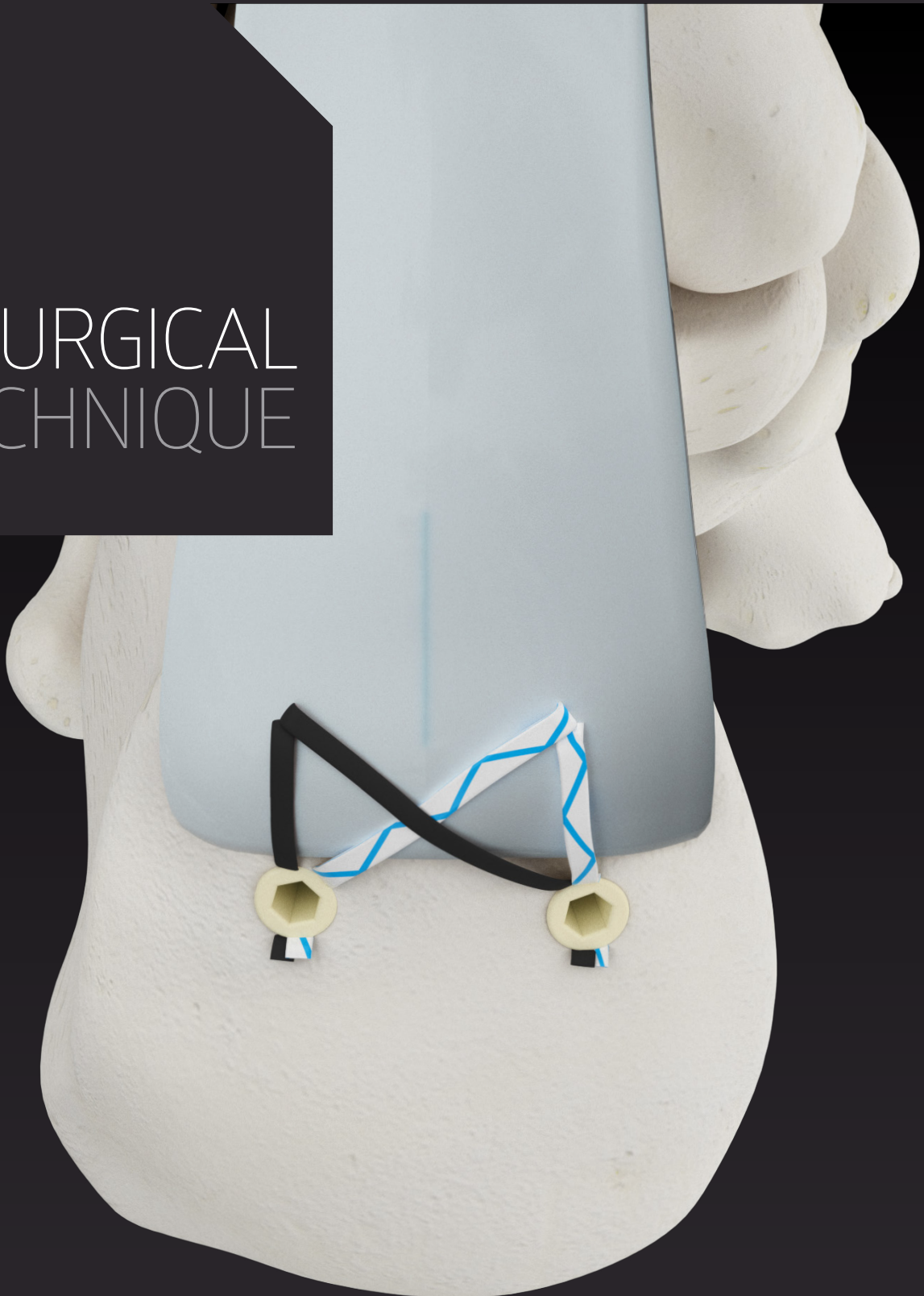




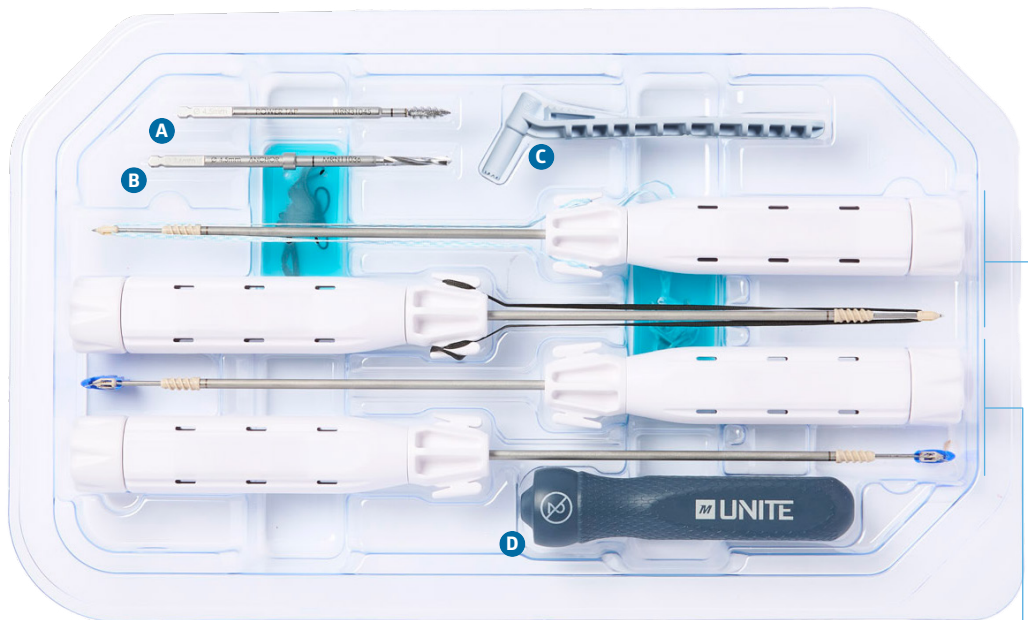
UNITE[®]
FOOT & ANKLE

Insertional Achilles Repair Kits
DEXLOCK[®] KNOTLESS Suture Anchors

SURGICAL TECHNIQUE



Achilles kit contents



Instrumentation

- A** (1) \varnothing 4.5 mm Tap
- B** (1) \varnothing 3.6 mm Drill
- C** (1) Drill Guide
- D** (1) AO/QC Handle

Implants

- (2) \varnothing 4.5 mm Knotless Anchors (Pre-Loaded with 2mm Tape and Needles)
- (2) \varnothing 4.5 mm Knotless Anchors (Unloaded)

DEVICE DESCRIPTION

The DEXLOCK® KNOTLESS Anchor & Delivery Systems are for use in the fixation of soft tissue to bone in the shoulder, elbow, knee, hip, foot, ankle, hand and wrist. These anchors consist of cannulated anchors with integrated suture attachment or separate suture punch eyelet. The anchors are provided loaded on individual inserters with and without integrated sutures, sterile, for single use only. The DEXLOCK® KNOTLESS Suture Anchors are designed to be used by healthcare professionals (surgeons) in accordance with the indications for use in adult patients.

INDICATIONS FOR USE

The DEXLOCK® KNOTLESS Suture Anchors are intended for use in soft tissue to bone fixation in areas such as the shoulder, elbow, knee, hip, wrist, hand, foot, and ankle.

Prior to use of the device, always verify the suitability of the device by verifying that the device is intended to be used according to the indications above and by verifying that the patient does not present any conditions listed in the Contraindications in the IFU.

