ST

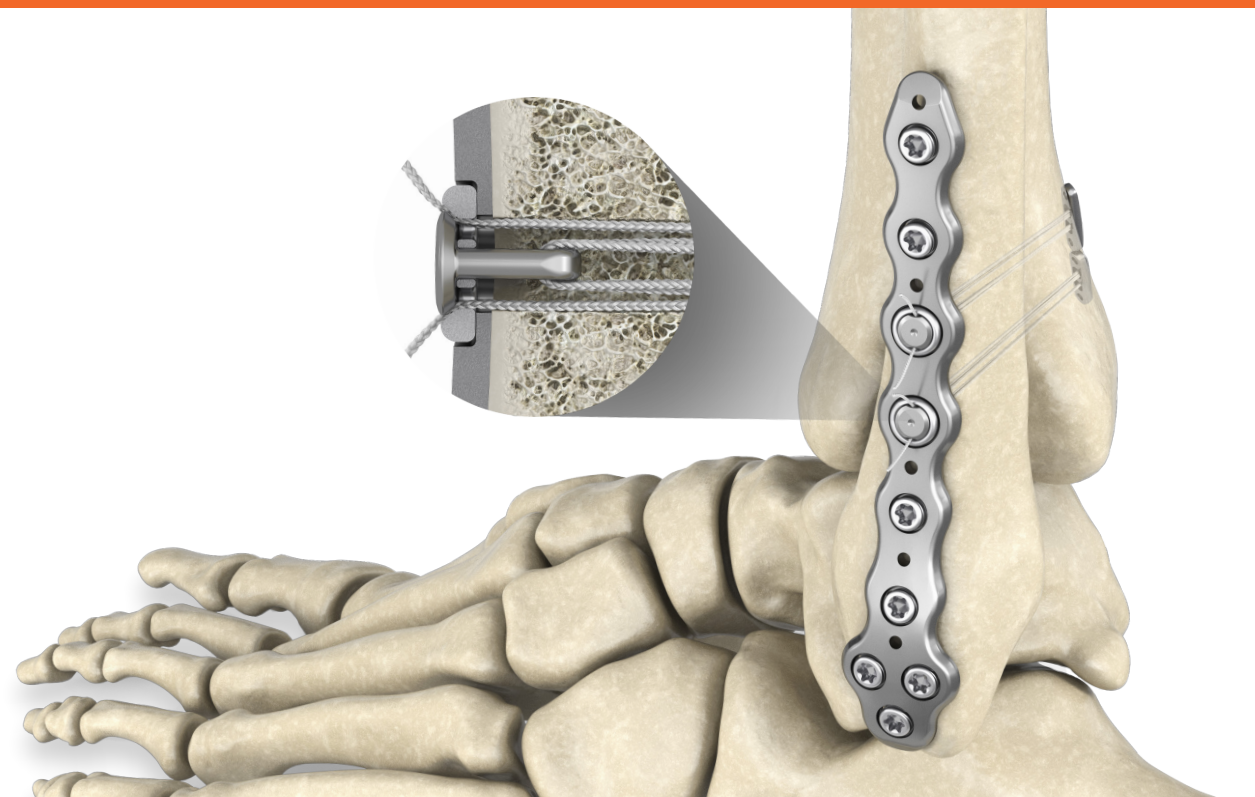
SURGICAL
TECHNIQUE

enovis™

ENOFIX™

WITH CONSTRICTOR® TECHNOLOGY

SOFT TISSUE REPAIR SYSTEM



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KNOTLESS SYNDESMOTIC REPAIR THAT DEMONSTRATES SUPERIOR FIXATION UNDER CYCLIC LOADING*

MedShape, Inc. is a manufacturer of orthopedic implants and does not practice medicine. This surgical technique was prepared in conjunction with licensed health care professionals. The treating surgeon is responsible for determining the appropriate treatment, technique(s), and product(s) for each individual patient.

See package insert for complete list of potential adverse effects, contraindications, warnings and precautions.

A workshop training is recommended prior to performing your first surgery. 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, if applicable. Please remember that the compatibility of different product systems has not been tested unless specified otherwise in the product labeling.

The surgeon must discuss all relevant risks including the finite lifetime of the device with the patient.

