GLOBUS MEDICAL

TENSOR™

Suture Button System

Surgical Technique Guide | Orthopedic Trauma

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Life moves us

The Surgical Technique shown is for illustrative purposes only. The technique(s) actually employed in each case always depends on the medical judgment of the surgeon exercised before and during surgery as to the best mode of treatment for each patient. Additionally, as instruments may occasionally be updated, the instruments depicted in this Surgical Technique may not be exactly the same as the instruments currently available. Please consult with your sales representative or contact Globus directly for more information.

SURGICAL TECHNIQUE GUIDE

TENSOR™

TENSOR™

Suture Button System

The TENSOR™ Suture Button System is designed to provide intraoperative efficiency for syndesmotic fixation procedures using a unique inserter that helps to redefine suture management.

The system features a self-locking suture and an inserter with integrated tensioning handles, to provide a streamlined method for tensioning of the lateral button.

The system is compatible with ANTHEM™ Ankle and One-Third Tubular Plates.

Integrated Tensioning Handles

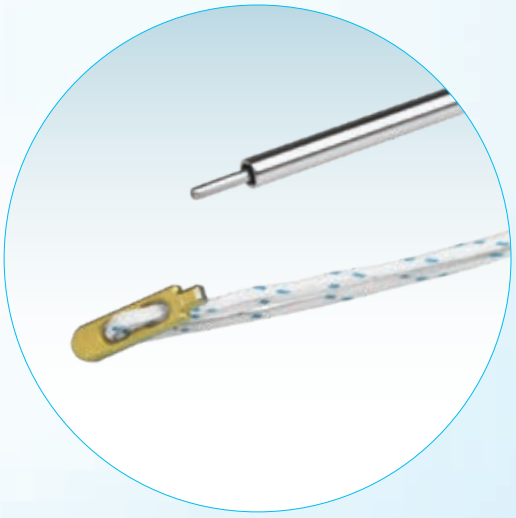
Designed to simplify tensioning of the lateral button

Pull-Back Trigger

Spring-loaded trigger engineered to enable controlled medial button deployment

Medial Flip Button

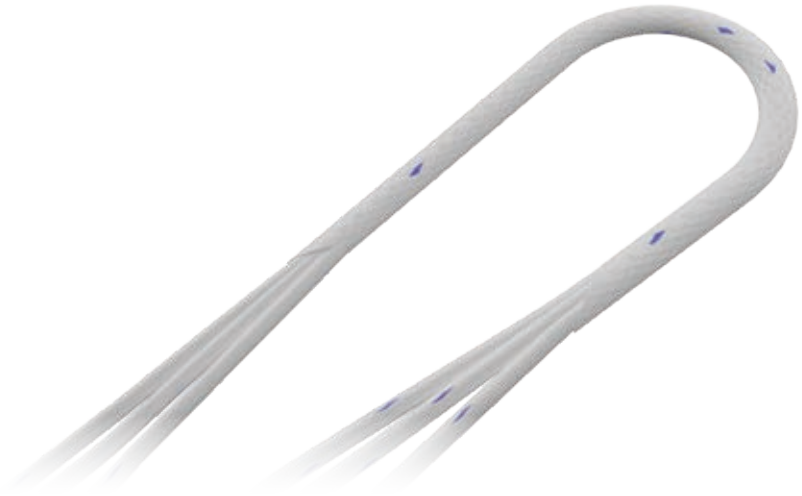
Flip button to facilitate passage through a single lateral incision and a 3.5mm bone tunnel



IMPLANT OVERVIEW

Knotless Locking Suture

- USP #5 Suture is routed and tensioned through the medial and lateral buttons.
- Designed to allow knotless fixation using a self-locking suture loop comprised of ultra-high-molecular-weighted polyethylene (UHMWPE) and polyethylene terephthalate (PET) fiber



Lateral Button

- Low-profile design to help minimize soft tissue irritation
- Compatible with ANTHEM™ Ankle and One-Third Tubular Plates

Two-Hole Washer

- Intended for isolated syndesmotic injuries
- Provides increased surface area on the lateral aspect of the fibula

*Additionally available

SURGICAL TECHNIQUE

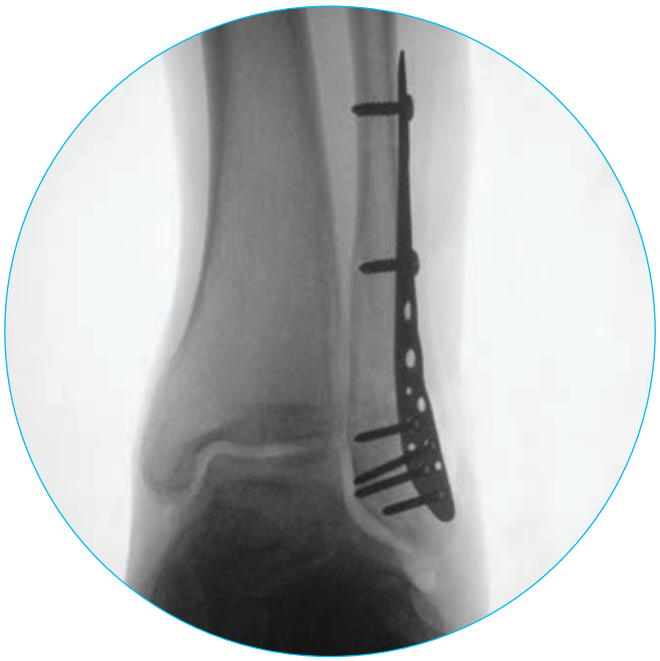
TENSOR™

Ankle Fractures with Syndesmosis Disruptions

Refer to the device insert (also printed at the back of this guide) for important information on the intended use/ indications, device description, contraindications, precautions, warnings, and potential risks associated with this system. The following surgical technique and associated images are for syndesmosis repair applications in the ankle. The same surgical technique is used for the other indicated anatomies.

STEP 1 Fracture Reduction

Prior to insertion of the TENSOR™ Suture Button device, ensure all fractures are stabilized using the appropriate plating construct or reduction instruments, as necessary. The TENSOR™ Suture Button implants may be used with or without plating.



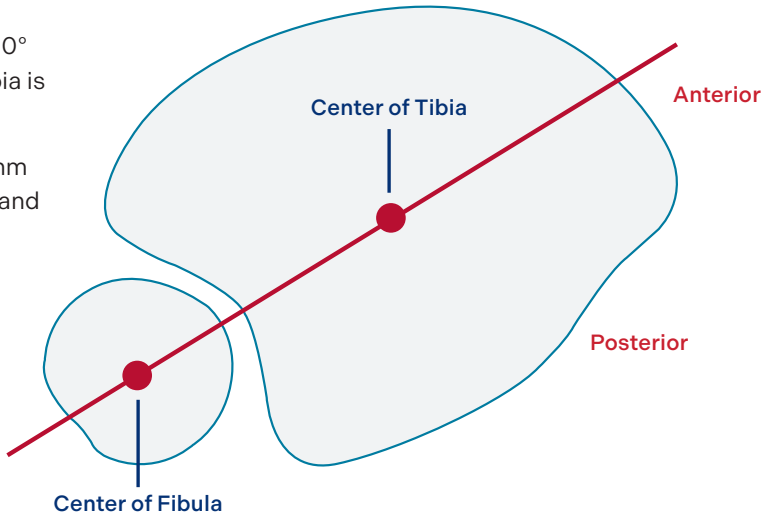
Fully reduced and stabilized fracture

STEP 2 Bone Preparation

The typical trajectory is to start the guidewire on the posterolateral side of the fibula and aim the guidewire 30° anterior in the axial plane, to ensure the center of the tibia is targeted.

