GRIPLASTY™

SURGICAL TECHNIQUE

GRIPLASTY™ SYSTEM

BASE OF THUMB WITH NEEDLES

A COMPONENT OF THE EXTREMITY ALL SUTURE SYSTEM

www.griplasty.com

FIELDORTHOPAEDICS

GRIPLASTY™

CONTENTS

GRIPLASTY™

INDICATIONS FOR USE

GRIPLASTY™ SYSTEM
BASE OF THUMB WITH NEEDLES

The Griplasty™ System Base of Thumb with Needles is a part of the Extremity All Suture System. Indications for the Extremity All Suture System include the following:

The Extremity All Suture System is intended to be used for suture or tissue fixation in the foot/ankle, knee, hand/wrist, elbow, and shoulder. Specific indications are listed below:

Elbow: Biceps tendon reattachment, ulnar or radial collateral ligament reconstruction.

Shoulder: Rotator cuff repair, Bankart repair, SLAP lesion repair, Biceps tenodesis, Acromio-Clavicular Separation Repair, Deltoid Repair, Capsular Shift or Capsulolabral Reconstruction.

Hand/Wrist: Scapholunate Ligament Reconstruction, Repair/reconstruction of collateral ligaments, Repair of flexor and extensor tendons at the PIP, DIP, and MCP joint for all digits, digital tendon transfers, Carpal ligament reconstruction and carpometacarpal joint arthroplasty (Basal thumb joint arthroplasty).

Foot/Ankle: Lateral stabilization, medial stabilization, achilles tendon repair, metatarsal ligament repair, hallux valgus reconstruction, digital tendon transfers, mid-foot reconstruction.

Knee: Medial collateral ligament repair, lateral collateral ligament repair, patellar tendon repair, posterior oblique ligament repair, iliotibial band tenodesis.

SYSTEM COMPONENTS

T-Handle preloaded with Anchors, Suture, V-Sling, and Needles (2)

Streamlining the surgical process for you and your team

1) 1.2mm x 80mm Single-Ended Trajectory K-wires (2)

Precise and reliable guidance

2) K-wire Guide Sleeve + Parallel Wire Guide

Innovative, precise, and reproducible deployment*[1]

3) 1.6mm x 100mm Single-Ended Guide K-wires (2)

Precise and reliable guidance

4) 1 x 2.4mm Cannulated Drill Bit

Predetermined drill trajectory

**Patent pending*

PROCEDURAL TECHNIQUE - DORSAL APPROACH

TIP: The dorsal approach provides better visualisation of the trapezium during excision however the flexor carpi radialis (FCR) tendon and the superficial branch of the radial nerve and artery are more at risk, therefore particular care must be taken.[12]

Preoperative Planning

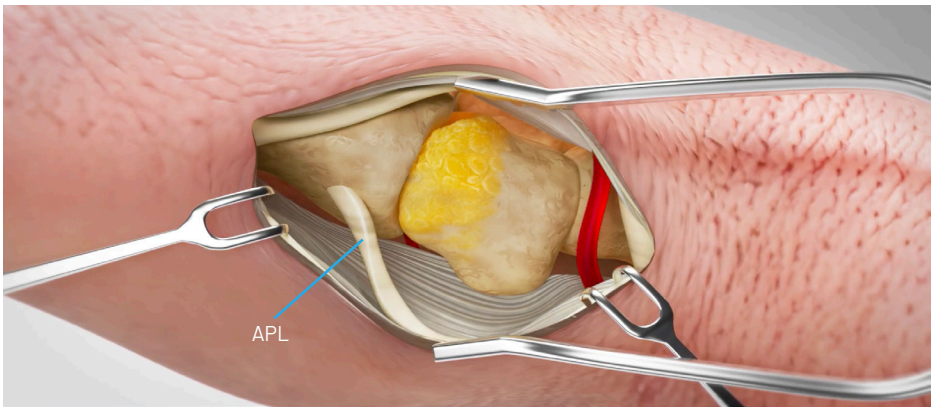
A comprehensive clinical examination inclusive of history and radiographic investigation will determine the need for surgical intervention. Ensuring all appropriate equipment is available for the procedure is essential.

Patient Positioning

The patient is supine and a tourniquet is applied. Anaesthesia is induced and the patient and table are rotated if required. The limb is prepped and draped. Anatomic landmarks and neurovascular structures at risk must be familiar to the surgeon and identified prior to commencing the procedure. The thumb carpometacarpal joint (CMCJ) is located by palpating on the proximal end of the thumb metacarpal and feeling for the soft spot proximal to the base. Incisions are drawn and the tourniquet is inflated. The hand should be in a neutral position.

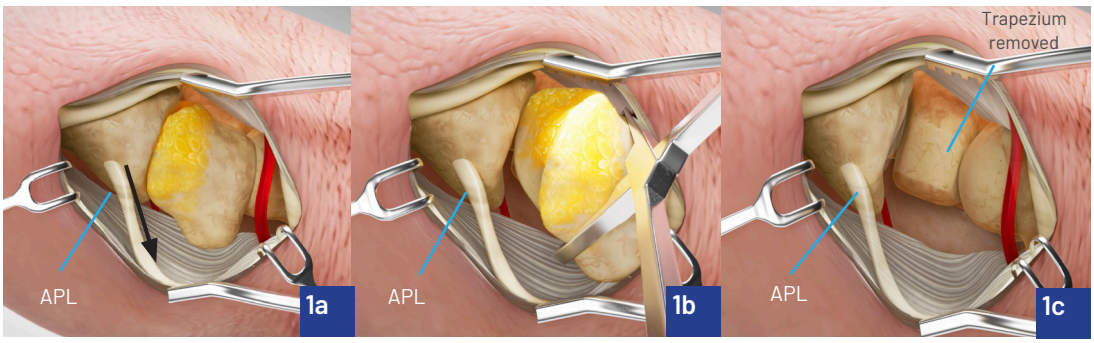
Soft Tissue Dissection

A dorsoradial incision centered over the thumb CMCJ at the border of the glabrous and non glabrous skin is utilized. The abductor pollicis longus (APL), extensor pollicis brevis (EPB), extensor pollicis longus (EPL), dorsal radial sensory nerve, and the radial artery are all in the vicinity. These structures are identified and protected. The soft tissue over the first dorsal extensor compartment is then bluntly dissected. The interval between the extensor pollicis brevis (EPB) and the abductor pollicis longus (APL) is incised and the tendons retracted ulnarly and radially, exposing the capsule over the trapezium. The capsule is then incised longitudinally.



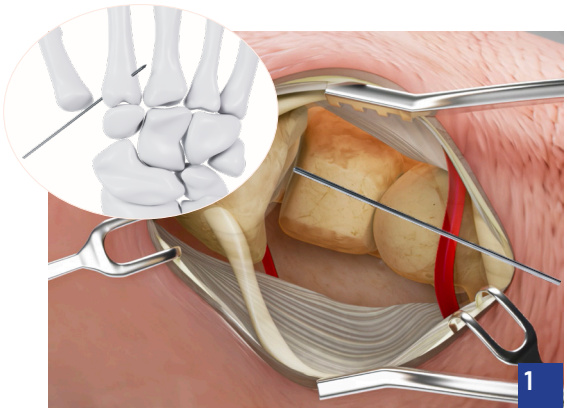
Trapeziectomy

The capsule is then elevated off the trapezium subperiosteally and an osteotome is used to perform a hemi or full trapeziectomy. Care is required to ensure the flexor carpi radialis (FCR) tendon on the volar side of the trapezium is identified and protected. A rongeur can be used to remove the trapezium and all loose bodies at the first and second metacarpal base. Thorough inspection to ensure the joint space is clear will assist in preventing impingement and ongoing pain. Remove any osteophytes, free bodies and synovitis.



PROCEDURAL TECHNIQUE - DORSAL APPROACH

Index Anchor Implantation



Open the Sterile Griplasty™ System - Base of Thumb with Needles:

- Sterile product should be inspected before use.
- Devices should only be accepted if the factory packaging and labelling arrive intact.
- Ensure packaging seals are intact and not damaged before opening.

  Do not use if seals or packaging are open, have been prematurely opened or damaged.
- Implant, instruments and packaging are single-use only.
- Do not use past the expiration date indicated on the label.

Step 1: Trajectory K-wire

Locate one of the 1.2mm Trajectory K-wires in the Griplasty™ System - Base of Thumb with Needles Kit (Item 1). The purpose of this Trajectory K-wire is to facilitate engagement of the far cortex across the base of the index metacarpal and determine the position of final index anchor placement. Start by positioning the 1.2mm Trajectory K-wire on the trapezium facet of the base of the index metacarpal.

TIP: A distal insertion point will assist in achieving a greater surface area of support with the Griplasty™ V-Sling.

Once the Trajectory K-wire is positioned, aim obliquely and advance with a recommended trajectory for exit in the mid-coronal section of the second intermetacarpal space.

TIP: Confirm the trajectory under fluoroscopy while advancing the K-wire. Using oscillation can maximise control of the K-wire.

TIP: Deployment of the anchor dorsal to the coronal midline may impinge or irritate soft tissue.

Ensure both cortices are penetrated as far cortex engagement of the anchor is recommended.

Step 2: Position Parallel Guide Assembly

A Guide K-wire must be inserted next. First, assemble the Parallel Guide Assembly by placing the K-wire Guide Sleeve into the Parallel Wire Guide (Figure 1). The K-wire Guide Sleeve and Parallel Wire Guide are labelled 2 in the Griplasty™ System - Base of Thumb with Needles Kit.

Slide the Parallel Guide Assembly over the 1.2mm Trajectory K-wire ensuring the leading end of the Parallel Wire Guide is seated on the base of the index metacarpal (Step 2). It is important in the next step (Step 3) that the 1.6mm Guide K-wire engages with solid bone and does not skive. If the Guide K-wire skives there is risk the wires may not be parallel.

TIP: The 1.2mm Trajectory K-wire must be inserted into the hole in the K-wire Guide Sleeve and not directly into the hole in the Parallel Wire Guide. Note that the shortest leading tip of the Parallel Guide Assembly is the correct pilot hole.

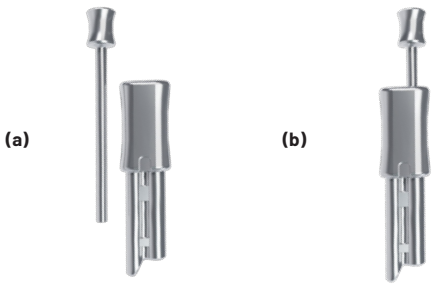
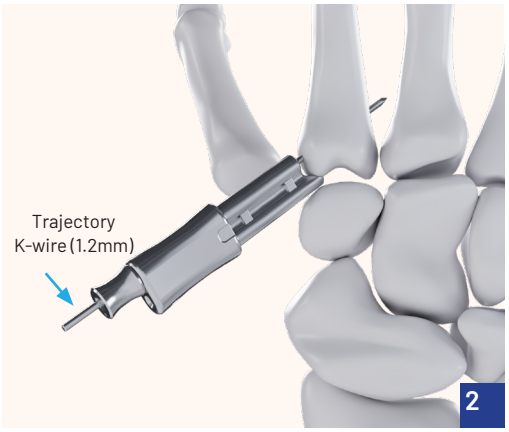


Figure 1: (a) K-wire Guide Sleeve (left) and Parallel Wire Guide (right) **(b)** Parallel Guide Assembly.



