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OIC FLEX-FIX™ System
Ankle Syndesmosis Repair Kit
Surgical Technique Guide

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The technique description herein is made available to the healthcare professional to illustrate the author's suggested treatment for the uncomplicated procedure. In the final analysis, the preferred treatment is that which addresses the specific needs of the patient.

System Features

INTRODUCTION

Syndesmotic injuries occur when the stabilizing distal tibiofibular ligaments are damaged during extreme ankle roll/rotation. These injuries may occur with or without fractures to the ankle. The forceful external rotation and abduction of the ankle widens the ankle mortise as the talus pushes the distal fibula laterally away from its articulation with the distal tibia. Stretching or tearing of the syndesmosis, deltoid and associated ligamentous structures results in severe pain, ankle instability and diastasis. A distal fibular fracture, usually above the joint line, is often involved in more severe injuries.

The OIC FLEX-FIXTM System is designed to be used with or without a bone plate depending on if an associated fibula fracture is present*. The kit is comprised of a suture button construct assembled on a deployment handle, a Ø3.7mm drill bit, and a 3.5mm washer.

The Ø3.7mm drill is provided to prepare a bone tunnel through the fibula and tibia. The suture button construct is comprised of two components; a medial body and a lateral body, connected by UHMWPE suture tape. The suture tape has a one-way sliding knot, which sits inside the lateral body and enables the reduction of the Syndesmotic injury.

DESIGN FEATURES

- Ti6Al4V metallic implants
- 1.5mm UHMWPE suture tape
- Low-profile to minimize soft-tissue irritation
- Designed to be used with or without a bone plate
- No need for a medial incision
- Simple and controlled deployment mechanism
- Allows for micromotion during healing which more closely mimics true joint mechanics
- Minimizes risk of hardware removal commonly associated with tradition rigid screw fixation
- System is provided as a single-use sterile kit.

*Bone plates are part of the OIC Small Fragment System and must be purchased separately. Washer must be used when no bone plate is implanted.

WARNING: The following surgical technique guide was prepared based on existing systems with clinical history. OIC does not provide medical advice and recommends that surgeons exercise their own professional judgment when determining a patient's course of treatment. This guide is provided for educational purposes only.

Indications and Warnings

INDICATIONS FOR USE

The OIC FLEX-FIX™ System is intended to provide fixation during the healing process following trauma to the Ankle Syndesmosis (syndesmosis disruption) and as an adjunct in connection with trauma hardware for ankle fractures such as Weber B and C. The device is intended for use in adults.

CONTRAINDICATIONS

- Sensitivity to implant material
- Active infection or latent infection
- Osteoporosis
- Insufficient quantity or quality of bone/soft tissue
- Conditions which tend to retard healing, blood supply limitations, previous infections, etc.
- Conditions that restrict the patient's ability or willingness to follow postoperative instructions during the healing process.
- Cases with malignant primary or metastatic tumors which preclude adequate bone support or fixations unless supplemental fixation or stabilization methods are utilized.

PREOPERATIVE PLANNING

Surgical Technique – Correct surgical technique is essential to a successful outcome. Proper placement of implants is necessary to effectively treat patients. Please review the surgical technique for effective surgical procedures. When treating a syndesmotic injury with a fibular fracture, the fracture must be fixed first. Refer to the OIC Small Fragment System surgical technique for more information. Wherever and whenever applicable, use fluoroscopic guidance to assure proper position and stable fixation.

Implant Suitability – The following factors should be considered:

- A patient's size, strength, skeletal characteristics, skeletal health, and general health. Overweight or musculoskeletal deficient or unhealthy patients may create greater loads on implants that may lead to breakage or other failure of the device.
- A patient's activity level during the time the implant is in the patient's body, including such factors as whether the patient's occupation or typical activities include running, heavy lifting, impact loading, or the like.
- Whether a patient has a degenerative or progressive disease that delays or prevents healing and leads to exceeding the effective life of the device.
- If a patient is suspected of having material or foreign body sensitivities, appropriate testing should be accomplished prior to implantation.
- Mental conditions or substance abuse problems that may prevent a patient from understanding or following directions or observing precautions.

Device Alterations – The implant assembly is not designed to be physically altered, bent, notched, gouged, reamed, scratched or cut.

Component Compatibility – The implants are compatible with OIC Small Fragment bone plates and 7mm Washer.

