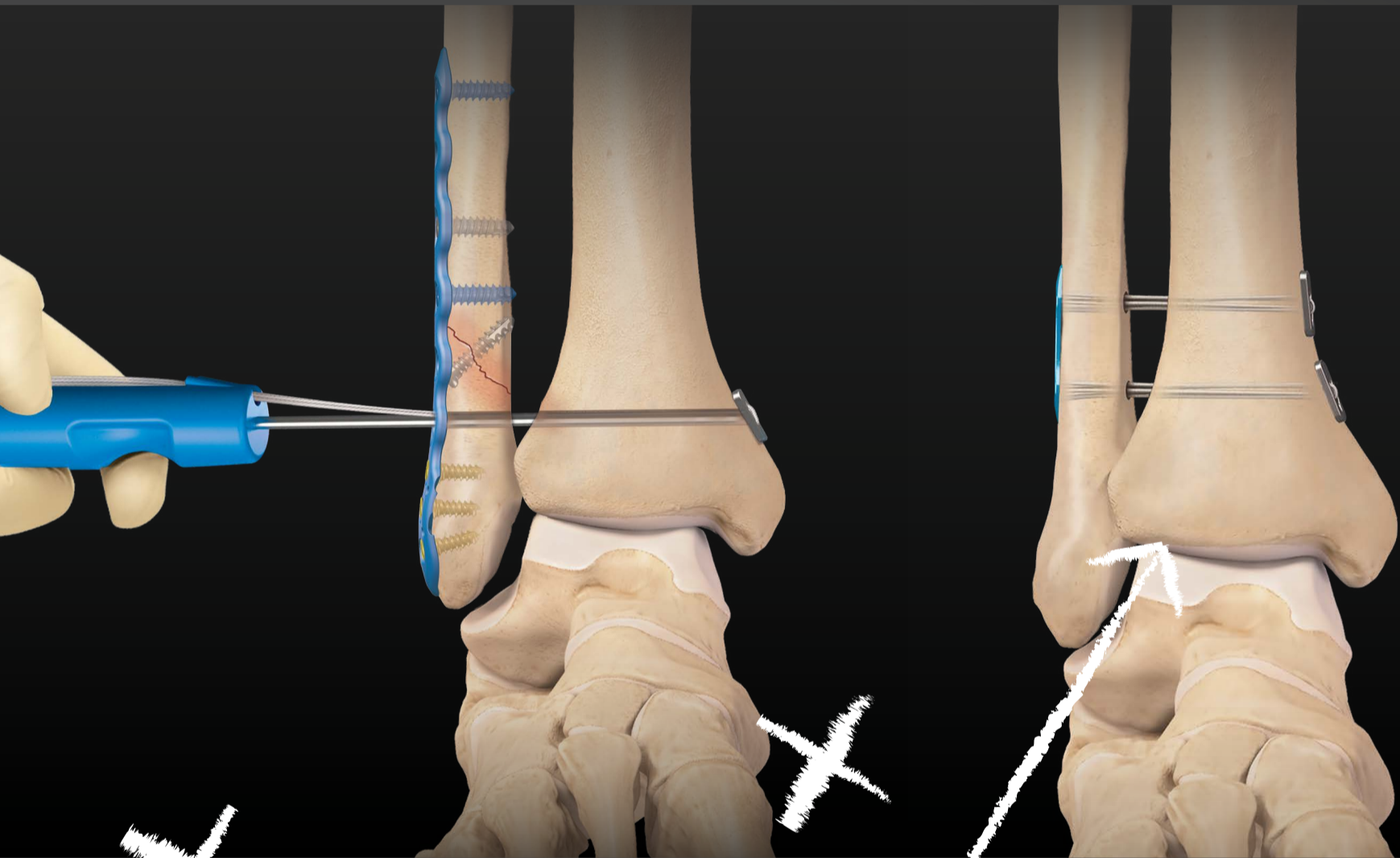




PLAYBOOK

# Syndesmosis TightRope<sup>®</sup> XP Implant



Arthrex<sup>®</sup> 



EDUCATE. CHALLENGE. INSPIRE.

Arthrex Customer Engagement™ Program



## Introduction

### ECI Playbook

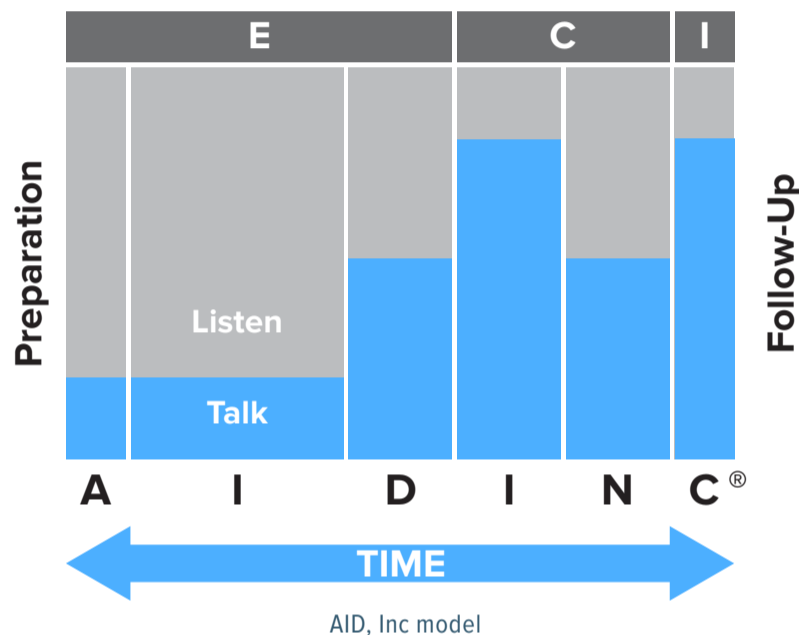
Welcome to the Syndesmosis TightRope® XP implant system playbook with the Arthrex ECI Customer Engagement program.

The Arthrex ECI playbooks are organized using the AID,INC® process model (ie, approach, interview, demonstrate, validate, negotiate, close), which will help you prepare and properly plan for each customer interaction. This playbook briefly reviews the Arthrex ECI Program concepts in the beginning of each section.

Combining the sales engagement model with the educational resources will help you apply what you have learned, engage, and interact with your customers and give you the confidence to approach your customers.

Using the AID,INC process model, we **EDUCATE** ourselves about customers' goals and priorities during the **approach** and **interview** by adapting to their behavior styles and asking thoughtful questions. Based on what we learn, we **EDUCATE** our customers by **demonstrating** viable solutions and differentiating our products.

From there, we **validate** our claims with scientific evidence, **negotiate** through our customers' concerns or potential objections, and **CHALLENGE** them to deliver value through improved treatment and patient outcomes.



Through this collaborative process, we are able to identify customers' wants, needs, challenges, and goals and provide them with solutions. It also simplifies the **closing** process and **INSPIRES** our customers to choose Arthrex as a valued partner.

- [Pre-Call Game Plan](#)
- [ECI Reference Guide](#)

Integrity Selling®, Behavior Styles®, AID,INC®, Action Guides™, GAP Model™, Customer Engagement™, and Sales Congruence Model™ are trademarks of Integrity Solutions, LLC. Developed from copyrighted content owned by Integrity Solutions, LLC. All rights reserved. Used with permission.

---

# Coach's Corner

## A Message From Arthrex President and Founder

---

Now more than ever, Arthrex is positioned to capture the majority of the syndesmosis repair market for ankle instability. The Syndesmosis TightRope® XP implant is the only anatomic, knotless solution on the market, allowing normal motion of the syndesmosis joint versus placement of an overly rigid metal screw construct. Our surgeon customers in the foot/ankle and trauma markets have taken notice of the scientific support garnered by the TightRope implant brand, and with the *AJSM* article proving the TightRope implant to be the most cost-effective solution available,<sup>2</sup> I urge you to consult with all of your sports customers to highlight this proven technology. A ligamentous sprain to the ankle is one of the most common injuries in sports, with an estimated 30,000 occurring every day<sup>1</sup>. Let's button up this huge market with the TightRope implant!



A handwritten signature in black ink, reading "Reinhold Schmieding".

**Reinhold Schmieding** | President and Founder



---

# Table of Contents

---

Introduction.....	02
Coach's Corner .....	03
<b>Approach</b> .....	<b>05</b>
Product Background and Rationale.....	05
Market Overview .....	06
Primary Target Customers .....	07
Targeting.....	07
<b>Interview</b> .....	<b>09</b>
Craft Compelling Questions .....	09
<b>Demonstrate</b> .....	<b>11</b>
Anatomy/Pathology .....	11
Value Proposition .....	12
Features and Benefits .....	12
Scrub Sink Pitch.....	13
Product Applications .....	13
Resources.....	15
<b>Validate</b> .....	<b>16</b>
Related Science .....	16
<b>Negotiate</b> .....	<b>23</b>
Clinical Objections .....	23
Nonclinical Objections.....	24
<b>Close</b> .....	<b>25</b>
Closing Question Examples .....	25
<b>Appendix</b> .....	<b>26</b>
Sales Tools .....	26
Ordering Information .....	27
References .....	28

# Approach

## Action Guides™

- **Tune** the world out and people in.
- **Put** people at ease and make them feel important.
- **Get** them talking about themselves.
- **Hold** eye contact and listen to how they feel.

### Pre-Call Game Plan

PRE-CALL GAME PLAN

Arthrex

DATE: \_\_\_\_\_

Customer: \_\_\_\_\_

Customer Profile (Product/Procedure/Problem/Personal Info/ Education/ Background, etc.): \_\_\_\_\_

Behavior Style: \_\_\_\_\_

Call Objectives (Based on Customer Profile): \_\_\_\_\_

Statement of Intent: \_\_\_\_\_

What information do we need to uncover? \_\_\_\_\_

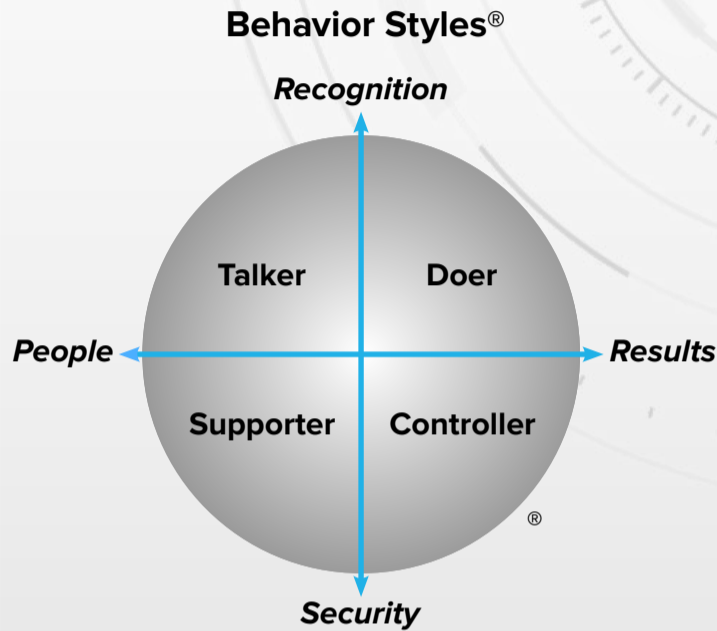
What questions will you ask to uncover customer wants, needs, challenges or goals? \_\_\_\_\_

Products/Procedures You Will Discuss: \_\_\_\_\_ Resources/Callateral Needs: \_\_\_\_\_ Best Price to Engage: \_\_\_\_\_

What is most valuable to this customer? (Circle)

<input type="checkbox"/> Front Cost	<input type="checkbox"/> Speed/Structure	<input type="checkbox"/> Front Cost	<input type="checkbox"/> Speed/Structure
<input type="checkbox"/> Speed Efficiency	<input type="checkbox"/> Support/Service	<input type="checkbox"/> Speed Efficiency	<input type="checkbox"/> Support/Service
<input type="checkbox"/> Improved Outcomes	<input type="checkbox"/> Reproducibility	<input type="checkbox"/> Improved Outcomes	<input type="checkbox"/> Reproducibility

Other: \_\_\_\_\_



For further information, see the [ECI Reference Guide](#).

