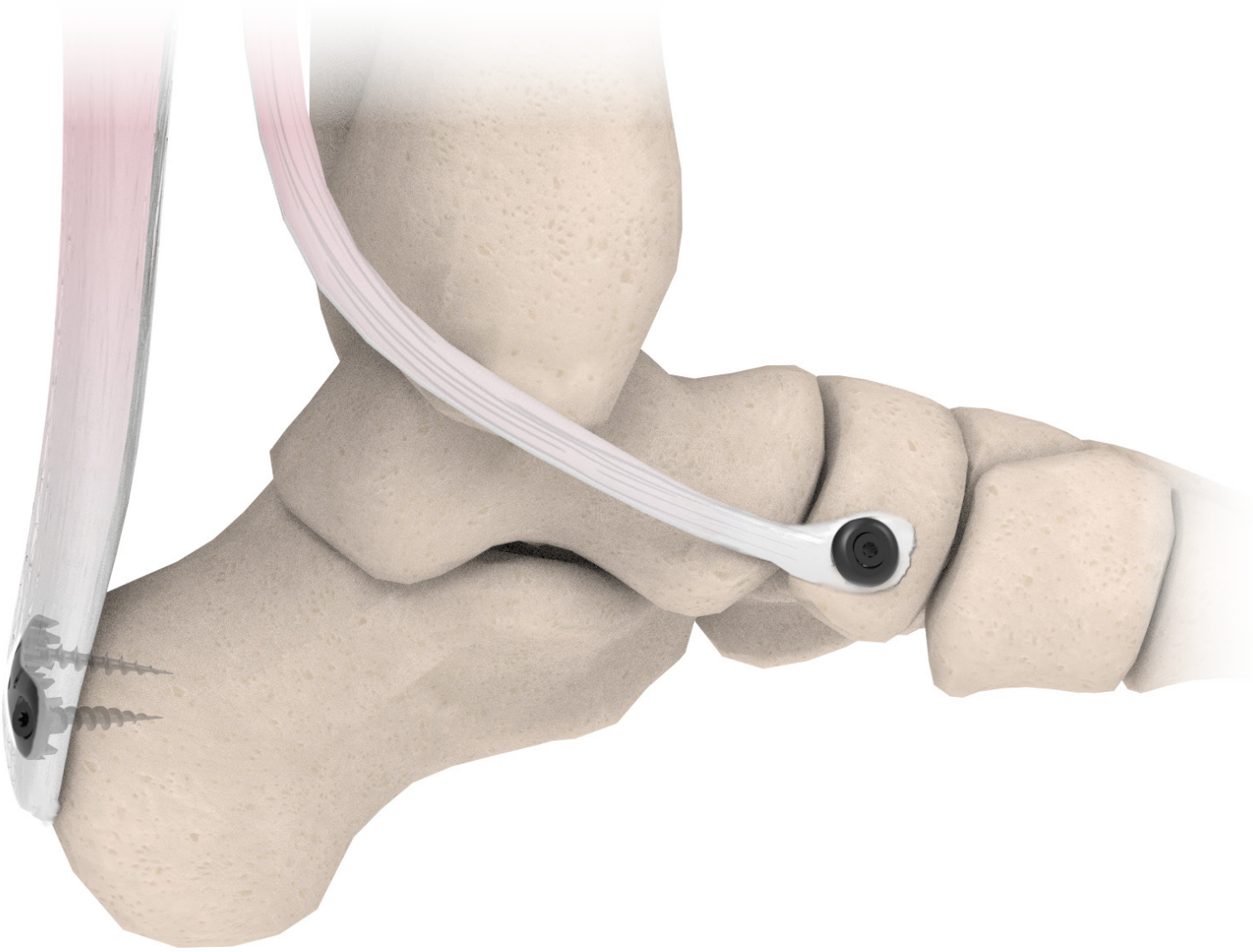
Biologically Oriented Prostheses

BIOPRO

# Tendon Anchor System

## Surgical Technique



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# Indications & Contraindications

**Indications for use:**
The BioPro Tendon Anchor System is indicated for use for soft tissue to bone fixation in the foot, ankle, knee, hip, hand, wrist, elbow, and shoulder. The BioPro TAS Plate and Screw(s) is supplied sterile and intended for single use only. The system is not intended for spinal use.