POSTOPERATIVE CARE

After completion of procedure normal wound care should be implemented. Postoperative follow-ups are advised. The fixation should be considered temporary until healing of bone to tissue is complete. Immobilize the ankle in a posterior splint or cast in the neutral position. The patient may be non-weight bearing for 4-8 weeks per surgeon's protocol. Early weight bearing, or other unsupported stresses substantially increase implant loading and increase the risk of loosening or breaking the device.

Patients should be cautioned against unassisted activity that requires movement of repaired area. Postoperative care and physical therapy should be structured to prevent loading of the operative extremity until stability is evident.

NO REUSE

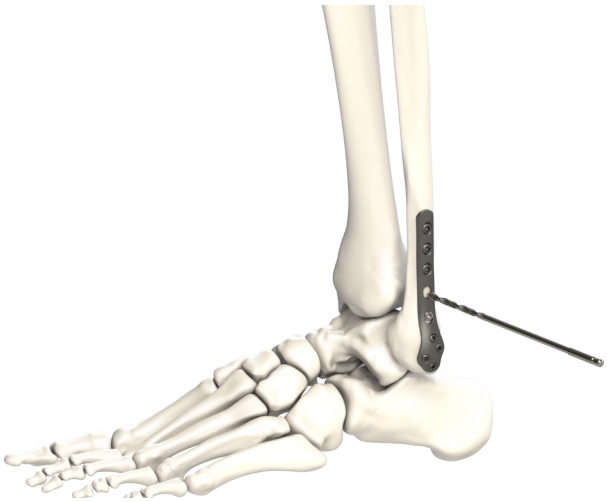
Surgical implants and components are NEVER TO BE REUSED. Single use devices should not be reused due to risks of breakage, failure or patient infection.

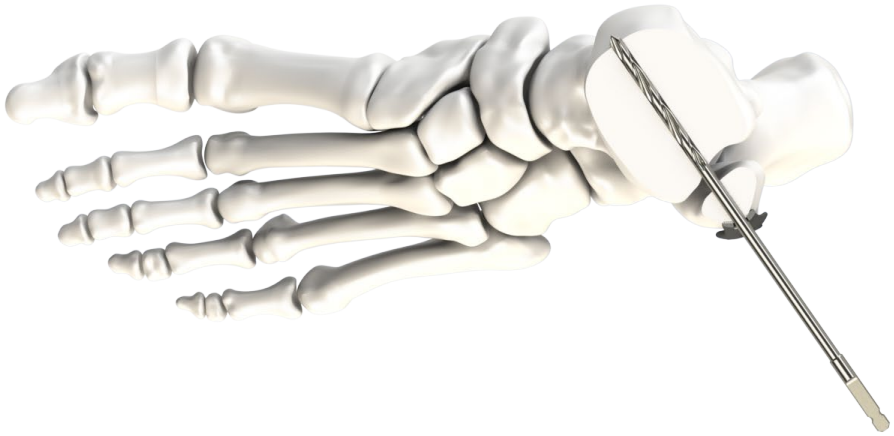
MAGNETIC RESONANCE IMAGING (MRI) SAFETY

The OIC FLEX-FIX™ System has not been evaluated for safety in the MR environment. It has not been tested for heating or unwanted movement in the MR environment. The safety of OIC FLEX-FIX™ System in the MR environment is unknown. Performing an MR exam on a person who has this medical device may result in injury or device malfunction. The system is to be used only in skeletally mature adult patients.

PREPARE TUNNEL

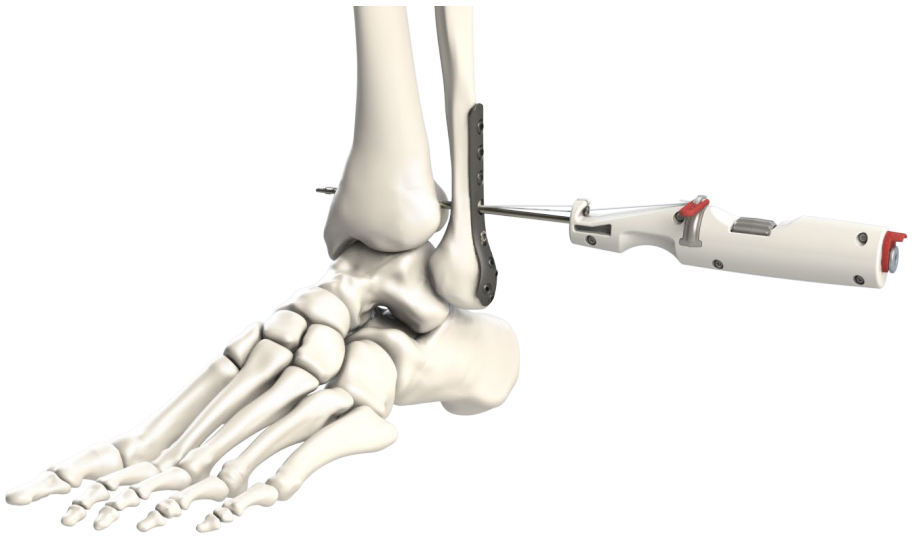
The Ø3.7mm drill (DR37-140) is used to prepare a tunnel through the fibula and tibia. Using either a screw hole or slotted hole in the plate approximately 1" to 1.5" above the joint line, advance the drill through a point slightly posterior to the midpoint of the fibula in the AP plane, aiming for the cross-sectional centroid of the tibia. This angle should be approximately 30 degrees anterior to the coronal plane. Advance the drill until the skin is tented on the medial side of the tibia, taking care to avoid damage to neurovascular structures. Remove the drill.