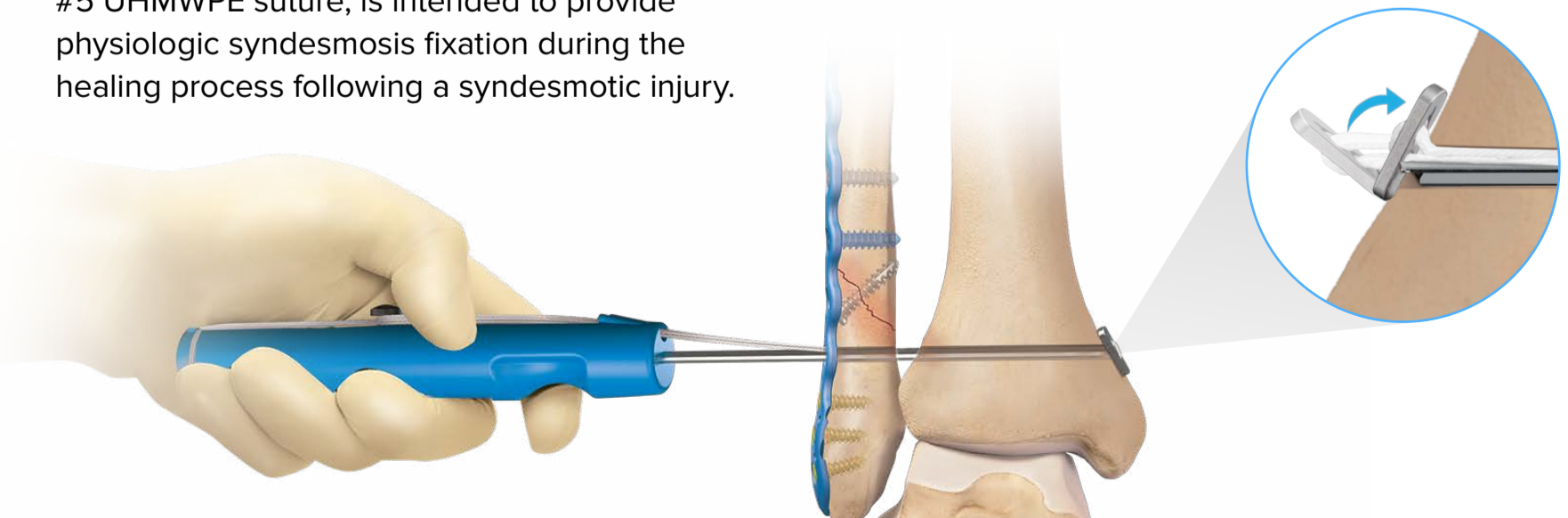
## Product Background and Rationale

Arthrex has quickly become a market leader in the foot and ankle arena, offering an extensive line in both soft-tissue and metal products for trauma. Through innovation, education, and a best-in-class organization, we offer surgeons the finest solutions available to treat their patients better.

The Syndesmosis TightRope® implant system, which consists of two metallic buttons and #5 UHMWPE suture, is intended to provide physiologic syndesmosis fixation during the healing process following a syndesmotic injury.

The Syndesmosis TightRope fixation system mimics the natural micromotion of the fibula and prevents the need for a second surgery to remove a rigid syndesmotic screw.

The Syndesmosis TightRope fixation system has been available since 2005, giving surgeons long-lasting confidence.



# Approach

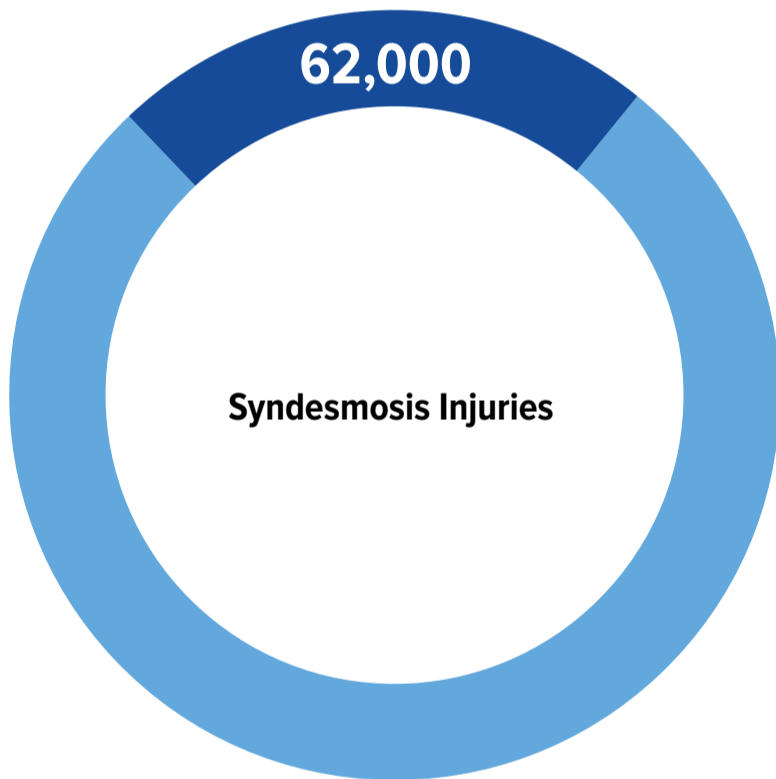
## Market Overview

Arthrex offers the finest and most innovative soft-tissue solutions for foot/ankle and trauma procedures. Our success began with a search for a solution to broken syndesmosis screws.

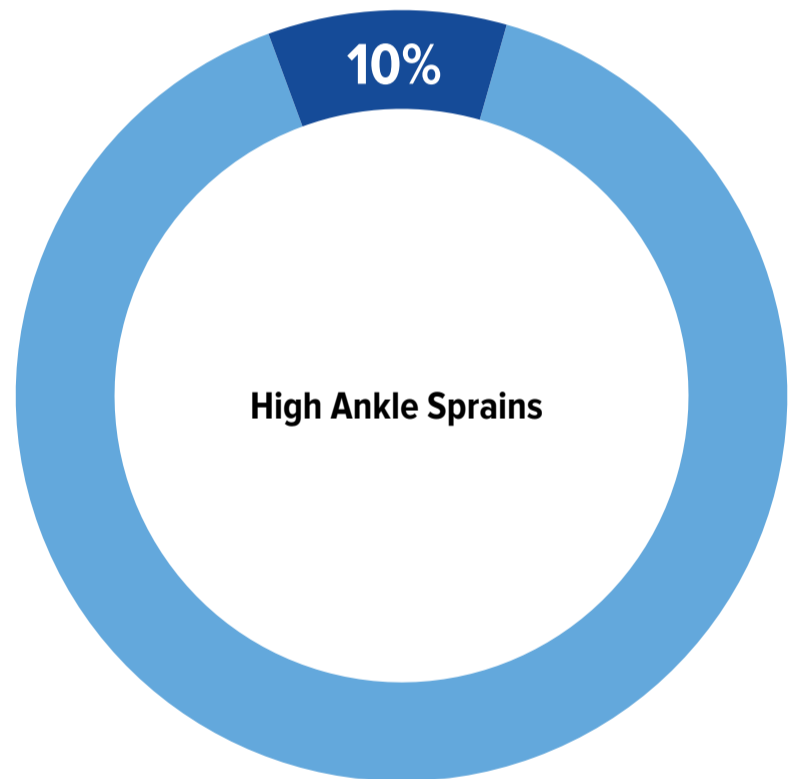
The Syndesmosis TightRope® fixation system proved to offer a biomechanical advantage by maintaining the syndesmosis reduction after cycling more than 27,000 times compared to 11,000 cycles for a 4.5 mm screw.<sup>3</sup> TightRope technology has been applied for implants all over the body, including the shoulder, hand, knee, ankle, and foot.

- Up to 20% of all operative ankle fractures will have a syndesmosis injury
- On average, 1.25 TightRope implants are used per case

**Total Operative Ankle Fractures: 270,000**



**Ankle Sprains Per Day: 30,000**



**Cycles to Failure**

**>27,000 vs 11,000**  
 TightRope Implant vs 4.5 mm Screw Cyclic Fracture<sup>3</sup>



**Market Opportunity**

**110,000** High Ankle Sprains Per Year  
 Syndesmosis Sprain (AITFL, PITFL, or IO)

Data gathered from surgeon input and literature.<sup>3-11</sup>

# Approach

## Primary Target Customers

### Positioning Syndesmosis TightRope® Implant

- Focus effort on customers currently using screws or competitive syndesmosis devices
- Position Syndesmosis TightRope XP implant to gain back business lost to competitive syndesmosis devices
- Convert Knotless TightRope implant users to Syndesmosis TightRope XP implant

## Targeting

Targeting is critical because multiple companies are flooding the market with their own dynamic fixation devices for syndesmosis fixation. The history and evolution of the TightRope implant positions it as the premier implant for syndesmotic fixation, whether it be for ankle sprains and instability or syndesmosis disruption in conjunction with ankle fracture.

Ideal targets for Syndesmosis TightRope implants are foot and ankle surgeons, sports surgeons treating ankle fractures and sprains, and trauma surgeons.

Competition	Construct	ASP <sup>12</sup>	Strength <sup>13,14</sup> (TR XP 206 lbf)
Biomet ZipTight™	Knotless	\$1065	118 lbf
S&N Invisiknot™	Knotted	\$980	150 lbf
Wright Synchronix™	Knotted	\$1330	180 lbf

ASP, average selling price; TR XP, TightRope XP implant

# Approach

## Primary Target Customers (Cont.)

### A Great Target



- Foot and ankle sports surgeons using competitive syndesmosis implants
- Trauma surgeons using screws

#### **A Great Target**

Focus on foot and ankle and sports surgeons taking trauma calls, as you work with these surgeons regularly in other cases. Ankle fractures are very common, and surgeons will fix the majority that come in through the ER. They also frequently see ankle instability and sprains. Most of these surgeons believe in the TightRope® implant technology but may be using a competitive device.