**Test data on file at Dunamis Medical.*

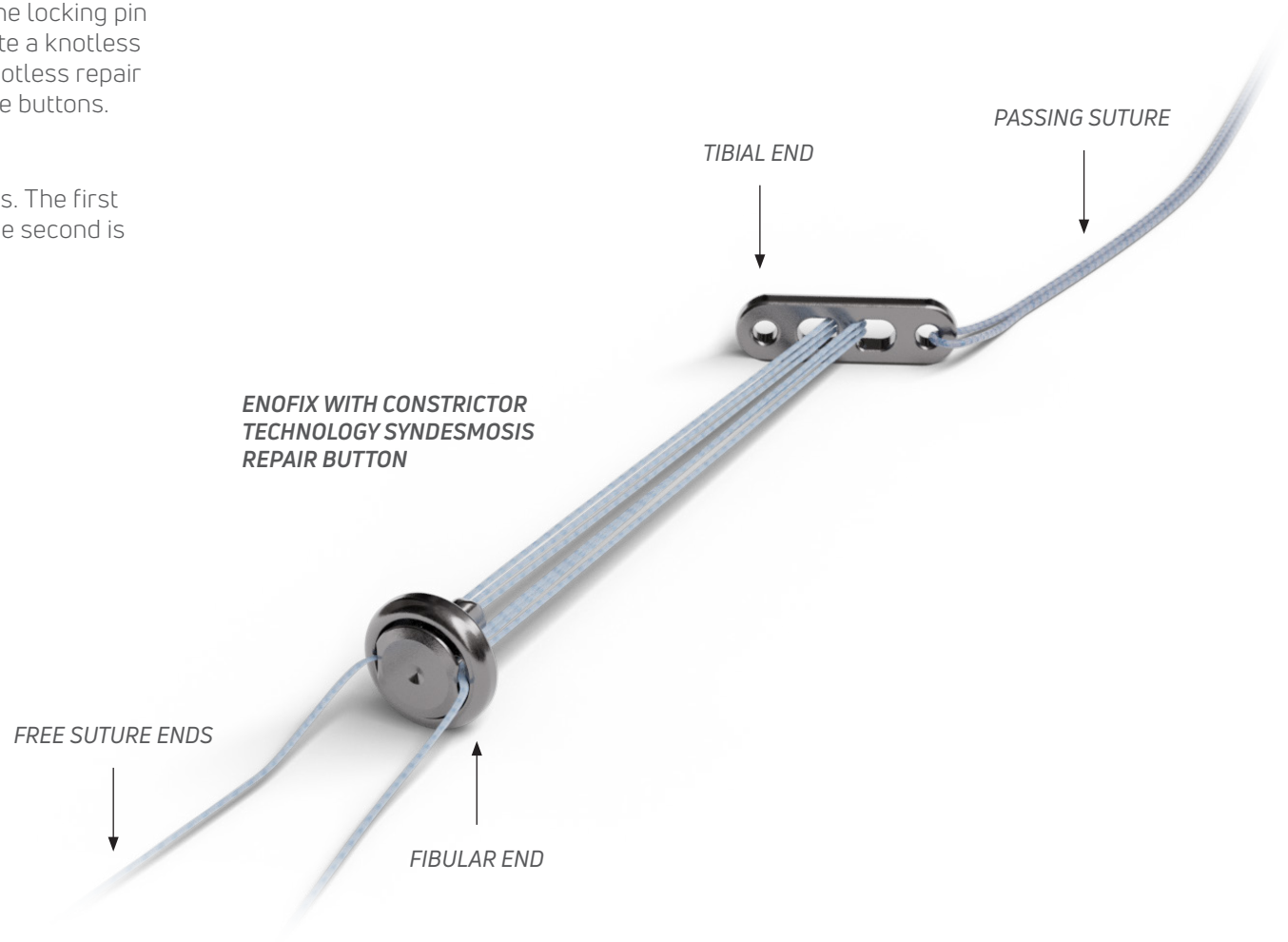
DESIGN FEATURES

ENOFIX™ WITH CONSTRICTOR® TECHNOLOGY

Enofix™ with Constrictor® Technology, Knotless Adjustable Button Technology for Syndesmosis Repair System, is a suture button construct with a novel locking design feature on the fibular side. This design allows for secure fixation upon completion of repair. The activation of the 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.