PROCEDURAL TECHNIQUE - DORSAL APPROACH

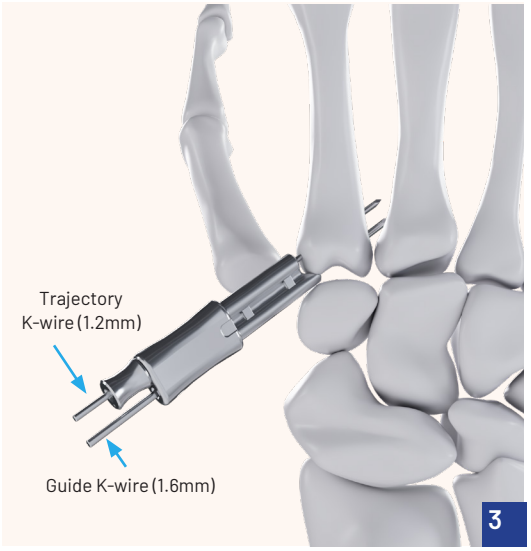
Step 3: Guide K-wire Insertion

Insert one of the 1.6mm Guide K-wires (Item 3 in the Griplasty™ System - Base of Thumb with Needles Kit) into the empty tunnel in the Parallel Wire Guide. Advance the K-wire and ensure both cortices are penetrated. Again, fluoroscopy may be used to confirm suitable placement.

TIP: It is important that the Guide K-wire is inserted into solid bone. Entering at a shallow angle is not encouraged as this can cause the Guide K-wire to skive.

TIP: Insert the Guide K-wire in a position which will allow suitable orientation of the T-Handle during anchor insertion.

Remove the K-wire Guide Sleeve (see Figure 1a) and retain for future steps. **NOTE: DO NOT DISCARD** the K-wire Guide Sleeve at this step. Leave the Parallel Wire Guide in-situ.



Step 4: Drill Bi-cortically

Place the 2.4mm Cannulated Drill Bit (Item 4) over the 1.2mm Trajectory K-wire (Item 1) where the K-wire Guide Sleeve was situated and drill bi-cortically. Remove the Cannulated Drill Bit (Item 4) and retain for future steps.

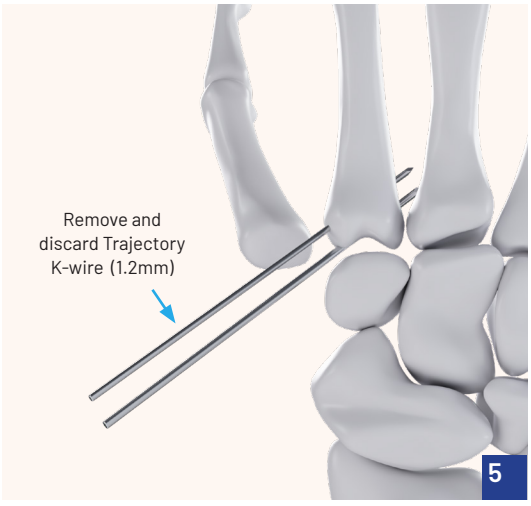
NOTE: DO NOT DISCARD the Cannulated Drill Bit (Item 4).

Remove the Parallel Wire Guide (Item 2 - right Figure 1a) by sliding it off the K-wires and retain for future steps.

NOTE: DO NOT DISCARD the Parallel Wire Guide (Item 2 - right Figure 1a).

Step 5: Remove Trajectory K-wire

Ensure that the 1.6mm Guide K-wire (Item 3) remains in the index metacarpal then remove and discard the 1.2mm Trajectory K-wire (Item 1).



PROCEDURAL TECHNIQUE - DORSAL APPROACH

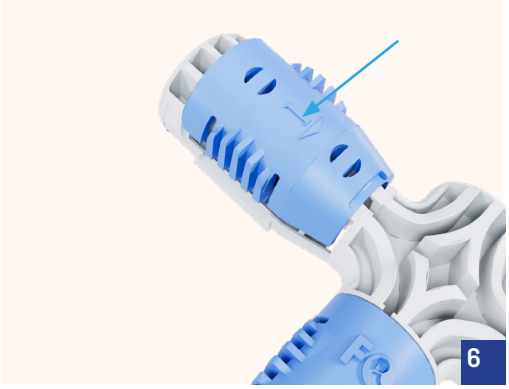
Insert Index Anchor

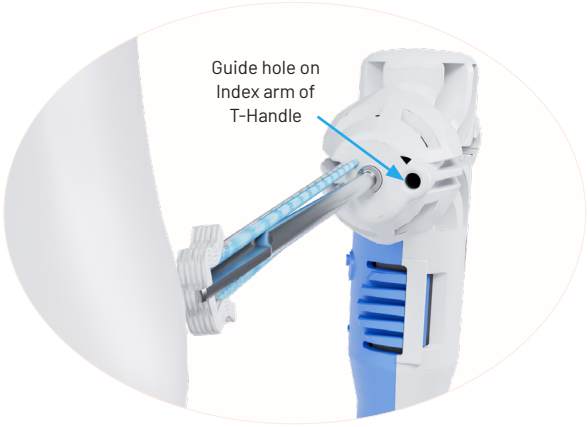
Remove the T-Handle from the kit, inspecting it to ensure that the anchors are located in the inserter tips on both the Index and Thumb arms.

TIP: The Index arm of the T-Handle is clearly identified by an "I" for "Index" on the Blue Clip.

The Index arm is pre-loaded with double suture inclusive of both blue and white suture lines connected to the anchor.

Slide the 1.6mm Guide K-wire (Item 3 in the Griplasty™ System - Base of Thumb with Needles Kit) into the guide hole on the Index arm of the T-Handle. Simultaneously align the Anchor Holder into the pilot hole created in previous steps.





Note: Ensure correct positioning of the T-Handle ensuring that the correct Anchor Holder (Index) is placed into the pilot trajectory hole. It is very important that the Index and Thumb arms do not get used out of sequence. **DO NOT USE THE THUMB ANCHOR HOLDER TIP AT THIS STEP.**

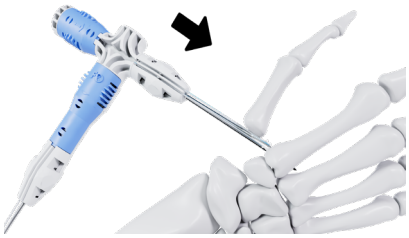


Figure 2 (a): correct position

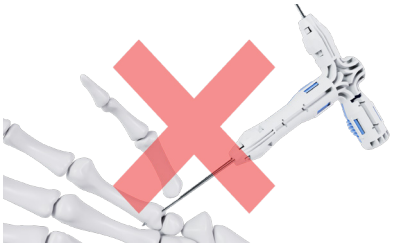


Figure 2 (b): incorrect position

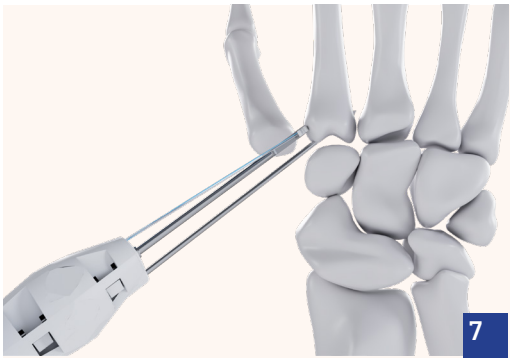
Figure 2 displays the **(a)** correct and **(b)** incorrect positioning.

TIP: Care must be taken to ensure that the anchor trajectory follows the trajectory of the pilot hole. Use soft taps of a small mallet on the T-handle insertion device to gently advance the anchor, minimizing misguiding its direction. If stronger strikes are required, grasp the handle around the Blue Clip proximal to the mallet to keep it secured. NOTE: DO NOT USE EXCESSIVE FORCE WHEN USING THE MALLET, AS THIS MAY LEAD TO DAMAGE OF THE T-HANDLE.

Ensure the Anchor Holder passes through both cortical walls of the index metacarpal.

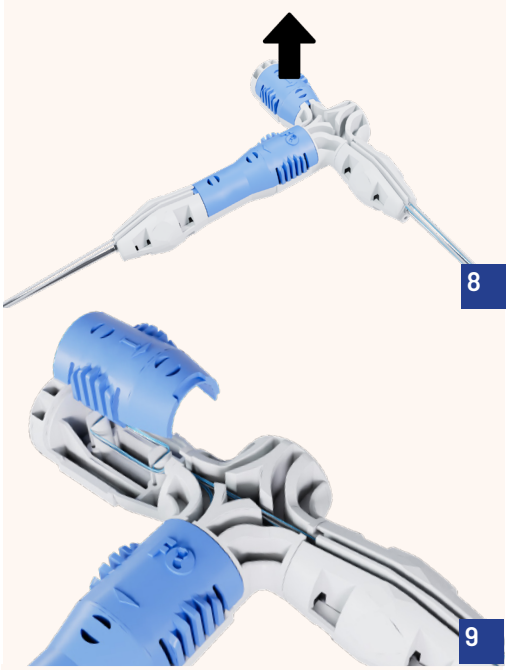
TIP: Full deployment of the anchor requires the inserter to be pushed well past the cortex. This will ensure no tails remain in the pilot hole.

TIP: Pull out strength is maximised when the anchor is deployed on the far cortex.[1,2]



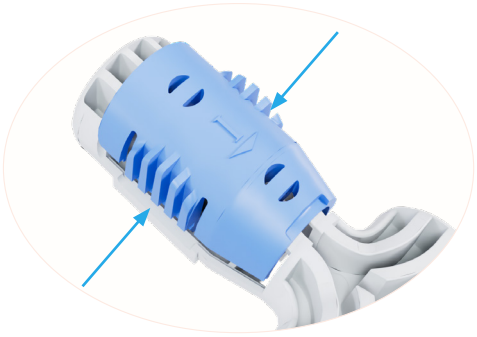
PROCEDURAL TECHNIQUE - DORSAL APPROACH

Seat Index Anchor



Once the anchor has made contact with the far side of the index metacarpal, it is important to ensure it is well seated.

Locate the Blue Clip (BoT Inserter Cover Rear Short) on the Index arm of the T-Handle. This was referenced earlier and identified by a clearly marked "I".

