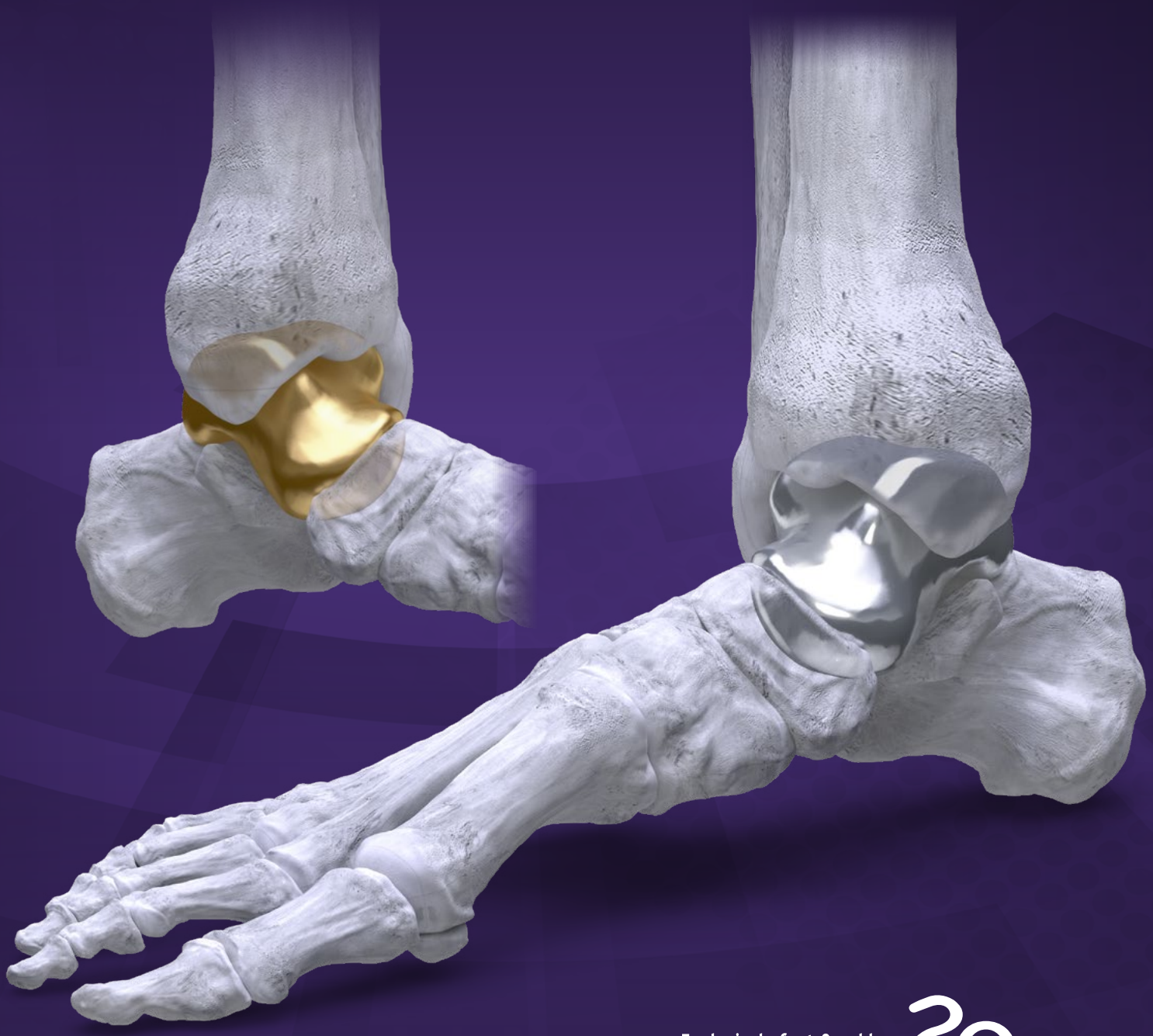
SURGICAL TECHNIQUE GUIDE

Patient Specific Talus Spacer



Exclusively foot & ankle

Paragon 28®

PARAGON 28®, INC
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Caution: Federal law (USA) restricts this device to sale by or on the order of a physician.

Humanitarian Device. Authorized by Federal law for use in the treatment of avascular necrosis of the ankle joint in adult patients. The effectiveness of this device for this use has not been demonstrated.

