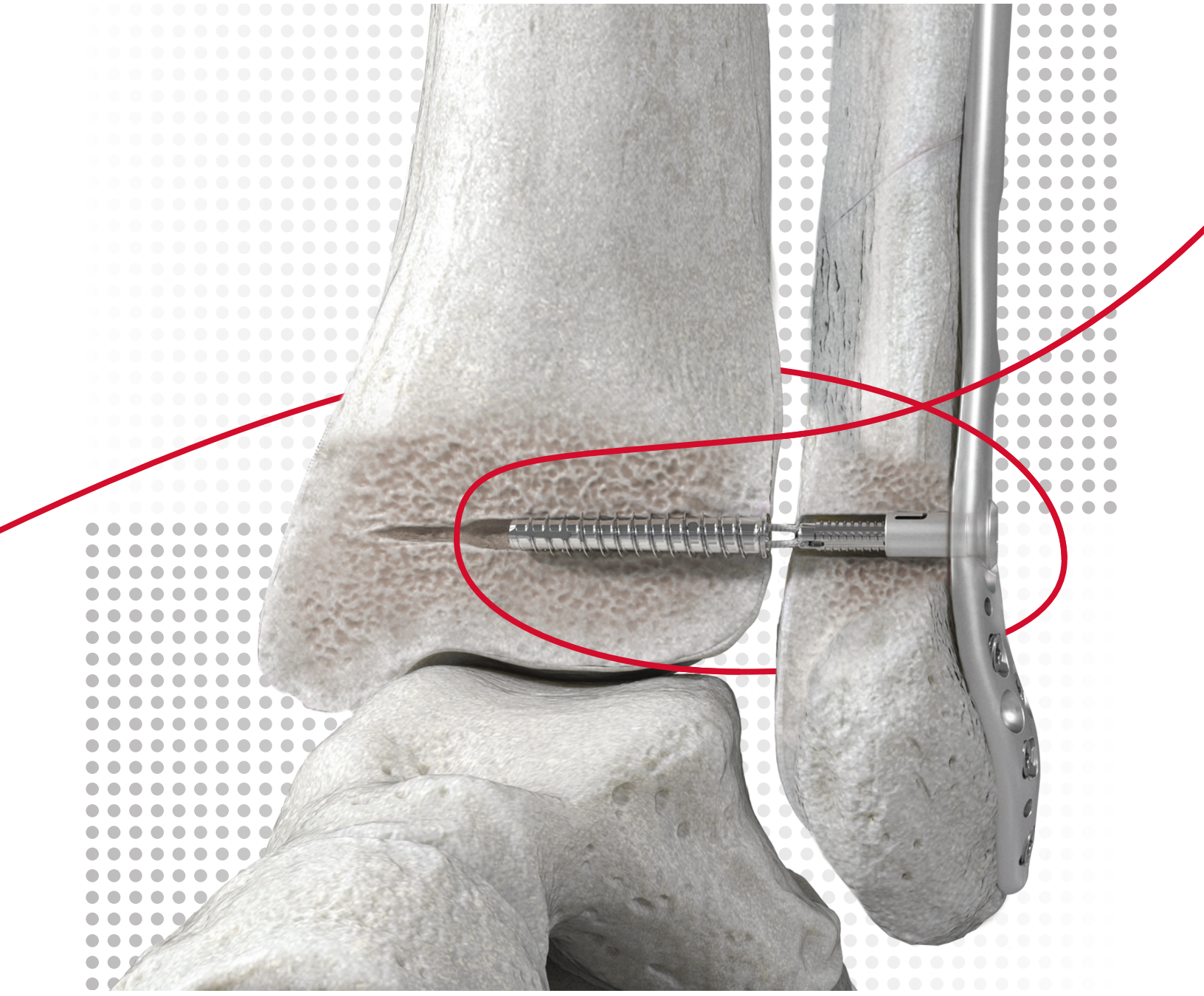
FIBULINK®

SYNDESMOSIS REPAIR SYSTEM

Value Analysis Brief



FIBULINK® Implant is the **first adjustable syndesmotic repair system** with a short, high-strength suture bridge designed to enable physiologic ankle motion.[30,32]