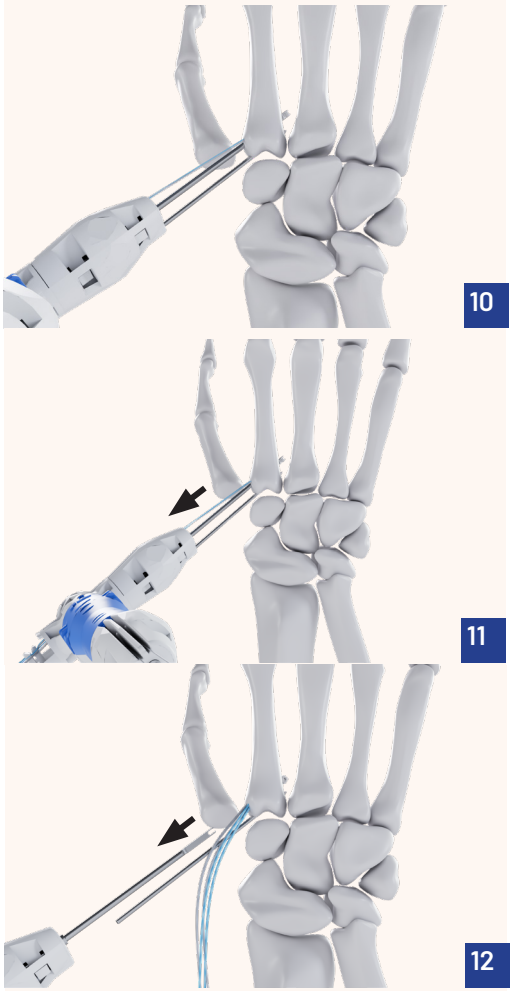


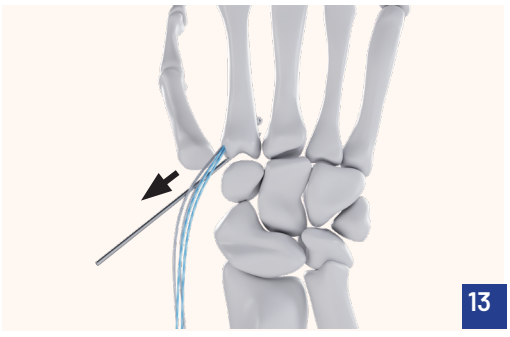
Remove the Blue Clip by pinching and squeezing the grip marks - see Illustrations 8 and 9. This will reveal the suture pre-loaded in the T-Handle. Loosen and remove the suture from the posts of the T-Handle.

Pull the T-Handle back, leaving the anchor on the far cortex of the index metacarpal. See Illustrations 11 and 12. Complete the deployment of the anchor by gently pulling back and forth on the two strands to alternately tension, or piston, the suture strands. This will help toggle the anchor into place and further secure and seat it to the bone.

Test the pullout strength of the anchor by pulling on all four strands of the suture material gently, but firmly.

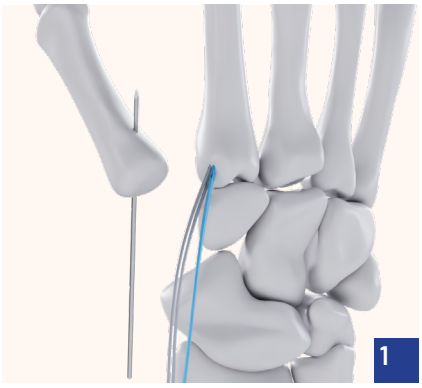
Remove and discard the 1.6mm Guide K-wire. See Illustration 13.





PROCEDURAL TECHNIQUE - DORSAL APPROACH

Thumb Anchor Implantation



Using the same incision created during soft tissue dissection prior to the trapeziectomy, expose the base of the thumb metacarpal to access the articular surface. With the hand in a neutral position, axial traction, palmar abduction, and extension can be applied at the base of the first metacarpal. This will assist with reducing and maintaining the metacarpal in an anatomical position.

Step 1: Trajectory K-wire

Locate the second 1.2mm Trajectory K-wire (Item 1) in the Griplasty™ System - Base of Thumb with Needles Kit. The purpose of this K-wire is to set trajectory, facilitate engagement of the far cortex across the base of thumb metacarpal, and determine the position of final thumb anchor placement.

Position the Trajectory K-wire on the most palmar aspect of the radial side of the thumb metacarpal base.

TIP: Ensure the K-wire is placed at a maximal distance from the APL tendon insertion.

TIP: The site of insertion should ensure a divergent construct base with APL as this will define the positioning of the Griplasty™ V-Sling.

Once the K-wire is positioned, aim obliquely and advance with a recommended trajectory of 45 degrees exiting in the intermetacarpal space.

TIP: Confirm the trajectory under fluoroscopy while advancing the K-wire. Using oscillation can maximise control of the K-wire.

Ensure both cortices are penetrated as bi-cortical engagement of the anchor must be achieved.

Step 2: Position Parallel Guide Assembly

A Guide K-wire must be inserted next. First, assemble the Parallel Guide Assembly (Item 2) by sliding the K-wire Guide Sleeve (left Figure 3a) into the Parallel Wire Guide (right Figure 3a) - see Figure 3.

TIP: The 1.2mm Trajectory K-wire must be inserted into the hole in the K-wire Guide Sleeve and not directly into the hole in the Parallel Wire Guide. Note that the shortest leading tip of the Parallel Guide Assembly is the correct pilot hole.

Figure 3: (a) K-wire Guide Sleeve (left) and Parallel Wire Guide (right)
(b) Parallel Guide Assembly

Slide the assembly over the 1.2mm Trajectory K-wire (Item 1) from the previous step, ensuring anatomical guiding on the leading end of the Parallel Wire Guide seats on the proximal base of the thumb metacarpal.

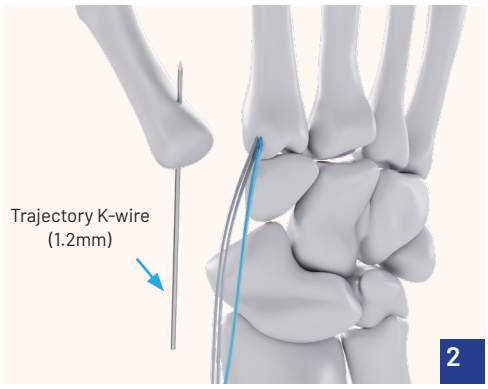
PROCEDURAL TECHNIQUE - DORSAL APPROACH

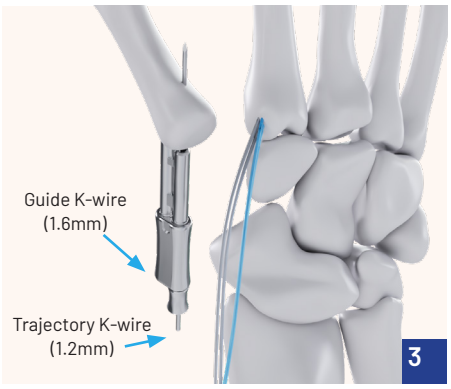
Step 3: Guide K-wire Insertion

Insert the second 1.6mm Guide K-wire (Item 3 in the Griplasty™ System - Base of Thumb with Needles Kit) into the empty tunnel in the Parallel Wire Guide. Advance the K-wire and ensure both cortices are penetrated. Again, fluoroscopy may be used to confirm suitable placement.

TIP: It is important that the Guide K-wire is inserted into solid bone. Entering at a shallow angle is not encouraged as this can cause the Guide K-wire to skive.

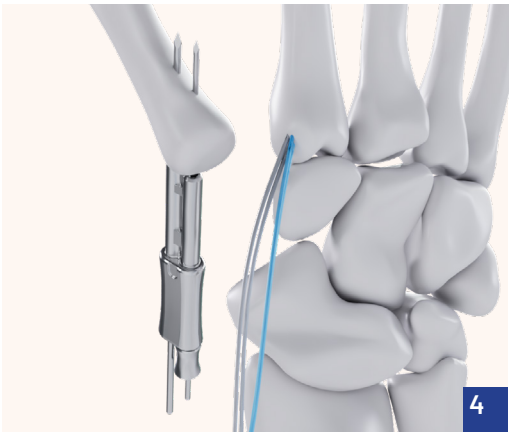
Remove the K-wire Guide Sleeve (Item 2 - left Figure 3a) . Leave the Parallel Wire Guide in situ (Item 2 - right Figure 3a).

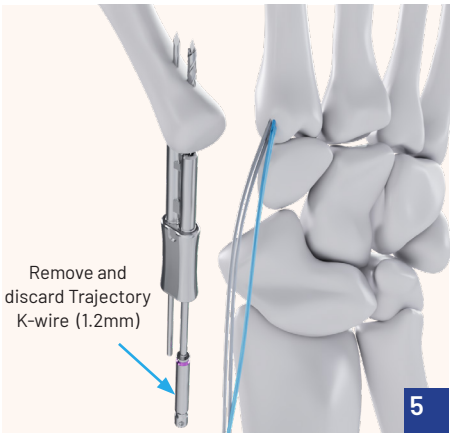




Step 4: Drill Bi-cortically

Place the 2.4mm Cannulated Drill Bit (Item 4) in Griplasty™ System - Base of Thumb with Needles over the 1.2mm Trajectory K-wire (Item 1) where the K-wire Guide Sleeve was situated and drill bi-cortically. Remove the Cannulated Drill Bit (Item 4), Parallel Wire Guide (Item 2 - right Figure 3a) and the 1.2mm Trajectory K-wire (Item 1). Ensure the 1.6mm Guide K-wire (Item 3) remains in the thumb metacarpal.



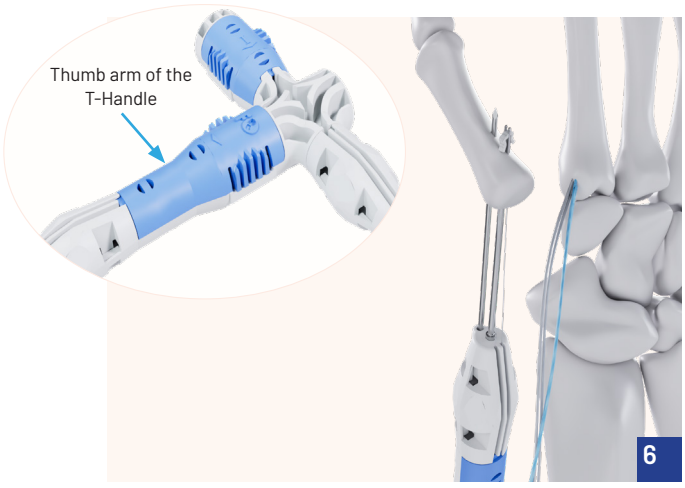


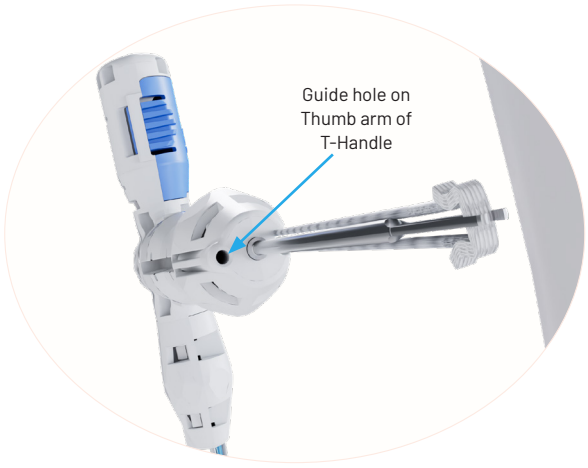
PROCEDURAL TECHNIQUE - DORSAL APPROACH

Implant Thumb Anchor

Identify the Thumb arm of the T-Handle. The Anchor Holder is pre-loaded with double suture inclusive of both blue and white suture lines connected to the anchor. Slide the 1.6mm Guide K-wire into the guide hole on the Thumb arm of the T-Handle. Simultaneously align the Anchor Holder into the pre-drilled trajectory pilot hole created in previous steps.

