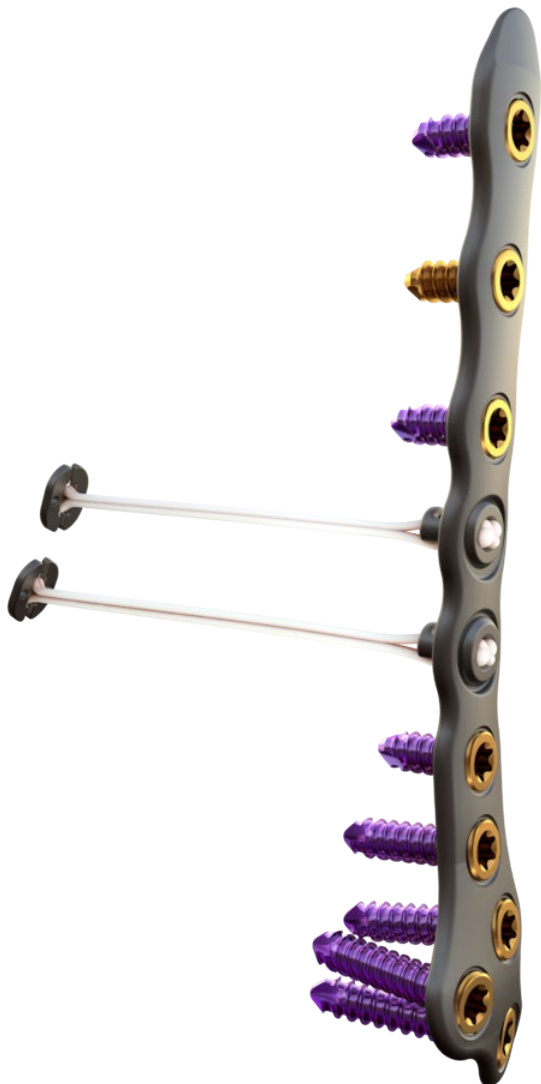


# Gravity™ Synchfix™

Syndesmotic fixation device



## Operative technique

# Gravity Synchfix

Syndesmotoc fixation device

Operative technique

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Proper surgical procedures and techniques are the responsibility of the medical professional. The following guidelines are furnished for information purposes only. Each surgeon must evaluate the appropriateness of the procedures based on his or her personal medical training and experience. Prior to use of the system, the surgeon should refer to the product package insert for complete warnings, precautions, indications, contraindications and adverse effects. Package inserts are also available by contacting the manufacturer. Contact information can be found on the back of this surgical technique and the package insert is available on the website listed.

Please contact your local Stryker representative for product availability.

# Preface

## Introduction

### Description

The Gravity Synchfix syndesmotic fixation device features a low-profile titanium design that utilizes #5 Forcefiber suture to provide secure dynamic fixation across syndesmosis joint of the ankle. Gravity Synchfix medial button footprint is comparable to other competitive designs. Additionally, sutures are attached extraosseously to the medial button, allowing for a bone sparing pilot hole with a reduced diameter. The technique for medial button suture attachment ensures optimal button placement, minimizing the likelihood of impingement of neurovascular structures. The lateral button is low profile and is designed to complement plate fixation or to allow use as a stand-alone device.

All of the instruments contained in the Gravity Synchfix syndesmotic fixation device kit are disposable.



Figure 1 | Knot capsule with #5 suture

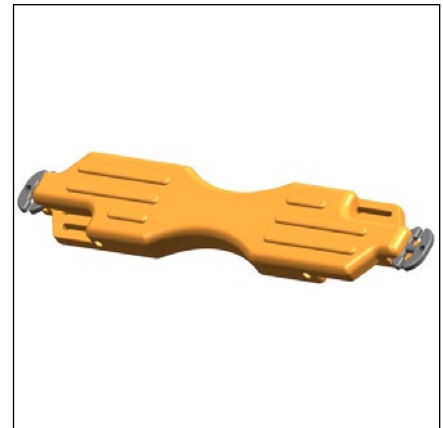


Figure 2 | Medial button holder

\* Forcefiber is a trademark or registered trade mark of Teleflex Inc

## Indications

The Gravity Synchfix syndesmotic LP 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.

## General contraindications

- Active infection
- Possibility for conservative treatment
- Growing patients with open epiphyses
- Insufficient quantity or quality of bone to permit stabilization
- Suspected or documented metal allergy or intolerance
- Blood supply limitations

There are no contraindications specific to the products. Prior to use of the system, the surgeon should refer to the product package insert for complete warnings, precautions, indications, contraindications, and adverse effects. Package inserts are also available by contacting the manufacturer. Contact information can be found on the back of this surgical technique and the package insert is available on the website listed.

# Chapter 1

## Surgical technique

### In plate surgical technique

#### Incision and bone prep

Through a lateral incision, position the 2.8mm guide wire in the syndesmotic plate hole and at a trajectory that will allow for fixation in the centroid aspect of the tibia. Drill a pilot hole through the plate, fibula and tibia. At the medial exit site of the guide wire make a medial incision (approximately 10mm) to visualize and protect the saphenous neurovascular structures and create a portal for medial button placement.

