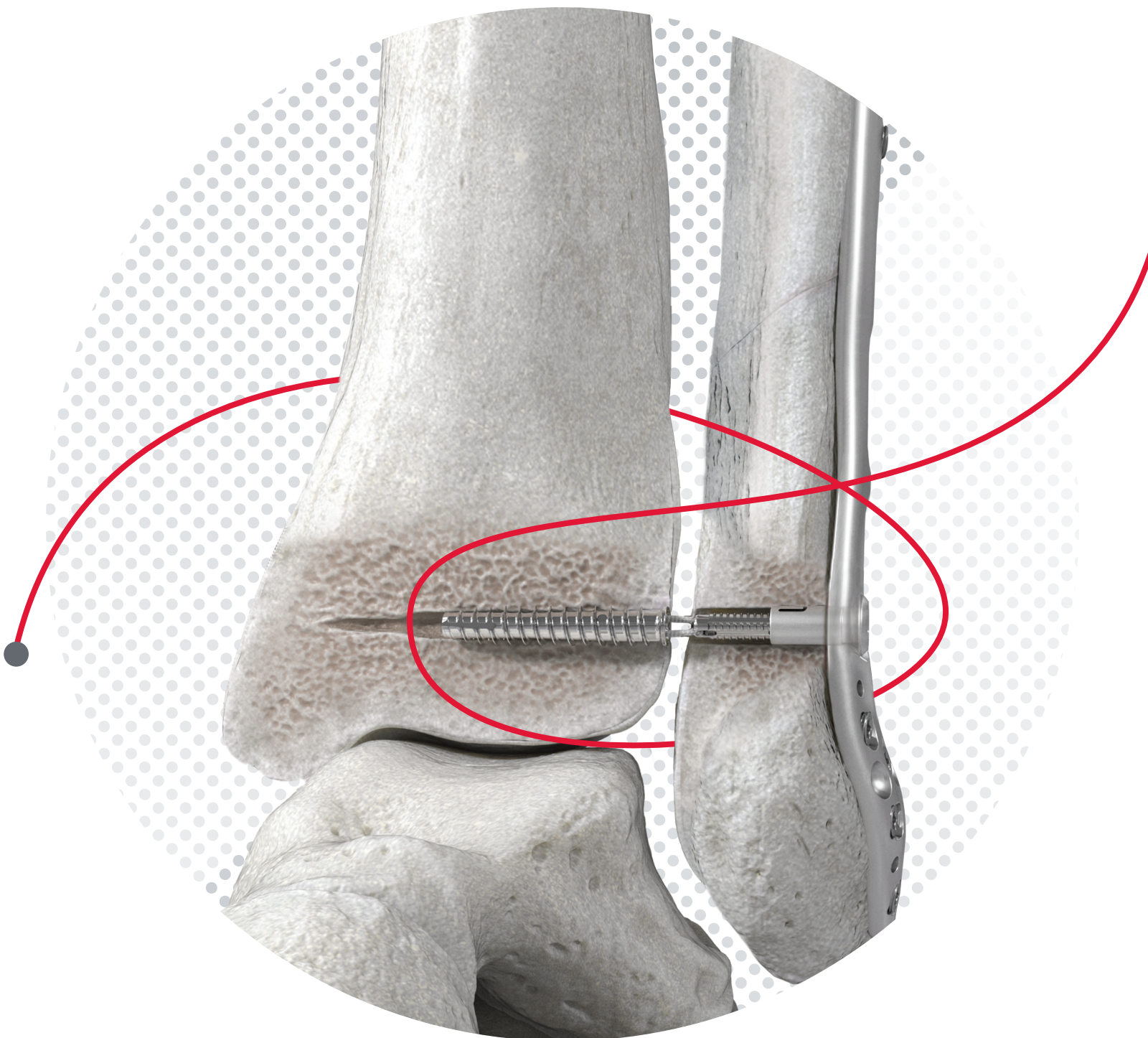


# FIBULINK™

Syndesmosis Repair System



## A Revolutionary Idea in Syndesmotic Fixation

The first adjustable syndesmotic repair system with a short, high-strength suture bridge to help restore the physiologic ankle motion<sup>1-3</sup>