**Contra-indications:**
1. A general health problem that might pose a significant threat to the life of the patient if subjected to a major surgical procedure.
2. An active infection or a previous infection of the lower extremity that has not been quiescent for at least six months.
3. A local or systemic infection.
4. Significant deficiency in the vascular supply to the extremity.
5. Severe structural deficiency of the sub-chondral bone that may result in insufficient support for the device.
6. Severe compromise of the supporting muscles or ligaments.
7. It is not intended for use in the spine.
8. Foreign body sensitivity to metals specifically titanium. Where material sensitivity is suspected, appropriate tests should be made prior to implantation.

**Precautions and Handling**
- Inspect the sterile blisters used for the implants prior to use. Sterilization cannot be assured, and implants should not be used if blister or seal is damaged.
- Implants are single use devices.
- Do not autoclave implants.

**Potential Complications and Adverse Effects**
- Allergic reactions to metal.
- Delayed healing.
- Loosening or migration of the implant.
- Pain due to bone remodeling or reaction to implant components.
- Use of longer screws could result in irritation and violation of adjacent joint spaces resulting in pain and discomfort.

Contact surgeon if a change in performance or pain level is noticed.

**MR Safety Information**
Warning: The Tendon Anchor System has not been evaluated for safety and compatibility in the MR environment and has not been tested for heating or migration in the MR environment. The safety of the device in the MR environment is unknown. Scanning patients who have these devices may result in patient injury.

# Implant Specifications

The BioPro Tendon Anchor System (T.A.S.) is a toothed, titanium anchor designed for soft tissue reattachment to bone. The sutureless design simplifies soft tissue reattachment and allows for increased pull-out strength.[1] The extremely low profile design allows the anchor to recess into the tendon preventing implant prominence, while still allowing for easy removal if necessary.

**Material**
The Tendon Anchor System is manufactured from titanium with type II anodization.

**Variations**
The Tendon Anchor System is available as a 1-Hole 10mm anchor and 2-Hole 26mm anchor design. The system is sterile packaged with a driver, 3.0x15mm screw(s), 3.0x20mm screw(s) and either an olive k-wire or implant holding device.

The profile is only 1mm thick with 2mm blunt teeth designed to reduce implant prominence while allowing for microcirculatory blood flow crucial to the healing process.

Anchors allow for greater surface area coverage and eliminate the suture-tendon interface allowing for improved pull-out strength vs traditional suture anchors.

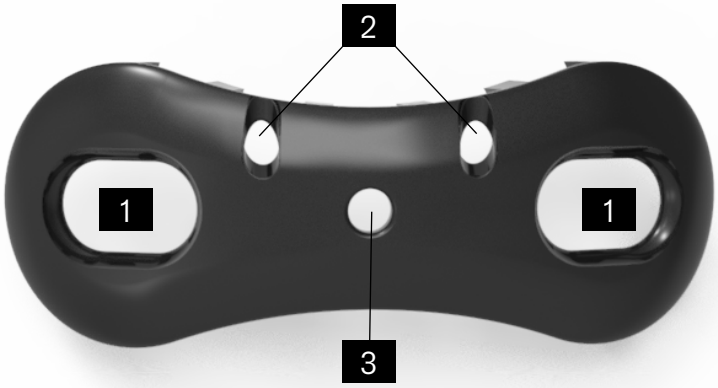
The 3.0mm self-drilling + self-tapping screws provide secure purchase into cancellous bone and don't require pre-drilling.

# Implant Specifications

The 26mm design features five holes.

1. The larger holes are recessed to accept the screw head. These holes are oval shaped to allow 1mm of freedom while maintaining a flush screw to anchor interface.
2. The top holes are optional and designed for sutures. Sutures can be used in conjunction with the implant for additional support if desired.
3. The middle hole accepts the temporary olive wire to hold the implant in place during implantation.

