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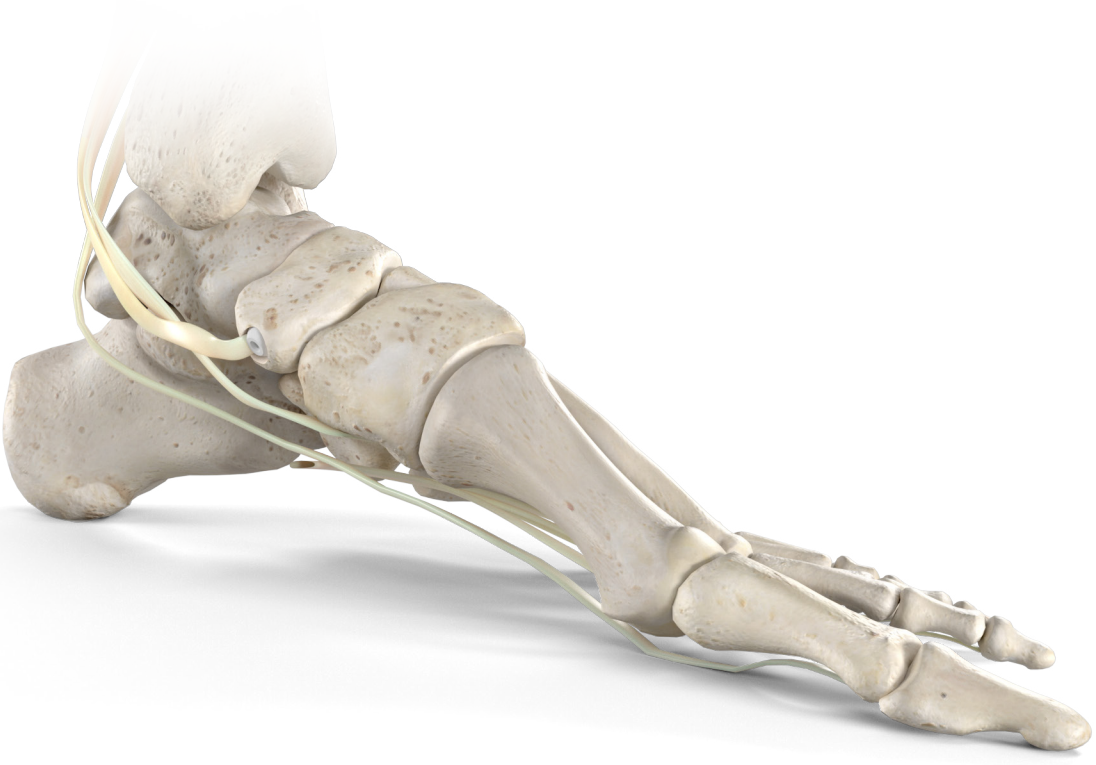
Citrelock™ Tendon fixation system

Operative technique

Flexor Digitorum Longus (FDL) tendon transfer



Citrelock™
Tendon fixation system

This publication sets forth detailed recommended procedures for using Stryker devices and instruments. It offers guidance that you should heed, but, as with any such technical guide, each surgeon must consider the particular needs of each patient and make appropriate adjustments when and as required.

⚠ WARNING

Follow the instructions provided in our cleaning and sterilization guide (PI-005).

⚠ WARNING

All non-sterile devices must be cleaned and sterilized before use. Multi-component instruments must be disassembled for cleaning. Please refer to the corresponding assembly/disassembly instructions.

Please remember that the compatibility of different product systems has not been tested unless specified otherwise in the product labeling.

Consult Instructions for Use (www.ifu.stryker.com) for a complete list of potential adverse effects and adverse events, contraindications, warnings and precautions.

⚠ WARNING

- The surgeon must advise patients of surgical risks, and make them aware of adverse effects and alternative treatments.
- The patient should be advised that the device cannot and does not replicate a normal healthy bone, that the device can break or become damaged as a result of strenuous activity or trauma and that the device has a finite expected service life.
- Removal or revision of the device may be required sometime in the future due to medical reasons.

