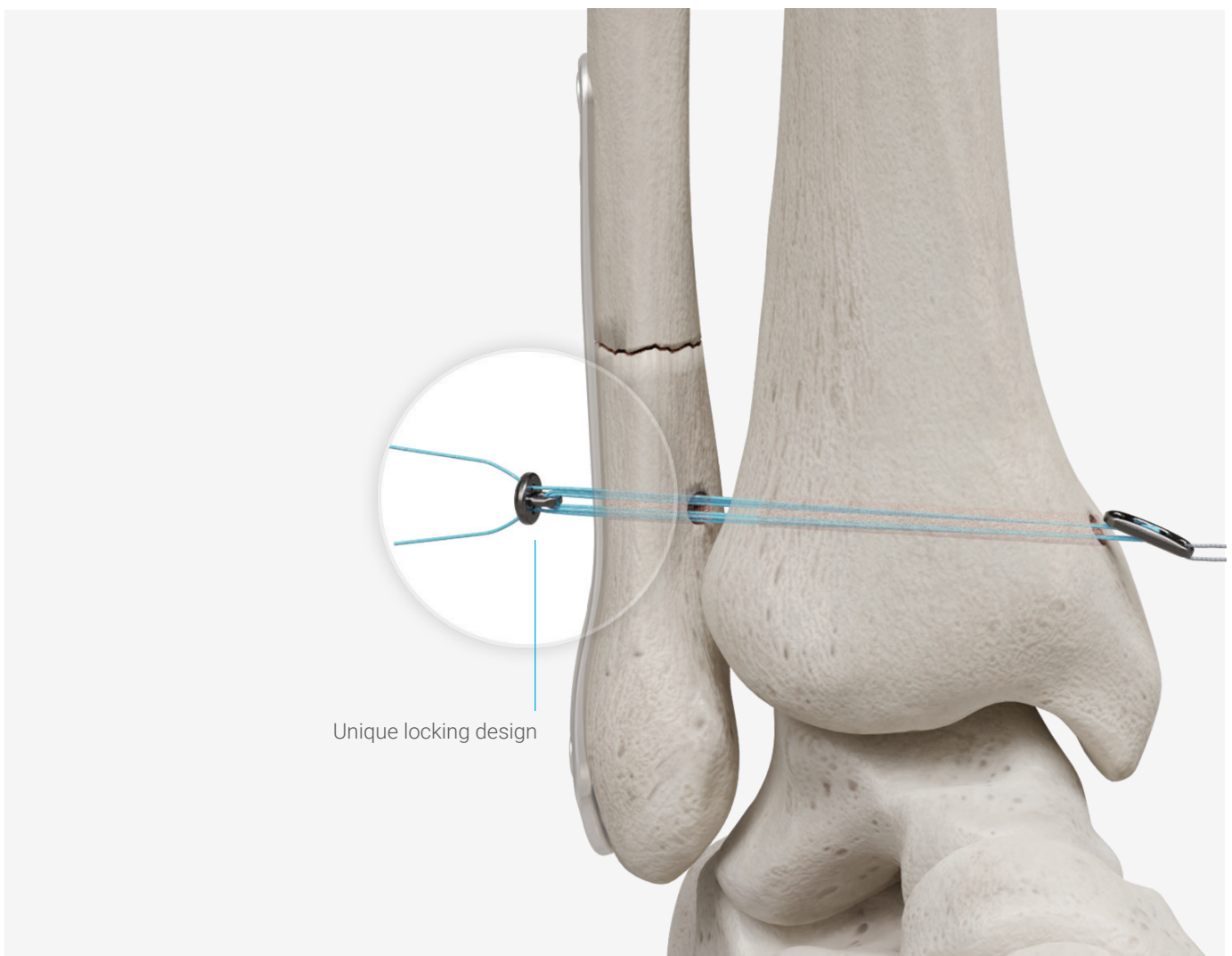


CONSTRUCTOR[®]

Knotless Adjustable Button Technology

Syndesmosis Repair – Surgical Technique



DUNAMIS[™] MEDICAL[™]