TIP: Care must be taken to ensure that the anchor trajectory follows the trajectory of the pilot hole. Use soft taps of a small mallet on the T-handle insertion device to gently advance the anchor, minimizing misguiding its direction. If stronger strikes are required, grasp the handle around the Blue Clip proximal to the mallet to keep it secured. NOTE: DO NOT USE EXCESSIVE FORCE WHEN USING THE MALLET, AS THIS MAY LEAD TO DAMAGE OF THE T-HANDLE.





Ensure the Anchor Holder passes through both cortical walls of the thumb metacarpal. See Illustration 6.

TIP: Full deployment of the anchor requires the inserter to be pushed well past the cortex. This will ensure no tails remain in the pre-drilled pilot hole.

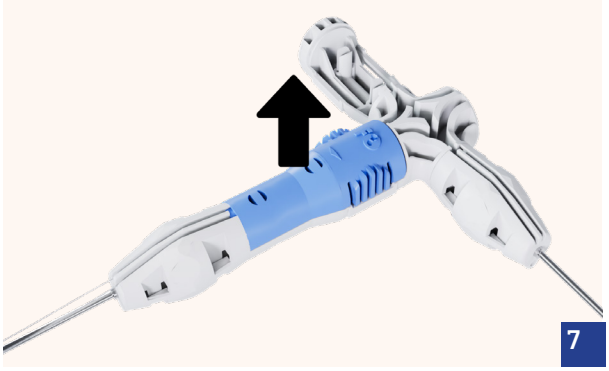
TIP: Pull out strength is maximised when the anchor is deployed on the far cortex.[1,2]

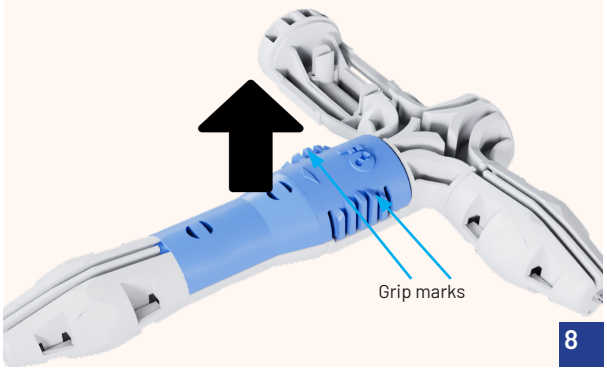
Once the anchor has made contact with the far side of the thumb metacarpal, it is important to ensure it is well seated.

Seat Thumb Anchor

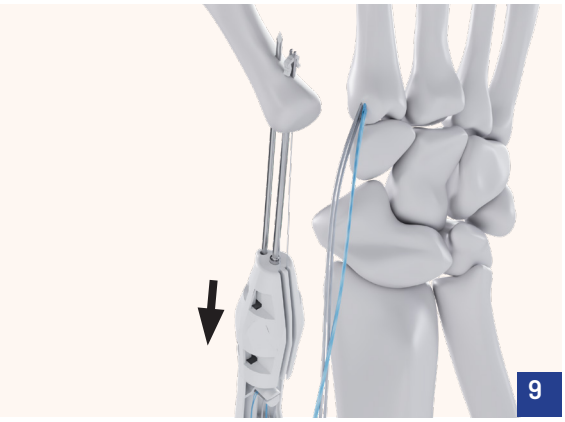
Locate the Blue Clip (BoT Inserter Cover Rear Long) on the Thumb arm of the T-Handle which still has the anchor preloaded on the Anchor Holder.

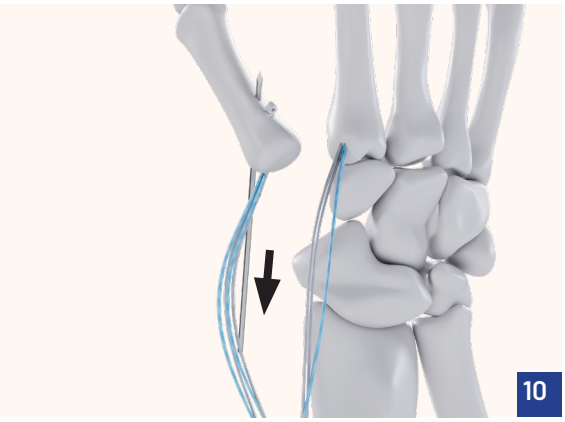
Remove the Blue Clip by pinching and squeezing the grip marks - see Illustrations 7 and 8. This will reveal the suture, V-Sling and two pre-loaded needles in the T-Handle. Loosen and remove the suture and V-sling from the posts of the T-Handle.





PROCEDURAL TECHNIQUE - DORSAL APPROACH





Remove the Inserter and deploy the remaining suture tail by pulling the T-Handle back out, leaving the anchor on the far cortex of the thumb metacarpal. See Illustration 9.

Using the single white suture strand loosened from the post in conjunction with the white suture strand connected to the implanted seat thumb anchor, complete the deployment of the anchor by gently pulling back and forth on the two strands to alternately tension, or piston, the suture strands. This will help toggle the anchor into place and further secure and seat it to the bone.

Test the pullout strength of the anchor by pulling on both strands of the suture material gently, but firmly. Remove and discard the 1.6mm Guide K-wire, see Illustration 10.

Tension and Position the V-Sling

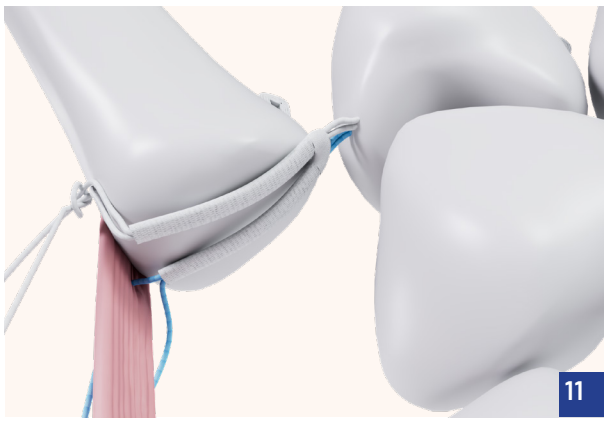
At this stage the V-Sling is free to slide on the suture. Push the apex of the V-Sling towards the base of the index metacarpal leaving the two arms of the sling positioned across the base of the thumb metacarpal. The arms of the V-Sling can be shortened by manually compressing the V-Sling along the length of either both arms, or the individual arm requiring shortening. This manipulation ensures the sling suits the size of the thumb metacarpal base and provides a precise and patient specific match.

TIP: Ensure the apex of the V-Sling is as close as possible to the base of the index metacarpal and the arms of the sling are sufficiently covering the base of the thumb metacarpal.

Tension V-Sling

To tension the V-Sling alternately toggle, or piston, the white suture lines whilst the thumb is distracted. Tension should enable full range of motion with sufficient thumb adduction, thumb abduction and a flat palm. Tie a provisional knot in the suture once adequate tension is achieved.

Do not cut the suture strands until the final surgical steps are completed.



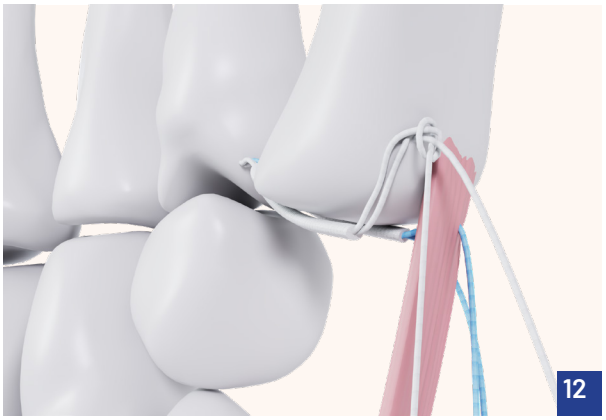
PROCEDURAL TECHNIQUE - DORSAL APPROACH

Involvement of APL

The blue suture line is sutured into the APL insertion using a horizonal mattress technique. At this stage, tie a provisional sliding knot until construct position and tension is confirmed. This suture knot can be secured either ulnar or radial of the APL tendon to create the third anchor point of the Griplasty™ construct.

TIP: Tension in the two arms of the V-Sling can be used to adjust rotation of the thumb metacarpal.

A ballottement test can now be performed to establish the longitudinal stability of the construct. This assessment will assist in avoiding impingement between the first and second while also ensuring the first metacarpal does not cause impingement on the scaphoid, even when axial pressure is applied. This assessment can be performed under live or spot fluoroscopy to visualise the space between the scaphoid and the first metacarpal. An axial load is then applied to the thumb metacarpal to ensure the suspension is adequate. Alternatively pulling and compressing the thumb will allow you to visualise the amount of subsidence present. Tension can be adjusted on the suture suspension as needed. Bring the thumb out to 90 degrees abduction to ensure there has been no overtightening.



TIP: Over tensioning of the V-Sling is not recommended as it may lead to decreased range of motion and possible impingement between the first and second metacarpal bases.

If FCR involvement is required please refer to page 25 prior to close.

Close

Once proper seating of anchors and appropriate tension is confirmed, tie final knots over the provisional knots. This will lock in the position of the construct. Cut off excess suture and the two needles. **Ensure that the 2 x needles, the needle backer card, 4 x K-wires, 1 x Cannulated Drill Bit, 2 x Blue Clips (BoT Inserter Cover Rear Short and BoT Inserter Cover Rear Long), 1 x K-wire Guide Sleeve and 1 x Parallel Wire Guide have been removed and accounted for** and then close the incision as preferred. Post-operative follow up to be prescribed per surgeon preference.

PROCEDURAL TECHNIQUE - VOLAR APPROACH

Preoperative Planning

A comprehensive clinical examination inclusive of history and radiographic investigation will determine the need for surgical intervention. Ensuring all appropriate equipment is available for the procedure is essential.

Patient Positioning

The patient is supine and a tourniquet is applied. Anaesthesia is induced and the patient and table are rotated if required. The limb is prepped and draped. Anatomic landmarks and neurovascular structures at risk must be familiar to the surgeon and identified prior to commencing the procedure. The thumb carpometacarpal joint (CMCJ) is located by palpating on the proximal end of the thumb metacarpal and feeling for the soft spot proximal to the base. Incisions are drawn and the tourniquet is inflated. The hand should be in a neutral position.