For additional information please refer to the instructions for use (IFU), Ref. No. PI-004 delivered with each implant and IFU, Ref. No. PI-005 delivered with each durable instrument, and/or IFU, Ref. No. PI-003 delivered with each single-use instrument kit. The surgeon must discuss all relevant risks, including the finite lifetime of the device, with the patient, when necessary.

Surgical Technique as described by: Wayne Berberian, MD

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Indications, precautions & contraindications

Indications

The Citrelock Tendon Fixation Device is intended for soft tissue reattachment, i.e. fixation of ligament and tendon graft tissue in surgeries of the shoulder, elbow, foot/ankle, knee, and hand/wrist. More specifically:

Shoulder: Rotator Cuff Repairs, Bankart Repair, SLAP Lesion Repair, Biceps Tendon Reattachment, Acromion-Clavicular Separation Repair, Deltoid Repair, Capsular Shift or Capsulolabral Reconstruction.

Foot/Ankle: Lateral Stabilization, Medial Stabilization, Achilles Tendon Repair, Hallux Valgus Reconstruction, Midfoot Reconstruction, Metatarsal Ligament Repair, Flexor Hallucis Longus for Achilles Tendon reconstruction, tendon transfers in the foot and ankle.

Knee: Anterior Cruciate Ligament Repair, Medial Collateral Ligament Repair, Lateral Collateral Ligament Repair, Patellar Tendon Repair, Posterior Oblique Ligament Repair, Iliotibial Band Tenodesis.

Elbow: Biceps Tendon Reattachment, Ulnar or Radial Collateral Ligament Reconstruction.

Hand/Wrist: Scapholunate Ligament Reconstruction, Ulnar Collateral Ligament Reconstruction, Radial Collateral Ligament Reconstruction, Carpometacarpal joint arthroplasty (basal thumb joint arthroplasty), Carpal Ligament Reconstructions and repairs, tendon transfer in the hand/wrist.

Precautions

Surgeons are advised to review the product-specific surgical technique prior to performing any surgery. Stryker provides detailed surgical techniques in print and electronic formats. The Stryker website also provides detailed surgical technique information and demonstrations. Or, contact your Stryker representative for an onsite demonstration.

1. Under insertion of the device may leave the proximal end of the implant protruding beyond the cortical bone, which could potentially cause soft tissue irritation and/or pain post-operatively.
2. Use the appropriate size Drill to create a pilot hole in the bone.
3. It is important to completely seat the screwdriver to prevent potential stripping of the hex and/or screw fracture during insertion or removal.

MR safety information

The device has not been evaluated for safety and compatibility in the magnetic resonance (MR) environment. This device has not been tested for heating, migration, or image artifact in the MR environment. The safety of the device in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

Warning

Surgeons must apply their professional judgment when determining the appropriate implant size based on the specific indication, preferred surgical technique, and patient history. Implant sizes that are smaller than 7mm may not be appropriate for the knee indication. A successful result is not always achieved in every surgical case. This fact is true considering other patient conditions that may compromise the outcome. No implant can withstand body loads without the support of bone. In this event, bending, loosening, disassembly and/or breakage of the device(s) will eventually occur. Preoperative and operating procedures, including knowledge of surgical techniques, proper selection and placement of the implant and good alignment are important considerations in the success of surgery. Never reuse an internal fixation device under any circumstances. Even when a removed device appears undamaged, it may have small defects or internal stress patterns that may lead to early breakage. Further, the proper selection and compliance of the patient will greatly affect the results. Patients who smoke have been shown to have an increased incidence of delayed healing. These patients should be advised of this fact and warned of this consequence. Obese, malnourished, and/or alcohol abuse patients are also poor candidates for surgery. DO NOT USE devices that are received in open or damaged packages. DO NOT USE past the expiration date. No Implant should be reused once the sterile packaging has been opened.