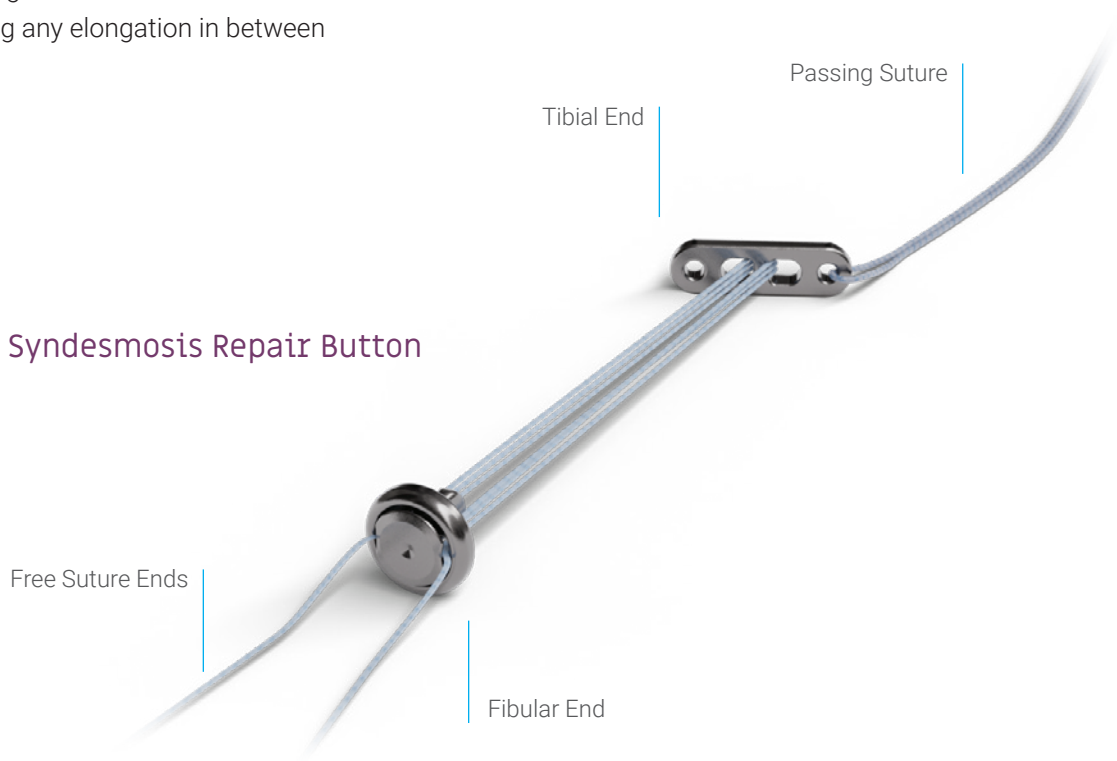
The Constrictor®

Knotless Adjustable Button Technology for Syndesmosis Repair System is a suture button construct with a **novel locking design** feature on the fibular side. This allows for a secure fixation upon completion of repair. Activation of locking feature occurs with alternate tensioning of the free suture ends of the fibular button. The fibular button slides and engages with the plate on the fibular side. The locking pin will then lock the sutures in place to complete a knotless repair. The locking pin design allows for a knotless repair while resisting any elongation in between the buttons.

Implantation System

The system for implantation requires two kits, the first contains one suture button construct and the second is the 3.7mm passing pin.