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

DESCRIPTION

The Paragon 28® Patient Specific Talus Spacer has two material options: a cobalt chromium metal alloy and a titanium alloy with a titanium nitride coating. The Patient Specific Talus Spacer in cobalt chromium is an additively manufactured implant made from cobalt chromium metal alloy and produced by laser sintering. The Patient Specific Talus Spacer in titanium alloy is an additively manufactured implant made from titanium alloy with a titanium nitride coating and produced by electron beam melting. The surgeon selects which material is best suited for his/her patient. The device allows the patient to regain motion and reduce pain without an amputation or fusion for the treatment of the current condition.

SYSTEM COMPONENTS

Patient Specific Talus Spacer Cobalt Chrome Cobalt-28 Chromium-6 Molybdenum (meeting the requirement of ASTM F75) in 3 sizes: small, nominal, and large. Patient Specific Talus Spacer Titanium-6 Aluminum-4 Vanadium ELI (Extra Low Interstitial) (ASTM F3001) with TiN coating in 3 sizes: small, nominal, and large.

INDICATIONS FOR USE

The Paragon 28® Patient Specific Talus Spacer is indicated for avascular necrosis of the ankle joint. The anatomical landmarks necessary for the design and creation of the Paragon 28® Patient Specific Talus Spacer must be present and identifiable on computed tomography scan.

CONTRAINDICATIONS

- Use of implant greater than 6 months from date of patient's computed tomography (CT) scan.
- Degenerative changes in the tibiotalar, subtalar or talonavicular joints.
- Presence of an active infection.
- Gross deformity in sagittal or coronal planes. More than 15 degrees of varus or valgus deformity in the coronal plane, or more than 50% subluxation anteriorly or posteriorly of the talus in the sagittal plane.
- Osteonecrosis of the calcaneus, distal tibia or navicular.
- Known history of existing malignancy, or any systemic infection, local infection, or skin compromise at the surgical site.
- Blood supply limitations and previous infections that may prevent healing.
- Physical conditions that would eliminate adequate implant support or prevent healing, including inadequate soft tissue coverage.
- Conditions which may limit the patient's ability or willingness to restrict activities or follow directions post-operatively during the healing period.
- Presence of neurological deficit which would prevent patient post-operative compliance.
- Sensitivity or allergy to the metal implant. Where material sensitivity is suspected, appropriate tests should be made, and sensitivity ruled out prior to implantation.

POTENTIAL COMPLICATIONS AND ADVERSE REACTIONS

- Infection, deep and superficial
- 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 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

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PRECAUTIONS

- Surgical implants may only be used for surgeries, for which the designated application of the implant is explicitly necessary and defined.
- Correct selection of the implant is extremely important. That patient's anatomy and indication will determine the size of the implant to be used.
- No partial weight-bearing or non-weight bearing device can be expected to withstand the unsupported stresses of full weight-bearing. Following surgery, the patient should employ adequate external support and restrict physical activities which would place stress upon the implant or allow movement of the implant and delay healing.
- Postoperative care is extremely important. The patient must be advised that noncompliance with postoperative instructions could lead to breakage of the implant or surrounding bones in the ankle joint. The risk of device failure may increase due to patient-related factors including activity level, weight, or noncompliance due to psychological condition.
- Patient Specific Talus Spacers are designed from patient data such as radiograph (Xray), CT scan, or magnetic resonance imaging (MRI). Over time, a patient's anatomy can change. If a significant amount of time has elapsed from the time of collection of the patient data (date of scan) to the time of surgery utilizing a Patient Specific Talus Spacer, the implant may not fit the patient's anatomy correctly.