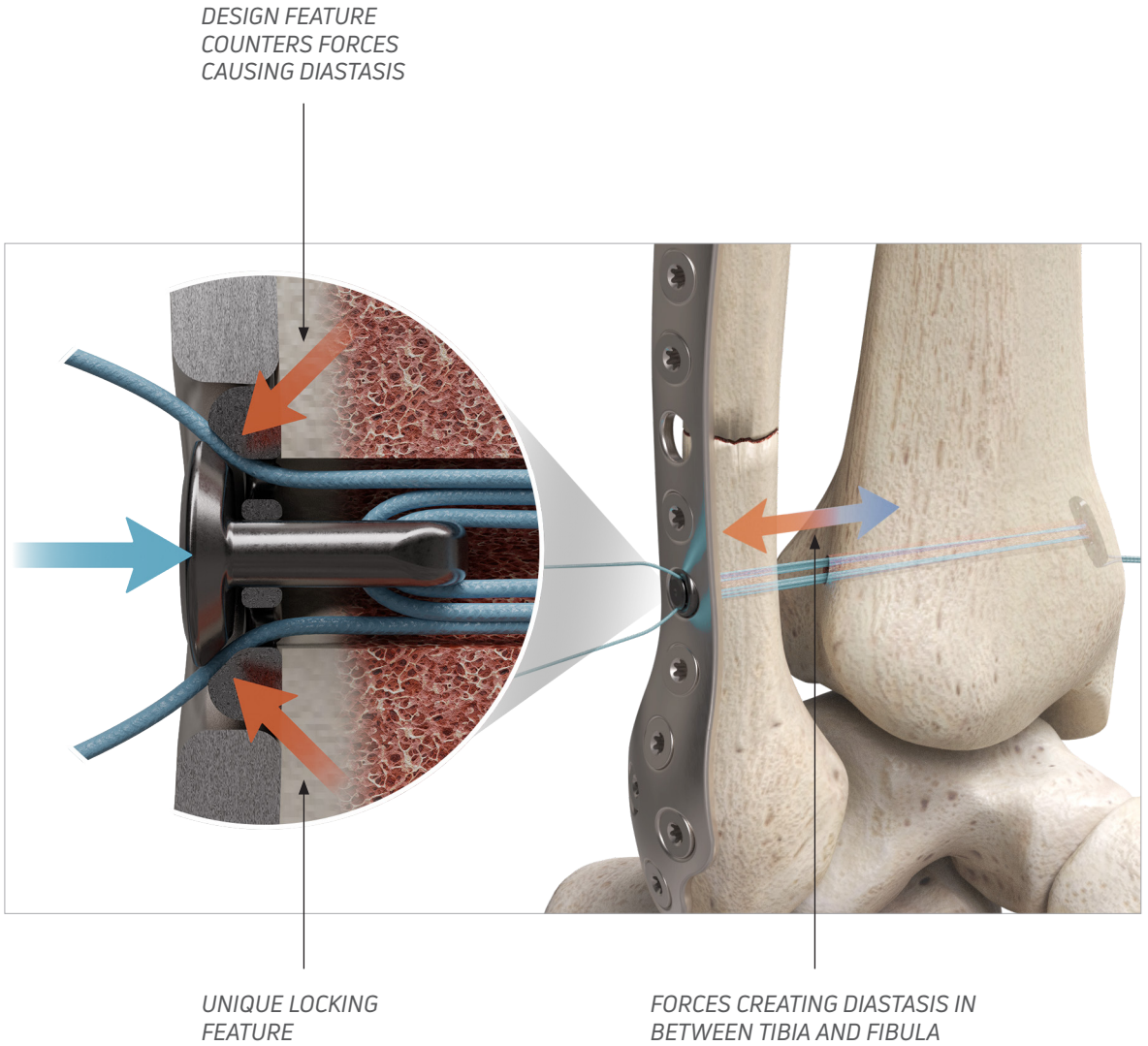


DESIGN FEATURES

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 secure fixation and avoid diastasis.

⚠ WARNING: Prior to performing this technique, consult the Instructions for Use (IFU) provided with the device, including indications, contradictions, warnings, cautions, and instructions.



INDICATIONS

Enofix™ with Constrictor® Technology is intended to repair syndesmotic trauma. Prior to performing this technique, consult the Instructions 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.