Constrictor® – Syndesmosis Repair Button

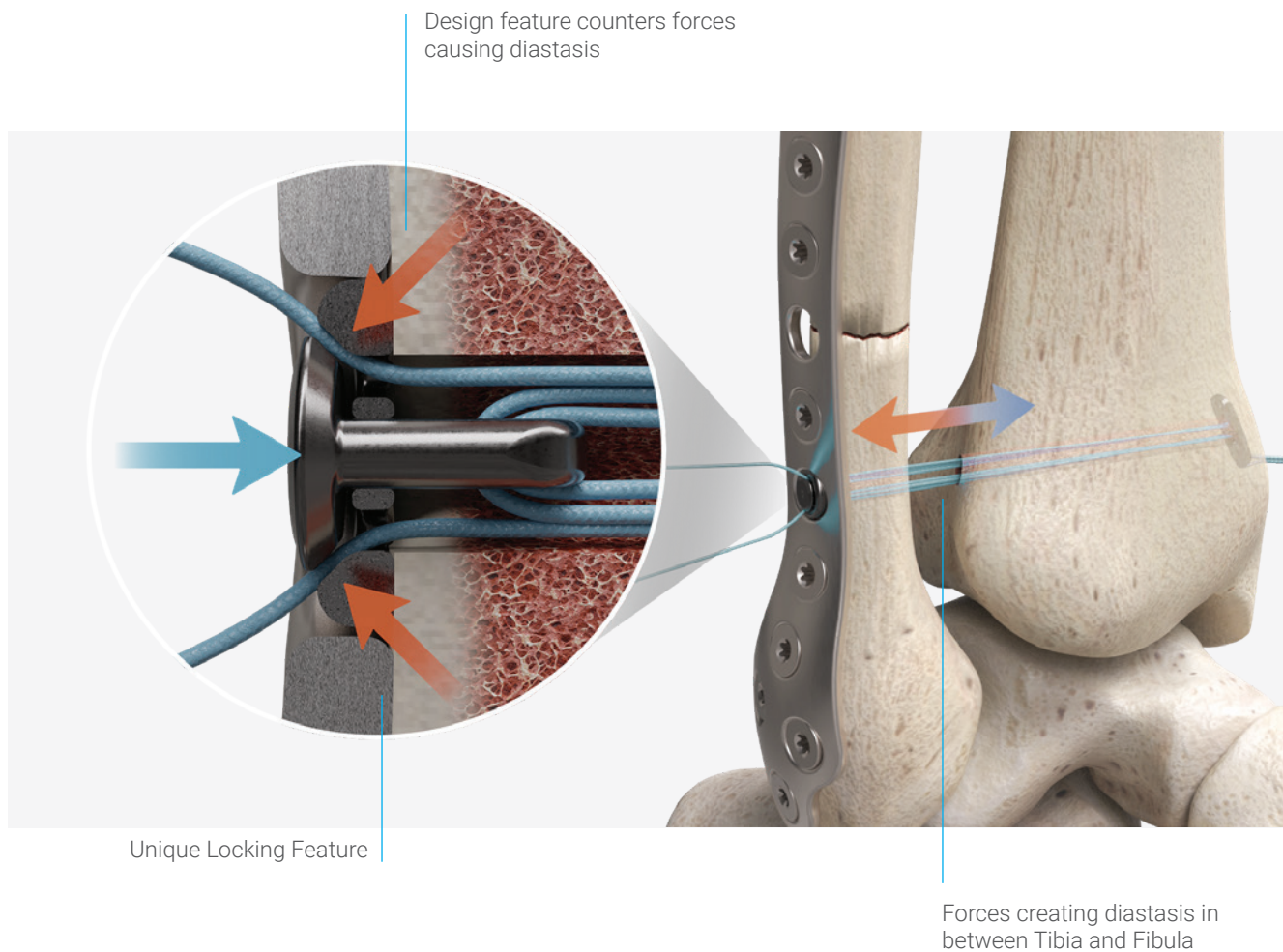


3.7mm Drill Bit



Device Design – Mechanism to Counter Elongation

The device and the locking feature are engineered to counter forces causing separation between the tibia and the fibula. The locking pin on the fibular side will resist loading and shearing forces creating diastasis of the syndesmosis by applying pressure on the suture in the direction opposite to these forces. This mechanism is designed to create a secure fixation and avoid diastasis.



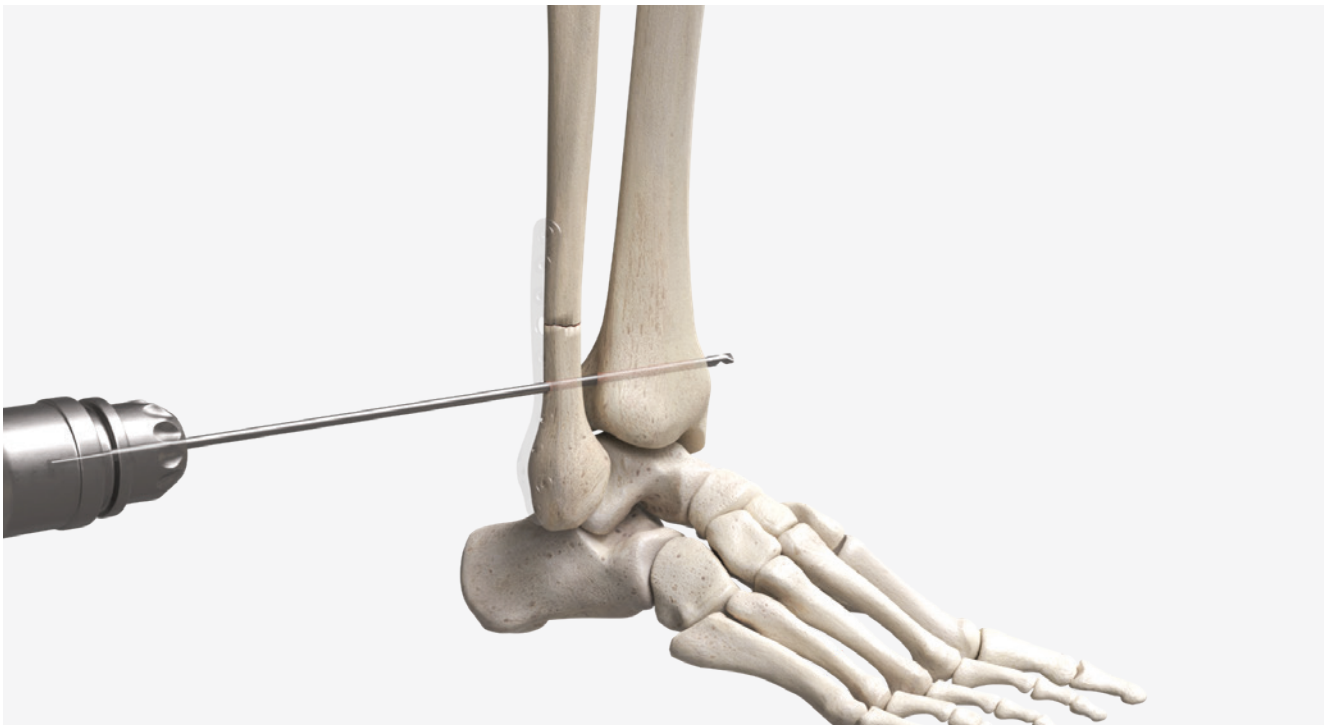
Warning: Prior to performing this technique, consult the Instruction for Use (IFU) provided with the devices – including indications, contradictions, warnings, cautions and instructions.

Indications

The Constrictor® is intended to repair syndesmotic trauma. Prior to performing this technique, consult the Instruction for Use provided with the device.