 **DePuy Synthes**  
THE ORTHOPAEDICS COMPANY OF *Johnson & Johnson*

The best of both worlds:  
**fixation of a screw,**  
**flexibility of a suture**

The DePuy Synthes FIBULINK™ Syndesmosis Repair System is designed to enable **precise, anatomic syndesmotic fixation.**<sup>1,4-6</sup>

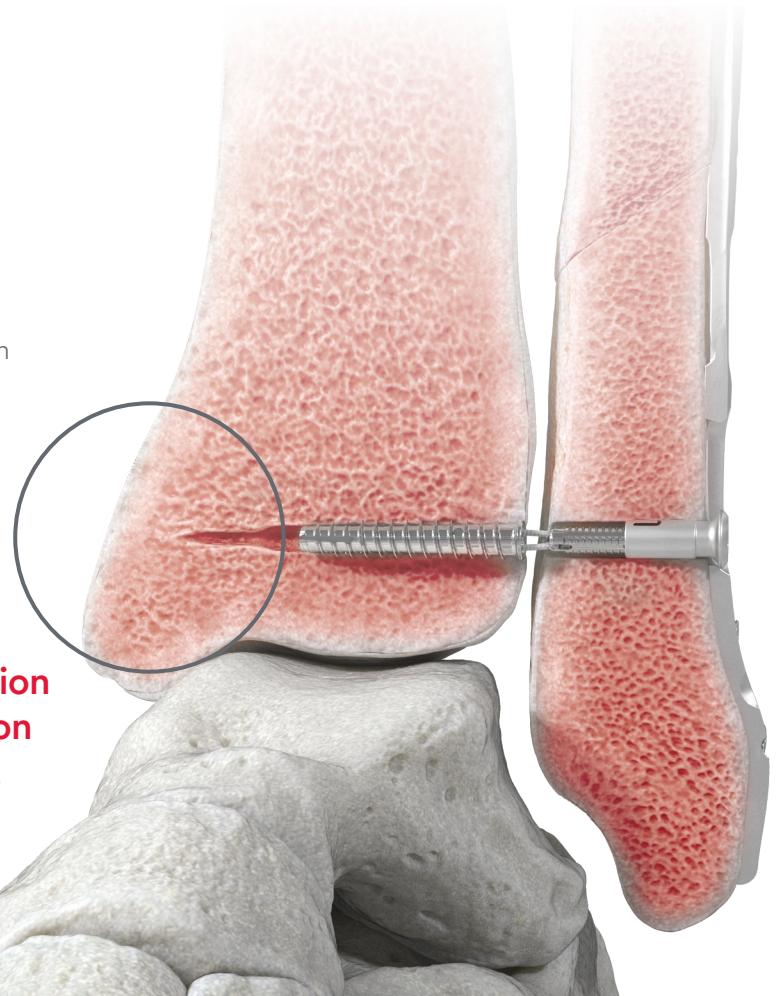
In addition, it addresses limitations of suture button constructs, including medial soft tissue disruption and lack of two-way tension control.<sup>1-3,5</sup>



## Eliminates medial disruption

### No medial incision or hardware

- Eliminates medial side complications such as damage to neurovascular structures and soft tissue entrapment associated with suture button constructs<sup>1,5,\*</sup>
- Helps improve procedural efficiency by delivering fixation through a single lateral incision<sup>1,5,\*</sup>



**No disruption  
with incision  
or fixation.**

\*Compared to suture button constructs.