Soft Tissue Dissection

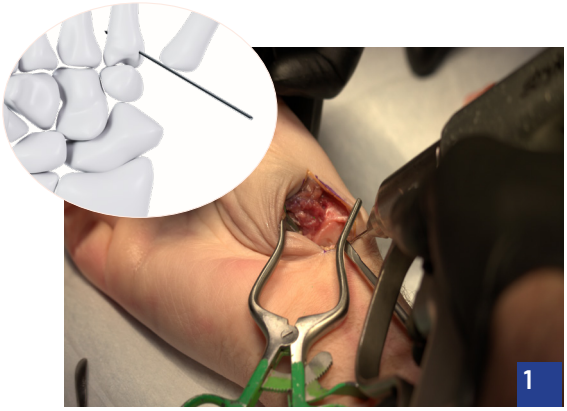
A curved incision at the proximal edge of the basal joint extends to the distal wrist flexion crease. The thenar muscle is retracted on the volar aspect until the carpometacarpal capsule is exposed. The joint capsule is then incised longitudinally and stripped subperiosteally for later preservation. The flexor carpi radialis (FCR) and abductor pollicis longus (APL) tendons are identified and protected.

Trapeziectomy

The capsule is then elevated off the trapezium subperiosteally and an osteotome is used to perform a hemi or full trapeziectomy. Care is required to ensure the FCR tendon on the volar side of the trapezium is identified and protected. A rongeur can be used to remove the trapezium and all loose bodies at the first and second metacarpal base. Thorough inspection to ensure the joint space is clear will assist in preventing impingement and ongoing pain. Remove any osteophytes, free bodies and synovitis.

PROCEDURAL TECHNIQUE - VOLAR APPROACH

Index Anchor Implantation



Open the Sterile Griplasty™ System - Base of Thumb with Needles:

- Sterile product should be inspected before use.
- Devices should only be accepted if the factory packaging and labelling arrive intact.
- Ensure packaging seals are intact and not damaged before opening.

  Do not use if seals or packaging are open, have been prematurely opened or damaged.
- Implant, instruments and packaging are single-use only.
- Do not use past the expiration date indicated on the label.

Step 1: Trajectory K-wire

Locate one of the 1.2mm Trajectory K-wires in the Griplasty™ System - Base of Thumb with Needles Kit (Item 1). The purpose of this K-wire is to facilitate engagement of the far cortex across the base of the index metacarpal and determine the position of final index anchor placement. Start by positioning the Trajectory K-wire on the radial aspect of the base of the index metacarpal.

TIP: A distal insertion point will assist in achieving a greater surface area of support with the Griplasty™ V-Sling.

Once the K-wire is positioned, aim obliquely and advance with a recommended trajectory for exit in the mid-coronal section of the second intermetacarpal space.

TIP: Confirm the trajectory under fluoroscopy while advancing the K-wire. Using oscillation can maximise control of the K-wire.

TIP: Deployment of the anchor dorsal to the coronal midline may impinge or irritate soft tissue.

Ensure both cortices are penetrated as far cortex engagement of the anchor is recommended.

Step 2: Position Parallel Guide Assembly

A Guide K-wire must be inserted next. First, assemble the Parallel Guide Assembly by placing the K-wire Guide Sleeve into the Parallel Wire Guide (Figure 1). The K-wire Guide Sleeve and Parallel Wire Guide are labelled 2 in the Griplasty™ System - Base of Thumb with Needles Kit.

Slide the Parallel Guide Assembly over the 1.2mm Trajectory K-wire ensuring the leading end of the Parallel Wire Guide is seated on the base of the index metacarpal. It is important in the next step (Step 3) that the 1.6mm Guide K-wire engages with solid bone and does not skive. If the K-wire skives there is risk the wires may not be parallel.

TIP: The 1.2mm Trajectory K-wire must be inserted into the hole in the K-wire Guide Sleeve and not directly into the hole in the Parallel Wire Guide. Note that the shortest leading tip of the Parallel Guide Assembly is the correct pilot hole.

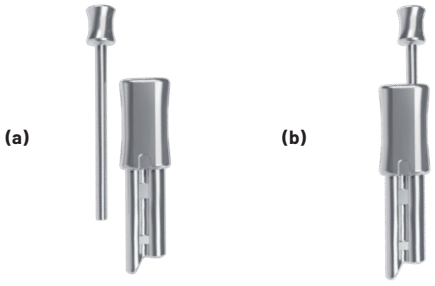
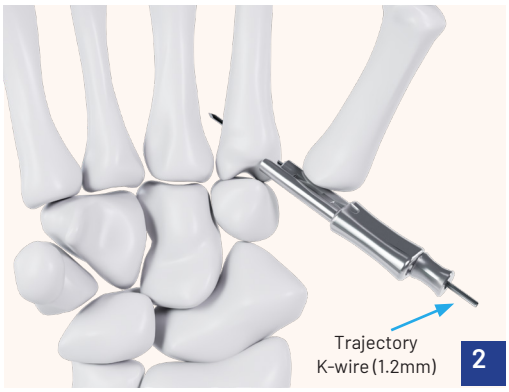


Figure 1: (a) K-wire Guide Sleeve (left) and Parallel Wire Guide (right) **(b)** Parallel Guide Assembly.



PROCEDURAL TECHNIQUE - VOLAR APPROACH

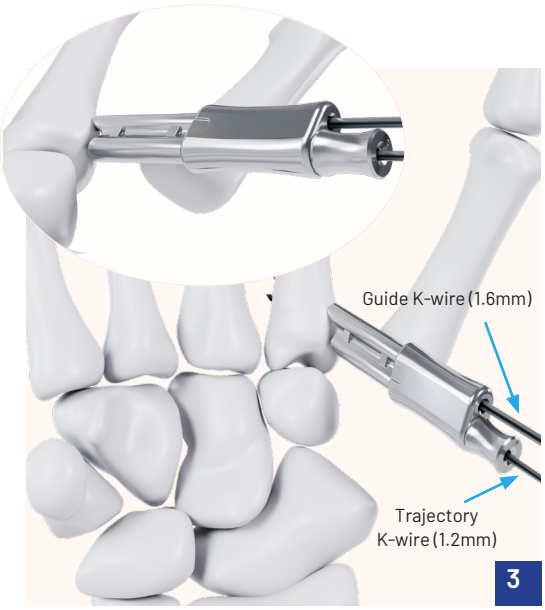
Step 3: Guide K-wire Insertion

Insert one of the 1.6mm Guide K-wires (Item 3 in the Griplasty™ System - Base of Thumb with Needles Kit) into the empty tunnel in the Parallel Wire Guide. Advance the K-wire and ensure both cortices are penetrated. Again, fluoroscopy may be used to confirm suitable placement.

TIP: It is important that the Guide K-wire is inserted into solid bone. Entering at a shallow angle is not encouraged as this can cause the Guide K-wire to skive.

TIP: Insert the Guide K-wire in a position which will allow suitable orientation of the T-Handle during anchor insertion.

Remove the K-wire Guide Sleeve (see Figure 1a) and retain for future steps. **NOTE: DO NOT DISCARD** the K-wire Guide sleeve at this step. Leave the Parallel Wire Guide in-situ.



Step 4: Drill Bi-cortically

Place the 2.4mm Cannulated Drill Bit (Item 4) over the 1.2mm Trajectory K-wire (Item 1) where the K-wire Guide Sleeve was situated and drill bi-cortically. Remove the Cannulated Drill Bit (Item 4) and retain for future steps.

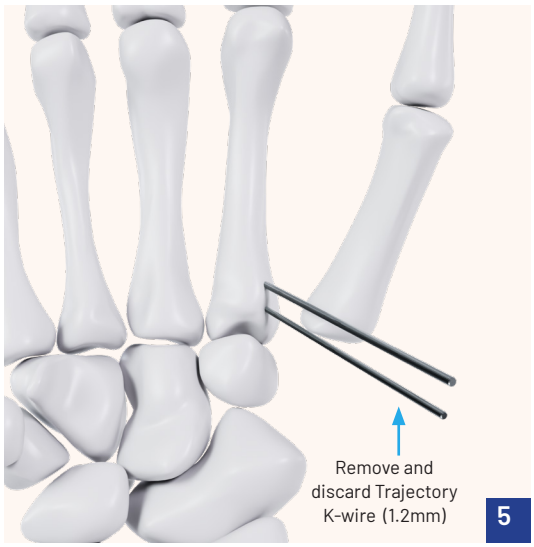
NOTE: DO NOT DISCARD the Cannulated Drill Bit (Item 4).

Remove the Parallel Wire Guide (Item 2 - right Figure 1a) by sliding it off the K-wires and retain for future steps.

NOTE: DO NOT DISCARD the Parallel Wire Guide (Item 2 - right Figure 1a).

Step 5: Remove Trajectory K-wire

Ensure that the 1.6mm Guide K-wire (Item 3) remains in the index metacarpal then remove and discard the 1.2mm Trajectory K-wire (Item 1).



PROCEDURAL TECHNIQUE - VOLAR APPROACH

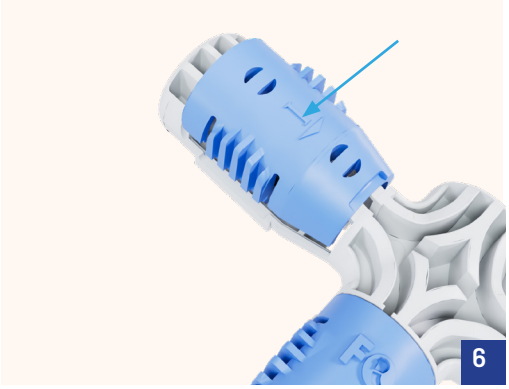
Insert Index Anchor

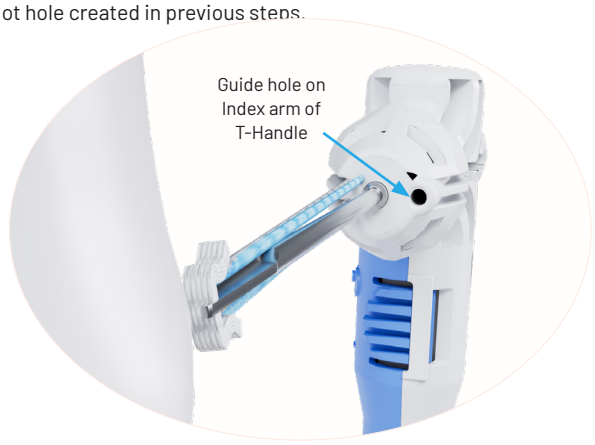
Remove the T-Handle from the kit, inspecting it to ensure that the anchors are located in the inserter tips on both the Index and Thumb arms.

TIP: The Index arm of the T-Handle is clearly identified by an "I" for "Index" on the Blue Clip.

The Index arm is pre-loaded with double suture inclusive of both blue and white suture lines connected to the anchor.