Use the TightRope XP implant as a way to generate NEW business from trauma surgeons, often your most challenging surgeon customers who have yet to adopt TightRope technology. Many of these surgeons are still using screws to treat syndesmosis injuries. In your sales call, be sure to include the innovative features and benefits that differentiate Syndesmosis TightRope XP from the traditional knotless design.

### A Good Target



- Surgeons using the original Knotless TightRope implant who have not yet been introduced to the Syndesmosis TightRope XP implant

#### **A Good Target**

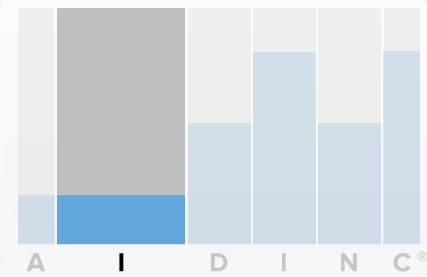
These surgeons already understand the efficacy of dynamic fixation for syndesmotic injuries. They are using our Knotless TightRope implant but have not yet been introduced to the TightRope XP implant. Be sure to emphasize the advantages that the handled inserter and tensioning handles bring to these procedures.



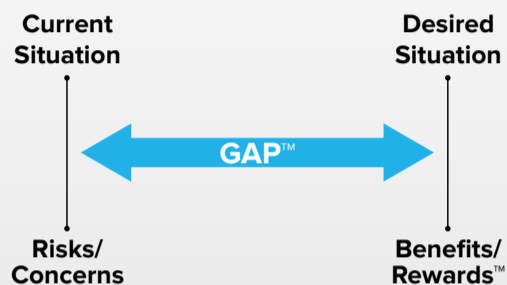
# Interview

## Action Guides™

- **Plan** and ask questions to uncover wants, needs, challenges, and goals.
- **Listen** to and paraphrase all points. If appropriate, take notes.
- **Identify** wants or needs and get agreement.
- **Communicate** your intent to create value by asking compelling questions.



### The Gap Model™



For further information, see the [ECI Reference Guide](#).

## Craft Compelling Questions

The ECI interview process is **all about asking good questions**. Whether you are introducing the Syndesmosis TightRope® XP implant system to your customer or converting them from another product, **you need to uncover their needs and challenges** to most effectively present how the Syndesmosis TightRope XP implant system is the right solution.

### Current

- How do you currently address syndesmosis instability? (Goal is to understand what they like most about what they are currently using.)
- What effect does your clinical data have on your choice of implants? (Goal is to point out the *JBJS* Westermann study that found the TightRope implant aided in the reduction of the syndesmosis compared to a syndesmotic screw on CT scan.<sup>15</sup>)

Following the ECI interview process, you will be able to identify strategies that best differentiate the Syndesmosis TightRope XP implant system from competitive products and upgrade the surgeon to the latest technology Arthrex has to offer.

- What experience do you have with dynamic fixation devices for syndesmotic disruptions?
- In your experience, how often do chronic ankle sprain patients have associated syndesmotic instability?
- What do you like about your current syndesmosis fixation preference?
- How often are you removing syndesmotic screws from your patients with syndesmosis injuries?

# Interview

## Craft Compelling Questions (Cont.)

### Desired

- What are your thoughts about using a dynamic implant for syndesmotic injuries?
- If your current technique for syndesmotic treatment could be enhanced, what would it look like?
- Knowing that you want to avoid a medial incision, are you open to learning more about a dynamic implant that doesn't require one?
- I know that cost is important to you. Did you know that the Syndesmosis TightRope® implant is actually more cost effective than screw fixation?

### Risks/Concerns

- What postoperative concerns do you have about broken or loose screws?  
(Goal is to communicate the benefits of TightRope implants because there is no need for a screw removal procedure.)
- The literature shows a high fibular malreduction rate with rigid fixation. What concerns do you have about potential long-term postoperative complications? (Most will say it's sometimes a problem.)
- What reservations do you have about early weightbearing and aggressive rehab with your current repair using syndesmotic screws?  
(Goal is to focus on the stability/strength of the TightRope implant and discuss with the surgeon that a second surgery for screw removal is not needed.<sup>16</sup>)
- What concerns do you have about making a medial incision for syndesmosis fixation with the device you're currently using?
- Do you have reservations about using products that don't have significant clinical data to back them up?

### Benefits/Rewards

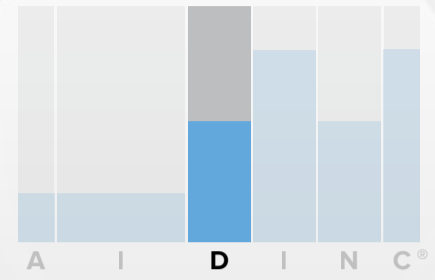
- If that enhancement you mentioned could be changed, how would that affect your outcomes?
- How might a dynamic implant affect your hardware removal rate for syndesmosis patients?
- Would you feel better about implanting a single-incision dynamic syndesmosis implant instead of one that requires two incisions?
- Do you get any peace of mind knowing that your implant has the most clinical data supporting it?
- Knowing that the Syndesmosis TightRope implant system is associated with faster rehab and quicker overall recovery, how might this affect your post-op rehab routine?

# Demonstrate

## Action Guides™

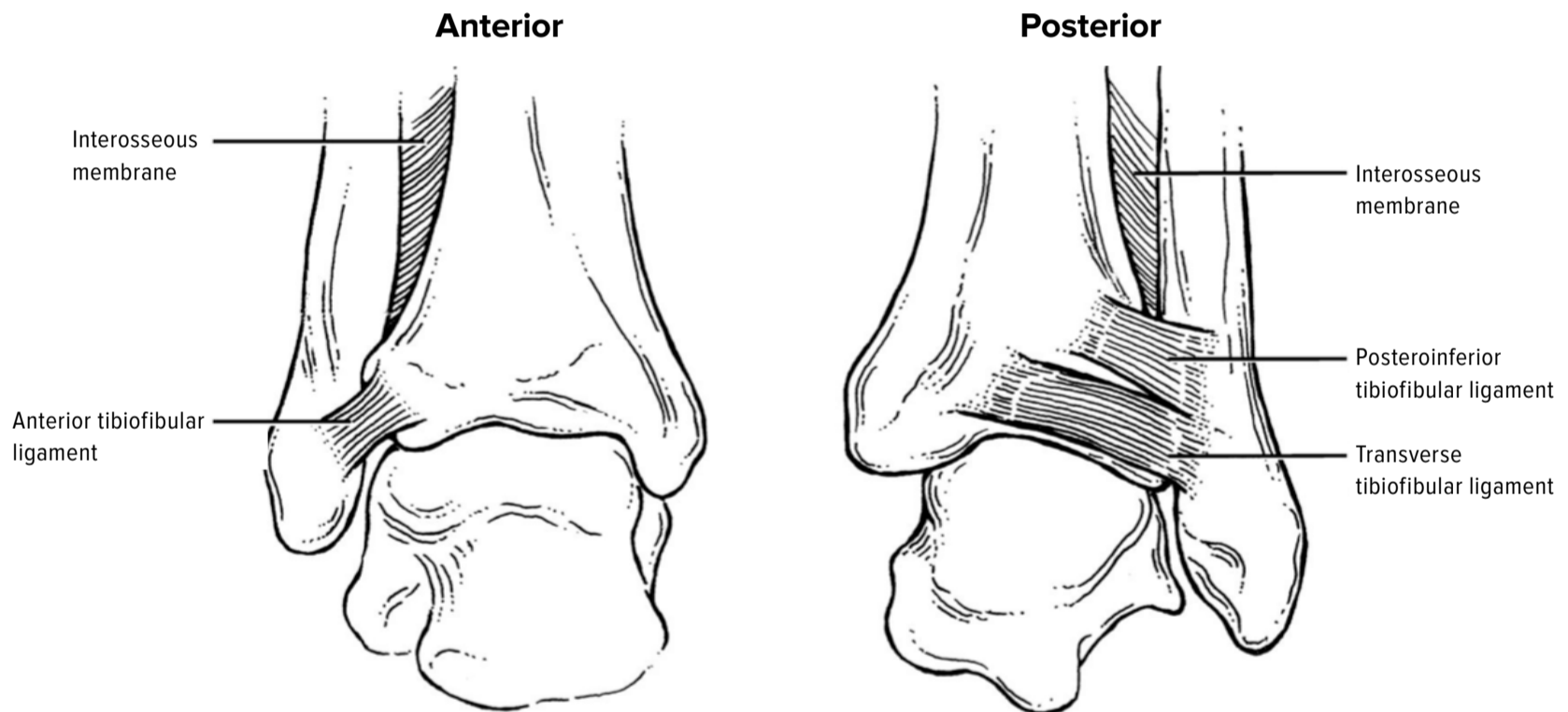
- **Repeat** the dominant wants, needs, or concerns.
- **Show** how Arthrex products fill wants/needs, solve problems, and create value.
- **Translate** Arthrex product features into customer/patient benefits.
- **Ask** for reactions, feelings, or opinions.

For further information, see the [ECI Reference Guide](#).



## Anatomy/Pathology

### Syndesmosis Anatomy



## Demonstrate

### Value Proposition

The Syndesmosis TightRope® implant is a dynamic syndesmosis fixation device that is supported by more clinical data than any other similarly indicated device on the market. The incorporation of knotless technology with unparalleled resistance to cyclic loads sets this device firmly above others on the market.

Furthermore, the addition of the handled inserter on the TightRope XP implant allows surgeons to confidently and consistently flip the button on the medial cortex without fear of nerve entrapment and without the need for a medial incision.