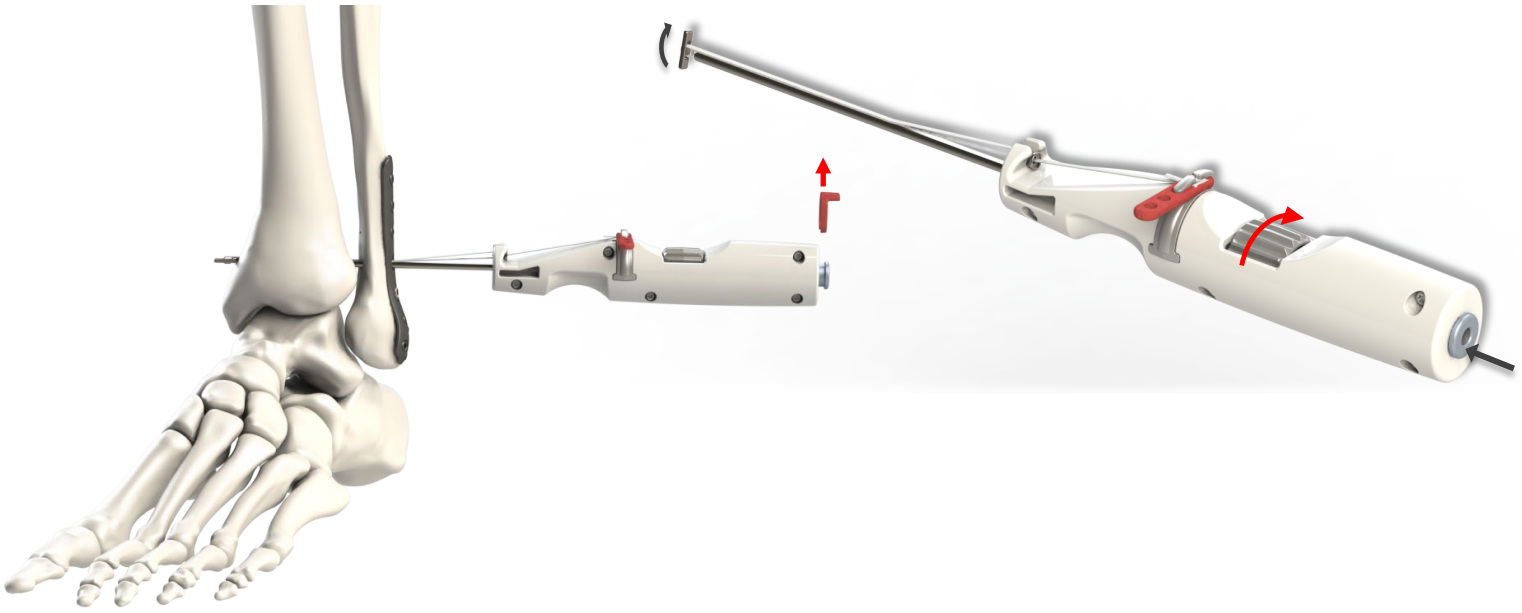
DEPLOY IMPLANTS

Using the handle, carefully insert the medial toggle body through the prepared tunnel and advance it to the medial cortex of the tibia. Use fluoroscopy to ensure the both eyelets are visible beyond the cortex before deployment. The skin on the medial side should be tented. To ensure proper orientation of the medial toggle body along the long axis of the tibia, ensure the top of the deployment handle is oriented up.