Indications, precautions & contraindications

Contraindications

Include, but are not limited to:

1. Fever or leukocytosis.
2. Infection, local to the operative site.
3. Mental illness.
4. Morbid obesity.
5. Pregnancy.
6. Insufficient quantity or quality of bone.
7. Signs of local inflammation.
8. Blood supply limitations and previous infections which may retard healing.
9. Foreign Body Reactions. See Adverse Effects-Allergic Type Reactions.
10. Any active infection or blood supply limitations.
11. Any patient unwilling to co-operate with postoperative instructions.
12. Foreign-body sensitivity. Where material sensitivity is suspected, appropriate tests should be made, and sensitivity ruled out prior to implantation.
13. Conditions that tend to limit the patient's ability or willingness to restrict activities or follow directions during the healing period.
14. The use of this device may not be suitable for patients with insufficient or immature bone. The physician should carefully assess bone quality before performing orthopedic surgery on patients who are skeletally immature. The use of this medical device and the placement of hardware or implants must not bridge, disturb or disrupt the growth plate.
15. Any patient having inadequate tissue coverage over the operative site or where there is inadequate bone stock, bone quality, or anatomical definition.
16. Rapid joint disease, bone absorption, osteopenia, and/or osteoporosis. Osteoporosis is a relative contraindication since this condition may limit the degree of obtainable correction and/or the amount of mechanical fixation. Severe osteoporosis may prevent adequate fixation and thus preclude the use of this or any other orthopedic implant.
17. Conditions that may place excessive stresses on bone and implants, such as severe obesity or degenerative diseases, are relative contraindications. The decision whether to use these devices in patients with such conditions must be made by the physician considering the risks versus the benefits to the patient.
18. Use of these implants is relatively contraindicated in patients whose activity, mental capacity, mental illness, alcoholism, and ability to follow postoperative restrictions, which may compromise outcome. These patients may place undue stresses on the implant during bony healing and may be at higher risk of implant failure.
19. Any condition not described in the indications for use.

NOTICE

For additional information please refer to the Instructions For Use (IFU), Ref. No. PI-004 delivered with each implant and IFU, Ref. No. PI-005 delivered with each durable instrument, and/or IFU, Ref. No. PI-003 delivered with each single use instrument kit.

Implant Selection

The selection of the proper size, shape and design of the implant for each patient is crucial to the success of the procedure. Plastic polymer implants are subject to repeated stresses in use, and their strength is limited by the need to adapt the design to the size and shape of human bones. Unless great care is taken in patient selection, proper placement of the implant, and postoperative management to minimize stresses on the implant, such stresses may cause material fatigue and consequent breakage, bending or loosening of the device before the healing process is complete, which may result in further injury or the need to remove the device prematurely.

PHYSICIAN NOTE: Although the physician is the learned intermediary between the company and the patient, the important medical information given in this document should be conveyed to the patients.