DePuy Synthes
THE ORTHOPAEDICS COMPANY OF Johnson & Johnson

Clinical & Economic Burden

Epidemiology and Burden of Syndesmosis Injuries

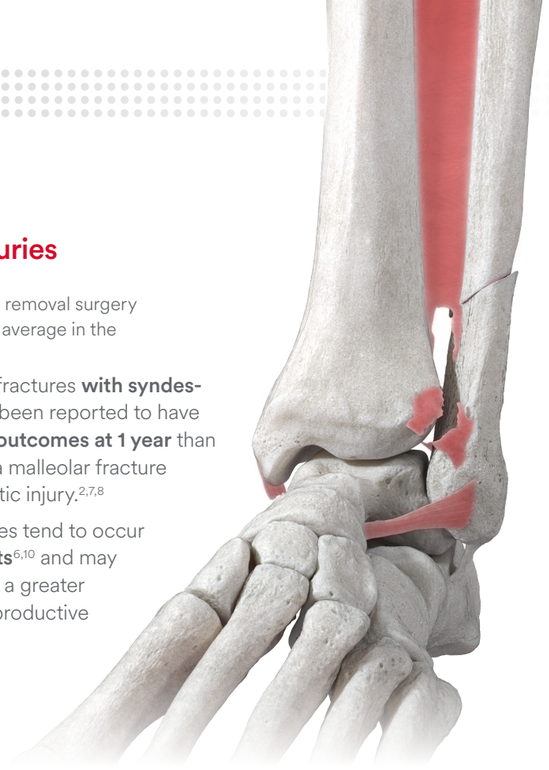
The ankle syndesmosis **maintains the proper relationship between the fibula and the tibia** at the ankle level. Small amounts of syndesmotic deformity can lead to **significant problems** with ankle function.[9]

Syndesmotic injuries or tears are **common** and are **frequently associated with ankle fractures**.[2-4]

- Projections estimate **35,300** syndesmotic disruption procedures in the United States in 2020.[35]
- Syndesmosis injury is believed to occur in **13-50%** of all ankle fractures and **1-18%** of all ankle sprains.[28]
- Secondary screw removal surgery costs **$14,768** on average in the United States.[36]

Isolated malleolar fractures **with syndesmotic injury** have been reported to have **worse functional outcomes at 1 year** than patients who had a malleolar fracture without syndesmotic injury.[2,7,8]

Syndesmotic injuries tend to occur in **younger patients**[6,10] and may subsequently have a greater effect in terms of productive years of life lost.[6]



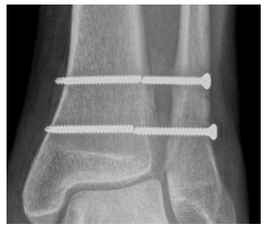
The Need for an Improved Solution

Due to the high prevalence of malreduction or post-traumatic ankle arthritis,[11,12] syndesmotic injury should be identified and addressed to help prevent long-term pain, disability, and progression of arthritis.[13]

Challenges with Surgical Fixation for Syndesmosis

The most common methods of surgical fixation are suture button constructs or syndesmotic screws. Each of these fixation methods has its drawbacks.

Suture Button Constructs



Syndesmotic Screws

Complications (and corresponding rates when applicable) with current syndesmotic fixation methods

	Suture Button Constructs	Syndesmotic Screws
Soft-tissue entrapment/irritation	Up to **55%**[14]	N/A
Poor joint mechanics	Once the suture is tightened, **tension cannot be relaxed/reversed,** potentially leading to **overcompression and displacement**[15]	**May inhibit the natural physiological motion** of the ankle[14,16]
Stability and healing	Up to **16.7%** osteolysis of the bone and subsidence of the device into the bone[5]	Up to **36% implant failure,**[19] **21.7% malreduction,**[18] **11.1% loss of reduction,**[19] **and 17.1% syndesmotic diastasis**[20]
Device removal	Up to **25.0%***[5]	Up to 51.9%[21]

*observed with Arthrex Knotless TightRope®

Common Clinical Complications

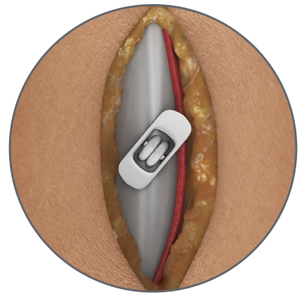
Suture Button Constructs

> The results of the present investigation have indicated that a **risk of entrapment** of superficial medial neurovascular structures exists with insertion of a **suture button** for syndesmotic fixation and that a **medial incision should be used** to ensure that structures **are not entrapped.**[14]