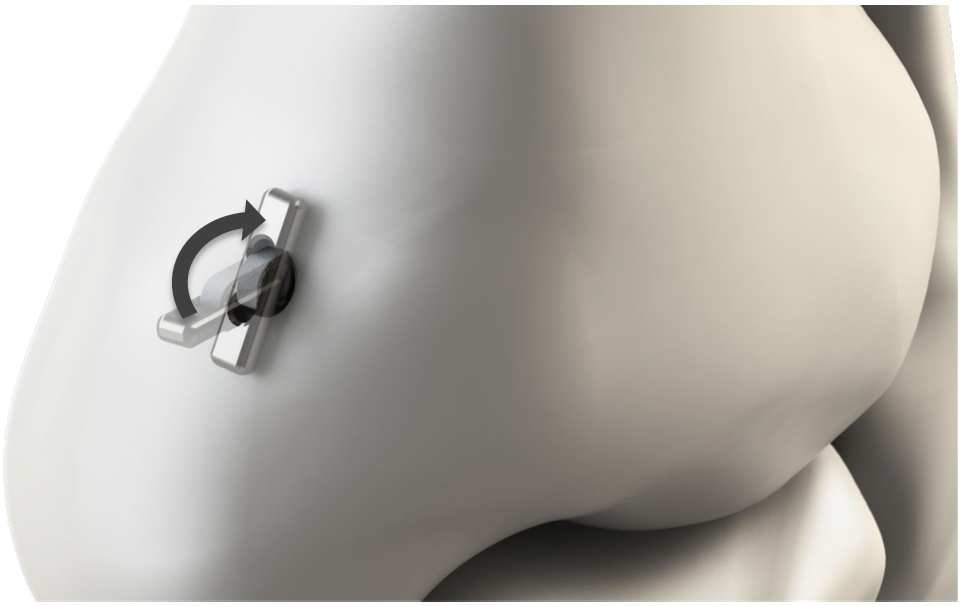
DEPLOY IMPLANTS (CONTINUED)

Remove the safety clip on the back end of the handle. Do not undo sutures from the handle yet.



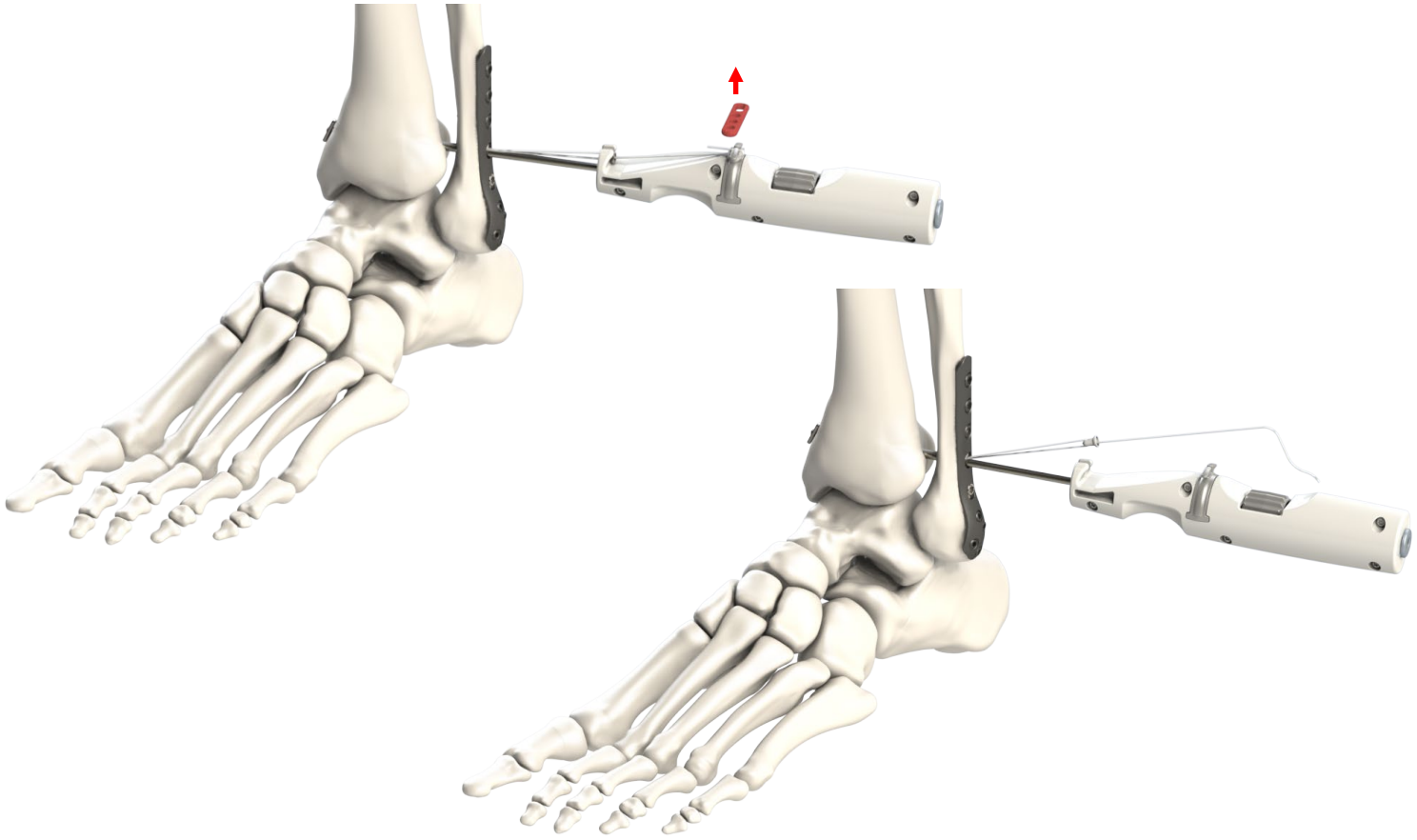
Rotate the thumb wheel on the handle clockwise until it stops to deploy the medial toggle body on the medial tibial cortex. Gently pull back on the handle to confirm proper deployment has occurred. Use fluoroscopy to visually confirm orientation.

