

FIBULINK™

SYNDESMOSIS REPAIR SYSTEM

Surgical Technique

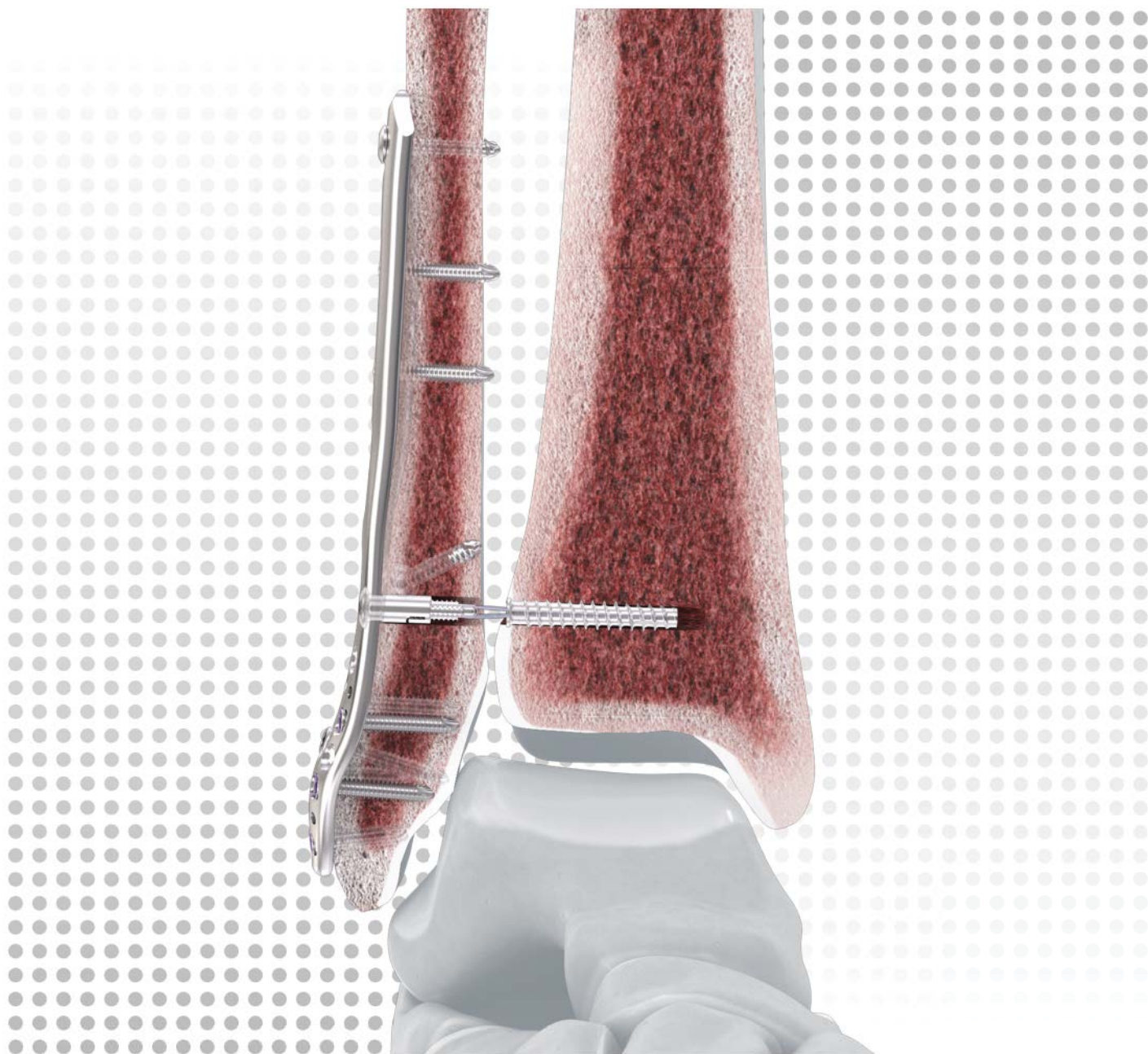





Table of Contents

Introduction	Indications, Contraindications, and MRI Safety Information	2
	Overview of the FIBULINK Syndesmosis Repair System	3
	FIBULINK Implant Kit Components	4

Surgical Technique	Implant Site Preparation	5
	Tibia Screw Insertion	7
	Tensioning Cap Selection	8
	Tibia Screwdriver Removal	9
	Fibula Tensioning Cap Installation	10
	Tensioning	12
	Remove Instrumentation	13
	FIBULINK Removal Kit Components	14
	Removal (Optional)	15

Product Information	Implants and Kits	19
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-  Image Intensifier Control
-  Notes
-  Precautions

Indications, Contraindications, and MRI Safety Information

Indications

The FIBULINK™ Syndesmosis Repair Kit is intended as an adjunct in fracture repair involving metaphyseal and periarticular small bone fragments where screws are not indicated and as an adjunct to fixation systems involving plates, with fracture braces and casting. Specifically, the FIBULINK Syndesmosis Repair Kit is intended to provide fixation during the healing process following a syndesmotic trauma, such as fixation of syndesmosis (syndesmosis disruptions) in connection with Weber B and C ankle fractures.

