Paragon 28 Bone 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 Paragon 28 Bone 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.

GENERAL DESCRIPTION

The Paragon 28® Bone Wedge System is a series of titanium wedge-shaped devices intended for angular correction of small bones in the foot and ankle. They are offered in a variety of shapes and sizes to correct skeletal deformities in the foot.

Instrumentation is provided to assist in the surgical implantation of the wedges. It is important that the instruments and trial implants used are those specifically designed for this device to ensure accurate installation.

SYSTEM COMPONENTS

- Wedges - Implantable Ti-6Al-4V ELI
- Wedge and Trial Inserters -Ti-6Al-4V ELI
- Wedge Trials - Surgical grade stainless steel (17-4
- SS)
- Handle -17-4SS and silicone

INDICATIONS FOR USE

The Paragon 28 Bone Wedges are intended to be used for internal bone fixation for bone fractures or osteotomies in the ankle and foot, such as:

- Cotton (opening wedge) osteotomies of the medial cuneiform
- Evans lengthening osteotomies

The Paragon 28 Bone Wedges are intended for use with ancillary plating fixation. The Paragon 28 Bone Wedges are not intended for use in the spine.

CONTRAINDICATIONS

- Pathological conditions of bone, such as cystic changes or severe osteopenia, osteoporosis, bony deficiencies, or comminuted bone surface
- Physical conditions that would eliminate, or tend to eliminate, adequate implant support or retard healing, including inadequate soft tissue coverage
- Conditions which tend to limit the patient's ability or willingness to restrict activities or follow directions during the healing period
- Sensitivity or allergy to the metal implant. Where material sensitivity is suspected, appropriate tests should be made and sensitivity ruled out prior to implantation
- Blood supply limitations and previous infections that may retard healing
- Presence of an active infection
- Pediatric patients with open epiphyseal plates
- Irreparable tendon system
- Possibility for more conservative treatment
- Malignant primary or metastatic tumors which preclude adequate bone support of screw fixations, unless additional supplemental fixation or stabilization methods are utilized

POTENTIAL ADVERSE EFFECTS

- Infection, deep and superficial
- Fracture of the implant
- Loosening or migration of the implant
- Nerve damage due to surgical trauma
- Inadequate healing
- Pain, soft tissue discomfort or abnormal sensation due to the presence of the device
- Deep and superficial infections
- Allergies or other reactions to implant materials
- Loss of anatomic position with non-union or malunion with rotation or angulation
- Bone resorption or over-production
- Untoward histological responses possibly involving macrophages and/or fibroblasts
- Migration of particle wear debris possibly resulting in a bodily response
- Embolism

PRECAUTIONS

- It is mandatory that the user, surgeon and surgery personnel are acquainted with the respective-surgical technique and implants used.
- Surgical instruments and implants may only be used for surgeries, for which the designated application of the instrument and implant is explicitly necessary and defined.
- The trained expert staff is obligated to examine the surgical implant and its sterile packaging for damages prior to each application i.e. use. In case of the implant or its packaging being damaged or deformed, it is not to be used.
- Only and exclusively Paragon 28 specially manufactured instruments and implants (contained in the respective set) are to be used. If using other instruments and implants, function, warranty and liability are omitted.
- Correct selection of the implant is extremely important. That patient's anatomy and indication will determine the size of the Paragon 28 Bone Wedge to be used.
- No partial weight-bearing or non-weight bearing device can be expected to withstand the unsupported stresses of full weight-bearing. Until firm bone union is achieved, the patient should employ adequate external support and restrict physical activities which would place stress upon the implant or allow movement of the fracture site and delay healing.
- Postoperative care is extremely important. The patient must be warned that noncompliance with postoperative instructions could lead to breakage of the implant or fracture or non-union. The risk of device failure may increase due to patient-related factors including activity level, weight, or noncompliance due to psychological condition.