NOTE: *If for some reason the medial toggle body is not completely flipped or is accidentally deployed in the drilled tunnel, carefully advance the handle to push it out and onto the medial cortex.*



DEPLOY IMPLANTS (CONTINUED)

Remove the silicone tab and unwrap the sutures from the cleat on the handle. Pull the lateral button up and free from the handle.



Remove and discard the deployment handle.

TIGHTEN IMPLANT ASSEMBLY

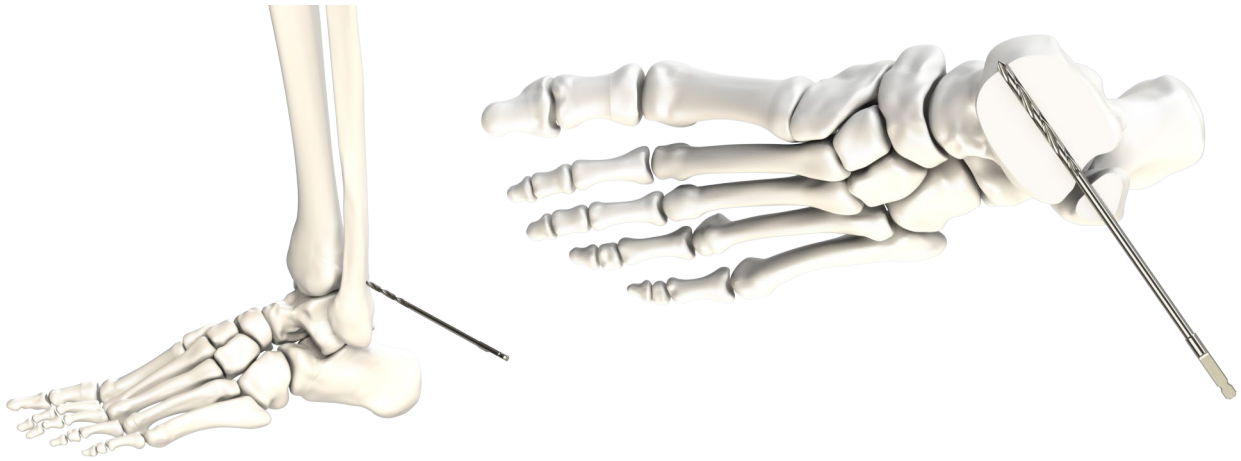
While maintaining lateral tension on the suture tape, pull on the free suture ends in an alternating fashion to reduce the assembly. Pulling the suture ends in an alternating fashion will prevent bunching of the suture tape. Once the lateral button is seated in the plate, pull the suture ends tight in opposing directions to set the desired tension.

Tie either a single square knot or a minimum of two alternating half-hitches to secure the lateral button. Take care to ensure that the knots are tight and sitting all the way inside the cavity of the lateral button.

Cut the suture tape flush with the back of the lateral button to complete the construct.