CHALLENGES WITH MEDIAL BUTTON[14]

Leading to soft tissue entrapment[14,22] or irritation and neurovascular damage,[14] oftentimes requiring a medial incision[14]

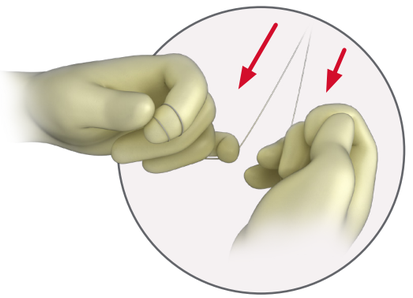
Up to **55.0%** of suture button constructs were inserted with some entrapment of a medial neurovascular structure.[14] Aseptic Osteolysis (2.0%)[23] of the bone and subsidence (16.7%)[5] of the device into the bone, heterotopic ossification within the syndesmotic ligament **(12.5%)**,[5] and osteomyelitis **(up to 2.9%)**[23,24] have also been observed.



TENSION CANNOT BE REVERSED OR RELAXED

Over tightening the structure can lead to poor joint mechanics due to overcompression[15] and lack of motion[1,5]

Biomechanical evidence has shown that, compared with the preinjury state, suture button repair can result in **significant volumetric and medial overcompression**, evidenced by a mean ± SD volume reduction of **337 ± 400 mm**^{3} and medial displacement of **1.9 ± 1.5 mm**.[15] **Overcompression was observed in all positions**, and could contribute to accelerated development of post-traumatic arthritis.[15]



STABILIZATION AND HEALING CONSIDERATIONS

Syndesmotic diastasis,[16] tunnel widening,[5,23,28] loss of fixation,[25] and inability to resist fibular shortening[27]

Suture button repair resulted in a **statistically significant increase** in the lower syndesmotic area volume and distal tibiofibular volume compared with the contralateral limbs,[16] indicating a potential loss of reduction.[26] **Postoperative creep and loss of fixation,**[26] **radiographic enlargement of the suture tunnel**, and **fibular shortening**[27] have also been observed.[5,23,28]

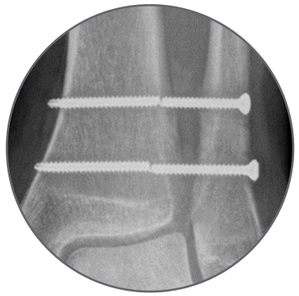
Common Clinical Complications
Syndesmotic Screws

Findings suggest that **neither traditional screw nor suture button fixations optimally stabilize the syndesmosis**, which may have **implications for postoperative care and clinical outcomes.**[1]

SCREW BREAKAGE AND SUBSEQUENT MALREDUCTION / LOSS OF REDUCTION

Potentially resulting in recurrent syndesmotic diastasis[20]

Up to **36%** of patients experience implant failure,[19] up to **21.7%** experience malreduction,[18] and up to **11.1%** have loss of reduction.[19] Weight-bearing after surgery **may be delayed** due to **concerns about screw breakage**.[13] Secondary screw removals have an average cost of **$14,768** per procedure in the US.[36]



IMPLANT-RELATED PAIN

Sometimes necessitating screw removal, which may be associated with loss of reduction[19,20]

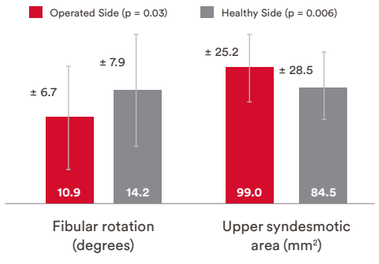
Up to **17.1%** experience **syndesmotic diastasis** and it is likely that the **loss of reduction occurs after screw removal**.[20] **60%** of patients treated for ankle fractures with associated syndesmosis disruption had **pain**, and syndesmotic disruption is associated with **poor long-term outcomes** after ankle fracture.[12]

INHIBITS PHYSIOLOGIC MOTION[14,16]

Joint mechanics are not fully restored[16]

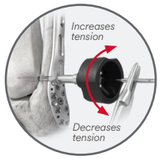
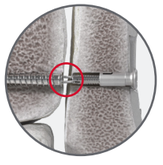
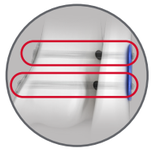
Evidence has shown a **statistically significant decrease** in the degree of fibular rotation and **an increase** in the upper syndesmotic area with screw fixation compared with the contralateral limb.[16]