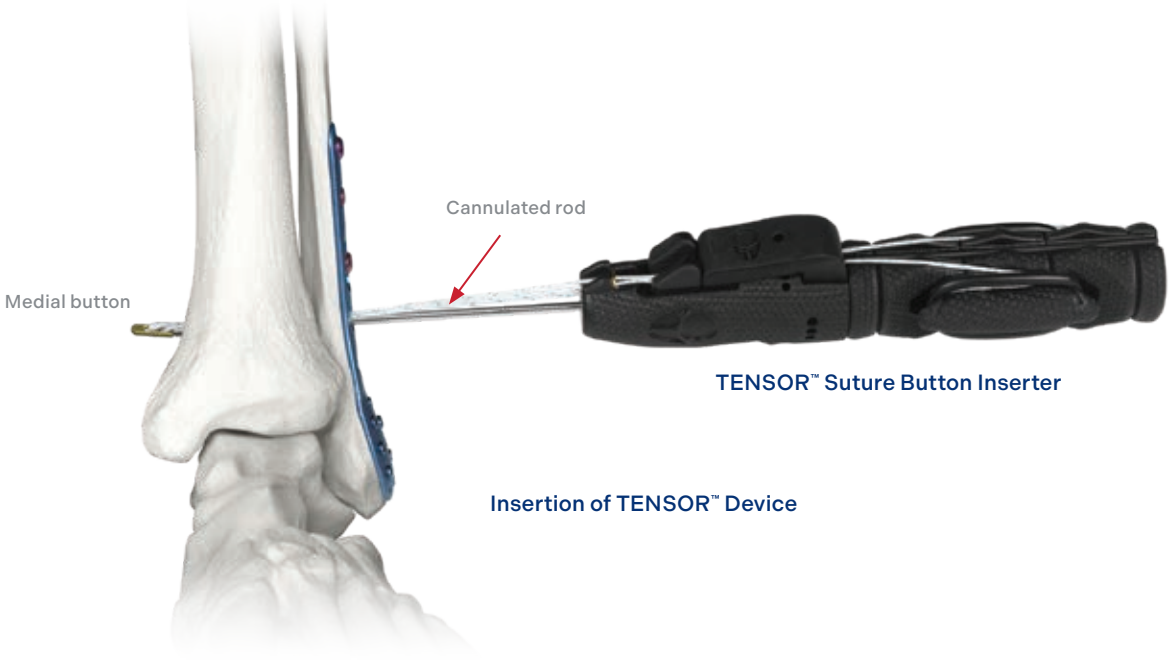
Using both the Cannulated 3.5mm Drill Bit and 3.5/1.4mm Soft Tissue Protector, place the drill over the guidewire and drill through all four cortices to create a bone tunnel.

A Solid 3.5mm Drill Bit is also available, depending on surgeon preference.



STEP 3 Device Insertion

Once the bone tunnel has been prepared, push the cannulated rod of the inserter through the tunnel until the medial button exits the medial tibial cortex and confirm button position via fluoroscopy. Once positioned, rotate the inserter so that the safety is facing either superiorly or inferiorly. As the medial button is deployed, this will help to ensure the button is in line with the medial axis of the tibia.

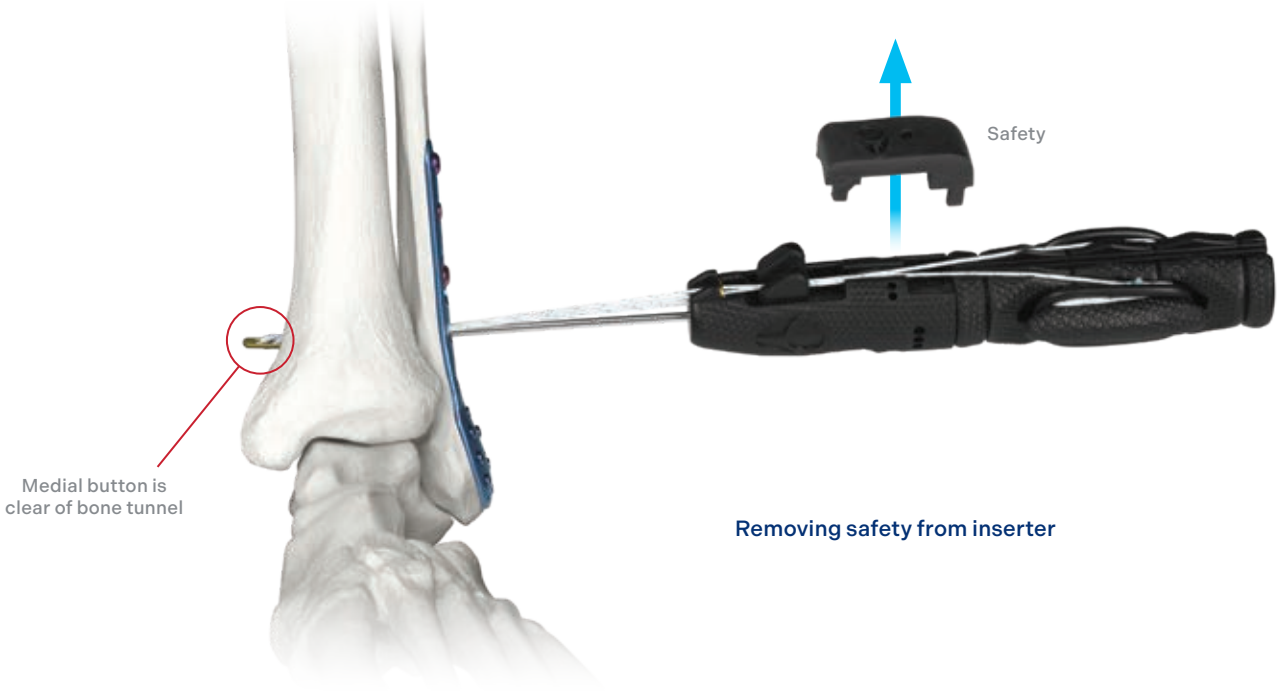


TENSOR™ Suture Button Inserter

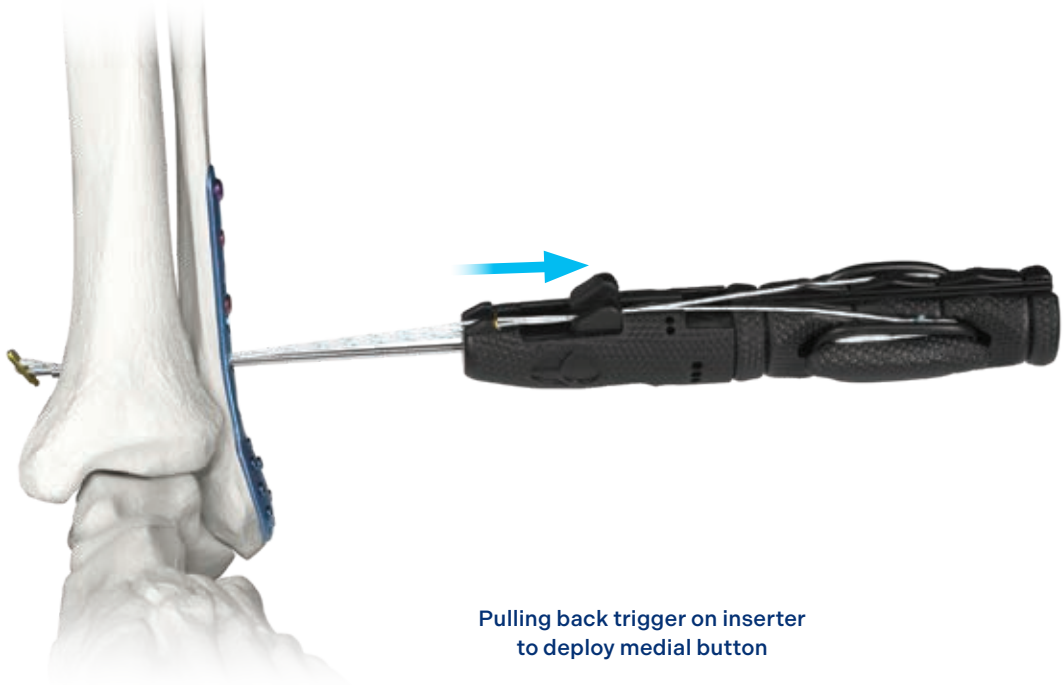
Insertion of TENSOR™ Device

STEP 4 Deploying the Medial Button

Be sure to keep the safety attached to the inserter until it is prepared for deployment of the medial button. To deploy the medial button, remove the safety and pull back on the trigger, away from the suture button construct. Once the trigger has been pulled back, push the inserter medially to ensure the medial button is clear of the bone tunnel. Pull back on the inserter handle to ensure the button is fully seated against the bone cortex. Use fluoroscopy to ensure the button is positioned in the desired orientation against the cortex of the bone (the button should be fully slipped and sitting in a "T" orientation against the medial cortex of the tibia).