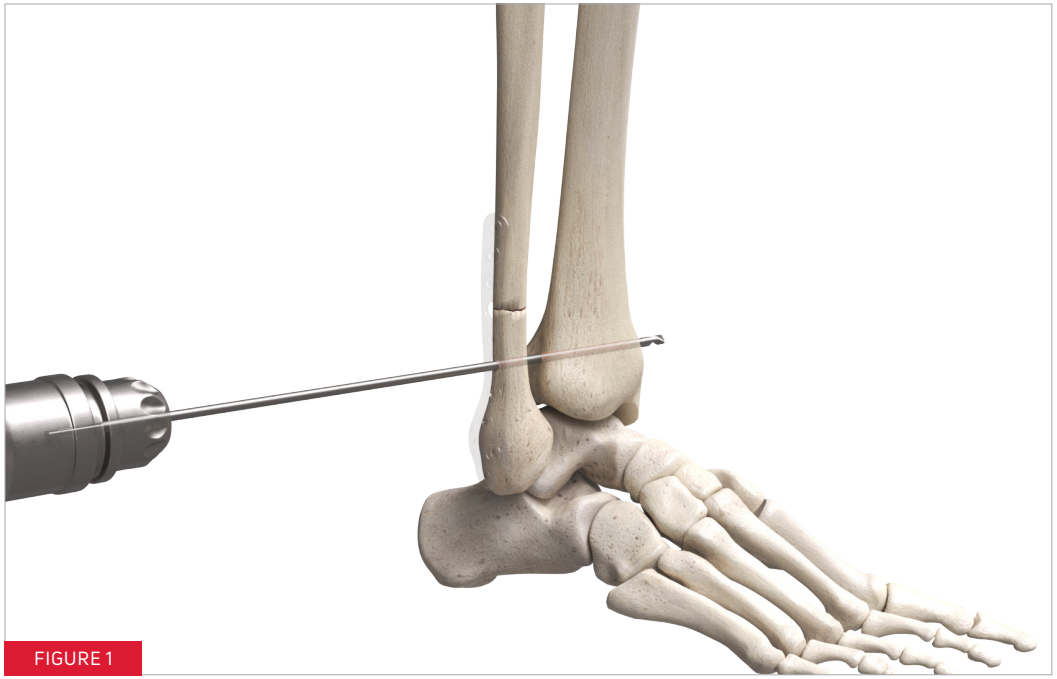


FIGURE 1

2.