WARNINGS

- Surgeon's must evaluate the patient's contralateral side in addition to the affected talus, to determine if the patient is a candidate for a Patient Specific Talus Spacer. If the surgeon believes there are deformities on the affected side or the contralateral side, then the patient may not be a suitable candidate for a Patient Specific Talus Spacer.
- It is mandatory that the user, surgeon and surgery personnel are acquainted with the respective-surgical technique and implants used.
- The trained expert staff is obligated to examine the surgical implant and its 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.
- Improper selection, placement, positioning, alignment and fixation of the implant may result in unusual stress conditions and a subsequent reduction in the service life of the prosthetic implant.
- Malalignment or inaccurate implantation can lead to excessive wear and/or failure of the implant or procedure.
- Inadequate preclosure cleaning (removal of surgical debris) can lead to excessive wear.
- Improper preoperative or intraoperative implant handling or damage (scratches, dents, etc.) can lead to crevice corrosion, fretting, fatigue fracture and/or excessive wear.
- Do not modify the Paragon 28® Patient Specific Talus Spacer.
- The surgeon is to be thoroughly familiar with the implant and surgical procedure prior to performing surgery. For further information, contact Paragon 28® and consult the Surgical Technique.
- Do not reuse the Paragon 28® Patient Specific Talus Spacer. 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.
- This is a patient specific implant, do not use in a patient other than the one listed in the product labeling and/or the physician order form.

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(meeting the requirements of ASTM F75)
in 3 sizes:
small, nominal, and large

Patient Specific Talus Spacer
Titanium-6 Aluminum-4 Vanadium ELI
(Extra Low Interstitial) (ASTM F3001) with TiN coating
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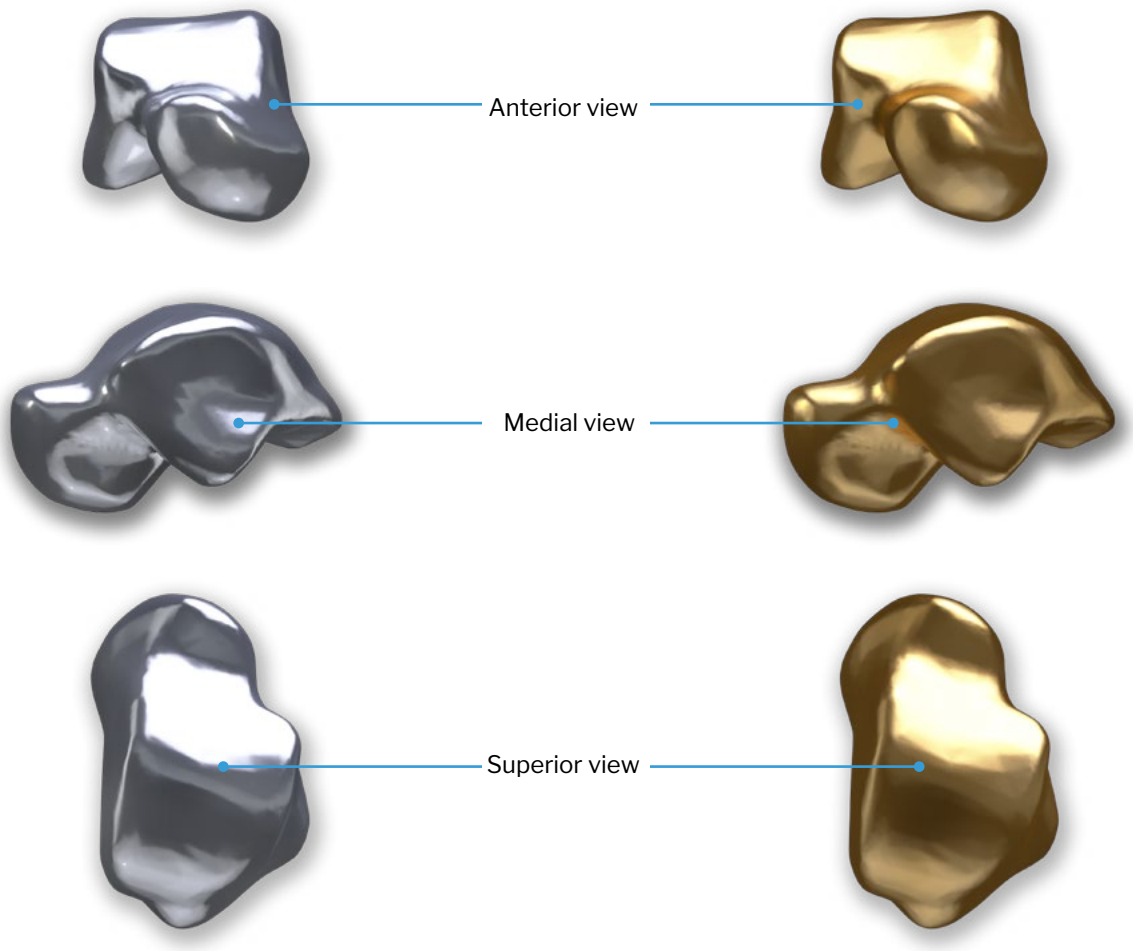