- The Syndesmosis TightRope XP implant provides a more accurate method of syndesmotic stabilization compared to syndesmotic screws<sup>17</sup>
- The Syndesmosis TightRope XP implant is stronger in cyclic loading than screws<sup>4</sup>
- No need to remove the implant as for syndesmotic screws
- Eliminates the risk of syndesmotic screw breakage
- Avoid late diastasis from having to remove a syndesmotic screw<sup>17</sup>
- Made in the USA
- Local, well-trained representation
- Medical education resources
- Unrivaled clinical support
- More cost effective than screws

### Features and Benefits

#### Stable dynamic construct for a natural dynamic joint

- Biomechanical testing and clinical results have shown equivalent strength and improved patient outcomes in multiple studies<sup>17</sup>
- No late diastasis since the TightRope implant remains in place compared to a screw removal
- Eliminates broken screw complications
- More cost-effective versus screws; average surgery cost for screw removal is \$14,768<sup>2</sup>
- Fewer malreductions compared to screws<sup>17</sup>

#### Syndesmosis TightRope XP implant

- Excellent control to flip the medial button
- No need for medial incision
- No needle through the medial skin, which means less medial soft-tissue interposition
- Low-profile knotless fixation with no prominent lateral knot stack
- No knot-tying variability

#### More than 29 articles of clinical support

- Surgeons can be confident the Syndesmosis TightRope XP implant is the best option for their patients

## Demonstrate

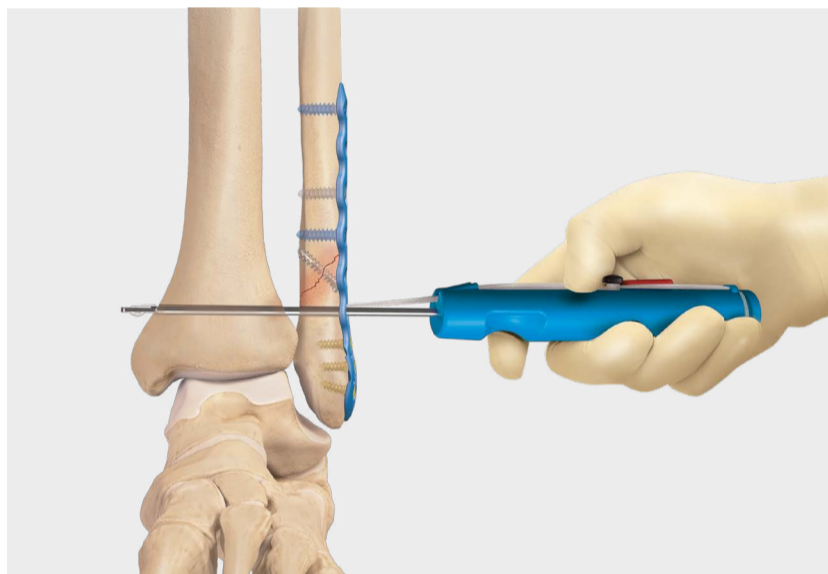
### Scrub Sink Pitch

The Syndesmosis TightRope® XP construct is a dynamic fixation implant that consists of two metallic buttons and #5 UHMWPE suture. It is intended to provide physiologic syndesmosis fixation during the healing process following a syndesmotic injury. The TightRope implant mimics the natural micromotion of the fibula and prevents the need for a second surgery to remove a rigid syndesmotic screw.

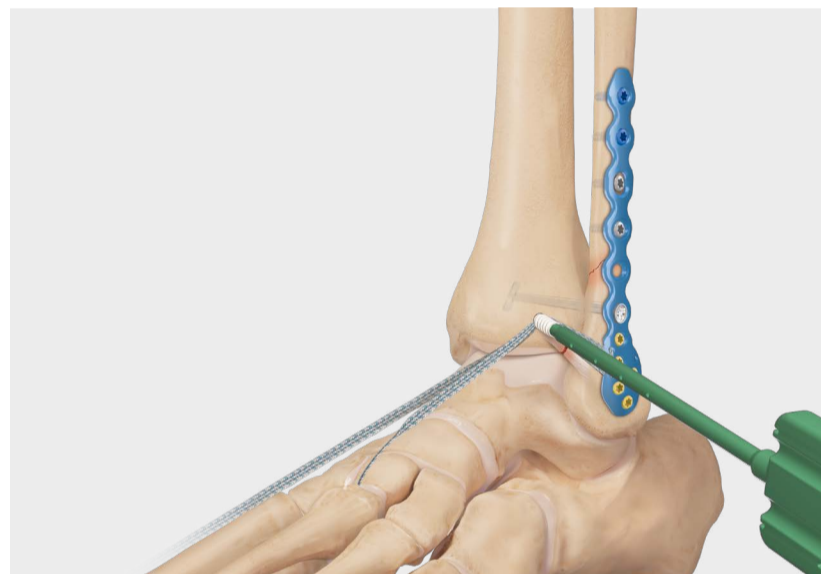
With more than 29 clinical articles of scientific support, it has out-performed screws and competing devices in initial reduction, maintenance of reduction, and even cost effectiveness. Because it is knotless, the implant is extremely low-profile, virtually eliminating any problems due to implant prominence. We feel that the data and track record of the TightRope implant have established it as the gold standard for syndesmosis fixation.

### Product Applications

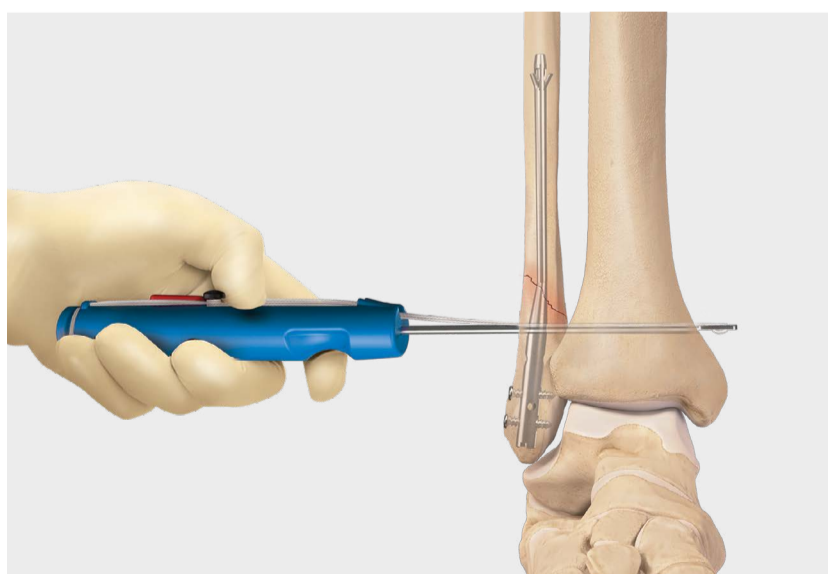
#### Ankle Fracture Plating



#### AITFL *Internal/Brace*™ Ligament Augmentation



#### FibuLock® Fibular Nail



#### Buttress Plate Implant System



# Demonstrate

## Video: The Perfect Demo

### Syndesmosis TightRope® XP Demo Kit DS-248

This selling tool features a Syndesmosis TightRope XP implant and a newly designed acrylic TightRope model. The model features predrilled holes and medial skin to demonstrate the subcutaneous button flipping. The model is reusable. Simply remove the clear medial tab and push the lateral button back through the hole. The Syndesmosis TightRope XP implant can also be reloaded if the surgeon does not tension the implant.

Surgeons will be able to see the technique of deploying the medial oblong button through the predrilled fibula and tibia bone tunnels of the model as well as the positioning of the oblong button after deployment. Ensure the black button is facing up before deploying the button.



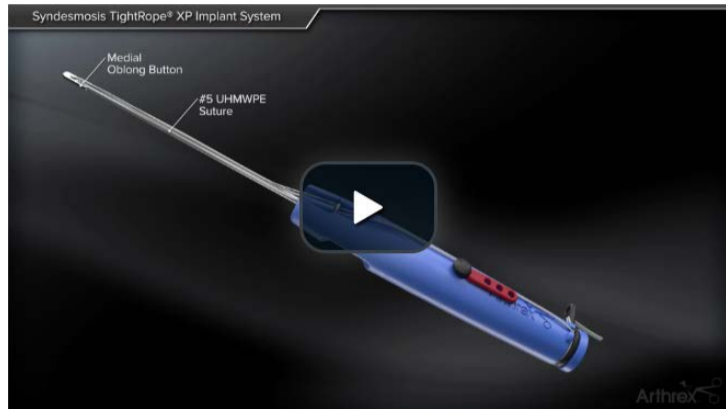
# Demonstrate

## Resources

### Animations

Syndesmosis TightRope® XP Implant System: [AN1-00289-EN](#)

Syndesmosis TightRope XP High Ankle Sprain: [AN1-000037-en-US](#)

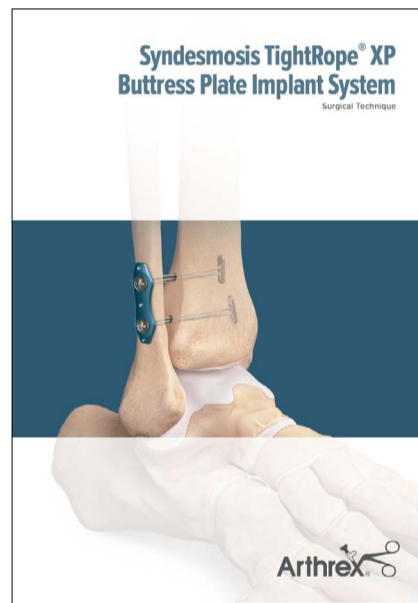
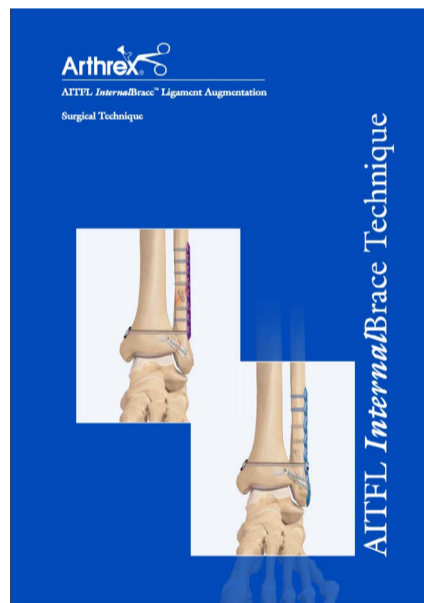
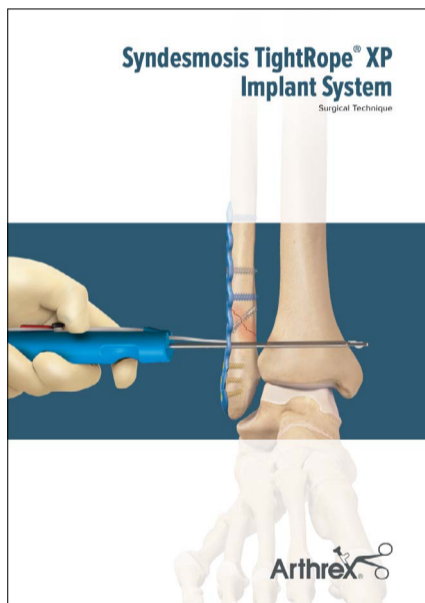


### Surgical Technique Guides

Syndesmosis TightRope XP Implant System: [LT1-00082-EN](#)

ATIFL *Internal*Brace™ Ligament Augmentation: [LT1-00132-EN](#)

Syndesmosis TightRope XP Buttress Plate Implant System: [LT1-000161-en-US](#)



### Technique Pearls:

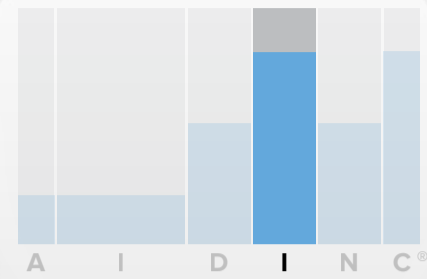
- When using a dual TightRope construct for treatment of high ankle sprains or Maisonneuve fractures, tension the distal TightRope implant first and the proximal TightRope implant second to reduce the risk of “bowing” of the fibula.
- Orient the black button on the TightRope XP inserter to face proximal or distal when deploying the medial button. This will better align the button in a vertical orientation on the tibia.
- Grasp the center sutures and slide the lateral button down to the plate before tensioning. This will help prevent any “bird nesting” of the suture.