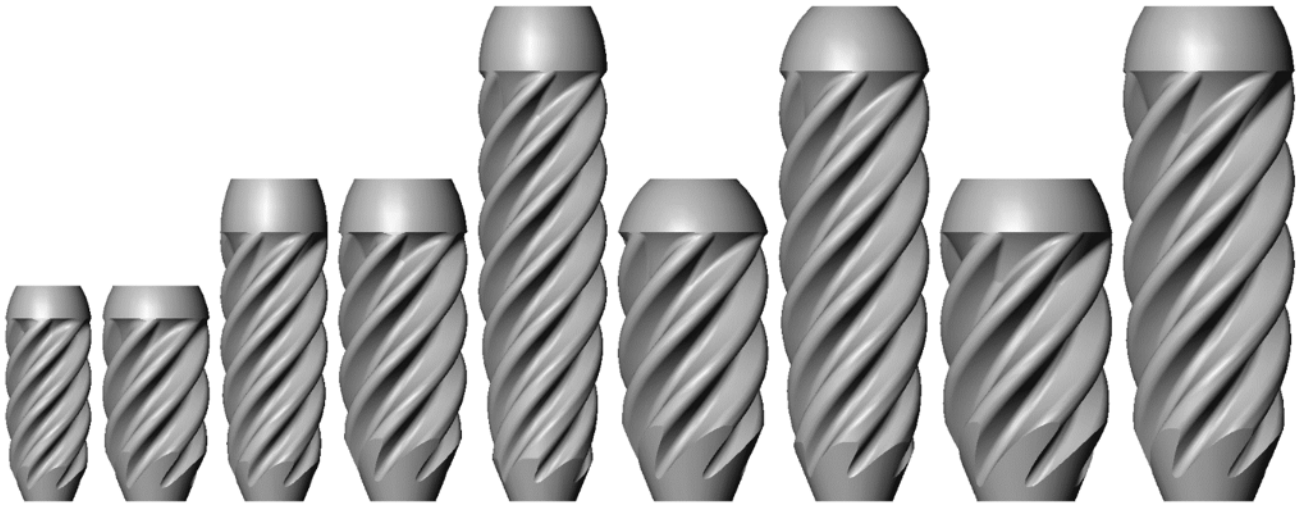
System general considerations

Flexor Digitorum Longus (FDL) tendon transfer

using the Citrelock™ Tendon fixation device

The FDL tendon transfer is indicated for patients with a dysfunction of the posterior tibialis tendon (PTT), where the tendon has extended beyond its functional length or has ruptured. As a result, the FDL tendon is transferred into a bone tunnel into the navicular and fixated with a device from the Citrelock Tendon fixation system. This transfer is not recommended as the sole procedure to address flatfoot and should be combined with adjunctive hindfoot techniques as needed.

Citrelock
Tendon fixation devices

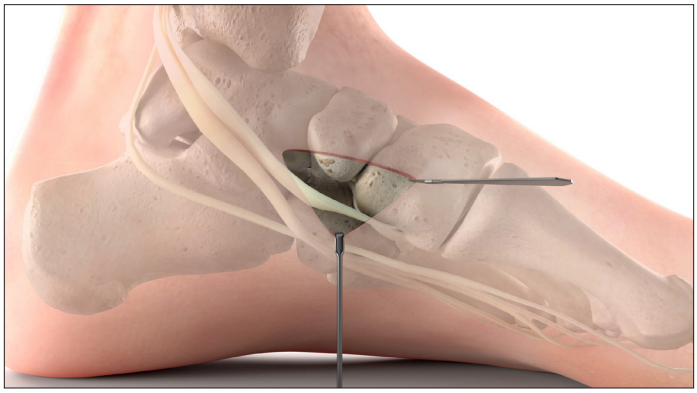


Sizes Ø4 to Ø8mm
Lengths 10 to 23mm

Operative technique

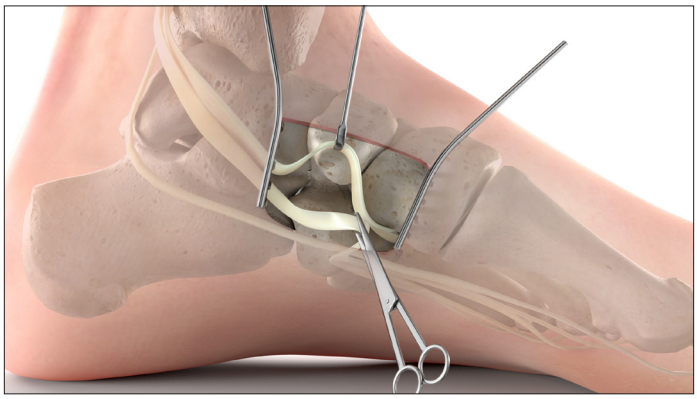
Exposure

Make a longitudinal incision over the course of the posterior tibialis tendon, extending distally to the level of the naviculocuneiform joint. Deeper dissection is necessary to identify the insertional expansion of the Posterior Tibialis Tendon (PTT). The posterior tibialis tendon tenosynovectomy is performed and all diseased PTT is excised. A longitudinal incision is made in the floor of the PTT sheath, carried down to the FDL.