**Important Note:** To achieve optimal anatomic reduction of the syndesmosis, it is recommended to orientate fixation parallel to the tibial plafond in the coronal plane<sup>1</sup>. Doing so will allow for fixation in the centroidal axis of the syndesmosis, minimizing the likelihood of mal-reduction | Figure 3. To help facilitate placement in the recommended plane, Ortholoc 3Di fibula and syndesmosis plates feature posteriorly offset syndesmotic holes.

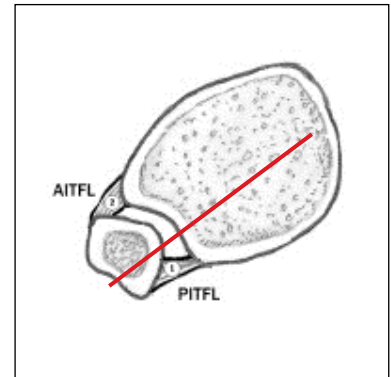
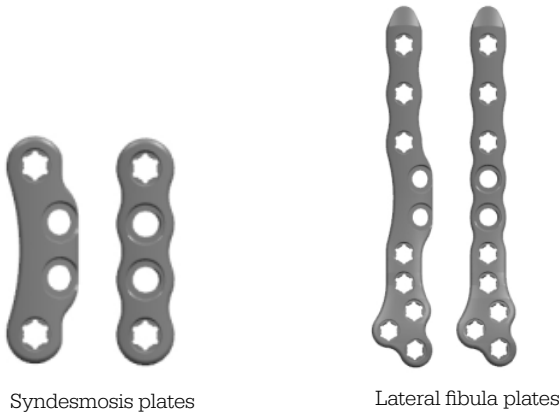


Figure 3 | Centroidal axis



**Note:** Syndesmosis holes are located in Ortholoc 3Di lateral fibula plates and the 4 hole syndesmosis plate (see above).

Attach the countersink to the driver handle found in the Ortholoc 3Di system | **Figure 4**. Using the pilot hole as a guide, countersink in the same trajectory as the pilot hole until the distal stop has reached the plate surface and can no longer be advanced. To help ease insertion of the countersink, gently torque the driver handle back and forth in a clockwise to counter clockwise orientation, while applying light pressure against the back of the driver handle.



Figure 4 | Driver handle

1. A computed tomography evaluation of two hundred normal ankles, to ascertain what anatomical landmarks to use when compressing or placing an ankle syndesmosis screw. Kennedy, M.T. et al. The Foot , Volume 24 , Issue 4 , 157 - 160

## Implantation of construct

Pass the blunt guide wire and suture loops lateral to medial through the previously drilled pilot hole. Continue passing the guide wire and shuttle suture until the two #5 white suture loops are visible beyond the medial tibial cortex | **Figure 5**.

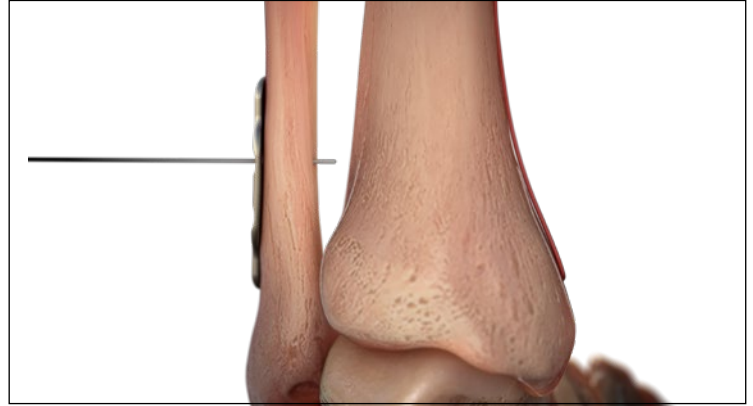


Figure 5 | Partial construct passing

Ensure that approximately 10mm of the two suture loops have passed beyond the medial tibial cortex and are visible | **Figure 6**. Cut the blue/white shuttle suture and discard along with the guide wire.

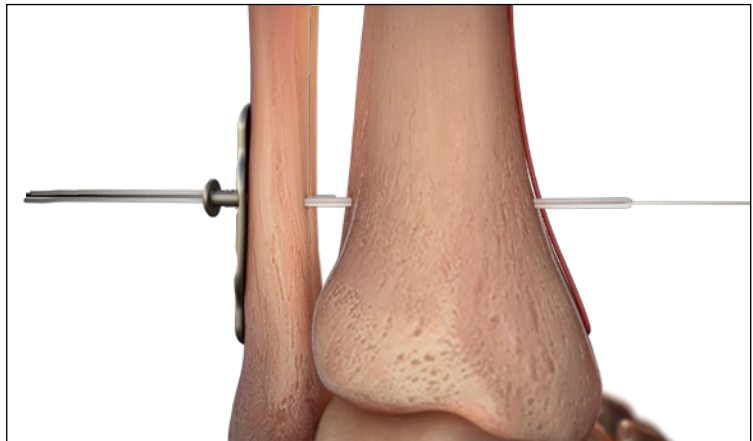


Figure 6 | Protruding loops ends and removed shuttle suture

## Attachment of the medial button

While grasping the dual-loaded medial button holder, ensure that both suture loops are wrapped around the central post of the medial button. To release the button, apply tension from the lateral side of the construct pull the button holder. Simultaneously push and pull the cutaway tabs of the button holder to facilitate release of the button | **Figure 7**.