WARNINGS

- This product may only be used with instruments from the respective Paragon 28 Bone Wedge System.
- Application and use of other instruments or implants is not permitted (with exception to the ancillary plate and screw system).
- Cutting edges, blades, tips etc. can be very sensitive to false handling. Thus, these instruments must be handled with care.
- Do not resterilize the Paragon 28 Bone Wedge. Resterilization could lead to mishandling and surface damage that could result in implant fracture and/or particulate debris.
- Please note that a single use device (SUD) which comes into contact with human blood or tissue should not be re-used and should be returned to the manufacturer or properly disposed.
- All implants are single use devices.
- Do not reuse the Paragon 28 Bone Wedge. Reuse of this product may result in infection or other systemic complications that may affect the patient's overall health.

Additionally, the reuse of this product could adversely affect function of the device. Any implant that has been damaged, mishandled, or removed from the sterile field may have surface damage that could result in implant fracture and/or particulate and should be discarded.

- Plates and screws chosen to secure the fracture or osteotomy that could contact the implanted wedge should be manufactured from titanium to reduce the likelihood of galvanic corrosion.
- It is important that immobilization of the fracture or osteotomy site be maintained until healing is achieved.

MR SAFETY INFORMATION

The Paragon 28 Bone Wedge 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 Paragon 28 Bone Wedge System in the MR environment is unknown. MR scanning of a patient who has this device may result in patient injury.

DIRECTIONS FOR USE

This outlines the basic procedure for device implantation and the use of the specialized surgical instrumentation. It is the responsibility of the surgeon to be familiar with the procedure before use of the products. Each surgeon must evaluate the appropriateness of the surgical technique used based on personal medical training and experience. As the manufacture of this device, Paragon 28 does not practice medicine and does not recommend this or any other surgical technique for use on a specific patient.

Evans Wedge

1. Prepare the insertion site using standard surgical techniques. A 2-3cm longitudinal incision lateral to the anterior process of the calcaneus is performed. A blunt dissection is carried down to the level of the peroneal tendons, which should be retracted plantarly. Once the incision is carried to the periosteum of the anterior calcaneal process, the calcaneal cuboid joint is then identified.
2. An osteotomy is performed approximately 1-1.5cm proximal to the joint. A distractor may be utilized.
3. Trials are inserted after connecting to the inserter handle. 9 sizes are available and should be used until the desired amount of correction is achieved. It is recommended to confirm the correction using fluoroscopy.
4. The corresponding implant is selected and should be connected to the inserter after the selected trial is removed. Place the wedge into the osteotomy and impact carefully until fully seated. If the use of an autograft or allograft is desired, the material should be placed into the center hole prior to implantation.
5. A plate should be used over the wedge as recommended. The incision should be closed.

Cotton Wedge

1. Following the surgical approach and standard osteotomy for the cotton procedure, follow steps 3-5 above.

HOW SUPPLIED

Wedges are packaged sterile using EO sterilization. If either the implant or the package appears damaged, is beyond the sterility expiration date, or if sterility is questioned for any reason, the implant should not be used.

Instruments and ancillary screws are non-sterile. To clean, disinfect and sterilize, follow the instructions below. Only sterile implants and instruments should be used in surgery. Immediately re-sterilize all instruments removed from the sterile field before handling. To reprocess the instruments, make sure all instruments are cleaned, inspected and sterilized between uses. Always immediately clean and decontaminate all devices used in surgery. Reusable instruments can be reused if not damaged or worn and should be inspected before each use.

RECOMMENDATIONS FOR CLEANING, DISINFECTION AND STERILIZATION OF INSTRUMENTATIONS

These instructions are recommended for the care, cleaning, maintenance and sterilization of reusable Paragon 28 manual surgical instruments. Sterilization instructions are also intended for implants and instruments provided nonsterile. They are intended to assist health care personnel in safe handling practices, effective reprocessing and maintenance of devices. The instructions are intended to assist the hospital and central supply management in developing procedures for safe and effective reprocessing of medical instruments. Hospital personnel, including those in receiving and central sterile supply departments (CSSD), as well as in the operating room (OR), may be directly involved in handling devices. Hospital directors and other management in each of these departments should be informed of these instructions and recommendations to ensure safe and effective reprocessing and to prevent damage or misuse of reusable instruments.