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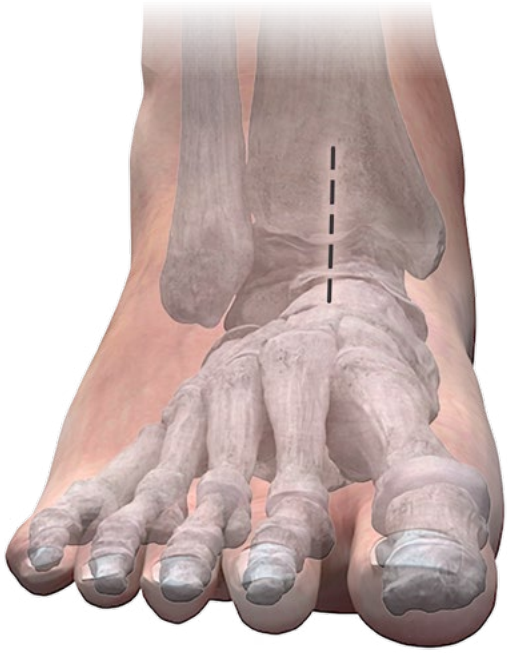
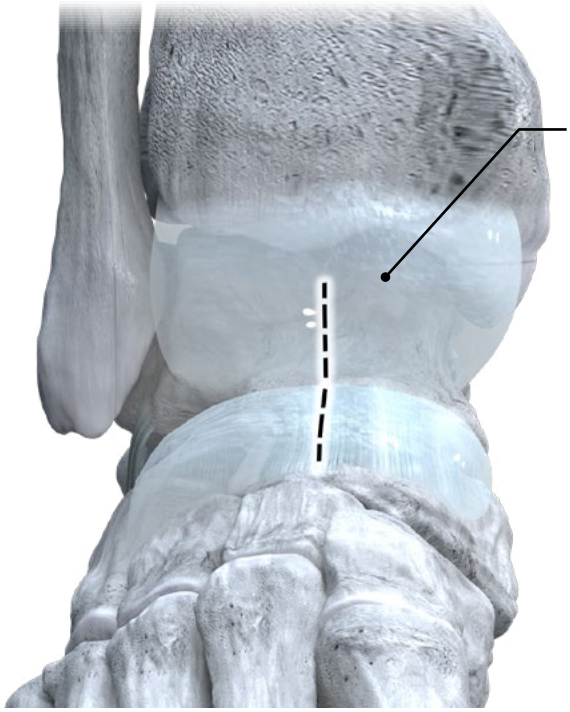
PROCEDURAL STEPS

The following procedural steps provide a recommended procedure for using the Paragon 28® Patient Specific Talus Spacer Implant. 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 straight skin incision is made over the anterior ankle, similar to the anterior approach used for a total ankle replacement, between the extensor hallucis longus (EHL) and extensor digitorum longus (EDL) interval. Mobilize the neurovascular bundle.