Contraindications

Use of the FIBULINK Syndesmosis Repair Kit is contraindicated in the presence of an acute local infection.

MRI Safety Information



Non-clinical testing has demonstrated the FIBULINK implant is MR Conditional. A patient with this device can be safely scanned in an MR system meeting the following conditions:

- Static magnetic field of 1.5 T and 3.0 T
- Maximum spatial field gradient of 1,900 gauss/cm (19 T/m)
- Maximum MR system reported, whole body averaged specific absorption rate (SAR) of 2 W/kg (Normal Operating Mode)

Under the scan conditions defined above, the FIBULINK implant is expected to produce a maximum temperature rise of 1.7° C after 15 minutes of continuous scanning.

In non-clinical testing, the image artifact caused by the device extends approximately 15 mm from this implant when imaged with a gradient echo pulse sequence and a 3.0 T MRI system.

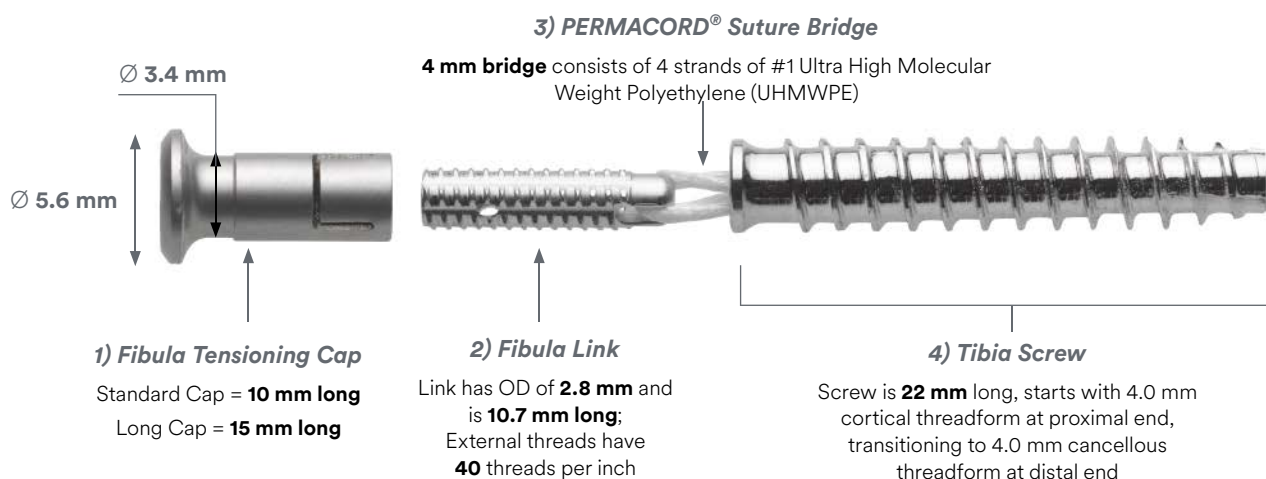
Overview of the FIBULINK Syndesmosis Repair System

Implant Components and Function

The FIBULINK Implant is a multicomponent anchor system for the treatment of syndesmotric disruption, and consists of four main components:

- 1) **Fibula Tensioning Cap** – Interfaces with the fibula link; rotation of cap applies tension to the construct
- 2) **Fibula Link** – Connects the suture bridge to the tensioning cap; interface is the primary tension mechanism
- 3) **PERMACORD® Suture Bridge** – Provides compression between the fibula and tibia components
- 4) **Tibia Screw** – Functions as an anchor in the tibia

Implant Specifications



Material Choice

Implants are available in stainless steel and titanium.