DEXLOCK[®] KNOTLESS Suture Anchors

Step 1 | Exposure and excision

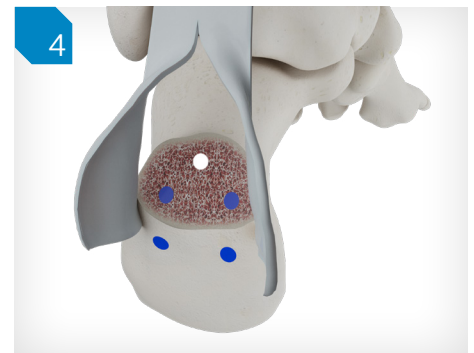
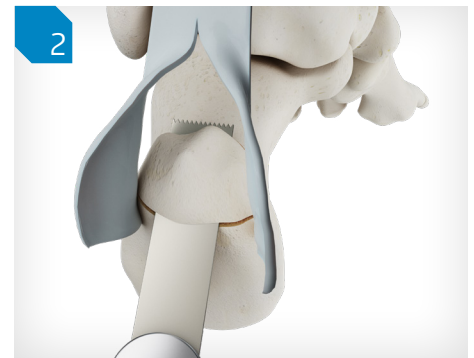
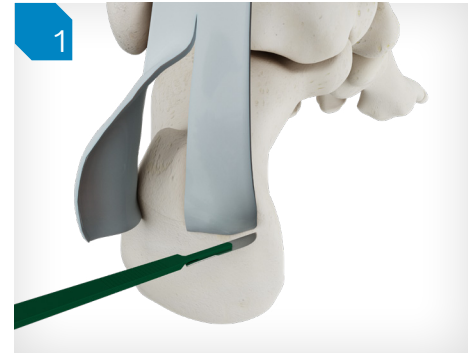
After making an incision, split the Achilles tendon from proximal to distal. Release the Achilles tendon at its insertion point distally to expose the Haglund's prominence (Fig. 1).

Remove the Haglund's prominence using a saw and osteotome or power rasp (Fig. 2).

Step 2 | Anchor placement planning

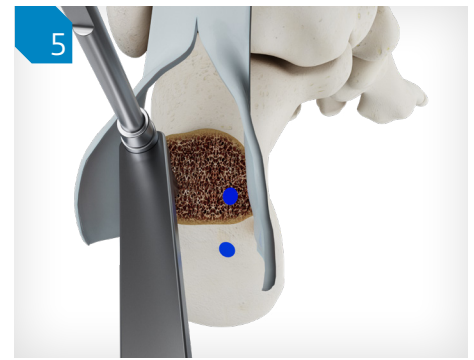
Following exposure and excision of the Haglund's deformity, mark the desired location for each anchor. The proximal row of anchors should be placed 1 cm proximal to the distal aspect of the Achilles insertion (Fig. 3).

Optional: if an FHL tendon transfer is required, position this bone tunnel 1 cm superior and central to the proximal row anchors (Fig. 4).



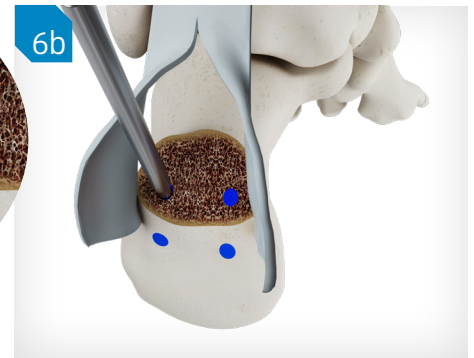
Step 3 | Drill for anchor

Using the Ø3.6 mm drill bit and drill guide, drill until the shoulder stop to prepare the bone for the anchor (Fig. 5).



Step 4 | Tap

Tap until the second laser line (Fig. 6a and 6b).



Step 5 | Insert first proximal anchor eyelet

Insert the pre-loaded anchor eyelet into the pre-drilled hole and gently mallet the inserter handle until the eyelet bottoms out (Fig. 7a and 7b).

Note: if a rip-stop is desired proximally, feed an additional 1.4 mm tape into each of the two proximal row anchors before inserting the eyelet.



Twist the knob clockwise at the proximal end of the inserter until tactile feedback is felt. This will release the anchor and allow for anchor advancement (Fig. 8).



Step 6 | Insert first proximal anchor body

Hold the distal collar of the handle, and twist handle body clockwise to advance the anchor down to the laser line on the driver shaft (Fig. 9).