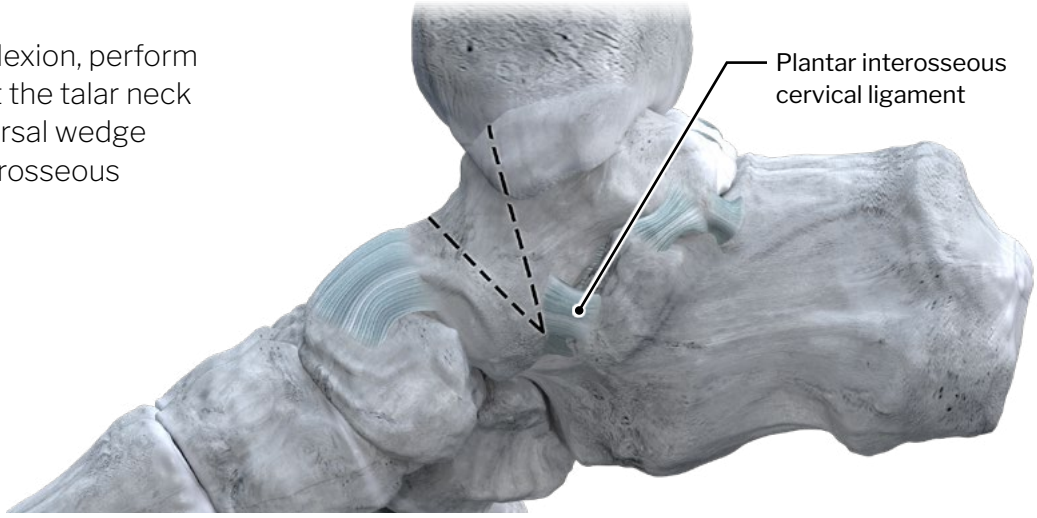




2. Open the anterior capsule of the tibiotalar joint. Subperiosteally, elevate the capsule medially and laterally. This should be performed from the tibial attachments of the capsule to the attachments on the talus. Care must be taken to not cut through the capsular tissue. Maintaining the integrity of the capsule and the ligaments is extremely important. The capsule should be elevated to the talar navicular joint. A cobb elevator can be placed into the talar navicular joint in order to facilitate the capsular release.

DORSAL CLOSING WEDGE OSTEOTOMY

3. With the ankle in maximal plantarflexion, perform a dorsal closing wedge osteotomy at the talar neck and remove the bone wedge. The dorsal wedge osteotomy will sever the plantar interosseous cervical ligament attachments.



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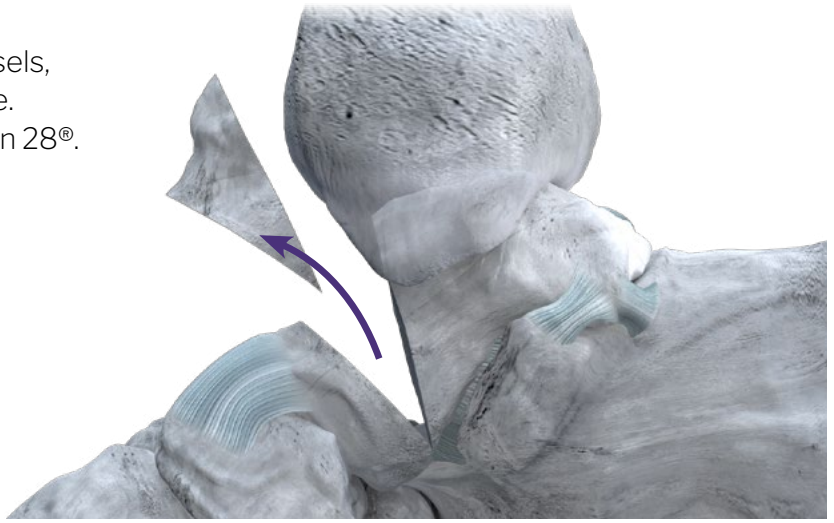
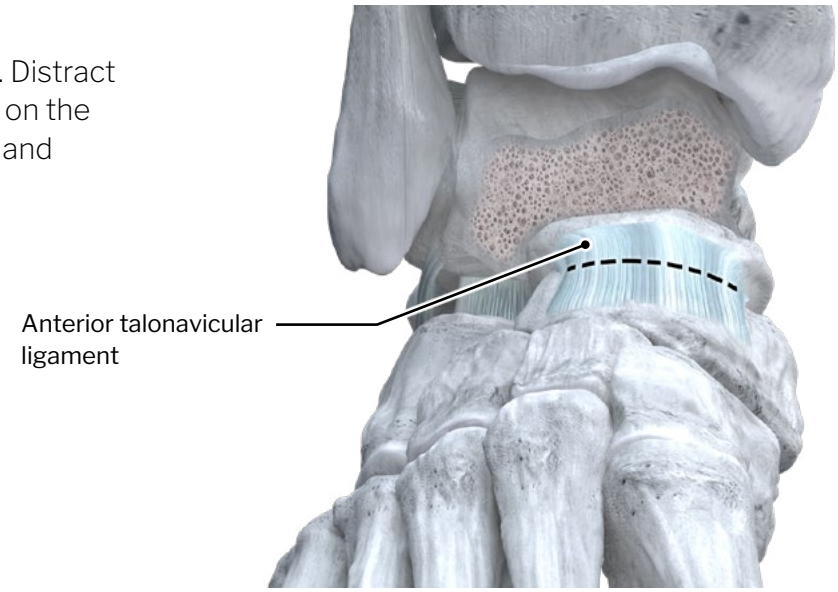
MIDDLE TALUS RESECTION

4. Use a combination of bone saws, osteotomes, chisels, tamps and/or mallet to resect the middle talar wedge.
NOTE: These instruments are not provided by Paragon 28®.