Compatibility

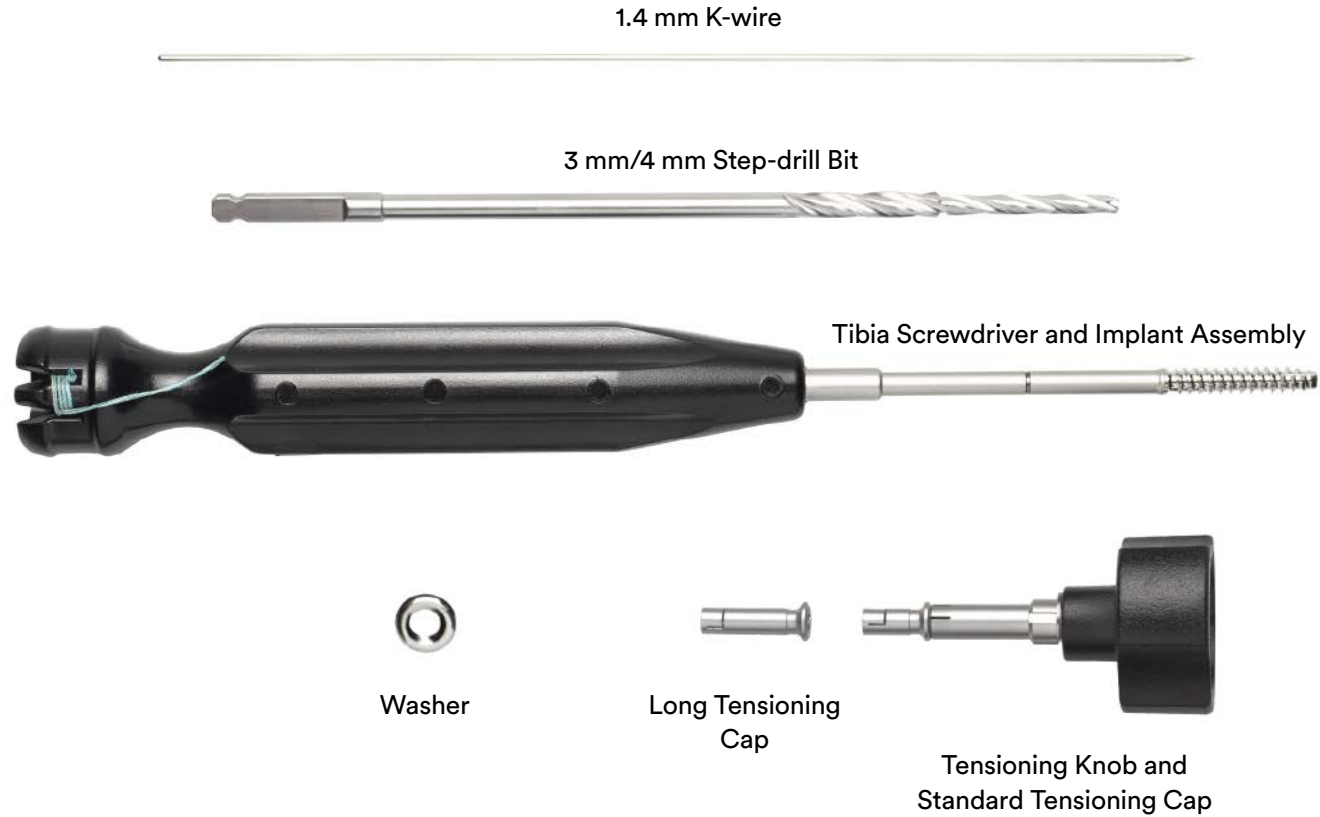
The FIBULINK System is compatible with DePuy Synthes Distal Fibula plates. Specifically:

- 1/3 Tubular Plate holes (LCP™ System and non-locking)
- The non-threaded portion of a combi hole in a 3.5 mm locking plate (LCP™ Plates)
- Syndesmotric slot (VA LCP™ Plates)

Additionally, the 4 mm FIBULINK Implant is compatible with distal fibula plate holes that accept a 4 mm non-locking cortex screw. Various 3.5 mm screw holes may accommodate the FIBULINK Implant but compatibility must be verified.



FIBULINK Implant Kit Components



Surgical Technique

Implant Site Preparation

1. Implant Site Preparation

1.1 K-Wire Placement

If required, fixate the fibular fracture using a FIBULINK System-compatible device (see page 3) and routine AO principles. Care should be taken to ensure that the material of the FIBULINK Kit selected for a procedure (stainless steel vs. titanium) matches the material of the fibula plate.

Reduce the tibiofibular joint and verify congruent tibiofibular joint articulation.

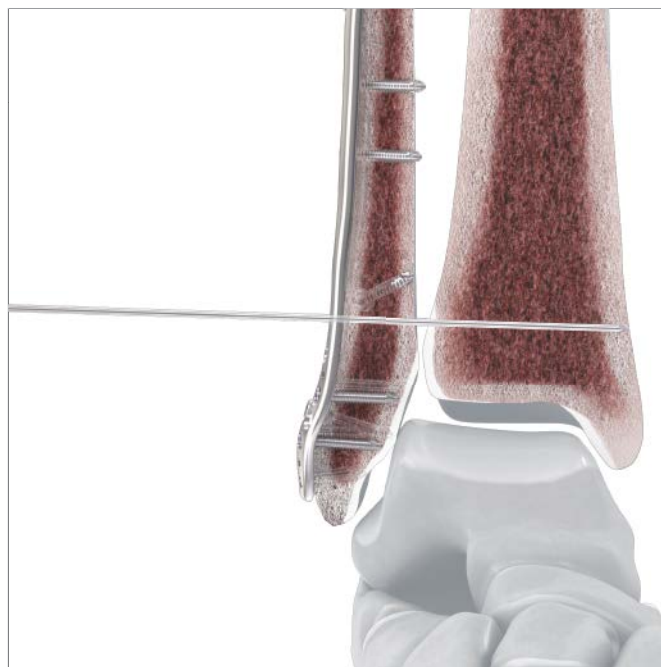
Insert the K-wire at the intended implant trajectory, through the fibula and into the tibia approximately 2 cm above the plafond or per surgeon preference. The K-wire must be inserted at 20°-30° of anterior deviation to accommodate the tibiofibular syntopy.

■ Notes:

- Placement should be verified under fluoroscopy.
- The K-wire does not need to penetrate the medial cortex of the tibia.

▲ Precaution:

The K-wire must be centered in the hole of the plate to ensure that the plate will not be damaged by the drill.