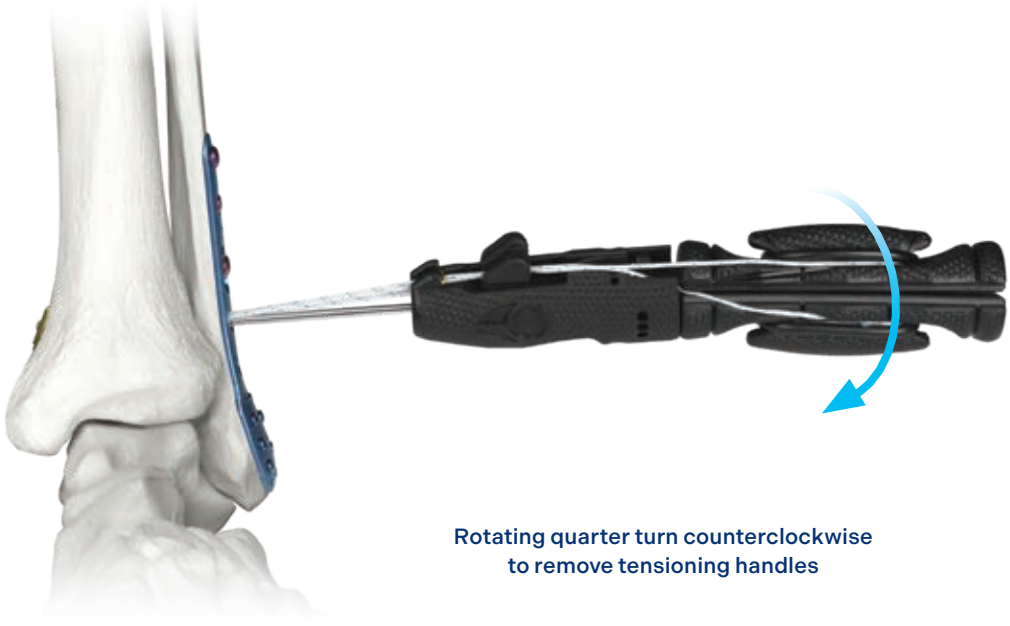
Removing safety from inserter



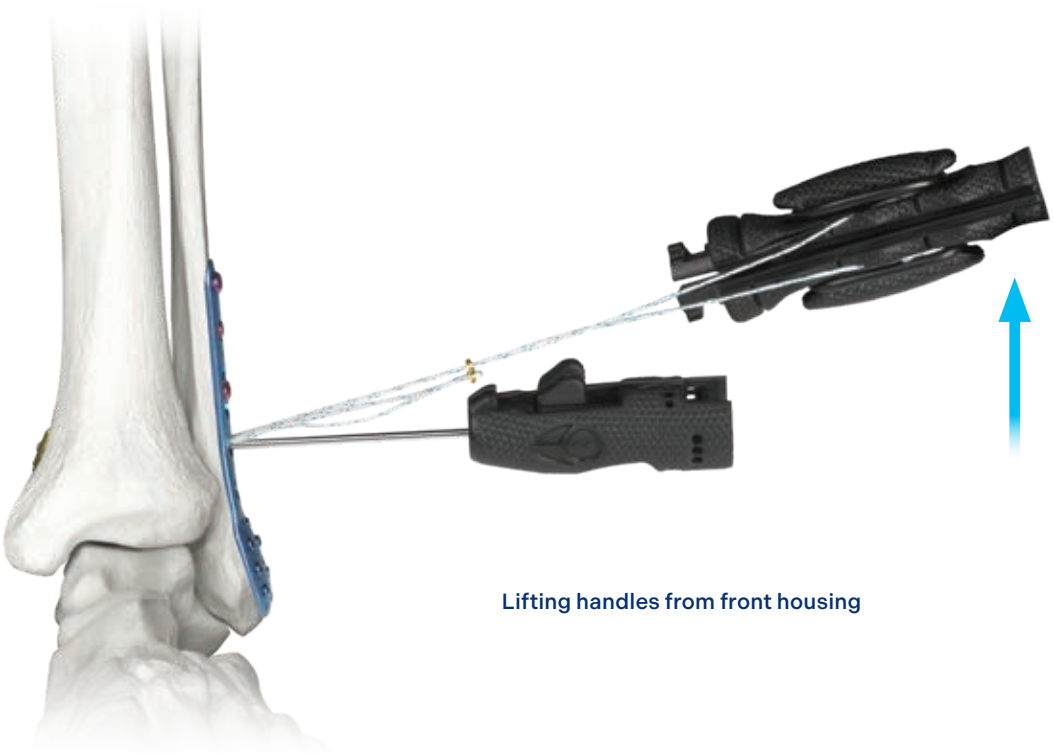
Pulling back trigger on inserter to deploy medial button

STEP 5 Tensioning the Lateral Button

To release the lateral button from the inserter, hold the front housing on the inserter and rotate the tensioning handles a quarter turn counterclockwise and lift the handles out of the front housing. Suture tension from the suture wrapped around the tensioning handles will release the lateral button from the front housing. Once the lateral button has been released, remove the front housing from the bone tunnel.



Rotating quarter turn counterclockwise to remove tensioning handles

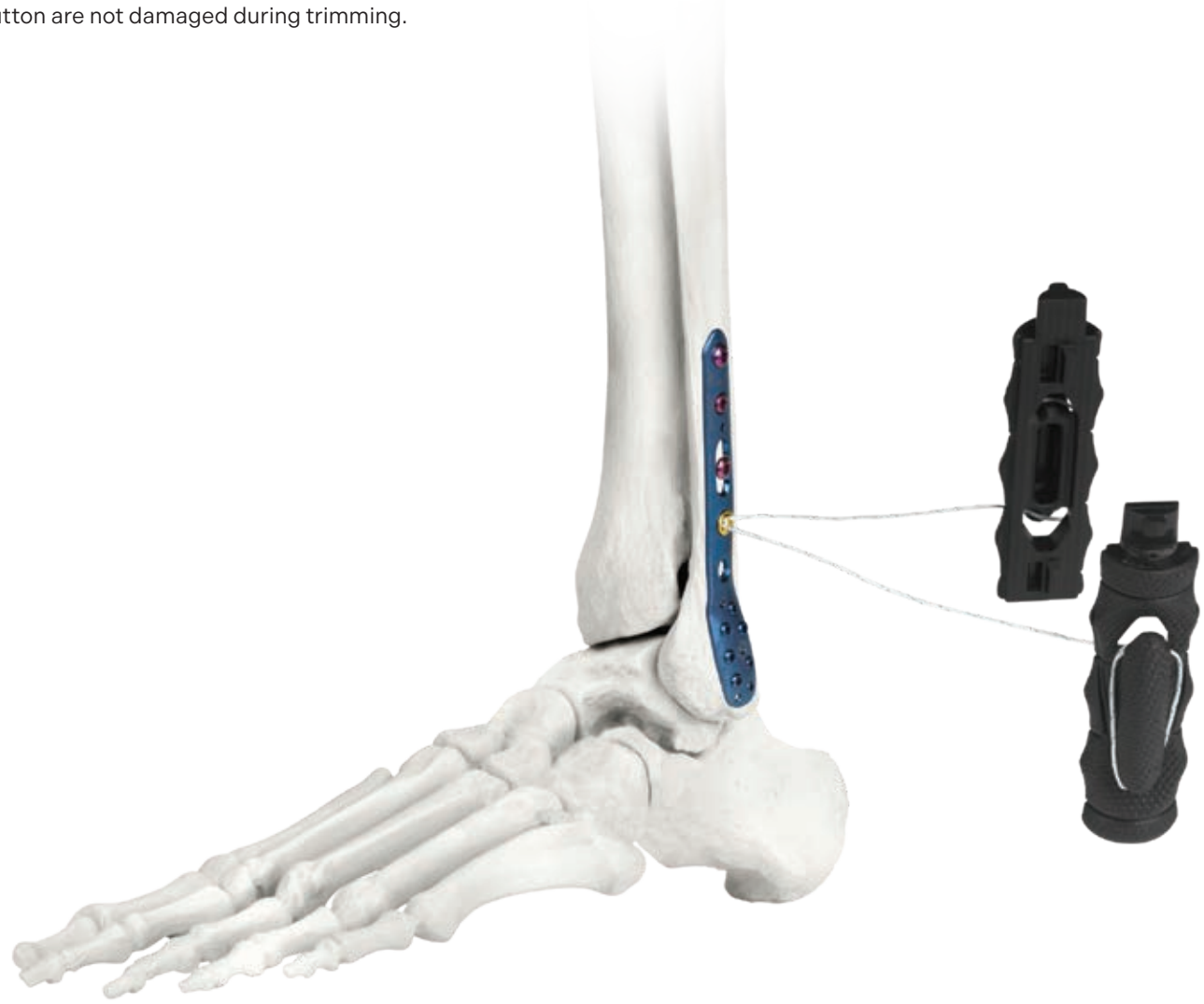


Lifting handles from front housing

Tensioning the Lateral Button (Cont'd)

While holding the tensioning handles in one hand, slide the lateral button down to the plate/bone. Tensioning of the lateral button can be achieved by separating the tensioning handles and alternately pulling each handle straight back, away from the construct. Continue to tension until the button sits flush with the plate/bone.