PREPARE TUNNEL

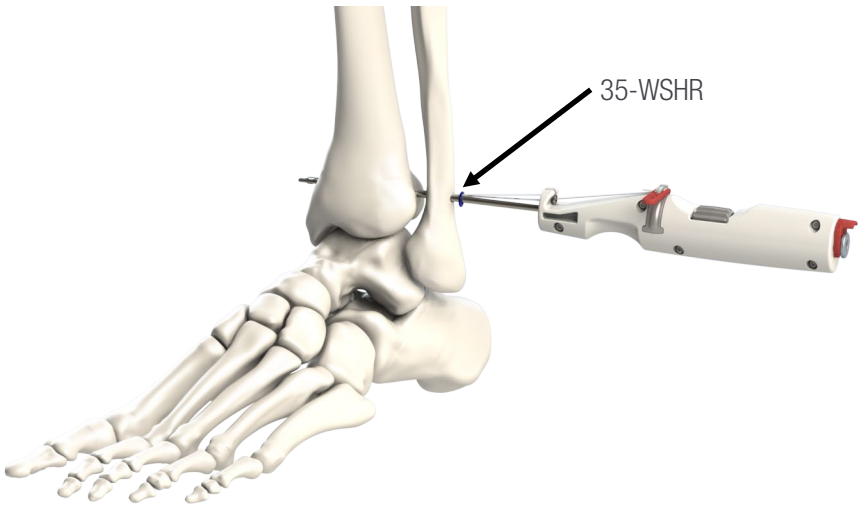
The Ø3.7mm drill (DR37-140) is used to prepare a tunnel through the fibula and tibia. Approximately 1" to 1.5" above the joint line, advance the drill through a point slightly posterior to the midpoint of the fibula in the AP plane, aiming for the cross-sectional centroid of the tibia. This angle should be approximately 30 degrees anterior to the coronal plane. Advance the drill until the skin is tented on the medial side of the tibia, taking care to avoid damage to neurovascular structures. Remove the drill.



DEPLOY IMPLANTS

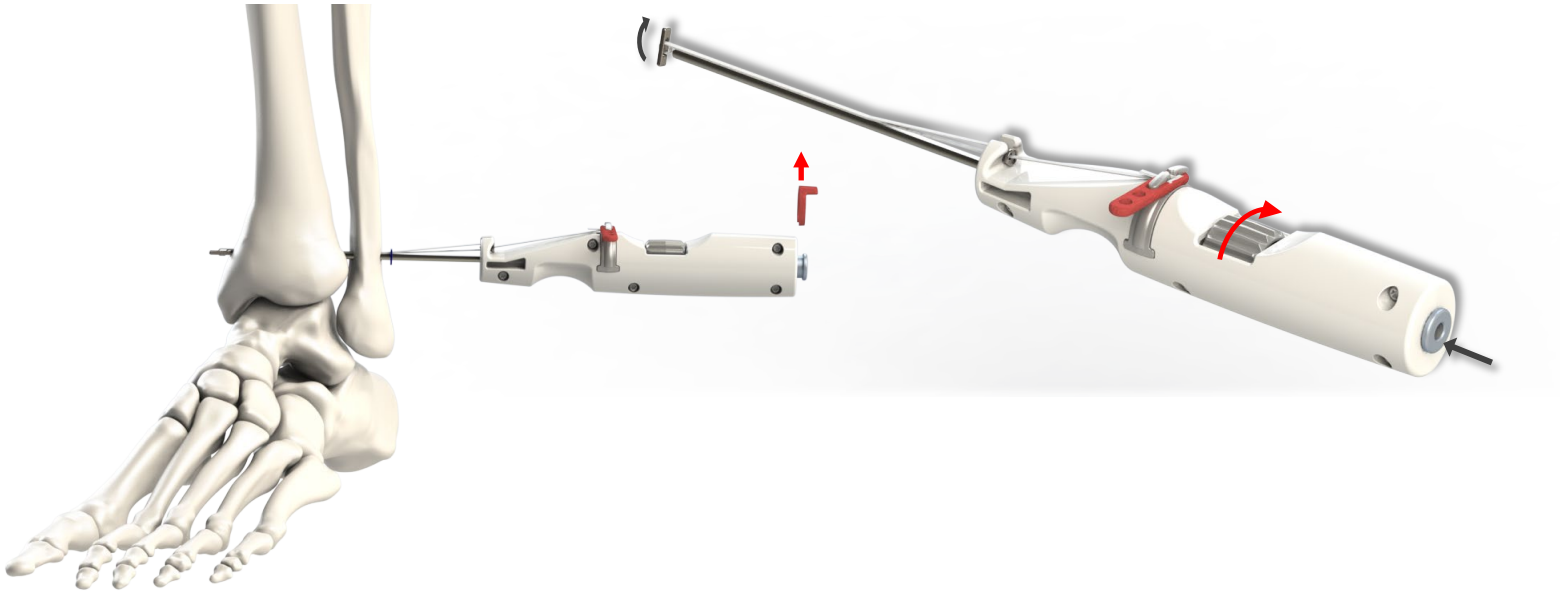
A WASHER MUST BE USED IF NO BONE PLATE IS PRESENT.

