APEX 3D™ Total Ankle Replacement 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 APEX 3D™ Total Ankle Replacement 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® APEX 3D™ Total Ankle Replacement System is a fixed bearing device comprised of a tibial component, a talar component and an Ultra-High Molecular Weight Polyethylene (UHMWPE) component used for ankle joint replacement. Components are available in varying sizes and design configurations intended for both primary and revision applications.

The Paragon 28® APEX 3D™ Total Ankle Replacement System Laser Alignment Guide is designed to provide a visual guide to verify alignment of the instrumentation associated with the APEX 3D™ Total Ankle Replacement System.

The laser alignment guide is removed from the sterile packaging, the paper pull tab in pulled, and the laser is ready for use. Insert the metal switch at the bottom into the appropriate instrumentation to activate the laser. To safely terminate operation, lift the laser out of the mating instrumentation and the laser line will turn off.

MATERIALS

The implants of the APEX 3D™ Total Ankle Replacement System are made from additively manufactured Titanium Alloy, UHMWPE with vitamin E, Cobalt-Chromium-Molybdenum Alloy, and commercially pure titanium, all of which conform to ASTM or ISO standards, or internal standards. The instrumentation is manufactured from medical grades of stainless steel, polymers, aluminum and titanium.

INDICATIONS FOR USE

The APEX 3D™ Total Ankle Replacement System is indicated as a total ankle replacement in primary surgery for patients with ankle joints damaged by severe rheumatoid, post-traumatic, or degenerative arthritis. Revision surgery for these patients is also indicated for patients with sufficient bone stock present. In the United States, components are intended for cemented use only.

CONTRAINDICATIONS

Use of the APEX 3D™ Total Ankle Replacement 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
- 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 (e.g. dementia, senility, alcoholism)
- Corpulence; an overweight or corpulent patient can strain the prosthesis to such a degree that stabilization or prosthesis failure can occur
- Excessive loads as caused by activity or patient weight
- Female of childbearing age, for whom a negative pregnancy test is not obtained
- Steroid use
- Inadequate neuromuscular status (e.g. prior paralysis, neuropathy, neuropathic joint, fusion and/or inadequate abductor strength)
- Muscular atrophy
- Osteomyelitis
- Poor bone stock, poor skin coverage, or excessive bone loss around the joint which would make the procedure unjustifiable
- Sepsis
- Skeletally immature patients (patient is less than 21 years of age at the time of surgery)
- Suspected or documented metal allergy or intolerance
- Musculoskeletal disease that may adversely affect gait or weight-bearing
- Neurologic disorder/instability and non-compliance that may adversely affect gait or weight bearing
- Vascular deficiency in the ankle joint

Other medical or surgical pre-conditions that could compromise the potentially beneficial procedure, such as:

- Congenital abnormalities
- Immunosuppressive pathologies
- Increased sedimentation rates that cannot be explained by other pathologies
- Marked bone loss, severe osteoporosis, or revision procedures for which an adequate fit of the prosthesis cannot be achieved
- Metabolic disorders that may impair bone formation
- Osteomalacia
- Poor prognosis for good wound healing
- Presence of tumors
- Increased leukocyte (WBC) count
- Pronounced left shift in the differential leukocyte count
- Uncooperative patient or patient with neurological disorders, incapable of following instructions

POTENTIAL COMPLICATIONS AND ADVERSE REACTIONS

In any surgical procedure, the potential for complications and adverse reactions exist. The risks and complications with these prosthetic components include:

- Asymptomatic, progressive bone resorption (osteolysis) due to foreign body reaction to particulate matter (See **Important Physician Information** section for more information)
- Sensitivity, allergy or other reactions to prosthetic component materials
- Peripheral neuropathies or nerve damage resulting in pain or numbness of the affected limb
- Loosening or migration of the prosthetic components
- Subluxation or dislocation of the prosthetic components with resulting reduction in range of movement
- Bending, disassembly and/or breakage of the prosthetic components
- Fractures resulting from unilateral joint loading
- Fatigue fracture of the prosthetic components as the result of trauma, strenuous activity, improper alignment, incomplete implant seating, or duration of service
- Bone fracture by trauma or excessive loading, particularly in the presence of poor bone stock
- Drop in blood pressure intra-operatively due to the use of bone cement
- Thrombosis, embolism, or myocardial infarction
- Wound hematoma and delayed wound healing
- Acute post-operative wound infections and late infections with possible sepsis
- Pain, a feeling of malaise or abnormal sensations due to the prosthetic components
- Inadequate range of motion due to improper selection or positioning of components or periarticular calcification
- Temporary and protracted functional neurological perturbation
- Corrosion with localized tissue reaction and pain
- Bone loss due to stress shielding
- Secondary necrosis of the talus

