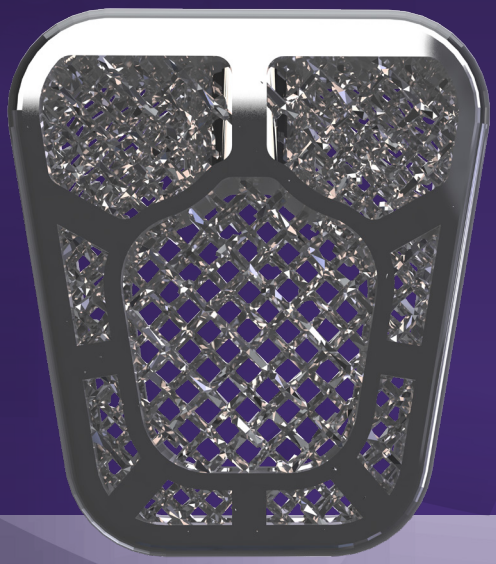
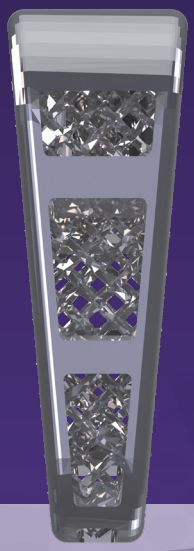
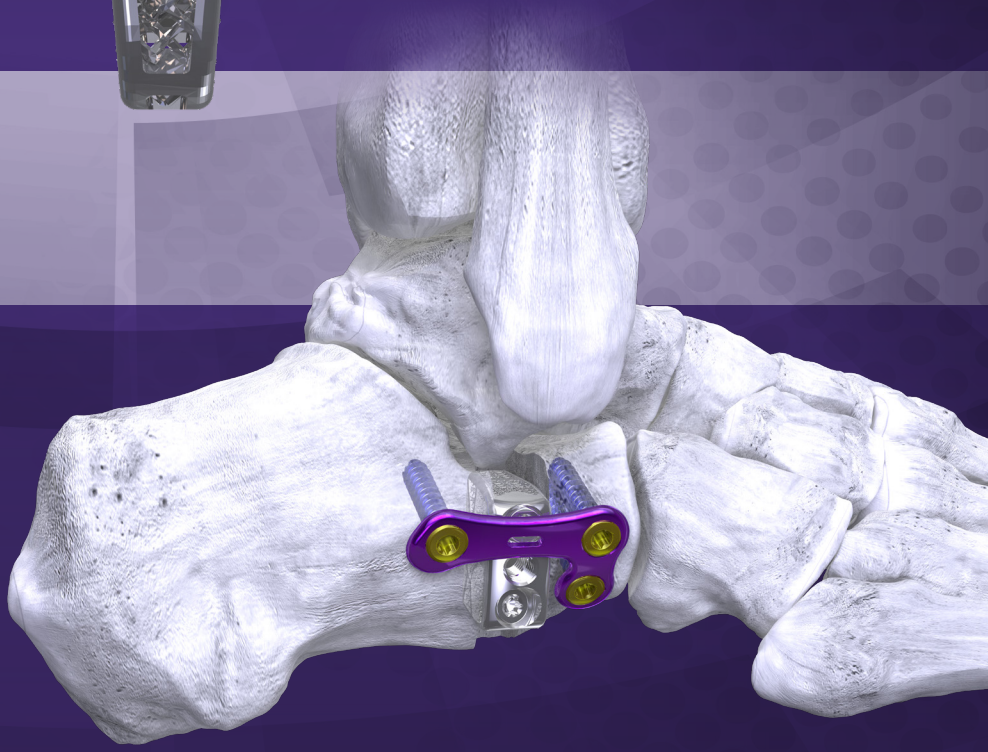
SURGICAL TECHNIQUE GUIDE