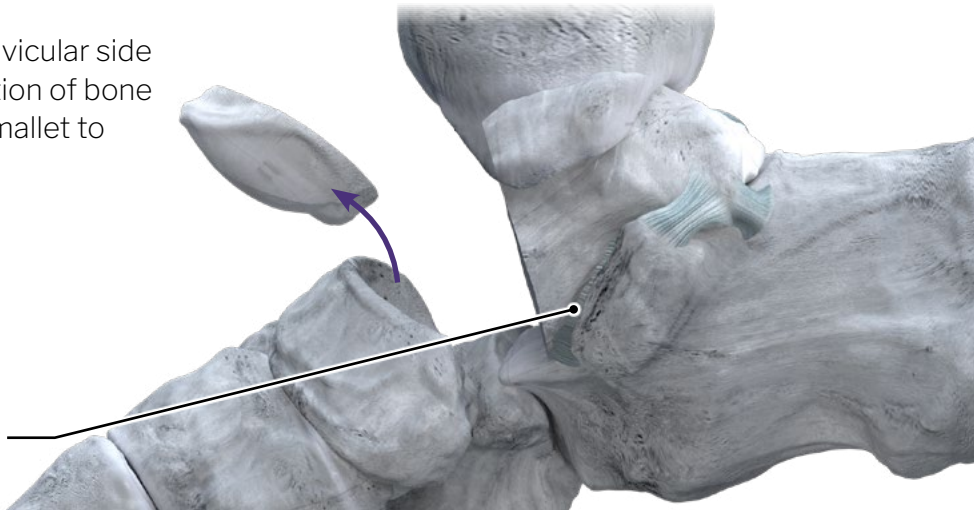
ANTEROMEDIAL TALONAVICULAR LIGAMENT RELEASE

5. Release the anterior talonavicular ligament. Distract the anterior segment posteriorly with tension on the interosseous talocalcaneal ligament. Release and remove the anterior segment.



TALAR HEAD RESECTION

6. Carefully protect the cartilage on the navicular side of the talar-navicular joint. Use a combination of bone saws, osteotomes, chisels, tamps and/or mallet to remove the talar head.