1.2 Drilling

Drill with the provided step-drill over the K-wire to prepare a 3 mm pilot hole in the tibia and a 4 mm gliding hole in the fibula. If desired, the step-drill can be performed by hand with a hand driver.

Note:

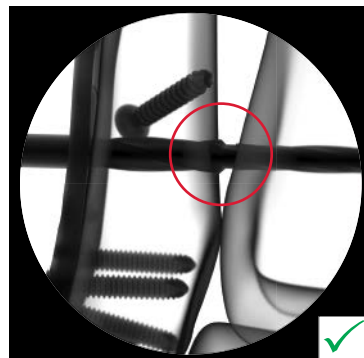
A mortise view can assist in verifying drill step location.

Precautions:

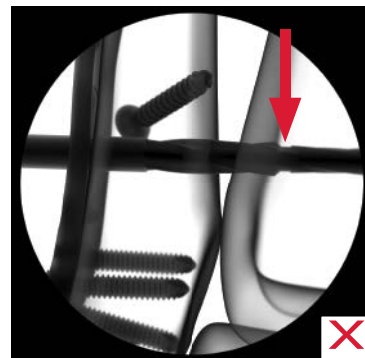
- Ensure the larger portion of the step-drill DOES NOT plunge into the tibia, as screw fixation could become compromised.
- Drill step location should be monitored with fluoroscopy during the drilling process.

Withdraw the K-wire and step-drill, leaving the pilot hole in the tibia and the gliding hole through the fibula.

Correct Depth



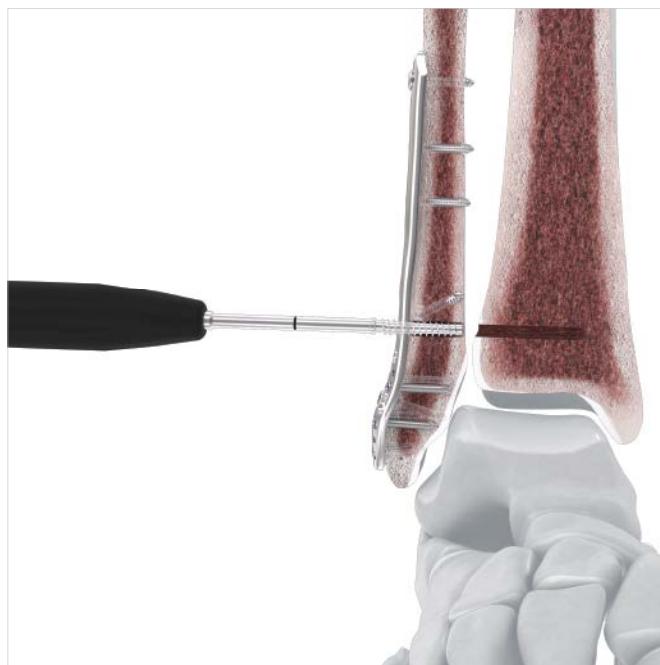
Too Deep



Tibia Screw Insertion

2. Tibia Screw Insertion

Insert the tibia screw using its preloaded screwdriver through the gliding hole in the fibula until it contacts the pilot hole in the tibia.



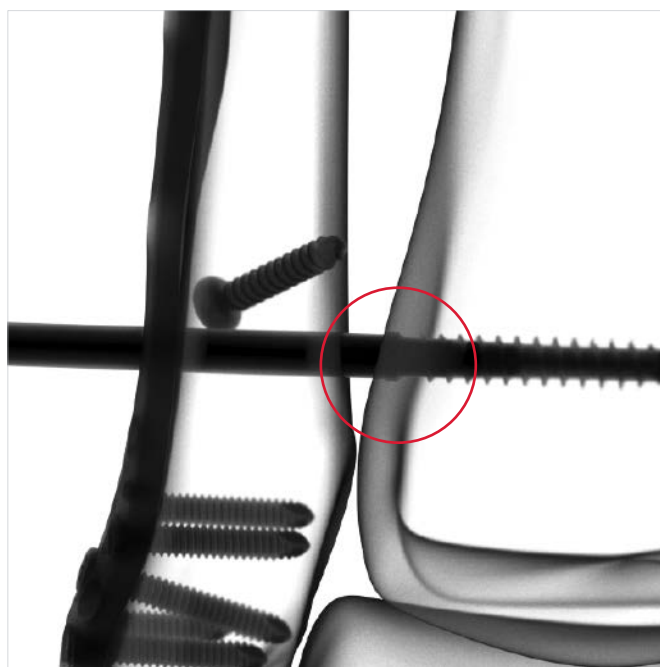
Drive the tibia screw into the tibia by turning the driver clockwise until it is flush with the lateral tibia wall.

■ Notes:

- An increase in torque indicates that the shoulder of the driver has contacted the lateral cortex of the tibia.
- Tactile feedback may be more subtle in less dense bone.

▲ Precautions:

- Proper flush placement of the tibia screw in the tibia should be verified under fluoroscopy.
- A mortise view should be used to provide additional verification.



Tensioning Cap Selection

3. Tensioning Cap Selection

With the syndesmosis reduced, note the indicator groove on the driver shaft.