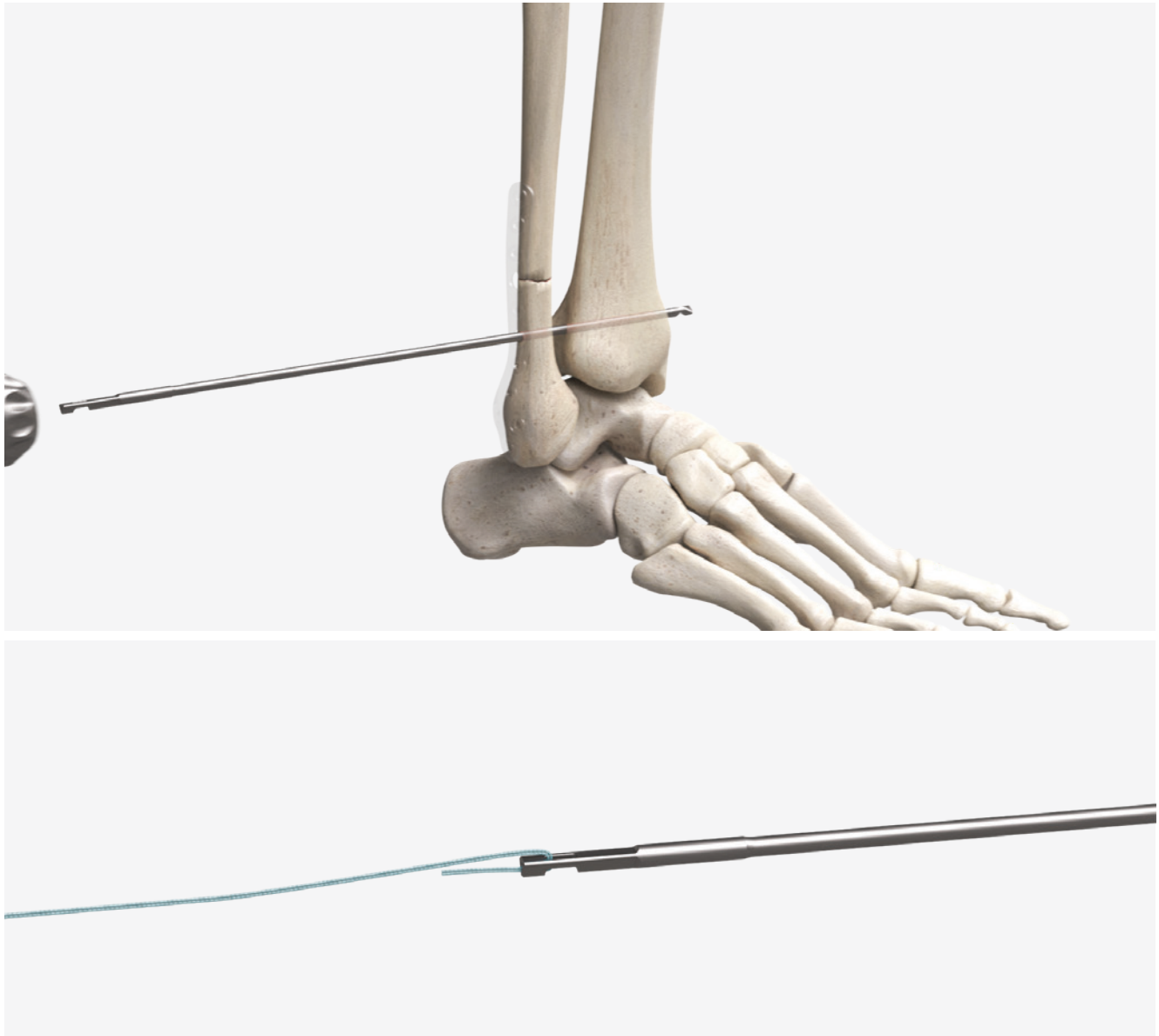
1

Stabilize all fractures prior to Syndesmosis repair. Use fluoroscopic guidance to ensure accurate positioning of device. Drill all 4 cortices approximately 1.5 – 2 cms above the ankle joint. (30° anterior to the coronal plane), using the 3.7mm drill bit. Advance the drill until the skin is tented on the medial side of the tibia. Make an incision over the tented skin to allow passing pin to exit.