Fig 1



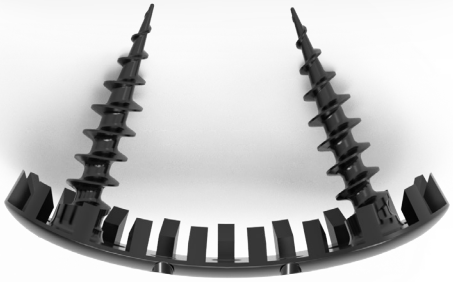



Fig 2

The 10mm design features an oval screw hole that will allow the included Ø3.0mm screws 1mm of freedom while maintaining a flush screw to anchor interface.

# Instrument Specifications

A disposable T-7 driver is included with both anchors.

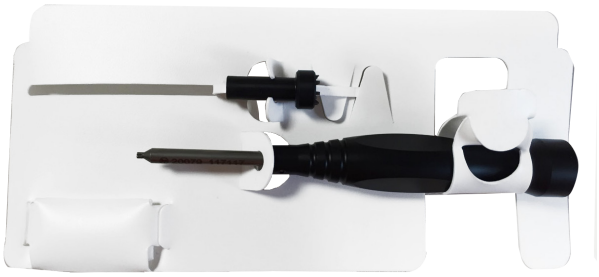
The 26mm Tendon Anchor System includes an olive wire for temporary fixation of the anchor to bone.

The 10mm Tendon Anchor System includes a cannulated holder which is preloaded with the anchor. The holder facilitates anchor placement and allows for easy screw insertion.

# Packaging Specifications

### 1-Hole 10mm Tendon Anchor System - 20070

| Qty | Description |
|---|---|
| 1 | 1-Hole 10mm Anchor |
| 1 | Insertion Holder |
| 1 | 3.0 x 15mm Screw |
| 1 | 3.0 x 20mm Screw |
| 1 | T-7 Screwdriver |

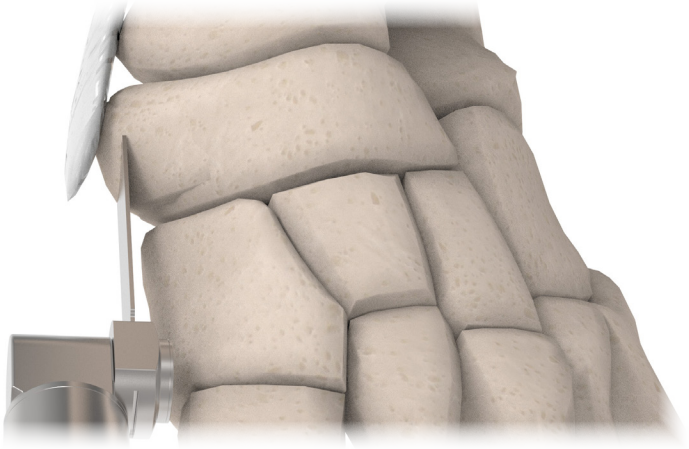


### 2-Hole 26mm Tendon Anchor System - 20159

| Qty | Description |
|---|---|
| 1 | 2-Hole 26mm Anchor |
| 1 | 0.045″ Olive K-wire |
| 2 | 3.0 x 15mm Screw |
| 2 | 3.0 x 20mm Screw |
| 1 | T-7 Screwdriver |

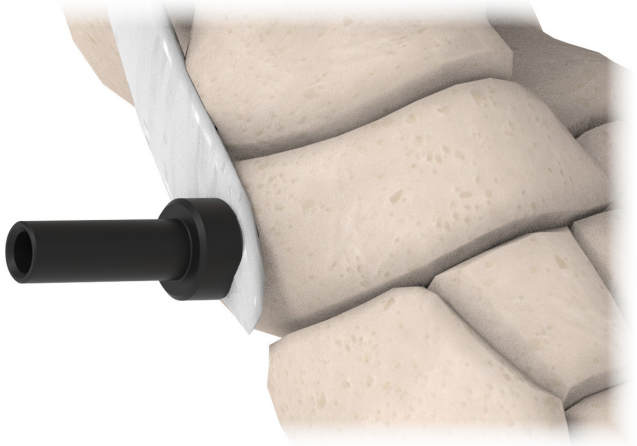
# Surgical Technique

The following steps detail a technique for the use of the 1-Hole 10mm Tendon Anchor System for reattaching the posterior tibial tendon during the Kidner procedure. This technique may be applied to any soft tissue to bone application.