Finally, cut the tail ends of the suture so they are flush with the lateral button. Ensure the center sutures on the lateral button are not damaged during trimming.



Tensioning suture until lateral button is flush with plate

Depending on surgeon preference, either tip can be utilized to facilitate tensioning of the lateral button. Facilitate seating of the lateral button by using tweezers or instruments to push the button down to the construct prior to tensioning.

The soft tissue protector can be used to pull back on the lateral button to prevent bunching of the suture during tensioning.

Final Placement

Optional: Implant Removal

If removal is required, use a scalpel to cut the suture routing through the medial button and then remove the medial button. Then remove the lateral button and attached suture.

TENSOR™
Isolated Syndesmosis Injuries

Refer to the device insert (also printed at the back of this guide) for important information on the intended use/indications, device description, contraindications, precautions, warnings, and potential risks associated with this system.

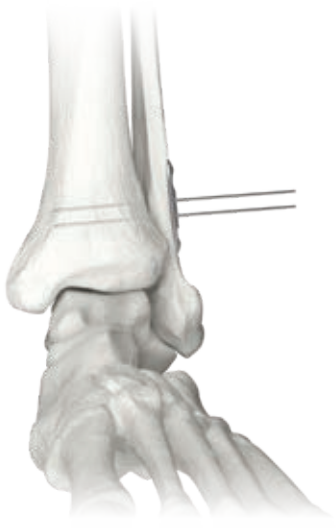
STEP 1 Syndesmosis Reduction

Reduce the syndesmosis and confirm that appropriate alignment and rotation are properly restored. Confirm using fluroscopy.

STEP 2 Optional: Washer Placement

For ankle syndesmosis procedures, an optional washer can be placed for additional fixation and support of the round button. Place the Two-Hole Washer on the posterolateral side of the fibula above the ankle joint before preparing the bone for suture button placement. The washer may be provisionally held using either 1.25mm K-Wires or 1.6mm Plate Holding K-Wires.

The plate holding K-wire may be used in either K-wire holes or washer holes to provisionally secure the plate to the bone.



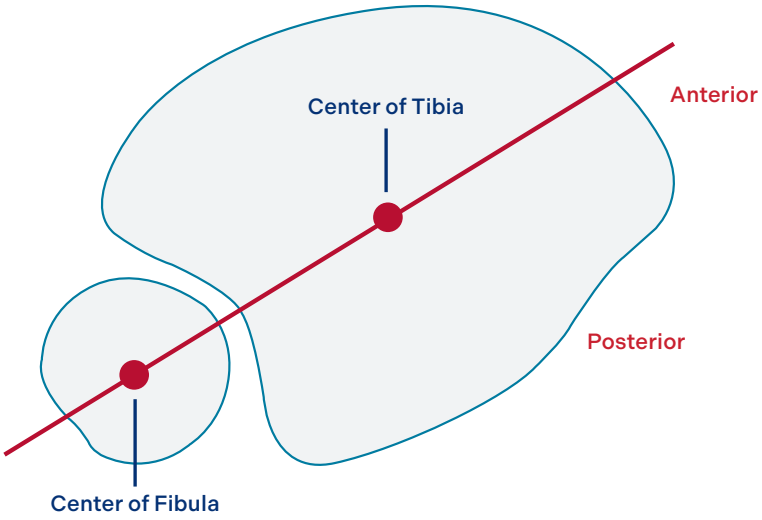
Placing Washer provisionally using K-wire

STEP 3 Bone Preparation

The typical trajectory is to start the guidewire on the posterolateral side of the fibula and aim the guidewire 30° anterior in the axial plane, to ensure the center of the tibia is targeted.

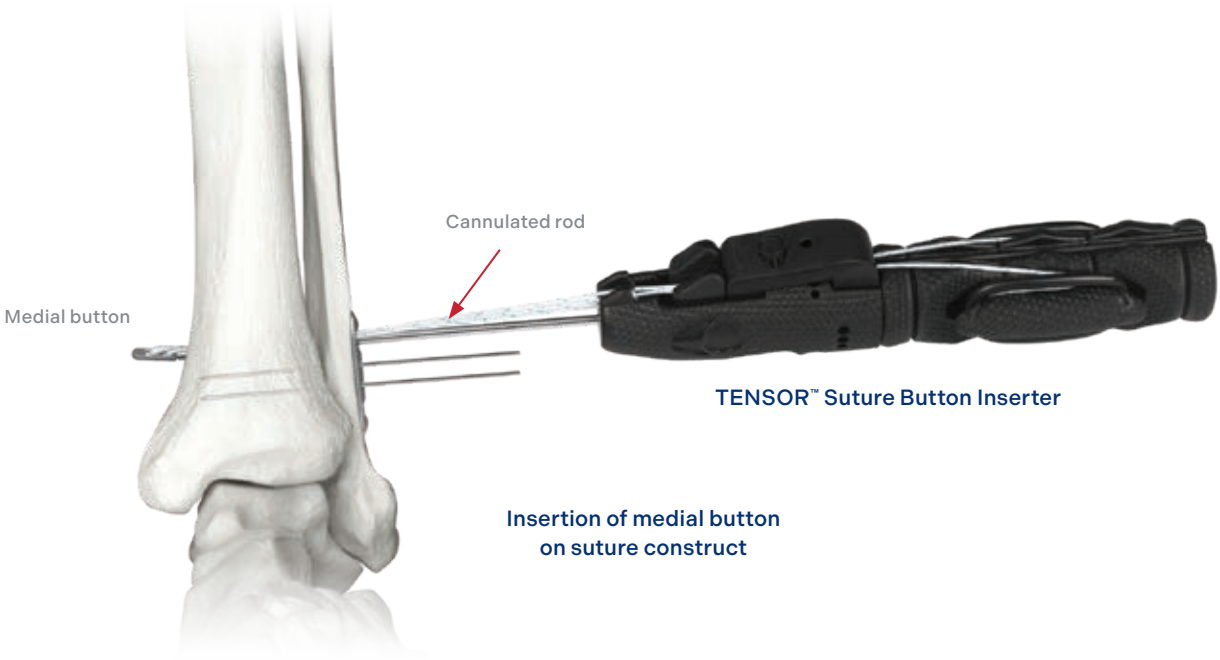
Using both the Cannulated 3.5mm Drill Bit and 3.5/1.4mm Soft Tissue Protector, place the drill over the guidewire and drill through all four cortices to create a bone tunnel.

A Solid 3.5mm Drill Bit is also available, depending on surgeon preference.



STEP 4 Device Insertion

Once the bone tunnel has been prepared, push the cannulated rod of the inserter through the tunnel until the medial button exits the medial tibial cortex and confirm button position via fluoroscopy. Once positioned, rotate the inserter so that the safety is facing either superiorly or inferiorly to the bone tunnel. As the medial button is deployed, this will help to ensure the button is in line with the medial axis of the tibia.