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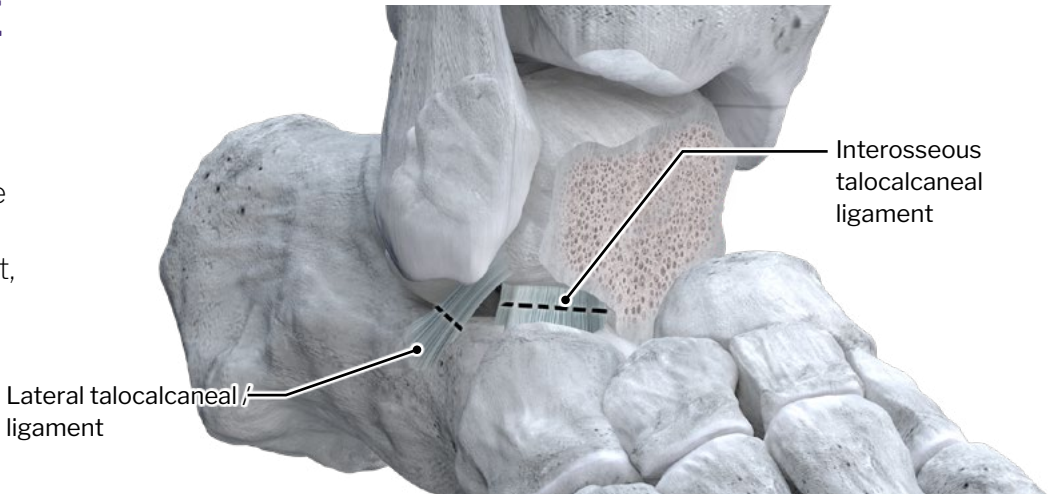
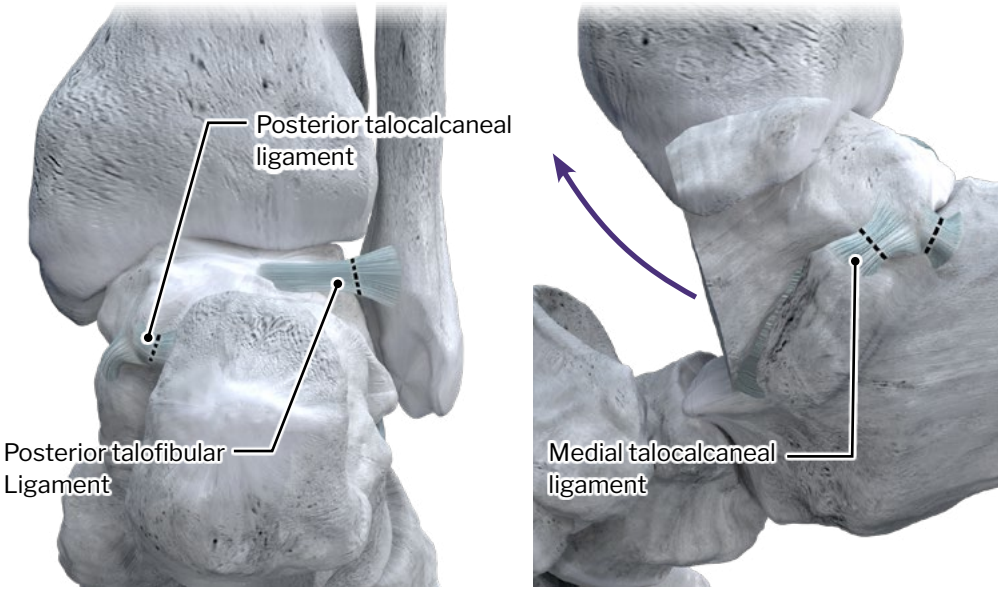
POSTERIOR INTEROSSEOUS TALOCALCANEAL LIGAMENT RELEASE

7. Release the lateral talocalcaneal ligament. Distract the posterior talar segment superiorly. Ligate the sinus tarsi artery in sulcus tarsi, and release the interosseous talocalcaneal ligament and any cervical attachment, if present.



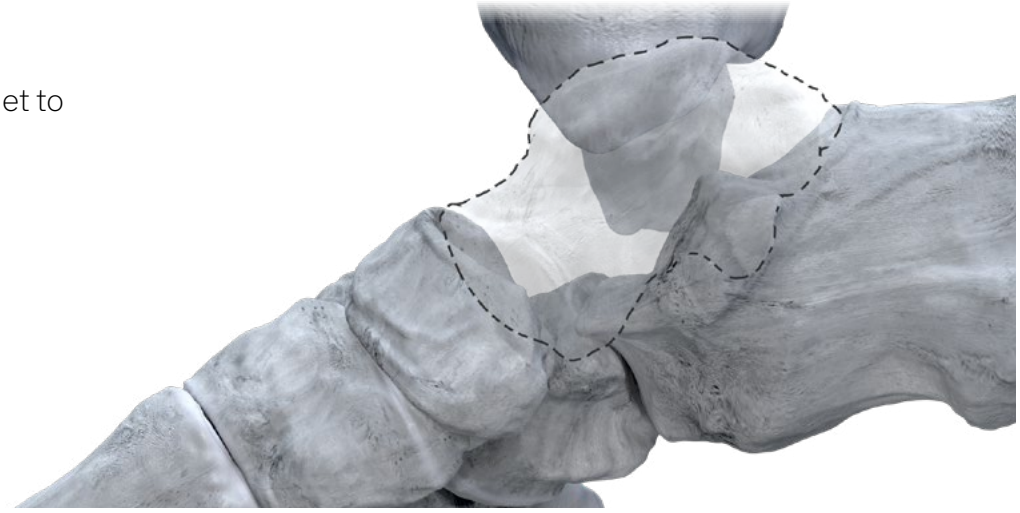
RELEASE OF LIGAMENTOUS ATTACHMENTS WITHIN THE POSTERIOR PROCESS OF THE TALUS

8. Distract posterior segment anteriorly, plantarflex the ankle and release the posterior talofibular ligament and the posterior tibiotalar segment of the deltoid ligament. The posterior segment can now be distracted superiorly and an inferior approach used to release the posterior talocalcaneal ligament and medial talocalcaneal ligament. The posterior segment can now be resected.