# Validate

## Action Guides™

- **Develop** trust and confidence in yourself, your products/procedures, and Arthrex.
- **Define** customer value.
- **Differentiate** the value you provide.
- **Provide** proof and evidence to support your claims.

For further information, see the [ECI Reference Guide](#).



## Related Science

### [Let's Talk Science: Syndesmosis TightRope® Implant System](#)

### [NEW Orthopedic Trauma Association Syndesmosis TightRope Implant vs. Screw Clinical Study](#)

Sanders D, Schneider P, Taylor M, Tieszer C, Lawendy AR; [Canadian Orthopaedic Trauma Society; Improved reduction of the tibiofibular syndesmosis with TightRope compared with screw fixation: results of a randomized controlled study](#). *J Orthop Trauma*. 2019;33(11):531-537. doi:10.1097/BOT.0000000000001559

#### **Conclusion:**

"The TightRope device seems to compare favorably with two, 3.5 mm, 3-cortex screw fixation for syndesmosis injuries."

Boyd BS, Doty JF, Kluemper C, Kadakia AR. [Anatomic risk to the neurovascular structures with a medially based all-inside syndesmosis suture button technique](#). *J Foot Ankle Surg*. 2020;59(1):95-99. doi:https://doi.org/10.1053/j.jfas.2019.07.016

- Cadaveric study using 40 Syndesmosis TightRope XP implants with no documented entrapment of the greater saphenous vein or nerve.
- There did not appear to be a substantial risk of entrapment of the medial neurovascular structures with use of a medially based all-inside suture button technique (Syndesmosis TightRope XP implant).
- The data suggests that a medial incision to evaluate for neurovascular entrapment may not be necessary with the Syndesmosis TightRope XP implant.
- The technique appears to be safe, accurate, and reproducible.

#### **Conclusion:**

This is a great article supporting the benefits of the Syndesmosis TightRope XP implant with no pull-through needle.



# Validate

## Related Science (Cont.)

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. doi:10.1097/BOT.0000000000000245

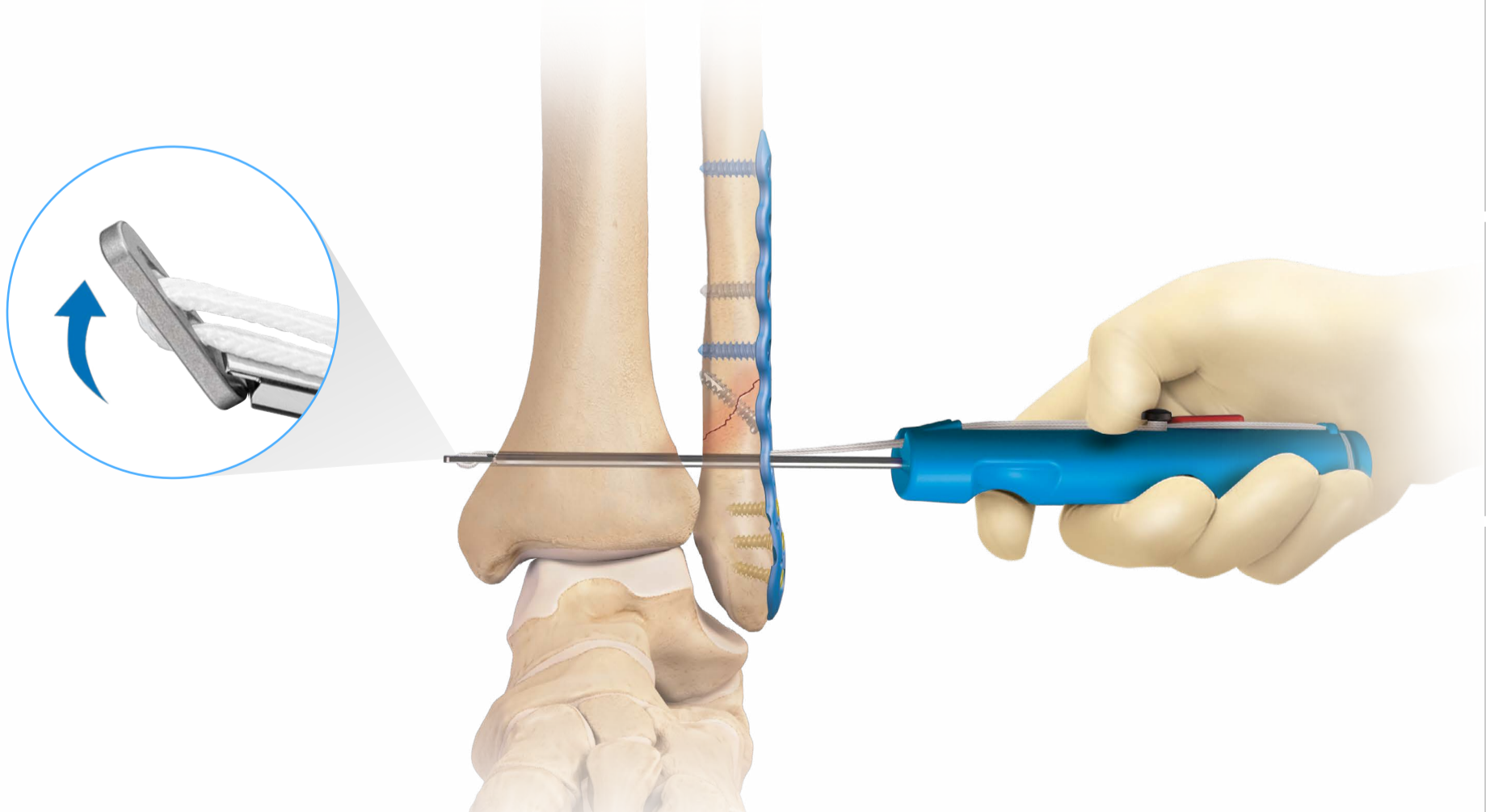
### How does the TightRope® implant compare to screws clinically?<sup>19</sup>

Screws (32 patients)	TightRope implant (33 patients)
Implant Failure: 36%	Implant Failure: 0%
Loss of Reduction: 11%	Loss of Reduction: 0%
Less Range of Motion	Better Range of Motion

Neary KC, Mormino MA, Wang H. **Suture button fixation versus syndesmotic screws in supination-external rotation type 4 injuries: a cost-effectiveness analysis.** *Am J Sports Med.* 2017;45(1):210-217. doi:10.1177/0363546516664713

### The TightRope implant is more cost-effective than syndesmotic screws<sup>2</sup>

Screws	TightRope implant
\$65 screw	\$880 Syndesmosis TightRope implant; \$1495 Syndesmosis TightRope XP implant, optional
\$14,768 second surgery cost	\$0 no second surgery
\$309 extra x-rays	\$0 no extra x-rays
2 extra clinic visits	No extra clinic visits
Lower quality of life and outcomes	Higher quality of life and outcomes



# Validate

## Competition

### Syndesmosis TightRope® Implant Competitive Product Breakdown Video

#### **Wright Gravity™ Synchfix™**

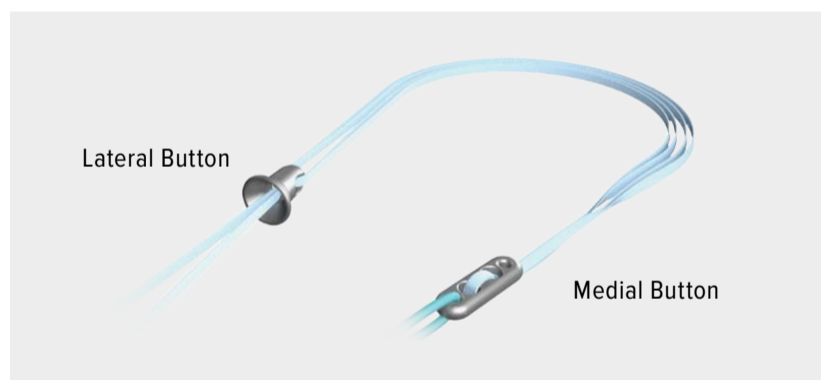
This is a knotted #5 Force Fiber suture construct that requires a large medial incision to attach a dog-bone type of button. Wright claims only a 2.8 mm drill hole through the fibula is needed. But you must advance a 4 mm drill through 8 mm of fibula for the top hat to sit flush. It takes 6 steps to complete the construct with 3 to 4 knots. Arthrex tested Synchfix in R&D, and the constructs failed at 180 lbf.<sup>13</sup>



Wright Gravity Synchfix	Arthrex TightRope Implant
Knotted	Knotless
#5 Force Fiber	#5 UHMWPE (coreless FiberWire® suture)
Large medial incision	No incision needed
Time-consuming to attach button	Medial button already attached
Titanium only	Stainless steel and titanium options
No scientific support	Supported by 27 scientific papers <sup>18</sup>
No long-term data	12 years of clinical use <sup>18</sup>

#### **Smith & Nephew Invisiknot**

This is a knotted 2 mm Ultratape construct with a lateral cone. The lateral cone allows the 3 or 4 knots of Ultratape and is designed to work with the star-shaped holes of the Smith & Nephew ankle fracture plates. This requires 4 steps and is old, knotted technology. Arthrex tested the Invisiknot in R&D, and the constructs failed at 150 lbf.<sup>13</sup>



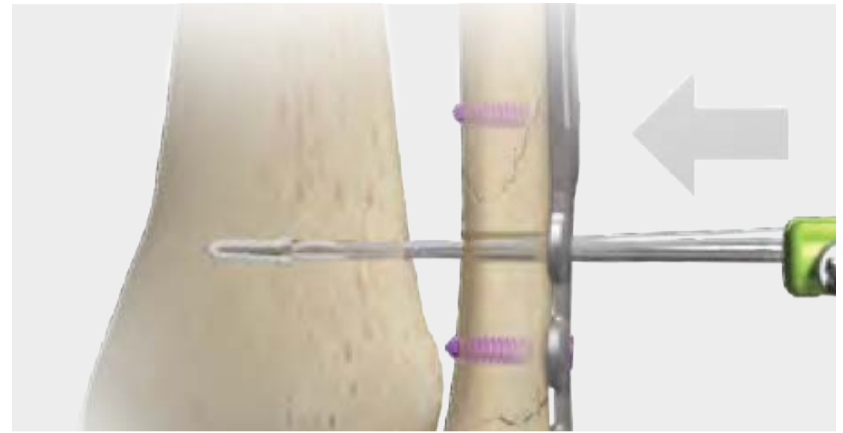
Smith & Nephew Invisiknot	Arthrex TightRope Implant
Knotted	Knotless
2-4 knots and could loosen	No knots, so no knot slippage
Stainless steel only	Stainless steel and titanium options
Ultratape	#5 UHMWPE (coreless FiberWire suture)
No scientific support	Supported by 27 scientific papers <sup>18</sup>
No long-term data	12 years of clinical success <sup>18</sup>
Prominent cone-shaped lateral button	Flat lateral button
Smith & Nephew plates only	Arthrex plates, but can be used with others
Step drill	Straight drill