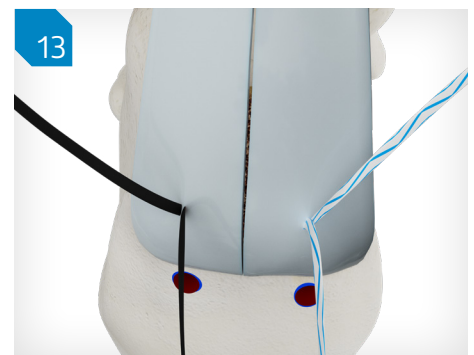
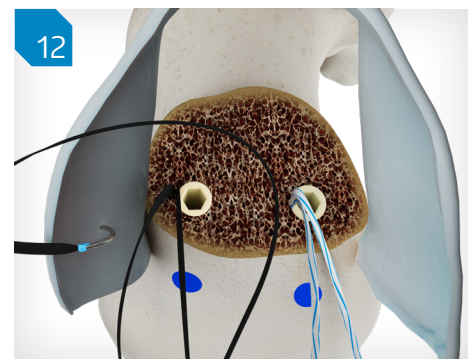
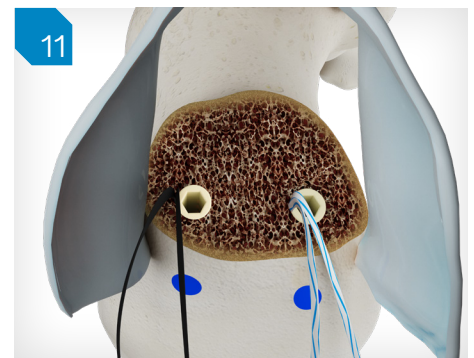
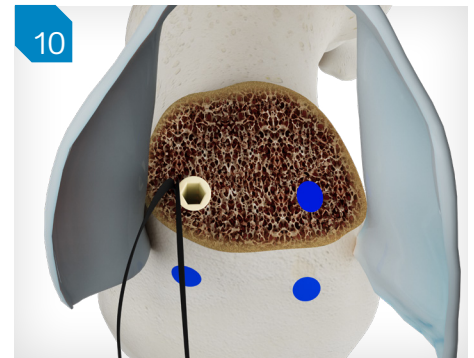
The laser line indicates the anchor body is 2 mm subcortical. Pull straight back on the inserter to release the driver tip from the anchor body (Fig. 10).

Note: a mallet may be needed to backslap the anchor handle to remove the driver in hard bone.

Repeat the steps to place the second proximal anchor (Fig. 11).

Step 7 | Close Achilles

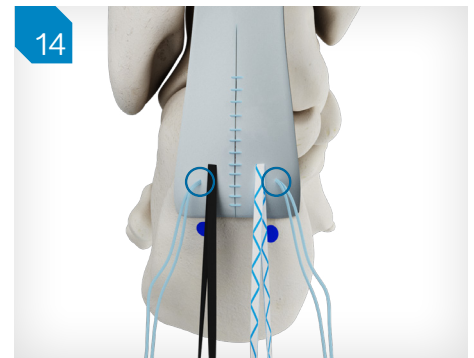
Pass the tape from each anchor through each side of the Achilles tendon (Fig. 12 and 13).



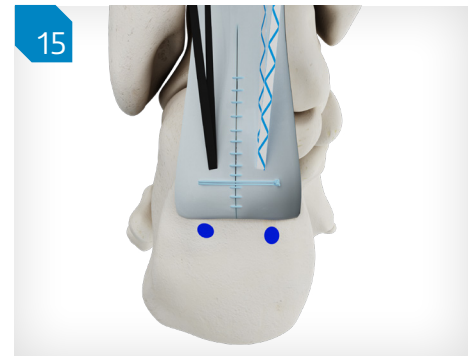
Step 8 | Optional rip-stop

If a rip-stop is desired, make a separate pass into the Achilles tendon distal medial and distal lateral to the already passed proximal tapes (Fig. 14).

Note: a looped whipstitch suture may be used to shuttle the tapes through the Achilles tendon.



Tie the medial sutures to the lateral sutures to create the horizontal rip-stop (Fig. 15).

