28®, Inc. for product inquiries, cleaning instructions and surgical techniques. To report any adverse event, please contact Paragon 28®, Inc. or it's EC Representative.

	EC REP	UK Responsible Person	CH REP
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CE 2797	**Class Ir, IIa, IIb**
CE	**Class I Self Certify**