# Validate

## Competition (Cont.)

### Zimmer Biomet JuggerLoc™

This is a knotless tricortical construct that uses a JuggerKnot® in the lateral tibia with a metallic button on the fibula.<sup>20</sup> This is a weaker all-suture construct.<sup>12</sup> It's not possible to see under fluoroscopy if you have fixation in the lateral tibia. This worries surgeons. Bone quality can be a concern when using an all-suture anchor or when repositioning the drill bit. Zimmer Biomet published the construct failure at 165 lbf.<sup>21</sup>



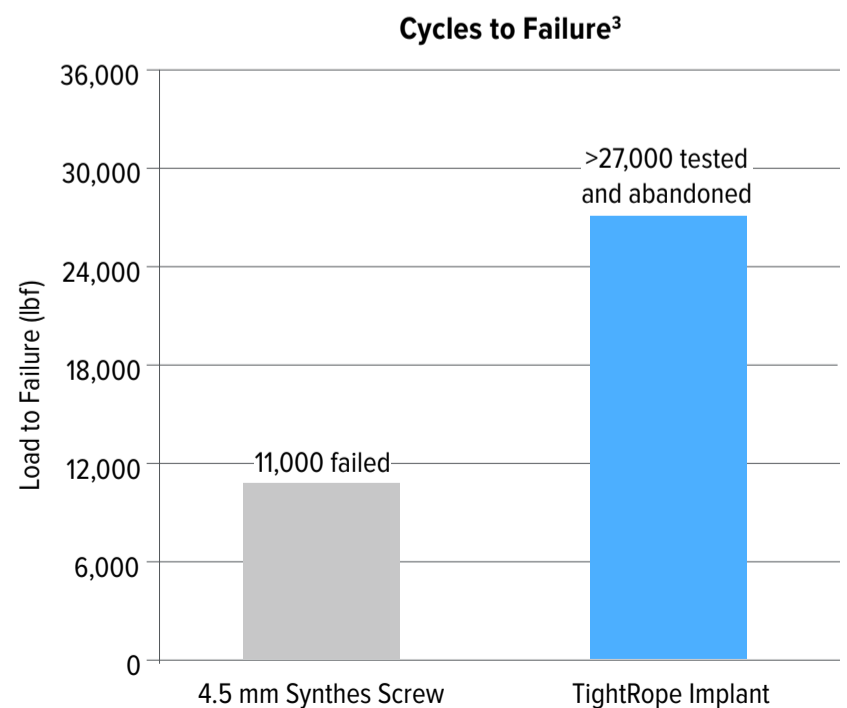
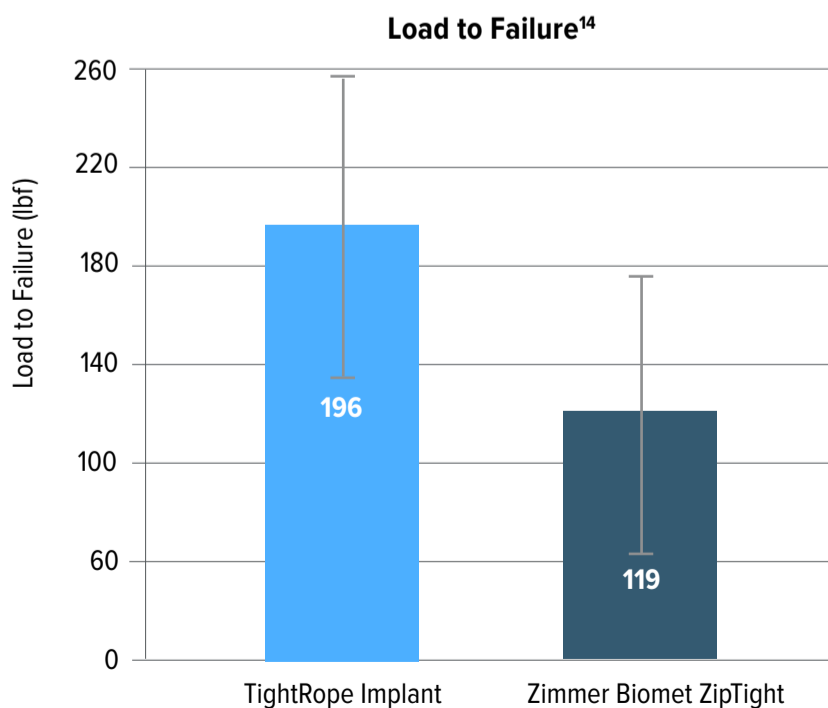
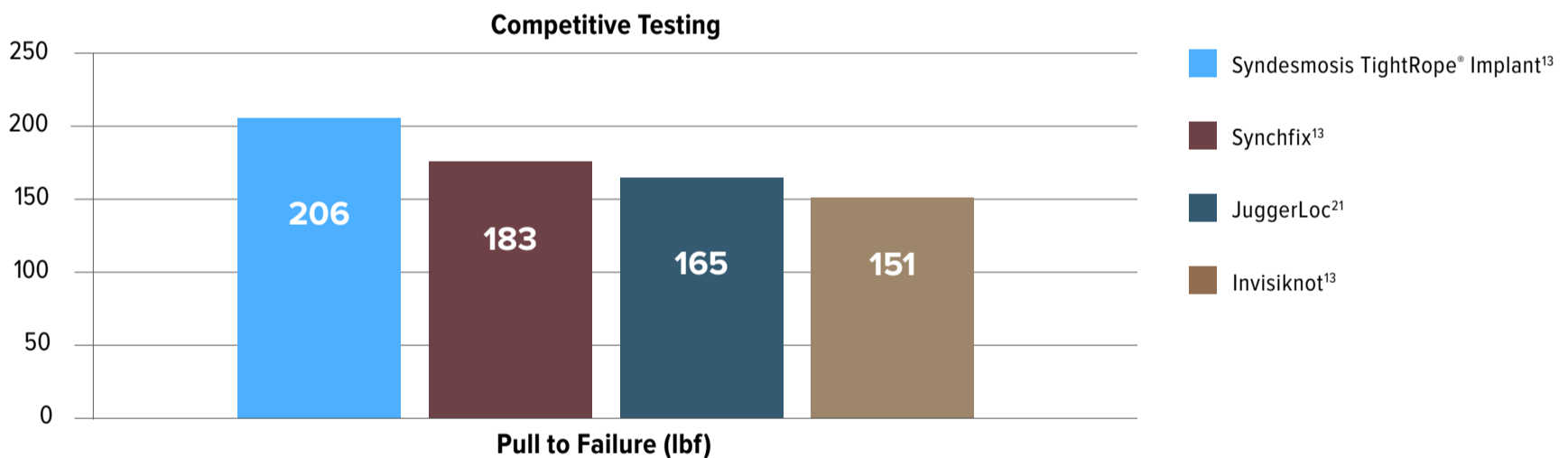
## Biomechanical Testing

### Zimmer Biomet ZipTight

The TightRope fixation system was superior with a load-to-failure of 196 lbf compared to Biomet ZipTight at 119 lbf.<sup>14</sup>

### 4.5 mm Synthes Screw

The TightRope fixation system was superior with more than 27,000 cycles compared to 4.5 mm screws failing at 11,000 cycles due to screw breakage.<sup>13</sup>

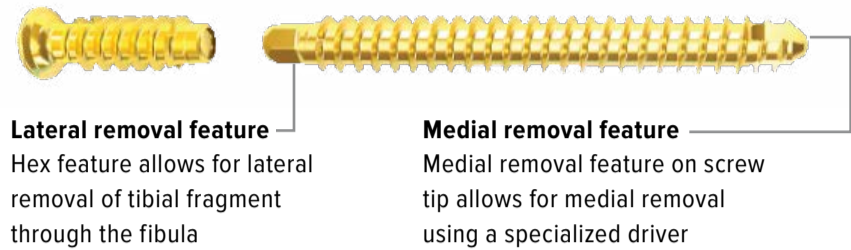


# Validate

## Competition (Cont.)

### Paragon 28 Breakaway Syndesmotic Screw

This 3.9 mm screw is designed to break when the patient begins weightbearing. The screws have two different notch lengths for the fibula and are designed to be removed laterally and medially. Coring instruments and special handles for removal are included in the P28 system.



### Science

This is a step backwards from the success of the Syndesmosis TightRope® implant. The Syndesmosis TightRope implant has been shown to have better syndesmotic reduction, lower recurrent diastasis, decreased reoperation, less implant failure, and better functional outcomes compared to syndesmosis screws.<sup>16,19,22-24</sup>

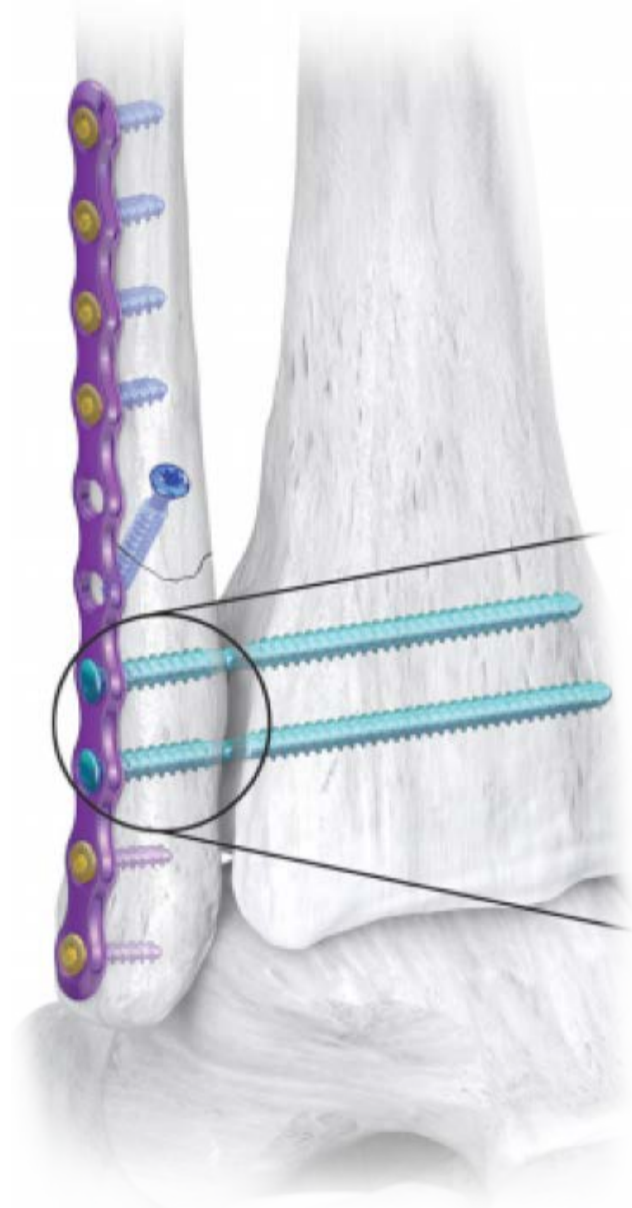
### Screw Breakage

The breakaway feature is also worrisome. A screw could break too early, which could cause syndesmosis reduction to be lost early, resulting in displacement.