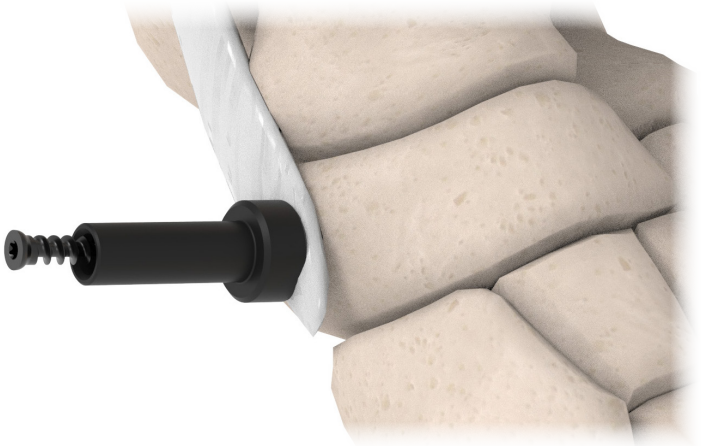


**Step One**
A linear longitudinal incision is made over the horizontal midline of the navicular. The incision is carried down to the navicular through the capsule, exposing the posterior tibial tendon.

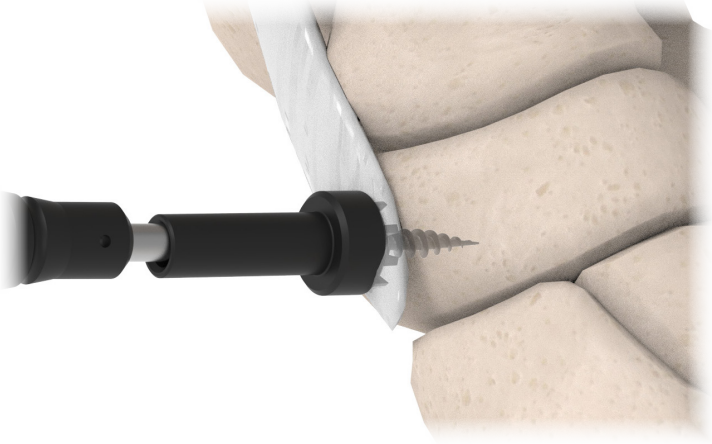
**Step Two**
The posterior tibial tendon is released and any tendinopathic tissue is removed. Sharply excise the accessory navicular (if present) with the surgeons preferred method. Free the surface of the navicular of soft tissues and rasp the area smooth.



**Step Three**
With the foot in STJ neutral or slightly inverted, position the posterior tibial tendon in the desired tension on the navicular, place the 1-Hole 10mm Tendon Anchor over the tendon applying hand pressure.

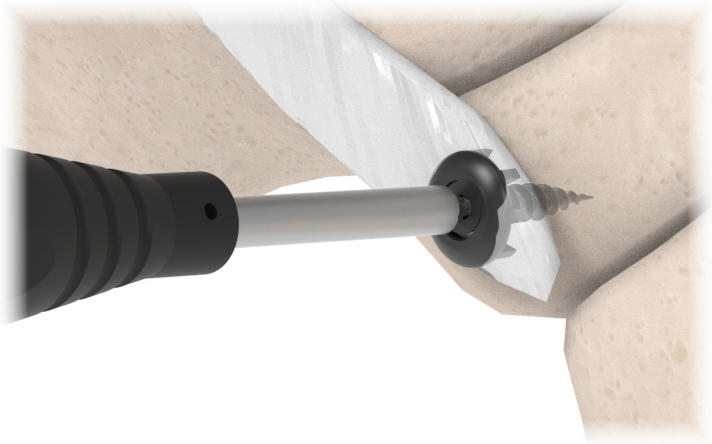


**Step Four**
Insert a 3.0mm self-drilling, self-tapping screw through the holder while it is still positioned over the tendon.