Slide the 1.6mm Guide K-wire (Item 3 in the Griplasty™ System - Base of Thumb with Needles Kit) into the guide hole on the Index arm of the T-Handle. Simultaneously align the Anchor Holder into the pilot hole created in previous steps.





Note: Ensure correct positioning of the T-Handle ensuring that the correct Anchor Holder (Index) is placed into the pilot trajectory hole. It is very important that the Index and Thumb arms do not get used out of sequence. **DO NOT USE THE THUMB ANCHOR HOLDER TIP AT THIS STEP.**

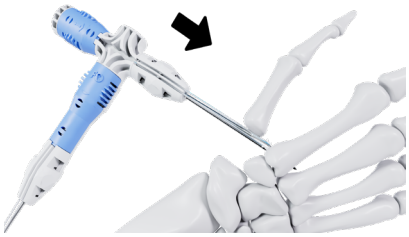


Figure 2 (a): correct position

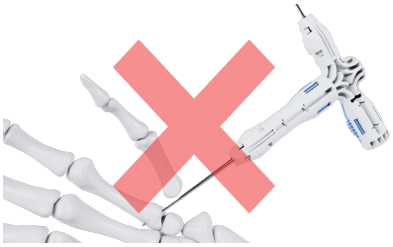


Figure 2 (b): incorrect position

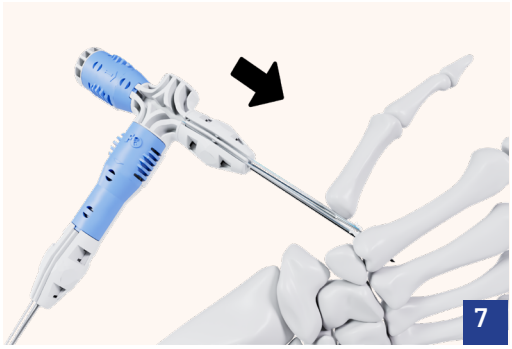
Figure 2 displays the **(a)** correct and **(b)** incorrect positioning.

TIP: Care must be taken to ensure that the anchor trajectory follows the trajectory of the pilot hole. Use soft taps of a small mallet on the T-handle insertion device to gently advance the anchor, minimizing misguiding its direction. If stronger strikes are required, grasp the handle around the Blue Clip proximal to the mallet to keep it secured. NOTE: DO NOT USE EXCESSIVE FORCE WHEN USING THE MALLET, AS THIS MAY LEAD TO DAMAGE OF THE T-HANDLE.

Ensure the Anchor Holder passes through both cortical walls of the index metacarpal.

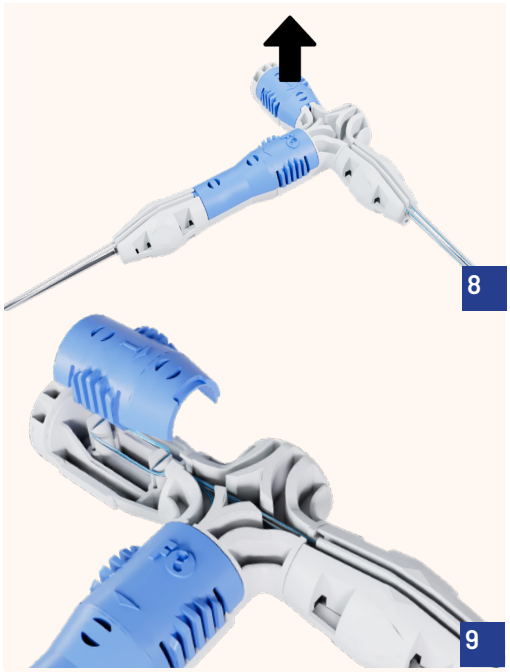
TIP: Full deployment of the anchor requires the inserter to be pushed well past the cortex. This will ensure no tails remain in the pilot hole.

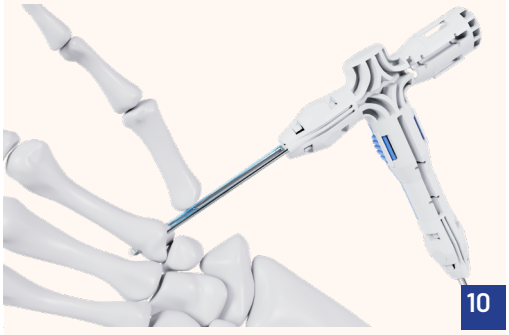
TIP: Pull out strength is maximised when the anchor is deployed on the far cortex.[1,2]

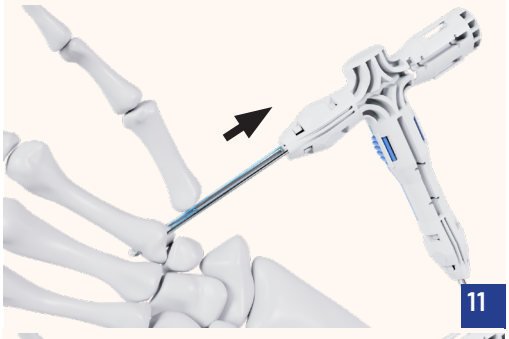


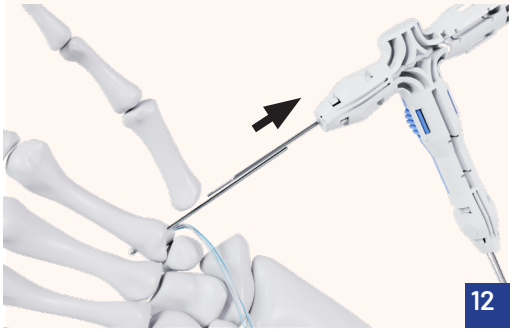
PROCEDURAL TECHNIQUE - VOLAR APPROACH

Seat Index Anchor



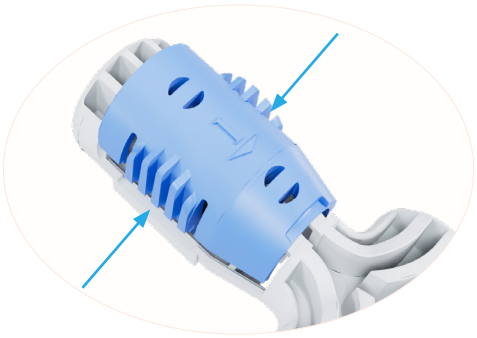






Once the anchor has made contact with the far side of the index metacarpal, it is important to ensure it is well seated.

Locate the Blue Clip (BoT Inserter Cover Rear Short) on the Index arm of the T-Handle. This was referenced earlier and identified by a clearly marked "I".

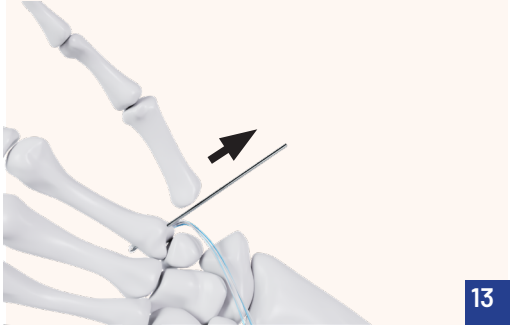


Remove the Blue Clip by pinching and squeezing the grip marks - see Illustrations 8 and 9. This will reveal the suture pre-loaded in the T-Handle. Loosen and remove the suture from the posts of the T-Handle.

Pull the T-Handle back, leaving the anchor on the far cortex of the index metacarpal. See Illustrations 11 and 12. Complete the deployment of the anchor by gently pulling back and forth on the two strands to alternately tension, or piston, the suture strands. This will help toggle the anchor into place and further secure and seat it to the bone.

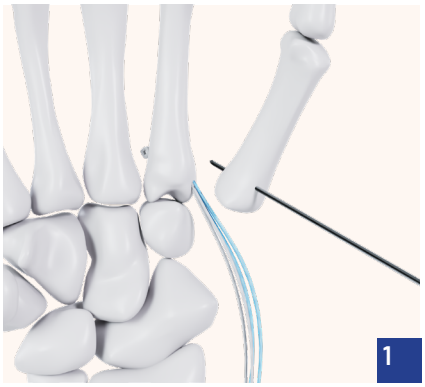
Test the pullout strength of the anchor by pulling on all four strands of the suture material gently, but firmly.

Remove and discard the 1.6mm Guide K-wire. See Illustration 13.



PROCEDURAL TECHNIQUE - VOLAR APPROACH

Thumb Anchor Implantation



Using the same incision created during soft tissue dissection prior to the trapeziectomy, expose the base of the thumb metacarpal to access the articular surface. With the hand in a neutral position, axial traction, palmar abduction and extension can be applied at the base of the first metacarpal. This will assist with reducing and maintaining the metacarpal in an anatomical position.

Step 1: Trajectory K-wire

Locate the second 1.2mm Trajectory K-wire (Item 1) in the Griplasty™ System - Base of Thumb with Needles Kit. The purpose of this K-wire is to set trajectory and facilitate engagement of the far cortex across the base of thumb metacarpal and determine the position of final thumb anchor placement.

Position the Trajectory K-wire on the most palmar aspect of the radial side of the thumb metacarpal base.

TIP: Ensure the K-wire is placed at a maximal distance from the APL tendon insertion.

TIP: The site of insertion should ensure a divergent construct base with APL as this will define the positioning of the Griplasty™ V-Sling.

Once the K-wire is positioned, aim obliquely and advance with a recommended trajectory of 45 degrees exiting in the intermetacarpal space.

TIP: Confirm the trajectory under fluoroscopy while advancing the K-wire. Using oscillation can maximise control of the K-wire.

Ensure both cortices are penetrated as bi-cortical engagement of the anchor must be achieved.

Step 2: Position Parallel Guide Assembly

A Guide K-wire must be inserted next. First, assemble the Parallel Guide Assembly (Item 2) by sliding the K-wire Guide Sleeve (left Figure 3a) into the Parallel Wire Guide (right Figure 3a) - see Figure 3.

TIP: The 1.2mm Trajectory K-wire must be inserted into the hole in the K-wire Guide Sleeve and not directly into the hole in the Parallel Wire Guide. Note that the shortest leading tip of the Parallel Guide Assembly is the correct pilot hole.

Figure 3: (a) K-wire Guide Sleeve (left) and Parallel Wire Guide (right)
(b) Parallel Guide Assembly

Slide the assembly over the 1.2mm Trajectory K-wire (Item 1) from the previous step, ensuring anatomical guiding on the leading end of the Parallel Wire Guide seats on the proximal base of the thumb metacarpal, as per the diagram.