Before insertion, place the provided washer (35-WSHR) over the medial toggle body and the suture at the tip of the handle and slide it to the middle of the shaft ensuring that the recess on the top of the washer faces the lateral button. Carefully insert the medial toggle body through the prepared tunnel and advance it to the medial cortex of the tibia. Use fluoroscopy to ensure the both eyelets are visible beyond the cortex before deployment. The skin on the medial side should be tented. To ensure proper orientation of the medial toggle body along the long axis of the tibia, ensure the top of the deployment handle is oriented up.



DEPLOY IMPLANTS (CONTINUED)

Remove the safety clip on the back end of the handle. Do not yet remove the silicone tab or the sutures from the handle.



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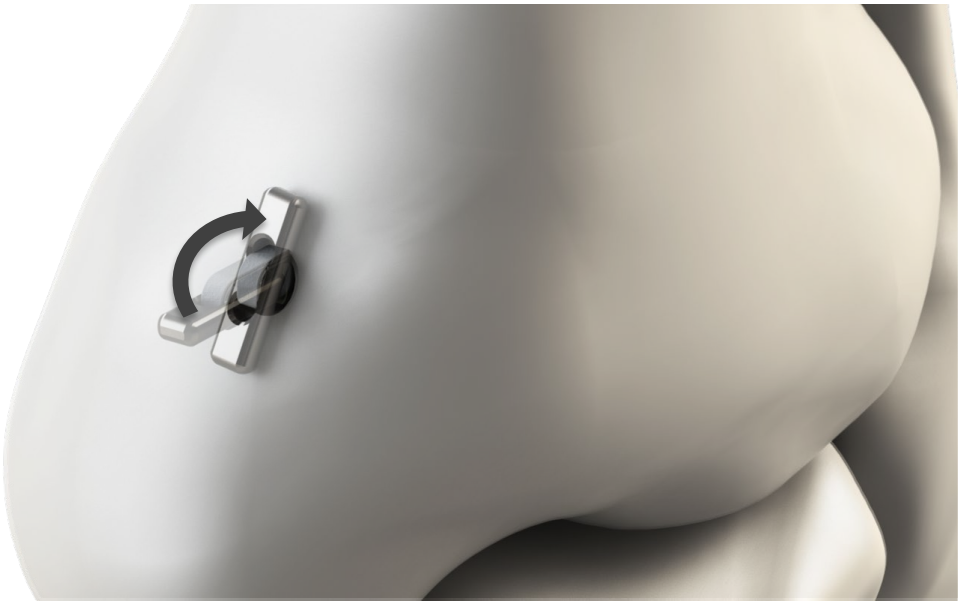
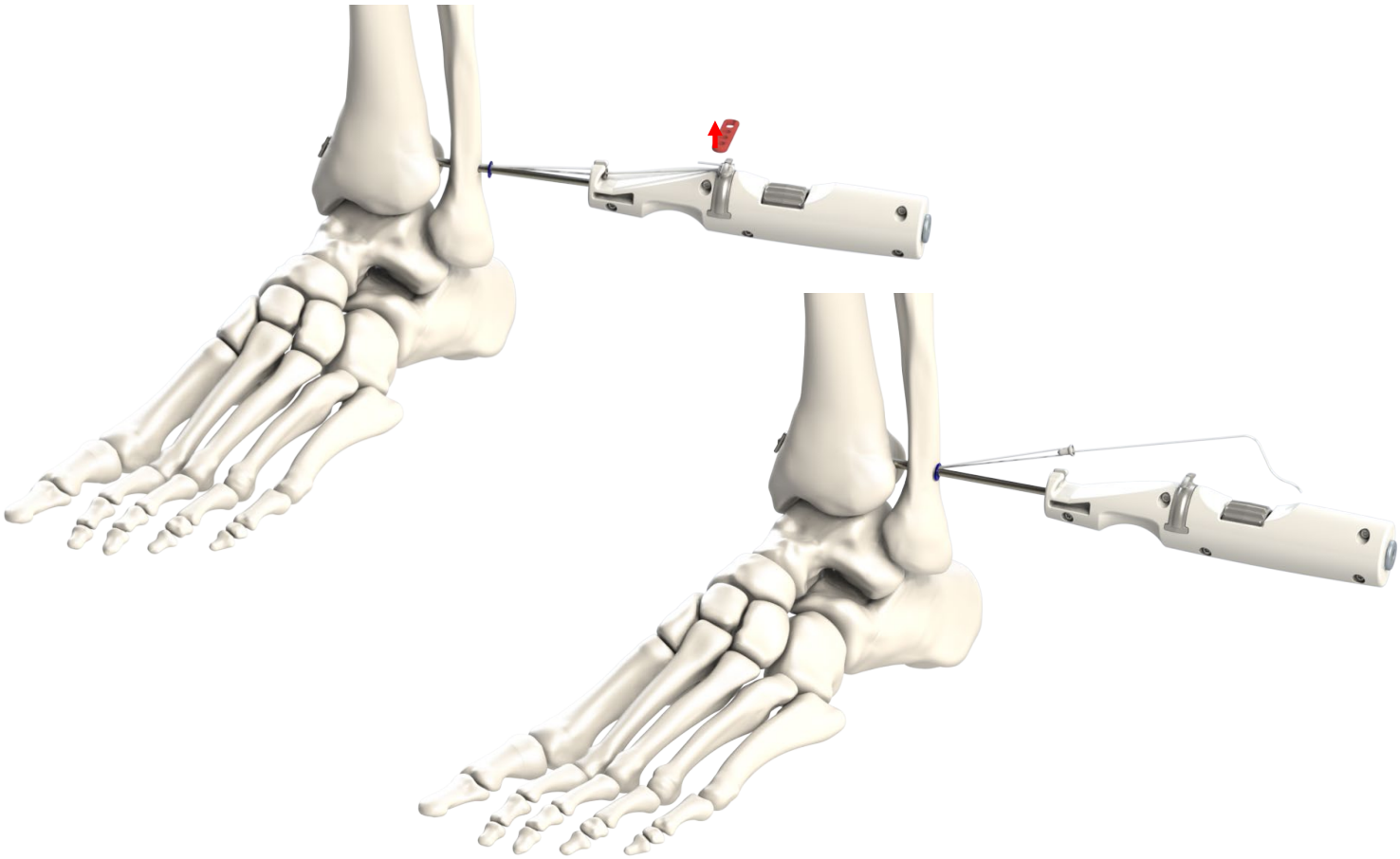