### Surgeon Opinion

A traumatologist, when asked about the breakaway screw, replied, “I can’t imagine why anyone would think this is a good idea.”

Another foot and ankle MD said, “This has two things I don’t want: increased risk of malreduction and unpredictable implant failure. This type of device tries to solve problems that may be avoided in the first place by using the Syndesmosis TightRope implant.”



# Validate

## Competition (Cont.)

### Panther Orthopedics PUMA™ System

#### Designer

Ken Hunt, MD, Denver, CO, developed the PUMA system and is actively marketing the product. It is being backed by a Taiwanese company called Medeon Biodesign.

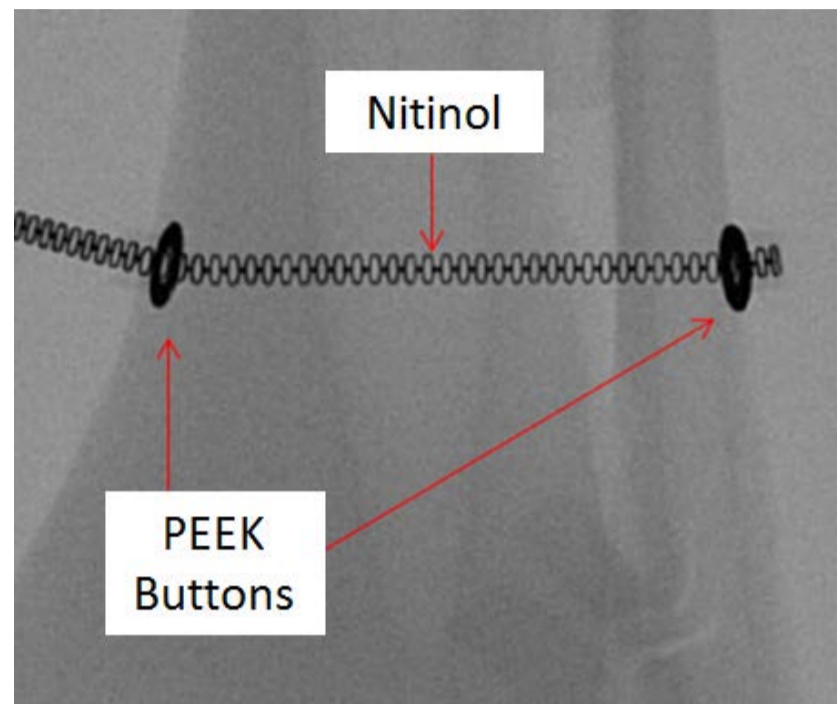
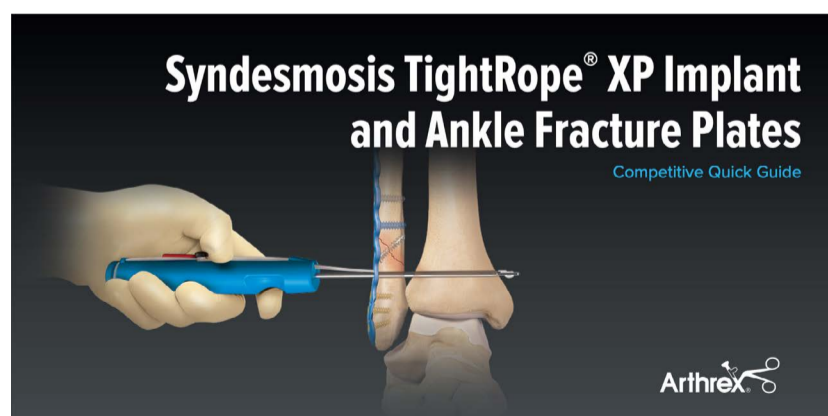
#### Implant Kit

1. The body is a small nitinol wire that looks like a woven lanyard or spring.
2. Two PEEK buttons. The buttons are designed to sit in the Arthrex plate per Gemini Mountain TC. It does not work well with the Synthes plate and is extremely prominent. The buttons must be attached with a large medial incision.
3. There is no drill in the kit. The users must pull a 2.5 mm or 2.7 mm drill from a different set.

#### Technique

1. There is only enough of the nitinol wire to throw the device once. A medial incision must be made and the medial button must be manually loaded. The lateral button must be loaded as well.
2. The device operates like a zip tie and the remaining portion of the nitinol wire must be cut with a wire cutter from the hospital.

### Syndesmosis TightRope® XP Implant and Competitive Ankle Fracture Plates



#### Pricing

It reportedly costs \$800 at UC Health (implant only with no instruments).

#### Summary

There are no clinical studies on this product. Users must also pull additional instruments to complete the procedure, making it more expensive and time consuming.

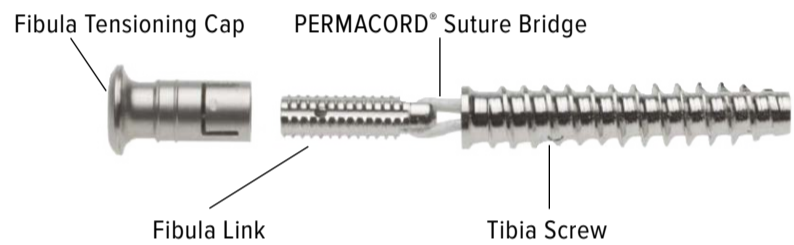
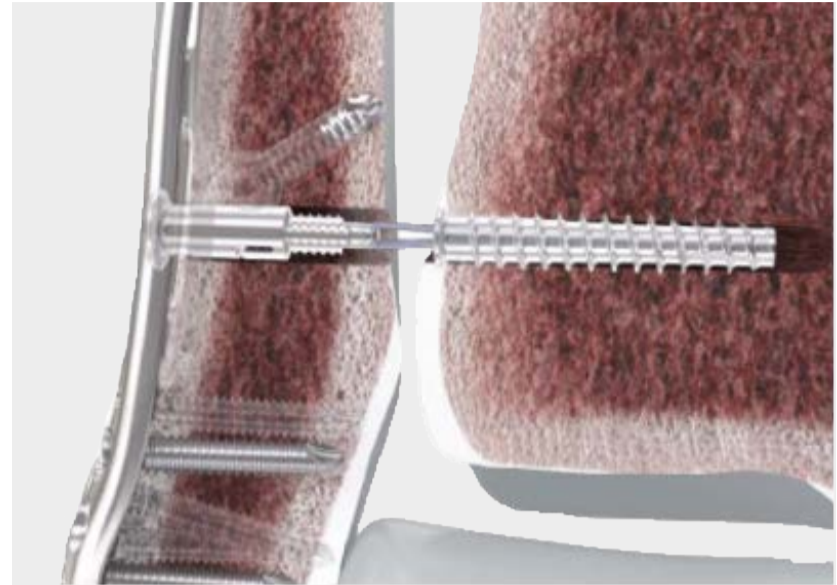
# Validate

## Competition (Cont.)

### DePuy Synthes FibuLink

The DePuy Synthes FibuLink is a tricortical, screw-suture hybrid implant. A 3.0 mm/4.0 mm step drill is used to facilitate the insertion of a 4 mm cancellous screw body into the tibia. A fibular link component is attached to the screw body by 4 strands of #1 Permacord suture. A threaded tensioning cap captures the fibular link and is used to tension the device through the fibula. The device requires six surgical steps to implant and can be used in conjunction with plates or with a washer as a standalone construct.

The increased rigidity of this construct relative to the TightRope® implant may limit its ability to anatomically reduce the syndesmosis. Positioning of the implant is crucial, and it can easily overtighten or undertighten the joint. There is no titanium option, and the removal process is very difficult.



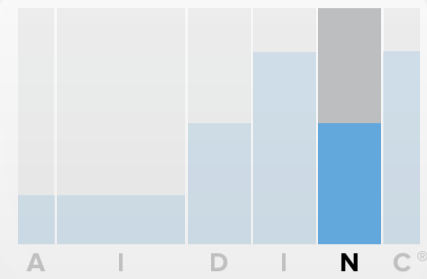
Feature	DePuy Synthes FibuLink
Locking Mechanism	Threaded cap and fibular component
Medial Incision	No
Drill	3.0 mm/4.0 mm step drill
Cortices	3
Fibula Countersink	Yes
Button Material	Stainless steel
Medial Button	Cancellous screw body – lateral tibia
Suture	UHMWPE Permacord
Scientific Support	0
Clinical Data	0
ASP	\$1400-1500
Surgical Steps	6

# Negotiate

## The ACR System

- **Acknowledge** – Listen emphatically and nondefensively
- **Clarify** – Understand the objection and identify additional concerns
- **Respond** – Respond with relevant data or additional information

For further information, see the [ECI Reference Guide](#).



Negotiate by identifying and working through concerns that keep customers from using the Syndesmosis TightRope® XP implant system. It is your responsibility to clearly identify any objections about the Syndesmosis TightRope XP implant system so you can address them with supporting evidence. Keep the discussion moving toward closing or gaining commitment to use the Syndesmosis TightRope XP implant system.

## Clinical Objections

### **Rigid syndesmotic screw fixation makes me feel more secure.**

Where in the body do you fix a ligament with a screw? The Syndesmosis TightRope fixation system mimics the natural syndesmosis by allowing micromotion similar to a ligament. The Syndesmosis TightRope fixation system also significantly outperformed a 4.5 mm screw in cyclic testing.<sup>3</sup>

### **I use the Zimmer Biomet ZipTight.**

Are you aware that the Zimmer Biomet product doesn't have a single clinical study that evaluates its efficiency? Zimmer Biomet uses #1 suture material versus #5 used for the TightRope implant, and the biomechanical comparison should concern you.<sup>14</sup> They are not equal.

### **I use the Wright Medical Gravity Synchfix.**

Are you aware that the Synchfix is older, knotted technology that depends on knot-tying strength? There is variability in knot tying and multiple knots can result in patient irritation on the lateral ankle. The Synchfix also uses a 4.0 mm drill for the fibula and requires an open medial incision.

### **How does the Syndesmosis TightRope XP implant work?**

The #5 UHMWPE suture is manufactured in a way that creates a "fingertrap" on itself. As the tails of the suture are pulled, the outer cove cinches on itself.