Double wrap instruments in accordance with local procedures, using standard techniques such as those described in ANSI/AAMI ST46-1993. Be sure to sterilize in FDA approved sterilization wraps or pouches.

This information is NOT APPLICABLE to implants or instruments that are sold sterile and cannot be re-sterilized, such as the Paragon 28 Bone Wedge.

1. Description and Intended Use

Paragon 28 reusable surgical instruments are intended for use in orthopaedic surgical procedures according to the Instructions for Use and Surgical techniques that accompany the implants. Reusable instruments are to be cleaned, inspected, and sterilized between uses.

2. Inspection Before Use

Reusable instruments can be used indefinitely if not damaged or worn. Device systems should be cleaned and then inspected between uses. DO NOT use broken or damaged devices. Contact Paragon 28 for repair or replacement of damaged items. If damage or malfunction is detected, the device should not be used.

Disposable instruments should be disposed of according to hospital procedure and any applicable laws.

3. Preparation/General Guidance for Cleaning

Cleaning protocol of Paragon 28 Wedge System has been validated to AAMI TIR12, AAMI TIR30 and FDA guidance documents. Verify that all instruments required for use are present in the case. For Manual Cleaning, instruments should be grouped according to similar metals before subsequent processing in order to prevent galvanic corrosion. In addition, it is not recommended to use chloride containing cleaning solutions since its use has been linked to corrosion of metallic instruments, especially stainless steel.

Please also note the following:

- Disinfect and clean instruments immediately after use in order to avoid device encrustations.
- Solutions used for cleaning must always be prepared in accordance with the manufacturer's instructions.
- Never use metal brushes or metal sponges for manual cleaning.
- Use a suitably sized non-metallic bristle brush for cleaning lumens, cannulations, blind holes, and cavities, making sure that every part of the inner surface can be properly accessed.
- Clean jointed instruments in closed as well as open positions.
- Disassemble instruments as far as possible before cleaning.
- Be sure to arrange the items so that the water can easily flow out of cannulations, blind holes, and cavities.

- For instruments with long or narrow lumens, standard processing should be used only if the disinfectant can flow easily through the lumens and safe rinsing is guaranteed.
- The cases/trays used for cleaning must always be loaded correctly to ensure proper cleaning.
- After cleaning, check instruments for cleanliness (visible dirt).
- This especially applies to cannulated instruments or those with blind holes and crevices.
- To ensure proper instrument functioning, verify that all movable parts have been thoroughly cleaned.
- Pay special attention to slots, ratchets, joints and box locks, narrow lumens, blind holes, and other areas that are hard to access.
- Demineralized or distilled water should be used for the final rinse.

4. Manual Cleaning Instructions

The following steps should be completed in sequence. Depending upon the detergent selection, minimum processing times and temperature settings may need to be adjusted for optimal processing:

a) Prepare a neutral pH enzymatic detergent as per the manufacturer's recommendation (e.g. Enzol® prepared at 1 oz. per gallon of lukewarm deionized water complying with AAMI TIR 34).
b) Disassemble instruments to lowest level.
c) Rinse instruments under lukewarm running water to remove all gross soil. Use a soft bristled brush to aid in the brushing. Agitate the instruments under the running water. Agitation includes actuating all movable parts such as opening and closing hinges and moving the instruments around under the running water. Use a clean soft bristled brush and/or pipe cleaner to brush and aid in the rinse for the exterior and interior of instruments. Use a syringe to flush any lumens.
d) Fully immerse each device in the prepared detergent and allow it to soak for a minimum of two minutes.
e) After soaking the instruments, scrub them using a soft bristle brush and circular strokes to remove any visible soil. Pay particular attention to all the areas where the soil could be imbedded (i.e. grooves, crevices, lumens, blind holes). Use a syringe to flush lumens and a pipe cleaner to clean lumens and holes. Perform cleaning under the surface of the prepared detergent solution to limit aerosolization of the cleaning fluid and soil, as well as for worker and environmental safety.
f) Rinse instruments in lukewarm water for a minimum of one and a half (1.5) minutes to remove any detergent residuals. In accordance with Step C, agitate the instruments under the running water, being sure to actuate all movable parts, and using a sot bristled brush for internal and exterior device surfaces.
g) Prepare a neutral pH enzymatic detergent (eg. Enzol) in a sonicator, as per the manufacturer's recommendation using lukewarm water. Temperature should be 68-104°F. Fully immerse the instruments in the detergent and soak for 20 minutes. Repeat as required and clean thoroughly. Scrub all external surfaces with a soft bristle brush until all visible soil has been removed. It is important to make sure that the ridges are effectively cleaned. Use a small diameter brush, a syringe, or a pipe cleaner to clean cannulation holes. Inspect for visible soil on exposed surfaces.
h) After sonication, rinse the instruments with running lukewarm water (use the highest grade of water available, distilled or deionized water is recommended) for three (3) minutes. Agitate the instruments under the running water, being sure to actuate all movable parts, and using a clean soft bristled brush for internal and exterior device surfaces, and flush all lumens with a syringe.
i) Place units in an ultrasonic cleaner (neutral pH) neutral making sure instruments are fully submerged for 10 minutes (68-104°F).
j) Rinse thoroughly for 3 minutes in warm, as delivered, hot water tap.
k) Dry the instruments using a clean lint free cloth and visually examine to determine if all adherent visible soil has been removed. Allow to air dry in clean area. Blow lumens with clean air using filtered air source or syringe.
l) Repeat the above cleaning procedure, if visible debris is detected.

5. Inspection After Cleaning

Following cleaning, the instruments must be macroscopically clean, i.e. free from visible dirt or deposits. All movable parts, working tips and blades (scissors) should be inspected with particular care.

Packaging:

- Replace instruments in an instrument tray to contain the instruments.
- If biological or chemical indicators (BIs or CIs) are used for monitoring the performance of sterilization processes, they should be placed in the middle racks within wrapped trays.
- Double wrap instruments in accordance with local procedures, using standard techniques such as those described in ANSI/AAMI ST46-1993. Be sure to sterilize in FDA approved sterilization wraps or pouches.
- Label the contents of the wrapped tray using indelible marker or other sterilization compatible label system.

6. Sterilization

Non-sterile instruments and implants should be sterilized in accordance with these instructions.

The validation protocols were performed in accordance with AAMI ST79:2006 Steam Sterilization and Sterility Assurance in Health Care and AAMI ST77-2006 Containment Devices for Reusable Medical Device Sterilization. **Be sure to sterilize in FDA approved sterilization wraps or pouches.**

In accordance with our validation results, the following cycles are recommended for wrapped goods:

- Use a validated, properly maintained and calibrated steam sterilizer following the manufactures recommendations to ensure that the maximum load is not exceeded.
- Effective steam sterilization can be achieved using the following cycles:
  - Dynamic Air Removal
  - Exposure Temperature-132°C (270°F)
  - Exposure Time-4 minutes
  - Minimal drying time-30 minutes
  - Minimal cooling time-30 minutes
- Store sterile packaged implants and instruments in a manner that provides protection from dust, moisture, insects, vermin, and extremes of temperature and humidity.

***Dry time data for the shared cells is based upon the highlighted sterilization challenge set for the device set family grouping (#3).**

STORAGE AND HANDLING

Store in a cool, dry place and in a manner that protects the integrity of the packaging of all implants and instruments.

PACKAGING AND LABELING

- Paragon 28 devices should be accepted only if the factory packaging and labeling arrive intact.
- Contact customer service if the package has been opened or altered.

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