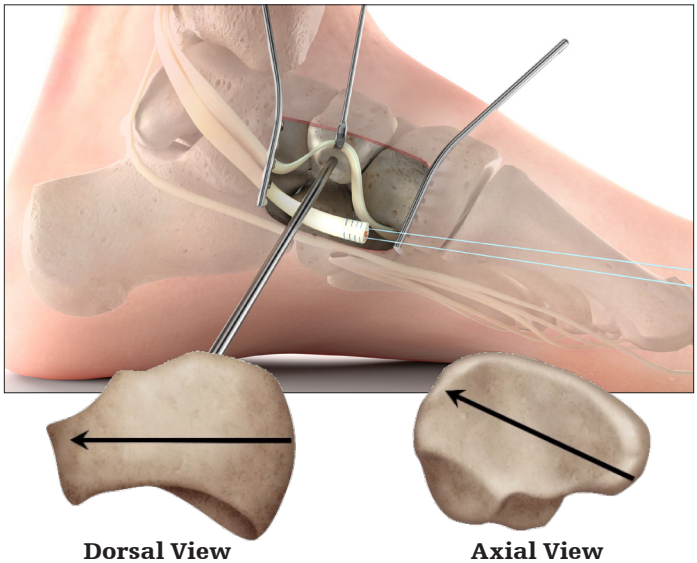
Isolation and preparation of FDL

The medial fascia is opened, and the FDL tendon is identified and dissected proximal to the Master Knot of Henry. The distal most exposed region of the FDL is identified. Using a scalpel, the tendon can be released distally while maintaining control with forceps. The FDL can then be mobilized to facilitate the tunnel preparation and protect the tendon.



Targeting tunnel orientation

Place the 2.4mm Guide Pin, from medial plantar-to-lateral dorsal in the navicular, under fluoroscopy to verify near central position. In the axial view the trajectory should follow the long axis of the navicular and in the dorsal view the trajectory should be in the middle of the navicular with care to avoid the concave proximal articular surface.



Dorsal View **Axial View**

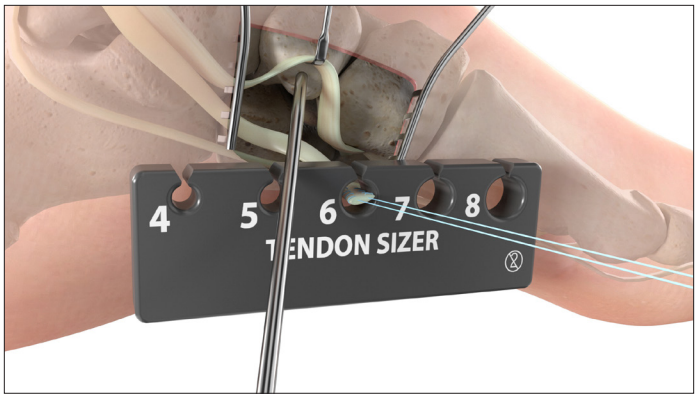
Tendon sizing

Using the modified Krackow stitch to apply tension, size the tendon through holes on the sizer.

NOTICE

Any nodules or bulbous protrusions from the tendon can be trimmed to provide a consistent diameter.

Start at a larger hole size on the sizer and progressively move to smaller holes until the tendon no longer fits. The tendon size will be the size of the last hole the tendon fits through. For example, if the tendon fits through and fills the size 6 hole but does not fit through the size 5mm, the tendon is sized 6mm.