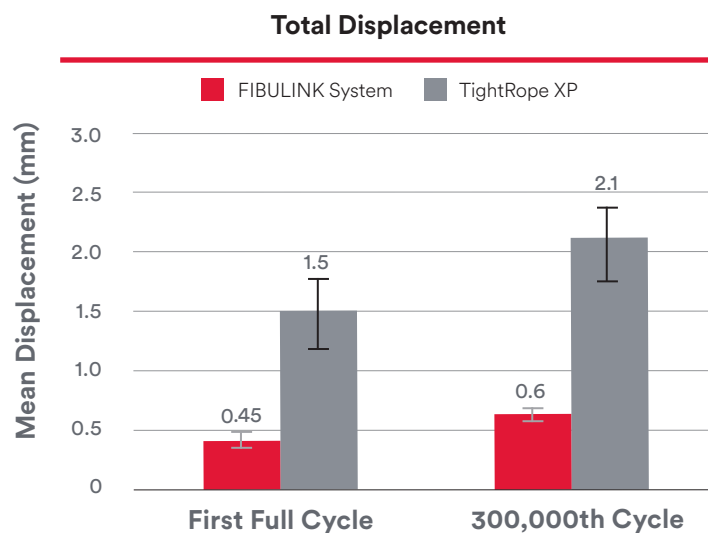
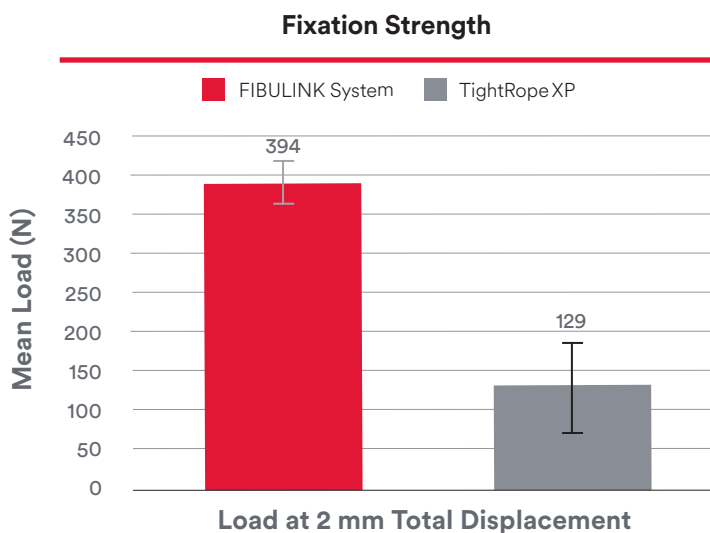
## Enables physiologic motion

**3x the fixation strength and less than 1/3 of the displacement of the Arthrex Syndesmosis TightRope® XP Implant System<sup>8,9,†</sup>**

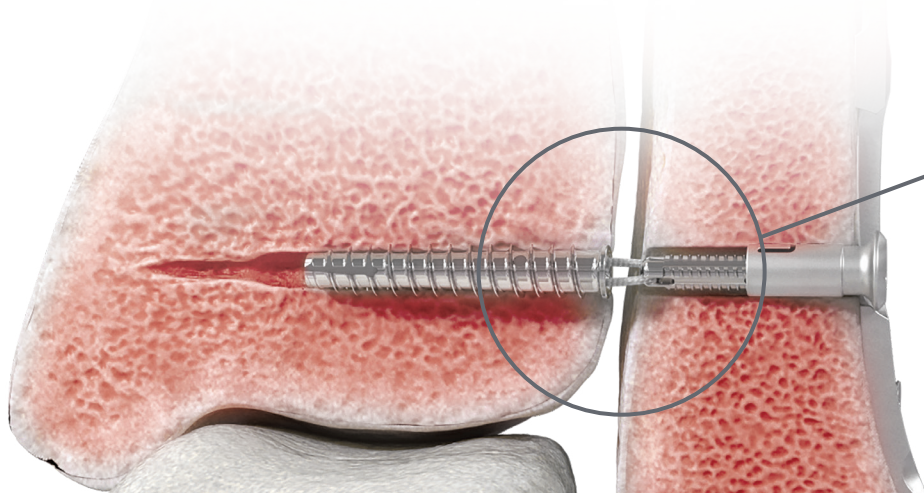
- Delivers **206% more fixation strength** than TightRope® XP in a poor quality bone model, which may provide a more secure fixation of the syndesmosis<sup>8,9,†</sup>
- Provides **71% less elongation** (displacement) than TightRope XP after 300,000 cycles, potentially reducing syndesmosis widening<sup>1,8,‡</sup>
- Provides fixation at the joint, reducing the span of anchor points compared to a suture button device and thereby eliminating the risk of tunnel widening<sup>1,3,10-12</sup>

<sup>†</sup>Bench testing may not be predictive of clinical performance. Sample size of n=8. Percentages and ratios based on averages. Attributes evaluated include fixation strength (load at 2 mm), displacement, and stiffness. P-value ≤ 0.001.