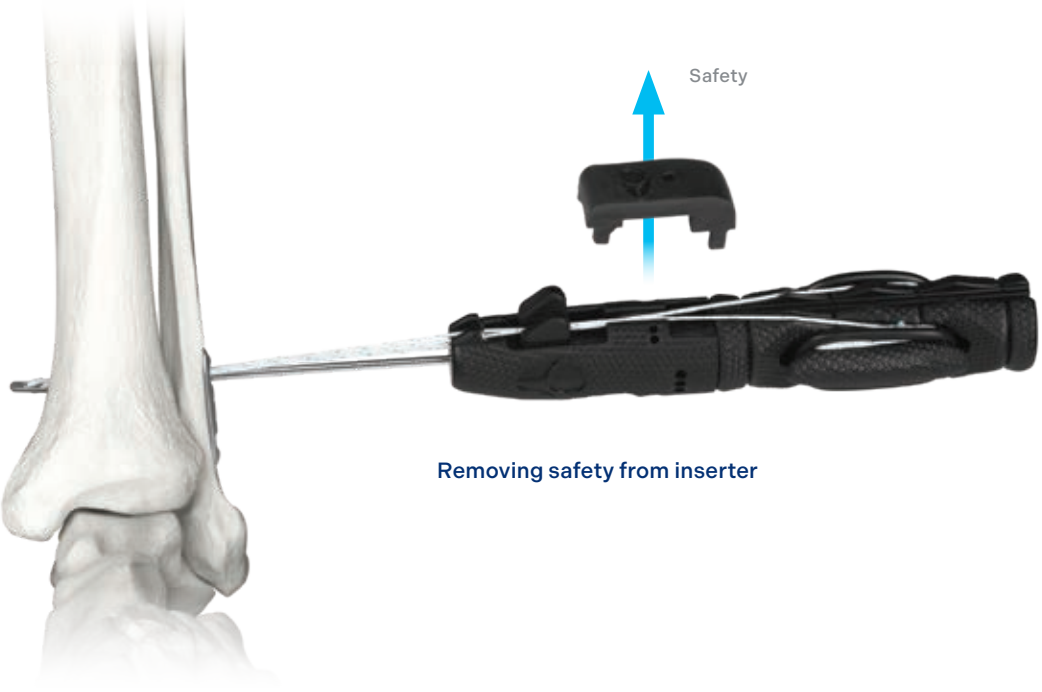


TENSOR™ Suture Button Inserter

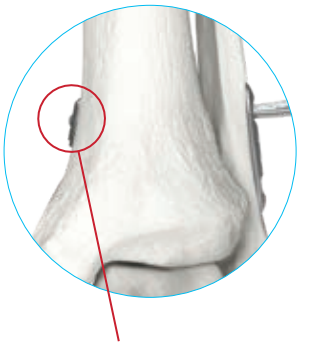
Insertion of medial button on suture construct

STEP 5 Deploying the Medial Button

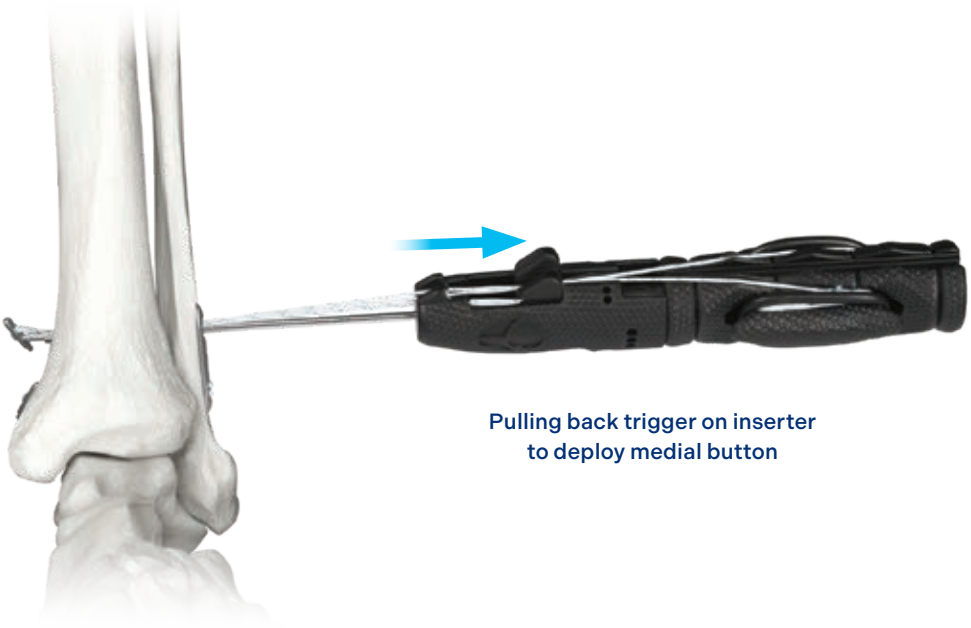
Be sure to keep the safety attached to the inserter until prepared to deploy the medial button. To deploy the medial button, remove the safety and pull back on the trigger, away from the suture button construct. Once the trigger has been pulled back, push the inserter medially to ensure the medial button is clear of the bone tunnel. Pull back on the inserter handle to ensure the button is fully seated against the bone cortex. Use fluoroscopy to ensure the button is positioned in the desired orientation against the cortex of the bone (the button should be fully slipped and sitting in a "T" orientation against the medial cortex of the tibia).



Removing safety from inserter



Medial button is flush on tibial cortex

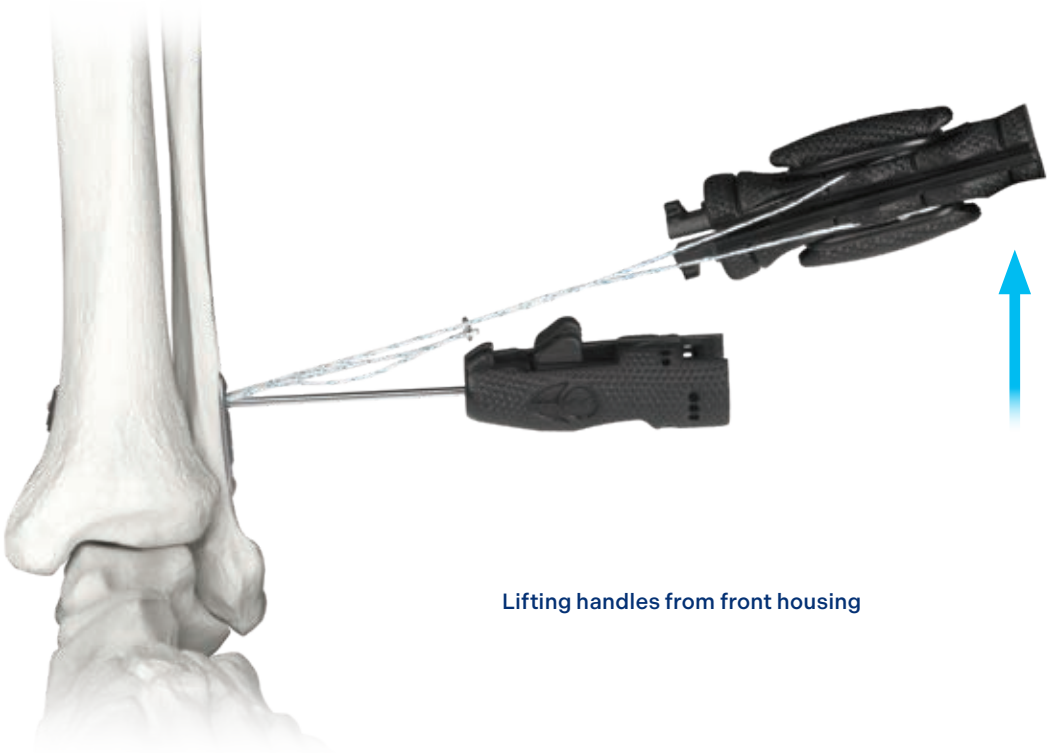


Pulling back trigger on inserter to deploy medial button

STEP 6 Tensioning the Lateral Button

To release the lateral button from the inserter, hold the front housing on the inserter and rotate the tensioning handles a quarter turn counterclockwise and lift the handles out of the front housing. Suture tension from the suture wrapped around the tensioning handles will release the lateral button from the front housing. Once the lateral button has been released, remove the front housing from the bone tunnel.