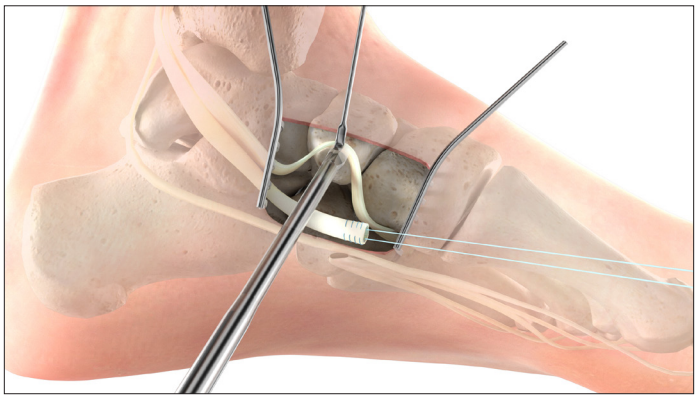
Creating bone tunnel

For the interference technique, a plantar-medial to dorso-lateral tunnel should be created in the navicular bone by reaming over the guidewire. With a 6.0mm tendon, ream over the guide pin with a 6.0mm reamer.

NOTICE

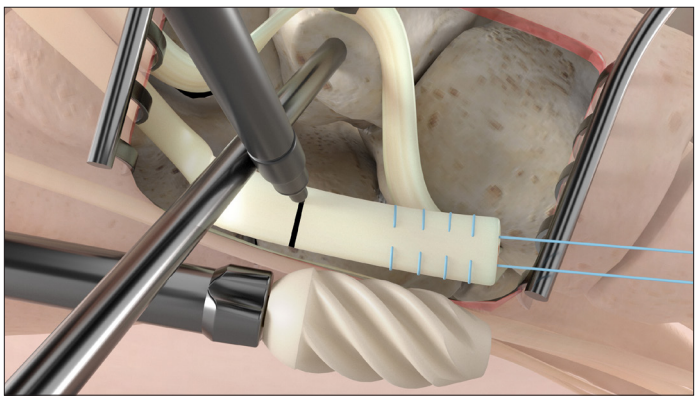
On creation of the bone tunnel, (1) Proper implant and pilot hole diameter depend on the diameter of the tendon graft and bone quality. (2) Bone tunnel diameter may be same size of the tendon (ex. 4mm graft requires 4.0mm diameter tunnel). (3) If the patient possesses dense bone it may be necessary to oversize tunnel to minimize impaction required to seat the implant. (ex. 5mm graft, create 6mm tunnel and use 5mm Citrelock implant). (4) If the patient possesses poor bone density it may be necessary to oversize the implant. (ex. 5mm graft, create 5mm tunnel and use 6mm Citrelock implant).

At this point the surgeon may consider performing adjunctive procedures such as calcaneal osteotomy, Achilles lengthening, spring ligament reconstruction, cotton osteotomy, lateral column lengthening, etc.

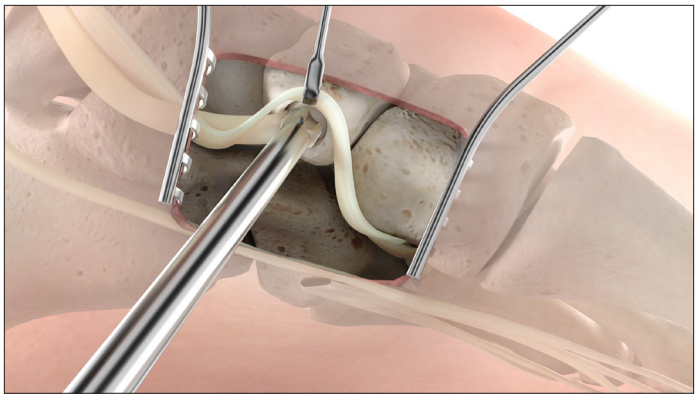


Determining tendon tension

Tension the FDL using the modified Krackow stitch to the desired resistance and mark the tendon at the entrance to the bone tunnel. Measure the implant length from the first marking on the FDL and make a second mark to provide a visual reference where the implant will be placed. Thread the #2 suture from the modified Krackow stitch through the eyelet in the 2.4mm wire, and pull the wire through, passing the suture. Tension the suture and pull the tendon into the tunnel.