<sup>‡</sup>Bench testing may not be predictive of clinical performance. Sample size of n=8. Percentages and ratios based on averages.



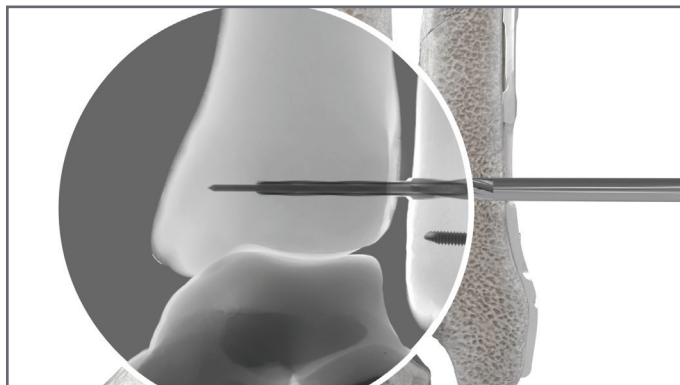
**Short PERMACORD™ Suture bridge and anchor construct provides superior biomechanical performance compared to Arthrex Syndesmosis TightRope® XP Implant System.<sup>8,9,†</sup>**



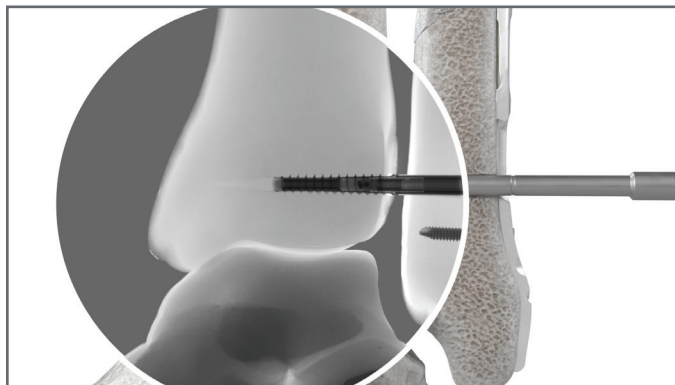
# Procedural steps

## Using the FIBULINK Syndesmosis Repair System

This step-by-step process is an illustrated representation of how to use the repair system properly.



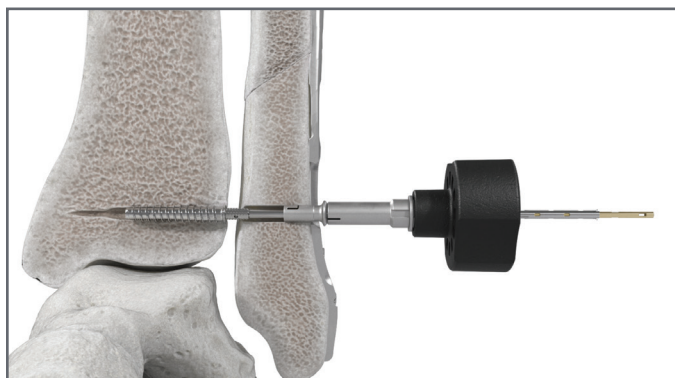
**1** Place K-wire and drill



**2** Insert tibia screw flush



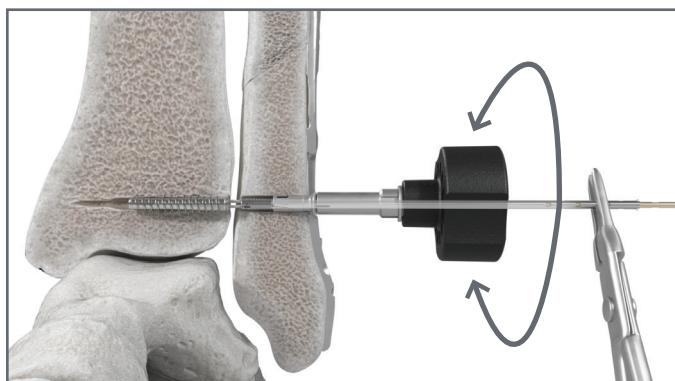
**3** Release green retention suture and remove handle