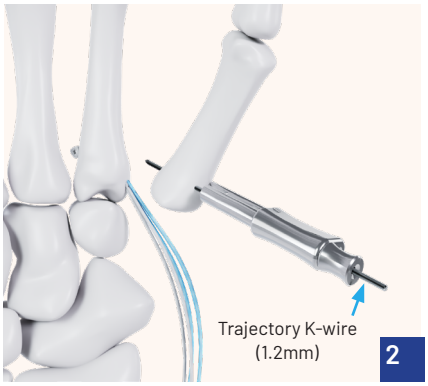
PROCEDURAL TECHNIQUE - VOLAR APPROACH

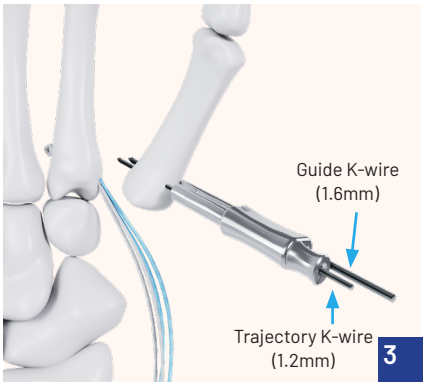
Step 3: Guide K-wire Insertion

Insert the second 1.6mm Guide K-wire (Item 3 in the Griplasty™ System - Base of Thumb with Needles Kit) into the empty tunnel in the Parallel Wire Guide. Advance the K-wire and ensure both cortices are penetrated. See Illustration 3. Again, fluoroscopy may be used to confirm suitable placement.

TIP: It is important that the Guide K-wire is inserted into solid bone. Entering at a shallow angle is not encouraged as this can cause the Guide K-wire to skive.

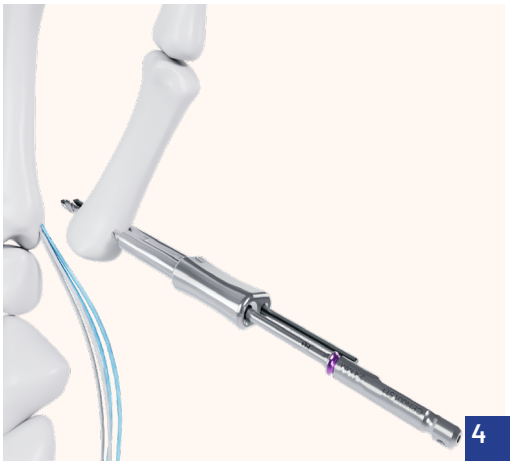
Remove the K-wire Guide Sleeve (Item 2 - left Figure 3a) . Leave the Parallel Wire Guide in situ (Item 2 - right Figure 3a).

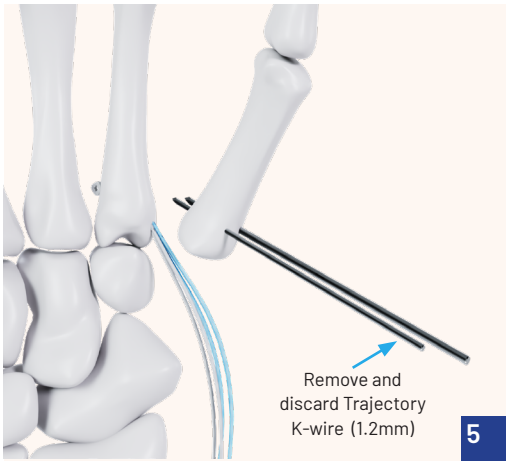




Step 4: Drill Bi-cortically

Place the 2.4mm Cannulated Drill Bit (Item 4) in Griplasty™ System - Base of Thumb with Needles Kit) over the 1.2mm Trajectory K-wire (Item 1) where the K-wire Guide Sleeve was situated and drill bi-cortically. Remove the Cannulated Drill Bit (Item 4), Parallel Wire Guide (Item 2 - right Figure 3a) and the 1.2mm Trajectory K-wire (Item 1). Ensure the 1.6mm Guide K-wire (Item 3) remains in the thumb metacarpal.



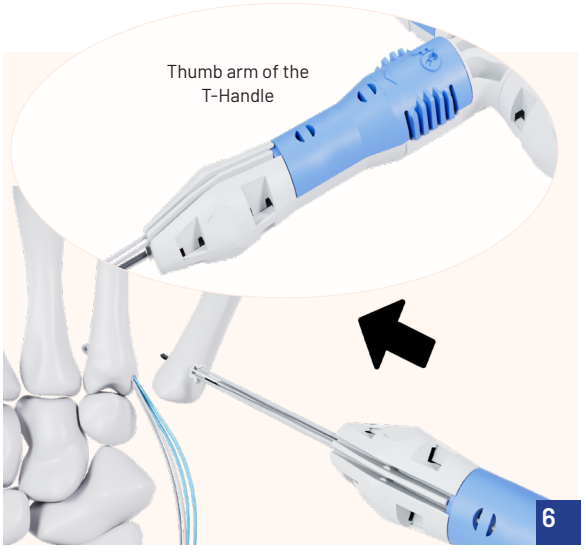


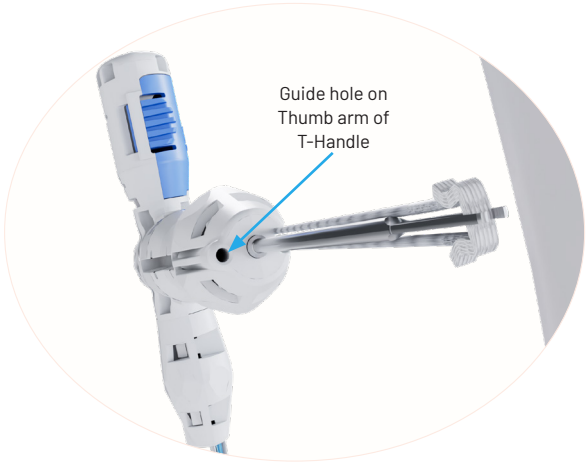
PROCEDURAL TECHNIQUE - VOLAR APPROACH

Implant Thumb Anchor

Identify the Thumb arm of the T-Handle. The Anchor Holder is pre-loaded with double suture inclusive of both blue and white suture lines connected to the anchor. Slide the 1.6mm Guide K-wire into the guide hole on the Thumb arm of the T-Handle. Simultaneously align the Anchor Holder into the pre-drilled trajectory pilot hole created in previous steps.

TIP: Care must be taken to ensure that the anchor trajectory follows the trajectory of the pilot hole. Use soft taps of a small mallet on the T-handle insertion device to gently advance the anchor, minimizing misguiding its direction. If stronger strikes are required, grasp the handle around the Blue Clip proximal to the mallet to keep it secured. NOTE: DO NOT USE EXCESSIVE FORCE WHEN USING THE MALLET, AS THIS MAY LEAD TO DAMAGE OF THE T-HANDLE.





Ensure the Anchor Holder passes through both cortical walls of the thumb metacarpal. See Illustration 6.

TIP: Full deployment of the anchor requires the inserter to be pushed well past the cortex. This will ensure no tails remain in the pre-drilled pilot hole.

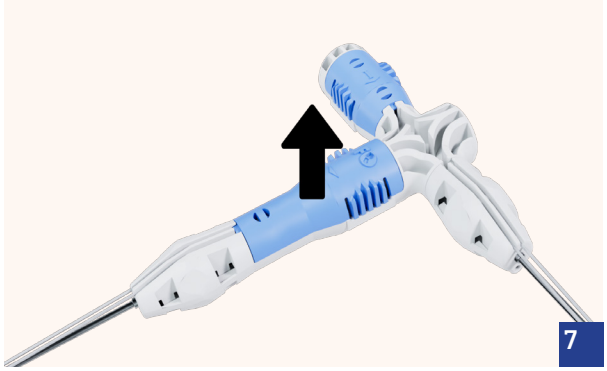
TIP: Pull out strength is maximised when the anchor is deployed on the far cortex.[1,2]

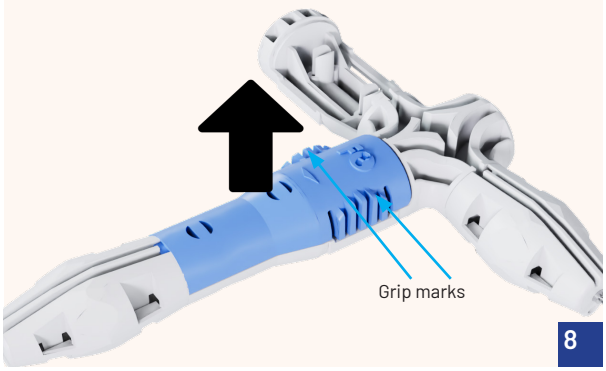
Once the anchor has made contact with the far side of the thumb metacarpal, it is important to ensure it is well seated.

Seat Thumb Anchor

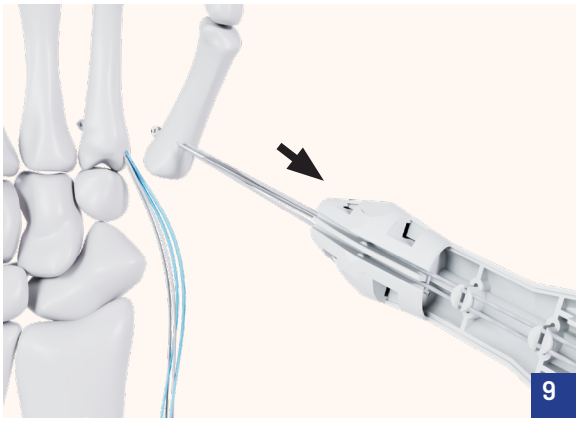
Locate the Blue Clip (BoT Inserter Cover Rear Long) on the Thumb arm of the T-Handle which still has the anchor preloaded on the Anchor Holder.

Remove the Blue Clip by pinching and squeezing the grip marks - see Illustrations 7 and 8. This will reveal the suture, V-Sling and two pre-loaded needles in the T-Handle. Loosen and remove the suture and V-sling from the posts of the T-Handle.





PROCEDURAL TECHNIQUE - VOLAR APPROACH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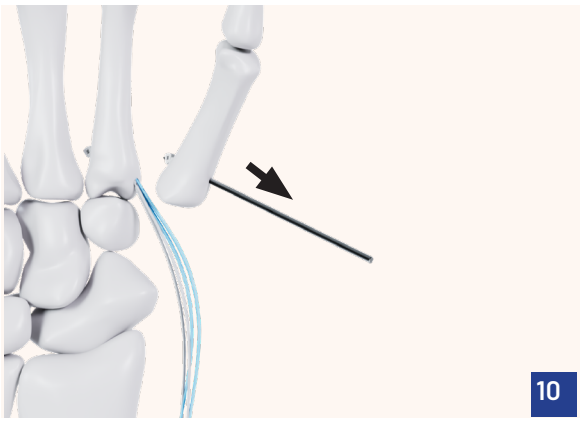

10

Remove the Inserter and deploy the remaining suture tail by pulling the T-Handle back out, leaving the anchor on the far cortex of the thumb metacarpal. See Illustration 9.

Using the single white suture strand loosened from the post in conjunction with the white suture strand connected to the implanted seat thumb anchor, complete the deployment of the anchor by gently pulling back and forth on the two strands to alternately tension, or piston, the suture strands. This will help toggle the anchor into place and further secure and seat it to the bone.

Test the pullout strength of the anchor by pulling on both strands of the suture material gently, but firmly. Remove and discard the 1.6mm Guide K-wire. See Illustration 10.