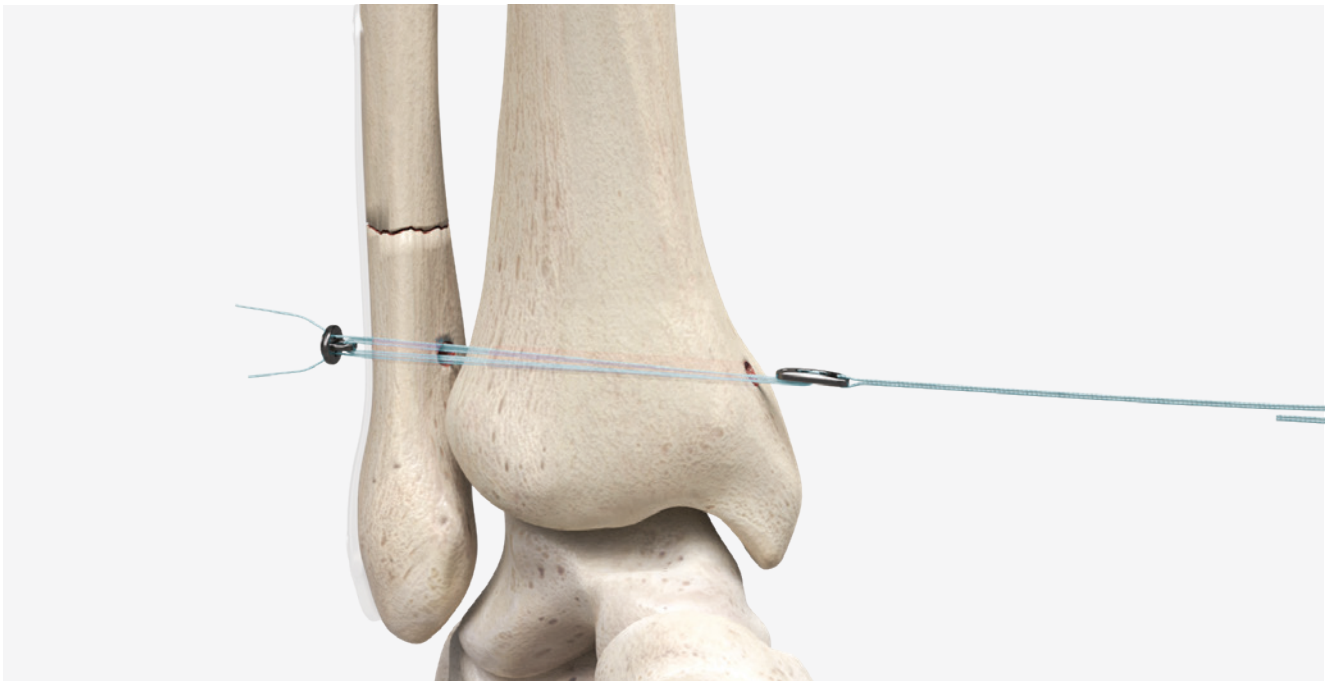
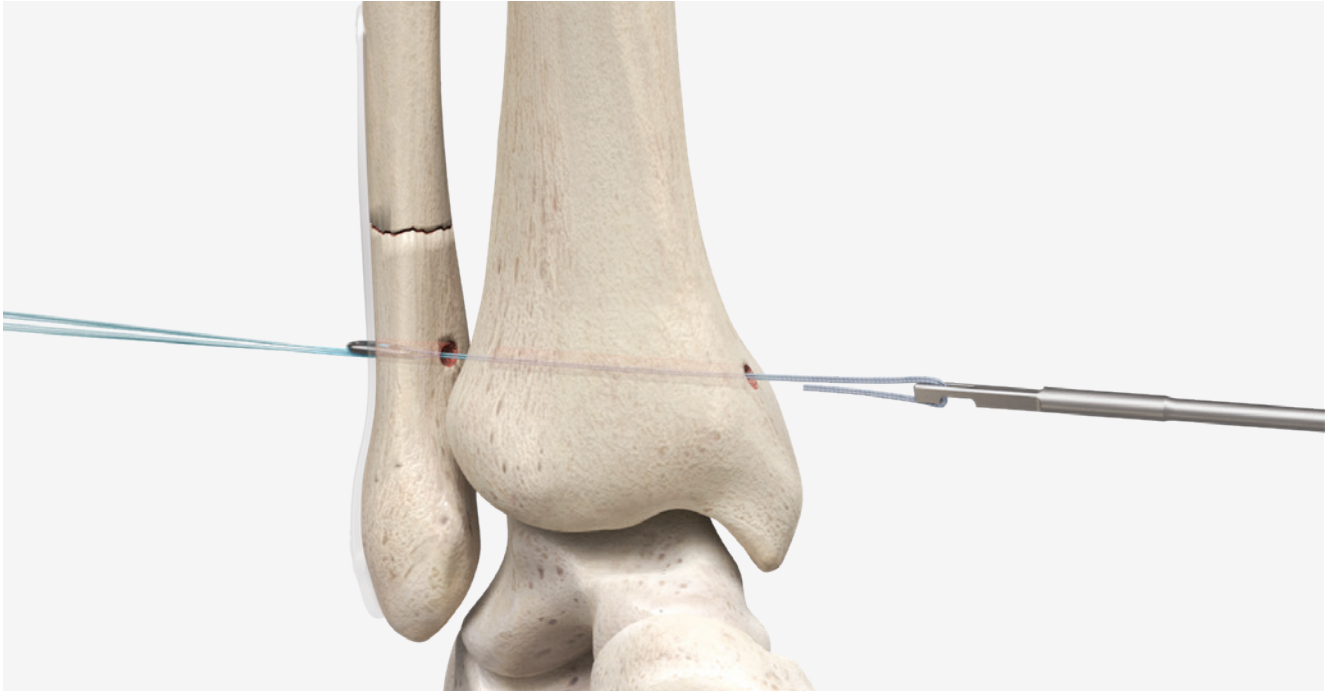
2

Disconnect the power drill and insert the passing suture through the eyelet of the 3.7mm drill bit