Statistically Significant Differences in Stability[16]



Features & Benefits
FIBULINK® Syndesmosis Repair System

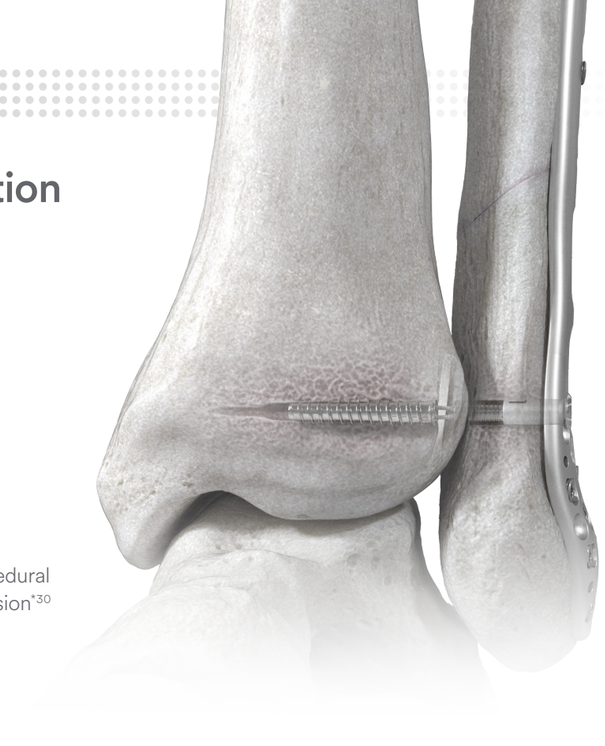
The FIBULINK® Syndesmosis Repair System combines the fixation of a screw with the flexibility of a suture and is designed to enable precise, anatomic syndesmotic fixation.[30,31] The FIBULINK System **improves tension control** and **eliminates soft tissue disruption** compared to suture button constructs, in addition to **enabling physiologic ankle motion.***[30,32]

Clinical Challenge	Our Solution
SUTURE BUTTON CONSTRUCTS	
 **Inability to Reverse Tension** Unidirectional tensioning leads to a lack of control in optimizing the final syndesmotic gap.[30]	 **Improves Tension Control** The FIBULINK System is the only flexible syndesmosis repair system with the ability to fine tune and readjust tension intraoperatively.*[30,32]
 **Medial Incision** A medial incision to seat the button properly on the medial cortex may add additional time to procedure.[30]	**Eliminates Medial Disruption** No medial incision or hardware, which eliminates medial side complications and helps improve procedural efficiency, delivering fixation through a single lateral incision.*[30]
 **Medial Fixation** Medial button fixation introduces potential complications such as neurovascular damage, tibialis anterior tendon entrapment and osteomyelitis.[30]	 **Enables Physiologic Motion** Short, high-strength suture bridge and anchor construct provides 3x the fixation strength (+206%) and less than 1/3 of the elongation (-71%) of Arthrex Syndesmosis TightRope® XP Implant System in a poor bone model.**[33]
 **Stabilization / Healing Concerns** A long suture bridge is not stiff and is susceptible to micromotion, which can lead to tunnel widening and suture toggling associated with suture button constructs.[5,23,28]	
SCREWS	
 **Screw Breakage & Removal** Screws break postoperatively in up to 36% of cases and may require costly removal surgery in up to 52% of cases.[19,21]	 **Enables Physiologic Motion** The FIBULINK System's flexible suture bridge helps eliminate the risk of complications and removal surgeries associated with broken syndesmotic screws.[19]

*Compared to suture button constructs
**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 2mm), displacement and stiffness. P-value ≤ 0.001.