If the indicator groove remains visible (above fibula or plate), then the standard tensioning cap that comes preassembled on the tensioning knob should be used.

If the indicator groove is below the surface of the fibula or plate, exchange the preassembled cap for the long tensioning cap.

■ **Note:**

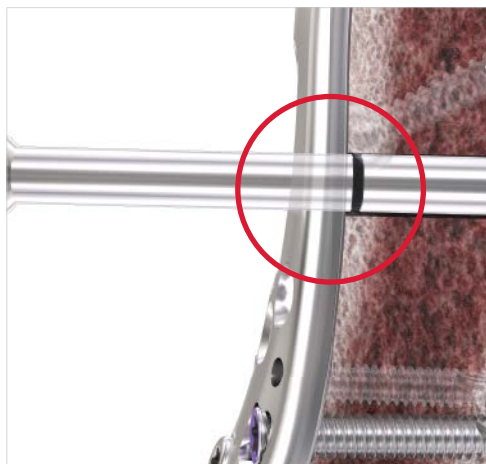
If the indicator groove is in between the fibula and plate, select the long tensioning cap.

Indicator groove visible
(above plate or bone)



Standard Tensioning Cap (10 mm)
Preassembled on Tensioning Knob

Indicator groove not visible
(below plate or bone) OR in between
plate and bone



Long Tensioning Cap (15 mm)

Tibia Screwdriver Removal

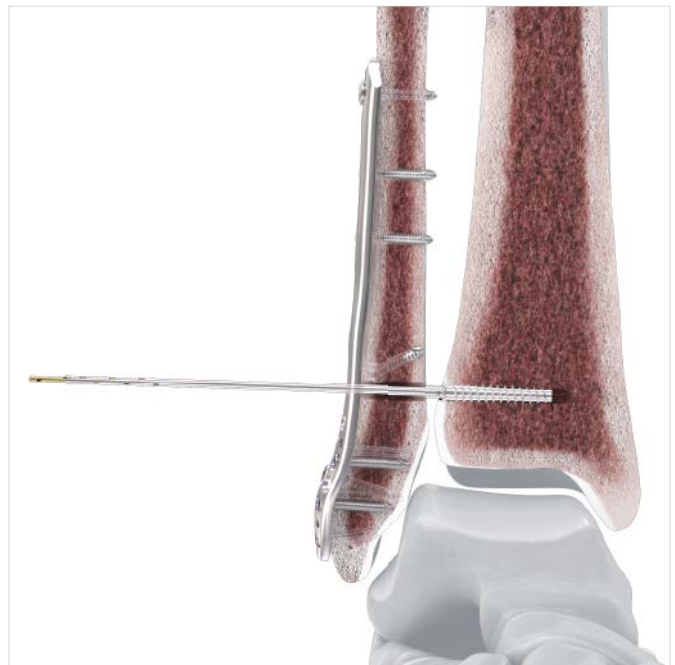
4. Tibia Screwdriver Removal

Unwind the green retention suture from the driver handle by pulling laterally on the free end of the suture.

Release the green retention suture and pull the driver handle out laterally. Discard the handle and attached green suture.

■ Notes:

- Toggling the handle may help disengage the handle from the implant assembly.
- The green suture will pull through the handle and guide tubes.
- The only purpose of the green retention suture is to keep the implant on the handle during insertion.



Fibula Tensioning Cap Installation

5. Fibula Link Deployment

5.1 Fibula Tensioning Cap Placement

Ensure that the appropriate sized tensioning cap is assembled onto the tensioning knob (refer to step #3). If a plate is not being used, assemble the supplied washer onto the cap so that the flat surface of the washer will be against the bone.

Slide the appropriate cap assembly over the guide tube and into the gliding hole in the fibula.

■ Notes:

- The silver guide tube has an etch band, similar to the screwdriver, to assist in reconfirming cap selection (standard or long).
- The use of the supplied washer is recommended if a plate is not used in the procedure.

5.2 Secure Clamp to Silver Tube

Clamp the silver portion of the guide tube (NOT the gold-colored most proximal portion) about 1cm from the end with a clamp (such as a needle driver) or hemostat.

▲ Precaution:

Do not contact the gold tube until the end of the procedure. Removal of the gold tube will disengage the guide tube construct from the link and will prevent procedure completion.