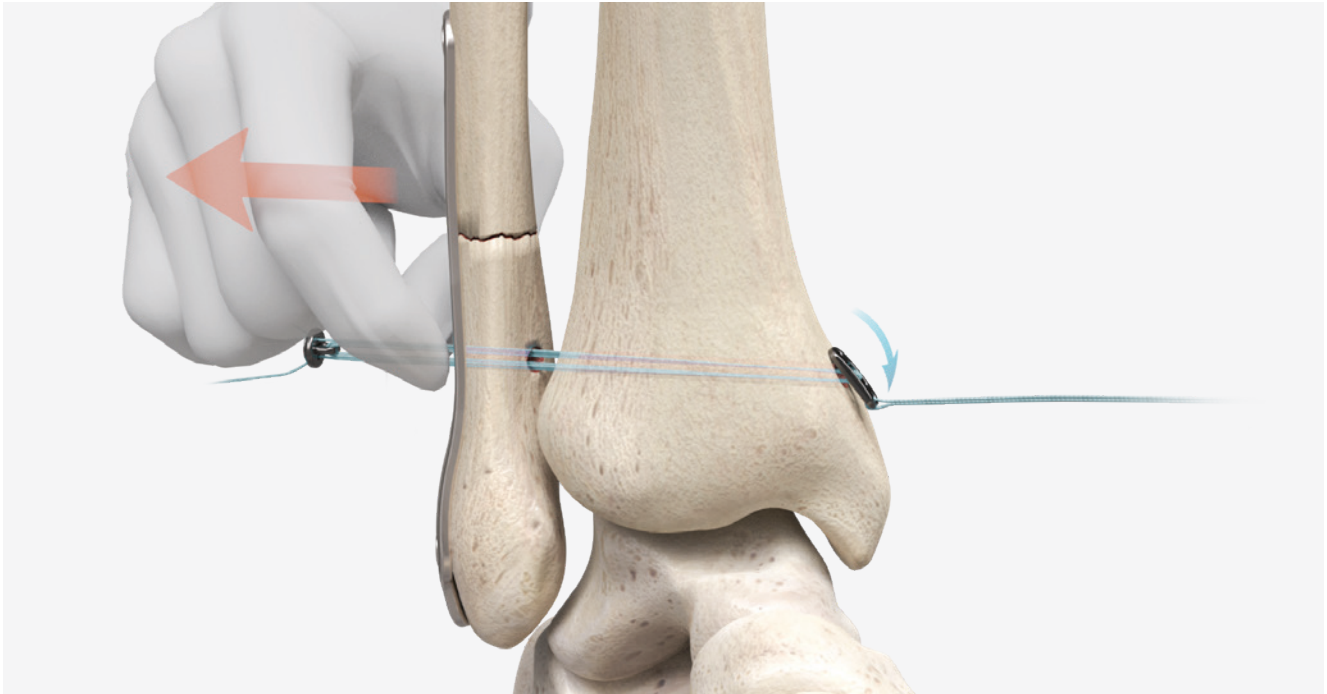
3

Pull the drill bit on the tibial side so as to advance the device through the fibula and the tibia, retrieve the passing suture on the medial side of the tibia.



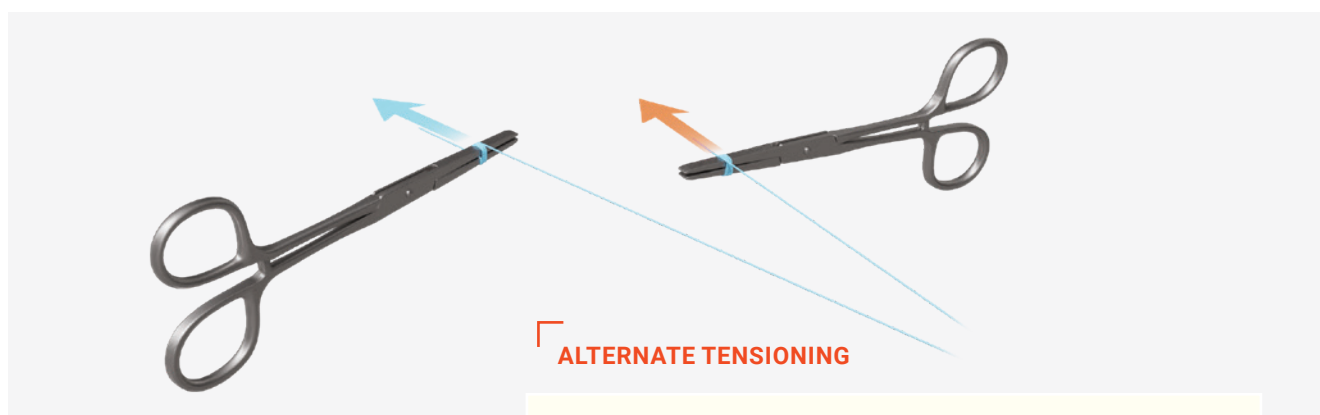
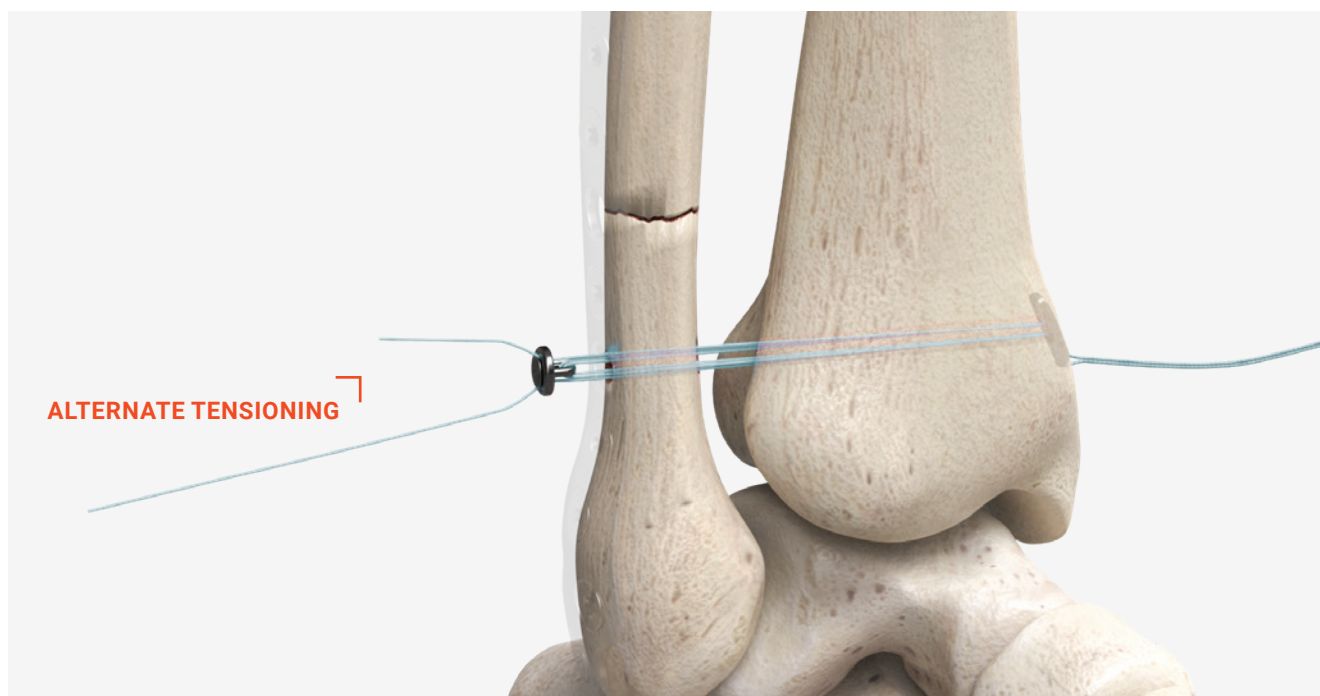
4

