

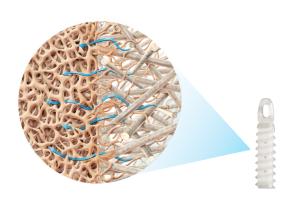
OSSIOfiber® Suture Anchor Surgical Technique Guide



Safety Unmatched

Bio-Integrative OSSIOfiber®

A first-of-its-kind material technology that delivers peace of mind through predictable implant integration without encapsulation or adverse inflammation, leaving nothing permanent behind.



SUPERIOR PULL-OUT RESISTANCE¹

Initial Pull-Out Strength (N)

Strength Unrivaled

Have confidence knowing OSSIOfiber® Suture Anchors provide superior initial pull-out resistance and maintain strength vs the leading biocomposite anchor, without the need for tapping.



Design Features

OSSIOfiber® Suture Anchor





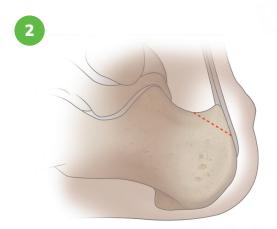
Surgical Technique





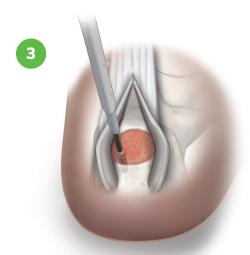
Incision (Central Splitting Technique):

With the patient in the prone position, a posterior midline incision is carried-out down to the Achilles tendon insertion point of the calcaneus. The tendon is split at the midline and released from the calcaneus, ensuring that the medial and lateral attachments are maintained if possible.



Haglund's Removal

Using the appropriate sagittal saw or osteotome, remove the Haglund's deformity taking care to take away any prominent bony formation that could cause soft tissue irritation.

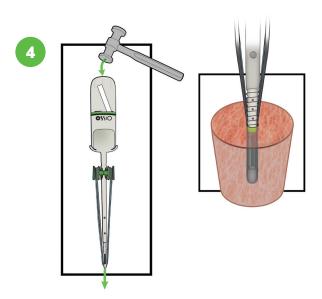


Bone Preparatic

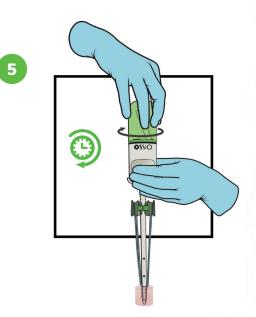
Using the designated drill bit and associated soft tissue protector, drill down until the shoulder on the drill bit contacts the opening on the tissue protector. The hole should be drilled 1cm proximal to the insertion point of the Achilles tendon.

Take care to avoid damage to surrounding soft tissue and neurovascular structures and that the drill trajectory and location provide sufficient bone structure for adequate fixation.

Tip: To ensure the required drill depth, it is very important to ensure that the shoulder on the drill bit meets the drill sleeve.



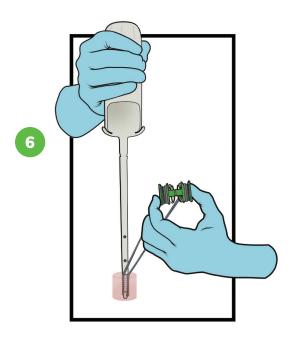
Insert the eyelet of the 4.75mm OSSIOfiber® Suture Anchor in the prepared bone hole. Using a surgical mallet, gently tap the end of the suture anchor handle until the first thread of the anchor is below the surface of the cortical bone.



While holding the stabilization handle of the driver stationary with the non-dominant hand, turn the driver handle in a clockwise direction with the dominant hand to drive the OSSIOfiber® suture anchor into the bone while applying axial pressure.

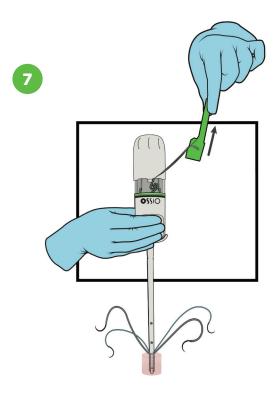
Continue to turn the handle until the anchor is fully seated in the bone.

Tip: If the threads of the anchor do not initially engage the bone, turn driver handle counterclockwise until the handle returns to its original position and repeat step four and five.

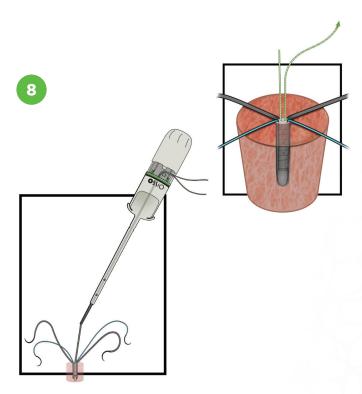


Remove the suture organizer from the driver by grasping on both ends of the spool and pulling away from the driver.

Unwind the suture from the suture organizer and remove the needles with a standard needle driver. Suture can be laid to the side of the foot.



To disengage the driver from the suture anchor, first remove the suture release tab from the handle by grasping firmly and pull axially along the handle. Once the pull-tab is removed and #1 round inner suture released, the driver can be disengaged from the anchor.