Tension and Position the V-Sling

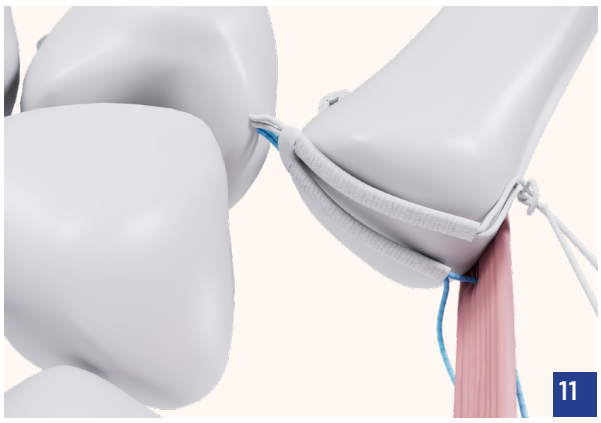
At this stage the V-Sling is free to slide on the suture. Push the apex of the V-Sling towards the base of the index metacarpal leaving the two arms of the sling positioned across the base of the thumb metacarpal. The arms of the V-Sling can be shortened by manually compressing the V-Sling along the length of either both arms, or the individual arm requiring shortening. This manipulation ensures the sling suits the size of the thumb metacarpal base and provides a precise and patient specific match.

TIP: Ensure the apex of the V-Sling is as close as possible to the base of the index metacarpal and the arms of the sling are sufficiently covering the base of the thumb metacarpal.

Tension V-Sling

To tension the V-Sling alternately toggle, or piston, the white suture lines whilst the thumb is distracted. Tension should enable full range of motion with sufficient thumb adduction, thumb abduction and a flat palm. Tie a provisional knot in the suture once adequate tension is achieved.

Do not cut the suture strands until the final surgical steps are completed.

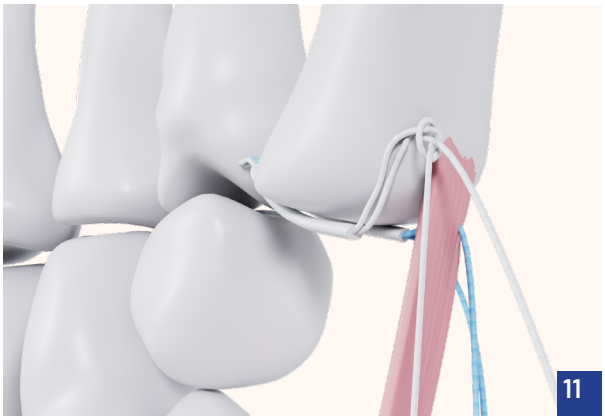

11

Involvement of APL

The blue suture line is sutured into the APL insertion using a horizonal mattress technique. At this stage, tie a provisional sliding knot until construct position and tension is confirmed. This suture knot can be secured either ulnar or radial of the APL tendon to create the third anchor point of the Griplasty™ construct.

TIP: Tension in the two arms of the V-Sling can be used to adjust rotation of the thumb metacarpal.

A ballottement test can now be performed to establish the longitudinal stability of the construct. This assessment will assist in avoiding impingement between the first and second while also ensuring the first metacarpal does not cause impingement on the scaphoid, even when axial pressure is applied. This assessment can be performed under live or spot fluoroscopy to visualise the space between the scaphoid and the first metacarpal. An axial load is then applied to the thumb metacarpal to ensure the suspension is adequate. Alternatively pulling and compressing the thumb will allow you to visualise the amount of subsidence present. Tension can be adjusted on the suture suspension as needed. Bring the thumb out to 90 degrees abduction to ensure there has been no overtightening.



TIP: Over tensioning of the V-Sling is not recommended as it may lead to decreased range of motion and possible impingement between the first and second metacarpal bases.

If FCR involvement is required please refer to page 25 prior to close.

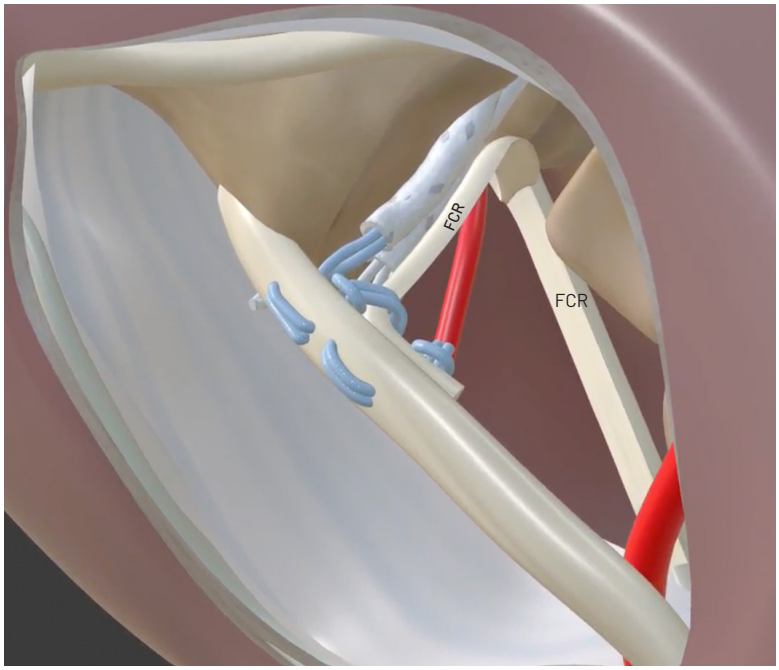
Close

Once proper seating of anchors and appropriate tension is confirmed, tie final knots over the provisional knots. This will lock in the position of the construct. Cut off excess suture and the two needles. **Ensure that the 2 x needles, the needle backer card, 4 x K-wires, 1 x Cannulated Drill Bit, 2 x Blue Clips (BoT Inserter Cover Rear Short and BoT Inserter Cover Rear Long), 1 x K-wire Guide Sleeve and 1 x Parallel Wire Guide have been removed and accounted for** and then close the incision as preferred. Post-operative follow up to be prescribed per surgeon preference.

GRIPLASTY™ SYSTEM - BASE OF THUMB WITH NEEDLES

OPTIONAL STEP: INVOLVEMENT OF FCR

If deemed clinically necessary, tendon transposition of flexor carpi radialis (FCR) is also possible with the Griplasty™ System. A portion of the FCR can be harvested through the trapezial space, thereby eliminating the need for a second incision. Transect the FCR proximally in the trapezial space and dissect longitudinally. FCR interposition can then be performed per clinical preference.

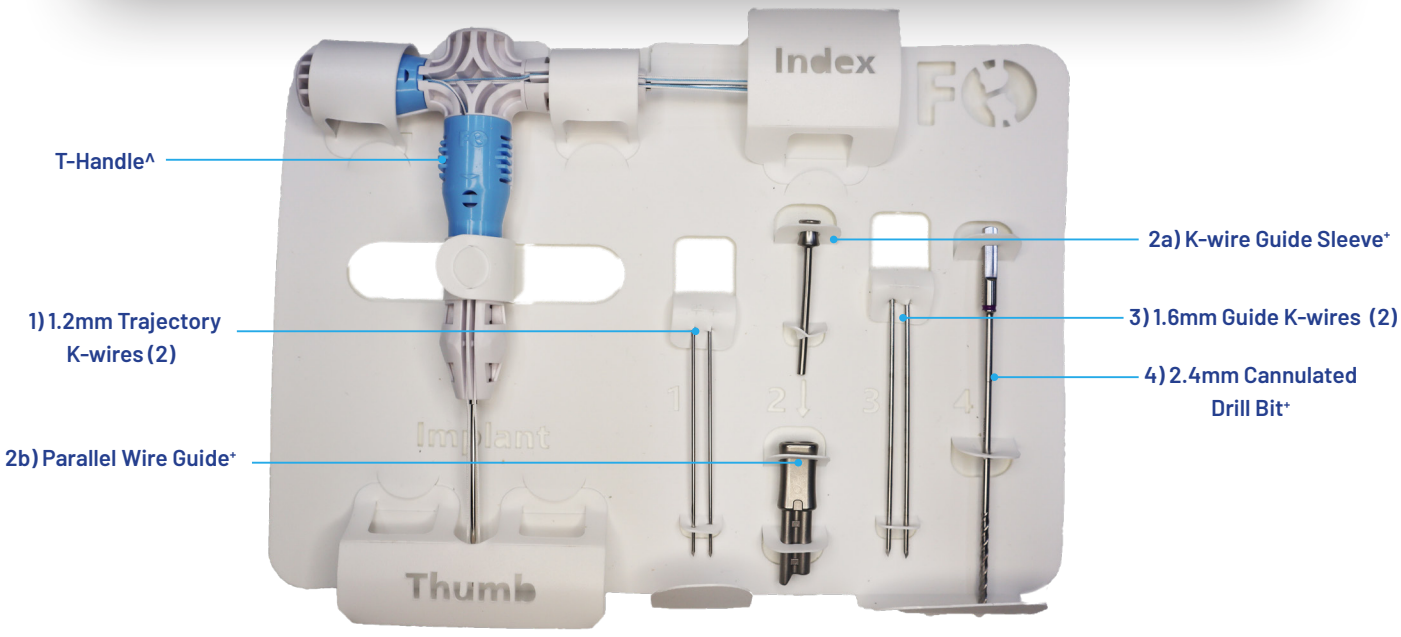


GRIPLASTY™ SYSTEM - BASE OF THUMB WITH NEEDLES

REMOVAL

If removal is required, a small incision over the original incision site can be made to gain access to the anchors and V-Sling construct. The sutures through the anchors can be cut, the anchors removed and the V-Sling construct also removed with forceps or similar instrumentation.

DESCRIPTION			QTY
GPBOTN	T-Handle	Griplasty™ System - Base of Thumb with Needles^	1
		BoT Inserter Cover Rear Short (Blue Clip on Index arm)	1
		BoT Inserter Cover Rear Long (Blue Clip on Thumb arm)	1
		BoT Inserter Body (White)	1
		USP 9 Anchor Holder	2
	1.2 x 2.4 mm K-wire Guide Sleeve		1
	2.4 mm Parallel Wire Guide		1
	1.2 x 80 mm Calibrated Single-Ended Trocar K-wire		2
	1.6 x 100 mm Calibrated Single-Ended Trocar K-wire		2
	2.4 mm Thermally Hardened Cannulated Drill Bit		1



+Items 2 and 4 are reused twice during the procedure.

^T-Handle preloaded with Anchors, Suture, V-Sling, and needle card with Needles (2).

Note: Two separate removable Blue Clips are located on the Index (BoT Inserter Cover Rear Short x 1) and Thumb (BoT Inserter Cover Rear Long x1) arms of the T-Handle. These house the pre-loaded suture, anchors, V-Sling and needle card with Needles (2).

**Patent pending.*

GRIPLASTY™

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FIELD ORTHOPAEDICS

Get in touch with your local sales representative today to discuss how Griplasty™ System - Base of Thumb with needles can meet your CMC suspensionplasty needs.

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