The FIBULINK® System Solution

Enables precise, anatomic syndesmotic fixation



Key Benefits

Improves Tension Control

The only syndesmotic repair system that has the ability to fine-tune and readjust tension intraoperatively*[30,32]

Eliminates Medial Disruption

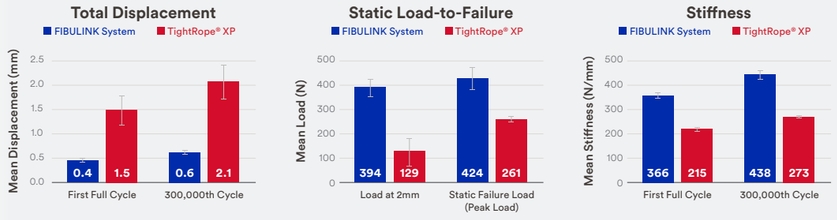
Eliminates medial soft tissue disruption and improves procedural efficiency by delivering fixation through a single lateral incision*[30]

Enables Physiological Motion

Enables the physiological motion of the syndesmosis utilizing a short, high-strength suture bridge[30,32]

Superior Biomechanical Performance to TightRope® XP

The FIBULINK Syndesmosis Repair System delivers superior biomechanical performance compared to the Arthrex Syndesmosis TightRope XP Implant System**[33]



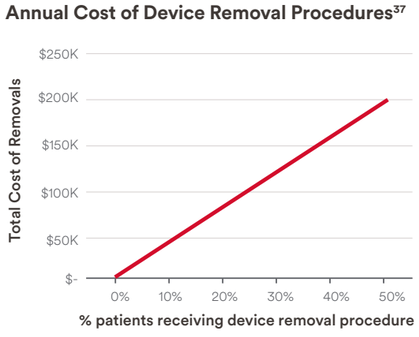
>3x Fixation Strength[33]

1/3 Displacement[33]

61% Increased Stiffness[33]

Potential Savings with Reduced Device Removal as Compared to Syndesmotic Screws

In a hospital conducting 100 syndesmotic repair surgeries a year, **reducing the % of device removals by 50% could save nearly $50K******[37]



Parameters

100 annual syndesmotic repair procedures***

$3,913[29] per patient reimbursement (mean)

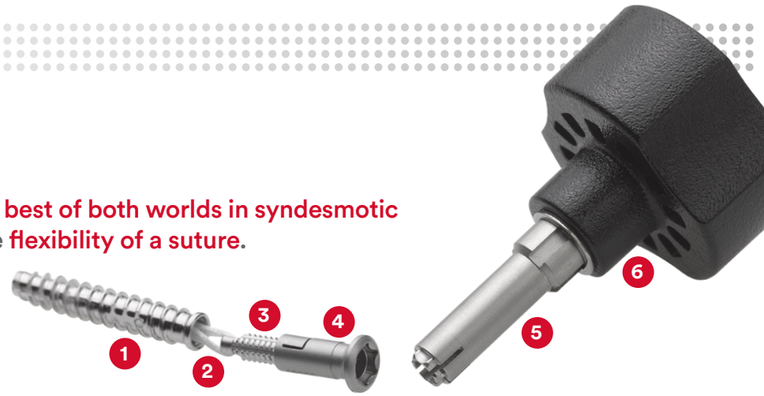
$391,300 total cost (per 100 patients)

25% of patients receiving 2nd surgery for device removal

*Compared to suture button constructs.
**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 2mm), displacement and stiffness. P-value ≤ 0.001.
***Values are hypothetical estimates.
****Savings based on assumed removal rate of 25%.

Product Offering

The FIBULINK System can provide the **best of both worlds in syndesmotic repair**; the **fixation of a screw**, with the **flexibility of a suture.**



Core System Components

① **Tibia Screw**
Serves as an anchor in the tibia

② **PERMACORD® Suture Bridge**
Provides tension between the Fibula and Tibia implant components and enables physiological syndesmotic motion[30,32]

③ **Fibula Link**
Connects suture bridge to tensioning cap
Link/Cap Interface is the primary tensioning mechanism that allows precise, reversible tensioning[30,32]

④ **Fibula Tensioning Cap**
Interfaces with Fibula link, with rotation of the cap either adding or releasing tension to the construct

⑤ **Tensioning Knob**
Facilitates placement and streamlined rotation of the Fibula

⑥ **Tensioning Cap**
Cap snaps onto tensioning knob, which has a torque limiter to prevent over tightening of the construct

Implant Kit Components

Additionally available: FIBULINK Removal Kit (FGS-1300)