Rotating quarter turn counterclockwise to remove tensioning handles



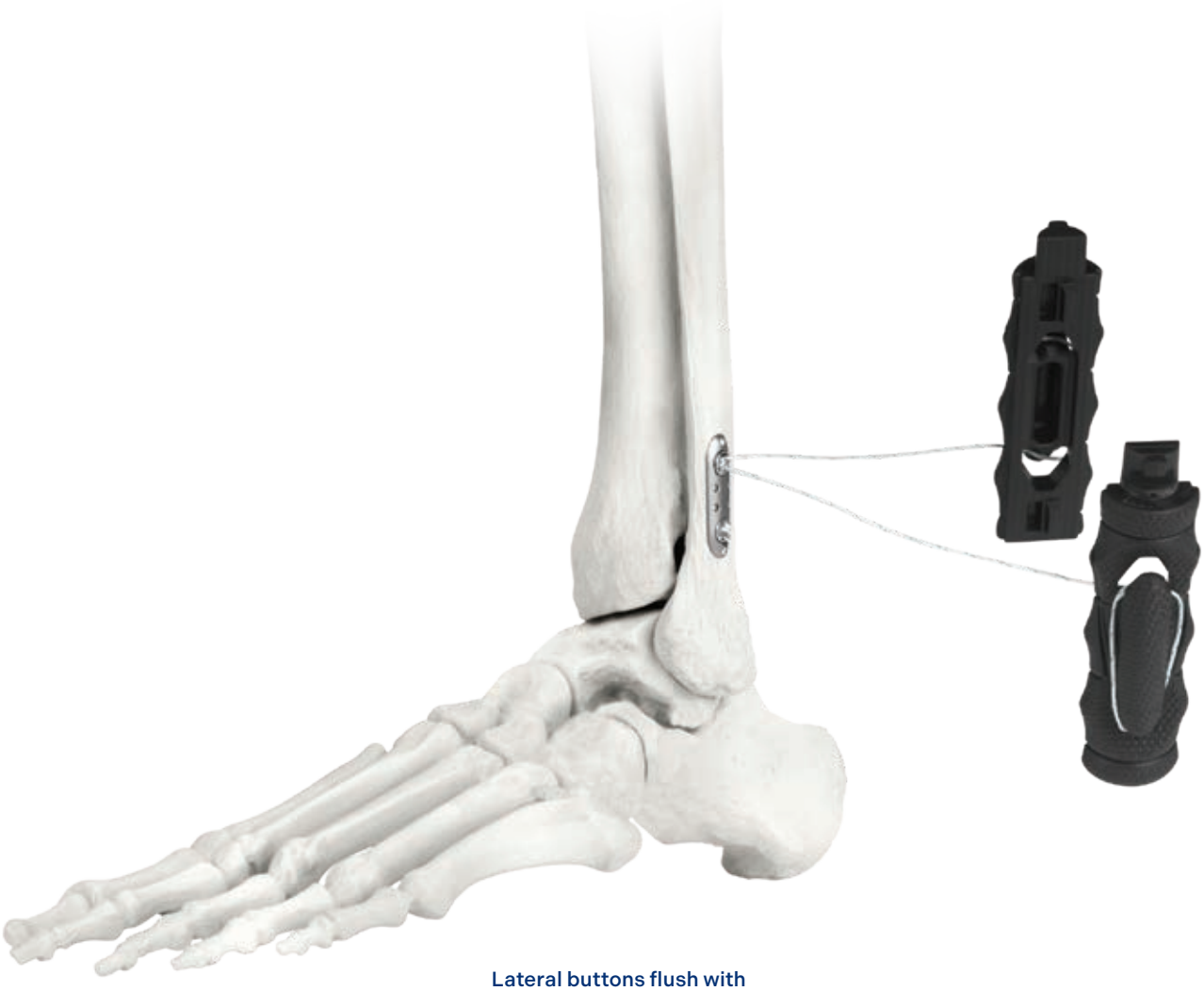
Lifting handles from front housing

Tensioning the Lateral Button (Cont'd)

While holding the tensioning handles in one hand, slide the lateral button down to the plate/bone.

Tensioning of the lateral button can be achieved by separating the tensioning handles and alternately pulling each handle straight back, away from the construct. Continue to tension until the button sits flush with the plate/bone.

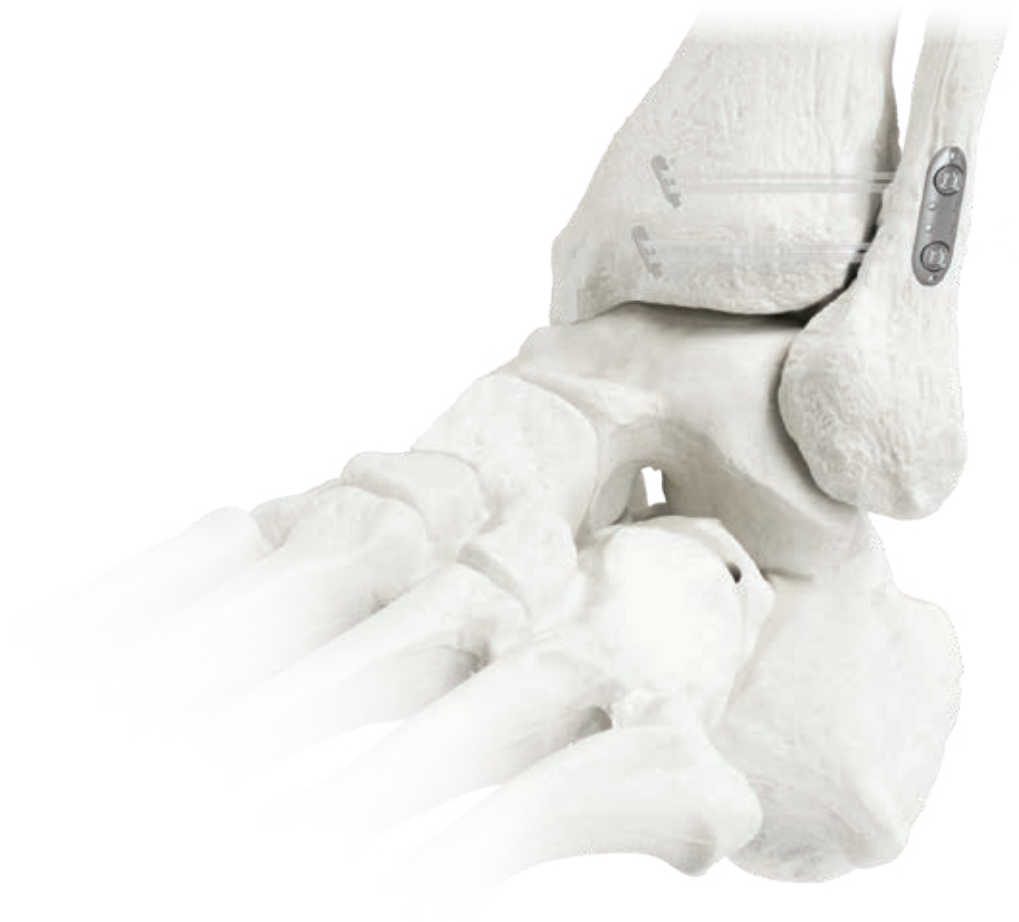
Finally, cut the tail ends of the suture so they are flush with the lateral button. Ensure the center sutures on the lateral button are not damaged during trimming.



Lateral buttons flush with two-hole washer plate

The soft tissue protector can be used as a fulcrum for the lateral button to prevent bunching of the suture during tensioning.

Final Placement



Optional: Implant Removal

If removal is required, use a scalpel to cut the suture routing through the medial button and then remove the medial button. Then remove the lateral button and attached suture.

INSTRUMENT OVERVIEW

STERILIZED SINGLE INSERTER KIT

TENSOR™ Inserter, Ti 1245.7000
TENSOR™ Inserter, SS 2245.7000

1.4mm Guidewire 6245.1220

3.5 Solid Drill Bit 6245.5035

3.5 Cannulated Drill Bit 6245.5135

Double Sided Soft Tissue Protector 6245.3500

STERILIZED TWO-HOLE WASHER KIT

TENSOR™ Two-Hole Washer, Ti 1245.0002
TENSOR™ Two-Hole Washer, SS 2245.0002

1.6mm Plate Holding K-Wire, 75mm 6179.1216

1.25mm K-Wires, 75mm 6245.1275

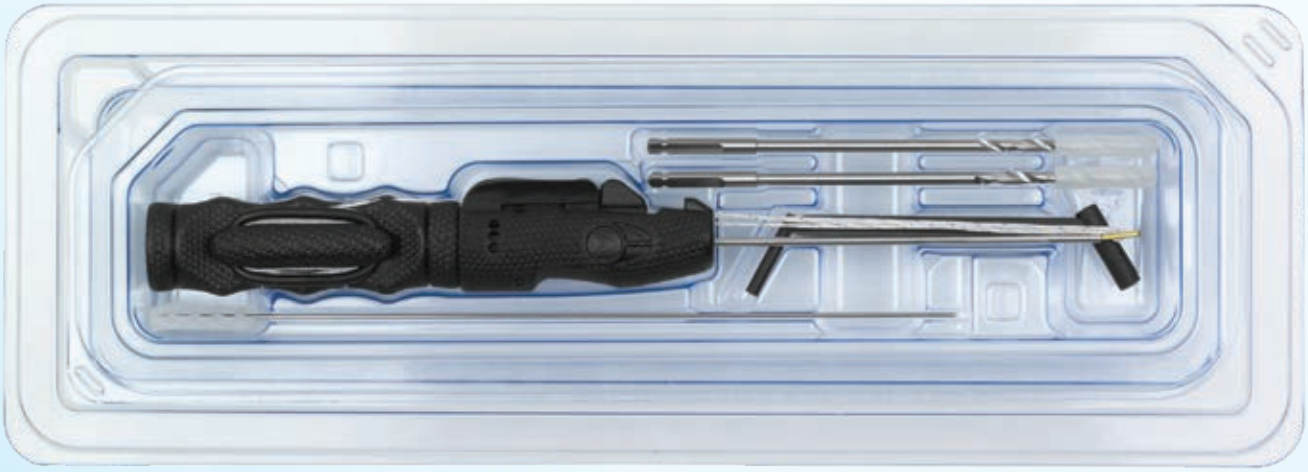
TENSOR™
Inserter Kit

1245.9000S TENSOR™ Single Inserter Kit, Ti

Part No.	Description	Qty
1245.7000	TENSOR™ Inserter, Ti	1
6245.1220	1.4mm Guidewire	1
6245.5035	3.5mm Solid Drill Bit	1
6245.5135	3.5mm Cannulated Drill Bit	1
6245.3500	Double Sided Soft Tissue Protector	1