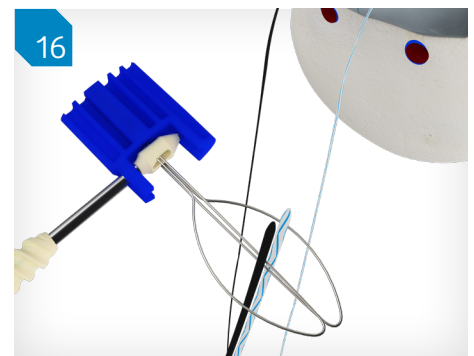


Step 9 | Distal anchor prep

Drill and tap for the distal row of anchors.

Step 10 | Load distal anchor

Retrieve one tape tail from each of the proximal anchors and pass through the nitinol loop of one of the distal anchors (Fig. 16). Then, pull the blue tab to shuttle the tape through the anchor eyelet.



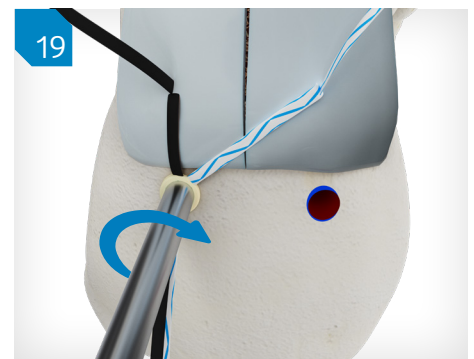
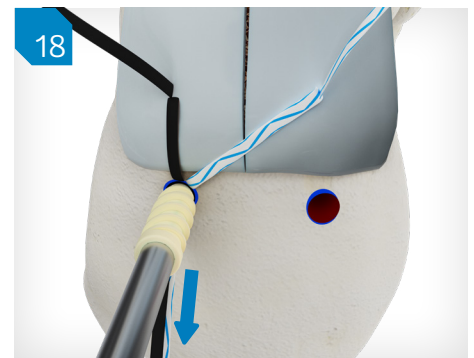
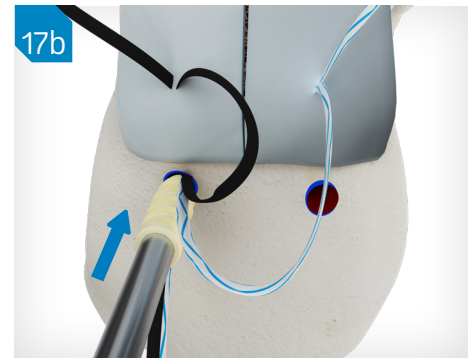
Step 11 | Insert 1st distal anchor

Tension adjustment is not required prior to insertion of the anchor eyelet. Insert the anchor eyelet and mallet (Fig. 17a) ...

... until the distal eyelet body fully buries into the pre-drilled hole (Fig. 17b).

Then, tension the tape before inserting the anchor body (Fig. 18). When tensioning, it is important to pull the tape in line with the inserter.

Insert the anchor following the instructions outlined in Steps 5 and 6 (Fig. 19).



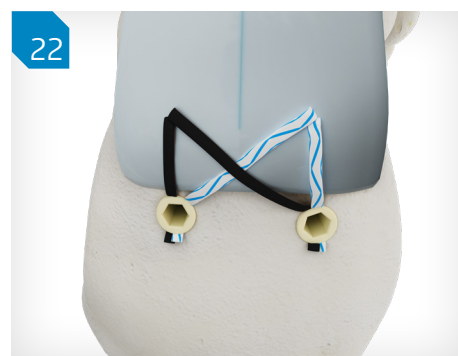
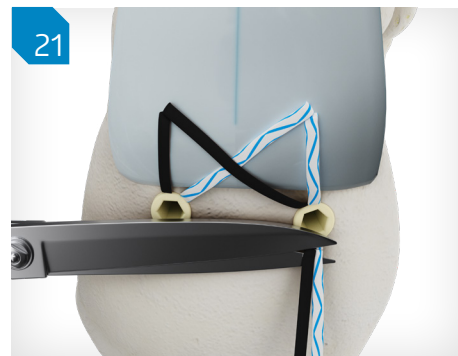
Step 12 | Insert 2nd distal anchor

Insert the 2nd distal anchor following the instructions in Steps 5 and 6 (Fig. 20).



Step 13 | Final construct

Cut the remaining tape flush with the anchors to finish the repair (Fig. 21 and 22).



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