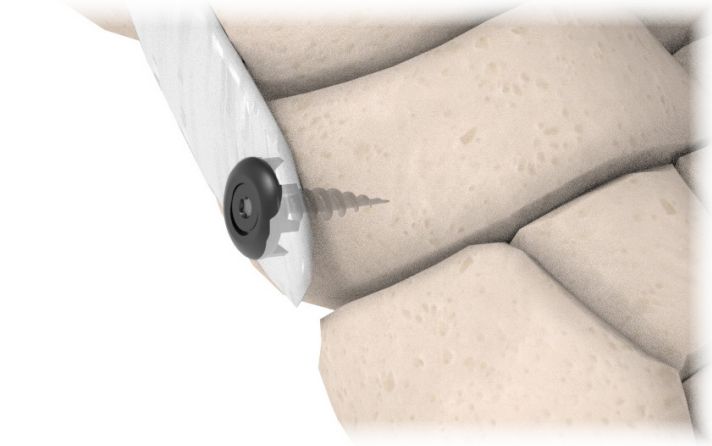


**Step Five**
Drive the screw into the bone with the provided disposable T-7 screw driver. Once the screw head engages the anchor, the holder will release.

**Note**
The system includes a 15mm and 20mm screw. It is recommended to secure the anchor with the 15mm screw initially. If sufficient screw purchase cannot be attained, replace it with the 20mm screw.



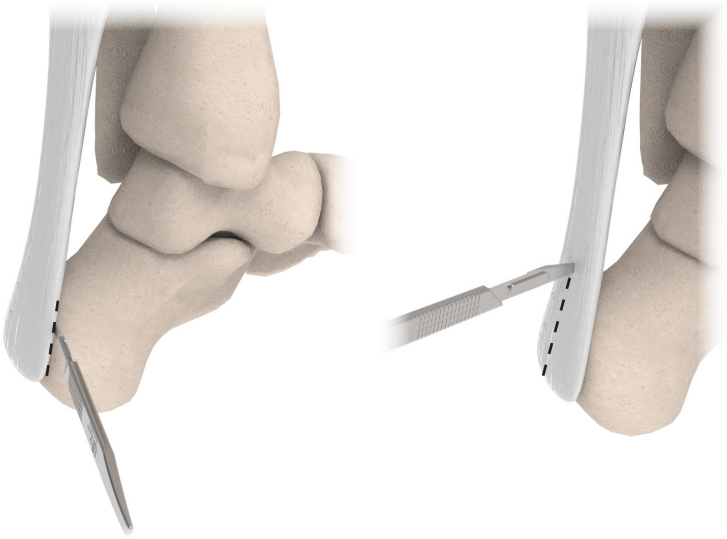
**Step Six**
Finish tightening the screw until the teeth of the anchor engage bone. Care is taken not to over tighten the screws and risk stripping the bone.



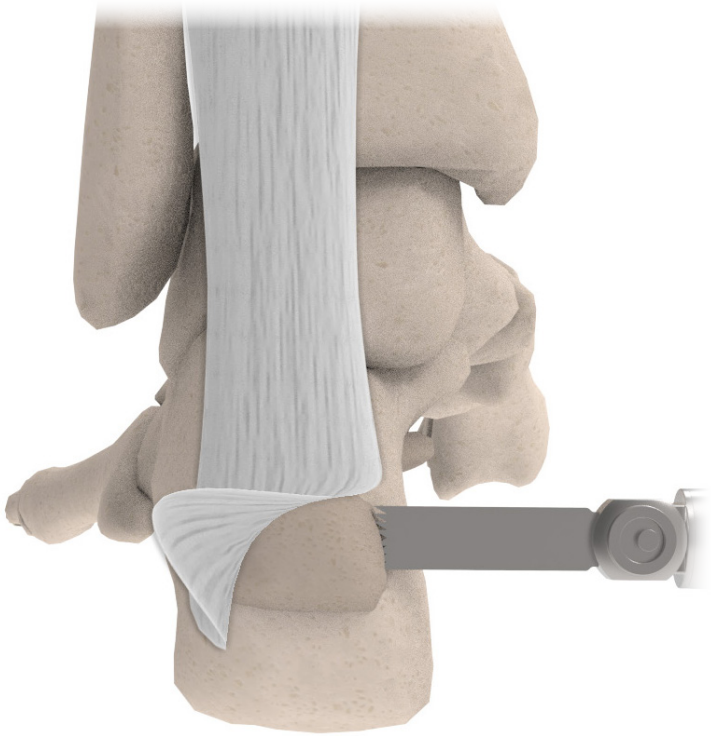
**Step Seven**
Ensure the anchor is at or below the surface of the tendon. The subcutaneous tissues and skin are closed per the surgeon's preference.