### **What is the optimal position for two TightRope implants?**

First TightRope implant: 1 cm to 1.5 cm above and parallel to the ankle joint. Second TightRope implant: 1 cm above the first. The two implants should be slightly divergent in the (transmalleolar) axial plane to increase stability.

# Negotiate

## Nonclinical Objections

### **The Syndesmosis TightRope® fixation system is too expensive.**

[The Neary article in AJSM](#) proves that the Syndesmosis TightRope fixation system is more cost-effective compared to using two \$65 screws. According to the study, the Syndesmosis TightRope fixation system may eliminate the second surgery cost at \$14,768 and has better patient outcomes. Even if you don't remove your screw for the second surgery, the TightRope fixation system is still the dominant treatment with improved patient quality-of-life measurement and decreased syndesmosis malreductions.<sup>2</sup>

### **What (metal) is the TightRope implant made from?**

Syndesmosis repair kits are available in stainless steel or titanium; both are designed to be compatible with the Arthrex Ankle Fracture System technology.

### **The hospital has a trauma contract with Synthes; they give me a hard time whenever I request another company.**

I would love to learn more about the contract. Keep in mind, the Syndesmosis TightRope implant differs greatly from the screws Synthes offers for these indications. As the data indicates, the TightRope implant is superior to screws for initial reduction, maintenance of reduction, and even cost effectiveness. I think with your support we can get this approved for use. I have all of the information that the value analysis committee would need.

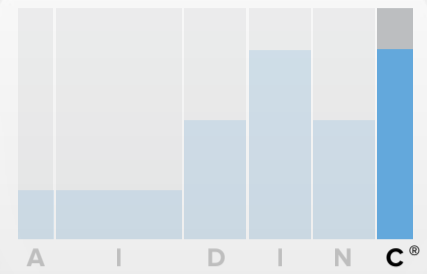


# Close

## Action Guides™

- **Identify** incremental commitments that lead to a decision
- **Listen** to and reinforce each response
- **Be** aware of buying signals
- **Ask** for an appropriate closing commitment

For further information, see the [ECI Reference Guide](#).



## Closing Question Examples

Gain commitment to use our TightRope® XP implant and watch for signals that they are ready to take the next step. Ask for an appropriate commitment to action.

- Would you be open to a demo of the TightRope XP implant?
- I would love to get you into our lab to trial our TightRope XP implant.
- Can I have the TightRope XP implant available at your next case?
- You're currently not stocking TightRope XP implant, can I get your support to have your facility put some on the shelf for you so they are readily available?
- Who is the best contact at your facility to submit for product approval? Can I include you on the initial email?

### Closing Opportunities

Invitation to:

- Sawbones demo
- Dry lab
- Wet lab
- Trial a product
- Stock the product on the shelf
- Propose product to a value analysis committee

# Appendix

## Sales Tools

### Videos

#### [Syndesmosis Repair Featuring the Syndesmosis TightRope® XP Implant System](#)

Surgical Technique - Thomas G. Harris -  
VPT1-00946-EN

#### [Syndesmosis TightRope® XP Implant](#)

Surgical Technique - Lorenzo Gamez -  
VPT1-00941-EN

#### [Ankle Fracture ORIF Utilizing the Syndesmosis TightRope® Fixation](#)

Surgical Technique - J. Chris Coetzee -  
VID1-00606-EN

### Animations

#### [Syndesmosis TightRope® XP Implant System](#)

Surgical Technique - AN1-00289-EN

#### [Syndesmosis TightRope® XP Implant System](#)

Surgical Technique - AN1-000037-en-US

### Surgical Technique Guides

#### [Syndesmosis TightRope® XP Implant System](#)

LT1-00082-EN

#### [Syndesmosis TightRope® XP Buttress Plate Implant System](#)

LT1-000161-EN

#### [Ankle Fracture Management System](#)

LT1-00109-EN

### Competitive Information

#### [Syndesmosis TightRope® Implant System](#)

#### [Competitive Matrix](#)

CI1-00006-EN

#### [Syndesmosis TightRope® XP Implant and Ankle Fracture Plates Competitive Quick Guide](#)

LI1-000008-en-US

### Scientific Updates

#### [NEW Orthopaedic Trauma Association](#)

#### [Syndesmosis TightRope® implant vs. Screw Clinical Study](#)

WH Bulletins - DE1-000037-en-US

#### [Syndesmosis TightRope® XP Implant Scientific Updates](#)

LL1-0401-EN

# Appendix

## Ordering Information

### Syndesmosis TightRope® XP Implant System, Stainless Steel

Product Description	Item Number
Drill Guide XP Drill Bit, solid, 3.7 mm Drill Bit, cannulated, 3.7 mm XP Suture Tensioning Handles, qty. 2 Syndesmosis TightRope XP Inserter Guidewire With Trocar Tip, 0.049 in Guidewire Sleeve	<b>AR-8925SS</b>

### Syndesmosis TightRope XP Implant System, Titanium

Product Description	Item Number
Drill Guide XP Drill Bit, solid, 3.7 mm Drill Bit, cannulated, 3.7 mm XP Suture Tensioning Handles, qty. 2 Syndesmosis TightRope XP Inserter Guidewire With Trocar Tip, 0.049 in Guidewire Sleeve	<b>AR-8925T</b>

### Dual Syndesmosis TightRope Implant System

Product Description	Item Number
Syndesmosis TightRope Implant, Ti, qty. 2 Two-Hole Plate, Ti BB-Tak, threaded Guidewire, qty. 2 Drill Guide Drill Bit, cannulated, 3.7 mm Drill Bit, solid, 3.7 mm TightRope Guidewire Sleeve	<b>AR-8958TDS</b>

### Syndesmosis TightRope XP Buttress Plate Implant System

Product Description	Item Number
Syndesmosis TightRope XP Implant, Ti, qty. 2 Two-Hole Plate, Ti BB-Tak, threaded, qty. 2 Guidewire Drill Guide Drill Bit, cannulated, 3.7 mm Drill Bit, solid, 3.7 mm TightRope Guidewire Sleeve	<b>AR-8959TDS</b>

### Individual Syndesmosis TightRope Plates

Product Description	Item Number
Two-Hole Plate, stainless steel, sterile	<b>AR-8959-01S</b>
Two-Hole Plate, titanium, sterile	<b>AR-8959-02S</b>

# Appendix

## References

1. Chan KW, Ding BC, Mroczek KJ. Acute and chronic lateral ankle instability in the athlete. *Bull NYU Hosp Jt Dis.* 2011;69(1):17-26.
2. Neary KC, Mormino MA, Wang H. Suture button fixation versus syndesmotic screws in supination-external rotation type 4 injuries: a cost-effectiveness analysis. *Am J Sports Med.* 2017;45(1):210-217. doi:10.1177/0363546516664713
3. Arthrex, Inc. LA0424A. Naples, FL; 2012.
4. Silvestri PG, Uhl TL, Madaleno JA, Johnson DL, Blackport RM. Management of syndesmotic ankle sprains. *Athl Ther Today.* 2002;7(5):48-49. doi:L10.1123/att.7.5.48
5. Norkus SA, Floyd RT. The anatomy and mechanisms of syndesmotic ankle sprains. *J Athl Train.* 2001;36(1):68-73.
6. Molinari A, Stolley M, Amendola A. High ankle sprains (syndesmotic) in athletes: diagnostic challenges and review of the literature. *Iowa Orthop J.* 2009;29:130-138.
7. Hermans JJ, Beumer A, De Jong TAW, Kleinrensink G-J. Anatomy of the distal tibiofibular syndesmosis in adults: a pictorial essay with a multimodality approach. *J Anat.* 2010;2017(6):633-645. doi:10.1111/j.1469-7580.2010.01302.x
8. Unal MA. Suture button fixation for syndesmosis injuries: review of the literature. *Clin Res Foot Ankle.* 2014;2:142. doi:10.4172/2329-910X.1000142
9. Vosseller JT, Karl JW, Greisberg JK. Incidence of syndesmotic injury. *Orthopedics.* 2014;37(3):e226-e229. doi:10.3928/01477447-20140225-53
10. Hunt KJ. Syndesmosis injuries. *Curr Rev Musculoskel Med.* 2013;6(4):304-312. doi:10.1007/s12178-013-9184-9
11. Hunt KJ, George E, Harris AHS, Dragoo JL. Epidemiology of syndesmosis injuries in intercollegiate football: incidence and risk factors from National Collegiate Athletic Association Injury Surveillance System data from 2004-2005 to 2008-2009. *Clin J Sport Med.* 2013;23(4):278-282.
12. IMS Health Data. 2019.
13. Arthrex, Inc. APT 3654. Naples, FL; 2017.
14. Arthrex, Inc. LA1-0425-EN\_B. Naples, FL; 2018.
15. Westermann RW, Rungprai C, Goetz JE, Femino J, Amendola A, Phisitkul P. The effect of suture-button fixation on simulated syndesmotic malreduction: a cadaveric study. *J Bone Joint Surg Am.* 2014;96(20):1732-1738. doi:10.2106/JBJS.N.00198
16. Qamar F, Kadakia A, Venkateswaran B. An anatomical way of treating ankle syndesmotic injuries. *J Foot Ankle Surg.* 2011;50(6):762-765. doi:10.1053/j.jfas.2011.07.001
17. 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. doi:10.1177/0363546512461480
18. Arthrex, Inc. LL1-0401-EN. Naples, FL; 2018.
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. doi:10.1097/BOT.0000000000000245
20. Zimmer Biomet bone-to-bone system for ankle syndesmosis fixation. 2017. Available at: <https://www.zimmerbiomet.com/medical-professionals/foot-and-ankle/product/juggerloc-bone-to-bone-system.html>
21. Zimmer Biomet. Data on file (Biomet Verification Test Report [BSM19.VR.1]). Warsaw, IN; 2017.

---

# Appendix

## References (Cont.)

---

22. Kortekangas T, Savola O, Flinkkilä T, et al. A prospective randomised study comparing TightRope and syndesmotic screw fixation for accuracy and maintenance of syndesmotic reduction assessed with bilateral computed tomography. *Injury*. 2015;46(6):1119-1126. doi:10.1016/j.injury.2015.02.004
23. Sanders D, Schneider P, Taylor M, Tieszer C, Lawendy AR; Canadian Orthopaedic Trauma Society; Improved reduction of the tibiobular syndesmosis with TightRope compared with screw fixation: results of a randomized controlled study. *J Orthop Trauma*. 2019;33(11):531-537. doi:10.1097/BOT.0000000000001559

24. Anderson 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. doi:10.2106/JBJS.16.01011



The information contained in this document is confidential and proprietary to Arthrex, Inc. It is provided/intended solely for internal Arthrex use. It is not intended for general distribution. Any unauthorized review, use, retention, disclosure, dissemination, forwarding, printing, or copying of this information is strictly prohibited.