Implant Specifications

Material

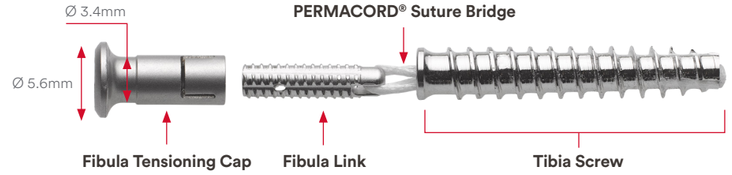
- Stainless Steel (FGS-1000) or Titanium (FGS-1100) kits available

Tibia Screw Length & Threadform

- 22mm long
- Proximal end: 4.0mm cortical threadform, transitioning to 4.0mm cancellous threadform at distal end

Suture Bridge Length & Material

- 4mm suture bridge consists of 4 strands of #1 Ultra High Molecular Weight Polyethylene (UHMWPE)



Fibula Link

- Outer Diameter: 2.8mm
- 10.7mm long
- External threads: 40 threads/inch

Fibula Tensioning Cap Lengths

- Standard cap: 10mm
- Long cap: 15mm

DePuy Synthes Plate Compatibility

- All ⅓ Tubular Plate holes (LCP™ System & Nonlocking)
- Nonthreaded portion of combi hole in a 3.5mm LCP™ Plate
- Syndesmotic slots (VA LCP™ Plates)[34]