# Surgical Technique

The following steps detail a technique for the use of the 26mm Tendon Anchor System for reattaching the Achilles tendon during haglunds correction. This technique may be applied to any soft tissue to bone application.

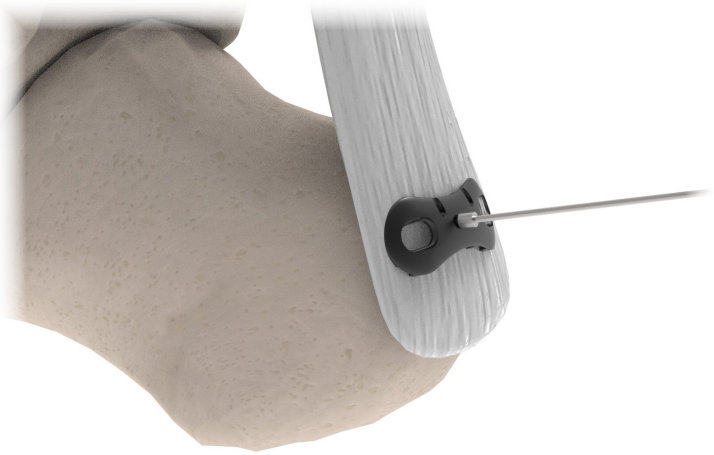


**Step One**
Use preferred technique to expose the Achilles tendon. Release the Achilles tendon by either a direct midline incision or reflect medially, exposing the whole calcaneal tuberosity with a Haglund's prominence. Care is taken to maintain some medial and lateral attachments to assist with the accurate restoration of the Achilles' length.



**Step Two**
The Haglund's prominence is removed using a micro-sagittal saw and osteotome. Care is taken to chamfer off the medial and lateral sides of the calcaneus so as not to leave a prominence which is palpable under the skin

If needed the Achilles tendon is re-approximated with a braided non-absorbable suture of choice. Care is taken to bury the suture knots.

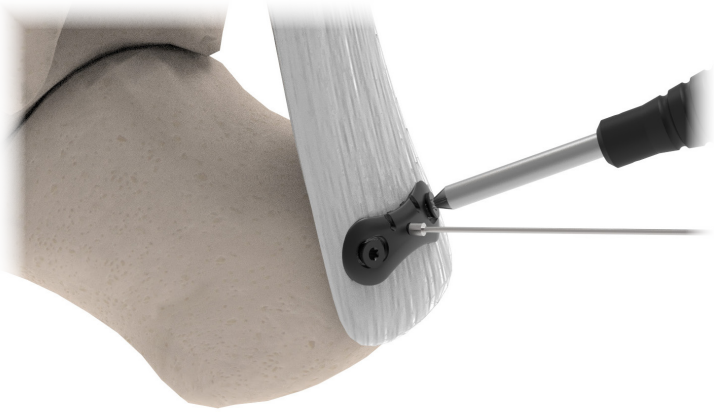


**Step Three**
Plantar flex the foot and pull down the Achilles tendon into the preferred position. Place the anchor over the Achilles tendon in the desired position and insert the provided olive wire through the center wire hole. Drive the provided olive k-wire into place, temporarily securing the anchor.

**Step Four**
Insert a provided 3.0mm self-drilling, self-tapping screw up to 80% depth or until the screw head contacts the anchor.

**Caution**

Do not tighten the screw until both screws have been inserted. It is advised to use an alternating technique when driving the screws into place.