All possible complications listed here are not typical of Paragon 28®, Inc. products but in principle, may be observed with any total joint replacement 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

- This device is not intended for subtalar joint fusion or subtalar joint impingement. Please carefully evaluate the anatomy of each patient before implantation.
- The surgeon should discuss with the patient prior to surgery possible risks, precautions, warnings, consequences, complications, and adverse reactions associated with the surgical procedure and implantation of the device.
- Improper selection, placement, positioning, and fixation of the prosthetic components may result in unusual stress conditions and a subsequent reduction in service life of the prosthetic component.
- Periodic, long-term follow-up is recommended to monitor the position and state of the prosthetic components, as well as the condition of the adjoining bone.
- Re-operation to remove or replace prosthetic components may be required at any time due to medical reasons or device failure. If corrective action is not taken, complications may occur.
- Patients need to be informed regarding expectations pertaining to performance and limitations following surgery. The prosthesis does not replace normal bone, has a finite service life, and future revision surgeries may be necessary. Protection of the prosthesis from full weight bearing is needed until adequate fixation and healing is achieved. Certain activities and loading trauma should be limited to prevent unreasonable stresses that could lead to breaking or damage of the prosthetic components.
- Do not attempt a surgical procedure with faulty, damaged or suspect instruments or implants. Inspect all components preoperatively to assure utility.
- Never modify an implant.
- The implants, guide wires, and Laser Alignment Guide are intended for single use only.
- Instruments and implants are to be treated as sharps.
- Do not implant the instruments.
- **LASER RADIATION – DO NOT LOOK INTO THE BEAM!** Do not look directly with optical instruments into the laser beam apertures, since doing so can be hazardous to your eyes!
- The Laser Alignment Guide is not adjustable and maintenance-free.
- Use of the Laser Alignment Guide adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.
- Use of accessories, transducers and cables other than those specified or provided by the manufacturer of the Laser Alignment Guide could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.
- Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the Laser Alignment Guide, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.
- **Do not use other manufacturer's instruments or implants in conjunction with the APEX 3D™ Total Ankle Replacement Device.**
- **Do not re-sterilize the APEX 3D™ Total Ankle Replacement Implants or Instruments.**

IMPORTANT PHYSICIAN INFORMATION

Bone resorption is a natural consequence of total joint arthroplasty due to changes in bone remodeling patterns. Bone remodeling is mediated by the changes in stress distribution caused by implantation. Extensive resorption around the prosthesis may lead to implant loosening and failure. It is generally agreed that osteolysis is the result of localized foreign-body reaction to particulate debris generated by cement, metal, UHMWPE, and ceramic. Regarding the etiology, it has been hypothesized that particulate debris generated by the components of a prosthesis migrate into the synovial cavity and the bone-implant interface, where they recruit macrophages and stimulate phagocytic action. The degree of recruitment is determined by the size, distribution and amount of particulate debris (rate of debris generation). The phagocytic action results in the release of cytokines and intercellular mediators (IL-1, 2, PE2) which encourage osteoclastic bone resorption. Clinical and basic research is continuing in order to provide scientific basis for the causes of this phenomenon and the potential ways to reduce its occurrence. Osteolysis can be asymptomatic and therefore routine periodic radiographic examination is vital to prevent any serious future complication. Presence of focal lesions that are progressive may necessitate replacement of the prosthetic component(s).