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

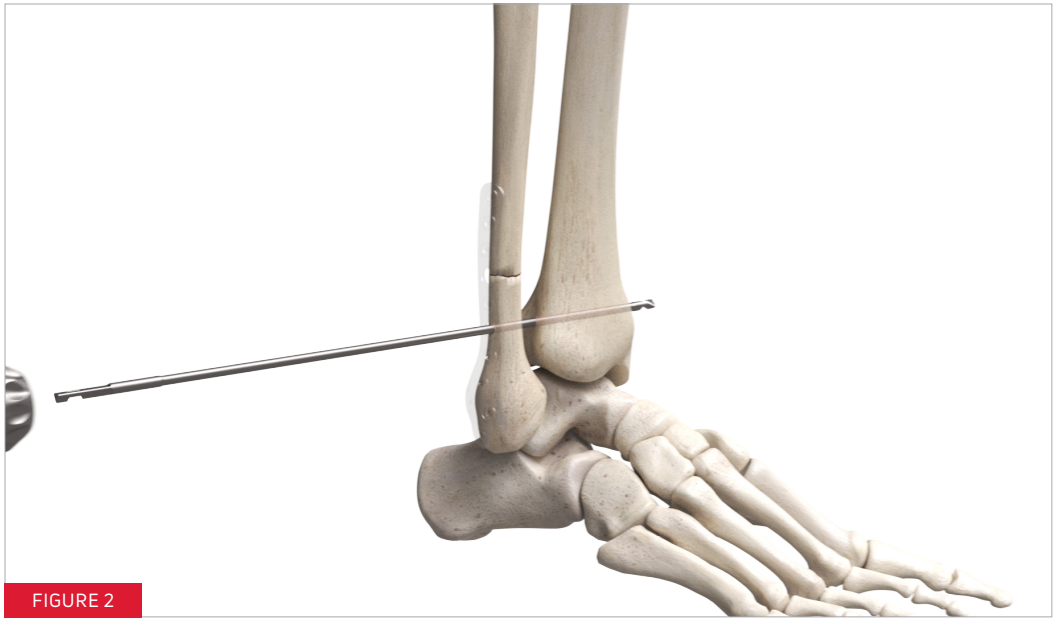


FIGURE 2

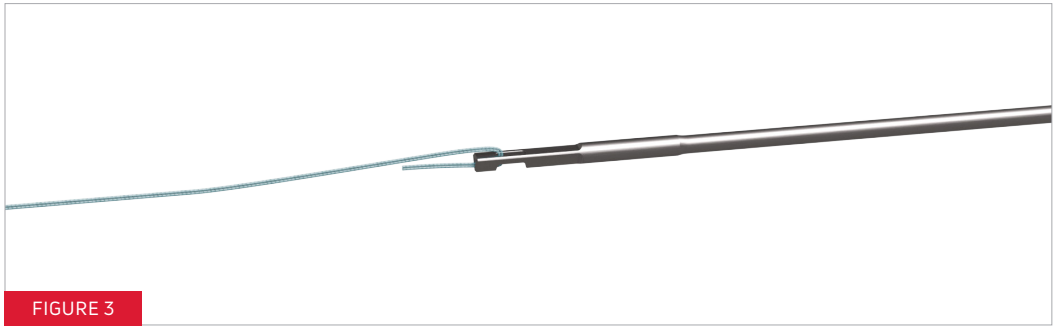


FIGURE 3

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.