Implanting Citrelock

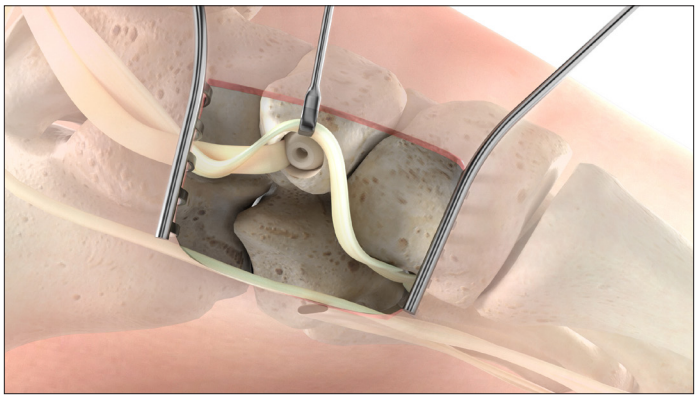


With the tendon in the bone tunnel and the foot in maximum plantar flexion/inversion, place the tip of the Inserter in the tunnel adjacent to the tendon. Align the inserter with the prior trajectory established during reaming. Correct tension can be confirmed when the initial pen marking on the tendon lines up at the bone tunnel and the tip of the Citrelock helical ridges are in contact with the cortex. To advance the Citrelock device, tap the strike plate on the inserter handle while holding the inserter stationary. Based on the bone quality and amount of interference several strikes may be required to fully seat the implant.

NOTICE

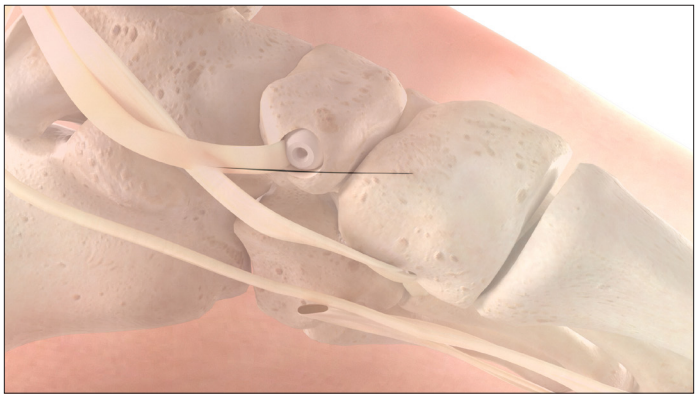
Care should be taken to ensure implant trajectory follows previously created tunnel trajectory.

Final seating



The Citrelock device is seated properly when it is flush with the cortical bone. Remove the inserter and cut the remaining sutures at their interface with the skin while retracting the skin so that the cut ends of the suture subside beneath it.

Closure



Under X-ray check the location of the implant if desired. After implantation of the Citrelock implant is complete, wound closure is performed according to the surgeon's standard protocol.

Removal

If for any reason after the implant has been seated the clinician decides it needs to be removed, it can be drilled out using a burr of a smaller diameter than the implant, utilizing fluoroscopy to check the trajectory of the tool.

Notes

Notes

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Foot & Ankle

This document is intended solely for the use of healthcare professionals. A surgeon must always rely on his or her own professional clinical judgment when deciding whether to use a particular product when treating a particular patient. Stryker does not dispense medical advice and recommends that surgeons be trained in the use of any particular product before using it in surgery.

The information presented is intended to demonstrate a Stryker product. A surgeon must always refer to the product label and/or Instructions for Use, including the instructions for Cleaning and Sterilization (if applicable), before using any Stryker product. Products may not be available in all markets because product availability is subject to the regulatory and/or medical practices in individual markets. Please contact your Stryker representative if you have questions about the availability of Stryker products in your area.

The Instructions for Use, Operative Techniques, Cleaning instructions, patient information leaflets and other associated labeling may be requested online at www.ifu.stryker.com or www.stryker.com.

If saving the Instructions for Use, Operative Techniques, Cleaning instructions from the above mentioned websites, please make sure you always have the most up to date version prior to use.

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