Evans and Cotton Bone Wedges





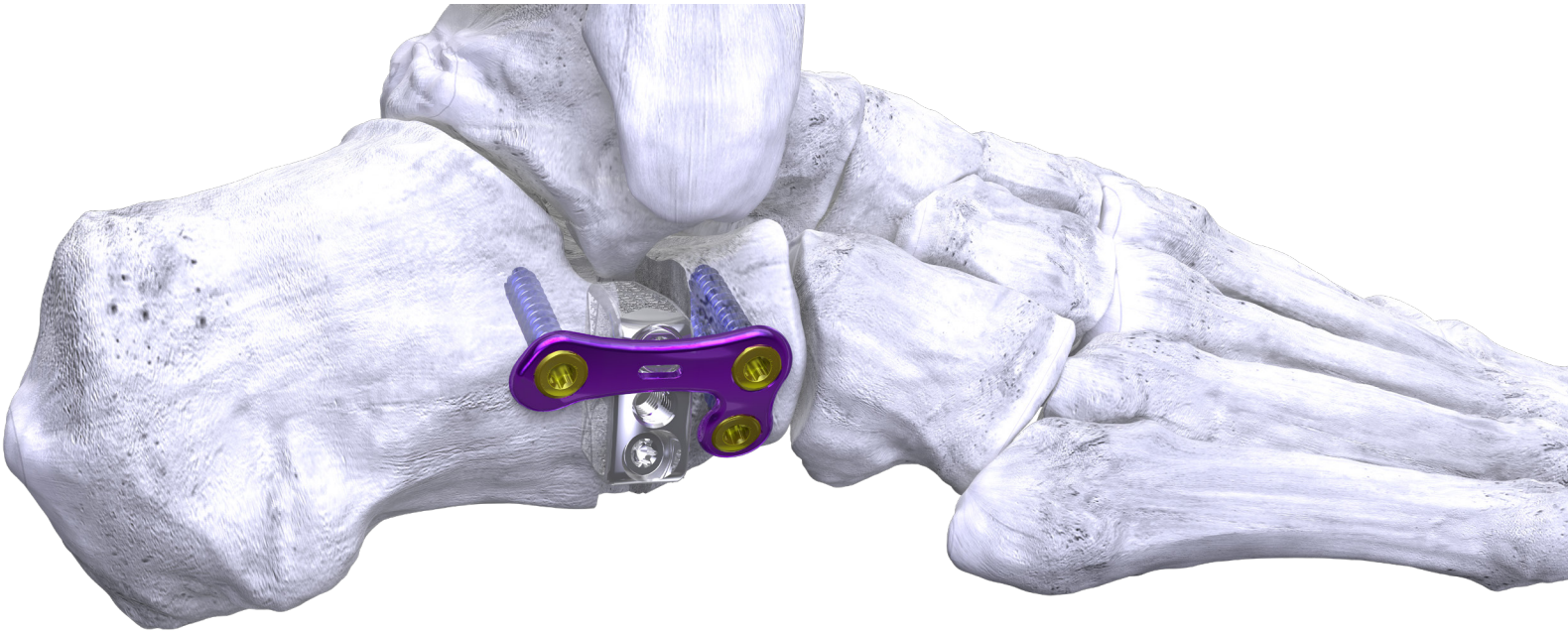


Exclusively foot & ankle

Paragon 28®

PROCEDURAL STEPS

The following procedural steps provide a recommended procedure for using the Paragon 28® Bone Wedge System. The content provided puts forth technique guidance, however, the surgeon must consider the individual needs of the patient making the appropriate adjustments when and as required.



SKIN INCISION / EXPOSURE

1. Prepare the insertion site using standard surgical techniques. A 2-3 cm longitudinal incision lateral to the anterior process of the calcaneus is performed. 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.

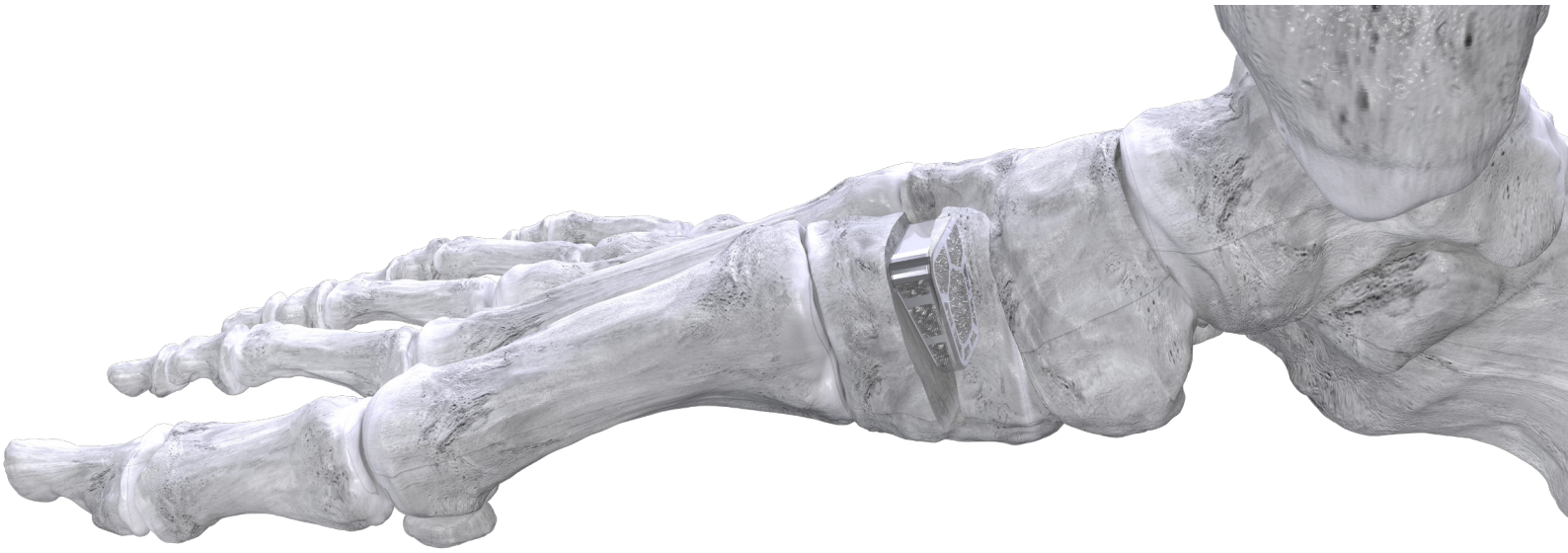
2. An osteotomy is performed approximately 1-1.5 cm proximal to the joint utilizing an oscillating saw, and finalizing the cut with an osteotome. A distractor may be used to provide controlled distraction and access to the osteotomy site.