DEPLOY IMPLANTS (CONTINUED)

Remove the silicone tab and unwrap the sutures from the cleat on the handle. Pull the lateral button up and free from the handle.



Remove and discard the deployment handle.

TIGHTEN IMPLANT ASSEMBLY

While maintaining lateral tension on the suture, pull on the free suture ends in an alternating fashion to reduce the assembly. Pulling the suture ends in an alternating fashion will minimize bunching of the suture tape. Once the lateral button is seated in the washer, pull the suture ends tight in opposing directions to set the desired tension.

Tie either a single square knot or a minimum of two alternating half-hitches to secure the lateral button. Take care to ensure that the knots are tight and sitting all the way inside the cavity of the lateral button.

Cut the suture tape flush with the back of the lateral button to complete the construct.

IMPLANT REMOVAL

Removal of the OIC FLEX-FIX™ device, like all flexible syndesmotic fixation, should not be required in most instances and is left to the discretion of the surgeon. If implant removal is deemed necessary, a small incision on the medial and lateral side is needed to expose both the medial toggle body and the lateral button.

Cut the suture tape where it is exposed between the eyelets on the medial toggle body. Be aware that the suture cannot be accessed from the lateral side. Once the suture is cut, the medial toggle body and the lateral button with the suture can then be removed separately.

STERILE KIT

FLEX-01-S OIC Flex-Fix Syndesmosis Repair Kit

- Deployment Handle and Implant Assembly
- Ø3.7mm Drill Bit
- 3.5mm Washer

*Bone plates are part of the OIC Small Fragment System and must be purchased separately.
See OIC Small Fragment Plating System surgical technique: https://www.orthoimplantcompany.com/resources

CAUTION: FEDERAL LAW RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A PHYSICIAN

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Pragati Maidan, Nadupuru, Visakhapatnam,
Andhra Pradesh 530032.