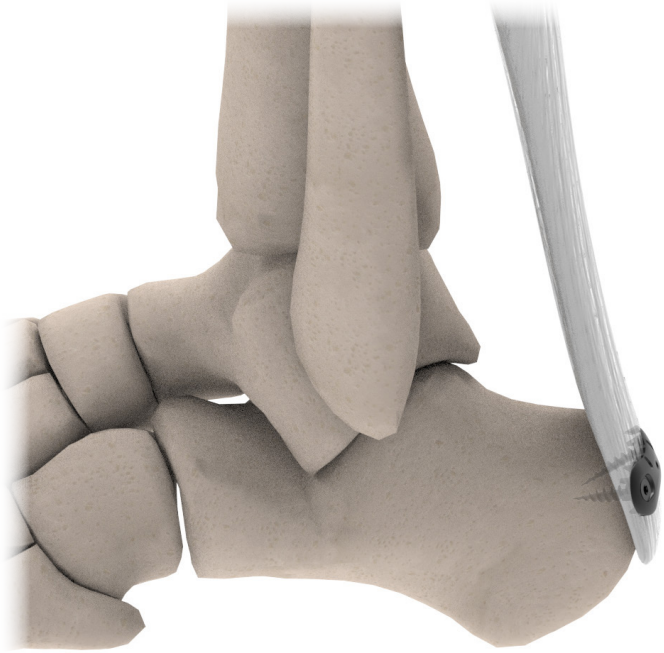


**Step Five**
Insert another 3.0mm self-drilling, self-tapping screw into the remaining screw hole up to 80% depth or until the screw head contacts the anchor.

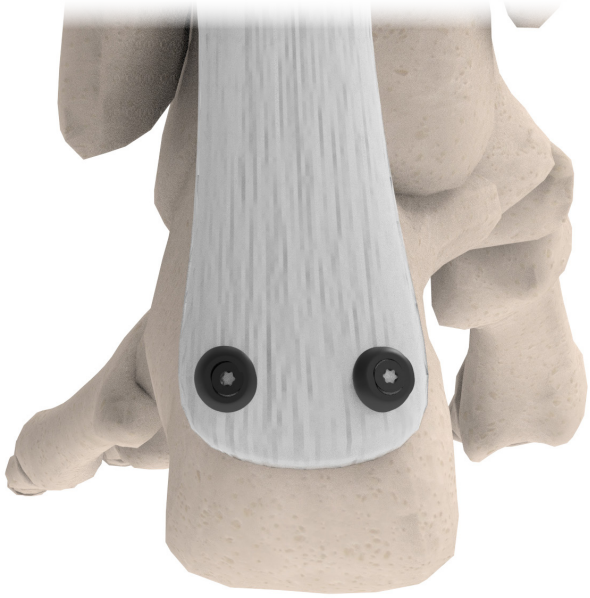
Complete fixation by tightening both screws down using a two-finger tightening method. Care is taken not to over tighten the screws and risk stripping the bone.

**Note**
The system includes both 15mm and 20mm screws. It is recommended to secure the anchor with the 15mm screws initially. If sufficient screw purchase cannot be attained, replace them with the 20mm screws.

**Note**
If 20mm screws do not provide sufficient length for secure fixation additional debulking of the Achilles tendon may be necessary.

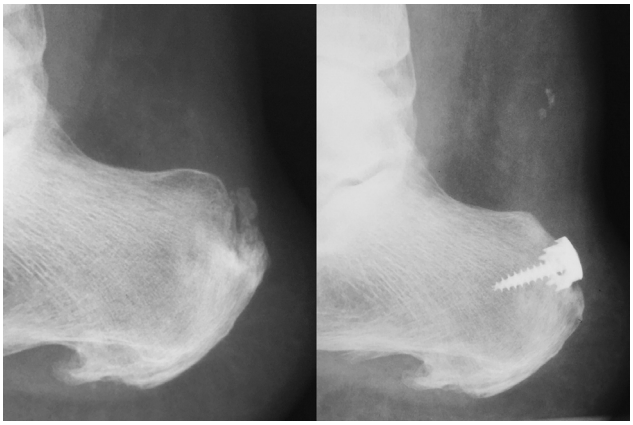


**Step Six**
All temporary instrumentation is removed. The subcutaneous tissues and skin are closed per surgeon's preference.