2245.9000S TENSOR™ Single Inserter Kit, SS

Part No.	Description	Qty
2245.7000	TENSOR™ Inserter, SS	1
6245.1220	1.4mm Guidewire	1
6245.5035	3.5mm Solid Drill Bit	1
6245.5135	3.5mm Cannulated Drill Bit	1
6245.3500	Double Sided Soft Tissue Protector	1



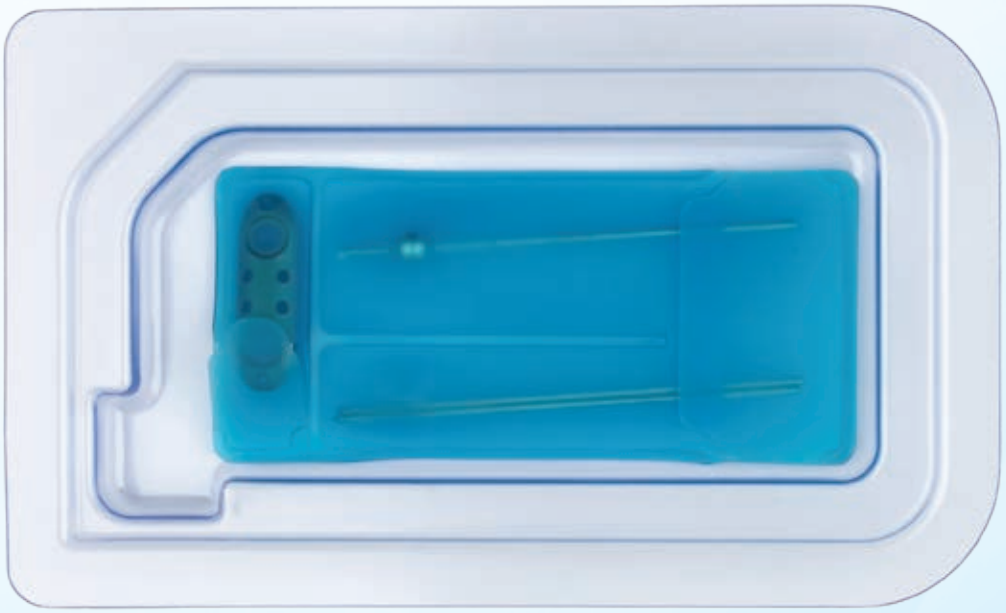
TENSOR™ SYNDESMOSIS TWO-HOLE
Washer Kit

1245.9002S TENSOR™ Syndesmosis Two-Hole Washer Kit, Ti

Part No.	Description	Qty
1245.0002	TENSOR™ Two-Hole Washer, Ti	1
6179.1216	1.6mm Plate Holding K-Wire, 75mm	1
6245.1275	1.25mm K-Wire, 75mm	2

2245.9002S TENSOR™ Syndesmosis Two-Hole Washer Kit, SS

Part No.	Description	Qty
2245.0002	TENSOR™ Two-Hole Washer, SS	1
6179.1216	1.6mm Plate Holding K-Wire, 75mm	1
6245.1275	1.25mm K-Wire, 75mm	2



Important Information on the TENSOR™ Suture Button System

DESCRIPTION

The TENSOR™ Suture Button System consists of metal buttons, a polymer suture prerouted through two buttons, and an optional two-hole washer. The buttons are available in various sizes to accommodate varying patient anatomy and surgical needs. The TENSOR™ suture and button implants are pre-routed on an inserter to aid in insertion, and provide fixation during the healing process for various injuries associated with ligamentous disruptions. TENSOR™ button and washer implants are manufactured from titanium alloy or stainless steel as specified in ASTM F136, F138 or F139. The suture is manufactured from ultra high molecular weight polyethylene (UHMWPE) as specified in ASTM F2848, and polyethylene terephthalate (PET). The implants are sterile packaged together with various instruments. All TENSOR™ components are single use only.

INDICATIONS

The TENSOR™ Suture Button System is intended to be used as an adjunct in fracture repair involving metaphyseal and periarticular small bone fragments where screws are not indicated, and as an adjunct in external and intramedullary fixation systems involving plates and rods, with fracture braces and casting.

Specifically, the TENSOR™ implants are intended to provide fixation during the healing process for the following indications:

Syndesmotic trauma, such as ankle syndesmosis fixation (syndesmosis disruptions), and as an adjunct in connection with trauma hardware for Weber B and C ankle fractures; fixation of dorsal distal radioulnar ligament (DRUL) disruptions; Acromioclavicular separations due to coracoclavicular ligament disruptions; Tarsometatarsal (TMT) injury, such as fixation of foot soft tissue separations due to a Lisfranc injury (Midfoot Reconstruction); Hallux Valgus reconstruction (correction) by providing for the reduction of 1st metatarsal-2nd metatarsal intermetatarsal angle; and, Carpal Metacarpal (CMC) joint arthroplasty as an adjunct in the healing process.

CONTRAINDICATIONS

Use of these implants is contraindicated in patients with the following conditions:

- Any active or suspended latent infection or marked local inflammation in or about the affected area.
- Compromised vascularity that would inhibit adequate blood supply to the fracture, injured or operative site.
- Bone stock compromised by disease, infection or prior implantation that cannot provide adequate support and/or fixation of the devices.
- Material sensitivity, documented or suspected.
- Obesity. An overweight or obese patient can produce loads on the implant that can lead to failure of the device itself.
- Patients having inadequate tissue coverage over the operative site.
- Implant utilization that would interfere with anatomical structures or physiological performance.
- Any mental or neuromuscular disorder which would create an unacceptable risk of fixation failure or complications in postoperative care.
- Other medical or surgical conditions which would preclude the potential benefit of surgery.

WARNINGS

The correct implant selection is extremely important. Failure to use the appropriate amount of fixation may results in loosening, subsidence, bending, cracking, or fracture of the implant and/or bone. Suture button based implants should not be used as the sole means of fixation for associated fractures and care should be taken to determine the correct number and type of implants in these situations. The correct implant size for a given patient can be determined by evaluating the patient's height, weight, functional demands and anatomy. Every implant must be used in the correct anatomic location, consistent with accepted standards of internal fixation.

PRECAUTIONS

The implantation of suture button fixation devices should be performed only by experienced surgeons with specific training in the use of this system because this is a technically demanding procedure presenting a risk of serious injury to the patient. Preoperative planning and patient anatomy should be considered when selecting implant size.

Surgical implants must never be reused. Even though the device appears undamaged, it may have small defects and internal stress patterns which could lead to breakage.

MRI SAFETY INFORMATION

These devices have not been evaluated for safety and compatibility in the MR environment. It has not been tested for heating, migration, or image artifact in the MR environment. The safety of these devices in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

CAUTIONS

Pre-operative

- These implants are for single use only.
- Implants that came in contact with body fluids should never be reused.
- Ensure that all components needed for surgery are available in the surgical suite.
- Inspection is recommended prior to surgery to determine if implants have been damaged during storage.
- While rare, intra-operative fracture or breakage of instruments can occur. Instruments which have experienced excessive force are susceptible to fracture. Instruments should be examined for damage prior to surgery.

Intra-operative

- Avoid surface damage of implants.
- Discard all damaged or mishandled implants.
- Implants are available in different versions, varying for example in length, diameter, and material. Select the required version carefully.
- During the course of the operation, repeatedly check to ensure that the connection between the implant and the instrument, or between the instruments, is secure.
- After the procedure check the proper positioning of all implants using the image intensifier.
- Do not use components from this system in conjunction with components from any other manufacturer's system unless otherwise specified.