References

1. Lubberts B, Vopat BG, Wolf JC, Longo UG, DiGiovanni CW, Guss D. Arthroscopically measured syndesmotic stability after screw vs. suture button fixation in a cadaveric model. Injury. 2017;48(11):2433-2437.
2. Egol KA, Pahk B, Walsh M, Tejwani NC, Davidovitch RI, Koval KJ. Outcome after unstable ankle fracture: effect of syndesmotic stabilization. J Orthop Trauma. 2010;24(1):7-11.
3. Stark E, Tornetta P, 3rd, Creevy WR. Syndesmotic instability in Weber B ankle fractures: a clinical evaluation. J Orthop Trauma. 2007;21(9):643-646.
4. Franke J, von Recum J, Suda AJ, Grützner PA, Wendl K. Intraoperative three-dimensional imaging in the treatment of acute unstable syndesmotic injuries. J Bone Joint Surg Am. 2012;94(15):1386-1390.
5. DeGroot H, Al-Omari AA, Ghazaly SAE. Outcomes of Suture Button Repair of the Distal Tibiofibular Syndesmosis. Foot & Ankle International. 2011;32(3):250-256.
6. Vosseller JT, Karl JW, Greisberg JK. Incidence of syndesmotic injury. Orthopedics. 2014;37(3):e226-229.
7. Still GP, Atwood TC. Operative outcome of 41 ankle fractures: a retrospective analysis. J Foot Ankle Surg. 2009;48(3):330-339.
8. Kohake MBJ, Wiebking U, O'Loughlin PF, Krettek C, Gaulke R. Mid- to Long-term Outcomes After Weber B-type Ankle Fractures With and Without Syndesmotic Rupture. In Vivo. 2019;33(1):255-261.
9. Lloyd J, Elsayed S, Hariharan K, Tanaka H. Revisiting the concept of talar shift in ankle fractures. Foot Ankle Int. 2006;27(10):793-796.
10. Lambers K, Ootes D, Ring D. Incidence of patients with lower extremity injuries presenting to US emergency departments by anatomic region, disease category, and age. Clin Orthop Relat Res. 2012;470(1):284-290.
11. Sagi HC, Shah AR, Sanders RW. The functional consequence of syndesmotic joint malreduction at a minimum 2-year follow-up. J Orthop Trauma. 2012;26(7):439-443.
12. van Vlijmen N, Denk K, van Kampen A, Jaarsma RL. Long-term Results After Ankle Syndesmosis Injuries. Orthopedics. 2015;38(11):e1001-1006.
13. de-Las-Heras Romero J, Alvarez AML, Sanchez FM, et al. Management of syndesmotic injuries of the ankle. EFORT Open Rev. 2017;2(9):403-409.
14. Pirozzi KM, Creech CL, Meyr AJ. Assessment of Anatomic Risk During Syndesmotic Stabilization With the Suture Button Technique. J Foot Ankle Surg. 2015;54(5):917-919.
15. Schon JM, Mikula JD, Backus JD, et al. 3D Model Analysis of Ankle Flexion on Anatomic Reduction of a Syndesmotic Injury. Foot Ankle Int. 2017;38(4):436-442.
16. Kocadal O, Yucel M, Pepe M, Aksahin E, Aktekin CN. Evaluation of Reduction Accuracy of Suture-Button and Screw Fixation Techniques for Syndesmotic Injuries. Foot Ankle Int. 2016;37(12):1317-1325.
17. Zhang P, Liang Y, He J, Fang Y, Chen P, Wang J. A systematic review of suture-button versus syndesmotic screw in the treatment of distal tibiofibular syndesmosis injury. BMC musculoskeletal disorders. 2017;18(1):286-286.
18. Naqvi GA, Cunningham P, Lynch B, Galvin R, Awan N. Fixation of ankle syndesmotic injuries: comparison of tightrope fixation and syndesmotic screw fixation for accuracy of syndesmotic reduction. Am J Sports Med. 2012;40(12):2828-2835.
19. Laflamme M, Belzile EL, Bédard L, van den Bekerom MP, Glazebrook M, Pelet S. A prospective randomized multicenter trial comparing clinical outcomes of patients treated surgically with a static or dynamic implant for acute ankle syndesmosis rupture. J Orthop Trauma. 2015;29(5):216-223.
20. Andersen MR, Frihagen F, Hellund JC, Madsen JE, Figved W. Randomized Trial Comparing Suture Button with Single Syndesmotic Screw for Syndesmosis Injury. J Bone Joint Surg Am. 2018;100(1):2-12.
21. Schepers T. Acute distal tibiofibular syndesmosis injury: a systematic review of suture-button versus syndesmotic screw repair. International orthopaedics. 2012;36(6):1199-1206.
22. Welck MJ, Ray P. Tibialis anterior tendon entrapment after ankle tightrope insertion for acute syndesmosis injury. Foot Ankle Spec. 2013;6(3):242-246.
23. 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.
24. Hong CC, Lee WT, Tan KJ. Osteomyelitis after TightRope® fixation of the ankle syndesmosis: a case report and review of the literature. J Foot Ankle Surg. 2015;54(1):130-134.
25. Ibnu Samsudin M, Yap MQW, Wei Luong A, Kwek EBK. Slippage of Tightrope Button in Syndesmotic Fixation of Weber C Malleolar Fractures: A Case Series. Foot Ankle Int. 2018;39(5):613-617.
26. Peterson KS, Chapman WD, Hyer CF, Berlet GC. Maintenance of reduction with suture button fixation devices for ankle syndesmosis repair. Foot Ankle Int. 2015;36(6):679-684.
27. Riedel MD, Miller CP, Kwon JY. Augmenting Suture-Button Fixation for Maisonneuve Injuries With Fibular Shortening: Technique Tip. Foot Ankle Int. 2017;38(10):1146-1151.
28. Desai S. Syndesmotic Injuries Treated With an Aperture Fixation Device. Techniques in Foot & Ankle Surgery. 2020;19(2).
29. Etter K, Villacorta R, Putnam M. Rate and Reimbursement of Ankle Screw Removal Procedures after Syndesmotic Fixation. Value in Health. 2018;21:S195.
30. DePuy Synthes. Syndesmosis Physiologic Motion & Soft Tissue Rationale. 5/22/20. Windchill Document #0000303937.
31. DePuy Synthes. FIBULINK Indications Memo. 5/12/20. Windchill Document #0000295747.
32. DePuy Synthes. FIBULINK Competitive Evaluation Memo. 5/21/20. Windchill Document #0000303949.
33. DePuy Synthes. Fatigue Loading and Static Failure (FIBULINK Implant vs. TightRope XP). 8/24/20. Windchill Document #0000304763
34. DePuy Synthes. FIBULINK Non-locking Plate Compatibility Memo 6/30/2020 Windchill Document #0000295062.
35. Medtech 360. Foot and Ankle Orthopedic Devices – 2019 US Market Insights. Millenium Research Group, Inc.
36. Neary et al. Suture button fixation versus syndesmotic screws in supination-external rotation type 4 injuries: a cost-effectiveness analysis. Am J Sports Med 2017.
37. DePuy Synthes. Internal Savings with Reduced Device Removal vs. Syndesmotic Screws Memo. 12/8/2020.

DePuy Synthes
THE ORTHOPAEDICS COMPANY OF Johnson & Johnson

Manufactured by:

Synthes GmbH
Luzernstrasse 21
4528 Zuchwil
Switzerland

depuysynthes.com