Maintain tension in the construct by holding the sutures between the lateral and medial button. Flip the medial button to place it flush on the medial cortex. Gentle tugging on the sutures between the fibula and the lateral button confirms firm placement of the oblong button on the medial cortex.



5

Wrap the two free ends of the sutures separately on a hemostat or a similar device. Wrap each suture tail 2 – 3 times around hemostat or similar device. Tension the suture by pulling on the free suture strand, one at a time. Alternate tensioning of free suture ends a few inches at a time.

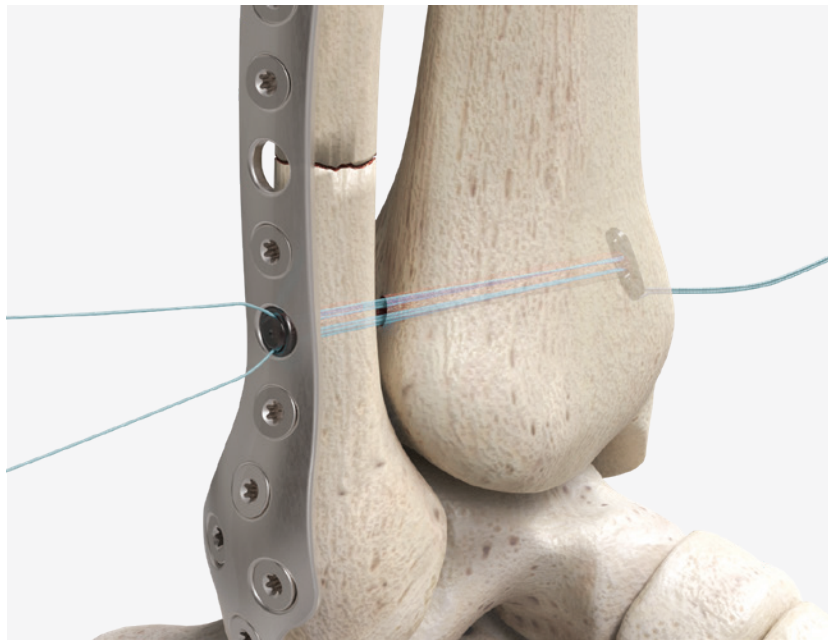


Note:

1. The surgeon should perform alternate tensioning of the sutures a few inches at a time. This will allow the button on the fibular side to slide down smoothly.
2. Direction of pull: During tensioning, the sutures should be pulled in a straight line towards the surgeon.