POSTERIOR TALAR BODY RESECTION

9. Use a combination of bone saws, osteotomes, chisels, tamps and/or mallet to resect the posterior talar segment.



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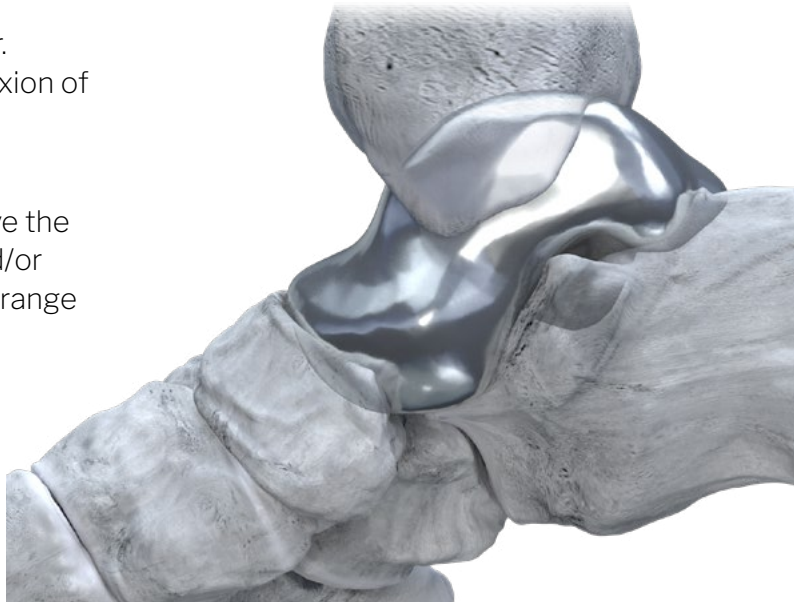
IMPLANT SIZING AND SELECTION

10. Insert the nominal size Patient Specific Talus Spacer. Assess articulations through dorsiflexion and plantarflexion of the ankle as well as inversion and eversion.

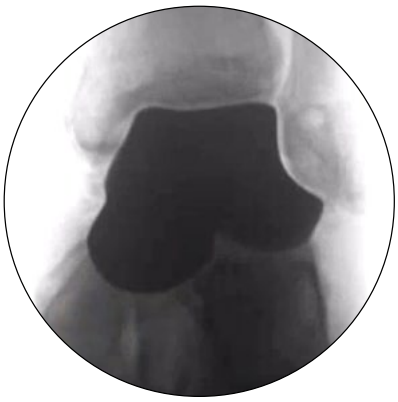
Flexibility at the midfoot should also be demonstrated through multiple planes of movement. If needed, remove the nominal size implant with forceps and trial the small and/or large implants one at a time, checking articulations and range of motion.



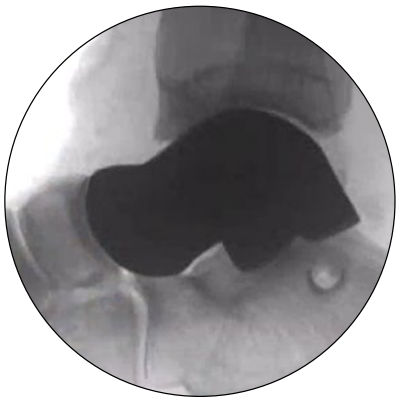
It is important to evaluate the patient's bone quality to ensure bone quality is adequate before implanting the Patient Specific Talus Spacer.

IMPLANTATION OF PATIENT SPECIFIC TALUS SPACER

11. Insert the appropriately sized Patient Specific Talus Spacer determined in step 10. It is recommended to confirm the fit of the implant using fluoroscopy.



Anterior view



Medial view

POST OPERATIVE

It is recommended that the patient remain non-weightbearing in a cast or splint for 3 weeks. The patient may then weight bear as tolerated in a CAM walker boot for the following 3 weeks. At 6 weeks post-op, the patient may return to a regular shoe and begin working with physical therapy.

NOTE: The remaining two Patient Specific Talus Spacers that are not implanted must be returned to Paragon 28® –or– destroyed by the hospital. If destroyed, a Certificate of Destruction must be provided to Paragon 28®.

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