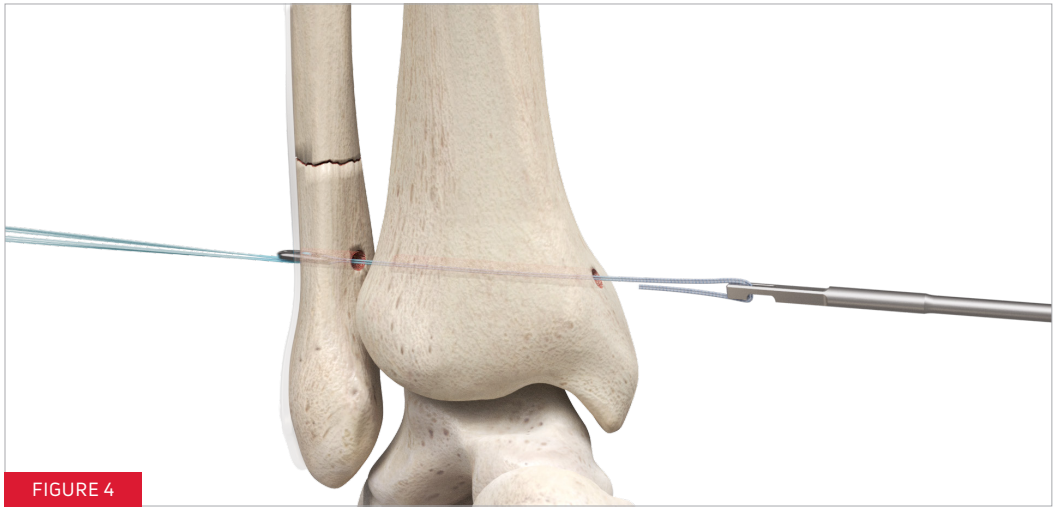


FIGURE 4

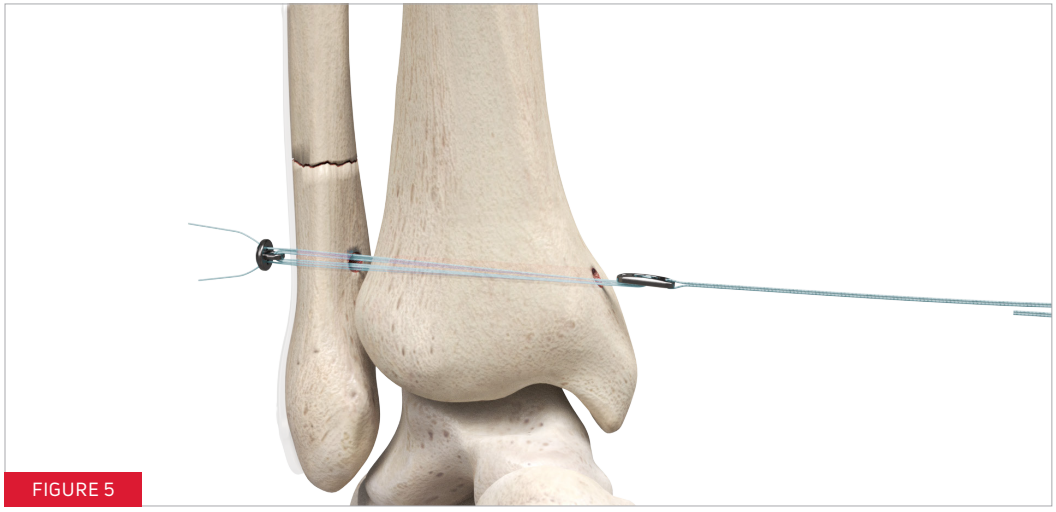


FIGURE 5

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.

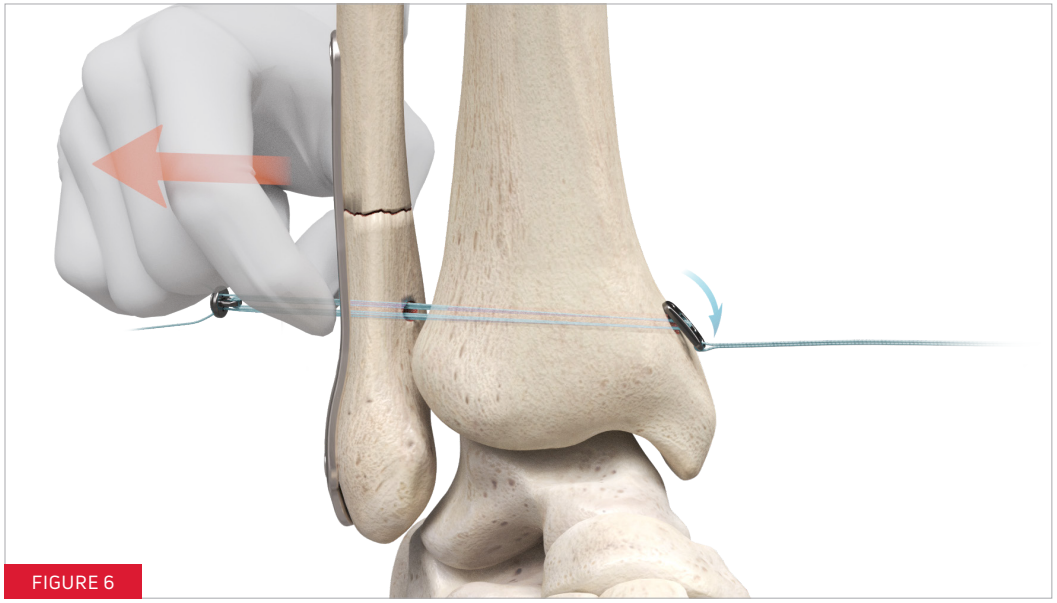


FIGURE 6

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 the 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. Doing so 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.