MR SAFETY INFORMATION

The APEX 3D™ Total Ankle Replacement 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 APEX 3D™ Total Ankle Replacement 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 all aspects of the prosthesis.
- The surgeon must exercise reasonable judgment when selecting the proper size, shape, and design of the prosthesis.
- When determining if the APEX 3D™ Total Ankle Replacement is ideal for a patient, the weight, occupation, activity level, mental health, and foreign body sensitivity of the patient should be taken into account.
- The APEX 3D™ Total Ankle Replacement System implants are not expected to withstand activity levels and loads as would normal healthy bone. The system, as well as the implant/bone interface, will not be as strong, reliable, or durable as a natural human joint.
- Failure to use dedicated, unique APEX 3D™ Total Ankle Replacement 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 prosthetic components 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. The battery pull tab and housing of the laser should be intact.
- Any noise or unusual sensation should be reported to the surgeon.
- Paragon 28®, Inc. recommends the use of Paragon 28®, Inc. products in a sterile environment.

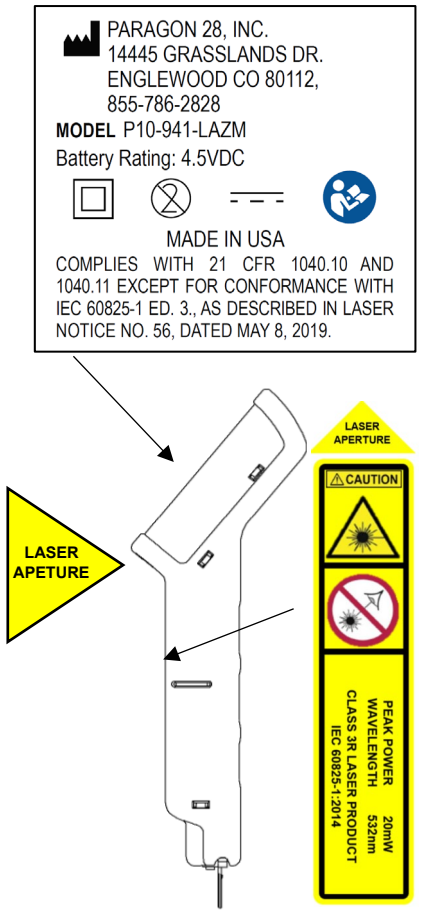
LASER SAFETY INFORMATION

The Laser Alignment Guide uses a diode laser module which emits laser radiation. Do not under any circumstances look directly at the laser beam or any scattered laser radiation – either with the naked eye or with optical instruments.

The Laser Alignment Guide is a Class 3R laser product according to IEC 60825-1:2014. Make sure to comply with all operating safety precautions when using the Laser Alignment Guide.

The maximum output of continuous laser radiation measured at the beam exit is 20mW. The wavelength of the emitted radiation is 532 nm. Beam divergence is measured to be 99° from one end of the line to the other. The Laser contains one Alkaline battery rated 4.5VDC. Environmental conditions of the Laser are those typical of a surgical suite, between 0°C and 60°C and 15% to 90% humidity.

User should refer to IEC 60601-1 *Medical electrical equipment – Part 1: General requirements for basic safety and essential performance* for requirements applicable to medical electrical systems.



ELECTROMAGNETIC SAFETY INFORMATION

The Laser Alignment Guide is medical electric equipment used in a surgical environment subject to EM emissions and disturbances. The Laser should function as described in the GENERAL DESCRIPTION. The Operator can expect the Laser to dim and turn off if the Laser is impacted by EM disturbances. Electronics such as cell phone that emit a frequency between 1700-1990 MHz may have the potential to interfere with the device by turning off the laser. When possible, such electrical equipment should be kept out of close proximity to the device. There are no cables, transducers, or other accessories to be used with the Laser Alignment Guide. The Laser is single-use only and is not subject to servicing or maintenance.

The Laser Alignment Guide is intended for use in the electromagnetic environment specified below. The customer or the user of the Laser should assure that it is used in such an environment.