Post-operative

- Post-operative patient activity: The implant may not support immediate full weight-bearing or other unsupported stress. For this reason post-operative instructions and warnings to patients are extremely important. External immobilization (e.g. bracing or casting) may be employed until X-rays or other procedures confirm adequate bone consolidation or ligamentous or tendinous healing.
- The implant is meant to act as a short-term implant, as the ligament(s) and or tendon(s) of the affected anatomy heal(s). In the event of a delay in bone consolidation or tendon or ligament healing, or if such consolidation or healing does not take place, or if explantation is not carried out, complications may occur, for example fracture or loosening of the implant or instability of the implant system. Regular post-operative examinations (e.g., X-ray checks) are advisable.
- The risk of post-operative complication (e.g. failure of an implant) is higher if patients are obese and/or cannot follow the recommendations of the physician because of any mental or neuromuscular disorder. For this reason those patients must have additional post-operative follow-up.
- Implant removal should be followed by adequate postoperative management to avoid fracture or refracture of the bone.

Informing the Patient

The implant affects the patient's ability to carry loads and her/his mobility and general living circumstances. The surgeon must counsel each patient individually on correct behavior and activity after the implantation.

The surgeon must warn each patient that the device cannot and does not replicate a normally healthy ligament or tendon, that the device can break or become damaged as a results of strenuous activity, trauma, mal-union or non-union and that the device has a finite expected service life and may need to be removed at some time in the future.

ADVERSE EFFECTS

In many instances, adverse results may be clinically related rather than device related. The following are the most frequent adverse effects involving the use of suture button fixation devices:

- Delayed union or non-union of the fracture site.
- These devices can break when subjected to the increased loading associated with delayed unions and/or non-unions. These types of internal fixation devices are load bearing devices which are intended to facilitate healing by holding the relative position of bones that have had a ligamentous disruption. If healing is delayed or does not occur, the appliance may eventually break due to fatigue. Loads on the device produced by load bearing and the patient's activity level will dictate the longevity of the device.
- Conditions attributable to non-union, osteoporosis, osteomalicia, diabetes, inhibited revascularization and poor bone formation can cause loosening, subsidence, bending, cracking, fracture of the device or premature loss of fixation with the bone.
- Improper alignment can cause bending, cracking or even breakage of the device.
- Early or late infection, deep or superficial.
- Deep venous thrombosis.
- Avascular necrosis.
- Shortening of the affected bone/fracture site.

Important Information on the TENSOR™ Suture Button System

- Subclinical nerve damage may possibly occur as a result of the surgical trauma.
- Material sensitivity reactions in patients following surgical implantation have rarely been reported, however their significance awaits further clinical evaluation.
- Osteomyelitis surrounding the suture.
- Rediastasis resulting from a failure of the implant insertion technique.
- Polyethylene wear-related painful aseptic osteolysis.

PACKAGING

These implants and instruments are supplied pre-packaged and sterile, using gamma irradiation or Ethylene Oxide sterilization. The integrity of the sterile packaging should be checked to ensure that sterility of the contents is not compromised. Packaging should be carefully checked for completeness and all components should be carefully checked to ensure that there is no damage prior to use. Damaged packages or products should not be used, and should be returned to Globus Medical. During surgery, after the correct size has been determined, remove the products from the packaging using aseptic technique.

All TENSOR™ instruments are provided sterile only and are single use. Additional general surgical instruments may be available nonsterile. Nonsterile instruments are steam sterilized prior to use, as described in the STERILIZATION section below. Following use or exposure to soil, instruments and instrument trays and cases must be cleaned, as described in the CLEANING section below.

HANDLING

All instruments and implants should be treated with care. Improper use or handling may lead to damage and/or possible malfunction. Instruments should be checked to ensure that they are in working order prior to surgery.

Implants are single use devices and should not be cleaned. Re-cleaning of single use implants might lead to mechanical failure and/or material degradation. Discard any implants that may have been accidentally contaminated.

CLEANING

Nonsterile instruments should be cleaned separately from instrument trays and cases. Lids should be removed from cases for the cleaning process, if applicable. All instruments that can be disassembled must be disassembled for cleaning. All handles must be detached. Instruments may be reassembled following sterilization. The products should be cleaned using neutral cleaners before sterilization and introduction into a sterile surgical field or (if applicable) return of the product to Globus Medical.
Cleaning and disinfecting can be performed with aldehyde-free solvents at higher temperatures. Cleaning and decontamination must include the use of neutral cleaners followed by a deionized water rinse. Note: certain cleaning solutions such as those containing formalin, glutaraldehyde, bleach and/or other alkaline cleaners may damage some devices, particularly instruments; these solutions should not be used.
The following cleaning methods should be observed when cleaning instruments and instrument trays and cases after use or exposure to soil, and prior to sterilization:

1. Immediately following use, ensure that the instruments are wiped down to remove all visible soil and kept from drying by submerging or covering with a wet towel.
2. Disassemble all instruments that can be disassembled.
3. Rinse the instruments under running tap water to remove all visible soil. Flush the lumens a minimum of 3 times, until the lumens flush clean.
4. Prepare Enzol® (or a similar enzymatic detergent) per manufacturer's recommendations.
5. Immerse the instruments in the detergent and allow them to soak for a minimum of 2 minutes.
6. Use a soft bristled brush to thoroughly clean the instruments. Use a pipe cleaner for any lumens. Pay close attention to hard to reach areas.
7. Using a sterile syringe, draw up the enzymatic detergent solution. Flush any lumens and hard to reach areas until no soil is seen exiting the area.
8. Remove the instruments from the detergent and rinse them in running warm tap water.
9. Prepare Enzol® (or a similar enzymatic detergent) per manufacturer's recommendations in an ultrasonic cleaner.
10. Completely immerse the instruments in the ultrasonic cleaner and ensure detergent is in lumens by flushing the lumens. Sonicate for a minimum of 3 minutes.
11. Remove the instruments from the detergent and rinse them in running deionized water or reverse osmosis water for a minimum of 2 minutes.
12. Dry instruments using a clean soft cloth and filtered pressurized air.
13. Visually inspect each instrument for visible soil. If visible soil is present, then repeat cleaning process starting with Step 3.

CONTACT INFORMATION

Globus Medical may be contacted at 1-866-GLOBUS1 (456-2871). A surgical technique manual may be obtained by contacting Globus Medical.

STERILIZATION

These implants and instruments are supplied sterile in kits. Washers and general surgical instruments may also be available non-sterile.

Sterile TENSOR™ Suture Button kits are sterilized by Ethylene Oxide. The sterile Two-Hole Washer kits are sterilized by gamma radiation, validated to ensure a Sterility Assurance Level (SAL) of 10^{-6}. Sterile products are packaged in a heat-sealed PETG Tray/Tyvek lid. The expiration date is provided on the package label. These products are considered sterile unless the packaging has been opened or damaged. Sterile implants meet pyrogen limit specifications.

Nonsterile implants and instruments have been validated to ensure an SAL of 10^{-6}. The use of an FDA-cleared wrap is recommended, per the Association for the Advancement of Medical Instrumentation (AAMI) ST79, *Comprehensive Guide to Steam Sterilization and Sterility Assurance in Health Care Facilities*. It is the end user's responsibility to use only sterilizers and accessories (such as sterilization wraps, sterilization pouches, chemical indicators, biological indicators, and sterilization cassettes) that have been cleared by the FDA for the selected sterilization cycle specifications (time and temperature).

When using a rigid sterilization container, the following must be taken into consideration for proper sterilization of Globus devices and loaded graphic cases:

- Recommended sterilization parameters are listed in the table below.
- Only FDA-cleared rigid sterilization containers for use with pre-vacuum steam sterilization may be used.
- When selecting a rigid sterilization container, it must have a minimum filter area of 176 in^2 total, or a minimum of four (4) 7.5in diameter filters.
- No more than one (1) loaded graphic case or its contents can be placed directly into a rigid sterilization container.
- Stand-alone modules/racks or single devices must be placed, without stacking, in a container basket to ensure optimal ventilation.
- The rigid sterilization container manufacturer's instructions for use are to be followed; if questions arise, contact the manufacturer of the specific container for guidance.
- Refer to AAMI ST79 for additional information concerning the use of rigid sterilization containers.

For implants and instruments provided NONSTERILE, sterilization is recommended (wrapped or containerized) as follows:

Method	Cycle Type	Temperature	Exposure Time	Drying Time
Steam	Pre-vacuum	132°C (270°F)	4 Minutes	30 Minutes

These parameters are validated to sterilize only this device. If other products are added to the sterilizer, the recommended parameters are not valid and new cycle parameters must be established by the user. The sterilizer must be properly installed, maintained, and calibrated. Ongoing testing must be performed to confirm inactivation of all forms of viable microorganisms.

CAUTION: Federal (U.S.A.) Law restricts this Device to Sale by or on the Order of a Physician.

DI226A Rev B

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