When the medial button is released from the holder apply additional tension on the lateral side to fully seat the medial button as shown above | **Figure 8**.

**Note:** Ensure that both suture loops are positioned parallel, around the central post as shown above to allow the suture to freely slide around the central post as the construct is tensioned.



Figure 7 | Medial button holder

## Final tensioning

To begin final tensioning, grasp the two strands of white #5 suture individually in both hands. Pull the two strands outward and in the same plane as the plate surface | **Figure 9**. Care should be taken to ensure that no suture is trapped between the lateral knot capsule and bone. Occasionally pulling the capsule backward or “walking” the construct while tensioning will help avoid this. Continue tensioning by pulling outward until the knot capsule is completely seated in the plate and the adequate amount of tension has been reached. Finish by tying a single square knot. The square knot may be recessed in the knot capsule to minimize prominence.

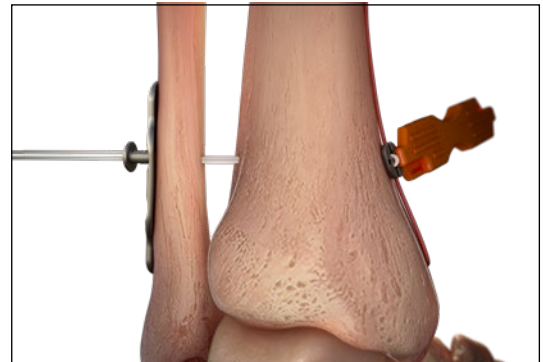


Figure 8A & B | Attached and secured medial button





The excess suture may be cut along the edge of the knot capsule leaving 1-5mm of suture tail | **Figure 10.**

## Non-plate surgical technique

The Gravity Synchfix syndesmotic fixation device may be used without plate fixation by following the previously outlined steps. The steps include:

- Assess the tibial centroid,
- Place the 2.8 mm guide wire in the centroid position,
- Make a small medial incision and protect the saphenous vein and nerve
- Counter sink the fibula laterally to accept the lateral capsule and washer (washer optional)
- Advance the suture medially and attach the low profile medial button
- Tension laterally and place a single square knot.



Figure 9 | Final tensioning.

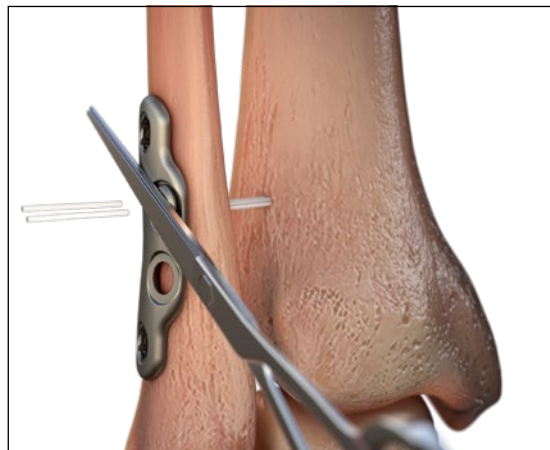


Figure 10 | Completed procedure

## Chapter 2

# Explant information

### **Explant information**

Removal of the Gravity Synchfix syndesmotic fixation device, like all flexible syndesmotic fixation, should not be required in most instances and is therefore left to the discretion of the surgeon. If removal is deemed necessary, then a small incision on the lateral and medial side is needed to expose the medial button and the knot capsule. Once both ends of the construct are exposed, cut the suture and remove the medial button, followed by the lateral knot capsule and remaining suture.

If the removal of the implant is required due to revision or failure of the device, the surgeon should contact the manufacturer using the contact information located on the back cover of this surgical technique to receive instructions for returning the explanted device to the manufacturer for investigation.

# Appendix

## Ordering information

Gravity syndesmosis LP		
#	Product	Contents
86SYN005	Gravity Synchfix syndesmotoc fixation device sterile packed implant/instrument kit	<ul style="list-style-type: none"><li>• 2.8mm guide wire</li><li>• Countersink, lateral knot capsule</li><li>• #5 suture construct</li><li>• Blunt guide wire</li><li>• Medial button holder</li><li>• Medial button (qty. 2)</li></ul>

## Foot & Ankle

This document is intended solely for the use of healthcare professionals. A surgeon must always rely on his or her own professional clinical judgment when deciding whether to use a particular product when treating a particular patient. We do not dispense medical advice and recommend that surgeons be trained in the use of any particular product before using it in surgery.

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