Tensioning Cap Assembly



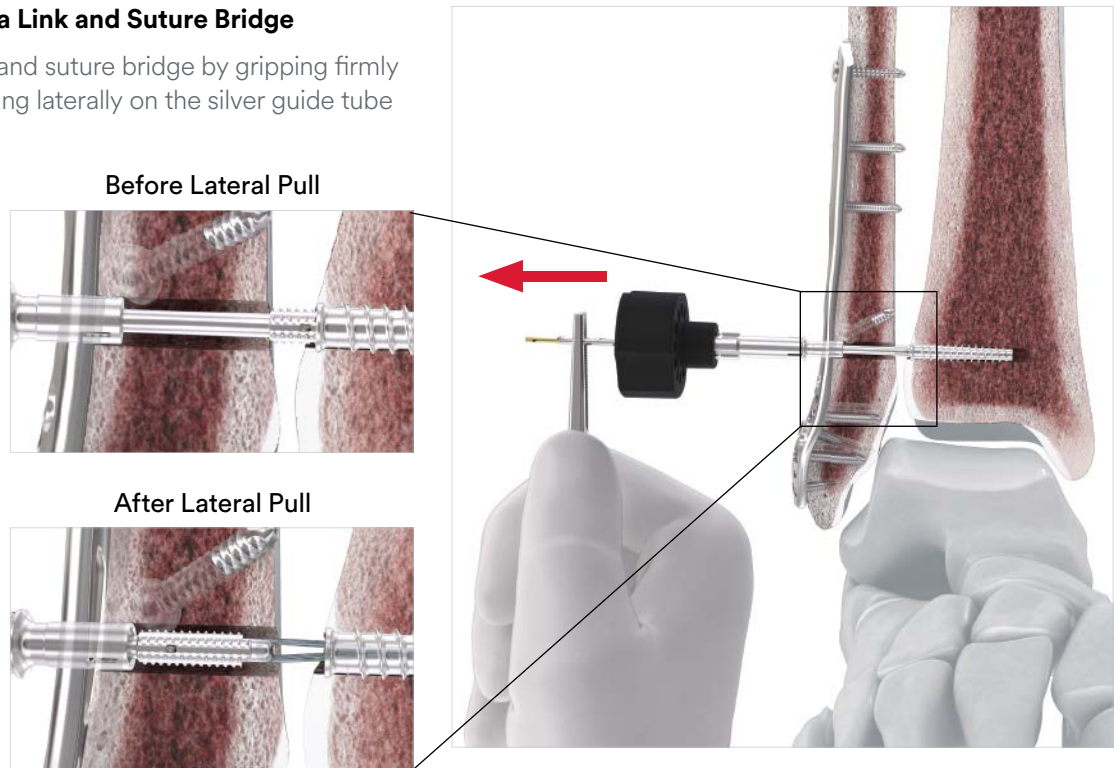
With plate

Without plate
(apply washer)



5.3 Deploy the Fibula Link and Suture Bridge

Deploy the fibula link and suture bridge by gripping firmly on the clamp and pulling laterally on the silver guide tube about 4 mm.



■ Notes:

- A firm grip closer to the jaws of the clamp may help maintain control of the clamp and prevent slippage off the guide tubes during link deployment.
- This step will place the link in the fibula and the suture bridge in the syndesmotomic space. The internal threads of the tensioning cap can now engage the external threads of the link in the following step.

Tensioning

6. Tensioning

6.1 Engage the Cap with the Link

While maintaining lateral tension on the clamp, engage the tensioning cap with the link by applying forward pressure on the tensioning knob and turning it clockwise. Ensure that the preliminary reduction is maintained.

■ Notes:

- To confirm link engagement, pull back slightly on the tensioning knob. If the cap can be removed, it is not yet threaded onto the link. Fluoroscopy may also be used to confirm engagement.
- If the standard cap will not engage with the link, switch to the longer cap.

▲ Precaution:

Ensure that the guide tubes remain firmly clamped and stabilized under lateral tension. Verify that the guide tubes are not rotating.

6.2 Tension Adjustment

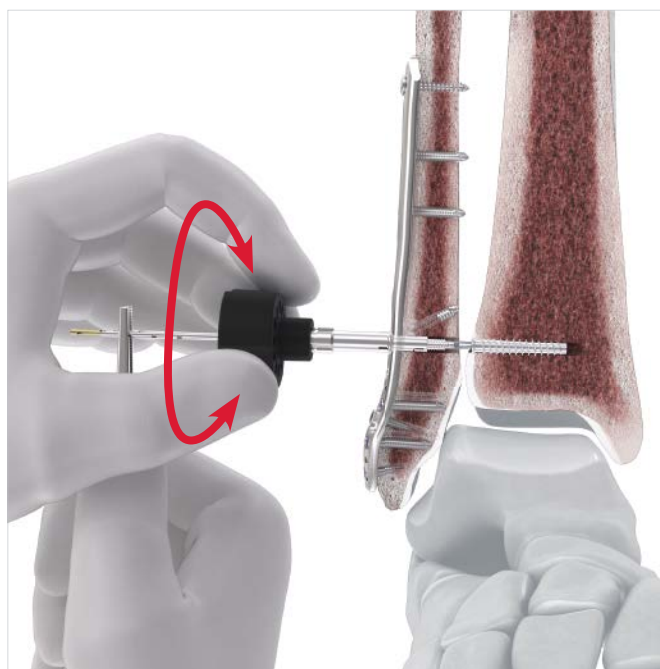
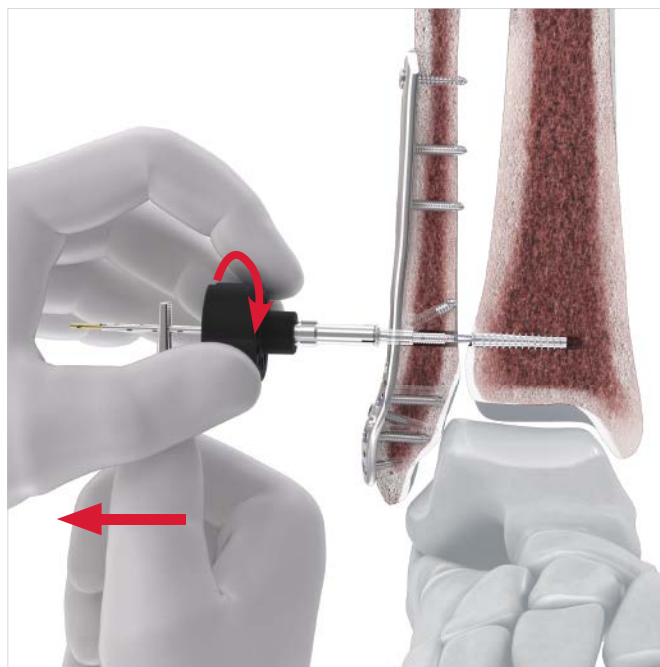
Advance the tensioning cap clockwise until it is “finger tight” and the desired level of correction is achieved, which must be confirmed by fluoroscopy.