**4** Insert tensioning cap over tubes



**5** Clamp silver tube and pull laterally to deploy link

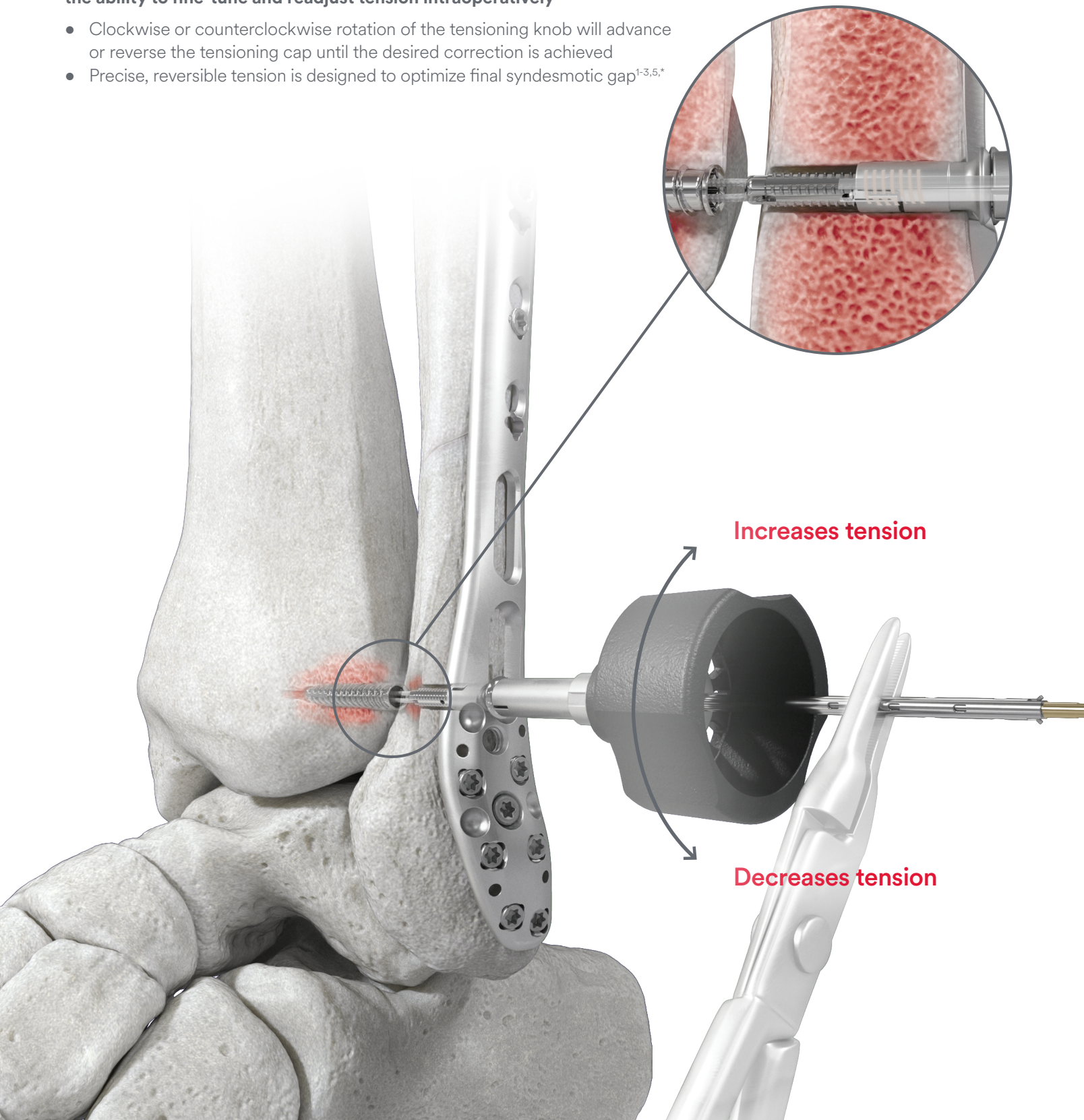


**6** Turn knob to engage link and adjust tension

## Improves tension control

The only flexible syndesmotic repair system that has the ability to fine-tune and readjust tension intraoperatively<sup>1-3,5,\*</sup>