Test	Compliance	Guidance
RF emissions CISPR 11	Group 1	The Laser uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
Electrostatic discharge (ESD) IEC 61000-4-2	±8 kV contact ±15 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
(50/60 Hz) magnetic field IEC 61000-4-8	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Radiated RF IEC 61000-4-3	3 V/m	Portable and mobile RF communications equipment should be used no closer to any part of the EQUIPMENT, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. $d = 1.2\sqrt{P}$ 80 MHz to 800 MHz $d = 2.3\sqrt{P}$ 800 MHz to 2.7 GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in metres (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey[a], should be less than the compliance level in each frequency range[b]

[a]Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the Laser is used exceeds the applicable RF compliance level above, the Laser should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the Laser.

[b]Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

NOTE: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

The Laser Alignment Guide is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Laser can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Laser as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter (W)	Separation distance according to frequency of transmitter (m)		
	150 kHz to 80 MHz $d = 1.2\sqrt{P}$	80 MHz to 800 MHz $d = 1.2\sqrt{P}$	800 MHz to 2.7 GHz $d = 2.3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Immunity to RF Wireless Communications Equipment						
Test Frequency (MHz)	Band [a] (MHz)	Service [a]	Modulation [b]	Maximum Power (W)	Distance (m)	IMMUNITY TEST LEVEL (V/m)
385	380 – 390	TETRA 400	Pulse modulation [b] 18 Hz	1.8	0.3	27
450	430 – 470	GMRS 460, FRS 460	FM [c] ± 5 kHz deviation 1 kHz sine	2	0.3	28
710	704 – 787	LTE Band 13, 17	Pulse modulation [b] 217 Hz	0.2	0.3	9
745						
780						
810	800 – 960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation [b] 18 Hz	2	0.3	28
870						
930						

Immunity to RF Wireless Communications Equipment						
Test Frequency (MHz)	**Band [a] (MHz)**	**Service [a]**	**Modulation [b]**	**Maximum Power (W)**	**Distance (m)**	**IMMUNITY TEST LEVEL (V/m)**
1720	1 700 – 1 990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	Pulse modulation [b] 217 Hz	2	0.3	28
1845						
1970						
2450	2 400 – 2 570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation [b] 217 Hz	2	0.3	28
5240	5 100 – 5 800	WLAN 802.11 a/n	Pulse modulation [b] 217 Hz	0.2	0.3	9
5500						
5785						

a) For some services, only the uplink frequencies are included.
b) The carrier shall be modulated using a 50 % duty cycle square wave signal.
c) As an alternative to FM modulation, 50 % pulse modulation at 18 Hz may be used because while it does not represent actual modulation, it would be worst case.

HANDLING AND STERILIZATION

Sterile Product:

Paragon 28® APEX 3D™ Total Ankle Replacement System product provided sterile are either sterilized using gamma irradiation or 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 implants after expiration date. Packages for implants must be intact upon receipt.

Paragon 28® APEX 3D™ Total Ankle Replacement System Laser Alignment Guide is provided sterile using EO sterilization methods. Do not re-sterilize. SINGLE USE ONLY. The risk of re-use of device includes potential for patient to develop infection. Do not use instruments after expiration date. Packages should be intact upon receipt. Instruments should be opened using aseptic technique. At the conclusion of the surgery, dispose of the Laser Alignment Guide as general electrical waste in accordance with local regulations. Take care to securely cover the laser aperture prior to disposal.

Implants and instruments 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 OR INSTRUMENT. Contact the manufacturer for further instructions. The implants and instruments should be opened using aseptic technique. The implant or instrument 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 APEX 3D™ Total Ankle Replacement System Instruments*** (P10-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 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® APEX 3D™ Total Ankle Replacement System. Refer to the APEX 3D™ Total Ankle Replacement System Surgical Technique P10-STG-2001 for complete instructions for use. The APEX 3D™ Recut Guide Surgical Technique P10-STG-2004 includes supplemental information, as necessary. The APEX 3D™ Decoupled Guide Surgical Technique P10-STG-2005 includes supplemental information, as necessary. The APEX 3D™ Dorsal Recut Guide Surgical Technique P10-STG-2007 includes supplemental information, as necessary. The APEX 3D™ Anterior and Poster Offset Poly Trials Surgical Technique P10-STG-2010 includes supplemental information, as necessary. Refer to the Laser Alignment Guide Surgical Technique P10-STG-2003. 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 APEX 3D™ Total Ankle Replacement System Surgical Technique (P10-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.

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