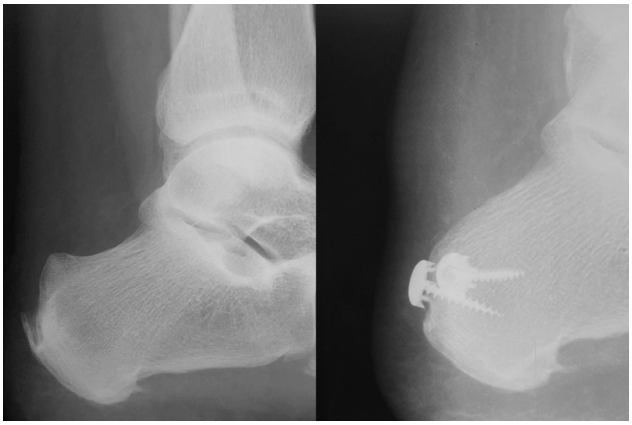


This technique involves using the 26mm anchor. If this anchor doesn't fit the patient's anatomy properly, use (2) 10mm anchors.

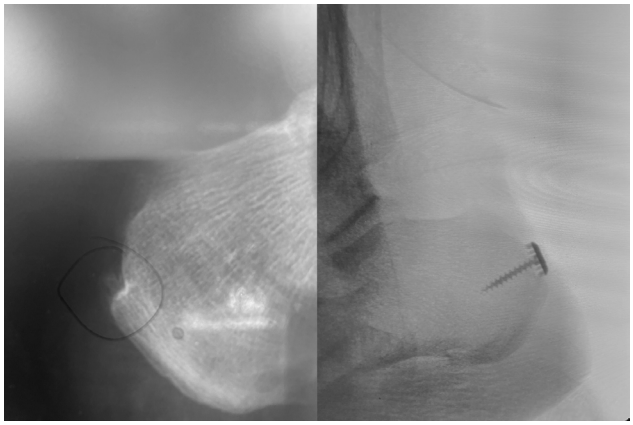
# Postoperative X-rays



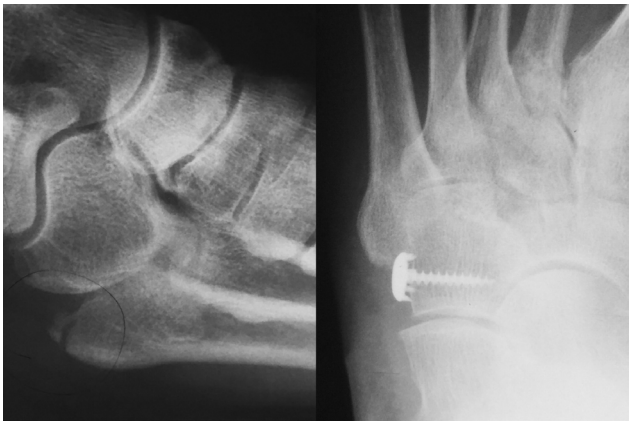
Haglunds correction with a 2-Hole 26mm anchor



Haglunds correction with two 1-Hole 10mm anchors



Haglunds correction with one 1-Hole 10mm anchors



Peroneus brevis transfer to cuboid due to non-healing avulsion fracture 5th metatarsal with 1-Hole 10mm anchor

# Suggested Postoperative Protocol

- Immediate post-op, patient is placed in a modified Jones compressive dressing and a non-weight bearing fiberglass posterior splint.
- First postoperative visit, post-op day four, the dressing is changed and incision is examined. Continue with the non-weight bearing posterior splint.
- Second postoperative visit, post-op day ten to twelve, a modified Jones compressive dressing as well as a walking boot are applied. Patient is allowed to bear weight as tolerated.
- Patient to remain in a walking boot for a total of four weeks.
- At four weeks post-op, patients are gradually weaned off the walking boot and may progress to regular shoe gear as tolerated. Physical therapy may be considered at this time.

# Ordering

| Item # | Description | Size |
|---|---|---|
| 20070 | One Hole Tendon Anchor System | 10MM |
| 20159 | Two Hole Tendon Anchor System | 26MM |

BIOLOGICALLY ORIENTED PROSTHESES

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