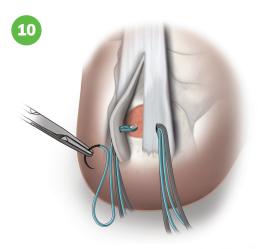
As the driver is removed, a #1 round suture used to hold the eyelet to the driver will be exposed. This suture can be removed from the construct by pulling on one end until fully detached. Alternatively, the #1 round suture can be used for additional fixation of the tendon.

Tip: After the driver is removed, the hex-shaped portion of the driver can be reengaged into the anchor if further adjustment is needed.



Repeat anchor insertion steps for the opposite side of the tendon.

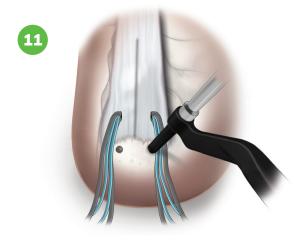
NOTE: Multiple tape and round color options are available to help differentiate between sutures.



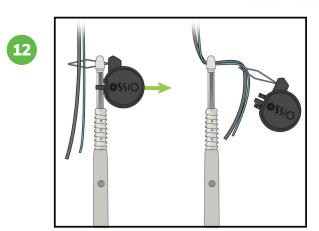
Using a standard needle driver, pass the needles attached to the suture through the midpoint of both the medial and lateral potions of the divided Achilles tendon.

Both the suture tape and/or the #2 round suture can be used in the fixation construct

Once the Achilles has been properly sutured, cut the needles from the end of each suture tail.

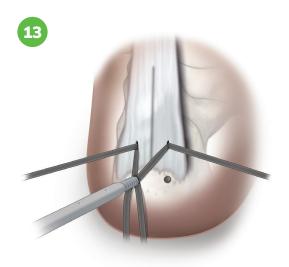


Following the drilling technique previously described, prepare two additional bone holes in-line with the proximal holes and just distal to the Achilles insertion.



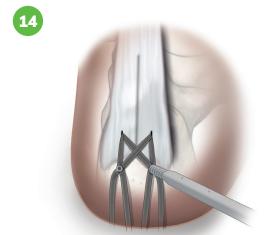
Grabbing one end of the lateral side suture and one end from the medial side suture, thread both ends though the stand-alone suture anchor snare.

Pull the snare handle away from the anchor, pulling both suture ends through the anchor eyelet.

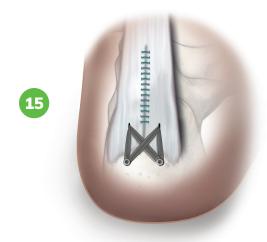


Adjust tension to the anchor before insertion to ensure no laxity exists between the two anchor points.

NOTE: Can utilize cleats to help maintain desired suture tension.



Insert the distal anchors per the technique previously described.



Cut the ends of all sutures to be flush with the bone and finish with the appropriate suturing of the Achilles incision. The blue sutures are left over to repair that midline split of the Achilles tendon.

Ordering Information Intelligent Healing For Achilles Tendon Repair

OSSIOfiber® Suture Anchor 2-Pack

1x OSSIOfiber® 4.75mm Suture Anchor, Black Tape w/ needles

1x OSSIOfiber® 4.75mm Suture Anchor, Black/White Tape w/ needles

1x Standard Instrument Set (drill bit & drill guide)

Part # OF2034756S



OSSIOfiber®
4.75mm Suture Anchor
Black/White Tape w/ needles,
#2 sutures w/ needles

Part # OF1034753S



OSSIOfiber®
4.75mm Suture Anchor
Black Tape w/ needles,
#2 sutures w/ needles

Part # OF1034752S

OF1032006S



OSSIOfiber®
4.75mm Suture Anchor
w/ Snare
No Suture
Part # OF1034751S

Description	Product Code
Standalone #2 round solid blue suture, box of 12	OF1032003S
Standalone #2 round white blue suture, box of 12	OF1032004S
Standalone 1.8mm solid black tape suture, box of 12	OF1032005S

Standalone 1.8mm black/white tape suture, box of 12

Indication for Use

The OSSIOfiber® Suture Anchors are indicated for fixation of suture (soft tissue) to bone in the shoulder, foot/ankle, knee, hand/wrist, and elbow in the following procedures:

- Shoulder: Rotator Cuff Repair, Bankart Repair, SLAP Lesion Repair, Biceps Tenodesis, Acromio-Clavicular Separation Repair, Deltoid Repair, Capsular Shift or Capsulolabral Reconstruction.
- Foot/Ankle: Lateral Stabilization, Medial Stabilization, Achilles Tendon Repair, Hallux Valgus Reconstruction, Mid-foot Reconstruction, Metatarsal Ligament Repair/Tendon Repair and Bunionectomy.
- Knee: Anterior Cruciate Ligament Repair (4.75-5.5 Anchors Only), Medial Collateral Ligament Repair, Lateral Collateral Ligament Repair, Patellar Tendon Repair, Posterior Oblique Ligament Repair, Illiotibial Band Tenodesis and Quadriceps Tendon Repair. Secondary or adjunct fixation of ACL/PCL reconstruction or repair (4.75 5.5 Anchors only).
- Hand/Wrist: Scapholunate Ligament Reconstruction, Ulnar or Radial Collateral Ligament Reconstruction. Elbow: Biceps Tendon Reattachment, Ulnar or Radial Collateral Ligament Reconstruction, Lateral Epicondylitis repair (Tennis Elbow).

1. Data on File at OSSIO.

Refer to the product Instructions for Use for warnings, precautions, indications, contraindications, and technique.