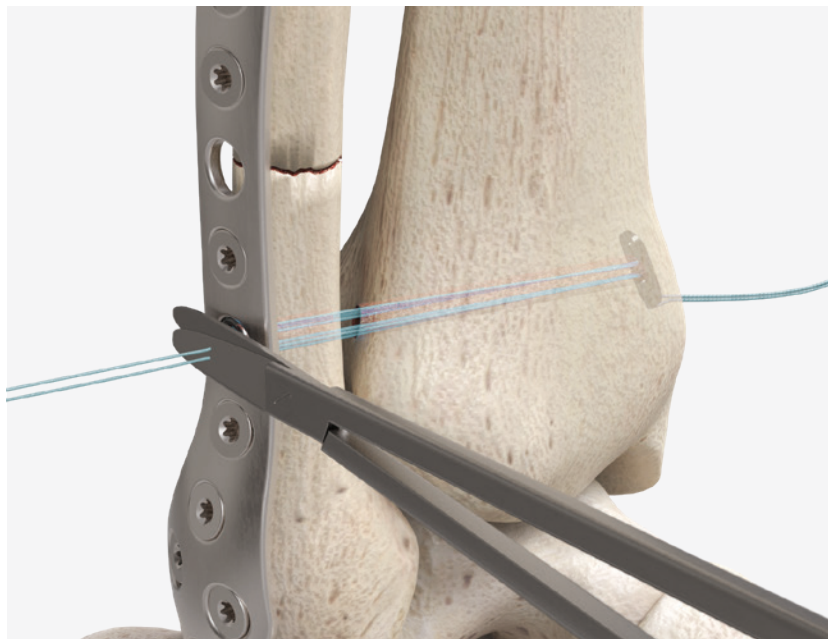
6

Perform alternate tensioning of each suture strand till the lateral button is fully seated within the plate.

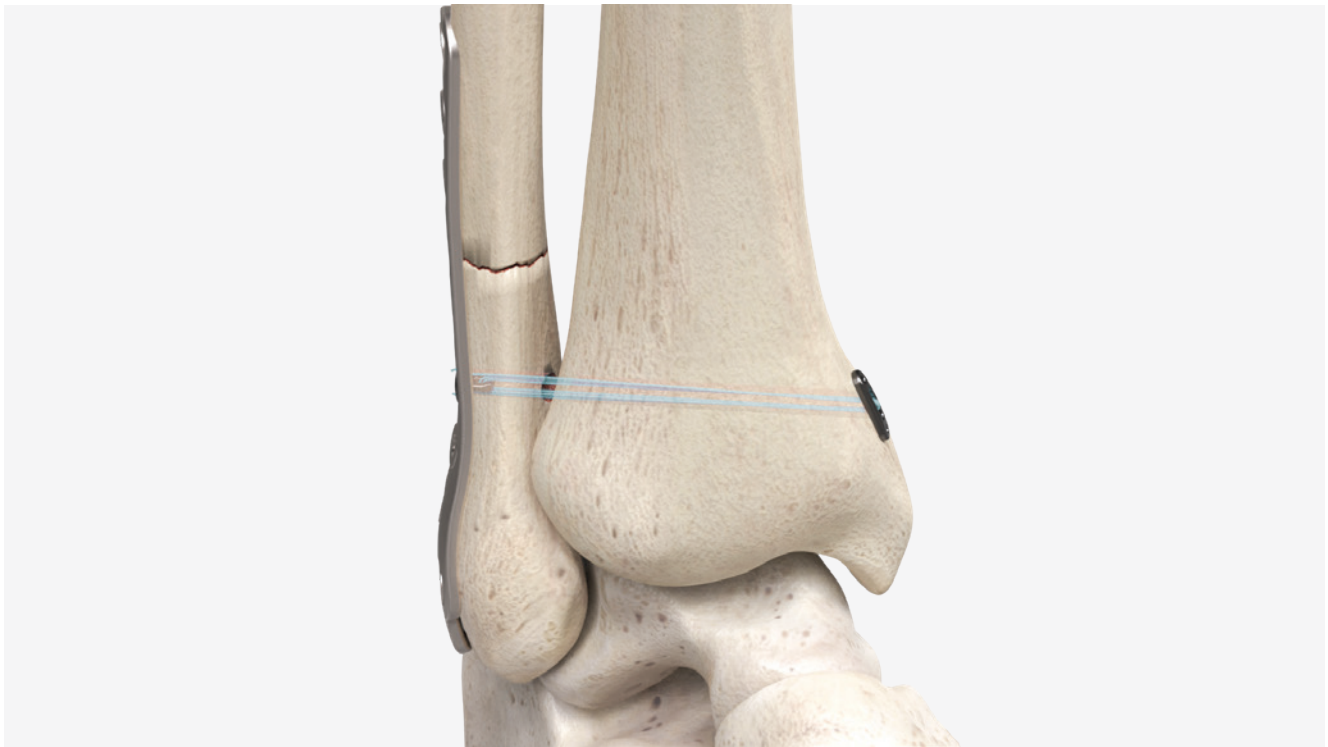


7

Cut the suture and leave 3 – 4 mm tail to ensure there is no damage to the sutures while cutting. Cut or remove the passing suture from the medial button.



Final Fixation



Postoperative Management

Following wound closure, immobilize the ankle in neutral dorsiflexion using a short-leg, postoperative splint. The patient may be non-weight bearing for 4-6 weeks per surgeons' protocol.

Note:

In case implant removal is necessary, cut the sutures over the medial button on the tibial side following which the medial button can be retrieved and the remaining construct i.e. lateral button and the sutures can be pulled from the fibular side.

We recommend leaving the passing suture in place till the final fixation is obtained to allow surgeons the ability to manipulate the medial button if needed.

Disclaimer: The following technique guide was prepared under close collaboration with several physicians. Dunamis Medical LLC does not provide medical advice and recommends that surgeons exercise their own professional judgement while treating their patients.

CONSTRICTOR®

Knotless Syndesmosis
Fixation System

DUNAMIS MEDICAL®

USS UNIQUE™
SUSPENSORY
SOLUTIONS

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