Turn the tensioning knob counterclockwise to decrease tension of the FIBULINK Implant as needed.

Use fluoroscopy, direct inspection, and/or ankle range of motion evaluation to ensure an anatomic reduction.

■ Notes:

- If the surgeon desires, the ankle may be placed in dorsiflexion prior to increasing tension of the FIBULINK Implant.
- The mechanical advantage provided by the link-cap interface means that the surgeon will not feel a “bite” the same way they will with an orthopedic screw.
- Due to this mechanical advantage, a torque limiter has been built into the tensioning knob to prevent applying too much tension to the system. In most instances this limit should not be reached.



Remove Instrumentation

7. Remove Instrumentation

Unclamp the silver guide tube. Clamp the gold proximal portion of the guide tube and pull laterally.

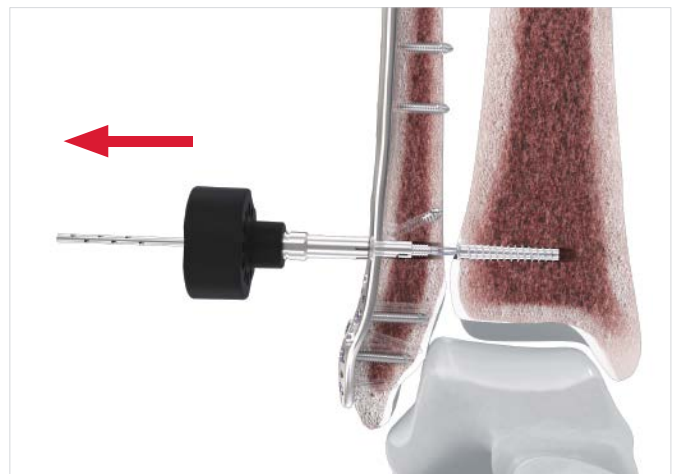
■ Notes:

- Removal of the gold tube allows for removal of the silver tube.
- The silver tube may be removed along with the gold tube.

▲ Precaution:

Final correction should be confirmed prior to removal of the gold tube.

Remove the silver tube.



Unsnap the tensioning knob from the tensioning cap. Implant installation is complete.

■ Note:

Tipping tensioning knob to the side may facilitate knob removal.

FIBULINK Removal Kit Components

Fibula Link and Tibia Screw Remover



Tibia Screw Remover



Fibula Tensioning Cap Remover



Instruments have male or female hexalobe interfaces to correspond to mating FIBULINK Implant components.

Removal (Optional)

8. Removal (Optional)

Removal of the implant is completed by reversing installation steps. The dedicated removal kit should be used for FIBULINK Implant removals in conjunction with an AO Quick Connect Handle.

8.1 Insert the Tensioning Cap Remover into the tensioning cap and turn counterclockwise to remove the cap.



8.2 There are two likely outcomes of cap removal depending on the condition of the implant at the time of removal.

- **Cap Removed Only:** The suture connecting the link and tibia screw remains intact and the cap spins counterclockwise off the link (see step 8.2.A).



- **Cap and Link Both Removed:** The link and the tibia screw are no longer connected and rotation of the cap does not separate it from the link. Both the link and cap can then be pulled laterally to remove as a unit (see step 8.2.B).

■ Notes:

The Tensioning Cap Remover from the FIBULINK Removal Kit is not compatible with implants implanted prior to July 2020. If an implant removal is required, use the following instruments:

- The FIBULINK Removal Kit (discard Tensioning Cap Remover).
- A commercially available T20 screwdriver or Conical Extraction Screw (309.520) from the DePuy Synthes Screw Removal Set (01.240.001) to remove the tensioning cap.



8.2.A. Cap Removed Only.