- Clockwise or counterclockwise rotation of the tensioning knob will advance or reverse the tensioning cap until the desired correction is achieved
- Precise, reversible tension is designed to optimize final syndesmotic gap<sup>1-3,5,\*</sup>

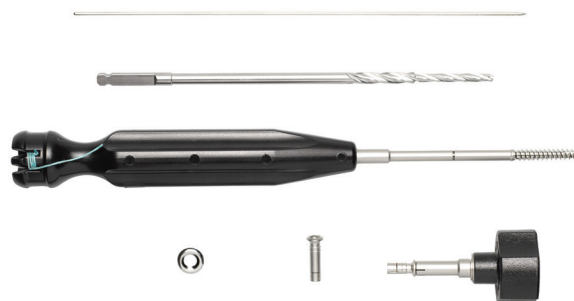


\*Compared to suture button constructs.

# Ordering information

## Sterile Implant Kits

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



## Sterile Instrument Kit

- **FGS-1300** FIBULINK™ Removal Kit



## Plate compatibility

The 4 mm FIBULINK Implant is compatible with any distal fibula plate hole that accepts a 4 mm non-locking cortex screw.

Within the DePuy Synthes distal fibula plate family, the FIBULINK Implant is compatible with:

- All 1/3 tubular plates holes (LCP™ System and non-locking)
- The non-threaded portion of a combi hole in a 3.5 mm locking plate (LCP™ Plates)
- Syndesmotic slot (VA LCP™ Plates)<sup>13,14</sup>

Additionally, plates with 3.5 mm screw holes may accommodate the FIBULINK Implant, but compatibility must be verified.

**References:** **1.** DePuy Synthes. Syndesmosis Physiologic Motion & Soft Tissue Rationale. 1/20/23. Windchill Document #0000303937. **2.** DePuy Synthes. Fibulink FDR Matrix. 9/2/21. Windchill Document #0000295660. **3.** DePuy Synthes. Fibulink Competitive Evaluation Memo. 1/20/23. Windchill Document #0000303949. **4.** DePuy Synthes. Fibulink IFU GP3134-A. <https://www.e-ifu.com/search-document-metadata/Fibulink>. Accessed February 28, 2023. **5.** DePuy Synthes. Fibulink Design Validation Report. 10/2/20. Windchill Document #0000306956. **6.** DePuy Synthes. Fibulink Indications Memo. 5/12/20. Windchill Document #0000295747. **7.** Schon JM, Mikula JD, Backus JD, et al. 3D Model Analysis of ankle flexion on anatomic reduction of syndesmotic injury. *Foot Ankle Int.* 2017; 38:364-442. **8.** DePuy Synthes. Fatigue Loading and Static Failure (Fibulink Implant vs. Tightrope XP). 8/24/20. Windchill Document #0000304763. **9.** DePuy Synthes. Fibulink Verification Fatigue and Pull to Failure Worksheet. 01/20/2023. **10.** Storey P, Gadd RJ, Blundell C, Davies MB. Complications of suture button ankle syndesmosis stabilization with modifications of surgical technique. *Foot Ankle Int.* 2012;33(9):717-721. doi:10.3113/FAI.2012.0717. **11.** Degroot H, Al-Omari AA, El Ghazaly SA. Outcomes of suture button repair of the distal tibiofibular syndesmosis. *Foot Ankle Int.* 2011;32(3):250-256. **12.** Desai S. Syndesmotic injuries treated with an aperture fixation device. *Techniques in Foot & Ankle Surgery.* 2018;19(2):96-103. doi:10.1097/btf.0000000000000215. doi:10.3113/FAI.2011.0250. **13.** DePuy Synthes. Fibulink Non locking Plate Compatibility Memo. 6/30/20. Windchill Document #0000295062. **14.** DePuy Synthes. Fibulink 1\_3 LCP Tubular Plate Compatibility Memo. 6/30/20. Windchill Document #0000297106.

Please also refer to the Instructions for Use, surgical technique, or other labeling associated with the devices identified in this brochure for additional information. CAUTION: Federal law restricts these devices to sale by or on the order of a physician. Please refer to the Instructions for Use for a complete list of indications, contraindications, warnings, and precautions.



Manufactured by:  
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