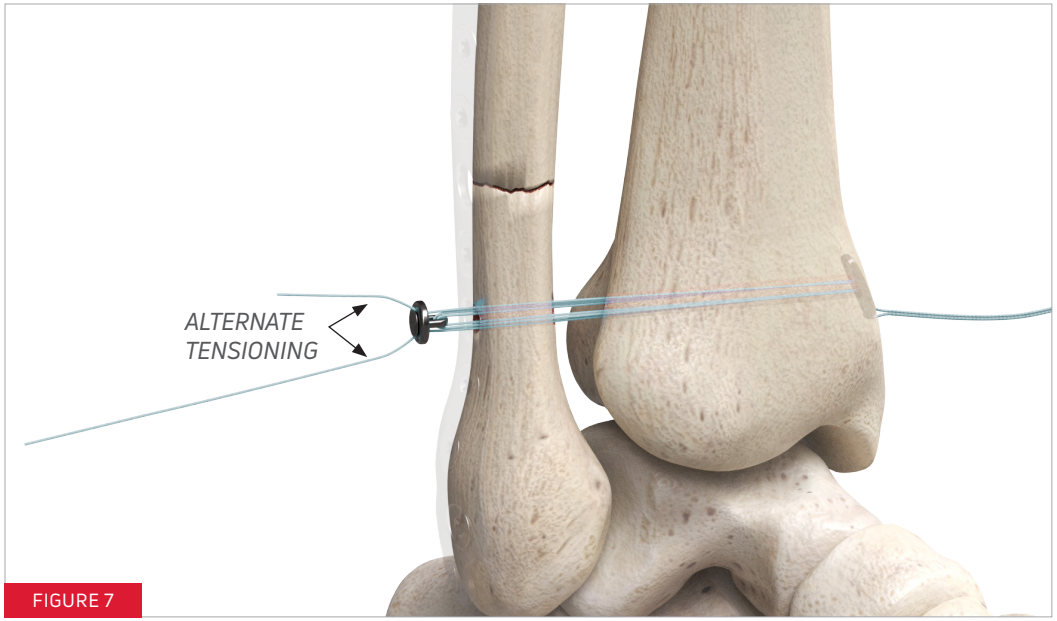


FIGURE 7

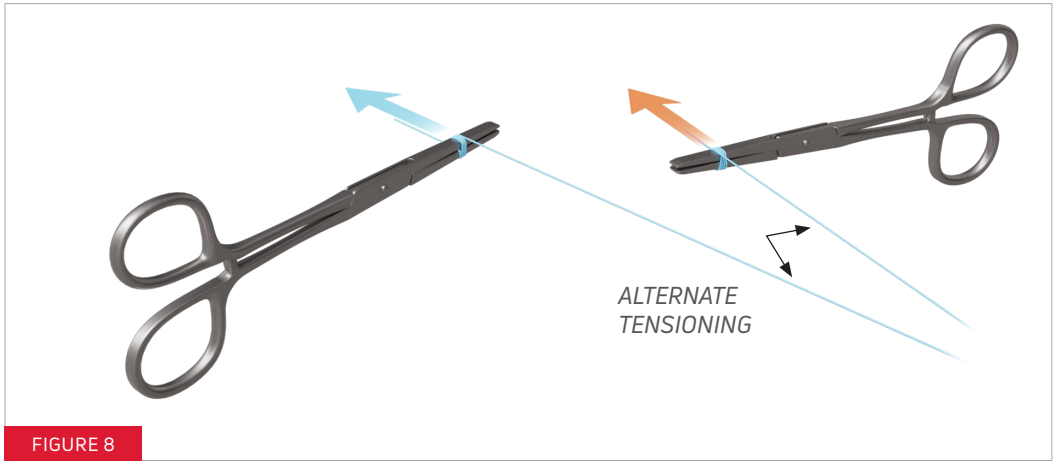


FIGURE 8

6.
Perform alternate tensioning of each suture strand until 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.

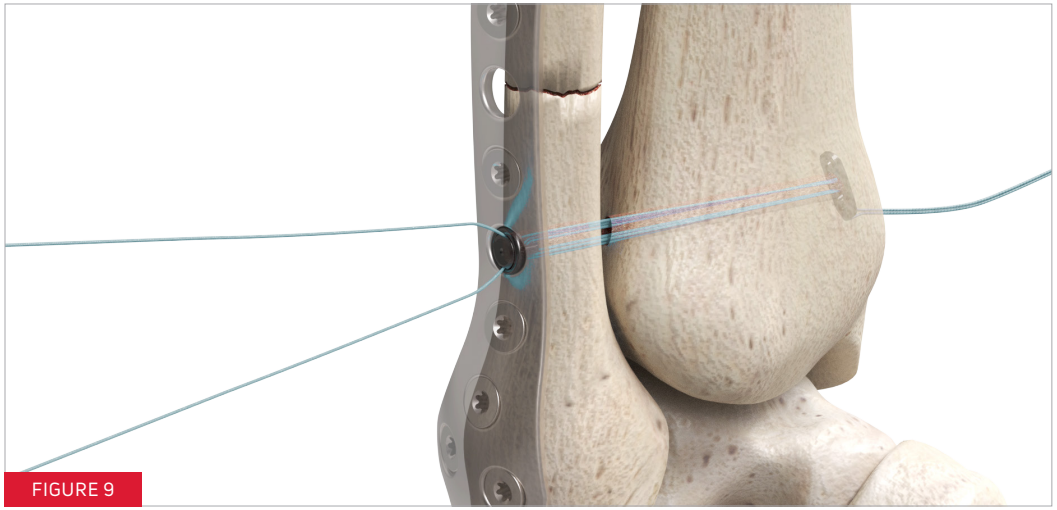


FIGURE 9

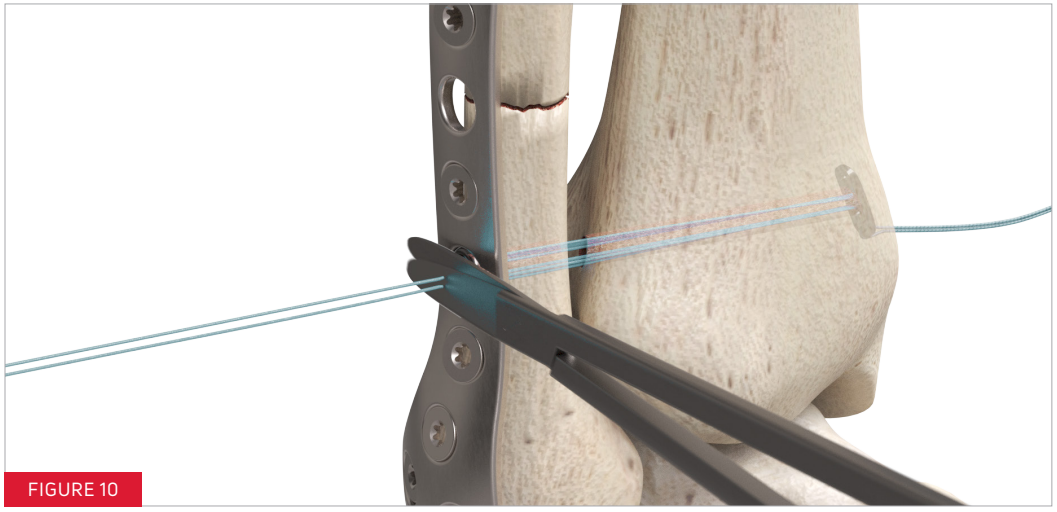


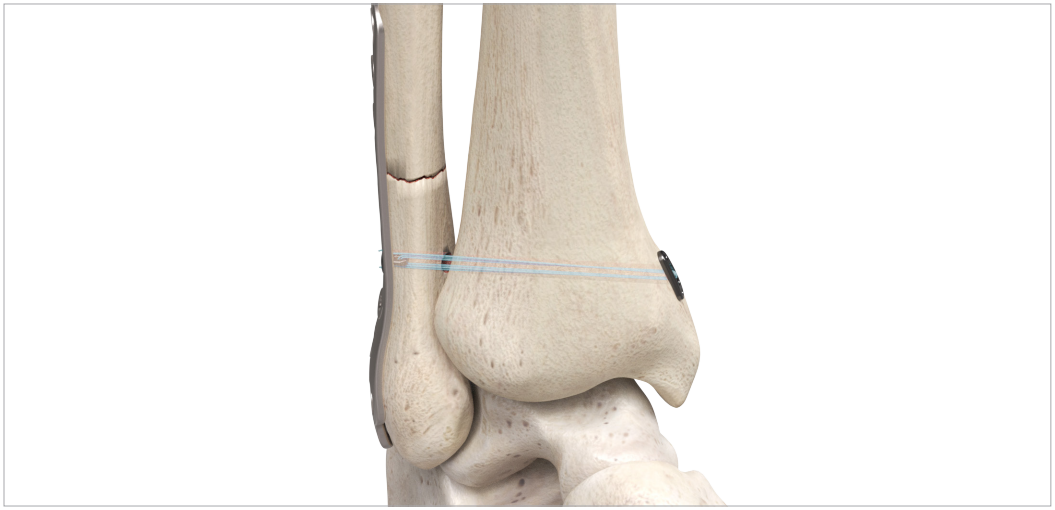
FIGURE 10

POSTOPERATIVE MANAGEMENT

Following wound closure, immobilize the ankle in neutral dorsiflexion using a short-leg, postoperative splint. The patient maybe non-weightbearing for 4-6 weeks per surgeon protocol.

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

It is recommend to leave the passing suture in place until final fixation is obtained to allow the surgeon the ability to manipulate the medial button if needed.



FINAL FIXATION

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MK-10317 Rev 00

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U.S. Pat. 11,109,855. Additional patents pending.