WEDGE SELECTION

3. Connect the Paragon 28® Evans Wedge trials to the inserter handle and insert into the osteotomy site. Nine (9) trial 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. Remove the trial. Select the corresponding size implant (AOEW-XX-XX). Connect the inserter to the inserter handle, making sure it is secure. Screw the inserter into the hole on the wedge. Insert the wedge into the osteotomy and impact carefully until fully seated. Confirm the correction using fluoroscopy. If the use of an autograft or allograft is desired, the material should be packed throughout the LatTi-Structure® by gently pressing it into the surfaces of the lattice structure prior to implantation.

5. An ancillary plate is required with use of the Paragon 28® wedge system. Follow the manufacturer's instructions for plate/screw fixation. Confirm final images under fluoroscopy.



SKIN INCISION / EXPOSURE

1. Prepare the insertion site using standard surgical techniques. Make a dorsal incision over the medial cuneiform. Retract the extensor hallucis longus, and dissect soft tissues down to the surface of the medial cuneiform.

2. A transverse osteotomy is performed on the dorsal surface of the medial cuneiform. An osteotome may be utilized to lever open the osteotomy.

WEDGE SELECTION

3. Connect the Paragon 28® Cotton Wedge trials to the inserter handle and insert into the osteotomy site. Nine (9) trial 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. Remove the trial. Select the corresponding size implant (AOCW-XX-XX). Connect the inserter to the inserter handle, making sure it is secure. Screw the inserter into the hole on the wedge. Insert the wedge into the osteotomy and impact carefully until fully seated. Confirm the correction using fluoroscopy. If the use of an autograft or allograft is desired, the material should be packed throughout the LatTi-Structure® by gently pressing it into the surfaces of the lattice structure prior to implantation.

5. An ancillary plate is required with use of the Paragon 28® wedge system. Follow the manufacturer's instructions for plate/screw fixation. Confirm final images under fluoroscopy .

EXPLANT INFORMATION

Evans and Cotton Bone Wedge System

Remove the ancillary plate using the same plate-specific instrumentation used to implant the plate following the manufacturer's instructions. Pull the wedge from its position using forceps or preferred choice of general instruments. If needed, a saw and a small blade may be used to cut along the surface of the wedge to bone interface to free the wedge from the bone.

Refer to www.paragon28.com/ifus for the complete and most current instructions for use document.

INSTRUCTIONS FOR USE:

DESCRIPTION:

The Paragon 28, Inc. 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 resportion 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. The 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).

Refer to www.paragon28.com/ifus for the complete and most current instructions for use document.

- 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 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 Paragon 28 Bone Wedge in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

NOTES

NOTES

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www.Paragon28.com

DISCLAIMER

The purpose of the Paragon 28® Bone Wedge System Surgical Technique Guide is to demonstrate the use of the Paragon 28® Bone Wedge System. Although various methods can be employed for this procedure, the fixation options demonstrated were chosen for simplicity of explanation and demonstration of the unique features of our device. CATUION: Federal law (U.S.A.) restricts this device to sale and use by, or on order of, a physician.