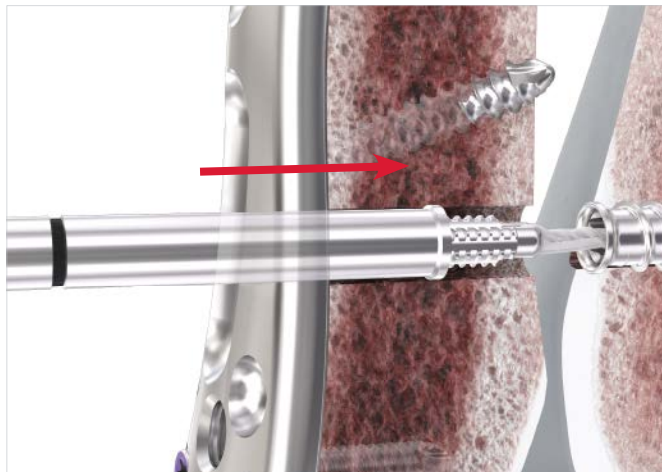
Capture the link with the female distal end of the Fibula Link and Tibia Screw Remover.

■ Notes:

- The Fibula Link and Tibia Screw Remover is the same instrument as the tibia screwdriver for installation.
- The distal end of the link is a male hexalobe matching the female hexalobe tibial screw.



Advance the driver and link into the female hexalobe in the proximal portion of the tibia screw.

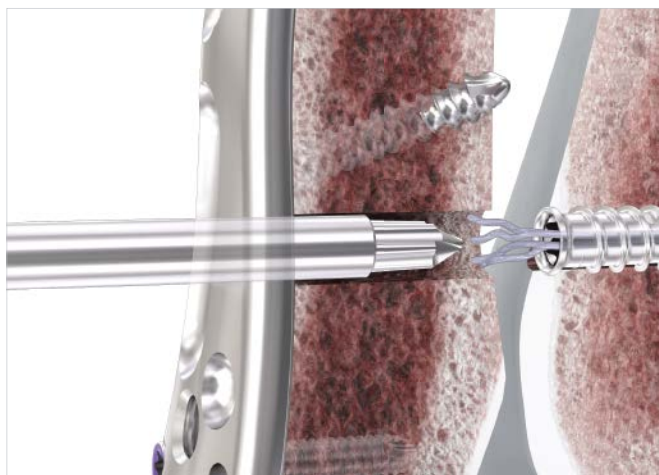


Reverse the tibia screw and engaged link out of the tibia and fibula.

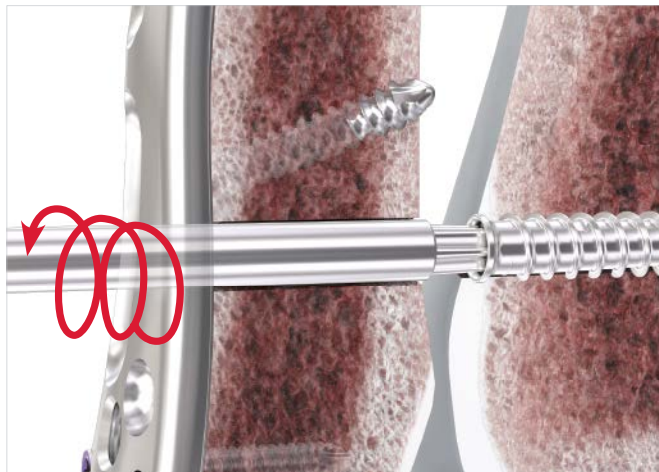


8.2.B. Cap and Link Both Removed.

Engage the female hexalobe in the proximal portion of the tibia screw with the Tibia Screw Remover (a hexalobe retrieval driver).



Reverse thread the tibia screw out of the tibia through the initial implant site.



8.3 Additional Removal Technique

The following steps will allow removal of the Cap and the Link at the same time.

Only use this technique if the FIBULINK Implant has been placed through the supplied washer or one of the DePuy Synthes Distal Fibula plates.

Engage the Fibula Tensioning Cap Remover into recess of the Tensioning Cap and rotate **CLOCKWISE**.

Continue rotating the Remover clockwise, twisting the suture until it breaks. This technique will create compression between the tibia and fibula and should be monitored under fluoroscopy.

Remove Tensioning Cap with Fibula Link.

Remove Tibia Screw with Tibia Screw Remover, following step 8.2.B from previous page.



8.4 Additionally available instruments to assist with removal

■ Note:

In case of difficult removal circumstances, the following screw extraction instruments can be used to remove the FIBULINK Implant:

- To remove the Fibula Tensioning Cap, use Conical Extraction Screw **309.510** or **309.520**
- To remove the Fibula Link, use Conical Extraction Screw **309.510** or **03.505.233**
- To remove the Tibia Screw, use Conical Extraction Screw **309.510**

The conical extraction screws are not part of the FIBULINK Syndesmosis Repair System. For details on using the conical extraction screws 309.510 and 309.520 and all the steps of the surgical technique, please refer to the Screw Removal Set Surgical Technique. 10/05/21. Windchill Document #DSUS/TRM/1016/1197.

Implants and Kits

Sterile Implant Kits

- FGS-1000 FIBULINK™ Syndesmosis Repair Kit, Stainless Steel
- FGS-1100 FIBULINK™ Syndesmosis Repair Kit, Titanium



Sterile Instrument Kits

- FGS-1300 FIBULINK™ Removal Kit



Additionally Available

- 03.118.001 Periarticular Reduction Forceps, Small



- 03.118.110 Periarticular Reduction Forceps, Medium



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